VISCERAL LEISHMANIASIS
CONTROL STRATEGIES AND EPIDEMIOLOGICAL SITUATION UPDATE
IN EAST AFRICA

REPORT OF A WHO BI-REGIONAL CONSULTATION
ADDIS ABABA, ETHIOPIA
9–11 MARCH 2015

World Health Organization
Visceral leishmaniasis: control strategies
and epidemiological situation update
in East Africa

Report of a WHO bi-regional consultation
Addis Ababa, Ethiopia
9–11 March 2015

I. World Health Organization.

ISBN 978 92 4 150965 7
Subject headings are available from WHO institutional repository
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1. **Background**

Visceral leishmaniasis (VL) is highly endemic in East Africa. Challenges to control of the disease include the remoteness of, and difficult access to, endemic areas, insecurity in some of those areas and the difficulties of transporting diagnostic tests and medicines for case management. At the initiative of the Leishmaniasis Control Programme, Innovative and Intensified Disease Management unit, WHO Department of Control of Neglected Tropical Diseases, and the WHO Regional Offices for Africa and the Eastern Mediterranean in collaboration with the Ministry of Health of Ethiopia, a meeting was held on 9–11 March 2015 in Addis Ababa, Ethiopia.

The opening remarks and welcoming address were delivered by Dr Pierre Mpele, WHO Representative in Ethiopia, and Dr Zufan Aberra, Senior Advisor, Federal Ministry of Health of Ethiopia as representative of the Ministry of Health of Ethiopia. Dr Daniel Argaw Dagne, Head, Leishmaniasis Control Programme, Innovative and Intensified Disease Management unit, WHO Department of Control of Neglected Tropical Diseases, explained the objectives of the meeting, which were:

- to discuss the progress and challenges for implementation of VL control strategies in East Africa in the context of the WHO roadmap on neglected tropical diseases;\(^1\)
- to review the status of implementation of the WHO AmBisome donation programme and assess needs for the coming years;
- to clarify the role and support of partners (VL-DFID consortium) regarding their contribution and specific engagement in VL prevention and control efforts in the subregion, for coordinated implementation of control interventions; and
- to update the epidemiological situation of VL and strategies for its prevention and control in the endemic countries in East Africa.

Dr Mpele urged endemic countries to invest more in neglected tropical diseases (NTDs) in order to integrate and accelerate control and elimination as outlined in WHO’s third global report.\(^2\) We must seize the momentum and commit to allocating adequate resources to alleviate suffering and prevent deaths from neglected tropical diseases. Only by eliminating such diseases can we create healthy and productive societies that will contribute to the development of our nations. He also reaffirmed WHO’s continued support to global and regional efforts to control and eliminate diseases such as leishmaniasis, and provision of technical assistance to national programmes in endemic countries.

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In her opening remarks Dr Aberra, representing the host country’s Ministry of Health, encouraged countries of the Region and subregion to engage in genuinely effective cooperation for a healthy nation. She stressed the significant impact of morbidity, mortality, loss of quality of life and economic development of their nations due to VL. The increasing numbers of cases of cutaneous and mucocutaneous forms of the disease also pose huge challenges for the availability of treatment options given the shortages of medicines and supplies and of trained human resources. Appreciating the strong support from WHO and other partners such as the UK Department for International Development (DFID), the Drugs for Neglected Diseases initiative (DNDi), Médecins Sans Frontières (MSF) and pharmaceutical companies Gilead and Sanofi, she highlighted the following major contributions:

- The increase in donated liposomal amphotericin B (AmBisome) from Gilead through WHO, from 5000 to 12 500 vials.
- The announcement of support from VL-DFID to East Africa through the KalaCORE Consortium, which will further strengthen regional control activities.
- The continued support of DNDi research activities in East Africa; two activities (in Gondar University Referral Hospital and Arbaminch Hospital) have helped the Federal Ministry of Health of Ethiopia to update the national guideline for prevention, control and treatment of leishmaniasis based on the evidence from a multi-centric clinical trial on shortening the duration of treatment and assuring the safety of patients from drug toxicity.
- The constant support from WHO to training and capacity-building of frontline health workers in prevention, control and treatment of VL.

After the technical and country presentations the participants were divided into two groups to discuss challenges, weaknesses and opportunities, and to propose concrete suggestions for improved collaboration in leishmaniasis control among countries of the WHO African and Eastern Mediterranean Regions. Having considered the epidemiological situation in those Regions and the outcomes of the working groups, the meeting declared some technical recommendations for consideration and implementation towards enhanced leishmaniasis control in both Regions in the future.

The rapporteurs of the meeting were Dr Mercè Herrero, Dr Mounir Lado and Dr Abate M. Beshah. Dr José Antonio Ruiz Postigo compiled the notes of the rapporteurs and wrote the meeting report.

Annex 1 contains the Agenda of the meeting and Annex 2 the List of participants.
1.1 Visceral leishmaniasis control: overview of global situation and perspectives

Daniel Argaw Dagne

The epidemiology of leishmaniasis is diverse and complex. VL is present in the Indian subcontinent, with Brazil and East Africa being highly endemic. More than 90% of new cases are reported from six countries: Bangladesh, Brazil, Ethiopia, India, South Sudan and Sudan. The number of new cases worldwide each year is currently estimated at 300,000. The South-East Asia Region is the only Region with a target for elimination of VL (kala-azar) as a public health problem (that is, < 1 case per 10,000 population per year at district or subdistrict level). This is due to the unique epidemiology of the disease, the availability of effective tools and the strong political commitment in the Region. The elimination programme has demonstrated a significant achievement in the Region by reducing the disease incidence trend and the case fatality rate.

Leishmaniasis in East Africa remains a major public health problem, with no signs of reduction in case trends. The situation is complicated by recurrent epidemics, a weak health system, lack of appropriate tools, malnutrition, and concomitant infections including coinfection with HIV and Leishmania. Coinfection is a serious concern. HIV infection increases the risk of developing VL, reduces the response to treatment and increases the rate of relapse; patients with coinfection also have high parasite loads. Coinfection has been reported in 35 countries, with most cases reported thus far from southern Europe, Brazil and Ethiopia. The incidence of coinfection has fallen dramatically in Europe since antiretroviral treatment for HIV was introduced. High incidence rates have been reported in Ethiopia (15–30%), Brazil (6.6%) and India (3–5%). WHO recommends a strategy of “provider-initiated counselling and testing” (PICT), surveillance in all coendemic areas and collaboration between the two programmes.

Significant challenges include: inconsistent performance of rapid diagnostic tests (RDTs) in different Regions; suboptimal efficacy of treatment with potentially toxic injectable medicines; lack of drug resistance monitoring; insufficient access to treatment; and lack of a test of cure.

There is a lack of timely updated epidemiological information, accurate disease trends, case management and disease distribution. In many countries leishmaniasis surveillance is either weak or absent.

The gap in knowledge includes the role of asymptomatic infections and post-kala-azar dermal leishmaniasis (PKDL) in transmitting VL. An innovative, evidence-based approach to vector control is needed particularly in East Africa. In several countries implementation of proven interventions is inadequate, programme management is weak and better planning is needed.

In 2014, WHO conducted an interactive online course on cutaneous leishmaniasis in collaboration with the Open University of Catalonia, Barcelona, for the African and Eastern Mediterranean Regions. The Organization has also developed a self-learning course for
leishmaniasis in the Region of the Americas; a self-learning online course on PKDL is in preparation.

Several opportunities, however, have recently appeared to improve leishmaniasis control. Three WHO Regions (Eastern Mediterranean, European and South-East Asia) have developed strategic frameworks and the WHO African Region has developed an NTD master plan. The Region of the Americas has prepared a regional guideline on leishmaniasis diagnosis and treatment. The WHO Technical Report Series published in 1990 was revised in 2010.\(^1\) The WHO roadmap on NTDs (2012–2020) sets targets for regional control and elimination. There is increased attention from the international community (donors, NGOs, signatories to the London declaration\(^2\)) and public–private partnerships with pharmaceutical companies (Gilead, Sanofi) that include donations of AmBisome.

### 1.2 Leishmaniasis in the WHO African Region vis-à-vis the NTD master plan

*Alexander Tiendrebeogo*

A Regional guide for preparing a master plan for NTDs was elaborated for countries of the WHO African Region in 2009–2011. A strategy for integration of preventive chemotherapy and case management of NTDs and guidelines were developed.

Countries received training on situation analysis and development of their NTD strategic agenda.

The NTD master plan has five strategic pillars: (i) strengthening coordination partnership and ownership; (ii) planning for results; (iii) scaling up access to interventions and service delivery capacities; (iv) enhancing NTD monitoring and evaluation; and (v) surveillance and research.

In 2012, 24 countries developed their NTD master plan. In 2014, 20 countries extended the plan period to 2016–2020. In 2015, 20 additional countries will extend the plan period up to 2020.

Significant challenges include the unknown burden and distribution of the disease. Cutaneous leishmaniasis (CL) is mainly managed in dermatology clinics, which is included under epidemic-prone diseases.

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1.3 Leishmaniasis in the WHO Eastern Mediterranean Region: strategy and targets
José Antonio Ruiz Postigo

Both CL and VL are endemic in the WHO Eastern Mediterranean Region. Three countries (Afghanistan, the Islamic Republic of Iran and the Syrian Arab Republic) account for 73% of the total number of CL cases in the Region. In the period 2001–2011, 100 000 cases of CL were reported annually. In 2012, 140 000 cases were reported. Underreporting is estimated at 3–4 times.

Anthroponotic VL is endemic in Somalia, South Sudan (currently a Member State of WHO’s African Region) and Sudan, where WHO has provided support for developing or updating the national guidelines on leishmaniasis, including tools for epidemiological surveillance, supplying health facilities with laboratory items and medicines, training national health personnel and implementing control field activities.

In 2014, WHO organized an interactive online course to disseminate the *WHO Manual for case management of cutaneous leishmaniasis in the WHO Eastern Mediterranean Region*. A total of 32 participants from five countries in the Eastern Mediterranean Region (Afghanistan, Morocco, the Syrian Arab Republic, Tunisia and Yemen) and two countries in the African Region (Algeria and Chad) attended the course, which was developed in collaboration with the Open University of Catalonia. The course lasted 3 months, with 12 hours of study per week.

The drop-out rate of 30% was considered acceptable for this type of long-distance training. The pros and cons of the online course are summarized below.

**Advantages**
- Lower cost (at least four times cheaper) than face-to-face trainings
- Fewer administrative procedures (no travel involved)
- Certificate recognized by the University-European Credit Transfer System
- Training of trainers (material can be reused or adapted)
- Compatible with daily work and family duties.

**Disadvantages**
- Requires Internet connection
- Demands computer skills
- Necessitates motivation.

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2. **Country presentations**

2.1 **Ethiopia**

*Oumer Shafi*

Anthroponotic VL in Ethiopia is mainly endemic in five out of nine regions, with 2000–4500 cases reported each year. The regions of Amhara and Tigray account for more than 85% of the cases.

The disease is caused by parasites of the *L. donovani* complex and transmitted by *Phlebotomus orientalis*, *P. martini* and *P. celiae* vectors. The disease has spread to new localities (Benishangul-Gumuz and Gambella).

There are currently 17 treatment sites in five regions (6 in Tigray, 5 in Amhara, 1 in Southern Nations, Nationalities, and Peoples’ Region, 3 in Oromia and 2 in Somali).

The surveillance system captures data on a monthly basis through the Health Management Information System. In one region, VL is part of the Integrated Disease Surveillance and Response network. There is, however, weak surveillance from hospitals.

The rate of coinfection with *Leishmania* and HIV was 7.4% in 2011, decreasing to 3% in 2014 (the HIV prevalence among adults at the national level is 1.2%).

The national guidelines were revised in 2013. The VL control strategy is mainly based on early diagnosis and treatment. Integrated vector management consists of distributing insecticide-treated nets and insecticide spraying within the malaria control programme. Health education is also done and an NTD pocket manual has been developed to facilitate this activity.

A pharmacovigilance system is in place and a pre-paid postal service is available to report adverse events. The reporting is, however, considered weak.

Significant challenges include: insufficient trained human resources; weak epidemiological surveillance with poor reporting; weak monitoring and evaluation; limited resources for outbreak investigation; inadequate medicine and diagnostic supplies (direct agglutination test not available), and nutritional supplements; increasing numbers of cutaneous and mucocutaneous cases diverting medicines from treatment of visceral disease; limited beds for inpatients; and insufficient health education in isolated groups at risk (migrants).

The major focus areas in 2015 are: supervision; training of health workers; case identification and treatment; strengthening surveillance; and properly quantifying and procuring medicines for the Ministry of Health to reconcile the gap of partners.
The discussion emphasized the importance of testing all VL cases for HIV. VL combination therapy has been endorsed by the Ministry of Health and was included in the 2013 guidelines as first-line treatment. The new combination therapy will be rolled out in 2015 in order to start by the next peak season of cases.

The National Task Force technical working group is coordinating academia, NGOs and government to tackle the entire programme and it is mandatory to work through it should any change need to be made to the national procedures.

New risk areas are now being traced, with focus on corridors such as Benishangul-Gumuz, bordering Sudan.

2.2 Kenya

Wachira Davis

VL in Kenya is caused by \textit{L. donovani}, which is transmitted by \textit{P. orientalis} and \textit{P. martini}. Some 4000 cases are estimated to occur annually and 5 million people are at risk. A total of 30 subcounties are considered to be endemic; six are highly endemic (Baringo, Isiolo, Marsabit, Turkana, Wajir and West Pokot).

Surveillance is done through active and passive case detection. During the outbreak in May–June 2014 in Marsabit, 49 cases were confirmed by rK39 test (86% were male). The case fatality rate was 4%.

The control strategy is based on vector control through long-lasting insecticide-treated bednets, health promotion and social mobilization (developing information, education and communication materials) and advocacy (World Health Day in 2014 focused on VL).

Pharmacovigilance is done by DNDi.

The main challenges are frequent drug and diagnostic supplies shortcomings (most endemic areas are not endemic for malaria so they do not benefit from malaria control activities); low knowledge of VL among health workers and high turnover of personnel; few health facilities provide treatment and transportation costs for patients are high; poor surveillance; and no entomological surveys and no trained entomologists.

The major focus areas in 2015 are: mapping disease distribution; training health workers on new diagnostic and treatment guidelines; advocating for support from the government; supporting health facilities for early case detection and treatment; elaborating information, education and communication materials; and strengthening surveillance and epidemic detection.
2.3 South Sudan

Thomas A. Ujjiga

Anthroponotic VL in South Sudan is endemic in four states (Upper Nile, Jonglei, Unity and Eastern Equatoria) and 28 counties. A total of 2.7 million people are considered to be at risk. In 2014 there were 15 treatment sites (26 in 2011). The peak season of cases is between August and March.

The main risk factors for VL in the country are insecurity leading to population movement, food insecurity and malnutrition, poor access to health services and poverty. No vector control activities are being implemented.

In the past 6 years (September 2009 – February 2015), 40 538 VL cases have been diagnosed and treated (primary kala-azar, 88.56%; PKDL, 5.2%; relapse, 6.2%). The case fatality rate is 2.5%.

Diagnosis is made through rapid tests (rK39). Medicines are provided free of charge (SSG plus paromomycin as first-line treatment, AmBisome as second-line treatment) and procured or donated through WHO.

There is no pharmacovigilance system in place.

Passive surveillance is done in health facilities and partners discuss disease trends at monthly VL meetings.

Significant challenges include: limited access to health services due to insecurity and poor infrastructure (roads); frequent flooding; weak health infrastructure with limited integration; insufficient qualified personnel; shortage of nutritional supplements for VL patients; protracted food insecurity; limited storage capacity (AmBisome); lack of funds for VL at the Ministry of Health: difficult maintenance of current activities; and limited programme activities.

The major focus areas in 2015 are: advocacy for integration of VL activities in primary health-care services; advocacy for active surveillance/case searches; capacity-building; support to supervision at health facilities; and development of information, education and communication materials.

The recommendations included continuing support to the Ministry of Health and partners on the current control activities, strengthening VL treatment centres, advocating for vector control and active screening activities, and fundraising for the current programme.

The discussion highlighted caution in interpreting the low case fatality rate because not all health facilities report accurately. Surveillance of VL remains weak, although IDSR is in place and includes VL.
Leishmania–HIV coinfection is not common, but patients are not systematically tested (WHO is revising the protocol to include HIV testing). HIV prevalence is 3.7–4%. MSF Holland reported that in Lankien the rate of HIV–VL coinfection is < 0.5% but that in Gambella it is high among South Sudanese refugees (around 6%, compared with the national prevalence in Ethiopia of 1.3% in 2014).

2.4 Uganda

Martin Mayanja

VL is endemic in the north-east Karamoja region of Uganda. The communities affected are semi-nomadic. There is only one treatment centre, Amudat hospital, where patients from Uganda and Kenya are treated.

*L. donovani* is the causative parasite. Termite hills, acacia trees and cracked cotton soil are the breeding sites for the vector, *Phlebotomus martini*.

In 2014, 136 patients were treated at Amudat hospital. In the period 2008–2013, 255 patients were from Uganda and 209 from Kenya; most patients were aged 6–18 years.

VL control activities are supported by partners (MSF previously and DNDi currently).

Significant challenges include: lack of an active control programme at the Ministry of Health level and only donor-supported activities; hard-to-reach endemic areas (impassable roads during rainy seasons); one treatment centre; and incomplete mapping for VL endemicity as the situation in other neighbouring districts (Kaabong, Katakwi, Kotido, Nakapiripirit and Napak) is not known.

The major focus areas for 2015 are: disease mapping; entomological surveys to determine the behaviour and infection rates of sandflies; increased case detection; and improved access to diagnosis and treatment.

The discussion highlighted that the situation analysis conducted in 2013, supported by WHO, consisted of a review of hospital records from 2008 to March 2013. Of the 255 cases recorded, 71% were from Amudat hospital and 27% from Moroto. In 2014, the 136 cases reported to the Ugandan Ministry of Health from Amudat hospital were neither categorized as Ugandan nor as Kenyan.

Often, surveillance reports from the hospital do not reach the Ministry of Health (leishmaniasis programme).

DNDi explained that active case detection is conducted in Amudat area: a vehicle goes to the village with a laboratory technician to test suspected cases and patients are transported to the hospital. The catchment area is expanding but active case detection relies on the DNDi activity. There are probably remote areas that are not reached because of difficult access.
There is no physical border in the area, so no differences between Kenya and Uganda in the number of VL cases.

The national leishmaniasis guidelines have not been revised since 2007. WHO supports the national programme in strengthening PICT in VL patients.

2.5 Somalia
*Abdurahman Ibrahim*

Somalia has a total population of 12.3 million. There is a health sector strategic plan for 2013–2016.

VL is caused by *L. donovani* and transmitted by *P. martini* around termite hills. The disease is considered anthroponotic and children are the most affected. Neither CL nor PKDL cases have been detected.

There are three diagnostic and treatment centres for VL in south and west Somalia: two in the Bakool region (Hudur and Tiyeglow) and one in the Bay region (Baidoa). WHO provides diagnostic tests and medicines.

In the period 2011–2014, a total of 290, 394, 673 and 843 cases were reported. In 2014, 58% of cases were male, 60% were aged 0–5 years and 35% were aged 5–14 years. The case fatality rate was 2.8%. There is no pharmacovigilance system in place.

The NGO SOS Children’s Villages has been working in Somalia since 1983 in mother and child care hospitals in Baidoa and Mogadishu to support VL and nutrition. Malnutrition is very high in Somalia and many children who do not respond to treatment for malnutrition have underlying VL.

There is no VL control programme as such but guidelines were developed in 2012 with WHO support. The control strategy is based on early diagnosis and treatment. Insecticide-treated nets are distributed for patients. Health education is also conducted. Indoor residual spraying is only done within the malaria control programme.

Significant challenges include: weak political commitment; lack of an NTD programme; lack of governmental funding; uncertainty about the future supply of medicines and diagnostic tests; insufficient human resources; lack of food for patients; difficult access for patients given the very long distances (> 100 km); insecurity; and low integration of VL services at primary health-care level.

The major focus areas for 2015 are: advocacy to increase commitment for NTD control; outreach activities; community sensitization; integration of treatment sites in primary health-care; vector control through insecticide-treated nets; mapping; resource mobilization; reestablished surveillance, monitoring and evaluation; capacity-building; and training.
2.6 Sudan  
Mousab Elhag

Sudan has a population of 36.4 million. VL is endemic in seven states and 17 localities.

VL is caused by *L. donovani* and transmitted by *P. orientalis*. All clinical forms exist (VL, PKDL, CL, MCL). The disease mainly affects children. In the period 2002–2011, a total of 29 700 cases were reported (3.7% case-fatality rate). There are 25 treatment sites (AmBisome is available in eight sites and has been donated through WHO since 2012). VL cases are registered through a computerized application. Pharmacovigilance is in place through a VL card on which serious adverse events are recorded (implemented in 17 centres).

Surveillance for VL is passive and there are 1520 sentinel sites (VL is reported weekly only in Gedaref State). Surveillance for sandflies is also in place.

The VL control strategy is based on early diagnosis and treatment, vector control (mainly done through the malaria control programme, except in Gedaref where there are campaigns targeting VL), health education and operational research.

Significant challenges include: high staff turnover, shortage of rK39 (embargo for BioRad tests) and medicines (sodium stibogluconate), insecurity, inaccessibility, ineffective vector control measures; and lack of outreach activities to diagnose more patients.

The major focus areas for 2015 are: establishing new treatment centres; rehabilitation of certain health facilities; operational research to identify better vector control measures; HIV testing for all VL patients; appointing information technology specialists in targeted states; and integrating pharmacovigilance in the national system.

**General discussion**

*On pharmacovigilance*

DNDi has finalized the pharmacovigilance efficacy study on SSG plus paromomycin, which showed more than 90% of efficacy of the combination after 6 months.

*On surveillance*

How many patients are there in the countries? In 2009, Bangladesh reported 4000 cases, when there were 40 000 estimated and TDR was estimating 140 000. As a result of this huge gap in information, no support was received from any sponsor.

There is a pressing need to provide up-to-date and more accurate information, including on asymptomatic persons and PKDL cases, if we want to succeed in creating a programme for East Africa.
Information should be routinely shared between the control programmes and partners.

On vector control

There is a need to improve data on the vector and the effectiveness of the vector control measures.

The challenge of vector control arises from the lack of entomologists in countries, although the situation in Sudan is much better. There are sentinel sites in Sudan for vector surveillance, integrated vector management units and 68 entomologists with Master degrees who collect other vector data from other diseases and monitor insecticide resistance.

On programmatic issues

All VL patients should be tested for HIV and the HIV programme should be sensitized about this.

In Somalia there are few staff and shortages of essential supplies. Partners are called upon to support implementing organizations.
3. **Control activities, epidemiology and partners**

3.1 **Research: updates on DND\(i\) research activities in East Africa**

*Fabiana Alves*

DND\(i\) deploys research capacities in disease-endemic countries through the Leishmaniasis East Africa Platform. Its major roles are:

- defining patients’ needs and target product profiles
- strengthening local capacities
- conducting clinical trials (Phase II/III studies)
- facilitating registration
- accelerating implementation (Phase IV and pharmacovigilance studies).

DND\(i\) conducts activities for capacity building in VL-endemic countries, supports the building of infrastructure for VL treatment centres and clinical research, and supports routine treatment of VL patients, outside clinical studies.

Five major studies are assessing the efficacy and safety of new treatments modalities for VL:

1. SSG versus SSG plus paromomycin
2. AmBisome single-dose versus multiple doses
3. Combination therapy with miltefosine plus SSG or miltefosine, and AmBisome or miltefosine monotherapy
4. Proof-of-concept study on fexinidazole
5. AmBisome high-dose and AmBisome plus miltefosine for treatment of VL patients coinfected with HIV.

In Africa, the clinical efficacies of treatment options were: SSG, 93%; AmBisome (liposomal amphotericin B), 33% to > 97% (depending on areas); miltefosine, 72%; paromomycin, 84%; SSG plus paromomycin, 91%; liposomal amphotericin B plus SSG, 79%. The efficacy at 6-months’ follow-up of SSG monotherapy was 93.9% and SSG plus paromomycin combination therapy 91.4% but the difference was not statistically significant. The results of this study were used by WHO to recommend the combination therapy for East Africa (WHO TRS No. 949, 2010).

Pharmacovigilance on SSG plus paromomycin combination therapy has been done in 3126 VL patients treated in 12 treatment centres in Ethiopia, Kenya, Sudan and Uganda. The initial cure at the end of treatment was 95.1% (2974/3126) [94.4–95.9, 95% confidence interval]. The overall mortality rate was 0.9%. Efficacy at the end of treatment was lower for patients aged > 50 years (81.4%, \(p < 0.001\)). Efficacy was also lower for HIV–VL coinfected patients (55.6%, < 0.001). Mortality was higher in patients aged > 50 years (9%). Patients aged > 50 years and coinfected with HIV–VL required alternative treatments and special care.
A randomized, parallel arm, open-label clinical trial on coinfection with HIV and *Leishmania* is under way in Ethiopia to assess the safety and efficacy of combined AmBisome plus miltefosine therapy and AmBisome monotherapy for the treatment of VL in patients coinfected with HIV. The two treatment arms are: AmBisome (5 mg/kg/day) on days 1–5, 10, 17 and 24 (total dose 40 mg/kg) or AmBisome (5 mg/kg/day) on 6 alternate days (30 mg/kg) plus miltefosine (2.5 mg/kg/day) for 28 days.

### 3.2 KalaCORE Consortium in East Africa

*Margriet den Boer*

Following strong advocacy for VL (mainly from WHO, MSF and DNDi) and the UK’s commitment to NTDs following the London 2012 Declaration, KalaCORE won the £27.3 million for 5 years (until April 2019) DFID bid for “Tackling VL in South-East Asia and East Africa” project in January 2014.

The project targets Bangladesh, India and Nepal in South-East Asia, and Ethiopia, South Sudan and Sudan in East Africa.

The KalaCORE Consortium comprises four organizations and will manage VL support on behalf of DFID: the Drugs for Neglected Diseases Initiative (DNDi), the London School of Hygiene and Tropical Medicine (LSHTM), Médecins sans Frontières (MSF) and Mott MacDonald (MM) (with MM holding the DFID contract). These organizations will be supported by a range of global experts on VL who constitute a Technical Advisory Group. The work will be carried out by partners of Consortium members and networks of local organizations in each country. In all cases, the partners will support the national effort by ensuring high-level communication and coordination with national VL control programmes.

The vision and mission of KalaCORE are to focus on supporting national programmes in achieving their respective control goals. KalaCORE activities encompass:

- treatment and access to VL care
- capacity-building
- vector control
- strengthening surveillance
- monitoring and evaluation
- behaviour-change communication
- operational research.

KalaCORE is not a direct implementer but rather a provider of technical support to country-implementing partners in the spirit of cooperation, harmonization and alignment. The implementation phase will be 2015–2019.
3.3 AmBisome donation programme

Daniel Argaw Dagne

The current WHO-negotiated price for AmBisome (vial of 50 mg) of US$ 18 per vial has recently been reduced to US$ 16.25 for public sector and not-for-profit organizations of the eligible low-income countries.

WHO has supported preparatory activities to roll out the AmBisome donation by facilitating readiness assessment and site selection, securing signed letters of agreement by governments, providing training, pharmaco-epidemiological monitoring and drug requests, and elaborating standardized reporting forms.

Challenges include the requirement for a cold chain, temperature monitoring, intravenous infusion, packaging, shipment, distribution and storage.

There is a need for training of health workers to reconstitute and administer the drug, and of store keepers for storage and temperature monitoring.

The relapse rate was 3% after 6 months of follow-up, but all patients responded to retreatment with AmBisome, even with a single dose (in Bangladesh).

The discussion emphasized that no serious adverse events were reported for AmBisome donated through WHO. Most relapses required only single doses; a few had other opportunistic infections that required multiple doses. WHO is negotiating with the company to renew the current agreement until 2020, as per the WHO roadmap; the current agreement expires in 2016.

The VL donation programme focuses on high-burden countries because donors require economical cost-effectiveness (value for money). WHO, however, is not neglecting low-burden countries and is also supporting them with the available yet limited resources. Finally, Dr Argaw Dagne stressed that given the long lead-time (4–6 months) after ordering the drugs, countries should submit their request well in advance for better planning to manufacture the drug and to avoid delays and stock-outs.

3.4 Antileishmanial drug forecasting, distribution and access issues

Margriet den Boer

At least half of all leishmaniasis patients are estimated to have inadequate access to appropriate diagnosis and treatment. The most important barriers to accessing care in East African countries were reflected in the WHO report published in 20121: “extremely remote and insecure areas, patients first seek care from traditional healers and present in very late

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stage of disease, low awareness among patients and health workers, people don’t seek care as staying away from work causes great financial loss”.

The most important barriers to accessing drugs in Africa are:

- dependency on NGOs or WHO for drug supply;
- irregular production, long lead-times and quality problems or single source manufacturers;
- lack of product registration in affected countries;
- poor reporting and lack of timely surveillance data;
- fluctuating caseloads and unexpected outbreaks;
- forecasting based on consumption;
- no central buffer stocks;
- irregular distribution to treatment sites;
- lack of trained health workers: overuse or underuse; and
- emergency use of SSG for CL outbreaks.

To minimize or solve some of these issues a joint procurement mechanism for VL supplies would be advantageous for: price negotiations; joint forecasting to enable production planning and secure availability; centralized quality control or assurance; and cost-sharing of buffer stocks for immediate response capacity (outbreaks).

KalaCORE will support three of the most endemic countries in East Africa, providing an important opportunity for support to regional supplies. To address the challenges in forecasting and the factors influencing the number of estimated cases and drug consumption, KalaCORE proposes the following strategy.

Immediate

- Purchase of drugs (SSG plus paromomycin) and diagnostics for maximum estimation of cases.
- Creation of a permanent buffer stock for 3000 patients held in Amsterdam to respond to outbreaks: accessible for all other stakeholders (WHO, MSF, other countries) so that it is rotational.
- Cost-sharing of WHO pre-qualification quality inspection that can be accepted by all East African countries (to be coordinated).
- Support to the Ministry of Health in timely drug distribution to treatment sites.

Longer term

- Support to the Ministry of Health in strengthening of surveillance and estimations of disease burden.
- Support to the Ministry of Health in developing yearly forecasts and distribution system in line with seasonal and unexpected burden.
- Support for a regional approach to forecasting/joint purchase.
- Support for a continued regional approach to quality assurance.
During the discussion the role of IDA and the coordination among different stakeholders was addressed. IDA has expertise in processing drug entry in countries. Consolidated requests would provide manufacturers with an appropriate forecast of annual drug production as countries normally buy supplies direct from manufacturers. It was acknowledged that a leishmaniasis technical working group for forecasting drug needs should be set up at country level comprising the Ministry of Health, WHO and partners.

3.5 Epidemiological surveillance

José Antonio Ruiz Postigo

In order to have a minimum set of indicators, common to all countries, to facilitate data analysis, reporting and comparing results WHO, in discussion with countries, has developed a series of monthly and annual variables and indicators.

The indicators chosen aim at describing the geographical distribution and burden of the disease as well as case management (diagnosis and treatment).

The monthly variables include: number of cases found actively; new VL cases diagnosed (laboratory and clinical); cases tested by direct examination (parasitology); laboratory (parasitological) confirmed cases; cases diagnosed clinically; suspected cases tested with RDTs; cases diagnosed by a positive RDT; people screened actively and passively; cases of VL–HIV coinfection; female cases; cases by age group (< 5 years; 5–14 years; > 14 years), new/PKDL/relapse VL cases treated; cases with initial cure; failure cases; deaths; cases with serious adverse events; and number of vials used. Annual variables include the number of new VL cases cured (after follow-up of at least 6 months) and relapse cases, and the number of months elapsed between onset of symptoms and diagnosis (median).

Current tools for data registration and reporting are mainly register books and Excel forms. These are not systematically used in all countries, do not always reach the central level (Ministry of Health, WHO) and/or do not lead to sufficient data analysis. In order to improve that situation WHO is proposing a new Excel-based tool (the NTD National Database Template) that can be customized and tailored to country needs and generate automated calculations for predetermined variables and reports in different formats (e.g. for donors, WHO). Training has been conducted for some countries in Africa (e.g. Uganda, Kenya).

3.6 Epidemiological updates and country profiles

José Antonio Ruiz Postigo

Resolution WHA60.13 on control of leishmaniasis, adopted by the World Health Assembly in 2007, defines the roles of WHO and Member States. Among others, WHO is expected to raise awareness of the global burden of the disease and monitor progress in its control. Member States are expected to establish surveillance systems, to collect and analyse data, to
conduct epidemiological assessments for mapping endemic foci, and to calculate the impact of the disease through prevalence and socioeconomic studies.

To fulfil its mandate, WHO in 2012 published *Leishmaniasis: epidemiology and access to medicines*\(^1\), which contains detailed country profiles. In 2013, the WHO Global and Eastern Mediterranean Regional Health Observatories incorporated leishmaniasis data and maps at national level from 1998 provided by the national leishmaniasis control programmes. A year later, the World Health Statistics 2014 report included leishmaniasis as one of the selected diseases for country statistics.

As the information contained in the 2012 country profiles dates back to 2008 or 2010, those country profiles need to be updated. To make that exercise quick and cost–effective, WHO has elaborated a new country profile template, which can be automatically obtained by entering the data in an Excel-based template. The new profiles will contain most of the indicators mentioned under the presentation on “epidemiological surveillance” (see section 3.5) as well as graphs and maps. Maps will be created with an open-access application and aim to capture data up to at least the second subnational administrative level.

3.7 MSF Ethiopia

*Elshafie Mohamed Ahmed*

MSF supports two projects in Ethiopia: one in Abdurafi north, west Amhara, targeting seasonal migrant workers, residents and settlers from the highlands; the other in Gambella, targeting South Sudanese refugees in Kule and Tirkidi camps.

Every year, around 300,000–500,000 migrant workers leave home for north-west Amhara (many others for Humera and Tigray regions) to find seasonal farm work in Metema, Quara and West Armachewo and Humera districts. They return home within 3–6 months and are at risk of contracting VL since being from the high land they have no immunity against the parasite.

In Abdurafi, the project provides case management of primary VL, relapses and coinfect ed cases (HIV, TB); training for clinicians as well as health-care workers in hospitals, health centres and health posts; community outreach, with special focus on midwives; operational research on better treatment options and prevention of VL relapse among patients coinfect ed with HIV; and advocacy and lobbying for better access to health care for migrant workers. In 2014, some 516 VL cases were treated, representing an increment of about 65% from the previous year, mainly due to the increase of disease incidence. The rate of HIV coinfection among primary kala-azar cases fell to < 7%, which could reflect the decreased HIV prevalence in the country. Overall mortality in VL patients has fallen from 8% in 2013 to

only 1% in 2014. Mortality in HIV coinfected patients has reduced dramatically from 26% in 2013 to 2.5% in 2014.

In Gambella, from September to December 2014, 40 VL cases were diagnosed and treated in the MSF health facility. All of them were South Sudanese refugees. The cure rate was 92.3% and the default rate 7.7%; no mortality was observed.

A new project will be established in Abrehajira, a new district hospital in the final stages of construction. MSF funded the construction of the VL ward which is 80% completed. Once the hospital is functional, MSF will train, capacitate, support and establish systems to provide good-quality VL services for non Leishmania–HIV-coinfected patients.

3.8 MSF South Sudan

Timothy Harrison

MSF Holland has been working in South Sudan since 1989. The disease trend shows a fluctuating caseload with outbreaks at 6–10-year intervals and an annual peak season between October and January. Until the 2009 outbreak, the response had predominantly been carried out by MSF Holland. During the 2009–2011 outbreak in which more than 25 000 cases were reported, WHO reinforced treatment centres: 78% of cases were managed in four health facilities (case fatality rate, 3.8%). In 2014 an unexpected and early surge of cases occurred in Lankien/Malakal region, related to mass displacement. Lankien was unprepared (in terms of human resources and supplies), the rainy season hampered access, many patients were severely ill or complicated cases, a rupture in drug stock led to an estimated 45 deaths, data collection and capturing were inadequate, and some patients had unrecognized severe illness and malnutrition. Despite these obstacles the response was successful: mortality rose to 6% in August but remained at 2% thereafter (an all-time low for outbreaks).

In 2014, MSF treated a total of 6754 cases (case-fatality rate, 3.0%). The main lessons learnt were the importance of deploying experienced additional staff as quickly as possible to maintain quality of care, reduce mortality and prevent staff burn-out; training staff to improve monitoring, including drug toxicity; and providing nutritional support for patients of all ages.

3.9 MSF Sudan

Silas Adamou

MSF has been operating two projects in Sudan since 2010 in Azaza Damos and Tabara-Kalla. In Azaza Damos 112 patient were treated in 2014. In Tabara-Kalla, from 2010 to 2014, more then 100 000 people were screen for VL and 3178 patients were diagnosed (87% primary, 7% relapses, 6% PKDL). The case fatality rate was 2.3%. Malnutrition (46%) and pneumonia (27%) were the two commonest comorbidities. The rate of Leishmania–HIV coinfection was 1.4%.
Diagnosis is made through rK39 and direct agglutination test as first line, and lymph node aspirate as second line. The first-line treatment is SSG plus paromomycin; the second-line treatment is AmBisome (for 23% of patients). HIV screening is done for all VL patients. Food is provided for patients and caregivers, alongside two mosquito nets. Post-treatment follow-up is done at 6 months (58% follow-up rate).

Training is an important component of the MSF projects. It is addressed to health educators in national NGOs, community health workers, medical staff (591 staff in 2014) and the community (awareness activities done in 80 endemic villages in Sinnar).

Challenges include: limited access to endemic areas during the rainy season; difficulties with importing medicines; delays in seeking VL treatment arising from visits to traditional healers; patients responding slowly or not all to treatment; low post-treatment follow-up rate; and difficulties in transfusing blood.

3.10 IMA World Health South Sudan

*Mounir Lado*

IMA provides support to the VL emergency response. More than two-thirds of counties where VL is highly endemic are currently under the control of opposition forces (Northern Jonglei and parts of Unity and Upper Nile State) or in active conflict. Furthermore, the division lines between opposition and government have strong ethnic ties, necessitating the need for two separate emergency response teams based on issues of access and security. Each team consists of 1 clinical officer, 2 nurses and 1 laboratory technician, primarily to carry out field activities.

In 2014, IMA collaborated with the Ministry of Health, MSF and WHO on a training targeting medical officers, clinical officers, nurses and laboratory technicians. The participants were from 12 NGOs, Juba Teaching hospital and Duk county health department.

The emergency teams visited Gorwai Payam in Ayod county and conducted community awareness activities. Gorwai primary health-care unit had only rapid tests for VL but no drugs; other medications were also lacking. After the visit the lead health agency was provided with the necessary supplies for case management. In Pagil primary health-care unit a total of 176 cases were admitted in week 8. During the visit there were 25 cases on treatment. The primary health-care unit has no rooms for hospitalizing cases or injection (treatment) rooms. Pagil has received some support from MSF from Lankien: drugs, treatment guideline and in-service training.

IMA also supports the national focal point at the Ministry of Health in carrying out his duties.
Several NGOs that offer VL diagnosis and treatment have begun sharing data and reports with IMA. Weekly reports are being submitted, albeit inconsistently. During the visit to Pagil the IMA staff also collected the weekly reports as from January 2015. Implementing partners are being encouraged to submit the reports as required. The locations currently sharing reports with IMA are Walgak, Pagil, Kodok, Rom and Ulang.

Challenges include the delay in signing the contract with KalaCORE, which is hampering formal agreements with the Ministry of Health and those NGOs that are to be supported. Most locations have very few staff and more efforts are required in response, including stationing a team for a longer period. The logistics of accessing some locations require the use of boats, which was not anticipated.
4. **Group work**

On the second day of the meeting the participants were divided into two groups to discuss the main challenges in controlling VL; specifically, prevention, diagnosis, treatment, control strategies and interventions. The following issues were identified.

**Visceral leishmaniasis diagnosis and treatment**

- Countries should establish or reinforce their national task force or technical working groups (based on the local context) to be led by the Ministry of Health, including the key partners, and review guidelines as applicable.

- The national task force or technical working groups need to meet regularly and prepare national forecasts of drugs and diagnostic supplies, which should be revised every 6 months based on epidemiological trends and disease burden.

- Given the epidemiology of the disease and the high turnover of staff, health-care workers should be trained on the revised diagnosis and treatment guidelines.

- Efforts have to be made to identify and improve access to specific at-risk or vulnerable population groups for VL.

- Countries should facilitate the registration or inclusion of new drugs in their national drugs list or essential drugs list as recommended by WHO and already included in the national guidelines.

- Countries should reinforce existing diagnostic and treatment centres for VL and/or expand diagnostic and treatment centres to improve access to services.

- Endemic countries should establish or strengthen pharmacovigilance of antileishmanial drugs and monitor adverse events.

- Endemic countries should start allocating funds and exploring other local sources to sustain VL control programme activities.

- Endemic countries should strengthen collaboration between the HIV and VL programmes and institute surveillance of coinfection.
Visceral leishmaniasis prevention and control strategies and interventions

- Endemic countries need to strengthen surveillance, data sharing and databases.

- Based on the situation on the ground in South Sudan, there is a need for close follow-up and support to epidemic preparedness and response activities.

- Efforts have to be made to assess all VL foci, update VL disease distribution and burden, and possibly develop risk maps for the disease.

- Although the current regional strategy targets control of VL in endemic countries, there is a need to generate evidence on active and intensive VL interventions for heightened control and to explore the possibility of elimination of VL at foci level.

- Endemic countries should ensure the inclusion of leishmaniasis in their national NTD master plan and national health policy to improve funding and eventually ensure sustainability of the Programme.

- Given the burden of the disease and the recurrence of outbreaks, attention should be provided for control of CL.

- To strengthen control interventions for leishmaniasis, there is a need for rapid implementation of innovative vector control methods and hence operational research to generate evidence for innovative vector control measures.

- While the main focus is on countries with high VL burden, WHO, DNDi and other potential stakeholders need to strengthen support to countries with low VL burden to strengthen regional programmes.

- Endemic countries and implementing partners should give attention to strengthening national coordination mechanisms and collaboration with other programmes.

- Endemic countries should establish cross-border collaboration to improve disease surveillance and information-sharing in border areas and explore existing platforms for cross-border collaboration (such as WHO, Intergovernmental Authority on Development, etc.).

- There is a need for regular bi-regional meetings to convene countries of the subregion and strengthen control interventions in countries where VL is endemic.
**Roadmap to implement the above recommendations**

1. Reactivate and/or establish a National Task Force or Technical Working Group involving key stakeholders including drug regulatory authorities.

2. Review diagnosis and treatment guidelines, if needed.

3. Include new drugs in the Essential Drugs List, or facilitate the registration process.

4. Conduct regular drugs and diagnostic quantification exercises.

5. Elaborate preparedness plans for outbreak management.

6. Ensure national funding and advocacy mechanisms.
5. **Recommendations**

The participants agreed the following recommendations for the improvement of VL control programmes in East Africa.

- To implement a Technical Working Group or National Task Force for leishmaniasis, including academia, NGOs, government and WHO, to guide the control programme.

- To urgently set up a forecast mechanism for drugs and diagnostic items at country level.

- To train health workers on the revised diagnostic and treatment guidelines.

- To increase access to specific at-risk or vulnerable populations.

- To have countries facilitate the registration or inclusion of the new drugs recommended by WHO and already recommended in the national guidelines.

- To reinforce and expand diagnosis and treatment centres, including active pharmacovigilance, in collaboration with national bodies (e.g. Food, Medicine and Health Care Administration and Control Authority of Ethiopia).

- To have countries allocate funds and pursue other local sources to sustain control of Programme activities.

- To establish collaboration between HIV and VL programmes and institute systematic surveillance of *Leishmania*–HIV coinfection at country level.

- To strengthen surveillance and data-sharing, including databases; partners to share their data with national programmes in the countries.

- WHO Regional Office for Africa to include leishmaniasis in its Regional Health Observatory.

- To follow up and support epidemic preparedness and response in South Sudan.

- To assess all foci and update disease distribution, burden and risk maps.

- To conduct active, intensive control interventions for heightened control and explore the possibility of elimination at foci level (e.g. Turkana).

- To have countries ensure the inclusion of leishmaniasis in the national NTD master plan.
• To provide the necessary attention to CL.

• To rapidly implement innovative vector control methods.

• To strengthen support to countries with low disease burden.

• To strengthen national coordination mechanisms and collaboration with other programmes.

• To strengthen cross-border collaboration and explore existing platforms (e.g. WHO, Intergovernmental Authority on Development).

• To conduct regular bi-regional coordination meetings for the subregion.

• To advocate the need for nutritional support to VL patients with the World Food Programme.

As emphasized by the WHO Representative, these recommendations should be translated into action plans. WHO will share the information with the six countries and facilitate cross-border meetings.
## Annex 1. Agenda

### Monday 9 March 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Responsible</th>
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<tbody>
<tr>
<td>08:30–09:00</td>
<td>Registration</td>
<td>Participants</td>
</tr>
<tr>
<td>09:00–09:30</td>
<td>Opening session</td>
<td>WR Ethiopia</td>
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<tr>
<td></td>
<td>• Welcome address</td>
<td>MoH Ethiopia</td>
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<tr>
<td></td>
<td>• Opening remarks</td>
<td>Dr D. Argaw Dagne</td>
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<tr>
<td></td>
<td>• Objectives of the meeting and introduction of participants</td>
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<td></td>
<td>• Selection of Rapporteurs</td>
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<tr>
<td>09:30–09:45</td>
<td>Visceral leishmaniasis control: overview of global situation and perspectives</td>
<td>Dr D. Argaw Dagne</td>
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<tr>
<td>09:45–10:00</td>
<td>Leishmaniasis in the African Region vis-à-vis NTD master plan</td>
<td>Dr A. Tiendrebeogo</td>
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<tr>
<td>10:00–10:15</td>
<td>Leishmaniasis control in the Eastern Mediterranean Region</td>
<td>Dr J.A. Ruiz Postigo</td>
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<tr>
<td>10:15–10:30</td>
<td>African Region countries</td>
<td>MoH Ethiopia</td>
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<td></td>
<td>• Ethiopia</td>
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<tr>
<td>11:00–11:45</td>
<td>African Region countries (cont’d)</td>
<td>MoH Kenya</td>
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<td></td>
<td>• Kenya</td>
<td>MoH South Sudan</td>
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<td></td>
<td>• South Sudan</td>
<td>MoH Uganda</td>
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<tr>
<td>11:45–12:00</td>
<td>Discussion</td>
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<tr>
<td>12:00–12:30</td>
<td>Eastern Mediterranean Region countries</td>
<td>MoH Somalia</td>
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<td></td>
<td>Overview of country-specific epidemiological situation, progress and challenges to implementation of VL control activities and plans:</td>
<td>MoH Sudan</td>
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<td>• Somalia</td>
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<td>• Sudan</td>
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<tr>
<td>12:30–12:40</td>
<td>Discussion</td>
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<tr>
<td>14:00–14:15</td>
<td>Research activities:</td>
<td>Dr Fabiana Alves</td>
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<td></td>
<td>• DNDi research activities in East Africa update</td>
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<tr>
<td>14:15–14:30</td>
<td>Discussion</td>
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<tr>
<td>14:30–15:00</td>
<td>KalaCORE Consortium – East Africa Region</td>
<td>Margriet den Boer</td>
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<td>15:00–15:30</td>
<td>Discussion</td>
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<tr>
<td>16:00–16:20</td>
<td>AmBisome donation programme</td>
<td>Dr D. Argaw Dagne</td>
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<tr>
<td>16:20–16:40</td>
<td>Antileishmanial drug forecast, distribution and access issues</td>
<td>Margriet den Boer</td>
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<tr>
<td>16:20–17:30</td>
<td>Discussion</td>
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</table>
**Tuesday 10 March 2015**

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<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>09:00–09:15</td>
<td>Epidemiological surveillance:</td>
<td>Dr J.A. Ruiz Postigo</td>
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<tr>
<td></td>
<td>- Standardized indicators</td>
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<td></td>
<td>- How to improve data collection and analysis</td>
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<tr>
<td>09:15–09:30</td>
<td>Epidemiological updates and country profiles:</td>
<td>Dr J.A. Ruiz Postigo</td>
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<tr>
<td></td>
<td>- To update the epidemiological situation of VL and strategies</td>
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<td></td>
<td>- for its prevention and control</td>
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<tr>
<td>09:30–10:30</td>
<td>MSF &amp; IMA VL activities update</td>
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<td>11:00–11:15</td>
<td>MSF Ethiopia</td>
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<td>11:15–11:30</td>
<td>MSF South Sudan</td>
<td>MSF South Sudan</td>
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<tr>
<td>11:30–11:45</td>
<td>MSF Sudan</td>
<td>MSF Sudan</td>
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<tr>
<td>11:45–12:00</td>
<td>IMA-SS VL epidemic response activity update and plan</td>
<td>IMA South Sudan</td>
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<tr>
<td>12:00–12:30</td>
<td>Discussion</td>
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<tr>
<td>12:30–14:00</td>
<td>Lunch Break</td>
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<tr>
<td>14:00–14:10</td>
<td>Introduction and guide to group discussion</td>
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<td>14:10–17:00</td>
<td>Group discussion</td>
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<tr>
<td>17:00–17:30</td>
<td>Group discussion wrap up and preparation for plenary presentation</td>
<td>Groups</td>
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**Wednesday 11 March 2015**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Responsible</th>
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<tbody>
<tr>
<td>09:00–10:00</td>
<td>Group presentations</td>
<td>Group rapporteur</td>
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<tr>
<td>10:30–12:00</td>
<td>Plenary discussion on the group presentations</td>
<td>All participants</td>
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<tr>
<td>12:00–12:20</td>
<td>Recommendations and wrap-up</td>
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<tr>
<td>12:20–12:30</td>
<td>Closing remarks</td>
<td>MoH, WHO</td>
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<tr>
<td>14:00–16:00</td>
<td>Informal and individual meeting with partners</td>
<td>All participants</td>
</tr>
</tbody>
</table>
Annex 2. List of participants

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