Review Article

Leishmaniasis in Sri Lanka: Surmounting obstacles toward achieving elimination as a public health problem by 2028

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Abstract

In the 1990s, Sri Lanka started reporting cases of cutaneous leishmaniasis (CL), which gradually increased to the current case incidence rate of over 3000/year. The causative strain of CL is *Leishmania donovani* MON-37, which is genetically different from the visceral leishmaniasis (VL)-causing strain in Sri Lanka. Visceral and mucosal forms are rare in Sri Lanka. The potential vector is *Phlebotomus argentipes*. Due to increasing CL case numbers, the Anti-Malaria Campaign was identified as the focal point in 2022 by the Ministry of Health (MoH) to control leishmaniasis and a WHO-funded situational analysis and the first National Strategic Plan (NSP) for prevention and control of leishmaniasis in Sri Lanka 2024–2028 were developed. During the situational analysis, a comprehensive literature review, meeting the stakeholders, visiting CL endemic areas and hospitals, and a SWOT analysis were carried out. The goal of the NSP is "To control cutaneous leishmaniasis for possible elimination as a public health problem in the future and prevention of VL and MCL." The two objectives are as follows: to reduce the annual incidence of CL < 5 per 10,000 population by 2028 (approximately 6600 cases) and to ensure zero mortality due to VL. The NSP had three strategic plans and five supporting areas. Each activity was well-described, and timelines were given to complete each task. This review describes the activities carried out by the MoH, the research work conducted so far, and the key points in the NSP recommended to eliminate leishmaniasis as a public health problem from Sri Lanka by 2028.

Keywords: Elimination, history, leishmaniasis, public health problem, Sri Lanka

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INTRODUCTION

Sri Lanka is a tropical island with a land area of 65,610 km^2, situated between 5° 55′ and 9° 51′ north latitudes and between 79° 42′ and 81° 53′ east longitudes, 32 km to the south of the main land of India. The central parts of the country contain mountains. Most rainfall is received from both northeast and southwest monsoons, but inter-monsoonal rains, depressions, and convectional evening showers also contribute to rainfall. The mean annual rainfall ranges from 900 mm in the driest parts to 5000 mm in the

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wettest parts. The mean annual temperature varies from 27°C in the coastal lowlands to 16°C to the central highlands.[1]

Sri Lanka has nine provinces and 26 administrative districts. It has a population of ~ 22 million,[2] an average life expectancy of 74.2 years for males and 80.1 years for females (as of 2021),[3] a crude birth rate of 13.8 and a crude death rate of 6.0 per 1000 population (as of 2020),[4] and has a GDP per capita of US $ 3340 (as of 2022) and a − 7.8 real GDP growth (as of 2022).[2] In 2022, the country faced an unprecedented economic crisis, but has achieved some signs of recovery by now.[5]

Historically, there has been a close relationship both geographically and culturally between Sri Lanka and India, with eternal travel taking place between the two countries. In spite of having a close relationship with the Indian mainland, Sri Lanka has eliminated filariasis as a public health problem in 2015 and eliminated malaria in 2012 and has maintained zero indigenous cases of malaria since 2013.[6,7] However, among vector-borne diseases, dengue and cutaneous leishmaniasis (CL) exist as major public health problems in the country at present.[8]

HEALTH SYSTEM IN THE COUNTRY

Sri Lankan healthcare facilities comprise both public and private sectors. The public sector provides nearly 95% of inpatient care and around 50% of outpatient care. The Ministry of Health (MoH) is responsible for stewardship functions, policy formulation and health legislation, program monitoring and technical oversight, and management of health technologies and human resources in the tertiary care and other selected hospitals. The Provincial Ministries are responsible for the functioning of secondary and primary care institutions. By the year 2022, there were a total of 1500 healthcare institutes which contained 588 hospitals. There are 517 primary care institutes and 335 Medical Officer of Health offices within the country.[9]

LEISHMANIASIS

Leishmaniasis is a vector-borne neglected tropical disease complex caused by the parasite belonging to the genus *Leishmania*. The disease presents in three main clinical forms: visceral leishmaniasis (VL), the most severe form; muco-cutaneous leishmaniasis (MCL), the most mutilating form; and CL, the most common form that is typically confined to the skin and heals with a disfiguring scar. The disease is transmitted by the bite of an infected female sandfly belonging to the subfamily Phlebotominae.[10]

HISTORY OF LEISHMANIASIS IN SRI LANKA

VL

Until the recent past, it was believed that leishmaniasis is a newly emerged and established disease in Sri Lanka.[11,12] However, a recent review into Sri Lankan archives[13] revealed that leishmaniasis had been reported in Sri Lanka since 1904, the same era when the Leishmania parasite was identified by Sir William Leishman and Sri Charles Donovan and when post kala-azar dermal leishmaniasis (PKDL) and treatment for kala-azar was described by Sir U. N. Brahmachari.[14]

Case reports of VL in Sri Lanka are scarce. According to archived reports, in 1904, Dr. Aldo Castellani, a pathologist and a microbiologist and the Director of the De Soyza Bacteriological Institute of then Ceylon (re-named as the Medical Research Institute (MRI) of Sri Lanka in 1946-)[15] had described a laboratory-confirmed VL case, detecting Leishman–Donovan bodies in splenic smears stained with Romanowsky's stain in a 20-year-old diseased male, who had symptoms of pneumonia and hepatosplenomegaly.[13,16] Altogether, there had been 75 archived records in 1900, from 1910 to 1916 and from 1936 to 1938, until 1947 mentioning the term "kala-azar." Furthermore, the same authors[13] reported that in 1947, a report published by the MRI of Sri Lanka had mentioned that 21 out of 21,772 specimens were positive for kala-azar when subjected to the formol–gel test. There had been no other positive cases of kala-azar reported thereafter.[13] After these reports, the next confirmed case of VL was reported in 1973, in a British girl who had a short transit in Colombo. The location where VL was contracted was inconclusive according to this case report.[17] After a long lapse, a recent confirmed endogenous case of VL was reported in 2007[12,18] in a 36-year-old woman from the north–central province of Sri Lanka who had never been abroad. Both liver and bone marrow biopsies and rK39 rapid diagnostic test (rK39 RDT) had yielded positive results in this patient, and she had complete cure with intravenous sodium stibogluconate (SSG) 20 mg/kg/day for 28 days with no relapse or PKDL in a follow- up of 9 years.[18] In 2011, another endogenous VL case was reported from the Northern Province[19] in a 57-year-old man. A few more confirmed and suspected VL cases have also been reported.[17] However, there had been no other VL cases reported in the literature since 2017. This shows that although there had been *ad hoc* cases of endogenous VL, it has not become a public health problem in the country to date.

CL

In the historic reports (Administration Report of The Director of Medical and Sanitary Services), CL had been first mentioned in 1928.[13] From 1928 until 1938, a total of 33,414 CL cases were reported in the archived records and had strangely reported 165 deaths among them, leaving inconclusive evidence of the type of the disease and their diagnosis.[13] Since the last possible case of CL that was reported in 1938, it was only in the year 1992 that the first recent confirmed endogenous case of CL was reported from a teacher in the Southern Province of Sri Lanka.[11]

Impact of malaria control on endogenous leishmaniasis

The Anti Malaria Campaign (AMC) in Sri Lanka was established in 1911, and dichloro-diphenyl-trichloroethane (DDT) had been introduced in 1945 for control of the malaria vector. In 1958, an island-wide malaria eradication program was initiated by the government, in keeping with the WHO recommendations.[7] Current CL-endemic areas overlap with previous malaria-endemic dry and intermediate zones of Sri Lanka.[8] Therefore, it could be hypothesized that the absence of leishmaniasis records in the National Archives may be due to the sandfly vector control that took place as a collateral effect of indoor residual spay (IRS) that took place for malaria control. Furthermore, in 1999, Roll Back Malaria Partnership Initiative commenced. As we report zero indigenous malaria case since 2012 and remain in the "prevention of re-establishment of malaria phase" the AMC started practicing only reactive and proactive targeted vector control measures while reporting of imported malaria cases with targeted IRS and long-lasting insecticidal net usage.[20] It is worth noting that the exponential rise of CL cases seen from 2008 onward[8] may be due to the change in vector control measures conducted by the AMC in those pre-malaria areas.

Recent clinical presentations of leishmaniasis

Sri Lanka mostly reports CL. A wide variety of clinical presentations in CL have been reported ranging from papules, nodules, and ulcers to plaques. These lesions are typically not itchy and not painful.[21,22] We have also reported atypical variants of CL.[23-25] Mucosal involvement has also been reported infrequently.[26] In many demographic studies on CL, it has been revealed that more males are infected than females and most are young outdoor working adults, lesions are commonly single, located in the exposed areas of the body, and they are mostly less than 2 cm in diameter. However, large atypical lesions are also reported. The common type of lesions seen here are ulcerated and non-ulcerated lesions, which usually last for > 3 months by the time they seek treatment.[21,27]

Spread of CL and the current burden

Since 1992 until the year 2000, few sporadic cases of CL were reported mainly from the soldiers who were engaged in the civil war that took place in the north and east of Sri Lanka.[28] Due to the rising number of CL cases since 2000, the Ministry of Health Sri Lanka, declared leishmaniasis as a notifiable disease in 2008 with a special circular.[29] As the CL case numbers were seen to be gradually increasing since 2000, more civilians, especially the community involved in farming and other outdoor activities, and school children contracted the disease, indicating possible establishment of peri-domestic and outdoor transmission.[27] Similarly, CL was initially seen mostly in two provinces: north–central and southern, and a gradual spillover of the disease with temporal expansion was observed to adjacent geographic regions over the past 3 decades, and it is now reported from 25 out of the 26 districts.[8,22] Currently, more than 90% of CL cases are however reported in five districts: Hambantota, Anuradhapura, Matara, Polonnaruwa, and Kurunegala districts. Alarmingly, the Hambantota district reported a case incidence rate of 117.2 cases/100,000 population in 2018, and by 2018, there were seven more districts reporting > 10 new CL cases/100,000 population.[22,30,31] New foci are also reported from previously non-endemic areas.[32] Furthermore, since 2018, more than 3000 CL cases have been reported annually, which is a three-fold rise compared to annual case numbers reported from 2010 to 1017.[8] The cumulative case number from 2009 to December 2023 is close to 30,000.[8] It is also worth noting that these case numbers are passive case detection values as there is no proper active case detection program taking place in the country to date and that these values therefore indicate the tip of an iceberg.

Etiological leishmania parasite in Sri Lanka

Causative agents for both CL and VL were identified predominantly as *Leishmania donovani* zymodeme Mon-37.[33-35] It was proven in several whole-genome sequencing and animal studies, as well as CL case follow-up studies, that the CL-causing strain in Sri Lanka is naturally attenuated and essentially dermatrophic and that the CL- and VL-causing *L. donovani* zymodeme Mon-37 strains are genetically different.[36-38] However, visceralization of CL in two HIV-infected patients was recently reported. One of the patients succumbed by the time VL was diagnosed, and the second patient was lost to follow-up after HIV infection was revealed to him (personal communication with two consultant microbiologists). However, none of those cases were reported as case reports, which is a limitation of the Sri Lankan notification system.

HISTOPATHOLOGICAL CHANGES SEEN IN SRI LANKAN CUTANEOUS LEISHMANIASIS (SL-CL) WOUNDS

Studies on histology of SL-CL is limited. A study conducted in 46 histopathologically confirmed CL samples (with positive amastigotes) containing one papule, 21 nodules, five plaques, and 19 ulcers, observed the presence of hyperkeratosis in 91.3%, irregular acanthosis in 54.3%, parakeratosis in 34.8%, follicular plugging in 21.7%, and hyperplasia in 10.9% of the tested lesions.[39] Those authors reported the presence of marked inflammatory cell infiltrates in the dermis (composed of histiocytes, plasma cells, and lymphocytes), organization ranging from diffuse inflammatory infiltrates with parasitized macrophages to varying degrees of granuloma formation, and formation of ill-formed histiocytic to epithelioid granulomata. However, they had not detected prominent necrosis in the SL-CL lesions.[17] Their findings were similar with previously described *L. major* and *L. tropica* findings.[40,41] Another study investigating 50 skin biopsy samples revealed hyperkeratosis in 90%, acanthosis in 44%, and epidermal atrophy in 34%.[42] Both studies showed that macrophage activation plays a major role in control of the parasite within the lesion. Ill-formed coalescent granulomata (OR = 14.83) and diffuse dense dermal plasma cell infiltrate (OR = 74.25) also are significantly associated with SL-CL when compared to other granulomatous dermatitis.[43] However, more studies with a larger number of samples will provide more useful evidence on tissue impact caused by SL-CL and on wound healing.

Immunological evidence

Immunological milieu in relation to the lesion

Few studies have been conducted on the immunological milieu in SL-CL. In one study, an *in situ* immunopathological response was investigated using gene expression.[39] It was found that there was a significant upregulation of IFN-γ ($P < 0.001$) and downregulation of IL-4 ($P < 0.001$) gene expression in the CL lesions compared to controls (biopsy samples collected from non-CL minor surgical wounds). There was no statistically significant difference in IL-10, IFN-γ, and TNF-α gene expression levels between the CL and the control groups. Furthermore, the same authors detected a significant increase in the expression of both IFN-γ ($P = 0.018$) and TNF-α ($P < 0.001$) genes in lesions lasting for > 6 months compared to lesions lasting for < 6 months.[39]

There is another study that had investigated the expression of immune checkpoint inhibitors in response to SSG treatment of SL-CL lesions. Here, the authors detected reduced expression of programmed death-ligand 1 (PD-L1) and indoleamine 2,3-dioxygenase 1 (IDO1) proteins in the lesions when treated with intra-lesional SSG (IL-SSG) for 4 weeks compared to before treatment (baseline). Therefore, the authors proposed that PD-L1 expression can be used as a predictor of response to IL-SSG in SL-CL lesions.[44]

Serological evidence

Some studies had reported sero-prevalence (positive IgG) in some patients with SL-CL with absence of symptoms of visceralization both at the point of study and with follow-up of several months.[45] These positive antibody results were mostly detected with in-house enzyme-linked immunosorbent assays (ELISAs) and rapid diagnostic tests (RDTs), where local parasitic antigens were used. Also, few studies report some CL patients showing positive results when tested with commercially available rK39 RDT kits (16%).[46] Serological data available on SL-CL are variable and need further investigation. However, serology is not used in Sri Lanka to diagnose CL. Whether Sri Lankan CL induces systemic immunogenicity in some individuals is worth investigating.

MICROBIOME AND BIOFILM IN SL-CL WOUNDS

There is only one study that had investigated the microbiome and biofilm of SL-CL wounds so far. This study investigated 39 confirmed CL wounds, which showed that both wound swabs and biopsies taken from SL-CL wounds had significantly distinct microbiome profiles and lower diversity compared to unaffected skin and that 61% of SL-CL lesions had biofilms. However, this study does not describe the correlation between wound healing and presence of biofilms as most of the patients were lost to follow-up during the COVID-19 pandemic period.[47] It will be important to investigate the role played by the wound microbiome and biofilm in the healing process of SL-CL wounds so that intervention to promote early wound healing could be implemented.

Diagnosis

a) **CL**

The most widely used routine diagnostic technique for SL-CL is the Giemsa-stained slit skin smear,[48] preceded by histology, which are both available in some of the government hospitals where a dermatologist, a histopathologist, and a medical laboratory technician (MLT) or a public health laboratory technician (PHLT) are available. In addition to those, few validated PCR methods and *in vitro* culture are available only in some universities,

where they perform investigations for research studies. There are a few studies that have investigated the sensitivity and specificity of loop-mediated isothermal amplification (LAMP), recombinase polymerase amplification assay (RPA), and florescent *in situ* hybridization.[49-51] However, more studies are needed for recommendations to be made to use these tests as standard investigations at the national level. Few real-time PCR methods with high sensitivity and specificity have also been developed for SL-CL.[52]

b) **VL**

The few VL cases reported were mainly diagnosed with bone marrow biopsy and histology and in a few instances aided with a positive rK39-RDT, culture, and PCR.[12,18,19] rK39-RDT is not available in the National Healthcare System so far. Asymptomatic VL was also reported with positive ELISAs, DAT, culture, and PCR in a few studies.[18,53] The available literature on diagnosis of Sri Lankan VL is very limited, most probably due to low case incidence.

Treatment

a) **CL**

First and only treatment guidelines for leishmaniasis were developed in 2013 by the Sri Lanka College of Dermatologists[54] which needs a timely update. Adhering to those guidelines, the first line of treatment for SL-CL is intra-lesional sodium stibogluconate (IL-SSG), if the lesions are small in size (< 3–4 cm in diameter), less than 5 in number, and are not located over a cartilage, joint, nose, or in periorbital areas. IL-SSG is administered until the lesion blanches (~ 1 mL/1 cm^2/week; containing SSG 330 mg BP/mL) until the lesion completely heal with complete re-epithelialization.[55] In those lesions where IL-SSG cannot be infiltrated, intra-muscular SSG is recommended. SSG has been included in the Ministry of Health Essential and Approved drug list annually.[56] However, SSG runs stockouts frequently.[57] There are two studies on radio frequency heat therapy (RFHT) reporting equally good response compared to IL-SSG in treating small lesions, but leading to more severe scarring due to 2nd-degree burns and blistering and rupture of blisters within the first week after RFHT treatment.[58] Meglumine antimonate, miltefosine, or pentamidine are neither registered nor available in the national health system so far.[56,57]

Non-responsiveness in CL to intra-lesional SSG

Non-responsiveness to IL-SSG was first reported in SL-CL in 2016.[23] Afterwards, development of treatment failure and delay in healing with IL-SSG had been reported in a cohort of 201 laboratory-confirmed CL cases which had shown 75.1% of treatment failure to IL-SSG.[55] However, there is no solid evidence yet to say that SL-CL has developed true resistance to SSG or not.

b) **VL**

Two cases of VL were successfully treated solely with intravenous (IV) SSG 20 mg/kg/day × 28 days.[18,19] Another patient was treated with liposomal amphotericin B (brand Fungizone) 3 mg/kg/day for 14 days in three cycles, and another was treated with IV-SSG 800 mg, daily for 26 days, followed by miltefosine 100 mg daily for another 24 days.[17] None of them develop recurrence or PKDL in the long-term follow-up.[17] Amphotericin B deoxycholate is a registered drug in the Ministry of Health Sri Lanka. However, AmBisome is neither registered nor available in Sri Lanka. Miltefosine is also neither registered nor available in Sri Lanka.

Vector in Sri Lanka

The potential sandfly vector *Phlebotomous argentipes* Annandale and Brunetti 1908 has been reported in Sri Lanka from as early as 1949.[59] There are three morphospecies of *P. argentipes* identified in Sri Lanka; *P. argentipes*, *P. anandale,* and *P. glaucus*.[60] *P. argentipes is* the predominant species reported in the country, and in addition, *P. stantoni* and *P. salehi* have also been reported. There are 16 *Sergentomiya* species reported in Sri Lanka.[61,62] *P. argentipes* have been reported in almost all leishmaniasis patients' peri-domestic environment, and Leishmania parasite DNA was detected in *P. argentipes* by molecular techniques.[17,63-65] So far, no other sandfly genus or species have been shown to harbor *L. donovani* DNA other than *P. argentipes* in Sri Lanka, demarcating *P. argentipes* as the putative vector. Unfortunately, there are still no studies that have demonstrated the full developmental cycle of the Leishmania parasite within *P. argentipes* to confirm it as the vector of leishmaniasis in Sri Lanka.

Climate change, CL case numbers, and sandfly density

There are limited number of studies comparing monsoonal rain patterns, temperature, windspeed etc., with CL case numbers. The available studies have shown to report different correlations between CL case numbers and climatic changes in different geographic areas of the country.[31] This may be due to delay in treatment-seeking behavior, prolonged incubation period of SL-CL, chronic nature of the disease, and variable climatic changes observed in different parts of the country. It will also be important to assess the sandfly density and its correlation with climate change, soil temperature, evaporation rate, etc.[66] One study reported that the sandfly density increases during a monsoonal period (October–February)

in the Anuradhapura district,[65] and the study conducted by another group[31] reported an increase in CL case numbers from March to April in the same geographic location. Comparing these two studies, it could be hypothesized that 1–2 months following the increase in the sandfly density and going through the incubation period (1–2 months), the CL case incidence could have increased by Mach–April following monsoon season. Therefore, it will be important to study the climate change, sandfly density, and CL case incidence patterns holistically to arrive at control measures in each geographic area where a high incidence of CL cases is reported. This will enable predictive modeling for epidemics and to initiate appropriate preventive measures.[67]

Insecticide susceptibility studies

Only two studies have been conducted in Sri Lanka to date on insecticide susceptibility on sandflies. One study had revealed elevated esterases and acetylcholinesterase as potential resistance mechanisms to insecticides in a catchment of *P. argentipes* in Northern Sri Lanka.[68] A more extensive recent study collecting sandflies from several CL-endemic areas of the country described that most sandflies are susceptible to deltamethrin and propoxur, except for malathion and DDT, which were used extensively in the country during malaria control.[69]

Reservoir host

Data available on the animal reservoir are inconclusive so far. There are only two studies investigating the animal reservoir, one reporting the presence of amastigotes in a Giemsa-stained slit skin smear and in only one of the blood smears in 151 screened dogs in a leishmaniasis-endemic area[70] and another study reporting one positive rK39-RDT in 114 screened dogs.[71] There are no further studies reported on animal surveillance for over a decade, and it has been recommended that active surveillance into animal reservoirs adhering to one-health approach be carried out. This is an important aspect in the control and elimination of leishmaniasis in Sri Lanka as well as from the South Asian region.[72]

Awareness

Social awareness and awareness among the health staff are supposed to be important in the prevention and control of both communicable and non-communicable diseases. In vector-borne diseases, not only about the disease, but awareness about the vector bionomics is also important to prevent man–vector contact and to interrupt transmission.[73] One recent island-wide study conducted among 252 confirmed CL cases and 2608 controls from the same geographic regions revealed that 79.1% interviewed knew that a fly induces CL, but the knowledge on vector breeding places, biting times, and preventive methods was poor. Knowledge on signs and symptoms of CL in this study sample had been good, and the awareness had been mainly obtained from the healthcare system and rarely from the mass media.[73] In contrast, another study reported lack of knowledge on early signs and symptoms of CL and therefore delayed health-seeking behavior in a different study cohort, and here the CL patients had commented that "we do not rush to hospital for ordinary wounds."[74] A third study in a different geographic region showed that only 28.9% of the study population knew about the vector and control measures.[75] This reveals that there is a dire need to improve social awareness among the community on vector control measures, early signs and symptoms of CL, and therefore motivation toward early health-seeking behavior to interrupt transmission and prevent disfigurement and also to ensure engagement of the community on vector control strategies.

Community engagement

Community engagement and use of appropriate interventions have proven to play a significant role in the control of communicable diseases.[76] There is only one community engagement study in CL in Sri Lanka reported to date; a multi-center study (ECLPISE), in which Sri Lanka was also a focal point. This study had a decolonial approach and had recruited community members, religious leaders, traditional healers, people with CL and their families, teachers, local administrators, and representatives of key community groups. They found out that the community involvement in Sri Lanka is culturally tailored and recommended that a better relationship between researchers and community members is vital to prevent mistrust and prevent the researcher from becoming an "uninvited guest" and make the community "doing engagement"[77] in the prevention and control of leishmaniasis.

Economic impact of CL

The economic cost had been evaluated in one study conducted in one of the CL-endemic areas in the country. This study reported that significant economic burden is caused due to CL. The total median economic loss to a household was calculated as 61.27 USD (Rs. 9927), and from the healthcare provider's perspective, the total median cost per patient was calculated as 22.83 USD (Rs. 3696).[78] Wider calculation of healthcare economics is also a dire need to the country, which has not been evaluated by the Ministry of Health so far.

Measures taken after leishmaniasis becoming a notifiable disease

After the Ministry of Health, Sri Lanka, declared leishmaniasis as a notifiable disease in 2008, the Epidemiology Unit was given the task of case detection through their well-established vertical surveillance system, and the AMC was given the task of sandfly vector control. In 2019, a national circular on "Guidelines on Prevention and Control of Leishmaniasis"[79] was issued by the Ministry of Health, Sri Lanka . However, in spite of having two management bodies as well as national circulars and conducting case surveillance to a certain degree, the CL case numbers continued to increase,[8] probably due to inadequate coordination between the two management bodies. Also, a recent study had reported inadequate notification; in this study, a survey conducted among 188 Medical Officers cited unavailability of notification forms, heavy workload, and inadequate supportive staff as the reported barriers for notification by the Medical Officers.[80] Due to rising CL case numbers, the Ministry of Health, Sri Lanka, identified the AMC as the focal point for control of leishmaniasis in August 2022, authorizing the AMC to handle both case surveillance and vector surveillance and control aspects, bringing control of leishmaniasis under one roof. Furthermore, since Sri Lanka reports more than 3000 new CL cases/year over the last 6 years consecutively (2018–2023) and the cumulative CL incidence is > 30, 000 from 2009 to 2024,[8] a WHO-funded first 5-year National Strategic Plan (NSP) for prevention and control of leishmaniasis 2024–2028 was developed by a team of experts selected by the WHO through an open bidding method requesting for proposals.[81]

Development of the national strategic plan for prevention and control of leishmaniasis in Sri Lanka 2024–2028

During the development of the NSP, the team of consultants selected by the WHO performed a situational analysis, and strengths and gaps were identified. For this process, the team performed an in-depth literature review, visited four of the five highest CL incidence-reporting districts and dermatology units in those hospitals, and met the stakeholders (dermatologists, academics from universities currently diagnosing leishmaniasis, clinicians, histopathologists, microbiologists, epidemiologists, hospital administrators, laboratory staff, CL patients, and villagers). In addition, the epidemiology unit, AMC (the focal point), and the Medical Supplies Division, which is responsible for the management of drug supply chain of the Ministry of Health, were also consulted. The strengths identified included having a vertical surveillance system in Sri Lanka, having a "Leishmaniasis case management guideline" developed in 2013 by the Sri Lanka College of Dermatologist;[54] having MLTs and PHLTs in the Ministry of Health, who are used to collect samples from leprosy and malaria patients (when malaria was prevalent in the country); having an entomology unit and entomologists and entomology assistants (EAs) at the AMC Headquarters and in the periphery; having a central drug management system under the Ministry of Health, Sri Lanka; and having performed important research activities in leishmaniasis over the years. However, the team identified many gaps during the review process; the notification system for leishmaniasis is not strong enough, having only a passive case detection system and absence of an active house-to-house case detection system even in the high CL prevalence areas; leishmaniasis case management guidelines needed updating and needed to be re-named as "National Guidelines"; MLTs and PHLTs were found to be *not* properly trained at national level for sample collection from CL lesions and to carrying out Giemsa staining of SSS; entomologist and EAs are not trained properly for sandfly collection, sandfly identification, and investigate sandfly bionomics and insecticide susceptibility, although few small-scale studies are available in the literature. Absence of a leishmaniasis reference laboratory and availability of PCR and culture being limited to only a few university laboratories were some of the key gaps identified. Also, absence of a national surveillance plan to screen for animal reservoir and frequent stockout of SSG and unavailability of any other WHO-prequalified drugs to treat CL and VL had also been identified as key gaps.[57]

Based on the situation analysis, the expert committee had identified the overarching goal as "To control cutaneous leishmaniasis for possible elimination as a public health problem in the future and prevention of VL and MCL" with two objectives to achieve the goal: to reduce the annual incidence of CL < 5 per 10,000 population by 2028 (approximately 6600 cases) and to ensure zero mortality due to VL.[57] To achieve the objectives, the NSP describes three strategic interventions: leishmaniasis surveillance including for CL, VL, and MCL, case diagnosis and management, and integrated vector management. The NSP further describes five supporting areas for the three strategic plans: leadership, program governance and management, community awareness and engagement on prevention and care, quality assurance, capacity building, and operational research.[57] The NSP has identified the monitoring and evaluation methods and indicators and describes the activity plan for 5 years with quarterly breakdowns and timelines. A mid-term review had been suggested by the 2nd quarter of 2026. The NSP also identified key challenges: CL being an NTD, financial commitment by the government, leadership, sustainability, and implementation of an integrated approach.[57]

DISCUSSION

Sri Lanka is an endemic country for CL now reporting CL over 3 decades, having a cumulative CL case of over 30,000 since 2009 and reporting over 3000 cases/year within the last 6 years.[8] We have also reported few cases of visceral and mucosal forms in an *ad hoc* manner. Although leishmaniasis was listed as one of the notifiable diseases in the country since 2008 and having certain strengths in the healthcare system, there were gaps in the notification and case surveillance systems.[80] Similarly, there were gaps in the diagnostic aspects due to lack of proper training of the laboratory staff, lack of a reference laboratory, and having only a few PCR laboratories. There was no proper training for entomologists on sandfly identification, and no guidelines were available for sandfly control. Sandfly bionomics and insecticide susceptibility were also not known adequately. More work is needed in vector incrimination and sandfly surveillance as well. Lack of information on reservoir host and frequent stockout of anti-leishmanials were also reported. Therefore, a recently carried out joint malaria, filariasis, leishmaniasis, and dengue program review 2024 conducted by the WHO had recommended to strengthen and sustain competencies in the surveillance system, enhance skills and capacities of healthcare workers, digitalize parasitological, entomological, and clinical data, strengthen governance and program management, enhance advocacy, risk communication, and community engagement, and strengthen cross-border collaboration.[82]

The program to eliminate VL as a public health problem from in Asia with regional strategies began in 2005. The countries included India, Bangladesh, and Nepal, where 70% of the global VL cases were reported and a memorandum of understanding was signed between the three countries.[83] On the 31st of October 2023, the WHO announced that Bangladesh had successfully eliminated VL as a public health problem (annual case incidence less than 1/10,000 population) and became the first country to do so.[84]

Currently, the prevalent species in Sri Lanka causing CL is *L. donovani,* and the abundant potential vector is *P. argentipes*.[85] Both parasite and vector species in Sri Lanka are genetically closely related to the species in the region than to other geographic regions in the world.[34,37,63] Therefore, it is important to implement a CL elimination program in Sri Lanka when considering elimination of VL from the region as genetic mutations in the SL-CL *L. donovani* or in Sri Lankan *P. argentipes* can provoke VL upsurges in the region and may lead to reemergence of VL in the region. Identifying this need, as well as due to the persistent rise of CL case numbers (> 3000/annum) over the last 6 years, the WHO-mediated first NSP for prevention and control of leishmaniasis in Sri Lanka 2024–2028 has now been drawn, and implementation had been initiated by the focal point AMC. Since Sri Lanka has an excellent track record of elimination of lymphatic filariasis and malaria, we are optimistic that together with community engagement, the Ministry of Health could successfully achieve the goal of elimination of leishmaniasis as a public health problem from Sri Lanka by 2028.

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Conflicts of interest
There are no conflicts of interest.

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