

Leishmaniasis in the WHO SEA Region

Epidemiological information on  
disease burden due to kala-azar in  
Bangladesh, India and Nepal

*Report of an informal consultation  
Paro, Bhutan, 8-10 March 2011*



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

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With the support of  
**WHO Department of Control of Neglected Tropical Diseases**  
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## Abbreviations

ASHA	accredited social health activist
CL	cutaneous leishmaniasis
EU	European Union
GIS	geographic information system
IRS	insecticide residual spraying
ITN	insecticide-treated nets
IVM	integrated vector management
L-AMB	Liposomal amphotericin B
LST	leishmaniasis skin test
MoH	Ministry of Health
MoU	memorandum of understanding
NGO	nongovernmental organization
NRHM	National Rural Health Mission
NVBDCP	National Vector-Borne Disease Control Programme
PCR	Polymerase chain reaction
PHC	primary health care
PKDL	post-kala-azar dermal leishmaniasis
RMRIMS	Rajendra Memorial Research Institute of Medical Sciences
RTAG	Regional Technical Advisory Group
SEARO	WHO Regional Office for South-East Asia
SSG	sodium stibogluconate
TDR	Special Programme for Research and Training in Tropical Diseases
VBDCP	Vector-Borne Disease Control Programme
VL	visceral leishmaniasis
WHO	World Health Organization



## 1. Background

Leishmaniasis is a parasitic disease transmitted by the bite of female sandflies that have previously fed on an infected reservoir host. There are two basic clinical presentations: visceral leishmaniasis (VL), or “kala-azar”, is the most severe and is fatal in almost all cases if left untreated; cutaneous leishmaniasis (CL) is associated with a strong tendency towards spontaneous resolution but causes important social and psychological stigma.

Leishmaniasis is prevalent in 88 countries, and there are an estimated 2 million new cases per year, of which 500 000 are VL and 1 500 000 are CL. The disease burden is calculated at 2 357 000 disability-adjusted life years, a significant ranking among communicable diseases.

As a neglected tropical disease, leishmaniasis shares the characteristics of a typical poverty-related disease: it is not recognized politically, it is not visible in proportion to its burden, there is no global strategy for its control, and updated information is missing for almost all areas where the disease occurs.

According to the transmission cycle, VL can be anthroponotic or zoonotic. Anthroponotic VL is caused by *Leishmania donovani* in a clustered transmission, and causes in the Indian subcontinent alone around 300 000 cases yearly, representing an estimated 70% of the total burden of VL. Although it is responsive to treatment, a varying proportion of cases may evolve into a cutaneous form known as post-kala-azar dermal leishmaniasis (PKDL), requiring a lengthy and costly drug regimen. The role of VL in the propagation of poverty is important. Treatment is expensive and therefore either unaffordable for patients or involves a loss of valuable assets.

India and Bangladesh are among the most severely affected countries in the world. In Nepal, the incidence of VL is somewhat lower. In 2005, a memorandum of understanding (MoU) was signed between Bangladesh, India and Nepal to eliminate VL by 2015, with elimination defined as a reduction of the incidence to less than one in 10 000 of the population. However, presently, precise official figures on the numbers of cases in the region are not available.

Obtaining updated epidemiological information is essential for developing future strategies for the elimination programme. The informal consultation on epidemiological information on the disease burden due to kala-azar in Bangladesh, India and Nepal, held from 8 to 10 March 2011 in Paro, Bhutan, focused on updating epidemiological data in order to fill an important gap in knowledge of the disease and to calculate the burden of leishmaniasis. It allowed for a better understanding of the epidemiology of leishmaniasis in the South-East Asia (SEA) Region and contributed to the formulation of recommendations for a successful execution of the elimination programme. In Bhutan, Sri Lanka and Thailand leishmaniasis is a newly emerging disease, and therefore these countries joined the meeting. The meeting was jointly organized by the Leishmaniasis Control Programme of the World Health Organization's (WHO) Department of Control of Neglected Tropical Diseases (Integrated Disease Management) and the WHO Regional Office for South-East Asia (SEARO), with the support of the WHO Country Office in Bhutan.

## **2. Proceedings of the meeting**

### **2.1 Opening session**

Dr Nani Nair, WHO Representative in Bhutan, welcomed participants. She expressed hope that in the future, leishmaniasis would lose its status as a neglected disease, and that the countries that signed up for the elimination programme would soon reach their set targets. She highlighted the importance of sharing experiences, especially for Bhutan, Thailand and Sri Lanka, where leishmaniasis is a newly emerging disease. Regarding Bhutan, she remarked on the success that Bhutan has achieved in controlling malaria with insecticide residual spraying (IRS) and insecticide-treated nets (ITNs) and hoped that this experience could be useful for the control of leishmaniasis. Bhutan, with a very good health system (nowhere do patients live further than three hours' walk from the nearest health facility) and an extremely committed government, will join in the renewal of the MoU regarding the elimination plan and serve as a model for reaching the elimination goal by 2015.

Dr Jorge Alvar, Head of the Leishmaniasis Control Programme, on behalf of Dr Lorenzo Savioli, Director of the WHO Department of Control of Neglected Tropical Diseases, expressed his gratitude to the Regional

Office and the Country Office in Bhutan for organizing this important meeting. More than other neglected tropical diseases, leishmaniasis lacks the attention of decision-makers. Regarding the construction of a political framework, in 2007 the Sixtieth World Health Assembly approved Resolution WHA60.13 to elaborate strategic plans and implement measures to prevent and eventually eliminate some forms of leishmaniasis. This political umbrella serves as the framework for highlighting the importance of leishmaniasis by governments, donors and organizations.

In order to determine the total burden of morbidity and mortality of each form of the disease together with its trend over time, and for awareness-raising and advocacy purposes, old estimates have to be set aside and replaced by reliable reporting systems. The systems needed for this purpose are weak or non-existent and therefore contribute to the lack of a suitable political framework.

In response to the need to improve the quality of information, determine the scale of the problem and undertake the required advocacy, the WHO Leishmaniasis Control Programme is conducting a number of regional meetings that will be complemented by the structuring of regional strategies. Updated epidemiological information will constitute the core of the "Country Profiles", soon to be published, which will serve as the basis for large-scale advocacy.

To consolidate the Global Strategy for Leishmaniasis, an Expert Committee met in March 2010 and an updated Technical Report Series (TRS 949) was published in December 2010. A Global Programme will be designed and eventually endorsed by politicians and donors.

## **2.2 Objectives**

The objectives of the meeting were:

- (1) to update information on the impact of leishmaniasis in each country and review the status of activities and existing problems in the Elimination Programme;
- (2) to make new estimates of the burden of leishmaniasis and understand the denominator of the population at risk;

- (3) to form a working group that can follow up on the recommendations of this meeting with a final goal of supporting the Regional Technical Advisory Group (RTAG) with information and advice.

## **2.3 Election of Chairperson and Rapporteur**

Professor N.K. Ganguly was elected as Chairperson and Dr M. den Boer as Rapporteur.

## **2.4 Session 1: Overview**

The presentations in this session covered various aspects relevant to the Elimination Programme, ranging from its objectives, targets and strategies (Dr Sujit Bhattacharya) to indicators of VL (Dr Marleen Boelaert), PKDL (Dr Philippe Desjeux), the role of asymptomatic carriers (Dr Caryn Bern) and HIV–*Leishmania* co-infection (Dr Sujit Bhattacharya). The presentations were followed by discussions and provided an opportunity to share experiences related to various disease control components.

### ***Kala-azar elimination in Bangladesh, India and Nepal***

*Dr Sujit Bhattacharya*

Visceral leishmaniasis is associated with poverty, marginalization and inequality and therefore its elimination is highly relevant to accomplishing the first Millennium Development Goal, the eradication of extreme poverty and hunger. Elimination of VL will foster economic growth in the area and region.

Elimination of VL was considered a realistic possibility in the SEA Region due to several factors such as its uniquely anthroponotic transmission, its confinement to limited areas, the available tools and a strong political commitment. The MoU regarding elimination now needs to be renewed and attempts will be made to secure a similar political commitment.

The objectives of the elimination plan included reducing the incidence and case-fatality rate of VL, reducing PKDL and preventing the

emergence of VL co-infections. Strategies to reach these objectives are capacity-building and effective surveillance, early case-finding and treatment, vector control via ITNs, IRS and vector surveillance, operational research into implementation of new drugs, validation of diagnostics and ways to reach patients, social mobilization and building partnerships such as India's with the World Bank and Bangladesh's with the Japan International Cooperation Agency. An important new development is that liposomal amphotericin B (L-AMB) was shown to be >95% effective in a single 10 mg/kg dose in Indian VL, and the RTAG in 2009 and the Expert Committee (TRS 949) in 2010 recommended this as the first line for the elimination programme.

The target of the elimination plan is to reduce the annual incidence of VL to <1/10 000 at sub-district level by 2015. How the population at risk should be defined remains open for discussion.

### ***Indicators of visceral leishmaniasis***

*Dr Marleen Boelaert*

In order to measure the success of the elimination programme, indicators need to be defined that, when regularly measured, will provide information on whether it is on track to reach its goal. Indicators for surveillance (collecting, analysing, and interpreting data about disease incidence), monitoring (measuring the implementation of a range of activities conducted by a programme) and evaluation (measuring the extent to which the programme reached its objectives) are needed. Surveillance needs strengthening; in India under reporting is common, the private sector is extensively used and PKDL is not part of reporting systems. However, a basic surveillance system exists on which the comprehensive surveillance system should be built upon. Indicators for monitoring and evaluation of the elimination plan were developed and approved by RTAG in 2009 and are published on the WHO/Special Programme for Research and Training in Tropical Diseases (TDR) website. Key indicators are detection rate, treatment completion rate and coverage rate of vector control. However, initial cure rates should also be monitored, while final cure rates (at six-month follow-up), treatment failure rates, loss to follow-up and mortality can be monitored at sentinel sites. Evaluation is the episodic assessment of the change in targeted results that can be attributed to the programme or project/project intervention. An example is a recently published cross-

sectional survey of 150 patients in Muzaffarpur district, India, where health-care-seeking behaviour for VL, effectiveness of routine VL treatment at primary health centre (PHC) level and cost of diagnosis and treatment to patient were measured. An important outcome was that 48% of patients received sodium stibogluconate (SSG) because the supply of miltefosine was irregular. A good question is how results of such evaluations should be acted upon. The certification of the elimination of VL needs to be better defined, including the definition of a disease-free period and the area-unit of analysis. Certification is not reliable when not based on well-functioning surveillance systems.

Discussions included the difficulty of phasing out SSG in India, where it is still commonly used. Stocks of SSG in-country need to be dealt with. It was also acknowledged that the 2015 elimination target was never clearly defined in terms of the disease-free period and the area-unit of analysis and that this needs further work. For Nepal, districts are useful as a denominator, and the elimination target (<1/10 000 population) has already been reached. For Bangladesh it is less clear what should be defined as the population at risk as VL is very focal and moves from village to village. The danger of reaching the elimination target is that it may simply be the downside of the epidemic curve and that support for the programme will not be continued. In India, VL comes back every 15 years. A long consolidation phase (5-10 years or longer) is needed in line with elimination programmes for other diseases (smallpox, malaria, onchocerciasis, filariasis). Another aspect of the elimination plan that needs further defining is how to implement vector control (IRS and ITNs).

### ***Post-kala-azar dermal leishmaniasis (PKDL)***

*Dr Philippe Desjeux*

Post-kala-azar dermal leishmaniasis develops after a clinical episode of VL, usually via hypopigmented macules to papules and eventually to nodules that can be very severe and disfiguring. Its incidence is largely unknown and estimates are mostly based on surveys. PKDL can also occur without previous VL (this has been reported in Bangladesh, India and Nepal). The incidence of PKDL in Bangladesh has increased significantly after a peak of VL cases in 2002 (2002: 1/10 000 and 2007: 21/10 000), and PKDL was reported to occur in 10% of cases of VL. In India data on PKDL are very limited: it is thought to occur in 5%-10% of cases of VL, and a decline was

reported after the introduction of amphotericin B and miltefosine in the programme, although prospective clinical trials with long follow-up of treated kala-azar cases are needed to verify this. In Nepal 50 PKDL cases occurred between 1998 and 2005. Diagnosis of PKDL is difficult and most reliably done by polymerase chain reaction (PCR) of blood or skin slits, but this is operationally not feasible. A small percentage of PKDL cases self-cures; in most cases treatment regimens are needed. In use are long courses of antimonials, miltefosine and amphotericin B, but evidence for their efficacy is missing or weak. Good alternatives might be offered by L-AMB and/or immunotherapy and combination therapy, but these still need validation. PKDL was shown to infect sandflies and initiate an outbreak of VL in India and is therefore considered an interepidemic reservoir of parasites. It is therefore an important challenge for elimination. Long-term follow up of VL patients, early detection and treatment of PKDL, distribution of ITNs, operational research and greater awareness of PKDL will all be needed to increase the feasibility of elimination.

Discussion included the difficulty of determining PKDL cure, how long follow-up should be after cure of VL, the lack of clinical trials for PKDL and the need to better determine infectivity of PKDL via xenodiagnosis.

### ***Asymptomatic carriers***

*Dr Caryn Bern*

Asymptomatic leishmanial infections are much more common than disease (6:1 to 50:1) but are difficult to define. Positive PCR, antigen and leishmaniasis skin test (LST) results appear and disappear at different moments in each stage of infection, and positivity varies with the method used (rK39 ELISA and rK39 dipsticks are not always congruent) and the antigen used. LST antigen is not produced under good manufacturing practice and may lack standardization. Risk factors for asymptomatic infection are therefore difficult to determine and interpret. LST positivity increases with age and proximity to VL patients and direct agglutination test positivity with proximity to ponds, family size, age >14, livestock ownership, male sex and house dampness. In a study of a highly endemic village in Bangladesh the following findings were of interest: 48% had no evidence of infection via serology or LST; a positive LST was strongly protective for VL; and being in the same household as a previous case, not always using bed nets and each 10-year increase in age were strongly

significant risk factors for VL. These were less significant for asymptomatic infection measured by ELISA. For asymptomatic infection measured by LST, being in the same household as, or being within 50 m of, a previous case and each 10-year increase in age were significant risk factors. Seroconversion to disease rate was 6.4:1. Zinc levels were lower in asymptomatics who later developed VL compared with those who did not. Risk factors for progression to VL were being in the same household as a previous case and each 10-year increase in age, whereas regular meat consumption seemed protective.

Discussion focused on defining asymptomatic infections. Of relevance are those that are infectious to sandflies, but there are no data apart from data generated on asymptomatic dogs that showed that they became highly infectious shortly before developing VL symptoms and a low CD4 count. Presymptomatic infections may therefore be more relevant than asymptomatic ones. A better definition of asymptomatic infection is thus needed, perhaps via CD4 counts. Better tools for diagnosis are also needed. It was suggested that studies on asymptomatic infections should be carried out.

### ***HIV–Leishmania coinfection***

*Dr Sujit Bhattacharya*

HIV–*Leishmania* coinfection is reported from 35 countries and is increasing in developing countries, with at present 8% of VL cases HIV-coinfected in Sudan and 35% in Ethiopia. Both infections exacerbate each other: VL progresses faster in T-cell-deficient patients, and it itself induces intracellular HIV replication. Diagnosis is problematic as typical VL symptoms may not be present and serological means of diagnosis such as rK39 ICTs may have diminished sensitivity. Treatment for VL is both less effective in coinfecting patients (especially in those not receiving antiretrovirals) and more toxic, especially so in the case of antimonials. Secondary prophylaxis reduces the number of relapses, but evidence is scanty. Coinfecting patients with often high parasitaemia, atypical clinical manifestations and poor access to care form an increased human reservoir that is difficult to control and may pose a serious threat to the elimination programme. Coinfection in Nepal is rare; in 2009-2010 only two patients were reported (1%). In India a coinfection rate of 1.4% was reported in Muzaffarpur. In Bihar the incidence of HIV is rising and coinfecting cases are increasingly reported among migrant

workers who have spent time in India's big cities. Not only HIV–VL coinfection but equally problematic TB–VL coinfections are seen in both Nepal and India.

### ***Surveillance in the control of visceral leishmaniasis***

*Dr Daniel Argaw*

Surveillance of VL is complicated as it is a clustering and focalized disease which occurs in remote areas with poor infrastructure and weak health-system capacity. It is often not a priority for governments. Good surveillance will create a better understanding of burden and epidemiology and be essential for advocacy on national and international levels. It will also enable monitoring and evaluation of the impact of control interventions, improve evidence-based planning and resource allocation and make it possible to observe changes in the trend of the disease. Notification of VL should be mandatory.

Surveillance for VL can be based on passive or active case detection. Passive case detection results in an underestimate of the incidence of VL, but the data can be useful for documenting trends in the burden of leishmaniasis. Active case detection can include a house-to-house search, the camp approach or the index case approach and is cost-effective in areas where disease incidence is high, people's awareness about the disease is poor and health services (and thus passive case detection) are weak. *Leishmania*–HIV coinfection surveillance should be in place in all areas where HIV and VL are coendemic and particularly where HIV prevalence is high.

For the system to function as an early warning system for outbreaks, reporting, confirmation, decision-making and response must be rapid. In epidemic-prone areas, frequent reporting (e.g. weekly) is essential for this reason. In more stable endemic areas, where the aim is to supply information to the control programme, reporting can be less frequent. A national surveillance system should therefore implement two-speed reporting mechanisms.

## 2.5 Session 2: Country presentations

### *Disease burden of visceral leishmaniasis elimination*

In this session, data on disease burden were presented in respect of Bangladesh, India and Nepal.

#### **Bangladesh**

*Dr Mahmudur Rahman, Dr Kazi Jamil and Dr A. Mannan Bangali*

After the massive DDT spraying campaign in the malaria elimination programme of the 1960s and 1970s, VL outbreaks resurged in the 1980s, after PKDL was reported again in 1977. Between 1994 and 2005 VL was reported from 33 districts, with the highest incidence in Mymensingh (6.5/10 000 population) and Pabna (4.2/10 000 population). The cumulative number of cases was 81 628, with 100 deaths. Between 1999 and 2009, 23 districts consistently reported VL, in 10 of which VL represented more than 10% of the total of reported cases. In 2006 there was a peak in the reported number of cases (9379) and deaths (23); since then, case numbers have remained steady at around 5000 yearly and reported deaths have declined to just one in 2010. The data seemed to show that there was a trend of decline in the VL burden, but this did not prove to be consistent.

Mymensingh was by far the most seriously affected district with 55% of reported disease being VL. In the last five years, VL emerged for the first time in three districts, and in five districts it stopped being reported. Although in 2008 VL was reported from 102 *upazilas*, the number of *upazilas* with a burden of more than 1/10 000 population (making them eligible for the elimination programme) was 13. However, reported cases are based on passive surveillance. The estimated incidence of VL according to recent studies is much higher than the reported incidence: 15.6/1000 person-years in Fulbaria, 27/10 000 population in Godagari and Rajshahi and 11/10 000 population in Mymensingh. The estimated incidence of PKDL is 6.2/10 000 population in Kanthal, Trishal and Mymensingh, 6.2/10 000 population in Mymensingh and 85 per 10 000 person-years and 46 per 10 000 person-years in 2004 and 2007, respectively, in Mymensingh. In Bangladesh there is at present no precise estimate of the burden of VL. A web-based surveillance system has recently been introduced but is not yet fully functional.

## **India**

*Dr Indranath Banerjee*

In India, the number of reported VL cases and deaths declined steadily after a peak in 2007 (44 533 cases and 18 deaths) until mid-2009, but since then numbers have gone up again. This is probably due to incentives for village health workers and patients for detection and treatment completion that were introduced at that point. Bihar has by far the largest VL burden (22 756 cases and 18 deaths in 2010), with Jharkand (4505 and 5 deaths) and West Bengal (1254 cases and 4 deaths) in second and third place. Between 2002 and 2008, over 70% of all VL cases in India occurred in Bihar. VL is declared endemic in four states of India (but not in all districts of these states) and occurs sporadically in another six states. The elimination programme is not yet fully functional: full coverage with miltefosine and rK39 ICTs has not yet been achieved. A World Bank evaluation found that in February 2011, miltefosine and ICTs were present in 8 out of 32 districts. At the time of the meeting, the districts covered are 15. Incentives are not consistently paid, standard operating procedures and guidelines are needed and not all districts are ready for implementation of the programme. The programme is not in “elimination mode”: there is a lack of urgency, advocacy, community awareness and human resources, and the private sector, which is used by most VL patients, is not yet engaged. There are important gaps in data collection. A reporting system including PKDL, death and treatment outcome is in place, but it is not uniformly used.

### **India: Disease burden of VL**

*Dr Pradeep Das*

Reported VL case numbers are based on passive case detection only and do not reflect the true incidence of the disease, but numerous surveys over the years have given an insight into the disease burden of VL in India. In 2006-2007 in a population screening (n=76 942) in all four endemic states 1.8% of the population were found to be a recent or past case of VL. In a survey in one district in Bihar (n=91 009) 227 cases, including 4 deaths, were identified. The estimated incidence was 10/10 000 population, with foci within the district with a much higher incidence (35/10 000 population). Among the cases, 45% occurred in those <18 years. Women appeared less likely than men to be diagnosed with VL but as likely to be suffering from

VL and more likely to die from it, suggesting their more limited access to health care. A later survey (n=50 000) in another district of Bihar, found a similar incidence. Recently, a large survey was started in two Bihar districts (n=544 000); this work is still continuing. A 2007 study to determine the rates of under reporting in Bihar found it to be 4.17, while in 2010, the survey revealed a PKDL rate of 0.5/1000 population.

## ***Nepal***

*Dr Nihal Singh*

So far 900 VL cases and one death were reported in 2010 (still incomplete). The coinfection rate is around 1% and PKDL is only rarely reported. VL is under reported; data are obtained by passive surveillance only and most cases live in very remote areas. VL is declared endemic in 12 districts, all bordering India. A large number of cases from these districts were non-residents. In 2003, case numbers peaked; since then a gradual decline has been observed, but it is not clear if this is part of the usual cyclical epidemiological pattern. At the same time, between 2007 and 2010, VL was notified from an increasing number of districts (14 in 2007 compared with 26 in 2010). The elimination programme was launched in 2006, including IRS and free care in hospitals with food provided, and transportation costs reimbursed to patients. A sharp decline in incidence in endemic districts has since been observed, and in 9 of 12 districts the elimination target (<1/10 000 population) has been reached. Challenges remain: the poorest people cannot easily be reached, there is a shortage of funding and cross-border cases (from India) form an increasing burden. Also, VL is not part of standard reporting systems outside the endemic districts and VL diagnosis and treatment cannot be obtained. The incidence of PKDL was estimated, based on screening of past VL cases treated by the B.P. Koirala Institute of Health Sciences, at 2.3% of VL cases. Onset was between 15 and 45 months after treatment. The main risk factor for developing PKDL was incomplete VL treatment with antimonials. Asymptomatic infection is widespread: in the Kalanet survey 9% of subjects were found to be infected and asymptomatic, and the infection to disease rate was 9:1.

Discussion focused on the importance of mapping, which is especially important with regard to many cross-border cases.

## 2.6 Session 3: New affected countries

In this session information was presented on Bhutan, Thailand and Sri Lanka.

### **Bhutan**

*Dr Thinley Yangzom, Dr Sujit Bhattacharya and Mr Rinzin Namgay*

In Bhutan VL has been reported sporadically since 1999. So far, 22 cases have been reported in total, scattered over 10 districts. All cases were indigenous, with no recent history of travel. No PKDL has been found. The most affected district is Mongar, with 10 reported cases. In 2010 active case finding was done with rK39 ICTs in Mongar around three reported cases, but no additional cases were found (of 7000 screened, 115 who had fever were tested). All cases were treated with antimonials. The *Leishmania* sp. is not known. Sandflies (including *P. argentipes*) were found to reside in houses (mud or stone walls and high humidity) and there are plans for IRS in selected villages in Mongar. Bhutan aims to join the elimination programme. Next steps are to develop a national strategy, treatment guidelines and training of health workers. The difficulty of applying IRS in remote villages in Bhutan was addressed. IRS in Nepal is not done in remote places.

### **Thailand**

*Ms Kobkan Kanjanopas*

Visceral leishmaniasis was first notified in 1960, and between then and 1987 six more cases were reported. CL was first seen in 1981 and 40 cases were reported up to 1997. All these cases were imported. After 1996 indigenous cases started to appear. Till 2010, 14 resident cases were reported from 10 provinces. Diagnosis was often late and under reporting is suspected due to a low awareness of leishmaniasis in the country. Four of these cases were confirmed to be coinfecting with HIV. Three cases died. One case (a five-year-old girl) did not respond to repeated treatment with amphotericin B and miltefosine. Different *Leishmania* spp. were found: *L. donovani*, *L. infantum* and a possible new species, *L. siamensis*, that appears non-detectable by rK39 ICTs. Sandfly surveys were done around

cases and 25 species were found, of which six were infected with *Leishmania* (including *P. argentipes*). On-the-spot control measures were introduced such as IRS, ITNs, insect repellent, clean-up around houses and awareness-raising among the population and health workers. Sporadic cases are expected to continue to occur, due to migration, tourism, and returning migrant workers. An extra risk factor is the current trend of HIV spreading to rural areas. The national programme has set an elimination target of <1/10 000 population before 2016, with a comprehensive approach involving surveillance, prevention, early diagnosis and treatment with miltefosine, control measures such as culling and IRS, and rehabilitation offered to cases, e.g. through counselling. Several comments were made including the fact that *L. siamensis* is not a species recognized by the Expert Committee. It was recommended that an IRS strategy be developed only after the vector is clarified and that culling of animals must only be done if they are proven reservoirs.

### **Sri Lanka**

*Dr Nadira Karunaweera*

In Sri Lanka, CL as well as VL is endemic. VL is very rare; since 2007 just three cases have been reported. The first local case of CL was seen in 1992. Since then it has spread rapidly, and since 2001, 2411 cases were reported in the dermatology unit of the National Hospital. The most affected age group was <20 years. Transmission seems to differ among regions; almost all patients were involved in outdoor behaviours in the North Central Region, while in the south, clusters of households have been affected, pointing to peridomestic/domestic transmission. In a survey in Padaviya/Welioya, Moneragala district and Mamadala in Ambalantota district, prevalences of CL of 2.4%, 0.5% and 3.5%, respectively, were found.

The causative parasite of CL is *L. donovani* zymodeme MON-37, closely related to zymodeme MON-2, the most common VL-causing zymodeme in India. The probable vector is *P. argentipes*. Dogs are a possible reservoir. Diagnosis is done via PCR/rK39/microscopy of skin samples. Among suspected CL cases, 60% were confirmed in this way. The formol gel test was negative in all CL cases. The type of lesions varied; papules, nodules and ulcers are seen, and sometimes mucosal involvement. Treatment is with cryotherapy or intralesional SSG. Leishmaniasis became a

notifiable disease in 2008 and an action plan for control of CL was agreed on in February 2009, including awareness-raising among clinicians and the general public, improvement of facilities and accessibility for laboratory diagnosis, better access to and availability of treatment, and further parasite, vector and host studies.

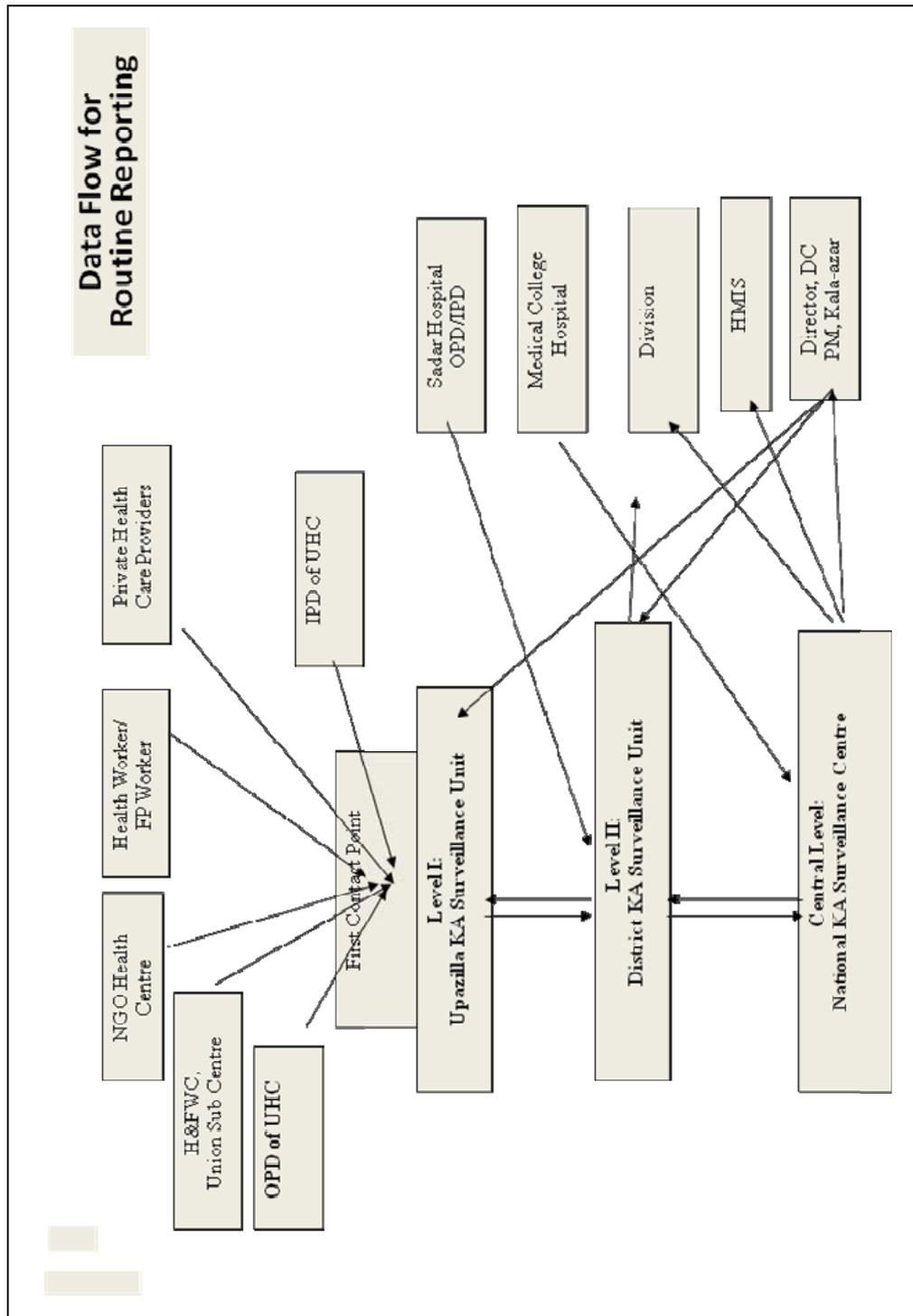
## **2.7 Session 4: Gaps – quality data collection (patient records), existing reporting systems and plan to improve disease surveillance**

This session focused on a major barrier for elimination: the lack of functioning surveillance systems for VL. Bangladesh, India and Nepal presented the reporting systems that are in place, identified weaknesses and proposed a way forward.

### ***Bangladesh***

*Dr Mahmudur Rahman, Dr Kazi Jamil and Dr A. Mannan Bangali*

The estimated number of VL cases in Bangladesh is 45 000, while annually 6000-9000 cases are detected and treated. All reporting of VL is based on passive case detection and is therefore not reflective of the true incidence. The reporting structure is shown in the following diagram.



In Bangladesh, level union and community clinic level suspected cases are identified and referred to the Upazila Health Complex (UHC) (460 in the country presently). At UHC level, diagnosis and treatment is initiated and complicated cases are referred to district hospitals (64 in the country) or medical colleges. About 80% of UHCs report electronically. Reports are compiled at district level and thereafter sent to civil surgeons' offices on a monthly basis. Data collection from medical colleges and referral hospitals is incomplete; these are expected to transmit data monthly, but this does not regularly happen. Despite the existing reporting system, there are multiple gaps, and capacity-building (human resources, new technology) is needed. There is a need to intensify active case-finding, to actively involve referral hospitals, nongovernmental organizations (NGOs) and the private sector, and to start mapping of cases.

## ***India***

*Dr Indranath Banerjee*

Reporting of VL falls under the National Vector Borne Disease Control Programme (NVBDCP), and national data are compiled and published by NVBDCP. The programme is centrally sponsored, but resources are distributed among the states, which are implementers of the programme. For this reason, official reporting is up to the state level; reporting from the state to national level is infrequent. Primary health care centres (where most diagnosis and treatment of VL takes place) report monthly to the district level, and districts report to states. At district and state level, there is no dedicated person for VL and there is no feedback of data to PHC centres. Medical college data are often not included in official reporting systems. Analysis of VL data is mostly done by the Rajendra Memorial Research Institute of Medical Sciences (RMRIMS).

In addition to this existing structure there is detection and reporting of VL within the National Rural Health Mission (NRHM). Via this system accredited social health activists (ASHAs) receive incentives for detecting and referring fever cases to primary health centres. This system seems to work well. In addition, auxillary nurse midwives detect and refer cases of fever, but this is less reliable. The NRHM reports are assembled at state and central level.

Another parallel reporting system of VL is the World Bank-funded integrated disease surveillance programme. It involves electronic reporting to district level, e.g. regarding outbreaks, but it is not implemented everywhere.

The consequence of these parallel reporting systems is that three data sets for VL exist that are not integrated and combined for analysis. A major gap in reporting is caused by the fact that most patients (~70%) use the private sector. Cases are either not reported or private doctors refer patients to the public sector for treatment; this then causes duplicate reporting. Another gap is that reports of death, treatment outcome and six-month follow-up data are incomplete or nonexistent, and there is no pharmacovigilance programme in place (a remark was made that ASHAs could be used to collect six-month follow-up data).

## ***Nepal***

*Dr Saroj Prasad Rajendra*

At PHC level, basic patient data are collected (handwritten), including diagnosis and treatment outcome, and reported as below.

Mapping of cases is done manually. District health offices have a dedicated person for VL. There is no analysis at central level. Visceral leishmaniasis is underreported and the following gaps exist in the reporting system: active case finding is not implemented, no reporting of PKDL, no vector surveillance, no data on completion of treatment and final cure rate, no good documentation of miltefosine resistance, a lack of awareness among health workers and no funds for capacity-building due to an absence of public-private partnerships. Another problem is that supplies and health workers trained for diagnosis and treatment of VL are only present in 12 districts of Nepal. In 2011 there are plans to implement active case-finding, nutritional supplementation, an early warning and reporting system and pharmacovigilance, vector surveillance and pesticide resistance, and distribution of ITNs. IRS policy will be updated, logistical gaps identified and financial partners sought.

### **General discussion**

A lack of accurate figures on the burden of VL is a major problem in all three countries. Active case-finding is currently done in only three or four districts per country and should be expanded. Regional workshops for reporting, data-cleaning and analysis could be very useful. Periodical central and regional collection and analysis of data would be helpful; this is not currently in place. Software for analysis of data needs to be developed. The quality of data also needs attention: How was the diagnosis made? How were data collected? The absence of six-month follow-up data is a problem in all three countries. Financial incentives for patients are useful: in India this was shown to bring back >90% of patients after three and six months. A lack of capacity of trained personnel is a major stumbling block. Incentives for training of health workers and for staying on in the appropriate positions would be helpful.

### **Round table: Role of research institutions**

In this session the following questions were addressed:

- Are research results used in the elimination programme?
- Which research results should be used?
- What can your institute contribute to the attack phase of the elimination programme?

The contributions of research institutes to the elimination programme are as follows:

### **India**

#### *RMRIMS (Dr Pradeep Das)*

- Monitoring of IRS, vector and insecticide assessments and monthly density surveillance
- Pharmacovigilance for miltefosine
- Training of VL technical support consultants to the VBDCP
- rK39 ICT quality control

- Monitoring of resistance to drugs and insecticides
- Promotion of use of geographic information system (GIS) in vector assessment and control.

*Institute of Medical Sciences (Dr Shyam Sundar)*

- Description of SSG resistance
- rK39 ICT evaluation
- Clinical trials of miltefosine, L-AMB and combination therapy
- rK16 evaluation
- ITN effectiveness evaluation
- Determining ratio asymptomatic to disease

***Nepal***

*Department of Internal Medicine (Dr Suman Rijal)*

- Resistance to SSG
- Miltefosine phase 4 study
- Validation of diagnostic tools
- A variety of operational research
- Future: validation of ICT in full blood, pharmacovigilance, miltefosine, parasite resistance

***Bangladesh***

*International Centre for Diarrhoeal Disease Research, Bangladesh  
(Dr Kazi Jamil)*

- SSG resistance documentation
- Development of national guidelines and strategic plan
- Quality control for rK39 ICT
- Development of improved surveillance system

- Development of VL recording forms
- Sentinel surveillance w six-month follow-up of patients
- Development of pharmacovigilance tools (not yet implemented)

*Institute of Epidemiology (Dr Mahmudur Rahman)*

- Miltefosine phase 4 study and L-AMB dose finding study
- Development of components of surveillance system
- Outbreak investigation and response
- Training
- Participation in steering committee elimination programme
- Quality control for Ministry of Health (MoH) purchases
- Various forms of technical support for programme

***International institutions***

*Institute of Tropical Medicine (Dr Marleen Boelaert)*

Bilateral European Union (EU)–India VL research programme resulted so far in the Kalanet and Kaladrug studies, and via Leishrisk (consortium funded by EU) vaccine and diagnostic research.

*Institute for OneWorld Health (Dr Philippe Desjeux)*

- Health-seeking behaviour
- Economic impact of VL
- Survey of incidence
- Paromomycin phase 3 and 4 trials
- Paromomycin implementation research
- Paromomycin combinations implementation research

**WHO and SEARO** have supported the elimination programme with the organization of RTAG and programme managers' meetings, grants for

research, development of guidelines (TRS 949) and tools for advocacy (the country profiles) and should continue with advocacy and capacity-building, financial support for research and training, and technical support in case of outbreaks.

The following gaps in research were identified:

The Region has contributed significantly in terms of clinical drug trials and validation of diagnostics, but there are important gaps in vector control-related research. There is a lack of research data on the effectiveness and application of IRS and ITNs, resulting in a lack of a clear vector control strategy, and there are few specialized entomologists in the Region. Furthermore, coordination between research institutes and the control programmes should be improved. The programmes should interface with the research institutes, influence and coordinate research agendas and integrate results in the programme's strategy. Sustainable research partnerships that include funding are needed.

Further research gaps identified were:

- Improved diagnostic tests
- Indian generic equivalent of AmBisome
- Strong operational research, especially regarding implementation of L-AMB single-dose and combination therapy
- Performance of rK39 in blood compared to serum
- Mapping of relapse and resistant parasites
- The role of PKDL and asymptomatic infection in transmission, and in HIV–VL coinfection

In the countries where leishmaniasis is a newly emerging disease the following research-related needs for the elimination programme were identified:

*Bhutan (Dr Thinley Yangzom)*

- Development of strategic plan and guidelines
- Identification of *Leishmania* spp., vector and transmission areas

*Sri Lanka (Dr Nadira Karunaweera)*

- Development of case definition for official notification
- Parasite typing (in VL and CL)
- Vector behaviour and insecticide susceptibility
- Identify reservoir hosts
- Capacity-building in diagnosis and entomology
- Improved surveillance
- Assessment of true burden
- Continued collaboration with European research institutes and support of South-South collaboration
- Establishment of national programme (already approved by MoH).

*Thailand (Ms Kobkan Kanjanopas)*

- Improved surveillance and capacity-building
- Identification of vector and reservoir
- Coinfection helminthic infections (filariasis) and VL.

## **2.8 Session 5: The roadmap**

*Consensus on number of annual cases and deaths in three countries (incidence, prevalence, mortality, PKDL, asymptomatics, HIV–Leishmania coinfection)*

In all three countries the reported incidence of VL does not reflect the true incidence, and the number of deaths is thought to be vastly under reported.

The reported numbers are mostly based on passive case detection, and are therefore an underestimate of the true incidence. Another major bias is that the private sector does not report cases, which is especially a problem for India. For better estimations of incidence, numbers based on short-term active case finding in selected sites are often used, but these estimations must not be thought of as the true incidence as they cannot be

extrapolated to other areas and do not reflect changes in time. The problems in each country are highlighted below, and possible solutions are given.

### ***Bangladesh***

Reporting by the public sector is incomplete: a web-based integrated surveillance system is in place but not yet fully functional. In 2009, 4200 cases were reported, but the true incidence was estimated at 40 000 cases while an earlier TDR study estimated 140 000 cases (Joshi et al, 2008). A recent study showed that the case fatality rate of VL was 10% (Dr Caryn Bern, personal communication). Very few patients resort to the private sector as VL drugs are not available outside the public sector.

Other problems (P) causing incomplete reporting and solutions (S) proposed were:

P: There is insufficient data to determine an estimate of the extent of under reporting.

S: All organizations, NGOs and research institutes involved should form a task force that meets regularly, shares figures and comes to a consensus on the under reporting factor. International presence in this task force is desirable.

P: No reporting from medical colleges.

S: Appoint someone who is on site and responsible for reporting.

P: Double reporting: migrants, traders, etc report at more than one UHC.

S: Identification through ID cards and correction via updated population figures.

P: Only one sentinel site in low-prevalence area where numbers of deaths are measured.

S: More active surveillance sites are needed with long-term follow-up of patients.

P: No PKDL reporting.

S: The reporting system needs to be modified and dermatologists should become involved.

### **India**

India has a strong surveillance network, but data on VL are reported from three different sources and are hard to reconcile. In 2009, 31 000 cases were reported. Indian studies showed under reporting factors of 8.13 in 2006, 4.2 in 2001-2003 and around 3 in 2006-2007 (Das, 2010). Currently the reported number of cases is thought to represent a three- to five-fold underestimation of the true number of cases. In Bihar alone there are (roughly estimated) 100 000 cases. Deaths are likely to be under reported. However, in the recent Kalanet household survey (n=20 000, followed for 2.5 years) of 291 deaths, none were due to VL.

Other problems and proposed solutions:

P: About 70% of patients seek private care and remain unreported.

S: Give incentives to private practitioners for reporting VL; use the connections between them and village health workers. Make free diagnosis and treatment available in all PHCs in endemic areas so that the private sector will be used to a lesser extent.

P: States where VL is endemic are underserved in terms of trained manpower and many VL cases remain undiagnosed.

S: Systematic reporting of fever is already in place. In the malaria programme all fever cases are tested with rapid diagnostic tests at village level; rK39 RDTs could be used in the same way. All fever cases would then be tested for VL. At PHCs a further check (spleen) can be done to verify cases.

P: Follow-up data are only collected in sentinel surveillance sites and not in the regular programme.

S: Financial incentives are needed so that patients are more likely to report back after 6 and 12 months..

- P: How can control activities be designed in a very large area (Bihar) where VL appears to be very focal?
- S: Perform active case-finding (with mobile teams if needed) around “hotspots” (outbreaks or new cases) and set up sentinel surveillance sites in high-risk areas.

### ***Nepal***

As incentives and free treatment have been provided for VL patients for the past three years in the context of the elimination programme, under reporting is relatively low. The under reporting factor is estimated at 1.5. In 2010, 900 cases were reported. The private sector is not used for VL treatment as drugs are not available outside the public sector. Factors that cause under reporting and proposed solutions are:

- P: A significant number of patients live in very remote areas, are very poor and lack the funds to travel.
- S: A research team will explore these remote areas.
- P: Outside the official endemic areas, VL diagnosis and treatment are not provided. Patients in these areas have no access to treatment.
- S: Centres that provide diagnosis and treatment in districts with sporadic cases are needed, and the VL reporting system must be put in place in these districts.

## **3. Recommendations**

A group representing all countries and technical expertise present in the meeting formulated the following recommendations for the strengthening of surveillance systems.

Define the population at risk:

- Each country should work out a better estimate of the population at risk for VL for each operational unit (district/subdistrict/*upazila*, and rural vs. urban) before the end of 2011.

- This can be done through the existing networks (ASHA's in India, community health volunteers in Nepal, and in Bangladesh). Existing supervisors such as kala-azar technical supervisors, could be involved.

Work with a key set of indicators:

- Each country programme should report on a regular basis the following indicators per operational unit (district/subdistrict/*upazila*):
  - (1) Case detection rate (per 10 000 per year)
  - (2) Treatment completion rate
  - (3) Initial cure rate (end of treatment)
  - (4) Final cure rate at six months
  - (5) Integrated vector management (IVM) coverage rate (percentage of households at risk protected by vector control),

Use standardized case definitions:

- All facilities should use the standardized case definitions endorsed by RTAG
- Reporting of deaths should be strengthened
- Quality control (spot check) of the proper use of these case definitions should be performed during supervision of reporting units.

Strengthen reporting systems:

- An electronic integrated reporting system must be put in place. It should be embedded in the regular surveillance system while allowing the extraction of specific information on VL.
- In regions where multiple parallel reporting systems exist, identify the most reliable channel and create synergies.

Strengthen capacity for analysis and feedback at all levels:

- Train district/sub-district/*upazila* managers on analysis of clinical information as well as vector control data by conducting country-level workshops.
- Ensure that data are analysed at country level and used for course correction in the programme.
- Examine the role of GIS-based decision support systems.
- Create a dedicated unit at SEARO to collate the data at the Regional level. WHO country focal points could play a role. The unit could produce a regular bulletin on progress towards elimination.
- Organize regular data-sharing and analysis for the local managers dealing with cross-border issues.
- Provide RTAG with the country programme information in a structured way (based on a template: case detection rates, cure rates, IVM coverage rate per endemic district).

Ensure comprehensive reporting of cases in the surveillance system:

- Involve the private sector in reporting through mechanisms such as:
  - alliance with medical associations
  - alliance with civil society organizations
  - incentives for case detection and reporting
- Increase access to free diagnostics and drugs the public sector to increase utilization.
- Keep track of the changes in under reporting ratio.

Set up vector surveillance:

- Apart from monitoring the routine vector operations, dedicated vector surveillance needs to be organized. This includes monitoring of vector density and infection rates in sentinel sites.

Audit the surveillance system:

- Organize periodic reviews of the surveillance and monitoring system. Evaluate the system for completeness, timeliness, sensitivity/specificity.
- Examine whether the information has led to action.

Certification of elimination:

- Sentinel surveillance sites, assessment of underreporting ratios and outbreak investigation should be set up by the programmes to track progress towards elimination.
- Elimination at country level should be certified by an independent process.
- An international committee with representation from the endemic countries and under the stewardship of WHO should be constituted to assess, certify and declare elimination in the countries and Region.

#### **4. An important final consideration**

The political message must be clear: after the attack phase a consolidation phase will start and minimal control activities and sentinel surveillance sites must remain in place for an indeterminate period of time, even after elimination has been certified. WHO should help to disseminate this political message and provide guidance on what activities should be part of the consolidation phase. The criteria for elimination are still unclear and should be defined by RTAG; a task force should be formed urgently to provide technical guidance to RTAG.

## Annex 1

# Agenda

Registration

### Opening Session

Welcome

Opening Session

Objectives and expected outcome of the consultation

### Session I

#### Technical Session

Kala-azar Elimination Programme: Objectives, Target, Strategies

Indicators of Visceral Leishmaniasis

PKDL (Post Kala-azar Dermal Leishmaniasis)

Asymptomatic Carriers

HIV-*Leishmania* co-infection

### Session II

#### Technical Session (Country Presentations)

##### Disease Burden of visceral leishmaniasis elimination

Bangladesh

India

Nepal

### Session III

#### (Country Presentations Contd....)

Bhutan

Thailand

Sri Lanka

**Session IV**                    **Gaps: Quality data collection (patient records), existing reporting system and plan to improve disease surveillance**

Bangladesh

India

Nepal

Round table: role of research institutions (Bangladesh: ICCRD, Inst. Epidemiology, IACIB; India: RMRI, IMS-Varanasi; Nepal: BPKI)

**Session V**                    **Technical Session**

Consensus on number of annual cases and deaths in three countries (incidence, prevalence, mortality, PKDL, asymptomatic, HIV-*Leishmania* co-infection).

Strengthening the surveillance system (regular reporting to WHO-SEARO)

- Possible use of data (resource mobilization, capacity building, etc.)
- Recommendations

Closing

## Annex 2

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The “Informal Consultation on Epidemiological Information on Disease Burden due to Kala-azar in Bangladesh, India and Nepal” was held from 8 to 10 March 2011 in Paro, Bhutan. It was jointly organized by the Leishmaniasis Control Programme of the World Health Organization’s Department of Control of Neglected Tropical Diseases (Integrated Disease Management) and the WHO Regional Office for South-East Asia (SEARO), with the support of the WHO Country Office in Bhutan.

Leishmaniasis is prevalent in 88 countries, and there are an estimated 2 000 000 new cases per year, of which 500 000 are cases of visceral leishmaniasis (VL). In the Indian subcontinent alone, around 300 000 cases occur yearly, which represents an estimated 70% of the total burden of VL. India and Bangladesh are among the most severely affected countries in the world. In Nepal, the incidence of VL is somewhat lower. In 2005, a memorandum of understanding (MoU) was signed between Bangladesh, India and Nepal to eliminate VL by 2015, with elimination defined as a reduction of the incidence to less than one in 10 000 of the population.



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