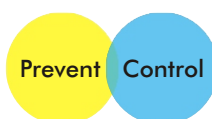




Regional Strategic Framework for Elimination of Kala-azar from the South-East Asia Region

2011–2015



Vector-borne diseases

Chikungunya • Dengue • Japanese encephalitis • **Kala-azar** • Lymphatic filariasis • Malaria • Schistosomiasis

Regional Strategic Framework for Elimination of Kala-azar from the South-East Asia Region

2011–2015



**World Health
Organization**

Regional Office for South-East Asia

© World Health Organization 2012

All rights reserved.

Reprinted in 2014

Requests for publications, or for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – can be obtained from Bookshop, World Health Organization, Regional Office for South-East Asia, Indraprastha Estate, Mahatma Gandhi Marg, New Delhi 110 002, India (fax: +91 11 23370197; e-mail: bookshop@searo.who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

This publication does not necessarily represent the decisions or policies of the World Health Organization.

Printed in India

Contents

Executive Summary.....	1
1. Introduction.....	2
1.1 Current burden of visceral leishmaniasis (kala-azar) in the SEA Region.....	2
1.2 Factors favourable for elimination of kala-azar.....	2
1.3 Major achievements	3
1.4 Constraints in elimination	3
1.5 Relevance of kala-azar elimination to Millennium Development Goals.....	4
2. Goal and target.....	5
2.1 Goal	5
2.2 Target	5
3. Objectives.....	6
3.1 Impact objective	6
3.2 Process objectives.....	6
4. Strategies	7
4.1 Early diagnosis and complete case management	7
4.2 Integrated vector management and vector surveillance	8
4.3 Effective disease surveillance through passive and active case detection	9
4.4 Social Mobilization and building partnerships	10
4.5 Implementation and operational research.....	11
4.6 Capacity building	12
5. Implementation of the elimination programme	14
5.1 Preparatory phase	14
5.2 Attack phase	16
5.3 Consolidation phase	17
5.4 Maintenance phase	17

6.	Regional update on kala-azar elimination	18
6.1	Intercountry consultative meeting, Varanasi, India, November 2003.....	18
6.2	Memorandum of Understanding for intercountry cooperation.....	18
6.3	Regional Technical Advisory Group	18
6.4	Advocacy materials.....	19
6.5	Drug quality, drug supply and logistics	19
6.6	Development of draft country operational plans.....	19
7.	Activities undertaken	20
7.1	Development of technical guidelines	20
7.2	Geographic Information System and mapping for IRS	20
7.3	Technical support at local levels.....	20
7.4	Research protocols and capacity development in operational research	21
7.5	Coordination with partners.....	21
7.6	Meetings/informal consultations held.....	21
8.	Monitoring and evaluation	23

Executive Summary

The preparatory phase for the elimination of kala-azar from South-East Asia is near completion and has pointed the way forward. The emphasis is now on the attack phase which will focus on the endemic villages and the primary health care units. This will include actively finding kala-azar cases and performing rapid point-of-care diagnosis and treatment with a single dose of liposomal amphotericin B at the primary health care unit. This will be the most effective way to rapidly reduce the kala-azar burden, reduce transmission and reduce the duration of hospital stay. Diagnosis and complete treatment on the same day using liposomal amphotericin B will be easier to manage by the primary health care system, ensure 100% treatment compliance and will be the best option for the patients. Combination therapies involving miltefosine, paromomycin, and liposomal amphotericin B should be used following elimination and as alternative treatments. This approach will be further supported by scaling up providing information, communication and education about kala-azar in the endemic villages to mobilize strong community support for elimination. Finally, sandfly vector control will be implemented using integrated vector control management and the recently developed monitoring and evaluation toolkit to improve the performance of existing vector control strategies. This multiple approach strategy will have a major impact on reaching the elimination target of one case in 10 000 by 2015 in South-East Asia.

1

Introduction

1.1 Current burden of visceral leishmaniasis (kala-azar) in the SEA Region

Leishmaniasis occurs in three forms: (a) cutaneous, (b) mucocutaneous and (c) visceral. Visceral leishmaniasis (kala-azar) is fatal if untreated. It is transmitted by the bite of the infected female phlebotomine sandfly. Leishmaniasis are endemic in 98 countries with an estimated yearly incidence of 1-1.5 million cases of cutaneous leishmaniasis (CL) and 500 000 cases of visceral leishmaniasis (VL). In WHO's South-East Asia Region, about 147 million people in three countries (Bangladesh, India and Nepal) are at risk of kala-azar. Recently, a small focus of kala-azar has been identified in Bhutan. Estimates indicate about 100 000 cases per year in this Region. The disease occurs predominantly in the poor and marginalized communities. Nearly 2.4 million disability-adjusted life years (DALYs) are lost each year due to kala-azar globally. The SEA Region accounts for the loss of about 400 000 DALYs. The economic burden of the disease in the affected areas of the Region is large even though precise estimates are not available.

1.2 Factors favourable for elimination of kala-azar

◆ Biological factors

In the SEA Region, man is known to be the only reservoir host for kala-azar and *Phlebotomus argentipes* is the only known vector.

◆ Technical factors

- Availability of a reasonably safe and effective oral drug (miltefosine). Alternative effective medicines (paromomycin, amphotericin B, lipid amphotericin B) are available. Recently, liposomal amphotericin B has been recommended as the first-line drug and may be implemented when training and infrastructure is ready.

- Availability of reliable and easy-to-use rapid diagnostic dipstick test 'rk39'.
- Positive experiences in the past in controlling the disease using indoor residual spraying (IRS) as a collateral benefit of malaria control.
- ❖ Strong political commitment in the four countries including Bhutan through intercountry collaboration favours feasibility of elimination of the disease.
- ❖ The disease is limited to 109 districts (45 Bangladesh, 52 India and 12 Nepal). Some districts in Bhutan are also affected with sporadic cases. Hence, elimination efforts should be focused in the four endemic countries.

1.3 Major achievements

- ❖ A memorandum of understanding was signed by health ministers from Bangladesh, India and Nepal in May 2005 for the elimination of kala-azar.
- ❖ Development of a monitoring and evaluation toolkit to support and improve vector control programmes.
- ❖ Major collaborative agreements established between WHO, SEA Region control programmes and NGOs (Gates, MSF, DNDi, iOWH and others) for implementation of interventions.
- ❖ Standard operating procedures have been developed by WHO- SEARO and country expert investigators for vector control, case detection and rapid diagnosis.
- ❖ Completion of the WHO technical report on control of leishmaniasis, produced with major inputs from experts from Bangladesh, India and Nepal and implementation into elimination strategy.

1.4 Constraints in elimination

- ❖ Absence of precise knowledge of the incidence of the disease is a constraint in the planning of elimination.
- ❖ Patients of kala-azar also seek treatment from private doctors/unqualified practitioners who provide incomplete or inappropriate treatment, which is expensive. Treatment is often delayed which favours continued transmission of the disease. The drugs that are currently used show variable efficacy and are relatively toxic. In India, resistance is reported in more than 50% cases treated with sodium antimony gluconate (SAG) in some districts in Bihar

and Jharkhand states. SAG has gradually been phased out in some of the countries e.g. Nepal.

- ◆ There is persistence of the reservoir in the form of cases of post-kala azar dermal leishmaniasis (PKDL). Cases of PKDL have been increasing steadily since the 1970s. These cases often remain undetected and untreated. Published information reports that the occurrence of PKDL has decreased with the use of amphotericin B compared to SAG. However, incidence of PKDL has been seen up to 20% of treated cases using SAG from Bangladesh.
- ◆ Vectors are in abundance in peri-domestic areas. Outdoor sleeping habits of people during the summer months favour transmission of the disease.
- ◆ The vector thrives in cracks and crevices of mud-plastered houses, heaps of cow dung, in rat burrows, and in bushes and vegetations around houses where spraying may not be done.
- ◆ The disease is increasingly affecting the poorest in the community and access to VL care may be difficult.
- ◆ There is a strong need for urgent cross-border collaboration.
- ◆ The role of asymptomatic cases needs to be determined.

1.5 Relevance of kala-azar elimination to Millennium Development Goals

Elimination of kala-azar will contribute to Millennium Development Goals 1, 4 and 6 to eradicate extreme poverty and hunger, improve maternal health and contribute to the elimination of major infectious diseases of the developing world.

2

Goal and target

2.1 Goal

To contribute to improving the health status of vulnerable groups and at-risk population living in kala-azar-endemic areas of Bangladesh, Bhutan, India and Nepal by the elimination of kala-azar so that it is no longer a public health problem.

2.2 Target

To reduce the annual incidence of kala-azar to less than one per 10 000 population, at upazilla in Bangladesh, sub-district in Bhutan, India and Nepal and districts in Bhutan and Nepal.

3

Objectives

3.1 Impact objective

To reduce the annual incidence of kala-azar and PKDL to less than one per 10 000 population at district (or sub-district) level by the end of 2015 by:

- ♦ reducing kala-azar in the vulnerable, poor and unreached populations in endemic areas;
- ♦ reducing case-fatality rates from kala-azar to negligible level;
- ♦ reducing cases of PKDL to interrupt transmission of kala-azar; and
- ♦ preventing the emergence of kala-azar/HIV/TB coinfections in endemic areas.

3.2 Process objectives

- ♦ To improve the effectiveness of programme management with a focus on implementation, monitoring and compliance ;
- ♦ To enhance capacity-building at all levels of the health system in kala-azar-endemic districts;
- ♦ To establish effective disease and vector surveillance system for planning and response supported by reliable laboratory diagnosis;
- ♦ To ensure early diagnosis and complete case management of kala-azar and PKDL;
- ♦ To undertake disease prevention and control by integrated vector management (IVM) through selective stratified indoor residual spray (IRS), insecticide treated nets (ITN) and environmental management with community participation and intersectoral collaboration;
- ♦ To conduct implementation and operational research to optimize existing interventions including diagnosis, treatment, case-finding and vector control; and
- ♦ To strengthen information, communication and education at the community level on the prevention and cure of kala-azar.

4

Strategies

4.1 Early diagnosis and complete case management

Effective case management includes early diagnosis, complete treatment and monitoring of adverse effects. Early diagnosis and complete treatment strategy would help reduce case-fatality rates and increase the credibility of the health system, in order to increase the utilization of health services by people suspected to be suffering from the disease. It is proposed to use an agreed case definition of the disease as a starting point. The case definition for suspecting kala-azar agreed at the informal country consultation (2003) and endorsed by the Regional Technical Advisory Group (2009) is: *history of fever of more than two weeks and splenomegaly in a patient from an endemic area*. This case definition is likely to be sensitive but not specific. Additional signs that are useful include weight loss and enlarged liver. Patients with the above-mentioned symptoms should be screened by 'rK 39' and, if positive should be treated with an effective drug. In cases with past history of kala-azar or in those with high suspicion of kala-azar but with negative rk39, confirmation of kala-azar can be done by examination of bone marrow/spleen aspirate for LD bodies but this is difficult and invasive. Therefore, it can be done only in some hospitals (district hospitals in Bangladesh and India and referral hospitals in Bhutan and Nepal). Treatment of kala-azar should only be undertaken after diagnosis is confirmed.

In the last few years, more anti-VL drugs have become available: miltefosine, paromomycin, amphotericin B and lipid amphotericinB (LAB). The choice of the drug would need to be based on the efficacy and the capacity and training of the health staff. A national drug policy based on drug combinations would appear the best strategy for protecting these medicines from resistance. Given the risk of development of resistance to established and new medicines, the use of monotherapy should be limited to LAB only. Combination therapy using (a) LAB and miltefosine (b) LAB and paromomycin and (c) paromomycin and miltefosine have been shown to be effective in studies from India.

Miltefosine, an oral drug has been registered in Bangladesh, India and Nepal. It cannot be used in pregnancy and in women of reproductive age who are not using contraceptives regularly. Miltefosine should be administered as directly observed treatment in order to retain its efficacy and delay the emergence of drug resistance by ensuring better compliance. Paromomycin, an injectable drug, is registered in India and Bangladesh and is in the WHO essential drug list. It is advantageous because of its low cost. Liposomal amphotericinB has been shown to be effective, single dose LAB (10 mg/kg) has a cure rate of 96% in a study from India. This single dose regime has been recommended as a first choice therapy by the WHO expert committee. Combination therapy using the above drugs has been recommended as a second choice. AmphotericinB and liposomal amphotericinB are rescue drugs in the treatment of kala-azar. Health system strengthening including training of the health staff in the proper use of the drugs is essential. Use of treatment cards will contribute to better compliance. Pharmacovigilance should be incorporated within the programme. Outcome of therapy to assess cure rate should be conducted at the end of treatment and six months after completion of treatment as relapses can occur.

PKDL perpetuates infection as it is difficult to diagnose and treat. Several regimens are being used (a) SAG for 120 days (b) amphotericin B 3-4 courses and (c) miltefosine 12 weeks. More evidence-based therapy using shorter regimens needs to be generated through research to standardize the therapy for PKDL.

4.2 Integrated vector management and vector surveillance

The mainstay of vector control is indoor residual spraying. The insecticides in use include DDT in India and pyrethenoides in Bangladesh and Nepal. Adoption of a uniform insecticide strategy is advisable through intercountry cooperation.

Through geographical information system (GIS) and remote sensing (RS), water bodies should be identified in the district selected and spraying operations carried out within a radius of one kilometre of these water bodies. Mapping of the district for water bodies would be useful in limiting spraying operations to those areas where maximum impact is likely to occur. This will help economize on insecticide consumption and help control environmental degradation. Selective IRS would be advisable only when surveillance is geared up and geographic mapping

with validation is available; until then, IRS based on incidence reporting may be continued.

Spraying operations should be undertaken at the most appropriate time of the year. IRS should achieve maximum coverage and be done thoroughly in order to have a lasting impact. Community mobilization is required to get maximum cooperation from households so that IRS helps in eliminating the vector effectively. IRS should be followed by entomological surveillance (reduction in density and longevity) to provide evidence on the efficacy of IRS. This strategy would help contain costs and also ensure good quality of IRS operation in order to produce the desired impact. Noncompliance with operational guidelines is a waste of money and moreover leads to environmental damage. Quality assurance systems with vector control monitoring toolkit developed by SEARO/TDR should be used to monitor the IRS activities. Insecticides should be rotated at regular intervals to prevent the emergence of resistance. The control programme should include studies of susceptibility before the selection of the insecticides and resistance should be monitored at sentinel sites in the programme.

Another strategy that will complement IRS is reducing human/vector contact through ITNs. Strategies for ITNs should be developed and the distribution monitored for impact. Sanitation in the household, peri-domestic environment and the community plays an important role in eliminating vector breeding and reducing longevity with consequent reduced risk of transmission. The success of ITNs and environmental sanitation would depend on effective behavioural change communication (BCC). Therefore a BCC strategy that includes ITNs and environmental management should be considered as part of IVM. This should be sustainable.

Surveillance of *P. argentipes* vector is important to determine the distribution, population density, major habitats, and spatial and temporal risk factors related to kala-azar transmission. The information on vector surveillance would be crucial for planning and programming IVM strategy. Integrated disease (including PKDL) and vector surveillance is recommended for kala-azar elimination.

4.3 Effective disease surveillance through passive and active case detection

Disease surveillance includes reporting of cases of kala-azar and PKDL. Currently, surveillance through passive case detection is done in government institutions.

This does not give a true picture since (a) a majority of cases of kala-azar go to private doctors including unqualified practitioners as there is no reporting from these health care providers; (b) treatment is often started without a definitive diagnosis of kala-azar, and (c) many cases do not seek health care at all because of poverty and socio-cultural constraints. Despite the above constraints, passive case detection and reporting is used to monitor the trends of the disease. The strategy will be to strengthen reporting through improved diagnosis and treatment and to establish partnership with private health care providers including private doctors and to ensure that the community is empowered with knowledge of risks of seeking services of unqualified practitioners for diagnosis and treatment. An effort should be made to provide appropriate treatment to the community through qualified professionals. For improved surveillance, kala-azar should be made a notifiable disease in the affected areas. Disease surveillance for kala-azar should comprise monthly reporting and feedback at district level, and evolving a system of regular reporting with state and national authorities. Reporting to WHO should be done on an annual basis (if possible twice a year) and endemic countries should send reports on an agreed reporting format.

As the programme improves and capacity is increased, passive case detection (PCD) should be supplemented with active case detection (ACD) that is supported by laboratory diagnosis. While ACD is recommended at least once a year in the beginning (if possible, twice per year). This will become more important as the number of cases reported by passive case detection declines.

The yield, feasibility and cost for different ACD strategies (camp, index case, incentive and blanket approach) in VL-endemic districts have shown a high yield of new cases. The programme costs vary according to the screening method chosen. Countries need the right mix of approaches according to the epidemiological profile, affordability and organizational feasibility.

4.4 Social Mobilization and building partnerships

Behavioural change interventions are important in the elimination of kala-azar and for the success of early diagnosis and treatment adherence. Effective BCC can also help in promoting early care seeking. Participation of the community and families in IRS and in reducing human/vector contact is necessary. Social mobilization should be an integral part of the elimination programme right from inception. National programmes should plan adequate resources for effective BCC.

Partnerships will be necessary at all levels i.e. at district and state levels, at national level and with international stakeholders. Some of the elimination and eradication programmes (polio, leprosy, lymphatic filariasis) owe their success to multi-partner leadership.

Partnerships, networking and collaboration will be required with other programmes like vector-borne disease programmes (malaria, dengue and filaria) and others, e.g. HIV/AIDS, TB, and leprosy. Anaemia control, improvement in nutritional status and poverty alleviation programmes should be made partners of the kala-azar elimination programme.

4.5 Implementation and operational research

Several drugs are available including miltefosine, paromomycin, amphotericin B and liposomal amphotericin B. Implementation research is required to identify the most effective use of these drugs and integration into the unique health care systems of the alliance countries. Recent studies have shown efficacy with a single dose of liposomal amphotericin B and combination regimens but their integration in the programme is needed. It is essential to monitor drug resistance for making rational drug policies, and specialized centres should be involved.

The current validated RDTs are based on antibody detection which has many drawbacks. Thus, there is an urgent need to develop tests based on antigen or nucleic acid detection (like PCR) from various biological fluids.

Operational research is also recommended to monitor quality of drugs and diagnostics and their use in the programme. PKDL is at present a serious constraint in the elimination of kala-azar. Research is needed in developing strategies for searching for cases of PKDL and for satisfactory (short, cost effective and safe) regimens for its treatment. Research on the role of asymptomatic infected individuals in the perpetuation of leishmania transmission needs to be elucidated.

As the diagnosis and outcome of treatment of HIV/VL co-infection may be different, a diagnostic test and treatment strategies need to be worked out.

It is well recognized that due to excite-repellent effect of DDT/other insecticides, vector species change their behaviour towards exophily and exophagy. Therefore, it is essential to monitor the vector species in respect of the following:

- ❖ Adult: Extent of indoor or outdoor resting, change in feeding behaviour and sites of transmission.
- ❖ Larvae: Breeding sites and mapping through GIS/RS for development of environmental management.
- ❖ ITN: Assessment of human blood index.

Implementation research is required in pilot districts where the programme should be monitored closely to identify constraints and lessons learnt. Research on increasing access of interventions to the poorest people and for operationalization of IVM is recommended. An important operational research issue is to evaluate the public-private mix. Networking is an important strategy to optimize operational research and link it with programme implementation.

4.6 Capacity building

Capacity building is defined as an approach to “the development of sustainable skills, organizational structures, resources and commitment to health improvement in health and other sectors, to prolong and multiply health gains many times over”. It can sometimes be described as the ‘invisible work’. This can include activities as diverse as canvassing the opportunities for a programme, lobbying for support, developing skills, supporting policy development, negotiating with management, guiding the establishment of partnerships, or contributing to organizational planning. Capacity building may occur both within programmes and more broadly within systems and leads to better capacity of people, organizations and communities. This means that capacity building activity may be developed with individuals, groups, teams, organizations, inter-organizational coalitions, or communities.

To make the elimination programme successful, it is necessary to build capacity to span the key areas like organizational development and workforce development. The following categories of personnel working within the programme and in kala-azar endemic areas would be required to be trained and retrained from time to time.

- ❖ Programme managers – national/divisional/district/upazilla (sub-district) level.
- ❖ Doctors and health care providers (e.g. nurses, paramedics and laboratory personnel).

- ◆ Epidemiological/Statistical Unit personnel (e.g. statistician and computer operator).
- ◆ Supervisors at all levels.
- ◆ Supervisors and health workers engaged in supervising the spraying squads.
- ◆ The health care providers and volunteers responsible for behaviour change communication (a) promote early care seeking if kala-azar is suspected; (b) convince the patients suffering from kala-azar to complete the treatment and (c) undertake advocacy with the community for participation in ensuring complete and uniform coverage of their households with insecticides.

5

Implementation of the elimination programme

The kala-azar elimination programme will consist of four consecutive phases.

5.1 Preparatory phase

The preparatory phase begins after the plan has been prepared and approved by the three countries and includes preparations for operations (including a pilot total coverage spraying operation and establishment of diagnosis and treatment facilities) in selected districts in endemic countries and monitoring (including passive and active case detection and vector monitoring). This is useful in identifying constraints and operational difficulties. The lessons learnt during this phase are useful in the attack phase of elimination.

The main activities proposed include the following:

- ◆ Development/review of national policy and strategic plans. National plans should include regulation, standards and norms (Member States). The policy should cover issues relating to intercountry cooperation. Regulations should cover uniform standards relating to diagnosis and treatment, insecticides to be used in IRS, tax exemptions, and making the disease notifiable in endemic areas (Member States).
- ◆ Development of operational plans to implement the national plan for elimination of kala-azar.
- ◆ Development of advocacy plans that include advocacy kits, donor profiles, and highlighting the close nexus of kala-azar with HIV/AIDS, and TB. Advocacy plans should showcase the importance of elimination of kala-azar as a strategy for poverty alleviation and to enhance socioeconomic development in affected areas (Member States).
- ◆ Preparation of national plans that include budget and resource gaps (Member States).

- ◇ Consolidation of national plans into project document for mobilizing resources (WHO-SEARO).
- ◇ Constitution of a national coordination committee and task force/working group (Member States).
- ◇ Signing of memorandum of understanding for intercountry cooperation and cross-border collaboration (WHO, Member States).
- ◇ Formation of regional alliance/partners' forum for resource mobilization, advocacy and assisting in periodic review for elimination of kala-azar (Member States, WHO and other partners).
- ◇ Mobilization of additional resources (Member States and WHO).
- ◇ Geographical information system, RS and information system for integrated vector management (WHO support to Member States).
- ◇ Validation of disease burden/cases of kala-azar (WHO support to Member States).
- ◇ Development and adoption of technical guidelines and reporting formats (WHO and Member States).
 - Technical guidelines (diagnosis and treatment of kala-azar and PKDL, IRS and ITNs);
 - Training package (doctors, nurses, health workers and spraying teams, supervisors);
 - Surveillance guidelines (disease surveillance, vector surveillance) ;
 - Reporting system, reporting formats;
 - Supervisory system, quarterly monitoring and checklists;
 - Country programme and review guidelines.
- ◇ Development of materials for behavioural change communication including guidelines for home care (Member States).
- ◇ Training of personnel (doctors, health workers, staff for IRS, survey team, laboratory staff, data management staff, supervisors) with assistance from WHO.
- ◇ Identification of research priorities and initiation of research on estimation, GIS, RS for IRS, development of new products (research on diagnostics and drugs) with assistance from WHO.

- ❖ Establishing a system of procurement, logistics and supplies (drugs and equipment) with support from WHO.
- ❖ Intensive implementation in selected districts (Member States).
- ❖ Development of partnerships in the health sector (HIV/AIDS, TB, leprosy, malaria and other vector-borne diseases, nutrition, anaemia, etc.) and outside the health sector (environment, poverty alleviation).

5.2 Attack phase

The attack phase begins when the preparatory phase has been completed. This phase will include implementation and monitoring.

The main activities proposed during this phase include the following:

- ❖ IRS in all the affected areas for five consecutive years in collaboration with the vector-borne disease control programme (Member States). This should be according to the agreement reached among the three endemic countries.
- ❖ Integrated vector management (IVM) including ITNs and environmental management. Monitoring expansion and coverage of ITNs (Member States).
- ❖ Access to early diagnosis and complete treatment (Member States).
- ❖ PCD, ACD and vector surveillance, case-based diagnosis and monthly feedback (Member States).
- ❖ Community mobilization for vector control and for seeking early treatment (Member States).
- ❖ Monitoring of treatment completion and analysis of treatment failure (Member States).
- ❖ Intercountry task force meeting to review progress and exchange information (Member States and WHO).
- ❖ Quarterly monitoring, annual review (input, process, output and outcome indicators) to be carried out by Member States. Annual reporting to WHO on an agreed reporting format.
- ❖ Household and health facility survey once every 2-3 years (Member States with support from WHO).

- ◊ External country evaluation (Member States with support from WHO).
- ◊ Increasing research capacity and networking among research institutions through a research coordination mechanism (WHO and partners with Member States).
- ◊ Active case search at least once a year in rural and urban areas (Member States).
- ◊ The attack phase is still on-going in all the three countries.

5.3 Consolidation phase

The consolidation phase will begin when total coverage by spraying has concluded i.e. at the end of the attack phase. This phase will end after the period of three years of active surveillance has shown no increase in the incidence rate at district and subdistrict levels in endemic countries.

The main activities to be carried out during this phase include the following:

- ◊ Limited indoor residual spraying based on geographical location of cases, and in areas with high vector density (Member States).
- ◊ Intensified ACD (Member States).
- ◊ Early diagnosis and complete treatment to be sustained with focus on co-infections (Member States).
- ◊ Treatment adherence (Member States).
- ◊ Continued activities of the attack phase such as monitoring, research, review meetings and periodic evaluation (Member States).

5.4 Maintenance phase

During this phase, surveillance against re-emergence of kala-azar will be the responsibility of the disease control programme in the country until kala-azar is no longer a public health problem. During this phase, the case incidence at district/sub-district or upazilla level should be less than 1 per 10 000 population. An independent review commission, coordinated by WHO, should verify the achievements of the programme. Countries or affected districts in the countries, where elimination targets have not been reached, would require corrective measures. The maintenance phase will be followed by certification of the elimination status. The partners will decide the duration of this phase.

6

Regional update on kala-azar elimination

6.1 Intercountry consultative meeting, Varanasi, India, November 2003

The consultation endorsed the Regional Strategic Plan in principle and recommended that Member States pursue the goal of elimination of kala-azar and develop national action plans with targets at different levels of programme implementation. Member States should define specific time-lines to measure progress towards the elimination of kala-azar. It was also recommended that national policies and strategies be prepared for advocacy, consensus, resource mobilization and sustained political commitment.

6.2 Memorandum of Understanding for intercountry cooperation

During an informal meeting on 5 September 2004 in Maldives, ministers of health from Bangladesh, India and Nepal, confirmed their strong political commitment for sustainable kala-azar elimination through intercountry collaboration and agreed on a common framework for intervention and monitoring. A memorandum of understanding among the three countries was signed in May 2005 in Geneva in the presence of donors and partners to affirm this commitment.

6.3 Regional Technical Advisory Group

WHO-SEARO has established a Regional Technical Advisory Group (RTAG) to advise on key issues such as policy, strategy and activities that are crucial for accelerating the elimination of kala-azar and for operational research. The first meeting of RTAG was held in Manesar, Gurgaon, India, in December 2004. The second meeting was held in Nepal in October 2006. It endorsed the Regional Strategic Plan and

Regional Guidelines for preparing the national plans in principle. The third meeting was held in Dhaka, Bangladesh, in December 2009. The meeting recommended that single dose AmBisome (10mg/kg) may be used as a first-line drug and this was endorsed in the expert committee meeting in WHO-HQ in Geneva in March 2010. Meetings of RTAG will be held at least once a year.

6.4 Advocacy materials

WHO-SEARO has prepared advocacy pamphlets and posters to promote the endorsement of elimination of kala-azar by decision-makers in the endemic countries and by the donors and stakeholders. The advocacy material developed has been shared during the signing of MoU in May 2005 and subsequently with the partners.

6.5 Drug quality, drug supply and logistics

WHO will develop standards of quality for drugs and laboratory supplies, guidelines on monitoring the quality of drugs, efficacy of drugs and drug resistance and diagnostic kits. These will be made available to national authorities.

6.6 Development of draft country operational plans

The countries have prepared country-specific plans for elimination of kala-azar. These plans have been consolidated into a project document by WHO-SEARO. Resource gaps have been identified in these documents.

7.1 Development of technical guidelines

Following the development of standards and standard operating procedures, WHO has developed and distributed necessary generic guidelines and tools to programme managers. They include: comprehensive guidelines on elimination of kala-azar; guidelines on preparation, implementation and monitoring of the programme; guidelines for preparing country strategic plan for elimination of kala-azar; training guidelines on diagnosis and case management, guidelines for home care and environmental management with the focus on improving the home and peri-domestic environment; indoor residual spraying for health staff and volunteers to be involved in the elimination of kala-azar and surveillance guidelines on disease and vector. The three countries have developed various guidelines suitable for their situation.

7.2 Geographic Information System and mapping for IRS

WHO provided assistance to Member States through training of staff to undertake geographical mapping in affected districts. The health mapper was used.

7.3 Technical support at local levels

WHO provides technical support for programme management and implementation at local levels (district and sub-district) by NPO/State Coordinator/District Coordinator (Consultants) etc. depending on the need of individual countries and the resources that are available.

7.4 Research protocols and capacity development in operational research

WHO-SEARO works with TDR and WHO collaborating centres and research institutions to determine research priorities and support the development of research protocols. It assists in enhancing the research capacity in these countries. Networking of research through multicentric research and coordination mechanisms would be facilitated.

7.5 Coordination with partners

WHO will assist in intercountry Task Force Meeting, cross-border meetings and coordination with partners (partners' forum/regional alliance) to mobilize additional resources needed to support the elimination of kala-azar. WHO will also facilitate periodic country reviews/evaluation of the regional programme for kala-azar elimination. Not much progress has been made on cross-border collaboration where about 40% of cases of kala-azar occur.

7.6 Meetings/informal consultations held

- ◆ Development of Regional Strategic Framework for Elimination of kala-azar in the South-East Asia Region (2005-2015).
- ◆ Meeting of the First Regional Technical Advisory Group (RTAG) on Elimination of kala-azar in South-East Asia Region, Manesar, 20-23 December 2004.
- ◆ Signing Ceremony of the Memorandum of Understanding among Bangladesh, India and Nepal on the Elimination of kala-azar, Geneva, Switzerland, 18 May 2005.
- ◆ Intercountry consultative meeting of partners on Elimination of kala-azar in South-East Asia, Behror, 29-31 August 2005.
- ◆ Intercountry meeting of National Programme Managers for kala-azar elimination, Behror, 1-2 September 2005.
- ◆ Meeting of the Second Regional Technical Advisory Group (RTAG) on Elimination of kala-azar in South-East Asia Region, Kathmandu, Nepal, 30 October – 2 November 2006.

- ◊ Meeting of the experts and programme managers for Guidelines and Standard Operating Procedures for kala-azar elimination in South-East Asia, Kolkata, India, 16-20 April 2007.
- ◊ Meeting of the Intercountry training of trainers' workshop on Elimination of kala-azar in South-East Asia, Patna, India, 19-23 November 2007.
- ◊ Programme Managers' meeting on the elimination of kala-azar in South-East Asia Region, Faridabad, Haryana, India, 17-19 February 2009.
- ◊ Meeting of the High-level Officials of Bangladesh, India and Nepal on Elimination of kala-azar in South-East Asia Region, New Delhi, India, 20 February 2009.
- ◊ Regional Technical Advisory Group Meeting, Dhaka, Bangladesh, 8-11 December, 2009.
- ◊ WHO Expert Committee Meeting on Leishmaniasis Control Programme, WHO, Geneva, Switzerland from 22 to 26 March 2010.
- ◊ Informal Consultation on Updating "Regional Strategic Programme for Elimination of kala-azar in SEAR", SEARO, New Delhi, 4-5 July 2011.
- ◊ Fourth Regional Technical Advisory Group Meeting on Kala-azar Elimination, Kathmandu, Nepal, 12-14 July 2011.

8

Monitoring and evaluation

A framework for monitoring and evaluation of kala-azar elimination Programme has been developed and is available in TDR/WHO Website (WHO.INT/TDR).

The preparatory phase for the elimination of kala-azar from South-East Asia is nearing completion. The emphasis is now on the attack phase which will focus on the endemic villages and through the primary health-care units. This will include actively finding kala-azar cases and performing rapid point-of-care diagnosis and treatment with a single dose of liposomal amphotericin B at the primary health-care unit. This will be the most effective way to rapidly reduce the kala-azar burden, transmission and the duration of hospital stay.

Sandfly vector control will be implemented using integrated vector control management and the recently developed monitoring and evaluation toolkit to improve the performance of existing vector control strategies. The consolidation phase will begin when total coverage by spraying has concluded, i.e. at the end of the attack phase. This phase will end after the period of three years of active surveillance has shown no increase in the incidence rate at district and subdistrict level in endemic countries. During this phase, surveillance against re-emergence of kala-azar will be the responsibility of the disease control programme in the country until kala-azar is no longer a public health problem.

This multiple approach strategy will have a major impact on reaching the elimination target of less than one case in 10 000 by 2015 in South-East Asia.



**World Health
Organization**

Regional Office for South-East Asia
World Health House
Indraprastha Estate
Mahatma Gandhi Marg
New Delhi-110002, India
www.searo.who.int



SEA-CD-239