

# Visceral Leishmaniasis (VL) baseline clinical presentations and association with initial treatment outcome among East African patients

Thaddeus Egondi<sup>1</sup>, Monique Wasunna<sup>1</sup>, Robert Kimutai<sup>1</sup>, Raymond Omollo<sup>1</sup>, Lillian Were<sup>1</sup>, Menza Peninah<sup>1</sup>, Gabriel Omwalo<sup>1</sup>, Jane Mbui<sup>2</sup>, Fabiana Alves F<sup>3</sup>, Séverine Blesson<sup>3</sup>, Alexandra Solomos<sup>3</sup>, Jorge Alvar<sup>3</sup>, Ahmed Musa<sup>4</sup>, Elthahir Khalil<sup>4</sup>, Asrat Hailu<sup>5</sup>, Joseph Olobo<sup>6</sup>

<sup>1</sup>Drugs for Neglected Diseases *initiative*, Nairobi, Kenya; <sup>2</sup>Centre for Clinical Research, Kenya Medical Research Institute, Nairobi, Kenya; <sup>3</sup>Drugs for Neglected Diseases *initiative*, Geneva, Switzerland; <sup>4</sup>Institute of Endemic Diseases, University of Khartoum, Khartoum, Sudan; <sup>5</sup>Faculty of Medicine, Addis Ababa University, Addis Ababa, Ethiopia; <sup>6</sup>Faculty of Medicine, Makerere University, Kampala, Uganda

## Background:

Visceral Leishmaniasis (VL) is among the most neglected of the tropical diseases, afflicting the poorest of the poor. It is characterized by irregular bouts of fever, weight loss, enlargement of the spleen and liver, and anaemia. It is highly endemic in the Indian subcontinent and in Eastern Africa. An estimated 200,000 to 400,000 new cases of VL occur worldwide each year.

Clinical presentation of VL is dependent on many factors but mainly age, severity, and geographical location. Presence of concomitant secondary infections such as malaria, tuberculosis, and pneumonia complicate the disease presentation. In children, malnutrition, anaemia and subsequent impaired immunity increase the likelihood of disease progression.

The assessment of VL cure is done at day 28-30 as initial cure or at 6 months as definitive cure. Therefore, understanding of baseline clinical symptoms is important in monitoring treatment response, and in identifying and reporting of adverse events in VL trials.

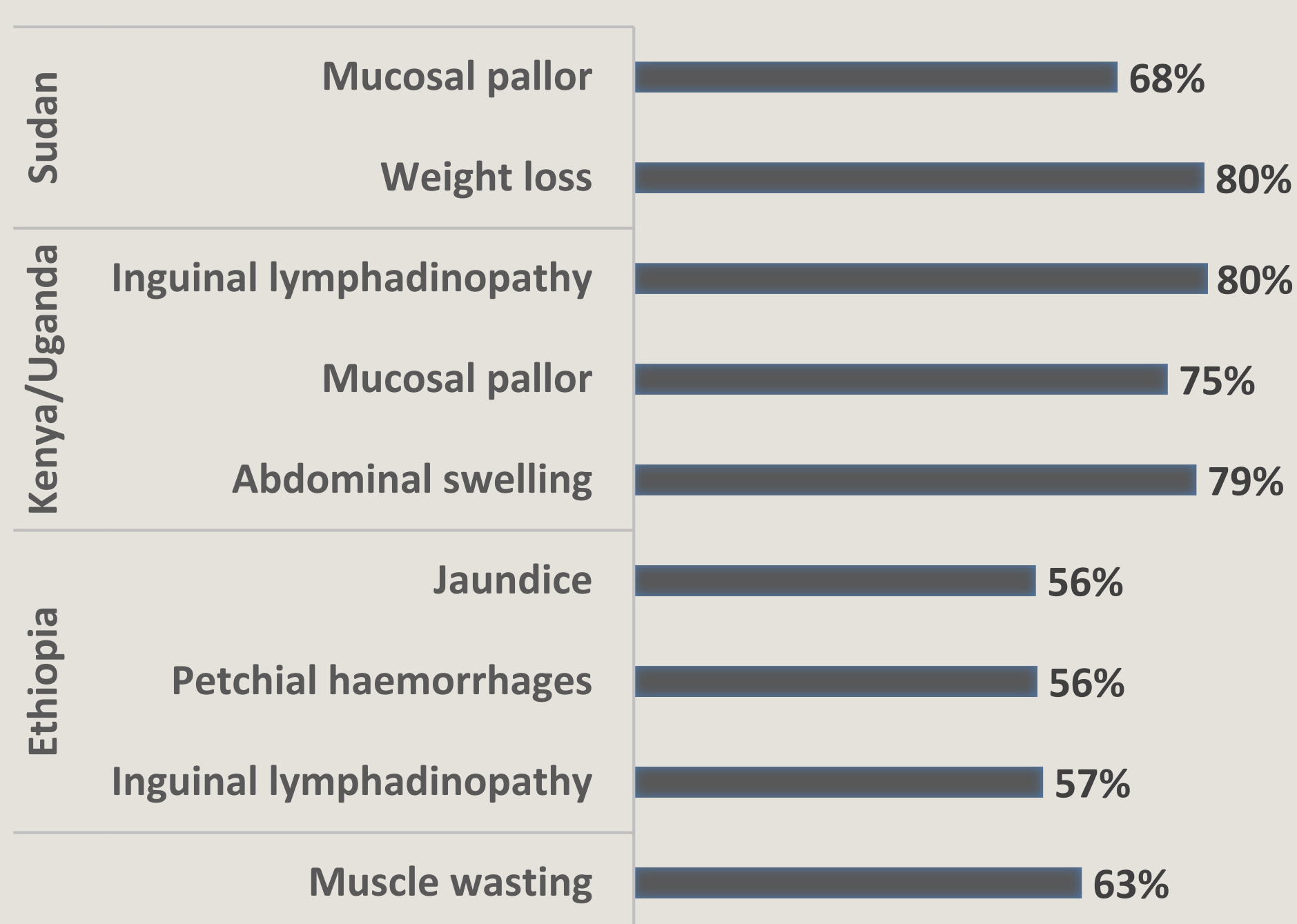
## Objectives:

The objective of the data review is to identify the prevalent symptoms and clinical signs among VL patients enrolled in LEAP clinical trials, describe baseline clinical presentation of VL patients by country and region, and assess the change of clinical symptoms and clinical signs from baseline to initial cure at 28-30 days.

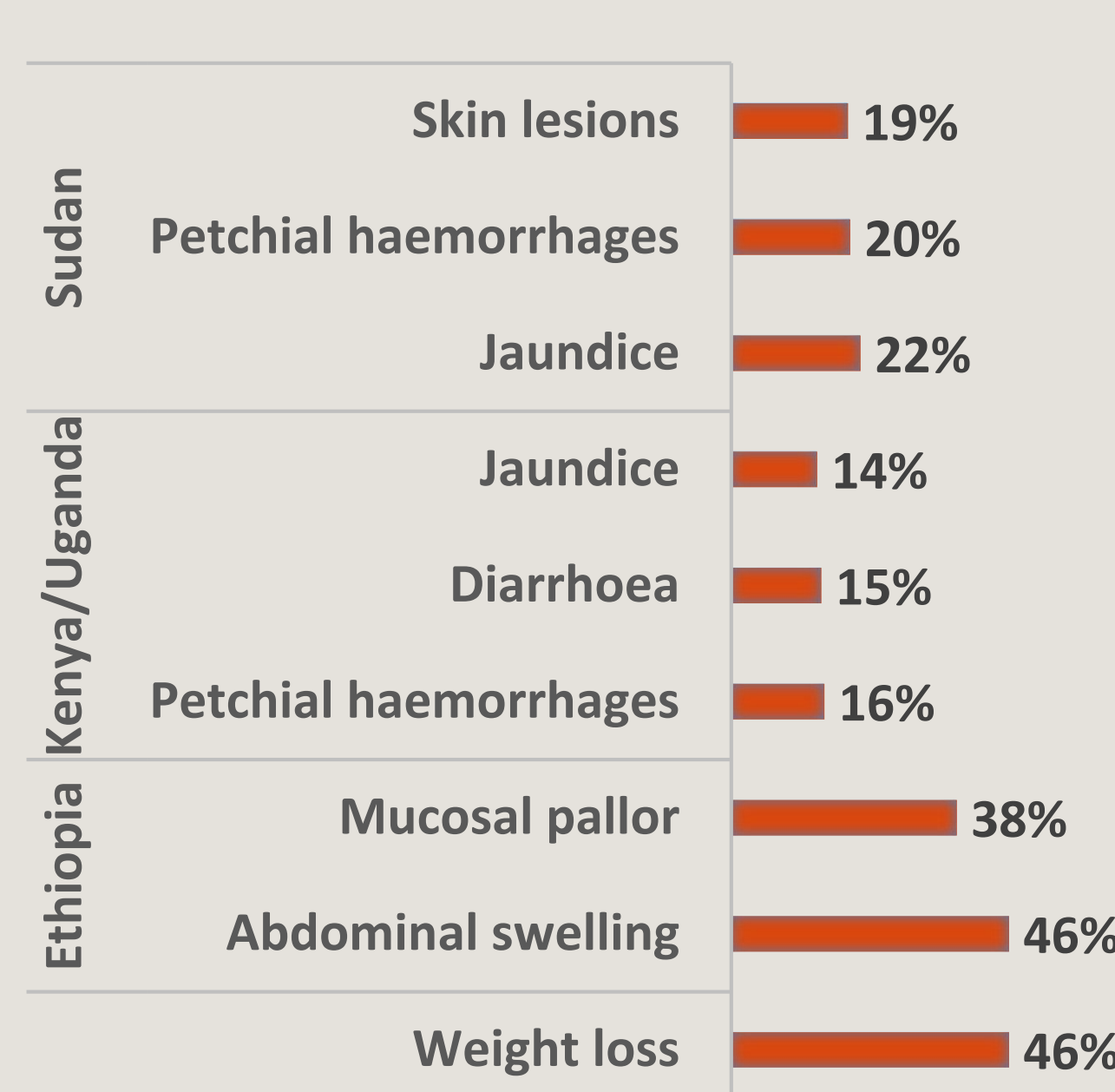
## Results:

### Proportion with different symptoms by region

#### Most common symptoms

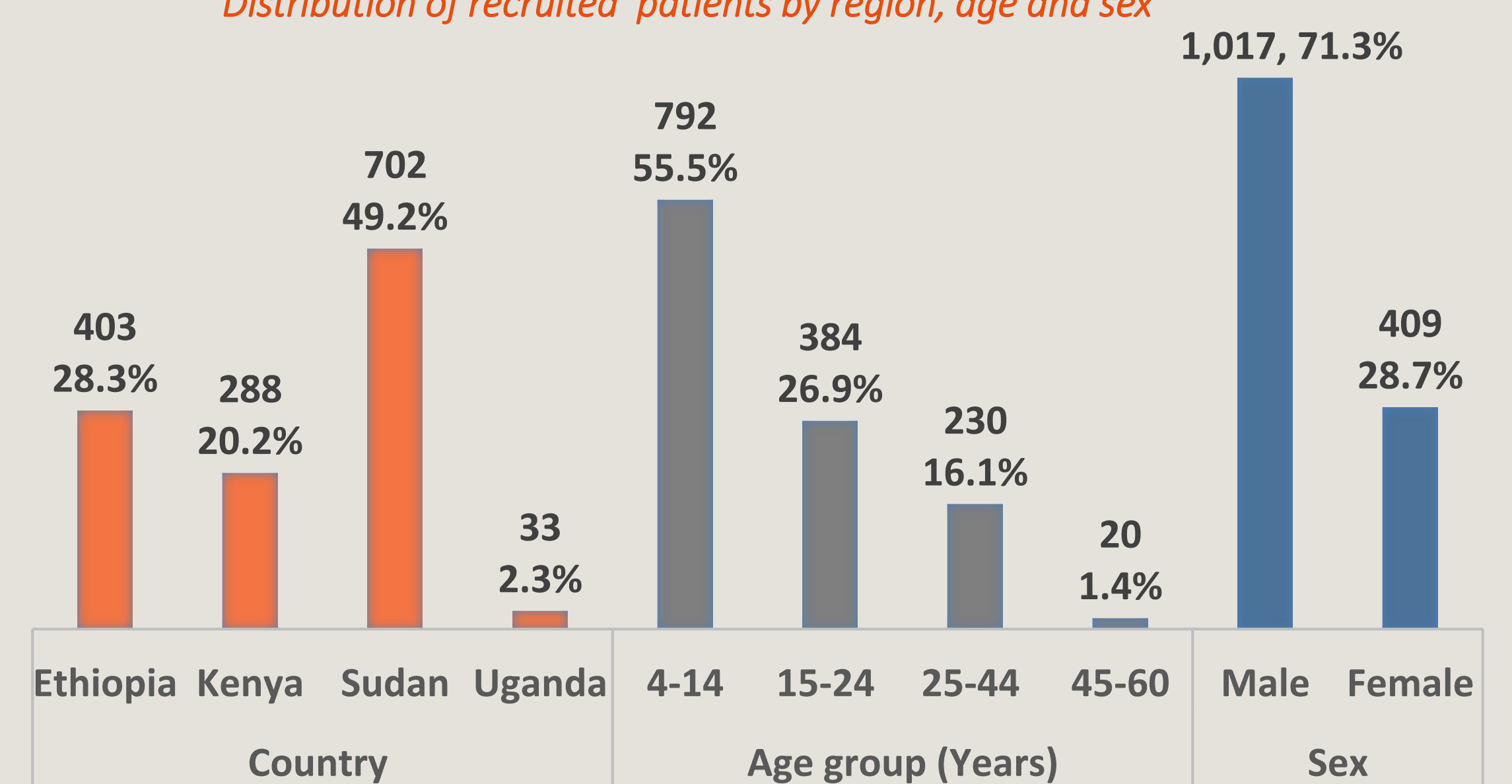


#### Least common symptoms

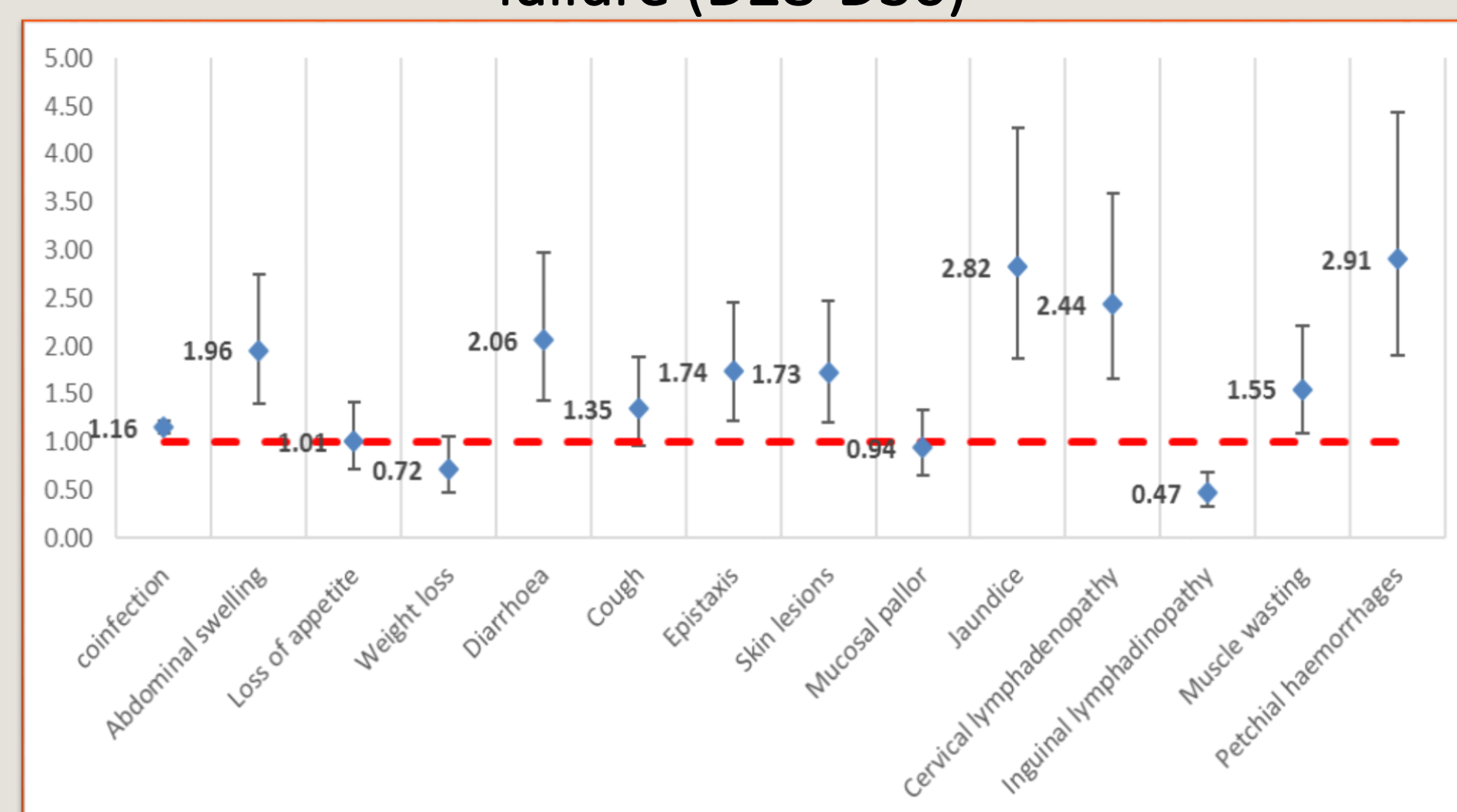


### Patient Demographics

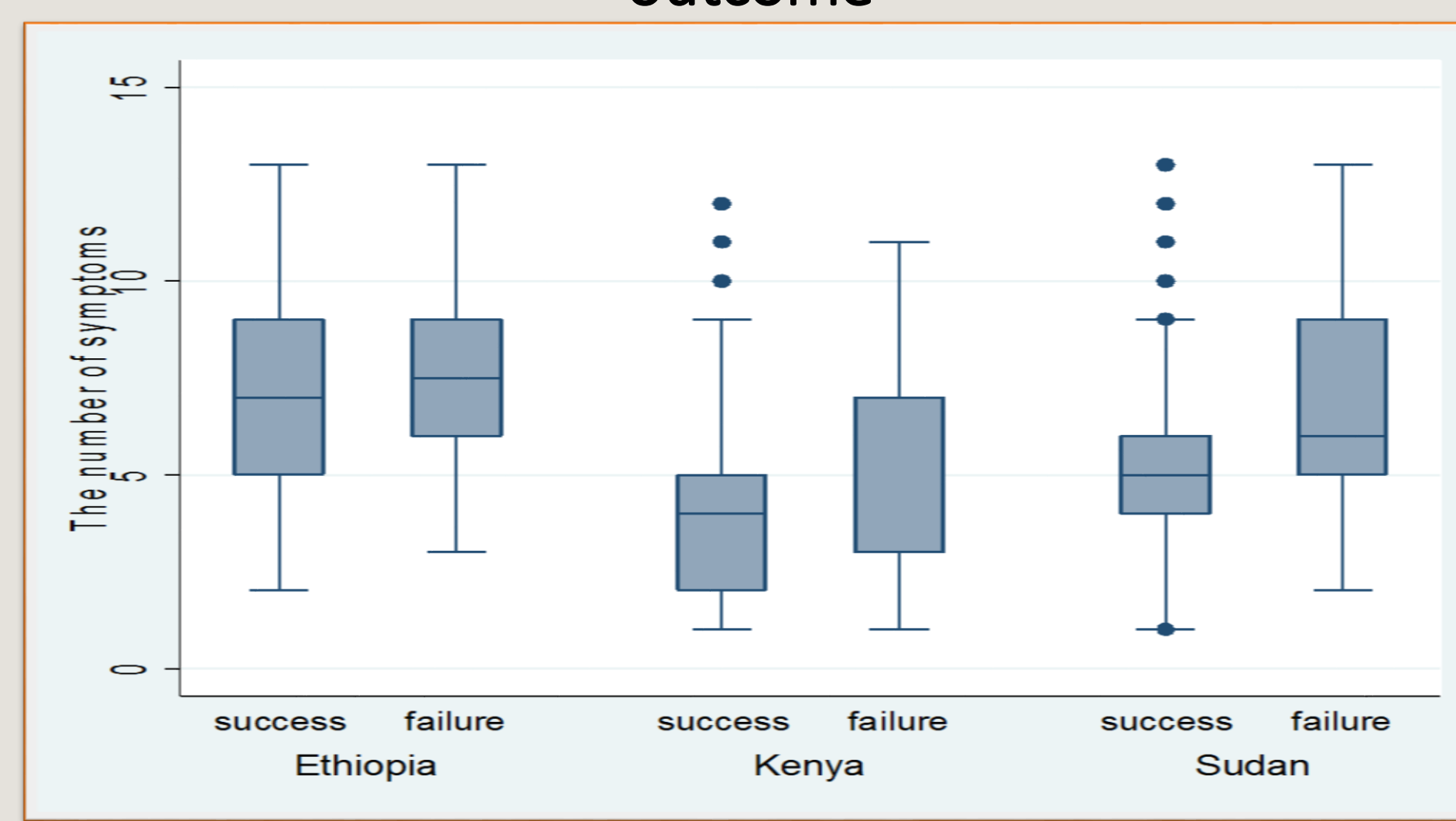
#### Distribution of recruited patients by region, age and sex



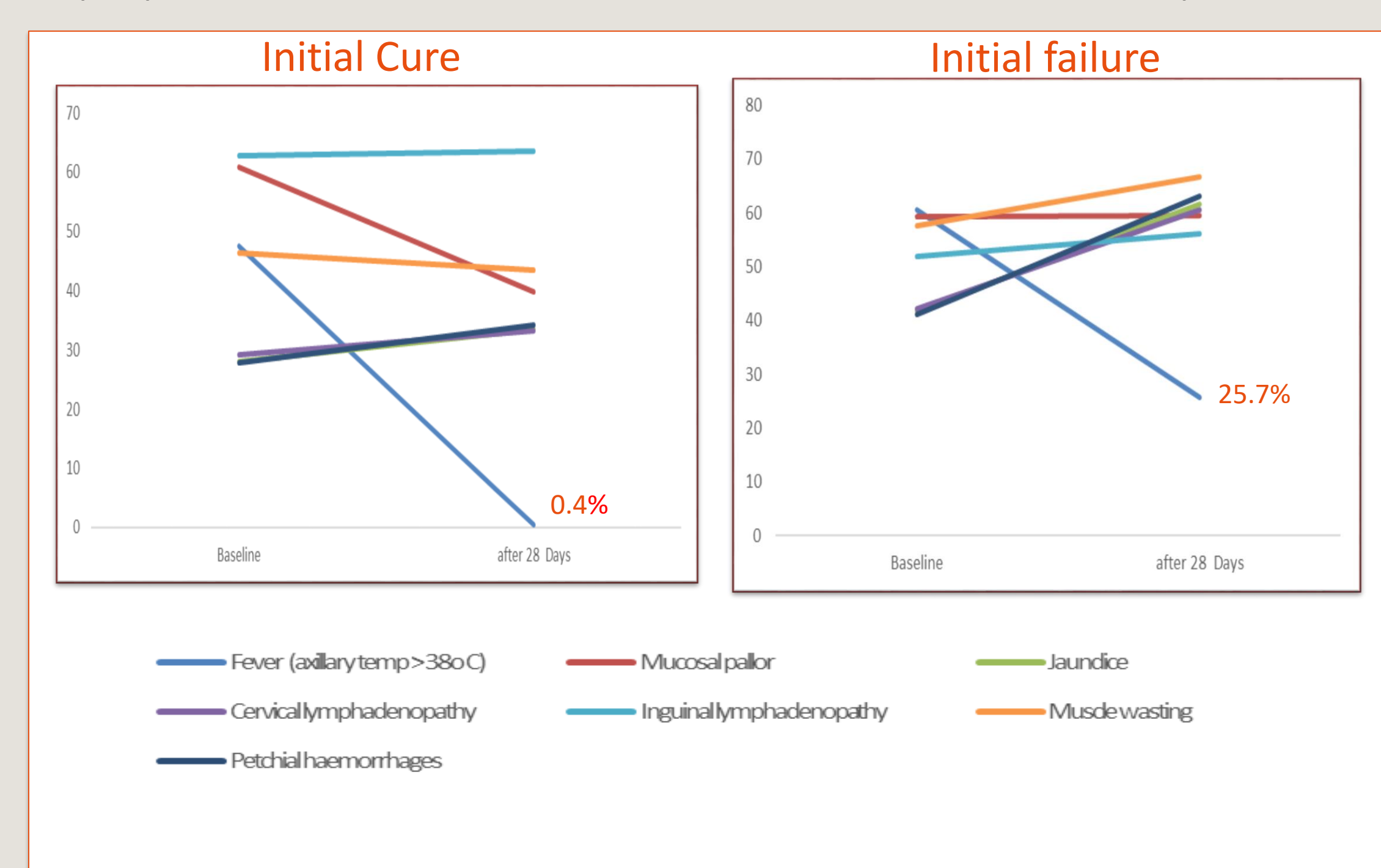
### Baseline symptoms associated with initial treatment failure (D28-D30)



### Multiple occurrence of symptoms by treatment outcome



### Symptoms evolution from baseline to initial cure Day 28-30



## Conclusion:

Majority of participants in the LEAP clinical trials were male, children (4-14 years) and from Sudan. There is variation in clinical presentation of symptoms among VL patients in the four countries. The most common baseline symptoms in addition to fever were abdominal swelling, weight loss, inguinal lymphadenopathy and mucosal pallor. These symptoms were however not significantly associated with initial treatment failure. The findings also point to fever clearance as a better indicator of initial treatment success.

The research leading to these results has received funding from the European Union Seventh Framework Programme under grant agreement no. 305178; French Development Agency (AFD), France; Department for International Development (DFID), UK; Dutch Ministry of Foreign Affairs (DGIS), The Netherlands; Federal ministry of Education and Research (BMBF) through KfW, Germany; Ministry of Foreign Affairs and International Development, France; Medcor Foundation, Liechtenstein; Spanish Agency for International Development Cooperation (AECID), Spain; Médecins Sans Frontières; Swiss Agency for International Development and Cooperation (SDC), Switzerland; Other Private donors