

Elimination of Kala-azar

*Report of the Fourth Meeting of the
Regional Technical Advisory Group (RTAG)
Kathmandu, Nepal, 12 - 14 July 2011*



**World Health
Organization**
Regional Office for South-East Asia

SEA-CD-243
Distribution: General

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Printed in India

Contents

	<i>Page</i>
Executive summary	v
1. Opening session.....	1
2. Objectives.....	2
3. Technical update on the global and regional kala-azar situation technical update	2
4. Technical update	3
4.1 Diagnosis of kala-azar:	3
4.2 Treatment.....	4
4.3 Vector control.....	6
4.4 Supportive strategies: policy support and advocacy, partnerships, resource mobilization, institutional support and cross-border collaboration	7
5. Community mobilization.....	8
6. Monitoring and evaluation	8
7. Updating of the Strategic Framework for Elimination of Kala-azar.....	9
8. Recommendations	9
9. Concluding session.....	10

Annexes

1. Programme	11
2. List of participants	13

Executive summary

Kala-azar is a disease of immense public health importance in Bangladesh, India and Nepal. It mostly affects the poorest population groups among marginalized communities living primarily in rural areas. About 150 million people are at risk of kala-azar in approximately 113 districts in the four endemic countries (Bangladesh, Bhutan, India and Nepal). Elimination of kala-azar in countries of the WHO South-East Asia (SEA) Region is feasible because of its unique epidemiological features: (i) human beings are the only reservoir (ii) there is only one vector species, which is amenable to control; and (iii) the limited geographical distribution of the disease. With the availability of new diagnostic tools and effective medicines, political commitment at the highest level in the endemic countries [Memorandum of Understanding (MoU) signed by Health Ministers of the three endemic countries] and the encouraging experience of collateral benefits of the malaria control programme, elimination of kala-azar in the Region has become achievable. Elimination of kala-azar will promote equity and poverty reduction, and lead to socioeconomic development of targeted areas and strengthen the capacity of the health system.

The Fourth Meeting of the Regional Technical Advisory Group (RTAG) jointly organized by WHO-SEARO and WHO Country Office, Nepal, was held in Kathmandu, Nepal from 12 to 14 July 2011. The meeting was held to review the progress and achievements of the kala-azar elimination programme, to assess the implementation of national plans of action, discuss developments in technology for incorporation in the elimination programme and make recommendations to the Regional Director. The meeting was attended by members of RTAG, experts, WHO staff from headquarters, the Regional Office, from Tropical Disease Research (TDR) as well as from the WHO Country Office, Nepal.

1. Opening session

Dr A.P. Dash, Regional Adviser, Vector-borne and neglected Tropical Diseases, Department of Communicable Diseases, WHO-SEARO, welcomed the RTAG members and other participants on behalf of the Regional Director. Dr Lin Aung, WHO Representative (WR) Nepal, could not attend due to indisposition. Dr Dash delivered the inaugural address on behalf of the Regional Director, Dr Samlee Plianbangchang.

In his message the Regional Director remarked that Kala-azar (or visceral leishmaniasis), is predominantly a disease of the poorest of the poor; this disease, if not treated, can kill. An estimated 147 million people in 109 districts in three countries, namely Bangladesh, India and Nepal are at risk. The disease affects the socioeconomic development in affected areas. Kala-azar can be eliminated in the SEA Region because the disease is transmitted only through humans and there is no vertebrate host. The sandfly, *Phlebotomus argentipes*, is the only vector responsible for transmission of the disease in the Region. A simple screening test, 'rk39', is available for the diagnosis of kala-azar and an effective oral drug – Miltefosine - has been registered in endemic countries. Other drugs such as injectible Paromomycin and AmBisome are also available. The disease is limited in its geographical distribution to only 109 districts and, therefore, focused efforts can be mounted for its elimination. There is a strong political will, commitment of resources, development of capacity and stronger surveillance. The five strategic elements for elimination of kala-azar are: (i) early diagnosis and complete treatment; (ii) integrated vector management including indoor residual spray; (iii) effective disease surveillance; (iv) social mobilization and building partnerships; and (v) operational research.

The Regional Director reiterated WHO's commitment to support the three Member States in the SEA Region in their quest for elimination of kala-azar. "We will continue to build partnerships and mobilize additional resources required in the elimination efforts. The elimination of kala-azar has been intensified and it is proposed to further accelerate efforts in the other affected districts in Bangladesh, India and Nepal. A roadmap has been

prepared. Miltefosine and 'rk39' have been procured in Bangladesh, India and Nepal. This meeting provides a forum for reviewing the progress towards elimination, exchanging information, and making recommendations on the way forward, based on the lessons learnt". Dr Samlee said.

2. Objectives

The objectives of the meeting were:

- (1) review the progress and achievements of the kala-azar elimination programme and implementation of the recommendations of the Third RTAG meeting;
- (2) assess the implementation of national plans of action of Bangladesh, India and Nepal for elimination of kala-azar, and to recommend appropriate strategies for additional improvement;
- (3) discuss other technical issues related to the development of new technology and recommend their inclusion in the programme;
- (4) review progress in programme implementation and discuss the future plan; and
- (5) develop recommendations for consideration by WHO-SEARO.

Prof. N.K. Ganguly was elected Chairman and Prof. Suman Rizal the Rapporteur of the meeting.

The Agenda for the meeting is given in Annex 1.

3. Technical update on the global and regional kala-azar situation

Worldwide, 98 countries are affected by leishmaniasis. Visceral leishmaniasis (VL) occurs in Bangladesh, India, Nepal, Bhutan, Sudan, Brazil, East Africa and a few other countries. Annually, 500 000 cases of VL occur worldwide and 100 000 cases occur in the SEA Region. Outbreaks continue to occur, causing high mortality, with a recent outbreak ongoing in south Sudan.

Based on the reported cases of VL from the Indian subcontinent, a declining trend in disease incidence is noted in Bangladesh and Nepal. In India, the incidence increased in 2010 with larger number of cases being reported particularly from some districts of North Bihar including Muzaffarpur district, the first district piloted for Miltefosine treatment. The cause for this increase is not very clear. Cases also appear in new foci and disease continues to affect the poorest of the poor from the lowest socioeconomic strata e.g. *musahar* community. It has also been observed that sodium stibogluconate (SSG), proven to be resistant to *L donovani* in Bihar, continues to be used there. The quality of drugs available in the market is not always reliable. The ratio of asymptomatic *L donovani* infection to VL cases is 4:1 in Bangladesh, while the same is 10:1 in India and Nepal.

The coverage of detection, treatment and vector control activities by *district/subdistrict/upazilla* in the three endemic countries is not very encouraging. The epidemiological definitions for calculation of the incidence with reference to the numerator and denominator also need to be clearly defined.

Indigenous VL cases have been reported from several foci in Bhutan including some foci at a height of 2000 meters. The causative agent is *L donovani*. Thus Bhutan should be included as the fourth country in the kala-azar elimination initiative of the Indian subcontinent.

4. Technical update

4.1 Diagnosis of kala-azar

Increase in access to care is a major challenge in VL case management. The only available rapid diagnostic test (RDT) suitable for field application (rk39 dipstick) is being used. However, it has limitations as it is not useful to diagnose relapse and ascertain cure. The high prevalence of antibodies in the endemic population can affect the specificity of serological tests. The performance of these tests with blood compared to serum, the recommended biological fluid, is not known and urgent research to validate this is required.

Recently a network of VL reference laboratories from Brazil, East Africa and Indian subcontinent validated five brands of the marketed RDT for accuracy, reproducibility, ease of use and heat stability. The report of this validation will be published by TDR very soon. There is also a need to establish a quality assurance system for diagnostic tests within the programme.

The recent reports from a pilot study of rk28, a polyprotein including 3 antigens, look very promising. However further validation during the field setting of Phase III study is required. Additional molecular diagnostic tests need to be further evaluated, standardized and simplified before they can be used in the field.

There is a need for diagnostic tests for cure and surveillance tools for drug resistance at reference centres. For this, newer technologies should be exploited. Cooperation with other partners e.g. Foundation for Innovative Diagnostics (FIND) should be explored to develop newer tools.

4.2 Treatment

The single-dose liposomal amphotericin B (SLAB) 10 mg/kg is the first choice regime for the Indian subcontinent, recommended by the WHO Expert Committee on Leishmaniasis given its high efficacy, safety, ease of use and cent per cent compliance. The results of a Phase 3 trial evaluating three regimens for combination therapy: Liposomal amphotericin B/Paromomycin; Liposomal amphotericin B//Miltefosine; and Paromomycin/Miltefosine, showed excellent efficacy and safety of all three regimens. The combination regimens have been recommended as the second choice regimen for the Indian subcontinent by the WHO Expert Committee. Monotherapy with Miltefosine or Paromomycin is the fourth choice (after amphotericin B) as per the recommendation of the Expert Committee.

Miltefosine, currently being deployed in the VL elimination initiative in the three countries has shown several drawbacks such as inadequate compliance. Also, serious adverse events have been observed in patients. It is contra-indicated in pregnancy and in women of childbearing age unless they practise contraception, and has the potential to develop resistance due to its long half-life. Furthermore, the existing capacity and weaknesses of

health facilities have not been able to ensure a directly-observed treatment for such long regimens. With just over four years left to achieve the kala-azar elimination target and the availability of a single-dose regimen, the group felt that liposomal amphotericin B should be the recommended drug in the attack phase for the elimination programme. In the long term, combination regimens are the best way to protect individual drugs from developing resistance. It is recommended that the combination regimen be adopted by the policy as the second choice regimen till the capacity of health facilities is improved to provide directly-observed therapy. As paromomycin and liposomal amphotericin B, used in combination regimens, are not registered in Bangladesh and Nepal, it is now very important that these drugs are registered soon.

Feasibility studies for the use of single-dose liposomal amphotericin B (SLAB) in primary health centres (PHCs) are under way in Bangladesh and India to examine the feasibility of their introduction at the primary health care (PHC) level. The strategy includes active detection of cases, point of care and vector control at the village level. This will increase the flow of patients to the PHC level and where necessary to the district level where they will be treated with Single dose Liposomal Amphotericin B (SLAB). Nepal should also start feasibility studies to introduce SLAB. Such studies should also closely record the adverse effects and cure rates to provide more feedback on the use of this regimen from this large cohort. Currently, pharmacovigilance is not in place in the programme in the three countries.

Post-kala-azar dermal leishmaniasis

Post-kala-azar dermal leishmaniasis (PKDL) is considered an important reservoir for VL and its treatment is an important public health measure to control the spread of kala-azar. It has been observed that the incidence of PKDL is declining in Bihar but it is still quite high in Bangladesh. It has also been seen that the incidence of PKDL is higher following treatment with SSG, as compared with to amphotericin B and miltefosine treatment. Management of PKDL cases is a challenge for the programme as they do not normally present to health services, confirmation of diagnosis is difficult and treatment is complex and not standardized. Microscopy for demonstration of *Leishmania donovani* (LD) bodies from skin lesions has low sensitivity. Treatment of PKDL requires long courses of therapy. Cohorts of PKDL have been treated with miltefosine in Bihar and Nepal. In Bangladesh PKDL is

treated with liposomal amphotericin B. The efficacy of current regimens in treating on PKDL should be documented as such experiences would be helpful for standardizing the regimens. The WHO-TDR study comparing the 8- and 12- week treatment has been completed and the 12- week treatment is encouraging. The PKDL detection within the programme should be through active case-finding as PKDL patients usually present themselves very late. Research is required: to develop shorter and safer treatment regimens for PKDL; develop better diagnostic tools for PKDL including the role of molecular tools; and find out the duration of infectiousness in a PKDL patient during treatment.

4.3 Vector control

The strategy for vector control should essentially be integrated vector management (IVM). The principles, objectives and the process of IVM were presented. IVM is 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 objective is to reduce longevity of the adult vectors, eliminate the breeding sites, decrease contact of vector with humans, and reduce the density of the vector. The five key elements of IVM include: capacity building and training; advocacy; collaboration; evidence-based decision-making; and integrated approach.

Presently three tools are considered to be useful for vector control in kala-azar transmission: indoor residual spraying of insecticides (IRS); longlasting insecticide impregnated bed nets (LLIN); and environmental control. The monitoring of IRS in India revealed several lacunae: delay in the timing of spraying; less than 40% coverage and patchy spraying. Also the results of the WHO-TDR studies on IRS show that the quality of IRS operations in India and Nepal needs to be improved. Programme managers need to be sensitized with results of these studies. A monitoring and evaluation toolkit has been developed for IRS by WHO-TDR for use in the programme. Ongoing research is being conducted on wall-lining sheets impregnated with insecticides. In some areas of Muzaffarpur in India, resistance of the sandfly to DDT has been observed. The concurrent use of synthetic pyrethenoids for both IRS and LLIN can predispose them to development of resistance. With regard to LLIN, studies have not been conclusive. LLIN may not be effective against vectors, biting/resting

outdoors. Most efficacy studies are based on the reduction of vector density and not on comparing the human biting index before and after use of LLIN, which is recommended. Environmental management as part of IVM should be encouraged. The group felt that capacity strengthening was essential for implementation of IVM. There was acute shortage of entomologists that needed to be addressed through intersectoral collaboration. IRS is currently the best available option for sandfly control and should be reinforced in each country. Its implementation needs to be harmonized. More studies are needed on vector behaviour, innovative vector control tools and also on strategies for integration. Vector control measures should be part of public health strategies in countries. Strategies should also include national insecticidal policy.

4.4 Supportive strategies: policy support and advocacy, partnerships, resource mobilization, institutional support and cross-border collaboration

There are numerous challenges for the elimination of kala-azar from the Region. The population at risk are among the poorest in the community and often malnourished. Access to care is difficult. The gap between reported and actual case numbers is creating difficulties in programme planning. The emergence of HIV-VL coinfection is a challenge. Population explosion due to urbanization affects vector dynamics. Migration of populations and cross-border movement is another issue. Climate change with movement of vectors to new areas has its potential to spread disease to non-endemic areas.

Partnerships with agencies like WB (World Bank), DNDi (Drugs for Neglected Disease Initiative), iOWH (OneWorld Health), WHO/TDR, and JICA (Japan International Cooperation Agency) should aid the development of better regimens for treatment and also support capacity-building of primary health-care facilities. Support to local manufacturers from the Region would bring down the cost of therapy.

Coordination among the four countries to generate evidence and develop common policies would aid in tackling cross-border issues. Multi-sectoral cooperation and capacity-building across all relevant sectors including health, education, agriculture, environment, water, forestry, urban

and rural development is required. Collaboration and support need to be provided to universities and specialized institutes to establish reference laboratories to ensure QC/QA for diagnostics, to monitor drug-resistant parasites, and to carry out surveillance of kala-azar transmission in communities.

5. Community mobilization

Community mobilization (COMBI) is a process that strategically blends a variety of communication interventions intended to engage individuals and families in considering recommended healthy behaviors 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 directed sharply and smartly to specific, precise behavioral outcomes in health. In the elimination programme COMBI is critical to achieving early diagnosis and completion of therapy, and cooperation during IRS, adoption and correct use of ITNs and environmental management. For effective implementation, partnership building at national, international, district and state levels is required. Also required are strengthening of partnerships and networking among institutions within the health sector (nutrition, anaemia control, HIV, TB control) and outside the health sector e.g. NGOs.

6. Monitoring and evaluation

The progress and the gaps within the programme in the three endemic countries were presented. All countries have adequate stock of drugs, RDT and insecticides. The WHO-TDR implementation research has developed a “monitoring and evaluation toolkit for indoor residual spraying”. Also, “indicators for monitoring and evaluation of kala-azar elimination” were adopted at a workshop convened in June 2009 in Dhaka; Bangladesh. Bhutan is taking steps to train its doctors and health workers.

The three key indicators for the elimination initiative are:

- (1) **detection rate:** number of new cases of kala-azar detected per year in the district/*upazilla*/subdistrict, divided by the total population in the same area;
- (2) **treatment completion rate:** percentage of cases of kala-azar who completed a full course of first-line drugs; and
- (3) **coverage rate of vector control:** percentage of households (and cattle sheds) protected divided by all households at risk.

In general it was felt that monitoring and evaluation of the VL elimination initiative should be strengthened and the programme should adopt the tools developed for IRS.

7. Updating of the Strategic Framework for Elimination of Kala-azar

The document that was prepared in 2005 was thoroughly updated, discussed and finally endorsed.

8. Recommendations

- (1) Miltefosine as monotherapy should be phased out and replaced by single-dose liposomal amphotericin B for kala-azar as it is safer and more effective, and ensures 100% compliance. Feasibility study(s) for its implementation should be started, keeping in mind the timeline of the elimination target. Combination therapy should be considered once the field study is complete. Pharmacovigilance data should be collected for all drugs used in the programme.
- (2) The VL elimination programme should be better coordinated. Also, it should be comprehensive to include drug delivery, integrated vector management, and improved housing and poverty alleviation strategies. A more effective implementation of activities is required through training and upgradation of facilities. Coordination mechanisms between countries need to be

strengthened for cross-border issues and migration. A better harmonization between drug policy agencies is needed.

- (3) An appropriate epidemiological definition and documentation should be established to decide on elimination since the distribution of cases is clustered/patchy. Data on disease incidence, treatment and vector control coverage should be provided annually using the elimination target indicators. Surveillance systems need to be strengthened for early detection and treatment of cases including PKDL.
- (4) Effective implementation of integrated vector management should be the mainstay of vector control. Results from the WHO-TDR studies show that the quality of IRS operations needs to be improved. The monitoring and evaluation toolkit developed by WHO-TDR should be adopted by country programmes.
- (5) Bio-markers should be developed and validated to accurately detect asymptomatic leishmania infections and determine the role of asymptomatic carriers in the transmission of infection.
- (6) A documentary film on kala-azar should be developed by WHO-SEARO for advocacy purposes.
- (7) A brainstorming meeting should be organized by SEARO on PKDL.

9. Concluding session

The conclusions and recommendations were presented, discussed and accepted. In his concluding remarks, the Chairman of the meeting, Dr N.K. Ganguly, expressed his satisfaction that the RTAG could capture all the developments and progress made in the implementation programme, as also the constraints faced by the programme in the three countries. Since the political will is strong, it should be possible to enhance cross-border collaboration. WHO will continue to provide technical support for the kala-azar elimination programme in the Region. Everything possible should be done to achieve the target of elimination of kala-azar by 2015.

Annex 1

Programme

Tuesday, 12 July 2011

Registration

Opening Session

RD's inaugural remarks

Objectives of the Meeting

Review of progress and implementation of recommendations of the Last RTAG -
Dr Sujit Bhattacharya

Global Kala-azar situation

Kala-azar in the South-East Asia Region

Country situation

Diagnosis: Current advances

Treatment: Miltefosine: compliance, resistance, adverse effect, serious adverse effect, etc.

Paromomycin: What role it can play in elimination programme?
Prof. Suman Rijal

Treatment with AmBisome

Recent development in combination therapy and their possible role in the Programme

TDR activities in SEAR

Wednesday, 13 July 2011

PKDL: diagnosis and treatment, challenges

Vector control strategies

Concept of IVM

Evidence based vector control options in interrupting KA transmission

How effective are LNs for VL vector control?

Supportive strategies: Policy Support and Advocacy, Partnerships, Resource mobilization, Institutional support, Cross border collaboration

Community mobilization/COMBI

For Kala-azar elimination programme

Monitoring and Evaluation of programme elements in the elimination Strategy - where do we stand with regards to elimination goal?

Thursday, 14 July 2011

Conclusion and recommendations

Drafting of Recommendations – drafting group

Plenary: Presentation of Final Recommendation

Rapporteur

Next Steps and Closure

Concluding Session

Annex 2

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Kala-azar is a disease of significant public health importance in Bangladesh, Bhutan, India and Nepal. About 150 million people are at risk of kala-azar in approximately 113 districts in these four endemic countries. Elimination of kala-azar in countries of the WHO South-East Asia Region is feasible.

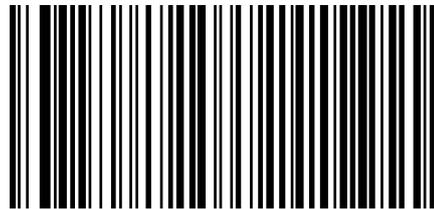
The Fourth Meeting of the Regional Technical Advisory Group (RTAG) jointly organized by WHO-SEARO and WHO-Nepal, was held in Kathmandu, Nepal, from 12 to 14 July 2011 to review the progress and achievements of the kala-azar elimination programme; assess the implementation of national plans of action; discuss developments in technology for incorporation into the elimination programme; and make recommendations to the Regional Director.



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SEA-CD-243