

REGIONAL STRATEGIC FRAMEWORK FOR ACCELERATING AND SUSTAINING ELIMINATION OF KALA-AZAR IN THE SOUTH-EAST ASIA REGION

2022–2026



World Health
Organization
REGIONAL OFFICE FOR South-East Asia

Regional Strategic Framework for accelerating and sustaining elimination of kala-azar in the South-East Asia Region: 2022–2026
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Abbreviations and acronyms

CL	cutaneous leishmaniasis
DHS	demographic and health survey
HIV	human immunodeficiency virus
IRS	indoor residual spraying
IVM	integrated vector management
NTD	neglected tropical diseases
VL	visceral leishmaniasis
PKDL	post-kala-azar dermal leishmaniasis
RDT	rapid diagnostic tests
RTAG	Regional Technical Advisory Group
WHO-SEARO	World Health Organization Regional Office for South-East Asia

Foreword



Devastating epidemics of visceral leishmaniasis, also known as kala-azar, have been recorded in the Indian subcontinent, namely Bangladesh, India and Nepal, since the early 19th century. Sporadic cases have also been reported in Bhutan, Sri Lanka and Thailand. In 2005, the WHO South-East Asia Region accounted for 70% of the global disease burden.

In 2005, high-level political commitment from the Member States of Bangladesh, India and Nepal helped launch the Regional Kala-azar Elimination Initiative. It led to intensification of efforts in the national programmes, along with particular emphasis to strengthen regional partnerships among Member States, WHO, development partners and donor agencies. This also helped to facilitate rapid translation of research findings into policy and practice, coupled with remarkable advances in R&D for better treatment and diagnostics and interruption of transmission.

The outcome is reflected in the steady decline in the disease incidence: reported new cases of kala-azar in the Region have reduced by 95% in the last seven years and the South-East Asia Region now accounts for less than 20% of the global disease burden. About 98% of implementation units in the Region have achieved the target for elimination as a public health problem. This exemplifies the importance of political will and partnership to advance our NTD goals.

With this unprecedented achievement, the South-East Asia Region is moving into a new phase. Given the current gaps in available tools to achieve and verify interruption of transmission of kala-azar, continued efforts and vigilance will be required to sustain the gains and maintain the validation of elimination as a public health problem once achieved. The programmes will need to evolve and realign strategies towards the post-validation phase through innovation and integration for sustainability and multisectoral engagement. Investments for innovation over new tools and strengthening of primary health care need to continue.

This Regional Strategic Framework is intended to guide Member States, WHO, donors and partners on the strategic priorities to optimize, integrate and sustain kala-azar and PKDL surveillance, and complete case management and integrated vector management without losing focus for kala-azar elimination. The South-East Asia Region has a unique opportunity to demonstrate further success in the elimination of kala-azar and beyond, and fundamentally change the global NTD landscape. Commitment to eliminating the scourge of kala-azar from this Region must be reiterated and renewed. I urge all policy-makers, managers, research and implementation partners and donor agencies to work together to accelerate and sustain kala-azar elimination through implementation of this Regional Strategic Framework.

Let us together illustrate this model to successfully integrate and sustain essential public health interventions and service delivery within the primary health care and health system to achieve and sustain kala-azar elimination as a public health problem in the South-East Asia Region.

A handwritten signature in black ink, reading "P. Khetrapal".

Dr Poonam Khetrapal Singh
Regional Director
WHO South-East Asia Region

Regional Strategic Framework at a glance



Vision

A South-East (SE) Asia Region free of kala-azar.



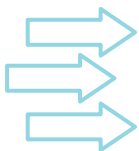
Goal

Achieve and sustain the elimination of kala-azar as a public health problem in the WHO South-East Asia Region.



Indicators and targets

- i) Annual incidence of kala-azar at the district or sub-district level in all endemic countries in the SE Asia Region: **less than one per 10 000 population**
- ii) Case-fatality rate due to primary visceral leishmaniasis (VL):^a **less than 1%**



Strategic aim and interventions

Optimize, integrate and sustain the strategic interventions towards and beyond validation of elimination of kala-azar as a public health problem:

Strategic intervention 1: Kala-azar and post-kala-azar dermal leishmaniasis (PKDL) surveillance;

Strategic intervention 2: Complete case management; and

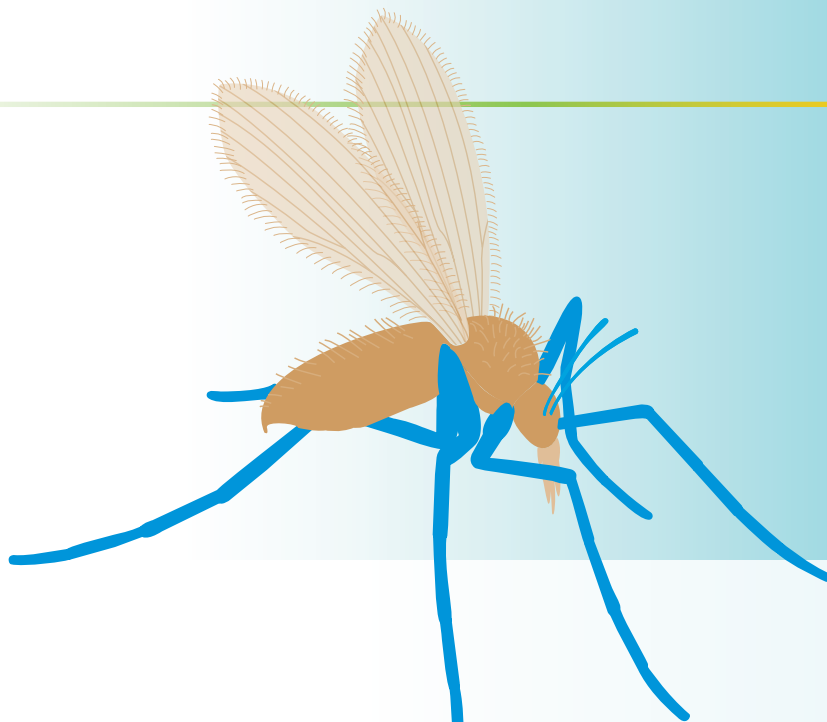
Strategic intervention 3: integrated vector management.



Supporting areas

1. Leadership, programme governance and management
2. Community awareness and engagement on prevention and care
3. Regional partnership and crossborder collaboration

Background



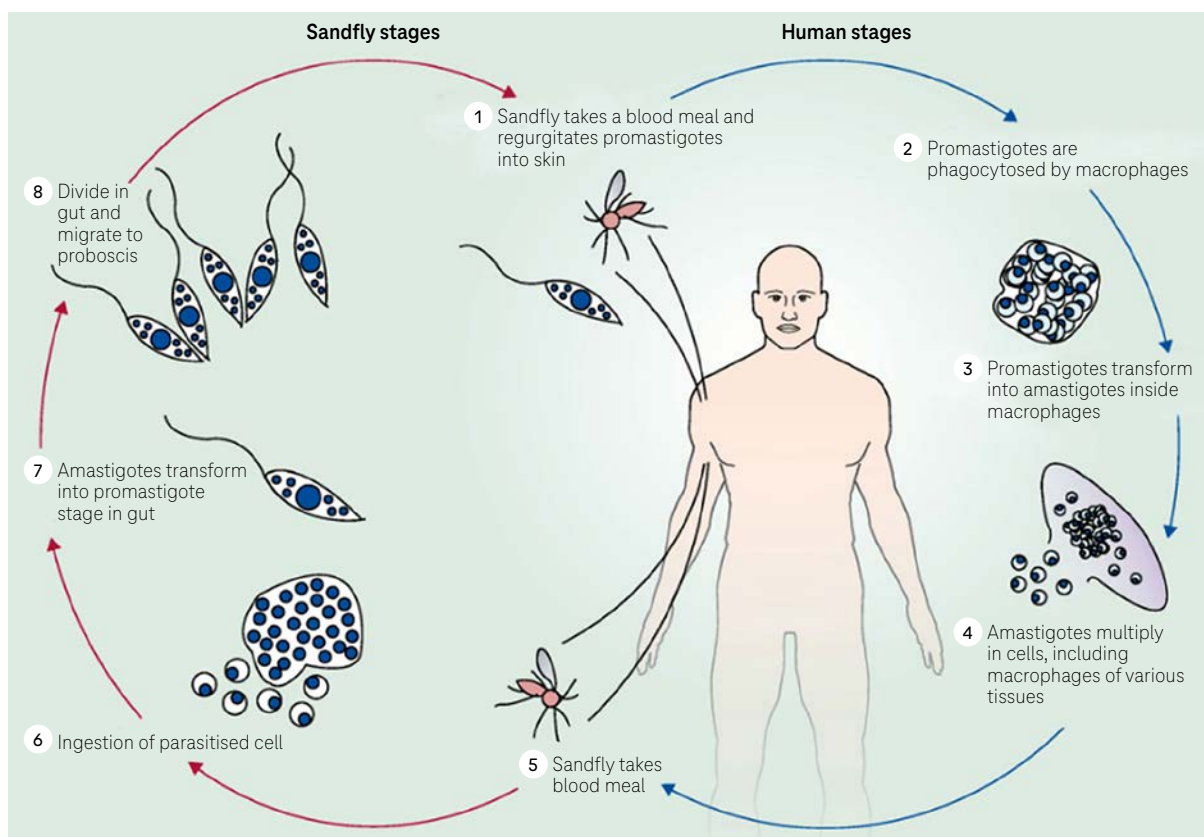
1.1 Disease

Leishmaniasis is caused by intracellular protozoan parasites, of which 20 species of *leishmania* can cause human disease. *Leishmania* parasites are transmitted through the bites of infected female phlebotomine sandflies, which feed on blood to produce eggs (Fig. 1). Globally, over 90 species of sandfly are known to transmit *leishmania* parasites while around 70 animal species, including humans, have been found as natural reservoir hosts of *leishmania* parasites.¹

The disease will develop in only a small fraction of those infected by *leishmania* parasites and the rest will remain asymptomatic. The disease occurs in three main clinical forms: (i) life-threatening visceral leishmaniasis (VL) or kala-azar with its dermal sequel, post-kala-azar dermal leishmaniasis (PKDL); (ii) self-healing or chronic cutaneous leishmaniasis (CL); and (iii) mutilating mucosal or mucocutaneous leishmaniasis.

Treatment of leishmaniasis depends on several factors, including type of disease, concomitant pathologies, parasite species and geographical location. In the South-East Asia Region, kala-azar and PKDL are the main forms of the disease; CL is endemic though.

Fig. 1. Leishmaniasis life-cycle in the context of the South-East Asia Region



Source: Burza S, Croft SL, Boelaert M. *Leishmaniasis*. *Lancet*. 2018; 392(10151): 951–970.

- Kala-azar is characterized by prolonged fever, weight loss, weakness, anaemia and hepatosplenomegaly. If untreated, the patient usually dies in about two years due to intercurrent infections.
- PKDL occurs typically within one to 10 years after apparent cure of kala-azar in up to 15% of kala-azar cases.^{2,3} PKDL has also been reported sporadically in patients, who do not have a history of kala-azar. Clinical presentation and progression of PKDL vary with geographical area. In Bangladesh, over 90% of patients have macular rash while in India, the rash is often polymorphic with a mixture of nodules, papules and macules.^{2,4}

Kala-azar and PKDL are diagnosed by combining clinical examination with parasitological, serological [such as rapid diagnostic tests (RDT)] or molecular testing. The WHO-recommended treatment regimens for kala-azar and PKDL in the Indian subcontinent, ranked by preference, are shown in Annex 1.

Kala-azar is a treatable and curable disease, which requires an immunocompetent system. Medicines will not eliminate the parasite from the body, thus the risk of relapse, if immunosuppression occurs. In absence of vaccines to prevent infection, control of the disease relies on early diagnosis and appropriate treatment of patients to contain human reservoirs for the infection, along with vector control to reduce sandfly vector density.

1.2 Regional epidemiology

In the South-East Asia Region, kala-azar is endemic in Bangladesh, India and Nepal. Sporadic cases are also reported in Bhutan, Sri Lanka and Thailand.¹ In the Indian subcontinent (Bangladesh, Bhutan, India, Nepal, Sri Lanka), kala-azar is caused by the parasite, *L. donovani*.¹ The life-cycle of leishmaniasis in the context of the South-East Asia Region is shown in Fig. 1.

In the South-East Asia Region, it is considered an anthroponotic disease without an animal reservoir as there is no direct evidence so far to prove animal reservoir for *L. donovani* transmission.⁵ Peridomestic sandfly (*Phlebotomous argentipes*) is the only known vector, which mainly breeds indoors, such as in cracks and holes of mud walls in rural houses and cattle sheds.⁶ In Sri Lanka, *L. donovani* is reported as a causative agent of both CL and kala-azar, and the Sri Lankan *L. donovani* is believed to be an attenuated strain with visceralizing potential.^{7,8}

In Thailand, autochthonous kala-azar is caused by two causative agents, *L. martiniquensis* and *L. siamensis*, but a particular species of sandfly that could serve as the vector for leishmaniasis has not yet been demonstrated.⁹

The disease typically affects the poorest and marginalized population. Major risk factors of kala-azar include poor housing and domestic sanitation conditions, such as a lack of waste management or open sewerage, which may increase breeding of sandflies and resting sites. Climate change has been implicated as one of the potential factors for the expanding endemicity of kala-azar in Nepal in recent years.¹⁰

1.3 Progress and achievements

Historically, the majority of the cases of kala-azar in the world occurred in the Indian subcontinent, comprising Bangladesh, India and Nepal. These three countries reported, on average, a total of about 42 000 cases every year between 2004 and 2008, with the highest tally being over 50 000 cases in 2007.¹¹ This accounted for 70% of the global burden of kala-azar. However, over the past 15 years, endemic countries in the South-East Asia Region have made unprecedented strides towards kala-azar elimination.

In 2004, the WHO Regional Office for South-East Asia (WHO-SEARO) constituted the Regional Technical Advisory Group (RTAG) for the kala-azar elimination programme. RTAG was tasked with advising on policies, strategies and priority activities that are crucial to elimination of kala-azar from the Region. RTAG has since served as a platform for regular dialogue involving national programmes, WHO, scientists, donors and implementing partners to identify programmatic gaps and research priorities and facilitate adoption of global and Region-specific recommendations by national programmes.

In 2005, the WHO Regional Office convened a Meeting of Partners on Tropical Diseases Targeted for Elimination/Eradiation on 17–18 November in Bangalore, India.¹² The meeting reviewed the situation of tropical diseases, including kala-azar, discussed the role of partners in joint efforts towards elimination of targeted tropical diseases and launched the Bangalore Declaration, advocating for intensive control and elimination of neglected tropical diseases (NTD).

In the same year, the Regional Kala-azar Elimination Initiative was launched wherein the governments of Bangladesh, India and Nepal signed a memorandum of understanding (MoU) to cooperate and jointly achieve regional kala-azar elimination by 2005, encouraged by a series of factors that demonstrate feasibility of eliminating kala-azar as a public health problem from the South-East Asia Region (Box 1).

The target was defined as an annual incidence of less than one case of kala-azar per 10 000 population at the district or sub-district level (upazilas in Bangladesh, blocks in India or districts in Nepal). This was further joined by Bhutan and Thailand through the renewal of the memorandum of understanding in 2014.¹³

Box 1. Factors favourable for elimination of kala-azar as a public health problem in the South-East Asia Region

- (1) Humans are considered the only reservoir of *L. donovani* in the South-East Asia Region.
- (2) *P. argentipes* is the only known vector of *L. donovani* in the South-East Asia Region.
- (3) Kala-azar is limited to confined and well-localized geographical areas in a few countries in the South-East Asia Region.
- (4) Field-friendly and high-performance diagnostic (rk39-based RDT) and safe and effective medicines and treatment options are available for kala-azar.
- (5) High-level political commitment was demonstrated through signing of the memorandum of understanding by the health ministers of endemic countries for the regional kala-azar elimination initiative.

The Regional Strategic Framework for Elimination of Kala-azar from the South-East Asia Region (2005–2015) was also launched by WHO-SEARO in 2005, with the following strategies: (i) early diagnosis and complete case management, (ii) integrated vector management and vector surveillance, (iii) effective disease surveillance through passive and active case detection, (iv) social mobilization and building partnerships, and (v) implementation and operational research.¹⁴ This was further updated for the period of 2011–2015 in 2012.¹⁵

Efforts of Member States, guided by RTAG and the Regional Strategic Framework and supported by donors and research and implementation partners, progressively strengthened the capacity and implementation of passive and active case detection, diagnosis and case management, vector surveillance and control towards elimination of kala-azar. This was made possible through (i) high-level political commitment and allocation of dedicated resources by Member States; (ii) partnership for research and innovation, which has facilitated the rapid translation of research findings into sound strategies, policies and practice; and (iii) timely donor support for improving access and delivery of essential drugs, diagnostics and public health and medical interventions.¹⁶

As a result, the number of reported kala-azar cases in the three endemic countries has declined by 96.2% from 2007 to 2021 (Fig. 2).¹⁷ By the end of 2021, 746 (99%) of 756 implementation units (IU) in the Indian subcontinent (i.e. sub-districts or upazilas in Bangladesh, blocks in India and districts in Nepal) achieved the elimination target and only 10 IUs (1%) remained above the elimination threshold (Fig. 3).¹⁷

Specifically, the elimination target for kala-azar was reportedly achieved in all endemic upazilas of Bangladesh, in 99% of the blocks in India and in 87% of the endemic districts in Nepal.¹⁷ Bangladesh has sustained the target of less than one kala-azar case per 10 000 population in all the IUs since 2017.

Fig. 2. The number of new kala-azar cases reported in the South-East Asia Region, 2005–2021¹⁷

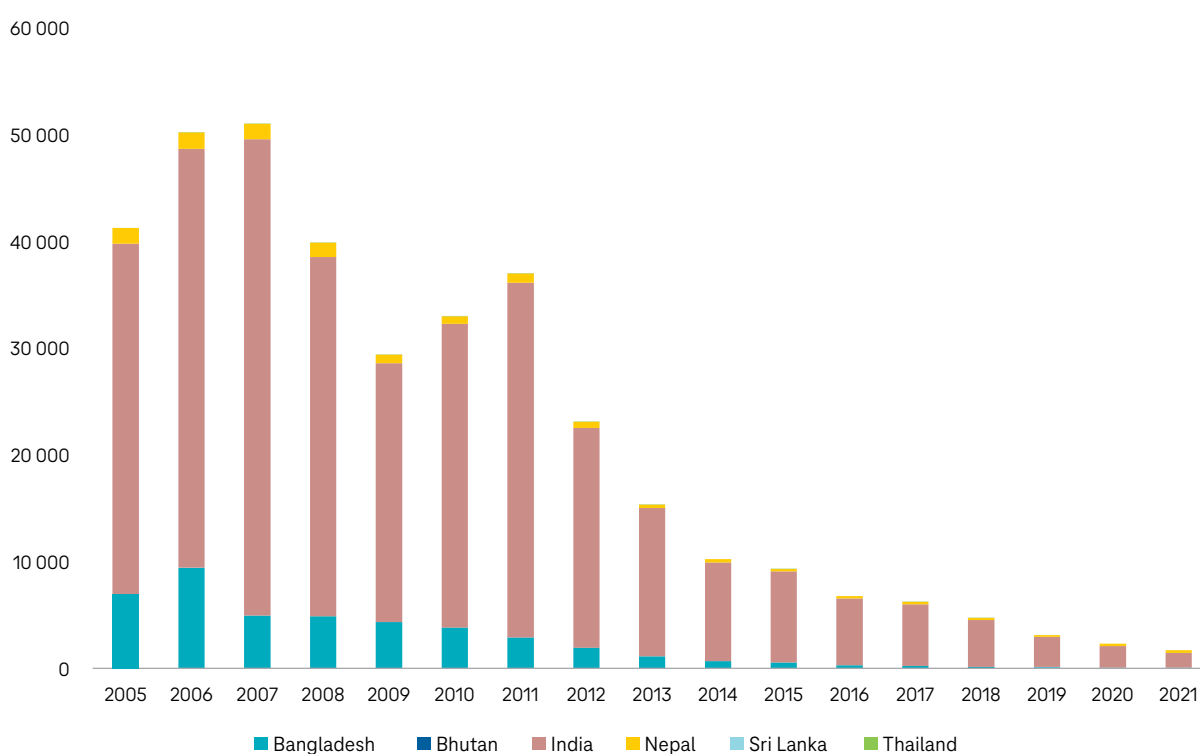
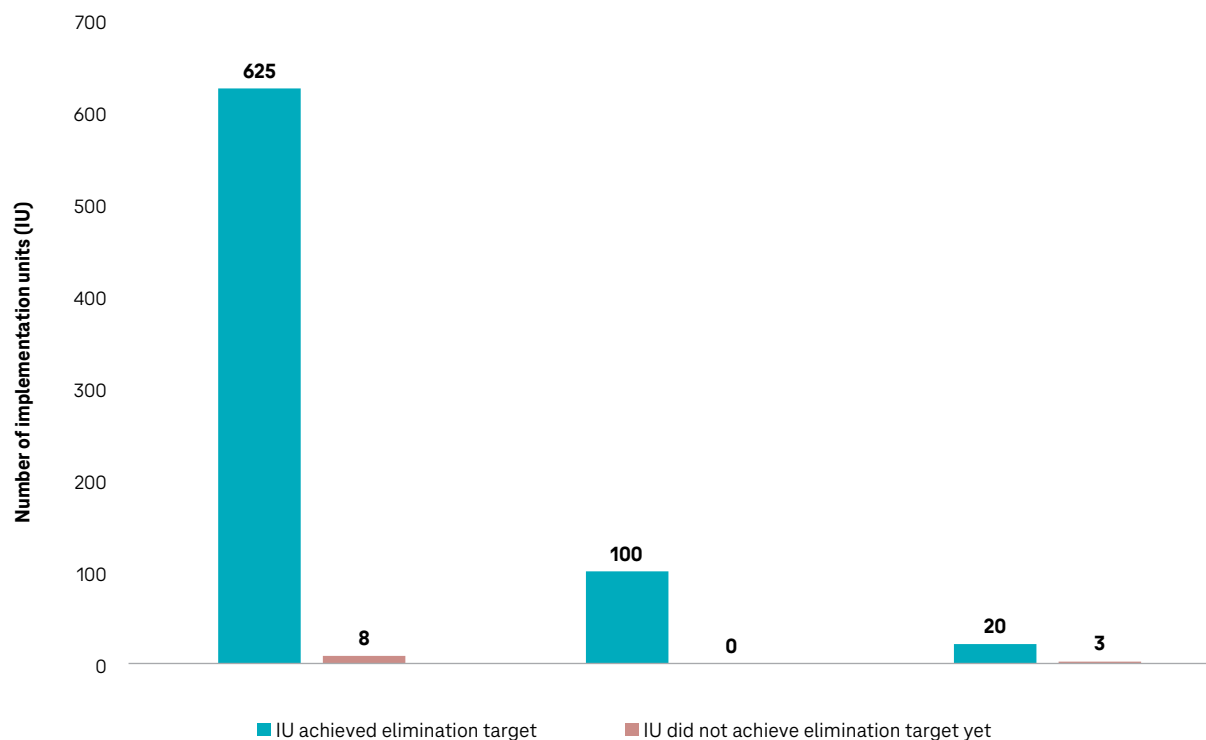


Fig. 3. Progress of kala-azar elimination from Bangladesh, India and Nepal made by implementation units, 2021¹⁷



1.4 Remaining gaps and emerging challenges

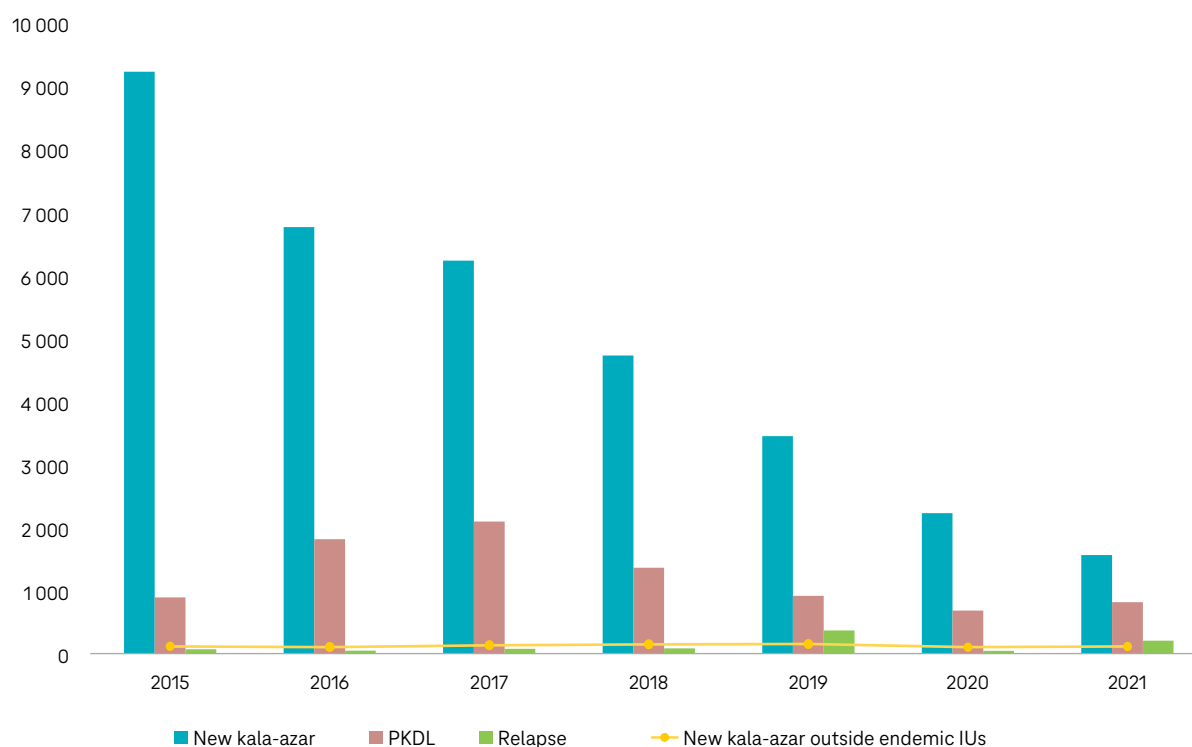
Despite substantial achievements in the Region to date, there remain a series of gaps and emerging challenges to accelerating and sustaining kala-azar elimination in the South-East Asia Region.

The currently available tools are not optimal for preventing infection and interrupting transmission of the parasite. Point-of-care rapid diagnostic tests, based on rK39 antigen (rK39 RDT), have been validated only in those with fever for two weeks or more. Importantly, rK39 RDT remains positive for several years and thus cannot differentiate between current and past infections. The test may also become inadequate in the post-validation phase as its positive predictive value may decrease rapidly when near-elimination is achieved.^{18,19}

PKDL and kala-azar-HIV co-infection cases have been recognized as important disease reservoirs of the parasite, thus likely to serve as potential reservoirs of transmission, if untreated.^{4,20,21} However, rK39 RDT has limitations in the diagnosis of PKDL and kala-azar-HIV co-infections.^{19,22,23}

PKDL cases require long treatment duration, which leads to poor treatment completion. The safety of the long duration of the current treatment has also not been studied. Diagnosis and treatment of kala-azar- HIV co-infection require specialized capacity at tertiary health-care facilities. Risk factors and appropriate treatment options for relapse are still being debated.^{24,25}

Fig. 4. The number of reported cases of kala-azar, PKDL and relapse and cases outside endemic implementation units (IUs) in the South-East Asia Region, 2015–2021



As a result, PKDL, relapse and kala-azar-HIV co-infections continue to be reported while the overall disease incidence has substantially declined (Fig. 4).

Asymptomatic infections with *L. donovani* do occur frequently, but the role of asymptomatic infections in maintaining transmission is not clear yet.^{4,26} Nonetheless, rK39 RDT also has limited use in detection of asymptomatic carriers and there are no treatments available for asymptomatic cases at present.

Integrated vector management (IVM) is one of the important elements highlighted in the regional kala-azar elimination strategies while indoor residual spraying (IRS) is the primary intervention for vector control that has been implemented. IRS is a resource-intensive exercise, which may not be sustainable in the long run, and alternative vector control tools are limited.

Despite a substantial reduction in the overall incidence in the Region, kala-azar outbreak continues to be reported from areas known to be endemic, formerly endemic and non-endemic. In Nepal, the disease endemicity is geographically expanding to the hilly and mountainous districts that were considered formerly non-endemic.¹⁰

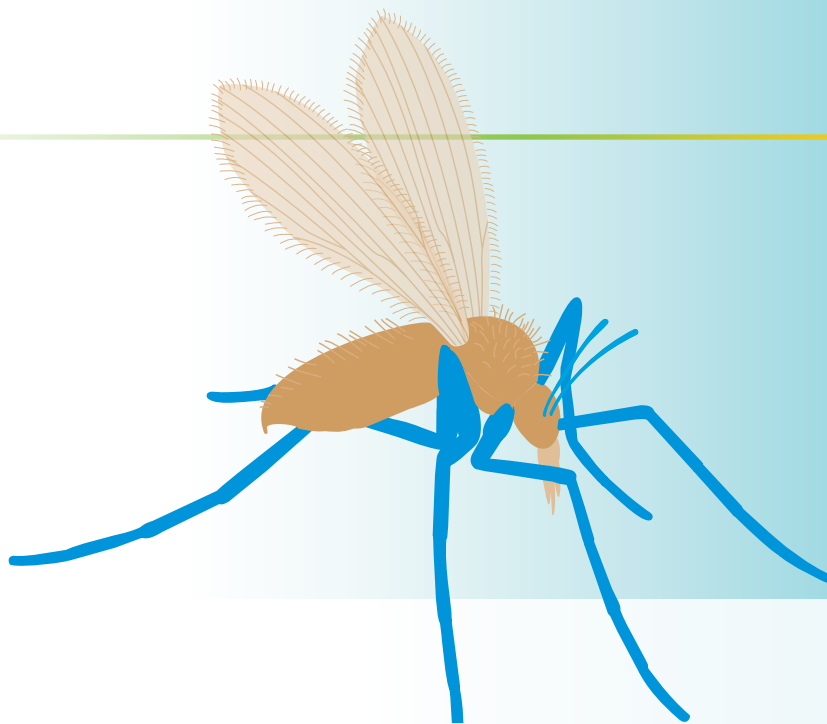
Furthermore, it has been observed that kala-azar cases in India show a temporal pattern with peaks roughly every 15 years, the cause of which has remained unknown.¹⁸ It could be attributed

to the fact that communities that had some form of herd immunity in the past may gradually become fully susceptible as the number of kala-azar cases gets reduced.

Given such gaps and challenges, continued vigilance to sustain the gains achieved through kala-azar elimination efforts, further advance the regional progress and prevent resurgence is of utmost importance. This is particularly relevant now since the COVID-19 pandemic has interrupted NTD interventions and activities, especially community outreach, such as active case detection, IRS activities and community awareness campaigns for kala-azar elimination, in the past two years.

Moreover, there is a high chance that elimination as a public health problem gets mistaken for elimination of transmission and both donor fatigue and programme complacency may shift attention and investment to the next unfinished agenda.¹² Therefore, there is a critical need to continue the investment in optimizing, integrating and strengthening surveillance, case management and vector control strategies within the primary health care and health system for sustainability, and in accelerating research and development of new tools and strategies for the post-validation phase.

Vision, goal, strategic aim, interventions and priorities



2.1 Vision

A South-East Asia Region free of kala-azar.

2.2 Goal

Achieve and sustain the elimination of kala-azar as a public health problem in the WHO South-East Asia Region.

2.3 Indicators and targets

- Annual incidence of kala-azar at the district or sub-district level in all endemic countries in the SE Asia Region: Less than one per 10 000 population
- Case-fatality rate due to primary visceral leishmaniasis:^b less than 1%

2.4 Strategic interventions and priorities

The goal of the Regional Strategic Framework will be attained through the strategic aim:

To **optimize, integrate and sustain** the three **strategic interventions** towards and beyond validation of elimination of kala-azar as a public health problem, namely:

Strategic intervention 1: kala-azar and PKDL surveillance;

Strategic intervention 2: complete case management; and

Strategic intervention 3: integrated vector management.

Implementation of the three strategic interventions is supported by the following supporting areas (Fig. 5):

Supporting area 1: leadership, programme governance and management;

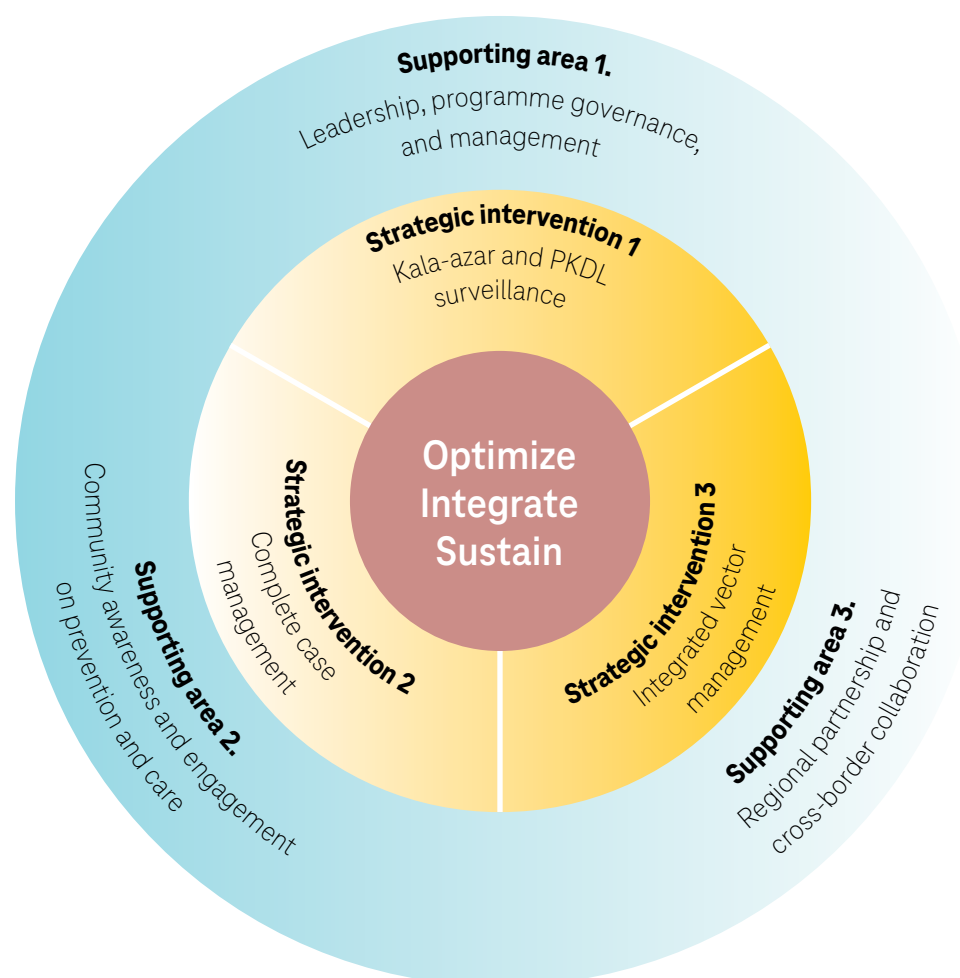
Supporting area 2: community awareness and engagement on prevention and care; and

Supporting area 3: regional partnership and cross-border collaboration.

Optimization and integration of the three strategic interventions with other diseases or public health programmes and eventually in similar functions within the health system will all contribute to strengthening and sustaining the overall health system and primary health care capacity in the context of universal health coverage, in line with the South-East Asia Regional Strategy for Primary Health Care 2022–2030.²⁷

^b Defined as an immunocompetent patient with no other concomitant condition that does not result from VL (e.g. transplantation, HIV, cancer, immunosuppressive medicines, diabetes, renal failure), as per *Ending the neglect to attain the Sustainable Development Goals: A roadmap for neglected tropical diseases 2021–2030*.

Fig. 5. Strategic aim, interventions and supporting elements to achieve the goal of the Regional Strategy of Accelerating and Sustaining Elimination of Kala-azar in the South-East Asia Region, 2022–2026



Strategic intervention 1: Kala-azar and PKDL surveillance

Epidemiological surveillance of kala-azar has improved considerably under the kala-azar elimination programmes over the past 15 years. The level of reporting has improved, providing more accurate estimates of the disease burden.¹⁸ A series of active case-detection strategies was validated for effectiveness and feasibility to complement passive surveillance and had contributed to detection of nearly 50% of the reported cases in the past decade.²⁸

However, as the disease incidence declines, awareness and knowledge of the disease too will decline among the public, clinicians and healthcare workers. The cost-effectiveness of active case detection, dedicated to kala-azar elimination, will fall. Strategies for case detection and surveillance will need to be re-designed through innovation and integration for sustainability. This will include case-based surveillance, utilizing geospatial mapping, and syndrome-based approach, such as fever surveillance and integrated skin disease surveillance (Box 2).

Population-based serosurveillance and established health demographic surveillance systems may offer a utility for integrated post-validation surveillance.^{18,29}

Cooperation with the private health sector (including local, unqualified health-care providers) as well as with skin specialists will be crucial to ensure that all patients of kala-azar and PKDL are reached. Ensuring the reach of the surveillance system not only in endemic and formerly endemic areas but also in non-endemic areas and establishing a mechanism to track and follow up on migration of cases within and between countries will also be essential, particularly in the post-validation phase, considering the spread of cases to new districts, formerly considered non-endemic, in Nepal in recent years.

Box 2. Integrated disease surveillance to sustain case detection in the post-validation phase

As the disease incidence declines, it is no longer seen as a public health priority, and hence, resource allocations are often reduced and expertise lost. Ensuring effective post-validation surveillance is a challenge that is faced by all NTD.^{29,31} At present, there is limited evidence for WHO to recommend any specific post-validation surveillance strategy. However, it is clear that post-validation surveillance will need to be country-specific and feasible to maintain government and donor commitment, and thus integrated with other existing platforms and mainstreamed in the health system functions.³²

There is an urgent need for countries, with support of research and implementation partners, to generate the evidence needed to determine feasible, cost-effective and sustainable post-validation surveillance options for NTD.

A syndrome-based approach to clinical management of fever is one example wherein patients with prolonged fever are systematically examined with rapid diagnostic tests for kala-azar and other conditions at primary health care centres.^{18,33} Another example involves the integrated skin diseases approach. Clinical presentation of PKDL is often similar to that of leprosy or other skin diseases.

In kala-azar-endemic communities that are typically poor and marginalized, multiple skin diseases are often co-endemic and have similar early manifestations. Therefore, strengthening the capacity of front-liners and health-care workers and basic dermatology of common skin diseases in an integrated manner may raise an opportunity to detect PKDL as part of routine community outreach activities.³¹

Nationally representative multiple indicator survey programmes, such as demographic and health surveys (DHS) and multiple indicator cluster surveys, may also offer a platform for active surveillance as many of them collect biomarker data.^{29,32} They already play an important role in epidemiological monitoring of infectious diseases, such as malaria and HIV, but have not been extended to include NTD.^{29,33}

Utilization of multiplex serological assays to collect data on a large number of diseases, using a single serum sample or dried blood spot, could provide new opportunities, particularly in post-validation surveillance.³³ Utility of such platforms to integrate post-validation surveillance of kala-azar should be explored as a priority operational research.

Strategic priorities

1. Reinforce implementation of **national notification** of kala-azar and PKDL through public health Acts towards and beyond validation of elimination as a public health problem.
2. Establish **indicators to monitor performance of surveillance** of kala-azar and PKDL towards and beyond validation of elimination as a public health problem and ensure continuous reporting and monitoring at all levels.
3. Establish a mechanism to ensure timely case reporting and referral of suspected cases of kala-azar and PKDL from all facilities, including the private sector, **skin clinics, dermatologists** and informal health-care providers.
4. Ensure investigation and **classification of endemicity** in all suspected areas and initiate strategic interventions in all areas, classified as newly endemic.
5. Ensure timely **availability and accessibility of rK39 RDT** through designated health-care facilities in endemic, formerly endemic and non-endemic areas, including provision of support for referral and transportation from remote communities.
6. Establish a mechanism to **track migration** of kala-azar and PKDL cases within and in between countries, and ensure complete case management.
7. Explore and operationalize **use of geospatial mapping** to optimize focalized, **case-based surveillance**.
8. Explore and operationalize **syndromic surveillance** to sustain recognition, clinical diagnosis, case management, referral, recording and reporting of kala-azar and PKDL, integrated with other diseases (Box 2).
9. Explore utility of **population-based serosurveillance and health demographic surveillance systems** as a platform for integrated surveillance to monitor the trend in infection rates and impact of kala-azar elimination in the post-validation context.

Strategic intervention 2: Complete case management

The progress towards kala-azar elimination in the South-East Asia Region has substantially benefited from rapid development, evaluation and operationalization of a series of new treatments as well as rapid diagnostic tests. With the rollout of new treatment guidelines, the health system capacity for diagnosis, confirmation and management of kala-azar and PKDL in endemic countries has been strengthened over time.

As the number of reported cases decreases and presents infrequently at health facilities, the knowledge and capacity of clinicians and healthcare workers with regard to the disease case management will also decline. This is particularly true for cases co-infected with HIV that are difficult to diagnose and treat, and coordination with HIV programmes remains poor. As stated earlier, there are also no treatment guidelines yet for relapse cases.

Due to long treatment duration and side-effects, treatment interruption is not uncommon in PKDL patients. It is, therefore, critically important to strengthen the network of designated health facilities and sustain health system capacity to effectively refer, diagnose and treat and follow up on kala-azar and PKDL, particularly relapse and kala-azar-HIV co-infection, for the post-validation phase.

Continued investment in research and development (R&D) for better point-of-care, antigen-based diagnostic tests and an effective, safe, oral therapy for patients, which can be integrated into primary health care, is needed. As R&D continues to search for alternative and better tools, monitoring of the safety and effectiveness of the current and new treatments and possible emergence of drug resistance as well as exploring and implementing combination regimens will also be of crucial importance in the post-validation phase.

Strategic priorities

1. Strengthen and **sustain the capacity** of designated tertiary or secondary-level facilities for **specialized diagnosis and treatment** of kala-azar, PKDL, relapse and HIV co-infection in all endemic countries.
2. **Reinforce referral**, confirmatory diagnosis and case management of kala-azar-**HIV co-infection, relapse and other complicated cases, such as kala-azar in pregnancy**, at specialized tertiary facilities, such as centres of excellence.
3. Ensure that all kala-azar patients are followed up on and clinically **re-assessed at least up to three years** to capture and treat the majority (>95%) of PKDL patients. Also, continue to monitor case fatality within the post-treatment follow-up period.
4. **Collaborate with HIV programmes** to ensure that all HIV patients, living in kala-azar-endemic areas, are screened for kala-azar and, similarly, all kala-azar patients, diagnosed at primary health care centres, are tested for HIV status.
5. Generate evidence and update guidance on **treatment options for relapse** cases and disseminate at all levels.
6. Integrate appropriate prevention, early management and reporting of adverse drug events, associated with kala-azar and PKDL treatments, into existing national **pharmacovigilance programmes** and make reporting of serious adverse drug reactions mandatory.

Strategic intervention 3: Integrated vector management

In the attack phase of kala-azar elimination, rigorous application of IRS in all affected areas has been implemented.^{15,16} However, such a practice is a resource- and effort-intensive undertaking, and often relies on support of partners. A general lack of entomological capacity remains a major issue not only for kala-azar elimination, but also for the overall control of vector-borne diseases across the Region. Moreover, vector surveillance and monitoring of insecticide resistance are mostly conducted by partners at limited sites, and vector control strategies, such as IRS period, are determined without considering vector surveillance data.³⁵

As the number of human cases declines, there is an increasing need to optimize efficiency and sustainability of vector control and vector surveillance through innovation and integration (Box 3), particularly with transition of ownership from partners to the government. There is an urgent need for countries, with support of research and implementation partners, to generate the evidence needed to determine an exit strategy for entomological interventions, and validate and operationalize integrated vector surveillance and control, along with other vectorborne diseases of public health importance, in local settings. At the same time, vector control and surveillance must be mainstreamed into the health system functions for sustainability.

Apart from vector control, addressing socioenvironmental determinants of kala-azar transmission, particularly housing conditions in endemic communities, to ensure control of transmission at source through comprehensive multisectoral cooperation is important in the pre and post-validation phase to sustain the impact gained to date and prevent recrudescence of transmission.

Box 3. Strengthening and sustaining entomological capacity for integrated surveillance and control of vectors of public health importance in the post-validation phase

Diseases transmitted by mosquitoes and other insect vectors continue to place a critical burden on the world's poor, particularly in tropical and subtropical areas, including countries of the South-East Asia Region. Nonetheless, the overall lack of entomologists in the Region has been a persistent challenge to control and elimination of many vector-borne diseases, including kala-azar. Strengthening entomological capacity in countries in a cost-effective and sustainable manner is of critical importance for the overall control of vector-borne diseases.

WHO promotes an integrated vector management (IVM), which was developed as a result of the lessons learnt from integrated pest management in agriculture. IVM is defined as “a rational decision-making process that encourages optimal use of resources for efficient, cost-effective and sustainable vector control”.³⁶ Vector control and surveillance are well suited for integrated approaches because some vectors are responsible for multiple diseases and some interventions are effective against several vectors.

Collection, detection, control and monitoring of multiple vectors and public awareness of multiple vector-borne diseases in view of the overlapping geographical distribution of multiple vector-borne diseases will help enhance the cost-effectiveness and sustainability of otherwise vertical vector control activities.

With the support of WHO, the Department of Health Services in Nepal organized an integrated field entomology training for control of vectors of public health importance in the country in July 2022. The training covered *aedes*, *anopheles*, *culex* and *mansonias* mosquitoes and sandflies and aimed to orient sub-national malaria inspectors, vector control offices, laboratory staff and health assistants to the basics of identification, collection and control of different vectors as well as to vector surveillance indicators and the concept of IVM.

This not only enhances strengthening of entomological capacity for multiple vector-borne diseases, but also facilitates integration of entomological activities across multiple vector-borne diseases. Given the progressive decline in the number of professional entomologists across the Region, this could be a solid example for gradually building up and sustaining the operational IVM capacity across the Region.

Strategic priorities

1. Explore and operationalize **use of geospatial mapping and modelling** to optimize focalized, case-based vector control as an exit strategy for kala-azar elimination.
2. Validate and operationalize feasible and effective approaches of **integrated vector surveillance and control** for kala-azar and other vector-borne diseases in local settings.
3. Operationalize **use of vector surveillance data** for overall vector control planning and mandate monitoring of impacts.
4. Institutionalize, strengthen and sustain **insecticide resistance monitoring** as part of the overall vector-borne diseases programme.
5. Institute **integrated vector control working group**, represented by key stakeholders at the national/state level, for regular, systemic planning and monitoring of entomological interventions for all relevant vector-borne diseases, including kala-azar.
6. Work with relevant authorities to **improve housing and sanitation**, including adaptation of screening, insecticide painting and plastering, as sustainable solutions for vector control.

2.5 Supporting areas

Supporting area 1: Leadership, programme governance and management

In the absence of adequate tools to achieve and verify interruption of transmission of kala-azar at present, continued actions are required to sustain the gains or to advance towards the interruption of transmission in countries even after achieving validation of elimination as a public health problem. In countries reporting only sporadic kala-azar cases, kala-azar elimination is of low priority in the national health agenda and domestic resources are yet to be mobilized.

Accelerating and sustaining kala-azar elimination through implementation of the Regional Strategic Framework requires sustained governance mechanisms through strategic policy frameworks, effective oversight mechanisms, regulation, collaboration with stakeholders, including the private and other sectors and appropriate workforce and financing at all levels. This in turn contributes to building strong and resilient health systems with robust primary health care in endemic countries that can provide effective, safe, good-quality, personal and population-based health services to those who need them and when they need them.

Strategic priorities

1. Develop or update the national strategic plan for accelerating and sustaining kala-azar elimination, with a clear division and linkage of responsibilities between different authorities and strategic direction towards optimization, integration and strengthening of the primary health care and health system.
2. Sustain a national task force at the central level to oversee the progress of elimination, coordinate with the authorities, national programmes and partners relevant to kala-azar elimination and guide strategic actions and sustain collaboration.

3. Ensure allocation of sufficient domestic funds for uninterrupted supply of quality-assured commodities and implementation of the regional and national strategic plans to accelerate and sustain kala-azar elimination.
4. Move towards integration of kala-azar elimination programme review with other programme reviews at all administrative levels for sustainability.

Supporting area 2: Community awareness and engagement on prevention and care

Effective surveillance relies on health-seeking behaviours of patients to reach out to appropriate health facilities and self-report their symptoms. Similarly, effective vector control interventions, such as community-accepted IRS application and improvement of housing conditions, require adequate health literacy, awareness and knowledge of villagers at risk with regard to the disease transmission and how to prevent the disease. Regular social and community sensitization and mobilization are particularly important in pre- and post-validation phase, when the number of cases gets significantly reduced and the general awareness of the disease declines.

As community awareness and participation are the most important prerequisites for the success of any disease elimination and control programme, community outreach and health promotion activities for kala-azar and PKDL should be integrated and coordinated with similar efforts for other diseases for better visibility, community acceptance and cost-effectiveness.

Furthermore, kala-azar is a disease of poverty. Improved housing, nutrition and targeted communications with such communities to address the social determinants of continuing kala-azar transmission are required to sustain the impacts of public health interventions in the long run.

Strategic priorities

1. Collaborate with other public health programmes, engaging communities, and sustain regular social and community awareness campaigns on kala-azar and PKDL, integrated with other diseases, for maximum benefits of community engagement in endemic areas, formerly endemic areas and non-endemic areas.
2. Help high-risk communities to explore options to improve housing (seal cracks, plaster internal walls, stop sleeping on the floor) in collaboration with other relevant programmes and schemes.

Supporting area 3: Regional partnership and cross-border collaboration

High-level political commitment and momentum of Member States are of utmost importance to achieve and sustain kala-azar elimination so that while interventions are progressively integrated with the health system, tracking the progress of kala-azar elimination remains focused. At the same time, countries alone cannot achieve all – continued commitment of resources from countries and partners is essential, particularly in the last mile of disease elimination.

Regional partnership of Member States, WHO, researchers, partners and donors will continue to advocate for high-level commitments and allocation of adequate resources at all levels, particularly towards progressive transition from partner reliance to country ownership. It will continue to offer a mechanism to share knowledge and coordinate efforts to tackle common cross-border challenges (Annex 2).

It will also foster continuous innovation through regular dialogue to understand programmatic gaps and identify innovative solutions towards and beyond validation of elimination as a public health problem. The current knowledge and tool gaps, which are considered the R&D priorities for accelerating elimination of kala-azar from the South-East Asia Region, are listed in Box 4.

Strategic priorities

1. Convene RTAG meeting and programme managers meeting regularly to review progress and challenges, provide necessary technical direction and advice, cultivate the culture of information-sharing and dialogues, and keep the high momentum of Member States, experts and partners towards kala-azar elimination in the Region.
2. Convene regular high-level meetings among endemic countries to sustain political motivation for kala-azar elimination and advocate for government ownership to enhance transition from partners to national programmes.
3. Establish a mechanism for cross-border surveillance and notification of kala-azar and PKDL, standardize reporting indicators between countries and facilitate cross-border data-sharing and analysis across the Region.
4. Establish a mechanism to ensure uninterrupted supply of quality-assured medical products, including drugs, RDT and WHO insecticide susceptibility test kits, in endemic countries.
5. Establish and sustain a regional and national network of health ministries, R&D and implementation partners and donors to regularly share programmatic and knowledge gaps and research updates, mobilize resources, catalyse collaboration and accelerate innovation and research to progress towards elimination of kala-azar in the Region.

Box 4. Priority areas for operational research, R&D and innovation for accelerating and sustaining kala-azar elimination in the South-East Asia Region

Intervention and service delivery

- Mechanisms to track migration of kala-azar and PKDL cases within and in between countries and ensuring complete case management
- Geospatial mapping to optimize focalized, case-based surveillance
- Syndrome-based approach to sustain recognition, clinical diagnosis, case management, referral, recording and reporting of kala-azar and PKDL, integrated with other diseases
- Population-based serosurveillance and health demographic surveillance systems as a platform for integrated surveillance to monitor the trend in infection rates and impacts of kala-azar elimination in the post-validation context
- Feasible and effective approaches of integrated vector surveillance and control for kala-azar and other vector-borne diseases in local settings
- Cost-effective vector control tools and strategies, especially an exit strategy in the post-validation phase
- Projection and investment case for elimination of kala-azar, based on a robust mathematical modelling

Knowledge

- Role of asymptomatic infections in the transmission of *L. donovani*
- Role of non-human reservoirs in the transmission of *L. donovani*
- Mechanisms or determinants of progression to PKDL or relapse
- Vector population characteristics and behaviour, including insecticide resistance, to guide vector control activities

Diagnostics and treatments

- Diagnostic tests that enable more prompt diagnoses of kala-azar and PKDL in low-incidence and resource-limited settings (antigen- or molecular-based)
- Diagnostic tools to detect asymptomatic cases
- Better diagnostic tools for HIV co-infection
- Less invasive test of cure for kala-azar, PKDL, HIV co-infection and relapse
- Simpler confirmatory diagnostic tests for PKDL in resource-limited settings
- Tests to detect drug resistance
- Treatment regimens for relapse cases, possibly combination therapy
- Ocular disorders, associated with miltefosine use in PKDL patients
- Affordable, safe and short-course treatment for PKDL
- Effective, safe, short oral therapy that can be integrated into primary health care services
- Preventative and therapeutic candidate vaccines to prevent *leishmania* infection and disease, and vaccines to block transmission of *leishmania*

2.6 Key milestones

By 2023

- A high-level ministerial meeting among endemic countries will be convened at the regional level and the memorandum of understanding for collaboration among endemic countries for regional kala-azar elimination will be renewed.
- Standard indicators to monitor the performance of surveillance of kala-azar and PKDL are to be developed by WHO and disseminated.
- A skin-NTD training package for primary health care, including PKDL, will be developed by WHO and disseminated.
- An integrated vector management training package will be developed by WHO and disseminated.
- A mechanism for cross-border surveillance and notification of kala-azar and PKDL across the Region are to be established by WHO and relevant Member States.
- At least one endemic country is due to be validated by WHO for having achieved elimination of kala-azar as a public health problem.

By 2024

- All the endemic countries in the Region will have reinforced national notification of kala-azar and PKDL.
- All the endemic countries in the Region will have mandated screening of kala-azar for all HIV patients living in kala-azar endemic areas and HIV screening of all kala-azar patients.
- All of the endemic countries in the Region will have operationalized follow-up and clinical re-assessment of all kala-azar patients at least up to three years.
- All of the endemic countries in the Region will have established a mechanism to ensure timely case reporting and referral of suspected cases of kala-azar and PKDL from all facilities, including the private sector, skin clinics, dermatologists and informal health-care providers, through integrated PHC and health system capacity strengthening.

By 2025

- Guidance on treatment options for relapse cases will be updated by WHO and disseminated.
- All the endemic countries in the Region will have determined feasible options of integrated surveillance of kala-azar and PKDL with other diseases or platforms.
- All the endemic countries in the Region will have operationalized integrated vector surveillance and control including kala-azar.

By 2026

- All the endemic implementation units in the Region will have achieved targets for elimination of kala-azar as a public health problem.
- Progress and impacts of the Regional Strategic Framework will be assessed and updated.

2.7 Measuring progress and impacts

National kala-azar elimination programmes should determine milestones for implementation of strategic priorities, as per the Regional Strategic Framework, and be evaluated at regular intervals for compliance with the targets and objectives to be achieved. Progress of the implementation of the Regional Strategic Framework will be monitored regularly at the regional level and guided by RTAG.

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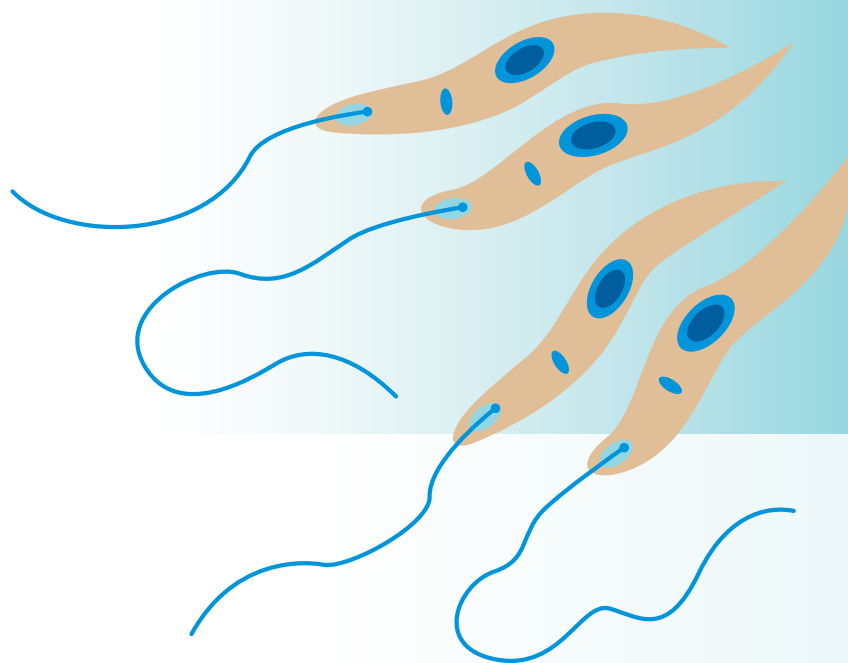
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Annexes



Annex 1. Recommended treatment regimens for kala-azar and PKDL, ranked by preference, relevant to the South-East Asia Region

Anthroponotic kala-azar caused by *L. donovani* in Bangladesh, Bhutan, India and Nepal

- (1) Liposomal amphotericin B: 3–5 mg/kg per daily dose by infusion, given over a period of 3–5 days, up to a total dose of 15 mg/kg (A) by infusion or 10 mg/kg as a single dose by infusion (A)
- (2) Combinations (co-administered) (A):
 - liposomal amphotericin B (5 mg/kg by infusion, single dose) plus miltefosine (daily for seven days, as below);
 - liposomal amphotericin B (5 mg/kg by infusion, single dose) plus paromomycin (daily for 10 days, as below); and
 - miltefosine plus paromomycin, both daily for 10 days, as below.
- (3) Amphotericin B deoxycholate: 0.75–1.0 mg/kg per day by infusion, daily or on alternate days for 15–20 doses (A)
- (4) Miltefosine: For children aged 2–11 years, 2.5 mg/kg per day; for people aged > 12 years, and <25 kg body weight, 50 mg/day; 25–50 kg body weight, 100 mg/day; >50 kg body weight, 150 mg/day; orally for 28 days (A)

or

Paromomycin: 15 mg (11 mg base) per kg body weight per day intramuscularly for 21 days (A)
- (5) Pentavalent antimonials: 20 mg Sb⁵⁺/kg per day intramuscularly or intravenously for 30 days in areas where they remain effective: Bangladesh, Nepal and the Indian states of Jharkhand, West Bengal and Uttar Pradesh (A)

Rescue treatment in case of non-response: Conventional amphotericin B deoxycholate infusions or liposomal amphotericin B at higher doses

Post-kala-azar dermal leishmaniasis in Bangladesh, India, Nepal

- (1) Amphotericin B deoxycholate: 1 mg/kg per day by infusion, up to 60–80 doses over four months (C)
- (2) Miltefosine orally for 12 weeks at dosage as above (A)

Reference: World Health Organization. Control of the leishmaniasis. Report of a meeting of the WHO Expert Committee on the control of leishmaniasis, Geneva, 22–26 March 2010. Geneva: World Health Organization. 2010.

Annex 2. Operational Framework for cross-border collaboration for elimination of kala-azar along the international border of India with Bangladesh, Bhutan and Nepal

WHO-SEARO had virtually convened the meeting on cross-border collaboration for elimination of kala-azar and malaria along the international border of India with Bangladesh, Bhutan and Nepal from 28 to 30 September 2021. The meeting was attended by kala-azar and malaria programme managers from Bangladesh, Bhutan, India and Nepal and partner agencies.

It reviewed the current situation in cross-border collaboration for elimination of kala-azar and malaria along the international border of India with Bangladesh, Bhutan and Nepal, and discussed the way forward. Overall, the participants agreed on the following action points as priorities to strengthen cross-border collaboration for elimination of kala-azar in the Indian subcontinent.

Regional level

- Facilitate signing of the cross-border collaboration MoU by the Member States.
- Define clear cross-border communication channels and lines of information relay.
- Develop SOP for cross-border surveillance and M&E.
- Establish standardized cross-border collaboration reporting system (electronic) for early and real-time data-sharing.
- Organize a regional meeting to review and discuss the situation and progress of kala-azar cross-border collaboration annually.

National level

- Enable the policy environment for the kala-azar cross-border collaboration to confirm the enactment of MoU at all administrative levels.
- Disseminate the cross-border collaboration MoU and operational framework to all premier institutions.
- Modify national data management systems to capture cross-border data.
- Conduct district-to-district coordination meetings regularly for joint review, planning and action.
- Ensure universal access to quality-assured diagnosis, treatment, referral, follow-up and prevention services to all kala-azar and PKDL cases at points of entry and bordering areas.

Local level

- Carry out situation analysis and epidemiological assessment of each border district within national boundaries and update periodically.
- Update/develop list of focal/nodal points and a local committee.
- Empower local officials for decision-making and data-/information-sharing.
- Organize appropriate outreach services at points of entry and at health facilities in the bordering areas. Engage front-line health workers, community members and civil society groups in trainings to ensure kala-azar care for all irrespective of nationality, ethnicity, gender, religion, race and caste.
- Facilitate referral of kala-azar and PKDL cases, who are crossing the international border, to ensure treatment follow-up. Organize health posts, camps and mobile clinics near international borders and at points of entry to fill gaps in service delivery or integrate detection, diagnosis, treatment and referral of kala-azar and PKDL in such existing systems.



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