LEAP
LEISHMANIASIS
EAST AFRICA PLATFORM
NewsLETTER

Issue 1 June 2013

Welcome to the Inaugural LEAP NEWSLETTER

Dr Ahmed Mudawi Musa, Institute of Endemic Diseases, Sudan, LEAP Chairman

Welcome to this first edition of the LEAP Newsletter. There are a lot of exciting developments in the East African Research and Development (R&D) landscape that we endeavour to share in this first issue. LEAP stakeholders have participated in key activities. We have marked our achievements, learned from our challenges, and valued the role of our stakeholders. We have included some food for thought captured in the viewpoint sections, in which we highlight the way forward for LEAP.

We asked members of the LEAP stakeholder community what they considered important in this newsletter and we were delighted with the responses and interest expressed in the survey carried out during our 18th LEAP meeting held in Sudan, on 2 and 3 September 2012. We look forward to your continued contributions and suggestions as we move towards a LEAP Newsletter on a bi-annual basis.

The overwhelming majority asked for this newsletter in PDF format so we will largely disseminate the publication via email. We will also produce a print version. With both regular and feature items, we hope you will find the newsletter to be a great source of useful information on the issues related to leishmaniasis in East Africa.

Do have a great 2013 and happy reading.

A Decade of LEAP

Q&A with Dr. Monique Wasunna

Dr Wasunna is the Assistant Director of Research at the Kenya Medical Research Institute (KEMRI) and the Head of DNDi Africa

Q: What comes to mind when you think of LEAP as a platform and its achievements?

A: It has been almost ten years since the Leishmaniasis East African Platform was launched. Since its inception in 2003, there are a number of milestones that have been achieved. Let me highlight a few.

In 2003, the LEAP participating countries (Kenya, Uganda, Sudan, and Ethiopia) demonstrated varying degrees of expertise in conducting clinical trials (CTs). For that reason, LEAP embarked on capacity building by infrastructure development and the training of personnel. These two activities contributed to the achievement of one key milestone: today, LEAP is in a position to carry out CTs at international standards.

When LEAP started, the infrastructure was terribly poor. For example, in some countries like Ethiopia, CTs were carried out in tents, leaving staff and patients exposed to the harsh environment. Consequently, when DNDi facilitated capacity building and the upgrading of hospital infrastructures, LEAP clinical sites benefited greatly.

To date, the LEAP achievements are as follows:

- 2010 saw the launch of sodium stibogluconate combined with paromomycin (SSG&PM) for 17 days as a new treatment against visceral leishmaniasis (VL). The results from clinical trials showed that SSG&PM combination therapy is as safe and effective as the SSG standard monotherapy for 30 days, with the advantage of offering a shorter and cheaper treatment course. SSG&PM was recommended by the WHO Expert Committee on the Control of Leishmaniasis as first-line treatment for VL in East Africa.
- The 2011 registration of PM in Uganda made it possible for the SSG&PM combination treatment to be made available for use in the country.
- In 2012, Kenya's Ministry of Health launched its National VL guidelines for national health workers for diagnosis and management of VL with SSG&PM combination therapy recommended as first-line treatment.
- On 26 February 2013, paromomycin (PM) was registered in Kenya.

Q: What led to the use of SSG&PM combination therapy, and what are some of the studies on SSG&PM combination therapy?

A: In 2003, LEAP carried out a patients' needs assessment and established that what VL patients needed was a safe, efficacious, easy-to-use, oral treatment. MSF had experience using SSG&PM for 17 days. LEAP maximized on this viable combination and tried it against the standard treatment SSG, which is administered intravenously or through intramuscular injection for 30 days. Through LEAP CTs, the standard treatment was compared with SSG&PM combination therapy that was administered for 17 days. Through the CT process, LEAP was able to demonstrate that SSG&PM combination was safe and efficacious. The benefits of SSG&PM include: reduced toxicity, shorter hospital stay, and lower cost of the drug administration.

Q: What are your views on regulatory harmonization in East Africa, specific to LEAP?

A: I think regulatory harmonization is a viable option for East Africa. Indeed when LEAP was set up, one of the main reasons was to enable East African countries to carry out CTs together. Therefore, it defeats the purpose for LEAP countries to work collaboratively in the development of new treatments and then for the same drugs to be registered at varying periods due to the different in-country policy structures.

Ideally, when a treatment is developed, it should be recommended and registered across the Eastern Africa region.

I feel that we should have a case where a drug is registered, for example, in Kenya and immediately have it accessible and registered in all other East African countries. After all, we worked together to achieve this result.

Fortunately, towards that end within the East African Union (EAU) this idea is being explored and is in development, with an established group working on regulatory harmonization. Therefore, this is something to look out for and if actualized will be a breakthrough for LEAP's Research and Development (R&D) work, enabling us to move quickly as an East African block, saving both time and money in the drug registration processes that would no longer need to take place per country.

LEAP Country Principal Investigators (PI's) from right to left: Prof. Eltahir Awad Gasim Khalil, Prof. Joseph Olobo, Dr. Monique Wasunna, Dr. Musa A Mudawi, Prof. Asrat Hailu

QUICK FACTS: Typical clinical trial approval process in LEAP countries

KENYA – On average the approval process is two months. The protocol is reviewed by the following committee in this order: from the KEMRI Center Committee, to the Kenya Medical Research Institute (KEMRI) Steering Committee, then forwarded to the KEMRI Ethics Committee (ECCT), after which it is finally sent to the Pharmacy and Poisons Board (PPB).

UGANDA – Submissions start with the University of Makerere. The principal investigator then submits the proposal to the Ethics Committee based at the University, and thereafter to the National Drug Authority, and finally to the National Council of Science and Technology.

SUDAN – The Institute of Endemic Diseases is the first to receive submissions for scientific ethical review. These are then passed on to the National Medicines and Poisons Board for final approval.

ETHIOPIA – First, the body initiating the trial (institutions, faculty, or NGO) submits a protocol, which often requires a support letter or ethical review from the regional health bureaus. The second step involves review by the National Ethics Review Committee at the Ministry of Science and Technology. The final step is the review and/or authorization by the Food, Medicines and Healthcare Administration and Control Authority (FMHACA).

VIEWPOINT

LEAP since its birth: presently and its future scope

Prof. Asrat Hailu (PhD), School of Medicine, College of Health Sciences, Addis Ababa University

(LEAP Press Conference - Nairobi, 2011)

It was in 2003 that LEAP was born in East Africa. DNDi was instrumental in the establishment of LEAP and remains a collaborative partner. At the time of its establishment, LEAP had a clear and well-articulated mission of seeking simplified treatments for visceral leishmaniasis (VL). It launched a multi-centre clinical trial in 2004, exploring the potential of sodium stibogluconate (SSG) and paromomycin (PM) as a combined treatment for VL. It was a remarkable achievement that LEAP could conduct its first Good Clinical Practice (GCP) compliant clinical trial.

The combination of SSG&PM, tested in one of the largest Phase III clinical trials in East Africa, has now become a first-line treatment for VL in sub-Saharan Africa. The wisdom behind this success story was in DNDi's management foresight. Needless to say, the engagement of key actors and scientists from within the region has been the main element of the successes. Our achievements are indeed home-grown solutions for local problems.

Starting from scratch was no easy business for LEAP. First and foremost, it was necessary to build clinical research facilities in Ethiopia, Sudan, Kenya, and later on in Uganda. Several capacity building training workshops had to be organized so as to meet international standards for the implementation of GCP compliant trials. These facilities had to be regularly refurbished, maintained, and staffed appropriately. Consequently, not only did the research facilities require the capacity to offer standard treatments for VL patients, but also needed to meet the minimum standards for conducting clinical trials.

After the first CT took place, LEAP launched clinical trials involving, for example, single-dose AmBisome, and a combination of the latter with other anti-leishmanial drugs. In the process, a lot was learned about VL in Africa. For example, we now know that East African VL is different from Asian or Mediterranean and South American VL and that it also varies within the region. We have a better picture of clinical and epidemiological characteristics of VL in East Africa. This includes post-kala-azar dermal leishmaniasis (PKDL). Thanks to this concerted effort, LEAP was in one way or another involved, in addition to the clinical trials, in molecular parasitological studies, drug sensitivity tests, and pharmacokinetic (PK) studies that enabled us to unravel the nature of this disease.

The challenges and opportunities that enfold LEAP are indeed some of the key points for discussion. While drug discovery efforts of DNDi and other stakeholders are continuing, the timelines for reaching upstream in the drug evaluation pipelines can be unpredictable. Given this constraint, LEAP will face the challenge of sustaining the stamina it has amassed.

LEAP has consciously shouldered the task of treating VL patients in seven sites within the region (two each in Ethiopia, Sudan, and Kenya, and one in Uganda), some of which are serving as training centres for the various country-specific national control programmes. Currently, these centres are probably covering 10-20% (conservative estimate) of the VL treatment services in each of the member countries. The ideal target product profiles (TPP) for VL diagnostics and treatments have yet to be attained. Therefore, VL in East Africa will remain a public health threat for some time to come. Given this untoward scenario, LEAP is poised to play its role as a partner of VL control programmes.

Presently, LEAP is in the best position to build on its expertise and resources, to continue its role as a partner of control programmes. Moreover, within its catchment of stakeholders and academia, LEAP has access to up-to-date knowledge and tools that it can add on to its expertise to make a difference in the global efforts of VL control and elimination plans. LEAP can become a vital organ of information sharing and an instrument for promoting research collaboration. It can also provide an institutional framework for control programmes in Sub-Saharan Africa.

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Ministry of Health

KACHELIBA KALA-AZAR PROJECT

MSF-Switzerland started VL case management activities in Amudat, Uganda in 2000. It was noted that more than 70% of the patients were coming from Pokot and Baringo districts in Kenya. The MSF project then moved to Kacheliba, Kenya in 2006, with satellite sites in Konyao, Alale, Kasei, Lomut, and Sigor. These sites are active in case management, sensitization, and advocacy activities.

On 18 December 2012, MSF handed over the Kacheliba site to the Ministry of Health (MoH), which will be working in partnership with DNDi. Free quality services will continue to be offered at the North Pokot District Hospital in Kacheliba (formerly known as the Kala-Azar Treatment Centre).

Kacheleba Elders during handing over ceremony

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18TH LEAP MEETING HIGHLIGHTS

Held on 2 and 3 September 2012

18th LEAP meeting – Khartoum, Sudan

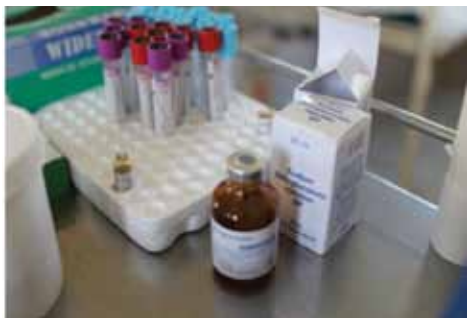
PKDL CONSORTIUM

A meeting held from 27 to 29 June 2012 in Delhi, India, officially launched the PKDL consortium, which is a non-legal entity, formed to aid collaboration in research, training, advocacy, communication, and coordination. Going forward, the consortium will meet every 1 to 2 years, in which case meetings will be integrated around the bi-annual LEAP forums.

This gathering was informed by conclusions of a WHO meeting that noted: lack of tools to control PKDL, severe gaps in PKDL research, and a need for a research agenda.

The transmission of PKDL is still a grey area vis-à-vis other possible transmission modalities. This led to the decision to hold discussions on how to go about research with regards to LEAP, having in mind that PKDL shows itself varyingly in different countries. Going forward it is necessary to be careful not to extrapolate data, bearing in mind that some countries, such as Uganda, register very few PKDL cases.

The PKDL consortium objectives include: mobilization of political and scientific commitment, resource mobilization for PKDL, increase the stakeholder base of the initiative, implementation of new preventive and control measures based on research end-products, review the current status of PKDL in South East Asia and in Eastern Africa, identify research needs based on gaps in control, and prioritize research projects.



PROGRESS IN DEVELOPMENT OF DIAGNOSTIC TESTS FOR LEISHMANIASIS:

Test for Detection of Urinary Antigens and for Detection of DNA in Blood

- The Foundation for Innovative New Diagnostics - Switzerland (FIND) currently has two main Leish projects: the loop-mediated isothermal amplification LAMP and the urinary antigen detection test (KAtex).

- FIND has partnered with the Royal Tropical Institute (KIT - Amsterdam, the Netherlands), Sanger Institute, the Institute of Primate Research (IPR - Nairobi, Kenya), and Eiken Chemical Co. Ltd. (Tokyo, Japan) on the LAMP for the leishmaniasis project.

- FIND has collaborated with DNDi, Prof. Marcel Hommel, Kalon Biologicals Ltd, and KEMRI on the KAtex project.

- A new version of the former KAtex urinary antigen detection test for leishmania is being developed to improve upon, simplify, and expand the use of the original test.A key advantage of the KAtex study is that it is non-invasive.

- The study is on-going in Kenya.

DATES	TRAINING	VENUE	NUMBER OF PARTICIPANTS
Short term Courses/ Training			
01 January 2012	PPD GCP/GCLP	Cape town	2
17 May 2012	PV training	Kimalel	17
02 August 2012	GCP training	Gondar	23
25 - 27 July 2013	PV training	Arba Minch	13
30 July - 01 August 2013	PV training	Gondar	23
18 - 20 March 2013	PV training (2 trainings)	Abdurafi	24
19 - 20 March 2013	GCP	Abdurafi	16
		Total	118

DATES	NUMBER OF PARTICIPANTS
Long term Courses	
BSc. Medical Lab	1
BSc. Applied Business	1
Masters Public Health	1
Bachelor's Pharmacy	1
MSc. Infectious Diseases	3
Masters in Tropical Medicine and Hygiene	1
Other MSc	5
Diploma	1
MBA	1
Total	15

CAPACITY STRENGTHENING

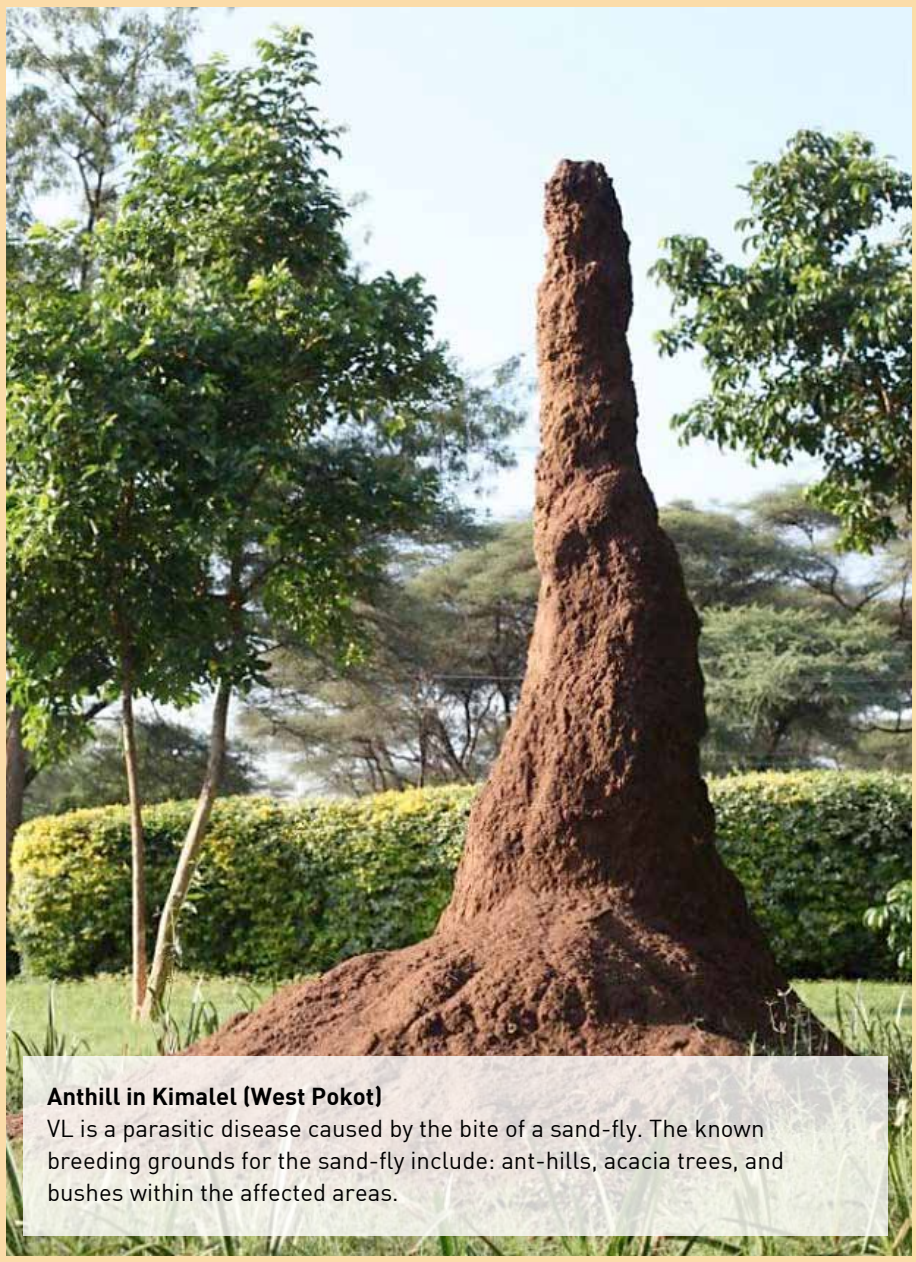
List of training workshops carried out during the period 2012-2013

LEAP was set up to strengthen clinical research capability in order to facilitate evaluation, validation, and registration of new treatments that address regional needs of visceral leishmaniasis (VL, or kala-azar) in East Africa. Below is a list of workshops planned for this purpose in 2012 and 2013.

KALA-AZAR IN EAST AFRICA

VL is fatal if left untreated. An estimated 300,000 cases occur per year in 70 endemic countries. Estimates suggest 20,000 new cases per year in Africa, with numbers rising sharply during an epidemic. Existing treatments for VL do not work the same way in all regions. Current treatments for VL in Africa are either toxic, costly, difficult to administer, or require long hospital stays. Untreated patients play a key role in the transmission cycle. Therefore, effective and cost-effective treatments and prevention of relapse play a critical role in the reduction of disease reservoir and the prevention of resistance to the treatments, forming a vital part of disease control.

East Africa remains one of the most prominent endemic areas for visceral leishmaniasis (VL) in the world. VL-HIV co-infection is an additional problem, reported in 35 countries worldwide, with the highest prevalence occurring in Ethiopia (15-30% of all VL cases). Co-infection leads to low cure rates for VL, increased drug toxicity, and more frequent relapse, contributing to a higher mortality, particularly in Ethiopia.



Anthill in Kimalel (West Pokot)
VL is a parasitic disease caused by the bite of a sand-fly. The known breeding grounds for the sand-fly include: ant-hills, acacia trees, and bushes within the affected areas.

PATIENT STORY
– Community Outlook

Akiru Tomelele, West Pokot, Kenya

Sitting at the local soda shop in West Pokot, on a hot sunny afternoon, DNDi has taken an opportunity to talk to a community elder, Akiru Tomelele. He says he is young, but his features tell a different story. Akiru is sitting on a plastic crate and those of us who can find a space, sit on the small wooden bench. As Akiru begins to speak, a few men gather around him. He then sips his cold soft drink to tell us about his community's experience with kala-azar (visceral leishmaniasis).

This is his story:
'The way things stand in my community, you will find that many people here have suffered from kala-azar. We are very aware of the disease. In the nineties, the disease killed a lot of people; we did not have treatment. Now things are much better, as not so many from my community are dying.

As a people, we are fortunate to have KEMRI and DNDi. These organizations have undoubtedly helped us by enabling access to drugs that provide treatment for kala-azar.

Not too long ago, a young girl called Chepsugo suffered from kala-azar. She is my neighbour's daughter. Chepsugo was treated with traditional methods for two weeks. However, when there was no marked improvement, she was admitted at the Kimelel District Hospital where she was treated with SSG&PM for 17 days. Since then her health is better.

We used to treat kala-azar through traditional methods. Bark from a special tree (Muchukwa) was pounded into powder and boiled to create a medicinal brew; children and adults would drink this for two weeks in the hope that they would be relieved of any ailments. For a long time, such traditional treatments were used. We have come a long way.

Going forward we would like to see the Ministry of Health set up clinics closer to our communities because transport is an issue. The roads are terrible and public transportation is not frequent: it's on a 'first come, first serve' basis, and only a small number of people can fit in one vehicle. The distance to the closest kala-azar treatment centre is far. We need to see our sick family members on a daily basis.'

Two patients admitted at the Kimalel District Hospital

Chepnangata Locilakol Chebareng (24 years of age) and Cesto Atodongora Lokwasia (12 years of age)

August 2012: It's just a few minutes past 9:30 a.m. The morning is warming up nicely, with birds chirping into the cool fresh breeze that makes the leaves sing. Nurses walk purposefully along the corridors, while the patients' waiting room begins to fill up. All patients at Kimalel* District Hospital have received their first daily treatment of SSG&PM combination therapy. For them, the day seems to slow down despite the fact that it has just started. Patients who would otherwise be tending to their livelihoods are sitting on beds waiting to get better from the disease that ails them, kala-azar. Two patients stand out amongst the rest (in the women's ward), one is named Cepnangata, who is literally shadowed by Cesto, a twelve–year-old girl.

This is their story:
'I have been here for five days since I started taking the VL treatment. I now feel so much better compared to when I first came here. We women need to be strong because we have so many responsibilities. I am in the hospital here with my child. He has malaria. So when I get my kala-azar treatment, he gets his malaria treatment. I also take care of Cesto, make sure she eats and is well. Her parents asked me to do so because they live so far away from the clinic, and visiting here is hard. The roads are not so good, nor is transport.

I am so glad that I have received this treatment because I need to get better. I have a child that depends on me, and a whole life to live. I am sad to be here but grateful that I will be well soon. Cesto came in two days ago. She is getting better. Her headache has subsided, and we can see that the medicine is doing its work.

Although we come from different communities, in both our neighbourhoods people are aware of kala-azar and word is spreading about the treatment offered at Kimalel. It is much better than traditional medicine.'

*Kimalel is located in Baringo constituency. DNDi, the Kenyan Ministry of Health, and KEMRI work as collaborating partners at the Kimalel District Hospital to facilitate the VL treatment centre.

VIEWPOINT

LEAP DATA MANAGEMENT

'The LEAP data centre has shown the ability to manage information to meet international standards, and we are looking forward to sharing experiences with other research groups within or even outside of the region – either to bring them up to speed or provide support where necessary.'

Raymond Omollo
DNDi Africa Regional Data Management Manager

The DNDi Africa Data Centre is responsible for data management and analysis to facilitate activities carried out by DNDi and LEAP in Africa. The data comes from leishmaniasis-related clinical trials, as well as other research work, not exclusively clinical trials.

Since its establishment in 2004, the Africa regional data centre has observed tremendous growth. This positive change is specific to having improved infrastructure in place, as well as improvements in human resource capacity. This has upgraded the centre's capacity to produce data based on international standards, i.e. ICH GCP (International Conference on Harmonization of Good Clinical Practices). In addition, there is now more focus on open source tools to manage data, by using software such as OpenClinica, which is used to manage clinical trials.

Initially Epi Info™ was used as a database management (DM) tool, but based on the kind of data LEAP was churning out through clinical trials, this system was not up to standard according to ICH GCP.

This is fundamentally because the database was not stable; it was unable to handle large amounts of data; maintaining an auto trail was difficult; and the process was purely manual.

Upgrading the DM tool to OpenClinical ensured that the LEAP DM is compliant with international standards and query management is faster. Moreover, because LEAP does not manually transcribe queries onto paper, the DM tasks are halved in terms of time.

There is always room for improvement, so the next crucial move is to be able to capture data electronically at source (at the point of clinical trials) to improve on data capture accuracy. With electronic data capture (EDC), data will not need to be transported form the sites by the clinical monitors. Instead, data will be keyed in at the site through an integrated system where data is available in real time. The challenge with this implementation is that currently the infrastructure modalities with regard to connectivity are not ideal. At site level, internet infrastructure connectivity is not exceptionally stable. However, this can still be worked around by having data transfers take place at a specific time of the day when internet traffic is at its lowest.

LEAP is growing specific to its sites; therefore, the DM function has been working around capacity building. This will ensure that the team is multi-disciplinary to mitigate effects of turnover. In addition, having training specific to EDC ensures buy in as well as understanding and capacity on the ground, so that when implementation is carried out, the needed resources are available to facilitate this new method of data transfer.

VIEWPOINT

Control of Visceral Leishmanaisasis in Kenya

Dr Davis Wachira Kala-Azar focal point,
Kenya MoH – NTD Division

Visceral leishmaniasis (VL), or kala-azar is among the 10 major diseases in most of Kenya's semi-arid and arid counties. The disease is transmitted by the bite of a sand-fly. It affects the internal organs, such as the liver and spleen. It mainly affects children above 2 years of age and young adults, those from poor and socially marginalized communities.

The management and control of VL has faced some challenges, including lack of health facilities in most endemic areas, lack of diagnostic kits and expertise, expensive drugs, prolonged hospital stays, and the poor conditions in which most of the affected community members live.

Until recently, diagnosis of visceral leishmaniasis relied mainly on splenic/ bone marrow aspirates, a procedure that can only be carried out by skilled health workers. Now, with the development of rapid diagnostic test kits, health workers can actively participate in case diagnosis even at the lowest health facility level. For a long time, the treatment of kala-azar was administered by the use of pentavalent antimonial drugs – sodium stibogluconate (SSG or Pentostam) and meglumine antimoniate (Glucantime). These drugs can only be administered by use of an injection. Moreover, the drugs are toxic, with many side effects and the treatment is given over a period of 30 days. Therefore, as an alternative treatment therapy, the new development and recommendation of SSG&PM combination therapy will go a long way in alleviating the suffering due to the disease.

The Ministry of Health is committed to the control of all neglected tropical diseases (NTDs), including kala-azar. Kenya's NTD programme was initiated to spearhead the control of these diseases. To achieve this, the Ministry has supported the development of a multi-year strategic plan (2011-2015) that is used to guide the implementation of NTD programmes in an integrated way, to maximize on the limited available resources cost effectively.

In September 2012, the Ministry of Health, in collaboration with DNDi and MSF, launched the revised Diagnosis and Management of Visceral Leishmanaisis Treatment Guidelines. The guidelines will play a pivotal role in guiding health workers and other health development partners in diagnosis, treatment, and management of the disease in endemic districts.

The Ministry will further continue to implement and promote other measures that can be used to control kala-azar in communities that are affected. These include distribution of bed-nets, awareness-raising, and integrated vector control and disease management.

Activities for the control of leishmaniasis include training health workers on the new diagnosis and treatment guidelines to improve their skills, improvement of diagnostic kits and drug supply, enlisting the drugs in the essential drugs list, awareness-raising among the affected communities, improving surveillance and reporting, and empowering the communities to be able to protect themselves from infection.

QUICK FACTS: PM REGISTRATION

PM was registered in Uganda at the end of 2011 and has been registered in Kenya following the sample and dossier submission to the Pharmacy and Poisons Board (PPB). In Ethiopia, PM is included on the national drug list. However, the registration dossier and samples are yet to be submitted to FMHACA until GMP inspection of the production site is arranged.

In Sudan, SSG&PM combination is the first-line treatment for VL in the Sudanese National Guidelines. Furthermore, in order to fast track PM registration in the country, an application for inclusion of PM in the country's National Drug List has been submitted. Since the end of the Phase II trial, 10,000 doses of SSG&PM have been distributed, mostly in South Sudan.

A pharmacovigilance (PV) study to monitor safety and effectiveness of SSG&PM was initiated in April 2011 and is currently ongoing in Kenya, Sudan, Uganda, and Ethiopia. The study is projected for completion in 2013. Ethiopia started recruitment for the same PV study in September.

LIST OF SCIENTIFIC PUBLICATIONS 2012

1. Liposomal amphotericin B as a treatment for human leishmaniasis. Balasegaram M, *et al. Expert Opinion on Emerging Drugs,* December 2012, Vol. 17, No. 4, pp. 493-510.

2. Miltefosine: a review of its pharmacology and therapeutic efficacy in the treatment of leishmaniasis. Dorlo TPC, *et al Journal of Antimicrobial Chemotherapy,* July 2012. doi: 10.1093/jac/dks275

3. Sodium Stibogluconate (SSG) & Paromomycin Combination Compared to SSG for Visceral Leishmaniasis in East Africa: A Randomised Controlled Trial. Musa A, *et al. PLoS NTDs,* June 2012, 6(6): e1674.

4. An image-based high-content screening assay for compounds targeting intracellular 'leshmania donovani' amastigotes in human macrophages. Siqueira-Neto JL, *et al. PLoS NTDs,* June 2012, 6(6): e1671.

5. Translational pharmacokinetics modelling and simulation for the assessment of duration of contraceptive use after treatment with miltefosine. Dorlo TPC, *et al. Journal of antimicrobial Chemotherapy,* May 2012. doi: 10.1093/jac/dks164

6. More efficient ways of assessing treatments for Neglected Tropical Diseases are required: innovative study designs, new endpoints, and markers effects. Olliaro P, *et al. PLoS NTDs,* May 2012, 6(5): e1545

7. Visceral leishmaniasis treatment: What do we have, what do we need and how to deliver it? Freitas-Junior LH, *et al. International Journal for Parasitology:* Drugs and Drug Resistance, Volume 2, January 2012.

AfriCoLeish Project

The EU FP7 funded project, 'Care Package for Treatment and Control of Visceral Leishmaniasis in East Africa' (AfriCoLeish), held its initiation meeting on 25 January 2013 and is set to run for three years, starting January 2013.

AfriCoLeish, is supported by the European Union Seventh Framework Programme (EU FP7) through a grant of €3 million. The project will run for three years and aims to test new treatments for kala-azar (visceral leishmaniasis, or VL) and co-infection of the disease with HIV in Ethiopia and Sudan.

The AfricoLeish project, 'Care Package for Treatment and Control of Visceral Leishmaniasis in East Africa', aims to develop and deliver a shorter combination treatment for kala-azar patients that is equally as safe and effective as the current WHO-recommended first-line treatment for the disease (SSG&PM, sodium stibogluconate and paromomycin) in East Africa. The project also aims to determine appropriate treatment strategies for kala-azar in patients that are also HIV positive, in order to treat and also prevent repetitive relapses that are common in co-infected patients.

Kala-azar (VL) is fatal if left untreated. An estimated 300,000 cases occur per year in 70 endemic countries. Estimates suggest 30,000 new cases per year in Africa, with numbers rising sharply during an epidemic. Existing monotherapies are toxic, costly, and difficult to administer, and the treatment duration is long, requiring extended hospital stays. Efficacious and cost-effective treatments as well as prevention of relapse play a critical role in the reduction of disease reservoir, forming a vital part of disease control. In addition, co-infection of kala-azar and HIV is a growing problem and renders treatment more difficult for both diseases.

'While we have managed to deliver a new first-line treatment for kala-azar in East Africa, sodium stibogluconate combined with paromomycin, SSG&PM, we need to continue searching for shorter, safer treatments', said Dr Monique Wasunna, Head of DNDi Africa and one of the four principal investigators of the AfriCoLeish project. 'Through a randomized clinical trial in Eastern Africa, the project will, for the first time, provide conclusive evidence-based data on the WHO recommendation to treat kala-azar/HIV co-infected patients using Ambisome 40 mg/kg total dose, and on the locally used regimen of AmBisome 30mg/kg in combination with miltefosine that is used by MSF in Ethiopia. To do this, AfriCoLeish has the right partners all focused on a clear goal: neglected patients' needs', she added. AfriCoLeish brings together six well-respected organizations from Europe and East Africa with vast experience in R&D and treatment of HIV and kala-azar, namely the Drugs for Neglected Diseases initiative (DNDi); the Institute of Tropical Medicine (ITM) in Antwerp; the London School of Hygiene & Tropical Medicine; Médecins Sans Frontières (MSF, The Netherlands); the Institute of Endemic Diseases, University of Khartoum (IEND), Sudan; and the University of Gondar (UoG), Ethiopia.

'We are convinced that AfriCoLeish combines the experience and expertise required to deliver new treatment options that effectively address the dire needs of patients with kala-azar and those co-infected with kala-azar and HIV in our countries', said Dr Ermias Diro, Medical Coordinator, University of Gondar, Ethiopia. 'At the same time, the project will contribute to strengthening capacities in our treatment centres', he added.

The dissemination of AfriCoLeish project results will facilitate uptake of new treatments for kala-azar and for co-infection of kala-azar with HIV in East Africa, and will provide support to national programmes in the adoption of the new treatments. The improved treatment options will allow patients in East Africa to benefit from safe, cost-effective, and shorter treatments, while also reducing the treatment costs for health providers.

Read more about the AfriCoLeish project:
www.africoleish.org

Listen to the podcast presenting AfriCoLeish: http://youtu.be/fX_CWfi86E0

LAUNCH OF KENYA'S VL GUIDELINES

On Wednesday, 26 September 2012, Kenya's Ministry of Health launched its national guidelines for diagnostic techniques and improved treatment regimens for patients suffering from VL.

Research and collaboration leading to the adoption of these revised VL Guidelines was carried out by the Ministry of Public Health and Sanitation (MoPHS) together with its partners: KEMRI - Drugs for Neglected Diseases initiative – DNDi Africa; Doctors without Borders – MSF; Kenya's Neglected Tropical Diseases Division – NTD; and the WHO.

The VL Guidelines aim to help health workers throughout Kenya to better diagnose and manage the disease. The most affected areas of Kenya include Baringo, West Pokot, and some parts of Wajir.

For a long time, case diagnosis has relied on painful splenic or bone marrow aspirates, which can only be carried out by skilled health workers at the Ministry of Public Health and Sanitation referral centres. The development of rapid diagnostic test kits that can now be used by health workers in remote areas is a significant step forward in terms of VL diagnosis.

An improved treatment option has been developed and is now recommended in the VL Guidelines as first-line treatment – SSG&PM, developed by DNDi, LEAP, and other partners in East Africa. SSG&PM is recommended as the first-line treatment for kala-azar recommended, by WHO in East Africa.

'SSG&PM will use lower doses, shorten treatment duration and cost. This is an important milestone in the treatment of kala-azar in East Africa.'
Dr S.K. Sharif, Director of Public Health and Sanitation (Kenya MoPHS)

2012 Launch of VL Guidelines

LEAP Calendar 2013

Past events

- AfriCoLeish induction meeting
  Geneva, 21 to 25 January 2013
- LEAP Principal Investigator (PI) meetings
  Nairobi, 25 to 26 February 2013
- 3rd KEMRI Annual Scientific & Health Conference
  Nairobi, 6 to 8 February 2013
- East African Health Sciences Congress (EAHSC), 4th Annual EAHSC
  Kigali, Rwanda, 27 to 29 March 2013
- 5th World Congress on Leishmaniasis
  Pernambuco, Brazil, 13 to 17 May 2013

Upcoming events

- A Decade of R&D for Neglected Diseases in Africa (DNDi 10th Anniversary Event)
  Nairobi, 3 to 7 June 2013
- 19th LEAP meetings, Nairobi, **6 to 7 June 2013**
- African Networks for Drugs and Diagnostics Innovation (ANDI), **Nairobi, October 2013**
- Seventh European & Developing Countries Clinical Trials Partnership (7th EDCTP) Dakar, Senegal, **20 to 23 October 2013**
- 62nd The American Society of Tropical Medicine and Hygiene (62nd ASTMH)
  Washington, DC, USA, 13 to 17 November 2013

The LEAP Newsletter is the platform's primary regular source of updates, news, and events relating specifically to leishmaniasis research and development in East Africa.

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