LEAP
LEISHMANIASIS
EAST AFRICA PLATFORM

NEWSLETTER

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IN THIS ISSUE

CONTENT

FOREWORD

Simon Bolo
Head of Leishmaniasis Access

DEAR FRIENDS AND PARTNERS,It gives me immense pleasure to welcome you to this special edition of the Leishmaniasis East Africa Platform (LEAP) Newsletter. This year, we are marking 20 years of innovation, growth, and success as LEAP. It is a time to reflect, celebrate our achievements, and acknowledge the challenges we face. In this 20th-anniversary edition of the LEAP newsletter, we are excited to present a collection of insightful articles, reflections, stories, and congratulatory messages.

Twenty years ago, LEAP was the vision and the hope that together we could bring new treatments and diagnostics to end the suffering of people with visceral leishmaniasis (VL) in Eastern Africa. Today, we stand together as an established platform celebrating the incredible journey to this milestone.

I feel privileged to have been a part of LEAP for 18 of the past 20 years. During this time, I have worked closely with a dedicated and motivated team of scientists, academics, and public health professionals to improve the care of people with leishmaniasis in our region. Our efforts have resulted in several clinical studies and numerous achievements: the development of the current standard of care – sodium stibogluconate and paromomycin (SSG&PM) – for primary VL, a new standard of care for people living with both HIV and VL (liposomal amphotericin B with miltefosine), and an alternative treatment of miltefosine and paromomycin (MF+PM) for VL and post-kala-azar dermal leishmaniasis (PKDL) that is yet to be recommended.

LEAP is celebrating its 20th anniversary at a time of great potential. We have transformed to incorporate access to diagnostics and treatment into our work in clinical trials and capacity building, and South Sudan is joining the other four countries (Ethiopia, Kenya, Sudan and Uganda) as a new member. The World Health Organization (WHO) launched a plan to eliminate VL as a public health problem in African countries by 2030 together with its partners by signing the 'Nairobi Declaration' Africa CDC's new Public Health Order for Africa is improving the health landscape across the continent. The Kigali Declaration is mobilizing resources to fight neglected tropical diseases (NTDs), and the first-ever Africa Climate Summit was held in Nairobi, resulting in the Nairobi Declaration on Climate Change. Later this year, the World Health Organization Guideline Development Group (WHO GDG) will review evidence from clinical trials, including those conducted by LEAP, and provide feedback on the use of MF+PM to treat leishmaniasis.

LEAP and DNDi have been collaborating to develop and introduce better treatments for leishmaniasis for 20 years. In 2010, the first combination treatment for VL (SSG&PM) came out of this partnership, greatly improving the associated toxicities by reducing treatment duration from 30 to 17 days.

The LEAP-led Phase III studies involving the use of miltefosine, the first-ever oral drug for leishmaniasis, have shown promising results, providing shorter treatment durations, eliminating SSG-related toxicities and reducing the risk of PKDL. The new, improved combination treatments are expected to be included in the region's treatment protocols for managing both VL and PKDL following on WHO's review and recommendation. LEAP and DNDi are also working on new chemical entities (NCEs) for leishmaniasis. These are expected to revolutionise treatment by bringing a patient-friendly all oral and safe treatment and making it possible to administer treatment at the primary healthcare level or at home.

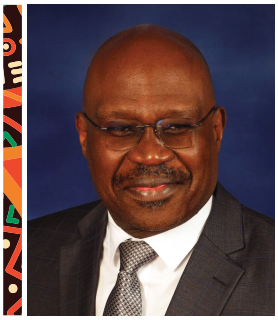
LEAP initially began as a platform to address VL, and now includes all forms of leishmaniasis – cutaneous leishmaniasis (CL), PKDL, and HIV/VL. With South Sudan joining the platform, we now comprise five countries. Access has been integrated into our operations to expedite diagnosis and treatment for affected people. Collaborations with ministries of health and leishmaniasis partners have helped identify gaps and respond to public health ecosystem needs. The expansion of treatment centres to bring treatment closer to patients has reduced the commute time of patients and their transportation costs.

Our simplified DNDi access framework focuses on four key dimensions: demand, supply, financing, and systemic obstacles. Currently, the top challenge in the region is supply chain, but we are taking measures to improve this. Two companies have applied for WHO pre-qualification to produce generic miltefosine, which could help end the problem of single manufacturers of leishmaniasis medicines. We plan to support the integration of the leishmaniasis commodity supply chain into national systems for more efficient delivery and to create a regional stockpile to address emergencies such as outbreaks or unexpected stock ruptures.

As we develop new treatments and improve access to medical care, LEAP aims to take a holistic approach towards vulnerable patients by addressing systemic challenges, for example, by helping to facilitate universal healthcare (UHC) at the community level. We need effective partnerships to eliminate VL in Africa – and LEAP is showing the way.

Happy 20th anniversary, LEAP!

THE CHAIR'S CORNER



Dr Sultani Matendechero

Deputy Director General for Health (State Department of Public Health and Professional Standards) and Chair of the LEAP Advisory Committee

HELLO EVERYONE,

Happy 20th anniversary to LEAP! Over the years, we've made incredible progress in fighting leishmaniasis and strengthening local research capacities in the region.

In 2003, we lacked the capacity to adequately diagnose leishmaniasis in our region, resulting in a bleak picture of sickness and death. Leishmaniasis was often misdiagnosed as other diseases with similar symptoms, and even when it was accurately diagnosed, we could not treat it appropriately. We had a shortage of test kits, and even when we had them, they lacked the specificity to give consistently reliable results.

Through the hard work of LEAP members and partners, we have improved the capacity of our health workers, particularly those working in endemic areas, to diagnose the disease and treat it effectively. We have provided them with adequate training to detect suspected cases and equipped them with laboratory tools, such as the rapid test kit, to confirm the diagnosis. Armed with expertise and adequate tools, they are better equipped to make accurate and timely diagnoses and thus provide better treatment.

We have also dramatically improved access to medicines to treat leishmaniasis. The medicines we were using 20 years ago were toxic and expensive. They had to be taken over a long period of time and were not user-friendly, as they could only be administered under hospital supervision. This meant families had to bear high treatment costs, including hospital stays that could last a month. Many families could not afford to bring patients to the hospital. This delayed treatment and resulted in suffering and even death. LEAP's consistent efforts over the years have resulted in new medicines and treatment tools that have greatly improved patient experiences and outcomes.

With the help of funding partners and regional research institutions, LEAP has conducted extensive collaborative research. This research has resulted in new treatment regimens that combined the antimonials with paromomycin. This has significantly reduced the treatment period while improving compliance and cure rates. Families now face fewer economic difficulties during treatment, resulting in better adherence. We are also exploring the possibility of developing more user-friendly molecules that will be efficacious, safe and can be taken orally, therefore more adapted to be used close to the communities affected by leishmaniasis.

Twenty years ago, countries and hospitals were working in isolation even though we know infectious diseases have the potential to cross local and international borders. This made it difficult to control the spread of the disease. Efforts to control the disease on one side of the border were not replicated on the other. As a result, the disease continued to spread. When LEAP was established, countries in Eastern Africa came together to discuss joint disease control strategies. This greatly improved the effectiveness of control interventions and produced much better results.

We did not have any partners 20 years ago. Now, we have many partners from the private sector helping us implement our programs. We also have research partners and county governments who contribute to partnerships with national governments. The LEAP platform has played a critical role in supporting the development and growth of these partnerships.

Given these achievements, I am confident that in the next 20 years, we can eliminate leishmaniasis. The first step towards this goal is establishing a unified regional strategy that includes all affected countries in Africa. I take great pride that we have made significant strides in this direction. If we can create a comprehensive regional strategy, backed by our growing network of partners, and ensure that each country plays its role, there is no reason why leishmaniasis should remain a public health concern in 20 years' time. We have seen this approach work in South-East Asia, and it can work here, too.

LEAP's consistent efforts over the years have resulted in new medicines and treatment tools that have greatly improved patient experiences and outcomes.

However, as we walk towards elimination, climate change poses a significant challenge. Vector-borne diseases are particularly vulnerable to the negative impact of climate change. But we must not allow it to impede our progress. We have the opportunity to integrate climate change not only into our strategy for combating leishmaniasis, but also into our strategy for improving healthcare overall. LEAP must actively participate in climate change discussions and incorporate meeting the challenges into our objectives. LEAP has demonstrated flexibility and adaptability, enabling us to adjust as we expand. Therefore, we must pay close attention to the direct impact of climate change on the incidence and burden of leishmaniasis and factor it into our plans moving forward.

I am grateful to all who have supported and contributed to LEAP on our 20-year journey and look forward to continued success in years to come.

A WORD FROM THE DIRECTOR, DNDi EASTERN AFRICA

Prof. Samuel Kariuki

Eastern Africa Director, DNDi

DEAR LEAP MEMBERS AND PARTNERS,

It has been 20 years since the Leishmaniasis East Africa Platform (LEAP) was established in 2003. Having witnessed the growth of this platform over the years, I am immensely proud of what LEAP has achieved. I would like to acknowledge all the members and extend my deep appreciation for their tireless work in driving progress in treating, controlling, and hopefully eliminating leishmaniasis in the region. Congratulations to all of you!

DNDi and LEAP have made remarkable progress in the fight against visceral leishmaniasis (VL) in Eastern Africa. Our first achievement 13 years ago was the introduction of a shorter and more affordable treatment option for visceral leishmaniasis. The combination treatment sodium stibogluconate and paromomycin (SSG&PM) reduced the difficulties associated with administering long courses of SSG and the prohibitive cost of liposomal amphotericin B. Following clinical trials carried out by this platform, the World Health Organization (WHO) Expert Committee on the Control of Leishmaniasis recommended SSG&PM as the first-line treatment for visceral leishmaniasis in East Africa in 2010. Since then, over 10,000 patients have been treated with SSG&PM in LEAP sites.

Together, we have demonstrated the efficacy of a new, shorter, and better visceral leishmaniasis treatment combining miltefosine and paromomycin (MF+PM). Working with AfriKADIA Consortium partners in Kenya, Ethiopia, Sudan, and Uganda, we conducted a Phase III clinical trial comparing SS&PM with MF+PM. Study results published in the journal Clinical Infectious Diseases in September 2022 showed that treatment with MF+PM was as effective as SSG&PM, but with fewer injections, a shorter treatment duration, and no risk of SSG-related cardiotoxicity.

Working with partners in both India and Ethiopia, we tested and delivered a safe and highly effective treatment to improve long-term survival for people living with both visceral leishmaniasis and HIV. In 2022, WHO recommended the combination of liposomal amphotericin B and miltefosine (LAmB+MF) as an improved treatment for this highly vulnerable population, giving hope to thousands of patients who faced poor outcomes – including a higher risk of relapse and death – with standard treatment regimens.

LEAP has also been instrumental in driving policy change and promoting the adoption of improved tools for diagnosing and treating leishmaniasis in Ethiopia, Kenya, Sudan, South Sudan, and Uganda. Additionally, LEAP has supported the establishment of new treatment sites at Moroto Referral Hospital in Uganda and Sigor Hospital in Kenya over the past two years to bring treatment closer to patients.

Although we have made significant progress in the past 20 years, leishmaniasis still poses a significant challenge requiring our continued efforts. As we look to the future, new challenges may become more pressing. We cannot ignore the impact of climate change, conflict, and artificial intelligence (AI) on our work going forward.

Climate change will have a major impact on leishmaniasis in Eastern Africa. Rising temperatures combined with increased humidity will make more areas ideal habitats for the proliferation and activity of disease-carrying sand flies, increasing transmission of leishmaniasis. Extreme weather events, such as flooding and droughts, will also cause climate-related migration and internal displacement, which may result in more people coming into contact with infected sand flies.

Recent events have underscored that it is crucial to reconsider how we provide services during times of conflict. There is a strong link between civil unrest and the emergence of VL epidemics. Our community health systems need to be strengthened to prevent any breakdown in control programs.

We must also acknowledge how technological advances, including AI, will influence how we work over the next 20 years. Advances in the use of AI and machine learning in healthcare can aid in research into leishmaniasis, and also assist in diagnosis and treatment of the disease. Although this rapid technological progress has the potential to improve healthcare, it also poses risks, particularly because AI is so dependent on gathering large volumes of data. As we continue to implement and rely on new tools to advance our work, we must be mindful of the risks, implementing strategies to protect patient data and privacy, ensure informed consent, and guard against potential discrimination.

Despite these challenges, I firmly believe collaboration is key to overcoming challenges and seizing opportunities.
I am particularly encouraged that discussions on the elimination of VL in East Africa have now started. Earlier this year, WHO and its partners held a stakeholder meeting to develop a strategic plan for the elimination of leishmaniasis in the region. These efforts serve as a testament to the fact that the fundamental structures and strategies for eliminating neglected tropical diseases (NTDs) are getting in place, and we must now work together to reach the final mile of elimination.

This significant anniversary is a time for us not only to celebrate LEAP's achievements, but also to reflect on our work as we plan for a future free of leishmaniasis. As the new DNDi Eastern Africa Director, I am excited to continue working alongside all our partners, donors, and stakeholders across this important platform. Let us remain committed to advocating for neglected patients in the region and carry their voices to the world.

Congratulations to all of you on 20 years of LEAP!

CONGRATULATIONS MESSAGES ON 20 YEARS OF LEAP

'LEAP's tireless efforts and collaborative model of work bridges healthcare gaps, brings innovative solutions, and contributes to a healthier future for the region. Let's celebrate LEAP's 20th anniversary as they continue transforming treatment and access to treatment for people with leishmaniasis in Eastern Africa.'

Eric Stobbaerts, Director of International Development, DNDi

'Two decades back, the lack of clinical research capacity to evaluate treatments was the biggest hurdle for endemic countries in their fight against visceral leishmaniasis. But LEAP demonstrated how regional multi-stakeholder partnerships from low-and-middle-income countries can build R&D capacity that meets international standards. With patients' needs always at the heart of its mission, LEAP is continuing to evolve and expand to bolster treatment access across Eastern Africa. The network has also set a precedent for future international alliances in global health. On its 20th anniversary, we hope LEAP continues to go from strength to strength and continues to be a beacon of hope in fighting leishmaniasis.'

- Kavita Singh, Director, DNDi South Asia

Congratulations to everyone as LEAP turns 20 years old this year. We have come a long way as partners. We are now like family! I'm grateful to be associated with such an incredible team. Let us keep up the good work, because together, we can make a difference in the management and control of VL in our region and beyond. Kudos to all the LEAP partners, and my best wishes for the future.'

- Dr Jane Mbui, Kenya Medical Research Institute (KEMRI)

'It is great to see how LEAP has worked so diligently over the years to strengthen clinical research in the region. It is certainly a successful collaboration that brings tangible benefits to people with VL in Eastern Africa. Congratulations!'

- Marina Boni, Senior Clinical Project Manager, DNDi

20 YEARS LEAP LEISHMANIASIS EAST AFRICA PLATFORM

'The County Government of West Pokot congratulates the Leishmaniasis East Africa Platform (LEAP) on 20 years of progress in improving treatments for leishmaniasis patients in Africa. Congratulations and happy anniversary!'

- Dr Claire Parklea, CEC Health, County Government West Pokot.

We extend our warmest congratulations to the Leishmaniasis East Africa Platform (LEAP) for reaching its 20th anniversary milestone. LEAP, with the support of DNDi, has made a significant contribution to enhancing the quality of Visceral Leishmaniasis (VL) treatment in Eastern Africa by conducting clinical trials for VL medications. They have achieved this through evidence-based research and effective coordination of clinical research activities across multiple countries.

One of LEAP's noteworthy achievements is its inclusive membership, which includes endemic countries and research institutions located within the affected regions. The END Fund is proud to be associated with LEAP and DNDi and looks forward to continuing the collaborative partnership. Together, we are committed to ensuring that VL patients have access to high-quality medicines and experience an improved standard of care.'

The END Fund

REFLECTIONS: THE PAST, PRESENT, AND FUTURE OF LEAP

By Prof. Ahmed Mudawi Musa

Professor of immunology and infectious diseases, Institute of Endemic Diseases, University of Khartoum.

Since its inception in 2003 under the auspices of the Drugs for Neglected Diseases initiative (DNDi), the Leishmaniasis East Africa Platform (LEAP) has recognized the need for medical innovation for new health tools for communities affected by leishmaniasis in the region. The opportunities and challenges were well identified and characterized in order to develop suitable and focused solutions in Eastern Africa. The multi-lateral approach taken by LEAP to control visceral leishmaniasis (VL) is unique. The objectives set out from early on were to strengthen local capacities in basic and clinical research, develop and improve access to new medications and diagnostics, and harmonize regulations and guidelines for the management of VL.

PAST

The dedication and commitment of the LEAP members at all levels – from leaders of Ministries of Health, universities, and academic and clinical investigators – paved the way for the achievements we accomplished. These included building and equipping state-of-the-art research centres in the heart of VL-endemic areas suitable for conducting clinical trials to international standards and facilitating the cost-effective conduct of clinical trials. Furthermore, working close to communities affected by VL and PKDL enabled an improved understanding of research and ethics within affected communities. This is an indirect added merit to the mission of LEAP.

Continuous training and sharing of experiences among members created strong South-South collaborations, which would not have been possible without LEAP. In addition, we now have several partners, including London School of Hygiene & Tropical Medicine, Institute of Tropical Medicine, Belgium, Thomas Dorlo institution, Uppsala University, Instituto Carlos III, and the University of Oxford, and a critical mass of investigators, managers, and finance officers. LEAP partners' great achievement is the development of two combination therapies for VL, namely SSG/PM and MF/PM.

PRESENT

Over the past two years, LEAP has embarked on new efforts to improve access to better treatments and diagnostics through the LeishAccess project in collaboration with DNDi and other partners. This project coordinates closely with LEAP member country principal investigators to facilitate the provision of treatments to patients with VL. LeishAccess will also work to map the true cost of delivering VL medications and diagnostics for patients with VL.

The opportunities and challenges were well identified and characterized in order to develop suitable and focused solutions in Eastern Africa. The multi-lateral approach taken by LEAP to control visceral leishmaniasis (VL) is unique.

LEAP has been credited for its contribution to reducing VL morbidity and mortality in LEAP countries, and the platform is positioned to serve as a leading supporter of new efforts and strategies to eliminate leishmaniasis in Eastern Africa, as envisaged in the January 2023 Nairobi Declaration. Our members have played an essential role in expanding the evidence base for VL and PKDL – in the areas of clinical patterns, methods of diagnosis, and response to treatments – and have built capacity for the management and finance of clinical trials and for clinical monitoring. Many of our members have transformed into true leaders who will secure the sustainability of LEAP.

FUTURE

Working to ensure the sustainability of LEAP in the face of the new challenges is a top priority, including by expanding the platform to include other countries in the region – such as South Sudan, Somalia, and Eritrea. The investment in basic scientific medical research and training in collaboration with the academic centres and facilities within Eastern Africa will make LEAP attractive and help in its stability and sustainability. We should promote with our partners short courses or professional certificates and diplomas in different aspects of research like clinical trials, financing and finance administration, project management, and leadership development.

LEAP@20: WALKING DOWN MEMORY LANE AND LOOKING TOWARDS THE FUTURE

By Dr Monique Wasunna,
DNDi Africa Ambassador

THE PAST: HOW IT ALL BEGAN

Twenty years ago in Khartoum, Sudan, we established the Leishmaniasis East Africa Platform (LEAP), bringing together experts from Kenya, Ethiopia, Sudan, and later Uganda to collaborate on research related to leishmaniasis. Our aim was to build these scientists' capacity to conduct clinical trials, as some of the sites had never implemented trials before, and the infrastructure for research was fragmented. Therefore, we had to undertake capacity building in terms of clinical trials, laboratory diagnosis, and the research infrastructure itself.

We came together as Africans to participate in projects for our people affected by leishmaniasis. We agreed that there would be a principal investigator (PI) who would also function as the leader in each country. I was the PI for Kenya, Professor Asrat for Ethiopia, Professor Musa and Professor Khalil for Sudan, and Professor Olobo for Uganda. In each country, there were research teams and experts that supported and worked with us. DNDi Eastern Africa, based in Nairobi, supported and supervised the operations in the field.

Initially, we had competing priorities because everybody was young and came from reputable research or academic institutions where the policy was that one needed to publish their research data or fail to advance professionally. In short, it was 'publish or perish,' especially for those working in universities with which we collaborated. However, what impressed me was the team's willingness to work together despite this. We embraced our passion to deliver treatments for the most neglected and decided to work collaboratively and make a difference for our people.

Let nobody tell us we can't. Like former President Obama's slogan, 'yes we can,' I also believe in my heart that, 'yes, we can!'

THE PRESENT: WHAT WE HAVE BEEN ABLE TO DO

Over the last 20 years, we have successfully delivered treatments for patients suffering from visceral leishmaniasis (VL), including combination treatments and treatment for HIV+VL co-infection, among others. We have proven that Africans can work together and provide solutions for Africans with the support of our friends in the North.

DNDi has been instrumental in creating and supporting LEAP and its impressive successes. Young people have been trained, and their capacities have been developed, with research infrastructure now in place. Previously, clinical trials for leishmaniasis were conducted in tents, but now, thanks to DNDi, we have 24-bed facilities in Ethiopia and Sudan namely the Leishmaniasis Research and Training Centre and the Professor El Hassan Institute of Tropical Medicine, respectively.

The capacity building efforts have helped to retain scientists because the facilities allow them to conduct their research comfortably without leaving for other parts of the world. This has resulted in fewer cases of 'brain drain.'

In 2016, we reviewed our platform and decided to expand its reach beyond the initial four countries of Kenya, Uganda, Ethiopia, and Sudan. Consequently, we extended our geography to include Somalia, South Sudan, and Eritrea, allowing them to join upon request. Currently, South Sudan has expressed interest in joining. This expansion of our geography is one of our greatest achievements.

In the same year, we also decided to expand our operations beyond VL clinical trials. So, we said, Why not work on post-kala-azar dermal leishmaniasis (PKDL) and other forms of leishmaniasis like cutaneous leishmaniasis?' As a result, we broadened the platform's scope and even added access work to it. Now, 20 years later, we are just starting our access work, which is crucial because there is no point in developing treatments if those who need them most cannot access them. It would be a disservice to both the people and our institution.

I am incredibly proud that we are now talking about VL elimination. When we started, we were just grappling with treating the people, making sure that they didn't die from this disease that is fatal without treatment. Now, the boat is steady, and we are looking towards the future with optimism. We are collaborating with other organizations, such as the Ministries of

Health of Ethiopia, Kenya, Uganda, and Sudan and with additional VL-endemic countries.

THE FUTURE: HOW I SEE THE NEXT 20 YEARS FOR LEAP

I see an oral treatment on the horizon. It has been a long journey of commitment from so many partners working with DNDi on drug discovery for VL. If all goes well, which I do not doubt in my mind that it will, we will stop using painful injectables. That is my dream, and I know it will be achieved soon.
I firmly believe we can achieve a leishmaniasis-free Africa within my lifetime. South-East Asia has already made significant progress towards controlling and eliminating VL, and they are on the verge of eliminating the disease. Therefore, I believe that if we work hard, we will eliminate leishmaniasis from our continent.

THE LEGACY OF LEAP

A hundred years from now, when none of us is here, I hope that students in a school somewhere will be taught that there used to be a deadly disease called leishmaniasis. I hope they will learn about a group of committed researchers and scientists who helped put an end to the disease, including a lady called Dr Monique Wasunna who was moved by the death of a young boy in her arms when she was starting her medical career and who said to herself, 'Surely, I can do something about this'.
This is how I imagine the story of LEAP will be told.
Together with DNDi, Monique and other like-minded scientists founded the Leishmaniasis East African Platform. Their goal was to deliver effective treatments for this disease. Although people doubted the possibility of their success, the LEAP team proved everyone wrong. They succeeded in building partnerships and commitment to their cause – out of a shared belief that every life is precious. With the help of a broad coalition of researchers, donors, and doctors, LEAP and DNDi delivered the best science for the most neglected – for their generation and for future generations. They proved that, with the right tools and support, Africans working together could achieve the elimination of VL on their continent.

That is what I hope LEAP's legacy will be.

Let nobody tell us we can't. Like former President Obama's slogan, 'yes we can,' I also believe in my heart that, 'yes, we can!'

Medical workers about to take a blood sample from a kala-azar patient at Kacheliba hospital in West Pokot, Kenya.

Dr Loyce Faith Nangiro

AGAINST ALL ODDS: THE INSPIRING JOURNEY OF A DOCTOR WHO OVERCAME MULTIPLE CHALLENGES AND TREATS KALA-AZAR TODAY

By Edith Magak and Linet Atieno

Dr Loyce Faith Nangiro, a medical officer at Amudat Hospital, was not meant to go to school. Her family expected her to be the family's herder and later to be married off.

'I was supposed to take care of the shepherds. My father made it a point that I shouldn't study, and even though I saw other children going to school, I wasn't allowed to,' she recalled.

At age five, she displayed a rebellious streak by secretly enrolling in a nearby primary school without her father's knowledge and began attending classes.

By the time he found out, it was too late to pull her out. She finished primary school but couldn't afford to attend high school. Fortunately, a well-wisher stepped in and paid her school fees.

But just before starting university, her relatives arranged a marriage for her.

'No one saw sense in me going for a five-year course, yet here I was telling them I wanted to be a doctor. My village had never seen a female doctor. So, there were already cows for dowry prepared, and meetings had already happened. But I went against their will and told them I wanted to study. I wanted to be the first doctor here and inspire other girls.

Nangiro stood up against her family for a second time.

'I had to fight with the relatives who sat me down to explain why marriage is better and how I was deterring them from getting the cows for us. In my community, they groom us for bride price. But I had to stick to my word. And that of course, came with its repercussions. I didn't have someone to take me to the university, but that didn't stop me from applying for scholarships here and there, as well as private scholarships,' she said.
Despite receiving a private scholarship to pursue a bachelor's degree in pharmacy, it was not the course she truly desired. She approached the university to request a change of course.

'I told them that if I did pharmacy, I'd work in the cities, but if I did my medicine, I would serve my community where I am much needed. The university was kind enough to admit me for Bachelor of Medicine and Bachelor of Surgery. And fortunately, God blessed me with Juliana Amal and Dr Violah Nyakato supported me with the tuition,' said Nangiro.

Nangiro completed her five-year course at the university and secured employment shortly after in Mbale City. However, only ten days into the job, she chose to resign.

'Everybody thought I was crazy. The pay was good; the working conditions were okay, but it wasn't serving my passion. I was working in a private setting where I was seeing all these well-off patients who had the luxury of choosing the specialists, they wanted to attend to them, and yet, where I come from, you had to be very lucky to even get a chance to be seen by a general doctor. So, I resigned and came to volunteer in Amudat Hospital,' said Nangiro.

For Nangiro, Amudat was not an ordinary village hospital. It held a special place in her heart because years ago, when she desperately needed assistance, an Amudat vehicle came to her rescue.

'When I was 16 years old, I was stuck in Mbale city as I returned from high school, about 100 kilometers from my home. I saw a vehicle with Amudat Hospital Kala-Azar Project written on it. I didn't

know what kala-azar was, but I knew the vehicle passes through my district so it could take me home,' she said.

Dr Patrick Sagaki was one of the people in the car who offered to give her a ride back home.

'He's my current supervisor today; but after that incident, I never met him again. I had planned to pay a courtesy visit to Amudat hospital, to come and volunteer for about a month without revealing who I was and after one or two months, say thank you for the lift. But when I came here, I saw that there was an actual need.'

According to Nangiro, the demand for services exceeded what the clinical staff could provide, especially in the maternity wards. Dr Sagaki was alone in the hospital. And besides being driven by the need to help her people, Nangiro also wanted to inspire the young girls in her community.

'I also wanted the parents to see the value of educating a girl child. So, when I came back and saw all these young girls delivering - I was operating on some of them - I knew I needed to do something. I usually go around to the schools and talk to the young girls and encourage them to study; sometimes, I receive support from friends who give me sanitary pads and other school items that I take to the girls.

Nangiro's efforts are paying off, as parents now use her as a positive role model for their children.

Experience with Kala-azar
During her time at university, Nangiro recalls that leishmaniasis was briefly mentioned, but they were only provided with a few details about the disease.

All I remember is they said it's in Amudat district in Karamoja. Nothing much, nothing about treatment, neither did I see a patient. And when I moved here, I saw that this hospital was a center of excellence for kala-azar – and offered mentorship. I started to learn more about Kala-azar and to treat the patients.'
Coming from the area and being fluent in the native language allows her to communicate effectively with the patients, including Village health teams,

Stella Akiror and John Oseluo attending to a patient at Amudat Hospital, Uganda

who have limited knowledge about the disease's presentation and treatment. She bridges the gap and facilitates training to address this issue.

'Now, because we have trained the health workers across the different districts of Karamoja, they can identify kala-azar. They can test and screen, and they reach out to us when the screening is positive. So, the patients come sooner, and we initiate the treatment early, reducing the mortality rate.'

Uganda's Ministry of Health, with funding from END FUND, supported activities to build the capacity of health workers and village health teams in VL case detection, screening, and access to care.

"We empowered 137 health workers and 192 village health teams from selected health facilities in the Karamoja sub-region. This has raised awareness, facilitating early detection and improved access to care, thereby improving the prognosis for many patients. With these interventions, the total number of admissions increased from 132 in 2020 to 340 by 2022.'

Although progress has been made, Nangiro continues to encounter some challenges at the facility.

'Some patients still present late, and the duration of treatment is 17 days. That's a long stay for some parents as they have other children at home and need to see to other things, like their farming activities. Most times, I must talk them into staying in the hospital for 17 days until the patient gets well. But we pray that the treatment time is reduced with time,' she explained.

Nangiros aspirations for the future. With her Little Faith Foundation, she aims to provide school fees and necessities to more girls in her community. As for her medical career, she plans to pursue a master's degree in pediatrics, followed by public health and research.

In the meantime, she's looking forward to participating in her first DNDi clinical trials and research at Amudat Hospital.

'Now, because we have trained the health workers across the different districts of Karamoja, they can identify kala-azar. They can test and screen, and they reach out to us when the screening is positive.

REFLECTIONS ON 20 YEARS OF LEAP

By Professor Joseph Olobo

Prof. Joseph Olobo

Professor of Microbiology and Immunology (Emeritus), Makerere University, Uganda.

ON THE BEGINNINGS

In 2006, Uganda became the fourth member to join LEAP, and I was the representative then. The region faced significant security issues, and the capacity to conduct clinical trials was inadequate and needed development. Transportation was also an issue, as many patients lived far away and had difficulty accessing the hospital for treatment. Moreover, a lack of awareness about the existence of treatment centres made it difficult to reach patients.

Initially, we were unsure how LEAP could combat these problems despite our high expectations. However, over time, our confidence grew. We were able to treat patients with active VL, and we trained more personnel to conduct clinical trials. We began to see that achieving our goals was possible.

Today, I am proud of what we have accomplished. We have made remarkable progress and achieved significant milestones.

OUR PROGRESS AND ACHIEVEMENTS

One of our greatest achievements has been reducing the treatment time for patients from 30 to 17 days. This has significant implications for both patients and the hospital. Amudat Hospital's participation in the SSG&PM trial has increased its capacity to conduct clinical research, and we are very proud of this. As a rural hospital, we participated in this trial and successfully established the first-line treatment for leishmaniasis in Eastern Africa.

The collaboration established by LEAP in the region is truly remarkable. Few South-South collaborations can be compared to LEAP in Sudan, Ethiopia, Kenya, and Uganda. Although this collaboration is very strong, and there is room for improvement. Other institutions can also learn from LEAP's success and try to replicate it, which will help us achieve even greater success.

The strategy adopted by DNDi and LEAP to involve the relevant government ministries and officials was very strategic and has helped all member countries. I can speak for Uganda, where it has been of great assistance, as LEAP's visibility in Uganda has increased significantly since its early days. It was only when DNDi and LEAP came in and created awareness of VL and promoted advocacy for treatment in the media and through meetings and interactions with Ministry officials that the disease started to gain prominence and recognition as one of the major diseases in the country and a cause deserving support. For instance, we had no data on leishmaniasis for a long time despite cases being reported at hospitals.

However, through the efforts of LEAP, the Central Ministry began keeping records, and doctors began assembling data on the epidemiology of leishmaniasis in the country. It has been a great help that Ministry data now reflects cases we did not previously know about. The addition of a programme manager for leishmaniasis has also assisted in creating awareness of the disease.

ON OUR CHALLENGES

Initially, the biggest challenge we faced was dealing with communities from various regions with different cultural backgrounds. We were unsure whether we could provide adequate medical treatments and find enough space to treat everyone. Today, we have successfully worked with different communities from diverse cultural backgrounds.

Another challenge was different governments' varying degrees of involvement in controlling VL. Uganda had the least government involvement in leadership, while Sudan and Kenya's governments had a reasonably large role in controlling the disease. However, in Uganda, it was only later that the national control program was established.

Patients basking in the sun at amudat hospital

Researching VL was also a significant challenge due to the impoverished and isolated communities affected by the disease. Patients had to travel long distances to reach hospitals, and bad roads and security issues compounded the difficulties. However, with community involvement and participation, we have overcome these enormous challenges over the years. As a result, we now have better access to the communities. The nurses' team has earned the trust of the patients and their families so much that they can even take the children to the hospital without adult accompaniment.

ON THE FUTURE OF LEAP

If we aim to eliminate VL, we must adopt tools and approaches that make the process easier. To achieve this, we should re-evaluate the epidemiology of the disease in Uganda and other LEAP regions. We require diagnostic tools to identify patients and the origin of the infection. Once patients have been diagnosed, we must treat them with better drugs. Currently, treating the disease involves hospitalization for 17 days, with injectable drugs disadvantaging Eastern Africa. Additionally, we must build capacity by training more personnel, especially young people interested in studying and treating the disease.

However, important challenges in our region still need to be addressed to achieve the goal of complete elimination. I am confident that we will make significant strides within the next 20 years. Thanks to rapid technological advancements, like artificial intelligence, much can be achieved in a shorter period. I envision LEAP expanding its membership, technology, and research areas and managing diseases more effectively. LEAP has the potential to become a virtual university, a regional hub of strong scientists, students, and impactful research, both domestically and internationally.

Lastly, advocacy needs to be continued, and more meetings with the relevant stakeholders must also be continued so that the disease is not forgotten.

Tegla Kamurut (Left) chatting with her mother Chepteyo Selina at their home in Abiliyep Parish, Lopedot Village in Amudat District Uganda.Tegla is a former kala-azar patient)

NEW INITIATIVES MAKE LEISHMANIASIS TREATMENT MORE ACCESSIBLE IN KENYA AND UGANDA

By Joy Malongo

Joy Malongo
Access Manager, DNDi

In the heart of Eastern Africa, where the battle against leishmaniasis rages on, a new chapter of hope is being written in the remote communities of Sigor, Kenya, and Moroto, Uganda. Poverty and disease have long plagued these regions, but change is on the horizon since the pressing need to bring treatment for leishmaniasis closer to communities in Sigor and Moroto was recognized by LEAP and the ministries of health in the two countries.

The strategy to bring diagnosis and treatment closer to communities began with an assessment to identify the gaps and needs in each community. Then, country-specific implementation plans were developed in collaboration with the Ministries of Health in both countries with the aim of making diagnosis and treatment more accessible than ever. In a collaborative effort between LEAP, DNDi, West Pokot County, and the Ministries of Health, laboratory equipment and health commodities were procured, and health professionals were trained and mentored. We also launched community awareness campaigns to inform communities about the services available and empower them to identify potential cases of VL. These efforts were met with enthusiastic support as communities began to understand the importance of early diagnosis and treatment.

The results have been transformative. In Kacheliba Hospital in Kenya, 680 patients came for treatment for VL in 2022, compared to 496 in 2021, and an average of 200 to 400 patients in previous years. Over 20% of these patients had come from Sigor, undertaking a journey of nearly 3 hours to obtain treatment.

With diagnostic and treatment services established at the Sigor Sub-County Hospital, patients could now be diagnosed and treated closer to their homes. In the first two months after the establishment of facilities for leishmaniasis diagnosis and treatment, Sigor Sub-County Hospital screened 182 patients and treated 60 patients. A number of complex cases, as well as cases in excess of the capacity at Sigor Sub-County Hospital, were referred to Kacheliba Hospital where DNDi has been supporting leishmaniasis treatments for the past 12 years.

Across the border in Uganda, the story is similar. Patients from Moroto (about two hours away) previously formed 30% of those seeking treatment at Amudat Hospital supported by DNDi since 2008. Establishing facilities at Moroto Regional Referral Hospital has drastically improved access to diagnosis and treatment for local communities who no longer face a 120-kilometre journey to Amudat should they have symptoms of VL.

These bold steps have come with their fair share of challenges. The two healthcare facilities needed to be upgraded to increase capacity and manage cases of VL. In Sigor, the main challenges were lack of capacity to manage complicated cases, limited bed capacity, and difficulties with follow-up for patients redirected to Kacheliba Hospital. In Moroto, the absence of nutritional support at the facility level posed a challenge. Patients still preferred Amudat Hospital, which provides food to VL patients for free.

Despite these hurdles, the commitment to improving access has not wavered. The success of the projects at Sigor and Moroto are a testament to the power of working together to prioritize patients, and control and ultimately eliminate leishmaniasis in Eastern Africa.

Simon Bolo and other health officials from West Pokot at Sigor Hospital.

CONGRATULATIONS MESSAGES ON 20 YEARS OF LEAP

'The Karamoja Diocese Church of Uganda – Amudat Hospital joins the Leishmaniasis East Africa Platform (LEAP) and its partners in celebrating 20 years of collaboration to bring new treatments and diagnostics to leishmaniasis patients in Eastern Africa.'

- Dr Patrick Sagaki, Amudat Hospital

'The Kenya Medical Research Institute (KEMRI) joins the Leishmaniasis East Africa Platform (LEAP) and partners in celebrating 20 years of research and progress in treating leishmaniasis in Eastern Africa.'

Prof Elijah Songok – Ag Director KEMRI,

'As LEAP reflects on its remarkable 20-year journey, we raise our glasses in celebration of this significant milestone. The achievements of the past two decades stand as a testament to the collective efforts of LEAP members to accelerating innovation and shaping the future of R&D for neglected patients. As a member of LEAP, the Institute of Endemic Diseases, University of Khartoum is pleased to have contributed to this journey since LEAP's inception back in 2003. We are looking forward to the next 20 years of collaborating and innovating together.'

- Prof Ahmed Musa Mudawi, The Institute of Endemic Diseases, University of Khartoum

'On behalf of the University of Makerere and the Department of Medical Microbiology, I extend my warmest congratulations on the occasion of your 20th-anniversary celebration. I would like to express our appreciation for all that LEAP has accomplished in such a short time. Your contribution to regional collaboration over the last two decades has been remarkable, and we are truly impressed by your achievements. We look forward to our continued partnership and wish you all the best in your future endeavours,'

Joseph Olobo, Professor of Microbiology and Immunology (Emeritus), Makerere University, Uganda.

'The past twenty years have seen LEAP achieve remarkable success in its mission to accelerate innovation and work towards a leishmaniasis-free Africa. This accomplishment is a testament to its members' collective efforts and collaboration. LRTC at UOG is proud to have been a part of this journey with LEAP. I would also like to take this opportunity to express our sincere gratitude for your continued support and partnership with us throughout the years,'

Dr Eleni Ayele, Leishmaniasis Research and Treatment Centre, University of Gondar.

'Congratulations, LEAP, on 20 years of impactful work. LEAP came at a time when medical research was not yet fully recognized as a crucial part of the solution to the health problems we faced. But now, as we have built capacity for clinical research, we are finding our own solutions. We truly value our partnership with LEAP and look forward to further strengthening it for the mutual benefit of our people. Let's continue to collaborate and innovate as we work towards eliminating leishmaniasis,'

Professor Asrat Hailu, Addis Ababa University, Ethiopia

From left: Scientists Mercy Tuluso, Dr Milkah Muthoni and Davis Siele from KEMRI at the Leishmania laboratory.

20 YEARS OF LEAP: REFLECTIONS FROM DR JANE MBUI

Dr Jane Mbui
Clinical Researcher /Epidemiologist, KEMRI

LOOKING BACK

Over the last two decades, the Leishmaniasis East Africa Platform (LEAP) has achieved remarkable success in conducting complex clinical trials in Eastern African. It is impressive to see how developing countries in the region have collaborated to conduct research in remote areas like Kacheliba, Kenya. Our team from KEMRI supported staff from Kacheliba's small sub-county hospital – including clinical officers, nurses, and laboratory technologists – to work as our backup team. We provided training and support to enable top-notch, world-class clinical trials with internationally recognized results despite the hospital's small size and remoteness.

It is inspiring to know that we can take clinical trials to affected communities, succeed in complex studies, and make a real difference in people's lives. Although these hospitals are small, we support them by empowering and training the staff to conduct GCP-compliant clinical trials like any other larger facility.

LEAP's model is replicable and demonstrates the importance of regional teamwork. This has been a critical factor in our ability to achieve significant progress. As the LEAP team, we have achieved a lot. Our collaboration has enabled us to obtain the required sample size for our studies much faster and maximize returns.
For instance, our latest study required >400 visceral leishmaniasis (VL) patients to be enrolled. With the strict inclusion/exclusion criteria of a clinical trial, it would have taken many years for a single site to recruit this number of VL patients. However, with the power of teamwork, regional cooperation across the various LEAP sites, and support from the DNDi Eastern Africa team, we achieved the required sample size in just three years. This success is attributed to working together as a region to solve our problems. As a result, we are taking control of our research agenda and no longer relying on results produced by others.

Understanding that drugs may have varying safety and efficacy in different populations is essential. Therefore, it is encouraging for us to have tested drugs that work effectively within our communities, and we are proud to have achieved this as a regional team. Furthermore, we have built local capacity and a critical mass of researchers to enable us to conduct research in any medical field. While there is room for improvement, notably at the field level, thanks to the teamwork spirit, we have accomplished a lot in 20 years.

LOOKING AHEAD

It is possible to eliminate VL within the next 20 years. However, we need the support of the government, policymakers, and counties since healthcare is now a devolved function, especially in Kenya. The counties must

Community mobilizer Isaac Nyeris interacts with patients outside the Kala-azar ward at Kacheliba Sub-County Hospital in West Pokot County, Kenya

allocate a budget for VL activities and ensure the necessary supplies are available. Unfortunately, this has not been the case. There is an over-reliance on donors to provide medical commodities, which is not sustainable. During a recent VL study in one of the affected counties in Kenya, we faced a shortage of one of the drugs used to treat VL and had to rely on donations. The county governments where VL is endemic should allocate a budget for VL activities just as they have for other diseases, such as malaria, TB, and HIV.

When we started conducting VL studies twenty years ago, there were only a few counties in Kenya where the disease was endemic. However, VL is spreading due to population movements of non-immune people to endemic areas due to the impact of climate change, including prolonged droughts. Therefore, we must act now to prevent further spread of the disease and take measures to achieve VL elimination in our region.

To begin with, we can conduct active case detection and provide the necessary treatment for all patients with VL. We should visit communities, screen individuals for the disease, and transport those with VL to nearby hospitals for treatment. For this initiative to succeed, we must have a continuous supply of rapid test kits for screening and ensure that VL drugs are readily available in local health facilities. Additionally, vector control specialists and entomologists must be involved to play their part in controlling the disease vectors. If we sustain this campaign for several years, we should be able to control and eventually eliminate the disease.

I want to encourage all LEAP members and partners to continue working together. Through teamwork, we have achieved a lot and registered high success rates in our collaborative multicenter studies.

It is crucial to understand the region where we conduct our research comprehensively. We have learned that investing in and economically empowering the communities where VL is prevalent improves living conditions and reduces VL infections. For instance, VL was commonplace in the Marigat area of Baringo County when our studies began in the 90s. However, the area no longer has VL cases today because living conditions improved when the government implemented an irrigation scheme. This enabled the community to undertake horticulture farming activities all year round, providing them with much-needed income, reducing poverty, and bettering the local economy. Therefore, we must also work towards improving the social and economic status of communities where VL is endemic.

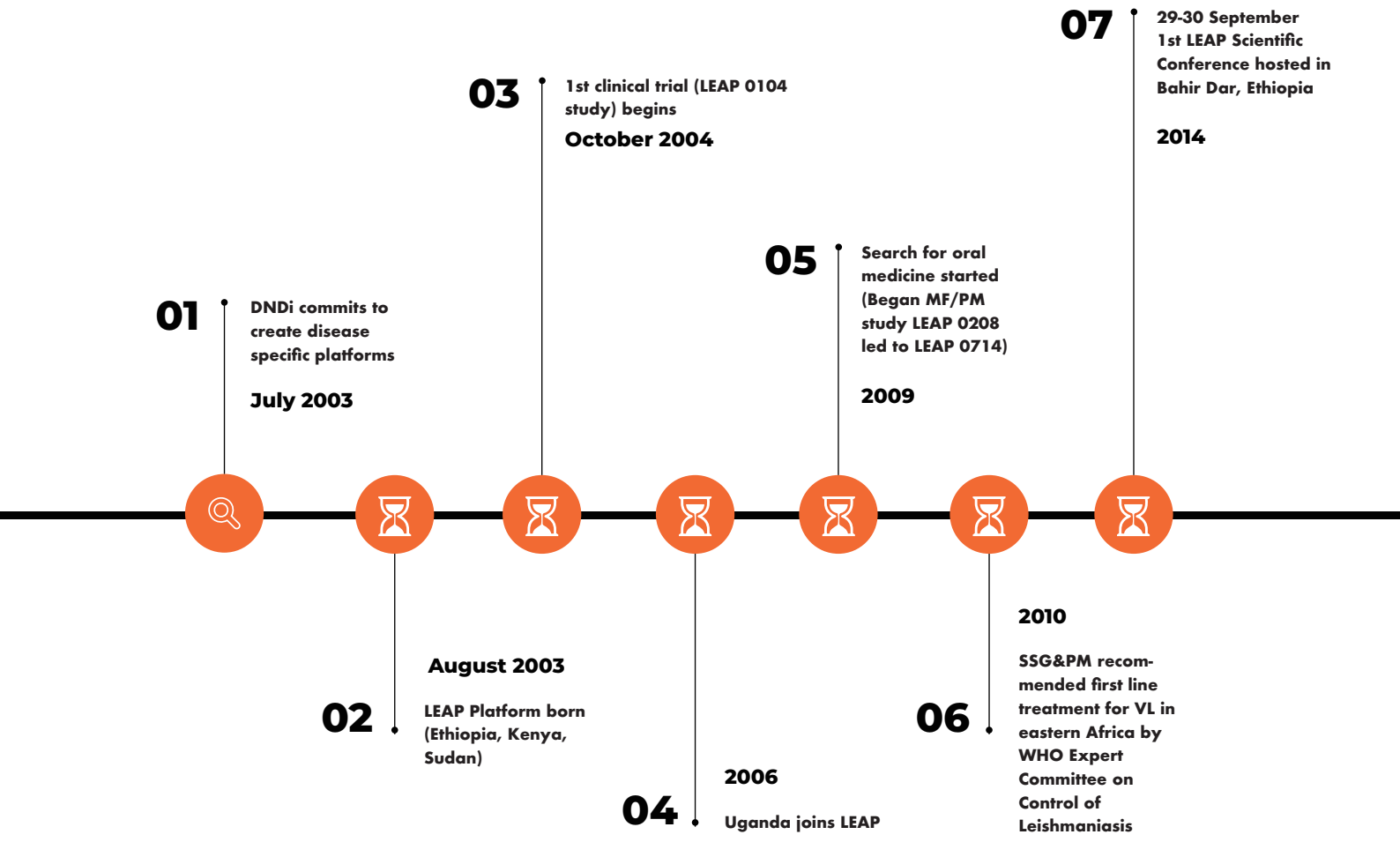
Since areas where VL is prevalent are typically hot and dry, bee farming is another economic activity that can improve communities' livelihoods. Harvesting and selling honey can empower communities economically, which has already happened in some areas of Baringo County.

IN CONCLUSION

Eliminating VL in less than 20 years is possible, but it requires the involvement of all stakeholders. To achieve success, we must adopt a holistic approach that focuses on treating VL patients, controlling vectors, and improving the socioeconomic conditions of affected communities. The team in Southeast Asia has demonstrated that this is achievable, and we can replicate their success in East Africa as well.

Understanding that drugs may have varying safety and efficacy in different populations is essential. Therefore, it is encouraging for us to have tested drugs that work effectively within our communities, and we are proud to have achieved this as a regional team.

LEAP ACTIVITY TIMELINE 2003-2023



08 **2017**
Initiated MF/PM Phase III study

09 **2021**

2-4 November 2021 hybrid 2nd LEAP Scientific Conference hosted in Nairobi, Kenya

10 **2022**
2022 (Leish Access activities.....)

Results of MF/PM Phase III clinical trial published and disseminated widely (across 28 local and international mass media outlets and to communities in Amudat, Uganda and Kacheliba, Kenya)

11 **2004 - 2023**

Capacity Strengthening activities (Lab upgrading, Training (2003 short-term and 2023 long-term)

Infrastructure development and upgrading (new clinical trial sites and treatment centres built in Ethiopia and Sudan) (renovations in Kenya and Uganda)
10+ clinical trials
30+ scientific publications
28 LEAP Annual Meeting
26 LEAP Principal Investigator's Meetings
3 LEAP Advisory Committee (LAC) Meetings
4 LEAP Leadership Meetings
8 LEAP Newsletters issued

12 **2010 – 2022**

Treated 20,823 routine VL patients, including 2,108 patients who participated in clinical studies

SSG&PM combination treatment implemented as first line for VL

13 **2023**

LEAP 20th anniversary

Apo Lokwarita, (right) a kala-azar patient from Masol, Central Pokot and his father Lokwalita Longelech during treatment at Kacheliba

HIGHLIGHTS FROM KENYA: LEAP'S 20 YEARS OF INNOVATION AND IMPACT IN THE FIGHT AGAINST LEISHMANIASIS

By Linet Atieno Otieno

Over the past two decades, the Leishmaniasis East Africa Platform (LEAP) has made significant progress in fighting leishmaniasis in Eastern Africa, which currently has the highest number of visceral leishmaniasis (VL) cases worldwide. In Kenya, the highest number of leishmaniasis cases are reported in the arid and semi-arid regions of the Rift Valley, Eastern, and Northeastern regions.

Since its inception, LEAP has been conducting research and access activities in Kenya. In 2004, in partnership with KEMRI, one of DNDi's founding partners, LEAP began conducting clinical trials in Nairobi. At that time, there was limited capacity to conduct clinical trials in the endemic regions. Therefore, patients had to be transported from Baringo in the Rift Valley region to Nairobi to one of the sites managed by the Centre for Clinical Research (CCR), KEMRI.

The first study in the CCR was a multi-centre clinical trial to explore the potential of a new combination treatment in Eastern Africa. The study was also conducted in Ethiopia, Sudan, and Uganda. This study was iconic because this was the first time in over 50 years that a clinical trial had been conducted for new leishmaniasis treatments. The combination treatment, known as SSG&PM, consisted of sodium stibogluconate (SSG) and paromomycin (PM). The previous treatment for leishmaniasis was SSG alone. This study, completed in 2010, found that the combination treatment was 91% effective in curing VL.

Afterwards, DNDi and KEMRI agreed to start clinical trials within Kimalel, Baringo County within the Rift Valley to ensure they were closer to the patients in endemic regions. LEAP played a vital role in setting up the leishmaniasis treatment centre in Kimalel Health Centre Baringo and strengthened healthcare workers' capacity to conduct clinical trials and diagnose and treat leishmaniasis. Several capacity-building training workshops were organized to meet international standards for implementing Good Clinical Practices (GCP) compliant trials.

Kenya played a key role in demonstrating the effectiveness of SSG&PM in the treatment of VL. SSG&PM is currently the first-line treatment for patients in Eastern Africa. In 2012, the Kenya Ministry of Health launched its National VL Guidelines for national health workers on diagnosing and managing VL with the combination therapy.

Following a significant reduction in patient numbers in Kimalel, DNDi and LEAP redirected their research efforts to Kacheliba, West Pokot, which had more patients. They subsequently transferred the management of the treatment centre in Kimalel to the Ministry of Health.

The new clinical trial site at Kacheliba Sub-County Hospital was established on 18 December 2012, after Médecins Sans Frontières (MSF) handed over its leishmaniasis activities to DNDi. MSF initiated its work in Kacheliba in 2006 after recognizing that more than 70% of the patients they were treating in Amudat, Uganda, originated from the Kacheliba region.

Over the years, the LEAP platform has conducted an additional four studies in the country, including one to find a more effective diagnostic test. Most recently, the country was part of a clinical trial to determine whether a combination treatment of miltefosine (currently the only oral treatment for leishmaniasis) and paromomycin was effective in treating VL.

In addition to conducting clinical trials, LEAP efforts in Kenya have included access-related activities. These initiatives encompass supporting the development of country guidelines aimed at facilitating patient access to new treatments, bolstering the capabilities of healthcare workers in the diagnosis and treatment of leishmaniasis, refurbishing treatment centres, and procuring essential laboratory equipment. Notably, these access activities have led to the expansion of our efforts to include Sigor Sub-County Hospital, approximately 100 kilometres from Kacheliba.

The platform also plays a crucial role in advocating for the rights of people with leishmaniasis by sharing the plight of patients and giving a voice to those who are affected in the country. As a result of sharing these stories, it has garnered support for leishmaniasis patients from around the world. Kenya has hosted many of the LEAP meetings, including a scientific conference held in November 2021.

LEAP's success is a testament to the power of collaboration. The platform brings together researchers, clinicians, healthcare workers, and community members to fight leishmaniasis.

The 20th anniversary of LEAP is a time to celebrate the platform's successes and to look to the future.

LEAP's success is a testament to the power of collaboration. The platform brings together researchers, clinicians, healthcare workers, and community members to fight leishmaniasis.

Pauline Chepachepunyo, (left) with her daughter Regina Chemnangor (right) who is undergoing kala-azar treatment at Kacheliba hospital.

THE CASE FOR INCLUSION OF LEISHMANIASIS IN CLIMATE ACTION

By Dan Masiga, Kennedy Senagi, David Tchouassi, Simon Bolo and Daniel Mwiti

A child herding cattle in Gondar, Ethiopia

The Africa Climate Summit (4-6 September 2023) concluded in Nairobi with the release of the Nairobi Declaration, focusing on the "bigger issues" in the public discourse – pollution, clean energy, new global financing models, etc. Little attention was given to the impact of climate change on infectious diseases despite its increasing recognition by health research and care ecosystems. Indeed, several institutions represented at the summit have observed that health was ignored in the published declaration.

This is unfortunate, considering that the United Nations (UN) Sustainable Development Goal (SDG) Goal 3 is on "Good health and well-being", and item 3.3 targets ending, "by 2030, epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases (NTD) and combat hepatitis, water-borne diseases and other communicable diseases". Efforts to end epidemics and progress to the elimination of neglected tropical diseases such as leishmaniasis will be undermined by climate change effects.

Visceral leishmaniasis (VL) is one of the fatal neglected tropical diseases with a case fatality rate of up to 95% if left untreated and affects the most marginalized communities. Today, the largest proportion of affected communities reside in the Eastern African countries of Ethiopia, Kenya, Somalia, South Sudan, Uganda and Sudan. These Eastern African countries are among the top 10 countries reporting the highest number of cases globally.

According to the current Kenya national strategic plan for leishmaniasis control (2020-2025), 11 out of the 47 counties have reported Visceral Leishmaniasis (kala-azar). This represents a significant increase from the previous nine (9) counties reporting cases. It is important to note that the disease foci are changing to areas previously not known to be endemic, attributed to climate change and population movements.

In the last year outbreaks/upsurges have been reported in various counties that include; Mandera (March 2021), Kajiado (May 2021) and Tharaka Nithi (September 2021) and most recently in Isiolo (June 2022). The expansion of the disease to new foci or previously endemic counties in the past years is a major concern to

public health specialists, and the link to climate change cannot be ignored.

As a result of prolonged droughts, communities move to forested areas or neighbouring communities in search of pasture for the livestock, thus exposing themselves to sandfly bites and spreading the disease to new areas. Additionally, the prolonged drought has led to increased malnutrition cases, which highly contributes to the host's susceptibility and severity of the disease.
In recent years, the eastern Africa region has experienced prolonged climate change-engendered droughts and unseasonal rainfall patterns that have led to poor agricultural harvests and devastating livestock losses. This has driven nomadic livestock herders to migrate over unusually vast areas, which, in the context of leishmaniasis, can promote the spread of disease to areas where competent vectors exist, but the parasites are absent.
Rain and other climate variables influence seasonal variations in the abundance of sandfly vectors of leishmaniasis. Peak abundance is often associated with the dry seasons or immediately after rain. It is unknown how the prolonged climate change enhanced dry season in the region may have contributed to sandfly population dynamics and leishmaniasis transmission.

We need to keep an eye on climate change and include mitigation strategies not to reverse disease management gains made through enhanced surveillance, better case management through early diagnosis and availability of new treatment regimens.

Truly, the role of climate change and the expansion of the disease to new foci cannot be ignored, and concerted efforts to mitigate this should be employed. Whether there is movement of the parasite with the population migration or migration of the infected vector to new areas needs to be researched and documented. This is, therefore, a call for resources to be availed to research and document this phenomenon even as we develop plans to eliminate VL in the region.

Farming in Metemma, Northwestern Ethiopia. Most of the patients affected by VL are usually migrant farmers.

Signboard outside the hospital.

HIGHLIGHTS FROM UGANDA: THE AMUDAT SITE EXPERIENCE

By Patrick Sagaki

Dr Patrick Sagaki
Medical Superintendent
Amudat hospital

Amudat Church of Uganda Hospital is a 120-bed facility established in 1957. The hospital is in Amudat District, part of the Karamoja region in Northeastern Uganda. This region is known for its high prevalence of kala-azar, although the full extent of the disease is not yet well documented.

Until recently, Amudat Hospital was the only treatment centre for kala-azar in Uganda. However, with the support of LEAP, DNDi and other partners, a second treatment centre has been opened at Moroto Regional Referral Hospital.

Médecins Sans Frontières (MSF) started offering kala-azar treatment at Amudat Hospital in 1996, but the organization relocated to Kacheliba in Kenya in 2006. This was because 70% of the patients treated at Amudat Hospital in Uganda came from Kenya. Following the relocation of MSF's project, people with suspected kala-azar were referred to Kacheliba Hospital, which was about 60 kilometres away from Amudat Hospital. This referral exercise lasted for six months, and it was a challenging time for patients as there was no reliable public transport, and transportation costs were high.

After six months of referrals, Professor Joseph Olobo from Makerere University announced some good news: DNDi, in collaboration with LEAP, would start supporting the management of kala-azar at Amudat Hospital. To facilitate this, healthcare workers from Amudat Hospital were trained in Kacheliba Hospital from July 2008.

The resumption of kala-azar management at the hospital in August 2008 brought hope to Ugandan patients with 2,113 patients with kala-azar treated at Amudat Hospital from August 2007 to August 2023. The support provided by DNDi also opened doors for conducting clinical trials on kala-azar medications at the hospital. This involved improving hospital infrastructure, equipping the hospital with the required medical equipment, providing transport for kala-azar patients from remote areas to and from the hospital, and training healthcare workers.

Some of the collaborative multi-centre clinical trials the hospital has been involved in include:

1. Safety and Effectiveness of Sodium Stibogluconate and Paromomycin Combination for treating Visceral Leishmaniasis.

2. Pharmacokinetics, Safety, and Efficacy of an Allometric Miltefosine Regimen for the Treatment of Visceral Leishmaniasis in Eastern African Children: An Open-label, Phase II Clinical Trial

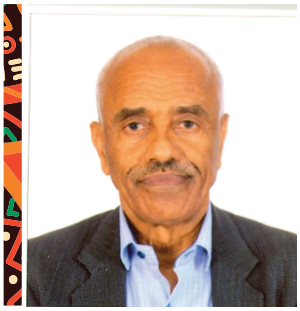
3. Safety and Effectiveness of Sodium Stibogluconate and Paromomycin Combination for the Treatment of Visceral Leishmaniasis in Eastern Africa: A Pharmacovigilance Programme

4.Paromomycin and miltefosine combination as an alternative to treat patients with visceral leishmaniasis in Eastern Africa

We appreciate the continued commitment of DNDi and LEAP to supporting this vulnerable community. I look forward to the possible elimination of kala-azar in Uganda in the coming years.

Happy anniversary, LEAP!

REFLECTING ON THE LAST 20 YEARS OF LEAP



Prof. Eyasu Makonnen Eshetu

founding member of LEAP and Deputy Head, the Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa, Addis Ababa University, Ethiopia

Prof. Eyasu Makonnen Eshetu- founding member of LEAP and Deputy Head, the Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa, Addis Ababa University, Ethiopia

Over the last 20 years, LEAP has accomplished many significant things. However, here are the top three achievements that stand out to me:

1. Establishing a robust research partnership among members:
Members from Ethiopia, Kenya, Sudan, and Uganda have partnered to conduct clinical trials and research, specifically to search for improved treatments for visceral leishmaniasis.

2. Building and strengthening research capacity in member countries:
LEAP has contributed immensely to establishing visceral leishmaniasis treatment and research centers in member countries, such as Ethiopia's Arbaminch and Gondar VL treatment and Research centers. Additionally, LEAP has provided comprehensive training to the research team to improve their capabilities in conducting research. Furthermore, it has also played a significant role in developing and strengthening the culture of clinical trials in member countries.

3. Conducting successful clinical trials for the treatment of visceral leishmaniasis:
The clinical trial on visceral leishmaniasis conducted by LEAP provided scientific evidence that helped include paromomycin-sodium stibogluconate in the national drug lists of LEAP member countries. As a result, paromomycin-sodium stibogluconate has already been included in the national drug lists of member countries for the treatment of visceral leishmaniasis.

I know the next 20 years will even be better. Happy 20th anniversary, LEAP!

CELEBRATING 20 YEARS OF LEAP: A PERSONAL REFLECTION

Ermias Diro

Clinical Assistant Professor of Internal Medicine, University of Washington

I started working with LEAP after starting my PhD research on visceral leishmaniasis and HIV co-infection in 2010. My primary clinical trial site was the Leishmaniasis Research and Treatment Centre established by DNDi at the University of Gondar in the northern part of Ethiopia. This is one of LEAP's clinical trial sites.

I have journeyed with LEAP through more than half of its existence – and these years have been filled with successes. Conducting clinical trials, completing my PhD, disseminating the findings, and making the evidence available to WHO and national guideline bodies has been an incredible privilege to share with LEAP.
LEAP has enabled me to acquire new skills in clinical trials, to understand the contexts in neighbouring countries with similar challenges and opportunities, and to meet scientists in a similar field and share experiences from across the globe.

The platform is a collaboration between partners in Ethiopia, Kenya, Sudan, and Uganda dedicated to finding better treatment options for leishmaniasis in the region, but it brings scientists in the field from all over the world together. Many clinical trials and pharmacologic studies have been conducted, and these findings have been used in developing new treatment guidelines.

LEAP is about finding solutions to local problems by developing scientists in the community. Its members are dedicated and enthusiastic, and the collaboration and friendship we share makes LEAP feel like family. I feel honoured to be part of LEAP as we continue to prosper and contribute to science and evidence-based practice.

I look forward to seeing LEAP expand its success to meet other challenges and become the leading medical research platform in Eastern Africa.

Happy 20th anniversary, LEAP!

FROM PRODUCTION TO PATIENT: SUCCESSES AND CHALLENGES IN SUPPLYING VL COMMODITIES

By Simon Bolo

Simon Bolo
Head of Leishmaniasis Access

This year started with hope for patients with VL: governments and stakeholders led by WHO launched the Nairobi Declaration with the commitment to join efforts towards the elimination of the disease as a public health problem in Eastern African countries. The strategy focuses on five elements, including case management based on early detection and treatment for VL including PKDL and VL/HIV coinfection .Such a high-level commitment sets an ambitious agenda for scaling up diagnostics and treatment and calls for a reflection on the ongoing challenges of the supply chain to ensure access for patients.

First, because of low and fragmented volumes, most of the existing tools have only one supplier (single source), and some are expensive, creating a complex scenario for procurement. Some manufacturers establish requirements such as a minimum quantity for procurement orders (for example, a batch). Over the years, the price of miltefosine, a key medicine in several therapeutic regimens, has only been increasing, while the global demand has not been met. Although liposomal amphotericin B is supplied through a donation program agreed between Gilead and WHO, there are concerns about the sustainability of this approach.

Second, we have been faced with an acute shortage of funds for VL commodities, mainly due to lack of a sustainable funding mechanism. In 2021, funding for commodities was reduced, thereby compromising the sustainability of access and leaving partners to pursue alternative solutions to fund VL commodities.

When it comes to storage and distribution, there are various levels and players along the way, also affecting the lead times between orders placed up to the last mile delivery at health facilities. First, the manufacturer supplies to WHO, which initially stores in Europe (MSF Logistique warehousing in Bordeaux, France) and then sends to the WHO country offices for onward distribution to the respective Ministries of Health who distribute to health facilities at the local and community level. Each country uses a different last-mile distribution channel, ranging from partial integration with the national medicinal products supply chain system (Ethiopia) to the use of partners. As I write this article in August 2023, several of the Eastern African countries have stock rupture due to long bureaucratic processes at the country level, which delays first-mile importation from France. Each consignment requires fresh importation documentation and a green light, which lengthens the process.

In 2021, with the support of various funders, DNDi together with partners established the LeishAccess project with the aim of accelerating and improving access to care for leishmaniasis patients, including vulnerable groups, for the various forms of the disease. Important progress has been made so far, such as strengthening the VL program in each of the Eastern African countries by supporting the work of the VL Technical Working Groups; expanding VL treatment closer to communities by strengthening the capacities at health facilities in Sigor (Kenya) and Moroto (Uganda); supporting WHO to procure the much-needed commodities; and so on.

Despite these achievements, there is a long way to go. We need to collaborate in exploring a coordinated approach to improving supply chain management, for example, exploring the possibility of a regional warehouse for security stock to address the challenge of lead times at different levels of distribution and ensure timely supply when there is an unforeseen stock rupture in the countries. Integrating the last-mile distribution process with national supply chain systems may eventually improve the lead times and ultimately be more sustainable. Developing approaches to systematically quantify the needs of VL commodities, linked to the monitoring of current stocks at the national level, might contribute to procurement processes, the ability to negotiate with manufacturers, and prevent stock-outs and waste.

Eshetei Manekito a VL patient from Debark (90 kilometers north of Gondar) receiving treatment at the Leishmaniasis Treatment and Research Centre at the University of Gondar

Community members entertaining guests during the MF/PM results dissemination meeting in Kacheliba, West Pokot County

MILTEFOSINE AND PAROMOMYCIN COMBINATION TREATMENT STUDY RESULTS DISSEMINATED IN KENYA AND UGANDA

By Mercy Mumo

Leishmaniasis is the deadliest parasitic killer after malaria. The disease affects people in resource-limited settings, arid and semi-arid areas. Half of them are children under the age of 15.

A shorter and less toxic treatment for people with visceral leishmaniasis (VL) was shown to be effective thanks to a study conducted in Eastern Africa by DNDi and its partners. The results were published in the journal Clinical Infectious Diseases in 2022. The study compared a new combination of two drugs, miltefosine and paromomycin (MF+PM), given for 14 days, to the standard of care of sodium stibogluconate and paromomycin (SSG&PM), given for 17 days.

One important component of a study is ensuring that results are disseminated to various stakeholders, including the community. It is for this reason that the results of the study were disseminated communities around two trial sites in Kacheliba, West Pokot County in Kenya, and Amudat District in Northern Uganda.

The dissemination events attracted the community, health officials from the respective countries, partners, and the media.

'This new treatment is great news for the thousands of patients affected by VL in the region. It will eliminate one painful and toxic injection from the treatment and is, therefore, safer for those affected. It also reduces hospitalisation time by 18 per cent and is 91% effective,' said Dr Simon Njenga, one of the lead Principal Investigator's at KEMRI. Children, who form the majority of patients with VL – were also shown to respond very well to this new treatment and will particularly benefit from it.

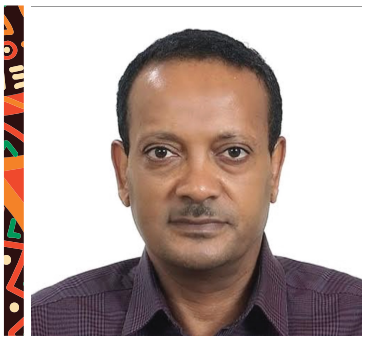
'The new treatment plays a critical role in preventing deaths related to leishmaniasis. We applaud DNDi and partners for the work they are doing in developing treatments for neglected populations,' said Wycliff Omondi, Head of Division of Vector-borne and Neglected Tropical Diseases at the Kenya Ministry of Health. The results dissemination meeting also took place in Amudat, Uganda, where Dr Alfred Mubangizi, Assistant Commissioner, Vector-borne and Neglected Tropical Diseases at the Ministry of Health – Uganda and other stakeholders attended the event.

DNDi and its partners are working towards finding better treatments that would completely remove the need for injectables and that are better adapted to local conditions. Plans are underway to commence clinical trials for new, promising, all-oral treatments for leishmaniasis.

Leishmaniasis is the deadliest parasitic killer after malaria. The disease affects people in resource-limited settings, arid and semi-arid areas.

NEXT-GENERATION DRUGS FOR VISCERAL LEISHMANIASIS: PROGRESS AND PROSPECT

Samuel Teshome



Samuel Teshome
Senior Clinical Project Manager, DNDi

Leishmaniasis is one of the major parasitic diseases among neglected tropical diseases with a high rate of morbidity and mortality. Human migration and climate change have spread the disease beyond previously more limited endemic areas all over the world, causing a significant health and economic burden. The currently available treatments are far from ideal due to host toxicity, elevated cost, and increasing rates of drug resistance. Safer and more effective drugs are urgently needed. Nevertheless, the identification of new chemical entities for leishmaniasis has proven to be incredibly difficult and exacerbated by the scarcity of well-validated targets. During the past years, several treatments for leishmaniasis have been developed or carried out through progress and prospect.

PROGRESS

A sense of urgency to treat these diseases has led to pragmatic approaches with short and long-term objectives, prioritising the assessment of combination therapy and repurposing of known drugs in a drug repositioning strategy. This considerably reduces the length of time and high costs by having an approved treatment with most of the toxicological data and clinical tests already available after efficacy confirmation.
Given the urgent need for better and more effective treatments for leishmaniasis, this strategy is acceptable in the short-term, but for a mid- or long-term solution, a different approach has to be considered to find optimal and specific treatments. The discovery of new drugs effective against VL is therefore a long-term objective. As with any other drug discovery programs, this is coupled with risk and attrition, and needs adequate human and financial resources.

PROSPECT

The target product profile (TPP) is an essential feature of the drug discovery management tools and plays a central role in the discovery process since it depicts the desired outcome of the research and development (R&D) program. The TPP needs to address the issues specific to VL and its epidemiology, such as patients living in vulnerable communities and remote areas with limited access to healthcare. The table below is the TPP for VL drug development.

LXE408 CLINICAL DEVELOPMENT

LXE408 is a first-in-class parasite-selective inhibitor of the kinetoplastid proteasome with potent and uniform anti-parasitic activity against all kinetoplastid parasites, including Leishmania species causing VL (L. donovani and L. infantum), as well as parasites causing Chagas disease (T. cruzi) and human African trypanosomiasis (T. brucei). The pharmacokinetic and metabolic properties of LXE408 were characterized in vitro and in vivo and support its further clinical development.

After a successful Phase I study sponsored by Novartis Institutes for BioMedical Research, preparation for a Phase II, randomized, open-label, single-centre study to assess the efficacy, safety, and pharmacokinetic profile of LXE408 in patients with primary VL in Ethiopia sponsored by DNDi is at startup phase. A similar study is ongoing in India.
If LXE408 (which is oral) is shown to be efficacious and to have a favourable safety profile in future confirmatory studies, it has the potential to significantly reduce the leishmaniasis disease burden in Eastern Africa. Work is continuing to identify other promising new chemical entities. Which drug to choose will likely rest on the drug's effectiveness in curing the disease, its safety profile, and ultimately, its price.

Target label	Optimal Target Profile	Minimal Target Profile
Target Label	**VL and PKDL**	**VL**
Specificity	All species	L.Donovani
Distribution	All areas	Either India or Africa
Target Population	Immunocompetent and Immunosuppressed	Immunocompetent
Clinical efficacy	>95%	>90%
Resistance	Active against resistant strains	
Safety and Tolerability	No adverse event requiring monitoring	One monitoring visit in mid/end point
Contraindications	None	Pregnancy/Lactation
Interactions	None, compatible for combination therapy	None for Malaria, TB, and HIV concomitant therapies
Formulation	Oral/IM depots	Oral/IM depots
Treatment regimen	1 per day for 10 days PO /3 shots over 10 days	Bid for <10days PO; OR >3 shots over 10 days
Stability	3 years in zone 4	Stable under conditions that can be reasonably achieved in the target region (> 2 yr)
Cost	<$10 per course (2008 Dollar)	<$80/course (2012 Dollar)

Table: The DNDi model for drug discovery and development for neglected diseases: target product profile for new VL drug development

Laboratory processes at the University of Gondar's Leishmaniasis Treatment and Research Centre, Ethiopia.

LEAP'S LEGACY: TWO DECADES OF PROGRESS AGAINST VISCERAL LEISHMANIASIS

By Yalemtsehay Mekonnen

Twenty years ago, a group of likeminded individuals came together to address a disease that affected the poorest and most marginalized communities in Eastern Africa. Joining hands from Kenya, Ethiopia, Uganda, and Sudan, the founding members of the Leishmaniasis East African Platform – LEAP – met for the first time to establish the platform at the DNDi Africa Conference in Nairobi, Kenya, in 2003. It is amazing how time flies, but much has been achieved in the past 20 years.

The top three achievements I would identify over the past two decades are LEAP's success in bringing together leishmaniasis experts and researchers from different countries across Africa and around the world; our success in conducting collaborative, highly ethical and scientific clinical trials that recommended affordable and effective drugs to better treat VL; and establishing and building physical infrastructure in LEAP member countries, such as the Arba Minch Leishmania Research Centre in Ethiopia.

Furthermore, many young professionals have been trained in good clinical practice (GCP), good laboratory practice (GLP), conducting ethical research, and more, and this has resulted in greatly strengthened research capacity and the development of sustainable solutions in the region.

We cannot have great successes without also acknowledging our challenges. Some of these challenges include the high turnover of professional staff who were engaged in different positions in clinical trials and government-held positions; the reluctance of some institutions to expedite the provision of materials needed for laboratory and clinical trial work; and in some cases, funding that was not adequate to accomplish all planned activities.

Identifying the areas where LEAP can improve, I believe we can pursue obtaining more commitment from LEAP member countries and sustained support from funders. In addition, we should consider how to involve different stakeholders in a more pragmatic manner, perhaps through a consortium model.

Twenty years from now, LEAP will not be exactly as it is today – and neither should it be. Together, we need to think about what we need to transform to become truly sustainable and ultimately eliminate leishmaniasis as a public health problem in Eastern Africa.

The top three achievements I would identify over the past two decades are LEAP's success in bringing together leishmaniasis experts and researchers from different countries across Africa and around the world;

TRANSLATING SCIENTIFIC EVIDENCE INTO POLICY: THE CASE OF VISCERAL LEISHMANIASIS IN EASTERN AFRICA

By Cherinet Adera

Visceral leishmaniasis (VL) is a disease that affects an estimated 50,000 to 90,000 people worldwide each year, with over 70% of cases occurring in Eastern African countries. Despite this high disease burden, there is a significant delay in conducting research and generating evidence from low- and middle-income countries (LMICs) amd translating the evidence into policy.
Additionally, there is a significant disparity in the development of therapeutics for NTDs compared to diseases with lower prevalence rates. Although some new treatments have been developed for NTDs, the time it takes for patients to access them is often prolonged by slow policy change processes.

One crucial step in improving access to treatments is to translate evidence generated by clinical research into policy through timely changes in therapeutic guidelines.

The current national leishmaniasis treatment guidelines for the region were updated following a Phase III clinical trial conducted in four Eastern African countries: Ethiopia, Kenya, Sudan, and Uganda. The combination therapy of SSG&PM is the recommended first-line treatment for uncomplicated VL management in Eastern African countries. The clinical trial was conducted between 2004 and 2010 and was recommended by WHO in 2010. The therapy was adopted by the countries in the region, with South Sudan adopting it in 2011, Somalia in 2012, Ethiopia in 2013, Sudan in 2014, and Uganda and Kenya in 2017.

Ethiopia has the highest burden of VL and HIV coinfection globally. HIV coinfection makes the diagnosis and management of VL very difficult. Treatment of VL in people living with HIV in Eastern Africa was based on limited evidence, mainly from Europe. Liposomal amphotericin B with miltefosine (LAmB and MF) combination therapy was recently recommended in this population after clinical trials were conducted in India and Ethiopia. The studies started in 2014 and 2017 in Ethiopia and India, respectively; the trial results from Ethiopia and India were published in 2019 and 2022 respectively.

WHO recommended this new treatment in June 2022, and two months later, Ethiopia adopted it.

This was achieved by running a parallel national guideline review process by the Ethiopia Leishmaniasis technical working group (TWG) alongside the WHO Guideline Development Group (GDG) process. The WHO guideline development process involves setting up a guideline panel and external review group, appraising the certainty of evidence and formulating recommendations, which takes up to 18 months. A similar parallel review process is being followed with new evidence for the management of VL using miltefosine with paromomycin combination therapy; the leishmaniasis technical working groups in Kenya and Uganda have reviewed the evidence awaiting the WHO review process to shorten the time between release of the WHO guideline and national adoption.

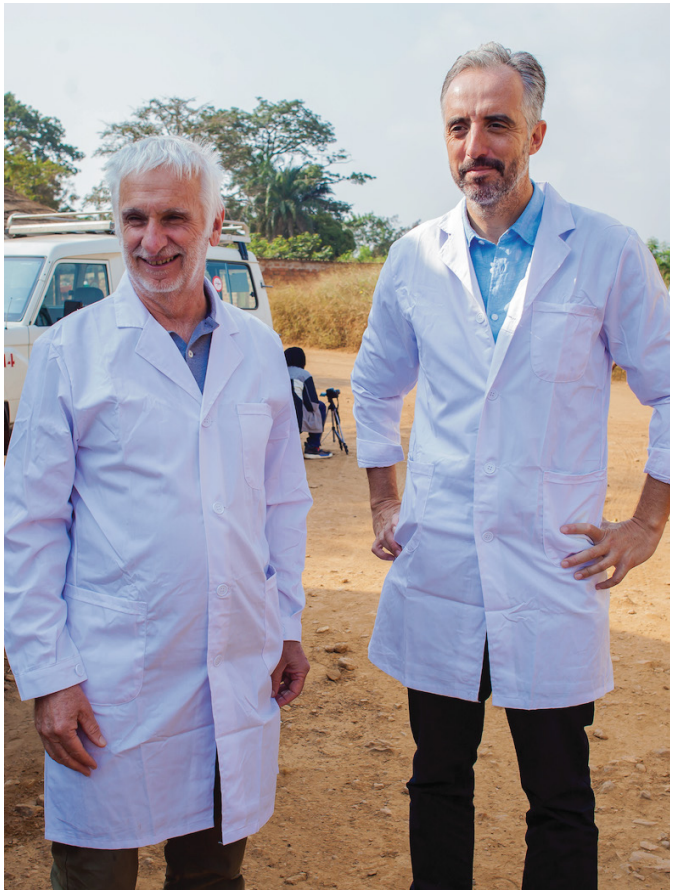
As stated above, the evidence generation and national guideline change in the context of SSG&PM combination therapy for managing uncomplicated VL patients took up to 7 years in some countries. The GDG review process for recommending LAmB and MF combination therapy for treating patients with both VL and HIV took three years, with the COVID-19 pandemic also contributing to the delay. However, the adoption at the country level only took two months from the time of the WHO recommendation.

This experience illustrates the importance of shortening the period between clinical trial evidence generation and translation into policy change. The longer it takes, the longer patients fail to benefit from new knowledge and improved treatment options. Affected countries must conduct a national-level guideline review process parallel to the WHO process of translating evidence into treatment recommendations, as this shortens the pathway to patients benefiting from much-needed therapeutics.

Physicians at the University of Gondar's Leishmaniasis Treatment and Research Centre, Ethiopia.

IN BRIEF

DR LUIS PIZARRO TAKES OVER FROM DR BERNARD PÉCOUL AS DIRECTOR OF DNDi



DNDi's Executive Director, Dr Bernard Pécoul, retired in 2022 after 19 years of leadership in the research and development of drugs for neglected diseases. His successor, Dr Luis Pizarro, is a seasoned scientist who has worked extensively in global health.

Under the leadership of Bernard Pécoul, a humanitarian doctor accustomed to working in the field, DNDi has made significant progress and developed 12 new treatments for six deadly diseases saving millions of lives. He also established public and private partnerships with universities, research institutes, and pharmaceutical companies, which had previously shown little interest in neglected diseases.

Building on this momentum, the new director, Dr Luis Pizarro, intends to advance medical innovation with the same vision of bringing the best of science to neglected populations.

'I am deeply honoured and excited to take on this new role,' said Dr Pizarro. 'Today's numerous global challenges – from climate change to economic instability – will continue to exert a disproportionate burden on the most vulnerable people on our planet. We are already seeing the rise of climate-sensitive diseases like dengue, and the ongoing COVID-19 pandemic has shown how the fruits of medical innovation continue to be denied to the majority of the world's population. More than ever, there is a need for patient-centric not-for-profit drug development models like DNDi.'

DNDi WELCOMES PROFESSOR SAMUEL KARIUKI AS NEW DIRECTOR EASTERN AFRICA

Professor Kariuki has taken over the helm from Dr Monique Wasunna, who stepped down in July 2023 after a successful 20-year tenure as the Director of DNDi Eastern Africa.

From 2003, Dr Wasunna served as DNDi Eastern Africa Director and contributed significantly to the expansion of the organization's clinical research capacity. During her tenure, over 10 clinical trials were conducted in the region to find new safe and accessible treatments for visceral leishmaniasis, visceral leishmaniasis and HIV co-infection, and PKDL. Additionally, the first-ever clinical trial for mycetoma and clinical trials for a new paediatric '4-in-1' HIV treatment were concluded.

Dr Wasunna is now the DNDi Africa Ambassador, further articulating DNDi's work in relation to Africa's health priorities and African stakeholders, as well as playing a vital role in raising awareness of neglected diseases and strengthening partnerships to amplify DNDi's impact.

Prof. Samuel Kariuki, her successor, is a former Acting Director General at KEMRI and brings more than two decades of experience in medical research and development in fields including antimicrobial resistance, foodborne infections, and NTDs. Before taking up the role of Acting Director General, he was KEMRI's Director of Research and Development and Director of the KEMRI Centre for Microbiology Research.

IN MEMORIAM

TRIBUTE TO DR MWELE NTULI MALECELA

Dr Mwele Ntuli Malecela served as the Director of the Department of Control of Neglected Tropical Diseases at the World Health Organization from 2018 until her passing in February 2022.

She used her tremendous skills to bring the health needs of neglected patients to the forefront of the global health agenda. She made plain that the struggle against NTDs is so much more than a fight against parasites and infections – that it is, first and foremost, a fight for human dignity and the health and security of vulnerable and marginalized people.

Dr Mwele was a trusted advisor and friend to many DNDi colleagues and partners. Early in her tenure as WHO NTD Director, she visited our offices to introduce her vision for progress toward NTD control and elimination – a vision that was instrumental in guiding the development of the WHO 2021-2030 Roadmap for NTDs.
Dr Monique Wasunna, DNDi Africa Ambassador, first met Dr Mwele at a scientific conference in Uganda early in their careers in the 1990s.

'I knew that Mwele was someone very special right from the the first time we met. She was very iintelligent and kind, such a beautiful soul. Mwele's impact throughout her career came from a very pure desire to improve people's lives especially for the most vulnerable. She accompanied DNDi in our evolution as an organization and we fondly remember her as a true ally and an invaluable friend. She was a fighter, and she set such an amazing example for our daughters to look up to and emulate. In the Roadmap, she worked so tirelessly to ensure that we have a clear path to reducing suffering and building resilience in communities affected by NTDs. It has been such a privilege to know Mwele as a both a colleague and dear friend. We will carry on the fight in her loving memory.'

Our teams will continue to be inspired by Dr Mwele's indelible legacy of hard work, compassion and commitment. May her soul rest in Eternal Peace.

TRIBUTE TO PROFESSOR AHMED M. EL-HASSAN

We were deeply saddened by the death of Professor Ahmed M. El-Hassan, Emeritus Professor of Pathology at the Institute of Endemic Diseases, University of Khartoum. Prof. El-Hassan passed away on 10 November 2022 in Sudan. He was 92 years old.

Prof. El-Hassan was one of Africa's most acclaimed leishmaniasis experts and an early witness to the first disease cases in Gedarif State, Sudan, as a young research assistant in 1958. In those days, little was known about the disease in the region. To understand leishmaniasis, Prof. El-Hassan immersed himself in clinical work and conducted numerous autopsies on patients who succumbed to the disease.

Prof. El-Hassan was a close friend of DNDi from the organization's earliest days, joining fellow scientists from the region in forming LEAP in 2003. With a deep-rooted commitment to meeting neglected patients' needs, he played a crucial advisory role in supporting DNDi leishmaniasis clinical trials in Sudan – all conducted in partnership with the Institute of Endemic Diseases. Named in his honour, the Ahmed Mohamed El-Hassan Centre for Tropical Diseases in Dooka, Sudan, has long been a key study site for DNDi leishmaniasis clinical trials, playing an essential part in propelling research to improve treatment for the disease.

A friend, father, and grandfather admired by many, Prof. El-Hassan will be remembered for his dedication to teaching and research and his committed service to poor and marginalised people. He was a compassionate scholar, inspirational leader, and generous mentor to young and aspiring researchers.

'Prof. El-Hassan was more than a mentor, he was a visionary clinician, an innovator, one of the kindest and most patient listeners – and always as modest as he was expert. He was also one the most modern researchers I have met, always keen to adjust to an evolving world. And he was also not devoid of a great sense of humour.' – Dr Nathalie Strub-Wourgaft, COVID-19 Response & Pandemic Preparedness Director, DNDi
The DNDi family is grateful for Prof. El-Hassan's vital contributions to science, leishmaniasis, mycetoma, and the medical field. He will be greatly missed.

THANK YOU DNDi!

Throughout the past two decades, LEAP has been fortunate to receive support from numerous friends and partners, who have been instrumental in enabling us to reach where we are today. Here is a list of some of the key members of the DNDi team (in no order) who have played a crucial role in helping us achieve our objectives during this time:

Monique Wasunna
DNDi Africa Ambassador and
LEAP founding chair

Bernard Pecoul
Founder And Former
Executive Director Of DNDi

Jorge Alvar Ezquerra
Senior Advisor of the
Leishmaniasis Programme at DNDi,

Manica Balasegaram
Executive Director of GARDP
and former Head of the Leishmaniasis
Clinical Program at DNDi

Fabiana Alves
NTD Leishmaniasis-Mycetoma
Cluster Director, DNDi .

Joy Malongo
Leishmaniasis Access
Manager, DNDi

Eric Stobbaerts
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Sally Ellis
Project Leader of the Children's
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and former DNDi Clinical trials
Coordinator for Visceral Leishmaniasis.

Alexandra Solomos
Senior Clinical Project
Manager, DNDi

Simon Bolo
Head of Leishmaniasis
Access, DNDi

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