WHO BI-REGIONAL CONSULTATION ON THE
STATUS OF LEISHMANIASIS CONTROL
AND SURVEILLANCE IN EAST AFRICA
NAIROBI, KENYA
12–14 JUNE 2017
# CONTENT

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbreviations</td>
<td>iv</td>
</tr>
<tr>
<td>1. Introduction</td>
<td>5</td>
</tr>
<tr>
<td>2. Meeting objectives</td>
<td>6</td>
</tr>
<tr>
<td>3. Presentations</td>
<td>7</td>
</tr>
<tr>
<td>3.1 Leishmaniaisis control and surveillance: progress and perspectives</td>
<td>7</td>
</tr>
<tr>
<td>3.2 Leishmaniaisis control and surveillance in the WHO African Region</td>
<td>9</td>
</tr>
<tr>
<td>4. Country presentations</td>
<td>10</td>
</tr>
<tr>
<td>4.1 Status of activities to control visceral leishmaniasis in East Africa: progress and challenges, 2016–April 2017</td>
<td>10</td>
</tr>
<tr>
<td>4.2 The KalaCORE Consortium: tackling VL in South Asia and East Africa</td>
<td>20</td>
</tr>
<tr>
<td>5. Research activities in relation to disease control</td>
<td>16</td>
</tr>
<tr>
<td>5.1 LEAP: contributing to strengthening clinical trial capacity, treatment and control of VL in eastern Africa</td>
<td>16</td>
</tr>
<tr>
<td>5.2 DNDi research activities in Eastern Africa</td>
<td>16</td>
</tr>
<tr>
<td>5.3 FIND leishmaniasis projects in Eastern Africa</td>
<td>17</td>
</tr>
<tr>
<td>5.4 Operational research for VL in East Pokot, Baringo</td>
<td>18</td>
</tr>
<tr>
<td>5.5 Training and research priorities for leishmaniasis elimination</td>
<td>18</td>
</tr>
<tr>
<td>5.6 VL control activities in Kenya: progress and challenges</td>
<td>19</td>
</tr>
<tr>
<td>5.7 ICIPE/Kenya: International Centre of Insect Physiology and Ecology</td>
<td>19</td>
</tr>
<tr>
<td>6. Other partner presentations</td>
<td>20</td>
</tr>
<tr>
<td>6.1 SURVEILLANCE – DHIS2 implementation plan</td>
<td>20</td>
</tr>
<tr>
<td>6.2 The KalaCORE Consortium: tackling VL in South Asia and East Africa</td>
<td>20</td>
</tr>
<tr>
<td>7. General discussion</td>
<td>22</td>
</tr>
<tr>
<td>8. WHO presentations</td>
<td>23</td>
</tr>
<tr>
<td>8.1 Surveillance of leishmaniasis: WHO country profiles, 2015</td>
<td>23</td>
</tr>
<tr>
<td>8.2 Epidemiological surveillance of leishmaniasis: DHIS2 update and lessons learnt</td>
<td>23</td>
</tr>
<tr>
<td>9. Field activities by nongovernmental organizations to control visceral leishmaniasis</td>
<td>24</td>
</tr>
<tr>
<td>9.1 MSF field activities in Ethiopia, South Sudan and Sudan</td>
<td>24</td>
</tr>
<tr>
<td>9.2 VL control activities: progress and challenges in South Sudan</td>
<td>24</td>
</tr>
<tr>
<td>10. Status of activities to control cutaneous leishmaniasis in East Africa</td>
<td>25</td>
</tr>
<tr>
<td>10.1 CL control activities in Ethiopia: progress and challenges</td>
<td>25</td>
</tr>
<tr>
<td>10.2 Kenya CL control activities: progress and challenges</td>
<td>26</td>
</tr>
<tr>
<td>10.3 Sudan CL control activities: progress and challenges</td>
<td>27</td>
</tr>
<tr>
<td>11. General discussion</td>
<td>28</td>
</tr>
<tr>
<td>12. Recommendations from Working Groups</td>
<td>29</td>
</tr>
<tr>
<td>12.1 Group work</td>
<td>29</td>
</tr>
<tr>
<td>12.2 Recommendations from Working Groups</td>
<td>30</td>
</tr>
<tr>
<td>Annex 1. Agenda</td>
<td>33</td>
</tr>
<tr>
<td>Annex 2. List of participants</td>
<td>35</td>
</tr>
</tbody>
</table>
ABBREVIATIONS

AAU  Addis Ababa University
ALERT  Africa Leprosy Rehabilitation and Training Center
CFR  case fatality rate
CL  cutaneous leishmaniasis
DHIS  District Health Information System
DNDi  Drugs for Neglected Diseases initiative
FIND  Foundation for Innovative New Diagnostics
HIV  human immunodeficiency virus
ICIPE  International Center of Insect Physiology and Ecology
IEC/BCC  information, education, communication/behaviour change communication
IMA  Interchurch Medical Assistance
IRS  indoor residual spraying
ITM  Institute of Tropical Medicine Antwerp
ITN  impregnated treated net
KAP  knowledge, attitude, practices
KEMRI  Kenya Medical Research Institute
KEMSA  Kenya Medical Supplies Authority
LCL  localized cutaneous leishmaniasis
LLIN  long-lasting insecticidal net
LST  Leishmanin skin test
M&E  monitoring and evaluation
MSF  Médecins Sans Frontières
NTD  neglected tropical disease
PKDL  post-kala-azar dermal leishmaniasis
SOS  SOS Children’s Villages International
SSG  sodium stibogluconate
UON  University of Nairobi
VL  visceral leishmaniasis
WHO  World Health Organization
1. INTRODUCTION

Both visceral and cutaneous leishmaniasis are endemic in East Africa. Visceral leishmaniasis (VL) is caused predominantly by infection with Leishmania donovani. It is transmitted mostly by *Phlebotomus orientalis* and *P. martini*. The disease is highly endemic. Some 11 000 new VL cases were reported to the World Health Organization (WHO) in 2016 from six countries (Ethiopia, Kenya, Somalia, South Sudan, Sudan and Uganda).

Cutaneous leishmaniasis (CL) is mainly caused by infection with *L. major* and *L. aethiopica*. It is transmitted by *P. papatasii*, *P. dubosci*, *P. pedifer*, *P. longipes* and *P. aculeatus*. Some 4000 new CL cases were reported to WHO in 2015 from Ethiopia, Kenya and Sudan.

A WHO Bi-regional consultation on the status of leishmaniasis control and surveillance in East Africa was organized by the WHO Global Leishmaniasis Programme in collaboration with the WHO Country Office for Kenya. The meeting was held in Nairobi, Kenya from 12 to 14 June 2017. Participants were from national programmes and the country offices of WHO’s African and Eastern Mediterranean regions, namely Ethiopia, Kenya, Somalia, South Sudan, Sudan and Uganda, as well as partners from the Drugs for Neglected Diseases initiative (DNDi), the Foundation for Innovative New Diagnostics (FIND), the International Center of Insect Physiology and Ecology (ICIPE), KalaCORE, the Kenya Medical Research Institute (KEMRI), Médecins Sans Frontières (MSF), the University of Nairobi, the University of Navarra and the University of Tunis. Annex 1 contains the meeting agenda and Annex 2 the list of participants.

The consultation was moderated by Dr Sultani Matendechero, Head of NTDs (neglected tropical diseases) at the Kenyan Ministry of Health, Dr José A. Ruiz-Postigo, Head of the Global Leishmaniasis Programme at WHO headquarters, and Dr Adiele Nkasiobi Onyeze, Medical Officer at the WHO Regional Office for Africa. The rapporteur Dr Mercedes Herrero, WHO consultant, wrote this report jointly with Dr Ruiz-Postigo.

The welcome address by Dr Ruiz-Postigo acknowledged the contribution of partners to VL control, including the commitment of governments and partners to advancing the agendas for control and elimination of the leishmaniases. Dr Onyeze noted that WHO headquarters and partners as well as the Regional Office for Africa have in place the platforms necessary to implement activities, that great efforts have been made against those NTDs amenable to preventive chemotherapy, and that similar progress is needed now on leishmaniasis. Data and surveillance gaps are a major concern, hence the need to prioritize leishmaniasis on global health agendas.

On behalf of the WHO Representative for Kenya, Dr Iheoma Ukachi Onuekwusi helped to explain how the discussions would assist in advancing control of the leishmaniases and reiterated WHO’s continuing support to the Ministry of Health of Kenya.

The address by Dr Jackson Kioko, Director of Medical Services, Ministry of Health of Kenya, emphasized the high attendance of leishmaniasis partners and their commitment to overcoming the disease. Kenya is significantly affected by NTDs, but VL and CL are marginalized. The Ministry of Health has prepared the second strategic plan for NTDs 2016–2020 and is finalizing the revised national guidelines on leishmaniasis. The guidelines recommend combination therapy as a first-line treatment; this major step will have an impact on lowering the cost of treatment compared with that of sodium stibogluconate (SSG) monotherapy. Management of NTDs should be integrated into regular health systems to ensure that diagnostics and treatment are available. A recent (first case on 16 May 2017) outbreak in Kenya shows why programmes should be owned from the first line at grass roots and why the responsibility for investigation and response must be with the local staff and communities. In his final message to affected countries Dr Kioko said that “they need to put in place functional surveillance systems and integrated methods for control … there is a need to develop a common strategy at regional level as it [leishmaniasis] is one of the most endemic [diseases] in the world”. 
2. MEETING OBJECTIVES

The objectives of the meeting were:

(i) to review the progress and challenges made in leishmaniasis control activities and strategies in the past year (2016), specifically in control of CL; and

(ii) to elaborate an action plan for 2017 and identify the role of each partner, including the WHO AmBisome donation programme and the roll out of the leishmaniasis online surveillance system.
3. PRESENTATIONS

3.1 Leishmaniasis control and surveillance: progress and perspectives
Dr Ruiz-Postigo, WHO headquarter

The main points of the presentation are summarized below.

Surveillance and country profiles
As part of a WHO-led effort to update the empirical evidence base for the leishmaniases, country profiles on the 25 most endemic countries from each WHO region were updated in July 2016. However, the data were available only for 2014, hence the need to improve data collection and the reporting system in order to obtain more updated data from countries in a timely manner. The new country profiles summarize information collected for 18 indicators for VL and 12 indicators for CL on epidemiology, control and surveillance, diagnosis and treatment outcome (http://www.who.int/leishmaniasis/burden/Country_profiles/en/). The 2015 country profiles are almost final and data are available online for countries and partners through the WHO Global Health Observatory (http://www.who.int/gho/neglected_diseases/leishmaniasis/en/).

Progress on real-time online surveillance
WHO has been supporting VL endemic countries to set up the health management online information system for leishmaniasis based on the DHIS2 (District Health Information System) software. Health ministries in countries that have chosen to use DHIS2 as the health information system are supported by WHO to gain expertise and become users of this friendly system. For countries where the health ministry uses another tool to collect or gather data, WHO has developed an application to easily import data from Excel to the online platform. In addition to the routine aggregate data collected every month, the district hospitals can use the DHIS2 tracker module or event capture to capture case-based data from inpatient admissions and deaths, enabling more accurate morbidity and mortality statistics and data analysis.

The DHIS2 platform has been set up or is in progress in several countries for VL surveillance (Bangladesh, India, Kenya, Nepal, Somalia, Sudan and Uganda). Training workshops were conducted in more than 12 countries in 2016, with over 60 participants.

AmBisome donation
In September 2016, WHO and Gilead Sciences signed a new agreement for the donation through WHO of an additional 380,400 vials of AmBisome (liposomal amphotericin B for injection), extending their previous agreement to 2021. The donation will benefit key endemic countries in South-East Asia, where the medicine is used as first-line treatment (Bangladesh, India and Nepal), but recipients will also include the eastern Africa subregion, where AmBisome is used as second-line treatment to treat severe or complicated cases (under discussion to include Kenya as part of the donation).
Manuals for surveillance of CL and VL were developed in 2016, e.g. for the WHO European Region, and support was provided to national programmes, such as the recently finalized national guidelines for VL in Kenya. The WHO South-East Asia Regional Office published a document on the process of validating the elimination of kala-azar as a public health problem in South-East Asia\(^1\) also in 2016.

Finally, in his presentation, Dr Ruiz-Postigo led discussions about managerial considerations, such as increasing human resources at country, regional and headquarters’ levels, in order to expand delivery of activities in response to the increased demands of national programmes and partners. Funding increases and accountability to donors were stressed in line with the messages: “\textit{risk of continuation of financial support if results are not tangible}” and “\textit{WHO has commitment with donors and beneficiaries of the programme and we need to ensure we deliver high-quality activities on time}”. Mechanisms to support countries were proposed, including monthly teleconferences to discuss programme challenges and achievements. Teleconferences are taking place with Sudan and Ethiopia; Kenya, Somalia and Uganda will be added soon. They improve communication through informal channels, such as telephone or WhatsApp instead of email, clarify and accelerate resolution of issues and avoid misunderstandings.

Dr Ruiz-Postigo made a proposal to encourage the organization of the next regional meetings by the WHO regional offices.

\(^1\) Process of validation of elimination of kala-azar as a public health problem in South-East Asia. New Delhi: World Health Organization Regional Office for South-East Asia; 2016 \url{http://www.who.int/leishmaniasis/resources/Process_of_validation_of_VL_elimination_SEA_CD_721.pdf}
3.2 Leishmaniasis control and surveillance in the WHO African Region

Dr Adiele Nkasiobi Onyeze

The main points of the presentation are summarized below.

VL and CL remain a significant NTD in the African Region. In response, the WHO Regional Office for Africa has prepared a regional integrated strategy to combat NTDs, including leishmaniasis based on Resolution AFR/RC63/R6 adopted in 2013, and an integrated strategy to control case management NTDs during the period 2014–2020.

The strategy is built on government policy through four main pillars: (i) expanding access to case management interventions; (ii) scaling up monitoring and evaluation, surveillance and research; (iii) reinforcing results-based planning, resource mobilization for NTDs amenable to case management; and (iv) enhancing advocacy, coordination, partnership and country ownership. These elements of the strategy are reflected in a strong platform: the national master plans for NTDs developed by the Ministry of Health (MOH) with WHO support.

The Regional Office for Africa has led the development of preventive chemotherapy and transmission control (PCT) programmes and an integrated NTD database to improve evidence-based planning and management of NTD programmes at the national and subnational levels. The database is free of charge and is intended for use by national NTD programme managers, monitoring and evaluation specialists, and/or data managers at the central level of NTD-endemic countries. The database is based on a Microsoft Access platform, with the potential to transition to a web-based, multi-user platform, and is a simple, user-friendly interface for data entry and reporting. It has been adapted to incorporate indicators and auto-generate reports for case management NTDs including leishmaniasis with support from WHO headquarters.

The region has provided support in developing NTD master plans and in guiding and directing countries to establish national technical working groups for NTDs. A regional Strategic and Technical Advisory Group on case management NTDs was established accordingly in December 2015.

Proposed plans by countries are needed to mobilize resources, guided by strategic documents and platforms produced by the Regional Office.

High-level advocacy is important as many countries still consider the programme as the responsibility of WHO or other partners. There is therefore a need to build up MOH ownership.
4. COUNTRY PRESENTATIONS

Status of activities to control visceral leishmaniasis in East Africa: progress and challenges, 2016–April 2017

Progress in and challenges to the implementation of VL control activities, surveillance and plans were presented by the representatives from Ethiopia, Kenya, Somalia, South Sudan, Sudan and Uganda.

SOUTH SUDAN

Dr Ayak Chol Deng Alak

Background & epidemiology

Dot map of the distribution of VL cases 2009–2013

Age distribution:
22.7% aged < 5 years,
36% 5–14 years,
31% > 15 years

Lack of data related with primary outcome (65% reported), but estimated mortality rate around 2.5%.

Screening & diagnosis

Most of the cases are diagnosed by rK39 test (72%), the rest by parasitology and < 1% by DAT. DAT testing was established at the National Public Health Laboratory and 12 laboratory personnel were trained.

Surveillance

Progress has been made to implement DHIS2 real-time (monthly) online surveillance or compatible forms with the WHO global surveillance programme since April 2016. DHIS is in place for other diseases (Guinea worm, HIV) and is ready to be adapted for leishmaniasis.

Due to active conflict, very few health facilities are reporting regularly and some treatment sites are inaccessible. During supervision, the data provided are monitored to check quality.

Challenges

Challenges to implementing VL control activities include:
Insecurity, inaccessibility to treatment centres, no Internet access, understaffing, electricity shortages, no funding to coordination office at MOH, no active screening conducted, neither vector control activities.

There is no adequate human resources and financial support to implement the plan.

Plan of action July–December 2017

- Procure drugs and RDT, provide training on diagnosis and case management as well as supportive supervision and on-the-job training; roll out DAT testing in three other locations; test IEC material (ongoing); and disseminate IEC material
- Support will be provided for the coordination office in upgrading 3 health facilities into referral centres for treatment of complicated kala-azar (KA) cases. Active screening is planned in targeted accessible areas (Eastern Equatoria, Melut, Palouj, etc.)
- Print and disseminate KA treatment guidelines and protocols
- IEC materials are being piloted in VL endemic areas

Total number of VL cases diagnosed and treated by 2016–2017 in South Sudan

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ETHIOPIA
Dr Henok Admassu

Background & epidemiology

VL distribution in Ethiopia

Some 2000–4500 cases are reported each year; males (93.5% vs 6.5% females) of whom 89.1% aged > 15 years (only 10.9% of VL patients are aged < 15 years).

Over 3.2 million people are at risk of VL. Two regions, Amhara and Tigray, account for > 85% of the cases.

Spread to new regions (Benishangul-Gumuz, Gambella and Afar) and localities (Welkait and Raya Azebo in Tigray, Sekota in Amhara).

The rate of VL–HIV coinfection was 7.4% in 2011, decreasing to 2.4% in 2015.

Currently, there are 22 VL treatment centres in six regions (6 in Tigray, 5 in Amhara, 2 in Southern Nations, Nationalities, and Peoples’ Region, 3 in Oromia, 5 in Somali, and 1 in Afar).

During the reporting period, 90.6% of the VL patients were cured (CFR [case fatality rate]: 2.2 % [3% defaulter, 0.1% treatment failure]). Follow-up at 6 months is challenging due to the characteristics of the population (mobile migrant workers).

Screening & diagnosis

Patients seek diagnosis in health facilities as active case detection is not conducted. From January to March 2017, 2103 people were passively screened. 67% of patients were diagnosed by rK39 test, 30.8% through spleen aspirate and 2.2% by direct agglutination test (DAT).

Treatment

The MOH started to roll out combination therapy with SSG and PM (paromomycin) in early 2016 in hospitals. In June 2017 the reported data showed that 27.2% received combination therapy versus 54.7% who received SSG: 15.4% of the patients were treated with AmBisome; the remainder are treated with different combination modalities on a compassionate basis.

Vector control

Activities carried out: distributing insecticide-treated nets (ITNs) and conducting indoor residual spraying (IRS) in the context of malaria prevention.


Surveillance

Progress has been made to implement DHIS2 real-time (monthly) online surveillance or compatible forms with the WHO global surveillance programme since April 2016. Implementation is due to start from July 2017.

Reporting rate: 77%
Completeness rate: data incompleteness needs to be revised
Data quality system in place through training, supportive supervision, mentoring of data collection by teams.

Challenges

Competing priorities: (i) Government policy is one plan, one budget and one report (report through HMIS where VL is neglected); (ii) Internal population movement (economic migration, settlement, etc.), refugees moving to the country; (iii) Weak monitoring and evaluation; (iv) Low performance of rapid diagnostic tests (RDTs) and low efficacy of antileishmanial medicines for HIV–VL coinfection; (v) VL disease spread to new localities; (vi) No well-established vector control measures; (vii) Lack of sufficient information on vector/vector behaviour

Plan of action July–December 2017

- Strengthen disease surveillance
- Distribute monitoring and evaluation (M&E) tools
- Facilitate the procurement and utilization of quality-assured VL supplies
- Plan until December: train NTD/Leishmania programme managers in VL endemic regions and train health care workers (HCWs) on VL case management
- Supportive supervision
KENYA
Dr Wachira Davis Wacheru

Background & epidemiology

2500 VL cases occur annually, while 5 million people are at risk of infection. VL mainly affects children aged > 2 years and young adults.

VL is endemic in semi-arid and arid areas of Rift Valley, Eastern and North-Eastern regions of Kenya.

Six counties are known to be endemic: Baringo, Isiolo, Turkana, Marsabit, Pokot and Wajir.

In Marsabit, an outbreak has been declared since March 2017, with 63 VL cases reported, mostly from Bubisa and Shurr.

In Wajir, 98 cases (CFR: 3.06%) have been reported since January 2017, the majority being children aged < 5 years (associated with drought in those areas).

In Turkana, FIND has partnered with MOH to improve diagnosis and management of VL.

In Isiolo, due to lack of diagnosis test kits cases, cases are being referred to Wajir county.

Baringo and Pokot-Kacheliba are reporting a few PKDL cases in addition to VL.

Screening & diagnosis
Diagnosis was mainly by rapid diagnostic kits (rK39) except in Kacheliba and Kimalel where splenic aspirate is carried out (with DNDi support).

Treatment
Main treatment is combination therapy with SSG plus paromomycin. However, some still use SSG as a monotherapy. Use of IRS has been at small scale, with low coverage. In 2016, Gilgil and Kipipiri sub-counties implemented control activities related to vectors of CL.

Vector control
Research on vectors is being carried out by ICIPE and the University of Nairobi (UON).

Surveillance
Active case detection is not carried out, being passive surveillance used in VL.

A record officer was trained on selection of leishmaniasis surveillance indicators and training of trainers (TOT) conducted on the use of DHIS2 tracker for individual and aggregate data entry.

Roll out of the system (DHIS2) at national level is planned for July 2017.

Challenges
- Frequent shortages of kits and drugs depending on county
- Government slow to embrace management of VL as its responsibility
- Few health workers have been trained on diagnosis and case management, coupled with high staff movement within or outside the endemic areas
- Frequent VL outbreaks associated with shortages of kits and drugs and a weak health infrastructure
- Weak surveillance and reporting system
- The current prolonged droughts in some northern parts of the country have left many people malnourished and weak, making them susceptible to VL and other infections.

Plan of action July–December 2017
- Launch the national guidelines for VL
- Train health staff on the use of DHIS2 tracker for individual and aggregate data entry
- Improve case management by training health workers on VL
- Present the draft guidelines on diagnosis and management of CL to stakeholders
- Support VC activities
- Support scaling up of awareness creation in communities, as in some areas it is very low
UGANDA
Dr Martin Mayanja

Background & epidemiology
Uganda (Karamoja region endemic for VL in red)
The most affected age group is 5–14 years (61%), followed by ≥ 15 years (33%); the least affected are those aged 0–4 years (6%).

Screening & diagnosis
Development of diagnostic and treatment guidelines (WHO, DNDi, etc.) with WHO financial and technical support.
Diagnosis in Amudat hospital: All suspected cases are screened using RDTs and all positive results are confirmed by parasitological testing. DAT is used for negative suspected VL. During 2016 until April 2017, out of a total of 445 suspected VL cases, 175 were actively screened by RDTs and 86 VL cases were found (49%) and 270 cases through passive screening, with 78 VL positive (28%). 124 cases were positive confirmed by parasitology and only 2 cases by DAT. The ratio male:female VL cases in Uganda is 4:1 (79% and 21% respectively).

Treatment
Out of 138 cases treated during the period 2016–April 2017, 13% received AmBisome and the rest (87%) combination therapy with SSG plus paromomycin.
Outcome: 94% cured with 8% relapses

Surveillance
Capacity building of VL and HMIS staff to improve data collection and reporting (WHO, HISP and DNDi). MOH has developed data collection tools for use at all levels to enhance reporting of monthly VL data (feed directly into the central HMIS)
VL outpatient and inpatient registers are available; VL monthly reporting forms are based at the health facilities in the endemic districts. Plans are under way to train data personnel in the resource centre and endemic districts on the new VL indicators.

Challenges
(i) Government support and ownership for sustainability; (ii) Magnitude and endemicity of the disease is not clearly known, resulting in underreporting; (iii) No existing budget to support programme operations at the centre; (iv) Access to diagnosis and treatment: only one treatment centre for the whole region may contribute to poor health-seeking behaviour; (v) Hard-to-reach areas without appropriate means of transport; (vi) Data reporting: timeliness, completeness and validation; (vii) Active case detection, although done, is still weak; (viii) Low awareness about VL among leaders and health workers for increased case referral to treatment centre.

Plan of action July–December 2017
- Convene workshop to implement VL surveillance through national DHIS2 online tool (WHO and DND)
- Review HMIS for VL indicators as well as WHO–VL indicators (WHO)
- Develop an addendum for VL reporting and primary data collection tools (WHO)
- Train HMIS staff on the developed VL monitoring tools
- Review and verify data quarterly
- Conduct an epidemiological survey to define geographical extension of the endemic area in order to scale up control activities
- Print, launch and disseminate the new national VL guidelines, including training of clinicians
- Convene taskforce meetings/NTD technical committee meetings
- Conduct advocacy and sensitization of district and sub-county leaders in Amudat and Moroto districts
Background & epidemiology

VL (kala-azar) in Sudan based on cases reported from 36 treatment centres. Cases are attributed to a population of 100,000.

Around 3000 cases have occurred annually in the past 5 years (2016: 3810, 2013: 2370); Sudan has a population of 37,419,625 that includes 88% settles, 32.7% urban, 8% nomads and 6% displaced. Most cases are males (71%) aged ≥14 years (55%); 19% are aged <5 years and 26% aged 5–14 years.

CFR: 2.8% in 2016 (1.47% up to April 2017)

Cure rate: 89% (4% relapses)

PKDL (post-kala-azar dermal leishmaniasis): 5%

Currently 36 treatment sites in the country.

Screening & diagnosis

Most of the VL cases are diagnosed through rK39 test (79%) versus 18% through lymph node aspiration, 2% DAT and only 1% bone marrow aspiration.

Treatment

Main treatment is SSG plus paromomycin combination therapy.

Vector control

IRS in 2 states, bednet distribution

Research is ongoing, led from KalaCORE fund, to develop innovative, sustainable and acceptable methods for vector control and prevention of transmission (impact of different control and personal protective measurements).

Surveillance

A DHIS2 workshop with the HMIS Directorate and WHO was conducted in February 2017.

Design format for DHIS2 and variables are ongoing; Training of the central team – printing the format; Customization of the variables to be started; Data collection will be aggregated by month

Reporting rate: 100% (but in most cases not timely)

Completeness rate: 76%

Data quality system is proposed to be through mentoring teams

Challenges

(i) CL is emerging as a major problem, guidance for clinical management included in the “Manual for diagnosis and treatment of leishmaniasis”, last version 2017; (ii) Sanctions are hampering importation of rK39 Bio-Rad – rK28; (iii) Delays in procurement, clearance and distribution; (iv) Accessibility challenges, wide distribution of the VL centre and emergence of new foci; (v) Reporting system – DHIS2; (vi) Turnover – training mentoring team; (vii) Delay of some activities due to length of administrative issues within WHO (contract signing with partner institutions); (viii) Sustainability after 2018?

Plan of action July–December 2017

- Provide medical training, health education, rehabilitation, research, surveillance, mentoring team, retrospective data collection, strengthening supply and management chain
- Refurbish health facilities
- Provide training on HIV diagnosis
- Conduct retrospective data collection
- Introduce VL in the university curriculum
- Implement hot line approach
During 2016 until April 2017, of 601 patients screened and suspected of VL, 408 were diagnosed (excellent positivity rate, 67%). Some 47% of these cases were among children aged < 5 years; 41% were aged 5–14 years and 12% aged > 14 years. Treatment provided: SSG plus paromomycin combination therapy for 17 days. Most of the patients were cured (93%) with a CFR of 4% and 3% defaulters. Vector control activities are limited to a few patients receiving ITNs. WHO donates leishmaniasis medical supplies and also provides support for training. Activities needing better support are mapping, IEC/BCC and entomological research for better vector control.

Treatment
There are two treatment sites in Somalia: Baidoa and Mogadishu. The main partners are WHO and DNDi. VL patients were screened with the rK39 test. A total of 2108 suspected VL cases were screened during the 4-year period 2013–2016, of whom 1373 tested positive for VL by serology. The positivity rate increased thereafter from 56% in 2013 to 71% in 2016. During 2017 (January–April), of the 601 VL suspects who were screened, 408 tested positive. The cases ranged in age from < 5 years (47%); 5–14 years (41%); and > 14 (12%). Combination therapy with SSG plus paromomycin was provided to the patients for 17 days. The treatment outcomes were cure (93%), default (3%) and death (4%).

Vector control
The unique strategy used for vector control involved the limited use of ITNs. During the reporting period, WHO provided support for diagnostic tests, anti-leishmanial drugs and training. There is a need for more support from WHO for other activities, mapping disease burden, additional funding, vector control (research vector characteristics), training and health education related activities.

Challenges
Challenges mentioned in the Somalia context include referral for inpatient care, vector control, health education, follow up of cases treated for VL and other competing priorities (e.g. acute malnutrition, acute watery diarrhoea and measles, among others).

Plan of action July–December 2017
- Continue the combination therapy regimen
- Develop IEC materials and BCC
- Train and mobilize communities for case detection
5. RESEARCH ACTIVITIES FOR DISEASE CONTROL

5.1 LEAP: contributing to strengthening clinical trial capacity, treatment and control of VL in eastern Africa
Dr Monique Wassuna

Dr Wassuna refreshed the audience on the objectives of the Leishmaniasis East Africa Platform (LEAP).

Ongoing studies, 2016–2017: (i) miltefosine pharmacokinetics, phase II study, 30 people enrolled; (ii) miltefosine–PM: plan for 2017 (phase III), to enrol 546 subjects; (iii) efficacy assessment (D29 and D58): AmBisome alone (59% efficacy) versus AmBisome–miltefosine (91% efficacy)

Future clinical research in 2017:
• PM–miltefosine phase III – planned to start Q3 2017
• PKDL study – planned to start Q3 2017
• HIV–VL coinfection cohort – Q4 2017
• PKDL infectivity study
• Explore CL studies
• New chemical entities in near future

After 13 years of LEAP, a group of scientists has been built, with infrastructure and experience to conduct high-quality studies through the successes and failures of the safety and efficacy studies:
• First treatment delivered (current first-line VL treatment in eastern Africa is SSG plus paromomycin). Potential second treatment delivered (HIV–VL)
• Paediatric dosing of miltefosine is better understood
• Capacity for phase II–IV studies has been developed
• Methods of pharmacokinetics and pharmacodynamics are continuously being improved
• Data management capacity has been built and is available
• The clinical trial study design has been reviewed

Lessons learnt have been used to plan studies in 2017 and will be used for studies on new chemical entities and foreseeable phase I studies.

5.2 DNDi research activities in Eastern Africa
Dr Fabiana Alvès

Dr Alvès explained the big challenge of treatments for VL working in Asia that are not working in Africa. Examples include the efficacy of AmBisome single dose (10 mg/kg) in Asia (≥ 95%) versus East Africa (58%) and paromomycin (15 mg/kg per day for 21 days) in Asia (94.6%) versus Africa (63.8%). Finally, the efficacy of AmBisome miltefosine in clinical trials was > 97% in Asia vs 77% in Africa. This difference was related to the underestimated dosage in children, as the distribution and pharmacokinetics of the drug are different than in adults. A study is planned for 2017-early 2018 as a phase II non-comparative, open-label clinical trial to assess the pharmacokinetics and safety of miltefosine allometric dose in the treatment of children with primary VL in East Africa.

A miltefosine pharmacokinetics (phase II) study was conducted in 2016 in Kacheliba, Kenya and Amudat, Uganda. The sample of 30 patients (children) showed a final cure rate of 90% at 6 months follow-up and 3 failures; “The allometric dose was an appropriate approach to improve efficacy, while keeping a good safety profile.”
To improve current treatments for patients coinfected with HIV and VL, a clinical trial to assess the combination of AmBisome plus miltefosine and AmBisome alone will be conducted in Ethiopia.

To reduce toxicity and costs of treatment, a study will be conducted in non-HIV VL patients to compare the efficacy of two combination regimens of paromomycin (14 days) and miltefosine (14 or 28 days) with the standard 17-day course of SSG plus paromomycin for the treatment of primary VL patients in eastern Africa.

For PKDL patients, there is a “need for safer, efficacious and field adapted alternative treatments”. The main gaps in knowledge are related to infectivity, pathogenesis, treatment optimization and drug skin penetration. A new study in Sudan will start in Q3 2017: paromomycin (intramuscular) for 14 days and oral miltefosine (allometric dosing) for 42 days, and AmBisome over 7 days and oral miltefosine for 28 days (allometric dosing).

Since 2016, progress has been achieved using new chemical entities, with 10 entering pre-clinical development.

The plan for 2024–2025 is to introduce new oral, high efficacy and affordable drug combinations for the leishmaniases, a new oral treatment for VL and/or CL, and an immune modulator for CL.

### 5.3 FIND leishmaniasis projects in Eastern Africa

**Dr Isra Cruz**

Dr Cruz noted that gaps in VL diagnostics remain, especially in eastern Africa, where the performance of rK39 RDTs is low and the high HIV coinfection rate makes the diagnosis difficult with antibody detection tests.

In an online survey conducted, the top four priorities in leishmaniasis diagnosis identified by experts were: (i) an RDT for VL with good performance across regions and in HIV1 patients; (ii) An RDT for dermal leishmaniasis (including PKDL); (iii) a test of cure/treatment monitoring for VL; and (iv) strategies to improve access to early diagnosis.

Activities to address the priorities:

- Development of an antigen detection test against different leishmanial species.
- FIND has developed point-of-care tests for *Leishmania* DNA detection in peripheral blood and antigen detection in urine, which can be used for less invasive confirmation of *Leishmania* infection in VL cases at district hospital/microscopy laboratory level, thus avoiding the use of more invasive approaches such as spleen aspirate microscopy. Evaluation of rK39 and rK28 RDT in Kenya and Sudan.
- FIND is addressing priorities in leishmaniasis diagnosis by: (i) developing RDTs for *Leishmania* antigen detection that can be used for VL and dermal leishmaniasis diagnosis at the primary health care level; and (ii) improving access to VL diagnosis in Turkana and Wajir, Kenya.
5.4 Operational research for VL in East Pokot, Baringo

Hellen Nyakundi, School of Public Health, University of Nairobi

The University has received support and funding for leishmaniasis from WHO and conducted the following VL control activities:

- received 280 rK39 test kits and procured 316 tests
- received funding of US$ 10 000 (includes VL–HIV co-testing)
- conducted active screening for VL with rK39 test (8 facilities in East Pokot), with 185 suspected screened and 30 positive cases identified (16% positivity rate). HIV testing was done for all VL patients
- developed a VL training manual for community health workers and used it to train 24 such workers in April 2017 in East Pokot
- attended training on DHIS2 VL
- activated a DHIS2 aligned data collection and reporting system (aggregated and individual-based) in Chemolingot
- procured drugs to kick start treatment at Chemolingot Hospital and provided support to hire staff to manage VL at Chemolingot Hospital

The team also conducted VC activities, including the destruction of inactive termite hills and smoothing cracked walls in 12 villages.

Collaboration with ICIPE and KEMRI in entomology survey (CDC light traps and sticky papers, > 5000 sand flies captured, sand fly processing and identification).

Conducted health education forums in 9 village centres, 4 primary schools and 2 secondary schools, distributed banners, posters, leaflets and T-shirts.

Challenges encountered: insecurity, remoteness, poor health systems infrastructure, lack of human resources, poor health-seeking behaviour.

5.5 Training and research priorities for leishmaniasis elimination

Dr Paul Ngewa, Director of Institute of Tropical Health, Navarra University, Spain

The Institute investigates tropical infections, in collaboration with research centres, universities and hospitals located in endemic countries. The aim is to transfer knowledge and technology, train researchers and cooperate; the scientific collaboration network includes medical research centres and universities in 25 countries, as well as international organizations.

Related with leishmaniasis, the Institute carries out activities in the fields of new formulations (studies with nanoparticles, topical formulations for CL), pharmacotherapy, molecular diagnosis, pathogen immunology, proteomics, genomics, bioinformatics, etc.). In addition to research there is a training component conducted in African countries.

The University is open for collaborative projects related to leishmaniasis control in countries.
5.6  **VL control activities in Kenya: progress and challenges**  
Dr Jane Mbui for the Center for Clinical Research (CCR) – KEMRI in collaboration with DNDi

The presentation was restricted to two sites (Kacheliba and Kimalel) for VL treatment that are supported by the institutions.

During 2016, Kacheliba treated 242 VL cases and 6 PKDL cases, while Kimalel treated 128 VL and only 2 PKDL cases. The mortality rate was 0%. Diagnosis is by RDTs and spleen aspiration (both techniques were used in 76% of the cases in Kacheliba and in 49% of the cases in Kimalel). Most of the VL cases (> 93%) received SSG plus paromomycin for 17 days. AmBisome was provided for relapses and for patients aged > 50 years. Supplies are always available through partner support (DNDi) and stock outs of rK39 tests have been only occasional.

DHIS2 will be rolled out later this year (2017) for both sites after successful a pilot project was completed at Kimalel in 2016. Active case-finding with follow-up for 6 months is conducted when there is an ongoing clinical trial.

KEMRI is looking forward to more collaboration in research with partners as they do not have enough funding.

During July-December 2017 both sites will be preparing for a clinical trial. KEMRI staff will supplement county staff at the sites during the study.

5.7  **ICIPE/Kenya: International Centre of Insect Physiology and Ecology**  
Dr Damaris Matoke-Muhia

Accurate knowledge about the distribution of sandfly species and their diversity is fundamental to understanding the epidemiology of leishmaniasis and for vector control.

The centre has conducted screening of vectors, parasite genotyping and blood meal analysis. The vector sampling was guided by health facility reporting from three sites in Marsabit County, Bubisa, Loglogo and Shurr.

Two *Phlebotomus* were identified, *P. martini* and *P. orientalis*, from more than 2500 sandflies catches. Also in East Pokot more than 500 sandflies were trapped / day in 6 villages and the vectors identified were *P. duboscqi*, *P. martini*, *P. sergenti*, *P. ansomerenae*. The main observations found from the study shown that abundant vectors were found outdoors and indoors; *L. tropica* and *L. donovani* from vectors were responsible for CL and VL transmission, respectively; the presence of *P. duboscqi* (a vector of *L. major*) in East Pokot indicates the possibility of CL in this site.

Recommendations provided by the presenter included the need for continuous vector surveillance, for vector control tools indoors and outdoors, and for innovative vector control activities.
6. OTHER PARTNER PRESENTATIONS

6.1 SURVEILLANCE – DHIS2 implementation plan
Dr Raymond Omollo, DNDi

During 2016, a pilot study of the DHIS2 tool was conducted in Kimalel after a two-day training of the staff involved in the process. The database is hosted at the DNDi data centre. Capturing data on patients is easy via DHIS2, and > 100 retrospective patient data were entered into DHIS2 between April and December 2016.

DHIS2 implementation roadmap: DNDi has collaborated with MOH and WHO in the DHIS2 trainings planned in 2017 (June 2016 in Machakos).

The DNDi data collection tool is harmonized with the MOH data collection forms.

A final database has been set up (identical to the WHO VL global database) and reports will be shared with MoH’s and WHO. DNDi plans to roll out DHIS2 across all DNDi clinical trials sites in Ethiopia, Kenya, Sudan and Uganda.

6.2 The KalaCORE Consortium: tackling VL in South Asia and East Africa
Dr Margriet den Boer

KalaCORE is not a direct implementer but a provider of financial and technical support to country-implementing partners. WHO is a key partner of KalaCORE and is involved at all levels. KalaCORE provides support for VL control and elimination in six countries: Ethiopia, South Sudan, Sudan in East Africa and Bangladesh, India and Nepal in Asia.

The main goals of KalaCORE are:

- improving access to prompt diagnosis and effective treatment of VL;
- identifying evidence on where different vector control approaches could be improved and evidence-based new approaches for East Africa; and
- developing capacity for surveillance, monitoring and evaluation and their use to inform plans and respond to emerging outbreaks.

Main activities in Ethiopia and Sudan:

- Providing drugs and diagnostics (this component is now handed over to WHO in Sudan) and nutritional support as part of the treatment (with advocacy for other parties to take over).
- Rehabilitation of treatment facilities.
- Health education, focused on groups at high risk.
- Clinical training, including clinical mentoring, to build capacity.
- Strengthening surveillance and national VL structures.
- Outbreak response preparedness (emergency stocks and support for outbreak investigation protocol).
- Development of innovative, sustainable and acceptable methods for vector control and prevention of transmission.

Activities in South Sudan:

- 35 VL treatment sites received SSG plus paromomycin and rK39 tests, and an additional 29 sites are capacitated for rK39 testing and referral.
• Second-line treatment with AmBisome was introduced in five facilities, and health workers were trained in Juba or in situ by mobile teams who also provided mentoring for clinical services.

Operational research:
A qualitative study entitled *Access to care for migrants in Ethiopia* showed “lack of awareness/money, prioritization of farming activities, inadequate training of health staff and unavailability of diagnostic tests at health centre level were significant barriers to diagnosis and care”. The results will provide recommendations to the control programme for health education and other prevention activities.

Vector control studies:
“novel approaches for control of Phlebotomus orientalis, the principal vector of VL in East Africa”. The studies are being conducted in Sudan and Ethiopia to test different control tools, including permethrin-impregnated sleep-mats and sandfly barriers made of permethrin/transfluthrin impregnated strips of clothing.

Challenges:
The main current challenge is sustainability and handover in 2018. Other challenges are that VL is more widely spread than previously thought, insecurity and nutritional crises, lifting VL out of neglect at all levels and supply difficulties of VL drugs (entire supply chain).
7. GENERAL DISCUSSION

**Medical supplies**

Kenya health management has been decentralized to 7–10 counties, showing poor commitment for the purchase of drugs and diagnostics. The Kenya Medical Supplies Authority (KEMSA) is responsible for distributing the drugs and WHO is linking with them to avoid stock ruptures at treatment sites.

**Surveillance and reporting**

There is a challenge in South Sudan related to reporting from the treatment sites, with 8–12 sites reporting intermittently and thus hampering data completeness. Ethiopia has risk maps for active and passive surveillance, so active surveillance could be implemented instead of waiting for an outbreak to happen.

**Vector control**

Sudan has 106 sites for vector monitoring (sentinel sites) for all vectors, not only sandflies, including 64 sites to monitor pesticides. In Uganda and Kenya, there is very little knowledge about vector control and biology, and effort is needed to improve the knowledge and biology of vectors if control and elimination is to be achieved. The team discussed establishing a regional strategy for vector control studies. *Luzomiya* species were mentioned during some of the presentations. As this species are found only in the Americas, there is a need to revise the capacity for entomology identification by technicians. In Sudan, *P. sergentomiya* is the more prevalent vector.

**Coordination**

Monthly teleconferences with WHO headquarters and countries, including partners, have shown to be very useful to discuss challenges and revise activities, and other countries will be added very soon.

**Outbreak investigation**

There are new localities of VL in Ethiopia, and a need for rapid assessment in Afar where the LST positivity rate is high, 11 children, before 2 weeks, in Sekota (Amhara region) 18 rK39 positive VL cases suspects referred to hospitals (3 are confirmed). Afar, Awash Valley, very well studied before, last year cases in few district, training, plus treatment centre, in Sekota also favourable for sandflies, people are travelling to Humera-Metema for seasonal harvest, high risk area according to risk mapping, treatment center in the area has been established, population movement has been a factor. New cases in Kassala and Red Sea (Sudan), patients are resident and they are going to do investigation.

**Refugees and VL**

In Ethiopia and Sudan, refugees from South Sudan are receiving VL treatment. South Sudan mentioned that health education materials can be used among South Sudan refugees (sharing programme outputs among countries).

**Gender and VL**

Boys in Sudan, aged > 7 years, are working with their fathers in the field, but not girls.
8. WHO PRESENTATIONS

8.1 Surveillance of leishmaniasis: WHO country profiles, 2015
Dr Serene Aimée Joseph

WHO is mandated to monitor the health situation and to assess trends and changes in health in order to provide recommendations on control activities to health ministries and partners and to anticipate treatment needs or better target populations and geographical areas. In addition, data are essential when reporting to donors.

Data at the national level are available on the websites of the WHO Global Health Observatory (http://apps.who.int/gho/data/node.main.NTDLEISH?lang=en) and the WHO Department of Control of Neglected Tropical Diseases (http://www.who.int/gho/neglected_diseases/leishmaniasis/en/). The country profiles contain variables represented by topic, epidemiological data and data on diagnosis and treatment. The key variables include: number of (new) autochthonous VL and CL cases, number of imported VL and CL cases, number of relapses, gender and age distribution, HIV/VL coinfection, diagnosis and treatment type, and treatment outcome.

WHO is updating the 2015 Country profiles (to be published soon) for 26 high-burden countries, focused on the 14 countries for VL and 12 for CL, gathering near to 95% of the new VL cases reported in the 2013 country profiles.

Most of the endemic countries need to improve operational systems to progress in data collection, data quality, data analysis and data sharing and to make proper evidence-based decisions.

8.2 Epidemiological surveillance of leishmaniasis: DHIS2 update and lessons learnt
Dr Serene Aimée Joseph

Global retrospective data are available and have been entered from 1998 to 2015; the data entered prospectively are ready to be used. The possibilities of entering the data by month (aggregate) or by individual patient (tracker) vary and depend on country preferences.

An additional tool has been developed to follow supplies and support on stock management of leishmaniasis medical supplies. Countries reporting actively to the system are Somalia, with data on individual patients collected since 2013, and South Sudan, where weekly and monthly data have been routinely collected since 2012. Countries can choose to use the DHIS2 open base tool for leishmaniasis data and WHO offers support in setting up the system and options of hosting also if needed. The portal allows the data to be shared with partners and links can be provided to other relevant departments such as vector control or the Disease Data Management System.
9. FIELD ACTIVITIES BY NGO TO CONTROL VISCERAL LEISHMANIASIS IN EAST AFRICA

9.1 MSF field activities in Ethiopia, South Sudan and Sudan

Dr Koert Ritmeijer

The MSF VL programme in Ethiopia is mainly at Abdurafi health centre and has been a stable project site since 2003. MSF in Abdurafi is conducting collaborative research with the University of Gondar, DNDi and ITM focusing on HIV–VL co-infection and other complicated VL cases (and snakebites). In Ethiopia, where rates of HIV–VL co-infection are high, 14% of the cases are new HIV infections, while 71% are relapses.

For surveillance, MSF is still using an Excel-based tool to generate patient line-lists and aggregated data, but a new DHIS2 for regular medical data was piloted in Ethiopia this year. Once successful, specific disease modules will be added.

In MSF programmes, most of the patients are diagnosed by rK39 test, others by aspirates and DAT.

MSF operations in South Sudan have been restricted by the civil war and insecurity. In 2016 six MSF operational sites were providing VL care across Jonglei, Upper Nile and Unity. In early 2017 three sites had to be closed due to insecurity and team evacuations.

Vector control is limited to distribution of long-lasting insecticidal nets to patients in East African countries and logistic support to KalaCORE entomological studies.

During 2016 and the first quarter 2017, MSF has treated in Ethiopia 229 VL cases, 17 relapses (6.3%) and 4 PKDL cases; in South Sudan 1995 VL cases, 144 relapses (8.3%) and 20 PKDL cases; and in Sudan (Bazura and Tabarakallah), 948 VL cases, 67 relapses (5.3%) and 28 PKDL cases. In Tabarakallah, up to 44% of the cases presented malnutrition associated with VL (65% of VL cases are aged < 14 years).

The treatment provided is SSG/paromomycin as combination therapy in most of the cases, being AmBisome monotherapy, AmBisome/miltefosine and SSG monotherapy other treatment regimens provided.

Data from 2016 show that cure rates were > 95% in Abdurafi, Jonglei and Upper Nile States, while 81.8% in Kule refugee camp (Gambella), with a high rate of defaulters (9.1%).

9.2 VL control activities: progress and challenges in South Sudan

Duncan Ochol, IMA

Interchurch Medical Assistance (IMA) is implementing the KalaCORE programme in South Sudan. During 2016 and January–April 2017, 3442 VL cases were diagnosed and treated. Combination therapy (SSG plus paromomycin) and AmBisome was provided; no cases were treated with SSG alone because the supply of SSG plus paromomycin from KalaCORE and of AmBisome from WHO was adequate during the period.

Progress has been made to support implementation of the DHIS2 real-time (monthly) online surveillance or compatible forms with the WHO global surveillance programme since April 2016. Data quality is assured through supervision, on-site data verification during field visits by the emergency team, training of health workers on data collection and provision of data collection tools.

Challenges: Access to some locations, especially due to the evolving conflict. IMA monitors the security situation and visits the locations when security allows.

Activities planned until the end of the year are training, finalizing and disseminating the IEC materials, continuing to support the health facilities to provide VL diagnosis and treatment, and conducting annual stakeholders meeting.
10. STATUS OF ACTIVITIES

10.1 CL control activities in Ethiopia: progress and challenges

Dr Abate Mulugeta Beshah

CL is a growing health problem in Ethiopia, with an estimated 20,000 to 40,000 cases per year. The more common vectors transmitting CL are *P. longipes*, *P. pedifer* and *P. sergenti*. CL, the commonest form of leishmaniasis (localized CL/diffuse CL, mucocutaneous leishmaniasis), is endemic mainly in the highlands (1400–3175 masl) with a population at risk of 28 million (risk mapping, recent (2014) published paper2). The parasite involved (*L. aethiopica*) is responsible for >99% of the cases. *L. major* and *L. tropica* are also endemic.

Treatment of CL cases is provided by MOH and ALERT [the Africa Leprosy Rehabilitation and Training Center] (in a few sites in Addis Ababa) and treatment centres in regions (11 centres in 5 regions plus Addis Ababa).

During the five-year period 2011–2016, 2422 CL cases were treated (in 2016, 1049 cases, as the treatment sites were expanded in Amhara).

**ALERT hospital and CL cases:** During 2016, 882 CL cases were treated. From January 2011 to December 2015, 478 CL cases were treated, of whom 80% were aged >15 years, 54% were males and 46% were females. In 87% of cases, the site of the lesion was above the neck and parasitological diagnosis was confirmed in 92% of the cases. Near to 48% of the cases were from Oromiya, 41% from Addis Ababa and the rest from Afar, Dire Dawa, Southern Nations, Nationalities, and Peoples’ Region (SNNPR) and Tigray. The clinical presentation was 70% CL and 30% MCL. The treatment regimen provided was systemic antimonials (44%) and cryotherapy (36%); the rest were treated by intralesional antimonials or combination therapy with cryotherapy. Of the patients, 71% were cured and/or their lesions improved, 26% were not documented and 2% failed treatment.

**CL data from Leishmaniasis treatment centres from MOH:** From January 2016 to February 2017, there were 11 centres in Ethiopia: in Addis Ababa (1), Amhara region (5), Tigray region (1), SNNPR (1) and Somali region (3), most of which are VL treatment centres. A total of 1085 CL cases were passively diagnosed. The diagnosis was clinical plus microscopy from lesion. The demographic characteristics of the patients were males (60%) and females (40%) aged >15 years (79%), 5–14 years (17%) and <5 years (4%). The CL data by address in 2016 are: AA (353), Oromia (325), Amhara (198), SNNPR (101), and the rest from Afar, Harari, Somali and Tigray.

**Challenges:** Lack of resources (financial, trained personnel) to improve access to diagnosis and treatment, lack of tools (point-of-care test, real burden unknown, effective therapy), lack of information and data, and lack of medicines.

**Activities conducted so far:** CL data have been collected to show the number of cases and to advocate support and advocacy for domestic funding. Amhara region procured four cryotherapy machines for CL treatment, while WHO provided support for procurement of medicines, conducted training and provided treatment.

**Needs of the programme:** Adequate resources (financial): training, case management, medicine and surveillance), tools to diagnose and treat, clinical trial required on CL treatment. Plan July–December 2017: train health care providers in hot-spot areas, procure and distribute medicine, treat ~1500 CL cases, strengthen disease surveillance and provide health education to the community.

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10.2 Kenya CL control activities: progress and challenges

Dr Davis Wacheru Wachira

CL is a zoonotic disease in Kenya and people become infected when they visit the forest for other activities. The main animal reservoirs are rocky hyrax, gerbils, rodents and mongoose.

The disease is mainly found in the central Rift Valley. Important transmission foci are in Gilgil and Kipipiri in Nakuru and Nyandarua counties respectively.

Despite the several studies conducted in Gilgil sub-counties since the 1980s, the research findings were not well disseminated to the MOH. No awareness was created in communities, no drugs were available in health facilities, health workers had poor knowledge and understanding about diagnosis and management of the disease, and most cases were treated with herbal medicines.

During 2016, 297 CL cases were treated in Gilgil and Kipipiri sub-counties (30% confirmed parasitological). Cases exist in clusters in villages bordering rocky cliffs infested with the rock hyrax.

Lesions are papules, nodules, ulcers and scars at different stages, affecting mostly the face but sometimes disseminated. Some of the risk factors described are forest activities in people living in the forest-caves including charcoal burning, bee keeping, hunting, fetching firewood, herding, location of households near forest edges and mud houses with many cracks (resting sites). Diagnosis is normally clinical because the parasitological positivity rate is very low (37%). Treatment is with systemic SSG or by-weekly intra-lesional injection of SSG for 12 weeks (0.8 to 3.0 ml).

Main challenges: Low treatment success rate (around 56%), use of monotherapy and high dropout rate with no follow up. Surveillance is very weak and cases are not captured in the DHIS system. Vector control activities have low coverage, with IRS carried out in a few villages and cracked mud houses making it only partially effective. No research has been conducted to guide the application of insecticides. Support for the MOH CL control programme is inadequate, with erratic provision of drugs and other supplies and inadequate means to access the hard-to-reach population.

The activities which need support to make the control programme more comprehensive are: development of diagnosis and treatment guidelines for CL, training of health workers on CL case diagnosis and management, creating community awareness on CL in endemic areas of Gilgil and Kipipiri sub-counties, and development of IEC materials for awareness creation in areas endemic for CL.
10.3 Sudan CL control activities: progress and challenges
Dr Mousab Siddig Elhag

CL is a neglected health problem in Sudan, endemic in various parts of the country, with serious outbreaks occurring periodically. There are little data on its epidemiology, burden, diagnosis and case management, and no structured control programme.

CL is reported in many areas of Sudan with four major outbreaks reported: (i) in 1976–1977 in River Nile; (ii) in 1985 in White Nile, (iii) in Khartoum State, with about 10 000 recorded cases during 1985–1987; and (iv) in South Kordofan in 2014 with 718 cases.

The causative parasite for CL in Sudan is *L. major* (El Hassan and Zijlstra, 2001) and *L. donovani* (Elamin et al 2008). The vector of *L. major* is *P. papatasi* while the vector for *L. donovani* is *P. orientalis* and *P. martini*. In 2014 there were 1053 cases reported, 3503 in 2015, and 3011 in 2016. From January to March 2017, 96 cases were reported.

**Challenges** of the CL control programme:

- Inadequate capacity of the surveillance system, with incomplete data collection and reporting.
- Absence of international recommendations on CL management for Africa, and a lack of evidence-based protocols for control interventions against sandflies and mammalian reservoirs.
- Patients affected by CL cannot access medical care as services are often limited and lack adequate infrastructure, particularly at the primary health care level; health workers are not trained.

**Planned activities until the end of 2017 include**: dissemination of the case definition and case suspect; integration of CL surveillance within the national integrated disease surveillance and response systems; developing and implementing a common monitoring and evaluation framework; tracking the spread of the disease, identification of outbreaks and rapid response; developing national guidelines on case management with recommendations for effective first-line treatment; and development of tools for health education and advocacy.
11. GENERAL DISCUSSION

The following issues arose from the general discussion.

The selection of the time of the studies conducted was between September, October, February and March to see if sandflies fed more in human blood and to assess any differences between indoors/outdoors and animals in the study. ICIPE is studying vector competence and establishing a colony and insectary in the field during the wet and dry period. Challenges include bar coding, finding primers, and the timing of selection depending on the cases, etc. Analysis of blood meals both outdoors and indoors, sandflies feeding on human, animals in the area (camels and sheep and goat) was not studied. There is a need to put funding aside for training (taxonomists are very few in Kenya). After the Marsabit outbreak, *P. orientalis* was identified but had not been reported before; it probably was not there. It is hypothesized that vectors flowed from another area as the density of *P. orientalis* found was very high. The ICIPE team is willing to support vector control activities from the control programme if there is funding for the country.

There is a need to establish effective data mechanisms from research projects to feed into the national control programme and WHO. In Ethiopia, this is done regularly by MSF, AAU (Addis Ababa University) and DNDi, despite there has been an inadequate link between the VL programme and the vector control department.

WHO publishes what has been reported to WHO, including under-reporting. There is a need to harmonize how data will be sent from DHIS partners to MOH/national control programme. Mapping of cases and health infrastructures is not finalized in Kenya.

Each country will be able to access DHIS stock from health facilities, as WHO donates AmBisome and other antileishmanial drugs; data need to be entered every month. DNDi has spent two years working on the tracker to be integrated with WHO and partners, and it needs to be only one system, with clinical trial data completely separated from DHIS2 (and shared at the end of the trial). Sudan team: “We need to have a buffer stock also at country level to address delays in customs, importation, etc.”

AmBisome in Kenya is used only by DNDi; procuring paromomycin and AmBisome (for high-risk groups) and SSG by the national control programme are problems. A task force or working group needs to be established, especially in Kenya and Uganda, where fewer cases occur and they are partner dependent.

The emergency stock at WHO is for all the world based on data foreseen. There is not a huge emergency stock for the East Africa region, so countries need to forecast and request for the year instead of using the emergency stock for regular supply. WHO headquarters sends funding to WHO country offices to procure directly or jointly from WHO Kuala Lumpur.

Active case detection in South Sudan during the outbreaks is cost efficient as very infected villages might be very remote. MSF actively detects cases rather than waiting for patients to go to the treatment sites.

The KalaCORE M&E study shows a large economic burden on VL patients. MSF provides treatment free of charge, so patients are going to their MSF site for free treatment. MSF continues advocating for free prescriptions for these very poor patients.

Ethiopia has a lack of supplies for treating patients, as most of the medical supplies go for VL; capacities to treat and diagnose CL are in the country. In East Africa in general, maps and figures of the disease are not available, and knowledge about species is lacking in some areas where there is also no treatment that works for these patients and there is no mandate by the World Health Resolution to pledge for money for affected Member States. The approach for CL must be regional, mapping has to be completed, clinical trials according to species must be conducted and the control programme needs to be established as the VL programme.
12. RECOMMENDATIONS
FROM WORKING GROUPS

12.1 Group work

The general comments of the group work are summarized by topic below.

Status of DHIS2 in countries. Kenya has aggregated and patient-based monthly data because WHO, DNDi and the Kenya MOH have sat together with partners and harmonized them: “A good system is the one that can support the needs of all the partners and MOH”. Sudan has agreed to set up DHIS2 for leishmaniasis through monthly aggregated data from treatment sites. The data will be collected in hard copy and entered in the States in DHIS. Ethiopia MOH has approved DHIS2 in the country and the system will start the set-up process from July 2017; variables and modality (individual or aggregated data) are under discussion. Somalia people were trained on DHIS2 (Uganda, in total 20 people trained from 3 sites), but MOH/HMIS people need to be trained. Variables and a form are in place and have been agreed by the MOH, and WHO is hosting these data in Geneva: “WHO has no problem if a country has its own server for DHIS2, but in the meantime, data can be hosted in the WHO server; also IT support can be provided”.

As a region there is no target for control or elimination, so a working group of 10 people needs to be created to identify a clear target to be presented as the objective from the region. Countries affected by leishmaniasis, especially VL, share the same control strategies, the same challenges, and similar solutions will be stronger if tackled as a group, also to pledge for funding. An agreement could be used for this purpose. Regular teleconference calls are taking place monthly between WHO headquarters, regions and countries including the MOH and partners, but must involve the Regional Office for Africa more frequently.

The impact of CL in the lives of patients suffering from this skin condition is devastating. An existing tool, the Dermatology Life Quality Index or DLQI, developed in 1994, was the first dermatology-specific quality of life instrument. This simple, 10-question validated questionnaire has been used in over 40 different skin conditions in over 80 countries and is available in over 90 languages. http://sites.cardiff.ac.uk/dermatology/quality-of-life/dermatology-quality-of-life-index-dlqi/

WHO could be involved as actors for CL control in East Africa, as the Organization is already conducting activities at global level. For example, the team could be involved in the discussion for the position paper and the DLQI study from partners treated in the field, in generating maps related to availability of funds and time (literature review), for species identification using the WHO Reference laboratory that will do the molecular testing. WHO involvement in entomology is to be decided. LAMB has been done in Afghanistan, Sudan (IED) and Suriname. Also to be decided is whether an App/Atlas (integrated management skin NTD scan) can be provided by an organization from the Netherlands, to study barriers. The skin test LST Institute Pasteur in Teheran may be supported to go to the GMP process. Other options are being explored, including whether companies producing vaccines of canine VL could produce the LST, or whether someone in the region that has laboratory capacity could do so. The CL network was created by WHO for countries in North Africa, the Middle East and Central Asia. Because the network is tackling a different epidemiological and clinical types of diseases, it was considered more pertinent for programmatic purposes to include the East Africa CL in the same meeting where VL is discussed for this sub-region. WHO is organizing online courses on CL in collaboration with the Open University of Catalonia (http://www.oceu.edu/portal/en/index.html) for the Old World and with PAHO for the New World. (The Ethiopian Public Health Institute is interested in producing LST but need support.) A systematic review of existing literature is pending to identify who will do it.

Online platform exists from WHO for CL.
12.2 Recommendations from Working Groups

Three working groups were agreed upon on the second day of the meeting. Discussions started the third day after the presentations and were participative, enthusiastic and fruitful. Outcomes from these are summarized below.

All six countries outlined three areas: (i) status of surveillance and data (DHIS2) and reporting; (ii) issues and challenges facing the adoption of VL (DHIS2) reporting; and (iii) a set of possible solutions or recommendations to overcome the challenges.

- **Status** update shows that all countries report VL data but these data are uneven across countries, implementing partners and facilities/sites providing VL services. WHO’s proposed VL reporting tools (Excel) have been adopted by all countries and DHIS2 is in place in some countries and under way in others. Countries have taken concrete steps towards implementation of the DHIS2, including partner meetings, agreement on WHO global control programme variables and development of additional country variables, training and piloting. *Countries have planned or are moving to implementation starting in July 2017.*

- **Challenges** reported are technical (personnel, variables consensus also with partners, training), infrastructural (electricity, connectivity, needed for DHIS2) and ecological (accessibility, rainfall, insecurity).

- **Recommendations** concern innovations in the following areas: (i) *data capture and recording* (using Excel in remote areas with inadequate network and patient files as source documents so that summaries are then transferred into the DHIS2); (ii) *repository systems* (uploading into the WHO database to later be transferred to countries’ MOHs when their own systems are ready); and (iii) *personnel* (employing and training data managers at various levels from MOH downwards; training a pool of health workers at sites to forestall attrition; sending local health records persons to VL sites to input the data in laptops that are then uploaded in the databases); (iv) *the specific VL DHIS2 tool* should be agreed by all in-country partners (with MOH ownership for sustainability); and in addition (v) *piloting* for the specific VL DHIS2 tool is recommended so that issues emanating can be addressed before full roll-out in all sites.

Six issue areas were raised in this working group: coordination, training and support supervision, procurement and supply chain, cross-border meetings, outbreak investigation, and awareness (IEC [information, education, communication] and BCC [behaviour change communication]). The discussions raised various issues on each area as well as the way forward, while identifying responsible persons to carry out the proposed or desired action. A summary of these areas and recommendations follows.

- **Coordination:** Poor coordination among stakeholders, infrequent coordination meetings, poor information-sharing and poor communication equipment were observed as current coordination shortcomings. **Recommendations** to overcome these are for (i) frequent leishmaniasis task force meetings, (ii) an annual NTD-leishmaniasis review meeting, (iii) improved communication by providing or supporting Internet services and connectivity. **Responsible parties** are the national VL–leishmaniasis programme manager, WHO and other partners.

- **Training and support supervision:** There are no unified or standardized training guides or manuals for VL but several partners use their own training material. Another issue was standalone supervision. **Recommendations** are (i) to develop a training guide or manual under the umbrella of WHO, (ii) support training of health personnel on the use of the manual and (iii) for supervision, to access the integrated support supervision
checklist developed by the WHO Regional Office for Africa on the WHO website. **Responsibility:** It is recommended that WHO review, gather and endorse the training manuals prepared by KalaCORE and other partners and publish them for use by countries on the WHO headquarters’ website.

**Procurement and supply chain:** WHO often provides funding through the WHO country offices for them to purchase the medical supplies and this is donated to the MOH for the leishmaniasis programme. There is lack of drugs and diagnostics, especially in Kenya, mainly due to inadequate capacity on timely forecasting and purchasing or even requests, although funding is available from WHO. The process of procurement is long, especially for exemption issues (especially for Kenya). **Recommendations** are: (i) in Kenya, KEMSA to stock SSG but assurance is needed from the government that the drugs will be bought (by counties); (ii) WHO to support the MOH to procure regular medicine and diagnostics supply for VL; (iii) WHO to procure and maintain a buffer stock for 1000 patients for the whole of East Africa in case of stock rupture or outbreak (WHO has the mentioned stock for the global leishmaniasis control and elimination programmes, handled by Geneva). **Responsible persons** are: MOH and pharmaceuticals, WHO Leishmaniasis programme leader (José A. Ruiz-Postigo), KalaCORE HQ (Margriet den Boer/MML) and WHO, MOH and partners.

**Cross border meeting:** Coordination is lacking among the VL countries in the region. In addition, countries lack VL diagnosis and treatment for refugees, especially in Kenya and Uganda (in Ethiopia support is provided by MSF). **Recommendations** are: (i) countries to make a resolution that the MOH (Minister) to include VL in the health budget; (ii) generate evidence to present to the Minister (for health) in the form of facts sheet; (ii) countries need to set a (joint) target to reduce the burden due to VL; (iv) countries without services for refugees should consider providing VL awareness and diagnostic services for these populations. **Responsibility:** to be shared by a group composed of 10 people, 60% MOH, 20% WHO and 20% partners.

**Outbreak investigation:** There is no outbreak assessment tool to investigate an outbreak. **Recommendations** are: (i) individual countries to develop a protocol for outbreak assessment with WHO support. **Responsible persons** are WHO, MOH and partners.

**Awareness (IEC and BCC):** Awareness and availability of activities and IEC materials for VL are scarce. **Recommendations** are: (i) to support the development of VL IEC materials and awareness activities, and (ii) to share existing materials (which can be adapted from one country to another). **Responsibility** for this lies with partners, WHO and MOH.

The CL group was prompted by three presentations on the disease in Ethiopia, Kenya and Sudan. It emerged that CL presents a substantive and unique problem and is severely neglected in the work on leishmaniasis. The group raised five issues: advocacy, epidemiology, diagnostics, case management, and access. Action points were raised for each issue. Responsible persons/institutions and timelines were not indicated. **Actions/recommendations** for each of the issues included the following:

- **Advocacy:** There is a need to raise donors’ and government awareness on the problem of CL in eastern Africa, which can be done through position papers (or policy briefs). A CL coalition is also proposed that is perhaps beyond eastern Africa.

- **Epidemiology:** Basic maps of CL distribution are needed. A review of existing published and grey literature is also needed. Studies on human disease and vector distribution and risk factors including environmental (and behavioral) factors are needed.
• **Diagnostics:** It is crucial to improve existing diagnostics and develop new ones, e.g. microscopy, and implementation of LAMP\(^3\) and LST. Diagnostics need to be tested and validated in the field.

• **Case management:** There is a need to conduct robust clinical trials (e.g. for *L. tropica* and *L. aethiopica*) to recommend case management. Trials would provide treatment monitoring and documentation. New chemical entities (?) are needed and an application or Atlas (on integrated management of skin NTDs) could be valuable. Guidelines should follow the WHO Technical Report Series No. 949 (blue book) on control of the leishmaniases and the manual published by the WHO Eastern Mediterranean Regional Office.

The WHO Global Leishmaniasis Programme has developed the fourth edition of the CL interactive online course and the first edition of the skin NTD course co-organized by the Catalan Open University (UOC) and WHO ([http://studies.uoc.edu/en/postgraduate-courses/health-sciences/skin-diseases/presentation](http://studies.uoc.edu/en/postgraduate-courses/health-sciences/skin-diseases/presentation)).

• **Access:** An assessment of health-seeking behaviour and costs of diagnostics and treatment (and availability) in countries is needed to determine access issues and barriers. This also calls for the development of effective forecasting and surveillance systems.

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\(^3\) Loop-mediated isothermal amplification (LAMP) is a novel molecular method for rapid DNA target amplification with high specificity in isothermal conditions. LAMP provides a simple and rapid diagnostic tool for early detection and species-specific identification.
# AGENDA

## ANNEXE 1

### Day 1: Monday 12 June 2017

<table>
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<tr>
<th>TIME</th>
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<tr>
<td>08:30–09:00</td>
<td>Registration</td>
<td>Participants</td>
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<tr>
<td>09:00–09:30</td>
<td>Opening session</td>
<td>WR Kenya, Director of Medical Services, MoH Kenya, Dr J.A. Ruiz Postigo</td>
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<tr>
<td>09:30–09:40</td>
<td>Leishmaniasis control and surveillance: progress and perspectives</td>
<td>Dr J.A. Ruiz Postigo</td>
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<td>09:40–09:50</td>
<td>Leishmaniasis control and surveillance in the WHO African Region</td>
<td>Dr A. Onyeze</td>
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<tr>
<td>09:50–10:00</td>
<td>Leishmaniasis control and surveillance in the WHO Eastern Mediterranean Region</td>
<td>Dr A. Gabrielli</td>
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<td>10:00–10:20</td>
<td>WHO African Region countries (10’ each): Progress in and challenges to the implementation of visceral leishmaniasis control activities, surveillance and plans: Ethiopia, Kenya</td>
<td>MoH Ethiopia, MoH Kenya</td>
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<td>10:20–10:50</td>
<td>Coffee break</td>
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<td>10:50–11:10</td>
<td>WHO African Region countries (cont.) (10’ each): South Sudan, Uganda</td>
<td>MoH South Sudan, MoH Uganda</td>
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<td>11:10–11:30</td>
<td>Discussion</td>
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<td>11:30–11:50</td>
<td>WHO Eastern Mediterranean Region countries (10’ each): Progress in and challenges to the implementation of visceral leishmaniasis control activities, surveillance and plans: Somalia, Sudan</td>
<td>MoH Somalia, MoH Sudan</td>
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<td>11:50–12:10</td>
<td>Discussion</td>
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<td>Lunch break</td>
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<tr>
<td>13:10–13:50</td>
<td>Research activities for disease control (10’ each): Leishmaniasis East Africa Platform-LEAP activities &amp; plans, Makerere University, Uganda, DNDi research activities in East Africa, FIND projects in East Africa</td>
<td>Dr M. Wasunna, Prof J. Olobo, Dr F. Alves, Dr I. Cruz / Prof J. Ndungu</td>
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<td>13:50–14:05</td>
<td>Discussion</td>
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<tr>
<td>14:05–14:45</td>
<td>Research activities for disease control (10’ each): NE university / Izumi foundation / UoN, Institute of Tropical Medicine, University of Navarra, KEMRI/Kenya, ICIPE/Kenya</td>
<td>Dr R. Wamai/ Ms H. Nyakundi, Dr P. Nguewa, Dr J. Mbui, Dr D. Matoke</td>
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<td>14:45–15:00</td>
<td>Discussion</td>
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<td>15:00–15:30</td>
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<td>15:30–15:40</td>
<td>KalaCORE consortium – East Africa (10’): Progress, challenges and plans</td>
<td>KC Consortium</td>
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<td>15:40–15:50</td>
<td>Discussion</td>
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<td>15:50–16:10</td>
<td>WHO 2015 country profiles (20’): Results from 2015 data and comparison with 2014</td>
<td>Dr S. Joseph, WHO</td>
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<tr>
<td>16:10–16:40</td>
<td>Epidemiological surveillance (15’ each): DHIS2: updates on aggregated, patient-based data and reporting, DHIS2: updates field implementation</td>
<td>Dr S. Joseph, WHO, Dr R. Omollo, DNDi</td>
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<td>16:40–17:00</td>
<td>Discussion and end of the day</td>
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### Day 2: Tuesday 13 June 2017

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<td>09:00–09:30</td>
<td>Lessons learnt from historical data import from Somalia and South Sudan</td>
<td>Dr S. Joseph, WHO</td>
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<td>Discussion</td>
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<td>09:30–10:30</td>
<td>NGOs VL field activities update (10’ each):</td>
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<td>MSF Ethiopia</td>
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<td>Discussion</td>
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<td>10:30–11:00</td>
<td>Coffee break</td>
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<tr>
<td>11:00–11:30</td>
<td>Progress in and challenges to the implementation of cutaneous leishmaniasis control activities, surveillance and plans: Ethiopia, Kenya, Sudan</td>
<td>MoH Ethiopia, MoH Kenya</td>
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<td>Discussion</td>
<td>MoH Sudan</td>
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<td>11:30–12:00</td>
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<td>12:00–13:00</td>
<td>Lunch break</td>
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<tr>
<td>13:00–15:30</td>
<td>Introduction and guide to group work:</td>
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<tr>
<td></td>
<td>• Data sharing/information use: surveillance data/DHIS2</td>
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<td></td>
<td>• Tackling implementation issues of control activities</td>
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<td>15:30–16:00</td>
<td>Coffee break</td>
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<tr>
<td>16:00–17:00</td>
<td>Group discussion wrap up and preparation for plenary presentation</td>
<td>Groups</td>
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### Day 3: Wednesday 14 June 2017

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<td>09:00–10:00</td>
<td>Group presentations</td>
<td>Group rapporteur</td>
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<td>Coffee break</td>
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<td>10:30–11:30</td>
<td>Plenary discussion on the group presentations</td>
<td>All participants</td>
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<td>11:30–11:50</td>
<td>Recommendations and Wrap up</td>
<td>MoH, WHO</td>
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<tr>
<td>11:50–12:00</td>
<td>Closing remarks</td>
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<td>12:00–13:00</td>
<td>Lunch break</td>
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<td>13:00–17:00</td>
<td>MOH–WHO–partners side-by-side meetings (45’ each):</td>
<td>All participants</td>
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<td>Ethiopia, Somalia, South Sudan, Sudan and Uganda</td>
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# LIST OF PARTICIPANTS

## ANNEXE 2

<table>
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<tr>
<th>Name</th>
<th>Position</th>
<th>Contact Information</th>
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<tbody>
<tr>
<td><strong>Professor Mourad Mokni</strong></td>
<td>La Rabla Hospital</td>
<td>Tel: +216 71 566 885</td>
<td><a href="mailto:mourad.mokni@rns.tn">mourad.mokni@rns.tn</a></td>
</tr>
<tr>
<td></td>
<td>Department of Dermatology</td>
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<td>Rue Jabbari</td>
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<tr>
<td><strong>Dr Jane Mbui</strong></td>
<td>Principal Research Officer</td>
<td>Tel: +254 20 272 6460</td>
<td><a href="mailto:jjmbui@kemri.org">jjmbui@kemri.org</a></td>
</tr>
<tr>
<td></td>
<td>Centre for Clinical Research</td>
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<td>Kenya Medical Research Institute</td>
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<tr>
<td><strong>Margaret Mbuchi</strong></td>
<td>Centre for Clinical Research</td>
<td></td>
<td><a href="mailto:mbuchi.margaret@gmail.com">mbuchi.margaret@gmail.com</a></td>
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<td>Kenya Medical Research</td>
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<tr>
<td><strong>Dr Paul Nguewa</strong></td>
<td>Director</td>
<td></td>
<td><a href="mailto:panguewa@unav.es">panguewa@unav.es</a></td>
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<tr>
<td></td>
<td>Instituto de Salud Tropical</td>
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<td>Department of Parasitology &amp; Microbiology</td>
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<td>Universidad de Navarra</td>
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## FOUNDATION FOR INNOVATIVE NEW DIAGNOSTICS (FIND)

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<th>Name</th>
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<tr>
<td><strong>Professor Joseph Ndung'u</strong></td>
<td>Head</td>
<td>Tel: +41 (0)22 710 0590</td>
<td><a href="mailto:Joseph.Ndungu@finddx.org">Joseph.Ndungu@finddx.org</a></td>
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<tr>
<td></td>
<td>Neglected Tropical Diseases Programme</td>
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<td>Foundation for Innovative New Diagnostics</td>
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<tr>
<td><strong>Dr Isra Cruz</strong></td>
<td>Senior Scientific Officer</td>
<td>Tel: +41 (0)22 710 0954</td>
<td><a href="mailto:isra.cruz@finddx.org">isra.cruz@finddx.org</a></td>
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## DRUGS FOR NEGLECTED DISEASES INITIATIVE (DNDi)

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Contact Information</th>
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<tr>
<td><strong>Dr Jorge Alvar</strong></td>
<td>Head of Leishmaniasis Programme</td>
<td>Tel: +41 22 906 9230 / 37</td>
<td><a href="mailto:jalvar@dndi.org">jalvar@dndi.org</a></td>
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Dr Fabiana Alvés
Visceral Leishmaniasis Programme
Drugs for Neglected Diseases initiative
15 Chemin Louis-Dunant
1202 Geneva
Switzerland

Tel: +41 22 906 9244
Email: falves@dndi.org

Dr. Gina Muthoni Ouattara
Clinical Trials Manager
Drugs for Neglected Diseases initiative
Africa Regional Office
Tetezi Towers, 3rd Floor, George Padmore Road
Nairobi
Kenya

Tel: +254 20 3995000
Mobile: +254 79 0203107
Email: gmouattara@dndi.org

Joy Malongo
Drugs for Neglected Diseases initiative
Africa Regional Office
3rd Floor Tetezi Tower, George Padmore Road
Nairobi
Kenya

Mobile: +254 722 876570
Email: jmalongo@dndi.org

Dr Raymond Omollo
Head of Data Centre & Statistician
R&D - Data Centre
Drugs for Neglected Diseases initiative – Africa
P.O Box 20778–00202
Nairobi
Kenya

Tel: +254 20 2077767
Mobile: +254 734 276516
Email: romollo@dndi.org

Dr Monique Wasunna
Director
Drugs for Neglected Diseases initiative – Africa
Africa Regional Office
c/o Centre for Clinical Research
Kenya Medical Research Institute
Nairobi
Kenya

Tel: +254 20 2403396
Mobile: +254 72 2700448
Email: africa@dndi.org

INTERNATIONAL CENTRE FOR INSECT PHYSIOLOGY AND ECOLOGY (ICIPE)

Dr Damaris Matoke-Muhia
Postdoctoral fellow
International Centre for Insect Physiology and Ecology
MBBU–EID
P.O. Box 30772–00100
Nairobi
Kenya

Email: dmatoke@icipe.org
dmatoke@kemri.org

IMA WORLD HEALTH – SOUTH SUDAN

Mr Duncan Ochol
Director of Programmes
Interchurch Medical Assistance – World Health
Nimra Talata, Plot 3, Block 1
Juba
South Sudan

Mobile: +211 955 645732
Email: duncanochol@imaworldhealth.org
KalaCORE CONSORTIUM – ETHIOPIA

Dr Cherinet Adera
KalaCORE Ethiopia Deputy Country Manager
KalaCORE Consortium
Yeka Subcity, Kebele
12–14 H. No. 679
Addis Ababa
Ethiopia

Dr Margriet den Boer
KalaCORE Consortium

Stefanie Meredith
Programme Director
KalaCORE Consortium
Mott MacDonald
10 Fleet Place
London EC4M 7RB
United Kingdom

MEDECINS SANS FRONTIERES – THE NETHERLANDS

Dr Koert Ritmeijer
Leader NTD Working Group
MSF Adviser
University of Amsterdam
Paramaribostraat 66-I
1058 VM Amsterdam
The Netherlands

MEDECINS SANS FRONTIERES – ETHIOPIA

Dr Lindsay Bryson
Medical Coordinator
Médecins Sans Frontières OCA
(MSF Holland), PO Box 34357
Yeka Sub City – Adwa Road
Addis Ababa
Ethiopia

IZUMI FOUNDATION

Professor Richard Wamai
Associate Professor, Public Health
Integrated Initiative for Global Health
Northeastern University
360 Huntington Avenue
220C Renaissance Park
Boston, MA 02115
United States of America

Ms Hellen Nyakundi
Adjunct Lecturer
School of Public Health
University of Nairobi
Kenyatta National Hospital Campus
P.O. Box 19676–00202
Nairobi
Kenya
MINISTRY OF HEALTH – KENYA

Dr Sultani Matendecherro  
Head  
Neglected Tropical Disease Programme  
Ministry of Health  
P.O. Box 30016  
00100 KNH Nairobi  
Kenya  
Mobile: +254 722 654291  
Email: sultani.matendecherro@health.go.ke

Dr Davis Wacheru Wachira  
National NTD Manager  
Neglected Tropical Disease Programme  
Ministry of Health  
P.O. Box 20750  
00202 KNH Nairobi  
Kenya  
Mobile: +254 723 003357  
Email: wachirad2000@gmail.com

Cecilia N. Wandera  
National Leishmaniasis Coordinator  
Neglected Tropical Disease Programme  
Ministry of Health  
P.O. Box 20750  
00202 KNH Nairobi  
Kenya  
Tel: +254 02 2608366  
Mobile: +254 721 654828  
Email: cecinw@gmail.com

Dr Sylvesters Eoko Ebei  
NTD Coordinator Turkana  
Public Health  
P.O. Box 18 Lodwar  
Turkana County  
Kenya  
Mobile: +254 717 7312573  
Email: sylvestersebei@yahoo.com

Hillary Orinde  
Journalist  
Standard Media Group  
Nairobi  
Tel: +254 726 050909  
Email: Hillary.orinde@gmail.com

Kajilwa Graham  
Journalist  
Standard Media Group  
Nairobi  
Tel: +254 710 167854  
Email: lgkajilwa@standardmediagroup.com

MINISTRY OF HEALTH – SOUTH SUDAN

Mr Lexson Mabrouk Manibe  
Director, Case management NTDs  
Directorate of Preventive Health Services  
Ministry of Health  
Ministerial Complex, P.O. Box 88  
Juba  
South Sudan  
Tel: +211 954 416870  
Mobile: +211 911 493132  
Email: mabroukmanibe@gmail.com  
mabrouk.manibe@yahoo.com

Dr Ayak Chol Deng Alak  
HAT&KA Focal Person and Deputy Director  
Case management NTDs  
Department of NTDs  
Directorate of Preventive Health Services  
Ministry of Health  
Ministerial Complex, P.O. Box 88  
Juba  
South Sudan  
Tel: +211 927 672217  
Mobile: +211 (0)927 7672217  
Email: ayakcholahalak@gmail.com
MINISTRY OF HEALTH – SUDAN

Dr Mousab Siddig Elhag
Dr Mohammed Taha Hussein Babickr
National NTDs Coordinator
Communicable and Noncommunicable Disease Directorate
Federal Ministry of Health
Nile Avenue
Khartoum
Sudan

Tel: +249 9123390551
Mobile: +249 912 288269
Email: mooosab33@yahoo.com
mousabsiddig@gmail.com

MINISTRY OF HEALTH – UGANDA

Mr Martin Mayanja
Mr Mohamed Maalim Dakane
Leishmaniasis Focal Person
Medical Director, SOS Mother & Child Hospital
P.O. Box 7272
Kampala
Uganda

Email: nmmayanja@yahoo.co.uk

SOS CHILDREN’S VILLAGES INTERNATIONAL – SOMALIA

Mr Mohamed Maalim Dakane
Medical Director, SOS Mother & Child Hospital
Department of Health and Nutrition
P.O. Box 76192–00508
SOS Children’s Villages Somalia
Nairobi
Kenya

Tel: +252 616968685
Mobile: +254 720413962
Email: Mohamed.dakane@sossomalia.org

WHO REGIONAL OFFICE FOR AFRICA

Dr Adiele Nkasiobi Onyeze
Dr Abate Mulugeta Beshah
Medical Officer
Neglected Tropical Diseases
WHO Country Office
P.O. Box CY 348 Causeway
Harare
Zimbabwe

Tel: (+263)4 788220 39
Email: onyezea@who.int

WHO COUNTRY OFFICES

ETHIOPIA

Dr Abate Mulugeta Beshah
Dr Henok Admassu
National Professional Officer
Leishmaniasis Officer
WHO Country Office
WHO Country Office
3069 Addis-Ababa
3069 Addis Ababa
Ethiopia
Ethiopia

Tel: +251 11 553 15 50
Email: abatem@who.int

Tel: +251 91 135 46 26
Email: hadmassu@who.int
SOUTH SUDAN

Ms Jane Pita Hillary  
National Laboratory Technologist/  
NTD Focal Point  
Department: Neglected Tropical Diseases  
WHO Country Office  
Ministry of Health, Ministerial Complex  
Juba  
South Sudan

KENYA

Dr Iheoma Onuekwusi  
Expanded Program on Immunization  
WHO Country Office  
P.O. Box 45335–00100  
Nairobi  
Kenya

Dr Joyce Kerubo Onsongo  
National Professional Officer  
WHO Country Office  
ACK Gardens House, 4th Floor  
1st Ngong Avenue/Bishops Road  
45335 Nairobi  
Kenya

Dr Jemima Mwakisha  
Communications Officer  
WHO Country Office  
ACK Gardens House, 4th Floor  
1st Ngong Avenue/Bishops Road  
45335 Nairobi  
Kenya

Mr Kennedy Chitala  
Data Manager  
WHO Country Office  
ACK Gardens House, 4th Floor  
1st Ngong Avenue/Bishops Road  
45335 Nairobi  
Kenya

Ms Millie Busolo  
Programme Assistant  
WHO Country Office  
ACK Gardens House, 4th Floor  
1st Ngong Avenue/Bishops Road  
45335 Nairobi  
Kenya

UGANDA

Dr Miriam Nanyunja  
National Professor Officer/DPC  
WHO Country Office  
P.O. Box 24578  
Kampala  
Uganda
WHO REGIONAL OFFICE FOR THE EASTERN MEDITERRANEAN

WHO COUNTRY OFFICES

SUDAN

Dr Atia Abdalla Atia
VL Project Coordinator
WHO Country Office
P.O. Box 2234
Othman Digan Street
Nile Avenue
Khartoum
Sudan

Mobile: +249 912 219811
Email: atia.alatiaby@kalacore.org

WORLD HEALTH ORGANIZATION HEADQUARTERS

Dr José Antonio Ruiz-Postigo
Head, Leishmaniasis Control Programme
Innovative and Intensified Disease Management
Department of Control of Neglected Tropical Diseases
World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

Tel: +41 22 791 3870
Mobile: +41 79 516 3882
Email: postigoj@who.int

Dr Mercedes Herrero García
Consultant, Leishmaniasis Programme
Innovative and Intensified Disease Management
Department of Control of Neglected Tropical Diseases
World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

Mobile: +34 689 02 54 97
Email: herrerom@who.int

Dr Serene Aimée Joseph
Consultant Leishmaniasis Programme
Innovative and Intensified Disease Management
Department of Control of Neglected Tropical Diseases
World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

Tel: +41 22 791 3870
Mobile: +41 79 170 8362
Email: josephse@who.int