

SSG & PM: Issues of Access to VL treatments

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Conference*

DNDi

Drugs for Neglected Diseases *initiative*



Outline

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Introduction



Visceral Leishmaniasis (VL) - most deadly parasitic disease after malaria



29,000 to **56,000** new cases every year in Eastern Africa and affects poorest people in arid regions.



For over 70 years, SSG alone was the first line VL treatment in Eastern Africa



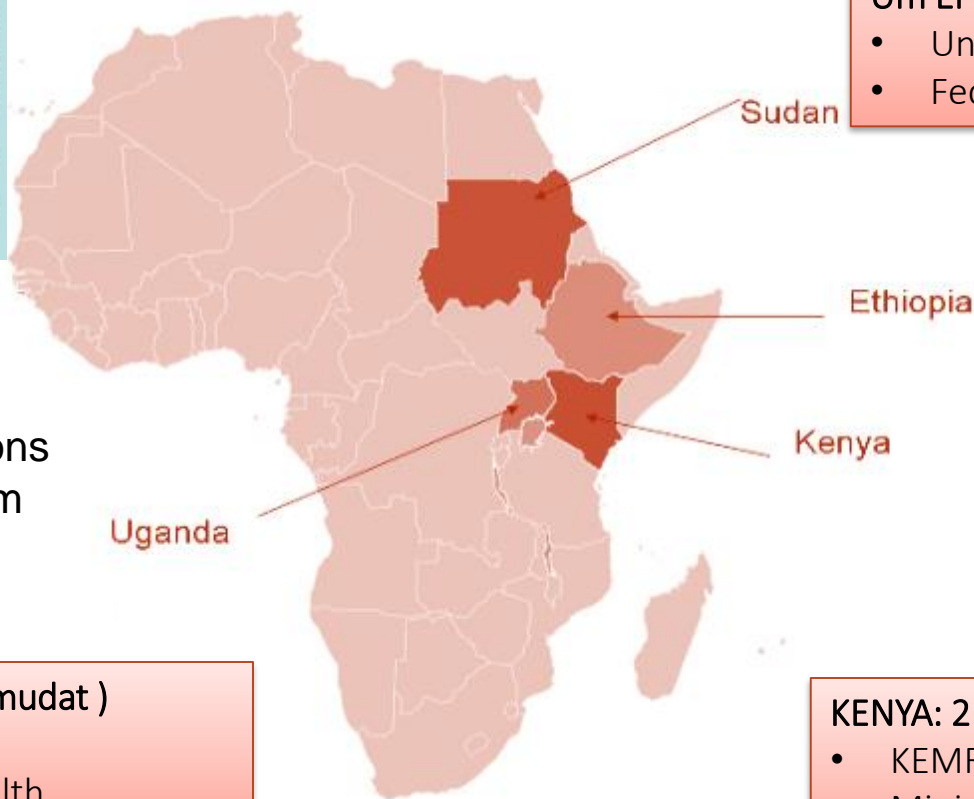
VL treatment access challenge

Leishmaniasis East Africa Platform



A group of scientists and institutions working on developing clinical trial capacity to bring new treatments to patients

In 2003, a group of Eastern African scientists and institutions came together to form LEAP



SUDAN: 3sites (Kassab, Dooka, Um El Kher)

- Univ. of Khartoum
- Federal Ministry of Health

ETHIOPIA: 3sites (Abdurafi, Arba Minch, Gondar)

- Addis Ababa Univ.
- Gondar Univ.
- DACA
- Ministry of Health

UGANDA: 1 site (Amudat)

- Makerere Univ.
- Ministry of Health

KENYA: 2 sites (Kacheliba, Kimalel)

- KEMRI
- Ministry of Health

LEAP collaborates with - DNDi, MSF, IOWH – India, IDA, TDR and industry partners in Visceral Leishmaniasis (VL) R&D work in East Africa

Objectives of LEAP – SSG & PM

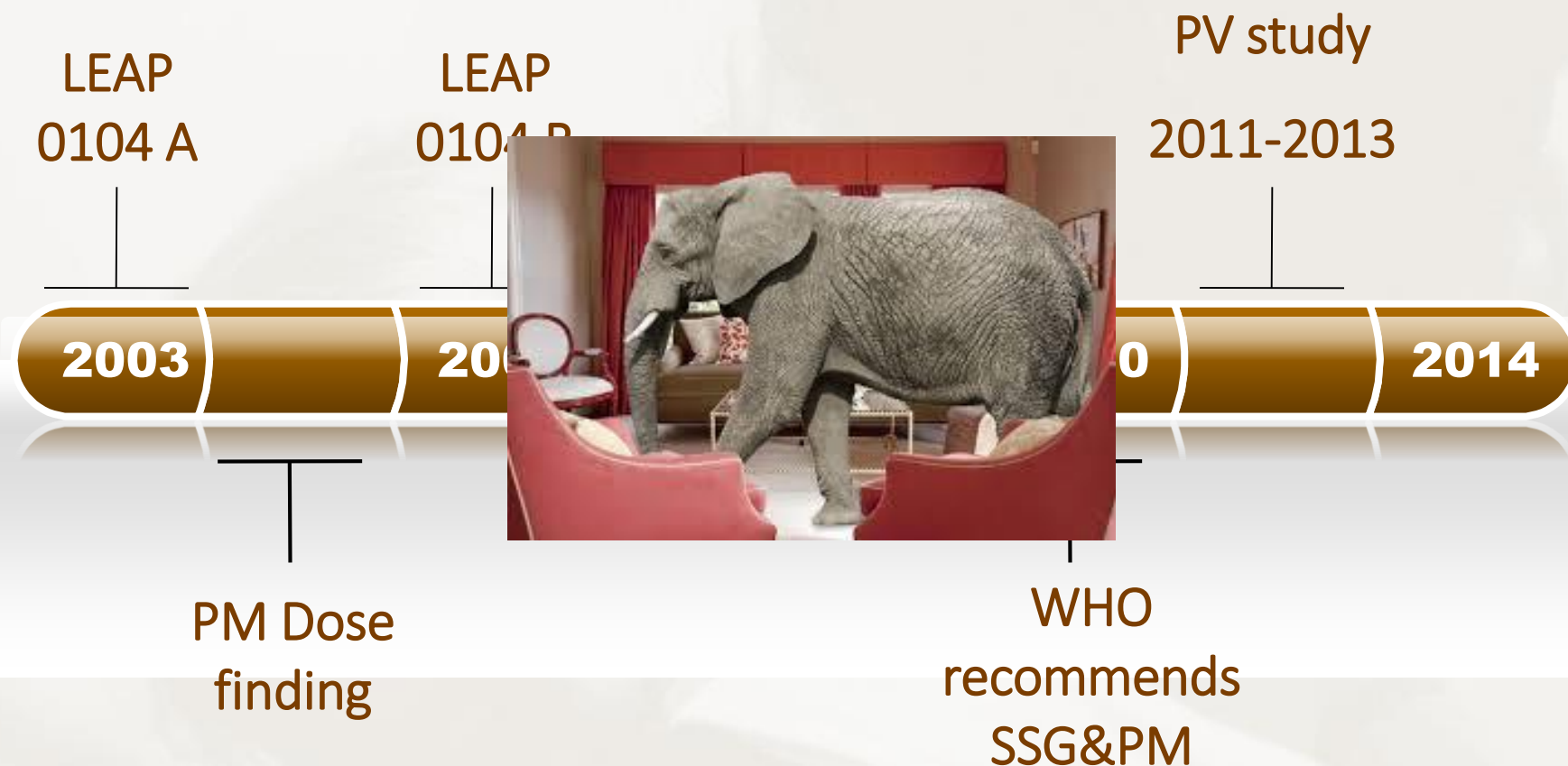
- To evaluate shorter course (17 days) combination of PM+SSG as alternative treatment for VL - ✓ **achieved**
- To build capacity involving stakeholders early in the trials - ✓ **achieved**
- To register PM as new treatment for VL in East Africa (Sudan, Ethiopia, Kenya & Uganda - as supported by data) - ✓ **mostly achieved**



SSG& PM Clinical Trials and PV summary

Study	Phase	Drug	No.	Countries	Results
LEAP 104A	III	SSG/PM	405	KE, SU, UG, ET	<ul style="list-style-type: none"> • Studies completed 2009 • Overall efficacy SSG & PM at 6 months 91% • The combination appeared to be as efficacious and safe as the standard treatment with SSG with no differences seen between sites and countries • The combination is cheaper and of shorter duration, thereby offering a potential advantage for health care providers and patients • Registration recommended for the combination in Sudan, Ethiopia, Kenya and Uganda after the CTs
LEAP 104B	III	SSG/PM	702	KE, SU, UG, ET	
LEAP 0104A (Dose Finding study)	II	PM	42	SU	
PV	IV	SSG/PM	3100	KE, SU, UG, ET	<ul style="list-style-type: none"> • Study completed 2014 • Overall effectiveness of 95% at EOT and overall mortality rate of 0.9% • Efficacy at EOT lower for patients > 50y: 81.4%; for HIV-VL co-infected patients: 55.6%

SSG & PM timeline



SSG & PM access achievements

- Early success
 - immediate incorporation and acceptance of SSG & PM to Essential Medicines List and the revision National Guidelines
 - WHO recommended SSG & PM as first line VL treatment in E Africa.
- Continued advocacy and lobbying based on evidence
 - Publications and
 - Policy change
- VL guideline training of health workers done in VL diagnosis & use SSG& PM



Collaborations and partnership for access



VL guidelines training



VL Stakeholder meeting to review guidelines



community leaders engagement



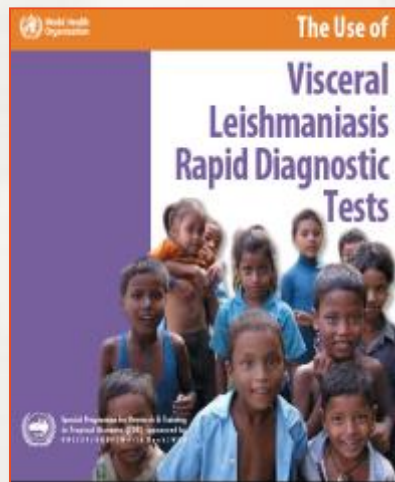
Publications and Policy

OPEN ACCESS Freely available online

PLOS NEGLECTED TROPICAL DISEASES

Sodium Stibogluconate (SSG) & Paromomycin Combination Compared to SSG for Visceral Leishmaniasis in East Africa: A Randomised Controlled Trial

Ahmed Musa¹, Eltahir Khalil¹, Asrat Hailu², Joseph Olobo³, Manica Balasegaram^{4,5}, Raymond Omollo⁵,

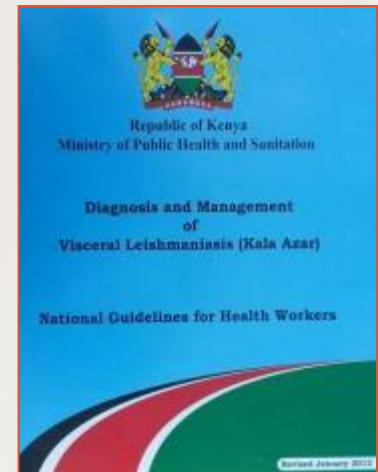


OPEN ACCESS Freely available online

PLOS NEGLECTED TROPICAL DISEASES

Geographical Variation in the Response of Visceral Leishmaniasis to Paromomycin in East Africa: A Multicentre, Open-Label, Randomized Trial

Asrat Hailu¹, Ahmed Musa², Monique Wasunna^{3*}, Manica Balasegaram^{4,5}, Sisay Yifru⁶, Getahun



Running title: Pharmacovigilance of Sodium Stibogluconate and Paromomycin Treatment in Visceral Leishmaniasis

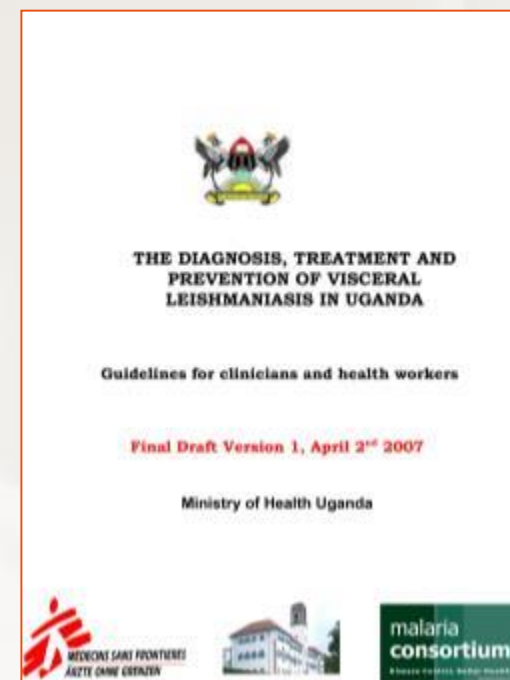
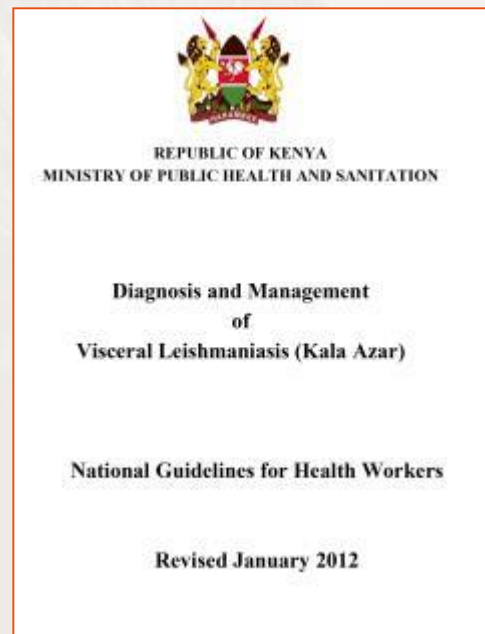
Robert Kimutai^{1,2,*}, Ahmed M Musa³, Simon Njoroge¹, Raymond Omollo², Fabiana Alves², Asrat Hailu⁴, Eltahir A.G Khalil³, Ermias Diro⁵, Peninah Sopei², Brima Musa³, Khalid Salman³, Koert Ritmeijer⁹, Francois Chappuis^{9,10}, Juma Rashid¹, Rezika Mohammed⁵, Asfaw Jameneh⁶, Eyasu Makonnen⁴, Joseph Olobo⁷, Lawrence Okello⁸, Patrick Sagaki⁸, Nathalie Strub², Sally Ellis², Jorge Alvar², Manica Balasegaram¹¹, Emilie Alirol^{9,10}, Monique Wasunna^{1,2}

EML, Registration, Availability

Product	Countries	Essential Medicines List	Registration status	Availability in health facilities
Paromomycin	Ethiopia	Yes	Submitted	+
	Kenya	Yes	Registered	+
	Uganda	Yes	Registered	+
	Sudan	Yes	Submitted	++
SSG	Ethiopia	Yes	Submitted	++
	Kenya	Yes	Registered	++
	Uganda	Yes	Registered	++
	Sudan	Yes	Registered	+++

Challenges

- Slow transition from clinical trial results to patient access
- Low prioritization of VL needs due to lack of data and inadequate advocacy
 - Inadequate funding both national and country (diagnostics, drugs, staffing)
 - Budgeting and procurement 'complex'
- Adoption VL diagnosis/treatment guidelines
 - Recommended diagnosis, treatment & specialized care facilities not available
 - Pressure in outbreaks, sporadic cases
 - Donated diagnostics and treatments not line with guidelines
 - High staff turnover – inadequate follow up after training, reluctance to change
- Patients presenting late due to distance, culture and traditional treatments
- Patients still not getting SSG &PM



Arid Lands



Solutions

1

2

3

4

5



Partnership
from early
with MOH
and
Stakeholders

Developing
VL data
collection
and
surveillance
tools

Sharing data
and advocating
for budgeting
and
prioritization
of VL in the
counties and
nationally

Training and
follow up
refresher
trainings of
health
workers

Long term
strategic
planning -
national and
international

Conclusions

1

Early engagement and involvement of stakeholders and regulators is key to early acceptance of new treatments

2

Scientifically and ethically sound research leads to registration and policy change to use new treatments. This is ongoing in Sudan, Ethiopia, Kenya and Uganda

3

Significant challenges still to be overcome for the patients to access treatment

4

Putting patients first includes addressing access needs
SSG&PM is effective, safe, cheaper and of shorter duration. It is not ideal but the best first line in eastern Africa

Acknowledgements



- **All our patients**
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A close-up photograph of a young girl with dark skin and her hair styled in many small braids. Each braid is adorned with a small, colorful plastic ring in shades of pink, blue, green, and orange. She is smiling broadly, showing her teeth. In the background, another child is partially visible, looking towards the camera. The image has a warm, slightly soft focus.

THANK YOU!

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