Intercountry Consultation on Elimination of Kala-azar in the South-East Asia Region

Kolkata, India, 9 – 10 November 2011
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**Contents**

<table>
<thead>
<tr>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Summary</td>
</tr>
<tr>
<td>1. Global kala-azar situation</td>
</tr>
<tr>
<td>2. Kala-azar situation in Bangladesh, India and Nepal</td>
</tr>
<tr>
<td>3. Post-kala-azar dermal leishmaniasis (PKDL) and asymptomatic infections</td>
</tr>
<tr>
<td>4. Cross-border collaboration</td>
</tr>
<tr>
<td>5. Diagnosis of kala-azar</td>
</tr>
<tr>
<td>6. Treatment regimens</td>
</tr>
<tr>
<td>7. Vector control</td>
</tr>
<tr>
<td>8. Behaviour change communication</td>
</tr>
<tr>
<td>9. Partnerships in kala-azar elimination</td>
</tr>
<tr>
<td>10. New technologies and research needs</td>
</tr>
<tr>
<td>11. Group work</td>
</tr>
<tr>
<td>11.1 Bangladesh</td>
</tr>
<tr>
<td>11.2 India</td>
</tr>
<tr>
<td>11.3 Nepal (activities and road map)</td>
</tr>
<tr>
<td>12. Recommendations</td>
</tr>
</tbody>
</table>

**Annexes**

<table>
<thead>
<tr>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Agenda</td>
</tr>
<tr>
<td>2. List of participants</td>
</tr>
</tbody>
</table>
Executive Summary

The annual global incidence of kala-azar cases reported is 58 200, of which 42 619 emanate from the Indian subcontinent (ISC). The revised estimated global and ISC annual incidence of kala-azar is 201 500–378 500 and 160 000–320 000, respectively. Outbreaks continue to occur, causing high mortality. Currently, an outbreak is ongoing in South Sudan.

The disease is endemic in 109 districts in Bangladesh, India and Nepal. Based on reported cases of visceral leishmaniasis (VL) from the Indian subcontinent, there has been a decrease in cases and deaths in Bangladesh and Nepal. It is estimated that the total number of cases in India is 2–4 times than the official numbers. The proportion of cases treated at private health facilities is 30%–50% of total cases compared to about 80% a few years ago due to improved capacity and provision of incentives to kala-azar patients treated at public health facilities.

Post kala-azar dermal leishmaniasis is considered to be an important reservoir for VL, although little is known on its role in transmission and the risk it may pose to the elimination programme. The potential of asymptomatic infections as a reservoir is also not clear. Recent studies have shown that the ratio of kala-azar cases to asymptomatic infection in the ISC varies from 1:4 to 1:9. Epidemiological studies are ongoing to identify the factors that lead to development of disease in asymptomatic leishmania infections.

Kala-azar endemic areas in the ISC are contiguous and large populations live in border areas. These populations are vulnerable to vector-borne diseases due to poverty, mass movement of people, difficult access to health care, and weak cross-border collaboration. Kala-azar cases from one country are being treated in another and this is not being captured by the respective public health authorities. This impedes control strategies, which are dependent on surveillance data and cross-border collaborative activities between countries.

Increased access to care is a major challenge in VL case management. The only available rapid diagnostic test (RDT) suitable for field application, the rk39 dipstick test, has already been adopted in the programme of the three countries in the VL elimination initiative.
Miltefosine, currently deployed in the VL elimination initiative in the three countries, has several drawbacks: a lack of compliance and a number of adverse events. It is also contra-indicated during pregnancy and in women of childbearing age unless they use contraception, and drug resistance may develop due to its long half-life. Moreover, the existing capacities of the health facilities are insufficient to ensure directly observed treatment (DOT) for such long regimens. To overcome these drawbacks, Accredited Social Health Activists (ASHA) have been engaged to implement DOT in India. In addition, the WHO Expert Committee on Leishmaniasis and the Regional Technical Advisory Group (RTAG) for the kala-azar elimination programme have recommended single dose AmBisome as a first choice and combination regimens as a second choice for the treatment of kala-azar in the ISC.

The strategic approach recommended is Integrated Vector Management (IVM) with a right mix of interventions. IVM is a rational decision-making process for the optimal use of resources for vector control.

Nongovernmental organizations such as the Drugs for Neglected Diseases Initiative (DNDi) and the Institute of OneWorld Health (iOWH) are actively involved in the development of new tools that can better control and sustain the elimination of VL, and in the optimization of existing drugs through the development of new treatment modalities until a new chemical entity is available.
1. Global kala-azar situation

The annual global incidence of kala-azar cases reported is 58,200, of which 42,619 emanate from the Indian sub-continent (ISC). The revised estimated global and ISC annual incidence of kala-azar is 201,500–378,500 and 160,000–320,000, respectively. Outbreaks continue to occur, causing high mortality, with an outbreak ongoing in South Sudan.

2. Kala-azar situation in Bangladesh, India and Nepal

In the ISC, the disease is endemic in 109 districts in Bangladesh, India and Nepal. Based on reported cases of visceral leishmaniasis (VL), there has been a decrease in case numbers and deaths in Bangladesh and Nepal. It is estimated that the total number of cases in India is 2–4 times the official numbers. The proportion of cases treated at private health facilities is 30–50% of total cases compared to about 80% a few years ago due to improved capacity and provision of incentives to kala-azar patients treated at public health facilities.

In every endemic district, one vector-borne disease consultant and six kala-azar technical supervisors have been appointed and trained. Active case-finding strategies including the camp approach, the incentive-based approach and kala-azar fortnights have been initiated. Intersectoral coordination and central monitoring have also started.

In Bangladesh, although 45 districts are endemic, the cases are concentrated in six districts, with Mymensingh district having more than 50% of the total kala-azar cases. Thus focused efforts in these six districts would have a significant impact on the reduction of the disease burden. Indoor residual spraying (IRS) of insecticides has recently been implemented in the control programme in Bangladesh.

Evidence of new foci of kala-azar transmission has been observed. Indigenous VL cases have been reported from several foci in Bhutan, including some at an altitude of 2000 metres. The causative agent is also *L. donovani*. In Nepal, in addition to 12 endemic districts, several others are reporting kala-azar cases including several hilly districts. Further
epidemiological and entomological studies are required to get a complete picture. Shifting of foci of transmission from immune to non-immune populations in Sudan was observed, which may be one of the reasons for the appearance of the new foci in the ISC. Therefore, surveillance should be strengthened to include these new foci.

A weak surveillance system and inadequate capacity of the vector control efforts are major limitations affecting the current programme activities. Other challenges are low acceptance of IRS by the community and insufficient funds, especially in Bangladesh and Nepal, to upscale activities.

3. Post-kala-azar dermal leishmaniasis (PKDL) and asymptomatic infections

Post-kala-azar dermal leishmaniasis is considered to be an important reservoir for VL, although little is known on its role in transmission and the risk it may pose to the elimination programme. The potential of asymptomatic infections as a reservoir is also not clear. Recent studies have revealed that the ratio of kala-azar cases to asymptomatic leishmaniasis infection in the ISC varies from 1:4 to 1:9. Epidemiological studies are ongoing to identify the factors that lead to development of disease in asymptomatic infections.

The incidence of PKDL is declining in Bihar, India, but is still quite high in Bangladesh where it has been observed in 10%-15% of treated VL cases, with a median interval of 22 months after treatment. Also, 2% of the PKDL cases had no history of kala-azar. Observations suggest that the duration, dose and type of drug may affect the occurrence of PKDL, e.g. the incidence of PKDL is higher after treatment with sodium stibogluconate compared to amphotericin B. Cohort studies with kala-azar patients are planned in Bangladesh to compare the occurrence of PKDL using different regimens.

Diagnosis and treatment of PKDL cases are challenges faced by the programme. Confirmation of diagnosis is difficult, and treatment is complex and not standardized. Microscopy for demonstration of Leishman-Donovan bodies from skin lesions has low sensitivity. Treatment of PKDL requires long courses of therapy. Further data are required to help standardize the regimens.
Surveillance of PKDL in the elimination programme is poor. Research is required to develop shorter and safer treatment regimens, to develop better diagnostic tools such as molecular tools, and to determine the duration of infectiousness in a PKDL patient during treatment.

4. Cross-border collaboration

Kala-azar endemic areas in the ISC are contiguous and large populations live in border areas. These populations are vulnerable to vector-borne diseases due to poverty, mass movement of people, difficult access to health care, and weak cross-border collaboration. Kala-azar cases from one country are treated in another and this is not being captured by the respective public health authorities. This impedes control strategies, which are dependent on surveillance data, and cross-border collaborative activities between countries should therefore be enhanced.

Collaboration should focus on sharing data in cross-border areas – including during outbreaks—particularly information on insecticidal resistance, drug resistance and pharmacovigilance. Efforts for coordination and harmonization of IRS activities are crucial and, to this end, local and central coordination activities, including meetings and presentation of data in web pages, should be explored.

5. Diagnosis of kala-azar

Increased access to care is a major challenge in VL case management. The only available rapid diagnostic test (RDT) suitable for field application, the rk39 dipstick test, has already been adopted in the programme of the three countries in the VL elimination initiative. However, as a serological test, it is not useful to diagnose relapse or assess cure after treatment. The prevalence of antibodies in a significant proportion of the healthy endemic population can affect the specificity of serological tests. The performance of these tests on blood compared to serum (the recommended biological fluid) is not known and thus urgent research to validate this is required.

Recently a network of VL reference laboratories from Brazil, countries in East Africa and the ISC validated five brands of marketed RDT for accuracy, reproducibility, ease of use and heat stability. Details of this
validation have been published.\(^1\) There is also a need for a quality assurance system for the diagnostic tests within the programme.

Recent reports from a pilot study of rk28, a polypeptide including three antigens, show the RDT to look very promising but further validation in the field is required. Additional molecular diagnostic tests need to be further evaluated, standardized, and simplified before they can be used in the field.

The markers currently used to document incident Leishmania infections (direct agglutination test, leishmanin skin test, and rk39 enzyme-linked immunosorbent assay, ELISA) have not been firmly established and thus epidemiological surveillance tools are required.

There is also a need for diagnostic tests for test-of-cure and surveillance tools for drug resistance at reference centres, for which newer technologies should be exploited. Cooperation with other platforms/partners such as the Foundation for Innovative New Diagnostics (FIND) should be explored to develop these new tools.

6. Treatment regimens

Miltefosine is currently deployed as the treatment of choice in the VL elimination initiative in Bangladesh, India and Nepal. However, lack of compliance has been observed along with a number of serious adverse events. It is also contra-indicated during pregnancy and in women of childbearing age unless they use contraception, and drug resistance is possible due to its long half-life. Moreover the existing capacities of the health facilities are insufficient to ensure directly observed treatment (DOT) for such long regimens. In India, Accredited Social Health Activists (ASHA) have been engaged to implement DOT.

To overcome the above drawbacks, the WHO Expert Committee on Leishmaniaisis and the Regional Technical Advisory Group (RTAG) for the kala-azar elimination programme have recommended single dose AmBisome as the first choice regimen, and combination regimens as a second choice for the treatment of kala-azar in the ISC. Public health

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studies are being conducted with these regimens in the three countries. The choice of regimen will depend on information generated, particularly on maintenance of the cold chain, the proportion of cases eligible to receive a particular regimen, the referral system, etc. Pharmacovigilance surveillance needs to be introduced/strengthened at sentinel sites in each country.

7. Vector control

The strategic approach recommended is Integrated Vector Management (IVM) with a right mix of other interventions. The principles and objectives of IVM were presented as a rational decision-making process for the optimal use of resources for vector control. The approach seeks to improve the efficacy, cost-effectiveness, ecological soundness and sustainability of disease-vector control. The main objectives are to reduce the longevity of adult vectors, eliminate breeding sites, decrease contact of vectors with humans, and reduce the density of the vector. The five key elements of IVM are: capacity building and training; advocacy; collaboration; evidence-based decision-making; and an integrated approach. Today, the following three tools are considered useful for vector control in kala-azar transmission: IRS; long-lasting insecticide-impregnated bednets; and environmental control.

Strong historical evidence supports the role of IRS in kala-azar elimination, but it requires rigorous implementation. Since IRS monitoring in India found several lacunae, e.g. delays in the timing of spraying, less than 40% coverage and patchy spraying, a monitoring and evaluation toolkit was developed by WHO/Special Programme for Research and Training in Tropical Diseases (TDR) for the elimination programme. Evidence on the effectiveness of long-lasting nets (LNs)/ insecticide-treated nets (ITNs) is not yet available. However, in the absence of better alternatives, it is considered prudent to strengthen IRS and maximize advantages. Both IRS and LNs are macro-level interventions. The elimination of kala-azar also requires environmental management strategies at the micro level. For this to succeed, housing conditions should be improved, with particular focus on dwellings where the poorest of the poor live. The effectiveness and feasibility of such environmental management should be evidence-based before justifying any major national investment.

Resistance of the sandfly to DDT (dichlorodiphenyl trichloroethane) in India has been reported in some studies, while others show that it is still
The concurrent use of synthetic pyrethroids for both IRS and LN may circumvent the development of resistance.

The acute shortage of entomologists needs to be addressed through intersectoral collaboration. The WHO Regional Office for South-East Asia (SEARO) has taken steps to build capacity for vector control based on the IVM model. Research should be conducted to generate evidence to guide the timing and place of IRS. Coordination of IRS activities across border areas should also be addressed.

8. Behaviour change communication

Despite medical and technological advances, improved health systems and information dissemination, knowledge and awareness about kala-azar is far from widespread. Appropriate and timely adoption of preventive and curative interventions by populations at risk vary due to several factors. The biggest challenge is getting people to act on what they know.

Community Mobilization Behavioural Change (COMBI) is a process that strategically blends a variety of communication interventions. These aim to engage individuals and families in considering recommended healthy behaviours, and to encourage the adoption and maintenance of those behaviours. The method effectively integrates health education, information-education-communication (IEC), community mobilization, consumer communication technologies and market research, all well targeted to specific, precise behavioural outcomes in health.

In the elimination programme, COMBI is critical to achieving early diagnosis and completion of therapy, cooperation during IRS, adoption and correct use of ITNs and environmental management.

For effective implementation, building partnerships at national, international, district and state levels is required. Strengthening partnerships and networking is also essential among institutions within the health sector (nutrition, anaemia, human immunodeficiency virus and tuberculosis control) and with NGOs outside the health sector.

9. Partnerships in kala-azar elimination

NGOs such as DNDi and iOWH are actively involved in the development of new tools that can better control and sustain the elimination of VL, and
in the optimization of existing drugs through the development of new treatment modalities until a new chemical entity is available. The development of paromomycin and the evidence of combination regimens for VL in the ISC are success stories of partnerships between the public sector (e.g. the Indian Council of Medical Research) and these NGOs. The activities and portfolio of DNDi and iOWH were presented. Current public health studies with the new regimens will generate evidence for the selection of the most appropriate tool(s) for the programme in the future.

10. New technologies and research needs

Recent research on the following fields in leishmaniasis was presented: immunogenicity of sandfly saliva and its application; fluorescent parasites in leishmaniasis studies; newer diagnostic tests including rk28; simplified molecular diagnostics, e.g. LAMP (loop mediated isothermal amplification), fluorescence-based multiplex PCR (polymerase chain reaction); molecular epidemiology and genome sequencing of Leishmania; and development of vaccines against leishmaniasis.

11. Group work

The three countries developed a document reviewing the accomplishments in the kala-azar elimination programme and planned a road map and activities towards meeting the recommendations of the RTAG and the WHO Expert Committee on Leishmaniasis.

11.1 Bangladesh

Achievements

- Strategic plan and national guidelines updated and diagnosis and treatment regimen revised to include rk39 RDT and miltefosine as the first-line drug;
- Technical working group formed at national level and advocacy to policy-makers;
- Kala-azar Research Centre established (SK Hospital in Mymensingh) in collaboration with the Japan International Cooperation Agency (JICA) and the International Centre for
Diarrhoeal Disease Research, Bangladesh (ICDDR,B). Kala-azar units set up at district and sub-district level;

- Active case-finding: camp approach and index case approach adopted in low and moderately endemic sub-districts respectively;
- Vector control: IRS initiated in October 2011;
- Surveillance, monitoring and reporting systems strengthened,
- Partnerships established with NGOs/other government sectors; and
- Capacity-building: doctors, laboratory technologists and nurses trained.

Road map

Diagnosis and treatment

- rk39 to be scaled up to community clinic (1/6000 population) level;
- Oral miltefosine dispensed in weekly schedule;
- Incentives for patients; referral; completion of treatment;
- Geographic information system (GIS) mapping of cases at village level; and
- Strengthening of monitoring and evaluation.

Vector control

- IRS in 14 highly and moderately endemic districts;
- Strengthening of monitoring and evaluation; and
- Vector control in IVM mode.

Programme implementation

- Manpower – local consultants for kala-azar endemic districts;
- Training of doctors, nurses, entomologists and other staff (field workers, community health and care staff, and spray men);
- Community health and care partnerships; and
- Advocacy at policy and local level.
11.2 India

Achievements

- Rapid diagnostic test introduced in all endemic kala-azar states;
- Upscaling of miltefosine capsule for kala-azar as first-line treatment and being expanded in all areas in phased manner;
- Training and capacity-building of medical officers (MOs), ASHA and other health workers;
- Incentive to health workers (ASHA) resulted in improved surveillance;
- Active kala-azar search fortnight/camp approach reduced from six-monthly to quarterly schedule;
- Free diet to patients and one attendant;
- IRS as per plan with effective monitoring;
- Improved behaviour change communication (BCC/IEC) activities with greater emphasis on interpersonal communication (IPC) and focus group discussion (FGD);
- Programme activities improved through provision of vector-borne disease consultant, kala-azar technical supervisor (KTS) at district and sub-district level and motorcycle for mobility;
- Decreased number of kala-azar cases from 32,803 in 2005 to 24,212 in 2009 (although the number of cases increased in 2010 to 28,941 and the trend may continue in 2011);
- Mortality reduced from 157 in 2005 to 105 in 2010 and 66 in 2011 (September);
- Better surveillance; and
- Community awareness for good drug and camp search modes.

Road map

Case detection/surveillance

- Passive surveillance: by all health facilities, mobile medical vans under National Rural Health Mission (NRHM) and the private sector (suspected and referral);
- Active surveillance: fortnight approach and camp mode.
Diagnosis

- To be performed in clinically compatible cases under guidance of MOs using rk39;
- Operational research on sensitivity of aldehyde test; and
- Generate a clear policy on PKDL.

Treatment

- Oral miltefosine to be continued until alternative affordable combi-regimen available, and the supply and logistics determined;
- DOT with patient-coding system; and
- Continued support for research into better drugs.

Integrated vector management

- IRS to continue with DDT taking the village as a unit with two rounds;
- Operational studies on vector population and susceptibility studies; and
- Studies on long-life insecticidal nets feasibility, wall hangings and curtains.

Supportive interventions

- Effective and greater role of BCC/IEC, social mobilization and service delivery in kala-azar endemic areas;
- Other;
- Treatment policy on PKDL in the Indian context;
- Cross-border collaboration on sharing of information;
- Pharmacovigilance studies; and
- Research on asymptomatic cases.

11.3 Nepal (activities and road map)

Surveillance

- Health system has improved since 2005. New case detection rate is <1/10 000 population in most endemic districts and the total number of cases is decreasing. New districts are reporting kala-
azar cases, thus epidemiological and entomological surveillance needs strengthening.

- When cases are reported from new areas, active case-detection is conducted by house-to-house search.

**Cross-border issues**

- Cases from India are treated at health facilities in Nepal and vice versa; notification to public health offices on both sides is essential.
- Coordination of IRS activities.

**Diagnosis**

- rk39 dipstick test made available up to primary health care level and parasitology in zonal and regional hospitals.

**Treatment**

- First-line: capsular miltefosine (to be phased out as recommended by RTAG); second-line: injected liposomal amphotericin B (as recommended by RTAG).

**Vector control**

- IRS (pyrethenoids on rotation) twice a year focal spraying;
- Plan to improve housing and environmental conditions;
- LN is being distributed to kala-azar patients;
- Strengthen vector control in IVM mode; and
- Strengthen IEC/BCC activities.

### 12. Recommendations

Given the evidence of local endemic disease, Bhutan is to be enlisted in the kala-azar elimination programme and included in a renewed Memorandum of Understanding, originally signed by Bangladesh, India and Nepal in 2005.

Recorded data show a decreasing number of cases and deaths due to kala-azar; however the current surveillance system does not capture all cases. Also, newer foci in non-endemic areas, e.g. hilly regions, have been
reported. Strengthening of the surveillance systems for both kala-azar, PKDL, including cases treated in non-public sectors, is required. Similar surveillance systems for pharmacovigilance, drug and vector resistance should also be put in place.

Gaps in knowledge exist on the role of PKDL and asymptomatic infections in disease transmission. Diagnosis and treatment need to be better defined. WHO-SEARO should convene an expert group to review these two important issues.

Cross-border collaboration activities at the local and central levels are currently not regularized. Collaboration to synchronize IRS and the exchange of data are crucial issues for control activities. Periodic (e.g. 3-monthly) data should be collated.

A periodic cross-border collaboration meeting is recommended, which may be coordinated by WHO-SEARO. Systems for sharing data should be facilitated.

IRS is the mainstay for vector control along with environmental management. Since limited data on the efficacy of LN exist, detailed studies are required. WHO-SEARO has taken steps for capacity-building on vector control on IVM mode and special attention will be given to Bhutan and Nepal. Strengthening entomology capacity and operational issues, e.g. timing of spraying, are required. IEC/awareness efforts also need to be increased.

New drug options and combination regimens have become available. The choice of regimen will depend on the information generated, particularly on maintenance of the cold chain, the proportion of cases eligible to receive a specific regimen, the referral system etc. Public health studies are reviewing these options, the results of which will inform a decision on the future drug policy.

PKDL incidence may depend on the duration and type of drug used to treat kala-azar. Long-term follow-up studies are being conducted in Bangladesh, the results of which will be reviewed to decide on the drug policy.

A road map to move towards RTAG strategic recommendations should be adopted by the countries to harmonize activities.
Annex 1

Agenda

Registration

Opening Session

Technical Session:

- Global situation of kala-azar
- Regional Strategic Framework
- Diagnosis, treatment, vector-control, behaviour change communication
- Country presentations (Bangladesh, Bhutan, India and Nepal)
- Partnership (DNDi Perspective; One World Health Perspective) in kala-azar elimination
- Cross-Border collaboration and sharing of information
- New technologies and research needs

Closing Session
Annex 2

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Kala-azar is endemic in 109 districts in Bangladesh, India and Nepal. There has been a shift of kala-azar patients, who were going to private practitioners. Nongovernmental organizations are now seeking treatment for kala-azar patients from the public sector due to its better public health facilities and provision of incentives to kala-azar patients. The kala-azar endemic areas are contiguous, and large populations live in border areas. These populations are vulnerable to vector-borne diseases owing to poverty, mass movement of population, difficult access to health care and weak cross-border collaboration and weak delivery of health services.

The Regional Technical Advisory Group for the Kala-azar Elimination Programme has recommended single-dose AmBisome as the first choice, and combination regimens as the second choice for the treatment of kala-azar in the Indian subcontinent.