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Regional Technical Advisory Group on Kala-azar Elimination

*Report of the Second Meeting
Kathmandu, Nepal, 30 October – 2 November 2006*

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Executive Summary

The second meeting of the Regional Technical Advisory Group (RTAG) was held organized in Kathmandu, Nepal from 30 October to 2 November 2006 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, programme managers, WHO staff from HQs, the Regional Office, from the TDR and the WHO country offices in Bangladesh, India and Nepal.

Since the first meeting of RTAG in December 2004, the Health Ministers of three Member States of WHO's South-East Asia Region, India, Nepal and Bangladesh signed on 18 May 2005 a Memorandum of Understanding pledging to collaborate to eliminate Visceral Leishmaniasis (Kala-azar) from their countries; a meeting of the partners endorsed the regional strategic framework (2005-2015); the national operational plans were developed at a meeting of the national programme managers of the three affected countries; miltefosine has been registered; a promotional docket, an advocacy kit and posters have been developed by WHO; and operational research on implementation of the key interventions and "kala nets" initiated. Political commitment has been sustained. The progress of implementation was reviewed in a side meeting that was organized during the 59th session of the Regional Committee in Dhaka in August 2006. The partnerships between WHO, the World Bank, TDR, GTZ, JICA etc. in the elimination of kala-azar continued.

The implementation of national plans of action was reviewed by the second RTAG. This included the status of implementation in 12 pilot districts. The constraints in implementation were identified. The technical updates covered the areas of vector control, diagnosis and treatment, surveillance, supportive strategies and research. During the meeting, the importance of complementarity of research with the programme, intercountry collaboration and partnerships was emphasized. The socio-economic impact of kala-azar and the critical importance of behaviour change communication was reiterated.

Conclusions and recommendations

The implementation of the kala-azar elimination programme in 12 pilot districts in accordance with the strategic framework has been delayed due to various operational and financial constraints. All three affected countries propose to accelerate the implementation of the strategies in these districts so that the experience gained can be used in rapid expansion of the elimination strategies in all the affected districts.

The following are the broad recommendations:

- The countries should allocate sufficient funds to undertake the activities identified: the action plan developed by the country. A resource mobilization plan should be developed to raise the additional funds required. **(Action: Member countries and WHO).**
- Evidence-based guidelines and standards for training, diagnosis and treatment, vector control, surveillance, pharmaco-vigilance, for training should be developed. The countries should adapt the regional guidelines and organize the necessary training courses required for capacity building **(Action: WHO, Member countries).**
- The national programmes should accelerate the implementation of the pilot programme to feed into the expansion of the programme **(Action: Member countries).**
- Common regional procurement of essential supplies for the elimination programme should be developed for achieving quality, obtaining preferential price and ensuring sustained availability **(Action: WHO).**
- For effective implementation, countries should develop an organizational structure for programme management with staff duly trained **(Action: Member countries).**
- Results-based monitoring, supportive supervision and periodic in-depth reviews should be an integral part of programme implementation **(Action: Member countries).**
- Partnerships at the district and the state level should be established with other sectors. Cross-border collaboration is crucial to programme success and a suitable mechanism should be developed for sustaining the partnerships **(Action: Member countries to be facilitated by WHO).**

- Institutions with expertise in kala-azar in the three affected countries should strengthen networking and linkages to enhance the technical support to the elimination programme (**Action: WHO, TDR and other research partners and Member countries**).
- Operational research should be an integral part of the implementation programme. Research to improve existing tools should be encouraged and results of research translated as interventions in the elimination programme (**Action TDR, other research partners and member countries**).

1. Opening session

Dr JP Narain, Director, Department of Communicable Diseases, WHO/SEARO, welcomed the participants on behalf of the WHO Regional Director for South-East Asia Region, Dr Samlee Pliambangchang.

In his address, the Regional Director stated that kala-azar (Visceral Leishmaniasis) was predominantly a disease of the poorest of the poor which, if not treated, could kill. It was reported from Bangladesh, India and Nepal in the Region. The efforts to control kala-azar had been hampered due to numerous constraints. However, kala-azar could be eliminated from the SEA Region because the disease was transmitted only through humans and the sandfly, *Phlebotomus argentipes*, was the only vector responsible for transmission of the disease in the Region. There was historical evidence of near elimination as a collateral benefit of Indoor Residual Spraying (IRS) in the malaria eradication/control programme. The vector continued to be sensitive to available insecticides and suitable tools are available to make the elimination possible. A simple screening test, 'rk 39' was available for the diagnosis and an effective oral drug, miltefosine, had been registered in the three endemic countries.

The disease was limited in its geographical distribution and focused efforts could lead to its elimination, the Regional Director added.

The Regional Director said a roadmap was needed for eliminating the disease, with close monitoring of the progress. There should be no delay in implementation of the elimination programme since co-infection between kala-azar and HIV which had emerged as a new entity, could spell devastation in the affected population. The escalating prices of insecticides and emergence of drug and insecticide resistance would become a constraint in the elimination of the disease. An increase in the pool of cases of post-kala-azar dermal lesions (PKDL) could offset the elimination efforts through continued transmission of the disease.

The first meeting of RTAG had given strategic direction to the proposed elimination programme, he said. A Memorandum of Understanding for elimination of kala-azar was signed by the health ministers from the three affected countries to enhance cooperation and

coordination. A number of international partners were interested in supporting the elimination of kala-azar.

At an intercountry meeting held at Behror, Rajasthan, India, in August 2005, the partners had endorsed the regional strategic framework and prepared a roadmap for implementation of the elimination programme.

The Special Programme for Research and Training in Tropical Diseases (TDR), World Bank, and WHO are supporting the affected countries in a sustained manner and would continue to support the elimination programme, the Regional Director said. Elimination efforts had been intensified in 12 pilot districts. Based on the experience in implementation, the elimination programme would be expanded. This meeting of RTAG provided a forum for reviewing the progress towards elimination, exchange information and experiences and make recommendations based on the lessons learned, the Regional Director concluded.

Dr Jorge Alwar, the focal point for Leishmaniasis, Neglected Tropical Diseases (NTD) CDS WHO HQs, stated that it is a unique opportunity to eliminate kala-azar from the 3 countries in SEA Region. WHO- CDS and TDR are committed to elimination. This is a priority for WHO HQs. The thrust areas are to build the capacity of the district, to develop linkages with Pharmaceutical industry and provide technical support to the elimination efforts. Elimination of kala azar should be a key component of neglected disease portfolio.

Dr NM Shreshta, Adviser Ministry of Health and Population, Government of Nepal, reiterated that kala-azar affected the poorest of the poor in three countries of the Region. It was important to develop, implement and monitor the plans of action based on the deliberations in the first RTAG. He hoped that the problems relating to kala azar elimination would be identified and common strategies used based on the latest knowledge. These should be implemented within the context of the country policies.

The meeting was attended by members of RTAG, experts, programme managers, WHO staff from HQs, SEAR, TDR and WHO country offices in Bangladesh, India and Nepal. A list of participants is given in Annex 1.

2. Objectives

- (1) To review the progress and achievements of the Kala-azar Elimination Programme and implementation of the

recommendations of the First Regional Technical Advisory Group Meeting on Kala-azar;

- (2) To assess implementation of the National Plans of Action of Bangladesh, India and Nepal for Elimination of Kala-azar, and to recommend appropriate strategies for additional improvements;
- (3) To discuss other technical issues related to the developments in new technology and recommend them for including in the programme;
- (4) To review progress on programme implementation in pilot districts and discuss the future plans;
- (5) To develop recommendations for consideration by WHO/SEARO.

Dr Manas Bannerjee was selected as the chairperson, Dr Mahmudur Rahman as the co-chairperson and Dr SK Bhattacharya as the rapporteur of the meeting.

The programme for the meeting is given in Annex 2.

3. Review of progress since the first meeting of RTAG

Progress in the elimination of kala-azar since the first meeting of RTAG was reviewed. The regional strategic framework (2005-2015, was recommended by the first meeting of RTAG to WHO. Since then, WHO had been engaged in building and coordinating partnerships for elimination of kala-azar. An advocacy kit and a poster was developed by WHO. An MOU was signed during the 58th World Health Assembly in Geneva in May 2005. Since the signing of the MOU, a consultative meeting of the partners was held at Behror, Rajasthan in August 2005 which endorsed the Regional Strategic plan for Kala azar. At a meeting of programme managers, national strategies and operational plans were developed at Behror in September 2005. Miltefosine, the new oral drug was now registered in all the three endemic countries. The implementation of the elimination programme was initiated in April 2006. Operational research, supported by TDR and other agencies, was progressing. It included implementation research and a study on the efficacy and effectiveness of “kala nets” as a personal protection measure. The World Bank had committed to support the elimination programme in India. Partnerships were continuing with participation of WHO, the World Bank, TDR, GTZ, JICA etc.

WHO had produced a docket and posters. These were advocacy materials and were distributed in an informal meeting presided by the health minister of Bangladesh during 59th session of the Regional Committee for South-East Asia in August 2006. The meeting resolved that elimination of kala-azar was an achievable goal. The roadmap prepared should be implemented and the experience from the pilot districts should be used in expanding the elimination efforts.

There was extensive discussion on the need for advocacy to increase the commitment and mobilize additional resources. The options discussed included showcasing of kala-azar as a disease of the poorest of the poor; convincing the highest level politicians at the state and the district levels to regularly monitor the progress in Kala-azar elimination; reflecting the resource gaps in the operational plans and accessing resources from better-funded programmes like TB and HIV.

Very good quality advocacy materials had been produced by WHO. The constraint was that these were shared only with country offices and with programme managers. It had not yet been shared widely in the endemic countries and with the partners. The key documents and advocacy material developed should be shared widely for advocacy and to promote exchange of information amongst medical colleges, researchers, programme implementers and other relevant persons. A strategy needs to be prepared for this purpose. If needed, the material can be suitably translated to ensure outreach.

Resource constraints continue to be a major bottleneck in the implementation of the elimination programme. WHO is in contact with several partners to mobilize additional resources. The partners would like to see a firm commitment at the implementation level. This required the use of operational plan as a tool for engaging the partners. JICA, at present, does not see a firm commitment of the government. This perception needs to be changed. A systematic approach is required to fill the resource gaps identified in the operational plans. Continuous engagement of the donors and partners is crucial and ongoing engagement of the international, national and local partners is necessary.

4. An update of the global and regional kala-azar situation

An update of the global and regional situation was provided. The situation is worsening due to asymptomatic cases, PKDL, undernutrition and kala-

azar/HIV coinfections. However, the mortality is stable because of improved case management. DALYs, as an indicator of disease burden, is a weak indicator. The use of information on DALYs is more relevant in non-communicable diseases. The information on disease burden is inadequate because of the large gap between the reported and the estimated cases. There is little information on the socio-economic impact of kala-azar. The positive developments include the availability of simple screening test, 'rk39', an effective and safe oral drug, miltefosine and encouraging experience with paromomycin in pregnant women. The price of rescue drug is being negotiated.

5. Review of the kala-azar situation and programme in the endemic countries

The status of the kala-azar elimination programme was presented by programme managers from Bangladesh, India and Nepal. The review showed that the disease is now being reported in 45 districts in Bangladesh, 52 in India and 12 in Nepal. The total number of districts reporting kala-azar exceeds 109. The at risk population is approximately 200 million. There are inadequacies in reporting since only government agencies are reporting the disease to the programme. The number of cases reported is increasing and this is probably a reflection of some improvement in the drugs and diagnostic services provided by the government. There is still a large gap between the reported cases and estimated cases. The situation with respect to PKDL is not clear. India estimates the PKDL to be about 2% while Nepal estimates it at 10%. There are difficulties in recognizing cases of PKDL.

Even though there is a high level of political commitment, the policy should clearly articulate elimination as the goal. The programme continues to use aldehyde test and Direct Agglutination Test (DAT) as screening tests and relies on Sodium Antimony Gluconate (SAG) or sodium stibogluconate (SSG). The diagnostic test, 'rk39', is not used by the programme. However, it is available in the private sector and is being used to some extent. Even in the pilot districts, miltefosine has not yet become easily accessible because of numerous problems relating to its procurement and supply. The guidelines have not yet been developed to implement Standard Operating Procedures (SOPs) in the pilot districts. These should be developed urgently by WHO and introduced through intercountry training organized for the trainers.

Amongst various vector control measures, India uses DDT. The policy recommends two rounds of DDT spray. The numerous implementation constraints, weak supervision and other problems have resulted in only 38% coverage in Bihar state with only one round of DDT. In Nepal, IRS is done with pyrethroids but the coverage is very meagre. In Bangladesh no IRS was done during 2006. The other vector control measures although potentially useful are not operationalized since evidence is needed of their efficacy and effectiveness before they are recommended for widespread application.

6. Technical update

6.1 Vector control

The strategic approach recommended is integrated vector management (IVM) and kala-azar elimination should be considered an integral part of the national vector control strategy. This is necessary since effective vector control requires a sound infrastructure and capacity. The strategy should effectively leverage the resources for a sustainable programme. A case has to be made that effective implementation of IVM is useful for control of vector-borne diseases and not elimination of kala-azar only. The strategy promotes a right mix of interventions i.e. IRS, ITNs and environmental manipulation and management. Amongst these interventions, IRS continues to be effective for the elimination of kala-azar.

The tools, norms and standards for effective IRS are available. This is an important intervention for the elimination of kala-azar but requires rigorous implementation to be effective. For this, planning for IRS should be district-based to estimate the national requirements. This includes planning the spray operations with a clear identification of the coverage to be achieved, timely procurement and distribution of insecticides, efforts to get maximal community participation, effective supervision and monitoring of IRS operations and a sustained effort. An assessment of the quality of spraying should be an integral part of IRS operations.

Evidence for the important role of IRS in vector control is strong and therefore it should be continued as a major component of the prevention strategy. There is strong historical evidence that supports the role of IRS in kala-azar elimination. The other intervention i.e. ITNs, is not yet evidence based. In the absence of better alternatives, it is prudent to strengthen IRS and obtain maximum advantage. Both IRS and ITNs are macro-level

interventions. In contrast, environmental manipulation and management should be considered as micro-level strategies for the elimination of kala-azar. For this to succeed, the housing conditions should be improved. The focus should be on dwellings where the poorest of the poor live. The cracks and crevices should be plugged through plastering or mixing of mud with wheat husk. The effectiveness and feasibility of environmental control should be evidence-based before justifying major national investments. These measures require community participation to be effective utilizing long-term sandfly control strategy through good sanitation of the household and the surrounding areas. The programme should take advantage of developments and support from other sectors for upliftment of the poor. Indira Awas Yojna, a scheme for the poor in India is an example which can have an impact on kala azar.

6.2 Diagnosis and treatment of kala azar

The screening and confirmatory tests for kala-azar were discussed. The test is not reliable while DAT, even though useful, is limited in scope since the test requires an incubation of 18 hours before results can be provided. Based on evidence, 'rk39' has been recommended but quality assurance is important to ensure that its usefulness under field conditions is sustained. The programme should make intensive efforts to make the 'rk39' test accessible and organize training of appropriate staff. Quality assurance mechanisms should be put in place expeditiously. The interpretation of the test should be based on both the clinical presentation and the test results since the results of serology alone will not be enough to diagnose kala-azar. Invasive tests like the bone marrow and splenic puncture are confirmatory and should be used only for referred cases, treatment failures and to serve as a gold standard as part of the quality assurance system.

The first-line oral drug, miltefosine, has been registered for use in Bangladesh and India and for limited use in Nepal. The drug is effective in more than 90% of the patients and the side effects are minimal and reversible. The limitation is the high cost of about 75 USD per course of 28 days. The drug should not be used in pregnant women and in women who are in the reproductive age group and are not using effective contraception. Paromomycin is an effective injectable drug which has completed phase III trials with very good results. It has to be injected for 21 days and the toxicity is minimal (ototoxicity). Ambisome is an effective rescue drug. The role of paromomycin and ambisome in the programme can be discussed at the next meeting of RTAG.

The efficacy of currently available drugs may not last long especially if quality issues, complete treatment and other precautions in the use of the drugs are not addresses. Research is underway to assess combination drugs. If these are effective, new windows for treatment will open up.

For success in treatment it is important to treat dehydration and anaemia before starting the specific treatment for kala-azar. This reduces the risk of complications. The price of miltefosine supply that WHO could procure would be around 54 USD, comparatively lesser than the prevailing market price. Miltefosine is a useful drug but it should be avoided by pregnant women. Pharmaco-vigilance needs to be an integral part of the elimination programme. The diagnosis and treatment of PKDL and the challenges posed by asymptomatic cases are important issues to be addressed.

Ways have to be explored to determine the factors that contribute to the pool of PKDL and assess the extent to which the asymptomatic cases are responsible for continued transmission of the disease. The strategy recommended for reducing the pool of PKDL is to ensure complete treatment of cases of kala-azar. At the same time, it is advisable to determine the criteria for complete cure.

The success of interventions on prevention, diagnosis and complete treatment depend on community participation. This includes accessing diagnosis and treatment, completing treatment and participation in IRS. In this context, strategic communication is important. Communication for behaviour impact should be considered as a strategy in the kala-azar elimination programme.

6.3 Surveillance in elimination of kala-azar

Reporting of kala-azar cases is mainly passive although India organizes a kala-azar fortnight annually. While kala-azar fortnights have not been organized in Bangladesh, this approach has been used in Nepal – one district only. The passive surveillance reports are derived from information provided by the government health facilities. The limitations are lack of uniform application of standard case definition, continued use of aldehyde test as a screening procedure and limited use of confirmatory diagnosis based on demonstration of the parasite. Reporting and feedback are also weak. When medicines and supplies are available, the reported cases increase, but when the supplies are exhausted then patients do not come to these facilities and therefore the cases are underreported.

The results of a pilot study carried out in a subdistrict in Bangladesh were shared. There were 109 cases reported over a three-month period and the treatment completion rates exceeded 90%. The possibility of another case of kala-azar in the home or in the vicinity is estimated to be 26 times greater. The strategy of active surveillance through an intensive search following reported cases is likely to be more productive than a routine house-to-house search. Surveillance should be linked to action. It is of no relevance if the access to diagnosis is unsatisfactory. Surveillance of kala-azar should be linked to integrated disease surveillance and HMIS. Vector surveillance is non-existent in the three countries and needs to be strengthened to make vector control more meaningful.

The strategies should be considered for revamping surveillance are: (1) Sentinel surveillance (2) Involvement of partners within the health sector (3) Partnerships with private providers who are effective (4) A system of quality control (5) Regular monthly reporting and feedback and (5) introduction of vector surveillance.

6.4 Supportive strategies

The three main strategies for elimination of kala-azar include vector control, early diagnosis and complete treatment and revamped surveillance. Effective implementation of these strategies requires application of supportive strategies which include: (1) Sustained political commitment at national and local level as an integral part of the national development plan and provision of the required resources determined on the basis of evidence and identification of resource gaps; (2) Partnerships within the health sector and with other sectors including the private and the corporate sectors as a part of healthy public policy; (3) Capacity development with a focus on men, material and money. Development of a single manual to be used by all the three endemic countries would help to unify the strategic approach (4) Monitoring and supportive supervision to track the progress. This should include country evaluation for applying corrective measures if required. (5) Innovations and operational research to continue to provide the evidence base and best practices. This requires networking and a system of ongoing exchange of information and improved communication between the research and programme units.

7. Socio-economic impact of kala-azar

Kala-azar may not affect the national economy or the national GDP, but it devastates the family. This is because the poorest of the poor who are maximally affected by the disease sink deeper into poverty following an attack of kala-azar.

A study compared the socio-economic aspects of malaria and kala-azar in Bangladesh. The living conditions of the people affected by kala-azar are very poor. The duration of illness was 62 days for kala-azar compared to 13 days for malaria. The number of work days lost was three times higher than for malaria and the expenditure for the treatment of kala-azar was considerably higher. Economically affected life years (EALY) were 22 years for malaria while it was more than 34 years for kala-azar. People who suffer from kala-azar are so poor that they sleep on the floor and not on a bed which makes them even more vulnerable.

Environmental manipulation and management may be an important intervention for kala-azar. It is most likely to occur where people live in mixed dwellings or in houses with a cattle shed. The strategy for elimination of kala-azar should focus on behaviour change and intersectoral coordination aimed at improving the socio-economic status of the poorest of the poor in the community.

Kala-azar elimination in the affected areas should be considered as a poverty alleviation programme and included as an integral part of the Millennium Development Goals.

8. Research in kala-azar

Discovery of effective drugs (miltefosine and paromomycin) has opened up a new window for elimination of the disease. However, every drug has a limited lifespan which can be enhanced through risk assessment and risk minimization. It is important to include in the SOPs the correct use of drugs and drug resistance. All adverse reactions should be recorded and reported by making pharmacovigilance an integral part of surveillance. This would help to generate the required data and reduce the expenses on research. These measures would help in containing the problem of drug resistance. There should be an ongoing dialogue between the producer, the government and other interested partners in this regard.

Risk communication is important to make the users aware of the side effects of the drug and risk minimization is to reduce the risk of prescribing the drug by irresponsible providers. The research priority should be to discover new molecules and develop drug combinations in order to reduce the risk of early development of drug resistance. Research on drugs and drug combinations should also include PKDL and kala-azar coinfections where information on drug interactions need to be evaluated.

The diagnosis and treatment of PKDL continues to be a challenge. The lesions are varied, innocuous and the patient is stigmatized since the lesions are often confused with leprosy. PKDL develops in about 5-10% of cases of kala azar after a lapse of about 2-10 years. Parasites are present in about 60% macules and more than 90% of the papules and nodules. Serological diagnosis is unreliable. Only prolonged and interrupted course of treatment can help in the cure of PKDL. There is very little motivation amongst the patients to complete the treatment since they do not suffer from any symptoms. The patients are not motivated since treatment would keep them away from work or from household chores. Trials are in progress to evaluate improved treatment of PKDL with miltefosine or ambisome. The results should help clarify the situation.

With regard to IRS its efficacy is established but not it's effectiveness. For ITNs, both efficacy and effectiveness have to be demonstrated. IRS requires effort by the state and central governments while the use of ITNs includes both the national and community participation component. Kala Net is a research effort in which seven institutions are participating with four institutions from the Indian subcontinent and three from Europe. The effort is supported by EU. People prefer using permanets to olyset since permanents are softer. The project proposes to assess their impact in containing infection. While baseline work has been completed, the project will conclude by 2009. There is provision for an interim, mid-term analysis to feed into the programme.

Important research on leishmaniasis was summarized. There is evidence to show that the cutaneous form of the diseases in the state of Himachal Pradesh in India and in Sri Lanka is caused by leishmania donovani. There is also some evidence that the rodent- eating (Moosahar) community may be at risk of kala-azar if the field rodents are harbouring the infection. The research papers reviewed provide some leads though they are not conclusive enough to justify programmatic decisions. Research findings can help in strengthening the evidence based for its appropriate utilization in the programme.

9. Monitoring and evaluation

Monitoring and evaluation of kala-azar is an important supportive strategy. A working group should be formed to prepare a framework that includes indicators that measure simply and reliably the outputs of the programme. Five key indicators were recommended which should be assessed as part of the programme and also evaluated through special studies. Drug and insecticide resistance, quality assurance of the diagnosis, and pharmacovigilance are important components. Programme review is an important part of M&E. It should be carried out during September 2007 and cover the experience of pilot districts in the implementation of the elimination programme.

10. Cross border collaboration

Cross-border collaboration is an important and challenging issue in the elimination of kala-azar. The mandate for cross-border collaboration is provided by the MoU signed by the three countries. Nearly 50% of the problem of kala-azar is in the districts located on the international borders. The porous international border between India and Nepal accentuate the problem through uninhibited population movement and migration. Regular exchange of information at the local level, institutional networking for capacity development, use of similar protocols for diagnosis and treatment and synchronization of prevention efforts can contribute significantly to the elimination efforts. This would enhance the spirit of solidarity and cooperation in the three countries. The operational plan should include cross-border collaboration and its implementation needs to be monitored. Action at the district level is particularly important.

11. Programme planning

Effective implementation of the strategic interventions is crucial for the success of the kala azar elimination programme. The operational plan should build in appropriate mechanisms for supervision and monitoring. This would require state and district coordinators and effective supervision at subdistrict level. The job descriptions for the state-level and district-level coordinators and supervisors at the subdistrict level have to be developed. It is important to prepare district implementation plans which should include an estimation of requirements for IRS, drugs and supplies and provisions for ongoing supervision of staff at different levels who are responsible for

diagnosis and treatment. The capacity of district staff in programme management needs to be strengthened and training of the staff in implementing the three strategies organized. Standard operating procedures should be developed by WHO in collaboration with the three countries and training of the trainers organized. While the programme needs to provide for adequate mechanisms for supervision and technical support, the medical colleges and research institutions need to contribute in the areas of quality assurance and quality control. Cooperation of the private sector and NGOs is important to increase the outreach of the programme and thus increase access.

It may be a useful strategy to build a limited number of diagnostic and treatment centre in the beginning and, based on the experience, progressively enhance the access to diagnosis and treatment. The IRS should be intensive in mapped areas. The mapping should be based on the kala-azar cases reported in the preceding two to three years. The success of the programme would to a large extent, depend on action at the district level. Local partnerships and mobilization of the community are necessary.

Mapping of interested partners and ongoing engagement as well as collaboration are required as a first step. The operational plans should keep the present situation in mind and then build up based on the availability of resources and on the experience gained. It would be helpful to advocate for resources from better-funded programmes like TB, and HIV where there is a link. It can be justified by articulating concern about adverse impact on these programmes if the elimination programme does not succeed. Advocacy is also needed to mobilize a greater proportion of funding and resources from the national budget allocated for vector-borne disease control.

12. Progress of implementation in pilot districts

The progress of implementation of the programme in pilot districts was presented.

In Bangladesh, a national steering committee and a technical task force has been established. Miltefosine is registered and linkages have been developed between medical colleges, IEDCR and NIPSOM. The pilot district selected is Mymensingh. The elimination of kala-azar is being implemented in Trishal upazila as a part of an operational research effort in collaboration with TDR and other partners. Disease burden studies, mapping of the disease and entomological spot checks have been carried as

preparatory activities. Miltefosine and 'rk39' will be used in the upazila. Training modules are being reviewed and finalized.

Preparations have been made in 10 pilot districts in India to use miltefosine for treatment and 'rk39' for diagnosis of kala-azar. Fungizone is the rescue drug. Completion of treatment is an important challenge and experience is required. This is possible to achieve since the treatment completion rates exceeded 90% in phase four trials. DOTS strategy in TB control has demonstrated that completion of treatment can be achieved in a high proportion of cases. Pilots studies should be able to provide experience in this regard.

A partnership is developing in Jharkhand in which Coal India Limited, a public sector company, has agreed to provide the treatment for kala-azar in four districts in the state. The operational constraints identified include resource gaps, non-availability of 'rk39' and miltefosine in the government programme, lack of trained of the staff, and planning which is resource-based and not need based.

An outline operational plan was presented along with the roadmap for the India programme. Lack of district planning and management, non-availability of 'rk39' and miltefosine, inadequacies in quality and coverage of IRS, and weak reporting (only from the government facilities) are limitations that need to be addressed. There are difficulties in the treating pregnant women and those who are in the reproductive age and not on contraceptives. Paromomycin can be useful and limited registration has been allowed for phase IV trials. This can not yet be introduced in the programme. In such cases, the use of ambisome is recommended until an alternative safe drug becomes available. Collaboration with the private sector and NGOs is promising, but should be undertaken carefully to ensure that the private sector and other partners achieve the standards recommended by the government.

In Nepal, one district has been selected. There is provision for 10,000 'rk39' tests, and 300 courses of miltefosine. The programme has also provided for 7000 ITNs while the requirement is for 100,000. There is a possibility of conducting IRS in a limited way, using synthetic pyrethroids. It would be advisable to initiate implementation after thorough preparation which includes the use of appropriate manuals and guidelines, training of staff, and monitoring of implementation. The resources should not be spread too thin and the experience should be carefully documented and thoroughly reviewed. This would be useful in mobilizing additional

resources since the partners are always keen to support a programme that is implemented well. The trained staff at this district can help train staff in other districts. The constraints identified during the pilot phase can be addressed effectively when the programme is expanded. However, the pilot phase should be implemented rapidly.

Elimination of kala-azar requires a special effort with the focus on district planning and programme management backed by technical and policy support from the state and the central governments. For it to be effective, it is essential to: develop job descriptions for kala-azar elimination at different levels; identify critical staff needs for dedicated staff; develop plans for capacity development; involve the private sector and NGOs with credibility; focus on a few facilities; undertake active case search through “hot.spot” approach; prepare the patient by treating anaemia and dehydration before starting definitive treatment; ensure complete treatment ; develop micro plans for IRS and implement them; prepare logistics of insecticides and equipment; undertake training of the spray squads; prepare the community for IRS ; monitor and supervise spraying operations; assess adequacy of IRS operation and intensify spraying of “hot.spots” and selected villages.

13. Action points emerging from group work

13.1 Technical support, capacity development and measuring progress

- There should be uniformity in the plans of action for implementation of activities related to the elimination programme in the three countries. To evaluate progress, regular intercountry meetings should be organized. Intercountry training should be organized for ensuring a uniform approach.
- Each country should allocate sufficient funds to implement the activities of the action plan developed by it. Efforts to raise additional funds are required and WHO assistance should be sought in this regard.
- Lead institutions in the three endemic countries, India, Bangladesh and Nepal, should network with institutes with similar interest and expertise in their own country who can provide necessary technical support. This would help to provide technical backing to the programme.

- WHO should generate uniform guidelines for diagnosis & treatment, vector control, surveillance and pharmaco-vigilance. This would help the countries to prepare training modules suitable for health functionaries at all levels in the elimination programme. Such guidelines and modules are urgently required.
- Appropriate experts needed to implement different activities at various levels should be made available by WHO to the three countries for the training of doctors and others health functionaries for community mobilization, and for mapping for IRS etc.
- The issue of availability of drugs and other supplies and their distribution should be discussed among the three countries to find out if it is possible to centrally coordinate this activity so as to get the best price.
- Research for improvement of existing tools and to integrate the results of the research into the elimination programme for achieving better outcome should be encouraged.
- Operational research should be an integral part of implementation programme.

13.2 Programme management, operations and resource mobilization

- The programme should implement the pilot projects as soon as possible. The implementation should follow the recommendations made by the first RTAG that were agreed to the intercountry consultation held in September 2005.
- Case definition should be used to identify suspected cases of kala-azar and the 'rk39' test should be carried out in patients who conform to the case definition. For estimating the requirement for 'rk39', calculations should be made at the rate of 5-10 times (the pilot will help to determine the needs of the programme), and validate the assumptions.
- Pilots would give information on completion of treatment, identify problems in filling up the treatment cards, proportion of patients who require hospitalization, develop criteria for hospitalization and determine to what extent the DOTS strategy works.

- Surveillance requirements for kala-azar and PKDL would include the following:
 - line listing of 'rk 39'
 - patients treated
 - patients completing treatment
 - patients hospitalized
 - case fatality rate
 - geographical information of patients
 - age and sex distribution
 - adverse drug reaction
- The pilots will help to determine if there are any additions or deletions that might be required in the indicators and also what the problems are in the reporting and the ways to solve the problem. The pilots will become the demonstration sites for training and capacity development in other sites selected for expansion. It would be possible to evaluate the various guidelines and tools.
- Two surveys on vector density and an insecticide susceptibility test in the pilot districts should be carried out. This would be useful in rationalizing and focusing on IRS intervention. "Hot.spots" identified on the basis of reported cases and active surveillance (around the "hot.spots") would require thorough spraying with two rounds at the designated period. It will be in addition to the routine IRS operation in the country (one case or more during the last five years) at the village level. The "hot.spots" should be continuously sprayed for a period of three years.
- District programme coordinators, district programme management guidelines and district planning should be produced, field tested and made available. This would be the starting point for implementation of the pilots and would be useful during the expansion of the programme.
- A strategy for ITN should be worked out according to the local situation and the experience/research carefully documented on its acceptability and impact on kala-azar.
- A one day workshop should be conducted and a plan prepared for implementation, and for advocacy. A plan with milestones

should be prepared and the programme implemented in the pilot area. The partners should be engaged in an ongoing manner. A profile of the partners should be developed to match their interest.

- National Operational Plans and the roadmap should clearly spell out the requisite calendar of activities within a specified timeframe with a focus on the pilot phase and plans for expansion.
- District programme management is the key component for operations. It should clearly define the inbuilt components of EDCT, IVM strategy, community mobilization and advocacy.
- Development of core-trainers from the three affected countries should be undertaken. This would help strengthen implementation in the pilot districts. It should mainly focus on the three strategic components. Standard training material is needed for capacity development. Core-trainers should be utilized for the peripheral level training. The training course should be documented to facilitate further training. Beside building capacity of medical and paramedical officers, there is need to train private practitioners, NGOs, Faith Based Organizations (FBOs) etc. Efforts should be made to train the participants in ratio of 2:1 (Govt. : Private/NGOs).
- Capacity building in terms of programme management should also be an integral part of training of the district managers. A matrix on programme management should be developed, refined and adapted for use in the programme.
- There is a need to decentralize the system of procurement to ensure timely supplies. Quality assurance should remain the top most priority with regard to drugs, insecticides & equipment etc.
- Frequent monitoring & Evaluation by independent agencies is required. An in-depth review should focus on areas that need strengthening.
- An action plan for the BCC needs to be made keeping in view the needs of the target groups. A strategy to foster behaviour change is required. The behaviour impact should be identified before implementing BCC. IEC messages should focus on the intervention gap in the strategic components.

- Areas of partnerships should be explored with other sectors at the district and state levels and also with private practitioners, NGOs, donors etc. defining their roles and responsibilities.
- To facilitate cross border collaboration, informal meetings should be organized by district officers to share information and for developing a common protocol for strategy implementation. A definite mechanism in this regard should be spelt out.

14. Concluding session

The conclusions and recommendations of the meeting were discussed and approved. In his concluding remarks at the closing session, Dr Kan Tun, WHO representative to Nepal said that the path towards the elimination of kala-azar was long and tortuous. The programme has to compete with other health programmes that are of priority concern. The task of policy makers and programme managers would become easier if the current loads of work in health programmes was rationalized. The political will was strong, as evidenced by the signing of the MoU. Cross-border collaboration was one of the best approaches to address the problem and WHO would provide technical support through multi-country activities, he added.

Annex 1

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Annex 2

Programme

Monday, 30 October 2006

08.00 – 09.00 *Registration*

09.00 – 10.00 **Agenda I: Opening Session**

RD's inaugural speech	WR Nepal
Objectives of the Meeting and remarks	Dr Jai P. Narain
Introduction of the participants	Dr Chusak Prasittisuk
Appointment of the Chairperson and Rapporteur	WR Nepal
Administrative Announcements	Dr Margarita Ronderos

Agenda II: Review of Progress and Implementation of the First RTAG

10.30 – 10.45	Review of progress and implementation of recommendations of the First RTAG	Dr Chusak Prasittisuk
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10.45 – 11.00 Discussions

Agenda III: Situation of Kala-azar

11.00 – 11.10	Global Kala-azar situation	Dr Jorge Alwar
11.10 – 11.20	Kala-azar in the South-East Asia Region	Dr Vijay Kumar
11.20 – 11.40	Discussions	

Agenda IV: Country presentations

11.40 – 12.05	Bangladesh	Programme Manager, Bangladesh
12.05 – 12.30	India	Programme Manager, India
13.30 – 13.55	Nepal	Programme Manager, Nepal
13.55 – 14.20	Discussions	

Agenda V: An update on technical issues

14.20 – 14.40	Integrated vector Management (IVM) for Kala-azar Elimination Programme	Dr Michael Nathan
14.40 – 15.00	Indoor Residual Spray	Mr N L Kalra
15.00 – 15.30	Discussions	
16.00– 16.20	Diagnosis of Kala-azar, Operational issues / Quality Assurance	Dr Kesara Na-Bangchang
16.20 – 16.40	Update on treatment	Dr Sujit K Bhattacharya
16.40 – 17.00	Discussions	
17.00 – 17.45	WHO Secretariat Meeting	

Tuesday, 31 October 2006

Agenda V: An update on technical issues (continued...)

08.30 – 08.50	Revamping disease and vector surveillance	Dr M K Banerjee/ Dr M Rahman
08.50 – 09.10	Discussions	

Agenda VI: Supportive Strategies

09.10 – 09.30	Supportive strategies	Dr N K. Ganguly
09.30 – 09.50	Policy Support and Advocacy	Dr C P Thakur / Dr S R Howlade
09.50 – 10.10	Discussions	
10.30 – 11.30	Partnerships	Dr Elil Renganathan, (Moderator) Representatives from World Bank, GTZ, JICA, Gates Foundation, DFID
11.30 – 12.00	Discussions	
12.00 – 12.20	Community mobilization / COMBI For Kala-azar elimination programme	Dr Anand B. Joshi
12.20 – 12.30	Discussions	

13.30 – 13.50	Monitoring and Evaluation	Dr M K Banerjee / Prof Mod. Zafor Ullah Chowdhury
13.50 – 14.00	Discussions	
	Agenda VII: Research in support of elimination	
14.00 – 14.20	Implementation Research	Dr Olaf Horstick
14.20 – 14.40	New Drugs/Combination drugs	Dr Janiz Lazdins/ Dr Juntra Laothavorn
14.40 – 15.00	Discussions	
15.00 – 15.10	PKDL	Dr Sujit K Bhattacharya
15.10 – 15.20	Discussions	
15.40 – 16.15	Environmental Management for Vector Control including Sanitation	Mr N L Kalra
16.15 – 16.30	Update on Kala-azar Research	Mr N L Kalra
16.30 – 16.45	Discussions	
16.45 – 17.30	WHO Secretariat Meeting	

Wednesday, 01 November 2006

Agenda VIII: Coordination and Cooperation

08.30 – 08.50	Inter-country cooperation	Dr Jai P. Narain
08.50 – 09.00	Discussions	
09.00 – 09.20	Linkages, Networking and Information Exchange	Dr Vijay Kumar
09.20 – 09.30	Discussions	
09.30 – 09.50	Resource mobilization, Advocacy	Dr CP Thakur and Ms Claire Creo
09.50 – 10.00	Discussions	
10.20 – 10.40	Institutional support, advocacy	Dr Manan Bangali