

Strategic framework

for the elimination of visceral leishmaniasis
as a public health problem in eastern Africa

2023–2030



**World Health
Organization**

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Abbreviations and acronyms

| | |
|----------|--|
| AU | African Union |
| BCC | behaviour change communication |
| COVID-19 | coronavirus disease |
| DNDi | Drugs for Neglected Diseases initiative |
| FIND | Foundation for Innovative New Diagnostics |
| IEC | information, education, communication |
| IGAD | Intergovernmental Authority on Development |
| ITN | insecticide-treated bed net |
| IVM | integrated vector management |
| MSF | Médecins Sans Frontières |
| NTD | neglected tropical disease |
| PKDL | post-kala-azar dermal leishmaniasis |
| RTAG | Regional Technical Advisory Group |
| SSG | sodium stibogluconate |
| TDR | Programme for Research and Training in Tropical Diseases |
| UNICEF | United Nations Children's Fund |
| VL | visceral leishmaniasis |
| WHO | World Health Organization |



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Ochieng Andrew, a community Health Mobilizer, examining Losur Emmanuel, a suspected Kala-azar patient in Lopodot Village in Amudat, Uganda.



**Strategic
framework for
the elimination
of visceral
leishmaniasis in
eastern Africa
at a glance**

Vision

Eastern Africa subregion free of visceral leishmaniasis (VL)

Goal

To contribute to improving the health status of vulnerable groups and at-risk populations living in areas endemic for VL in eastern Africa by eliminating VL as a public health problem.

Targets

The road map target for elimination of VL as a public health problem is defined as < 1% case-fatality rate due to primary VL. A low mortality due to VL is an indicator both for early access to diagnosis and treatment and for quality of care.

Regional and country-level subtargets

During the Programme Managers' Review Meeting of Central and East Africa and South-East Asia (online meeting, June 2022), experts proposed additional regional and national subtargets related to VL incidence, as defined below. These targets can be revisited as progress is reviewed and access to diagnosis and treatment and surveillance improves.

Regional targets

The overall regional targets are to achieve:

- 90: 90: 100 – fewer than 1500 new cases reported per year in eastern Africa by 2030 (about a 90% reduction from the 13-year average including an estimated 25% underreporting in 2010–2022);
- 90% of VL cases detected and started on treatment within 30 days of onset of symptoms by 2030;
- 100% decline in VL deaths in children by 2030;
- 100% of VL–HIV coinfecting patients started on antiretroviral therapy and referred to HIV clinics or services for long-term management; and
- all PKDL cases detected, reported and managed.

The mid-term regional targets are to achieve:

- 60% reduction of new VL cases by 2027;
- 100% HIV screening for all detected VL cases, and 100% of results reported by 2027;
- 75% of VL cases detected and started on treatment within 30 days of onset of symptoms by 2027; and
- to consider a mid-term target for case fatality reduction.

1

Introduction

Eastern Africa is the region most affected by visceral leishmaniasis (VL), accounting for 66% of cases globally that were reported to the World Health Organization (WHO) in 2021.



1. Introduction

1.1 Background

Eastern Africa is the region most affected by visceral leishmaniasis (VL), accounting for 66% of cases globally that were reported to the World Health Organization (WHO) in 2021 (1). In this region, VL is considered endemic in Chad, Djibouti, Eritrea, Ethiopia, Kenya, Somalia, South Sudan, Sudan and Uganda; it is caused by infection with the parasite *Leishmania donovani*. The disease is generally considered anthroponotic, although indications for zoonotic reservoirs exist. Transmission of infection in the main endemic foci is by the sandfly *Phlebotomus orientalis* (in Sudan, northern South Sudan and north Ethiopia) which is abundant in savannahs dominated by *Acacia seyal* and/or *Balanites aegyptiaca* trees. These sandflies breed inside the cracks of black cotton soil and rarely go inside rooms, but bite humans in the courtyards of houses as well as in peridomestic habitats. They show a marked seasonality, with a peak abundance in the dry season (March–June). This correlates with a corresponding annual fall and rise



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Assistance to the Mursi tribe in Omo Valley affected by kala-azar by identifying cases and referring patients to the hospital. Ethiopia, February 2023.

in the caseload of VL. *Phlebotomus martini* and *Ph. celiae* are the predominant vectors in the southern foci, which include Kenya, Somalia and Uganda, and in the south of Ethiopia and the southern foci of South Sudan. The habitats of *Ph. orientalis*, *Ph. martini* and *Ph. celiae* do not overlap; *Ph. martini* and *Ph. celiae* live mostly inside old *Macrotermes* termite hills in red-soil areas, in a distinctly different ecological setting.

VL affects the poorest populations, living in remote locations: low-income households in rural villages, semi-nomadic pastoralists, seasonal agricultural workers and displaced populations. HIV and other comorbidities or coinfections are substantial risk factors for developing clinical disease, as is malnutrition. Spending time outdoors during the hot, dry season in proximity of *Balanites* or *Acacia* trees (or, in the southern foci, near termite mounds) increases the risk of infection. Large outbreaks regularly occur in endemic areas where *Ph. orientalis* is the vector but are less frequent in endemic areas where *Ph. martini* is the vector. Population movements and climate change influence the epidemiology of VL. Outbreaks often occur when the infection is introduced in new foci. These outbreaks can initially be mistaken for those of malaria or other acute febrile illnesses. They can spread rapidly and cause large numbers of cases. During outbreaks, individuals of all ages and of both sexes are roughly equally affected, whereas in longstanding endemic foci 60% of cases occur in children aged under 15 years; except in Ethiopia where seasonal migrant labourers travelling to endemic zones to plant and harvest cash crops are at highest risk (2).

Access to diagnosis and treatment is generally limited due to weak health systems. Few data are available, and it has been estimated that the time period between the onset of symptoms and treatment is up to 90 days in Ethiopia (3,4), Kenya (5) and Sudan (6), and, most likely, longer in countries such as Eritrea, Somalia and South Sudan. The distances to facilities providing diagnosis and treatment can be considerable, and patients often incur large out-of-pocket expenses in seeking care. Once at the facility, understaffing and stock-outs of diagnostics and medicines are common. A lack of awareness among the population, financial barriers, political instability and a resulting lack of security as well as poor knowledge of the disease among health providers, especially in areas with low endemicity, compound the difficulties. Data on morbidity and mortality are based on case numbers reported to WHO. There is a discrepancy between the true burden of the disease and the actual numbers of cases reported due to poor national reporting mechanisms and patients who remain unseen. As a consequence, there is a lack of accurate information on the prevalence and spatial distribution of VL in most countries. Furthermore, the case-fatality rate is underreported because deaths are often not recognized as being caused by VL and cases are not followed up to the standard period post-treatment to ascertain definitive cure.

1.1.1 Methods

The draft strategic framework was prepared after a thorough literature review and circulated to all stakeholders in advance of the stakeholders' meeting on developing a strategic plan for the elimination of VL in eastern Africa (Nairobi, Kenya, 24–27 January 2023). The draft document was extensively deliberated during the meeting, which was organized by WHO/NTD in collaboration with The END Fund and DNDi. Participants were divided into working groups to review and finalize the text. The group work was presented during the plenary.

During the meeting, the Nairobi Declaration was also discussed and adopted by the health ministries of Member States and other stakeholders.

This is a consensus document of all the participants who attended the meeting. The participants are listed in Annex 2 of the report of the stakeholders' meeting on developing a strategic plan for the elimination of visceral leishmaniasis in eastern Africa, Nairobi, Kenya, 24–27 January 2023 (7).

1.1.2 Declarations of interest

Before the stakeholders' meeting, all external experts and contributors involved in the initial development of this strategic framework completed "Declarations of interests for WHO experts" forms, which were assessed by the WHO Secretariat. After evaluation, WHO found that none of them had declared a conflict of interest.

1.2 Epidemiology and population at risk

1.2.1 Chad

Chad is endemic for visceral and cutaneous leishmaniasis. During the sudden upsurge of cases in 2019–2020, the parasite species causing VL was identified as *L. donovani*. The proven vector species is *Ph. orientalis*. The main endemic provinces are Borkou, Ouaddai and Tibesti. However, the provinces of Baguirmi, Chari, Ennedi East and West, Mayo Kebbi East and West, Salamat, Sila and Wadi Fira are also considered at risk (Annex). In 2022, 96 VL cases and 1089 CL cases were reported (8,9).

The actual disease burden and spatial mapping of VL cases is not fully known; 90% of the reported cases come from gold mines or surrounding areas. VL diagnosis and treatment facilities are available in a limited number of hospitals (four) and it is estimated that a significant number of cases may be missed and are not able to access VL services.¹

1.2.2 Djibouti

Djibouti is endemic for VL. The first case was reported in 1971. According to the published data, *L. donovani* is the causative parasite species. *Ph. orientalis* is considered the main vector responsible for VL transmission in Djibouti.

During 2005–2014 Djibouti did not report on cases. Since 2015, cases have been reported annually with 16 cases in 2022 (8). Most cases (63%) are reported from the age group 1–4 years, followed by 5–14 years. The least affected age group is over 15 years. Males and females are affected in nearly equal proportions. Northern regions in the country account for nearly 60% of the cases reported, where Obock region alone reported 52% of cases. Ali-Sabieh, Arta, Dikhil and Tadjourah regions also reported cases.²

¹ Oral presentation by Dr Mahamat Abakar, Focal point for VL, Ministry of Public Health, Chad.

² Oral presentation by Abdourahman Djama Guedi, national NTD programme manager, at the Twenty-first meeting of the Regional Programme Review Group and national NTD programme managers, Sharm El Sheikh, Egypt, 19–21 September 2023.

1.2.3 Eritrea

Little is known about the VL burden in Eritrea. The disease is endemic in the western states. Recently, Eritrea has observed a sharp increase in the number of VL cases with the majority coming from Anseba, Debub and Gash Barka areas (10,11).

1.2.4 Ethiopia

Ethiopia has six VL-endemic regions (Afar, Amhara, Oromia, Tigray, Somali and the Southern Nations, Nationalities and Peoples' Region). The population at risk exceeds 3.2 million people.¹ *Ph. orientalis* is the vector responsible for transmission in the arid and semi-arid lowlands of Amhara and Tigray regions where the majority of cases occur, mostly among adult male migrant labourers working in fields in agro-industrial schemes. They report very poor access to diagnosis and treatment and considerable economical loss as a result (4). The rate of *Leishmania*-HIV coinfection in this group (around 20%) is the highest in the world.

In southern Ethiopia, the main vector is *Ph. martini*. There are not many reported cases and the disease occurs in a microfocal pattern, depending on the altitude. This area is inhabited by nomadic or semi-nomadic pastoralist communities (12).

A third and relatively new ecological foci is found in the highlands of Amhara, where in 2005–2007 a large-scale outbreak in Libo Kemkem and Fogera districts was initially misdiagnosed as drug-resistant malaria and affected thousands of people (13).

Foci of VL are continually extending, and the disease is underreported due to incomplete access to diagnosis and treatment (14). In recent years, political instability in Tigray region has resulted in fewer migrant workers, very poor access to treatment and fewer reported cases of VL.

1.2.5 Kenya

VL is endemic in the arid and semi-arid regions of the Rift Valley and eastern provinces, with small foci in the north-eastern province. In the Rift Valley the disease is most common and has been documented in Baringo, Kajiado, Laikipia, Samburu Turkana and West Pokot counties. In the former eastern province the disease has been reported from Isiolo, Kitui, Machakos, Makueni, Marsabit, Mwingi and Tharaka-Nithi counties. The area endemic for VL is extending because of population movements and, possibly, climate change. Outbreaks, especially in new foci, are common. Three recent surges of cases were reported in 2021, all in areas where VL had not been seen before.

The total population at risk is estimated at 5 million people.² Most at risk are nomadic pastoralists who spend time outside in areas where the vector, *Ph. martini*, is abundant (termite hills) (15). Risk factors include the proximity of houses or temporary settlements to termite hills, having a low socioeconomic status and not owning a mosquito net (16). VL affects about twice as many males as females, as cattle herding is usually done by young and adult men who stay with their animals for months in grazing areas before returning to their households. VL used to affect more children

¹ Oral presentation by Tesfahun Bishaw, NTD Officer, Federal Ministry of Health, Ethiopia.

² Oral presentation by Daniel Mwitii, Leishmaniasis Manager, Division of Vector Borne & Neglected Tropical Diseases, Ministry of Health, Kenya.

than adults, although this pattern is now changing due to the recent introduction of free primary education in Kenya (17), which has reduced children's exposure to the vector.

1.2.6 Somalia

Little is known about the disease distribution and burden of VL in Somalia because of the continued conflict and the national emergency situation. VL has been described throughout the southern half of Somalia, with ecological features similar to those of foci in southern Ethiopia and Kenya. Currently, VL is reported most frequently from the Bakool and Bay regions in South West State. Since 2012, new cases have also been reported from the regions of Bari, Banaadir, Gedo, Hiraan and lower Juba (see the report of the stakeholders' meeting (7)). In 2000 and 2006, outbreaks were reported in Hudur (Bakool region), after unusual rains and widespread malnutrition. The main vector is *Ph. martini*. VL affects the rural poor, pastoralists and agro-pastoralists. Most cases occur in children aged under 5 years. Access to treatment is very poor due to the security situation and the low number of treatment centres. The reported number of cases does not reflect the real burden of the disease and is based only on the numbers of people able to reach treatment centres.

1.2.7 South Sudan

VL is endemic in Jonglei, Upper Nile and Unity states in the north, where the vector responsible for transmission is *Ph. orientalis*. Other foci in South Sudan exist in Eastern Equatoria State in the south of the country where the main vector is *Ph. martini*. In the northern foci, sleeping outside under *Acacia* trees is an important risk factor for transmission and is common practice among pastoralist populations or displaced people during conflict. South Sudanese tribal people appear to be exceptionally susceptible to developing full-blown kala-azar, whether because of genetic factors or other underlying vulnerability factors related to displacement (such as nutritional status). Changes in the habitat (destruction, reforestation), mass movements of people from non-endemic to endemic areas (immigration, war, displacement) and decrease of immunity (malnutrition) have led to large-scale epidemics, the latest of which caused tens of thousands of cases in Jonglei State in 2010–2011. The main risk factor for these epidemics is introduction of the disease in non-immune populations through migrations from endemic to non-endemic areas.

The population at risk in South Sudan is estimated at 5 million.¹ Patients are extremely poor and live mostly in very remote areas with no health facilities and transport and often receive treatment at a very late stage of the disease, or not at all. Flooding and ongoing insecurity affect both the ability of patients to access care and of health care providers to provide medical services. The number of treatment facilities was halved because of the interruption of donor support in 2019. Extensive flooding in Jonglei and Upper Nile states, probably related to climate change, may have caused the sandfly population to decrease. In recent years the caseload in known hyperendemic foci (Lankien and Old Fangak) has been significantly reduced.

¹ Oral presentation by Dr Lexson Mabrouk Manibe, Director for NTDs, Directorate of Preventative Health services, Ministry of Health, South Sudan.

1.2.8 Sudan

Sudan has the highest VL burden of eastern Africa. In 2022, it reported 4347 cases (7). VL is commonest close to rivers and at low altitudes; the hyperendemic area of Gedaref State, which represents about 80% of the annual incidence, lays around the basins of the Rahad and Atbara rivers and has extended over the years into Blue Nile and Sennar states. Very high incidences in villages have been reported of over 50–1000 people per year (18). VL affects poor people, living in villages and engaged in agriculture and small animal husbandry. Males aged 5–14 and 15–44 years are those most affected. *Ph. orientalis* is the only vector responsible for VL transmission in Sudan, and people spending time outside, close to *Acacia* and *Balanites* trees in and around the villages are at risk. During the rainy season many roads are impassable and travelling to treatment centres becomes very difficult or impossible (19). Access to treatment is incomplete and has recently worsened due to interrupted donor support.

1.2.9 Uganda

A pocket of stable kala-azar endemicity is found in Baringo and West Pokot counties in West Kenya, extending over the border into the Amudat district in Karamoja subregion. It is one of the poorest regions in Uganda where most of the population are tribal, semi-nomadic pastoralists. Recently, VL has been found in all other districts of Karamoja subregion as well, where there is probably ongoing low endemicity. No VL has been reported from other areas in Uganda.

1.3 Considerations for elimination: modelling results

Modelling studies capturing disease transmission dynamics and control measures have contributed to shaping the VL elimination strategy in India (20). They can predict if and when elimination targets will be reached with existing or new treatment and vector control strategies or help determine the elimination threshold required for resurgence of cases.

No modelling studies exist yet to inform VL elimination strategies in eastern Africa. In the human African trypanosomiasis elimination programme, modelling has been helpful to demonstrate the benefit of screening high-risk groups, the impact of early diagnosis and treatment and the role of vector control in achieving elimination (21).

Mathematical models make assumptions based on available information, which in the case of VL in eastern Africa remains scarce. It has also been considered that models

need to be informed by observations of on-the-ground operations rather than national programme data (22).

Factors to consider for VL elimination modelling in eastern Africa are:

- estimation of the population at risk, incidence and mortality;
- population movements;
- level of underreporting;
- time from onset of first symptoms to treatment;
- efficacy of first- and second-line treatments;
- how long immunity will last after infection;
- incidence and length of episodes of post-kala dermal leishmaniasis (PKDL) and relapse;
- incidence of asymptomatic infection and proportion that progresses to active infection;
- incidence of HIV–*Leishmania* coinfection;
- role of animal reservoirs in transmission;
- efficacy and coverage of prevention and control methods;
- seasonality of sandfly density;
- socioeconomic factors in affected groups; and
- behavioural factors that put people at risk of infection.

1.4 Major achievements

VL control programmes in eastern Africa, supported by WHO, nongovernmental organizations, philanthropic organizations and bilateral support, have achieved the following:

- A highly effective first-line treatment for VL, a rapid test for diagnosis, validated diagnostic algorithms, a highly effective treatment for HIV–*Leishmania* coinfection, and an improved new treatment in the final stage of development for VL and PKDL.
- VL diagnostic and treatment centres in all the main endemic areas.
- Medicines and diagnostics donated through WHO to cover the full needs of countries.
- Free diagnosis and treatment of VL.

- National guidelines on diagnosis and treatment of VL and WHO-recommended diagnostic and treatment algorithms.
- National strategic plans that include VL.
- National training materials.
- Rapid response to outbreaks.
- Behavioural change communication materials and awareness campaigns in most countries.
- Identification of areas of promising vector control research.
- Improved surveillance with enhanced timeliness and completeness (although the overall reporting rate from the WHO African and Eastern Mediterranean Regions is low (43%)).
- Studies to better understand barriers to access in Ethiopia and Sudan.

1.5 Constraints

In the context of vast, scattered and remote endemic areas, long distances to treatment centres, and poor socioeconomic infrastructure and health systems, it must be recognized that the VL control programmes in eastern Africa are not yet functioning adequately.

Major limitations exist.

- Patients are among the poorest of the poor, and access to VL care is often difficult. Although diagnosis and treatment are provided free of charge, there is largely no support for bed occupancy fees and provision of meals, comorbidities, additional laboratory investigations or transport.
- Imperfect tools for diagnosis and treatment (see section 4.1: Early diagnosis and complete case management).
- Poor reporting, and a subsequent lack of accurate information on the prevalence and spatial distribution of VL.
- Limited country ownership.
- Inadequate numbers of trained personnel at all levels in case management and diagnosis, and high staff turnover.
- Lack of a proper supply chain management system for leishmaniasis supplies, leading to frequent stock-outs.
- Inadequate surveillance systems, which can cause late detection of outbreaks.
- No proven, effective or scalable vector control strategy.

- PKDL prevalence and incidence are not well documented. The disease is often mild and self-limiting, mostly remains undetected and untreated, and is a reservoir of infection.

1.6 Relevance of elimination to the road map, the Sustainable Development Goals and universal health coverage

Mobilizing stakeholders to support the WHO road map *Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021–2030* (“the road map”) (23) target for elimination of VL as a public health problem in eastern Africa is an important opportunity to realign health-care priorities and to more effectively address the severe neglect, poverty and inequity in eastern Africa. It is in accordance with the first goal of WHO’s 13th General Programme of Work 2019–2023, of which universal health coverage, target 3.8 of the Sustainable Development Goals, is a cornerstone. Elimination of VL as a public health problem is also aligned with other Goals, especially its health-related target 3.3 which calls to “end the epidemics of ... neglected tropical diseases” by 2030. Furthermore, it will also help to end poverty (Goal 1), end hunger (Goal 2), improve access to quality education (Goal 4), promote productive working lives (Goal 8), and thereby reduce inequalities (Goal 10). The availability of resilient infrastructure (Goal 9) should facilitate the delivery of medicines and outreach to remote communities. The goal of climate action (Goal 13) can support the environmental management necessary to control disease vectors.

2

Vision, goal, targets and assumptions of the framework

Goal

Contribute to improving the health status of vulnerable groups and at-risk populations living in areas endemic for VL in eastern Africa by eliminating VL as a public health problem.



2. Vision, goal, targets and assumptions of the framework

2.1 Vision

Eastern Africa subregion free of visceral leishmaniasis.

2.2 Goal

To contribute to improving the health status of vulnerable groups and at-risk populations living in areas endemic for VL in eastern Africa by eliminating VL as a public health problem.

2.3 Targets

The road map target for elimination of VL as a public health problem is defined as < 1% case-fatality rate due to primary VL (23). A low mortality due to VL is an indicator both for early access to diagnosis and treatment and for quality of care.

Regional and country-level subtargets

During the Programme Managers' Review Meeting of Central and East Africa and South-East Asia (online meeting, June 2022), experts proposed additional regional and national subtargets related to VL incidence, as defined below. These targets can be revisited as progress is reviewed and access to diagnosis and treatment and surveillance improves.

Regional targets

The overall regional targets are to achieve:

- 90: 90: 100 – fewer than 1500 new cases reported per year in eastern Africa by 2030 (about a 90% reduction from the 13-year average including an estimated 25% underreporting in 2010–2022);
- 90% of VL cases detected and started on treatment within 30 days of onset of symptoms by 2030;
- 100% decline in VL deaths in children by 2030;
- 100% of VL–HIV coinfecting patients started on antiretroviral therapy and referred to HIV clinics or services for long-term management; and

- all PKDL cases detected, reported and managed.

The mid-term regional targets are to achieve:

- 60% reduction of new VL cases by 2027;
- 100% HIV screening for all detected VL cases, and 100% of results reported by 2027;
- 75% of VL cases detected and started on treatment within 30 days of onset of symptoms by 2027; and
- to consider a mid-term target for case fatality reduction.

Country target

The country target, as detailed in the report of the stakeholders' meeting (7) is to achieve:

- overall, a 90% reduction in new cases per year at the country level by 2030 from a baseline average of 13 years, with country-specific targets defined on a case-by-case basis, and with some countries having more ambitious targets than others, in line with national plans (and possibly defined with subnational targets within the country); it was suggested that the 2030 target should not be below a 75% reduction; and
- a mid-term country target of 60% reduction of new VL cases by 2027.

2.4 Assumptions

Subtargets related to VL incidence are the direct measures of decreases in disease burden. A 13-year average allows adjustments for outbreaks, underreporting or other surveillance factors (improvement or lack of (e.g. decline due to the coronavirus disease (COVID-19) pandemic)).



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Visceral leishmaniasis, also known as kala-azar, is one of the case-managed neglected tropical diseases (NTDs). It causes immense human suffering and deaths in this subregion, especially in South Sudan, Sudan, Ethiopia and Kenya.

3

Objectives

- By 2030, to achieve the global, regional and country targets by reducing:
 - health impacts;
 - socioeconomic impact of the VL burden in the population at risk;
 - risk of VL transmission by managing all VL and PKDL cases
 - reducing and preventing *Leishmania*-HIV-TB coinfections, malnutrition and other co-morbidities in endemic areas.



3. Objectives

3.1 Impact objectives



- By 2030, to achieve the global, regional and country targets by reducing:
 - health impacts (morbidity and mortality);
 - socioeconomic impact of the VL burden in the population at risk;
 - risk of VL transmission by managing all VL and PKDL cases;; and
 - reducing and preventing *Leishmania*–HIV–TB coinfections, malnutrition and other co-morbidities in endemic areas.

3.2 Process objectives

- To strengthen advocacy and political commitment at national and local levels;
- To improve the effectiveness of the elimination programme through better planning, resource mobilization, implementation, monitoring and evaluation;
- To enhance VL capacity-building at all levels of the health system in VL-endemic districts;
- To establish effective disease surveillance systems for planning and response supported by reliable laboratory diagnosis for VL;
- To ensure early diagnosis and complete case management of VL and PKDL complications and comorbidities;
- To establish effective and integrated vector management (IVM) and vector surveillance systems;
- To undertake disease prevention and control by IVM through selective vector control interventions and environmental management with community participation and intersectoral collaboration;
- To conduct implementation and operational research to optimize existing interventions including diagnosis, treatment, case-finding and vector control; and
- To strengthen information, communication and education at the community level on the prevention and cure of VL.

4

Strategies



Diagnosis of VL in eastern Africa is currently done with a rK39-antigen-based rapid test, which is highly specific and has a sensitivity of around 85% when used in a suspected case who meets the clinical case definition.

4. Strategies

4.1 Early diagnosis and complete case management

Diagnosis of VL in eastern Africa is currently done with a rK39-antigen-based rapid test, which is highly specific and has a sensitivity of around 85% when used in a suspected case who meets the clinical case definition (a history of prolonged fever (≥ 2 weeks) with splenomegaly and/or lymphadenopathy and/or weight loss) in a person who lives in, or has a travel history to, a VL-endemic area. This test can detect the majority of patients, but the diagnostic algorithm includes the following additional diagnostic tests: detection of amastigotes in stained smears from lymph node punctures, bone marrow or spleen aspirates and the direct agglutination test, which is available in a limited number of VL diagnostic centres and should be scaled up to selected centres. The positivity rate of serological tests in HIV-*Leishmania* coinfection is very poor. However, the parasitological tests have a better yield in those patients due to high parasitic load related to severe immune suppression. Diagnosis of such VL is complex and needs well-equipped laboratories. The COVID-19 pandemic has enabled the availability of the use of molecular methods at the district level. These methods can be explored for use in VL diagnosis, which can limit the requirements for tissue aspirates for parasitological diagnosis.

The first-line treatment consists of a 17-day combination regimen of antimonials (sodium stibogluconate, SSG) and paromomycin. Given the potential toxicity of SSG, the regimen is not suitable for all patients. Pregnant women, severely ill patients or those aged older than 45 years are treated with multiple-dose liposomal amphotericin B. Cure rates are generally high, but HIV and TB coinfections cause high relapse and mortality rates. HIV-coinfected patients are treated with a combination of liposomal amphotericin B and miltefosine. PKDL generally is mild and self-limiting and remains untreated, although in chronic (> 6 months duration) and severe cases, treatment is necessary. Diagnosis and treatment of VL should be based on approved updated national guidelines and WHO recommendations. Treatment of VL is complex and must be given in a hospital or well-equipped health centre.

New treatments are under development: a clinical trial of a 14-day treatment with paromomycin and miltefosine also showed good efficacy and safety, with a lower risk of PKDL development, and this treatment can become part of the treatment algorithm. It is not suitable for women of childbearing age, unless they use contraception during and after treatment. There are new compounds under development by DNDi and an oral form of liposomal amphotericin B developed by the University of British Columbia (Vancouver, Canada) that show promise as oral treatments of short duration. For PKDL, a phase II trial of paromomycin and miltefosine and liposomal amphotericin B and miltefosine combinations showed good efficacy and safety.

VL treatments should be made available in all VL-endemic areas and selected non-endemic areas (for management of referred patients and those who get infected after travel to endemic areas). Diagnosis and treatment of VL should be free of charge including treatment of anaemia, malnutrition and comorbidities. Provision of reimbursement of transport cost to VL cases could be considered.

To ensure access to early diagnosis and prompt treatment, VL diagnostic and treatment services should be expanded in primary health care facilities, refugee camps, areas affected by armed conflict in VL-endemic districts and sentinel sites in order to treat VL patients identified from mobile fever clinics. Mobile fever clinics can focus on identification of multiple febrile infectious diseases. Strengthening referral linkages from VL screening sites to treatment centres is very important. Understanding the level of health care in VL treatment centres and health system strengthening is recommended.

To enable the integration of VL diagnosis and treatment at primary health-care level, the development of a highly sensitive and specific rapid test and short-course, safe and preferably oral treatments for both VL and PKDL needs to be encouraged and fast-tracked. Integrated interventions in diagnosis with other disease groups can also be explored, such as the development of a standardized approach to the diagnosis of persistent fevers in primary health-care facilities.

Measures to be taken to improve the quality of care include availability of updated guidelines, standard operating procedures, trained health-care workers, medicines, diagnostic kits and quality assurance methods. Practical training of physicians and other medical staff in VL-endemic regions and neighbouring countries is essential. A regional clinical consultation platform to provide technical advice on management of challenging VL cases could be set up.

4.2 Integrated vector management and vector surveillance

Vector-borne disease results from the interplay of the pathogen, vector, human, animal and environmental determinants. Vector-borne diseases are widespread throughout eastern Africa, and many diseases coexist in the same geographical areas. A sub-Saharan map of the global distribution of risk for major vector-borne diseases suggests co-endemicity of falciparum and vivax malaria, lymphatic filariasis, dengue, onchocerciasis, cutaneous and visceral leishmaniasis, human African trypanosomiasis and yellow fever.

IVM, is defined by WHO as a rational decision-making process to optimize use of resources for vector control (i.e. an adaptive management approach for controlling vector-borne diseases). More specifically, IVM is the control of one or more vector-borne diseases (where diseases are coendemic) using multiple interventions, either chemical or non-chemical, or both selected based on good evidence. IVM also incorporates interventions, actors and, potentially, resources, coordinated between the health and other sectors, including communities, the private sector and non-health sectors such as agriculture and housing. Thus, IVM differs from routine vector control, which has been historically heavily reliant on insecticides, is largely vertical, single disease and intervention-focused campaign-based and runs solely through the health sector.

The aim of the IVM approach is to help control and eliminate vector-borne diseases by making vector control more efficient, cost-effective, ecologically sound and sustainable. IVM increases the effectiveness of vector control by encouraging the use of local evidence to select and target vector control by integrating interventions, where appropriate, and collaborating within the health sector and with other sectors. Given their many advantages, mentioned above, IVM programmes face serious challenges of accommodating for variations in distribution, seasonality and bionomics of different disease vectors. Effective control of VL vectors should be based on IVM principles after adjustments for species' characteristics.

The transmission of VL in the nine high-burden countries of eastern Africa (Chad, Djibouti, Eritrea, Ethiopia, Kenya, Somalia, South Sudan, Sudan and Uganda) involves three main vectors and occurs in two distinct ecological settings: the *Acacia-Balanites* savannah regions in the north, where *Ph. orientalis* is the major vector; and the savannah and forest areas in the south, where *Ph. Martini* and *Ph. celiae* are found in association with *Macrotermes* termite mounds. Vectors in Somalia and Uganda have not yet been incriminated, although limited studies suggest that *Ph. martini* is responsible for *L. donovani* transmission in the endemic foci of these countries. The potential non-human sylvatic reservoir hosts have not yet been fully identified.

Vectors in eastern Africa are predominantly exophilic/exophagic, and seasonality is governed by changes in the ambient temperature, relative humidity and rainfall. *Ph. orientalis* in Ethiopia, South Sudan and Sudan is mainly abundant during the second half of the dry season and the early rainy season (March–June). *Phlebotomus orientalis* in northern Kenya is also abundant during the late dry season, whereas *Ph. martini* shows higher abundance during the rainy season. The sylvatic/peridomestic behaviour of the adult vectors limits the use of vector control options of indoor spraying of residual insecticides, and data – though limited on resting and breeding sites – precludes attacking the adults and/or immature stages at outdoor sites.

In areas where insecticide-treated bed nets (ITNs) have been distributed through malaria control programmes, it is observed that the majority of householders tend not to use ITNs in the sand fly biting season (March–June) because of the intense heat, when they usually sleep outside. However, previous mass distribution of insecticide-treated sandfly-proof bed nets in Gedaref State, eastern Sudan, resulted in a significant reduction in the incidence of VL. Seasonal migrant agricultural workers and migrant populations, in general, do not use bed nets. Despite these limitations, ITN use remains as a strong evidence-based IVM measure for reducing transmission of both sandfly and mosquito-borne pathogens. Provided that adjustments are made to increase their efficacy against sandflies, and community mobilization to increase compliance is intensified, long-lasting insecticidal nets can be a fundamental IVM intervention measure against VL. As indoor residual spraying is not an appropriate intervention for exophilic species, the use of targeted outdoor residual spraying of houses and village boundary fencing has been explored in a pilot study in Sudan against *Ph. orientalis*, with highly promising success.

This approach is based on strong evidence that fences used to provide privacy for houses in Sudan act as a sandfly barrier that reduces the numbers of *Ph. orientalis* reaching the courtyards, where people usually sleep during the VL transmission season (24). Spraying of these fences profoundly reduces vector density, both at courtyards (referred to as outdoor sites) and the immediate peri-domestic surroundings. The approach can also be potentially used for the seasonal farms in northern West Ethiopia by building and spraying fences around the shelters that are

provided for night sleep of agricultural workers. The spraying of fences and screening of the shelters should be evaluated further as a control strategy. Research should also evaluate the effects of creating sandfly buffer zones for seasonal workers.

In the southern foci of VL, previous work suggested that transmission can be reduced through health education and behavioural change, so that people keep sufficient distance from the vicinities of termite mounds, where exposure to the bites of *Ph. martini* and *Ph. celiae* takes place. IVM programmes can strengthen this intervention measure by dedicated risk-mapping and behavioural epidemiology studies. Studies should examine the population structure of sandflies and their distance of flight. Risk communication and community engagement will play a profound role in reducing exposure to the infection.

Exposure to the bites of the vector can also be reduced through use of repellents and other personal protection measures. Additionally, insecticide treatment of animals and attractive toxic sugar-baited stations are potential intervention measures that should be subjected to validation studies both in the southern and the northern VL foci.

Effective VL control relies on precise knowledge of the spatial and temporal distribution of the vectors of diseases. There is a need to develop proper VL vector surveillance programmes that rely on high-resolution maps. This surveillance should be integrated with other vector surveillance programmes by personnel with strengths in sampling and identification of sandflies, mosquitoes and other disease vectors. To provide a cost-effective, sustainable integrated vector surveillance system, the same personnel should be responsible for recording abundance of different vectors throughout the year. Operational research is needed to identify correct sentinel sites for different vectors of diseases. Current sentinel sites are biased for mosquitoes and are not designed for collection of VL vectors. Proper sandfly sentinel sites should be based in locations with active VL transmission and on predictive ecological features. For the purpose of the VL elimination programmes, the sentinel sites should be expanded to provide wider coverage for evaluation of intervention tools and prediction of disease burden.

4.3 Effective disease surveillance through case detection

The key to the VL elimination strategy is to improve case detection and reduce morbidity, case fatality and transmission by reducing the period of time between the onset of first symptoms and treatment. In most countries of eastern Africa, diagnosis and treatment are provided only in a limited number of government hospitals or advanced health centres in remote endemic areas, where health systems are often poorly developed and under-resourced and have little capacity to integrate the complex diagnostic and treatment services for VL. Improved case detection will require diagnosis and treatment provision to be decentralized, but opportunities for this with current tools are limited. However, diagnosis can be decentralized to an extent by introducing rapid tests in selected primary health-care facilities, with careful orientation, instructions and follow up to avoid their overuse.

Case detection can be improved by:

- increasing awareness among front-line health care providers in endemic areas to enable them to refer suspected cases;
- developing standard operating procedures for active case detection in order to identify and refer suspected cases to primary health facilities for diagnosis and treatment;
- extending the number of treatment facilities based on case distribution mapping;
- introducing the rapid test and a referral system of confirmed cases at selected primary health-care facilities and outreach clinics;
- initiating behavioural change communication for affected populations on the importance of promptly seeking diagnosis and treatment for VL;
- involving basic health-care workers in case detection, as was done in Ethiopia where VL was included in the manual for health extension workers who were provided with job aids which included VL treatment centre locations and clinical case definition;
- motivating and training health volunteers or village health workers who detect suspected and confirmed cases of VL (and VL comorbidities) as well as PKDL;
- providing free diagnosis and treatment services for VL (and VL comorbidities) as well as for PKDL patients to cover the costs related to hospital beds, laboratory investigations, meals, and managing malnutrition and other concomitant infections;
- in countries where hospitals are required to generate their revenues for operational costs, the government should provide financial support to compensate the additional costs to health facilities;
- using the Health Management Information System (HMIS) and District Health Information System (DHIS) to improve the use of data for surveillance;
- using information technology (e.g. mobile phones) for systematic follow-up of patients after treatment to identify treatment failures, PKDL and new patients;
- integrating case detection and diagnosis with other diseases, such as during mass drug administration, or with community-based health services;
- integrating leprosy programme screening with screening for PKDL, or integrating PKDL into platforms for skin-related neglected tropical diseases (skin NTDs) for the differential diagnosis of skin conditions; and
- following up all treated VL cases for at least 6 months to assess the definitive cure of VL and incidence of PKDL.

Active case detection has proven useful in outbreak settings with high numbers of cases in relatively small foci. In selected areas, integrated active case-finding with that for other diseases is recommended.

4.4 Advocacy, social mobilization and partnership-building

The population at risk for VL is among the poorest in the community and often poorly nourished with a low level of education. Access to care remains an issue in at-risk populations and other underprivileged sections of communities. Inadequate health services and poor health-seeking behaviour are major challenges in achieving elimination.

Specific affected populations in high-burden areas are:

- displaced populations living in a context of food insecurity, civil unrest, geographical remoteness and difficult terrains devoid of basic amenities (shelter, food, safe drinking-water) and access to health care (South Sudan);
- migrant labourers coming from non-endemic areas, working in large agricultural schemes where they are offered no shelter, no access to safe water and food, no transport and no access to health care (Ethiopia);
- populations living in small and remote settlements, engaged in subsistence farming (Sudan);
- (semi) nomadic tribal populations (Kenya, Uganda), with young and adult males spending a lot of time outside in proximity to vector habitats; and
- gold miners (Chad), refugees and internally displaced populations.

These populations generally live in areas with a poor socioeconomic infrastructure, in absolute poverty and have low literacy skills. For many, the rainy season causes an almost insurmountable barrier to seeking health care as transport becomes impossible or unaffordable.

Studies in Ethiopia and Sudan have shown that patients experience very significant difficulties in accessing care. The care-seeking pathway is long, and patients incur catastrophic expenses. VL generally is misdiagnosed as malaria, typhus or another bacterial disease at various health centres, before finally presenting at a secondary health facility that offers VL diagnosis and treatment. VL diagnosis and treatment is generally provided free of charge, but the patient has to pay associated costs such as bed fees and food, and for additional diagnostic procedures and medicines.

Initiating more treatment centres in the endemic areas is only part of the solution. Social mobilization strategies are necessary to help communities address the various misperceptions about VL and in negotiating their access to care. This can be addressed by intensive awareness campaigns with the involvement of communities and community leaders at all levels (youth groups, women's groups, elected leaders), health-care workers, civil societies, etc. There is a need for advocacy, communication and social mobilization through all the existing methods (banners, pamphlets, media – jingles, etc.) as per the local context and language. Opportunities should be explored to spread messages during market days, local bazaars, schools or any other mass gathering (country context as applicable).

These strategies should be developed considering the characteristics of the affected populations and be directed towards behavioural change through effective communication strategies. Social messages should be designed to fit the social characteristics of affected communities. Some considerations for behaviour change communication (BCC) are suggested below.

- Since VL disproportionately affects poor communities, BCC will require messages that resonate with people's unique lifestyles and context.
- For BCC to succeed, it is important to know the main behavioural objectives that are to be identified by the people.
- BCC messages should be clear and simple and should match the understanding of affected communities seamlessly.
- Linkages need to be established with ongoing poverty mitigation programmes and health social campaigns (e.g. sanitation, mass drug administration for important preventive chemotherapy-based NTDs, polio immunization) and other locally prevailing communicable diseases..
- Social marketing of key interventions (e.g. free treatment, referral and nutritional support).
- Public-private partnership will be needed for sustainability and impact.
- Special groups (gold miners in Chad, refugees and internally displaced populations) should be studied to understand risk factors and messages adapted accordingly.

Partnerships will be necessary at all levels (i.e. at subnational and national levels) and with international stakeholders. Some of the elimination and eradication programmes (polio, human African trypanosomiasis, lymphatic filariasis) owe their success to multi-partner leadership. Partnerships, networking and collaboration will be required with other programmes including vector-borne disease programmes (malaria and dengue) and others (e.g. HIV/AIDS, TB, and leprosy). Anaemia control, improvement in nutritional status and poverty alleviation programmes should be made partners of the VL elimination programme. Examples are: the World Food Programme to provide food rations for VL patients, and the United Nations Children's Fund (UNICEF) to enable access to ready-to-use therapeutic food (Plumpy'nut®) for treatment of moderately and severely malnourished VL patients. Within WHO, possible collaborations should be explored, such as with the Health Emergencies Programme in case of outbreaks.

Transversal partnerships with non-health departments (e.g. agriculture, education, transport, security agencies, investment office, mining) can be useful. Public-private partnerships can be made with investors (e.g. agricultural investors in Ethiopia and mining companies in Chad).

Local partnerships and collaborations can provide solutions. In Sudan, the Zakat Islamic Fund has been successfully approached to finance transport for VL patients in remote areas. In the Amhara region in Ethiopia, the regional authorities set up temporary health posts in farms where nurses were equipped with malaria and VL rapid tests, coupled with a health education campaign.

4.5 Implementation and operational research

An important pillar of the strategic plan for disease elimination is research for its implementation. "Research and innovation are fundamental enablers of programmatic progress for all NTDs" as stated in the road map (23).

Research and innovation comprise upstream basic and clinical research that will enable the development of new tools for VL elimination (e.g. new diagnostics,

treatments and/or vaccines) to downstream operational research. Along with implementation research, there is a need to make space for upstream research, given the current critical gaps in knowledge and effective tools such as the need for a diagnostic test with improved sensitivity, the need for a safe, efficacious, and a short course orally administered treatment, innovations in vector control (tools development) and prophylactic vaccines for possible use in the consolidation phase. Upstream research should be initiated and accelerated during the preparatory phase of the VL elimination programme.

This section focuses on the downstream implementation and operational research that can be deployed with the currently available tools.

Implementation research is the systematic approach to improving access to efficacious health interventions, strategies and policies through understanding and addressing barriers to effective implementation and expansion. It provides the evidence from which to develop strategies to improve access and uptake of health interventions by the populations in need and can play a critical role in improving the delivery of disease control intervention, enhancing programme performance and strengthening health systems. This type of research is driven by a range of stakeholders, such as health-care practitioners, policy-makers, researchers and community members, all working together to frame the research questions emerging from local needs in a real world context, using a range of methodologies appropriate to the question, conducting the study and implementing the results. The end goal is improved public health through the delivery of effective, efficient, safe and equitable care (25).

The VL elimination experience in the Indian subcontinent has demonstrated the value and significance of implementation research in informing strategies and ensuring effective implementation of evidence-informed policies into practice. It identified barriers and enablers, and developed and tested innovative best practices, continually seeking solutions to challenges that emerged under the changing epidemiological situations in endemic areas and their surroundings, including those resulting from progress in elimination. Implementation research developed and validated cost-effective interventions and strategies while promoting country empowerment and research capacity strengthening through the training of in-country investigators. It relied on building local, regional and global partnerships and ensuring close interaction and interdependence of implementation research with technical advice (Regional Technical Advisory Group, RTAG), and policy (VL Elimination Programme). The RTAG endorsed research priorities, which were proposed and implemented by national programmes and stakeholders (e.g. World Bank, SPEAK India, KalaCORE, ASCEND (Accelerating Sustainable Control and Elimination of Neglected Tropical Diseases), WHO/TDR). Coordination among all stakeholders, including implementers, research organizations and donors, was key for a successful programme.

The model followed in South-East Asia involved research priorities that were defined based on gaps identified by the national control programmes and stakeholders. These were presented and endorsed by the RTAG. The list of research priorities was used as a reference for the purposes of fundraising and donor funding allocation.

Implementation issues often arise from the contextual factors operating in a given setting. Understanding the real-world driving factors and how these affect implementation is crucial. While several lessons can be learnt from the experience in the Indian subcontinent, it is evident that not all are directly transferable to the eastern Africa regional focus, and context-specific optimization will be necessary where this applies.

Much research is needed to increase our knowledge on VL in eastern Africa to inform strategies and policies of the regional elimination programme. It is likely that VL control in this region will pose more challenges than in the Indian subcontinent (26) for a number of factors, including lack of a highly sensitive rapid test for VL diagnosis, a complex treatment regimen requiring well-equipped health facilities, difficulties with vector control, remoteness and broad distribution of affected populations suffering from conflicts, poverty and comorbidities, and underfunded national programmes.

Research and development should alongside address the limitations of the currently available tools, such as the development of new point-of-care diagnostic tests and test of cure; and new oral safe treatments that can be deployed at health centres, close to the communities.

Investment in implementation and operational research is a critical initial step for a regional elimination programme (26). Both are needed to improve VL and PKDL case detection and surveillance, treatment, referral and follow-up, pharmacovigilance and vector management, and for better community mobilization and partnerships.

Some of the priority evidence gaps and research needs may include the following.

Early diagnosis and treatment: case management

- Explore the barriers and opportunities to accessing health services among specific groups of individuals who may fall outside of the health system (internally displaced persons, refugees, migrants); this is critical to inform strong policy recommendations.
- Develop new rapid tests, ideally affordable antigen-based tests, that can be used for diagnosis and test of cure for VL and PKDL; the rk39 rapid diagnostic test has less sensitivity in Africa (85%) than in Asia (95%).
- Devise new treatments, ideally oral, safe, efficacious therapies that can be implemented in health centres, close to the communities.
- Urge policy uptake of proven regimens by strengthening regulatory systems to facilitate rapid introduction of scientific advances into practice (e.g. paromomycin and miltefosine for selected eligible patients and for HIV-VL treatment).
- Implement pharmacovigilance and resistance monitoring surveillance in the region.

Vector surveillance and integrated vector management

- Identify effective, innovative and acceptable vector control measures.
- Conduct operational research to identify correct sentinel sites for different vectors of diseases.
- Develop and test a monitoring and evaluation toolkit for vector control.
- Although the infectivity of PKDL and VL patients has been demonstrated in the Indian subcontinent, no such studies have yet been reported from eastern Africa. Similarly, more studies are needed on HIV-VL coinfecting patients. Possible zoonotic reservoirs need to be explored.
- Environmental risk factors such as the presence of acacia trees and termite hills as well as black cotton soils are also associated with a higher risk of VL.

The marked exophagic and exophilic behaviours of *Ph. orientalis* represent a profound challenge for VL control. The other two main sandfly species, *Ph. celiae* and *Ph. martini*, have not been studied. In addition, the availability and accessibility of preventive measures against sandfly bites for seasonal migrant workers, nomadic populations and those in refugee camps, and their knowledge, attitude and practices towards such measures, as well as a feasibility study on creating better access to them, should be encouraged.

- Build capacity to address provision of facilities for vector identification, insecticide resistance monitoring, and training of personnel on VL vectors surveillance and control.
- Identify and map vectors (in Chad, Eritrea, Somalia, South Sudan and Uganda) and explore the preference and use of the types of ITNs and other vector control measures.
- Conduct systematic reviews of VL research (including unpublished research) from African research institutions.

Effective disease surveillance

- Epidemiological baseline data per country: incidence per age groups is partially known, mortality is unknown, and underreporting is not known either due to access difficulties; the time between onset of symptoms and treatment is another indicator deeply needed before implementing a control/elimination programme.
- Risk mapping: in order to prevent outbreaks, the establishment of sentinel sites and the understanding of areas of risk is very important. Risk maps have been developed for visceral and cutaneous leishmaniasis in Ethiopia, but they still require validation in terms of skin test studies and sandfly presence. There is no similar exercise in other countries in eastern Africa.
- Strengthening surveillance: is critical to improving early detection of outbreaks, which must then be addressed by rapid epidemiologic assessments. Incorporating VL in the national Integrated Disease Surveillance and Response (IDSR) or Early Warning, Alert and Response (EWARN) system so that it triggers early detection of an impending outbreak. Operational research should solve barriers to effective reporting and the appropriate use of recording and reporting forms with standard indicators.
- Cost-effectiveness of different active case detection methods in the different settings (e.g. endemicity levels) should be explored.

Social mobilization

- Develop and test tools for impact on improving the treatment-seeking behaviour of VL and PKDL patients (e.g. information, education, communication (IEC), social mobilization, community engagement).
- Elaborate IEC tools as research needs evolve; engage communities in research by giving their voice to the programme; consider how to enable all this through research. Community interest and knowledge, etc.

4.5.1 Research prioritization

Questions for implementation research arise from implementers on the ground and are formulated through the active engagement of disease programme staff, policy-makers, national in-country researchers and other stakeholders, including national partners, funders and community members. Prioritization is an active exercise that needs to be owned at the country level based on the local context but also considers relevant regional and international experience, guidelines and global recommendations. Programme staff and policy-makers are informed of research findings for possible potential uptake as appropriate (27). Research priorities can be revisited regularly, as part of country strategy review.

4.5.2 Challenges of implementation research in eastern Africa

Although several institutions in eastern Africa have been active in implementation research on VL and have increased knowledge in the field, there still remains a huge gap in understanding including of some basic facts such as the eco-epidemiology, the true magnitude of the burden and its geographical and socio-demographic dynamics. A major constraint is inadequate and inconsistent funding, often limited from national sources; and limited research capacity and its retention. Research is often fragmented, descriptive and not linked with national disease programmes. Platforms for national and regional collaboration of investigators have promoted relevant VL research output. These have, however, often addressed specific objectives such as clinical trials on drugs or diagnostics rather than implementation and operational research, with the objective of facilitating improved programme performance towards a defined VL control/elimination target. There is, however, some basic core competence and accumulated experience on which capacity can be strengthened rapidly provided appropriate support is made available.

4.5.3 Capacity strengthening

Strengthening capacity for implementation research may consider the following:

Mapping research capacity status

- Mapping and engagement with national in-country investigators, including programme staff at all levels, interested in VL, PKDL and NTD research and defining their relative strengths and weaknesses
- Identifying gaps in skills that may help define training needs and providing opportunities for training (including self-learning online with massive online open courses, TDR implementation research toolkit) and a career path for local researchers.

Enhancing collaboration towards a shared agenda

- Supporting mechanisms or platforms for in-country researcher–policy-maker joint meetings to encourage alignment of implementation research agendas with disease control programme priorities
- Providing access to or developing and sharing useful resources (such as generic protocols, templates, standard operating procedures and data) relevant to implementation research on VL elimination across partner countries

- Promoting linkage between graduate programmes/fellowships, internships in academic and research institutions with implementation and operational research for VL elimination programmes
- Promoting international collaboration (South–South and North–South), with emphasis on skill knowledge transfer.

Sustained funding

- Identifying resources for strengthening infrastructure and human resources
- Identifying funding opportunities for implementation research through calls for proposals
- Increasing the visibility of VL research needs in the funded national and regional research agendas
- Advocating for the long-term commitment of funders in supporting implementation research in countries of eastern African implementing the regional VL elimination programme.

4.6 Capacity-building

Capacity-building is defined as the process of developing and strengthening the skills, instincts, abilities, processes and resources that organizations and communities need to survive, adapt and thrive in a fast-changing world (28). An essential ingredient in capacity-building is transformation that is generated and sustained over time from within; transformation of this kind goes beyond performing tasks to changing mindsets and attitudes.

Within this context, to make the elimination programme successful, capacity must be built to span key areas such as organizational development and workforce development. This can include a diverse range of activities as supporting policy development, contributing to organizational planning, negotiation skills, establishing partnerships and programme management.

Identification of centres of excellence for management of patients who fail to respond to treatment and for training of health workers should be considered. The following categories of personnel working within the programme and in VL-endemic areas would be required to be trained and retrained from time to time:

- programme managers at national/state/district/subdistrict levels;
- health care providers (clinicians, pharmacists, nurses, paramedics and laboratory personnel), vector control staff, and inclusion of leishmaniasis training curriculum in medical schools;
- epidemiological/data management/statistical unit personnel (e.g. statistician and computer operator);
- supervisors at all levels;

- programme coordinators for integration and partnerships (e.g. NTDs, HIV, TB, nutrition and poverty alleviation);
- logistics and supply managers;
- health care providers and volunteers responsible for BCC to (i) promote early care seeking if VL is suspected; (ii) convince patients suffering from VL to complete treatment; and (iii) undertake advocacy with the community for participation in ensuring early case referral;
- community health workers for screening and raising awareness; and
- civil society organizations, religious leaders, community and tribal leaders.

5

Implementation phases of the elimination programme

There are four phases of the elimination programme: planning phase, attack phase, consolidation phase and maintenance phase.



5. Implementation phases of the elimination programme

There are four phases of the elimination programme: planning phase, attack phase, consolidation phase and maintenance phase. As recommended by countries in the eastern African region, the implementation of the elimination programme will be initiated by the WHO Secretariat (i.e. the African and Eastern Mediterranean regional offices and headquarters), which will lead the process of defining subregional targets and developing a strategic action framework. In parallel, political and donor support will be mobilized.

The preparatory phase begins after the strategic framework has been launched and incorporated by all the countries. During this phase, important knowledge gaps in epidemiology should be addressed, and research into better tools (prevention, diagnosis, treatment and vector control) supported and initiated where necessary. Innovative tools and interventions will be pilot tested in selected endemic areas. Once the tools are decided upon, knowledge gaps addressed and all regional targets and timelines are set, the attack phase will start, followed by a consolidation and a maintenance phase to ensure sustainable elimination.

5.1 Planning phase (1–2 years)

The planning or preparatory phase will begin within the first year of the launch and last 1–2 years.

5.1.1 Policy and strategy

The policy and strategy phase will initially focus on a review of national policies and strategic plans. Countries will need to adapt individual strategic plans and targets. Each country will develop a costed national action/operational plan for elimination of VL, which can be integrated with existing NTD guidelines and strategic master plans. Resource gaps should become clear during this phase and measures be taken for mobilization. Country strategic plans should be developed within 6 months of release of the regional strategic framework, with clear targets defined at national and subnational levels. The current country strategic plans are mainly focused on control. Country strategic plans should be revised to align with the elimination programme and set the new targets.

- (Q1) A commitment from countries for domestic fund allocation for key areas will be needed (e.g. procurement of diagnostics and the first line treatments, strengthened with resource mobilization efforts towards achieving VL elimination).
- (Q2) Setting up national task forces, the programme will be structured and organized nationally and subnationally with a clear hierarchy, flow of decisions and implementation.
- (Q2) Forming and strengthening partnerships and integrating services within (e.g. HIV/AIDS, TB, malaria, nutrition) and beyond the health sector (e.g. poverty alleviation programmes), with special emphasis on integrating vector control with other vector-borne diseases and case detection and diagnosis with other diseases.
- (Q3) A regional level multidisciplinary expert group (e.g. leishmaniasis experts, clinicians, vector control experts, disease and vector surveillance, social scientists, civil society, environmentalists, researchers, academia) should be established as a scientific advisory board. At national level, there will be national technical advisory group.
- (Q4, after Regional Office for Africa/Regional Office for the Eastern Mediterranean regional meetings with stakeholders) Advocacy plans should be developed to include mapping and mobilizing international donors and partners through various channels and forums for support. Roles and responsibilities of stakeholders are to be defined, under the leadership of the countries and the WHO regions.
- (Q4) Cross-border collaborations and agreements on common measures for elimination where applicable.
- (Q4) Collaboration of the countries for sharing data and information and harmonization of guidelines within the region.

5.1.2 Burden assessment (Q1–Q2)

A rapid VL and PKDL burden assessment will be conducted in the countries to establish disease endemicity. This should include:

- updating estimates of VL incidence, rate of under-reporting, mortality, population at risk including verbal autopsy to detect VL deaths in the community;
- mapping of endemic foci;
- developing environmental risk maps that can predict outbreaks;
- determining time between the onset of first symptoms to treatment in most affected groups and understanding barriers to access; and
- assessing existing programme capacity to implement VL elimination guidelines to address gaps in countries, as part of programme capacity assessment.

5.1.3 Establishing preconditions/defining terms of reference for initiation of attack phase (Q1)

This will include the following activities:

- recruitment and deployment of human resources for diagnosis and management of VL cases, disease surveillance and vector control, to include seeking mechanisms to cope with the high turnover of human resources;
- strengthening surveillance and reporting systems, and making VL a notifiable disease;
- deciding upon and updating guidelines and tools for case management, surveillance and vector control, and updating national protocols for VL, PKDL and *Leishmania*-HIV coinfection according to WHO guidelines;
- development of a communication strategy and materials for behavioural change;
- strengthening forecasting and secure supply of drugs and diagnostics;
- introducing incentive schemes for community volunteers;
- introducing financial support mechanisms for patients;
- devising a monitoring and evaluation plan;
- designating reference laboratories and model treatment centres (i.e. centres of excellence); and
- designing a decentralization plan based on an antigen-based diagnostic test and oral drug.

5.1.4 Research

Innovation should be focused on the development of new diagnostics; new oral, safe and efficacious treatments; and vaccines for the prevention or immunochemotherapy of VL. Given the time required to develop these new tools, research activities should be accelerated and initiated during the preparatory phase of the VL elimination programme.

Research priorities should be identified and take some important points into consideration.

- Research into innovative vector control measures, the development of new diagnostic and treatments products for case management and prevention including prophylactic vaccines, and other major gaps, should be supported and/or initiated including social science research.
- Any innovative vector control initiatives should be pilot tested and then scaled up.

- National research institutes should be encouraged to carry out implementation research to obtain better figures on burden, asymptomatic infections, spread and incidence as well as evaluation of performance of existing tools such as rapid diagnostic tests, acceptability, feasibility and uptake of new treatment recommendations.
- National research institutes should be supported to perform research that will lead to a better understanding of the eco-epidemiological factors responsible for disease transmission (reservoir, vector, climate).
- Capacity-building and financial support should be provided for Africa-based research institutions to develop/produce VL diagnostics.
- Tools/procedures/models should be developed for rapid mapping of VL.
- Operational research should be undertaken to better understand PKDL epidemiology in the region: estimation of incidence, prevalence, percentage self-healing, and risk factors associated with PKDL.
- New therapies for PKDL should be sought to treat all cases, including early cases.

5.1.5 Provisional timeline

To be achieved at the meeting following the launch of the elimination framework

- Regional strategic plan for preparatory phase; presented and discussed
- Plan by country, presented and discussed following a matrix with objectives, milestones and deliverables
- Financial aspects, national and international resources, gaps
- Agreement on programme preconditions
- Operational research prioritization (3–4 main studies)

Q1:

- Drug access plan
- Plan for burden assessment (this research will likely last up to 2 years)

Q2:

- National task forces organized and appointed
- Cross-collaboration partnerships formed in and outside the health sector
- Cross-border collaboration mechanisms

Q3:

- Financial plan by country consolidated
- Ministry of Health and Governmental statement aiming elimination at national level and regional commitment including request to the Organization of African Unity
- Vector control regional framework and strategy defined
- A regional level multidisciplinary expert group established

Q4:

- WHO African and Eastern Mediterranean regional offices – regional meetings with stakeholders
- WHO African and Eastern Mediterranean regional offices and WHO headquarters –agreement signed to ensure one single WHO voice

5.2 Attack phase (4–5 years)

The attack phase lasts 4–5 years and includes the following activities:

- Implementation of strategies to improve access to early diagnosis and treatment for VL, PKDL, and HIV-*Leishmania* coinfection
- Monitoring of treatment quality, analysis of treatment failure and pharmacovigilance
- Implementation of evidence-based integrated vector control activities
- Strengthening the surveillance system
- Early detection and rapid response to outbreaks
- Implementation of a decentralization plan
- Scaling up of the elimination programme in all endemic areas
- External country evaluation
- Functional RTAG and national technical advisory groups for reviewing the program progress and exchange information
- Periodic internal and external review of the programme
- Reporting to WHO
- Increasing research capacity and networking among research institutions through a research coordination mechanism

5.3 Consolidation phase (2–3 years)

The consolidation phase lasts 2–3 years and includes the following activities:

- Continued activities of the attack phase and strengthen activities where needed
- Identification of remote foci and vulnerable populations
- Ensuring diagnosis and treatment for VL, PKDL, and HIV/VL accessible within defined targets for all
- Early identification of minor outbreaks and rapid response
- Surveillance system fully operational
- Follow up on treated VL, PKDL, and HIV–*Leishmania* coinfecting cases
- Active case detection for VL and PKDL
- Sand fly surveillance (density, infectivity rate, insecticide resistance, etc.)
- Decentralized programme and integrated in health system international monitoring in line with WHO
- Development of a validation process for elimination

5.4 Maintenance phase

The maintenance phase is the final phase. It includes the following activities:

- National programme transferred to the health system, after training and evaluation of capacity
- Surveillance fully active and integrated into the national surveillance system
- Maintaining early case detection and rapid response
- Adoption of new treatment and diagnostic tests (at primary health centre level) and innovative vector control methods
- Political feedback, communication activities, and certification of elimination by WHO.



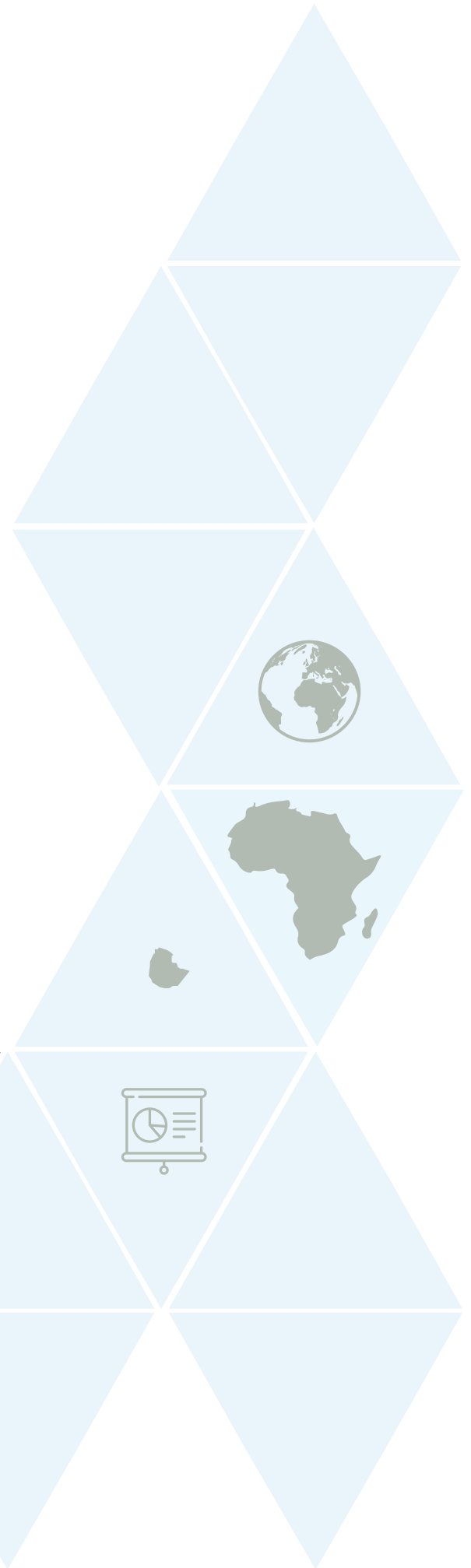
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A section of the Suam River in Kacheliba, West Pokot County, Kenya.

6

Eastern Africa subregional update on visceral leishmaniasis elimination

Contribute to improving the health status of vulnerable groups and at-risk populations living in areas endemic for VL in eastern Africa by eliminating VL as a public health problem.



6. Eastern Africa subregional update on visceral leishmaniasis elimination

6.1 The Nairobi Declaration

The Nairobi Declaration, with its call for action for intercountry cooperation, is included as a Web Annex.

6.2 The Eastern Africa subregional Technical Advisory Group

To accelerate efforts towards the elimination of VL, a Bi-Regional Technical Advisory Group (RTAG) needs to be established with the following key objectives:

1. To periodically review the progress and advise the regional directors for the African and Eastern Mediterranean regions, on policies, strategies and activities that are critical for accelerating the elimination of VL and achieving the road map targets;
2. To provide strategic directions for implementing the WHO Bi-Regional VL elimination strategy;
3. To advise on the use of appropriate and new technologies and translating evidence into policy and practice for the effective implementation of elimination;
4. To review cross-border issues and advise on corrective measures to improve case detection, treatment, cross-referrals and reporting; and
5. To advise the regional directors for the African and Eastern Mediterranean regions on research priorities for VL including operational research.

6.3 Advocacy materials

Appropriate advocacy materials will be needed with the endorsement of elimination of VL by decision-makers in the endemic countries and by the donors and stakeholders. Such advocacy materials will have to be translated into local languages adequately.

6.4 Procurement, drug quality, logistics and costs

The mainstay of VL control and elimination depends upon the availability of highly performing diagnostic tests, quality-assured effective medicines and appropriate and effective IVM supplies. While there are positive signals as all the antileishmanial medicines are included in the WHO Essential Medicines List and two serological tests – rK39-based rapid diagnostic tests and direct agglutination tests – are included in WHO's in vitro diagnostic test list, there are country-level challenges in the registration of medicines and diagnostics. Currently, there are several challenges in ensuring the seamless availability of key health products, as summarized below. Other details of discussions are given in the report of the stakeholders' meeting (7).

6.4.1 Financing

- There is a lack of sustained funding mechanisms for both domestic funds from countries and from donors.
- Currently, the first-line treatments and diagnostic tests are procured entirely from donor funds. There is no donation programme for the first-line drugs except that of liposomal amphotericin B, a second-line drug for complicated cases, which is donated through WHO.

6.4.2 Forecasting

- Lack of estimates of disease burden, frequent outbreaks, use of the same medicines in the treatment of cutaneous forms, and lack of coordination, result in a less accurate forecast or in excess orders leading to expiration.

6.4.3 Pricing, planning and procurement

- Since VL treatment regimens are eco-epidemiology specific, there is a less attractive market.
- Most of the diagnostic tests and drugs are supplied through single manufacturers.
- There are high batch sizes and minimum ordering quantities restricting availability and supplies of low volumes.
- Mismatch among production cycle, availability of funds, placement of orders and peak transmission season.
- For some drugs, lack of safety stock warehouse at the manufacturer site.
- Currently, one patient treatment is approximately US\$ 50–60. Medicine availability at affordable prices remains a challenge.
- Policy change and registration of new medicines and diagnostics
- There are no standardized specifications for the full spectrum of VL commodities and inputs (e.g. for IVM, laboratory supplies and reagents, as well as microscopes, for the management of VL).

6.4.4 Logistics and supply chain

- rK39 rapid diagnostic test and liposomal amphotericin B require cold chain maintenance.
- Supply chain challenges include delayed customs clearance at country level, poor communication and planning for last-mile delivery, stock-outs, black market (e.g. in Sudan where at the hospital there is no SSG but outside in the kiosks it can be found; this can lead to poor quality administration. Limited national capacity in procurement planning and supply management at central, regional, and local levels (i.e. the last mile).
- Minimum order quantities: small quantities demanded at country level raises need for pooling and bulk procurement (e.g. batch size for PM is approximately 70 000 ampoules but the entire region needs just about 120 000 per year; as such, each country ordering has lower demand, which can then lead to wastage).

6.4.5 Possible solutions to overcome challenges

- Overall, develop a framework encompassing short-, medium- and long-term solutions. The first step towards ensuring the availability of health products is sustainable financing. This can be achieved through the inclusion of VL elimination in national governments plans and domestic allocation of government funds and expenditure, with long-term donor commitments.
- Create a revolving fund mechanism by participating agencies and pool procurement at the global or regional level. In the long term, learn from the Strategic Fund of the Pan American Health Organization (PAHO), which ensures quality assurance and cost-saving by reducing operational/procurement costs.
- To deal with stock-outs implement, a system of reverse logistics where a site at country-level or in another country can redistribute excess stocks.
- Emergency stockpile at the global or regional level with adequate funding and expertise to maintain it. Exploring similar mechanisms of keeping buffer stocks with the suppliers.
- Accelerating the uptake of WHO guidelines at the country level.
- Tackle the black market or leakage of medicines. Strong country regulations and also creating an accountability system such as an identification system could be done (e.g. an artwork indicating source as the health ministry (as done in India). Ensuring there is enough supplies to meet demand (includes updating patients records in HMIS on time) in the health facilities could mean patients do not need to seek it outside.
- Devise a standard drug and diagnostic tests forecasting tool. This tool should factor country-specific underreporting rates, outbreaks, relapses, available shelf-life and other aspects which affect estimates.

- Integrate VL supplies into countries logistic management system to take full ownership of the clearance of the shipment, storage, and internal distribution.
- Establish a stock dashboard for better monitoring, and communication of stock status.
- Create a regional product registration system, with help from local agencies such as IGAD and the African Union.

6.5 Incorporating the leishmaniases into master NTD plans and health sector plans


Leishmaniasis-endemic countries in the WHO African Region have included NTDs and the leishmaniases in their multi-year National Health Policy documents as diseases of public health importance in line with the road map (23) and the *Framework for the integrated control, elimination and eradication of tropical and vector-borne diseases in the African Region 2022–2030* (29). This is true, especially in leishmaniasis high-burden countries (e.g. Ethiopia included NTDs/leishmaniasis in its *Health sector development programme IV* (30) and *National health equity strategic plan 2020–2025* (31); the *Kenya Strategic plan for control of leishmaniasis, 2021–2025* (32); and the *Uganda Ministry of Health Strategic Plan 2020–2025* (33). The *Third national health equity strategic plan, 2020–2025* for Ethiopia (34) states “Enhance Integrated Neglected Tropical Diseases (NTD) prevention, treatment, and case management.” The national goal of the *Strategic plan for control of leishmaniasis* is to control leishmaniasis in Kenya through comprehensive and integrated efforts by 2025 and aim to achieve a reduction in cases fatality due to VL to less than 1% by 2025 (32).

Leishmaniasis is also incorporated in the national multi-year NTD master plans for leishmaniasis in the endemic countries in the African Region, where an integrated approach (for active case detection, capacity building, disease surveillance, monitoring and evaluation, and integrated vector control) is promoted for the control of NTDs including leishmaniasis (29).



7

Activities



Develop technical guidance and provide technical support at district/ local levels,
Foster networking among institutions, and
Enhance cross-border collaboration.

7. Activities

7.1 Develop technical guidance and provide technical support at district/local levels

The district or implementation unit is the basic administrative unit of health care delivery in endemic countries. District-level management guidelines and standard operating procedures should be made available to the local implementing health workforce so that VL elimination is possible through the adoption of a decentralized integrated approach.

Remote sensing and geographical information systems

In recent times, remote sensing and geographical information systems (GIS) have demonstrated their increasing role in improving health services. For example, the GIS tool has the potential to promote equitable access to essential health services. GIS can be implemented to improve surveillance of VL in the following areas.

- 1. Mapping vulnerable populations and health-care facilities:** By identifying the locations of high-risk populations and the health-care facilities that serve them, GIS can help prioritize resources and interventions, ensuring that those most in need receive the necessary care.
- 2. Coverage Evaluation Survey (CES):** Assessing geographical access to health-care facilities through GIS data can help monitor programme effectiveness and identify areas where additional resources are needed.
- 3. Workforce distribution:** GIS can be used to analyse the distribution of health-care workers and identify areas that may require additional staffing or resources.
- 4. Emergency preparedness and response:** GIS can help identify outbreak-prone areas and support the development of emergency response plans, ensuring that resources are available when and where they are needed.
- 5. Mobile health clinics:** By identifying migratory at-risk populations, GIS can help plan and organize mobile health clinics to provide services to those who may not have access to fixed health-care facilities.
- 6. Digital microplanning for active surveillance:** GIS can be used to develop targeted surveillance strategies, focusing on high-risk areas and populations to detect and respond to potential outbreaks more effectively.
- 7. Integrated vector management planning:** By using GIS data, authorities can develop more effective vector control strategies, targeting the specific habitats and environmental conditions that contribute to the spread of VL.

8. Inventory management: GIS can be utilized to monitor the availability of essential medicines, supplies and equipment in health-care facilities, ensuring that resources are distributed effectively and that treatment is available when needed.

9. Data analysis: Integrating GIS data with other health information systems can provide valuable insights into disease trends, intervention effectiveness and resource allocation, supporting evidence-based decision-making and continuous improvement of public health programmes.

10. VL Data Portal: Building a data portal as a one-stop-shop for all information and data about VL to include all current and historical data on cases from all affected countries by year (or month) to enable authorized users to visualize the data, filter them by year or region or country/countries and perform queries. An advanced version could let them also bring in other layers such as climate, land use/land cover, topography and water bodies. Some of this information could be made available to the public, as and when determined by the NTD team.

7.2 Foster networking among institutions

The sustainability of the elimination initiative relies on continued funding support, capacity-building, translation of research into policies and practices, and coordination of activities. Networking among local institutions such as universities, departments, centres of excellence and organizations should be arranged through national mechanisms. Networking with dermatologists and clinicians experienced in management of PKDL is necessary for the confirmation and management of PKDL. Some areas of engagement for programmatic aspects include:

- epidemiological and entomological field studies;
- capacity-building;
- research and development for new diagnostics and treatments;
- quality assessment and assurance;
- communication for behavioural impact (COMBI) strategies;
- outbreak investigations;
- integration into skin NTD platform for the differential diagnosis of skin conditions;
- IR and translation of findings into programme activities; and
- cross-border assessments.

7.3 Enhance cross-border collaboration

Eastern Africa has unique features of cross-border endemicity in several highly endemic countries (Ethiopia–Sudan, Ethiopia–South Sudan, Kenya–Ethiopia, Kenya–Uganda, South Sudan–Uganda, Chad–Sudan, Ethiopia–Somalia, Eritrea–Ethiopia, Eritrea–Sudan, Sudan–South Sudan). VL patients are reported from several cross-border areas such as patients from Ethiopia, coming to refugee camps (Um Rakuba camp, Tenedba camp) in Gedaref State, Sudan just at the border with Tigray region.

MSF also sees VL patients from South Sudan in Kule Refugee Camp (Gambella, Ethiopia) and VL patients from Ethiopia in Lankien Hospital (Jonglei State, South Sudan) and Ulang Primary Health Care Centre (Upper Nile State, South Sudan).

There are also VL cases among South Sudanese refugees living in camps close to the border with Sudan (White Nile and South Kordofan).

Some identified health centres along the border areas are:

1. Ethiopia–Sudan
 1. Abdurafi health centre, Humera Kahsay Abera hospital and Metema Lutheran Hospital in Ethiopia
 2. Um Rakuba and Tenedba refugee camp, Doka VL treatment centre, Um El Kheir VL treatment centre in Sudan
2. Kenya–Uganda
 1. Kacheliba District Hospital and Sigor Sub-District Hospital in Kenya
 2. Amudat Hospital and Moroto Regional Referral Hospital in Uganda
 3. Namoruputh Health Centre (Turkana, Kenya)
3. Kenya–South Sudan
 1. Lopiding Hospital, Kakuma Mission Hospital, Kakuma Refugee Hospital, AIC Lokichoggio Health Centre (Kenya)
 2. Kapoeta Mission Hospital, Kapoeta Civil Hospital, Chukudum health centre (South Sudan)
4. Kenya–Ethiopia
 1. Moyale Sub county Referral Hospital (Marsabit) and Kaikor Subcounty Hospital (Turkana, Kenya)

5. South Sudan–Sudan
 1. Renk State hospital (South Sudan)
6. South Sudan–Ethiopia
 1. Maiwut County Hospital (South Sudan)
 2. Gambella General Hospital

There should be a way to create a platform for sharing data of imported cases between neighbouring countries. The establishment of a regional technical advisory group is essential to provide technical advice on VL diagnosis and management and ensure the seamless movement of drugs and diagnostic kits across borders. This will solve shortages of commodities in neighbouring countries thus avoiding unnecessary stockout of the supplies. Additionally, a regional clinical consultation platform can play a vital role in providing technical advice on management and challenging VL cases to clinicians.

A major limitation is the lack of full data on imported cases. Limited data on imported cases is available for Uganda (imported from Kenya) and Ethiopia (cases imported from South Sudan, reported mainly from refugee camps in Gambella); see Table 1.

Table 1. Reported numbers of imported VL cases, 2014–2022^a

| | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 |
|-----------------|------|------|------|------|------|------|------|------|------|
| Uganda | 103 | 93 | 58 | 80 | 60 | 89 | 68 | 43 | 45 |
| Ethiopia | 116 | 73 | 9 | 34 | 36 | 7 | 7 | ND | 0 |

ND: no data.

^a *Data source: WHO/Global Health Observatory (35).*


7.4 Proposed actions

The following actions are suggested in future.

1. Implement cross-border situational analysis and mapping of endemic areas vis-a-vis health facilities providing VL services.
2. Improve capacity (uninterrupted supplies of diagnostics, drugs and logistics, capacity-building of human workforce) of border area health facilities for detection and management of patients. Ensure seamless movement of drugs and diagnostic kits across borders to avoid unnecessary stockouts of supplies.
3. Ensure cross-referrals and reporting.
4. Ensure regular reporting to RTAG and bi-regional review and feedback mechanisms.
5. Convene cross-border local meetings at least once in six months as well as monthly reporting from border districts.
6. Use regular cross-border meetings, interactions and use of other fora to share information between borders. Integrate VL in the NTD cross-border fora.
7. Develop contextual IEC materials for cross-border areas for in local languages raising awareness in the population and dissemination in appropriate places.
8. Encourage cross-border collaborations and commitments from health ministries and country governments with special attention to seasonal workers, nomadic people and migrants, etc.
9. Foster communication with interdepartmental ministries such as agriculture, mining, road and transport, customs and education for better coordination.
10. Identify gaps in affected areas.
11. Engage with and sensitize health workers on VL diagnosis and treatment.
12. Train health workers in cross-border areas on the importance of reporting imported cases.
13. Identify and sensitize informal health-care providers/traditional healers for early referral to public facilities.
14. Learn from other diseases such as dracunculiasis (and its reward system).
15. Collect information on seasonal workers, nomads and migrants who cross borders.
16. Encourage use of disaggregated data for health facilities in cross-border areas.

8

Monitoring and evaluation



Monitoring is the routine tracking of a programme or project's performance.

Evaluation is the periodic assessment of the change in targeted results that can be attributed to the programme or project intervention.

8. Monitoring and evaluation

8.1 Definitions

Monitoring is the routine tracking of a programme or project's performance.

Evaluation is the periodic assessment of the change in targeted results that can be attributed to the programme or project intervention.

Indicators can be categorized according to the level at which they measure achievements: moving from input and process indicators that measure the resources and activities going into the project, through output indicators which measure knowledge gained or services provided, to outcome and impact indicators which measure changes in desired practice and ultimately health impact.

An example of a framework for monitoring and evaluation of VL elimination in eastern Africa is given below.

8.2 Impact

The road map has defined elimination of VL as a public health problem as < 1% case fatality rate due to primary VL.

8.3 Outcome

Strengthened capacity for an effective response to VL in eastern Africa.

Indicators (annually)

- Number of new VL and PKDL cases
- Time between onset of symptoms and treatment of VL
- Estimated proportions of VL, VL-HIV and PKDL cases detected, reported and managed
- VL case fatality in children

8.4 Outputs

8.4.1 Improve access to prompt diagnosis and effective treatment

Indicators

- Proportion of diagnostic and treatment centres that meet readiness and quality criteria and are accessible to the population at risk
- Proportion of estimated population covered with IEC/BCC interventions
- Proportion of health workers in endemic areas trained in diagnosis and treatment of VL and PKDL; community workers and others such as private sector providers able to recognize and diagnose VL and PKDL

8.4.2 Ensure coverage of the population at risk with suitable evidence-based vector control approaches

Indicators

- Effective, accessible, and acceptable vector control tools and methods are identified
- Vector control guidelines developed, adopted and rolled out
- Proportion of implementation units where vector control tools and methods are utilized

8.4.3 Develop capacity for data management, surveillance, monitoring and evaluation and their use to inform routine programme implementation and response to emerging outbreaks

Indicators

- Proportion of health facilities providing reports meeting required data quality standards
- Proportion of outbreaks detected and timeliness of response
- Number of health workers trained in surveillance and outbreak response

Other output indicators to be considered

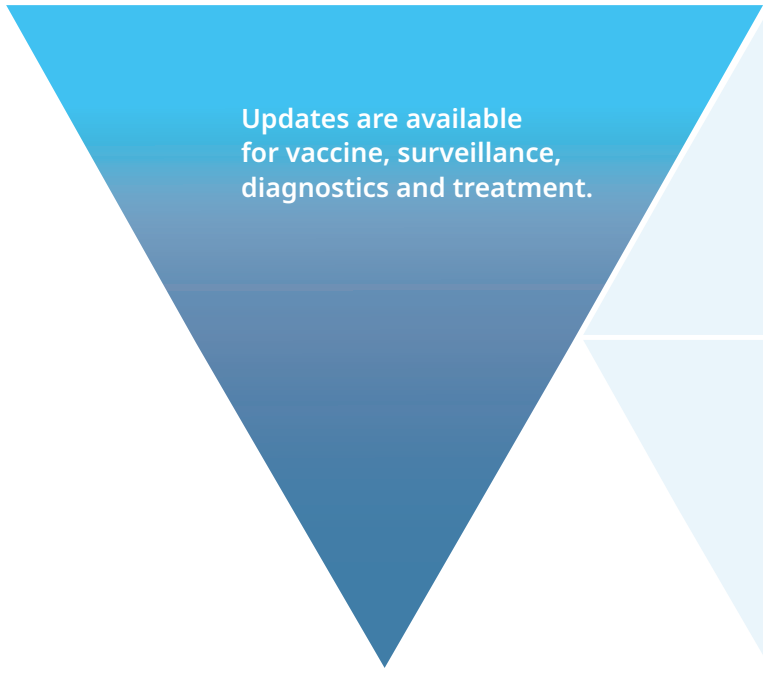

- Number of newly reported foci
- Number of private health facilities and practitioners involved in surveillance and/or VL care
- Value for money demonstrated in VL elimination (economic, efficient, effective, and equitable)
- Number of operational or implementational research studies conducted
- Number of innovative vector control methods developed and adopted
- Rolling out antileishmanial medicines in existing pharmacovigilance programme

Collecting baseline information is essential. It can provide information for the preparatory phase of the elimination programme and can be used later to evaluate progress. The following are examples of baseline data collection.

- A cross-sectional survey of VL patients treated at facilities, to understand their treatment pathway, the time between symptoms, diagnosis and treatment and barriers to access.
- Retrospective and prospective data collection at VL treatment facilities where there are known problems with recording and reporting accurate data, in order to provide a more accurate picture of the VL burden in the most endemic areas.
- Assessments of VL treatment facilities to evaluate their “readiness” to treat VL patients. Readiness can be defined as health facilities with (i) integrated VL services, (ii) where at least one member of medical and laboratory staff has been trained in the national standardized VL training in the last year, (iii) appropriate diagnostic tests and first- and second-line antileishmanial drugs are in place without stock ruptures in the past 3 months, (iv) availability of VL guidelines and standard operating procedures, (v) wards and laboratories with basic standards (physical structure and equipment to provide VL services), including safe waste disposal, (vi) a functional cold chain and (vii) existence of operational referral mechanism; nutritional support system.

9

Recent updates



Updates are available
for vaccine, surveillance,
diagnostics and treatment.



9. Recent updates

9.1 Vaccine

Currently, three vaccines – LEISH F2/F3 (HDT Bio.), LmCen-/- (Gennova Biopharma, India) and ChAd63-KH (University of York) – are at various stages in the pipeline (Fig. 1). LEISH F2/F3 is a messenger RNA-based vaccine, while LmCen-/- is live-attenuated vaccine and ChAd63-KH is based on viral vector mechanisms (Fig. 1).

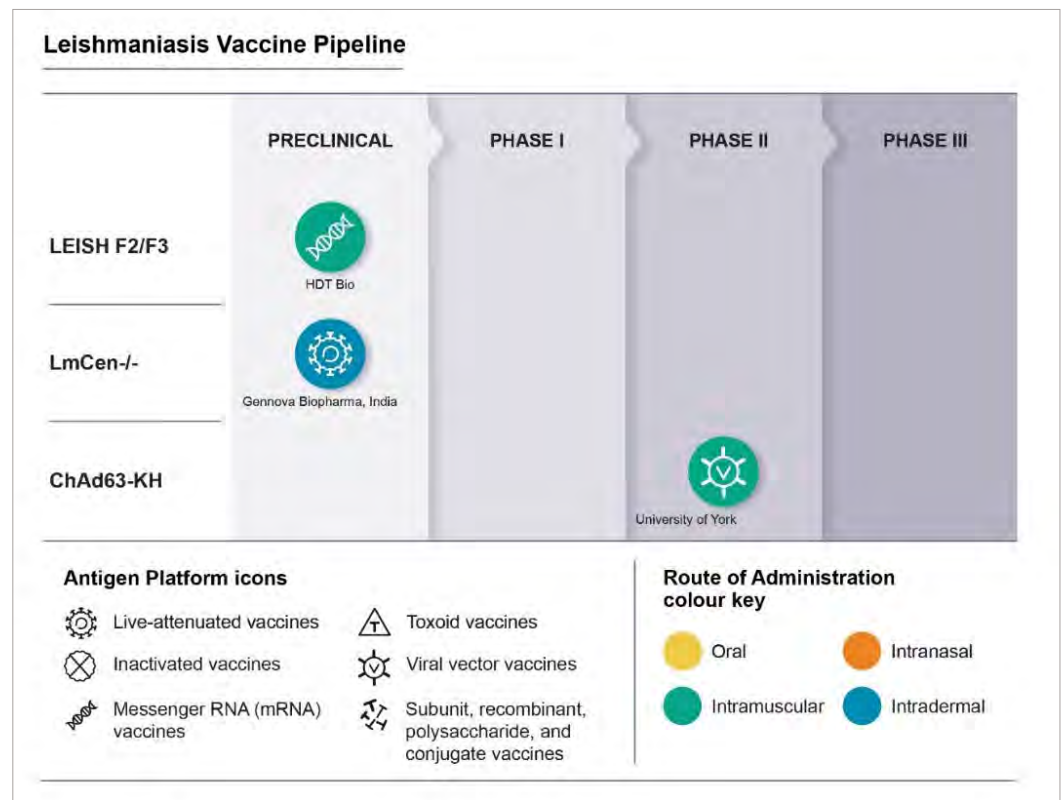


Fig. 1. Status of the leishmaniasis vaccine pipeline in 2023

9.2 Surveillance

A new updated leishmanin skin test produced from *Leishmania donovani* (in process) is expected to strengthen epidemiological studies. It is being developed by Gennova Biopharma, India.

9.3 Diagnostics

A WHO target product profile for VL diagnostics (in preparation) offers two use cases (confirm/exclude diagnosis and a test of cure). WHO will introduce expert review panel mechanisms to evaluate quality-assured diagnostics for key NTDs.

9.4 Treatment

New treatment combination trials for VL (published) and PKDL (under development) are in progress by DNDi and partners.




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Assistance to the Mursi tribe in Omo Valley affected by kala-azar by identifying cases and referring patients to the hospital. Ethiopia, February 2023.

10

Resource mobilization and sustainable financing



An evidence-based, sustainable financing strategy targeting subnational, national and international resources should be developed for the region.

10. Resource mobilization and sustainable financing

Countries of eastern Africa with limited resources will need external funding for their VL elimination programmes. An evidence-based, sustainable financing strategy targeting subnational, national and international resources should be developed for the region. An important part of this strategy is the transition from external to domestic resources in time. Partners provide catalytic support based on the commitment of governments to take over VL elimination activities within an agreed timeline. Countries are the owners and beneficiaries of their VL elimination programmes, and allocation of domestic resources and political ownership are essential for sustainable financing.

For domestic resource mobilization, costed national NTD strategies inclusive of VL elimination and analysis of current government funding and gaps are necessary. A national VL financing channel should be embedded in the national health budgeting and planning system. Planning to integrate VL services into primary health care, integrate VL vector control into IVM and procure diagnostics and medicines through the national supply chain is important. Domestic resources could be generated through building public-private partnerships, expanding the tax base for health services or creating special taxes to contribute to health budgets.

Regional resource mobilization can be supported by the African Union (AU), which could identify and support head of state NTD champions, collaborate in fundraising and hold side events at annual summits. Coordination and advocacy with AU regional economic committees and the NTD AU new frameworks documents are other opportunities. The WHO regional committees for Africa and for the Eastern Mediterranean can provide support for promoting NTDs and mobilizing domestic resources. The African Development Bank and the Islamic Development Bank are potential donors as are regional corporate and private philanthropies such as the Africa Business Forum and the African Philanthropy Forum. A coalition of VL endemic countries could be formed to champion the elimination of VL in the African continent and mobilize funding. This coalition could include endemic country governments (national and sub national, health ministries, public health institutes, finance ministries), research institutions, academic institutions, nongovernmental organizations, donors, not-for-profit organizations, the private sector, and pharmaceutical companies.

International donors that can be approached to support the elimination programme include bilateral donors, private foundations, individual philanthropists, corporate partners, United Nations agencies and WHO.

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Annex. Reported incidence of visceral leishmaniasis, 2010–2022

| Country | 2022 | 2021 | 2020 | 2019 | 2018 | 2017 | 2016 | 2015 | 2014 | 2013 | 2012 | 2011 | 2010 | Total | Average of 13 years (2010–2022) |
|--------------------|------|------|------|------|------|--------|--------|------|--------|------|--------|--------|--------|---------|---------------------------------|
| Chad | 96 | 59 | 74 | 0 | 2 | 0 | ND | ND | ND | ND | ND | ND | ND | 231 | 18 |
| Djibouti | 16 | 35 | 9 | 1 | 12 | 34 | 9 | 10 | ND | ND | ND | ND | ND | 126 | 10 |
| Eritrea | 283 | 268 | 1034 | 514 | 502 | ND | ND | ND | ND | ND | ND | ND | ND | 2601 | 200 |
| Ethiopia | 881 | 794 | 1077 | 1360 | 1828 | 1490 | 1593 | 1990 | 2705 | 1732 | 2381 | 2032 | 1936 | 21 799 | 1677 |
| Kenya | 1573 | 1746 | 1178 | 1621 | 590 | 950 | 692 | 894 | 880 | 181 | 457 | 406 | ND | 11 168 | 859 |
| Somalia | 793 | 831 | 471 | 294 | 411 | 857 | 780 | 1165 | 1045 | 936 | 394 | 290 | ND | 8267 | 636 |
| South Sudan | 1058 | 792 | 827 | 1013 | 1867 | 3567 | 4285 | 2840 | 7472 | 2364 | 4353 | 10 468 | 9166 | 50 072 | 3852 |
| Sudan | 4347 | 3323 | 2563 | 2851 | 2711 | 3894 | 3810 | 2829 | 3415 | 2389 | 5153 | 7418 | 6957 | 51 660 | 3974 |
| Uganda | 262 | 129 | 55 | 101 | 29 | 31 | 35 | 34 | 32 | 141 | 86 | 77 | 78 | 1090 | 84 |
| Total | 9309 | 7977 | 7288 | 7755 | 7952 | 10 823 | 11 204 | 9762 | 15 549 | 7743 | 12 824 | 20 691 | 18 137 | 147 014 | 11 309 |

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