Conference Programme

2014

# 1st LEAP Scientific Conference

## 29-30 September, 2014, Bahir-Dar, Ethiopia

LEAP
LEISHMANIASIS
EAST AFRICA PLATFORM

**BRIDGING THE GAP:**

Progress on the Current Research Innovation &
Access to Visceral Leishmaniasis Treatment in Africa

DNDi
Drugs for Neglected Diseases *initiative*

**Drugs for Neglected Diseases *initiative* (*DNDi* )** is a not-for-profit research and development organization, *DNDi* works to deliver new treatments for neglected diseases, in particular leishmaniasis, Human African Trypanosomiasis, Chagas disease, Malaria, specific Helminth infections and Paediatric HIV.
www.dndi.org

**Kenya Medical Research Institute (KEMRI)** is a state corporation established through the Science and Technology (Amendment) Act of 1979, which has since been amended to Science, Technology and Innovation Act, 2013.

www.kemri.org

**Makerere University (UoM)** was established in 1922 as a humble technical school, named Uganda Technical College. On July 1970, UoM became an independent national university of the Republic of Uganda offering Undergraduate and post graduate courses.

http://mak.ac.ug/

**Addis Ababa University (AAU)** was established in 1950 as the University College of Addis Ababa (UCAA). Addis Ababa University is the oldest and the largest higher learning and research institution in Ethiopia. Since its inception, AAU has been the leading centre in teaching-learning, research and community services.
www.aau.edu.et

**Institute of Endemic Diseases (IEND)** was established in 1993 as a research and training centre for endemic diseases. It acts as a platform for biomedical and clinical research within the University of Khartoum.

www.iend.edu.sd

**Médecins Sans Frontiéres (MSF**) is an independent, medical, emergency relief organization that provides assistance to people worldwide, regardless of their background, religion, or political convictions. Above all, it aims to save lives and offer medical care to victims of disasters, wars and epidemics.

# CONFERENCE MESSAGES

# MESSAGE FROM DRUGS FOR NEGLECTED DISEASES *initiative* EXECUTIVE DIRECTOR

On the occasion of the Leishmaniasis East African Platform (LEAP) Scientific Conference, in Bahir Dar, Ethiopia, I would like to take this opportunity to welcome all of you engaged in R&D for neglected diseases in East Africa. The conference theme, ***Bridging the Gap: Progress in Current Research Innovation and Access to Visceral Leishmaniasis Treatment in Africa,*** promises to examine a broad range of perspectives on kala-azar in Africa today, from geographical differences in treatment response, challenges in drug development, diagnostic issues, all the way to regional regulatory and ethics harmonization endeavours, and finally to the challenges in ensuring patient access to diagnosis and treatment.

Drugs for Neglected Diseases initiative (DND*i*) has invested significantly in developing and delivering new treatments for kala-azar, be they new regimens and combinations of existing drugs, or the discovery and development of entirely new drugs – each strategy with its own challenges and opportunities. We have also engaged in leishmaniasis drug development more broadly, with studies on HIV-VL, post-kala-azar dermal leishmaniasis (PKDL), and cutaneous leishmaniasis (CL) on three continents. Our work in Africa is a key priority of the organization, which is why LEAP and DND*i* Africa have worked diligently to ensure that research capacity in East Africa is built and maintained. From the initial tents that were used for clinical trials, LEAP has come a long way, in terms of the professionals that have been trained, the infrastructure that has been built, the clinical trials conducted, and the treatment with SSG&PM delivered.

Today, we invite you all to reflect with us on how to best address the challenges that remain today in bringing down the burden of kala-azar in Africa. As an organization that can only be as strong as its partners, we invite you to join us as researchers, clinicians, public health experts, and advocates, in bringing the best science to the most neglected patients in the region. Finally, I would also like to thank the generous donors that continue to support DNDi's activities in the field of leishmaniasis.

**Dr Bernard Pécoul**

Executive Director, Drugs for Neglected Disease *initiative*

Geneva, Switzerland

# MESSAGE FROM DIRECTOR KENYA MEDICAL RESEARCH INSTITUTE

I am extremely delighted to welcome you to the 1st LEAP Scientific Conference, in Bahir Dar, Ethiopia, from the 29 to 30 September 2014. As one of DND*i* founding partners and being a key LEAP partner in research and development (R&D) work in Eastern Africa, Kenya Medical Research Institute (KEMRI) is pleased to be associated with this conference. It is a great achievement for the platform and will greatly contribute towards promoting South-South networking for researchers and scientist in the area of Leishmaniasis, in the Eastern African region.

I am equally pleased to note the LEAP Conference themed ***'BRIDGING THE GAP: Progress on the Current Research Innovation and Access to Visceral Leishmaniasis Treatment in Africa'***, is geared towards strengthening clinical research capacity, which is lacking in part due to the remoteness and geographical spread of the patients, most of whom live in the most impoverished regions of Africa. None-the-less, while we have made some strides in the development of treatments for kala-azar, gaps still remain. Greater investment needs to be targeted towards delivering effective, affordable and efficacious treatments to communities in kala-azar endemic disease regions. In addition, kala-azar patients need treatment and there is still room for more to be done by governments and their partners in controlling kala-azar in endemic disease regions.

I would like to thank the ministries of health of LEAP member countries for continued partnership and collaboration and all of you here today for working towards improved diagnosis and treatment for Leishmaniasis in the region, as well as raising awareness about this neglected tropical diseases (NTDs). Kala-azar is an NTD that affects the poorest of the poor and marginalized communities; hence our regional work has a role in advocating and eventually influencing policy and funding priorities.

Today, we take pride and congratulate DND*i* and LEAP members for convening the First LEAP Scientific Conference. As we move forward, KEMRI and her partners will continue to stimulate efforts in R&D, prevention and the treatment of Kala azar; one of the most deadly neglected diseases in Kenya. I wish all participants a successful conference.

**Prof. Solomon Mpoke**
Director, Kenya Medical Research Institute
Nairobi, Kenya.

# MESSAGE FROM CHAIR, LEISHMANIASIS EAST AFRICA PLATFORM

It is my pleasure as the current chair of the Leishmaniasis East Africa Platform (LEAP) to formally welcome all the participants to the first LEAP Scientific Conference, in Bahir Dar, Ethiopia, from the 29 to 30 September 2014. This conference marks an achievement for the platform and will contribute towards promoting South-South networking for researchers and scientist in the area of leishmaniasis, in the Eastern African region.

We as LEAP understand the urgency of addressing the most challenging questions in research and development (R&D) for leishmaniasis, in Africa. Consequently, to date the LEAP countries continue to work as one through an innovative and inclusive process. Today's scientific conference is an example of this united effort.

Over the years, LEAP has worked towards time bound and quantifiable targets in order to address the R&D needs of patients suffering from visceral leishmaniasis (VL), also known as kala-azar. To date, LEAP has 9 clinical trial sites and over 80 members, most of whom are attending this scientific conference.

LEAP's R&D work would not be what it is today without the strong support of the communities on the ground, research institutes, ministries of health, regulatory bodies, DND*i* and donors. Ten years on, we are still making positive strides towards a collective R&D goal. Through the LEAP0104 clinical trial we were able to show that Sodium Stibogluconate and Paromomycin (SSG&PM) combination therapy for 17days was a marked improvement from the previous 30 day regime of SSG alone. SSG&PM combination therapy is now recommended by the World Health Organization as a first-line treatment for kala-azar in the Eastern Africa region. Today, LEAP is prioritising improving access of SSG&PM in our Eastern African countries.

As we deliberate over the next few days, it is my hope that we will take the lessons learned and recommendations into consideration; and work towards building on what we have so far achieved as LEAP, DND*i* and partners. Our choice to do so will make a difference to the populations in Eastern Africa, affected by NTDs, and the generation to come. Furthermore, it is my hope that through the conference discussions it will become clear that R&D goals are achievable, but we must also distinguish how countries can use this message to chart out long-term outcomes based on collaborative R&D approaches. As a scientific community we can achieve much more if we continue to work together for there is strength in numbers.

**Prof. Ahmed Mudawi Musa**

Chair, Leishmaniasis East Africa Platform

Director, Institute of Endemic Diseases (IEND), University of Khartoum, Sudan

# MESSAGE FROM CHAIR, CONFERENCE ORGANIZING COMMITTEE

*Karibu!* It gives us great pleasure to welcome you to the 1st Leishmaniasis East Africa Platform (LEAP) Scientific Conference in Bahir Dar, Ethiopia; the city of palm trees and colourful flowers; the source of the Blue Nile.

The conference theme, ***'Bridging the Gap: Progress on the Current Research Innovation and Access to Visceral Leishmaniasis Treatment in Africa'*** highlights the positive developments in the treatment of Visceral Leishmaniasis (VL). We have come a long way, but we still have far to go.

They say time is a milestone to measure progress; this journey started eleven years ago, and day by day we are reminded of the important steps we have taken together as an engaged research community. This is the first time that LEAP hosts such a Scientific Conference and we believe it is an opportunity to celebrate the journey so far, to explore what good South-South, North-South, and multi-stakeholder cooperation looks like in practice.

But, even as we look back, this is a chance to look to the future, to foster the ongoing collaborations and develop new partnerships to cover an even greater path. The two-day conference will provide a platform for exchange of knowledge, experiences, practices, and we hope the discussions will propel us into the future. Our scientific programme is rich and varied with one keynote speech, invited talks around thematic areas, and over 40 technical papers, presented both orally and as posters.

We are honoured with the presence of researchers, health professionals, academicians and representatives from Drug Regulatory Authorities, National NTD Programmes, Ministries of Health, MSF and the World Health Organization, from 18 countries.

We believe that we have chosen a venue that will guarantee a successful conference amid the sights and sounds of scenic Bahir Dar.

The success of the conference depends on all of you who have contributed immensely to the comprehensive programme.

We would like to say thank you, to the authors for submitting abstracts and to the Scientific Committee for their thorough and timely review. The Organizing Committee worked extremely hard in ensuring that the programme came together. Your efforts are appreciated. To LEAP Platform members, asanteni sana for generating great ideas. To DND*i* and its donors, we are forever grateful for sponsorship, support, and partnership. As a partnership model, we at DND*i* know the value of solid collaboration with our many and diverse partners. To all of you here today, we say amesegenalehu!

On behalf of the Organizing Committee, it is my honour to welcome you to the 1st LEAP Scientific Conference.

**Simon Bolo**

Regional Operations Manager,

Drugs for Neglected Disease Initiative Africa Regional Office, Nairobi

# MESSAGE FROM CHAIR, CONFERENCE SCIENTIFIC COMMITTEE

**Dear Colleagues,**

On behalf of the Scientific Committee of the **1stLeishmaniasis East Africa Platform (LEAP) Scientific Conference**, I am delighted to welcome you to Bahir Dar!

Our conference theme **'BRIDGING THE GAP: Progress on the Current Research Innovation and Access to Visceral Leishmaniasis Treatment in Africa',** illustrates the growth we envisioned when the LEAP platform was established in 2003. During the last decade, we as LEAP partners have walked hand in hand to strengthen clinical research capacity in the most impoverished regions of Africa - where this capacity has lagged behind due to the remoteness and geographic spread of the patients we serve. It is with great pleasure that we now ***step together in the right direction*** to hold our first scientific conference.

The Scientific Conference objectives are to:

- Promote South-South and North-South networking for researchers in the region by creating a forum to discuss critical issues affecting research, innovation and access to visceral leishmaniasis (VL) treatment in Africa.
- Create an environment for stakeholders to assess evidence and deliberate on progress and challenges in the treatment of VL and other Neglected Tropical Diseases (NTDs).
- Nurture young researchers in the area of VL and other NTD research.

We have divided our conference into 10 sessions to run over two days covering four thematic areas: Visceral Leishmaniasis; Regulatory and Ethics Harmonization; Other Neglected Tropical Diseases; and a roundtable discussion on Access to SSG&PM in Eastern Africa. We hope that the presentations will lead to discussions in which there will be: knowledge exchange, sharing of experiences and practices, and issues affecting the treatment of VL not only in Africa but on other continents, and other NTDs will be highlighted.

Forty five abstracts were reviewed for this meeting which will comprise both oral and poster presentations. We anticipate that these presentations, combined with the special sessions from invited speakers, will facilitate the outcomes we expect from this meeting which include:

- Strengthened multi-stakeholder partnerships and sharing of knowledge, experience, and best practices.
- Commitment, by key stakeholders, to support, adopt, and implement recommended actions to enhance access to SSG&PM in Eastern Africa.
- Emphasis on progress made in research and development (R&D) for leishmaniasis in Eastern Africa (diagnosis, treatment, and access).
- Closer collaboration with partners as an essential part of achieving LEAP's objectives.
- Strengthened resolve and commitment to regulatory and ethics harmonization in Eastern Africa.

I have great expectations for this scientific conference and I am convinced that the collective wisdom of this group of experts will help to advance R&D endeavours for and in Africa!

**Dr Monique Wasunna**

Assistant Director, Research, KEMRI

Director, Drugs for Neglected Diseases initiative Africa Regional Office, Nairobi

# ORGANIZING COMMITTEE

**Chair**

Simon Bolo

**Secretary**

Duncan Nyakaya

**Members**

Dr Monique Wasunna

Nicholas Bonyo

Prof Asrat Hailu

Joy Malongo

Dr Robert Kimutai

Renee Olende

Dr Nekoye Otsyula

**Scientific Committee**

Chairpersons

Dr Monique Wasunna

**Secretary**

Joy Malongo

**Members**

Dr Robert Kimutai

Prof Asrat Hailu

Prof Eltahir Khalil Awad Gasim

Prof Ahmed Mudawi Musa

Prof Joseph Olobo

Dr Juma Rashid

Dr Jorge Alvar

Dr Fabiana Alves

Dr Nekoye Otsyula

Mr Raymond Omollo

Dr Tansy Edwards

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DND*i*

Drugs for Neglected Diseases *initiative*

## ORGANIZATION OVERVIEW

DND*i* is a collaborative, patients' needs-driven, not-for-profit drug R&D organization. In 2003, seven organisations from around the world joined forces to establish DND*i*: the Oswaldo Cruz Foundation from Brazil, the Indian Council for Medical Research, Kenya Medical Research Institute (KEMRI), the Ministry of Health of Malaysia and Institut Pasteur', Médecins sans Frontières (MSF), WHO's Special Programme for Research and Training in Tropical Diseases (TDR), which acts as a permanent observer to the initiative.

True to its vision and mission, DND*i* works closely with a wide range of partners through clinical research platform mechanisms. The overall aim of such platforms is to strengthen clinical research capacity in neglected disease endemic countries; crucial to researching and developing treatments for neglected diseases where they actually occur i.e. in very remote areas.

DND*i* has three disease specific platforms in Africa and Latin America, these include:

- **The Leishmaniasis East Africa Platform (LEAP)** for the diagnosis and treatment of visceral leishmaniasis also known as kala-azar, and cutaneous leishmaniasis
- **The HAT Platform** for sleeping sickness, or Human African Trypanosomiasis
- **The Chagas Clinical Research** Platform (CCRP) for Chagas disease

## THE LEAP PLATFORM

LEAP
LEISHMANIASIS
EAST AFRICA PLATFORM

LEAP serves as a base for on-going educational cooperation between the countries in the Eastern Africa region and facilitates standardization of clinical R&D procedures and practices within the region. LEAP evaluates, validates, and registers new treatments that address regional needs for leishmaniasis, both cutaneous and visceral forms.

Members of the platform include: Centre for Clinical Research, Kenya Medical Research Institute, Kenya; Ministry of Health, Kenya; Institute of Endemic Diseases, University of Khartoum, Sudan; Federal Ministry of Health, Sudan; Addis Ababa University, Ethiopia; University of Gondar, Ethiopia; Federal Bureau of Health, Ethiopia; Makerere University, Uganda; Ministry of Health, Uganda; Médecins Sans Frontières; i+ Solutions; Institute of One World Health (iOWH); AMC/KIT/University of Slotervaart, Amsterdam, The Netherlands; London School of Hygiene and Tropical Medicine (LSHTM), UK.

## LEAP objectives include:

- To evaluate, validate and register improved treatment options that address regional needs for leishmaniasis
- To facilitate clinical testing and registration of new treatments for VL in the region
- To bring together key regional actors in the health field, namely: representatives of ministries of health, national control programmes, regulatory authorities, academia, civil society groups, and pharmaceutical companies, as well as clinicians and health professionals
- To provide capacity strengthening for drug evaluation and clinical studies in the region (Ethiopia, Kenya, Uganda and Sudan) and strengthen clinical capacities in endemic regions, and address infrastructural requirements where necessary

# LEAP ACHIEVEMENTS

**Over the years MoH, KEMRI, DND*i*, MSF and other partners have made significant achievements with regard to Kala Azar treatment, notably:**

- Development of multi-centre clinical trial sites in Eastern Africa
- Strengthening of clinical trial capacity within LEAP countries through Good Clinical Practices, Good Clinical Laboratory Practices & Good Financial Practices training for: investigators, nursing staff, laboratory technicians and technologists
- Establishment and training for clinical trial monitors and the Data Safety Monitoring Board's (DSMBs)
- Set up an operational data center with collaborative support from the London School of Hygiene and Tropical Medicine (LSHTM).
- Developed a new combination treatment (SSG&PM) that reduces treatment time from 30 days to 17 days, recommended by WHO as a first-line treatment for kala-azar in the region
- Registered Paromomycin (PM) in Kenya and Uganda
- Conducted research for the introduction of an easy-to-use rapid diagnostic test (Opti Leish) to detect primary cases of Kala Azar.
- Contributed to the revision of the national treatment and diagnosis guidelines for Kala Azar in Ethiopia, Kenya, Uganda and Sudan
- Scientific publications


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**LEAP** consists of a group of scientists and institutions working on developing clinical trial capacity to bring new treatments to patients

**LEAP SITES**

- **Sudan: 3 sites**
  (Kassab, Dooka, and Um El Kher)
- **Ethiopia: 2 sites**
  (Gondar, and Arba Minch)
- **Kenya: 2 sites**
  (Nairobi, and Kimalel)
- **Uganda: 1 site**
  (Amudat)

**DND*i* Africa Regional Office, Nairobi** ¦ Kenya Medical Research Institute (KEMRI) ¦ P.O. Box 20778 KNH 00202 Nairobi
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# CONFERENCE PROGRAMME

# BRIDGING THE GAP: Progress on the Current Research Innovation and Access to Visceral Leishmaniasis Treatment in Africa

***29-30 September 2014 – Avanti Blue Nile Hotel, Bahir Dar, Ethiopia***

| Monday, 29 September 2014 - Programme | | | |
|---|---|---|---|
| **Session 1: Opening Session** | | | |
| **8:00-9:10** | 7:30-08:00 | Registration | |
| | | Master of Ceremony | **Prof. Yalemtsehay Mekonnen,** Addis Ababa University, ***Ethiopia*** |
| | | Welcome and Introduction | **Prof. Asrat Hailu Mekuria,** Addis Ababa University, ***Ethiopia*** |
| | | | **Prof. Ahmed Mudawi Musa,** Institute of Endemic Diseases, University of Khartoum, ***Sudan*** |
| | | | **Dr Nathalie Strub-Wourgaft,** DND*i*, ***Switzerland*** |
| | | | **Mr Ayeligne Mulualem,** Chief Head of the Health Bureau, Amhara Regional State, Federal Democratic Republic of ***Ethiopia*** |
| | | | **Dr Daniel Argaw Dagne,** Leishmaniasis Control Program, World Health Organization, ***Switzerland*** |
| | | | **Dr John H. Amuasi,** Kumasi Centre for Collaborative Research in Tropical Medicine, School of Medical Sciences, ***Ghana*** |
| **Session 2: DND*i* R&D Portfolio: What is new** | | | |
| 09:10-10:10 | 9:10 -9:40 | DND*i* R&D Portfolio | **Dr Nathalie Strub-Wourgaft,** DNDi, ***Switzerland*** |
| | 9:40-10:10 | Discussion | |
| **Break** | | | |
| **Session 3: Visceral Leishmaniasis in Three Continents: What is different?** | | | |
| | | **Chair:**<br>**Co-Chair:** | **Prof. Kirana Bhatt,** University of Nairobi, ***Kenya***<br>**Dr Fabiana Alves,** DND*i*, ***Switzerland*** |
| | 10:40-11:00 | Global Overview of Visceral Leishmaniasis | **Dr Daniel Argaw Dagne,** Leishmaniasis Control Program, World Health Organization, ***Switzerland*** |

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|---|---|---|---|
| 10:40-1:30 | 11:00-11:15 | African Visceral Leishmaniasis | **Prof. Eltahir Khalil Gasim,** Institute of Endemic Diseases, University of Khartoum, ***Sudan*** |
| | 11:15-11:30 | The Leishmaniasis East Africa Platform (LEAP) | **Prof. Asrat Hailu Mekuria,** Addis Ababa University, ***Ethiopia*** |
| | 11:30-11:45 | Visceral Leishmaniasis in Asia | **Dr Bhawna Sharma,** DND*i*, ***India*** |
| | 11:45-12:00 | Visceral Leishmaniasis in Latin America | **Prof. Carlos Costa,** University of Brasilia, ***Brazil*** |
| | 12:00-12:30 | Discussion | |
| | 12:30-12:40 | The Challenges of managing Patients with Kala-Azar in Sudan | **Prof. Ahmed Mudawi Musa**, Institute of Endemic Diseases, University of Khartoum, ***Sudan*** |
| | 12:40-12:50 | Paromomycin/Sodium Stibogluconate Combinations, Safety and possible Efficacy for Treatment of Post Kala-Azar Dermal Leishmaniasis Case series | **Dr. Brima Musa Younis,** Institute of Endemic Diseases, University of Khartoum, ***Sudan*** |
| | 12:50-1:00 | Secondary Prophylaxis of Visceral Leishmaniasis Relapses in HIV co-infected Patients using Pentamidine as a Prophylactic Agent: A Prospective Cohort Study (NCT01360762) | **Dr Ermias Diro,** University of Gondar, ***Ethiopia*** |
| | 1:00-1:10 | A Screen and Treat Strategy targetting Visceral Leishmaniasis in HIV infected individuals in endemic East-Arican countries: The way forward ? | **Johan van Griensven,** Institute of Tropical Medicine, ***Belgium*** |
| | 1:10-1:30 | Discussion | |
| **Lunch** | | | |
| **Session 4: Visceral Leishmaniasis: Diagnosis and Immunology** | | | |
| | | **Chair**<br>**Co-Chair:** | **Prof. Joseph Olobo**, Makerere University, ***Uganda***<br>**Prof. Ed Zijlstra,** DND*i*, ***Switzerland*** |
| | 2:30-2:40 | Impact of the use of a rapid diagnostic test for visceral leishmaniasis on clinical practice in Ethiopia: a retrospective study | **Dr Ermias Diro**, University of Gondar, ***Ethiopia*** |
| | 2:40-2:50 | Simplified molecular detection of Leishmania parasites in various clinical samples from patients with leishmaniasis | **Dr Claire Mugasa,** Makerere University, ***Uganda*** |

| | | | |
|---|---|---|---|
| **2:30-4:00** | 2:50-3:00 | Testing of VL Urine Samples from Kenya by quantitative ELISA | **Severine Monnerat,** FIND**, *Switzerland*** |
| | 3:00-3:10 | The Pharmacokinetics of Single Intramuscular Dose of Paromomycin Sulfate, Sodium Stibogluconate and their Combination in Healthy Volunteers | **M.M.E. Mudawi**, Northern Border University, ***Saudi Arabia*** |
| | 3:10-3:20 | Evaluation of Complement Activation Related Pseudo Allergy (CARPA) among Sudanese visceral leishmaniasis patients treated with high single dose liposomal Amphotericin B (Ambisome®) | **A.J.S. Mohammed**, Institute of Endemic Diseases, University of Khartoum, ***Sudan*** |
| | 3:20-3:30 | Alternative Approaches for Anti-Leishmania Vaccine Development: In Silico Prediction of Immunogenic T cell epitopes of Leishmania donovani GP63 protein as Vaccine Candidates | **Dr Mona Elfaki**, Institute of Endemic Diseases, University of Khartoum, ***Sudan*** |
| | 3:30-3:40 | Immunochemotherapy of Post Kala Azar Dermal Leishmaniasis: Sudanese Experience | **Prof. Ahmed Mudawi Musa**, Institute of Endemic Diseases, University of Khartoum, ***Sudan*** |
| | 3:40-4:00 | Discussion | |
| **Break** | | | |
| **Session 5: Visceral Leishmaniasis: Some Pertinet Issues** | | | |
| **4:30-5:45** | | **Chair**<br><br>**Co-Chair** | **Prof. Eltahir Awad Gasim Khalil**, Institute of Endemic Diseases, University of Khartoum, ***Sudan***<br>**Dr Nekoye Otsyula**, DND*i*, *Kenya* |
| | 4:30-4:40 | Leishmaniasis in Uganda: Historical Account and a Review of the Literature | **Dr Patrick Sagaki,** Amudat Hospital, ***Uganda*** |
| | 4:40-4:50 | Nutrition and Leishmaniasis Control in Sudan, Current Challenges and Future Strategies : A guide for the Formulation of Regional Policy | **Dr Faiza Osman,** Institute of Endemic Diseases, University of Khartoum, ***Sudan*** |
| | 4:50-5:00 | Economic Impact of Visceral Leishmaniasis in Baringo, Kenya | **Simon Bolo,** DND*i*, ***Kenya*** |
| | 5:00-5:10 | Innovative approaches to Clinical Data Management in Resource Limited Settings using Open Source Technologies | **Raymond Omollo**, DND*i*, ***Kenya*** |
| | 5:10-5:20 | Lessons Learned from Collaborative Research and Development Program on Leishmania in University of Gondar | **Dr Ermias Diro**, University of Gondar, ***Ethiopia*** |
| | 5:20-5:45 | Discussion & Close of Session | |
| **7:00 Networking Cocktail** | | | |

# BRIDGING THE GAP: Progress on the Current Research Innovation and Access to Visceral Leishmaniasis Treatment in Africa

***29-30 September 2014 – Avanti Blue Nile Hotel, Bahir Dar, Ethiopia***

| Tuesday, 30 September 2014 - Programme | | | |
|---|---|---|---|
| **Session 6: Regulatory and Ethics Harmonization: A Possibility or a Mirage?** | | | |
| 8:00-11:00 | 8:00-8:10 | **Chair:**<br>**Co-Chair:** | **Dr Nathalie Strub-Wourgaft**, DND*i*, ***Switzerland***<br>**Prof. Eyasu Makonnen**, Addis Ababa University, ***Ethiopia*** |
| | 8:10-8:30 | An Overview on Drug Regulation and Harmonization in Africa | **Ms Gugu Nolwandle Mahlangu**, Medicines Control Authority of Zimbabwe, ***Zimbabwe*** |
| | 8:30-8.45 | An Overview on Drug Regulation in Uganda: Approaches towards harmonization | **Dr Helen Byomire Ndagije,** National Drug Authority, ***Uganda*** |
| | 8:45-9:00 | Promoting access to quality, safe and efficacious pharmaceutical products, PPB's Perspective. | **Dr Edward Abwao,** Pharmacy & Poisons Board, ***Kenya*** |
| | 9:00-9:15 | An Overview on Drug Regulation in Sudan: Approaches towards harmonization | **Alia Bakri Mergany Ahmed,** Drug Importation Department, FMPH, ***Sudan*** |
| | 9:15-9:30 | Prospects on Regulatory Harmonization: The Ethiopian perspective | ***Ms Heran Gerba, FMHACA, Ethiopia*** |
| | 9:30-9:40 | Challenges in Ethical Review in Kenya | **Prof. Kirana Bhatt,** University of Nairobi**,** ***Kenya*** |
| | 9:40-9:50 | Integration, Collaboration or Joint Review: Which way to Speed up Research Ethics Review in Eastern Africa | **Dr Simon Langat,** National Commission for Science, Technology and Innovation, ***Kenya*** |
| | 9:50-10:00 | Institutional Review Boards and Clinical Research in East Africa: Challenges, Opportunities and Proposed Solutions | **Dr Faiza Osman,** Institute of Endemic Diseases, University of Khartoum, ***Sudan*** |
| | 10:30-11:00 | Discussion<br>Conclusion | **Ms Chimwemwe Chamdimba**, NEPAD**,** ***South Africa*** |
| **Break** | | | |

| Session 7: Neglected Tropical Diseases 1 | | | |
|---|---|---|---|
| **11:15-12:45** | | **Chair:**<br>**Co-Chair:** | **Dr Mérce Herrero,** DFID Consortium, Ethiopia<br>**Dr Juma Rashid,** Kenya Medical Research Institute, *Kenya* |
| | 11:15-11:35 | Neglected Tropical Diseases 2020 Elimination Targets –Is Africa on Course? | **Dr Pauline Mwinzi,** Kenya Medical Research Institute, ***Kenya*** |
| | 11:35-11:45 | Monitoring Implementation of a Pharmacovigilance Plan for a Neglected Tropical Disease in East Africa | **Peninah Soipei Menza**, DND*i*, ***Kenya*** |
| **12:45-1:00** | 11:45-11:55 | Factors Influencing Compliance with Mass Drug Administration for Lymphatic Filariasis Elimination in Kenya | **Dr Doris Njomo**, Kenya Medical Research Institute, ***Kenya*** |
| | 11:55-12:05 | Evaluating Drug Delivery Strategies to Pre-primary School Age Children for Treatment of Soil-Transmitted Helminthiasis and Schistosomiasis Infections in Malindi District, Coastal Kenya | **Gladys Odhiambo,** Kenya Medical Research Institute, ***Kenya*** |
| | 12:05-12:15 | Behaviour Change is required for Elimination of Active Trachoma in Narok County, Kenya | **Dr Doris Njomo,** Kenya Medical Research Institute, ***Kenya*** |
| | 12:15-12:25 | Predictors of non-compliance with Mass Drug Administration for Schistosomiasis Control in Western Kenya - The SCORE Project | **Omedo Martin Owino,** Kenya Medical Research Institute, ***Kenya*** |
| | 12:25-12:35 | A Qualitative Description of Community Participation in Water and Sanitation Activities in the Control of Bilharzia in Nyalenda B, an Informal Settlement in Kisumu City, Western Kenya | **Rosemary Musuva**, Kenya Medical Research Institute, ***Kenya*** |
| | 12:35-1:00 | Discussion | |
| **Lunch** | | | |
| **Session 8: Neglected Tropical Diseases 2** | | | |
| | | **Chair:** | **Prof. Asrat Hailu**, Addis Ababa University, ***Ethiopia*** |
| **2:00-3:00** | 2:00-2:10 | Burden of Cystic Echinococcus in Selected Pastoral and Agropastoral Districts of Uganda | **Emmanuel Othieno**, Makerere University, ***Uganda*** |
| | 2:10-2:20 | Cystic Echinococcosis in Eastern Africa – A Public Health Problem | **Dr Eberhard Zehyle**, AMREF, ***Kenya*** |
| | 2:20-2:30 | Host Preference Analysis of Phlebotomus (Larroussius) Orientalis (Diptera: Psychodidae) using Cytochrome b PCR and Reverse Line Blotting in the Visceral Leishmaniasis Endemic Area of Tahtay Adiyabo District, Northern Ethiopia | **Araya Gebresilasie**, Addis Ababa University, ***Ethiopia*** |
| | 2:30-3:00 | Discussion | |

| Session 9: Access to SSG&PM in Eastern Africa Roundtable Discussion | | | |
|---|---|---|---|
| **3:00-4:30** | | Facilitators | **Prof. Paul Lalvani,** Empower Manpower Solutions Pvt. Ltd, ***India***<br><br>**Dr Nathalie Strub-Wourgaft**, DND*i*, ***Switzerland*** |
| | | Keynote Speaker | **Dr Daniel Argaw Dagne,** Leishmaniasis Control Program, World Health Organization**,** ***Switzerland*** |
| | | Panelists | **Dr Daniel Argaw Dagne,** Leishmaniasis Control Program, World Health Organization**,** ***Switzerland***<br><br>**Dr Margriet den Boer,** DFID Consortium**,** ***United Kingdom***<br><br>**John Kabuchi,** Kenya Medical Supplies Agency, MOH**,** ***Kenya***<br><br>**Dr Abate Mulungeta Beshah**, World Health Organization, ***Ethiopia***<br><br>**Osama Babiker Hassan Malik**, Ministry of Health, ***Sudan***<br><br>**Mayanja Martin Nsubuga**, Ministry of Health, ***Uganda***<br><br>**MSF Access Campaign** |
| **Break** | | | |
| **Session 10: Closing Session** | | | |
| **4:45-5:30** | | | **Dr Robert Kimutai**, Chief Rapporteur, DND*i*, ***Kenya***<br><br>**Prof Ahmed Mudawi Musa**, LEAP Chair, Sudan<br><br>**Dr Nathalie Strub-Wourgaft**, DND*i*, ***Switzerland***<br><br>**Mr. Yehulu Denekew**, Director General, FMHACA, ***Ethiopia***<br><br>**Dr Monique Wasunna**, KEMRI/DND*i*, ***Kenya*** |

## Poster Presentations

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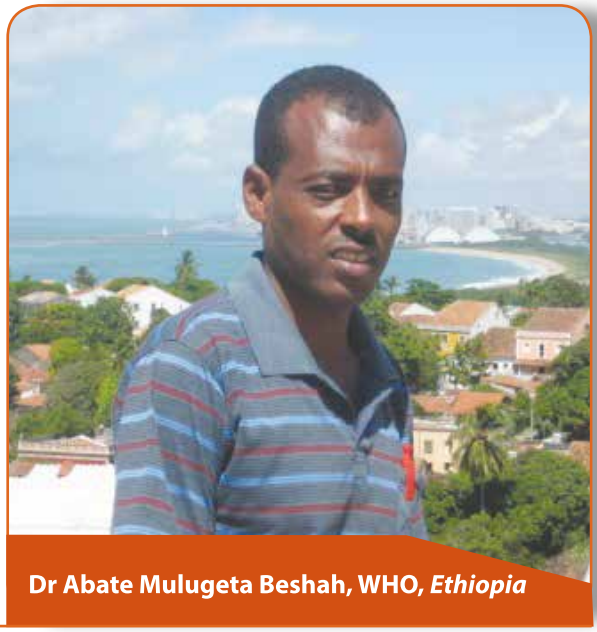
|---|---|---|
| Monday, September 29-Tuesday, September 30, 2014 | Bacterial Sepsis in Patients with Visceral Leishmaniasis in NorthWest Ethiopia | **Mengistu Endris,** University of Gondar, ***Ethiopia*** |
| | Method for Quantification of Helminthes Eggs in Human in Field Research, Modification of Kato/Katz Method | **Emmanuel Igwarro Odongo-Aginya,** Gulu University, ***Uganda*** |
| | Managing Clinical Data Queries Using and In-House Built Query Management System QMSPlus | **Seth Okeyo,** DNDi, ***Kenya*** |
| | The Current Status of Cutaneous Leishmaniasis in Ocholla, Southern Ethiopia | **Gessessew Bugssa Hailu**, Institute of Biomedical Sciences, Mekelle University, ***Ethiopia*** |
| | The Origin of the Leishmania Parasite: An African Prospectus | **Sarah H. Elgawi,** Institute of Endemic Diseases, University of Khartoum, ***Sudan*** |
| | Study on Knowledge, Attitudes and Practices (KAP) of Communities towards Kala-azar in Kafta-Humera, Northwestern Ethiopia | **Shewaye Belay,** Institute of Biomedical Sciences, Mekelle University, ***Ethiopia*** |
| | Comparison of Safety and Efficacy of Sodium Stibogluconate and Liposomal Amphotericin B for Treatment of Visceral Leishmaniasis in Patients with and without HIV co-infection in Gondar, North west Ethiopia, Gondar. | **Aschalew Tamiru**, University of Gondar, ***Ethiopia*** |
| | Bionomics of phlebotomine sandflies (Diptera: Psychodidae) in a highland kala-azar focus in Libo-Kemkem district, Northwestern Ethiopia | **Esayas Aklilu**, Addis Ababa University, ***Ethiopia*** |
| | Species composition, abundance and seasonal dynamics of Phlebotomus species in a visceral leishmaniasis endemic area of Northwest Ethiopia | **Solomon Yared**, Aklilu Lemma Institute of Pathology, ***Ethiopia*** |
| | Antileishmanial Activity Xanthium brasilicum Vell. Leaves and Isomeric Mixture of Xanthumin & Xanthinin isolated from Petroleum ether & n-hexane Extracts | **E.E. Hassan A**, Institute of Endemic Diseases, University of Khartoum, ***Sudan*** |
| | An Epidemiological Study of Visceral Leishmaniasis in Selected Villages of Raya Azebo Woreda (North East Ethiopia) using Serological Leishmanin Skin Tests | **Desaley Tadese,** Mekelle University, ***Ethiopia*** |
| | Prevalence of kala-azar infection in Pokot county, Amudat District, Northeastern Uganda | **Walter Odoch,** East, Central and Southern Africa, Health Community, Arusha, ***Tanzania*** |
| | The role of the enzyme arginase in human leishmaniasis | **Tamrat Abebe,** Addis Ababa University, ***Ethiopia*** |
| | Test of cure for Visceral Leishmaniasis | **Hashim Ghalib,** University of Lausanne, ***Switzerland*** |
| | Residual Prevalence of Trachoma after Six years of MDA in Two Endemic Segments of Narok County, Kenya | **Dr Ernest Barasa,** Ministry of Health, ***Kenya*** |
| | Identification of Environmental Parameters and Risk Mapping of Visceral Leishmaniasis in Ethiopia by using Geographical Information Systems and Statistical Approach | **Teshome Tsegaw**, Armauer Hansen Research Institute, All-Africa Leprosy and TB Rehabilitation and Training Center, ***Ethiopia*** |
| | Visceral Leishmaniasis (Kala-Azar) Risk Mapping Using Geo-Spatial Tools: A Case Study in Kafta Humera District, North Western Ethiopia | **Negussie Solomon,** GIS & Remote Sensing Specialist, ***Ethiopia*** |

# INVITED SPEAKER BIOGRAPHIES

Dr Abate Mulugeta BESHAH is currently National Professional Officer for Neglected Tropical Diseases including Leishmaniasis, in WHO-Ethiopia. Prior to his current assignment, he served as a General Practioner at government hospitals, and later as HIV/AIDS Care and Treatment Officer in MSF-Holland and FHI-Ethiopia before joining WHO-Ethiopia as Leishmaniasis Officer.

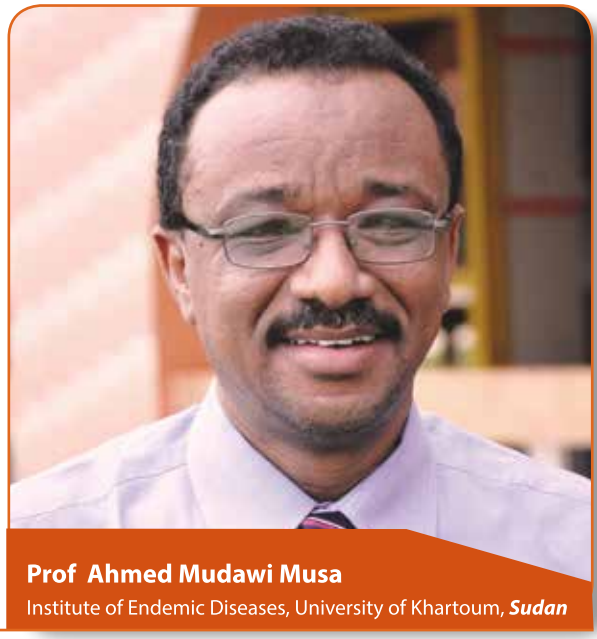
Dr Beshah carried out his post graduate studies in public health in the University of South Africa. He has publications on leishmaniasis while serving in technical position in WHO office.



**Dr Abate Mulugeta Beshah, WHO, *Ethiopia***

Dr. Ahmed Mudawi Musa is an Associate Professor of Immunology and Director of the Institute of Endemic Diseases (IEND), at the University of Khartoum. He is the secretary of the Leishmaniasis Research Group at the IEND. Prof. Musa is a physician and infectious and Tropical Medicine expert. He had his MBBS in 1994 from University of Khartoum. He joined the IEND as A teaching and a research assistant in 2000. His Ph D thesis was on immunology and immunochemotherapy of PKDL. He also got his MSc in tropical Medicine and International from The London School of Hygiene and Tropical Medicine and a diploma of Tropical Medicine and Hygiene From the Royal College of Physicians in the UK. Professor Musa is a qualified Clinical Trials Monitor by The WHO. He participated in many GCP and ethics courses as a facilitator. His main interest is to develop new options for prevention and treatment of Leishmaniasis.

As a member of the Leishmaniasis East African Platform (LEAP), Prof Musa is the principal investigator, in Sudan, for LEAP clinical trials in the country.



**Prof Ahmed Mudawi Musa**
Institute of Endemic Diseases, University of Khartoum, ***Sudan***

Dr. Asrat Hailu is a Professor of Immunoparasitology in the School of Medicine, College of Health Sciences - Addis Ababa University (AAU). He teaches in the Department of Microbiology, Immunology & Parasitology (DMIP).

Prof. Asrat holds a Ph.D degree from the University of Amsterdam, the Netherlands where he studied in the Department of Infectious Diseases, Tropical Medicine and HIV/AIDS.

Prof. Asrat has over 30 years of research experience on leishmaniasis in Africa, and has published over 120 articles in peer reviewed journals. He had been leading the Leishmaniasis Research Group at the Aklilu Lemma Institute of Pathobiology (ALIPB) for several years; and later on, he also established the Leishmaniasis Research & Diagnostic Laboratory (LRDL) in the School of Medicine, AAU.

Prof. Asrat has been leading several international projects on leishmaniasis, and has been engaged in clinical trials of LEAP funded by DNDi. He is presently engaged in a multidisciplinary research on transmission dynamics of visceral leishmaniasis in Ethiopia, which is funded by Bill & Melinda Gates Foundation

**Prof. Asrat Hailu Mekuria,**
Addis Ababa University, ***Ethiopia***

**Ayeligne Mulualem**
Chief Head of the Health Bureau
Amhara Regional State, Federal Democratic Republic of ***Ethiopia***

Ayeligne is the Amhara Regional health bureau chief head. He also the member of Amhara regional state administrative council. He takes the lead in the development, implementation and evaluation of the national and regional different development programs.

Ayeligne has over 24 years' experience in different professional and head area at governmental organization, more than half of which spent within the head of administrative area and he also served as the Amhara regional health bureau chief head for more than four consecutive years.

He holds a master of IOL(Master of International Organizational Leadership from AZUSA Pacific University at USA and a Bachelor's degree (BSc) in Biology.

**Dr Bhawna Sharma,**
Director of R&D Operations, DNDi, ***India***

Dr. Sharma joined DND***i*** as a consultant in December 2004 and served as Head of the Support office until recently, contributing to the growth of DNDi in India. She is now the newly appointed Director, R&D Operations DNDiIndia. In this role she coordinates clinical research projects and supports R&D initiatives in the region.

Before joining DND***i***, Dr. Sharma served as a research scientist with the Indian Council of Medical Research, where she gained research and regulatory affairs experience. She also previously taught pharmacology at the All India Institute of Medical Sciences (A.I.I.M.S.) in New Delhi and served as an editor for the JAMA India Medical journal.

During her post graduate work, she was involved in pharmacokinetic and cardiovascular studies. Bhawna Sharma received her PhD and completed post-doctoral fellowships in pharmacology and drug assay at A.I.I.M.S.

**Prof. Carlos Costa,**
University of Piauí, ***Brazil***

Prof Carlos Costa graduated in Medicine in 1976 from the University of Brasilia, where he trained in Internal Medicine, graduating with a Master's Degree in Tropical Medicine in 1984. As a medical student Prof Costa started his research in tropical disease, particularly epidemiology of the Chagas disease.

In 1985 Prof Costa moved back to his home town where he then began to study kala-azar. Through his research work he was able to describe the epidemiology of the first major Urban epidemic of Urban kala-azar, a phenomenon that spread to other cities of South America. Soon after this achievement Prof Costa graduated from the Harvard School of Public Health; his thesis covered the topic of the 'Human Transmission of Leishmania Infantum'. Since then he has been involved in research focusing on various aspects of kala-azar.

Presently, Prof Costa is an associated professor of Medicine at the Federal University of Piaui, at the Institute of Tropical Diseases,

Dr Daniel Argaw Dagne is currently Medical Officer and manager of the Global Leishmaniasis Control Programme, in the Department of Neglected Tropical Diseases Control, WHO, Geneva. Prior to his current assignment, he served as a director of a regional health bureau in Ethiopia and communicable disease officer at the WHO country office, in Ethiopia, with short assignments in other African countries.

Dr Dagnecarried out his post graduate studies in infectious & tropical diseases epidemiology, surveillance, control and public health fields in, Japan, China, Swiss Tropical Institute and Austria. He has several publications on leishmaniasis, malaria, HIV, TB and other communicable diseases and health systems while serving in various technical positions in the government and WHO offices.

**Dr Daniel Argaw Dagne,**
Leishmaniasis Control Program, World Health Organization, ***Switzerland***

Currently the Head of Clinical Trials Section of the Pharmacy and Poisons Board (PPB) which is the drug Regulatory Authority of Kenya. I am also the secretary to the Experts Committee on Clinical Trials of PPB

I am Pharmacist by training from University of Nairobi with eleven years of experience four years of which are in pharmaceutical regulation. We are currently working on how to streamline the review and approval of clinical trials applications in Kenya so as to promote clinical trials research in the country

**Dr Edward Abwao,**
Pharmacy & Poisons Board, ***Kenya***

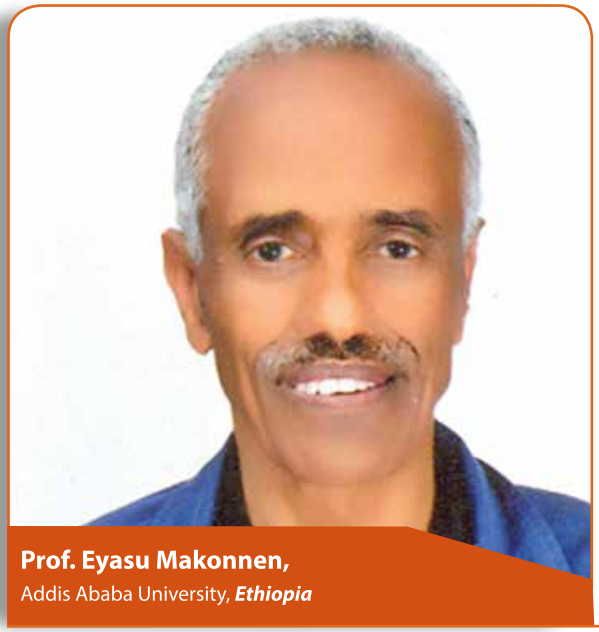
Professor Eltahir Awad Gasim Khalil graduated in the Faculty of Medicine, University of Khartoum, Sudan. He also had Post-graduate training in hematology, in Britain. Currently Prof. Eltahir is a Consultant/associated professor in hematology at the Faculty of medicine, University of Khartoum. In addition he is the Professor at the Department of Clinical Pathology & Immunology at the Institute of Endemic Diseases, University of Khartoum, Sudan.

Current position: Director General, Central Laboratory, Ministry of Science & Communications, Sudan

Research interest: Vaccines for visceral leishmaniasis, sickle cell anaemia, Hepatitis B, Latent TB infections.

Professor Eltahir is also a Fellow of the Royal Society of Pathologists, Britain; Member of the Leishmaniasis Research Group/Sudan; Member Leishmaniasis East Africa Platform; and is well published with more than 100 publications to his name.

**Prof. Eltahir Khalil Gasim,**
Institute of Endemic Diseases, University of Khartoum, ***Sudan***



**Prof. Eyasu Makonnen,**
Addis Ababa University, ***Ethiopia***

Prof. Eyasu Makonnen got his B. Pharm from AAU in 1980, his MSc in Pharmacology from University of Ljubljana in 1985, and his PhD in Pharmacology in same University in 1987. He served as Vice President of Ethiopian Pharmaceutical Association, chair of the Ethiopian Health Science and Technology Research Council, Chair of Ethiopian National Ethics Committee, Member of Ethiopian National Drug Advisor Committee and president of Ethio-Korean Alumni Association at various occasions. He is the founding member of LEAP. Prof. Makinnen's research interests are in the area of clinical trials and Phototherapy. Over the years, he has published around 100 pear reviewed publications in reputable journals. Prof. Eyasu Makonnen has been working as a professor of Pharmacology since February 2003. He is currently heading the department of Pharmacology, School of Medicine, Addis Ababa University.

**Dr Fabiana Alves,**
DND*i*, ***Switzerland***

Fabiana Piovesan Alves joined DNDi in 2008, initially as a consultant on the Chagas disease and leishmaniasis projects. She was subsequently the Leishmaniasis program manager in the Latin America region. Fabiana is now the Clinical Manager for leishmaniasis in Geneva.

Fabiana is a medical doctor, who graduated from the University of São Paulo, Brazil, with residency in Pediatrics. Her PhD thesis on the molecular epidemiology of malaria in the Amazon region was followed by a post-doctoral position at TDR/WHO. She was a professor of parasitology at the University of São Paulo, coordinated projects at research institutes and also worked as a project manager for a clinical research organization.

Fabiana has 15 years of experience in research on tropical diseases, including malaria, leishmaniasis, Chagas disease and schistosomiasis, with the last 10 years principally in clinical research for the development of new treatments for neglected diseases, managing clinical trials from Phase II through to Phase IV.

**Ms. Gugu Nolwandle Mahlangu, MSc, MBA, MPS**
Medicines Control Authority of Zimbabwe, ***Zimbabwe***

Gugu Nolwandle Mahlangu is a pharmacist by profession. After completing her pharmacy training Ms Mahlangu worked in hospital pharmacy, community pharmacy and was engaged in teaching pharmacy technicians and pharmacy students. She was involved in the preparation of the Proposed Essential Drugs List for Zimbabwe.

As a pharmacist/inspector of the predecessor of the Medicines Control Authority of Zimbabwe, Ms Mahlangu was responsible for computerisation of the Drugs Registration system and was the training officer for the WHO supported training programme for regional medicines regulatory authority personnel and local staff amongst other regulatory activities.

Ms Mahlangu has been involved in several other bodies related to the profession. She is a member and past President of the Pharmaceutical Society of Zimbabwe, former chairperson of the Pharmacists Council, Chairperson of the Medical Research Council of Zimbabwe and a board member of the National Pharmaceutical Company. She is also a member of several WHO Expert Committees

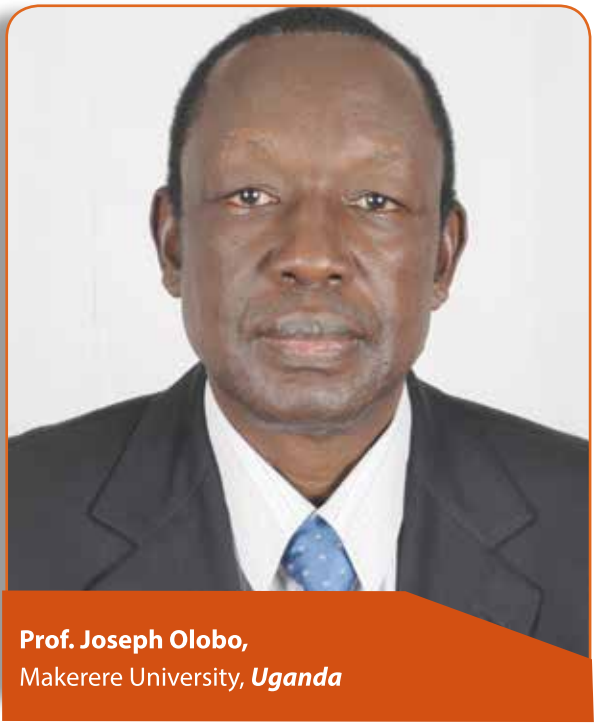
Helen Byomire Ndagije is a pharmacist and clinical epidemiologist, who currently heads the Drug Information Department at the National Drug Authority, in Uganda. She has holds a Masters degree in business administration and has also been head of the National Phamacovigilance Centre since 2006.She is known for having introduced a decentralised system of pharmacovigilance in Uganda. She has also been the Vice Chairperson of the African Vaccine Regulator's Forum (AVAREF), a network that has seen the regulatory system for clinical trials of medicines and vaccines uplifted in the last 10 years. The WHO supported AVAREF initiative of the 24 member countries meets annually and the last meeting was hosted by Uganda.

In August 2014, Helen also participated as a member of the expert panel to advise WHO of the ethical considerations for the use of unregistered interventions for the Ebola Viral disease. She is also a member of the Tuberculosis Technical Expert group and various such other groups. Currently, Helen is also part of the East African Community Pharmacovigilance Expert working group.
Previously, Helen was a clinical trial manager for a project by the Medical Research Council in Uganda; Development of Anti-retroviral Therapy, after her excellent performance and completion of a phase II microbicide project in Uganda.

**Dr Helen Byomire Ndagije,**
National Drug Authority, ***Uganda***

John holds an undergraduate degree in human biology and was trained as a medical doctor, both at the Kwame Nkrumah University of Science and Technology-Kumasi, Ghana. John also graduated from the University of Minnesota School of Public Health, USA, with an MPH in Public Health Policy and Administration and an MS is Health Services Research. Earlier this year, he completed a PhD in Health Services Research, Policy and Administration also at the University of Minnesota. In between his Masters and PhD studies, he served as head of the R&D Unit at the Komfo Anokye teaching Hospital in Kumasi, Ghana for 3 years. Dr. Amuasi has been consulted by a number of international organizations including the Drugs for Neglected Diseases initiative (DNDi), Medicines for Malaria Venture (MMV), World Health Organization (WHO), Health Action International (HAI) Africa, Dalberg Global Development Partners, the International Centre for Trade and Sustainable Development (ICTSD), and France Expertise Internationale (FEI) on a wide range of issues related to health services, policy and systems in Ghana and other parts of Africa. John is currently a Senior Research Fellow at the Kumasi Centre for Collaborative research in Tropical Medicine (KCCR) in Kumasi, Ghana

**Dr John H. Amuasi,**
University Of Minnesota, School of Public Health, ***USA***

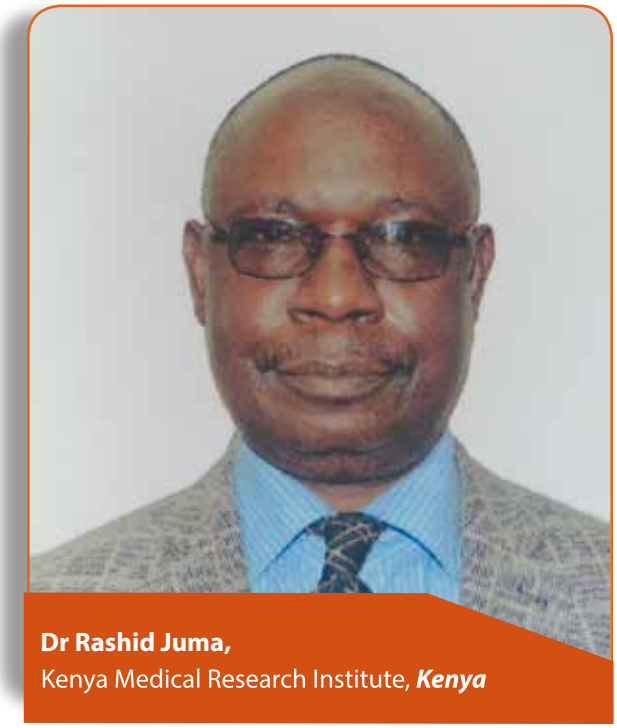


**Prof. Joseph Olobo,**
Makerere University, ***Uganda***

Joseph Olobo is currently a professor of Immunology and Microbiology at the College of Health Sciences, Makerere University, Kampala, Uganda. He is a veterinarian by training and has a master's degree in Immunoparasitology and a PhD degree in Immunobiology.

His interest in Tropical Diseases spans back to late 1970's when he studied the epidemiology of Trypanosomiasis and Leishmaniasis at the ICIPE, Kenya and later an ambitious study at ILRAD (now ILRI), Kenya, in early 1980's to produce cow monoclonal antibodies against trypanosomes. Utilizing the murine model at WEHI, Australia, Prof Olobo demonstrated for the first time that antibodies had no protective role during infection with cutaneous leishmaniasis. A finding which later shifted the focus of research on immunology of leishmaniasis. While at the Institute of Primate Research, Kenya, and with funding mainly from the WHO/TDR, Prof Olobo established the non-human primate model for testing anti-leishmania vaccines.

Prof Olobo has over the years contributed to capacity building having trained young scientists from mainly Eastern Africa including Kenya, Ethiopia and Uganda.He has and continues to sit on a number of international and local scientific committees and regulatory bodies including; immunotherapy of TB (TDR), Control of Leishmaniasis (TDR), National Certification Committees of Guinea Worm Disease and Onchocerciasis (Ministry of Health, Uganda).



**Dr Rashid Juma,**
Kenya Medical Research Institute, ***Kenya***

Dr Rashid joined the Kenya Medical Research Institute (KEMRI) in 1983 as an assistant research officer, during which time he contributed to research work at the institute. By 1988 Dr Rashid had obtained a certificate in tropical medicine from Nairobi University and then moved on to become a specialist in internal medicine after obtaining a Masters in Medicine (Mmed) in 1989 by obtaining.

Despite his accomplishment Dr Rashid over the years continued to participate in training, between 1990 and 2003, he signed up for several short courses in ethics, GCP and clinical monitoring; after which he proceeded to participate in several refresher courses . Then between 2004 and 2006, Dr Rashid was the Clinical Trials manager at the Drugs for Neglected Disease Initiative (DNDi ), during which time he contributed immensely to the development of study trial sites in Ethiopia and Sudan and the improvement of the Centre for Clinical Research (CCR), KEMRI. Other organizations that have benefited from Dr Rashids expertise are Glaxosmithkline (GSK), which hired him between 2009 and 2013 as one of the clinical monitors for the RTSS, malaria.

Currently, the Dr Rashid is a principle investigator (PI) of a phase I clinical trial aimed at developing an oral chemotherapeutic agent, a derivative of miltefosine, for visceral leishmaniasis and hopefully for cutaneous leishmaniasis too. He has extensively published and supervises a number of post graduate students from Jomo Kenyatta University of Agriculture and Technology

Kirana Bhatt, was born in Kenya and is a professor of internal medicine in the department of medicine of university of Nairobi. She did her masters in internal medicine from the University of Nairobi and specialized in tropical medicine from London school of Hygiene and Tropical Medicine. She did her training in bio Ethics from University of Washington. Currently she is the chair of National Bioethics committee of Kenya. She has also been a member of ethics committee of Kenya Medical Research institute and chair of ethics and research committee of university of Nairobi. She has been a council member of National council of science and technology of Kenya. She is a member of scientific advisory committee of Drugs for Neglected Diseases Initiative. Has been a recipient of staff merit award from the university of Nairobi for the out-standing contribution towards the mission of the university. She was awarded elder of the burning spear by the president of Kenya in recognition of the outstanding contribution to the Nation in the field of health. She is a recipient of Malaria Afya award for contribution towards control of malaria in Kenya. Has widely published and presented papers in numerous conferences. Her research interests are in the field of tropical disease and HIV.

**Prof. Kirana Bhatt,**
University of Nairobi, ***Kenya***

Dr Merce Herrero (MD, MPH), is a family doctor with a master in clinical research and international health by the University of Barcelona, Spain. She has been working in the Horn of Africa for the last 10 years, since leishmaniasis became her passion after working in the VL Libo Kemken outbreak in 2006-2007 in the MSF-Spain Kalazar project.

She worked with the WHO-Ethiopia supporting the leishmaniasis national control program mainly from Ethiopia but also Sudan, South Sudan, Eritrea and Kenya. She has been involved in several program activities; revitalizing the national VL taskforce and working groups, updating the VL guidelines, conducting trainings and participating in the National Master Plan for NTDs in AFRO VL countries which have allowed putting leishmaniasis in the MOH agendas of affected countries. She has collaborated on epidemiological studies and outbreak assessments of leishmaniasis in Ethiopia, resulting in publications with an international team of leishmaniasis experts. She's currently working as independent consultant with the Kalacore Consortium(funded by DFID) during the inception phase for the Ethiopia country program development.

**Dr Merce Herrero,**
Kalacore Consortium, ***Ethiopia***


**Dr Monique Wasunna,**
KEMRI/DND*i*, ***Africa***

Dr Monique Wasunna is the Assistant Director, Research, KEMRI and the Director of Drugs for Neglected Diseases Initiative (DND*i*), Africa Regional Office.

Dr Wasunna is a physician and an infectious disease and tropical medicine specialist. She holds a Bachelor of Medicine and Bachelor of Surgery degree from the University of Nairobi. Her postgraduate training in medicine was sponsored by WHO-TDR at the London School of Hygiene and Tropical Medicine, University of London, where she obtained an MSc and a PhD in medicine and a diploma in Tropical Medicine and Hygiene from the Royal College of Physicians of London. She is a Fellow of the Royal Society of Tropical Medicine and Hygiene, a member of the Kenya Medical Association and Kenya Association of Physicians.

In 2008, Dr Wasunna was appointed by the Director General, UNESCO, as a member of the International Bioethics Committee (IBC), a position she holds to date. She is currently a vice Chairperson of IBC. She is a member of the National Bioethics Committee, member of KEMRI Ethics Committee and a member of Kenyatta National Hospital and University of Nairobi Scientific and Research Ethics committee.

Dr Wasunna's research interest is primarily focused on clinical trials in visceral leishmaniasis, malaria, and HIV. She has been a principal investigator in many clinical trials that have attracted funding from WHO and other international organizations. She is a member of the Expert Committee of Clinical Trials of the Pharmacy and Poisons Board and the founding Chairperson of the Leishmaniasis East Africa Platform (LEAP). LEAP is a clinical research platform that brings together scientists and institutions in Eastern Africa to develop clinical trial capacity to bring new treatment options to neglected visceral leishmaniasis patients in the region. Dr Wasunna co-ordinates all LEAP activities in the region supported by DND*i*. She is well published in peer review journals

**Dr Nathalie Strub-Wourgaft,**
DND*i*, ***Switzerland***

Dr Nathalie Strub-Wourgaft joined DND*i* in 2009 to supervise the clinical activities conducted by the not-for-profit organisation in the field of Neglected Diseases. Her background is of 20 years' experience in clinical development gained through senior positions in the pharma and later biotech companies. At DND*i* she has also been involved with regulatory challenges and participates in working groups focusing on the ethics review of clinical trials.

Dr Strub-Wourgaft graduated as Medical Doctor from Necker Hospital, Université René Descartes in Paris, France, in 1983.

Dr Nekoye Otsyula joined DND*i* as a Project Coordinator in July 2014. She most recently served as a Research Officer at the KEMRI Walter Reed Project in Kisumu, Kenya where she worked as a Co-Investigator and Principal Investigator on drug and vaccine clinical trials and epidemiological studies in HIV, malaria and other infectious diseases from 2006 to 2014

Dr Otsyula graduated as a medical doctor from The University of Nairobi in 2005 and is an infectious disease specialist having obtained a Masters in Science in Emerging and Neglected Infectious Disease from the University of Edinbugh in 2011. She recently completed a course in Advanced Vaccinology (ADVAC) at the Fondation Mérieux.

**Dr. Nekoye Otsyula,**
**DND*i*, *Africa***

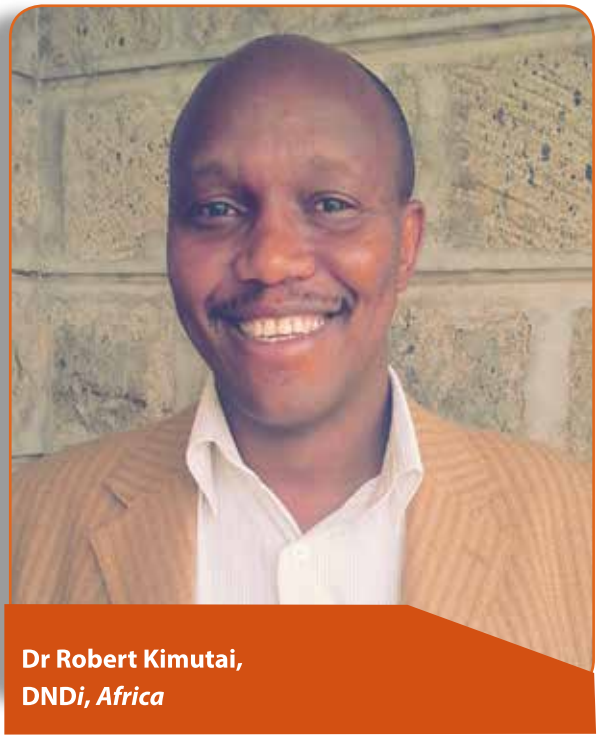
Dr Pauline NM Mwinzi, is currently the Chief Research Officer and Head of the NTD Research Unit, Center for Global Health Research (CGHR), Kenya Medical Research Institute (KEMRI), Kisumu, Kenya. Her specialization is in Parasitology and Immunology (PhD, 2005) after training at the Universiteit Utrecht Medical School in the Netherlands, CDC Atlanta on an ISID scholarship and at the Kenyatta University on a WHO/TDR scholarship.

Dr Mwinzi research interests are focsed on unraveling the immune mechanisms related to development of resistance to schistosome infections, as well as operational research for the control of Neglected Tropical Diseases (NTDs). She is also a Principal Investigator with SCORE (www.uga.edu/score) and with EFINTD (EFINTD.org) and currently mentoring over over 10 graduate fellows.

Dr Mwinzi was one of the founders of the Annual KEMRI NTD Conference, which is now in its 8th year, and sits as the current Chair of the KEMRI Annual Scientific Health Conference (KASH). Dr Mwinziis also the founding Chair of the African Research Network For NTDS (www.ARNTD.org). She also serves from time to time as a Temporary Advisor to the WHO AFRO on NTD mapping and implementation of national control programs.

In addition to her research work, Dr Mwinzi also contributes to teaching graduate Bioethics at Jaramogi Oginga Odinga University of Science and Technology (JOOUST) and Immunology at Maseno University. In addition, she also makes an effort to give back by participating in community activities especially those related to education opportunities for disadvantaged children.

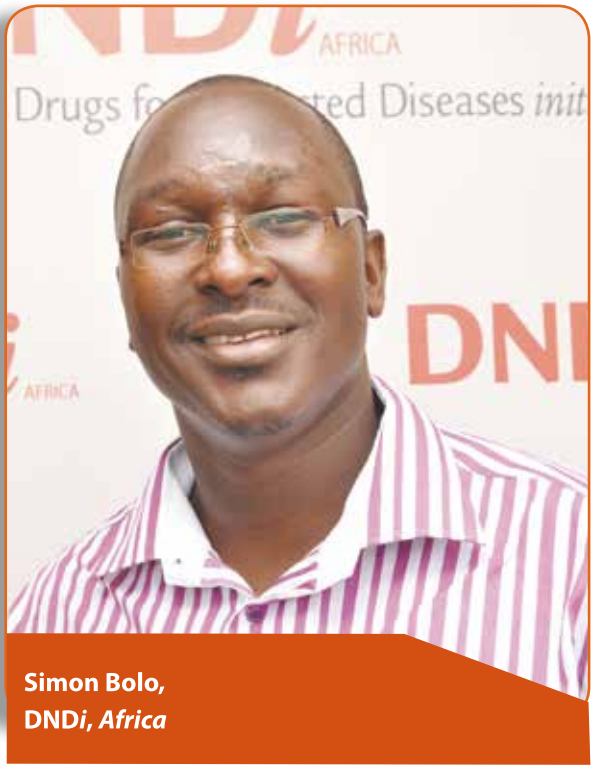
**Dr Pauline Mwinzi, PhD**
Kenya Medical Research Institute, ***Kenya***



**Dr Robert Kimutai,**
**DND*i*, *Africa***

Dr Robert Kimutai is a Clinical Trial Manager at the DNDi Africa Regional Office, Nairobi. He is a Paediatrician and General Public Health Specialist having trained at the University of Nairobi for Master of Medicine in Paediatrics and Master of Public Health at the Institute of Tropical Medicine in Antwerp.

He has worked in KEMRI Centre for Clinical Research since 1995. He joined as Assistant Research Officer and has since worked in several clinical research projects including KEMRI Walter Reed Project as Medical Officer and Principal Investigator in HIV vaccine trial; KEMRI Wellcome Trust as Paediatrician and Clinical Trialist and currently with DNDi /KEMRI (Drugs for Neglected Diseases Initiative) as a Clinical Trial Manager. He has been involved in in Clinical Trials Management of Leishmania protocols Phase II, III and IV trials. He has also participated in malaria and HIV clinical research. He has also participated as Safety Review Board member in HIV vaccine trials.




**Simon Bolo,**
**DND*i*, *Africa***

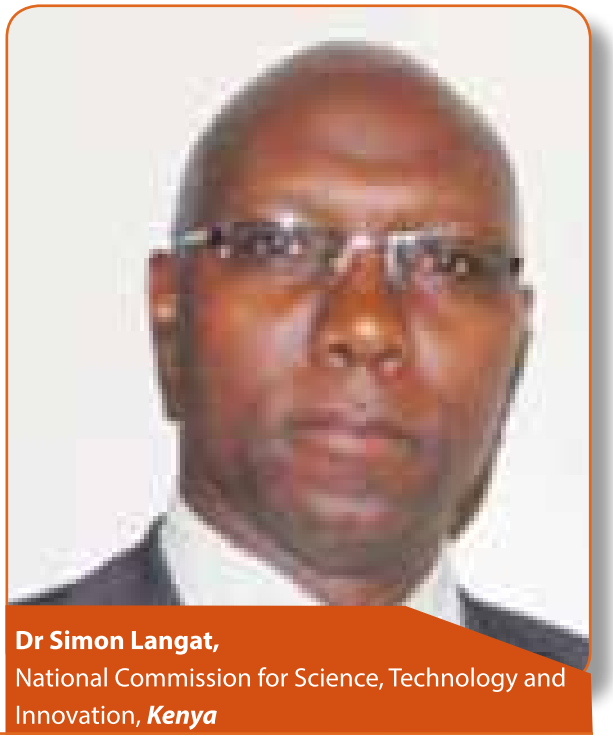
Simon is the Regional Operations Manager for the DNDi Africa Regional Office in charge finance, administration and operation functions of the Nairobi office. He also takes the lead in the development, implementation and evaluation of the Nairobi office strategy and annual action plan.

Simon has over 15 years' experience progressively gained in the private and non-profit sector, nine of which within the clinical trials sector. He has immense experience in Budget proposal development; Financial Management, Training in accounting and finance; Strategy formulation and implementation; Operations Management, Partnership Management; Human Resource Management and general administration.

Simon has been able to develop and implement a standard for financial reporting (Good Financial Practice – GFP) for DNDi implementing partners across the region as well as develop simple financial tools for non-finance professionals to assist in financial reporting.

He holds an MBA from Strathmore Business School (SBS) and a Bachelor's degree (BSc) in International Business Administration from the United States International University in Nairobi and is a qualified Accountant of Kenya – CPA.

Dr Langat is a Senior Research Officer Department of Research Development, Ministry of Finance & Planning, Kenya. In the Health Sciences Division he deals with health research issues and policy including ethics and is currently involved in the process of developing review guidelines for research involving human subjects. For his practicum project, Dr. Langat researched the practices of IRBs in Kenya with respect to access for research purposes to stored biological material, a topic of great relevance and interest both in Kenya, where a great deal of research takes place, and throughout the continent.



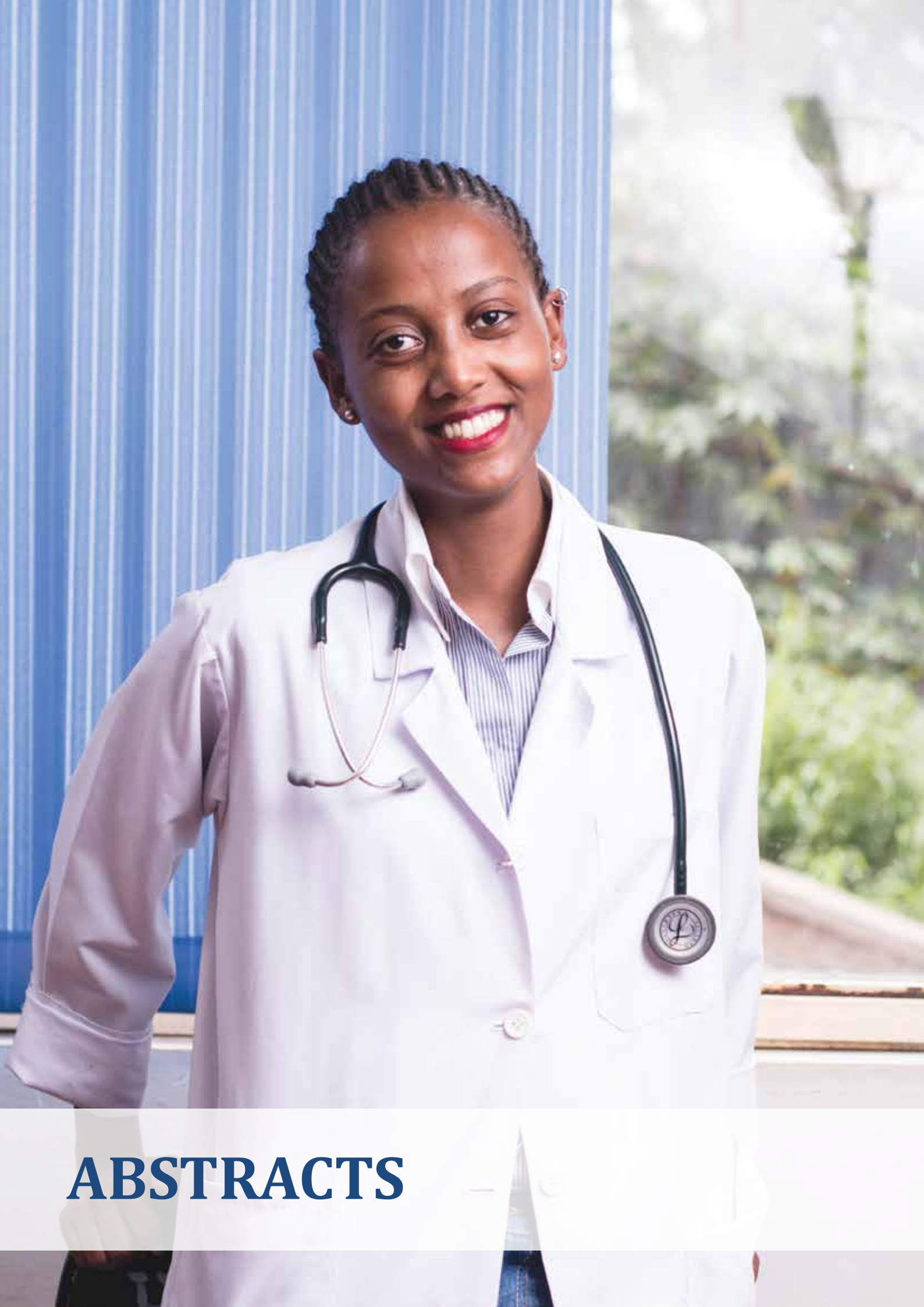
**Dr Simon Langat,**
National Commission for Science, Technology and Innovation, ***Kenya***

Prof. Yalemtsehay Mekonnen joined the Addis Ababa University (AAU) in 1971 and obtained a BSc. degree in Biology in 1978. She started her career as a graduate assistant in the Department of Biology, Faculty of Science. Thereafter, she joined the first graduate programme launched in the Department obtaining an M.Sc degree in Biology in 1980. At this time she was not only part of the first batch of graduates but also the first woman in AAU. In 1988, she persue a PhD degree at the University of Heidelberg in Germany, in the area of Human Physiology. In May 1992 she returned to AAU serving the Department of Biology at the rank of Assistant Professor. Thereafter, from 1993 to 1995 she served as the Head of the Department of Biology. By 1999, Prof Mekonnen had been promoted to the rank of Associate; l from Feb. 2003 to Oct.2007. ater she took up the role as the Director of the Aklilu Lemma Institute of Pathobiology. Finally, in 2009, she was promoted to the role of full Professor.

Over the years Prof Mekonnen has received a number of awards in her field, She has also contributed to and initiated a number of national and international research networks and collaborations; serving as Vice President and President of the Biological Society of Ethiopia. In addition, she has presented numerous presentations at national, regional and international scientific and professional meetings and conferences.

Prof Mekonnen has a keen interest to encourage female students. One such activity is exemplified in my role in taking part in project development for soliciting funds for the establishment of a resource centre with computer facilities for female students of the Faculty of Science that was launched at the beginning of 2005. Currently, Prof. Mekonnen is teaching, carrying out research and is also the Head of the Gender Office of the Faculty of Science in Addis Ababa University

**Prof. Yalemtsehay Mekonnen,**
Amhara Regional State, Federal Democratic Republic of Ethiopia
Addis Ababa University, ***Ethiopia***



# ABSTRACTS

# THE CHALLENGES OF MANAGING PATIENTS WITH KALA-AZAR IN SUDAN

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Visceral leishmaniasis (kala-azar) is an increasingly recognized major health problem and it is unique in Sudan. Control measures, that include case-detection, treatment with antimonial drugs and vector control, have been disappointing. Recent epidemics have been responsible for displacement of large populations, high morbidity and mortality. Practicing physicians face major problems: kala-azar endemic areas are geographically remote with inadequate health facilities. Transport from the endemic areas to central hospitals is difficult, costly and impossible during the rainy season. Moreover, civil unrest and social instability limit access to the available health services. Accurate data on the burden of kala-azar does not exist in many kala-azar foci as large proportions of kala-azar cases are not recorded. Non-governmental organizations (NGOs) are using their own protocols for diagnosis and treatment. Sodium stibogluconate (SSG) alone or in combination, although still efficient, they are not free from toxicity. Alternative drugs are numerous yet none registered in Sudan. Post kala-azar dermal leishmaniasis (PKDL) ensues in 60% of treated kala-azar. The cost of supportive treatment and treatment of concurrent diseases like AIDS and TB is always beyond the financial capabilities of the patients.

In conclusion, remote harsh endemic areas, poverty, civil unrest, toxic drugs, emerging resistance to conventional antimonials and concurrent infectious diseases remain the main challenges of managing patients with kala-azar in the Sudan.

# PAROMOMYCIN/SODIUM STIBOGLUCONATE COMBINATIONS, SAFETY AND POSSIBLE EFFICACY FOR TREATMENT OF POST KALA-AZAR DERMAL LEISHMANIASIS CASE SERIES

**Brima Younis; Hatim Mohammed; Mohammed Dafalla; Abubakr Adam; Mohammed Elamin; Ahmed Musa; Ahmed El-Hassan and Eltahir Khalil***

***Department of Clinical Pathology and Immunology, Institute of Endemic Diseases, University of Khartoum; Khartoum, Sudan***

Post kala-azar dermal leishmaniasis (PKDL) is a recognized dermatologic complication of successfully treated visceral leishmaniasis (VL). PKDL lesions are suspected to be important reservoirs for VL transmission in Sudan. Prolonged treatment schedules, feeling of general well-being and the social stigmata of PKDL prevent most patients seeking treatment. The mainstay of treatment is cardiotoxic sodium stibogluconate (SSG) for 60-120 days. Recently, liposomal amphotericin B (Ambisome®) and immunochemotherapy gave promising results. Ambisome® is expensive and difficult to prepare under field conditions. Paromomycin/SSG combination has been shown to be safe, efficacious and can save time in VL treatment. This report aims to prove that Paromomycin/SSG combination can cure and reduce PKDL treatment duration.

Nineteen cases of patients with PKDL lesions of ≥ 6 months duration who were diagnosed by clinical signs, histopathological/immunohistochemical and PCR. Patients' mean age was 14.9 ±5.9 years. Nine patients (9/19; 47.4%) among whom (3/19; 15.8%) patients failed previous SSG treatment of 2-3 months duration responded completely to 40 days of Paromomycin (single)/SSG (single) combination daily doses while (5/19; 26.3%) responded to 30 days of the Paromomycin (single)/SSG (single) combination. One patient (1/19; 5.26%) relapsed following the 30 days combination regimen.

A second group of ten patients (10/19; 52.6%) with (2/19; 10.52%) patients who failed previous SSG treatment, responded to 15-20 days of Paromomycin (double)/SSG (single) daily doses.
In conclusion, Paromomycin/SSG combinations are time-saving, safe and efficacious for PKDL treatments.

# SECONDARY PROPHYLAXIS OF VISCERAL LEISHMANIASIS RELAPSES IN HIV CO-INFECTED PATIENTS USING PENTAMIDINE AS A PROPHYLACTIC AGENT: A PROSPECTIVE COHORT STUDY (NCT01360762)

**Ermias Diro[1],[2], Koert Ritmeijer[3], Lutgarde Lynen[2], Sally Ellis[4], Kolja Stille[3], Helina Fikre[1], Rezika Mohammed[1], Alan Pereira[3], Raffaella Ravinetto[2], Maaike de Crop[2], Joris Menten[2], Marleen Boelaert[2], Asrat Hailu[5], Johan van Griensven[2]**

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The relapse rate of visceral leishmaniasis (VL) among HIV coinfected patients in the first year of treatment reaches 60%. This is despite being on antiretroviral treatment (ART). Established risk factors for VL relapse include previous episodes of VL, low CD4 count and advanced HIV clinical stage. No single study has evaluated the value of secondary prophylaxis in VL-HIV coinfection in L donovani endemic regions. Such strategies should be safe, effective and feasible to implement in low-income settings. Since pentamidine (PM) is not used for VL treatment in many countries, it has been proposed for secondary prophylaxis in regions with anthroponotic transmission.

To share preliminary findings of an ongoing clinical trial on use of pentamidine as a secondary prophylaxis for VL in HIV positive patients

The effectiveness, safety and feasibility of PM infusion (4 mg/kg; monthly infusion for at least one year) in VL-HIV co-infected adults were evaluated in a prospective cohort study in Northern Ethiopia. ART is systematically provided. Three groups of patients were recruited: 1) Current primary VL: active VL during the study period and with risk factors for future VL relapse (CD4 count< 200 cells, WHO stage IV HIV disease; 2) Current VL relapse: presenting with VL relapse during the study period; 3) Past VL: a history of VL but presenting with risk factors for VL during the study period. Exclusion criteria include pre-existing renal dysfunction or diabetes mellitus, pregnancy and lactation.

A total of 161 patients were screened at the two clinical trial sites, and 74 patients were recruited from Nov 2011 to Sept 2013. The main reasons of screening failure were high CD4 count and too far away residency from the study sites. So far seventeen (23%) patients have relapsed, seven died (including two after VL relapse) and four were lost to follow up. The other causes of death were to renal failure and infections such as meningitis, pneumonia and sepsis. One patient was made to discontinue PM due to (reversible) hyperglycemia.

This is the first large-scale prophylaxis study in VL-HIV coinfection that is assessing the effectiveness, safety and feasibility of the intervention. The study is still ongoing and the final results of the clinical trial will be available by the end of this year.

# A SCREEN AND TREAT STRATEGY TARGETING VISCERAL LEISHMANIASIS IN HIV INFECTED INDIVIDUALS IN ENDEMIC EAST-AFRICAN COUNTRIES: THE WAY FORWARD?

**Johan van Griensven, MD, MSc, PhD[1], ErmiasDiro, MD[1,2] Rogelio Lopez-Velez, MD, PhD[3] KoertRitmeijer, MSc, PhD[4] Marleen Boelaert, MD, PhD[5] Ed Zijlstra, MD, PhD[6] Asrat Hailu,MSc, PhD[7] Lutgarde Lynen, MD, PhD[1]**

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In the wake of the HIV epidemic, visceral leishmaniasis (VL) has been re-emerging, particularly in North-Ethiopia where up to 40% of patients with VL are co-infected with HIV. Management of VL in HIV co-infection is complicated by increased drug toxicity, and high mortality and treatment failure rates, despite initiation of antiretroviral treatment. Tackling L donovani infection before disease onset would thus be a logical approach. A screen and treat approach targeting latent or the early stage of infection has successfully been implemented in other HIV-associated opportunistic infections. While conceptually attractive in the context of VL-HIV, the basic understanding and evidence underpinning such an approach is currently lacking. As a first step, studies will have to be conducted to quantify the risk of VL in different risk groups and across CD4 cell count levels. This study aims to develop and test a "screen and treat" strategy for VL in HIV-infected individuals.

We propose to conduct a multi-centre prospective cohort study in a VL endemic region in North-Ethiopia, where large numbers of HIV-infected patients are enrolled in HIV care. A pilot study will be started in Metema before the end of 2014. As residents of this region with high VL-endemicity, these HIV patients are exposed to L donovani infection and are in regular medical follow-up. Patients will be monitored for leishmania infection and VL for a period of up to three years with three-monthly clinical and laboratory evaluation. In addition, the immunoprofile of the different types/stages of leishmania infection and the associated risk profiles will be determined.

Based on this information, we aim to develop and evaluate prognostic clinical tools, integrating host, HIV and Leishmania infection markers, to detect individuals at high risk of VL. Ultimately, this could lead to a "screen and treat" strategy for VL in HIV-infected individuals living in VL-endemic areas.

# IMPACT OF THE USE OF A RAPID DIAGNOSTIC TEST FOR VISCERAL LEISHMANIASIS ON CLINICAL PRACTICE IN ETHIOPIA: A RETROSPECTIVE STUDY

**E. Diro[1,2], M. Assefa[3], L. Lynen[2], Y. Takele[1], B. Mengesha[1], E. Adem[1], R. Kimutai[4], A. Hailu[5], M. Boeleart[2], J. van Griensven[2]**

*[1]University of Gondar, Gondar, Ethiopia*

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Clinical diagnosis of visceral leishmaniasis (VL) is inaccurate with the probability of disease being 40-60% with clinical case definition, and should be supported by a standardized diagnostic algorithm. Guidelines recommend the use of rK39 rapid diagnostic test as a first step followed by a second test (DAT or tissue aspiration) if negative. A properly screened patient fulfilling the clinical case definition and positive with rK39 will have a positive predictive value above 85%. We assessed the routine practice applied in diagnosing VL at a research center in a teaching hospital in Ethiopia. Retrospective record analysis was done for all patients who had rK39 rapid diagnostic test at Leishmaniasis Research and Treatment Center (LRTC) of University of Gondar (UoG) Hospital, Northwest Ethiopia between June 2012 and June 2013.

From a total of 928 patients tested 308 (33.2%) were rK39 positive. Tissue aspiration was done for the 237 (77.2%) rK39 positive patients and parasitological confirmation was made in 165 of the patients showing positive predictive value of rK39 to be 69.6%. If the 71 rK39-positive patients that had not undergone tissue aspiration would all be considered to be VL cases, the PPV would increase to 77%. Only 126 (20.3%) of the 620 patients with a negative rK39 test underwent tissue aspiration.

The VL diagnostic algorithm appeared to be applied in a reverse manner: a negative test was most of the time not followed by a second test. Unlike the previous evidences the PPV was found to be low, maximum of 77%. While further studies are required to know why the guidelines are not followed, implementation of quality control for leishmania RDT and trainings may help improve the practices in VL diagnosis.

# SIMPLIFIED MOLECULAR DETECTION OF LEISHMANIA PARASITES IN VARIOUS CLINICAL SAMPLES FROM PATIENTS WITH LEISHMANIASIS

**Claire Mugasa, Thierry Laurent, Gerard J Schoone, Frank Basiye, Alfarazdeg Saad, Sayda El Safi, Piet Kager, Henk Schallig**

***Dept. of Biotechnical and Diagnostic sciences College of Veterinary Medicine, Animal resources and Biosecurity (COVAB) Makerere University Kampala***

Molecular methods to detect Leishmania parasites are considered specific and sensitive; but despite this, the tests are at present not ideal for field diagnosis as they employ equipment that is not practical in field conditions moreover often expensive. In the present study isothermal, nucleic acid sequence based amplification (NASBA) was coupled to a single step detection technique oligochromatography (OC) to simplify and reduce time for the diagnosis of leishmaniasis.

Blood was collected 30 from Sudanese visceral leishmaniasis patients, confirmed by microscopy; and 50 healthy individuals (endemic controls) were included. For cutaneous leishmaniasis, skin biopsies were collected from Brazil (n=43), Suriname (n=27) and control skin biopsy samples (n=5). NASBA assay in this study targeted a 170-bp region in the 18S rRNA, and was performed using the NuclisenseBasicKit™ on Boom-extracted DNA. Amplicons were detected using an oligochromatographic dipstick at 55°C for 5min. Test accuracy was determined in a 2X2 table and level of test agreement with microscopy was determined by the Kappa (K) values with 95% confidence intervals using Epi-info version 6.

Ethical clearance for sample collection in Sudan was approved by the Faculty of Medicine, University of Khartoum and from the National Ethical Committee at the Federal Ministry of Health Sudan; in Suriname by the Medical Ethical Committee of the Academic Medical Centre, Amsterdam, The Netherlands (MEC 03/228); in Brazil, the Brazilian National Review Board of the Ministry of Health (Commissão Nacional de ÉticaemPesquisaParecer no. 1142/2005). Written informed consent was obtained from study cases before clinical samples for research purpose were collected.

Diagnostic sensitivity of NASBA-OC was 93.3% (95% CI: 76.5%-98.8%) and specificity was 100% (95% CI: 91.1%-100%) on blood samples, while sensitivity and specificity on skin biopsy samples was 98.6% (95% CI: 91.2%-99.9%) and 100% (95% CI: 46.3%-100%), respectively.

This NASBA-OC is more sensitive than previously documented PCR tests, and thus offers hope for diagnosis of leishmaniasis especially in Sudan, where generally parasitaemia is reported to be low. The NASBA-OC format brings implementation of molecular diagnosis of leishmaniasis in resource poor countries one step closer by eliminating the need of a thermocycler and use of ethidium-stained agarose gel while reducing the test-time.

# THE PHARMACOKINETICS OF SINGLE INTRAMUSCULAR DOSE OF PAROMOMYCIN SULFATE, SODIUM STIBOGLUCONATE AND THEIR COMBINATION IN HEALTHY VOLUNTEERS

**Mahmoud M.E. Mudawi[1, 2], Eltahir A.G. Khalil[2], Idris B. Eltayeb[3], Sania A.I. Shaddad[3], Gilbert O. Kokwaro[4,5], Isaiah M. Githiga[4], Ahmed M. Musa[2]**

*[1]Faculty of Pharmacy, Northern Border University, Saudi Arabia*

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*[3]Faculty of Pharmacy, University of Khartoum*

*[4]Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi, Nairobi, Kenya,*

*[5]Kenya Medical Research Institute (KEMRI)/Wellcome Trust Research Programme, Centre for Geographic Medicine Research (Coast), Kenya.*

Pharmacokinetic properties of drugs used for treatment of visceral leishmaniasis (VL) are implicated in the variation in their efficacy. Although Sodium stibogluconate (SSG) is still in use in East Africa with acceptable efficacy and safety, there is a growing interest to combine it with paromomycin (PM) to bring down its cost and improve its efficacy and safety. Available information on the pharmacokinetics of PM and SSG is limited, this study was conducted to characterize the pharmacokinetics of PM, SSG and their combination in healthy Sudanese participants and to investigate the pharmacokinetics of drug- drug interaction.

Following informed consent, 18 healthy males were enrolled in this study. Of these 8 participants received SSG 20 mg/kg IM, 5 participants received Pm 15 mg/kg IM and 5 participants PM 15 mg/kg plus SSG 20 mg/kg. Plasma was collected at 0.25, 0.5, 1, 2, 4, 6, 8, 12 and 24 hours after administration of PM, SSG and the combination of both drugs. Urine samples were collected during 0 to 2, 2 to 4, 4 to 6, 6 to 8, 8 to 12, and 12 to 24 hours of the injections. The analysis of plasma and urine samples for PM detection and quantification was performed with a high-performance liquid chromatographic (HPLC) whereas detection and quantification of Sb was performed in a graphite furnace atomic absorption spectrometer. Pharmacokinetic parameters were analyzed using the pharmacokinetic program Kinetica 4.4.

Peak PM concentrations were achieved within 2 hours and it was undetectable beyond 8 hours in both participants who received PM alone and PM/SSG combination. SSG was detected after 24 hour in both in participants administered SSG alone and PM/SSG combination. The mean concentrations of urinary PM at 2-4 and 4-6 hours were higher in the participants administered PM/SSG combination ($p<0.05$). Generally, most of the administered dose was excreted in the urine of volunteers within 24 hours suggesting that absorption was complete. PM half-life 2.58 (hr), C max 19.5 (µg/ml), T max 2 (hr), AUC total 78.8 ((hr)*(µg/ml)), Clearance 12.5 (mg/kg*hr/(µg/ml)), and volume of distribution 47.11 (mg/kg/( µg/ml)), when given alone. PM when given in combination with SSG showed half- life 1.85 (hr), C max 18.09 (µg/ml), T max 1.25 (hr), AUC total 70.64 ((hr)*(µg/ml)), Clearance 12.76 (mg/kg*hr/(µg/ml)), and volume of distribution 33.41 (mg/kg/( µg/ml)).

SSG half-life 3.07 (hr), C max was 48.3 (µg/ml), T max 1.75 (hr), AUC tot 240.97 ((hr)*( µg/ml), clearance 5.52 (mg/kg*hr/( µg/ml)), and volume of distribution 23.18 (mg/kg/( µg/ml)), when given alone; it showed half-life 2.81(hr), C max 40.56 ( µg/ml), T max 1.81 (hr), AUC tot 197.74 ((hr)*( µg/ml), clearance 6.05 (mg/kg*hr/( µg/ml)), and volume of distribution 24.19 (mg/kg/( µg/ml) when given in combination with PM.

Variation in the efficacy of drugs in the treatment of leishmaniasis is frequently due to differences in drug sensitivity of leishmania species, the immune status of the patient, or the pharmacokinetic properties of the drug (Simon; et al., 2006).

The pharmacokinetic parameters for paromomycin in healthy volunteers in this study generally are in agreement with results obtained in previous studies (Kanyok, 1997). However, the pharmacokinetics of aminosidine was not affected significantly when it was administered with sodium stibogluconate in healthy volunteers.

Similarly there was no significant difference between mean plasma drug concentrations of Paromomycin (15 mg/kg) alone and (paromomycin 15 mg/kg +Sodium stibogluconate 20 mg/kg), and no significant difference between sodium stibogluconate 20 mg/kg alone and (sodium stibogluconate 20 mg/kg + Paromomycin 15 mg/kg) in healthy volunteers.

Generally, although not significant; aminosidine seems to decrease the concentration of sodium stibogluconate, this in contrast with results obtained by Belloli and colleagues (1995), who reported that serum concentrations of antimony was increased when it was administered with aminosidine in dogs, but antimony did not significantly modify the kinetics of paromomycin.

# EVALUATION OF COMPLEMENT ACTIVATION RELATED PSEUDO ALLERGY (CARPA) AMONG SUDANESE VISCERAL LEISHMANIASIS PATIENTS TREATED WITH HIGH SINGLE DOSE LIPOSOMAL AMPHOTERICIN B (AMBISOME®)

**A. J. Suliman, E.A.G. Khalil, Brima Musa, Abuzaid A. Abuzaid, A. M. Musa**

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Despite the fact that Liposomal Amphotericin B (Ambisome®) is in common use to treat many protozoal and fungal diseases, it was only recently studied to be used in single high dose for treatment of visceral leishmaniasis (VL). Although it has been documented that complement activation related pseudo allergy (CARPA) due to Ambisome® occurs in animals, its safety when given in high single dose was not studied in humans. Therefore, this study aimed at evaluation of CARPA among Sudanese patients with VL treated with high single dose of Ambisome®.

A longitudinal study was conducted at the Field Stations, Institutes of Endemic Diseases and University of Khartoum as part of a ClinicalTrials.gov.NCT00832208 to develop Ambisome® at a single high dose treatment for VL. All patients with parasitological confirmed VL who gave written consent to participate were enrolled and allocated to receive Ambisome® either 10mg/kg single dose at day 1 or standard treatment (3mg/kg at day 1,2,3,4,7,14 and 21). Blood samples were obtained immediately before treatment, day 3, 7 and 14 following Ambisome® and used for C3a, C5a and sC5b-9 measurement using Human ELISA kits. Quantitative PCR was performed serially to look for parasite load and pattern of clearance. Clinical data were collected to assess CARPA. Epi Info 7 was used for data processing and analysis.

Thirty-six (n=36) patients participated in this study. Nineteen patients treated with high single dose (G1) and 17 patients treated with standard dose of Ambisome® infusion (G2).The mean age was 10 ± 4.1 years and 11 ± 6 years respectively. None of the patients developed CARPA. Before treatment the levels of MAC, C5a and C3a were high ($p=0.0001$) and comparable in either group ($p>0.05$). At day 3 the mean levels of MAC, C5a and C3a were low in G1 and G2 compared to baseline ($p=0.01$, 0.6, 0.1), ($p=0.02$, 0.1, 0.7) respectively. This could be due to waning of the inflammatory response due to reduction of the parasite load (G1 $p=0.04$, G2 $p=0.0001$). At day 7 MAC mean level was significantly low in G2 ($p=0.02$) and also tended to decrease in G1 ($p=0.1$). C5a mean level tended to increase in both groups but not significant (G1, $p=0.1$ & G2, $p=0.5$). This could be attributed to liposomes since the parasite load is low at this stage. Also Parasite load showed significant reduction among G2 ($p=0.0001$) as well as G1 ($p=0.0001$). The parasite load showed direct relationship with the levels of the complement components till day 7.

Visceral leishmaniasis manifests with high levels of MAC, C3a and C5a as a result of the inflammatory process. Ambisome® given in high single dose of 10 mg/kg correlates positively with activation of MAC, C5a and C3a but not sufficient to induce CARPA. Its use at such a dose is safe for patients with VL.

# ALTERNATIVE APPROACHES FOR ANTI-LEISHMANIA VACCINE DEVELOPMENT: IN SILICO PREDICTION OF IMMUNOGENIC T CELL EPITOPES OF LEISHMANIA DONOVANI GP63 PROTEIN AS VACCINE CANDIDATES.

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Visceral leishmaniasis (VL) is a major parasitic childhood disease in sub-Saharan Africa. Expensive and toxic anti-leishmanial drugs are current control methods. Safe, effective and cheap vaccines are potentially powerful strategies to control VL. Traditional vaccine development techniques have failed to deliver an effective vaccine. The prospects for vaccine development may benefit from immunoinformatic tools. This paper describes an in silico prediction method for immunogenic Leishmania donovani-GP63 T cell epitopes as VL candidate vaccines.

Using the EpiMatrix algorithm, the amino acid sequence of L. donovani donovani GP63 protein (GenBank accession: ACT31401) was screened for putative T cell epitopes that would bind to the most common HLA class II alleles among at-risk populations. Nine epitopes were initially identified using the EpiMatrix. Based on cluster score, number of EpiMatrix hits, hydrophobicity, and number of EpiBars, four peptides (P1-P4) were selected for synthesis.

In a proof of concept study, consenting healthy, leishmanin skin test (LST) reactive and non-reactive volunteers' blood was stimulated and IFN-γ, IL-4, and IL-10 were measured. IFN-γ and IL-4 levels were similar in both groups. However, mean IL-10 levels were significantly reduced in LST reactive individuals. To evaluate the potential cross-reactivity with the human genome (HG), the human gut microbiome (HM) and common human pathogens (HP), the sequences of the evaluated peptides were screened using JanusMatrix. One of the peptides (P1), which increased IL-10 in the LST reactive volunteers, showed high cross-reactivity with HG, suggesting that P1might induce a regulatory immune response in humans.

Immunoinformatic tools provide a promising alternative approach for anti-parasite vaccine development. Data obtained can be used in the development of epitope-based Leishmania vaccine.

# IMMUNOCHEMOTHERAPY OF POST KALA AZAR DERMAL LEISHMANIASIS: SUDANESE EXPERIENCE

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Post-Kala-Azar dermal leishmaniasis (PKDL), a dermatosis that follows apparently successful treatment of Visceral Leishmaniasis (VL) caused by Leishmania donovani. It is believed to be immunologically mediated. The skin lesions are viewed as reservoirs for leishmania parasites. Therefore treatment could help in the control of VL. The available treatment options are far from satisfactory as they are either expensive (liposomal amphotericin B) or toxic (antimonials), or resistant parasites have either emerged or are imminent with monotherapy.

Sodium stibogluconate (SSG) combined with first generation candidate vaccine (Alum-precipitated autoclaved L major plus BCG) for leishmaniasis was tried in 2 studies; and in combination with second generation candidate vaccine (LeishF2 plus MPL-SE) for leishmaniasis in one study. The Treatment was evaluated by the clinical outcome, safety and the immune responses.

Interestingly, the first option was found to be safe, strongly immunogenic and efficacious and studies leading to phase III are underway. In contrast, latter option was found to be safe and immunogenic but not promising in terms of efficacy.

Immunochemotherapy is a novel option whereby a low-dose or short course of an effective drug is given with one injection of a vaccine or immunomodulator to rapidly induce the effector immune response. This is instead of relying on chemotherapy alone to reduce the parasite burden, and waiting for the effector immune response to develop which may take longer time, to control the parasites.

# LEISHMANIASIS IN UGANDA: HISTORICAL ACCOUNT AND A REVIEW OF THE LITERATURE

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Visceral leishmaniasis (VL) or kala azar is a disease caused by protozoan parasites and occurs worldwide. Eastern Africa forms the second largest focus of VL after Asia (India, Bangaladesh and Nepal). But the disease is more neglected in Uganda compared to its Eastern African neighbors. In this paper we give a historical account and review available literature on visceral leishmaniasis in Uganda to raise more awareness about the disease in the country and worldwide. Information was collected from Amudat hospital records, MEDLINE, records of Ministry of Health (Uganda), reports from non-governmental organizations, dissertations and personal communication.

Reports on VL in Uganda first appeared in the 1950's, followed by almost four decades of silence. Earlier records on VL in Amudat hospital are also incomplete. This is indicative of neglect for VL for long. From early 2000, reports, mainly on the disease management and risk factors, started to appear. Management of VL has mainly been by non-governmental organizations including MSF, Swiss. Currently DND*i* is funding management of VL and clinical trials on drugs in Amudat hospital through LEAP. New foci of VL were identified recently in Moroto and Kotido districts, about 100 and 250 km North of Amudat hospital respectively.

The history of VL in Uganda is incomplete because there is a gap of nearly 40 years when reports on the disease is missing. Visceral leishmaniasis is apparently more widespread in north-eastern Uganda than originally thought. Disease management is well established in Amudat hospital and is currently funded mainly by DND*i* through LEAP. However its sustainability and wider coverage remains a challenge. Strengthening the capacity of local institutions to; conduct research and surveillance combined with effective management should mitigate VL in Uganda.

# NUTRITION AND LEISHMANIASIS CONTROL IN SUDAN, CURRENT CHALLENGES AND FUTURE STRATEGIES: A GUIDE FOR THE FORMULATION OF REGIONAL POLICY

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Nutritional risk factors determining development of Leishmaniasis are not totally understood. The influence of nutrition on the outcome of Leishmania infection needs to be assessed by comparing the quantitative body composition measurements and nutrients consumption with susceptibility, severity and treatment of leishmaniasis. This includes research focused on interactions between nutrition and the chronic infection of leishmaniasis.

Results from these assessments will inform the design of intervention strategies to reduce childhood morbidity and mortality and possible provide insight on how to improve drugs, efficacy, availability and absorption.

All global research done in nutrition and leishmaniasis (1969-2014), was evaluated and reviewed, gaps identified and (short and long term) strategic plans formulated according to international needs in health planning and resources available in the African context. Stakeholder meetings along with PRA were also done.

Apart from diagnostics, prevention and control strategies for leishmanaisis, no formal complete quantitative work for the evaluation of nutritional factors had been carried out. A 6 year strategy was developed for the evaluation and adoption of control nutrition strategy and policy in all preventive, agnostic and curative settings. This strategy is intended for use as guidance for the formulation of nutrition policy in LEAP participating countries

A clear research strategy must be adopted. A wide spectrum of studies ranging from development of strategies to be implemented at field sites and scaling up of new policy interventions is planned. Suggested areas for study include research on detection of nutritional biomarkers for disease susceptibility, severity and response for treatment
This will open a new attractive corner for research important for the achievement of MDGs

# THE ECONOMIC IMPACT OF VISCERAL LEISHMANIASIS IN BARINGO, KENYA

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Visceral Leishmaniasis (VL) is a deadly parasitic disease transmitted by the bite of a female sandfly. According to the World Health Organization, VL is ranked as the third most important parasitic disease after malaria and lymphatic filariasis in terms of disease burden (Desjeux 2004; WHO 2009). The main objective of the study was to examine the economic impact of VL on households (HHs) in Baringo County, Kenya.

A random sample of 84 out of 108 VL patients was calculated using the Creative Research Online sample calculator. Questionnaires were used to collect data from 30 HHs and analyzed using descriptive methods.

A single VL episode costs Kshs. 31,200 (USD.390, at exchange rate of 80) which is triple the average monthly income for the affected HHs or 1.6 times their annual per capita income. These costs are beyond the reach of majority poor HHs, 70% living in the first two poorest quintiles, and they are forced to employ a combination of coping strategies. In most cases, patients could still not meet the cost of treatment even after exhausting available coping strategies. Comparisons of cost lines indicate that short-term direct costs outweigh short-term indirect costs. We concluded that the economic burden of caring for VL patients and the subsequent stripping and compromise of coping mechanisms can institute a vicious cycle of poverty in a household and may undermine sustainable development of disease endemic communities

We recommended that VL disease control programmes need to adopt novel mechanisms to fast track VL patients' diagnosis and treatment so as not to compromise livelihood and food security of their HHs. The support systems are necessary if the communities have to sustain good health, welfare and development in order to achieve the economic and health aspirations enshrined in the Vision 2030.

# INNOVATIVE APPROACHES TO CLINICAL DATA MANAGEMENT IN RESOURCE LIMITED SETTINGS USING OPEN SOURCE TECHNOLOGIES

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Clinical Data Management of clinical trials for Neglected Tropical Diseases in endemic countries can be difficult due to limited resources and expertise. There is a need to develop improved systems for data management which are efficient and affordable without violating the principles of Good Clinical Practice. Open source tools offer good alternatives when compared to proprietary systems but challenges in validation still abound.

We have developed an offline version of Open Clinica, making it possible to collect data in areas with limited internet infrastructure, together with an in-house system for query management which is a crucial component in data management. Both have been possible as a result of our experience in managing large multi-centre clinical trials in Africa on Neglected Tropical Diseases such as Visceral Leishmaniasis, with sites located in very remote areas.

We demonstrate that innovative approaches to clinical data management are possible and that open source tools with good functionality are available and can be further developed to assure production of high quality and reliable data. It is also important to share knowledge on best practices, such as on systems validation and source code development, for better management of data from clinical trials in resource limited settings

# BENEFITS ACCRUING FROM COLLABORATIVE RESEARCH AND DEVELOPMENT PROGRAM ON LEISHMANIA IN UNIVERSITY OF GONDAR

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The burden and challenges of neglected tropical diseases is especially noticeable in hospitals close to endemic sites. University of Gondar (UoG) hospital in north-west Ethiopia is the only referral hospital close to the main visceral leishmaniasis (VL) endemic focus in the country. VL is one of the most severe and fatal neglected diseases. The management of VL has been a significant problem not only for the hospital but also for the country at large and the neighboring countries where the disease occurs.

The ten years research and development collaboration with Drugs for Neglected Diseases initiative (DND*i*) and Leishmaniasis East African Platform (LEAP) was described. The records of both clinical and administrative activities were used.

The University Hospital is one of the clinical trial sites for VL in the LEAP consortium of four East African countries (Ethiopia, Sudan, Kenya and Uganda). It hosts a research and treatment center that conducts clinical trials aimed at improving the management of VL patients. The research outputs have provided scientific evidence that has helped to improve international guidelines (WHO guidelines and that of the LEAP countries). One of the studies conducted recently evaluated a short (17 day) regimen combination therapy of sodium stibogluconate plus paramomycin. Annually, more than 700 patients are screened while close to 350 VL patients get treatment. Site staffs have developed skills in clinical research and good clinical practices. The outputs and the research setting developed have attracted additional collaborators that helped strengthen the consortium thus attracting bigger research grants such as FP7.

The north-to-south research and development collaboration has helped for skill transfer, sharing of experiences, resource mobilization and conduct of GCP compliant trials in resource limited setting that brought changes on several guidelines. The experience from this collaborative platform can be adopted for other similarly challenging diseases of public health importance.

# CHALLENGES IN ETHICAL REVIEW IN KENYA

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The Kenya National Bioethics committee is set up by an act of parliament. It is responsible for policy issues, preparing various guidelines, arbitration, international collaboration and accreditation of all the ethics committees in the country. There are many new institutions established which are involved in research. To reduce the burden on the few previously established ethics committees we have allowed some institutions to establish their own ethics committees which have to be accredited by the National Bioethics committee. This paper will cover challenges at different levels.

Information about the functioning of the various ethics committees and the challenges faced were gathered during conversations with chairs of various ethics committees at different informal meetings. Also independent Observations were made by the National Bioethics Committee during visits to various institutions before accreditation process was established. Challenges faced after accreditation process were identified during deliberations of NBC meetings.

It was noted that there were major challenges in the review process, in monitoring, dissemination of results and communication, material transfer agreements, study extension, collaborative research, clinical trials and the role of Pharmacy and Poisons Board.

There are gaps between ethical review process ideals and reality. Establishment of new committees has come with its own challenges. There is a need for harmonization of ethical review process, streamlining of proposal review, strengthening of the monitoring process and empowering local researchers in collaborative research projects with international institutions.

# INTEGRATION, COLLABORATION OR JOINT REVIEW: WHICH WAY TO SPEED UP RESEARCH ETHICS REVIEW IN EASTERN AFRICA

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Progress of Research ethics review in Africa has been slow for various reasons. It has in the last few years been reinvigorated by the growing research enterprise. African countries, all with a vibrant young population have seen the number of universities grow. This has led to more research activities and the accompanying need for review. Research ethics establishments in the eastern Africa region are mainly traditional. Established in large hospitals, they are usually medical ethics establishments.

The paper looks at research ethics review in four countries in eastern Africa: Kenya, Uganda, Tanzania and Ethiopia. It explores the differences and similarities in organization and focus. We looked at the documents that are available, describing the processes and compared them to make observations and conclusions that may assist in deciding whether to integrate or collaborate in other ways.

Results will explain the governance structures adopted in the four countries and highlight the areas of similarity and those that are different. The most relevant ones for discussions on integration will be picked out.

The paper will present the current position in the countries and contribute to the current discussions regarding closer collaboration among ethics review committees.

# INSTITUTIONAL REVIEW BOARDS AND CLINICAL RESEARCH IN EAST AFRICA: CHALLENGES, OPPORTUNITIES AND PROPOSED SOLUTIONS

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Ethics in clinical research focuses largely on identifying and implementing the acceptable conditions for exposure of some individuals to risks and burdens for the benefit of society at large. The Ethics Committee stands as the bridge between the researcher and the Ethical Guidelines. IRBs are an important link between subject protection program and their function defines ethical credentials of clinical research.

A review of documents, African publications and future strategies in bioethics was conducted. Key interviews were conducted using a semi structured questionnaire.

Regional requirements differ from the international guidelines. IRBs face numerous challenges, in establishment, composition, and implementation. Some of these challenges are due to conflict of guidelines, some inherent to guidelines, and other reasons. There is need to study the problems of IRBs in depth to assess their needs.

There is urgent need for oversight of IRB functions and the regulators need to have a division which will have oversight over IRB functions, monitoring them regularly, auditing them sometimes, and help to protect human subjects. There should be national or regional ethics forums which will work with the IRBs so that subjects are protected better and clinical research gains ground.

Some organization at regional level takes the lead in setting up a Forum of ECs. The Forum can lay down the requirements for training of IRB members, and also create a core team of trainers to actually deliver the training modules, and other needed responsibilities:

The formation of local forum and regional ethics committees can be considered as a viable solution. This will also speed up the EC review process, and bring about the much needed fertile landscape for the growth of clinical research in Africa.

# MONITORING IMPLEMENTATION OF A PHARMACOVIGILANCE PLAN FOR A NEGLECTED TROPICAL DISEASE IN EAST AFRICA

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Pharmacovigilance is key to identifying rare adverse events. Neglected diseases like leishmaniasis currently use toxic drugs. To improve data quality, monitoring is necessary but the standard clinical trial monitoring is stringent and far less adapted for monitoring Pharmacovigilance in resource limited settings.

DNDi introduced a Pharmacovigilance plan for Sodium Stibogluconate and Paromoycin (SSG/PM) in Eastern Africa following successful completion of Phase III clinical trials in Sudan, Ethiopia, Kenya and Uganda. The objective of the plan was to monitor efficacy and safety of the combination treatment in the immediate post approval period. The plan was approved by Regulatory Authorities and Ethical Committees accordingly and a monitoring plan was developed to improve data quality. Health staff were trained on Pharmacovigilance data collection, reporting of SUSARs and treatment failure. Routine monitoring visits were undertaken 3 monthly to assess consent forms, CRF completion, adverse events reporting and confirmation of treatment failures.

A total of 3,112 patients were recruited across 11 PV sentinel sites and data entry has been completed. Overall, data quality was good, the PV plan was adhered to, AEs and SAEs and treatment failures were reported. Common queries noted in some of the Case Report Forms were related to consenting, incomplete data, patient IDs and SAE follow up. Three Periodic Safety Update reports have been reviewed by the PV Plan Steering Committee. Monitoring was not intense.

Despite challenges of treating Neglected Tropical Diseases in remote rural facilities in Sub Sahara Africa, good PV data has been obtained and forwarded to Regulatory Authorities. The Pharmacovigilance data quality was enhanced through training and monitoring of sites.

# FACTORS INFLUENCING COMPLIANCE WITH MASS DRUG ADMINISTRATION FOR LYMPHATIC FILARIASIS ELIMINATION IN KENYA

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The main strategy adopted for Lymphatic Filariasis (LF) elimination globally is 4 to 6 rounds of mass drug administration (MDA) annually. At least 65% of the total population (100% of the eligible population) should be treated in each round for LF elimination to occur. In Kenya after 3 MDA rounds using diethylcarbamazine citrate (DEC) and albendazole, data showed declining compliance (proportion of eligible population who receive and swallow the drugs) levels (85%-62.8%). A retrospective cross-sectional study based on 2008 MDA was conducted between January and September 2009 in Kwale and Malindi Districts to determine the factors influencing compliance with MDA.

In each district, one location with high and one with low compliance levels was selected. Through systematic sampling, nine villages were selected from the four locations and quantitative data collected from 965 systematically sampled household heads. Qualitative data were generated from 80 opinion leaders, 80 LF patients with clinical signs and 15 community drug distributors (CDDs) all purposively selected and interviewed. Sixteen focus group discussions (FGDs) were also conducted with single-sex adult and youth male and female groups.

Several socio-economic factors including; religion, primary occupation, ownership of property, knowledge of LF signs and cause, risk perception ($P<0.001$) and disease stage ($P<0.05$) influenced compliance with MDA. Personal opinions and experiences also influenced compliance with MDA; house-to-house method of drug distribution, lack of perceived need to take the drugs, CDD not visiting to issue drugs and being absent. A dislike for modern medicine and experience of side effects ($P< 0.001$) also influenced compliance. Social support, alcohol and substance use were not associated with compliance with MDA ($P>0.05$). Additionally, knowledge about MDA was not associated with compliance with MDA ($P>0.05$) but frequency of receiving information on MDA influenced compliance ($P< 0.001$). Factors that positively influenced the CDDs motivation were: higher education levels, trust and familiarity with community members, feeling of recognition and desire to help their communities. Negative factors included: inadequate training, drug supplies, community sensitization and lack of supervision.

There is need to have different strategies to reach specific religious groupings and those in casual employment. Community sensitization on treatment, drugs used and their potential side effects and that the health personnel are on standby for management is necessary for confidence building. Factors that motivate CDDs are those that enhance their capacities to perform their duties and endear respect in the communities where they serve.

# EVALUATING DRUG DELIVERY STRATEGIES TO PRE-PRIMARY SCHOOL AGE CHILDREN FOR TREATMENT OF SOIL-TRANSMITTED HELMINTHIASIS AND SCHISTOSOMIASIS INFECTIONS IN MALINDI DISTRICT, COASTAL KENYA

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The Government of Kenya through the National School-based deworming program treats children in Early Childhood Development (ECD) Centres. However, the Program does not consider the ECD Center teachers as eligible for training to conduct deworming of the ECD Centre children. The Program therefore requires that ECD children whose centers are not within (standalone) the Primary Schools be taken to the nearby primary schools to receive treatment from the trained primary school teachers. This type of ECD centre children therefore have to travel an average of 5km or more to receive treatment. This may have negative implications in terms of accessing the nearest school and majority of the ECD Centre children are likely to miss the treatment. This study therefore aimed at developing and implementing an alternative drug delivery method in order to help maximize treatment coverage for this vulnerable age group.

The study adopted a comparative cross-sectional study design. We conducted 64 Key Informant Interviews with Community Health Extension Workers (16), Primary School Health teachers (12), Early Childhood Development Centre (ECD) Teachers (18) and Community Opinion leaders (18). Purposive sampling technique was used to identify participants and the sample was based on saturation model. Health teachers and CHEWs were trained to treat children in primary schools and standalone ECDs respectively. The data was collected by trained and experienced KEMRI staff, transcribed, coded and analysed using ATLAS.ti version 6.

In our preliminary findings, many participants displayed a strong preference for ECD centre treatment highlighting that the young children should not be subjected to walking long distances for treatment. Abdominal pain was a major side effect among consumers of Praziquantel, while those who took albendazole only, reported no reaction. ECD teachers were widely used during treatment with children being the main mobilization strategy.

ECD teachers have the capacity to treat children and all they need is training. To maximize treatment coverage, pre-school children should be treated at their centers and other mobilization techniques should be employed to enhance community participation.

# BEHAVIOUR CHANGE IS REQUIRED FOR ELIMINATION OF ACTIVE TRACHOMA IN NAROK COUNTY, KENYA

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Trachoma, a leading infectious cause of blindness found in areas with poor hygiene is controlled by implementation of AFE: Antibiotic treatment, Facial cleanliness and Environmental improvements. Active trachoma is monitored by the prevalence of trachomatous follicles (TF) in children 1-9 years old (the reservoir). Surveys are conducted after every 3 to 5 years and mass drug administration MDA conducted if TF prevalence is ≥ 5%. A baseline survey was conducted in Narok in 2004 followed by impact assessment surveys in 2010 and 2014. Trachoma remains endemic in Southern Narok despite uninterrupted MDA since 2008. A qualitative study was conducted to investigate this.

The study was conducted in two segments in Narok South where prevalence survey results had confirmed a prevalence of TF >20%. Qualitative data was collected through 12 Focus Group Discussions (FGDs) and 12 Key Informants Interviews (KIIs) so as to assess Knowledge, Attitude and Practices of community members on trachoma transmission and control. The group members and opinion leaders were purposively selected. Data was analyzed manually by study themes.

Majority of the community members complied with MDA and were willing to continue in subsequent rounds. Non-compliance was due to lack of awareness and fear of side effects. Majority of FGD participants were aware that keeping domestic animals away from human dwellings helps reduce transmission, but this was impossible as the animals needed protection from raiders, wild animals and harsh weather conditions. Children washed their faces every morning but shared water, basins and towels and toilets were unacceptable due to socio-cultural reasons therefore bushes were preferred. Majority of the informants stated that community members dispose faeces of young children in bushes and that flies are regarded as blessings, sign of rain and future richness.

Health education is needed for behaviour change and improved compliance with MDAs among the communities living in endemic areas.

# PREDICTORS OF NON-COMPLIANCE WITH MASS DRUG ADMINISTRATION FOR SCHISTOSOMIASIS CONTROL IN WESTERN KENYA-THE SCORE PROJECT

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Mass drug administration (MDA) is being used to control schistosomiasis, lymphatic filariasis and other neglected tropical diseases of public health significance. However, achieving optimal community participation during implementation remains challenging. When a critical proportion of the population fails to participate in MDA, a potential reservoir for the parasite is left untreated, opening the opportunity for resurgence of the infection and reducing the probability of successful transmission control. This study was designed to identify predictors of non-compliance with MDA in western Kenya in villages with ≥25% prevalence of schistosomiasis in order to develop more effective health educational and delivery strategies.

We used a population based unmatched case-control study design nested within a cross sectional household survey employing a structured questionnaire administered to 550 heads of households. Both univariate and multivariate analyses were used to identify the independent predictors of non-compliance.

Two hundred and forty respondents (44.9%) reported being non-compliant. By univariate analysis, non-compliance was significantly associated with the household head not asking the community health workers (CHWs) questions about the program, crude odds ratio (COR) 10.3, 95% CI [6.61-15.93], not having heard about the program COR 2.4 [1.6-3.6], and low schistosomiasis risk perception COR 3.1 [1.89-5.03]. In a logistic regression model, the odds of being non-compliant significantly increased amongst household heads who perceived their CHW not to be doing good work during the MDA exercise; adjusted odds ratio (AOR) 4.9, 95% CI [1.82-13.74], heads of households who lacked knowledge about schistosomiasis control methods AOR 7.5 95% CI [3.3-16.8], and those who did not know how the CHW was selected AOR 2.5 95% CI [1.3-5.0]..

In order to improve compliance with MDAs, effective strategies should be identified to ensure CHWs are well-trained and supervised to ensure quality service provision. Health education is also necessary to increase the knowledge levels of the disease in the community

# A QUALITATIVE DESCRIPTION OF COMMUNITY PARTICIPATION IN WATER AND SANITATION ACTIVITIES IN THE CONTROL OF BILHARZIA IN NYALENDA B, AN INFORMAL SETTLEMENT IN KISUMU CITY, WESTERN KENYA

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Community participation is central to the success of primary health care. However, over 30 years since the Alma Ata declaration, absence of universal community participation remains a main obstacle to achieving the millennium development goal of combating diseases. This study investigated community participation in water and sanitation activities towards Bilharzia control in Nyalenda B, an informal settlement in Kisumu City

Eight key informant interviews (KIIs) and eight focus group discussions (FGDs) were conducted. In addition, data on NGOs dealing with water and sanitation activities in Kisumu was collected from the local NGO registration Board. Qualitative data was organized into themes and concepts and analyzed using Atlas.ti.

Most participants felt that project implementers did not involve them in key levels of project implementation leading to unsustainable projects and unacceptance from the community. Community structures identified that could be used as avenues of engaging the community in improving water and sanitation situation included use of organized groups such as youth, gender-based, farmers and HIV support groups, and merry-go rounds. Factors mentioned that hindered community participation included negative attitude from community members, poor monitoring and evaluation strategies, limited disclosure of project details, and over-dependence from the community. Poor drainage systems, low latrine coverage, broken pipes and leakage of the sewerage systems were the leading factors associated with poor water and sanitation conditions.

Effective community participation in water and sanitation activities requires a multi-pronged paradigm that incorporates change of attitude from the community, information sharing and consultation, improved monitoring and evaluation, transparency and accountability. All levels of community leadership and engagement need to be considered before planning and executing a development project in the community for acceptance and sustainability.

# BURDEN OF CYSTIC ECHINOCOCCUS IN SELECTED PASTORAL AND AGROPASTORAL DISTRICTS OF UGANDA

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Echinococcosis is one of the neglected infections found throughout the developing world. While a prevalence of 66.3% of echinococcosis was reported in dogs in Karamoja, studies on prevalence of echinococcosis in human among communities living in Agro-pastoral and Pastoral areas of Uganda are scanty.

A cross sectional study was done in selected agro-pastoral districts of Uganda to determine the knowledge gap and attitude of the community about echinococcosis and to establish its prevalence.

2,903 participants were interviewed in selected pastoral and agro-pastoral districts in Eastern, Northeastern, Central and Western regions. 80% had not heard about echinococcosis and 85% did not know mode of transmission or treatment. 3% believed it was acquired through eating raw meat or unboiled milk. Only 23% the health workers were aware about the disease in all the selected districts.

3601 participants (1107 males; 2494 females) were screened. Fifty eight cases of suspected cystic Echinococcosis lesions were identified in all the regions. 17 and 41 were in the male and female subjects respectively. Northeastern region had the highest cases (n=25) compared to other regions (Central n=15; Western n=10; Eastern n=8).

Liver had 37 lesions with 30 cases in the right lobe. The kidney had 11 lesions; spleen 6; omentum 6 and one lesion in the lung. Other diseases included; fibroids, polycystic kidney disease, Kalazar, hapatomas and ovarian cyst.

Most of the respondents in Pastoral and Agro –Pastoral communities of Uganda are not aware of echinococcosis. The cases of echinococcosis were found in all the study regions with North Eastern having the highest prevalence. Other diseases were also detected in the survey. There is need to sensitize the communities about the disease and establish intervention centers in the affected areas.

# CYSTIC ECHINOCOCCOSIS IN EASTERN AFRICA -A PUBLIC HEALTH PROBLEM-

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Cystic Echinococcosis (CE) is a neglected, debilitating, zoonotic disease, caused by the larval stage of the tapeworm Echinococcus granulosus. CE has a worldwide distribution and is more frequent in livestock rearing areas. CE is endemic in pastoral nomadic communities in Eastern Africa with Northern Turkana in Kenya, having one of the highest infection rates in humans in the world. CE is a public health problem. Its importance and socio-economic impact is fairly underrated due to lack of reliable prevalence data in the region and information on the relationship between the parasite, domestic animals, wildlife and humans. Data on CE in East Africa are scanty. More data are available from Kenya, especially from Turkana, where a hydatid disease control programme has been running since 1983.

The objectives of the presentation are to introduce CE, create awareness of the disease, linking it to other diseases, coexisting in the same areas such as visceral leishmaniasis and possible common approaches for prevention and control.

# HOST PREFERENCE ANALYSIS OF PHLEBOTOMUS (LARROUSSIUS) ORIENTALIS (DIPTERA: PSYCHODIDAE) USING CYTOCHROME B PCR AND REVERSE LINE BLOTTING IN THE VISCERAL LEISHMANIASIS ENDEMIC AREA OF TAHTAY ADIYABO DISTRICT, NORTHERN ETHIOPIA

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Knowledge of the host preferences of phlebotomine sandflies under natural conditions is an important factor for understanding the epidemiology and for developing efficient control strategies for visceral leishmaniasis. However, in Ethiopia and other parts of East Africa there are large remaining gaps in identifying the feeding habits of Phlebotomus orientalis, the vector of Leishmania donovani. The aim of the study was to determine the host preference patterns of P. orientalis from Tahtay Adiyabo district, Northern Ethiopia.

For blood meal analysis, sandflies were collected from three villages (i.e., Ademeyti, Lemlem and Mentebteb) of Tahtay Adiyabo district using CDC light traps and sticky traps. DNA was individually extracted from blood fed sandflies and PCR amplified for vertebrate-specific cytochrome (cyt) b region, followed by reverse-line blot (RLB) analysis.

Out of 180 P. orientalis tested for the source of blood meals by cyt b PCR and RLB, the blood meals of 135 were successfully identified. P. orientalis mainly fed on cattle followed by human, goat, sheep and camel. Mixed blood feeding was also identified in ten female P. orientalis.

Results obtained from bloodmeal analysis using cyt b PCR-RLB revealed that P. orientalis is mostly an opportunistic in its host preference with higher level of zoophilic feeding behavior. The epidemiological significance of these domestic animals as blood sources for P. orientalis and possible reservoir hosts of L. donovani should be thoroughly investigated for better understanding the transmission dynamics of visceral leishmaniasis in northern Ethiopia.

**Members of Staff - DND*i* Africa Office, Nairobi**

**Back Row:** Simon bolo, Seth Okeyo, Michael Ochienge, Renee Olende, Josephine Kesusu, Raymond Omollo, Robert Kipmutai, Moses Waweru

**Front Row:** John Ambasa, Brian Muthida, Truphosa Omollo, Rhoda owiti, Peninah Menza, Punam Amratia, Godfrey nyakaya, Joy Malongo, Nicholas Bonyo, Monique Wasunna


# POSTER PRESENTATIONS

# BACTERIAL SEPSIS IN PATIENTS WITH VISCERAL LEISHMANIASIS IN NORTHWEST ETHIOPIA

**Mengistu Endris[1] Yegnasew Takele, [2]Desalegn Woldeyohannes,[3],[4]Moges Tiruneh,[1] Rezika Mohammed, [2]Feleke Moges,[1]Lutgarde Lynen,[5] Jan Jacobs, [5] Johan van Griensven, [5] and Ermias Diro[5],[6]**

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Visceral leishmaniasis (VL) is one of the neglected diseases affecting the poorest segment of world populations. Sepsis is one of the predictors for death of patients with VL. This study aimed to assess the prevalence and factors associated with bacterial sepsis, causative agents, and their antimicrobial susceptibility patterns among patients with VL.

Across-sectional study was conducted among parasitologically confirmed VL patients suspected of sepsis admitted to the University of Gondar Hospital, Northwest Ethiopia, from February 2012 to May 2012. Blood cultures and other clinical samples were collected and cultured following the standard procedures.

Among 83 sepsis suspected VL patients 16 (19.3%) had culture confirmed bacterial sepsis. The most frequently isolated organism was Staphylococcus aureus (68.8%; 11/16), including two methicillin-resistant isolates (MRSA). Patients with focal bacterial infection were more likely to have bacterial sepsis ($p < 0.001$).

The prevalence of blood culture confirmed bacterial sepsis was high, predominantly due to S. aureus. Concurrent focal bacterial infection was associated with bacterial sepsis, suggesting that focal infections could serve as sources for bacterial sepsis among VL patients. Careful clinical evaluation for focal infections and prompt initiation of empiric antibiotic treatment appears warranted in VL patients.

# METHOD FOR QUANTIFICATION OF HELMINTHS EGGS IN HUMAN IN FIELD RESEARCH, MODIFICATION OF KATO/ KATZ METHOD

**Emmanuel Igwarro Odongo-Aginya.**

***Gulu University, Faculty of Medicine, GULU UGANDA***

The Odongo-Aginya method is a modification of the classic Kato-Katz method. It has advantages over the Kato-Katz method because it's quick and shows the eggs of hookworms, Strongyloides larvae and protozoa cysts for a long period.

This method, substitutes the malachite green in the Kato/Katz method with a compound stain that contains 5% eosin yellow in 10% formalin, and 7.5% negrosin in 10% formalin mixed 1:1. This modification conserves the hookworm eggs for a long time and shows strongyloides larvae in slide where the Kato-Katz is not able to. Essentially stool specimen strained through stainless steel sieve of 250µ mesh size to remove artifacts is used to fill a hole in a template measuring 41.7 milligram. A drop of about 50µl of the compound stain is then added to the measured stool smear on the slide. And the stain is stirred in the stool smear on the slide. A wettable cellophane cover slip cut 32 x 41 mm pre-soaked in 50% glycerin is placed on the stained stool smear and pressed down. The prepared slides can be examined immediately using x10 and x40 objectives.

The Kato-Katz and the Odongo-Aginya methods both use 41.7mg of sieved stool sample. In practice Odongo-Aginya method has been found to revealed more eggs than Kato/Katz method under the same condition and time point (Mahdi, et al.1999). This is because, it is easier to examine the slides in Odongo-Aginya prepared slide than the Kato/ Katz methods due to the fact that, in well prepared smear parasites eggs, cysts, and larvae are well stained. More over in Odongo-Aginya method the prepared slides can be examined immediately. The long waiting clearing time in Kato/ Katz makes some fragile eggs like those of Hookworm collapse under the cellophane cover slips and disappears or become difficult to recognise under the Microscope (Mahdi, et al.1999). Both Malachite green and the negrosin-eosin compound stain sometime obscure the good visualization of parasites eggs on the slide especially when dealing with hard stool specimens. Nevertheless these dyes are bactericidal especially in the nigrosin-eosin compound stain which has 10% formalin as the base. This helps to fix and kill most microorganisms thus rendering the sample safe to handle especially in this era of HIV (Mahdi, et al.1999).

Based on the long use of the Kato/Katz method and since the two method are comparable, any or both of the two methods could be used for field research as desire.

# MANAGING CLINICAL DATA QUERIES USING AN IN-HOUSE BUILT QUERY MANAGEMENT SYSTEM - QMSPlus

**Seth Okeyo[1], Michael Ochieng[1]**

*[1]Drugs for Neglected Diseases initiative,* DND*i*

Query management is a key process in data management used in identification and resolution of data discrepancies. It directly impacts on data quality and also the integrity of research outcome. At DND*i* Data Center we developed QMSPlus, a system that enables a simple yet rigorous, structured and semi-automated approach to QM for data managers and clinical trial managers.

QMSPlus is a web-based application which runs on Tomcat Server using Postgres Database Management System. Once QMS is installed, a study is setup using a simple interface. New users are defined and the necessary query related ".csv" files are uploaded. These include Query Definition file and Query Variable file. When new queries are generated in STATA based on the edit check program logic they are exported from STATA in csv format and continually uploaded onto QMSPlus. The Data Manager prints out data query forms are then sent to the respondents.

On receiving Query responses from the sites, the Data manager updates the QMSPlus with the necessary corrections and generates a STATA do-file which is executed to apply changes on the dataset extracted from OpenClinicaand clean it. QMSPlus simplifies Query Management process and helps generate Query report based on different parameters.

QMSPlus has greatly impacted Data Management activities at the DNDi Data Center providing useful features such as;

- An automated clinical data Query management system developed on an open source software platform.
- Allows import and export of data in different formats hence easy to use with diverse data management systems
- It is 100% web-based - a user therefore only needs a computer, a web browser and internet connection to use the software.

Includes automated query analytics module for query analysis and query report generation

# THE CURRENT STATUS OF CUTANEOUS LEISHMANIASIS IN OCHOLLO, SOUTHERN ETHIOPIA.

**Gessessew Bugssa Hailu**

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Leishmaniases are a group of vector borne diseases caused by the obligate intracellular protozoan leishmania.
A study was done to assess the prevalence of cutaneous leishmaniasis in Dega Ochollo primary school students, Ochollo, southern Ethiopia.

A cross-sectional study was carried out among 523 school children aging between 6 to 25 years. The students were physically examined for the presence of scar and active lesions. Skin slit and blood were collected from students with suspected active lesions of cutaneous leishmaniasis. Scraps were cultured in Nicolle-Novy-MacNeal(NNN) medium and serological tests were performed using direct agglutination test.

The overall prevalence of tegumentary leishmaniasis including both scar and active lesions among the 523 students which underwent physical examination was 65.8 %. Besides, the study revealed that 64.8% of the participants had current and/or past lesion of cutaneous leishmaniasis. The prevalence of Mucocutaneous leishmaniasis and recidivan was 0.2% and 0.8%, respectively. Three hundred and thirteen (59.8%) students were with scar and 21(4.01%) were with active lesions whereas 8(1.5%) of the cases had both scar and active lesions. Majority (49.71%) of the participants belonging to the age group 11-15 years old were the most affected group (p-value<0.05). The average number of scars and lesions per patient was calculated to be 1.5 and 1.7, respectively. Majority (64.17%) of the cases had single scars while 22.74%, 7.48%, and 5.61% of them had double, triple, and four and above, respectively. The scars were more localized above the neck (82.16%) where the highest (54.56%) proportion of the scars was distributed on check. Of the 29 participants who had active lesions, 4(13.8%) of them were found to be culture positive.

Cutaneous leishmaniasis is prevalent in the area causing disfigurement and resulting social stigmatization. This calls for the implementation of prevention and control measures including treatment of infected individuals.

# THE ORIGIN OF THE LEISHMANIA PARASITE: AN AFRICAN PROSPECTUS.

**Sara H. Elgawi, Brima M. Younis, Mona E. E. Elfaki, Ahmed M. Musa, Ahmed M. Elhassan, EltahirA.G.Khalil**

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**See paper**

# STUDY ON KNOWLEDGE, ATTITUDES AND PRACTICES (KAP) OF COMMUNITIES TOWARDS KALA-AZAR IN KAFTA-HUMERA, NORTH-WESTERN ETHIOPIA.

**Shewaye Belay, Asrat Hailu, Mekonen Yohannes**

***Mekelle, Tigrai, Northern Ethiopia***

Evaluating communities KAP concerning Kala-azar can be one of the most crucial bases for prevention and control of Kala-azar. In spite of its importance, there is no literature in Ethiopia specifically focusing on KAP towards Kala-azar. Thus, this first KAP survey will help health program planners to distinguish between communities' perception about the disease, and their role for future prevention strategies.

A descriptive cross-sectional field based study using structured questionnaire was carried out between 16 Oct 2007 and 07 May 2008 in the Kafta-Humera District.

A total of 741 subjects were participated in this study and 89.2% of them had received information about Kala-azar through different mechanisms: 53.6% from health facility workers, 37.2% sick family member and only 125(18.9%) heard through radio. From symptoms of Kala-azar, fever and abdominal swelling were frequently stated (85.6% and 78.1%) respectively. Only 38.0% identified sandfly and 47.7% of them implicated mosquitoes for Kala-azar transmission. Respondents had theoretical knowledge about sandfly residing sites: 38.4% black cotton soil, 32.4% riverside sand soils, 29.5% tree cracks and canopy (Balanitea egptica and Parikisonia aculeata) shaded ground, and 6.5% termite hills. About 97.4% believed that Kala-azar is killer disease and 98.6% knew that Kala-azar is curable. Almost all respondents placed modern health facilities (hospitals) as their first choice for treatment and 98.6% agreed that Kala-azar is preventable; 96.9% owned bednet and 90.3% had sleeping habit of using bednet.

Although the communities' awareness about Kala-azar is encouraging, there is a lack of strategic interventions. The low awareness concerning vectors of Kala-azar and the presence of a gap in information dissemination by the state media and concerned authorities, as well as the absence of formal surveillance and treatment centers nearby indicate the fact that Kala-azar is still a poorly recognized and neglected disease in Ethiopia.

# COMPARISON OF SAFETY AND EFFICACY OF SODIUM STIBOGLUCONATE AND LIPOSOMAL AMPHOTERICIN B FOR TREATMENT OF VISCERAL LEISHMANIASIS IN PATIENTS WITH AND WITHOUT HIV CO-INFECTION IN GONDAR.NORTH-WEST ETHIOPIA.

**Aschalew Tamiru**

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Visceral leishmaniasis (VL) is a cause of morbidity and mortality mainly in endemic regions of the world. It causes an estimated 0.2 to 0.4 million new cases of the disease each year worldwide. The main stay of VL treatment has been sodium stibogluconate (SSG) in Ethiopia and AmBisome has been in use since 2006. Human immune deficiency virus (HIV) co-infection is a challenging problem in East Africa including Ethiopia. It results in poor treatment response, drug toxicity, and death. Comparative study of SSG and AmBisome safety and efficacy has never been conducted in Ethiopia.

A retrospective medical record review of 340 VL patients admitted between January 2009 and December 2012 was conducted. Data were entered into statistical package for social science (SPSS) version 16.0 and Epi-info version 3.5.3. Finally, analyzed by chi-square, Fisher exact test, and Mann-Whitney U test.

In the overall treatment response analysis, the efficacy of SSG (91%, n=232) was significantly higher as compared to AmBisome (74%, n = 63), OR = 3.52, 95% CI: 1.76 – 7.07. In HIV positive VL patients the efficacy of both drugs was very low (38.1%, n = 8) Vs (40%, n = 4) for SSG and AmBisome with no significant difference [OR = 0.9, 95% CI: 0.15 – 5.61]. However, in HIV negative patients the cure rate of SSG (95.7 %, n = 202) was significantly higher as compared to AmBisome (78.9%, n =56), OR =6.01, 95% CI: 2.32 – 15.83. Severe adverse events like Pancreatitis in 20 (7.8%) and cardiac arrhythmia (in one patient) occurred only in the SSG treated patients. Mild Infusion related reactions (fever and back pain) occurred in 12 (14.2%) of AmBisome treated patients. Mild hypokalemia was more common in AmBisome than SSG (35, 41.2%) Vs (5, 2%). The other adverse events like dyspepsia and increased alanine transaminase occurred frequently in SSG treated patients.

Sodium stibogluconate is highly effective for treatment of Ethiopian VL patients without HIV infection but more toxic than AmBisome. AmBisome is less efficacious but safer than SSG. Both drugs have low efficacy for VL treatment in HIV positive patients. Therefore, development of an effective therapy for VL treatment particularly in HIV positives is recommended.

# BIONOMICS OF PHLEBOTOMINE SANDFLIES (DIPTERA: PSYCHODIDAE) IN A HIGHLAND KALA-AZAR FOCUS IN LIBO-KEMKEM DISTRICT, NORTHWESTERN ETHIOPIA.

**Esayas Aklilu, Habte Tekie, Meshesha Balkew, Alon Warburg, Asrat Hailu, Teshome Gebre-Michael**

***Addis Ababa University***

The bionomics of phlebotomine sandflies was studied for one year from May 2011 to April 2012 in three villages of Libo-kemkem district, a highland area where visceral leishmaniasis has become a major public health problem. The aim of study was to elucidate species composition, resting habits, seasonal fluctuations and incrimination of the vector.

CDC light trap, sticky trap and space spray were used for collection of sandflies. Dissection and molecular approaches were used for Leishmania detection from female Phlebotomus.

A total of 10, 776 sandflies comprising of two species of the genus Phlebotomus and five species of the genus Sergentomyia were collected. Phlebotomus orientalis was the predominant species accounting 86.6% of the total captured. The remaining species in descending order were Sergentomyia bedfordi group (6. 5%), S. squamiplueris (4.2%), S. schewtzi (2.02%), S. africanna (0.68%), and S. clyedi (0.001%)and P. rodhaini (0.0001 %). Variation in species of sandflies among the three villages was observed. Phlebotomus orientalis exhibited two peaks of density, a smaller in January 2012 (6.5flies per trap night for CDC light trap; 0.98flies/m2/night for Sticky traps) and the larger one in March for Sticky traps (1.06flies/m2/night) and April for CDC light trap (18. 7flies per trap-night) were observed. Although statistically insignificant, abundance of the flies were positively correlated with average monthly temperature (r= 0.530, P> 0.05 for CDC light trap; r=0.563, P>0.05 for Sticky traps) and negatively correlated with rainfall (r= -0.272, P=0.392 for CDC and r= -0.171, P=0.594 for Stick traps). A total of 1067 P. orientalisand 1 P. rodhaini dissected did not reveal any infection microscopically. A similar result was obtained when 247 P. orientalisfemales wereprocessed by using Polymerase chain reaction for detection of the parasite.

Although natural infection was not detected in the current study, P. orientalis is no doubt a vector of VL in this highland area of the country mainly due to its denser populations and other circumstantial evidences. Therefore, control of the disease in this particular area should involve designing of tactics that mainly target the vector of the disease by considering its seasonal abundance and behaviors.

# SPECIES COMPOSITION, ABUNDANCE AND SEASONAL DYNAMICS OF PHLEBOTOMUS SPECIES IN A VISCERAL LEISHMANIASIS ENDEMIC AREA OF NORTHWEST ETHIOPIA

**Solomon Yared, Meshesha Balkew, Alon Warburg, Asrat Hailu and Teshome Gebre-Michael**

***Aklilu Lemma Institute of Pathobiology, Addis Ababa University***

Visceral leishmaniasis (VL) is significant public health problem in northwest Ethiopia particularly in Kafta Humera district. This study was conceived to investigate the species composition and population dynamics of sandflies (altitude 500-600masl) in five urban and semi-urban area of Kafta Humera district namely Setit Humera, Mykadra, Rawiyan, Bereket and Adebay.

Sand flies were collected for three nights monthly from May 2011 to April 2012 using CDC light-traps and sticky traps. Traps were placed within villages, at periphery of villages and farm fields. Sticky traps were also used for sampling indoor active sandflies.

A total of 13097 sand flies comprising of six Phlebotomus species of four subgenera were indentified: Phlebotomus (Larroussius) orientalis, P.(Phlebotomus) papatasi, P.(Ph.) bergeroti, P.(Ph.) duboscqi, P. (Paraphlebotomus) alexanderi, and P. (Anaphlebotomus) rodhani. In addition, two Parvidens (P. lesleyae and P. heischi) species were recorded in the study area.Among these, P. orientaliswas the most predominant species, accounting for (58.12%) followed by P. papatasi(29.62%), P. lesleyae (5.61%), P. bergeroti(3.80%), and P. duboscqi(2.07 %), P. alexandri(0.37%), P. heischi(0.24%) and P. rodhaini(0.18 %). On average, significantly higher densities of P. orientalis were caught in the periurban area of Adebay with compared to the urban area of SetitHumera. Overall, 684 Phlebotomus females were dissected for detection of Leishmania infection, but none was infected. Significant positive correlation was found between the monthly abundance of P.orinetalis and P.papatasiand the monthly averages temperature ($P<0.05$) whereas negatively correlated with monthly average rainfall and relative humidity ($P<0.05$). Abundance of P. orientalis and P. papatasi significantly increased during the dry season (January- May) but decreased in the wet season (June - September) ($P<0.05$) in the study areas. With regard to habitat preferences, a large number of P. orientalis was collected from outdoors especially in the farm fields with cracked vertisol. In contrast, P. papatasi was highly abundant indoors as well as outdoors within and the periphery of villages.

P. orientalis is a predominant species and highly abundant during the dry season and possibly able to transmit VL in the study area. Appropriate control methods should be designed according to the knowledge of P. orientalis habitat preferences and seasonal dynamics in relation to climate condition.

# ANTILEISHMANIAL ACTIVITY XANTHIUM BRASILICUM VELL. LEAVES AND ISOMERIC MIXTURE OF XANTHUMIN & XANTHININ ISOLATED FROM PETROLEUM ETHER & N-HEXANE EXTRACTS

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Visceral leishmaniasis (Kalazaar) is the fatal form of leishmaniasis if not treated; it is highly endemic in Indian sub-continent and in East Africa. According to WHO 2014 report about 200 000 to 400 000 of VL new cases worldwide with 20 000 to 30 000 deaths occur annually. Problems associated with the current drugs like development of resistance, cost, and serious side effects and need for hospitalization makes the search for new molecules is highly necessary.

i) Extraction: Xanthium brasilicumleaves were extracted successively by soxhlet apparatus using six solvents; extracts were dried under vacuum and kept in a refrigerator. ii) Fractionation & isolation: Column chromatography and crystallization were used for fractionation of the active extracts & purification of the compounds. iii) Structure elucidation: Ultraviolet spectroscopy, infra-red spectroscopy, mass spectroscopy, nuclear magnetic resonance, specific rotation and melting point were used for identification of the active compound. iv) antileishmanial activity (promastigotes of L. donovani) was carried according to Atta-ur-Rahman et al. (2005) method using 96 well plates, SSG & amphotericin B were used as positive control. Antiamastigotes for the isolated compounds was performed by Dr. Vanessa Yardley, London School of Hygiene & Tropical Medicine.

N-hexane extract exhibited the highest activity (>50 % inhibition at 5µg/ml), followed by petroleum ether, and chloroform extracts with moderate activity. n-hexane extract was fractionated to fourteen fractions, two of them were found to be active, but with less activity than the original crude extract. Compounds A& B, isolated from petroleum ether extract and n-hexane extract respectively, co-chromatography proved that they are the same compound. The compound was very active against Leishmania promastigotes (>50 % inhibition at 3.5 µg/ml). The activity of the compound against intracellular amastigote was very good, but unfortunately toxic to macrophages. The compound was found to be a racemic mixture and identified as xanthumin with its epimerxanthinin. Melting point and specific rotation indicated that xanthumin predominates in the mixture.

X. brasilicum leaves have a good antileishmanial activity which is attributed to the group of compounds known as sesquiterpene lactones which are abundant to the family Asteraceae; xanthumin&xanthinin belong to the same group and showed a remarkable leishmanicidal activity.

# SERO-EPIDEMIOLOGICAL AND LEISHMANIN SKIN TEST SURVEYS FOR VISCERAL LEISHMANIASIS IN NORTH EAST ETHIOPIA

**Desaley Tadese**

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In Ethiopia, visceral leishmaniasis is caused by Leishmania donovani. The reported and estimated country-wide incidence of VL in Ethiopia is 2000 and 3700-7400 cases/year respectively. The balance between anthroponotic and zoonotic transmission is still unknown even though most authors believe that VL in east Africa is anthroponotic. Asymptomatic leishmania infections occur more frequently than clinically apparent VL cases. In endemic area of Ethiopia the prevalence of asymptomatic leishmania infection ranges from 5-30% using LST and as high as 5.4% using DAT. An estimated 10%–20% of persons with asymptomatic infections develop clinically overt VL.

To determine the prevalence of asymptomatic L. donovani infection and assess the degree of exposure among residents in Raya AzeboWoreda villages where cases of VL were recently diagnosed.

Community based cross-sectional study was conducted between May and July 2013, employing Direct Agglutination Test (DAT) and leishmanin skin tests after clinical screening. In North east Ethiopia, where VL cases had been diagnosed before, were selected for the epidemiological assessment. Data was entered into excel and transported to SPSS version 17 for statistical analysis. Finally conclusions and recommendations were forwarded based on the findings.

A total of 1099 subjects comprising 401 males and 698 females were included in the study. After clinical screening, 1040 sera were tested to determine prevalence of anti-leishmanial antibody using DAT. The positive DAT rate varied from 0.33% to 5.88% among the different localities & overall positivity was 0.87%. Leishmanin Skin Test positivity was varied from 6.2% to 28.6%, with 9.08% over all prevalence. The difference in leishmanin positivity by age group and sero-prevalence by sex were all statistically significant ($P < 0.01$ and $P < 0.05$ respectively). Out of the 9 sero-positive individuals, 7 had no history of travel out of Raya Azebo.

The survey results do not suggest stable endemicity of VL in the study area but it shows that VL occurs sporadically among the human populations presumably acquired from a zoonotic cycle.

# PREVALENCE OF KALA-AZAR INFECTION IN POKOT COUNTY, AMUDAT DISTRICT, NORTH- EASTERN UGANDA

**Walter Odoch, Joseph Olobo**

***East, Central and Southern Africa, Health Community, Arusha, Tanzania***

Visceral leishmaniasis (kala-azar) caused by Leishmania donovani and transmitted by the sand-fly Phlebotomus martini, is endemic in certain foci in North-Eastern Uganda where it is thought to be confined to Amudat District, Pokot County.. Amudat Hospital records (April 1998-March 1999) indicated that kala-azar accounted for about 17% of hospital in-patient visits. However the actual prevalence of kala- azar infection in the community in Pokot County is unknown. This lack of information limits efforts geared towards its control.

To determine the prevalence of kala-azar infection in Pokot County, a cross-sectional study was conducted in Pokot County in March 2010. The study participants were ≥ 5 years and were randomly selected from age and sex strata in the chosen clusters. A questionnaire was used for data collection. Standard procedure for direct agglutination test was performed using dried blood spots on filter paper. Data was entered in EPIINFO 3.3 and exported to STATA 10, where descriptive statistics were generated

The overall prevalence of kala- azar infection in Pokot County was 17.2% (49/285) [95%CI: 13.1%-22.2%] and that of symptomatic infection was 2.5% (7/285) [95% CI: 1.08%-5.22%]. The ratio of symptomatic to asymptomatic kala-azar was 1:6. Kala-azar infection prevalence in Loroo and Karita sub-counties at 31.9% and 14.6% respectively were significantly different from Amudat Sub-county prevalence of 5.3%; Adjusted Odds Ratio (AOR) being 7.18 (95% CI 2.57 - 21.6) and AOR 2.75 (95% CI: 0.93 - 8.12) respectively.

With kala-azar infection prevalence at 17.2% in the community, there is an urgent need to institute a control program in the region spearheaded by the Ministry of Health. Furthermore, there is a need to evaluate recent reports of cases from other districts within the region, the heterogeneous distribution of infection within the county and the current risk factors, including the possible role of animals in kala-azar transmission in this area. More detailed discussions will be held on the above results.

# ARGINASE ACTIVITY - A MARKER OF DISEASE STATUS IN PATIENTS WITH VISCERAL LEISHMANIASIS IN ETHIOPIA

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*[6]Immunology and Infection Department, London School of Hygiene and Tropical Medicine, United Kingdom*

*[7]Department of Cellular Immunology, Max-Planck-Institute for Immunobiology and Epigenetics, Freiburg, Germany*

*[8]Third Department of Medicine (Hematology, Oncology, and Pneumology), University Medical Center Mainz, Germany*

*[9]Department of Biochemistry, WHO Immunology Research and Training Center, University of Lausanne, Switzerland*

**See poster**

# TEST OF CURE FOR VISCERAL LEISHMANIASIS

**Hashim Ghalib, Asrat Hailu, Aarthy Vallur, Denish Mondal, Maowia Mukhtar, Malcolm Dutjie, Randy Howard and Steve Reed**

***Infectious Disease Research Institute (IDRI), Seattle Washington. USA***

Visceral Leishmaniasis invasive parasitological diagnosis remains the practice in East Africa where the k39 RDT is not sensitive like the case in the Indian subcontinent. We have addressed limitations of the rK39 with a new synthetic polyprotein, rK28, followed by development and evaluation of new rK28-based RDT prototype platforms which includes the k39, rk26 and rk9 in the diagnosis of visceral leishmaniasis. This was followed by Phase II studies that showed high sensitivity and specificity of rk28 RDT in detection of VL in East Africa. Based on these results a larger phase 3 clinical study was initiated in Sudan using fresh whole blood samples and serum. This study is currently under analysis.

We used high through put ELISA to look at antibody levels and dynamic changes to specific L. donovani antigens in longitudinal patient serum samples collated at 0, 7, 14, 21 30, 90, 180 days from Southern Ethiopia site and 0, 30, 90, 180 and 365 days post treatment from Bangladesh. The main goal and purpose is to define the antigenic nature of the specific antigen significant antibody level and dynamic changes of the levels of these antigen specific antibodies and to see whether these changes correlate with treatment outcome and cure.

Antibodies against rk39 and rk28 were high in infected patients and remained high for 180 days in Sudan and 365 days in Bangladesh. Antibodies against rk26 in Bangladesh and rk18 in southern Ethiopian were high in infected patient but showed significant drop in titer post treatment that correlated with treatment success and cure. Similar was observed in a limited samples in Brazil where decline in K26 antibodies correlated with success of treatment. Please see figures1, 2,and 3.

The correlation between the decline in antigen specific antibody titer and success of treatment is a step towards the development of test of cure in VL.

# RESIDUAL PREVALENCE OF TRACHOMA AFTER SIX YEARS OF MDA IN TWO ENDEMIC SEGMENTS OF NAROK COUNTY, KENYA

**Ernest Wanyama**

***Ministry of Health Ophthalmic Services Unit Nairobi***

Trachoma is a Neglected Tropical Disease and leading cause of infectious blindness. Control of infection includes implementation of the full SAFE strategy. Narok baseline prevalence survey was conducted in 2004 with impact assessment surveys in 2010 and 2014. In both Impact surveys, two segments are still endemic despite un-interrupted MDA since 2008. A quantitative study was conducted to assess the residual prevalence of trachoma. The backlog of TT in the two segments had grown by 60%. The prevalence of TF decreased marginally and the UIG for the A component of SAFE was not achieved.

The study was conducted in two segments where prevalence survey results had confirmed a prevalence of TF>20%. A segment is a geographical area with between 100,000 and 200,000 and corresponds to the population size of World Health Organization recommended trachoma intervention unit. Quantitative data was collected through clinical graders for TF and TT. Quantitative data were analyzed using Predictive Analytics Software (PASW version 18.0) computer package.

A total of 1,140 adults aged >40 years were examined: 600 in South Eastern segment and 540 in South Western segment. The prevalence of TT was 5.9% (SE segment 5.8% and SW was 5.9%). TT surgical coverage for people was 17.3% while the TT recurrence rate for people was 57.1%. A total of 1,520 children 1-9 years old were examined: 800 in South Eastern segment and 720 in South Western segment. The mean prevalence of TF was 21.4% (SE segment 21.8%, SW 21.0%).

Conclusions/Recommendations: The backlog of TT is growing due to population increase, high prevalence of TT and inadequate TT surgical services. High prevalence of active TF also leads to high incidence of TT. There is a high risk of re-infection due to cross-border migrations. Full SAFE Interventions are still required for the next three years.

# IDENTIFICATION OF ENVIRONMENTAL PARAMETERS AND RISK MAPPING OF VISCERAL LEISHMANIASIS IN ETHIOPIA BY USING GEOGRAPHICAL INFORMATION SYSTEMS AND STATISTICAL APPROACH

**Teshome Tsegaw, Endalamaw Gadissa**

***Armauer Hansen Research Institute, All-Africa Leprosy and TB Rehabilitation and Training Center, Jimma Road, Addis Ababa, Ethiopia;***

Visceral leishmaniasis (VL), a vector-borne disease strongly influenced by environmental factors, has (re)-emerged in Ethiopia during the last two decades and is currently of increasing public health concern. Based on VL incidence in each locality (kebele) documented from federal or regional health bureaus and/or hospital records in the country, Geographical Information Systems (GIS), coupled with binary and multivariate logistic regression methods, were employed to develop a risk map for Ethiopia with respect to VL based on soil type, altitude, rainfall, slope and temperature. The risk model was subsequently validated in selected sites. This environmental VL risk model provided an overall prediction accuracy of 86% with mean land surface temperature and soil type found to be the best predictors of VL. The total population at risk was estimated at 3.2 million according to the national population census in 2007. The approach presented here should facilitate the identification of priority areas for intervention and the monitoring of trends as well as providing input for further epidemiological and applied research with regard to this disease in Ethiopia.

# VISCERAL LEISHMANIASIS (KALA-AZAR) RISK MAPPING USING GEO-SPATIAL TOOLS: A CASE STUDY IN KAFTA HUMERA DISTRICT, NORTH WESTERN ETHIOPIA

**Negussie Solomon, K.V. Suryabhagavan and Endalamaw Gadisa**

***Armauer Hansen Research Institute, All-Africa Leprosy and TB Rehabilitation and Training Center, Jimma Road, Addis Ababa, Ethiopia;***

Visceral Leishmaniasis (VL) is a severe vector-borne parasitic disease. In Ethiopia, the estimated incidence of VL ranges from 2,000 to 4500 cases per year. Based on this, the main objective of this research was to develop an area risk map of VL and to estimate the total population at risk in KaftaHumera District, Northwestern Ethiopia. To achieve the stated objective, geospatial tools were used to extract and develop risk cover map of VL using variables including rainfall, temperature, vegetation cover, soil type, altitude, slope and population data. Multivariate logistic regression analysis was used to assign weight of influence for the variables in spatial weighted overlay analysis model. The result revealed that temperature, elevation, soil, slope, rainfall and NDVI were the major predictors of VL presence with percentage influence of 29%, 22%, 15%, 13%, 12%, and 9%, respectively. From the produced risk map, 3453.69 km2, 2210.38 km2 and 269.59 km2 representing 58.21%, 37.25%, and 4.54%, of the total area of KaftaHumera District are at high, medium and low VL risk, respectively. In addition, the estimated population at high, medium and low risk level are 92,831 (68.98%), 34,864 (25.91 %) and 6,874 (5.11%), respectively. Based on the output, villages such as Bereket, Rawoyan, Baeker, Adebay, May Kadra and Humera town were identified with high population at risk for VL. Identification of priority Villages requiring immediate attention from health agencies as well as the local community greatly reduces the cost, time and energy for designing effective VL control measures.

In search of better health

## BACKGROUND

The Kenya Medical Research Institute (KEMRI) is a state corporation established through the Science and Technology (Amendment) Act of 1979, which has since been amended to Science, Technology and Innovation Act, 2013.

The 1979 Act established KEMRI as a National body responsible for carrying out health research in Kenya. It spells out the mandate and responsibilities of KEMRI.

## MANDATES

- To carry out research in human health.
- To cooperate with other research organizations and institutions of higher learning on matters of relevant research and training.
- To liaise with other relevant bodies within and outside Kenya carrying research and related activities.
- To disseminate and translate research findings for evidence based policy formulation and implementation.
- To cooperate with the Ministry responsible for Health, the National Commission for Science, Technology, and Innovation, and the Medical Sciences Advisory Research Committee in matters pertaining to research policies and priorities.
- To do all such things as appear to be necessary, desirable or expedient to carry out its functions.

## VISION

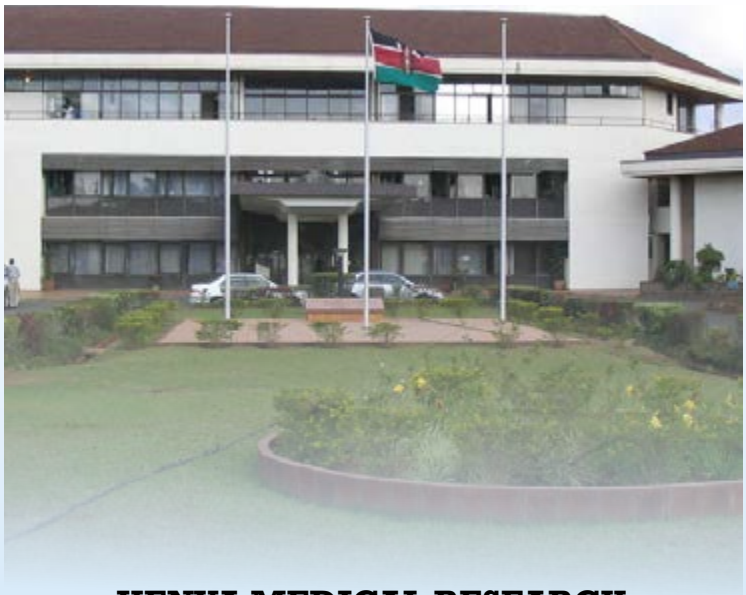
To be a leading Centre of Excellence in Research for Human Health

## MISSION

To Improve Human Health and Quality of life through Research, Capacity Building, Innovation and Service Delivery

## MOTTO

The motto of the Institute is "In Search of Better Health"



# KENYA MEDICAL RESEARCH INSTITUTE (KEMRI)

### Research Programmes

KEMRI has Six (6) Main Programmes, that are aligned to the KEMRI Strategic Master Plan and the Vision 2030 as follows:-

1. Biotechnology Programme
2. Traditional Medicine & Drug Development
3. Infectious and Parasitic Diseases
4. Public Health and Health Systems
5. Non Communicable Diseases
6. Sexual, Reproductive, Adolescent & Child Health

### Research Centres

The following are the Research and Training Centres in the Institute

- Centre for Biotechnology Research and Development (CBRD) Nairobi.
- Centre for Clinical Research (CCR) Nairobi.
- Centre for Public Health Research (CPHR) Nairobi.
- Centre for Infectious and Parasitic Diseases Control Research (CIPDCR) Busia.
- Centre for Microbiology Research (CMR) Nairobi.
- Centre for Respiratory Diseases Research (CRDR) Nairobi.
- Centre for Traditional Medicine and Drug Research (CTMDR) Nairobi.
- Centre for Global Health Research (CGHR) Kisumu.
- Centre for Virus Research (CVR) Nairobi.
- Centre for Geographic Medicine Research, Coast (CGMRC) Kilifi.
- Eastern and Southern Africa Centre of International Parasite control (ESACIPAC) Nairobi.
- KEMRI Graduate School of Health Sciences (KGSHS), Nairobi.

### Human Resource Capacity

KEMRI has developed a critical mass of scientists, technical and administrative support staff to rank as one of the leading

centre of excellence in health research development. KEMRI has trained all cadres of professionals totalling 1250 and it boasts of Professors, about 100 PhD's, over 200 Masters & medical doctors, over 900 highly trained technologists , technicians and career administrators.

## Major Achievements

### MAJOR REGULATORY FUNCTIONS

- KEMRI is the Medical Research arm of the Government and provides advice to the Ministry on various aspects of healthcare and delivery.
- National diseases surveillance and rapid response capacity for major disease outbreaks (cholera, chikungunya virus, H1N1 flu, yellow fever, rift valley fever, ebola, aflatoxicosis etc)

### GUIDELINE DEVELOPMENT

- Technical and research support for the ETAT (emergency care of critically ill children) guidelines
- KEMRI provided Technical Facilitation in development of National Guidelines for Prevention of Cervix, Breast and Prostate cancers
- Developed a curriculum and guidelines on biosafety and biosecurity for Health Care Workers in collaboration with Ministry of Health
- Rationalization and regulation of traditional medicine
- Human resource capacity development for research though attachments and in the KEMRI-JKUAT INTROMID collaboration

### SIGNIFICANT RESEARCH OUTCOMES

- KEMRI Researchers were part of the team that demonstrated prevention of HIV using antiretroviral drugs- (Pre exposure prophylaxis and treatment as prevention) which was hailed as a scientific breakthrough and No 1 Discovery of the year 2011 by Science Magazine, 2011
- KEMRI scientists participated in research on combination therapy for treatment of Visceral Leishmaniasis which reduced the treatment of Leishmaniasis from 30 days to 17 days;
- Development of treatment regimens that have reduced treatment period for leprosy and Tuberculosis (TB).
- KEMRI is hosting three (3) of eleven sites participating in RTSS (Malaria prevention vaccine) where Phase II and III Clinical Trials results were hailed as Scientific Discovery No. 4 of the year 2011.

### INTERNATIONAL RECOGNITION IN THE PROMOTION OF GLOBAL HEALTH RESEARCH INITIATIVES

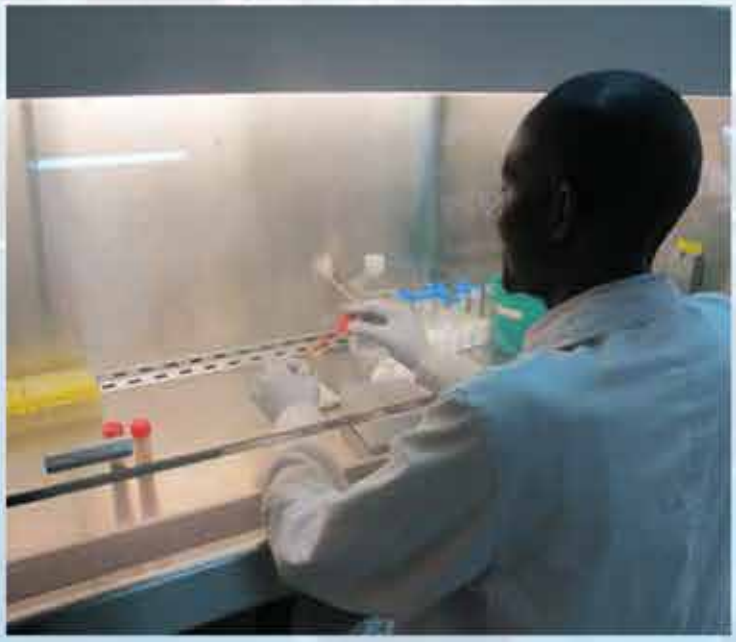
- Regional laboratory capacity building in operation research under the East African Public Health Laboratory networking project (EAPHLN).
- WHO designated International Training Center to implement capacity strengthening training courses to support Neglected Tropical Diseases (NTDs) control Programmes.
- WHO designated Centre of excellence in Malaria, Nutrition and Virology
- World Health Organization (WHO) Collaborating Centre for HIV/AIDS, Tropical Diseases Research, Polio Immunization, Viral Hemorrhagic Fevers and Anti-Microbial Resistance (WHO-NET).
- USA National Research Council recognized training institute for postdoctoral and senior research awards
- The Africa Regional headquarters for Drugs for Neglected Diseases Initiative (DNDi).
- Africa's regional center for International Union against TB and Lung Diseases, the International Union against Cancers and the Global Health Initiative on Climate Change and Health.
- Africa Network for Drugs and Diagnostics Innovation (ANDI) Centre of Excellence in the Manufacturing and Development of Diagnostic Kits and as a Centre of excellence for HIV Operational research.
- A designated "Good Clinical Practice Centre" for Clinical Trials.
- Global Centre of Excellence in Parasite Control under Hashimoto Initiative Programme.
- Regional Headquarters for Emerging and Re-Emerging Disease and Climate Change & Health.

Dr Lillian Apadet
Chairperson KEMRI Board of Management

Prof. Solomon Mpoke
Director, KEMRI

Dr. Elizabeth Bukusi,
Deputy Director, (Research & Training)

Ms. Linah Boit,
Deputy Director,
(Administration & Finance)



## INTERNATIONAL RECOGNITION OF KEMRI SCIENTISTS

- Dr. Andrew Githeko, a KEMRI Scientist was one of the winners of the Nobel Peace Prize 2007 jointly with Inter-Governmental Panel on Climate Change (IPCC). The Nobel Prize was also awarded to the panel together with US Vice President Albert Arnold (Al) Gore Jr. for their efforts to build up and disseminate greater knowledge about man-made climate change, and to lay the foundations for the measures that are needed to counteract such change.

- Dr. Alexis Nzila, a Kenyan scientist won the inaugural Royal Society Pfizer Award 2006 for his research on a new anti-malarial drug. He was crowned for his novel study on a drug to combat the disease's resistant strains winning about Shs. 7.8 Million Award Grant.

- Dr. Abdisalan M. Noor KEMRI –Wellcome Trust Scientists was awarded African Union National Young Scientists Award in Life and Earth Sciences in 2009. The US dollar 5,000 award is designed to celebrate the achievements of African scientists and to promote all efforts to transform scientific research into entrepreneurship, attract investments to Africa, and create research centers of excellence.

- Dr Faith Osier, a KEMRI –Wellcome Trust Scientists was awarded the prestigious African Research Leader (ARL) Fellowship in 2013. During the fellowship, Dr Osier intends to work on a project that will define the targets of protective immunity against Plasmodium falciparum malaria using multi-centre cohort studies, combined with bio-informatics and proteomic approaches. The ARL Fellowship, is supported by The Medical Research Council, UK and the UK Department for International Development (DfID), and is designed

to strengthen research leadership across sub-Saharan Africa (SSA). The Fellowship does this by putting in place incentives to attract and retain exceptionally talented researchers to lead research on key global health issues pertinent to SSA

➔ Dr. Samuel Kariuki, a KEMRI scientist received the Royal Society Pfizer Award 2012 for his work on invasive Non-Typhoidal Salmonella (NTS) infections in Kenya. Kariuki received the £60,000 (Sh8.22 million) prize to further his research. He also received a personal prize of £5,000(685,000).

## Corporate Social Responsibility

The Institute promotes the spirit of Social Action through Corporate Social Responsibility activities such as Community Involvement and Public Health Education, as well as clinical, laboratory and diagnostic services.

## Research Committees

KEMRI's research regulation is comprised of the following research committees:-
Scientific Programme Committee (SPC)
Scientific Steering Committee (SSC)
Ethical Review Committee (ERC)
Animal Care and Use Committee (ACUC)
Publications Committee (PC)

## Products and Services

Through its research activities KEMRI has over period of time developed various research products and service namely;-

### Products

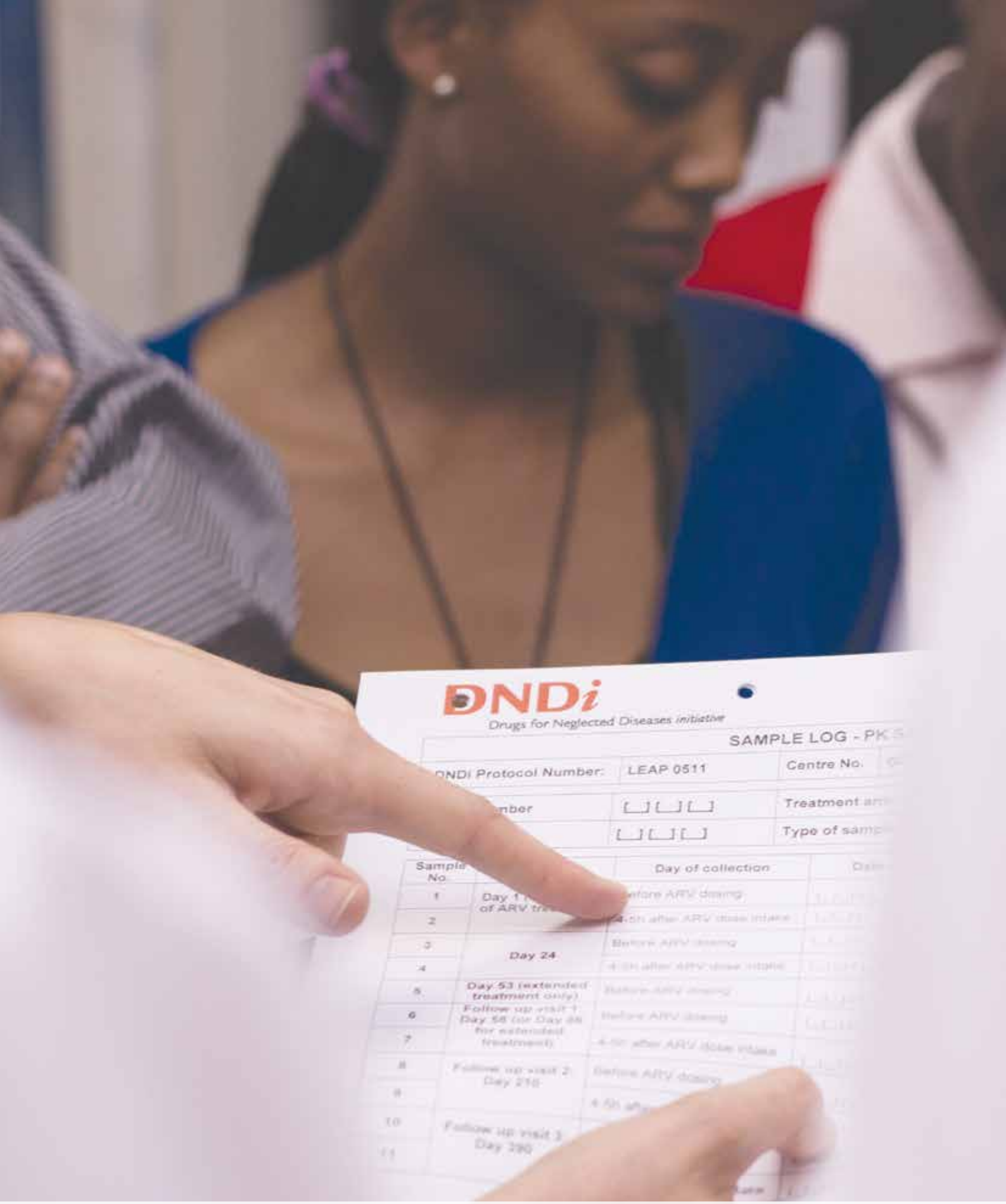
HEPCELL Rapid®
KEMCOM Rapid®
KEMPAC Rapid®
TBcide®
KemTAQ®
KEM - rub®
KEMpreg Rapid®

### Services

Ethics Review for research protocols
The Wellness Programme
Conference Facilities
Incineration Services
Cancer Registry
Rapid Emergency Response and Disease Surveillance
Clinical Laboratory diagnostic services

**Contact us:**
The Director, KEMRI
P.O Box 54840 00200, Nairobi, KENYA
Tel. +254 (020) 2722541, 2713349
Fax. +254 (020) 2720030
Email: director@kemri.org
Website: www.kemri.org

KEMRI is ISO 9001:2008 Certified


DNDi
Drugs for Neglected Diseases initiative
SAMPLE LOG - PK
DNDi Protocol Number:
LEAP 0511
Centre No.
Treatment
Type of sam
Sample No.
Day of collection
Day 24

# INDEX

# ACKNOWELDGEMENTS

The Leishmaniasis East Africa Platform (LEAP) would like to thank the following:

## Donors

Department for International Development (DFID), UK; Federal Ministry of Education and Research (BMBF through KfW), Germany; Médecins Sans Frontières/Doctors without Borders, International; Medicor Foundation, Liechtenstein; Ministry of Foreign Affairs (DGIS), The Netherlands; Ministry of Foreign and European Affairs (MAEE), France; Region of Tuscany, Italy; Spanish Agency for International Development Cooperation (AECID), Spain; Swiss Agency for Development and Cooperation (SDC), Switzerland, Canton de Genève, European Union (EU).

**DND*i*, Geneva Switzerland**

**Conference Chief Guest,** Dr. John Amuasi

**Invited guest and participants**

**Ministries of Health (Ethiopia**, Kenya, Uganda and Sudan)

**LEAP Partners and Institutions**

**LEAP countries –** the communities where we work

**All DND*i* Africa Staff**

# ADDITIONAL USEFUL INFORMATION

# General information

**Dear Participant,**

Welcome and Happy Ethiopian New Year!
The 1st LEAP Scientific Conference will be held between September 29th and 30th in Bahir Dar, Ethiopia.

**Venue**
Avanti Blue Nile Hotel
PO.Box 1387Bahir Dar
Kebele/Wereda: 03
Bahir Dar Ethiopia

Telephone numbers:
Ms. Ulian Fikre: +251 911 38 95 02
Ms. Zefun Mekonnen: +251 914 30 24 26

**Email Address:**
avantibluenilehotel@ethionet.et
reception@avantibluenilehotel.com
reservations@avantibluenilehotel.com

Avanti Blue Nile Hotel is located onthe shores of Lake Tana, Bahir Dar, Ethiopia. It features a Bar, a Restaurant and a Garden. All rooms in the Hotel are fully air conditioned with flat screen TV, Mini bar and safe box. Blue Nile Avanti offers a 24 hour front desk service, 24 hours electricity, free WiFi internet access, money exchange services, luggage storage facilities, Private parking and laundry services. City and airport shuttle services are available on request. The premises are also guarded by security personnel.

**Registration (at the conference)**
Meeting registration will start on the afternoon of Sunday September 28, 2014, at the Avanti Blue Nile Hotel. Kindly look out for the registration desk at the lobby

**Language**
The meeting will be conducted in English. Meeting documents are available in English.

**Useful Information for Presenters**
Individuals making oral presentations are asked to send their presentations and short biographies (150 words) to leap@dndi.org latest Tuesday 23rd September 2014.

**Ticket reconfirmation**
Our travel agent, Incentive Travel will reconfirm all the tickets at least one day before departure.

**Transportation**
The hotel is 6.8km from the airport (approximately 11 minutes' drive). Airport transfers have been pre arranged.

Please confirm the time of your arrival in Bahir Dar with Joy (jmalongo@dndi.org) to allow her to arrange airport transfers for you. You may also contact her on telephone +254731006784.

The person meeting you at the airport will be holding a sign with **'DNDi LEAP'** written on it.

**Accommodation**
DNDi will be happy to give you all necessary logistical assistance for visa application and/or hotel booking. **Conference participants will be accommodated at Avanti Blue Nile Hotel and hotels nearby.**

**Once you confirm your arrival details, Joy will confirm to you the name of your hotel**

The hotel will request some **proof of identity** (such as an ID card or passport) at check-in.Hotel Check-out is by 11:00 a.m on the morning of departure.

**The hotel is booked on bed and breakfast basis. Any extras will be billed to you**

Visas and other entry requirements
Visas are required for all visitors to Ethiopia, **except Kenya and Djibouti nationals.** You are strongly adviced to get your visa in your country, before departure. Please check with your local Ethiopian Embassy for visa requirements.**Tourism visas** can be obtained **on arrival** at Bole International Airport at **USD20**. Visa fees will be reimbursed. Please ensure you retain your receipt to facilitate reimbursement.

**Ethiopia - Useful Information**
**Money/ Credit Cards**
The unit of currency here is Ethiopian Birr (100 cents make a Birr) available inthe following denominations: 1,5,10, 50 and 100 birr notes and a 1, 5, 10,25,50 cents coins.

The exchange rate to the US Dollar is approximately:1.00 USD= 19.8645 Ethiopian Birr.
Foreign currency can be exchanged at any commercial bank, including branches located at larger hotels and at the airports. Exchange rates are the same everywhere.

ATMs are available in Bahir Dar. They accept international Visa cards but they don't work with Cirrus and Plus systems and also don't accept MasterCard. Credit cards can be used in large hotels in Addis Ababa but are not widely accepted outside the capital. Travelers' cheques can be cashed in banks, but are difficult to exchange outside Addis Ababa.

**Vaccination and malaria prophylaxis**
Please carry your International Certificate of Vaccination with proof of yellow fever vaccination as it may be required. Your doctor may recommend additional vaccinations prior to travel.

For optimal prevention of malaria, protection from mosquito bites is essential: carry mosquito repellent cream and/or spray. Your doctor may advice on prophylaxis.

## Electrical Plugs

In Ethiopia the standard voltage is 220 V. The standard frequency is 50 Hz. The power sockets that are used are of type C / E / F / L. Below you find pictures of these power sockets and corresponding plugs.

**Type F: This socket can also be used with plug C.**

**Type C: This socket can also be used with plug F.**

**Type E: This socket can also be used with plug C. Plug F will also do, but only with an additional pinhole.**

**Type L**

## Time

UTC/GMT +2 hours

## Weather in September

September is at the end of the rainy season in Bahir Dar. The week of the conference, temperatures in Bahir Dar are expected to be 12-23°C (54- 73 Farenheit).

## Tourism information

Bahir Dar or Bahar Dar (Amharic for "sea shore") is a city in north-western Ethiopia. The city is the capital of the Amhara Region (kilil) and is one of the leading tourist destinations in Ethiopia. It has a small daily market and some entertainment spots, and a variety of attractions in the nearby Lake Tana and Blue Nile River. Blue Nile Falls (Tis Issat) are located about 30 km to the south of the city.

The most common and convenient way of traveling in Bahir Dar is cycling. Taxis also provide efficient transportation in the city.
(Source: http://en.wikipedia.org/wiki/Bahir_Dar)

Trips from the Avanti Blue Nile Hotel to the Monasteries and The Blue Nile falls can be organised at the reception of the Hotel at an additional charge.(Source:http://webcache.googleusercontent.com/search?q=cache:http://www.jovago.com/en-gb/ethiopia/bahar-dar/hotel/o5477/avanti-blue-nile-hotel).

Wishing you a safe journey!

# EVALUATION FORM
# 1ST LEISHMANIASIS EAST AFRICA PLATFROM (LEAP) SCIENTIFIC CONFERENCE

**Bahir Dar, Ethiopia,**
**29th September – 30th September 2014**

**Dear Participant,**

We hope that you have found the LEAP scientific conference, to be informative and useful. In this regard, we would be most grateful if you could provide feedback to the organizers on your experience at the conference. On a scale of 1 to 5 represented as below:

**5 = Excellent  4 = Very Good  3 = Good  2 = Average  1 = Below Average**

## I. GENERAL ASSESSMENT

1. What is your overall assessment of the event?

5 ☐  4 ☐  3 ☐  2 ☐  1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

## II. CONTENT

1. . How would you rate the relevance of the topics presented to you/ your organisation?

5 ☐  4 ☐  3 ☐  2 ☐  1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

- **Session** Three: VL: Diagnosis and Immunology

5 ☐  4 ☐  3 ☐  2 ☐  1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

- **Session Five:** Regulatory and Ethics Harmonization : A Possibility or a Mirage ?

5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

- **Session Six:** Neglected Tropical Diseases 1

5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐

*Please feel free to provide further comments / suggestions*

***Comments***:

- **Session Seven:** Neglected Tropical Diseases 2

5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

**2.** To what extent do you expect to use the information obtained at this conference in your work?

5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

3. How would you rate the appropriateness of the content of the conference as a whole?

5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

## III. SPEAKERS/FORMAT

**1.** How would you rate the quality of the discussions held during each session?

5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

**2.** How would you rate the time allocated for presentations and discussion?

5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

## IV. ORGANISATION

**1.** How would you rate the quality of background documents and materials provided and their relevance for your organization?

5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

**2.** How would you rate the venue of the conference?

5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

**3.** How would you rate the organisation of the conference room?

5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

**4.** How would you rate the organisation of the conference (support from organisers)?

5 ☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐

*Please feel free to provide further comments / suggestions*

***Comments:***

**Any other comments regarding the organization of the conference?**

## V. FUTURE CONFERENCES TO BE ORGANISED BY LEAP/ DND*i*

1. Please identify possible future topics and areas for discussion with high relevance to R&D in Africa or policy impact that should be covered at the future conferences to be organised by LEAP.

2. Please indicate if you are interested in attending future conferences organized by LEAP, DNDi or her partners (Please share email address to receive future information)

YES ☐ NO ☐

***Name*** *(optional):* .....

***Telephone*** *(optional):*.....

***Email address*** *(optional):* .....

# LEAP

## LEISHMANIASIS EAST AFRICA PLATFORM

# 1st LEAP Scientific Conference

**Bridging the Gap: Progress on the Current Research Innovation & Access to Visceral Leishmaniasis Treatment**

*29th - 30th September 2014*

*Bahir Dar, Ethiopia*

MEDECINS SANS FRONTIERES

DNDi

Drugs for Neglected Diseases *initiative*

DNDi AFRICA

Drugs for Neglected Diseases *initiative*

**CONTACT US**

**DNDi Africa Regional Office, in Nairobi** ¦ Kenya Medical Research Institute (KEMRI) ¦ P.O. Box 20778 KNH 00202 Nairobi

**Tel**: +254 20 273 0076 ¦ Email: africa@dndi.org ¦ **Website:** www.dndi.org