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GLOBAL PROGRAMME

TO ELIMINATE

LYMPHATIC FILARIASIS



World Health Organization

Annual
Report
on Lymphatic
Filariasis

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Annual Report on Lymphatic Filariasis



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1

Global Programme to Eliminate Lymphatic Filariasis (GPELF)

PROGRAMME HIGHLIGHTS

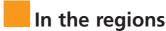
2001 – The Programme gains momentum



In the countries

- A total of 26 million people in 22 countries were administered a 2-drug, once-yearly treatment in the second year of mass drug administration (MDA) in 2001, almost a ten-fold increase from the year 2000.
- Eleven countries, whose national plans and requests for donated drugs were reviewed and approved, will implement their national programmes in 2002.
- A total of 44 million albendazole tablets were shipped by GlaxoSmithKline to 26 countries for either the first or a subsequent round of mass drug administration.
- A total of 22 million ivermectin tablets (Mectizan®) were shipped by Merck & Co., Inc. to 8 countries covered by the African and Eastern Mediterranean Programme Review Groups; 15.5 million were for MDA in areas with only lymphatic filariasis (LF) while 6.5 million were for areas where lymphatic filariasis and onchocerciasis are co-endemic.
- Surveys continued in all the regions to map implementation units with LF transmission.

PROGRAMME HIGHLIGHTS



- Four of the six regional programme review groups met for the first time in 2001, and two had their first meeting in January 2002. In these meetings, roles and effective working mechanisms were discussed and new plans and re-applications for drugs were reviewed.
- Four workshops on mapping were conducted
 three in Africa and one for the countries of the Mekong-Plus programme review group.
- Ten participants from India and 12 from other countries in the South-East Asian Region were trained on disability prevention and alleviation in Pondicherry, India.
- Twenty-two programme managers were trained in an interregional workshop for countries in the South-East Asian and Western Pacific Regions in programme planning, implementation, management and monitoring held, in Kuala Lumpur, Malaysia.
- The 3rd PacELF Annual Meeting took place in Nadi, Fiji on 24-29 September 2001 with twenty-eight participants from 17 countries.

At the global level

- The Technical Advisory Group (TAG) met for the second time to discuss the issues of monitoring the safety of mass drug co-administration regimens, verifying the absence of infection and interruption of transmission, preventing and alleviating disability caused by lymphatic filariasis, and the supply and dosage forms of diethylcarbamazine citrate (DEC). On the recommendation of the TAG, the Chairman continued working in close collaboration with the Programme from the second half of 2001. In association with the Secretariat, the current priorities
- The process of regionalization of the Programme Review Group was completed. Six regional programme review groups were created, where necessary, based on epidemiological requirements rather than the WHO regional organization.

were examined and the topics for discussion

by the next TAG identified.

- As a follow-up to the recommendation of the TAG, the data accumulated from the active surveillance were reviewed with the pharmacovigilance specialist of the TAG. The results indicated that the co-administered regimens were safe for wide-scale use. The reactions were qualitatively and quantitatively similar to those reported previously and appeared to be related to the therapeutic effects of the co-administered drugs.
- Training modules for drug distributors on disability prevention and control were published.

Introduction

This report highlights the progress made during the year 2001 in activities aimed at the elimination of lymphatic filariasis (LF) worldwide.

There are more than a billion people who are at risk of lymphatic filariasis, which is not a killer disease. The infection is caused by thread-like worms (filariae) which lodge in the lymphatic system, producing millions of minute larvae (microfilariae) that circulate in the blood. Although infection often occurs in childhood, the symptoms are commonly delayed until adulthood.

Over 120 million people are currently living with the disease, including about 40 million who are incapacitated and disfigured by it. Of all diseases, lymphatic filariasis is the second leading cause of permanent and long-term disability.

Until recently, the diagnosis of lymphatic filariasis depended on night blood examinations to detect microfilariae. Now, there is an antigendetection test that can be taken at any time of the day, making it feasible to map the disease geographically. Drugs, which are available free or at low cost, kill the microfilariae in the blood. Simple methods of hygiene and self-care can reduce the effects of the disease. With such effective tools to hand, the Fiftieth World Health Assembly, in 1997, resolved to eliminate lymphatic filariasis as a public health problem. This report discusses the progress so far.

- Chapter 1 outlines the causes and effects of the disease, showing how an understanding of the transmission mechanisms led to a consensus on the most effective strategy to pursue. This strategy has two goals: first, to interrupt transmission of infection so as to protect future generations; and second, to prevent or alleviate the suffering of those who already have the disease.
- Chapter 2 describes the creation and development of the WHO Programme to Eliminate Lymphatic Filariasis (PELF). One of the dynamic outcomes of this Programme is the launching of a global alliance, comprising ministers of health of endemic countries, the private sector, international development agencies, nongovernmental organizations, international organization and academic institutions.
- Chapter 3 looks at the activities in the regions and countries, showing how the global strategy is being implemented in practice and how the programme is finding innovative ways to overcome the specific challenges that countries and communities face. In this respect, advocacy and awarenessbuilding are vital components of the programme, as the whole population at risk must be convinced of the importance of taking anti-filarial drugs.
- Chapter 4 views the Programme to Eliminate Lymphatic Filariasis from a health systems perspective. Obviously, the Programme does not exist in a vacuum. It relies on the health systems in endemic countries to deliver the necessary drugs and promote proper care for those affected by the disease. Moreover, it strengthens health systems by providing training and expertise in disease mapping, drug delivery strategies, and social mobilization. Efforts to eliminate lymphatic filariasis also provide a welcome bonus in terms of reducing the problems related to soil-transmitted helminths. Finally, this chapter identifies future challenges and sets out the targets to be met in order to reach the goal of eliminating lymphatic filariasis.



Chapter 1 Understanding the problem

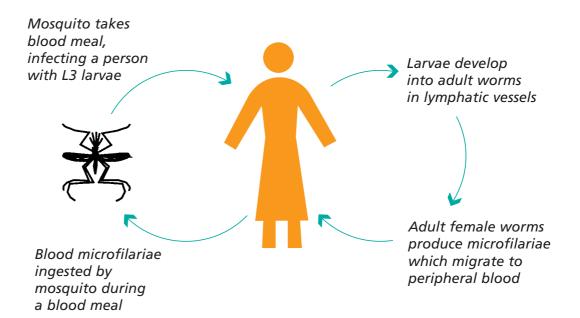
The disease

Lymphatic filariasis, also known as elephantiasis, is caused by the threadlike parasitic worms *Wuchereria bancrofti*, *Brugia malayi* and *Brugia timori*. These worms lodge in the lymphatic system, which is a network of lymph nodes and vessels maintaining the fluid balance between the tissues and the blood, and an essential component of the body's immune defence system. The worms live for 4–6 years, producing millions of minute larvae (microfilariae) which circulate in the blood.

Transmission of lymphatic filariasis

The disease is transmitted by mosquitoes, but the reservoir of infection is 90% human. The mosquito bites an infected person and picks up the microfilariae which develop inside the mosquito into the infective stage, in a process that usually takes 7–21 days. The larvae then migrate to the biting mouthparts of the mosquito, and enter the punctured skin of the person who is next bitten by the mosquito. The life-cycle of lymphatic filariasis is illustrated schematically in Figure 1.1.

Figure 1.1. Lymphatic filariasis life cycle



Clinical forms

Although the majority of people infected with the parasites that cause lymphatic filariasis have no outward symptoms, virtually all of them suffer subclinical lymphatic damage. Some 40% of those infected suffer renal damage, resulting in blood in the urine (haematuria) and an excess of serum proteins in the urine (proteinuria).

Infection can lead to a variety of clinical manifestations, including lymphoedema and elephantiasis of the limbs, as well as genital diseases, especially hydrocoele, chylocoele, and elephantiasis of the scrotum and penis. Infection can also lead to acute, recurrent secondary bacterial infections, known as "acute attacks".

The most significant factor in producing lymphoedema and elephantiasis, which compounds the damage caused by filarial parasites, is bacterial and fungal 'superinfection' of the skin. These infections cause severe, febrile syndromes in patients, while further destroying the delicate lymphatic vessels and exacerbating both progression of the disease and frequency of clinical symptoms.

The most obvious manifestations of lymphatic filariasis are enlargement of the entire leg or arm, the genitals, vulva or breasts. In endemic communities, 10–50% of men and up to 10% of women can be affected.

■ Chapter 1 Understanding the problem

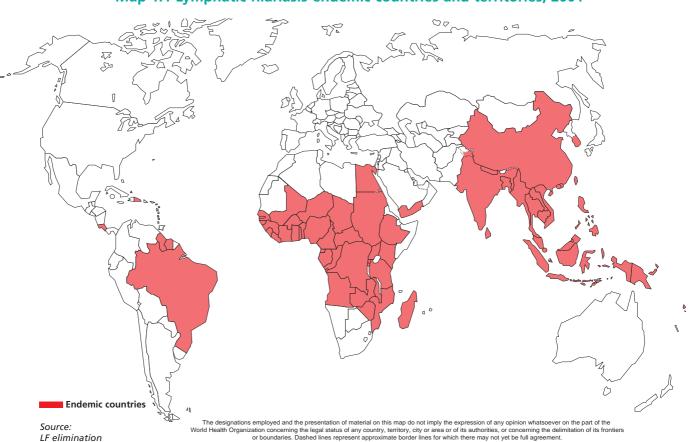
Global burden

LF elimination programme

Lymphatic filariasis is primarily a disease of the poor because of its prevalence in remote rural areas and in disfavoured peri-urban and urban areas. In recent years, lymphatic filariasis has steadily increased because of the expansion of slum areas and poverty, especially in Africa and the Indian subcontinent. Some 120 million people are infected worldwide, and the disease is endemic in more than 80 countries and territories (Map 1.1). Globally, lymphatic filariasis is thought to be the second leading cause of permanent and long-term disability.

An estimated 118 million people have one form or other of the clinical disease.

Of these, 74 million who are microfilaraemic but asymptomatic have hidden lymphatic and renal pathology. Another 27 million men in endemic areas are believed to have hydrocoele due to filariasis. In addition, approximately 16 million people have lymphoedema or elephantiasis along with the accompanying recurrent episodes of acute adenolymphangitis. Lastly, a million individuals have cryptic infections resulting in conditions such as tropical pulmonary eosinophilia (TPE).



Map 1.1 Lymphatic filariasis-endemic-countries and territories, 2001

Most infections are acquired in childhood, with a long period of subclinical disease before the characteristic, overt clinical manifestations appear in adults. The re-evaluation of previous underestimated figures of lymphatic filariasis in children may well lead to the disease being identified as the leading cause of permanent and long-term disability worldwide. Recognition of this fact means that children will be the principal beneficiaries of any programme for the elimination of lymphatic filariasis, and they represent a particularly important target population for the programme to achieve its twin goals of interrupting transmission and preventing disease.

Among tropical diseases, only malaria causes a greater burden, as measured in disability-adjusted lifeyears (DALYs). Lymphatic filariasis reduces peoples ability to work, resulting in loss of family income. Furthermore, sufferers often waste money on costly but ineffective treatments. In India alone, the economic losses resulting from decreased productivity and lost workdays are estimated to be of the order of US\$ 1 billion annually.

Box 1.1

FIFTIETH WORLD HEALTH ASSEMBLY

WHA50.29 13 May 1997

Agenda item 20

Elimination of lymphatic filariasis as a public health problem

The Fiftieth World Health Assembly,

Deeply concerned at the widening spread and increased distribution of lymphatic filariasis throughout the world in both urban and rural areas and concerned that it affects all ages and both sexes;

Appreciating with grave concern the human suffering, social stigma and costs to society associated with lymphatic filariasis morbidity;

Recognizing that there is a general lack of awareness concerning this disease and its impact on health status, and that there are insufficient data on its prevalence and distribution:

Welcoming the recent studies which have defined new, simplified, highly effective strategies;

Acknowledging that an international task force on disease eradication has recently identified lymphatic filariasis as one of only six "potentially eradicable" infectious diseases,

URGES Member States:

- (1) to take advantage of recent advances in the understanding of lymphatic filariasis and the new opportunities for its elimination by developing national plans leading to its elimination, as well as for the monitoring and evaluation of programme activities:
- (2) to strengthen local programmes and their integration with the control of other diseases, particularly at the community level. in order to implement simple, affordable, acceptable and sustainable activities based on community-wide treatment strategies, but supplemented where feasible by vector control and improved sanitation;
- (3) to strengthen training, research, diagnostic laboratory, disease and data management capabilities in order to improve clinical, epidemiological and operational activities directed toward eliminating lymphatic filariasis as a public health problem..
- (4) to mobilize support of all relevant sectors, affected communities and non-governmental organizations for the elimination of the disease.
- INVITES other specialized agencies of the United Nations system, bilateral
 development agencies, nongovernmental organizations and other groups concerned.
 to increase cooperation in the elimination of lymphatic filariasis through support of
 national and international programmes relevant to the prevention and elimination of
 lymphatic filariasis;

REQUESTS the Director-General:

- (1) to bring to the attention of the other specialized agencies and organizations of the United Nations system, bilateral development agencies, nongovernmental organizations and other groups concerned the need for closer collaboration in the elimination of lymphatic filariasis as a public health problem;
- (2) to mobilize support for global and national elimination activities;
- (3) to keep the Executive Board and Health Assembly informed as necessary of progress in the implementation of this resolution.

Ninth plenary meeting, 13 May 1997 A50/VR/9

WHO's global strategy to eliminate lymphatic filariasis

In 1997, the World Health Assembly decided that lymphatic filariasis should be eliminated as a public health problem, and outlined a strategy to achieve that goal (Box 1.1).

Elimination of lymphatic filariasis means a reduction of the disease incidence close to zero as a result of deliberate efforts requiring continued and coordinated activities. WHO's strategy comprises two components — interruption of transmission, and care for those who already have the disease.

To interrupt the transmission of infection, the entire population at risk must be covered by mass drug administration (MDA) for a period long enough to ensure that the level of microfilariae in the blood remains below that which is necessary to sustain transmission. The following drug regimens are recommended, which must be administered once a year for at least 5 years or until the transmission has been interrupted:

- 6 mg/kg diethylcarbamazine (DEC) + 400 mg albendazole; or
- 150 µg/kg ivermectin
 - + 400 mg albendazole.

A third option is to follow a treatment regimen using DEC-fortified cooking salt daily for a period of 6–12 months.

Although vector control is not advocated as an operational component, the programme encourages its application as part of other ongoing integrated vector control activities. This approach is primarily intended to channel the available resources in national programmes towards achieving a high level of drug coverage. During the last quarter of

2001, preparations were made to conduct an informal consultation (in Geneva, Switzerland on 29–31 January 2002) to define the role of vector control and xenomonitoring in the Global Programme to Eliminate Lymphatic Filariasis.

The elimination of lymphatic filariasis is possible but it is important to act quickly. Both the combined drug regimens and the enriched salt regimen are effective. However, the combination with a second drug increases the microfilaricidal effect and sustains it for longer periods. The use of two drugs, in principle, also reduces the risk of development of resistance to either drug. Because of the human reservoir of infection for Wuchereria bancrofti (accounting for more than 90% of persons with lymphatic filariasis) and bearing in mind the difficulty associated with vector control, the most effective strategy to eliminate lymphatic filariasis is to treat the entire population at risk in defined geographical areas. This is possible because an easy-to-use diagnostic test enables endemic areas to be mapped rapidly, and because the drugs required for mass campaigns are available free of charge. Thus, all members of the population who are eligible should be covered by MDA, thereby eliminating the need to assess (laboriously and with recognized inaccuracy) the presence of infection in each individual. In the case of Brugia malayi and B. timori, however, a number of other animals (particularly felines and monkeys) may also harbour the infection. This is an important issue that must be addressed as the elimination effort goes forward.

While the drug regimens outlined above can interrupt transmission of the disease in the future, they will not cure people who are already affected by it, although the drugs do reduce some of the symptoms. Thus, in addition



Figure 1.2: Simple hygiene to alleviate and prevent disability. From "Lymphatic Filariasis", a comic book for primary and secondary schoolchildren.

to aiming at interrupting transmission, the elimination strategy has a second objective: to prevent the occurrence of any disability or deformity that is not already present, to prevent the worsening of existing disabilities and deformities, and to alleviate the social burden due to the disease.

Impairment and disability in lymphatic filariasis are due to either lymphoedema and the associated repeated attacks of adenolymphangitis, or urogenital manifestations of the disease such as hydrocoele. The Programme emphasizes care and support for the patients who are affected by the chronic consequences of lymphatic filariasis, such as lymphoedema and the urogenital manifestations like hydrocoele. It utilizes scientific knowledge that identifies secondary bacterial infection as a key factor for the progression of the disease in patients with lymphoedema. Simple methods of self-care and hygiene can rid patients of their bacterial infection, and the patients (especially with help from the community) can easily carry out these tasks themselves.

Preventing bacterial super-infection removes some of the factors responsible for disease progression, and thus makes it possible to stop the disease. Such prevention can be effected through regular washing (Figure 1.2) and skin care. Other simple practices, such as exercise, elevating the affected limb and wearing appropriate footwear, will also relieve symptoms due to lymphoedema.

During the year 2001, the Programme attempted to identify the elements and

the process of defining a strategy for the prevention and alleviation of disability associated with lymphatic filariasis. Meetings were organized with groups that have experience in similar activities (e.g. Handicap International, International Foundation for Dermatology, and International Skin Care Nursing Group) and with national programme managers to help evolve the principles of the global strategy. The conceptual framework of this strategy is to be presented at the 3rd meeting of the TAG in 2002.

Finding the answers

The World Health Assembly has provided guidance on how the problem of lymphatic filariasis, as outlined above, should be solved. Translating that guidance into practical application is no small task and will require the active participation of the endemic communities, ministries of health, international organizations and the private sector. The WHO Programme to Eliminate Lymphatic Filariasis pursues the scientific approach of framing questions and trying to find answers to questions such as:

- What is the population at risk?
- What is needed in the way of management, financing and logistics?
- How can surveillance and follow-up be ensured?

The chapters that follow describe the progress made so far in these matters, focusing on the activities carried out in the year 2001.

Chapter 2

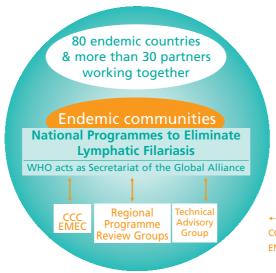
Supporting the Global Initiative

The start of the global initiative

The WHO Programme for the Elimination of Lymphatic Filariasis (PELF) enjoys the backing of the international health community — represented by the World Health Assembly — which meets every year and brings together health ministers from 199 countries to discuss matters of public health importance and to direct the work of WHO. As mentioned above, the World Health Assembly in 1997, considered the problem of lymphatic filariasis and decided that WHO should work towards its elimination. That decision is embodied in resolution WHA50.29 (see Box 1.1 above).

It was clear from the outset that such a huge programme would require a dynamic and flexible structure to ensure that the resources and the activities were well managed. The relationship between the partners involved in the global programme are illustrated in Figure 2.1. The activities of the various components of the global programme are discussed below, as well as aspects of financing, in-kind support, and logistics.

Figure 2.1 Global Alliance to Eliminate Lymphatic Filariasis



The Global Alliance to Eliminate Lymphatic Filariasis

While preparing the technical basis for the massive public health undertaking to eliminate lymphatic filariasis, WHO endeavoured to bring together a broad coalition of partners to share in this global effort.

A global coalition was forged between many organizations, each with a different mandate but all having a common goal: to tackle the wide-ranging and complex process of science and practice that will result in the elimination from the world of lymphatic filariasis as a public health problem.

Early support in the task of eliminating lymphatic filariasis came from the ministries of health of the endemic countries and a number of international organizations, including the Arab Fund for Economic and Social Development (AFESD), the United States Centers for Disease Control and Prevention (CDC), and the Department for International Development in the United Kingdom (DFID).

In 1998, the coalition was given a powerful boost when GlaxoSmithKline (formely SmithKline Beecham) announced its commitment to collaborate with WHO in a unique partnership

Coordination/Communications/Technical Advice
 GSK/WHO Collaborating Coordination Committee
 EMEC: Expanded Mectizan® Expert Committee

between the private sector and the public sector to support the Global Programme to Eliminate Lymphatic filariasis, by donating albendazole (one of the drugs used against lymphatic filariasis) free of charge for as long as necessary. The two parties 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 for onchocerciasis (river blindness) to cover treatment of lymphatic filariasis with ivermectin in all African countries where the two diseases occur together. The donations will enable countries which are in need, but which are without the necessary resources, to acquire the drugs and to pursue their national elimination programmes.

These drug donations triggered a process that has evolved continuously since its inception. To date, GlaxoSmithKline has provided more than 58 million tablets of albendazole to WHO for use in LF-endemic countries, and Merck & Co., Inc. has provided more than 17 million tablets of ivermectin directly to the African lymphatic filariasis programmes, in addition to its donation for those areas where PELF is being implemented in onchocerciasis co-endemic areas. The Mectizan® Donation Program and its Expert Committee are responsible for the approval of ivermectin donation in African countries where onchocerciasis is co-endemic with lymphatic filariasis.

In 2000, the Bill and Melinda Gates Foundation donated US\$ 20 million to support lymphatic filariasis activities from 2000 to 2004. The grant proposal to the Bill and Melinda Gates Foundation was developed by representatives of most of the principal partners in the Global Alliance and was finalized at a meeting of more than 20 individuals representing these partners in Atlanta, GA, USA, during the first week of September 2000. The structure of the proposal was such that there were to be four 'nodes' of activity receiving funds: that of WHO; a group based in Atlanta, USA (primarily comprising Rollins School of Public Health, the Centers for Disease Control and Prevention, and the Carter Center); a group of nongovernmental development organizations; and the Liverpool LF Support Centre (together with other academic partners).

WHO uses the grant to finance the implementation of activities in the following fields: 1) field interventions; 2) training, communication and information; and 3) technical meetings, coordination and monitoring. In addition to the endemic countries, the Alliance has broadened to include more than 30 organizations from various sectors of society, including the public and private sectors, academia, government bodies, and nongovernmental development organizations (Box 2.1).

■ Chapter 2 Supporting the Global Initiative

Box 2.1 List of the partners of the Global Alliance to Eliminate Lymphatic Filariasis

National Ministries of Health

■ Ministries of Health of the 80 endemic countries

International Organizations

- The World Bank
- United Nations Children's Fund UNICEF
- World Health Organization WHO

Private Sector

- Binax, Inc., USA
- Merck & Co., Inc., USA
- GlaxoSmithKline, UK

International Development Agencies and Foundations

- Arab Fund for Economic and Social Development (AFESD), Kuwait
- Bill and Melinda Gates Foundation, USA
- Centers for Disease Control and Prevention (CDC), Atlanta, USA
- Department for International Development (DFID), UK
- Directorate General for Development Cooperation (DGCS), Italy
- Japan International Cooperation Agency (JICA), Japan
- Ministry of Health and Welfare, Japan
- Ministère fédéral des Affaires sociales, de la Santé publique et de l'Environnment, Belgium
- Ministerio de Sanidad y Consumo, Spain
- Ministry of Health, Welfare and Sport, The Netherlands

Nongovernmental Development Organizations

- Amaury Couthino, Brazil
- Global 2000 of the Task Force for Child Survival, USA
- Handicap International, France
- Health and Development International (HDI), Norway
- International Foundation for Dermatology, UK
- International Skin Care Nursing Group, UK
- Interchurch Medical Assistance (IMA), USA
- International Volunteers in Urology, USA
- The Carter Center, Atlanta, USA
- The Centres for Partnerships in Health, Australia
- The Mectizan® Donation Program, USA
- World Alliance for Community Health, Canada

Academia and Research Institutions

- Ain Shams University, Egypt
- Bernhard Nocht Institute for Tropical Medicine, Germany
- Chinese Academy of Preventive Medicine, China
- Danish Bilharziasis Laboratory (DBL),Denmark
- Emory University, Atlanta, USA
- Institute for Medical Research (IMR), Malaysia
- James Cook University, Australia
- Lymphatic Filariasis Support Centre
 Liverpool School of Tropical Medicine, UK
- Michigan State University, USA
- Notre Dame University, USA
- Universidade Federal de Pernambuco, Brazil
- Vector Control Research Centre (VCRC), Indian Council of Medical Research, India
- Washington University in St. Louis -Barnes-Jewish Hospital, USA

The Global Alliance was formed during a meeting at Santiago de Compostela, Spain, in May 2000. During this first meeting the discussions focused on support (including funding) for effective country action, communication and information needs, the role of non- governmental development organizations in national programmes to eliminate lymphatic filariasis, critical elements for successful programmes, and on maximizing regional cooperation.

The second meeting of the Global Alliance (to be held in New Delhi, India, in May 2002) will focus on empowering countries and their people to manage public health development and pursue poverty alleviation through the elimination of lymphatic filariasis. Representatives of the Global Alliance will discuss national ownership of elimination programmes, poverty alleviation and sustainable development related to lymphatic filariasis elimination, and the commitment to global partnership as well as national-level partnerships.

The Global Alliance to Eliminate Lymphatic Filariasis can now envisage the elimination of the disease as the focus of a widely beneficial public health intervention, organized through existing or strengthened national health systems. Individually, none of these partners can eliminate lymphatic filariasis; but by working together, and working through the ministries of health in the endemic countries, the goal can be achieved. Not all partners will work in every country, but together they will cover all the affected countries and will have a positive impact on many millions of lives. Annex 1 contains the reports of major international supporters and partners.

■ Chapter 2 Supporting the Global Initiative

The Technical Advisory Group (TAG)

The TAG advises WHO on key issues (policy, strategy and operations) relevant to implementation, monitoring of the progress and success of the elimination effort. It also identifies research questions that need to be addressed to enhance the acceptability and the sustainability of the Programme.

During its first meeting, which was held parallel to the meeting of the Global Alliance in Spain in 2000, the TAG examined the following issues:

- a) indicators for monitoring programmes to eliminate lymphatic filariasis;
- b) disability prevention and control strategies;
- c) lymphatic filariasis as a childhood disease; and d) ensuring supplies of quality DEC.

The second meeting of the TAG, held in Geneva in March 2001, considered issues related to: a) disability alleviation and prevention; b) verifying the absence of infection or interruption of transmission; c) DEC supply; and d) safety monitoring of drug combinations. Following the recommendations of the TAG, WHO organized a consultative meeting in December 2001 to examine the safety data that had been collected by the Programme. A review of the accumulated data further reaffirmed that the co-administered drugs were safe and there was very little concern about the safety of their wide-scale use. The side-effects observed were conventional reactions, consistent with past experience with the drug combinations.

The TAG recommended that PELF should critically evaluate the role of vector control in the Programme and defined its need in special epidemiological situations.

Accordingly, an informal consultation on

the role of vector control in PELF was planned for January 2002. On the recommendation of the TAG, a social scientist has been included as a TAG member. The Chairman of the TAG collaborated closely on all the activities of the Programme during the second half of 2001. In association with the WHO Secretariat he conducted an analysis of the current priorities of the PELF. Based on this analysis and the current needs of the Programme, the topics for discussion at the next TAG meeting were identified.

The regionalization process

The Global and Regional Programme Review Groups (GPRG and RPRG)

A GPRG was set up under the drug donation Memorandum of Understanding with GlaxoSmithKline, with the task of reviewing applications for donated drugs received from national ministries of health for lymphatic filariasis programmes. With the rapid increase in programme activities, it became clear that programmes could be reviewed more efficiently at regional level.

The seventh meeting of the GPRG, which took place at WHO headquarters, Geneva, Switzerland, on 26–27 February 2001, agreed on the terms of reference of the Regional Programme Review Groups (RPRGs) and six RPRGs were proposed. In the case of the South-East Asian and Western Pacific regions, interregional and subregional groups of countries were created, rather than on the basis of WHO's regions. These groups were based on the epidemiological distribution of lymphatic filariasis in the two regions. Box 2.2 presents the terms of reference of the RPRGs.

Box 2.2 Terms of reference of the RPRGs

- Review and provide guidance to countries in the development of their national plans of action for the elimination of lymphatic filariasis, which are consistent with national public health policies and global and regional strategies for the elimination of disease, and which take into consideration the specific conditions of the region, so that the countries will build on their existing capacities rather than create vertical structures.
- Review the applications and re-applications for drug donations of albendazole (and ivermectin in the onchocerciasis co-endemic countries of the regions concerned), where such drugs form part of the national plans consistent with safe and rational use and the approved prescribing information in all areas where lymphatic filariasis is endemic; in countries where onchocerciasis is co-endemic, the request will be forwarded to the Expanded Mectizan® Expert Committee (EMEC) for final authorization.
- Review the implementation and progress of national programmes and ensure consistency with the regional and global strategies and targets, and make

- recommendations to the WHO Regional Directors on future requests for albendazole and ivermectin, and on scaling up the programmes in the coming years.
- Provide technical guidance on the implementation of the recommendations of the Technical Advisory Group that are relevant to the countries of the region.
- Identify operational research issues arising from the implementation of programmes in the region, and refer them to the relevant research institutions of the region, the Technical Advisory Group, the relevant WHO Regional Office, and the WHO Task Force on Filarial Intervention Research.
- Advise WHO on matters relating to the confirmation of interruption or absence of lymphatic filariasis in the countries of the region.
- Advocate and support WHO Member
 States in seeking political commitments
 from governments and ministries of health
 for the elimination of lymphatic filariasis.

■ Chapter 2 Supporting the Global Initiative

It is clear that a crucial role is going to be played by the Regional Programme Review Groups (RPRGs) in monitoring, assessing, and facilitating the progress of country activities.

A meeting between the chairperson of the GPRG and the chairpersons of the six RPRGs will take place in New Delhi, India, following the second meeting of the Global Alliance. During this meeting the modalities of how to best maintain regular communication among these groups will be discussed.

1. African Programme Review Group

The first meeting of the African PRG on 29–31 October 2001 in Cotonou, Benin, provided an opportunity to bring to the members of the group the results of the operations of the global programme to eliminate lymphatic filariasis and information on the activities of the Technical Advisory Group. Members of the regional group took note of the follow-up actions taken and still outstanding in response to the recommendations of the Global Programme Review Group.

The African PRG reviewed the national plans for Benin, Burkina Faso, Ghana, Kenya, Nigeria, Togo, Uganda, and the United Republic of Tanzania. Some of these plans had already been reviewed by the Global Programme Review Group for the purpose of approving drug applications. The regional group considered its working methods and identified areas of operational research that would be likely to result in improving programme implementation in the countries of the region.

2. American Programme Review Group

The first meeting of the American PRG took place in Georgetown, Guyana, on 23 August 2001. The meeting set in motion the regionalization of the albendazole application process, and identified the technical and non-technical aspects of national plans that could benefit from feedback from the American PRG and the TAG. The meeting reviewed the national plans for Brazil, Costa Rica, Guyana, Haiti, Suriname, and Trinidad and Tobago. None of these plans had been reviewed previously by the Global Programme Review Group. Other issues highlighted during the meeting were: the importance of emphasizing the role of the WHO Representatives in countries in identifying funding; the designation of subcommittees to follow up on funding strategies at country level; and the importance of using the WHO procurement process as the most costeffective mechanism for obtaining drugs and other essential tools.

3. Eastern Mediterranean Programme Review Group

The WHO Regional Office for the Eastern Mediterranean (EMRO) organized the first meeting of the Eastern Mediterranean PRG from 23 to 24 December 2001 in Cairo, Egypt. The agenda of the meeting included a review of the plans of action for the year 2002; review of current global activities on the elimination of lymphatic filariasis; review of progress in elimination activities in Egypt and Yemen; approval of the reapplication request from Egypt and Yemen for drug donation; and discussion on the organization of mapping activities in Sudan.

4. Mekong-Plus Programme Review Group

The first meeting of the Mekong-Plus PRG, which was originally scheduled for December 2001, took place on 8-9 January 2002 in Kuala Lumpur, Malaysia. This interregional group was established to deal with the problem of lymphatic filariasis spreading across the borders of the countries of the WHO South-East Asia and Western Pacific regions. Because of the cross-border migration of people, efforts to eliminate lymphatic filariasis will require the coordinated efforts of countries from both WHO regions. In the light of these epidemiological concerns, an interregional programme review group was established for the countries of the Mekong and the surrounding region, known as the Mekong-Plus PRG. This group consists of Cambodia, China, Lao People's Democratic Republic, Malaysia, Philippines and Vietnam from the WHO Western Pacific Region, and Indonesia, Myanmar and Thailand from the WHO South-East Asian Region.

5. Indian Subcontinent Programme Review Group

The Indian subcontinent PRG is composed of the countries of the WHO South-East Asian Region that are not covered by the Mekong-Plus PRG, along with Bangladesh, India, Maldives, Nepal and Sri Lanka. The first meeting of the Indian Subcontinent PRG, originally scheduled for December 2001, took place on 14–15 January 2002 in New Delhi, India.

This Group will play a key role in the Global Programme as the major burden of filariasis is borne by countries in this region. The Group extensively reviewed the progress being made by these countries and approved the request for albendazole for the second round of mass drug administration (MDA) in Bangladesh and Sri Lanka, and for the first round of MDA in Nepal. The need for rapid scaling-up of operations in these countries was emphasized.

6. PacELF Coordination and Review Group (PacCARE)

The 22 Pacific island countries and territories in the Western Pacific Region (American Samoa, Cook Islands, Federal States of Micronesia, Fiji, French Polynesia, Guam, Kiribati, Marshall Islands, Nauru, New Caledonia and Dependencies, Niue, Northern Mariana Islands, Palau, Papua New Guinea, Pitcairn Islands, Samoa, Solomon Islands, Tokelau, Tonga, Tuvalu, Vanuatu, and Wallis & Futuna Islands) had, already established a lymphatic filariasis elimination programme in 1999 in coordination with the Secretariat for the Pacific Community. This programme is called the Pacific Initiative for the Elimination of Lymphatic Filariasis (PacELF). These Pacific island countries constituted the PacELF Coordination and Review Group (PacCARE) to review the national plans of the Pacific island endemic countries and requests for albendazole. The first meeting of the PacCARE was held in October 2001, and the second in February 2002. The PacELF headquarters is located in Suva, Fiji, and acts as the central warehouse for supplying albendazole to the island countries participating in PacELF.



Chapter 3 Implementing the Programme

This chapter looks first at some of the major areas of activity of the Programme to Eliminate Lymphatic Filariasis (PELF), and then gives examples of how those activities are being carried out within countries.

Initial assessment and mapping of LF distribution

Objective for 2001: To strengthen the capacities of endemic countries to assess and map the distribution of lymphatic filariasis in preparation for mass drug administration.

The initial assessment and mapping of the distribution of lymphatic filariasis within endemic countries continued to be one of the priorities in 2001. The principal strategy for interrupting transmission of infection is to treat the entire 'at risk' population either with a single administration of two drugs, given together once yearly for 4-6 years, or with DEC-fortified salt intake. Before mass drug administration can be planned and implemented in LF-endemic countries, implementation units (IU) need to be defined and units where transmission occurs have to be identified. Based on recently available information on the prevalence of lymphatic filariasis, IUs are categorized as (a) endemic or with transmission, (b) non-endemic, or (c) uncertain. Further surveys to verify the LF status are carried out in the "uncertain" units, preferably by detection of antigenaemia with ICT cards in areas where W. bancrofti is endemic or by night blood surveys in brugian filariasis endemic areas. The ICT test can be performed on a fingerprick blood droplet taken at any

time of the day, and gives a result within a few minutes. Annex 2 contains a list of countries and territories which are lymphatic filariasis-endemic. The survey results are plotted on the map of the country and, based on the results, the uncertain IUs are categorized as endemic or non-endemic.

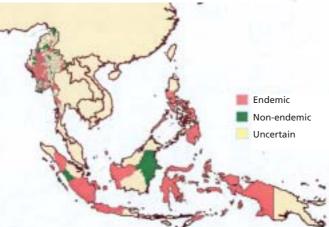
In January 2001, a workshop was held in Bangkok in collaboration with SEAMEO Tropmed, the Liverpool LF Support Centre, and WHO for the Mekong-Plus countries. Eight countries (Cambodia, Laos, Indonesia, Malaysia, Myanmar, Philippines, Thailand and Vietnam) reviewed the distribution of lymphatic filariasis in the country on the basis of published reports and surveys undertaken by the national programmes. Implementation units, as defined by each country, were categorized on the basis of such information as endemic, non-endemic or uncertain (Map 3.1). A plan for further surveys in the uncertain areas was prepared by each country. Technical and financial assistance is being provided to the countries in the surveys, as well as in mapping which is currently in progress.

The first cluster of West African countries (Benin, Burkina Faso, Ghana, and Togo), which had completed the antigenaemia surveys in 2000 were brought together in a final data analysis workshop in Ouagadougou in March 2001. The data were cleaned, validated and entered in HealthMapper by the participants. Training on the spatial analysis of the data was organized by WHO/TDR to create the contour maps of varying levels of endemicity. The second phase of the workshop included categorization of the implementation units into those with transmission and those without, on the basis of the sampled villages by implementation units and the spatial

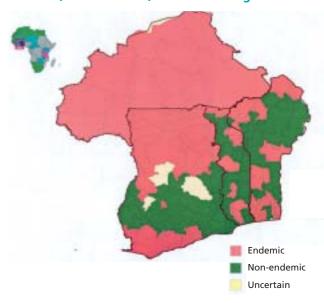
analysis (Map 3.2). In the third phase of the workshop, draft plans for implementing and monitoring PELF in those units which were identified as having LF transmission were drawn up by the participants. The workshop was also supported by funds from TDR and the Liverpool LF Support Centre.

To strengthen the capacities of endemic countries in mapping the distribution of lymphatic filariasis in preparation for mass drug administration, two workshops were held, one in Dakar primarily for the West African French-speaking countries (Cameroon, Central African Republic, Guinea, Mali, Niger, Senegal, and the Republic of the Gambia), and the second in Nairobi for the anglophone countries mostly in East Africa (Kenya, Liberia, United Republic of Tanzania, Uganda, Zimbabwe and Zambia) (Map 3.3). More specifically, these workshops aimed to present the participants with the standardized methodology for LF mapping, facilitated the compilation of existing information on LF prevalence, assisted the participants in developing a plan for LF mapping in their respective countries, and trained them in the use of the HealthMapper as a tool for mapping, monitoring and evaluating the implementation of mass drug administration.

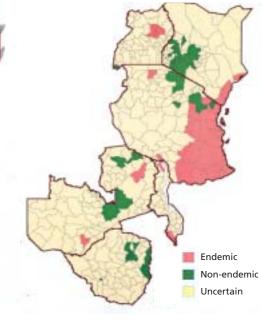
Map 3.1 Status of implementation units in the Mekong-Plus countries



Map 3.2 Status of implementation units in Benin, Burkina Faso, Ghana and Togo



Map 3.3 Status of implementation units in Kenya, Malawi, Uganda, UR Tanzania, Zambia and Zimbabwe



■ Chapter 3 Implementing the Programme

Progress in mapping in individual countries is summarized in Table 3.1.

The HealthMapper, an integrated database management and mapping tool developed by WHO, is a software package which helps users through the following steps: choosing the implementation units; drawing the preliminary map of disease distribution based on existing data; selecting sample villages for survey, data entry and analysis of survey results; overlaying prevalence contour maps or other relevant layers; classifying the implementation units into different LF status; preparing a plan of action; monitoring the coverage by mass drug administration; and monitoring the impact indicators.

Table 3.1 Progress in initial assessment of LF distribution

In the African countries **Completed** In progress **Planned** ■ Benin ■ Kenya ■ Cameroon ■ Burkina Faso ■ Nigeria ■ Central African ■ Côte d'Ivoire ■ Tanzania, United Republic of Republic ■ Ghana ■ Gambia, the ■ Uganda ■ Togo Republic of the ■ Guinea ■ Liberia ■ Madagascar ■ Malawi ■ Mali ■ Niger ■ Senegal ■ Zambia In the American Completed In progress ■ Dominican Republic ■ Guvana ■ Haiti ■ Costa Rica ■ Trinidad & Tobago ■ Suriname In the Eastern Mediterranean countries ■ Egypt ■ Yemen In the Mekong Plus Completed In progress ■ Thailand Indonesia ■ Myanmar ■ Cambodia ■ Laos ■ Philippines In the Indian sub-continent countries Completed In progres ■ Maldives ■ Bangladesh ■ Nepal ■ Sri Lanka

Mass drug administration

Objective for 2001: To cover 25 million people with MDA.

The drugs needed to interrupt transmission of lymphatic filariasis already exist. They are albendazole, diethylcarbamazine (DEC), and ivermectin. Mass treatment calls for the distribution of huge numbers of tablets, and hence for innovative logistics. An example from a small island country is described in **Box 3.1**.

Box 3.1 Distribution of albendazole and DEC in French Polynesia

Since joining the Pacific Programme to Eliminate Lymphatic Filariasis (PacELF) as a founder member in 1999, French Polynesia has carried out two rounds of mass drug administration, in 2000 and 2001, achieving coverage rates of 92% and 95% respectively. During Filariasis Week, the public health service and the education service jointly distribute tablets in all schools, as well as through distribution points in all the islands. On Filariasis Day, which is the Friday in filariasis week, tablets are distributed in the streets to all adults. Distribution continues through public health offices and private chemists during the following week, and is maintained throughout the year. The DEC tablets are produced in different colours to denote the dosage (100 mg, 400 mg and 600 mg), and are packed in plastic bags for the major centres. Before, during and after Filariasis Week, a mass advertising campaign via the media provides a constant flow of information in both French and Tahitian.

Within the Programme to Eliminate Lymphatic Filariasis, a total of 22 countries have already started mass drug administration, as shown in Figure 3.1. The total population at risk of the 22 countries is 679.8 million which represents 61.8% of the total at-risk population in all 80 endemic countries. The increase in the numbers of people covered by MDA overall and by country, between 2000 and 2001, is evident from Figure 3.2. and Table 3.2., respectively. The percentage of the target population (that is, the population at risk in endemic countries) that had been targeted by MDA by the end of 2001 is shown in Figure 3.3.

Table 3.2 Population covered by MDA in 2000 and 2001

| PRG Region | Country Po | pulation covere | d by MDA |
|---------------|--|-----------------|------------|
| | | 2000 | 2001 |
| AFRICAN | ■ Burkina Faso | | 431 399 |
| | ■ Comoros | | 53 308 |
| | ■ Ghana | 114 947 | 393 677 |
| | ■ Nigeria | 159 698 | 675 701 |
| | ■ Togo | 51 722 | 342 398 |
| | United Republic of Tanzar (excluding Zanzibar) | | 316 494 |
| | ■ Zanzibar, part of UR of Ta | nzania | 638 909 |
| AMERICAN | ■ Haiti | | 105 750 |
| EASTERN | | | |
| MEDITERRANEAN | ■ Egypt | 1 759 553 | 2 325 724 |
| MEKONG PLUS | ■ Philippines | 331 526 | 2 236 110 |
| | ■ Myanmar | | 1 803 306 |
| INDIAN | ■ Bangladesh | | 808 697 |
| SUB-CONTINENT | ■ India | | 13 433 322 |
| | ■ Sri Lanka | | 1 666 389 |
| PacELF | ■ American Samoa | 11 081 | 29 991 |
| | ■ Cook Islands | 13 344 | 11 562 |
| | ■ French Polynesia | 205 000 | 214 149 |
| | ■ Kiribati | | 46 047 |
| | ■ Niue | 1 802 | 1 706 |
| | ■ Samoa | 91 613 | 119 100 |
| | ■ Tonga | | 79 969 |
| | ■ Tuvalu | | 6 742 |
| | ■ Vanuatu | 154 739 | 155 517 |
| Grand Total | | 2 932 265 | 25 895 967 |

Figure 3.1 Population at risk in the 22 endemic countries that implemented PELF IN 2001

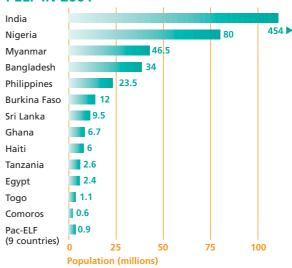


Figure 3.2 Progress in mass drug administration in 2000 and 2001

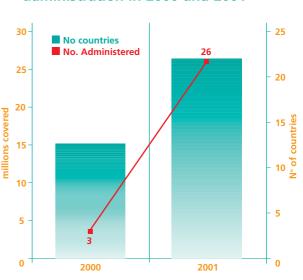
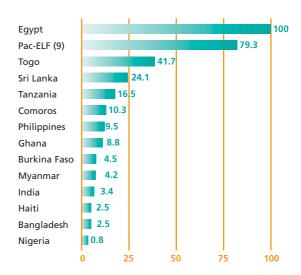


Figure 3.3 Percentage of at-risk population targeted for MDA in 2001



■ Chapter 3 Implementing the Programme

The strategy of mass drug administration is central to one of the objectives of the Global Programme for the Elimination of Lymphatic Filariasis. This strategy not only requires awareness-raising efforts, but also presents a logistic challenge Figure 3.4.

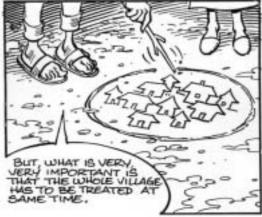


Figure 3.4: Advocacy for mass drug administration. From "Lymphatic Filariasis", a comic book for primary and secondary schoolchildren.

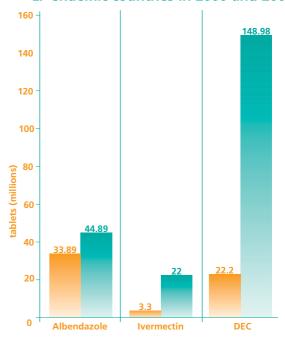
Albendazole is a widely-used antiparasitic drug that cures intestinal worm infections in children. When co-administered as a single treatment with either of the older anti-filarial drugs, DEC or ivermectin, it enhances the ability of these drugs to stop the spread of filarial infection. Albendazole is donated to the programme free of charge by GlaxoSmithKline.

DEC was developed over 50 years ago, and is inexpensive, safe and effective. A single annual dose can reduce microfilariae for at least one year. If DEC is given in combination with albendazole or ivermectin, its effectiveness is enhanced and transmission can be interrupted. Unfortunately, DEC cannot be used to treat lymphatic filariasis in most of Africa because of severe side-reactions when other parasitic infections, such as onchocerciasis, are also present. DEC costs less than US\$ 0.01 per person per year.

Common edible salt can be fortified easily and cheaply with DEC. The drug is very stable, survives cooking, and is tasteless. Small amounts taken over a period of months to years can eliminate microfilariae and interrupt stransmission completely.

A WHO audit team, in collaboration with the National and State Regulatory Authorities, carried out on-site audit visits to the manufacturers of DEC tablets and DEC starting material, to evaluate Good Manufacturing Practices (GMPs) and Good (Quality Control) Laboratory Practices, and coordinated the validation of an HPLC assay for DEC starting material and DEC tablets. The new HPLC assay for DEC and for evaluation of dissolution is now in USP25 (2002). Future audit visits to the manufacturers of DEC starting material and DEC tablets have been planned and will be carried out in 2002. WHO procured DEC for some of the LF-endemic countries, on request. Ivermectin is a drug that is safe and easy

Figure 3.5 Shipments of drugs to LF-endemic countries in 2000 and 2001



to use. A single dose quickly kills immature forms of the filarial worms (microfilariae) within the human body. When ivermectin is used with albendazole or DEC, the transmission of lymphatic filariasis is reduced dramatically for one year. Millions of people in Africa and the Americas are already receiving ivermectin annually for the treatment of onchocerciasis (river blindness). Merck & Co., Inc. is donating ivermectin free of charge to the African countries that are endemic for both lymphatic filariasis and onchocerciasis, and where DEC should therefore not be used. The numbers of drugs shipped to endemic

countries by the Programme in 2000 and 2001 are shown in Table 3.3. The massive increase in the number of drugs shipped between those two years is shown in Figure 3.5.

As can be seen from Figure 3.6, the major part of the Programme's activities in mass drug administration in 2001 was concentrated in South-East Asia. This focus reflects the vast population at risk in that area. The next chapter describes how the Programme assesses the population at risk and how activities to eliminate lymphatic filariasis are implemented.

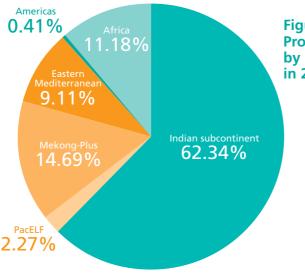


Figure 3.6
Proportion of poulation covered by MDA in different PRG regions in 2001

Table 3.3 Shipment of drugs to endemic countries in 2000 and 2001

| | | Year 2000 | | | Year 2001 | |
|-----------------------|-------------|------------|------------|-------------|------------|-------------|
| Region | Albendazole | Ivermectin | DEC | Albendazole | Ivermectin | DEC |
| Africa | 2 318 600 | 3 300 000 | | 6 847 321 | 21 875 000 | 3 150 000 |
| Americas | 475 000 | | | 470 000 | | 1 512 500 |
| Eastern Mediterranean | 2 900 000 | | 10 000 000 | 1 887 000 | 125 000 | 11 022 000 |
| Mekong-plus | 4 021 000 | | 11 300 000 | 5 609 450 | | 107 800 000 |
| Indian subcontinent | 23 100 000 | | | 28 267 523 | | 25 500 000 |
| PacELF countries | 1 065 000 | | 920 000 | 1 767 750 | | |
| TOTAL | 33 879 600 | 3 300 000 | 22 220 000 | 44 849 044 | 22 000 000 | 148 984 500 |

Social mobilization and advocacy

Objective for 2001:

To provide technical assistance to countries in order to achieve high coverage during mass drug administration.

The high coverage rates required to reach the goal of elimination can be achieved only if the target populations are motivated to receive and take the drugs that are supplied to them.

High coverage rates need to be sustained for at least 4–6 years. The lower the coverage is the longer the period necessary to achieve interruption of transmission will be. Such sustained high coverage requires intense social mobilization through advocacy and effective communication. Strong political and administrative commitment will engage the population to participate actively. People need such information so that they can act in their own interests and those of their children. Yet communication through interpersonal or group contacts, or via the mass media, is still needed to motivate people to take the decision to accept health interventions.

Social mobilization is a planned process which enlists the support of any or all sectors of society that can play a role in achieving an agreed social objective. To be sustainable, the process has to be rooted in the community. Planning for social mobilization begins with a situation analysis and identification of the behavioural change required to achieve the health goal. The analysis identifies potential allies and points of resistance, ways to improve the knowledge and motivation of the beneficiaries, effective media channels, and the potential for community participation. An example of successful social mobilization is described in Box 3.2.

Box 3.2 Communication for behavioural impact: the experience of Zanzibar

In October 2001, a first round of mass drug administration took place in Zanzibar, United Republic of Tanzania. Zanzibar comprises two main islands, Unguja and Pemba, with a population of 941 546. Filariasis is highly endemic in both islands, with microfilaraemia ranging from 5% to 30% of the adult population. A survey carried out one week after the drug distribution showed an overall drug coverage rate of 76%.

A key factor in achieving this high coverage rate was an active social mobilization campaign which started about three months before the mass drug administration day (promoted as Filaria Day) and which continued until Filaria Day. The campaign focused on the behavioural result expected: the ready acceptance of taking the tablet on Filaria Day. A variety of means of communication were used, including:

- The use of drug distributors as social mobilizers, through two preparatory visits to households.
- The intensive use of mass media, posters and banners.
- The active involvement of religious and political leaders.

In India, the State of Orissa recognized the need to ensure adequate social mobilization before implementing the mass administration of albendazole and DEC. A WHO communications adviser visited Orissa and, following preliminary observations in villages and discussions with officials at district and state levels, drafted a plan for communication for behavioural impact (COMBI). The plan was later discussed at a workshop in Hyderabad in May 2001 (Photograph 3.2). The workshop was attended by national and state-level programme managers and communications experts from different endemic states, as well as by social scientists from research institutes and universities and media experts. Using a participatory approach, the workshop drafted a document highlighting the principles of COMBI, as well as model plans for Orissa. Tamil Nadu and Kerala. The WHO communications adviser subsequently collaborated with state programme managers and local research institutions in Orissa and Tamil Nadu to draw up detailed operational plans for model social mobilization projects to be carried out in those two states. With funding from the Gates Foundation, these projects are scheduled to be implemented in January and February 2002.

PER OF NAMP WORLD HEALTH ORGANISATION National Workshop to develop strategy for SOCIAL MOBILISATION AND COMMUNICATION to Elliminate Lymphatic Filteriasis 21-25 May, 2001. Hyderahad.

Materials for advocacy purposes

Pamphlets for advocacy purposes have been produced in collaboration with country officers and have been adapted to local situations. In particular, in order to raise awareness of the importance of ongoing lymphatic filariasis mass drug administration campaigns and to convey basic messages on disability prevention and control, it was decided to produce a comic book, targeting schoolchildren and their families in sub-Saharan African countries.

A similar comic book, developed in collaboration with schoolteachers, was field tested in primary and secondary schools in Egypt as part of a KAP (knowledge, attitude, practice) survey. The results were both positive and encouraging towards the use of this kind of material in schools, and the book will be widely distributed. Indian officials have seen the Egyptian comic book and are interested in having a similar book developed for India.

The production of a package of advocacy films has started. Filming of mass drug distribution, education and social mobilization activities has already taken place in India and the Philippines, and filming in Africa will provide a global overview of the programme. The end product will be a package of three films (of approximately 2, 5 and 15 minutes' duration), which can be used in the promotion of activities to eliminate lymphatic filariasis.

Photograph 3.2 Participants of the Social Mobilisation and Communications Workshop, Hyderabad, India

■ Chapter 3 Implementing the Programme

Website

Following the distribution of a questionnaire to all interested parties to gather information on the objectives and the intended target audience (speed, page size, layout, appearance, overall usefulness, site structure), as well as navigation and content of the Eliminating Lymphatic Filariasis website, the site has been completely redesigned to become the website of the Global Alliance to Eliminate Lymphatic Filariasis.

The website contains documents on the Lymphatic Filariasis Elimination Programme, covering strategy, policy, project management, operational and research issues comprised of reference materials for national programme managers and other national officials involved in the Elimination Programme, relevant scientific papers covering both the public health and clinical health aspects of the disease, iconographic materials, and links to relevant partners. A crucial part of the site is the extranet that enables partners to communicate with one another and exchange data. Figure 3.7 shows a screenshot of the home page of the website.

Preventing and limiting disability

Objective for 2001:

To develop a global strategy for disability prevention and control.

With a view to preventing and limiting disability, the strategy of PELF is encourages patients with lymphoedema to practise regular skin care and hygiene and to wear appropriate footwear. Surgery is recommended for individuals with hydrocoele. This requires training of health workers, as well as health education and mass communication. The comic book produced for sub-Saharan African countries places great emphasis on simple methods of hygiene and lifestyle habits that can contribute enormously to preventing or decreasing clinical manifestations of the disease (Figure 3.8).

A training module for health workers on disability prevention and control has been produced.

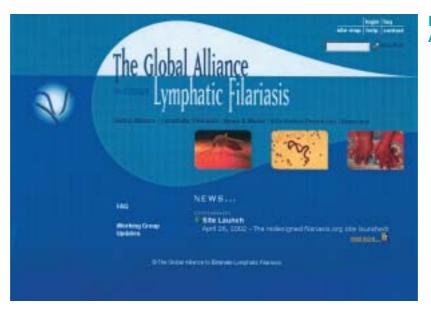


Figure 3.7 The Global Alliance website

The focus of health education is on:

- thorough washing and careful drying of the affected part of the body;
- wound care;
- exercise, but not during acute attacks;
- elevating the affected limb; and
- wearing of comfortable footwear (i.e. open sandals rather than constricting shoes or bare feet).

Health staff need to understand the reasons why patients fail to follow advice on hygiene and care, and they must be educated to listen to, observe, train and encourage the patients. Much can be done at the peripheral level, and much can be achieved in disability prevention and limitation at very little financial cost per patient by using commonly available items. Protective footwear is the most expensive item, but it is relatively durable. It is therefore important to make the best possible use of locally-available resources, and to guide the patient to do likewise.

Effective prevention and limitation of disability requires:

- practice of simple hygiene measures using soap and water;
- early recognition and prompt treatment of entry lesions;
- referral of patients with lymphoedema who do not respond to treatment at home; and
- referral of patients with hydrocoele for surgery.

Training of physicians and health workers on the principles of alleviation and prevention of disability associated with lymphatic filariasis commenced n Bangladesh, Haiti, India, Nigeria, Philippines, Sri Lanka, Togo, and the United Republic of Tanzania. In Sri Lanka, over 2 500 patients with lymphoedema underwent treatment at the regional centres while another 6 500 were treated at village health centres. In addition, it was reported that 1 876 hydrocoelectomies were performed in the country.

Figure 3.8 From "Lymphatic Filariasis" a comic book for primary and secondary schoolchildren.



■ Chapter 3 Implementing the Programme

Training

Objective for 2001:

To organize the first workshop to train programme managers, to finalize a training module for drug distributors, to train health personnel in disability prevention and control techniques, and to commence the preparation of a training package on disability prevention and control for community health workers.

SEARO Workshop on the Treatment and Prevention of Lymphoedema in Lymphatic Filariasis, Pondicherry, India

A training workshop was organized from 29 January to 3 February 2001 by the Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), with technical support from the World Health Organization and financial support from the Ministry of Health and Welfare of the Government of Japan. The workshop was intended to provide senior health personnel (doctors and nurses) with the competence required for effective assessment and management of lymphoedema in lymphatic filariasis. There were 22 participants — 10 from India and 12 from other countries in the South-East Asia Region (Bangladesh, Indonesia, Maldives, Myanmar, Nepal and Thailand). The emphasis of the workshop was on the theoretical, practical and programmatic aspects of disability prevention and control in LF. The training followed a problemsolving approach and a substantial amount of time was spent on interaction with the participants.

SEARO-WPRO Training Workshop for Programme Managers of Lymphatic Filariasis Elimination Programme, Kuala Lumpur, Malaysia

The workshop was organized from 22 to 27 October 2001 by the Institute of Medical

Research (IMR), Kuala Lumpur, Malaysia, with technical support from the World Health Organization and financial support from the Bill and Melinda Gates Foundation, the Liverpool LF Support Centre, and SEAMEO-TROPMED (Southeast Asian Ministers of Education Organization - Tropical Medicine and Public Health Network). The aim of the workshop was to train programme managers and WHO country desk officers from the WHO South-East Asian and Western Pacific Regions how to develop, conduct and evaluate filariasis elimination programmes that respond to the needs of their countries. The training was interactive and, wherever possible, the participants worked with national data which they were asked to bring with them to the workshop. The main topics covered included: situation analysis, health mapping, plan for interruption of transmission, plan for disability control, surveillance, social mobilization, training and capacity-building, and monitoring and supervision (see Photograph 3.3).

To follow up this training of national programme managers, an average of US\$ 5 000 per country was made available to the Regions to enable national programmes to organize workshops at district level in their respective countries. These funds were allocated to the WHO South-East Asia and Western Pacific Regional Offices.

Training module for programme managers

A two-part training module (Learner's Guide and Tutor's Guide) for national programme managers has been developed and will be published in June 2002. The module was tested in the SEARO-WPRO Training Workshop for Programme Managers of Lymphatic Filariasis Elimination Programme, in Kuala Lumpur; comments and suggestions were gathered from the participants and tutors,

and these are being incorporated in the revised version. The Learner's Guide contains technical principles, exercises and suggestions on the best way to achieve the learning objectives, and the Tutor's Guide is designed to give support to the trainers, providing practical guidance on the organization and presentation of the training course, suggesting a step-by-step approach to training, and listing the basic resources required for optimal running of the course.

Disability prevention and control training package for community health workers

Simple guidelines for lymphatic filariasis patients, together with materials to train trainers at community level are being developed. The materials will be field-tested in pilot training workshops during 2002, following a series of surveys that will be carried out in Burkina Faso, Togo, and the United Republic of Tanzania (including Zanzibar). Feedback from the pilot

workshops will be incorporated and the training materials will then be used in other countries. The preparation of these materials will involve thorough examination of the professional profile of health workers involved at community level.

Training materials for drug distributors

A training module for drug distributors (Learner's Guide and Tutor's Guide) has been completed. The module was extensively field-tested during several mass drug administration campaigns, and is ready to be printed and distributed. It can be used equally well for basic training and for refresher training.

An information sheet for drug distributors has been produced and will be made available to health personnel involved in mass drug administration campaigns.



Photograph 3.3 Participants of the SEAR-WPRO training Workshop for Programme Managers of Lymphatic Filariasis Elimination programme, Kuala Lumpur, Malaysia

■ Chapter 3 Implementing the Programme

Research

The Programme to Eliminate Lymphatic Filariasis, like any other public health programme to control or eliminate a disease, needs to include a strong operational research component in order to be sustainable and successful. Strategies or techniques can always be improved, and problems will always develop that need to be resolved. The programme, in association with TDR, has promoted research in key areas that are relevant to the Programme's implementation and monitoring.

The Programme has been concerned with the problem of low coverage during the MDAs and has accorded high priority to developing cost-effective drug delivery strategies for achieving high and sustained treatment coverage (based on studies in Ghana, India, Kenya, Myanmar, and Vietnam) and also to examining the strategies for effective drug delivery in urban areas (India).

Where onchocerciasis and lymphatic filariasis co-exist, there is need for the development of an integrated drug delivery strategy. Studies in Ghana and Mali are examining this issue. Since advocacy and communication are vital elements for the elimination programme, strategies to enhance drug delivery are ongoing in India. Long-term transmission studies to answer key questions relating to the impact of MDA in achieving elimination for the main vector-parasite complexes are being undertaken in Ghana, India, Kenya, Mali and Papua New Guinea. Methods for community-based management of lymphoedema and related adenolymphangitis are being examined in Ghana, Kenya, Mali, Nigeria, and the United Republic of Tanzania with TDR support.

Strategies and tools for monitoring and evaluating filariasis elimination programmes are being developed in laboratories in Germany, Ghana, Indonesia, Malaysia, Netherlands, and Uganda. A rapid assessment method for identifying areas where there is a risk of loa-associated encephalopathy after ivermectin administration was developed after studies were completed in Cameroon and Nigeria.

The efficacy and safety of the albendazole + ivermectin co-administered regimen in decreasing microfilaraemia was the subject of studies conducted in Ghana, Kenya and Zanzibar. In addition, the pharmacokinetics of regimens using two drugs simultaneously were studied in Ghana and India.

Finally, in the area of basic and strategic research the Programme is supporting studies on filarial genomes and drug discovery, especially targeting filaria-specific aminoacylt-RNA transferases.

Monitoring PELF and information system

The monitoring of programme implementation is an important component which needs to be carried out at all levels — national, regional and global. The Programme Manager's Guidelines* provide a framework of the country's information needs, together with formats for collection of the relevant data. Countries are encouraged to modify the formats, if required, to match local data collection systems. However, to ensure standardization across countries for compilation of information at regional or global levels, a standard annual reporting format was



^{*} Preparing and Implementing a National Plan to Eliminate LF: a Guideline for Programme Managers.

developed in consultation with the Programme Review Group and the Technical Advisory Group. Countries were expected to send the reports of each calendar year by 28 February of the following year. A summary of the reports received from countries which initiated PELF in 2000 and 2001 is given in Table 3.4.

Countries were advised to report on the progress made in their respective programmes to eliminate lymphatic filariasis as a public health problem.

As the programme progresses, the format will undergo revision. National programme managers were advised and encouraged to closely monitor the implementation of their activities (Table 3.5 and Figure 3.9).

Table 3.4 Reports from countries that initiated PELF in 2000 and 2001

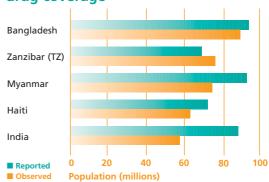
| | Number of countries | | | | | |
|-----------------------|----------------------------|--|----------------------------|---------------------------------|--|--|
| PRG Region | Implemented MDA in 2000 | Submitted annual report for 2001 | Implemented MDA in 2001 | Submitted report for 2001 | | |
| African | 4 | 2 | 6 | 6 | | |
| American | 0 | 0 | 1 | 1 | | |
| Eastern Mediterranean | 1 | 1 | 1 | 1 | | |
| Mekong-Plus | 1 | 1 | 2 | 2 | | |
| Indian subcontinent | 0 | 0 | 3 | 3 | | |
| PacELF | 6 | 6 | 9 | 7 | | |
| Total | 12 | 10 | 22 | 20 | | |

Table 3.5 Analysis of reporting on PELF activities (21*annual reports received)

| Reported on | No. of reports | % |
|----------------------------------|----------------|--------|
| Initial assessment | 18 | 85.71% |
| Sentinel sites identified | 17 | 80.95% |
| Baseline mf only | 10 | 47.62% |
| Baseline CFA only | 2 | 9.52% |
| Baseline mf and CFA (both) | 4 | 19.05% |
| Baseline hydrocoele | 7 | 33.33% |
| Baseline elephantiasis | 10 | 47.62% |
| Total population of IUs | 19 | 90.48% |
| Number covered as reported by IU | ls 18 | 85.71% |
| Coverage cross-checked | 7 | 33.33% |

^{*} United Republic of Tanzania submitted two annual reports: one for the mainland and one for Zanzibar

Figure 3.9 Reported and observed drug coverage*



^{*} Drug coverage calculated as percentage of people administered the drugs over total population in IUs

■ Chapter 3 Implementing the Programme

Information flow

To help countries in compiling and presenting programme-related and epidemiological data, especially through maps and charts, the HealthMapper (software developed by WHO/CSR) was modified to include a module for PELF. As most national programme managers have access to computer systems, the HealthMapper will be a simple and useful tool for programme managers to assess programme implementation (See "Initial Assessment and Mapping of LF Distribution", page 19).

Systems for adverse event monitoring

The programme has put in place two systems for monitoring the safety of the coadministered drugs. The first is an active surveillance system which requires countries initiating mass drug administration programmes to document the occurrence of any side-effects (usually resulting from killing of microfilariae by the drug and subsequent host response to dying parasites) in the first 2000 to 3000 individuals receiving the drug. A standard questionnaire to record the possible adverse drug reactions (ADR) is provided to countries and data from this monitoring are being collected by the PELF at WHO. A review of the accumulated data showed that the co-administered drugs were safe and there was very little concern about their safety through wide-scale use. The side-effects seen were conventional reactions, consistent with past experience with these combinations. In addition, the reactions were qualitatively and quantitatively similar to those reported previously and seem to be related to the therapeutic effects of the co-administered drugs.

The second system, which is to be continued for the life of the programme, is "passive" reporting of any serious adverse experience (SAEs) in subjects following co-administered drug treatment. SAE report forms have been developed, in consultation with the two donor pharmaceutical companies (GlaxoSmithKline and Merck & Co., Inc.), for reporting SAEs associated with DEC + albendazole regimens (Annex 3) and for reporting SAEs associated with the ivermectin + albendazole regimens (Annex 4). SAE reports are required to be forwarded to the drug regulatory authorities within 15 days. WHO receives these SAE reports concurrently with the concerned pharmaceutical companies and interacts closely with them and the local health authorities. During the year 2001, no SAE was observed or reported in any country implementing MDA.

Activities in regions and countries

1 African Programme Review Group

Of the 46 countries in the African Region, 39 are LF-endemic. In total, approximately 420 million people are considered to be at risk. Filariasis and onchocerciasis are co-endemic in 28 countries.

In 2001, 6 of the 39 countries with LF initiated mass drug administration.

Over 3.3 million people were covered by MDA using ivermectin + albendazole in Burkina Faso, Ghana, Nigeria, Togo and the United Republic of Tanzania, and using DEC + albendazole in the Islamic Federal Republic of the Comoros.

Other countries, such as Benin, Kenya, Madagascar and Uganda initiated planning and training activities related to PELF. The plans and application for drugs have been approved for Benin, Kenya and Uganda, and the drugs have been shipped to these countries.

Benin

Studies carried out in 1983 and 1995 in the sub-prefecture of Comé indicated a disease and microfilariae prevalence of 24.6% and 46.3%, respectively. In the year 2000 a nationwide survey was completed in villages sampled in each sub-prefecture. Based on the survey, the following departments were identified as endemic — Mono, Ouémé, Zou and Atacora. The total population in these four departments is 4.2 million, all of whom are at risk. A national plan for PELF was developed and has been approved by the Programme Review Group and the Mectizan® Donation Program. Drugs for the first round of treatment have been provided to Benin. Financial support for the programme has been provided by the Liverpool LF Support Centre.

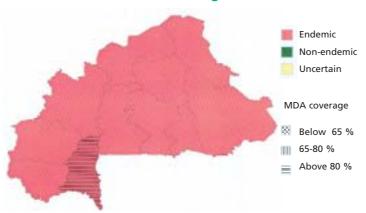
Burkina Faso

Initial assessment of the distribution of lymphatic filariasis was completed in Burkina Faso in 2000. According to the survey findings, which were later confirmed, all 53 health districts (implementation units) in the country were endemic. The entire population of the country, estimated at 12 million, is considered to be at risk for lymphatic filariasis.

Following the initial assessment of the LF situation in the country, the Ministry of Health (MoH) launched a national plan to eliminate lymphatic filariasis. A national task force was set up and a dynamic and efficient coordinator for PELF was nominated. A plan for initiating and scaling up PELF activities was submitted to WHO and the Mectizan® Donation Program for review and supply of drugs. The request was favourably considered and drugs were made available to Burkina Faso, targeting 558 552 people in four implementation units in the Gaoua region in the south. WHO and the Liverpool LF Support Centre provided financial assistance for the start-up operational costs in the first year. During the first round of MDA from December 2001 to January 2002, a total of 431 399 people received ivermectin + albendazole. The reported drug coverage was 77.2% (range: 71.6–80.6%) — see Map 3.4. The drug administration was carried out by community drug distributors after two days of training. The base-line survey carried out in the sentinel site in Gaoua had a prevalence of microfilariae of 11.4% (N° of mf+/N° of slides read). Another sentinel site in Dano (village of Gora) had a prevalence of mf of 14.2%. The Ministry of Health is also collaborating with Handicap International in the alleviation and prevention of disability

■ Chapter 3 Implementing the Programme

Map 3.4 Burkina Faso: LF endemicity status and MDA coverage 2001



Map 3.5 Comoros: LF endemicity status and MDA coverage 2001



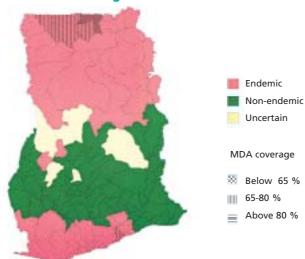
caused by lymphatic filariasis. Knowledge, attitude and practice (KAP) studies are underway for the formulation of the strategy and inclusion in the national PELF.

WHO staff from HQ and AFRO provided technical assistance to the national programme in planning the activities and in establishing, with the MoH team, the strategies for good monitoring and evaluation of the PELF activities. Financial assistance for the first round of MDA was provided by WHO and the Liverpool LF Support Centre.

The Islamic Federal Republic of the Comoros

WHO provided technical support to develop the national plan and to train health professionals to undertake mass drug administration. All the 600 000 inhabitants in the Islamic Federal Republic of the Comoros are considered to be at risk for LF, as shown in the mapping of LF which was completed in 2000. The entire population is distributed among three islands: Moheli, Grand Comore and Anjouan. In July 2001, a total of 53 308 people in two islands (Moheli and Grand Comore) were covered by MDA using DEC + albendazole. The coverage for the two islands was reported to be 85.7% (range: 81–92%) — see Map 3.5. Financial assistance was provided by a grant from the Arab Fund for Economic and Social Development.





Ghana

Mapping for lymphatic filariasis was carried out in 2001. The population at risk in Ghana was estimated to be approximately 6.57 million in 41 districts. The first round of MDA was begun in August 2000 in Ahanta West district, covering 114 947 persons. In January and February 2001, a further four districts with 393 677 people were covered by MDA using ivermectin + albendazole; the reported drug coverage ranged between 63% and 75%, with an average of 68.5% for all five districts

(Map 3.6). Baseline surveys carried out in 21 sentinel sites indicated a microfilaria prevalence of between 11% and 41%, and circulating filaria antigen (CFA) between 30% and 49%.

In addition to the Ministry of Health, the Catholic Medical Missions Board (CMMB) supported part of the Ghanaian Programme. Additional resources were provided by Health and Development International (HDI), the Liverpool LF Support Centre, WHO, and a grant from the Gates Foundation (received through HDI).

Kenya

Six of the coastal districts are currently known to be LF-endemic, microfilaria prevalence ranging between 9% and 28%. The prevalence of hydrocoele ranges from 10% to 40% and that of elephantiasis from 6% to 10%. A plan for nationwide mapping has been prepared and a list of villages for the survey identified. The Ministry of Health submitted a plan for initiating a programme to eliminate lymphatic filariasis, starting in one district (Kilifi) and expanding to cover other areas. The plan was reviewed and approved by the Programme Review Group and drugs for MDA were shipped to Kenya. Further assistance was provided by WHO for preparing a district-level action plan. The first round of MDA is expected to take place in July 2002.

Madagascar

Madagascar is one of the four most highly LF-endemic countries in the African Region. In December 2001, at the request of the Minister of Health, WHO sent a team to support the Ministry in preparing a strategy to eliminate lymphatic filariasis in the country. The Ministry of Health came to the conclusion that mass drug administration using DECfortified salt might be the most appropriate strategy to reach the population at risk. Only the district of Tuleare in the west, which produces local salt, might have a problem because the iodized salt programme is having difficulty. This district could be covered by administering a single dose of DEC + albendazole once every year.

Nigeria

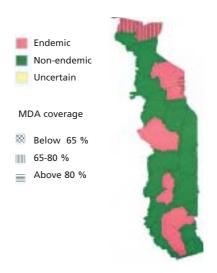
Nigeria ranks third in the world, after India and Indonesia, in terms of population at risk, which is estimated at about 80 million, distributed in Local Government Areas (LGA). LF mapping was carried out in two states and nationwide mapping was proposed. The first round of MDA in September 2000, using ivermectin + albendazole, covered a total of 159 948 people; the average observed coverage was 56.7% (with the total population in the implementation units (IU) as denominator). In 2001, 675 701 people received ivermectin + albendazole. A total of 22 sentinel sites have been selected. The pre-MDA baseline circulating filarial antigenaemia ranged from 5% to 64%.

A KAP study identified the misconceptions and superstitions that attempted to explain the disease etiology. A negative attitude towards men with hydrocoele was observed. While patients with hydrocoele consult both modern and traditional medical practitioners, lymphoedema and elephantiasis patients mostly consult traditional practitioners. The programme in two states is supported by the Carter Center.

Togo

National mapping of the entire country was completed in 2000. The population at risk was estimated to be 1.1 million, distributed in 7 prefectures. The first round of MDA in April 2000 covered 51 722 persons (reported coverage 80.6%) in Binah prefecture. In the second round in April 2001, 342 398 people received ivermectin + albendazole in three prefectures (Binah, Toné and Kpendjal); the average reported coverage rate was 74.7% (range: 65–80.6%) — see Map 3.7. The pre-MDA baseline survey carried out in three sentinel sites (one each in Binah, Toné and Kpendjal) showed the prevalence of microfilaraemia to be between 0.6% and 10%, that of circulating filaria antigen (CFA) between 5% and 31.3%, hydrocoele between 0.2% and 1%, and elephantiasis between 0.2% and 2%. Training of health personnel at provincial and district levels was organized for mass drug administration and for the prevention and alleviation of disability.

Map 3.7 Togo: LF endemicity status and MDA coverage 2001



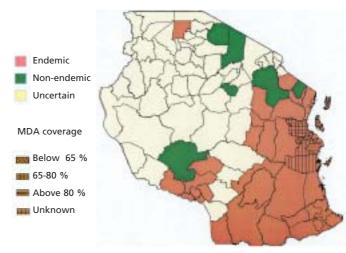
Uganda

Surveys undertaken by the Vector Control Division of the Ministry of Health had identified four endemic districts in Uganda. Mapping in the rest of the country is in operation. The Ministry of Health prepared a plan for treatment in the identified LFendemic districts, starting with two districts (Lira and Katakwi) in the first round. Since both districts were also endemic for soil-transmitted helminths and Lira for schistosomiasis as well, the plan for these districts included helminth control. After the first round of ivermectin + albendazole covering the entire population for LF, a second round with albendazole (after six months) will be implemented for school-age children. The national plan has been approved by the Programme Review Group and the Expanded Mectizan® Expert Committee. Ivermectin and albendazole have been shipped to Uganda. At the request of the Ministry of Health, WHO provided technical assistance to develop district action plans and training. Sensitization of local political and administrative personnel in the two districts was carried out. The district teams have been trained and an action plan developed for MDA in March 2002. Financial support for the programme has been provided by the Liverpool LF Support Centre and WHO, with the Ministry of Health bearing the rest of the cost.

United Republic of Tanzania

Mainland. Mapping the distribution of LF is in progress in the mainland. Of the 101 districts, 48 have been surveyed, of which 43 are endemic. The surveys in 53 districts are expected to be completed by 2002. The at-risk population is estimated to be 2.6 million. In the first round of MDA in October 2000, a total of 32 240 persons received ivermectin + albendazole (reported coverage, 76%).

Map 3.8 United Republic of Tanzania: LF endemicity status and MDA coverage 2001



The second round in 2001 targeted 6 districts, and reports from four showed that 316 494 individuals were covered (average coverage, 59.6%; range, 55.2–64.4%) — see Map 3.8. Reports from the other two districts are still awaited. Care was given to 150 patients with lymphoedema, and 100 operations for hydrocoele were carried out in one district-level health facility.

The United Republic of Tanzania (mainland) programme received financial assistance from the Gates Foundation through the NGO node.

Zanzibar. The entire population of 941 546 is considered to be at risk of LF. The first round of MDA was carried out in October 2001 using ivermectin + albendazole in 12 districts. The number of people covered was 638 909 (reported coverage, 67.9%; range, 62-77%) — see Map 3.8. An extensive assessment of actual drug coverage was carried out in 39 random sites and interviews with 26 143 individuals indicated a coverage rate of 76%. Pre-MDA baseline surveys in two sentinel sites indicated a prevalence of microfilaraemia from 7% to 18%, that of hydrocoele from 1.4% to 7.8%, and lymphoedema from 2.2% to 8% WHO provided technical assistance to the Ministry of Health in Zanzibar in planning the social mobilization campaign and monitoring the drug coverage. Financial assistance to the Zanzibar programme was provided through WHO by the Gates Foundation.

2. American Programme Review Group

Seven countries in this region are considered LF-endemic: Brazil, Costa Rica, Dominican Republic, Haiti, Guyana, Suriname, and Trinidad and Tobago, with a total of 7.6 million people at risk in the LF-endemic areas.

Dominican Republic

The Dominican Republic is currently carrying out mapping of LF-endemic units in the country. At present, 10 out of 14 provinces are endemic and surveys are in progress in four. The country submitted a national plan and a request for drugs. The programme was reviewed and supplies of drugs have been shipped for initiating an MDA programme. The programme involves partnership with a local regional hospital in the south-west to treat lymphatic filariasis patients and to act as a reference unit for the region. A surgical training course was organized in which 11 urologists participated, including 4 from Haiti. An Agreement for the Performance of Work has been signed with the "Instituto Dermatologico y Cirugia de la Piel" for the management of lymphoedema.

The Institute will act as a reference health centre as well as training centre for field personnel in lymphoedema management. The routine activities of field staff will include detection of lymphoedema patients. A field epidemiologist is carrying out a census of patients with lymphoedema in the community, identifying local organizations, and organizing groups for lymphoedema management.

Financial assistance to the Dominican Republic is provided through the Atlanta node by the Gates Foundation.

Guyana

Mapping of LF distribution in Guyana has been completed, following the lot quality assurance sampling method. Antigen positive persons were found in all 10 regions; however antigen positive persons in the interior generally reported periods of exposure in Georgetown or other locales on the coast.

Financial assistance was provided for the Guyana mapping exercise through the Liverpool LF Support Centre, and CDC in Atlanta provided ICT cards and technical assistance.

Haiti

Haiti has completed the initial assessment and mapping of endemic areas.

The number of "communes" to be chosen as implementation units is probably around 73. The population at risk for the whole country was estimated at 6 million.

The first round of MDA in Leogane in October 2001 covered 105 750 people with DEC + albendazole (reported coverage, 70.5%); the observed coverage in sentinel sites was 61.9% — Map 3.9. Evaluation of the microfilarial density in the areas covered by MDA showed a reduction of 50%.

A national plan for Haiti is being developed.

Map 3.9 Haiti: LF endemicity status and MDA coverage 2001



3. Eastern Mediterranean Programme Review Group

The endemic countries in this region are Egypt, Sudan and Yemen. Egypt is the only country which has been implementing a national programme to eliminate lymphatic filariasis since 2000. Yemen initiated LF distribution mapping and planned to carry out MDA in two districts. Egypt and Yemen received financial assistance for programme implementation with a grant, through WHO, from the Arab Fund for Economic and Social Development.

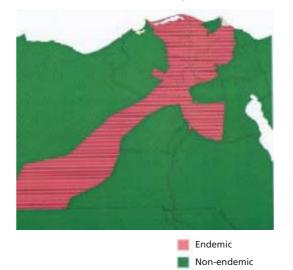
Egypt

According to surveys that were carried out, the population at risk is currently 2.41 million. The first round of MDA in September 2000 targeted the entire population at risk and covered 1 759 553 people (reported coverage, 96.4%). The second round with DEC + albendazole in September 2001 covered a total population of 2 325 724 in all 178 endemic villages in 25 districts (reported coverage, 96.4%) — see Map 3.10. Pre-MDA baseline surveys were carried out in two sentinel sites and spot-check sites in each district. The baseline prevalence of microfilaraemia ranged from 0.2% to 4.2% in the sentinel sites and the disease prevalence ranged from 1% to 11.5%.

Yemen

At the request of the Yemeni Ministry of Health, technical assistance was provided by a WHO consultant to help in training and mapping the distribution of lymphatic filariasis. Of the 284 districts, 11 are considered endemic and 5 are uncertain and need verification. The remaining 268 units are considered non-endemic. In 2001, the Ministry of Health planned to start MDA in 2002 in two implementation units, with a total target population of 52 000.

Map 3.10 Egypt: LF endemicity status and MDA coverage 2001





MDA coverage

- Below 65 %
- 65-80 %
- Above 80 %

■ Chapter 3 Implementing the Programme

4. Mekong-Plus Programme Review Group

In this region there are 11 endemic countries: Brunei Darusalaam, Cambodia, China, Indonesia, Korea, Lao People's Democratic Republic, Malaysia, Myanmar, Philippines, Republic of Thailand, and Vietnam.

Indonesia

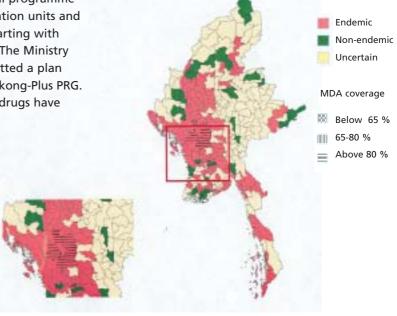
Indonesia is home to all three strains of filariasis — *W. bancrofti, B. malayi* and *B. timori*. Recently a rapid assessment survey, of lymphoedema and hydrocoele, undertaken through a questionnaire indicated an estimated 150 million people at risk in 20 out of 23 provinces. This puts Indonesia in second place, after India, in terms of population numbers at risk. While extensive data on microfilarial prevalence are available from past surveys, there are still gaps in areas where the LF status needs to be assessed. A further operational challenge for programme implementation is posed by the numerous islands that make up the country.

At the request of the Indonesian Ministry of Health, a WHO consultant and staff collaborated with the national programme in identifying the implementation units and drawing up a phased plan, starting with 1 million population in 2002. The Ministry of Health finalized and submitted a plan to WHO for review by the Mekong-Plus PRG. The plan and the request for drugs have been approved.

Myanmar

Myanmar has an estimated 46 million population at risk. The mapping of LF distribution is in progress; 153 townships out of a total of 324 are endemic, 22 non-endemic, and 149 still uncertain and targeted for surveys. In November 2001, MDA was started in ten townships (total population: 1 939 964), of whom 1 803 306 were covered (average reported coverage, 93%; range, 91–97%) — see Map 3.11. The coverage was cross-checked by teams from the national level in 8 sites by interviewing 14 995 individuals; the average observed coverage was 74.3% (range, 75.8–92.9%, except for one site with 13.6%). Subsequently, the defaulters in this last area (13.6%) were covered. The treatment given was a combination of DEC + albendazole. The pre-MDA baseline surveys carried out in four sentinel sites showed a prevalence of microfilaraemia between 1.1% and 7.1%; the microfilaria (mf) density ranged from 115 mf/ml to 675 mf/ml.

Map 3.11 Myanmar: LF endemicity status and MDA coverage 2001



Philippines

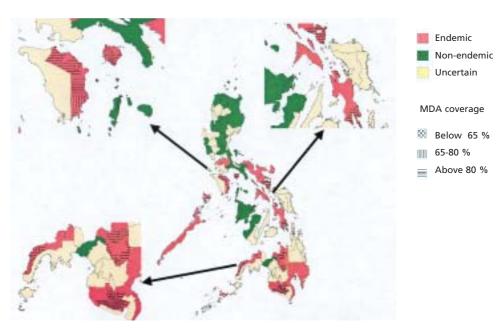
The Philippines has designated municipalities as the implementation unit for MDA. There are 1566 municipalities in the country; 290 are considered endemic and 545 non-endemic; surveys are in progress to assess the 731 municipalities in the uncertain category. The population currently at risk is estimated at 23.5 million. MDA was initiated in 2000 and covered 331 526 persons in 26 implementation units (average reported coverage, 83%). In 2001, a total of 2 236 110 received DEC + albendazole (average reported coverage, 73.2%) — see Map 3.12. Mass drug administration was mostly organized through Filaria Health Fairs, organized by the health services with

the full participation and ownership of the communities. The local government supported the Filaria Health Fair and approved the allocation of funds for a Filaria Day each year for the next four years. In some areas a national immunization- day-type of approach is adopted for mass drug administration.

Thirty health staff have been trained in the prevention and alleviation of disability associated with filariasis at the provincial level.

Patients with lymphoedema are given advice on disability control and patients with hydrocoele are referred to district/provincial/ regional hospitals for surgery.

Map 3.12 Philippines: LF endemicity status and MDA coverage 2001



■ Chapter 3 Implementing the Programme

5. Indian Subcontinent Programme Review Group

Half the global population at risk for LF live in five countries in this group — Bangladesh, India, Maldives, Nepal and Sri Lanka. Three of these countries initiated MDAs in 2001.

Bangladesh

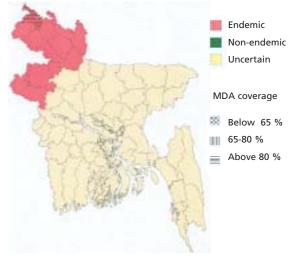
The population at risk of LF in Bangladesh is currently estimated at 34 million. Out of 64 districts, 12 are known to be endemic. Additional data on the target population will come from the mapping of LF which is in progress and is expected to be completed by 2002. In November 2001, MDA was initiated in the Panchagarh district with a population of 846 880, of whom 808 697 received DEC + albendazole (reported coverage, 95.5%) — see Map 3.13. The Ministry of Health organized a cross-check of the reported drug coverage, which found the coverage in sentinel sites to be 93%. The MDA was carried out by door-to-door administration in the presence of health and family welfare field staff and volunteers. Drugs were not left with family members for absentees or for later intake. To increase the coverage, the drugs were also administered in schools, colleges, madrasas (Koranic schools), mosques, cinema halls, markets, shopping complexes, etc. by volunteers and scout leaders. Each investigator covered 120 to 150 persons in a day. MDA was completed in ten days. To achieve high coverage, the communities were mobilized through an information, education and communication (IEC) campaign and the programme was launched by the Speaker of the National Assembly and the Director-General of Health Services.

Fifteen physicians from district and subdistrict (upzila) levels of Panchagarh were trained in 2001 on disability management, e.g. washing of limbs and exercise for lymphoedema, which they will practise in district and subdistrict hospitals from January 2002. It is planned to train 75 field staff in disability management in January 2002. Financial assistance for the programme was provided by WHO and for social mobilization by Aus-AID and the Liverpool LF Support Centre.

India

With an estimated population at risk of 454 million in 261 districts and with 22.5 million individuals with filarial disease manifestations (14 million with hydrocoele and 8.5 million with lymphoedema/ elephantiasis), India is the most LF-endemic country in the world. In 1997 the Indian programme initiated a revised strategy based on annual single-dose administrations of DEC, which targeted 40 million of the population at risk in 13 districts. In 2000, the programme planned mass drug administration with DEC + albendazole, which targeted a population of 20 million at risk in nine districts (six in Tamil Nadu, two in Orissa, and one in Kerala), in

Map 3.13 Bangladesh: LF endemicity status and MDA coverage 2001



collaboration with the Indian Council of Medical Research. In February 2001, a total of 13 433 322 people received a combination of DEC + albendazole in 6 districts of Tamil Nadu and 1 district of Kerala (average reported coverage, 88%); the observed coverage in sentinel sites was 59.3% — see Map 3.14. The other districts were covered by MDA using DEC alone.

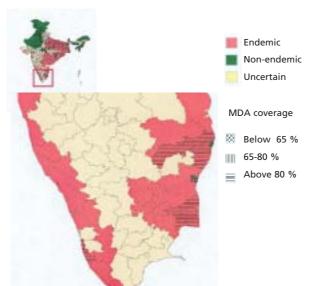
In view of the big difference between reported and observed coverages, the national programme, in collaboration with WHO, organized a workshop on social mobilization in May 2001 (see "Social Mobilization and Advocacy" above). Technical support was provided by a WHO consultant to plan for social mobilization in Orissa and Tamil Nadu for the next round of MDA in 2002.

Sri Lanka

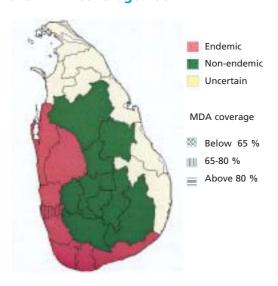
Out of a total population of 18.9 million, nine million are considered to be at risk for LF. Eight of the 25 districts are endemic and nine are non-endemic. Since 1999, all eight endemic districts have been carrying out single-dose MDA with DEC alone at sixmonth intervals. Following the launch of WHO's global programme to eliminate lymphatic filariasis, Sri Lanka planned the phased implementation of annual single-dose administrations of DEC + albendazole, starting in 2001 in the Colombo district (population, 2.1 million). In May 2001, this was carried out on 1.7 million people, with a reported coverage of 76.7%, — see Map 3.15. Seven other districts continued with only DEC administration. For the next round in June 2002, it is planned to scale up the MDA in order to cover the entire population of 9 million at risk using DEC + albendazole.

For the prevention and alleviation of disability associated with filariasis, Sri Lanka trained 50 health staff at a national-level workshop. In 2001, 2666 filarial patients were cared for at the central Anti-Filaria Headquarters and another 6856 at 14 different health centres. A total of 1876 patients with hydrocoele were operated as part of routine surgical management.

Map 3.14 India: LF endemicity status and MDA coverage 2001



Map 3.15 Sri Lanka: LF endemicity status and MDA coverage 2001



■ Chapter 3 Implementing the Programme

6. PacELF Coordination and Review Group

The population at risk in this region is estimated at 4.13 million, distributed in 16 endemic countries (American Samoa, Cook Islands, Marshall Islands, Fiji, French Polynesia, Kiribati, Micronesia, New Caledonia, Niue, Palau, Papua Guinea, Samoa, Tonga, Tuvalu, Vanuatu, and Wallis & Futuna). Papua New Guinea is the country with the highest estimated at-risk population — around 2 million — i.e. 50% of the total population at risk in the region. In 2001, nine out of the 16 countries at risk in this region — designated as PacELF (Pacific Elimination of Lymphatic Filariasis) implemented MDA and other PELF activities. By the end of 2001, at least 850 000 people were covered by MDA.

American Samoa

American Samoa was one of the first countries that started the PELF. The prevalence of LF was assessed to be 16.5% by ICT cards. At the beginning of 2000, 11 081 people out of a total population of 46 757 inhabitants accepted mass drug administration with DEC + albendazole (reported coverage, 23.7%). In September 2001, a total of 29 991 people were covered by MDA, with a reported coverage of 52%.

Cook Islands

The first MDA was started in 2000 for the whole country. Out of a total of 18 034 inhabitants, 13 344 were covered by MDA, with a reported coverage of 74%. In the second round in February 2001, 11 562 persons received DEC + albendazole, with a reported coverage of 64.7% of the total population.

French Polynesia

This country, with a population of 230 000, is LF-endemic. In March 2000, some 205 000 people were covered by MDA, with a reported coverage of 93.2%. In March 2001,

214 149 people received DEC + albendazole, with a reported coverage of 95.1%.

Kiribati

The first MDA round in PELF was started in August 2001 with a population of 85 778 at risk. In 2001, 46 047 individual were adminestered DEC and albendazole.

Niue

Niue started the first MDA round in PELF in 2000 for the whole population of 1913 inhabitants. The treatment offered was DEC + albendazole in a single dose (reported coverage, 94%). The second round of MDA was in February 2001, wherein 1 706 with a reported coverage of 89.2%.

Samoa

In 2000, a total of 91 613 people were covered by MDA, with a reported coverage of 96.4%. In October 2001, a total of 119 100 people were covered by MDA with a reported coverage of 68.4%.

Tonga

The whole country is considered to be LF-endemic. The first MDA round (DEC + albendazole) in April 2001 covered a total of 79 969 people (reported coverage, 81.6%).

Tuvalu

The whole country is considered to be LF-endemic. In the first MDA in August 2001, an estimated 6 742 individuals in nine islands received DEC + albendazole drug coverage 81.2%.

Vanuatu

The country's 186 678 inhabitants were considered to be at risk of LF. The first MDA (DEC + albendazole) in June 2000 covered 154 739 people. In the second round in June 2001, a total of 155 517 individuals received the drugs (reported coverage, 83.3%).

Table 3.6 A comprehensive overview of MDA coverage in 2001

| | | Total population | Population reported | Drug cov | erage %* |
|---------------|---|---|----------------------------|--------------------|--|
| Region PRG | Country | of all IUs targeted for MDA in 2001 | to have ingested the drugs | As reported by IUs | As observed in cross-check sites |
| Africa | Burkina Faso | 558 552 | 431 399 | 77.2% | 90.4%** |
| | Comoros, Islamic Federal Republic of | 62 239 | 53 308 | 85.7% | nd |
| | Ghana | 574 834 | 393 677 | 68.5% | nd |
| | Nigeria | nd | 675 701 | | nd |
| | Togo | 458 337 | 342 398 | 74.7% | nd |
| | United Republic of Tanzania (mainland) | 675 087 | 316 494 | 71.4% | nd |
| | United Republic of Tanzania (Zanzibar) | 941 546 | 638 909 | 67.9% | 76% |
| Americas | Haiti | 150 000 | 105 750 | 70.5% | 61.9% |
| Eastern Medit | erranean Egypt | 2 412 170 | 2 325 724 | 96.4% | nd |
| Mekong-Plus | Philippines | 3 054 445 | 2 236 110 | 73.2% | nd |
| | Myanmar | 1 939 964 | 1 803 306 | 93.0% | 74.3% |
| Indian Sub-co | ntinent Bangladesh | 846 880 | 808 697 | 95.5% | 93% |
| | India | 15 267 529 | 13 433 322 | 88.0% | 59.3% |
| | Sri Lanka | 2 171 386 | 1 666 389 | 76.7% | nd |
| PacELF | American Samoa | 57 291 | 29 991 | 52.3% | nd |
| | Cook Islands | 18 034 | 11 562 | 64.1% | nd |
| | French Polynesia | 225 300 | 214 149 | 95.1% | nd |
| | Kiribati | | 46 047 | | nd |
| | Niue | 1 913 | 1 706 | 89.2% | 99%** |
| | Samoa | 174 140 | 119 100 | 68.4% | nd |
| | Tonga | 98 036 | 79 969 | 81.8% | nd |
| | Tuvalu | 8 307 | 6 742 | 81.2% | nd |
| | Vanuatu | 186 678 | 155 517 | 83.3% | nd |
| | 22 countries | 29 882 668 | 25 895 967 | | |

^{*} Drug coverage calculated as percentage of persons administered the drugs over total population in IUs

^{**:} Observed coverage is for drug coverage among eligible population nd: data not reported in annual report



Chapter 4 Facing future challenges

Fighting diseases of poverty

The pursuit of health as an ethical objective for individuals and societies is unquestionable. However, health is also a fundamentally necessary component of development, which scholars like Amartya Sen have made clear in their research (Development as Freedom, 1999). Poverty is not simply a lack of money or income: it is a lack of access to choices, resources and opportunity. The WHO Commission on Macroeconomics and Health (Investing in Health for Economic Development, December 2001) places disease control and elimination squarely and centrally within the framework of "any comprehensive development strategy". In this perspective, the Commission argues, the control or elimination of diseases such as lymphatic filariasis becomes not simply a "good thing to do", nor even a laudable objective of health sector policy — it is a centrally important factor in the elimination of barriers to overall development and to poverty alleviation. Such diseases are the causes of both poverty and non-development and they compound the problems of poverty alleviation and development the longer they persist. Actions such as those of the Global Alliance to Eliminate Lymphatic Filariasis must break that connection and both strengthen national health systems so that they can deliver sustainable public health, and improve very concretely the human development potential at individual, family, community and national levels.

On the individual and family level, according to extensive research, good health is the primary desire of people since it provides the basis on which they can gain a reasonable livelihood and achieve a decent quality of life. On the societal level, unless quality of health is set as a priority goal, the potential of society for socioeconomic growth and

profitable participation in the global economy is subject to severe, long-lasting limitations. The pursuit of health is an essential goal of development per se.

Eliminating lymphatic filariasis will free millions of people in low-income countries from the threat or the effects of a debilitating and potentially disfiguring disease. Caring for those who are already infected will reduce untold suffering. But can this be done? The answer is an unequivocal yes. Earlier programmes eliminated filariasis in Japan, and from large parts of China, Malaysia, the Republic of Korea, and certain islands in the Pacific. Lymphatic filariasis has also disappeared from endemic areas in south-east USA and north-east Australia. The fact that these successes were achieved even without the currently available, much improved tools for controlling and monitoring the infection augurs well for the future success of the filariasis elimination efforts now being undertaken.

Comprehensive health planning

The Global Programme to Eliminate Lymphatic Filariasis is the focal point of a wide-ranging and beneficial public health intervention. Because progress towards the elimination of lymphatic filariasis requires approaches and implementation techniques which are not purely medical, it is essential to involve sectors other than health in implementing and managing a successful programme. For example, social mobilization is a vital factor and requires input from the media, schools, religious organizations and community leaders. This calls for collaboration between the ministry of health and a host of other groups. However, from the point of view of overall vision, management and guidance,

the process of eliminating lymphatic filariasis must be embedded in the existing structure of national health systems.

Moreover, with a programme of which the duration will cover a period of years and which depends so strongly on local commitment and persistence, it is necessary that the national health systems should both "own" and benefit from the programmes to eliminate lymphatic filariasis. Similarly, unless the national authorities are committed to the goal of eliminating LF, it will not be given the priority it merits in terms of national development goals per se.

Collaboration with other programmes

The drugs used to control lymphatic filariasis have a broad anti-parasitic effect (Table 4.1). One collateral benefit of the programme will be to control or prevent hookworm in teenage girls and women. Hookworm is linked not only to anaemia, but also to growth stunting and cognitive deficiencies in children. Stunting, in turn, is a predisposing factor for low birth weight in the next generation of infants. As far as

children are concerned, most of the pathophysiology of worm infections is nutritional in nature. Protein-energy malnutrition, iron deficiency anaemia, vitamin A deficiency, and iodine deficiency disorders affect hundreds of millions of people, especially children, and girls and women of childbearing age.

Albendazole, one of the drugs used by the Global Programme to Eliminate Lymphatic Filariasis, is also used by the Programme on Soil-Transmitted Helminth Infections, either as albendazole or as mebendazole, an almost identical molecule. The Programme on Soil-Transmitted Helminths distributes albendazole or mebendazole generally once or twice a year to schoolchildren, depending on the worm load. Control of such helminths will also greatly benefit the health and social welfare of women (especially their pregnancy outcomes), their families, and future generations. Potential collaboration between the two programmes is focused on the administration of albendazole. The lymphatic filariasis programme administers albendazole (plus DEC or ivermectin, depending on the geographical area), and six months later the programme on soil-transmitted helminth infections provides the drug to schoolchildren.

Table 4.1 Broad anti-parasite effectiveness of drugs used to control LF

| Ivermectin | | Albendazole | |
|----------------|--------|---------------------------|--------|
| Ascaris | 100% | Ascaris | 100% |
| Strongyloides | 95% | Strongyloides | 45% |
| Enterobius | 85% | Enterobius | 85% |
| Trichuris | 10-50% | Trichuris | 40-60% |
| Hookworm | 0-20% | Hookworm | 95% |
| Larva migrans | 100% | Larva migrans | 80% |
| Onchocerciasis | 95% | Cysticercosis*/Hydatids* | |
| Lice | 100% | Giardia* / Trichomonads* | |
| Scabies | 100% | Micro- / Crypto-sporidia* | |

^{*} Requires more than 1 dose of albendazole

■ Chapter 4 Facing future challenges

Challenges to collaboration include the different target populations and the necessary synchronization of activities, especially as in most situations there are different focal points at the national level: the lymphatic filariasis programme targets the total population (except very small children and pregnant women) and may be implemented in LF-endemic areas in the country, while the helminth programme targets only school-age children. Another difference between the programmes concerns the felt needs of the community. In the helminth programme, teachers act as drug distributors and health educators, and the children are the main "captive population". In contrast, the lymphatic filariasis programme has to rely on social mobilization to convince apparently "healthy" people that they should take the drugs.

In the Onchocerciasis Programmes in Africa, the administration of ivermectin to the populations at risk in the hyper- and meso-endemic areas takes place once a year. Lymphatic filariasis is more widespread than onchocerciasis since the latter is endemic only in the river basins whilst LF occurs in many other places. Thus, where LF is concerned, there is a need to cover the total population of the implementation units targeted for MDA. However, since the Onchocerciasis Programme has been operating for a number of years and has established a system for communitydirected ivermectin treatment, the LF Elimination Programme can take advantage of this experience by synergizing the drug administration activities in co-endemic areas at sub-national level and similarly, with other programmes. Collaborative efforts along these lines are underway in Benin, Burkina Faso, Ghana, Nigeria and Togo.

Targets for 2002 and beyond

To achieve the goal of eliminating lymphatic filariasis as a public health problem by 2020, transmission needs to be reduced to a point where the 5-year-cumulative incidence in children born after initiating MDA in the area is below 1 per 1000 by the year 2015. The five-year period from 2015 to 2020 is reserved for surveillance in these last areas.

Mapping

Mapping the distribution of lymphatic filariasis within endemic countries is the first priority. Knowledge of endemic lymphatic filariasis through implementation units and their geographical distribution will lead to better and more accurate assessment of the population at risk and the burden of disease in a country. This information is essential to enable ministries of health to carefully plan national programmes to eliminate lymphatic filariasis and estimate the resources required. Recent experience in Burkina Faso and Togo confirmed that estimates of populations at risk could change substantially after completion of mapping. The population at risk in Burkina Faso almost doubled compared with the pre-mapping estimates. It is planned to complete such mapping in most countries by 2005. This would require planning for the surveys following the standard operational guidelines and ensuring the supply of quality antigen detection card tests. For areas where brugian filariasis is endemic, the surveys will have to be undertaken using night blood surveys un til the recently-developed antibody detection test kits are standardized for use in community surveys and are available on a commercial basis.

Interruption of transmission

The Programme for the Elimination of Lymphatic Filariasis has made a good start and is on a firm footing. Yet the challenges facing it are enormous (Fig. 4.1). The national programmes need to scale up to cover at least 350 million people at risk by the end of 2005 (Fig 4.2). The major challenge in such up-scaling will be respectively in the African region, the Indian Subcontinent and the Mekong-Plus area (Figs. 4.3 to 4.8). The challenge is to strike a careful balance between scaling up the programmes to cover entire at-risk populations within countries which have already initiated programmes to interrupt transmission, and extending support to endemic countries which have not yet initiated an elimination programme. It may be necessary to rapidly expand the programmes already initiated so as to cover the entire at-risk population and to make a significant epidemiological impact in the shortest period of time. The decision will depend on the political will and capacity of those countries to scale up and on the part of those who will initiate new national programmes in the near future. The key would be to implement programmes that achieve the highest drug coverage possible which would require closer monitoring and impact assessment than that currently carried out.

Figure 4.1 Ratio between population at risk covered in 2001 and remaining population to be covered in the 22 countries that implemented PELF

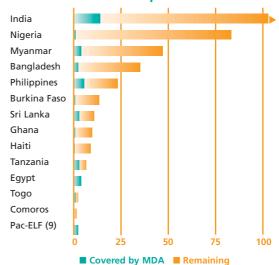


Figure 4.2 MDA up-scaling required in the next three years

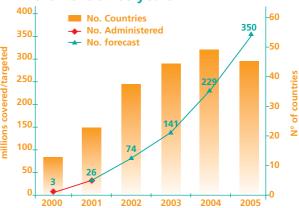


Figure 4.3 MDA up-scaling required in the next three years in the African region

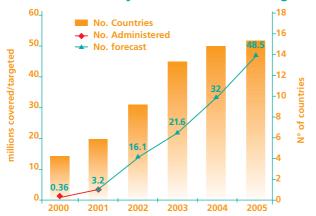
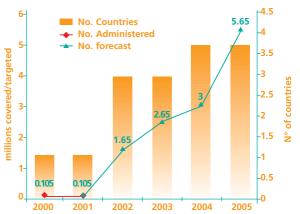


Figure 4.4 MDA up-scaling required in the next three years in the Americas



■ Chapter 4 Facing future challenges

Alleviation and prevention of disability associated with LF

The alleviation and prevention of temporary and permanent disability associated with LF is an integral component of national programmes to eliminate lymphatic filariasis. However, this component, which targets those persons with LF-associated disabilities, has not progressed much in most countries. Although the management of patients has been defined and several health personnel have been trained in these procedures, programmes to eliminate lymphatic filariasis need to provide all LF patients with access to home-based longterm care and decentralized health services for hydrocoelectomies. Further, there is a need to recognize and reduce the social, economic, cultural and psychological setbacks that patients with lymphatic filariasis suffer. Again, the key would be to integrate such services within the health system so that access to those services are available at community level where they are required most.

Figure 4.6 MDA up-scaling required in the next three years in the Indian region

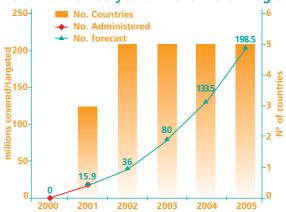


Figure 4.7 MDA up-scaling required in the next three years in Mekong-Plus region

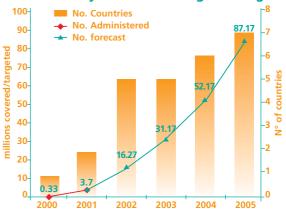


Figure 4.5 MDA up-scaling required in the next three years in the Eastern Mediterranean region

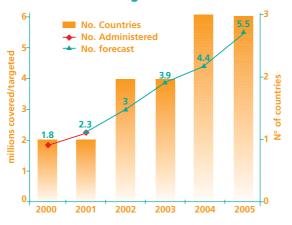
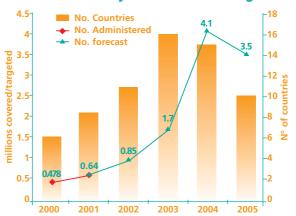


Figure 4.8 MDA up-scaling required in the next three years in Pac ELF region



Financial resources

Based on projection and estimates from national control programmes, at least US\$ 100 million will be needed to scale up LF elimination activities at country level to cover a population of 350 million at risk of LF by 2005. These funds would cover areas such as social mobilization, activities related to training, mass drug administration, monitoring and evaluation and supply of DEC.

Ways and means to achieve the targets

- The Global Alliance must generate political commitment at the national and subnational levels and societal awareness to support the efforts needed to cover the total population at risk in endemic countries. The national and local authorities in the endemic countries must have real ownership of the programme.
- Fortunately, the programme benefits from the support of members of the Global Alliance. GlaxoSmithKline will continue to donate albendazole free of charge until the disease is eliminated. Merck & Co., Inc. will expand the Mectizan® Donation Programmes for onchocerciasis to cover the countries co-endemic with lymphatic filariasis and targeted for mass drug administration in all the countries in

Africa where both diseases occur. Partners from the public sector (such as DFID-UK, the Arab Fund for Economic and Social Development, the Ministry of Health and Social Welfare of Japan), from the private sector (such as the Bill and Melinda Gates Foundation) and academia (such as the Lymphatic Filariasis Support Centre, Liverpool) have provided assistance in cash to fund the start of both the global and the country programmes. Annex 1 contains the reports of major international supporters and partners which show the extent of their commitment to the Global Programme to Eliminate Lymphatic Filariasis.

■ Global Alliance members will seek to obtain the additional funds needed from bilateral agencies and private sources — while making a special effort to identify International Financial Institutions (IFI)/ World Bank funds which are already available and could quickly be applied to activities in the Global Programme to Eliminate Lymphatic Filariasis (GPELF).

The Global Alliance has achieved a great deal since it met in Santiago de Compostela, Spain, in 2000. The future should be devoted to moving ahead quickly and efficiently with the actions needed to achieve the goal the Global Alliance has set itself – particularly in terms of scaling up national programmes.

Reports of major international supporters and partners

Arab Fund for Economic and Social Development (AFESD)

The AFESD is an Arab regional financial institution, whose objectives are to assist member countries* in eliminating development constraints, increasing absorptive capacity and achieving higher rates of growth; and to foster economic integration and cooperation among Member countries. Its function is to assist the economic and social development of Arab countries through:

- financing economic and social development projects, giving preference to overall Arab development and to joint Arab projects;
- financing private sector projects in Member States by providing all forms of loans and guarantees to corporations and enterprises possessing juridical personality and participating in their equity capital, as well as providing other forms of financing and furnishing the requisite financial, technical and advisory services;
- forming or participating in the equity capital of corporations possessing juridical personality for the implementation and financing of private sector projects in Member States;
- establishing and administering special funds whose purpose is compatible with that of the Arab Fund, and whose resources are provided by the Fund or other sources;
- encouraging the investment, directly or indirectly, of private and public capital in a manner conducive to the development of the Arab economy; and
- providing expertise and technical assistance in the various spheres of economic development.

The AFESD supports country activities in the WHO Eastern Mediterranean Region including disease detection, mapping, disability prevention and control activities, and logistical support.

Atlanta

In 2001 the Atlanta Node was established with funds from the Bill and Melinda Gates Foundation as a collaborative effort of the Lymphatic Filariasis (LF) Support Center of Emory University, the Centers for Disease Control and Prevention and the Carter Center. During that year these collaborating organizations developed and coordinated activities that included both programmatic initiatives ("model programmes" in three countries) and thematic activities in three spheres of expertise (economics, monitoring and evaluation, and morbidity/disability management).

Model programmes

Since the twin goals of the LF Elimination Programme (interrupting transmission through mass drug administration [MDA] and alleviating disability) are so distinctly different, melting these two activities into single national programmes where both components complement each other provides a formidable, but essential challenge. In 2001 the Atlanta Node's CDC and Emory staff worked closely with the Ministries of Health in the Dominican Republic and Guyana to develop 'model programmes' incorporating both components effectively and across the entire countries. In the Dominican Republic disability alleviation activities are being integrated with an MDA based on the yearly single-dose, two-drug treatment approach, while in Guyana, the disability component is being integrated with an MDA based on the alternative strategy of using DEC-fortified table/cooking salt throughout the country. In 2001, both countries completed their strategic plans, mapped the distribution of infection, initiated training programmes for disability management, laid the groundwork for MDAs beginning in 2002, and established regional intercountry linkages facilitated through PAHO.

The model programme in Nigeria - supported by the Carter Center, the Federal Ministry of Health and the Ministries of Health in Plateau and Nasawara States - has a different purpose. Since LF and onchocerciasis overlap in endemicity, the principal purpose of this project is to demonstrate the feasibility and cost-effectiveness of adding (i.e., piggybacking / integrating) LF-elimination programme elements to those already well established and on-going in the African Programme for Onchocerciasis Control. In 2001, the Nigerian programme expanded its combined treatment efforts (with ivermectin and albendazole) to reach a total of 675,400 individuals in all 12 endemic local government areas (LGAs) of these two States. In addition, more than 800 children participated in a survey that will be used as baseline for monitoring the MDA impact on reducing LF transmission; concurrent entomological studies, carried out with assistance from CDC, aimed to develop techniques to measure the MDA impact on transmission entomologically; and a needs assessment was conducted to determine the surgical requirements for repairing the urogenital damage caused by LF in men.

Economics

Programme costing, cost-effectiveness and cost-benefit are essential for sustaining country and donor investment in the Global Programme to Eliminate LF. In 2001, the Atlanta Node's Emory staff developed the research agenda for economic studies to be conducted in the Gates grant-funded activities. Because of the necessity to use consistent economic methods across countries, firstyear activities focused on the development of standard protocols (for programme costing and cost-effectiveness analysis), training programmes (in programme costing), and measures of effectiveness of LF programmes in terms of health status (i.e., 'quality-of-life' indicators). Studies were

completed in Haiti, and protocols were developed for Dominican Republic, Guyana, Egypt, Nigeria and Papua New Guinea.

Monitoring and evaluation

Monitoring and evaluation is an absolutely essential element in national programmes to eliminate LF. Only by having strong M&E can these programmes document the success of their activities and, even more importantly, identify programme elements in need of strengthening. The goal of the Atlanta Node is to provide support to national LF programmes to ensure their ability to monitor and evaluate activities in accord with the recommendations of the Guide for Programme Managers entitled "Preparing and Implementing a national Plan to Eliminate Lymphatic Filariasis" (version for countries that are co-endemic with onchocerciasis and those that are not co-endemic - WHO/CDS/CPE/CEE/2000.15 and 16). In 2001, the Node's activities included streamlining the M&E component of the Guide, developing specific M&E guidelines for countries using the DEC-salt MDA strategy, drafting an assessment protocol and strategy to identify barriers or potential barriers to programme monitoring that could limit the abilities of countries to provide the essential outcome data needed at both national and Global Programme levels, creating an 'e-group' to share in attending to the Programme's M&E needs and activities, and working with scientist colleagues to refine and make available effective monitoring tools for detecting parasite antigen and DNA.

Reports of major international supporters and partners

Morbidity and disability management

Clinical management of filarial disease is the essential element around which the entire disability-alleviation pillar of national LF elimination programmes is built. The Atlanta Node represents a particularly strong focus of clinical expertise in lymphatic filariasis and, indeed, has a long and unparalleled experience in the support, development, organization, and teaching of courses to train health workers at all levels in both the clinical and public health management of lymphoedema and hydrocoele. In 2001 the Node's CDC staff completed a definitive manual for lymphoedema management, as well as other video and printed training materials, and it supported the initiation of training activities in Haiti, Guyana, Dominican Republic, India and Brazil. The beginnings of a network to link the fledgling disability management programmes of recent trainees were also developed.

Department for International Development (DFID) of the United Kingdom

The Department for International Development (DFID), a UK Government department, is responsible for promoting development and reduction of poverty, and its current focus is to contribute to the halving of the proportion of people living in extreme poverty by 2015. Associated targets include basic health care provision and universal access to primary education by the same date.

DFID seeks to work in partnership with governments committed to these targets, with business, civil society and the research community. DFID also works with multilateral institutions such as the World Bank, United Nations agencies such as the World Health Organization, and the European Community.

DFID is helping to ensure the process of change brings benefits to all people, particularly the poorest, and for this reason is a strong supporter of lymphatic filariasis elimination.

Bill and Melinda Gates Foundation

In November 2000, the Foundation made a generous contribution of US\$20 million towards the elimination of LF. Funds are held pending disbursement in a Trust Fund in the World Bank.

At a meeting in early 2001, the groups participating in the use of the grant, comprising the Atlanta USA group (LF Support Center of Emory University, Centers for Disease Control and Prevention and Carter Center), the LF Support Centre, Liverpool, UK, WHO and the Non-Governmental Development Organizations group (led by InterChurch Medical Assistance), agreed on the following strategic outline for the use of the Gates grant:

- demonstration projects to show interruption of LF transmission; to move towards national level coverage; to develop, implement and evaluate Disability Prevention strategies; and to evaluate cost-effectiveness
- to ensure national momentum by providing support to countries for mapping and country scale implementation of ELF programmes
- to ensure global momentum through a development strategy covering regionalization, increase in the number of partners, advocacy and leverage of additional funding
- evaluation and monitoring of the demonstration projects, the country programmes and the partnership development.

The implementation of the Gates grant is now in its second year and the Foundation has expressed its satisfaction with the current level of progress.

GlaxoSmithKline (GSK)

Since 1998, GSK has been playing a major role in the Global Alliance to Eliminate LF. Working closely with WHO headquarters and Regional Offices, as well as the Ministries of Health in countries, GSK is an active and involved partner. The company provides tens of millions of albendazole treatments to communities, and more than \$1 million in cash grants to other Alliance partners each year. In addition, GSK has a dedicated LF Team of five full-time staff who support the global effort. GSK believes that, in addition to donating drugs and funds, it has many private-sector management skills that its staff can contribute to the planning and delivery work of the Alliance.

GSK is fully committed to the long-term LF elimination programme and realizes that the work is still in its early phase. By the year 2010, if all goes according to plan, more than 600 million community prevention treatments will be provided each year in over 80 participating endemic countries. GSK has set no time limits or special conditions on its participation. The company does not make any decisions about selecting countries or communities to be treated — it leaves this to the WHO-appointed regional Programme Review Groups. GSK also works closely with the Mectizan® Donation Programme in Atlanta, USA, in a collaboration that provides a simple harmonized approach for drug requests from the countries of sub-Saharan Africa where LF and onchocerciasis co-exist.

In 2001, GSK produced an LF advocacy video entitled "LF - The Patients Perspective", which has been made widely available to Alliance partners.

Lymphatic Filariasis Support Centre, Liverpool, United Kingdom

The Centre, which is situated within the Liverpool School of Tropical Medicine, benefits from the School's experience in river blindness control programmes and has substantial links with LF endemic countries. The Centre also has an extensive research portfolio and technical background on the filarial parasites and their mosquito vectors.

The Centre's role is to provide advice, funding, liaison and facilitation to eliminate lymphatic filariasis. It acts as a key interface between science and operations by facilitating activities on mapping in Africa and South-East Asia, supporting operational research with NGDOs and co-founding, with the WHO/World Bank/UNDP Special Programme for Research and Training (TDR), priority research activities for evaluation and monitoring.

Reports of major international supporters and partners

Mectizan® Donation Program

During the past year there has been significant expansion of activities in the Lymphatic Filariasis Section of the Mectizan® Donation Program (MDP). The position of Associate Director for Lymphatic Filariasis was filled in August 2001 by Dr Nana A.Y. Twum-Danso. Since joining the MDP, she has been actively working on streamlining the operations of the Lymphatic Filariasis Section and strengthening the partnership with Merck & Co., Inc., GlaxoSmithKline, WHO, and the Ministry of Health personnel in LFendemic countries. In the first year, the Mectizan® Donation Program and WHO developed an integrated application process to meet the needs of countries that are co-endemic with onchocerciasis and LF. In 2000, the provisionally established Expanded Mectizan® Expert Committee (EMEC) approved initial applications for ivermectin and albendazole from the Programme to Eliminate Lymphatic Filariasis (PELF) in Ghana, Togo, Nigeria, and the United Republic of Tanzania. Continuing applications for these four countries were approved in 2001, as well as initial applications from Benin, Burkina Faso, Uganda, and Yemen.

Non-Governmental Development Organizations (NGDOs)

Two NGDOs, Health & Development International and Interchurch Medical Assistance supported mass drug distributions by National LF Elimination Programmes in Ghana and Tanzania during 2001 as a result of funding received from the Gates Grant/ World Bank Trust Fund project. The two NGDOs, along with support of other bilateral and NGDO partners, were also able to help strengthen National LF Coordination Offices, and provide new equipment, technical support and funding for awareness-raising activities, in support of both mass drug administration (MDA) and disability alleviation and prevention, for LF elimination in these countries.

Ghana

Ghana reached approximately 394,000 people with mass drug administration, in 5 of the 35 endemic districts during 2001. The plan is to reach approximately 1.9 million people in 14 districts during 2002, and 4 million people in 20 or more districts during 2003. This rapid expansion is resulting from strong political and local popular demand for the LF Elimination Programme. Health & Development International (HDI), and Catholic Medical Mission Board (CMMB) are the two main NGDOs currently supporting activities in Ghana, with CMMB having taken on disability alleviation and mass drug administration activities for the entire Upper West Region. HDI supports the national LF elimination secretariat, as well as disability alleviation and prevention activities at the national level.

Tanzania

Tanzania's Programme is being managed by the National Institute for Medical Research of Tanzania. The Programme treated 635,000 persons in six districts in 2001, with MDA taking place in October. This was an achievement of approximately 75% of the targeted population. The programme was also able, with the assistance of financial support of the Gates Foundation and World Bank, through the NGDO Node and other partners, to complete the development of procedures and materials for supporting the National Programme. The NGDO Node support also enabled the Programme to conduct 12 training sessions for district-level political leaders and medical personnel, with 60 persons trained. Financial support enabled Programme personnel to make 25 field trips during the year for purposes of programme assessments, baseline data collection and monitoring of programme implementation activities.

Partners to the Programme include Interchurch Medical Assistance, The LF Support Centre of the Liverpool School of Tropical Medicine, DFID-UK, Michigan State University, The World Health Organization, GlaxoSmithKline and the Mectizan® Donation Program.

Support of other NGDOs

Encouraging additional NGDOs to join the LF elimination effort is a key task for which the NGDO Node members have taken on particular responsibility, stimulated by the Gates Foundation funding for this purpose, although all Alliance members are encouraged to do the same. International Volunteers in Urology (IVU) was (along with CMMB mentioned above), the first major NGDO to join the original group of agencies, offering to help improve technical expertise in the management of the diseases urogenital manifestations, through efforts by its members in many countries. To facilitate recruitment of new NGDOs, GlaxoSmithKline (GSK) hosted an initial meeting of NGDOs, in their Philadelphia office during October 2001.

List of lymphatic filariasis endemiccountries and territories by Regional Programme Review Groups

African PRG Dominican Republic

Angola Guyana Benin Haiti Burkina Faso Suriname

Burundi Trinidad and Tobago

Cameroon Eastern Mediterranean PRG

Cape Verde Egypt
Central African Republic Sudan
Chad Yemen

Congo Mekong-Plus PRG
Côte d'Ivoire Brunei Darussalam

Democratic Republic of Congo Cambodia
Equatorial Guinea China
Ethiopia Indonesia

Gabon Lao People's Democratic Republic

Ghana Malaysia
Guinea Myanmar
Guinea-Bissau Philippines
Comoros Republic of Korea

Kenya Vietnam Liberia Thailand

Madagascar Indian subcontinent PRG

Malawi Bangladesh Mali India Maldives Mauritius Mozambique Nepal Niger Sri Lanka Nigeria **PacELF PRG** Réunion American Samoa Rwanda Cook Islands

Sao Tomé and Principe Fiji

Senegal French Polynesia

Seychelles Kiribati

Sierra Leone Micronesia (Federated States of)

The Gambia New Caledonia

Togo Niue

Uganda Papua New Guinea

United Republic of Tanzania Samoa

Zambia Solomon Islands

Zimbabwe Tonga
American PRG Tuvalu
Brazil Vanuatu

Costa Rica Wallis and Futuna

COLLABORATIVE GLOBAL PROGRAMME TO ELIMINATE LYMPHATIC FILARIASIS

SERIOUS ADVERSE EXPERIENCE REPORT

for the

Global Lymphatic Filariasis Treatment Program Where the Combination of DEC and Albendazole is Used

A serious adverse experience (SAE) is defined as an adverse experience following treatment with a drug that results in any of the following:

- death
- life-threatening adverse drug experience
- in-patient hospitalization or prolongation of an existing hospitalization
- persistent or significant disability/incapacity
- · congenital anomaly or birth defect
- cancer
- overdose (accidental or intentional)

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject, and may require medical or surgical intervention to prevent one of the outcomes listed in the definition above: such events should also be reported.

COMPLETE THIS FORM ONLY IF THE ADVERSE EXPERIENCE MEETS THE ABOVE CRITERIA

and

send it promptly to:

Mrs Sue Rees

GlaxoSmithKline
Global Clinical Safety & Pharmacovigilance
New Frontiers Science Park (South)
Third Avenue
Harlow, Essex, CM19 5AW, U.K.
Telephone number:44-1279-644693

Fax number: 44-1279-644260



| Country: | | | Da | ate of Report: | // (day/month/year) |
|---------------------------|---------------------|----------------|---------------|-------------------|------------------------|
| 1. Patient Informa | ition | | | | |
| Name (First/Middle/Las | st) | | | | |
| Age (years) | | Sex 🗆 M | 1 🗆 F | | |
| Village | | District | | Province State | |
| 2. Pre-existing Con | nditions | | | | |
| Health Status before t | reatment w | ith DEC and | albendazole | : | |
| ☐ Good ☐ Poor [| Unknown | ı If "Poor | " give detail | ls: | |
| Parasitic Infections | Confirmed | Suspected | Unknown | De | etails |
| 1. Lymphatic Filariasis | | | | | |
| 2. Onchocerciasis | | | | | |
| 3. Loiasis | | | | | |
| Other parasitic infection | | - | | | |
| Other medications bei | ng taken (cu | urrently or re | ecently): | | |
| | | | | | |
| Is patient pregnant? | | | [| ☐ Yes ☐ No | ☐ Unknown |

| 3. Information on Recent All | pendazole 8 | & DEC Treat | ment | |
|--|-------------------|--------------------------------------|---------------------|---------------------|
| Were albendazole & DEC given tog | gether? | ☐ Ye | es 🗌 No | ☐ Unknown |
| If No, explain: | | | | |
| Date of treatment//_ (day/month/year) | | | | |
| Source of treatment: | Dose of DEC | Dose of albendazole (no. of tablets) | Patient's height | Patient's weight |
| ☐ Community treatment program ☐ Clinic or physician treatment ☐ Other method | (iio. or tablets) | (iio. or tablets) | (CIII) | (kg) |
| Was this a first treatment with DE | C? | □ Y€ | es 🗆 No | ☐ Unknown |
| Was this a first treatment with albendazole for mass treatment of | LF? | ☐ Y€ | es 🗌 No | ☐ Unknown |
| If "No", explain when and circums | tances of past | treatment(s): | | |
| | | | | |
| 4. Description of the Serious | Adverse E | xperience (S | SAE) | |
| Date of onset//_ (day/month/year) | | | | days were taken? |
| Clinical signs and symptoms (pleas | e describe) | | | |
| | | | | |
| | | | | |
| Were there signs of acute alcohol i | ntoxication o | n initial exam | ination? | ☐ Yes ☐ No |
| Do you think this adverse experier | nce is/was life | -threatening? | , | ☐ Yes ☐ No |
| Laboratory results (please provide | name of test) | | | |
| | | D | ate of tests | // |
| | | | | (day/month/year) |

| a) Hospitalization | ☐ Yes ☐ No | | | | |
|------------------------|-----------------------------------|------------------|-------------|----------------|-----|
| If "Yes", indicate: | 1. Date of admission (day/m | onth/year) | //_ | _ | |
| | 2. Reason for admission: | | | | |
| | 3. Date of discharge (day/mo | onth/year)/ | | - | |
| b) Drug treatments a | ndministered: | | | | |
| | | | | | |
| c) Clinical course: | | | | | |
| | | | | | |
| | | | (Attach any | relevant repor | ts) |
| 5. Condition/Ou | tcome at time of last obs | servation | | | |
| Full recovery: | | ☐ Yes | □ No | ☐ Unknow | /n |
| Ongoing illness: | | ☐ Yes | ☐ No | ☐ Unknow | /n |
| If yes describe curren | t condition: | | | | |
| Persistent/Significan | t Disability/Incapacity: | ☐ Yes | □ No | ☐ Unknow | /n |
| If yes describe: | | | | | |
| Death: | No | | | | |
| If "Yes", indicate: | 1. Date of death (day/month) | /year)/ | ′ | | |
| | 2. Cause of death: | | | | |
| | 3. Circumstances at the tim | e of death, in | detail: | | |
| | | | | | |
| Report any autopsy fin | dings made including tissues take | en for histopath | ology and | d any additior | ıal |
| studies done or reques | ted (use additional pages necess | ary to complete | your ans | wers): | |
| | | | | | |

| 6. Conclusions (to be completed by the health care provider) |
|--|
| Presumptive Diagnosis: |
| Do you think the combined drug treatment with DEC & albendazole was a possible |
| causative factor in this Serious Adverse Experience? ☐ Yes ☐ No ☐ Not sure |
| If "Yes", explain: |
| |
| If "No" or "Not sure", what do you believe was the cause of the experience? |
| |
| |
| |
| 7. Source (reporter(s) of the data in this form) |
| Name of person making the report |
| Title |
| Organization |
| Address |
| |
| Telephone number Fax number |
| E-mail |

Within one working day of receipt, the report will be distributed by GlaxoSmithKline Clinical Safety Group to:

Dr Mark Bradley Manager Scientific Support Global Community Partnerships GlaxoSmithKline GSK House, 980 Great West Road Brentford, Middlesex TW8 9GS, U.K. Telephone number: 44 208 047 5521 Fax number: 44 208 047 0684 E-mail: mark.h.bradley@gsk.com

Dr G. Biswas Lymphatic Filariasis Elimination World Health Organization 20 Avenue Appia, CH-1211 Geneva 27, SWITZERLAND Phone number: 41-22-791-3850 Fax number: 41-22-791-4777 E-mail: biswasg@who.int

PRIMARY CONTACT INDIVIDUAL

Mrs. Sue Rees
Head, Postmarketing Group
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Global Clinical Safety & Pharmacovigilance
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Third Avenue
Harlow, Essex, CM19 5AW, U.K.

Telephone number: 44-1279-644693 Fax number: 44-1279-644260 E-mail: Susan_H_Rees@sbphrd.com

COLLABORATIVE GLOBAL PROGRAMME TO ELIMINATE LYMPHATIC FILARIASIS

SERIOUS ADVERSE EXPERIENCE REPORT

for the

African Lymphatic Filariasis Treatment Program

A serious adverse experience (SAE) to a drug is defined as an adverse experience following treatment with a drug that results in any of the following:

- death
- life-threatening adverse drug experience
- in-patient hospitalization or prolongation of an existing hospitalization
- persistent or significant disability/incapacity
- congenital anomaly or birth defect
- cancer
- overdose (accidental or intentional)

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject, and may require medical or surgical intervention to prevent one of the outcomes listed in the definition above should also be reported.

COMPLETE THIS FORM ONLY IF THE ADVERSE EXPERIENCE MEETS THE ABOVE CRITERIA and send it promptly to:

Mectizan Donation Program 750 Commerce Drive, Suite 400 Decatur, GA 30030 USA



| Country: | | | Da | te of Report: | // (day/month/year) |
|---------------------------|--------------|----------------|---------------|-------------------|------------------------|
| 1. Patient Informa | ntion | | | | |
| Name (First/Middle/Las | st) | | | | |
| Age (years) | | Sex 🗆 N | 1 🗆 F | | |
| Village | | District | | Province State | |
| 2. Pre-existing Co | nditions | | | | |
| Health Status before to | reatment wi | th Mectizan® | , and albend | azole (including | any CNS disability): |
| ☐ Good ☐ Poor | Unknowr | ı If "Poor | " give detail | s: | |
| Parasitic Infections | Confirmed | Suspected | Unknown | De | etails |
| 1. Onchocerciasis | | | | | |
| 2. Lymphatic Filariasis | | | | | |
| 3. Loiasis | | | | | |
| If Loiasis is confirmed | mf/ml (blo | od): | mf/n | nl (CSF): | |
| Other parasitic infection | ons, known (| or suspected | (e.g. Malari | a) | |
| Other medications bei | ng taken (cı | irrently or re | ecently): | | |
| | | · | - | | |
| Is patient pregnant? | | | [| ☐ Yes ☐ No | ☐ Unknown |
| Alcohol intake within | 24hrs of tak | ing drugs? | | ☐ Yes ☐ No | ☐ Unknown |

| 3. Information on Recent All | oendazole 8 | & Mectizan® | , Treatmer | it |
|--|--|--------------------------------------|---------------------|------------------------|
| Were albendazole & Mectizan®, giv | en together? | | Yes 🗌 No | ☐ Unknown |
| If No, explain: | | | | |
| Date of treatment//(day/month/year) | | | | |
| Source of treatment: | Dose of Mectizan® (no. of tablets) | Dose of albendazole (no. of tablets) | Patient's height | Patient's weight |
| ☐ Community treatment program ☐ Clinic or physician treatment ☐ Other method | (no. or tablets) | (no. or tablets) | (CIII) | (kg) |
| Was this a first treatment with Me | ctizan®? | □ Ye | es 🗆 No | ☐ Unknown |
| Was this a first treatment with albendazole for mass treatment of LF? ☐ Yes ☐ No ☐ Unknown | | | | |
| If "No", explain when and circums | tances of past | treatment(s): | | |
| | | | | |
| 4. Description of the Serious | Adverse E | xperience (S | SAE) | |
| Date of onset// (day/month/year) | | | | days were taken? |
| Clinical signs and symptoms (pleas | e describe) | | | |
| | | | | |
| | | | | |
| Were there signs of acute alcohol i | ntoxication o | n initial exam | ination? | ☐ Yes ☐ No |
| Do you think this adverse experier | nce is/was life | -threatening? | | ☐ Yes ☐ No |
| Laboratory results (please provide | name of test) | | | |
| | | D | | // (day/month/year) |

| a) Hospitalization | ☐ Yes ☐ No | | | |
|------------------------|----------------------------------|-----------------|------------|-------------------|
| If "Yes", indicate: | 1. Date of admission (day/m | nonth/year) | | _ |
| | 2. Reason for admission: | | | |
| | 3. Date of discharge (day/m | onth/year) | <i>!</i> ! | - |
| b) Drug treatments a | dministered: | | | |
| | | | | |
| c) Clinical course: | | | | |
| | | | | relevant reports) |
| 5. Condition/Ou | tcome at time of last ob | servation | | |
| Full recovery: | | ☐ Yes | □ No | ☐ Unknown |
| Ongoing illness: | | ☐ Yes | □ No | ☐ Unknown |
| If yes describe curren | t condition: | | | |
| Persistent/Significant | t Disability/Incapacity: | ☐ Yes | □ No | ☐ Unknown |
| If yes describe: | | | | |
| Death: ☐ Yes ☐ |] No | | | |
| If "Yes", indicate: | 1. Date of death (day/month | n/year)/ | / | |
| | 2. Cause of death: | | | |
| | 3.Circumstances at the tim | ne of death, in | detail: | |
| | | | | |
| Report any autopsy fin | dings made including tissues tak | en for histopat | hology and | d any additional |
| studies done or reques | ted (use additional pages necess | sary to complet | e your ans | wers): |
| | | | | |

| 6. Conclusions (to be completed by the health care provider) |
|---|
| Presumptive Diagnosis: |
| Do you think the combined drug treatment with Mectizan®, & albendazole was a possible causative factor in this Serious Adverse Experience? Yes No Not sure |
| If "Yes", explain: |
| |
| If "No" or "Not sure", what do you believe was the cause of the experience? |
| |
| 7. Source (reporter(s) of the data in this form) |
| Name of person making the report |
| Title |
| Organization |
| Address |
| |
| Telephone number |
| E-mail |

Please send this report to the following:

Mectizan® Donation Program 750 Commerce Drive, Suite 400 Decatur, Georgia 30030 U.S.A.

Telephone number: 404-371-1460 Fax number: 404-371-1138 E-mail: mectizan@taskforce.org

Within one working day of receipt, the report will be distributed by the Mectizan® Donation Program to:

Dr. Philippe Gaxotte Laboratoires Merck Sharp & Dohme Interpharma Fax number: 33-1-30-82-10-90 106, Avenue Jean Moulin 78170 La Celle Saint Cloud, FRANCE

Telephone number: 33-1-30-82-10-37 E-mail: philippe_gaxotte@merck.com

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Linda S. Hostelley **Executive Director** Adverse Experience Reporting Worldwide Worldwide Product Safety & Epidemiology Merck Research Laboratories P. O. Box 4, BLB-30 West Point, PA 19486, U.S.A.

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Telephone number: 44-1279-644693 Fax number: 44-1279-644260 E-mail: Susan_H_Rees@sbphrd.com

Glossary of acronyms and Programme to Eliminate Lymphatic Filariasis definitions

Acronyms

ADL Adenolymphangitis
ADR Adverse Drug Reactions

AFRO African Regional Office (of the WHO)

AMRO American Regional Office (of the WHO)

APOC African Programme for Onchocerciasis Control

CDS Communicable Diseases Cluster of WHO

CEE Strategy Development and Monitoring for Elimination and Eradication Unit
CPE Department for Communicable Disease Control Prevention and Eradication

CHW Community Health Worker

CSR Department for Communicable Disease Surveillance and Response

DEC Diethylcarbamazine citrate
DOT Directly Observed Treatment
ELF Elimination of Lymphatic Filariasis

EMRO Eastern Mediterranean Regional Office (of the WHO)
GAELF Global Alliance to Eliminate Lymphatic Filariasis

GIS Geographic Information System

GSK GlaxoSmithKline

ICT Immuno-chromatographic test

IEC Information, Education and Communication

ITN Insecticide Treatment Nets
IU Implementation Unit

KAP Knowledge, Attitude and Practices

LF Lymphatic Filariasis

LQAS Lot Quality Assurance Sampling
MDA Mass Drug Administration
MDP Mectizan® Donation Program

MIES Management Information and Evaluation System

MoH Ministry of Health MSD Merck & Co., Inc.

NFCP National Filaria Control Programme

NGDO Non-Governmental Developmental Organization

NGO Non-Governmental Organization
NPS National Pharmacovigilance System

NTF-ELF National Task Force to Eliminate Lymphatic Filariasis

PacELF Pacific Initiative for the Elimination of Lymphatic Filariasis

PAHO Pan American Health Organization

PELF Programme to Eliminate Lymphatic Filariasis

PHC Primary Health Centre PRG Programme Review Group QA Quality Assurance QC Quality Control

SAE Serious Adverse Experience

SB SmithKline Beecham

SEARO South East Asian Regional Office (of the WHO)

TAG Technical Advisory Group

TCC Technical Consultative Committee (of APOC)

TDR WHO/World Bank/UNDP Special Programme for Research and Training

UN United Nations

UNDP United Nations Development Programme

UNFPA United Nations

UNICEF United Nations Children's Fund WHO World Health Organization

WPRO Western Pacific Regional Office (of the WHO)

PELF Definitions

A Serious Adverse Experience (SAE): an event which is fatal, life threatening, disabling or incapacitating or results in hospitalization, prolongs a hospital stay or is associated with congenital abnormality, cancer or overdose (either accidental or intentional). In addition, any experience which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event

Case classification

Lymphatic Filariasis case: an individual having current infection with Brugia malayi, Brugia timori or Wuchereria bancrofti, whether or not microfilaraemic.

Clinical case: individual with any of the clinical findings of hydrocoele, chylocoele, lymphoedema, chyluria, haematochyluria, haematuria, hyper-eosinophilia or tropical pulmonary eosinophilia syndrome; for which other causes have been excluded in a resident of, or long-term visitor to, an endemic area, plus specific antibody elevations in visitors to endemic regions.

Probable case: a case that meets the clinical case definition.

Confirmed case: a case confirmed by laboratory or ultrasonography examinations.

Laboratory criteria for diagnosis of infection: presence of microfilariae, circulating filarial antigen or detection of adult worm(s) by ultrasonography or biopsy.

Glossary of Acronyms and LF Definitions

Endemicity

Countries are classified as:

Implementation Unit (IU) for MDA: the designated administrative unit in a country, for which the decision to administer the entire population with recommended anti filarial drugs if identified as having indigenous transmission or endemic.

Endemic IU: IU whose average or any of its population sub-unit (village or urban area) has an LF infection rate of 1% or more among its native population.

Endemic country: country where any of its IU is known or has reported to be endemic after 1980.

Never endemic: country with no history or evidence of endemic filariasis.

Post-endemic: country with known history of endemic filariasis before 1980, but with no evidence of transmission or new infection since 1980.

Unknown: Countries with history of endemic filariasis before 1980 or where evidence of infection in immigrants is present but clear evidence of indigenous transmission is absent.

Drug administration and monitoring

Drug coverage for a designated [area]: The proportion of all individuals of the [area] who ingested the drug(s) in the adequate dosage

Number of individuals who ingested adequate dosage recommended antifilarial drugs x 100

Total population of the [area]

[area] refers to any geographical area up-to the level of the designated IU, e.g. if the designated implementation unit is the district which is sub-divided into counties/blocks, villages or urban areas, area could refer to villages, urban areas, counties/blocks or to the district.

For reporting coverage for administrative units above the level of the IU, drug coverage to be calculated as:

Sum of all individuals in the targeted IUs ingested the recommended AF drugs x 100

Total population of all the targeted IU under the administrative unit

Reported coverage: The coverage based on reports received from reporting units.

Geographical coverage: Proportion of IUs targeted covered by MDA during the reporting year

Number of IU covered by MDA in the year x 100

Total number of endemic IU during the year

Proportion of villages/urban areas covered by MDA in the targeted IU during the reporting year

Number of villages/urban areas in the targeted IU covered by MDA x 100 Total number of villages/urban areas in the target IU

Observed drug coverage: the coverage based on actual verification by supervisory tier (done on a sample population).

Proportion of all verified individuals who ingested the drug(s) in the adequate dosage

Number of verified individuals who ingested adequate dosage antifialrial drugs x 100

Number of individuals in the verified households

Population at risk (or at-risk population): Total population in the endemic Implementation Unit(s)

Microfilaria prevalence (mf%): Proportion of blood slides (20µl) found positive for microfilariae (Wb, Bm or Bt) species.

Number of individuals whose slides are positive for mf x 100

Total number of individuals examined for mf

Microfilaria density (mfd): Average number of microfilarae in slides positive for microfilaria expressed as per ml of capillary blood

Total count of microfilariae in the slides found positive x 50 (presuming 20 μl per slide)

Number of slides found positive

Antigen prevalence: Proportion of individuals surveyed testing positive for CFA

Number of individuals testing positive x 100

Total number of individuals with a valid test result

Please note: When Lot Quality Assurance Sampling (LQAS) is undertaken as in initial assessment and mapping and the survey stopped on finding a positive result, it is inappropriate to calculate prevalence. The result would only indicate that the antigenaemia is above the cut off percent.

Grading of Lymphoedema

Grade I: mostly pitting oedema; spontaneously reversible on elevation

Grade II: mostly non-pitting oedema; not spontaneously reversible on elevation

Grade III: gross increase in volume in a Grade II lymphoedema with dermatosclerosis

and papillomatous lesions