



# Preparing and Implementing a National Plan to Eliminate Lymphatic Filariasis

(in countries  
where onchocerciasis  
is *co-endemic*)



World Health Organization  
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**PREFACE**

This document is a guideline for managers for planning and establishing a programme for the elimination of lymphatic filariasis.

It is intended for use by national programme managers, programme officials and consultants to the ministries of health in countries where lymphatic filariasis is known, or suspected, to be endemic, but not for use in countries where onchocerciasis is co-endemic with lymphatic filariasis or where the use of diethylcarbamazine citrate (DEC) is contraindicated. National programme managers of these countries may consult the respective guideline relevant to onchocerciasis co-endemic countries. The epidemiology and clinical manifestations of lymphatic filariasis are not described in this document as extensive information on the subject is readily available elsewhere.

Throughout this document, the terms “region” and “district” are used to describe administrative divisions. Each country may have its own nomenclature to describe them. Some comparable terms are listed below:

<b>Region</b>	<b>District</b>
State	Local government area (LGA)
Province	sector

Some countries have advanced into implementation of LF programmes while others have yet to start programmes using the revised recommended strategies. This guide is written in a logical order of programme development and implementation so as to be helpful to programme managers in different situations. The guide is structured so that it may also be used as a reference manual.

The manual will be adapted and changed as the LF community “learns-by-doing”, and all comments and suggestions for changes to the manual are welcome. Suggestions should be addressed to [filariasis@who.int](mailto:filariasis@who.int). (or, WHO, 1211 Geneva 27, Switzerland, through the relevant WHO Regional Office).



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## INTRODUCTION

## I

Lymphatic filariasis (LF) is a disabling, disfiguring infection caused by parasitic worms. It is estimated that 120 million people are infected in around 80 countries throughout the tropics and subtropics. Lymphatic filariasis is a major cause of disability, social stigmatization, psychosocial and economic reductions in life opportunities, and a major burden on health and hospital resources, especially on account of the costs for surgical intervention. The disease is a major contributor to poverty, and the programme to eliminate it will reduce suffering and disability, improve reproductive and sexual health (through reduced male genital morbidity) and will improve child and maternal health and development, through the ancillary benefits arising from effects on intestinal parasites. The programme will significantly contribute to reducing the numbers living in absolute poverty by 2015.

Until recently, little could be done to relieve the suffering and disability caused by this disease. Today, however, significant advances have been made in understanding both the disease and its control. A global coalition has been forged among many organizations, each with a different mandate but all having a common goal: to tackle the wide-ranging and complex process of science, practice and management that will result in the elimination of LF as a public health problem\* from the world.

A strong start was made in 1997 when the World Health Assembly passed a resolution<sup>1</sup> calling for ‘...the elimination of lymphatic filariasis as a public health problem...’\*. Following this, WHO, with support from organizations including donor countries, the World Bank, the Arab Fund for Economic and Social Development, and the United States Centers for Disease Control and Prevention, began developing a coalition to eliminate the disease.

The following year the coalition received further impetus when SmithKline Beecham (SB) announced its commitment to support the global programme to eliminate lymphatic filariasis (PELF) through the supply of the entire requirement of albendazole to the LF-endemic countries for the PELF. WHO and the company pledged to work together closely to undertake this massive international public health effort. Subsequently, Merck & Co., Inc. pledged to expand its ongoing Mectizan® Donation Program (MDP) for onchocerciasis to cover treatment of lymphatic filariasis in all African countries where the two diseases occur together.

Individually, none of these organizations can eliminate LF; but by working together through the Ministries of Health in the endemic countries, this partnership can both succeed and ensure an extraordinarily positive impact on many millions of lives.

The National Ministries of Health (MoH) of LF endemic countries, as the major stake-holders in this partnership, need to develop their National Programmes and Plans of action for Elimination of Lymphatic Filariasis in order to achieve **the global goal of elimination of lymphatic filariasis as a public health problem by the year 2020**. A global strategic plan<sup>2</sup> has been prepared in consultation with the partners and is available on the internet worldwide website <http://www.filariasis.org>.

\* Throughout this manual, the word ‘elimination’ is used to describe the more complete text used in the World Health Assembly resolution WHA 50.29.

## **1.1. Make a commitment to the goal of lymphatic filariasis elimination**

Programmes and efforts to eliminate lymphatic filariasis will only succeed when backed up by the necessary political will and commitment of the National Ministries of Health. This may require adequate advocacy and convincing the decision-makers to recognize LF as a significant health problem leading to social and economic deprivation of the LF-endemic communities, especially those who are already marginalized. Recent advances in treatment methods, both for controlling transmission and simple, successful approaches to disease management, along with remarkable improvement in techniques for diagnosing the infection, have opened up a window of opportunity to eliminate this disease. Studies have indicated that economic returns far outweigh the investment made towards LF elimination.

## **1.2. Establish a National Task Force ( NTF-ELF)**

A first step towards establishing and implementing a National plan for the PELF is to form a National Task Force for the Elimination of Lymphatic Filariasis (NTF-ELF). The NTF-ELF should be established or convened by the MoH itself.

The Task Force should be located within, or at least have strong links with, decision-making and policy-making levels of the government. Some countries may need more than one committee, one at the national level to deal with broad policy and management issues and another at regional levels to implement and coordinate programme implementation.

- The head of the country's health services or if not feasible his/her nominee should act as the Chairman of the Task Force.
- The Task Force should have a member-secretary to convene and follow up on the recommendations of the Task Force. The national manager/coordinator for the programme would be the best person to act as the member-secretary of the Task Force to ensure effective implementation of the PELF.
- The other members of the Task Force (total of 6–10 members) could be administrators, health planners, representatives of the regional health departments and non-governmental development organization (NGDO), epidemiologists, sociologists from academic or research institutions working in filariasis and managers from the regions and the private sector.

### *Terms of Reference of the NTF-ELF*

- Establish national policies for lymphatic filariasis elimination
- Define the national objectives and the elimination strategy
- Promote political will and commitment through appropriate and targeted advocacy
- Obtain the cooperation of other ministries, the private sector, major nongovernmental organizations, and international organizations
- Integrate PELF into other disease control programmes and health activities
- Identify key issues requiring operational research for improved implementation of PELF in the country
- Mobilize resources from national and international donors
- Monitor and evaluate programme implementation

The Task Force should meet at least twice a year; a core group within the NTF-ELF may meet as and when necessary.

### **1.3. Appoint a national programme manager/coordinator**

A senior-level officer within the Ministry of Health should be identified and empowered with adequate authority as the national manager/coordinator for the programme to:

- draft the strategic plan for the elimination of lymphatic filariasis for the approval of the task force;
- be responsible for implementing and monitoring the PELF;
- follow up on the decisions of the national task force.

The national programme manager/coordinator should be a senior level official in the ministry of health with an interest in lymphatic filariasis and considerable knowledge, experience, influence and authority. He or she may also have other responsibilities but should be the focal person for programme execution.

## Notes

One of the first steps in the planning process is to assess the disease situation in the country. Because implementation is likely to be organized within the locally defined administrative boundaries, the health authorities should decide on the administrative unit, or level, at which mass treatment will be implemented.

### **2.1. Designate the implementation unit (IU)**

The degree of centralization of health services within a country will influence this decision. Therefore, even before developing a strategy to assess the geographical distribution of filarial infection, the national government should identify the smallest (lowest-level) administrative unit that will be responsible for implementing mass treatment (district, town, city block), within which everyone will be treated, regardless of infection status. The larger the IU, proportionately the fewer the resources that will be needed in the initial epidemiological assessment. Resources can thus be conserved for implementing the programme. However, if very large administrative units are chosen and the disease is confined to small areas of the administrative units, drugs and effort may be spent unnecessarily. The choice of the size of the IU is important, but when in doubt choose the larger IU. In most situations, the district would be the most feasible size for the IU.

### **2.2. Assess the distribution of infection and disease**

Once IUs are designated, the next step is to identify the units in which LF is endemic and in which mass chemotherapy is to be undertaken. This can be done in three steps:

- Reviewing the existing information on the distribution of LF.
- Collecting new information through a questionnaire and mapping implementation units according to three categories:
  - confirmed filaria-endemic units (red areas)
  - confirmed non-endemic units (green areas)
  - units contiguous to the confirmed filaria-endemic units and units for which adequate information is not available [categorized as doubtful units (grey areas)].
- Carrying out a survey in the grey areas to detect the presence of filarial antigenaemia in order to establish boundaries of filaria-endemic areas.

### **2.2.1. Review of existing information on lymphatic filariasis**

In most filariasis-endemic countries, some information on the occurrence of the disease already exists. This information may be found in:

- historical records;
- published and unpublished reports of filaria surveys;
- medical and health department records;
- theses and dissertations in university libraries, and
- hospital discharge data on repair of surgical hydrocoele.
- The existence and recognition of local names for hydrocoele and lymphoedema of the leg may also point to the occurrence of lymphatic filariasis within a particular area.
- Documentation on the vector(s) responsible for LF transmission in the country can be derived from studies by other vector control programmes or research or academic institutes; the distribution of the filaria vectors can aid in the development of the filaria endemicity map.
- Where appropriate, mapping for filariasis should be integrated with other health-related geographical information system (GIS) data.

The above steps should help identify areas which are definitely endemic and those for which more data are required, especially in areas bordering the definitely endemic (red) areas. Further steps need to be taken to define endemicity in the grey areas. This can be undertaken rapidly and at low cost by administering a questionnaire.

### **2.2.2. Rapid assessment through questionnaire**

A simple questionnaire (Annex 1) seeking information on the prevalence of hydrocoele and elephantiasis in the community, can be sent by post to key informants in the villages or towns. Key informants are persons who are most likely to be aware of such information; these will vary from country to country and at times within a country. Possible key informants can be:

- village headmen or elected leaders in urban areas;
- local school teachers;
- postmen; or
- health workers

The responses to the questionnaires are compiled at the level of the district or primary health centre for every village and town and then used to demarcate IUs as endemic (red), non-endemic (green) or still undetermined (grey) areas.

In countries where the postal system cannot be used to reach key informants, health workers can administer the questionnaires to key informants and compile the information.

Only communities with high levels of transmission (greater than 5% microfilaraemia-positive) are likely to be identified by this method, since in communities with lower level of transmission, the prevalence of hydrocoele may be low and unrecognized by key informants. Thus, while positive reports classify areas as endemic, a negative report does not confirm absence of disease; IUs with a negative report should be assessed further by population survey and detection of filarial antigenaemia or microfilaraemia.

### **2.2.3. Direct physical examination**

In areas where the questionnaire cannot be administered or the informants are not knowledgeable about disease prevalence, physical examinations can be used as a rapid assessment tool for lymphatic filariasis. In this approach, mobile teams of health workers visit villages and examine adults for lymphoedema of the leg or hydrocoele in males. In some communities, the prevalence of hydrocoele has offered good indirect evidence of transmission of LF in the area.

For units which still are undetermined (grey), further studies examining for presence of filarial antigenaemia or microfilaraemia in the population need to be carried out. Lot Quality Assurance Sampling (LQAS) can be used for this purpose.

### **2.2.4. Lot Quality Assurance Sampling to detect filarial infection**

LQAS sampling can be used to assess whether prevalence of microfilaraemia in an IU is high enough to trigger mass treatment.<sup>3</sup> A sample of 250 schoolchildren (older age groups are preferable) should be selected in each of the IUs where LF endemic status is still undetermined (grey) and sequentially examined for filarial antigenaemia using the immuno-chromatographic test (ICT card test). If any child has a positive result, the unit should be classified as endemic. Testing of further children is not required after getting a positive result (if the 36th child is positive, further testing from the 37th child onwards is not required). However, in some cases programme managers may decide to complete at least a minimum number of tests, e.g. 50 or 100 tests, in order to get an approximate estimation of prevalence of filarial antigenaemia. The children should be selected from schools located in areas which are most likely to have the disease. If such information is not available then the schools can be selected randomly to represent the entire implementation unit.

#### **2.2.4.a Antigen detection in the blood**

The advantages of the antigen detection method are its simplicity, high sensitivity, specificity for *W. bancrofti* infections and usefulness with finger-prick blood samples collected either during the night or day. Its major disadvantage is its inability to detect brugian infections and the cost, which is at present approximately US\$1.30 per test. If ICT card tests are not available, the standard night-blood film examination for detection of microfilaraemia can be done as indicated below.

#### **2.2.4.b Detection of microfilariae in the blood**

For epidemiological screening, 20 µl of "finger-prick" blood can be dried on a slide, stained, and examined under a microscope in accordance with the standard procedure.<sup>4</sup>

Advantages of using microfilaraemia detection in finger-prick blood for initial assessment include the general availability of materials and trained staff in many filariasis-endemic countries, and the fact that positive specimens are "parasitologically confirmed". Disadvantages include the need to collect blood at night (the microfilariae in peripheral blood peak between midnight and 2 a.m., in most regions of the world) where the parasite is 'nocturnally periodic', and the labour-intensive-ness of preparing and examining slides.

#### **2.2.4.c Estimate requirements for diagnostic supplies**

All LF-endemic countries need supplies of ICT cards initially for mapping LF distribution and identifying implementation units for mass drug administration, and again after 5-6 years of operation, for estimating interruption of transmission. Microscopic slides and stains will be required for baseline parasitological surveys in sentinel surveillance sites before the first round and subsequently at intervals of 2 or 3 years.

Initially, order 275 ICT cards (includes a 10% reserve) for each implementation unit where an assessment of microfilaraemia prevalence is needed to establish whether mass treatment should begin. Later (see section **7.2.9**), 3,300 ICT cards (includes a 10% reserve) will be useful for each IU that has achieved, or is expected to achieve, a reduction in microfilaraemia prevalence to less than 1%. Note: this is not required till at least 5 years of mass drug administration).



**REVIEW AVAILABLE HUMAN RESOURCES AND INSTITUTIONAL LINKAGES****3****3.1. Within the Ministry of Health;**

Review the human resources available, institutions and infrastructure which could be used in endemic urban and rural areas. Define the responsibilities that can be assigned to them, keeping in view the capabilities needed for the following aspects of the programme:

Activity	Personnel	Institution
Programme management and monitoring		
Logistics		
Training		
Case-management of disease and morbidity (disability) control		
Drug administration		

**3.2. Other ministries**

A plan should be made to reach all ministries of the government so that their employees can receive the drug.

Alliances should be formed with at least the:

- ministry of education: for health education and drug distribution among students;
- ministry of social welfare;
- ministry of information and broadcasting: for information, education and communication (IEC) campaigns through the mass media;
- armed forces, police and the other uniformed services: for drug distribution among their personnel;
- Ministry of labour: health insurance schemes for industrial workers;
- Ministry of natural resources, agriculture, etc.

### 3.3. Private sector

The private health sector represents a substantial resource, especially in urban areas. Private medical practitioners can be motivated through their professional organizations. These organizations can also identify the areas in which the support of private physicians could be best utilized in mass drug administration and in morbidity (disability) control.

3.3.2. The commercial organized private sector industry, and the commercial and private educational institutions are also important groups for organizing mass treatment campaigns for their employees. Large industries provide health services to their employees and their families and sometimes also provide health services to the industrial township or rural area where they are located. An inventory of private establishments will enhance planning for drug distribution.

3.3.3. Religious organizations can influence the community for participation in beneficial health practices.

### 3.4. Identify the NGDOs which can collaborate

Non-governmental development organizations can play an important role in LF elimination. NGDOs should be invited to discussions when the strategic plan is being prepared, so that they can identify areas of interest to them which could be incorporated in the national plan. A list of national and international NGDOs with the possible areas of partnership should be prepared.

	Nongovernmental development organizations	Possible areas of partnership
International		
International		

### 3.5. Outside the country

The possibility of resource mobilization through bilateral and multilateral partners, in both the public and the private sectors, should be assessed. Agencies which are likely to provide financial, material or technical support should be identified. Proposals for seeking support should be initiated as early in the implementation phase as possible. In fact their involvement in the planning phase itself helps to ensure that the potential

## ASSESS THE SOCIAL AND ECONOMIC IMPACT OF LYMPHATIC FILARIASIS, ESPECIALLY IN DEPRIVED COMMUNITIES

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- 4.1.** Information on the burden that lymphatic filariasis places upon people, their communities, and their economies can be persuasive in convincing decision-makers in the MoH to invest in the PELF. **[It has been conservatively estimated that filariasis in India - where one-third of cases occur - costs over one billion dollars each year in lost productivity, and the burden on hospital services is increased.]**
- 4.2.** When information on this burden is coupled with estimates of the potential returns on investments in eliminating the disease, a sound investment package can be presented for funding or implementation. [In China, where transmission of lymphatic filariasis has been interrupted, the primary motivation behind the elimination campaign was the impact of the disease on agricultural productivity. **It is now estimated that every US dollar invested in filariasis control in China has produced more than US\$15 in benefits.]**
- 4.3.** In addition to its economic impact, lymphatic filarial disease imposes a heavy psychosocial burden upon affected individuals. Persons with hydrocoele and lymphoedema are often shunned and become isolated within their communities. Ridicule and social stigmatization are the fate of individuals with gross lesions. Because persons with chronic manifestations of the disease are often unable to work or to marry, they become dependent for care and financial support, a situation leading to further insecurity, shame, isolation and consequent economic loss.
- 4.4.** Socio-economic impact studies can be costly and time-consuming to conduct; however, there is a growing body of literature documenting the impact in countries across the globe. A programme manager who wishes to develop country specific information on socio-economic impact of LF can refer to this body of literature and apply existing information on medical costs and productivity losses to the prevalence of infection, acute attacks, and chronic manifestations of lymphatic filariasis of the country.
- 4.5. Sources of Information:** Information on burden of disease by region and country, a bibliography on socio-economic burden studies, and guidelines for preparing a compelling case for funding and implementing lymphatic filariasis programmes will soon be available on the WHO web-site for lymphatic filariasis.

**Notes**

The PELF has two principal strategies:

- **Interruption of transmission:** This strategy is directed at the population at risk and aims to reduce the microfilarial load in the community below the level at which transmission of LF is interrupted. The interruption of transmission should be measured by looking for infection in children born subsequent to the launch of the mass drug administration.
- **Disability prevention and control:** Managing individual patients presenting with the acute or chronic phase of the disease. This not only reduces the suffering of the individual and improves their physical, social and economic well-being but also gives credibility to the programme in the community.

### 5.1. Plan for disability prevention and control

The adult filarial worms cause lymphatic vessel dilatation, which leads to lymphatic dysfunction and predisposes the lower limbs, in particular, to recurrent bacterial infections resulting in acute attacks of adenolymphangitis (ADL). The acute attacks, in turn, cause further lymphatic damage, lymphoedema, and fibrosis. For the estimated 15 million persons worldwide with lymphoedema of the extremities caused by lymphatic filariasis, effective treatment is now available that is both inexpensive and sustainable.

Disability prevention and control, or relief of suffering for persons who already have the chronic manifestations of lymphatic filariasis, is a critical component of filariasis elimination programmes. Antifilarial drugs have little or no short-term effect on the prevalence of chronic disease, particularly elephantiasis of the leg and advanced urogenital disease. Addressing the needs of those affected will not only help the patients but will also enhance community acceptance of measures to interrupt transmission and thereby increase population compliance and coverage for drug treatment regimens. An estimated 29 million men have urogenital manifestations of lymphatic filariasis, including hydrocoele, chylocele, and lymphoedema and elephantiasis of the scrotum and penis.

The central core of lymphoedema management is the prevention of acute ADL attacks through basic hygiene (using soap and water) and prevention and treatment of small skin lesions (with application of topical antifungal and antibiotic cream). Exercises and elevation of the leg help mobilize lymph fluid.

Like the legs, the skin of the scrotal wall and penis is prone to secondary bacterial infections and acute attacks. Basic hygiene can stop the acute attacks in the genital area and improve the patient's condition.

Experience from Brazil and Haiti suggests that this approach is feasible at the community level and that it can stop acute attacks, prevent lymphoedema progression and cause a degree of regression, even in advanced cases. Patient education is the key to the success of this approach, and patient-led support groups can be an important tool to maintain motivation.

Educational materials have been developed and are available for patients and their families (e.g. Hope Club brochure<sup>5</sup>).

Hydrocoele can be treated with surgery. The ability to provide this treatment will depend on the resources and infrastructure of each country.

### **5.1.1. Develop facilities in the health care system for disability control**

**5.1.1.a** At national, regional and district level: Facilities should be identified in hospitals and medical colleges for surgical repair of hydrocoele and management of complicated lymphoedema.

**5.1.1.b** At primary health centre and village level: Local and district health centres should be identified for the management of LF disease and provided with antibiotics, soap and antiseptics when necessary.

**5.1.1.c** With proper education and support, the patients themselves must incorporate lymphoedema treatment into their daily routines and prevent acute attacks.

**5.1.1.d** Role of private medical practitioners: A large proportion of patients with lymphoedema and hydrocoele consult private physicians. Most private physicians who come in contact with these patients are not yet aware of the developments in lymphoedema management. They need to be reached individually or through their medical associations and updated on recent advances so that the patients seeking care from them are benefited.

**5.1.1.e** Incorporate the newer approaches to disability control in the training curricula of medical and health workers.

## **5.2. Plan for interruption of LF transmission through mass drug administration**

The strategy to be adopted for interruption of transmission is the use of mass drug administration. This is based on the evidence of the effectiveness of a single dose of ivermectin (150 $\mu$ /kg) or diethylcarbamazine citrate (DEC, 6 mg/kg) in the clearance of microfilaraemia and sustaining this over a period of at least one year. The addition of albendazole (400 mg) enhances this effect on microfilarial clearance. In addition, albendazole has dramatic impact on intestinal helminths (hookworm, ascaris, enterobius and trichuris) which are also usually highly endemic in LF-endemic areas. SmithKline Beecham has pledged to provide the entire requirements of albendazole for the global programme for elimination of LF in endemic countries.

The recommended strategy for countries where lymphatic filariasis is co-endemic with onchocerciasis is single annual dose mass drug administration of ivermectin and albendazole. The dose of ivermectin can be standardized at country level by age groups or height for convenience in administration in the field.

Please note that mass treatment with DEC is contraindicated in areas where onchocerciasis or loiasis might coexist; hence, its use is precluded from most of Africa.

## **5.2.1 Describe the single annual dose mass drug administration strategy**

The delivery strategy for the ivermectin and albendazole coadministration needs to be planned in line with the epidemiology of LF and the availability of resources.

### **5.2.1.a Distribution of drugs**

Achieving a high level of coverage is of crucial importance to decrease the microfilarial load in the population to levels where LF transmission is no longer possible and thereby ensure the success of the programme. Achieving a high coverage will depend on the:

- availability of both drugs in adequate quantities at the right time;
- efficiency of the drug delivery system;
- motivation and productivity of the drug distributor;
- education and motivation of the beneficiary communities;
- surveys to identify population groups being missed.

**The ingestion of the drug should always be supervised by the person administering the drug.**

Managers should plan drug delivery strategies, appropriate for local conditions. A number of approaches may be adopted:

- **House-to-house administration:** The drug distributor collects the drug from a designated centre and goes from house to house to administer the drug. This approach ensures coverage of all households but is labour intensive, especially in areas where population density is low and household members might not be present during the time of drug distribution.
- **Booth distribution:** Drug distribution booths are set up at sites selected to be accessible to the community. Drug distributors administer the drugs to the beneficiaries who come to the booth. Suitable in urban situations, coverage depends on the motivation of the beneficiaries. Supplying drugs and ensuring potable water at the booths involves increased logistics.
- **Administering drugs in special population groups:** Certain population groups can easily be reached at particular locations: students in schools, patients in hospitals, workers in commercial establishments, major building sites, industries, prison inmates, and displaced persons in refugee camps.
- **Areas of community aggregation:** Market places, bus and railway stations, fairs and festivals, religious gatherings, and other sites where people congregate can also be used to reach the community.

The mass drug administration may be organized as a national day or a week with an intensive campaign approach. If such a focused approach cannot be adopted due to logistical constraints, the distribution could be staggered over a period of two months. The period of the campaign should be acceptable to both the health authorities and the communities. Communities through their representatives should be involved in decisions on the timing of drug distribution at local levels. Mass drug administration through a community-directed approach has been found feasible in Africa, where the communities take decisions on the timing and drug distributor, with the health services playing a supportive role.

#### **5.2.1.b Treatment of individual microfilaria-positive patients**

Individuals found to be microfilaria-positive or filaria antigen-positive during the initial assessment period, monitoring, or on voluntary examination should be treated with a single dose of Ivermectin plus albendazole; or if there is no concomitant onchocerciasis or loiasis in that individual after appropriate medical examination, the individual can be treated with a 12-day course of 6 mg/kg/day of DEC<sup>9</sup>.



### 5.2.1.c Exclusion criteria

For ivermectin and albendazole co-administration, the following groups should be excluded from treatment:

- Sick and infirm.
- Children less than 15Kg body mass or less than 90 cm in height (coincide with 5yrs).
- Pregnant and lactating women within one week of giving birth.

*It should be noted, however, that the exclusions related to pregnancy are a precaution in the absence of definitive information, since there is no direct or anecdotal evidence of complications resulting from treatment with single doses of either of these drugs in pregnant women.*

### 5.2.1.d Management of adverse reactions

Ivermectin and albendazole are both safe and well-tolerated drugs. However, intake of these drugs can lead to adverse reactions that occur almost exclusively in infected individuals since they result from death of the parasite after treatment. These reactions are usually self-limited and resolve without any action, although symptomatic treatment with analgesics or antipyretics is helpful. There are two groups of adverse reactions, general and local.

- Generalized reactions, in decreasing order of frequency, are: headache, body ache, fever, dizziness, decreased appetite, malaise, nausea, urticaria, vomiting, and sometimes bronchial asthma. General reactions and fever are positively associated with the level and intensity of microfilaraemia. Reactions occur early during the treatment and generally do not last more than 3 days.
- Local reactions are most commonly scrotal nodules due to death of the adult worm. Others include lymphadenitis, funiculitis, epididymitis, orchalgia, and lymphangitis. Rarely, abscess formation, ulceration or transient lymphoedema have been reported. They tend to occur later (1-3 weeks after treatment) and last longer.

Improper management of adverse reactions can lead to an adverse impact on, and response to, the programme. Hence, measures should be taken to:

- Advise the community to avoid taking the drugs on an empty stomach and forewarn that some adverse reactions will be encountered in some individuals, particularly those who have the infection and therefore need the treatment. Inform the community and their leaders of places where patients can get help for adverse reactions if needed. The news media, policy makers and the politicians should be adequately briefed on the adverse effects in order to avoid 'panic' when there are such reactions, especially in high LF-endemic areas.

- Identify health centres with facilities for treating adverse reactions and make available antipyretics and analgesics for approximately 1% of the target population, as well as adequate quantities of intravenous fluids for emergency use.
- Educate drug distributors and health workers to reassure patients with mild side-reactions. Refer and help patients with severe adverse reactions to reach designated treatment facilities.
- Inform local practitioners how to treat patients who may report to them with adverse-effects

### **5.3. Integrate vector control measures with existing malaria and/or vector control programme**

Special efforts for vector control for lymphatic filariasis may not be required. However, the vector control measures should be carried out under other vector control programmes such as the anti-malaria vector control operations.

In particular the insecticide treated net (ITN) programme is likely to have an important impact as *Anopheles*, the target of ITN to control malaria, is also an important vector of LF in certain endemic countries.

Source reduction can be achieved through better environmental hygiene. This could be achieved through information, education and communication campaigns, enactment and enforcement of civil by-laws to prevent mosquitogenic conditions, the use of polystyrene beads in the pit-latrines, etc.

Development programmes which might change breeding sites of potential filarial vectors should incorporate strategies for drug distribution.

## **6.1. Design drug procurement and distribution strategy and quality assurance**

**6.1.1.** The distribution system for supplies is the lifeline of the programme. The goal of the system is for all supplies to be available at all locations in sufficient quantities when they are needed.

This section describes how a supplies distribution system should be planned.

Major supplies: ivermectin tablets and albendazole tablets.

Other supplies: lancets, antiseptics, soap, analgesics, cortisone, intravenous fluids, antibiotics.

Note: If a country, or an area within the country, is using DEC-fortified salt, the salt distribution should be carried out by the salt manufacturers and their retailers.

**6.1.2.** Below, information is given on how to calculate requirements (sections **6.2.1**), followed by a description of the activities needed to ensure successful drug supplies distribution:

- ordering supplies (sections **6.2.2**);
- distribution from the airport to the central store (section **6.2.4**);
- distribution from the central store to the regional store and to the district store and health centre (sections **6.2.5** and **6.2.6**);
- distribution from the health centre to the population to be treated (section **6.2.6**).

**6.1.3.** Drugs for LF elimination should be distributed using the same transport and storage systems used for other drugs and vaccines. If the storage and distribution of LF drugs is not feasible using the existing distribution system, this need should be taken as an opportunity to improve the existing system.

**6.1.4.** The distribution system needs to be flexible enough to enable all agencies working in LF elimination to have access to the drugs: nongovernmental development organizations, private practitioners, other ministries (for example, the ministry of education for school drug distribution programmes), and the ministry of health. In each case, agreement is needed on whether drugs will be collected from the store or delivered by the health authorities.

## **6.2. Calculating requirements and procuring drugs**

- 6.2.1.** The table below gives a method for estimating yearly drug requirements based on a minimum treatment age of five years for regimens using ivermectin and albendazole co-administration. The albendazole tablets being made available under the programme are of 400mg strength. It is estimated that only 80% of the total population will be eligible for treatment after excluding under fives, pregnant women.

**Table for calculating the requirements for drugs used in PELF**

Drug	Calculation of requirement
albendazole (400mg)	Multiply the total population in the endemic areas by 0.8 (as 80% of the population is estimated to be eligible)
Ivermectin (3mg)	Multiply the 80% of the total population in the endemic area by 3

## **6.2.2. Application procedures to obtain supplies of ivermectin and albendazole**

### **6.2.2.a Initiation of application**

Applications for cost-free supplies of albendazole (for use in combination with DEC) in PELF must originate from the MoH which will be responsible for their own actions in the programme, as well as for those of any organizations working in association with (or permission of) the government. The MoH will be required, as a first step, to draw up a detailed implementation plan in concert with WHO.

The Application<sup>8</sup> should be forwarded with a covering letter from the responsible ministerial authority directly to the Expanded Mectizan<sup>®</sup> Expert Committee (EMEC) at the same time as it is submitted to WHO. The EMEC will be responsible for the review and final approval of albendazole and Mectizan<sup>®</sup> donations for LF elimination programmes in these co-endemic countries. *This Group's primary objective is to facilitate the earliest and widest possible initiation of such national programmes, consistent with their safe and rational implementation.*

### 6.2.2.b Approval Criteria

The nine 'minimum requirements' for Application approval are the following:

- 1- Ministerial commitment to the elimination of lymphatic filariasis
- 2- Sufficient epidemiological and parasitological data to begin operations, and provision to expand that data progressively as needed to support the requirements of a full national programme (a phased approach generally being anticipated for larger countries)
- 3- Potential to integrate with other public health services/programmes
- 4- Existence of a NTF-ELF or a similar body; where technically and managerially appropriate, the Programme should be encouraged to ensure the coordination or, optimally, integration of operations of NTF-ELF and National Onchocerciasis Task Force (NOTF).
- 5- Clear identification of resource requirements needed to implement the intervention programme; for Applications requiring expansion of initial operations, the provision of evidence that:
  - the targets for the initial operations are being met
  - the epidemiological data are available to justify the expansion
  - the resources for that expansion are adequate
- 6- Technical capacity present already or a clear statement of how such capacity will be created
- 7- Guaranteed exemption from fees or counter-part payments to cover customs duties, acceptance and clearance; evidence of mechanisms in place for appropriate drug handling and warehousing
- 8- A plan for impact assessment on transmission in a subset or sentinel group of the treated population
- 9- The capacity to adequately identify, manage, report and monitor serious adverse experiences with the drugs being used

### 6.2.3. Receipt, storage and shipment of drugs from airport to central store

**6.2.3.a Prepare storage space.** Before the drugs are scheduled to arrive ensure that adequate, well-managed storage space is available. The table below gives estimates of the volume of the drugs in their bulk packaging. Estimate the storage space needed for the drugs you are using and ensure that at least the indicated amount of space is available before the drugs are scheduled to arrive.

#### Estimating storage space needed for drugs

For:	10 000 population	100 000 pop.	1 000 000 pop.	10 000 000 pop
Ivermectin	0.17 cubic metres	0.60 cubic metres	3.6 cubic metres	31 cubic metres
Albendazole	0.087 cubic metres	0.528 cubic metres	4.416 cubic metres	43 cubic metres

**6.2.3.b** The table is based on the total population of the areas where treatment is taking place. The space requirement assumes an annual order with a 25% reserve stock (that is, a 10% reserve stock plus any remaining stock from the previous treatment round).

**6.2.3.c** While albendazole has a shelf life of five years, ivermectin has a shelf life of 2 years (13 months after the bottle is opened). They are labelled “store at room temperature”. These drugs can be stored in non-air-conditioned stores in all climates, but efforts should be made to keep the room temperature below 30°C (86°F).

**6.2.3.d** Receipt of the drugs. Customs clearance for albendazole is the responsibility of the WHO National Representative, or a delegated organization. This is likely to be UNICEF or an NGDO. The WHO office will inform the country programme when the drugs are scheduled to arrive at the port of entry.

**6.2.4.e** In all cases, the quantities of imported drugs need to be compared to the shipping bill. Any differences need to be reported to the shippers, the freight company, the customs office and the insurance company before the drugs are taken from the port of entry.

**6.2.3.f** When delivered to the central store, bulk packages should be stored above floor level and on shelves to prevent the lower packages from being crushed.

**6.2.3.g** All imported drugs should be cleared for use by the responsible drug control authority before being distributed to regional stores.

#### **6.2.4. Central store to the regional store, and to the district store**

**6.2.4.a** Similar principles apply to storing and distributing drugs at lower administrative levels. At each level, the drugs need to be kept dry and secure and good stock records should be maintained.

**6.2.4.b** The yearly supplies of drugs are likely to be bulky and special truck transport will probably be needed.

**6.2.4.c** Stocks remaining in the store after distribution to lower levels can be retained until the following year's distribution. The drugs remaining from the previous year should be used first in the following year. Thus, most of the drugs will pass through the distribution within two to four months of being procured and no drugs will remain in store for longer than 14 to 16 months.

#### **6.2.5. District store to health centre**

Typically, the health centre worker will collect the drugs at the same time as other supplies. If the health centre is responsible for a large population, special bulk transport will be needed to transport the quantity of drugs needed.

#### **6.2.6. Health centre to population group (schools, under-fives, workers, farmers)**

**6.2.6.a** In each implementation unit, the population to receive drugs will fall into several categories: young children, schoolchildren, employed people, individual workers (farmers, taxi drivers, housekeepers etc.), older people.

**6.2.6.b** Each of these groups will need special attention to achieve high coverage. Strategies to attain high coverage will probably be different in urban and rural areas.

**6.2.6.c** The following distribution points will probably be needed:

- Health centres
- Outreach centres
  - MoH (also called booths)
  - Community outreach centres (temporary stations set up in markets, temples, taxi stands etc.)
- NGDO outreach (to reach populations served by the NGDO: for example, rehabilitation centres)
- Private clinics and pharmacies
- House-to-house distribution
- Workplace distribution, sometimes achieved by the industry's health service, sometimes by an outreach visit.
- Army and prison health services

## Notes



## SURVEILLANCE FOR LYMPHATIC FILARIASIS

7

### 7.1. Background surveillance

As the objective of the programme is to achieve interruption of transmission, a surveillance system for LF has to cover the entire country, not merely LF endemic areas. LF elimination programmes should establish surveillance that will identify foci of transmission. Efforts should be made to integrate filariasis surveillance within an integrated disease surveillance system of the country.

- Filariasis (microfilaraemia, hydrocoele or elephantiasis) should be a reportable event throughout the country; a monthly report should be sent from health institutions to the district; a quarterly report from district to state or national headquarters would be adequate.
- Include examination for lymphoedema or hydrocoele in population surveys for other diseases or purposes such as leprosy, family planning, school health or active guinea worm case searches.
- Screening for LF should be done during medical examinations of recruits in the uniformed services such as the military, and the police.
- Random testing for filarial antigenaemia by ICT cards should be done among blood donors in non-endemic areas

Any positive report received from a facility in a LF-free area should be investigated to identify whether the report indicates indigenous transmission or an importation from a LF-endemic areas.

If the case has migrated into the area, the health authority of the area of previous residence should be informed so that investigation for endemicity may be carried out in that area. All microfilaraemia-positive cases should be treated as described in section 5.2.1.b.

### 7.2. Sentinel surveillance

#### 7.2.1. Monitor progress in endemic areas

Because of the focal nature of LF distribution, cluster sampling techniques are not effective, nor will monitoring the entire population of the programme IUs be feasible. Monitoring of populations in sentinel sites is therefore recommended.

**7.2.2.** Select two sentinel surveillance sites for every million population or in each of the programme IUs whichever is operationally feasible. The selected sites should have relatively stable populations.

**7.2.3.** The sites may be geographical units which have a population of at least 500, such as a village, ward, block, sub-district in rural areas and municipal wards or localities in urban areas. If the population of these units is normally greater than 500, then a subunit or locality within the village or area may be selected as a sentinel site.

**7.2.4.** Sentinel sites can be selected randomly or on the basis of factors that would be expected to increase the difficulty of eliminating transmission, such as areas of high prevalence, with high vector densities, etc. A list of the selected sentinel sites should be recorded and maintained in a monitoring register. Once selected, the two sentinel sites will continue to operate throughout the period of mass drug administration.

**7.2.5. Collect baseline data**

In the two sentinel sites, before administering the first round of treatment, examine at least 500 individuals for microfilaraemia by night blood smear examination and filarial disease, and calculate the baseline microfilaraemia prevalence, mean microfilaraemia density, lymphoedema and hydrocoele prevalence.

**7.2.6.** After the completion of each round of drug distribution, in addition to the sentinel sites selected as described above, randomly select two spot-check sites each year (i.e., each year select two different spotcheck sites)

**7.2.7.** Activities to be undertaken in the sentinel sites and the spotcheck sites after every round of drug distribution include the following and should be undertaken by personnel at least one supervisory level above those who were responsible for drug distribution:

- Monitor drug coverage through interviews carried out in every household of the sentinel site. Calculate a coverage of ingested drugs (Annex 2b).
- Monitor the proportion and nature of adverse reactions by interviewing the entire population in the sentinel site.
- Assess reasons for non-acceptance of the drug by interviewing the entire population.
- Compare coverage in each age group (2-5, 6-14, >14) of the sentinel sites longitudinally over the years and every year with the spot-check site populations.
- Find reasons for inadequate or drop in coverage and take measures to improve coverage through better and focused management.
- Determine whether a pattern can be found in the defaulters, e.g. adult males being missed due to their absence during drug administration.
- Report on findings, with plans for improvement

**7.2.8.** Before the fourth round of drug distribution and subsequently before every second round thereafter (i.e. before the 4th,6th,8th..), in addition to the yearly activities listed above:

- Calculate the microfilaraemia prevalence rate and the mean microfilaraemia density. This is done by night blood survey by finger-stick method covering every individual in the sentinel sites and the two spot-check sites selected for that particular round.
- Compare the microfilaraemia prevalence rate and the mean microfilaraemia density in the sentinel sites with the baseline and longitudinally. Compare the rate and density between the sentinel sites and the spot-check sites for format (see Annex 3).
- When the microfilaraemia prevalence in all four sites, i.e., the two sentinel sites and the two randomly chosen spot-check sites, are all less than 1% and a minimum of 5 yearly rounds of mass chemotherapy has been completed, shift to the Lot Quality Assurance Sampling (LQAS) technique as described below.

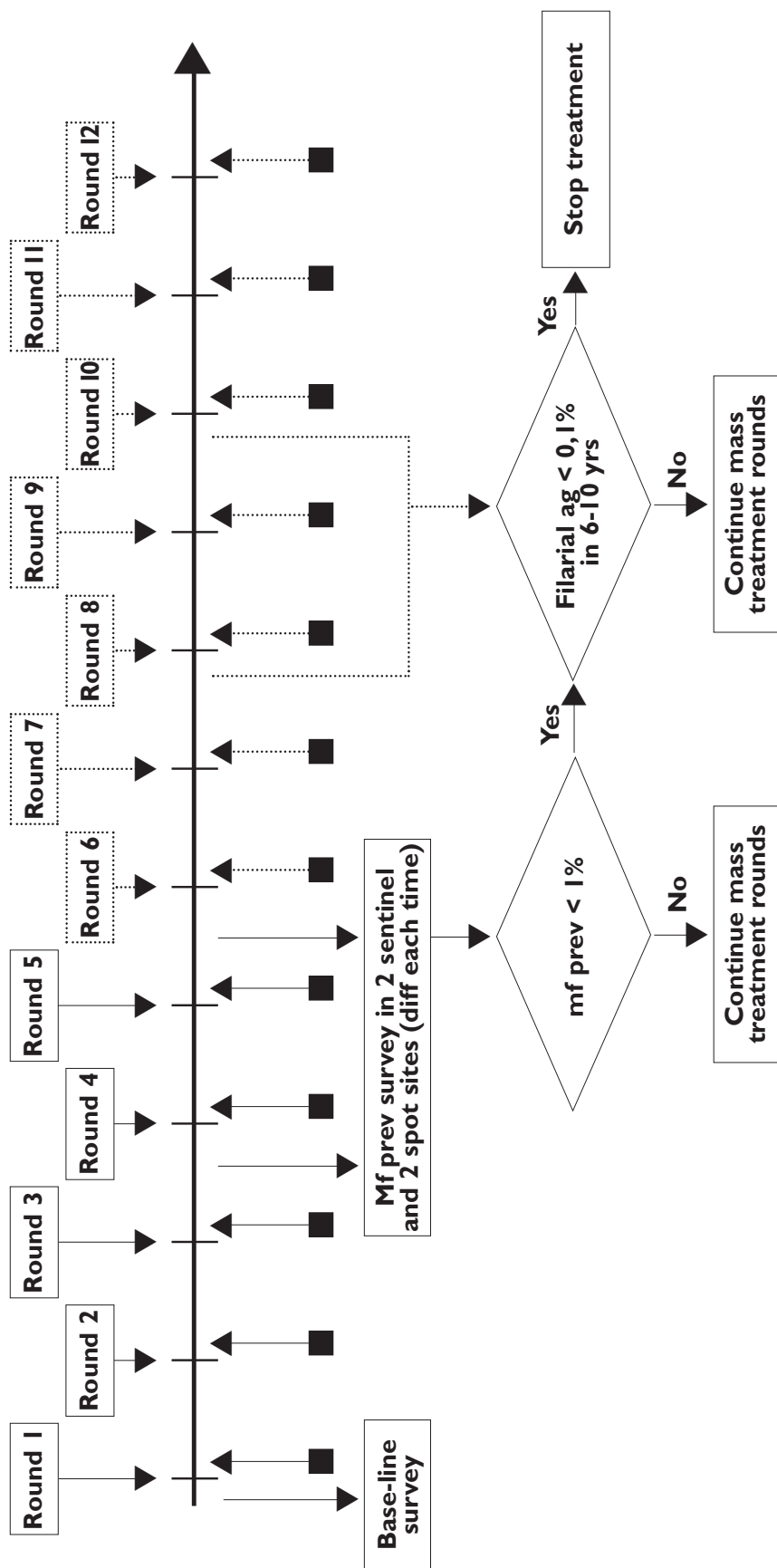
**7.2.9. Lot Quality Assurance Sampling (LQAS) for assessing interruption of LF transmission**

**7.2.9.a** After achieving a microfilaraemia prevalence rate of less than 1%, a sample of 3 000 children in the 6-10-year age group should be tested for filarial antigenaemia with ICT cards. This evaluation should be done by an agency which is independent of the IU, preferably from the national or regional level. The sample should be chosen from an area where the prevalence was high or coverage was the lowest. If all the children test negative for filarial antigen, then the mass drug distribution can be discontinued in the particular IU. If any one or more of the children test positive, then mass drug administration needs to be continued and after every two rounds of mass drug administration filarial antigenaemia is tested in another sample of 3 000 children until all 3 000 children test negative. Any child testing positive should be investigated and treated for microfilaraemia described in section **5.2.1.b**

**7.2.9.b** The ICT card test should be carried out again 5 years after cessation of drug distribution to test whether the filarial antigenaemia still continues to be below 0.1%. That is, not a single one of a sample of 3 000 in the 6-10-year age group tests positive.

**7.2.9.c** Once all the programme implementation units in the country achieve less than 0.1% antigenaemia in the 6-10-year age group, the country will be considered to have achieved elimination and be eligible for certification

# LF PROGRAMME MONITORING FLOWCHART



Indicates coverage survey

**PLAN INFORMATION AND EDUCATION CAMPAIGN STRATEGIES****8****8.1. Define target groups**

One of the initial steps in design of information, education and communication (IEC) strategies should be to define the different target groups at which the campaigns will be directed, e.g.:

- Decision-makers in the ministry of health;
- Health and administrative authorities in the regions and districts who have a direct impact on the programme implementation;
- Communities at risk;
- LF patients;
- Special groups such as teachers, religious leaders, physicians in the private sector, and NGOs which can act as catalysts in motivating the communities.

**8.2. Assess local knowledge, attitude and practice (KAP) of the target groups.**

For IEC campaigns to be effective, levels of awareness and misinformation and current beliefs need to be assessed. This will help in planning a well-directed IEC campaign. At the community level, the programme of mass chemotherapy is directed towards achieving and sustaining high coverage throughout the period of drug distribution. Coverage depends on:

- Perception of lymphatic filariasis as a major health problem in the community and its impact on the community and individuals;
- Perception of lymphatic filariasis as a serious threat to individuals and their families;
- Confidence in the treatment being offered;
- It is therefore helpful to review the results of studies carried out in the country, or in other countries with similar social characteristics.

**8.3. Design appropriate messages for each target group**

Develop short and crisp messages for each target group. The IEC bureau within the ministry of health or the ministry of information and publicity can be utilized for this purpose. The messages should be field-tested to ensure that they are correctly understood.

**8.4. Choose appropriate media through which the messages will be broadcast**

Communication experts can provide guidance on the choice and mix of media which will give the best coverage of an IEC message in a defined target group.

### **8.5. Decide on the timing of broadcasts**

Some messages, such as those directed at the LF patients for morbidity reduction, will be broadcast regularly throughout the year, while those directed at communities for mass chemotherapy campaigns will gradually be broadcast more frequently to coincide with the onset of the mass campaign.

**8.6.** Plans should be made for regular monitoring and periodic evaluation of the IEC campaign to assess the infiltration of the IEC messages among the target groups and the impact of the messages in bringing about the desired changes in the target groups. After the first round of drug distribution, a study should be commissioned to assess KAP with regard to the disease and the mass chemotherapy campaigns.

**8.7.** Programme managers may consider engaging professional services or media experts in planning and implementing social mobilization strategies and advocacy campaigns.

## DEFINE A PROGRAMME IMPLEMENTATION INFRASTRUCTURE

9

For the efficient implementation of the PELF an infrastructure needs to be designed. It will be most cost-effective to develop this infrastructure within the existing health system rather than creating a new one which would be more expensive and difficult to maintain and sustain.

**9.1. Organizational placement:** A network among the health services, teaching and research institutions needs to be developed. These three key groups should have linkages at each level of programme implementation: national, regional and district. This could be achieved by identifying the institutions and the nodal persons at each level and forming technical or managerial groups which would oversee the implementation of the PELF at each administrative level.

**9.2. Identify personnel:** For every level of programme implementation, identify the personnel who will be responsible for a particular activity of the programme:

- Programme administration and management
- Surveillance and disease distribution
- Morbidity (disability) control - treatment of microfilaraemia carriers and management of ADL attacks and lymphoedema
- Training
- Mass drug distribution
- Management of adverse drug reactions
- Organizing IEC campaigns
- Operational research
- Information system

A number of the above activities could be performed by one individual. For instance, the medical officer in charge of a primary health centre would probably be responsible for programme management, disability control, training of field staff and management of side-effects; at the district level the responsibility for disability control would probably be in the district hospital, and for programme management the district medical or health officer would be responsible.

### 9.3 Defining responsibilities and skills required :

Personnel	Responsibilities
National programme manager (policy and coordination)	<ul style="list-style-type: none"> <li>• Development of a national strategic plan for LF Elimination</li> <li>• Ensure political and bureaucratic willingness through advocacy at federal and regional government level</li> <li>• Coordinate with other ministries, national NGDOs, major industrial organizations, regional governments</li> <li>• Coordinate with WHO Regional Office, WHO Collaborating Centres and international agencies</li> <li>• Coordinate with national academic and research institutions working on LF</li> <li>• Develop linkages with the private sector</li> <li>• Mobilize and allocate resources to different regions on the basis of epidemiology and priorities</li> <li>• Coordinate LF assessment in the country</li> <li>• Coordinate with national level training institutes on training of personnel</li> <li>• Organize IEC campaigns, coordinate with mass media in the public and the private sectors at the national level</li> <li>• Monitor drug coverage across regions and send feedback to regions</li> <li>• Review microfilaraemia / antigenaemia in regional sentinel surveillance centres</li> </ul>
Regional programme manager (programme planning and monitoring at regional level)	<ul style="list-style-type: none"> <li>• Develop a plan of action for the region</li> <li>• Coordinate with other departments, regional NGDOs, major industrial organizations</li> <li>• Coordinate with regional academic and research institutions and departments working on LF</li> <li>• Mobilize and allocate resources to different districts on the basis of epidemiology and priorities</li> <li>• Undertake LF assessment in the region</li> <li>• Coordinate with regional training institutes on training of personnel</li> <li>• Organize IEC campaigns, coordinate with mass media organizations in the public and private sectors at the regional level</li> <li>• Manage programme implementation and logistics</li> <li>• Monitor drug coverage across districts, transmit information to the national level, and send feedback to district health authorities</li> <li>• Monitor microfilaraemia / antigenaemia in the sentinel surveillance centres in the implementation unit.</li> <li>• Once the unit reports microfilaraemia / antigenaemia less than 1%, organize cross-checking and periodic evaluation by LQAS for achievement of elimination</li> </ul>



Personnel	Responsibilities
District programme manager (Implementation level -functions will depend on the administrative level of IU)	<ul style="list-style-type: none"> <li>• Develop a plan of action for the district</li> <li>• Coordinate with local NGOs</li> <li>• Allocate resources to different health centres on the basis of epidemiology and priorities</li> <li>• Undertake LF assessment in the district</li> <li>• Undertake background surveillance through collecting reports from various health institutions on microfilaraemia / antigenaemia and filarial disease</li> <li>• Organize training for field health staff as well as staff from other departments, such as schools</li> <li>• Organize IEC campaigns, coordinate with local media organizations</li> <li>• Manage programme implementation and logistics</li> <li>• Monitor drug coverage across districts, transmit information to the regional level, and send feedback to the primary health centre</li> <li>• Undertake periodic surveillance for microfilaraemia / antigenaemia in the sentinel surveillance and cross-check sites in the implementation units in the district</li> </ul>
Medical officer, primary health centre	<ul style="list-style-type: none"> <li>• Organize periodic training and reorientation for field health staff</li> <li>• Organize IEC campaigns, especially group meetings with the community using local folk media</li> <li>• Calculate the quantity of drugs required and indent for drugs from the district</li> <li>• Arrange distribution of drugs to personnel delivering drugs</li> <li>• Maintain stocks of drugs for managing side-effects</li> <li>• Monitor drug coverage in the health centre area and transmit information to the district level.</li> <li>• Undertake night blood surveys/ antigenaemia surveys in the sentinel surveillance and cross-check sites if one is in the health centre area</li> </ul>
Health worker	<ul style="list-style-type: none"> <li>• Administer questionnaires to key informants in the village and send the questionnaires to the health centre</li> <li>• Report to the health centre any case of lymphoedema or hydrocoele encountered</li> <li>• If the village(s) fall within an endemic area targeted for mass chemotherapy, develop liaison with the village headman and other influential individuals on motivation for mass chemotherapy</li> <li>• Impart health education and motivate communities for mass chemotherapy, and filaria patients on foot hygiene, etc. during routine visits to the communities</li> <li>• Collect drugs from the health centre on designated dates</li> <li>• Administer drugs in communities through house-to-house delivery or through establishing a booth, as decided by the programme manager</li> <li>• Watch for adverse reactions in the community, manage the mild adverse reactions and refer the serious ones to the health centre</li> <li>• Prepare reports on drug distribution and submit to health centre</li> </ul>

The above list is merely indicative. Programme managers/coordinators will need to prepare their own lists based on their local situation.

## Notes

**TRAINING AND CAPACITY BUILDING****10**

**10.1.** For effective implementation, every individual involved in PELF needs skills to perform the assigned responsibilities. Training, both general and specialized, is the basis for strengthening the capacity of the PELF to interrupt LF transmission and control morbidity.

**10.2.** Training needs are specific to each country. Training programmes will need to be developed and adapted at national level. People must be trained to recognize and assess their local problems, to plan, implement and manage elimination activities within their communities, and to evaluate the impact of programmes on the health of the population.

**10.3.** A general strategy for training and capacity building is given below.

**10.4. Stage 1 of training and capacity building**

**10.4.1.** Exchange information between MoH, WHO Representative, WHO Regional Office and CPE/CEE/FIL at WHO headquarters; arrange orientation meetings on possible training strategy and synergy with other partners. In addition to MoH, other ministries, relevant national health programmes, potential partners, WHO Collaborating Centres, LF support centres and NGOs should be involved;

**10.4.2** Choose key decision-makers - MoH staff - to be briefed on Lymphatic Filariasis Elimination Programme management and activities. This staff will be a high-level coordination group for LF-related activities at ministerial and interministerial level;

**10.4.3** Technical briefing of key decision-makers - MoH staff.

**10.5 Stage 2 of training and capacity building**

**10.5.1** Needs assessment for training and capacity building

The functions of each position in the PELF should be listed as described above. Then, the following should be defined and prioritized:

- Areas for training and capacity building;
- How to implement training more efficiently;
- Which types of personnel need to be trained;
- How many need to be trained and at which level;
- How many trainers are available;
- What is the main content of the training activities;
- What is the status of the training facilities.

- 10.5.2.** Develop a national training strategy and curricula. This will be a collaborative effort between the country, the WHO Regional Office and WHO headquarters;
- 10.5.3.** Select the first regions and districts which will implement training activities;
- 10.5.4.** Adapt training materials in collaboration with involved agencies;
- 10.5.5.** Select and train the first group of nationals;
- 10.5.6.** Train national health personnel and trainers at various levels in the areas of programme management, morbidity (disability) control, logistics/drug distribution, epidemiology, mapping, etc.;
- 10.5.7.** Implement community-based activities in the areas of disability control, drug distribution and community education/information;
- 10.5.8.** Monitor the training activities;
- 10.5.9.** Plan for the evaluation of training activities undertaken and training material utilized; the characteristics that should be considered when setting up an evaluation strategy are validity, reliability and relevance.
  - Evaluate the extent to which each of the learning objectives has been attained and determine the quality of the teaching techniques and of the tutors.
  - Evaluate training activities with a clear definition of objectives. Decide what is to be evaluated: learners, tutors, methods.
  - Evaluate training activities in the short and long term. Short-term evaluation is carried out on completion of the training activity; long-term evaluation is carried several months, or even years, after the training activity.
- 10.5.10.** Review the evaluation findings in close collaboration with national programmes.
- 10.5.11.** Validate the training programmes and determine whether they conform to the training needs.

### **10.6. Stage 3 of training and capacity building**

Training courses on economic impact evaluation, epidemiological monitoring and surveillance, and criteria for certification.

### **10.7. Possible training activities - as required by national programme**

- Train programme managers and field operation staff;
- Train medical doctors, nurses and CHWs on morbidity (disability) control;
- Incorporate the recent concepts of interruption of transmission and morbidity control in the curricula of medical and public health schools;
- Train in the area of epidemiology, surveillance and geographical information system;
- Integration with other health programmes such as school-based activities
- Train in basic economics and cost analysis;
- Workshops for technical personnel on: drugs distribution, adaptation of training materials, advocacy at country and community level, etc.

## Notes

## PREPARE THE BUDGET FOR THE PELF

11

**11.1.** An estimate of the funds required for implementation of LF elimination should be prepared. Two financial estimates are helpful to decision-makers and partners: the total cost of elimination of LF in the country, and the budget by national plan period. The yearly budgets are useful for fiscal management. Programme effectiveness depends on accurate and well-planned programme budgeting and continued financial management.

This section is a guideline for fiscal management of PELF. It is comprehensive, but not complete because many costs depend on the country's resources and particular situation. For example, is the programme an independent intervention or is there cost and resource sharing with other health initiatives?

In order to capture financial resources, programme managers must be able to estimate the cost of the intervention programme.

### **11.2. Determining start-up costs**

Start-up costs are the one-time expenditures that are necessary to get the programme operating. They are the expenditures prior to active programme intervention. Examples of start-up costs include the acquisition of office and storage space, furnishings, equipment and vehicles.

Once the programme manager has identified financial resources for programme implementation, he needs to allocate the various start-up costs for those resources. The programme manager also needs to decide whether the more costly items are to be purchased, leased, or cost-shared with other programmes.

### **11.3. Calculating recurrent costs**

Recurrent costs will continue throughout the life of the programme and are necessary to keep the programme running. These normally include fixed costs (those that do not fluctuate with the number of persons receiving treatment) and variable costs (those that vary with the number of programme participants). Examples include personnel, maintenance of buildings and vehicles, supplies, communications and utilities.

The allocation of financial resources to cover recurrent costs of the PELF is crucial to the implementation of the programme. Attached is a tool (Annex 4) to be used for this purpose. Many of the decisions involved will be based on the government's fiscal policy.

The capital costs and the recurrent cost estimates for the first five years can be prepared:

	1 <sup>st</sup> year	2 <sup>nd</sup> year	3 <sup>rd</sup> year	4 <sup>th</sup> year	5 <sup>th</sup> year	Total
Capital cost						
Recurrent cost						
Total						

## Notes



## SET NATIONAL OBJECTIVES AND TARGETS

12

**The global programme has set the goal of achieving global elimination of lymphatic filariasis by 2020, which means that transmission should be interrupted in all countries by 2015, as the last 5 years are for pre-certification surveillance.**

Each WHO region will set its own goals and targets for lymphatic filariasis elimination. The national PELF should be planned in a phased manner so that it can be implemented starting in smaller areas and increasing in manageable steps to cover the entire population at risk. The programme may be expanded to cover more areas, or activities may be expanded in the same area, or both activities and areas covered may be expanded together. The initial areas should be chosen from among those:

- with relatively higher endemicity - where longer duration of chemotherapy is anticipated
- where filariasis is perceived as a health problem
- where programme implementation and achieving high coverage will be relatively difficult and longer duration of mass chemotherapy is expected
- with relatively good health services

The experience gained in the initial phase of programme implementation can be utilized in the planning for extension of the programme into other areas. Each country will have to set its goals and targets within this context. The periodic goals and targets will keep programme implementation on course.

### **12.1. Set final objectives as**

**12.1.1.** Get certification of LF elimination after a 5-year pre-certification period by <insert year>

**12.1.2.** To interrupt LF transmission by <5 years before certification>

### **12.2. Set intermediate objectives as**

**12.2.1.** Mapping the distribution of LF for all implementation units completed by <insert date>

**12.2.2.** 25% of endemic implementation units to be under mass chemotherapy by <as early as possible>

**12.2.3.** 50% of endemic implementation units to be under mass chemotherapy by <set year >

**12.2.4.** 100% of endemic implementation units to be under mass chemotherapy by <should be at least 5-6 years before the target date set for achieving interruption of transmission >

### **12.3. Set immediate objectives as**

- 12.3.1. NTF-ELF set up by the year 2000
- 12.3.2. National PELF Strategic plan and plan of action prepared by the year 2000
- 12.3.3. Mapping for disease distribution initiated by the year 2000
- 12.3.4. Start mass chemotherapy in pilot implementation units during 2000-2001
- 12.3.5. Train all involved health personnel by <within first three years>
- 12.3.6. Create morbidity (disability) management centres within the public health care delivery system and in the private sector by <within first 5 years>

### **12.4. Set operational targets for the first five years of programme implementation as**

- 12.4.1. Regional plans of action ready by 2000
- 12.4.2. Training curriculum for different levels of health staff prepared by <date>
- 12.4.3. Training manuals for programme managers ready by <date>
- 12.4.4. Training material for physicians and nurses on management of lymphoedema, ADL attacks, etc. by <date>
- 12.4.5. Training manuals for field staff ready by <date>
- 12.4.6. Training of national core trainers held by <date>
- 12.4.7. <n> district officials trained in first and second year
- 12.4.8. Send application for supply of drugs to WHO by <date>
- 12.4.9. Procure <n> ICT cards/microslides, cotton, lancets by <date>
- 12.4.10. ICT cards/microslides, lancets, cotton, spirit to be supplied to <n> regions by <date>
- 12.4.11. Adequate drugs supplied to <n> pilot districts by <at least one month before date of initiation of mass chemotherapy>
- 12.4.12. Mass drug chemotherapy initiated by <date/month> in <n> pilot districts and completed by <date/month>

The above objectives and targets are only indicative; programme managers will have to set their own objectives. Once the objectives are decided, operational targets for the first year or two can be stated. The objectives should be reviewed by the NTF-ELF each year and modified if necessary.

Once the objectives and targets are finalized, all activities required to meet the targets should be spelled out with estimated durations and personnel responsible for them and a Gantt chart prepared to keep track of programme implementation.

**IMPLEMENTATION OF ACTIVITIES****13**

Once the plan for PELF has been approved by the NTF-ELF and the MoH, initiate implementation of the programme. Essential steps are the following:

- 13.1. Initial assessment and mapping of LF distribution in the country**
- 13.2. Seek support of regions**
- 13.3. Regions and districts to prepare their respective action plans**
- 13.4. Publicize programme launch**
- 13.5. Prepare training materials and start training**
- 13.6. Social mobilization: Implement IEC messages**
- 13.7. Initiate disability management in defined health centres**
- 13.8. Define sentinel sites and collect base-line microfilaraemia and disease prevalence data**
- 13.9. Implement mass chemotherapy**
- 13.10. Regularly monitor the programme through a management Information and Evaluation System (MIES)**
- 13.11. Periodically evaluate the programme with the help of external experts**
- 13.12. Review programme strategies to make the programme more effective and efficient**

Most of the above are not necessarily sequential and many of the activities can be started concomitantly.

## Notes

**MONITOR AND SUPERVISE ACTIVITIES AND OUTCOMES****14**

For the success of the programme, the programme needs to be closely monitored at different levels of implementation. Indicators for monitoring programme implementation can be divided into Process indicators and Health outcome indicators for transmission control and disability control/reduction.

**14.1. Process indicators****1) Supplies - drugs and diagnostics**

- Logistics is the life-line of the programme. The quantity, quality and timely availability of programme supplies at every level of implementation should be checked at regular intervals and through surprise checks.

**2) Staff Resources - Training and quality**

- Assess whether staff are available in adequate numbers to implement programme activities in all IUs.
- Compare the training activities completed against the targets set for each year and at each level of programme implementation.
- Assess the quality of training as described in section 10.5.9.

**3) Village/IU reporting system**

- Efficiency with which designated reporting units submitting reports to the higher administrative levels

**4) Drug coverage**

Regular assessment and evaluation of drug coverage needs to be done immediately after each round of drug administration through:

- Reported coverage: every peripheral reporting unit/drug distributor to report on the drug coverage (Annex 2a,c,d)- number of individuals actually ingested the drug/ total population
- Observed coverage: The reported coverages should be cross-checked by supervisors from higher administrative levels through surveys in sentinel and spot-check sites (refer section 7.2.7 and annex 2b).

Special reviews should be made of sections of the population not being reached by the drug distribution. Which age groups are missed? Which occupational groups are missed? Are women missed more frequently than men? Do urban populations have a lower coverage than rural populations?

**5) Adverse events**

- During the start-up phase of national programmes, each programme must undertake 'active surveillance' for adverse reactions in a subpopulation of 1 000-2 000 individuals in addition to the 'routine monitoring' as detailed in Annex 5.

## **6) Morbidity (disability) control/reduction - Lymphoedema and hydrocoele management**

- Monitor the number of treatment centres that manage lymphoedema and ADL attacks and the number of centres created/designated for hydrocoele surgery.
- Monitor the number of patients with ADL attacks, lymphoedema under treatment and repair of filarial hydrocoele undertaken.

## **7) IEC campaigns**

- Monitor the frequency of broadcasts being carried out through radio and TV stations.
- Monitor production and utilization of IEC material: flyers, pamphlets, posters, etc.
- Monitor IEC activities being carried out at each level of programme implementation- group meetings, folk art, school health education campaigns, with religious groups, etc.

## **8) Indicators for other relevant control practices in the programme area**

- ongoing vector control activities
  - anti-larval
  - insecticidal bed-net programme
- deworming campaigns
- improved sanitation

### **14.2. Outcome or impact indicators to be assessed**

At periodic intervals the impact of programme implementation should be monitored by higher levels of programme managers, e.g. regional or district managers, academic or research institutions in the area

- 1) Microfilaraemia by night blood surveys undertaken in the sentinel sites (section **7.2.8**)
- 2) Disease prevalence rates- lymphoedema rate, hydrocoele rate
- 3) Antigenaemia in the 6 to 10 years age-group to detect interruption of transmission once the microfilaraemia rates have fallen below 1% (section **7.2.9**).
- 4) Assessment of community awareness and behaviour through KAP surveys
- 5) Surveys for vector infections for assessment of transmission.

### **14.3. Design a Management, Information and Evaluation System (MIES)**

For effective monitoring, the data on various process and impact indicators collected should be compiled and analysed for programmatic decisions to be taken promptly. Every country needs to design its own MIES system for PELF. It could be integrated with any existing health management information system already existing. Healthmap version 2.0 developed at WHO is a cost-free software with GIS capabilities which can be used as a tool for the PELF information system.

## PERIODIC INDEPENDENT EVALUATIONS

15

The elimination programme should be evaluated periodically by independent experts, both national and international. It is recommended that the first independent evaluation should be carried out after three years of programme implementation; that is after two rounds of mass drug administration. Subsequent evaluation should take place at intervals of two or three years. The findings of the evaluations should be utilized in strengthening or revising programme strategy. These evaluations should address aspects of both programme implementation and impact on infection and disease.

## Notes



**GLOSSARY OF TERMS**

ADL	Adenolymphangitis
CHW	Community health worker
DEC	Diethylcarbamazine citrate
GIS	Geographical information system
ICT	Immuno-chromatographic test
IEC	Information, education and communication
ITN	Insecticide treated net
IU	Implementation unit
KAP	Knowledge, attitude and practice
LF	Lymphatic filariasis
LQAS	Lot Quality Assurance Sampling
MDP	Mectizan® Donation Program sponsored by Merck & Co., Inc.
MIES	Management information and evaluation system
MoH	Ministry(ies) of Health
NGDO	Nongovernmental Development Organization
NTF-ELF	National Task Force for the Elimination of Lymphatic Filariasis
PELF	Programme for Elimination of Lymphatic Filariasis
SB	SmithKline Beecham plc
UNICEF	United Nations Children's Fund
WHO	World Health Organization

## Notes

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## Notes

**ANNEX I****Interview of Key Informants****Rapid Assessment of Community Burden of Disease**

1. State: .....
2. District: .....
3. Name of village/urban area: .....
4. Name of the informant: .....
5. Age: ..... years
6. Sex: .....
7. Occupation .....
8. How many years have you lived in this village/urban area? ..... years
9. What is the number of households in the village/urban area? .....
10. What is the population of the village/urban area? .....
- 11.1. Have you seen local inhabitants of the area with elephantiasis of the leg? Yes  No
- 11.2. How many people in the village have elephantiasis? .....
- 11.3. Do you consider elephantiasis to be a health problem in this village/urban area?  
.....
- 12.1. Do you know of people in this village with hydrocoele? Yes  No
- 12.2. How many people in the village have hydrocoele: .....
- 12.3. Do you consider hydrocoele to be a health problem in this village/urban area?  
.....

**ANNEX 2a**

**Proforma for recording household members for mass drug administration**

1. State/Region: .....
2. Implementation Unit: .....
3. Autonomous Community / Village: .....
4. Ward: .....
5. House Hold identifier: .....

Details of household members and history of being administered ivermectin and albendazole

S. No.	Name (surname/family name)	Relation to head of household	Age (years)	Sex (m/f)	Treatment received (y/n), reasons for not taking(code*)	Date received	Nbr of tablets (S/L)@
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
17.							
18.							
19.							
20.							
21.							
22.							
23.							
24.							
25.							
26.							
27.							
28.							
29.							
30.							

Note: List should include all the members of the household even if they did not receive or refused the drugs

\*code for reasons for not taking drugs: 1- Pregnant; 2- Lactating; 3-Sick; 4-No knowledge; 5-Not present; 6-did not receive; 9-others  
 @ S- small tablet (ivermectin) L- large tablet (albendazole)

## ANNEX 2b

**Proforma for recording actual coverage**

(To be carried out within one month of completion of drug distribution by a supervisor and not by the drug distributor)

Sentinel/spot site: ..... Block: ..... District: .....

Date drug distribution started: .... / .... / 20... Date drug distribution completed: .... / .... / 20...

Name of evaluator: ..... Designation: .....

Date coverage evaluation started: .... / .... / 20... Date coverage evaluation completed: .... / .... / 20...

Total number of households in the site: ..... Total population:.....

Ref. No. a	Name of head of household b	No. in family			No. present*			No. ingested drug°			No. had s/reactions		
		2-5 c	6-14 d	>14 e	2-5 f	6-14 g	>14 h	2-5 i	6-14 j	>14 k	2-5 l	6-14 m	>14 n
1.													
2.													
3.													
4.													
5.													
6.													
7.													
8.													
9.													
10.													
493.													
494.													
495.													
496.													
497.													
498.													
499.													
500.													
	TOTAL												

Coverage (%) in 2-5 yrs : ..... i \* 100/f

Coverage (%) in 6-14 yrs: ..... j \* 100/g

Coverage (%) in adults : ..... k \* 100/h

Side reaction (%) in 2-5 yrs : ..... l \* 100/i

Side reaction (%) in 6-14 yrs: ..... m \* 100/j

Side reaction (%) in adults : ..... n \* 100/k

**Proforma for district compilation of drug coverage and reporting**

District: ..... State: .....

Total census population: ..... Reference Census year: ..... Estimated population for: ..... (distribution year)

Mass drug administration cycle: ..... Period of Mass drug administration: ..... to .....

S. NO	Reporting unit/Urban area	No. of villages/wards		No. of tablets shipped		No. of tablets consumed		Population estimate for the year	Individuals received adequate treatment	Reported coverage rate	Observed coverage in cross-check sites			
		in the unit	covered	Albendazole	ivermectin	Albendazole	ivermectin				Individuals cross checked	Individuals ingesting tablets	Observed coverage	
	<b>Brought forward</b>													
	<b>Total for</b>													

Village coverage rate: ..... Signature of Reporting Officer: .....  
 Reported MDA coverage rate: ..... Name of Reporting Officer: .....  
 Observed MDA coverage rate: ..... Designation of Reporting officer: .....  
 Date Reported: .....



**Proforma for regional compilation of district-wise drug coverage and reporting**

Region: .....  
 Total census population: ..... Reference Census year: ..... Estimated population for: ..... (distribution year)  
 Mass drug administration cycle: ..... Period of Mass drug administration: ..... to .....

S. NO	Reporting District	No. of villages/wards		No. of tablets shipped		No. of tablets consumed		Population estimate for the year	Individuals received adequate treatment	Reported coverage rate	Observed coverage in cross-check sites	
		in the District	covered	Albendazole	ivermectin	Albendazole	ivermectin				Individuals cross checked	Individuals ingesting tablets
	<b>Brought forward</b>											
<b>Total for</b>												

Village coverage rate: ..... Signature of Reporting Officer: .....  
 Reported MDA coverage rate: ..... Name of Reporting Officer: .....  
 Observed MDA coverage rate: ..... Designation of Reporting officer: .....  
 Date Reported: .....

**ANNEX 3**

**Proforma for recording longitudinal coverage and microfilaraemia rates**

Administrative unit: ..... District: ..... Region: .....

Sentinel site one: ..... Sentinel site two: .....

Round			Coverage rate (%)				mf rate per 100				Average mf density			
	End-Date of MDA	End-date of Survey	Sentinel site 1	Sentinel site 2	Spot 1	Spot 2	Sentinel site 1	Sentinel site 2	Spot 1	Spot 2	Sentinel site 1	Sentinel site 2	Spot 1	Spot 2
Base														
1.														
2.														
3.														
4.														
5.														
6.														
7.														
8.														
9.														
10.														
11.														
12.														
13.														
14.														
15.														

Note: Sentinel sites 1 and 2 continue to remain the same while after every round the spot-check site is changed (see text for details)

ALLOCATION OF LF EXPENSES

ANNEX 4

START-UP FUNCTIONS:..... PROGRAMME FUNCTIONS: .....

	PROGRAMME		TRAIN THE TRAINER	DEVELOPING IEC PRGM	DRUG DISTRIBUTION:		MASS CHEMO	MONITOR/EVOLUTION:		TRMT. OF CLINICAL DIS.	ADVERSE REACTION	LAB SERVICES	VECTOR CONTROL	SALT FORTIFICATION
	DEVELOP	MAPPING			CENTRAL	PERIPHERAL		EPI	FISCAL					
	(ADMIN COSTS)													
<b>START-UP COSTS:</b>														
BUILDING/REAL ESTATE														
VEHICLES														
EQUIPMENT: OFFICE														
LAB														
WAREHOUSE														
CONSULTANTS														
INITIAL DRUG INVENTORY														
<b>RECURRENT COSTS:</b>														
OFFICE:														
PERSONNEL														
RENT														
UTILITIES														
SUPPLIES														
PHONE USAGE														
POSTAGE/SHIPPING														
MAINTENANCE														
OTHER DIRECT COST														
FIELD:														
PERSONNEL														
ALLOWANCES/PER DIEM														
OFFICE USE														
COMMUNICATIONS														
SUPPLIES/RECORDS														



**ANNEX 5****Guidelines for monitoring the distribution of co-administered albendazole and ivermectin during filariasis elimination programme**

The following WHO **recommendations** emerged from independent reviews (see appended summary) that Merck & Co. Inc, SmithKline Beecham and WHO conducted during November 1999 of the safety documentation developed by Dr John Horton (SmithKline Beecham) and Prof. Jens Schou (consultant for WHO). The purpose of this document is to advise and support the expansion into the next phase of programmes by the participating countries.

**I. Implementation**

In all countries (or regions of large countries) where the albendazole + ivermectin co-administration regimen will be used, **active surveillance/monitoring should be established during the initial roll out of a programme.** In practice, such monitoring should cover 1 000-2 000 subjects per programme.

This active surveillance (monitoring at day 5, 6 or 7 post treatment) to collect safety data should be conducted to a standard methodology that will permit comparison of data from diverse sources. It should concentrate on the incidence of clinical events, reported in detail according to an established list. Based on the current experience, any unusual (not seen in the current data set) or serious (sufficient to hospitalize subjects or death temporally associated with treatment) events must be reported through a defined process to WHO and to the manufacturers, both Merck & Co., Inc. and SmithKline Beecham. Prompt reporting will permit review and evaluation of these events in context.

As programmes increase in size (and anywhere where active surveillance is not underway), a **passive reporting process** should be established. In all programmes, during the treatment phase there should be sufficient access to primary health care (village clinics, health posts, village paramedics, community nurses, etc.) to enable programme participants to report any problems that arise (in contrast to the active follow-up and questioning envisaged in the active monitoring above).

An **onward reporting process** should be established within all programme areas. A method of data collection of the non-urgent reports from active and passive surveillance must be established. This should be centralised and clearly defined. There are two reasons for this:

- 1) There is a need for the programme to have a regular review of safety data to ensure that there are no concerning issues.
- 2) The companies have a legal obligation to report on safety relating to their products in several jurisdictions. This is of greater importance in the area of severe adverse events, but should encompass a review of all recorded events.

## **2. Management of Adverse Reactions**

The most important principle underlying the management of adverse reactions is that the community should be informed in advance of the possibility that such reactions can occur and that when they do occur, they will be primarily in those individuals with moderate to heavy infections whose parasites are being killed by the drugs. Equally important is the ensuring of access to, and provision of, appropriate medical attention for all those who need it following the administration of the drugs. Health centres and local practitioners should be familiarized with the symptoms that might occur and be prepared to administer treatment, either palliative (e.g., paracetamol, phenergan) or therapeutic (e.g., intravenous fluids, cortisone) as required.

## **3. Monitoring and Reporting of Adverse Experiences**

- a) For all communities receiving co-administered albendazole and ivermectin as part of a programme to eliminate lymphatic filariasis, any serious adverse event (SAE) must be identified and handled in the most medically responsible way possible.
- b) The SAE must then be reported immediately on an appropriate form (to be supplied) to WHO, to SmithKline Beecham and to Merck & Co., Inc. This requirement means that there must be a defined route of communication and access from the patient to the healthcare system that is well understood and available during at least the first week (and preferably, 2 weeks) following drug administration.
- c) For other side reactions that might develop, medical care must also be available, but no specific monitoring or reporting of side reactions is required.
- d) Reviews of all safety data (including Periodic Safety Update Reports) should be carried out at least annually (or ideally every 6 months during the first 2 years and then annually up to 5 years). This evaluation should be done in the context of programme achievements and particularly with efficacy indicators. This will provide a detailed review of data at a close enough frequency to identify any issues of concern during the early roll-out.
- e) Specific persons in WHO and the involved companies should be identified for the reporting of adverse events and for the conduct of regular reviews.

## **4. Current contra-indications to use the 2-drug regimen**

The use of the albendazole + ivermectin co-administration regimen is contra-indicated in:

- a) Pregnancy (the methods to exclude such individuals should be established before wide distribution is implemented)
- b) Children <15 kg body weight or <90 cm height (approx. 5 yrs old).
- c) Loa loa endemic areas
- d) Individuals with obvious clinical illness (especially fever at the time of treatment)
- e) Breast-feeding mothers (during the infant's first week of life).

**5. Continuing investigation is needed to elucidate/expand information on:**

- a) Efficacy: It is important to continue to acquire data on the efficacy and the specific advantages to the programme of the regimens used. These should include observations on the comparative microfilaricidal efficacy of single drug regimens and 2-drug co-administration regimens.
- b) The effects of albendazole + ivermectin in:
  - onchocerciasis patients with LF co-infection (especially those not previously treated with ivermectin)
  - Loa loa infected patients
  - LF or onchocerciasis patients coinfecting with Loa loa
  - Patients with heavy intestinal helminth infections
- c) Pharmacokinetic studies on albendazole + ivermectin in LF patients
- d) Clinical laboratory data following treatment with albendazole + ivermectin regimen.

**6. The current “safety” datasets should be made available to LF elimination programmes as part of the documents provided to allow decisions to be made at the local level.**

I Defined formally as an event which is fatal, life-threatening, disabling or incapacitating; which results in hospitalization or a prolonged hospital stay; or which is associated with congenital abnormality, cancer or overdose (either accidental or intentional).

**Notes**



**APPENDIX TO ANNEX 5****Summary of assessment of safety data from the use of co-administered *Albendazole + Ivermectin* in individuals with or without lymphatic filariasis****A. Dataset under review**

Observations on subjects receiving single doses of co-administered albendazole + ivermectin (8 986), ivermectin alone [9 626], albendazole alone [1 325]), or placebo (1 002) in WHO- coordinated studies were reviewed for safety. These studies ranged from detailed in-hospital evaluations, to field studies with active surveillance for drug safety and large scale programmes with passive monitoring for safety.

**B. Appropriateness of dataset**

The geographical distribution of studies mirrored that of the distribution of lymphatic filariasis. The studies included sufficient numbers of both sexes and all age ranges, together with an adequate ethnic mix to provide data relevant to the target populations. Of the 8 986 persons treated with ivermectin and albendazole, only 608 were identified as being microfilaraemic at the time of treatment, and of these 183 with reported events were assessed.

Whilst the results with the known microfilaraemic patients (the potentially high risk group) are encouraging (i.e., lack serious adverse side effects) these observations on comparatively small numbers of individuals should be built upon by acquiring data in the treatment programmes as they develop.

**C. Principal Findings**

1. The observed safety event profiles for the single-dose, co-administration regimen were similar to the clinical responses induced by the destruction of microfilariae by any microfilaricidal drug.
2. These safety event profiles for the co-administration regimen differed little from those known historically for ivermectin when administered alone as a single dose and confirmed by single drug data in the studies themselves.
3. In patients with microfilaraemia, the addition of albendazole to the treatment regimen did not appear to increase the frequency or intensity of adverse events seen when the microfilaricidal drug (ivermectin) was used alone.

## D. Conclusions

1. No Serious Adverse Events (SAE) were identified in the relatively small study populations with documented microfilaraemia. Neither were any obvious safety concerns identified either in 'non LF-infected' or in LF-infected individuals, including cases with overt lymphatic disease. However, it is important to continue to build upon these findings with an even greater data base of safety related information.
2. Sufficient safety data exist to support expansion of the LF elimination programme to all areas where albendazole + ivermectin would be used. However, there remains (and will always remain) an obligation for due diligence in the monitoring and management of treatment in 'at risk' populations (see Recommendations attached).
3. Other areas in which safety-related information on the co-administration of albendazole + ivermectin was considered to be limited or to require additional observations include:
  - a. Use in the following clinical situations:
    - 1) Pregnancy
    - 2) Children <15 kg body weight or <90 cm height (approx. 5 yrs)
    - 3) Children breast-feeding from mothers receiving treatment
    - 4) Patients with Loa loa infection
    - 5) Patients with onchocerciasis-LF coinfections
    - 6) Individuals having both LF and heavy intestinal helminth infections or cysticercosis.
  - b. Clinical laboratory data on the co-administration regimen.
  - c. Pharmacokinetic data for the co-administration regimen.

### Patient monitoring form albendazole and ivermectin co-administration

Form number: .....

Interviewer: .....

Family name: ..... First name: ..... Village: .....

Age: ..... Sex: ..... Height .....(cm/ft) Weight: .....(kg/lbs)

Occupation .....

Treatment location: ..... Date: .....

Patient's response to: ..... Day/month/year. ....

1. How have you been feeling since taking the tablets? Good ..... Otherwise .....

(if OTHERWISE please fill in treatment effect table)

2. When did you take the tablets?  morning  afternoon  night  before  after meal

3. How many tablets did you take? albendazole (large tablets) ..... DEC (small tablets) .....

This form is being filled out on Day-5 / Day-6 / Day-7 (circle one) post-treatment .....

Indicate an answer in each box below, using the following code\* for responses

0 = did not feel sick, 1 = mild, 2 = moderate, 3 = severe

If very severe, please complete Serious Adverse Experience Form

Symptom/Sign	Days post-treatment when symptoms were present							
	0	1	2	3	4	5	6	7
Headache								
Fever								
Dizziness								
Fatigue								
Nausea								
Vomiting								
Diarrhoea								
Abdominal Pain								
Joint/Muscle Pain								
Oedema								
Swelling:								
upper/lower limb								
skin/nodes/scrotum								
Rash								
Scrotal reaction								
Presence of nodules								
Passing worms								
Other (specify below)								

Comments and observations (use back of page, if necessary): .....

\* The definitions are provided separately