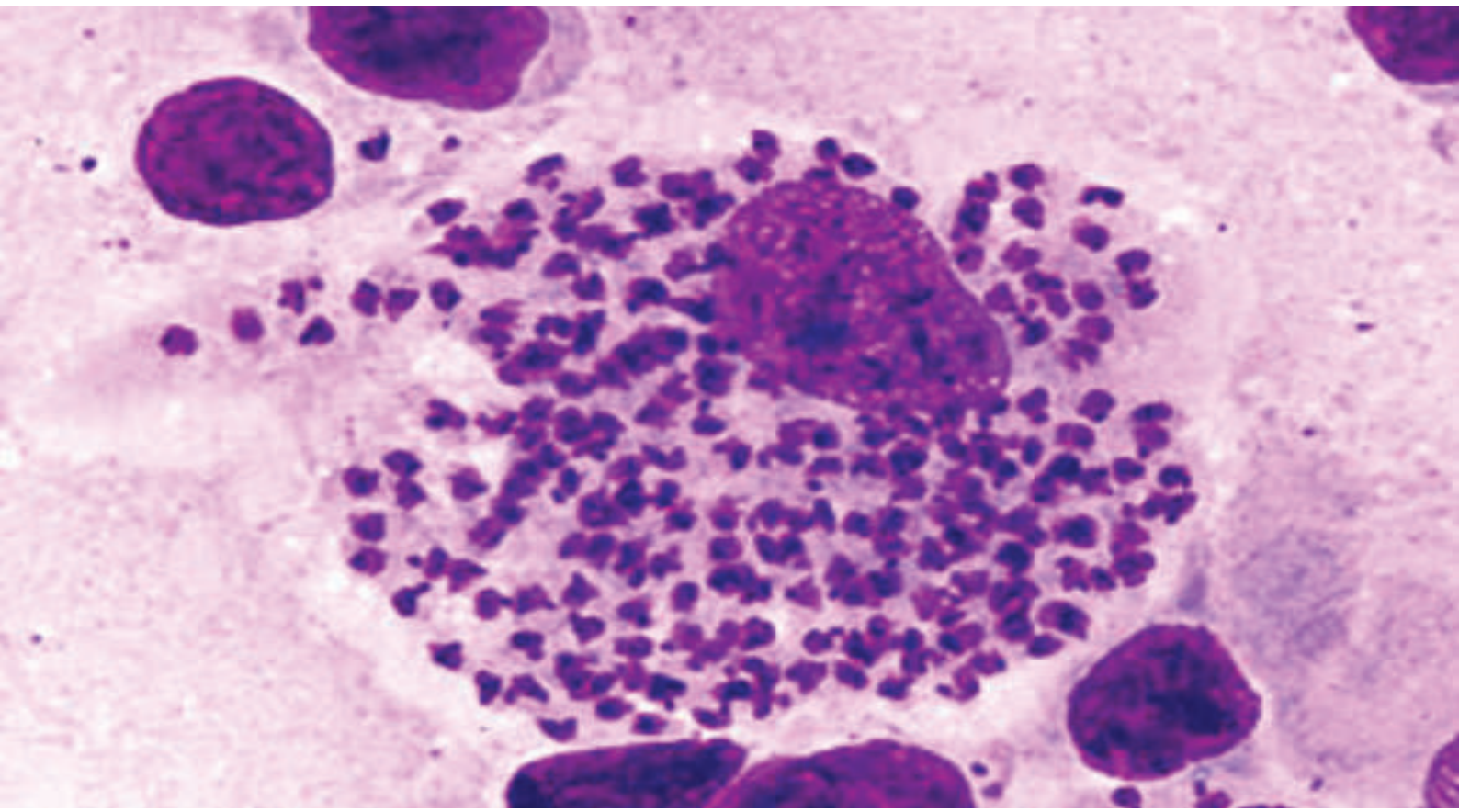
National Strategic Plan for prevention and control of Leishmaniasis in Sri Lanka 2024-2028



Anti-Malaria Campaign
Ministry of Health
Sri Lanka

Ministry of Health

REVIEW OF LEISHMANIASIS AND ITS CONTROL IN SRI LANKA

AND

THE NATIONAL STRATEGIC PLAN FOR PREVENTION AND CONTROL OF LEISHMANIASIS IN SRI LANKA

2024 - 2028

Ministry of Health

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2024-2028

Message from the Director General of Health Services

The National Strategic Plan (NSP) for the prevention and control of leishmaniasis in Sri Lanka, spanning the years 2024 to 2028, represents a transformative initiative in our nation's journey to combat this neglected tropical disease. Leishmaniasis, primarily in its cutaneous form, poses a significant public health challenge, with over 3,000 cases reported annually in Sri Lanka. This strategic plan not only aims to control the disease but also strives for its possible elimination as a public health problem while safeguarding against the emergence of visceral and mucocutaneous forms.

This comprehensive plan encapsulates key interventions, including intensified surveillance, enhanced diagnostic capacities, robust case management protocols, and integrated vector control strategies. These interventions are supported by critical pillars such as community engagement, capacity building, operational research, and quality assurance mechanisms. The goal is ambitious but achievable: to reduce the annual incidence of cutaneous leishmaniasis to less than five cases per 10,000 population and to achieve zero mortality from visceral leishmaniasis by 2028.

The success of this initiative depends on a multi-stakeholder approach. The Ministry of Health, alongside partners such as the Anti Malaria Campaign, Dermatologists, Public health officials, Academics and international organizations like the WHO, is committed to implementing evidence-based strategies. It is imperative that we address the gaps identified during the situational analysis, such as discrepancies in case reporting, insufficient surveillance systems, and a lack of standardized training for healthcare personnel.

Moreover, the NSP emphasizes the importance of community involvement. The inclusion of affected populations in awareness campaigns and preventive measures ensures that public health initiatives resonate at the grassroots level. By leveraging technological advancements and fostering collaborations across sectors, we can overcome barriers and make substantial progress in our fight against leishmaniasis.

As the Director General of Health Services, I reaffirm the Ministry’s commitment to this cause. I urge all stakeholders to take ownership of this plan and work collaboratively towards its implementation. The health and well-being of our communities depend on our collective actions. Together, let us strive to control and ultimately eliminate leishmaniasis as a public health threat in Sri Lanka. I extend my heartfelt gratitude to all those who have contributed to the development of this strategic plan and look forward to witnessing its impactful implementation.

Dr. Asela Gunawardena
Director General of Health Services
Ministry of Health

Ministry of Health

Message from the Deputy Director General of Public Health Services

Leishmaniasis, a vector-borne disease, continues to pose a growing public health challenge in Sri Lanka. The National Strategic Plan (NSP) for the prevention and control of leishmaniasis, 2024-2028, is a testament to our resolve to address this challenge through an evidence-based and collaborative approach. This plan outlines a clear path to achieving measurable reductions in disease incidence and mortality, focusing on strengthening existing systems while introducing innovative solutions.

The situational analysis conducted as part of the NSP development process revealed critical gaps in our response mechanisms. These include underreporting of cases, inconsistent diagnostic practices, inadequate surveillance, and the absence of formal vector control programs. The NSP addresses these issues comprehensively by proposing strategic interventions in surveillance, diagnosis, case management, and integrated vector management. Additionally, the plan underscores the importance of supportive areas such as leadership and governance, community awareness, operational research, and capacity building.

Key interventions include the development of a parasitological surveillance plan, training healthcare personnel in diagnostics and case management, and establishing quality assurance mechanisms. The introduction of active case detection and enhanced reporting systems will bridge existing gaps in surveillance, ensuring timely and accurate data collection. Furthermore, integrated vector management strategies will be pivotal in addressing the sandfly populations responsible for disease transmission.

This ambitious initiative requires unwavering support from all stakeholders, including public health professionals, healthcare providers, community leaders, and international partners. The Ministry of Health is committed to providing the necessary resources and technical guidance to facilitate the plan's implementation. However, achieving the outlined goals will also depend on the dedication of field-level staff and the active participation of affected communities.

As the Deputy Director General of Public Health Services, I call upon all stakeholders to embrace this plan with enthusiasm and commitment. Let us recognize the urgency of this mission and act decisively to protect our communities from the debilitating effects of leishmaniasis. Together, we can transform this vision into a reality, ensuring a healthier and more resilient Sri Lanka.

Dr. S.M. Arnold
Deputy Director General (Public Health Services) 1
Ministry of Health

Message from the Director, Anti Malaria Campaign

The National Strategic Plan (NSP) for the prevention and control of leishmaniasis in Sri Lanka for 2024-2028 is a critical milestone in our efforts to combat this neglected tropical disease. As the focal point for leishmaniasis control, the Anti Malaria Campaign (AMC) is proud to lead this initiative, which reflects our collective commitment to addressing the escalating burden of cutaneous leishmaniasis and preventing the emergence of its visceral and mucocutaneous forms.

The NSP outlines a multifaceted approach to controlling leishmaniasis, combining enhanced surveillance, diagnostic accuracy, effective case management, and vector control. These core interventions are supported by essential pillars such as operational research, community engagement, capacity building, and governance. The plan's overarching goals—to reduce the incidence of cutaneous leishmaniasis to less than five cases per 10,000 population and to eliminate mortality from visceral leishmaniasis—are ambitious but attainable with coordinated efforts.

Our role at the AMC extends beyond technical guidance; we aim to foster collaboration among stakeholders and build capacity at all levels of the healthcare system. The situational analysis revealed significant challenges, including inconsistent case reporting, limited diagnostic facilities, and gaps in vector control measures. Addressing these requires a concerted effort to implement the proposed activities, such as training personnel, establishing quality assurance systems, and strengthening supply chain management for essential medicines.

Community involvement is a cornerstone of the NSP. By engaging with affected populations, raising awareness about preventive measures, and empowering local leaders, we can ensure the sustainability of our interventions. Operational research will further enhance our understanding of disease dynamics, informing evidence-based strategies for future action.

As we embark on this journey, I extend my gratitude to all those who contributed to the development of this strategic plan. The AMC remains steadfast in its mission to lead the fight against leishmaniasis, and I am confident that, with collective dedication and perseverance, we will achieve our goals. Let us work together to create a future where leishmaniasis is no longer a public health burden in Sri Lanka.

Dr. Champa Aluthweera
Director
Anti Malaria Campaign (Focal point- Leishmaniasis)
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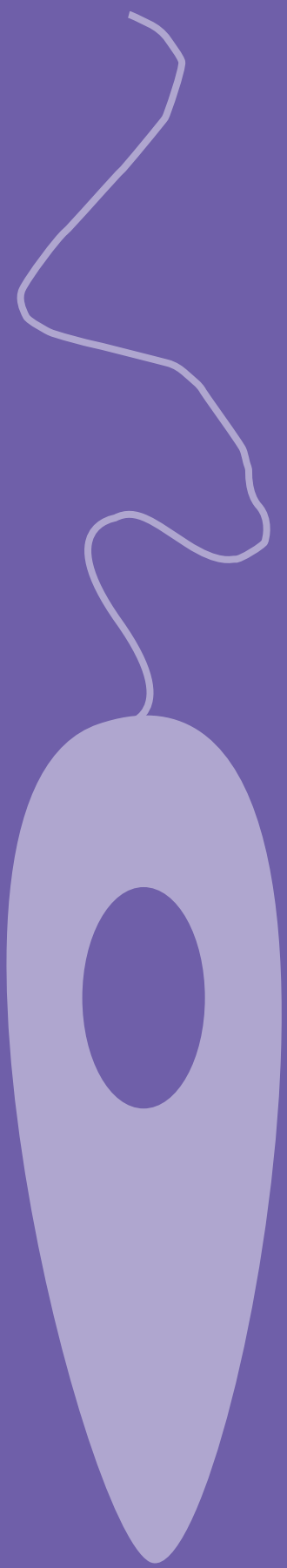
Abbreviations used

ACD	Active Case Detection
ACL	Atypical Cutaneous Lesions
AMC	Anti Malaria Campaign
AMC HQ	Anti Malaria Campaign, Headquarters
CDD	Cosmetics Devices and Drugs
CL	Cutaneous Leishmaniasis
DAT	Direct Agglutination Test
DGHS	Director General of Health Services
DHIS2	District Health Information System 2
ELISA	Enzyme Linked Immunosorbent Assay
GNP	Gross National Product
HECT	Handheld Exothermic Crystallization Thermotherapy
HEO	Health Entomology Officers
HS	Hypertonic Sodium chloride
ICNO	Infection Control Nursing Officer
ID Register	Infectious Disease Register
IEC	Information, Education and Communication
IFA	Indirect Fluorescent Antibody Test
IL	Intralesional
IL-SSG	Intralesional Sodium Stibogluconate
IM- SSG	Intramuscular Sodium Stibogluconate
IVM	Integrated Vector Management
IV- SSG	Intravenous Sodium Stibogluconate
ITS1	Internal Transcribed Spacer 1
LAg	*Leishmania donovani* membrane antigens
LAmB	Liposomal Amphotericin B
LAMP	Loop-mediated isothermal Amplification Assay
MCL	Mucocutaneous Leishmaniasis
MLT	Medical Laboratory Technicians
MOH	Medical Officer of Health

MoH	Ministry of Health
MSD	Medical Supplies Division
NAAT	Nucleic Acid Amplification Tests
NDQAL	National Drug Quality Assurance Laboratory
NMRA	National Medicines Regulatory Authority
NSP	National Strategic Plan
OPD	Outpatients Department
PCD	Passive Case Detection
PCR	Polymerase Chain Reaction
PHI	Public Health Inspector
PHLT	Public Health Laboratory Technician
PUO	Pyrexia of Unknown Origin
RDT	Rapid Diagnostic Test
RE	Regional Epidemiologist
RFHT	Radio Frequency Induced Heat Thermotherapy
RMO	Regional Malaria Officer
RPA	Recombinase Polymerase Amplification Assay
Sb (V)	Pentavalent Antimony
SLCD	Sri Lanka College of Dermatologist
SL-CL	Sri Lankan Cutaneous Leishmaniasis
SL-VL	Sri Lankan Visceral Leishmaniasis
SMS	Short Message Service
SOP	Standard Operating Procedure
SPC	State Pharmaceuticals Corporation
SSG	Sodium Stibogluconate
SSS	Slit Skin Smear
TSG	Technical Support Group
VEN	Vital, Essential and Non-Essential
VL	Visceral Leishmaniasis
WER	Weekly Epidemiological Report
WHO	World Health Organization
WoR	Waiver of Registration



Executive Summary

Leishmaniasis, a tropical vector-borne disease caused by *Leishmania* species transmitted through bites of infected female phlebotomine sandflies, is on the rise in Sri Lanka. The parasite, *Leishmania donovani* MON 37 is the causative agent, while *Phlebotomus argentipes* is the proven vector in Sri Lanka. The distribution of *P. argentipes* in Sri Lanka has been significantly influenced by the presence of hot and humid weather conditions.

All three types of leishmaniasis i.e., visceral leishmaniasis (VL), the most critical form of the disease; cutaneous leishmaniasis (CL), the commonest type; and mucocutaneous leishmaniasis (MCL), the most disabling form of the disease have been reported in Sri Lanka. Currently, over 3000 cases are reported annually in the country. Leishman-Donovan bodies have been demonstrated in Sri Lanka (then Ceylon) in 1904 and described in the archives. Both CL and VL cases were reported in Sri Lanka until about 1953. However, thereafter no cases of cutaneous leishmaniasis were reported till 1992. It is postulated that the large-scale indoor residual spraying with DDT that commenced in 1951 by the Anti Malaria Campaign (AMC) probably controlled the spread of leishmaniasis in the country. Twenty-two species of sandflies of the genus *Phlebotomus* and *Sergentomyia* have been reported.

Although leishmaniasis was made a notifiable disease in 2008, no formal control programme was instituted in the country. With the reporting of leishmaniasis cases (both CL and VL), guidelines were given on control activities that need to be taken at different levels by a General Circular dated 14th November 2019 issued by the Director General of Health Services. Control activities were conducted by field public health staff. In August 2022, the AMC was made the focal point for leishmaniasis in the country.

This report reviews the situational analysis conducted in Part A and presents the National Strategic Plan (NSP) for the prevention and control of leishmaniasis in Sri Lanka 2024-2028 in Part B.

The review team had an initial briefing with key members of the AMC, followed by several meetings with all other AMC staff including Regional Malaria Officers (RMOs) and other officers from the regions. Field visits to four districts were undertaken to study and observe the current surveillance mechanisms in place, methods used for diagnosis of leishmaniasis,

management protocols practiced by the Dermatologists and various aspects of prevention and control of leishmaniasis. In addition, virtual meetings were conducted with the RMOs of Kurunegala and Moneragala regions. At the district level, the team held discussions with relevant authorities; in hospitals, discussions were held with the hospital directors, clinicians and other relevant staff. In some districts, discussions were held with the villagers and patients to assess their knowledge and obtain their views and opinions regarding their approach to treatment when diagnosed with leishmaniasis, knowledge regarding the vector and the vector control measures currently being practised.

A situation analysis was conducted involving AMC staff and other stakeholders including Dermatologists, regional staff, academics from universities currently diagnosing leishmaniasis and staff of the Epidemiology Unit and the Medical Supplies Division of the. Ministry of Health. In addition, consultations with experts in the field facilitated by the World Health Organisation (WHO) Country Office were conducted on various aspects such as vector control, case diagnosis and treatment and indicators to monitor and evaluate programme implementation. Based on these discussions, a draft strategic plan was developed. The preliminary draft was circulated and discussed among the AMC staff and comments were incorporated in the revised draft NSP presented at a multi-stakeholder meeting. The NSP was further revised based on the comments and recommendations made by the stakeholders.

Review of situational analysis

The situational analysis was conducted to assess surveillance, diagnosis, treatment, vector control, human resources and supply chain management.

Surveillance

Parasitological Surveillance

Leishmaniasis was made a notifiable disease in 2008; surveillance, suspected and confirmed cases definitions are now available. In the hospitals visited, the system used for reporting suspected CL cases to a central level were being practiced based on the General Circular (2019) which outlines the process in detail. However, many suspected cases are not notified for various reasons. The patient may also be treated on clinical suspicion at the dermatology clinic or referred for confirmatory Slit Skin Smear (SSS) or biopsy. Other than the notification, no additional information is collected such as number of patients screened

especially when a suspected case is not notified; most notifications are made after confirmation of the diagnosis.

There are no laboratory data regarding the number of tests done or how many were positive with *Leishmania* parasites. There is also a delay for the patient and the investigating Public Health Inspector (PHI) to receive the test results. The AMC does not get any direct information of notifications made to the Medical Officer of Health (MOH). There is no active screening to detect VL in the country. Overall, there is a wide discrepancy in the actual incidence of CL due to different systems being used. It is highly likely that the case load reported is a gross underestimate.

Entomological surveillance

No formal entomological surveillance programme for sandflies is in place. Where there is clustering of *Leishmania* cases, the MOH is expected to arrange entomological surveillance with the assistance of district entomological teams.

Although guidelines issued by the Ministry of Health (MoH) are available, field visits revealed that such activities are not carried out in a regular manner. There are no guidelines on entomological surveillance or formats for data reporting. No formal training has been provided to Health Entomology Officers (HEOs); some have been trained on an *ad hoc* basis by a few universities that conduct leishmaniasis research. There are technical and financial limitations to conducting entomological surveillance.

Case diagnosis

Different laboratory tests have been used to diagnose leishmaniasis. Skin sampling (slit skin smear (SSS)) is the commonly used technique to diagnose CL. SSS is performed by Public Health Laboratory Technicians (PHLTs) and Medical Laboratory Technicians (MLTs) and is available at all institutions having such personnel. However no formal training has been provided to them. Biopsies are reported by Histopathologists. There is no rapid diagnostic test (RDT) available to screen and detect VL. There is no quality assurance programme for diagnosis. Currently, SSS, culture, polymerase chain reaction (PCR), examination of bone marrow aspirates and RDT facilities are provided to some of the hospital referrals by the expert Parasitologists in the universities based on the availability of resources.

Case treatment

Treatment guidelines for leishmaniasis was first developed by the Sri Lanka College of Dermatologists (SLCD) in 2013. However, it has not been updated since and is currently under revision. Different treatment regimens are being used despite clear guidelines been given by SLCD. Dermatologists have observed that the drugs currently being used are less effective than previously used drugs. There is a shortage of drugs. Emergency stocks may be obtained from WHO on request.

Vector control

Specific guidelines have not been developed for sand fly vector control nor is there a coordinated vector control programme implemented. Key health messages to be given during case investigations have reference to some vector control measures. However, there was a general lack of awareness regarding the measures stated above. There is no monitoring mechanism to determine if this information is provided during case investigations.

Human resources

Many categories of personnel are engaged in the diagnosis, treatment, prevention and control of leishmaniasis. Dermatologists are key to diagnosis and treatment of leishmaniasis in Sri Lanka. In addition to Dermatologists, PHLTs and MLTs are involved in diagnosis of CL by SSS. Although these officers report on SSS, they have not been formally trained. There is also no quality assurance programme in place.

Consultant Histopathologists, Haematologists from the MoH and Parasitologists from the universities are also involved in diagnosis of leishmaniasis. The field health staff involved in preventive and control measures are primarily the PHIs. Although there are guidelines that they should follow there is no monitoring system.

There is a dearth of expertise on leishmaniasis prevention and control in the country. Staff cadres have had no formal training on leishmaniasis except for some *ad hoc* programmes conducted by some universities to selected categories. There are no guidelines and teaching-learning materials for staff cadres to follow.

Supply chain management

The process of purchasing drugs for the national annual requirement is managed by the Medical Supplies Division (MSD), National Medicines Regulatory Authority (NMRA), and the State Pharmaceuticals Corporation (SPC) of Sri Lanka adhering to the Cosmetics Devices and Drugs (CDD) Act.

There are stockouts of medicines. Forecasting anti-leishmanials need to be done well ahead and adequately. There is a need to look at the possibility of obtaining some medicines through WHO as is done for some other diseases. There is also a need to look at the possibility of purchasing paromomycin ointment for children with CL through MSD or getting it donated through the WHO.

National Strategic Plan for the prevention and control of Leishmaniasis in Sri Lanka 2024-2028

The goal of the National Strategic Plan (NSP) for the prevention and control of leishmaniasis in Sri Lanka 2024-2028 is " to control cutaneous leishmaniasis for possible elimination as a public health problem in the future and prevention of visceral leishmaniasis and muco-cutaneous leishmaniasis " with the following objectives:

- To reduce the annual incidence of cutaneous leishmaniasis < 5 per 10,000 population by 2028 (approximately 6600 cases).
- To ensure zero mortality due to visceral leishmaniasis.

The NSP was developed based on the situational analysis and its review after a detailed literature review, discussion with stakeholders, field visits and advice of experts.

The plan comprises three strategic interventions and 5 supporting areas:

Strategic intervention 1: Leishmaniasis surveillance including cutaneous leishmaniasis (CL), visceral leishmaniasis (VL) and muco-cutaneous leishmaniasis (MCL);
Strategic intervention 2: Case diagnosis and management;
Strategic intervention 3: Integrated vector management.

Supporting area 1: Leadership, programme governance and management;
Supporting area 2: Community awareness and engagement on prevention and care;
Supporting area 3: Quality assurance;
Supporting area 4: Capacity building; and
Supporting area 5: Operational research.

Strategic intervention 1: Leishmaniasis surveillance

The aim of this intervention is to intensify and strengthen the case surveillance system. The following activities are proposed to strengthen parasitological surveillance:

1. Development of a comprehensive parasitological surveillance plan that will capture all aspects of disease surveillance.
2. Notification in passive case detection (PCD) to be based on suspicion from all institutions including the private sector.
3. Active case detection (ACD) to be conducted for CL, MCL and VL.
4. Active surveillance to identify animal hosts (zoonotic reservoir hosts).

To strengthen entomological surveillance, the following activities are proposed:

1. Development of an entomological surveillance plan.
2. Training of personnel in surveillance and integrated vector management including insecticide resistance monitoring.

Strategic intervention 2: Case diagnosis and management

Diagnosis and case management plays an important role in leishmaniasis prevention and control. The following activities are proposed:

1. Develop training material for diagnosis of leishmaniasis.
2. Conduct training programmes for staff.
3. Establishing a monitoring system for quality assurance.
4. Establishing a reference laboratory for leishmaniasis.
5. Ensuring availability of rapid diagnostic tests (RDTs) [rK-39] for screening for VL.
6. Ensuring availability of commodities for diagnosis of leishmaniasis.
7. Developing National Treatment Guidelines.
8. Ensuring adequate supply of quality assured medicines.

9. Ensuring access to treatment.
10. Providing a counselling service to patients.
11. Conduct mobile/outreach diagnostic and treatment clinics in the community.

Strategic intervention 3: Integrated vector management

The aim of this strategic intervention is to plan and carry out vector control using an appropriate integrated vector management (IVM) approach. The following activities are proposed:

1. Continue disseminating messages already developed and recommended by the Ministry of Health for vector control.
2. Develop an integrated vector management strategy and a national IVM implementation plan using information from the proposed entomological surveillance activities and study of the vector bionomics.
3. Training of all categories of staff engaged in planning and implementation of vector control based on an IVM approach.
4. Procurement of equipment and regular supplies for integrated vector management (e.g. spray equipment, entomological equipment, susceptibility test kits).

Supporting area 1: Leadership, programme governance and management

Leadership, programme governance and management are essential for developing and implementing a disease control programme for leishmaniasis control, implementation of the proposed NSP and advocacy for enhanced resources in Sri Lanka as there was no organized programme before. The following activities are proposed:

1. Conduct advocacy sessions for policy makers and health administrators.
2. Develop and integrated control programme structure within the administrative framework of the Anti Malaria Campaign (AMC).
3. Ensure supervision and oversight of all anti-leishmania activities.
4. Establish a Technical Support Group (TSG) to assist and advice the AMC.
5. Develop a monitoring and evaluation plan.
6. Strengthen the procurement and supply chain management process.
7. Conduct a mid-term programme review in mid-2026.

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

Community awareness and engagement will play a key role in augmenting community support for leishmaniasis control activities. The objectives will be to increase awareness on CL and to seek early diagnosis and treatment and harness community participation in vector control activities. The following activities are proposed:

1. Continue with the messages given during case investigation.
2. Develop a communication strategy and plan.
3. Develop suitable Information, Education and Communication (IEC) material and training of staff.
4. Engage school children in the programme.

Supporting area 3: Quality assurance

Quality assurance of all activities will be maintained. The activities will include surveillance, diagnosis, case management and vector control. The following activities are proposed:

1. Develop Standard Operating Procedures (SOPs).
2. Establish a quality assurance programme for diagnosis.
3. Procure WHO pre-qualified medicines and other commodities.

Supporting area 4: Capacity building

Training will be a major part in the initiation of leishmaniasis control activities. The following activities are proposed:

1. Develop training material.
2. Develop a training schedule.
3. Include modules on leishmaniasis prevention and control in allied health training programmes and undergraduate medical curricula.
4. Conduct Continuing Professional Development programmes.
5. Specialised training.

Supporting area 5: Operational research

The paucity of information regarding strategic plans to control leishmaniasis makes operational research an important supporting area. Some priority areas for research include:

- Parasite related studies: drug resistance, identification of aetiological agent of MCL
- Vector sand fly distribution and bionomics in endemic and non-endemic areas.
- Vector infectivity studies to detect natural *Leishmania* infection (by microscopic and polymerase chain reaction [PCR] methods).
- Vector susceptibility studies.
- Study of sand fly host preferences.
- Evaluation and/or comparison of different vector control approaches.
- Clinical trials of different case treatment regimens.

It is proposed to have a research colloquium in early 2026 to present findings that may be used to review the national strategic plan for the control of leishmaniasis in Sri Lanka during a mid-term review scheduled for the middle of 2026.

ACTIVITY PLAN

A detailed activity plan is presented.

1. Introduction

Leishmaniasis is a tropical vector-borne disease, which is on the rise in Sri Lanka in contrast to the declining trend in other South Asian countries (Karunaweera, et al., 2021). Leishmaniasis is a disease caused by *Leishmania* species where the parasites are transmitted through the bites of infected female sandflies (WHO, 2023). There are three main types of leishmaniasis: visceral leishmaniasis (VL), the most critical form of the disease; cutaneous leishmaniasis (CL), the commonest type; and mucocutaneous leishmaniasis (MCL), the most disabling form of the disease (WHO, 2023). 102 countries remain endemic for leishmaniasis, with more than one billion people living at risk of acquiring the disease (WHO, 2023).

In Sri Lanka, the parasite, *Leishmania donovani* MON 37 is the causative agent (Karunaweera et al., 2003), while *Phlebotomus argentipes* is the prevalent vector (Siriwardana *et al*., 2012; Abeygunesekara *et al*., 2007; Rathnayake *et al*., 2010). The distribution of *P. argentipes* in Sri Lanka has been significantly influenced by the presence of hot and humid weather conditions (Lane *et al.,* 1990).

The NSP, based on the Regional Framework and other WHO documents, proposes to establish and maintain a sustainable plan for the prevention and control of leishmaniasis in the country which is now becoming a major public health problem. The NSP provides a framework for the programme to work within the existing structures and defines specific milestones towards prevention and control of leishmaniasis in the country. As specific guidelines for prevention and control of CL globally are scanty, the NSP was developed taking into consideration guidelines for the prevention, control and elimination strategies for VL. Although only a few cases of VL have been reported in Sri Lanka, the same strategies may be applicable for the prevention and control of CL in Sri Lanka; at present, there are over 3000 new cases of CL caused by *L. donovani* reported in the country annually which has the potential to develop as VL, especially in immunocompromised individuals.

2. Methodology

The WHO Country Office recruited a team to provide technical support for a situational review and development of the first National Strategic Plan for the prevention and control of leishmaniasis in Sri Lanka.

The team comprised the following:

Prof. Rajitha Wickremasinghe (Team lead and Public Health specialist)
Prof. Nayana Gunathilaka (Entomologist)
Prof. Deepika Fernando (Parasitologist)
Prof. Shalindra Ranasinghe (Parasitologist)
Dr. Kanchana Mallawarachcchi (Dermatologist)

The team had an initial briefing with key members of AMC staff, the focal point for leishmaniasis in the country designated by the Ministry of Health, Nutrition and Indigenous Medicine, Sri Lanka. Thereafter, the team held several meetings with other AMC staff including Regional Malaria Officers (RMOs) and other officers from the regions.

Field visits to the districts of Polonnaruwa, Anuradhapura, Matara, and Hambantota which are reporting the highest incidence of leishmaniasis in the country were carried out by the team in order to study and observe the current surveillance mechanisms in place, methods used for diagnosis of leishmaniasis, management protocols practiced by the Dermatologists and various aspects of prevention and control of leishmaniasis. In addition, virtual meetings were conducted with the RMOs of Kurunegala and Moneragala regions. At the district level, the team held discussions with the Provincial Directors, Regional Directors of Health Services, Regional Epidemiologists (RE), Medical Officers of Health (MOH) of regions reporting a high number of cases in each district, Public Health Inspectors (PHI), Health Entomology Officers (HEOs) and Public Health Laboratory Technicians (PHLTs). At Tertiary care hospitals, meetings were held with the Hospital Directors, Consultant Dermatologists and the Medical Officers working in Dermatology Clinics, Pharmacists, Infection Control Nursing Officers (ICNOs), Medical Laboratory Technicians (MLTs) and PHLTs. Field visits were carried out on days of the Dermatology Clinics so that patients with leishmaniasis could be interviewed at each Tertiary Care Hospital. Peripheral hospitals which had no Consultant Dermatologists or where satellite clinics are currently being conducted by the Dermatologists were visited to determine how diagnosis and management

of CL is being carried out. In addition, in each district, a MOH area where a large number of patients are being reported were visited and discussions were held with the villagers in order to assess their knowledge and obtain their views and opinions regarding their approach to treatment when diagnosed with leishmaniasis, knowledge regarding the vector and the vector control measures currently being practised.

A self-administered questionnaire was distributed among Dermatologists, General Physicians, Parasitologists, Histopathologists, Haematologists and Paediatricians to assess current practices with regard to suspecting, diagnosing and treating leishmaniasis.

A situation analysis was conducted with the staff of the AMC and other stakeholders including Dermatologists, regional staff, academics from universities currently diagnosing leishmaniasis and staff of the Epidemiology Unit. Discussions were held with the staff of the Medical Supplies Division (MSD) of the Ministry of Health to obtain a broad view on the process of purchase and distribution of medicines for the management of leishmaniasis. In addition, consultations with experts in the field facilitated by the WHO Country Office were conducted on various aspects such as vector control, diagnosis and treatment and indicators to monitor and evaluate programme implementation. Based on these discussions, a draft strategic plan was developed. The preliminary draft was circulated and discussed among AMC staff. Their comments were incorporated and the revised draft NSP was presented at a multi-stakeholder meeting. The NSP was further revised based on the comments and recommendations made by the stakeholders.

This report is presented in 2 parts; Part A describes the findings of the situation analysis and Part B presents the National Strategic Plan for prevention and control of leishmaniasis in Sri Lanka 2024-2028.

3. Country profile

Sri Lanka is a tropical country having a land area of approximately 65,610 square kilometres, and a population of approximately 22 million (Department of Census & Statistics Sri Lanka, 2022). It has a central mountainous region surrounded by plains stretching to coastal areas. The mean temperature varies between 26ºC–28ºC in the low country, and between 14ºC-24ºC in the central hill country. For administrative purposes, the country is divided into 9 provinces, 26 districts and 277 Divisional Secretariat areas. The Ministry of Health (MoH) usually considers a Divisional Secretariat Area as a health unit;

preventive health care in a health unit is provided by the MOH of the area and the Primary Health Care team (Ministry of Health, 2019).

Approximately 23% of the country's population inhabits urban areas. The country has a high population density of 341 persons per km^2. Life expectancy is around 75 years and the literacy rate is 96.9%. Sri Lanka's economy has contracted by about 12% in the third quarter of 2022 and inflation at the beginning of 2023 was around 60%. The Sri Lankan rupee depreciated by about 45% in 2002 (Department of Census & Statistics, Sri Lanka, 2022).

The road network in the country is reasonably well developed and organized with all areas being largely accessible. There are some areas with human habitation which are remotely situated from healthcare facilities with limited transport facilities.

4. Burden of disease

Sri Lanka has one of the fastest ageing populations in South Asia and Asia. With the control of infectious diseases, morbidity and mortality due to non-communicable diseases is now the major burden of disease. The immunization coverage is over 98%; the maternal mortality ratio was 25.7 per 100,000 live births (2014 data) and the infant mortality rate was 8.5 per 1000 live births (2014 data) (Ministry of Health, 2019).

The country has successfully eliminated polio and malaria; it has successfully eliminated filariasis, rubella, measles and leprosy as public health problems. No mother-to- child transmission of HIV has occurred since 2017; two cases of congenital syphilis per 100,000 live births have been reported for many years, much less than the 50 per 100,000 live births required for WHO certification (Ministry of Health, 2019).

Among the infectious diseases, currently the highest morbidity and mortality burden is due to dengue fever. Dengue is endemic in the country and has been progressively increasing in incidence in recent years with epidemics occurring every 2-3 years. When cases reach epidemic proportions, the AMC staff are often called upon for dengue control work, especially to engage in vector control activities.

5. Health sector profile

Government health expenditure as a percent of Gross National Product (GNP) was 1.8% in 2019. Government health expenditure as a percent of total government expenditure in 2019 was 6.44% giving a per capita health expenditure of SLR 12,037 (Ministry of Health, 2019).

Healthcare services in Sri Lanka are provided by both the public and private sectors. In the public sector, the Department of Health Services, represented by the central, provincial and local government healthcare services is responsible for the provision of the entire range of promotive, preventive, curative and rehabilitative healthcare services. Over 90% of inpatient care is provided by the extensive network of public sector hospitals. Specialist care is provided in government hospitals. There is approximately 1 doctor for 1069.8 persons (Ministry of Health, 2019).

50% of national health expenditure in 2016 was financed by out-of-pocket-expenditure while the government sector contributed 44% (including central, provincial and local government agencies); 6% was financed by voluntary health insurance schemes (Rajapakse et al., 2021). The private sector is mainly responsible for the provision of outpatient curative care services. In addition to western medicine, traditional medicine is widely practised in the country.

Currently, there are about 362 health units in the country, referred to as Medical Officer of Health (MOH) areas that provide grassroots level public health services. The MOH is in charge of the Primary Health Care team comprising Public Health Midwives, Public Health Inspectors, Public Health Nursing Sisters, and Supervising Public Health Midwives and Inspectors. The Primary Health Care team is supported by other staff.

Health care including tertiary care is provided free of charge in government hospitals. Less than 5% of the population has health insurance. Almost 85% of inpatient care is provided by government hospitals; approximately 50% of outpatient care is provided by the private sector. On average, a health care facility is available for Sri Lankans within a distance of 3-5 kilometres.

With devolution of powers in 1989, the health sector was devolved. Currently each province has a Provincial Health Authority under the Chief Minister and the Governor of the

Province. Funding for health care is provided by the Centre and the Province. A few large hospitals in provinces are managed by the central line ministry of health and supported by the Centre.

Preventive health services are organized through the general health services of the country and through vertical programmes under the Ministry of Health. Where preventive services are provided through the general health services, technical guidance is provided by specialized units within the Ministry of Health, the Anti Malaria Campaign being one of them.

6. Anti Malaria Campaign

The Anti Malaria Campaign (AMC) is a directorate of the Ministry of Health under the Director General of Health services (DGHS) and the Deputy Director General of Public Health Services I primarily focusing on prevention of re-establishment of malaria in the country. In the past, the AMC conducted activities as a vertical programme through RMOs attached to the AMC. With devolution of powers in 1987, RMOs were incorporated into the Provincial Health Authority and activities were decentralised to the respective MOHs under the guidance of the RMOs; however, links were maintained with the AMC Headquarters (AMC HQ) which provided technical guidance and financial assistance as and when required. This administrative structure has been in place for over 35 years and malaria elimination was achieved during this period.

In the past the RMOs were appointed only to malaria endemic regions and were solely responsible for anti-malaria work. With the emergence of dengue as a major public health problem in the country, RMOs were designated to carry out dengue control activities with the responsibility of case surveillance being retained by the Epidemiology Unit of the Ministry of Health. Since August 2022, with the increase in the number of cutaneous leishmaniasis cases being reported in the country, the AMC was also designated as the focal point for leishmaniasis; however, there is no organised surveillance or programme for leishmaniasis control in the country. The organogram of the Anti Malaria Campaign Headquarters in Colombo is given in Figure 1. The organogram of Regional Malaria Offices is shown in Figure 2.

The AMC HQs, based in the capital city of Colombo, has provided technical guidance to successfully eliminate indigenous malaria transmission in Sri Lanka. The Campaign is

staffed with 4 Consultant Community Physicians, a few Medical Officers, a Parasitologist, 4 Entomologists and other support staff to conduct its activities. The AMC along with its Regional Offices have the capacity and necessary expertise to take on the additional responsibility of prevention and control of leishmaniasis in the country.

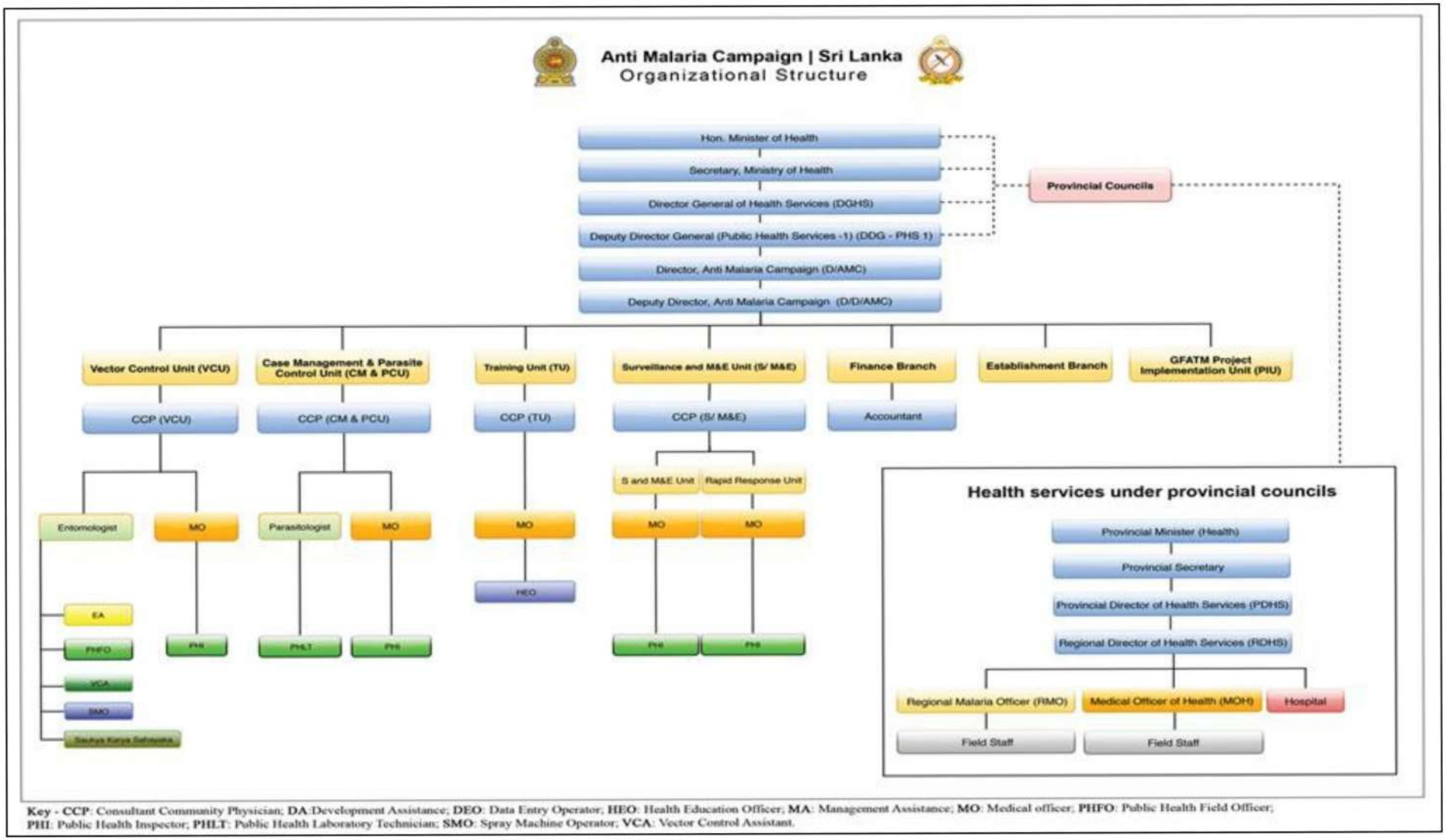


Figure 1. Organogram of the Anti Malaria Campaign Headquarters

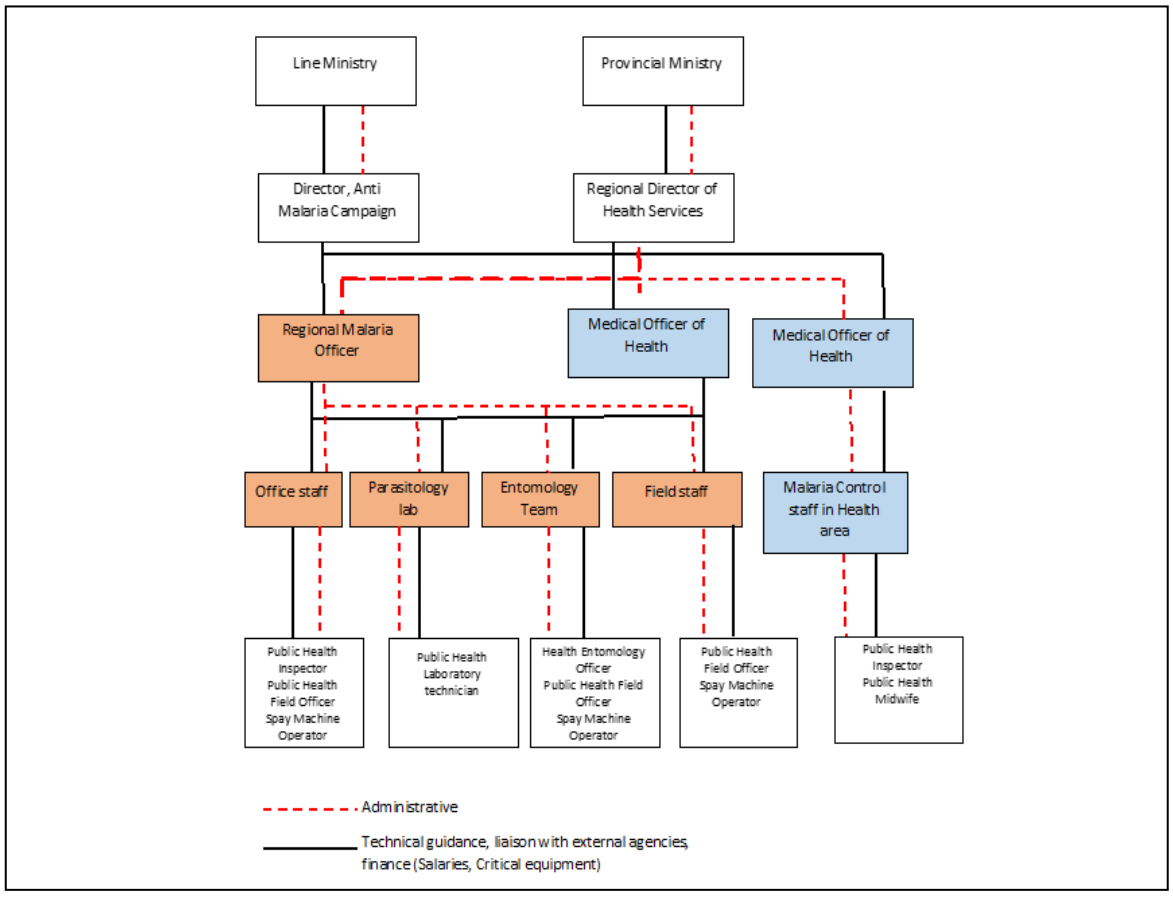


Figure 2. Organogram of Regional Malaria Offices

7. Historical perspectives and epidemiology of leishmaniasis in Sri Lanka

a. Early 20th Century

Leishman-Donovan bodies have been demonstrated in Sri Lanka (then Ceylon) in 1904 and described in the archives. *Leishmania* cases (both CL and VL) were reported till about 1953, after which, no cases of cutaneous leishmaniasis were reported till 1992 (Nuwangi et al.,2022, Athukorala et al., 1992). It is postulated that the large-scale indoor residual spraying with DDT that commenced in 1951 by the AMC probably controlled the spread of leishmaniasis in the country.

Sandflies *Phlebotomus argentipes* and *Sergentomyia zeylanica,* were first reported in Annandale's report (1910). *P. stantoni* and *S. arboris* were reported by Theodor (1938). Carter and Antonipulle (1949) reported *Sergentomiya punjabensis* in the northernmost regions of Sri Lanka.

b. Late 20th Century and beyond

7.2.1 Cutaneous leishmaniasis

According to previous health records, leishmaniasis clinical cases has been first reported from Sri Lanka in 1992 (Athukorale, et al., 1992). Since 1992, the case numbers have remained low and sporadic until 2001 (Karunaweera, 2009). The reported cases increased from 2001 to 2010, 15-fold, which was followed by a 10-fold increase for the next nine years; from 2010 to 2019. A clear outbreak occurred between 2017–2018 (Karunaweera, et al., 2021). When reporting the cases of leishmaniasis, there is a significant gap evident in Sri Lanka (Hewawasam, et al., 2020). With the rapid rise in the number of CL cases, leishmaniasis was identified as a notifiable disease in the country in 2008.

Since 2018, about 3000 or more cases have been reported annually (Figure 3). The districts reporting the highest number of cases include Anuradhapura, Polonnaruwa, Kurunegala, Hambantota and Matara; since 2018 a large number of cases are also reported from Matale and Ratnapura.

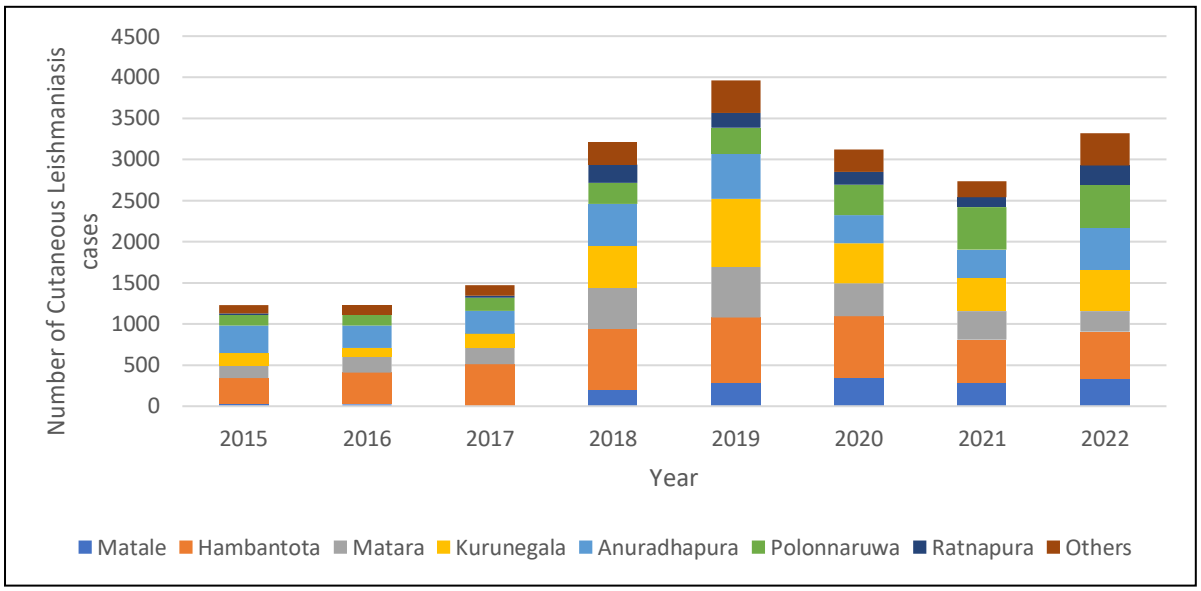


Figure 3. Cutaneous leishmaniasis cases by district 2015-2022

7.2.2 Visceral leishmaniasis

The WHO defines diagnosis of VL as having fever for > 2 weeks, weight loss with splenomegaly, living in an endemic area with demonstration of the parasite in viscera or a positive serological test; rK-39 rapid diagnostic test (WHO, 2023; de Ruiter, 2014). Few cases of confirmed indigenous visceral leishmaniasis (Sri Lankan visceral leishmaniasis: SL-VL) has been reported in Sri Lanka in the recent past. Three primary case reports of VL have been reported (Abeygunasekera et al., 2007; Ranasinghe et al., 2011 & 2012; Siriwardana et al., 2017) with a reported cumulative of nine cases since 1992. There are two other publications describing the presence of VL in Sri Lanka in an uncertain manner (Chapman, 1973; Nuwangi et al., 2022). One described a 10-year-old girl acquiring VL having a short 1-hour transit in Colombo and a few other transit travel histories through a few VL endemic countries (Chapman, 1973) while travelling to the UK. The location where VL was contracted by this child was not confirmed. The other was a literature review which describes searching the Ceylon archives and finding reports from 1903- 1953 on both CL and VL (Nuwangi et al., 2022). The information available in the archives (Nuwangi et al., 2022) were too difficult to assess as it describes deaths associated with CL.

Diagnosis of the first indigenous VL case was made though Hematoxylin & Eosin-stained histology of a liver biopsy, Giemsa-stained bone marrow aspirate and a positive rK 39 rapid diagnostic test (rK 39 RDT) (Abeygunasekera et al., 2007; Siriwardana et al., 2017). The second case of VL was verbally informed by the Histopathologist where the diagnosis was made during a post mortem examination (verbal communication with Dr. Priyanka Abeygunasekera, Consultant Histopathologist, 2010); the 3rd case was reported with confirmation of presence of amastigotes in the Giemsa-stained bone marrow aspirate and trephine biopsy, positive in vitro culture in medium N199 and a positive rK-39 RDT in 2010 (Ranasinghe et al., 2011 & 2012).

The VL causing strain in Sri Lanka has been identified with multilocus enzyme electrophoresis, and whole genome sequencing as *Leishmania donovani* MON-37 (Ranasinghe et al., 2012; Zhang et al., 2014). Out of the seven VL cases reported by Siriwardana et al., 2017, the first case was a repetition of Abeygunasekera et al., 2007, and there were three other cases where there was pyrexia of unknown origin (PUO) and hepatosplenomegaly. The rest of the three patients had only PUO with no hepatosplenomegaly. All these 6 patients were positive by both

bone marrow biopsy and histology or bone marrow biopsy and culture. None of these six patients were positive by rK-39 RDT. More recently at the end of 2023, another VL case has been detected in Kandy which has still not been reported (personal communication – Histopathologist, Kandy National Hospital).

There are few VL surveillance studies conducted in Sri Lanka, some directly targeting VL surveillance and some investigating the possibility of CL visceralization. One study conducted in Thalawa and Eppawela MOH divisions incorporating 954 randomly selected individuals reported a seroprevalence of 1/954 (0.1%), when tested with a commercially available rK-39 RDT kit (*Kala-azar Detect*™; InBios International Inc.); this patient was asymptomatic at presentation and 1-year of clinical follow up. Repeat rK-39 after 1 year was not performed in this subject (Ranasinghe et al., 2013).

Another study describes the presence of anti-leishmania antibodies among 4 out of 170 patients (2% seroprevalence) in a renal unit situated in a CL endemic area in Anuradhapura following testing with the well- established rK-39 Enzyme Linked Immunosorbent Assay (ELISA) and Direct Agglutination Test (DAT) However, none of these patients showed symptoms and signs of VL (Menike et al., 2022). Therefore, these four patients were considered as being exposed to VL within last 2 years probably due to repeated blood transfusions. The known sensitivity and specificity of rK-39 ELISA and DAT were; DAT (94% and 100%) and ELISA (99% and 100%).

No molecular tools have been experimented with or validated in SL-VL patients yet, probably due to low numbers reported.

7.2.2.1 Visceralization potential of Sri Lankan cutaneous leishmaniasis causing *L. donovani* Mon- 37 strain

There are a few studies that looked at the evidence on visceralization potential of the Sri Lankan CL (SL-CL) strain. The findings are variable. Some studies have not detected any anti-leishmania antibodies in SL-CL patients while some have detected anti-leishmania antibodies in a small proportion of SL-CL patients.

The SL-CL *L. donovani* Mon-37 strain is naturally attenuated with inability to visceralize and is genetically different from the Sri Lankan VL; SL-VL strain. The natural attenuation of SL-

CL was first described by McCall et al. (2013) and Zang et al. (2014). This evidence was further proven by another study conducted a few years later (Kariyawasam et al., 2018). In the second study, 250 CL patients who were successively treated with intra-lesion sodium stibogluconate were followed up six monthly up to four years; no evidence of visceralization when tested clinically and with rK-39 RDT was observed. In this study, the patients were enrolled from several CL endemic and non-endemic areas in the country; Hambantota, Anuradhapura, National Hospital of Sri Lanka, and Colombo North Teaching Hospital. Studies done in BALB/C mice have also shown inability of SL-CL strain to visceralize further providing evidence that the *L. donovani*- Mon 37 SL-CL strain is essentially dermotropic in nature (McCall et al., 2013; Kariyawasam et al., 2018).

Contrasting evidence was reported in several other studies, describing the presence of anti-leishmania antibodies in a proportion of CL patients. One study describes a 34% seroprevalence in 50 confirmed SL-CL patients tested with an in-house ELISA which detects anti-leishmania antibodies (Siriwardana et al., 2018). Another study reported 9% seroprevalence rate in 100 SL-CL cases tested with a rK-39 RDT commercially available kit (*Kala-azar Detect*™) and with an in-house ELISA detecting serum rKRP42 anti-leishmania antibodies having a sensitivity of 93% and a specificity of 50% (De Silva et al., 2022a). De Silva et al. (2022a) reports that anti-rKRP42 urine ELISA was suboptimal as a diagnostic test. Another study reported a CL seroprevalence of 82.0% when tested in 200 confirmed CL patients using another in-house ELISA using crude cell lysate of SL-CL *Leishmania donovani* promastigotes (Deepachandi et al., 2020). Piyarasiri et al. (2022) also reported an in-house ELISA prepared with SL- CL *Leishmania* soluble antigen as a high-performance diagnostic tool in identifying exposure in endemic individuals (sensitivity: 98%, specificity: 90.3%).

Although some studies have reported prevalence of anti-leishmania antibodies in variable percentages among SL-CL patients, none of the studies have reported any evidence of clinical visceralization of SL- CL giving rise to clinical features of VL which required treatment. Three cases of mucocutaneous leishmaniasis have been reported in Sri Lanka (Rajapakse et al., 2005; Rathnayake et al., 2010; Sujanitha et al., 2018). Several more cases having lesions in the inner lip have been detected in Sri Lanka, but have not been reported in the literature or notified (personal communication with Consultant Dermatologists).

7.2.2.2 *Leishmania*-HIV coinfections in Sri Lanka

Two cases of CL visceralization was reported from Teaching Hospital Kandy in HIV-infected patients. Both were diagnosed with bone marrow biopsy & histology and PCR. In one case, the patient succumbed before VL treatment could be initiated (personal Communication with the Consultant Parasitologist, University of Peradeniya, 2017) while the 2nd case was treated with Liposomal amphotericin B, cured and relapsed after a period of 3 years recently when the CD4 counts dropped below 200 cells/mm^3. However, the second patient had not come for the treatment of relapse of VL (Personal Communication with the Consultant Microbiologist Kandy, October 2023).

8. Economic burden of leishmaniasis in Sri Lanka

The public health importance of leishmaniasis in Sri Lanka is undervalued due to lack of knowledge on the burden of leishmaniasis, including socioeconomic aspects. In a study conducted in the Kurunegala District in which all leishmaniasis patients were diagnosed and treated at public hospitals, the total median direct and indirect costs were estimated to be 78.47 USD (IQR 67.20 – 101.85) (LKR 10,831 (IQR 9,273.6 – 14,055.30)). When a consultation was done at a private clinic, only the consultation charges were included, as treatment was done in a public hospital which provides services free-of-charge. The median direct cost was estimated to be 58.32 USD (8,050 LKR) of which 99.7% was for non-medical costs. 44% patients were accompanied by a caregiver to visit a treatment facility; among them, 26% were economically active. The total median indirect cost at the end of the treatment was estimated to be 20.67 USD (2,853 LKR) (Wijerathna, et al., 2018a).

As all patients were diagnosed and treated at public hospitals, the provider costs for diagnosis and treatment of one patient was estimated to be 26.78 USD (3,696 LKR) for those who obtained both cryotherapy and SSG treatments. The average cost of diagnosis for a single patient was 2.32 USD (320 LKR) for both direct smear and skin biopsy. The minimum expenditure for a single treatment episode was 3.83 USD (528 LKR). Based on the data, a family spent about 5.4% of the mean annual household income for the diagnosis and treatment of a single case of leishmaniasis in a family member (Wijerathna, et al., 2018a).

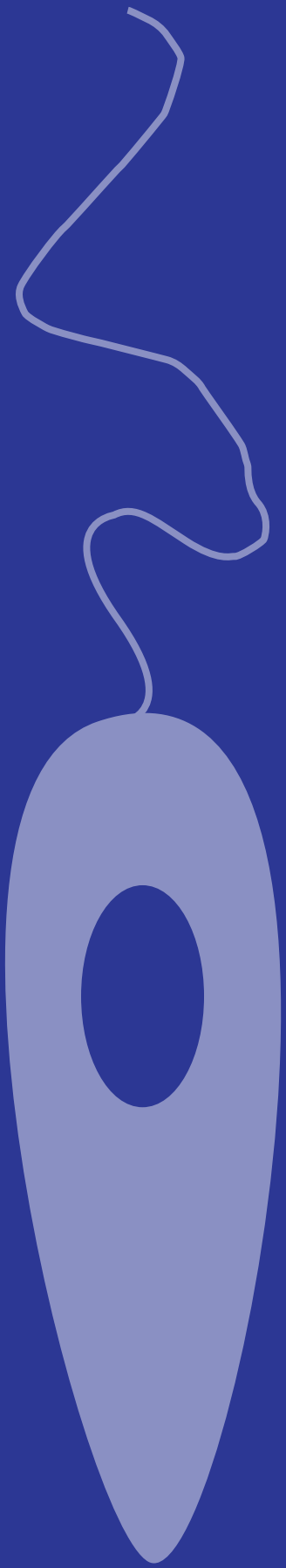
9. Sand fly fauna in Sri Lanka

Phlebotomine sandflies, belonging to the Diptera: Psychodidae family, are medically significant insects with a global distribution. They play a crucial role in the transmission of protozoan parasites and arbovirus infections to humans and animals (Kumar et al*.,* 2012a; WHO, 2010). Worldwide, approximately 1000 species of sandflies have been documented, thriving in diverse climates, from tropical and temperate regions to arid deserts (Lewis, 1978; Kalra & Bang, 1988; Shimabukuro et al*.,* 2017). These species are classified into six genera, including New-World genera such as *Brumptomyia*, *Lutzomyia*, and *Warileya*, and Old-World genera like *Phlebotomus*, *Chinius*, and *Sergentomyia* (Akhoundi et al*.,* 2013).

The earliest recorded studies on Sri Lankan sand fly fauna date back to 1910, with Annandale's report (Annandale, 1910) highlighting the presence of two species, *Phlebotomus argentipes* and *Sergentomyia zeylanica*. Subsequently, Theodor (1938) expanded the list to include two additional species, *P. stantoni* and *S. arboris*. Carter and Antonipulle (1949) contributed by documenting the presence of *S. punjabensis* in the northernmost regions of Sri Lanka. Despite these early efforts, scientific interest in Sri Lanka's sand fly fauna waned until more recent times, leaving the region relatively under-studied (Lane et al*.,* 1990).

After declaring leishmaniasis as a notifiable disease in the country in 2008, more attention was drawn to investigate the presence of sand fly species and their relative abundance in the country. Ozbel et al., (2011) report on the occurrence of three sand fly species of genus *Sergentomyia* in Sri Lanka, namely: *S. jamesi*, *S. indica* and *S. barraudi*. Gajapathy & Surendran (2012a) added *P. salehi* to the list. Gajapathy & Surendran (2012b) included eight additional species of Sergentomyia: *S. dreyfussi*, *S. malayae*, *S. baghdadis*, *S. bailyi*, *S. grekovi*, *S. modii*, *S. rudnicki* and *S. dentata*. Some studies have been useful in determining the distribution of sandflies in Sri Lanka and their infectivity rates in wild populations (Surendran et al*.,* 2005; Premachandra et al., 2012; Ranasinghe *et al.,* 2012; Senanayake et al., 2015; Wijerathna et al*.,* 2017; Wijerathna et al*.,* 2018b). According to all the published literature related to sand fly fauna of Sri Lanka, a total of 22 species belonging to two genera, *Phlebotomus* and *Sergentomyia*, are listed (Wijeratha and Gunathilaka 2019 & 2020). Six species under three different subgenera are reported for *Phlebotomus* including three sibling species of *P. argentipes.* Sixteen species of four subgenera are reported for *Sergentomyia*. The most commonly reported species with the widest distribution, *P. argentipes*, is the only confirmed disease transmitting species.

However, plenty of published information from other countries are available to indicate the potential of other species to act as vectors of parasitic and viral diseases (Geevarghese et al., 2005; Kumar et al., 2012b; Chusri et al., 2014; Siripattanapipong et al., 2018).



Part A

Report of Leishmaniasis Situation Analysis

10. Surveillance

10.1 Parasitological surveillance

10.1.1 Passive case detection

Leishmaniasis was made a notifiable disease in 2008 and part of the Communicable Disease Surveillance Programme of Sri Lanka, a national network covering the whole country. The following definitions are used for leishmaniasis surveillance.

Surveillance case definition

"An illness with one or more localised skin lesions (macules, nodules, papules or ulcers) that commonly appear on the exposed areas of the body (e.g., face, neck, arms, legs) or rare involvement of viscera (liver or spleen) with or without fever/history of fever or the mucosal tissue in mouth and nose."

Suspected case definition

"A patient compatible with the surveillance case definition."

Confirmed case definition

"A suspected case with laboratory confirmation."

Cutaneous leishmaniasis may be confirmed by positive microscopy for parasites (stained smear either direct or following culture) or positive histology or PCR.

Visceral or mucosal leishmaniasis may be confirmed by positive serology, namely Indirect Fluorescent Antibody Test (IFA), ELISA or RDT, positive microscopy for parasites (stained smear either direct or following culture), or positive histology or positive PCR.

Notification

It is mandatory for cases of suspected leishmaniasis be notified to the MOH of the area in which the patient is resident through the Communicable Disease Surveillance using the H544 form. Once the MOH receives the notification form, the details are entered in the Communicable Disease Notification Register maintained at the MOH office. The Public Health Inspector of the area should investigate the case within 7 days of notification.

All clinically / laboratory confirmed cases should be entered into the Infectious Diseases Register (ID register, H 700) and should be sent to the Epidemiology Unit by filling the Communicable Disease Part II form (H – 411a). A duly filled special leishmania specific case investigation form (named as the Surveillance of Leishmaniasis- Case investigation form) for each confirmed case of leishmaniasis (entered in the ID register) should also be sent to the Epidemiology Unit.

At the Epidemiology Unit, on timely and complete receipt of all Weekly Return of Communicable Diseases Returns (H 399) from all the MOH areas, all data are compiled and disseminated through the Weekly Epidemiological Report (WER). The online system alerts areas which report more than 5 cases per week.

The data flow is given in Figures 4 and 5.

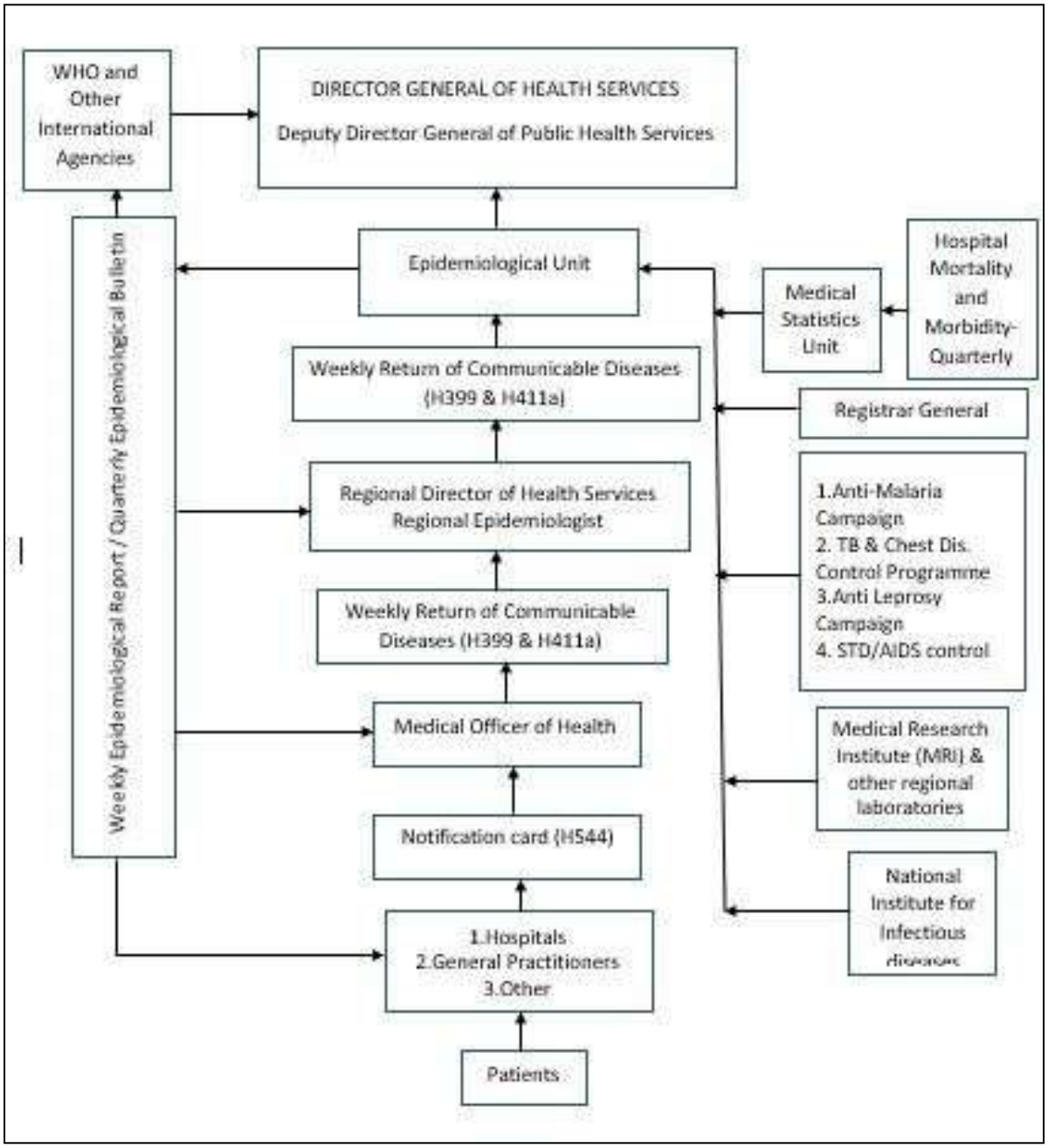


Figure 4. A flowchart indicating the notification of a communicable disease in Sri Lanka.

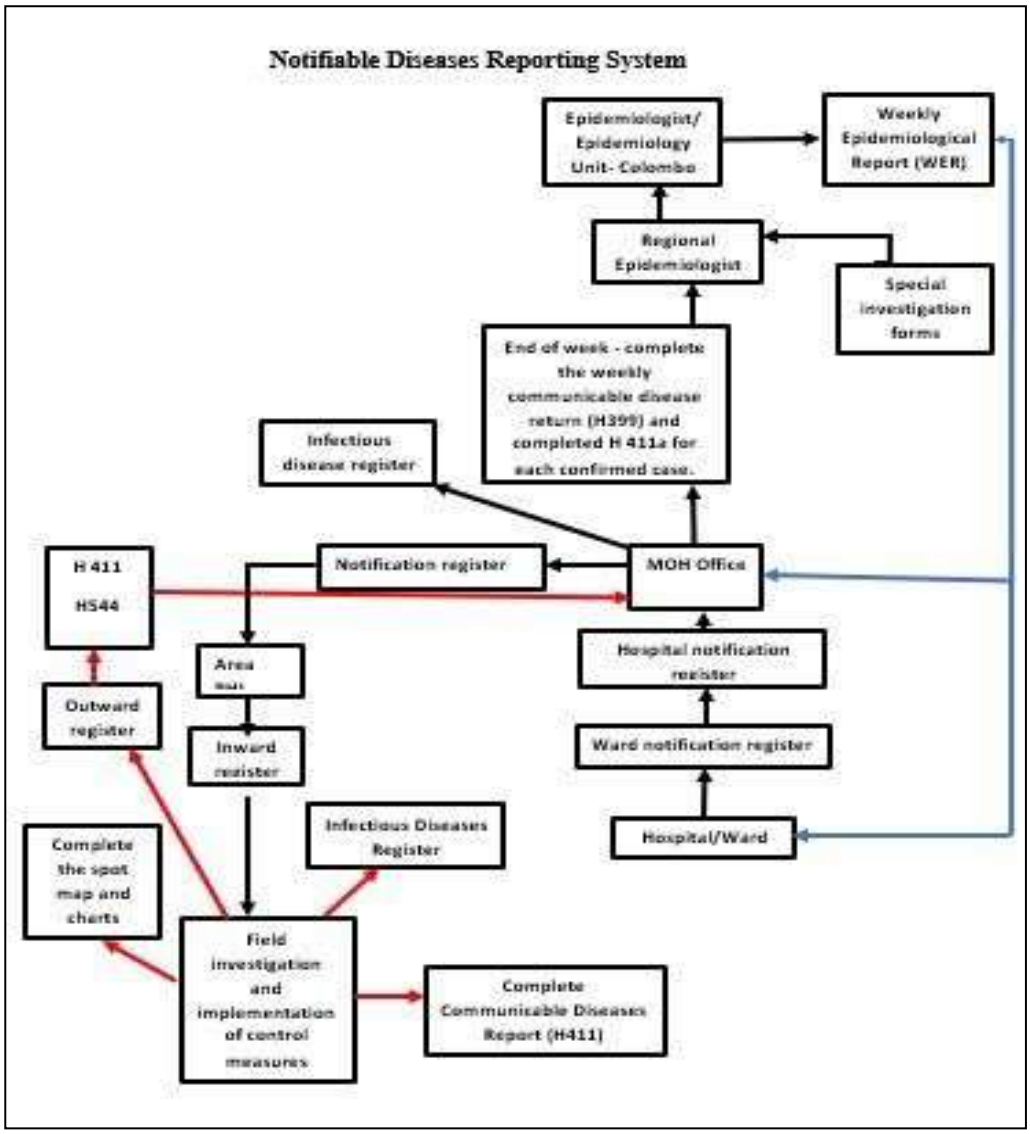


Figure 5. A flowchart indicating the investigation of a notifiable disease and reporting mechanism in Sri Lanka.

Since the AMC was made the focal point for leishmaniasis, the AMC also has started obtaining surveillance data from PHLTs who do slit-skin smear examination (SSS). The data are transferred to the RMO via WhatsApp messaging.

10.1.2. Active case detection

All household contacts of the index patient are screened for CL through Dermatology clinics. During investigation of a notification of a suspected or confirmed case, the PHI of the area is required to visit around 50 houses in the immediate vicinity of the residence of the case to check if there are other persons with suspected cutaneous leishmaniasis lesions; if any are

found, they should be referred to a Dermatology clinic. If there is clustering of cases, MOHs are expected to organize an active surveillance programme in the area, with a view to identifying and early referral of suspected leishmaniasis cases.

Observations and findings regarding reporting of suspected and confirmed cases of CL

Five field visits were conducted (Polonnaruwa, Anuradhapura, Kurunegala, Hambantota and Matara). During these field visits, the following observations were made.

- In the hospitals visited, the system used for reporting suspected CL cases to a central level were being practiced based on the circular which outlines the process in detail. In brief, a patient with a suspected lesion can present to the Dermatology clinic or, in hospitals with no Dermatologist, to the Out Patients Department (OPD). Any suspected case of leishmaniasis should be reported by the respective Medical Officer to the Infection Control Nursing Officer (ICNO) of the hospital via the H544 form. The ICNO posts this form to the respective MOH in which the patient is a resident. After investigating the notification, the MOH passes on the information to the RE from where it is forwarded to the Epidemiology Unit.

- Many suspected cases are not notified - e.g. the Medical Officers may not fill the H544 form due to a heavy work load at the Dermatology clinic; in peripheral hospitals the OPD doctors may not fill the H544. The patient may be treated on clinical suspicion at the Dermatology clinic or referred for confirmatory SSS or biopsy.

- Other than the notification of suspected CL lesions via the H544 form to the ICNO, no additional information is collected such as number of patients screened at the Dermatology clinic/OPD, especially when a suspected case is not notified.

- Most notifications are made after confirmation of the diagnosis.

- Once CL is suspected, the patient is referred to the laboratory for confirmation of diagnosis. The diagnostic test used in all the hospitals is a SSS. Diagnosis could be carried out by a MLT or PHLT. The laboratory issues the report which is sent back to the place of referral e.g. Dermatology clinic or OPD or the report is kept in the laboratory until collected by the patient. The results of investigations are not sent to the MOH. Whether a diagnosis of CL

was made or not can only be ascertained by the MOH when the PHI visits the patient's residence during case investigation and follow up and, that too, only if the patient has obtained the report. The special investigation form filled by the PHI is forwarded directly to the Epidemiology Unit.

- Since the AMC was made a focal point, the AMC has been obtaining information from PHLTs. This information is provided via WhatsApp messaging. The AMC provides consumables for testing. SSS done by Medical Laboratory Technicians are not reported to the AMC.

- The AMC does not get any direct information of notifications made to MOHs. In some RMO regions, an officer is sent to the MOH to collect the data but only summary data with no patient details are made available to the RMO. Summary data is also available through the WER. The findings of the investigations conducted by the PHIs are not available to the AMC. As the AMC has to wait sometime to obtain this information, there is a delay in response.

- Discussions with Dermatologists revealed that some Dermatologists usually notify only confirmed cases. At times, they treat patients, on clinical suspicion, even before the results of investigations are available so as to not miss non-returning patients due to other factors such as travel time and cost. These data are missed by the surveillance system.

- There is no information on cases detected by type of detection e.g. passive or active case detection.

- In the special "Surveillance of Leishmaniasis – Case Investigation Form" prepared by the Epidemiology Unit contains information regarding the clinical status of the patient; some of the information to be obtained from the patient may not be available to the PHI or the PHI may not have the competencies to provide the same.

- In Dermatology clinics, more detailed information is collected in another paper-based format prepared by the College of Dermatologists. Some information duplicates that obtained from the special "Surveillance of Leishmaniasis – Case Investigation Form".

- There is no active screening to detect VL in the country.

- Overall, there is a wide discrepancy in the actual incidence of CL due to different systems being used. It is highly likely that the case load reported is a gross underestimate.

10.2. Entomological surveillance

There is no formal entomological surveillance programme for sandflies in place. Where there is clustering of leishmaniasis cases, the MOH is expected to arrange entomological surveillance with the assistance of district entomological teams.

Health Entomological Officers (HEOs) are expected to carry out entomological surveillance for leishmaniasis based on the need of the district. HEOs should submit a detailed report following entomological surveillance to the respective MOHs with a copy to the RE. Once the report is received, the RE should refer the report to the District Entomologist/Regional Malaria Officer/ Regional Filariasis Officer for necessary action.

Observations and findings

- Although guidelines (see Annexure I) are available, field visits by the Technical team revealed that such activities are not carried out in a regular manner.
- There are no guidelines on entomological surveillance or formats for data reporting.
- No formal training has been provided to HEOs; some have been trained on an *ad hoc* basis by a few universities that conduct leishmaniasis research. However, training on vector speciation has not been conducted.
- There are technical and financial limitations to conducting entomological surveillance.

10.3. Recommendations

Parasitological surveillance

- ✓ Development of a parasitological surveillance plan
- ✓ Notification via Communicable Diseases Surveillance Programme should be continued and an agreement should be reached between the Epidemiology Unit and the AMC for data sharing.
- ✓ In institutions where PHLTs/MLTs carry out SSS for diagnosis and in institutions where biopsies are done for confirmation- test results should be notified to the AMC.

- ✓ For passive case detection, the personnel responsible for reporting should be specified. The mechanism for reporting data from case notification to case investigation and reporting the findings of case investigations should be clearly stated. It also has to be mentioned whether the case investigated is a confirmed case.
- ✓ A separate notification system be established to obtain information of confirmed cases reported and treated from Dermatology clinics.
- ✓ Establish a programme for active case detection for CL, MCL and VL.
- ✓ Conduct active surveillance to identify animal hosts.

Entomological surveillance

- ✓ Development of an entomological surveillance plan guided through entomological indices and updated periodically.
- ✓ Training of personnel.

11. Diagnosis of leishmaniasis

Early diagnosis and effective and prompt treatment are some of the key strategies described by WHO to prevent mortality and morbidity due to visceral and mucocutaneous leishmaniasis and to minimize disfigurement and subsequent social stigma in cutaneous leishmaniasis (WHO, 2023). Correct diagnosis using highly sensitive diagnostic tests is important for treatment and management of cases (WHO, 2023; Sundar et al., 1998).

Laboratory diagnosis is performed to confirm the clinical suspicion of CL and there is a wide array of investigations performed in Sri Lanka in different institutions based on the facilities and trained human resources available in the institution. The investigations could be broadly categorized into direct parasitological identification, indirect serological diagnostic methods and nucleic acid amplification tests (NAAT).

11.1 Direct Parasitological diagnosis available to diagnose CL in the Sri Lankan Settings

In the advanced search in PubMed using search terms (cutaneous leishmaniasis) AND (Sri Lanka) AND (diagnosis), 65 publications appeared. After reading the title, abstract and methodology, 12 studies had a primary diagnostic tool evaluation performed. SSS, biopsy and histology, and *in-vitro* culture were performed in most studies. Slit skin smear was performed in every diagnostic method comparison study (Wijesinghe et al., 2020; De Silva et al., 2022a & 2022b; Siriwardana et al., 2015; Jayasena Kaluarachchi et al., 2019; Herath et al., 2010;

Ranasinghe et al., 2015; Deepachandi et al., 2020; Piyasiri et al. 2022; Ghosh et al., 2021; Kothalawala et al., 2016; Silva et al., 2021a). Similarly, almost all epidemiological case surveillance studies had used SSS as one of the tools in diagnosing CL.

In the SSS method using Geimsa stain, CL is diagnosed by detecting the *Leishmania* amastigote. Since the sensitivity of SSS has shown to be between 73-81% (De Silva et al., 2017; De Silva et al., 2022a & 2022b) and a specificity of 100% in many Sri Lankan studies, SSS could be considered a useful tool in active and passive case detection in the control of leishmaniasis in Sri Lanka. Furthermore, the cost of SSS is less than two USDs, the cheapest compared to all the other investigations. It is minimally invasive and could be performed by trained personnel in a field setting.

11.2 Cutaneous leishmaniasis cases diagnosed by an antigen detection Rapid Diagnostic Test

There is only one study in the literature (search terms: ((cutaneous leishmaniaisis) AND (Sri Lanka)) AND (rapid diagnostic tool), that used an anti-leishmania antigen detection test to diagnose CL in Sri Lanka. This was a validation study of a commercially available RDT (*CL Detect*™; InBios International Inc.); the RDT had a sensitivity of 36% compared to SSS. Specificity was 100%. Therefore, this tool cannot be recommended for any surveillance programmes/as a diagnostic tool in Sri Lanka. The cost of a kit (USD 4–5 per test) (De Silva et al., 2017).

11.3 Nucleic Acid Amplification Tests (NAATs) for CL

There are only a limited number of studies that have validated NAATs to diagnose CL in Sri Lanka. With the search terms (cutaneous leishmaniasis) AND (PCR) AND (Sri Lanka), 21 articles appeared. However, out of them, only 9 evaluated a NAAT with the Sri Lankan CL samples (Kothalawala et al., 2016-Loop Mediated Amplification Assay (LAMP); Gunaratna et al., 2018-Recombinase Polymerase Amplification Assay (RPA); Jayasena Kaluarachchi et al., 2021-Flourescent in situ Hybridizarion (FISH); Deepachandi et al., 2019-Nested PCR; Ghosh et al., 2021; Ito et al., 2014; De Silva et al. 2022a &2022b- ELISA & Internal Transcribed Spacer 1 (ITS1) targeted nested PCR; Kariyawasam et al., 2015; Galgamuwa et al., 2019-kinetoplast DNA (kDNA) targeted PCR ; Ranasinghe et al., 2015 -ITS1 and kDNA PCR).

In this group, two point-of-care tests for SL-CL have been validated. One study described a new LAMP with a sensitivity of 82% compared to SSS. Specificity was 100% and the per test cost was 6 USD. RPA assay is the other (Gunaratna et al., 2018). However, the sensitivity of RPA with SL-CL was only 65.5% compared to PCR and the per test cost was 10 USD. Both these tests have the potential to improve in a multi-country validation study.

Fluorescent in-situ hybridization was performed both on SSS samples and formalin-fixed paraffin-embedded sections with sensitivities of 79.1% and 80.9% and specificities of 96.7% and 93.4%, respectively, compared to PCR. The estimated cost for each test was around 4 USD (personal communication with the 1st author). Background noise was a limitation of this study and further validation is required before using it for surveillance and using it as a diagnostic tool (Jayasena Kaluarachchi et al., 2021).

11.4 Conventional PCR for CL

Although highly recommended globally (WHO, 2010), there are only few studies that have properly validated PCR methods to diagnose SL-CL. Ranasinghe et al., (2015) validated two conventional PCR methods in diagnosing SL-CL using previously described Internal Transcribed Spacer 1 (ITS1 primers) (LITSR & L5.8S) (El Tai et al., 2000) and a kinetoplast DNA (kDNA) PCR using JW 11 & 12 primers (Rodgers et al., 1990) with a 92% sensitivity and 100% specificity compared to clinical diagnosis. ITS1 primers were further used in many subsequent studies as the gold standard by the same authors (De Silva et al., 2017; Gunaratna et al., 2018; Jayasena Kaluarachchi et al., 2019; Jayasena Kaluarachchi et al., 2021). Since this test has been successfully used in many studies with high sensitivity and specificity, conventional PCR with ITS1 (LITSR & L5.8S) (El Tai et al., 2000; Ranasinghe et al.. 2015) could be considered as a useful tool for future leishmaniasis control programme surveillance/ diagnosis in the country. Furthermore, ITS1 PCR with Restriction Fragment Length Polymorphism would enable speciation with low cost (Ranasinghe et al., 2015).

11.5 Nested PCR for CL

There are two studies that describe highly sensitive nested PCR for the diagnosis of SL-CL (Deepachandi et al., 2019, De Silva et al., 2022b). Considering the high sensitivity and specificity, both these techniques may be recommended for the future leishmaniasis control programme

in the country. The only limitation is that no further studies have used these two techniques to detect SL-CL so far.

11.6 Real-time PCR for CL

Although real-time PCR had shown the highest sensitivity and specificity in detecting cutaneous leishmaniasis and use in species identification (Galluzzi et al., 2018), there were no studies validating the sensitivity and specificity in diagnosing SL-CL in literature when using search terms ((cutaneous leishmaniasis) AND (real-time PCR)) AND (Sri Lanka). Therefore, it is highly recommended that the newly developed real-time PCR is validated to detect CL causing *L. donovani* (SL-CL).

11.7 Diagnosis of mucocutaneous leishmaniasis in Sri Lanka

There are three case reports describing the presence of mucocutaneous leishmaniasis in Sri Lanka (SL-MCL) **(**Sujanitha et al., 2018; Rathnayake et al., 2010, Rajapakse et al., 2005). They were diagnosed by SSS, histological detection of Leishman Donovan bodies and /or by PCR. Whether MCL is under-reported is a concern and needs further observations.

11.8 Diagnosis of visceral leishmaniasis in Sri Lanka

As mentioned above, the few reported cases of VL had been diagnosed with bone marrow biopsy & histology, rK-39 RDT (available only at few University laboratories for research purposes), PCR and culture (available only at few University laboratories for research purposes). All these investigations are globally accepted and could be performed in Sri Lanka.

One study showed 2/3 (66%) previously diagnosed SL-VL cases becoming positive with a newly developed RDT using *Leishmania donovani* membrane antigens (LAg) (Ejazi et al., 2019). This was a multicenter study and will need further validation before getting recommended as a standardized test. This LAg -RDT had shown an overall sensitivity and specificity of 97.10% and 93.44%, respectively. The case numbers in Sri Lanka are too small to arrive at any conclusions related to Sri Lankan *Leishmania* spp.

More recently, Deepachandi et al., 2023 has described the development of an in-house ELISA to detect laboratory confirmed SL-VL in patients' (n=15) serum samples that were negative when tested with established and commercially available rK-39 RDT and DAT kits. These cases were initially confirmed with bone marrow biopsy and microscopy, *in vitro* culture or

PCR. This newly described in house ELISA showed a sensitivity of 100.0% and a specificity of 98.3% compared to microscopy, culture and PCR (Deepachandi et al., 2023). However, the sample size of 15 may not be sufficient to recommend its use in for island-wide surveys and needs further validation.

rK-39 RDT has shown to be user friendly in the field and have high sensitivity and specificity rates in detecting Kala-Azar in the Indian subcontinent (Sundar et al., 1998) and therefore, is recommended for surveillance in the Regional Strategic Framework for accelerating and sustaining elimination of kala-azar in the South-East Asia Region: 2022–2026 (WHO, 2022a).

Observations and findings

- SSS is the commonly used technique to diagnose CL.
- SSS is performed by PHLTs and MLTs and is available at all institutions having such personnel. However no formal training has been provided to them.
- Biopsies are reported by Histopathologists.
- There are no RDTs available to screen and detect VL.
- There is no quality assurance programme for diagnosis.
- Culture is not readily available.
- PCR is not readily available.

11.9 Recommendations

- ✓ Develop training material for diagnosis of leishmaniasis
- ✓ Conduct training programmes
- ✓ Establish a monitoring system for quality assurance
- ✓ Establish a reference laboratory for leishmaniasis
- ✓ Ensure availability of RDT to screen for VL
- ✓ Ensure availability of commodities for diagnosis of leishmaniasis

12. Treatment

12.1 Treatment guidelines in Sri Lanka

Treatment guidelines for leishmaniasis was first developed by the Sri Lanka College of Dermatologist in 2013 (SLCD, 2013). However, it has not been updated since and is currently under revision (personal communication with the Secretary, SLCD Dr. K. Mallawaarchchi). SLCD (2013). It is the only guideline document available in Sri Lanka to date for treatment of leishmaniasis and it is pivotal to get these guidelines updated and to get the recognition of the document as the national guidelines on the management of leishmaniasis in Sri Lanka.

12.2 Evidence Based Treatment Measures and Case Management in Sri Lanka

12.2.1 Cutaneous leishmaniasis

a. Sodium Stibogluconate (SSG) Therapy

The treatment of choice for SL-CL is local infiltration of sodium stibogluconate (Sb (V); SSG), intramuscular SSG or cryotherapy with application of liquid nitrogen (SLCD, 2013). As per standard guidelines (SLCD, 2013) in Sri Lanka, 1-3ml of SSG is injected intra-lesionally (IL) every 5-7 days (SLCD, 2013). The average number of intra-lesional sodium stibogluconate (IL- SSG) injections required currently for healing is estimated as 10 injections given at weekly intervals (Silva et al., 2021b). The recommended criteria for IL-SSG in Sri Lankan include that the patient should have, less than 5 lesions with the longest diameter of the lesion less than 5 cm, and the lesions should not be affecting cartilaginous part of the ear, periorbital skin, eye lid or nose. Following treatment of ten or less IL-SSG weekly injections, usually there should be a complete flattening of papules, nodules or plaques with no open ulcer or induration or any signs of inflammation to confirm as complete cure (SLCD, 2013; Silva et al., 2021b).

Intramuscular injection of SSG (IM-SSG) is not widely used for treatment of CL in Sri Lanka due to more side effects when compared with local infiltration. Intramuscular Sb is indicated for patients with > 5 lesions, larger (> 5 cm in diameter) lesions, lesions affecting cartilaginous part of the ear, periorbital skin, eye lid and nose, children who cannot tolerate IL- SSG due to pain and for those who fail to respond to IL-SSG after 10 treatment sessions (SLCD, 2013). The SLCD (2013) recommended IM-SSG dose is 10 – 20 mg/kg/day for 14 days. If the response is not adequate on day 14, the treatment can be extended for 7 more days. Continuous monitoring for systemic adverse effects should be done during the period of treatment (SLCD, 2013).

b. Liquid Nitrogen Cryotherapy

Even though liquid nitrogen cryotherapy is an accepted method, local pain, ulceration, depigmentation, and scarring were reported with a recurrence rate of 1.6% (Ranawaka et al., 2011). Low compliance and smear positivity for long periods following treatment were also reported (Siriwardena et al., 2003). Recent clinical observations at most treatment centers in Sri Lanka have revealed that CL lesions have started showing poor response to liquid nitrogen monotherapy (personal communication with several Consultant Dermatologists by Dr. K. Mallawarachchi).

c. Intralesional Metronidazole Therapy

The efficacy of intralesional metronidazole on *L. donovani* cutaneous leishmaniasis has also been assessed in Sri Lanka. 188 patients with CL were randomly allocated to IL- SSG and intralesional metronidazole. This study showed that IL-SSG has the best response against CL, while intralesional metronidazole was an effective alternative treatment (Somaratne et al., 2019).

d. Intralesional Hypertonic Sodium Chloride (HS) Therapy

Intralesional hypertonic sodium chloride (HS) has been shown to be effective against CL in Sri Lanka, in a randomized clinical trial comprising 444 patients with CL; the safe concentration of HS for this treatment was 10% HS (Ranawaka et al., 2015). However, cutaneous necrosis was observed in 3.1%. HS was estimated to cost <1 USD per 100 ml, whereas SSG was priced at USD 160 per 100 ml at the time the study was conducted. Even though Ranawaka et al. (2015) reported high cure rates with HS, there was only one more study available in the global literature on HS treatment (Sharquie, 1995). Not many Sri Lankan Dermatologists use HS widely (personal communication with several Consultant Dermatologists by Dr. K Mallawarachchi) due to the difficult procedure in the preparation of HS in a sterile manner or/and due to lower cure rates or/and skin necrosis observed with individual experience. However, the reasons for the non-usage of HS have not been reported in the literature so far.

e. Thermotherapy

The impact of thermotherapy towards *L. donovani* was first assessed in Sri Lanka in 2017 when it was reported that a single application of radiofrequency-induced heat therapy (RFHT) (ThermoMed Model 1.8, Thermosurgery Technologies, Inc., Phoenix, AZ) was safe, cost effective and convenient when compared to multiple doses of IL-SSG (Refai et al., 2017).

Following this, a randomized controlled proof of principle clinical trial, with two arms was carried out in Tangalle, Hambantota, and Anuradhapura, from January 2017 to January 2018, to assess the effect of thermotherapy as a therapeutic response in cutaneous leishmaniasis lesions which did not respond to IL – SSG using two types of thermotherapy devices; RFHT ThermoMed Model 1.8, Thermosurgery Technologies, Inc., Phoenix, AZ) and handheld exothermic crystallization thermotherapy for CL [HECT-CL] device (Pristech Products, San Antonio, TX) (Silva et al., 2021b). 40 CL treatment failures to IL- SSG were enrolled and randomized to the two arms, in an allocation ratio of 1:1, without masking. Patients were allocated to receive 1) RFHT by a ThermoMed™ device (Model 1.8) which was applied as a single application at 50°C for a duration of 30 seconds, under local anesthesia with 2% lidocaine, and 2) thermotherapy by a handheld exothermic crystallization thermotherapy for CL [HECT-CL] device, one application daily starting at 52 ± 2°C for 3 minutes in one to three fractions (depending on the pain tolerance of the patient), under anesthesia with a topical anesthetic cream. Latter treatment was repeated for seven consecutive days. The primary outcome assessed was the cure rate, and the occurrence of second-degree burns and their healing was assessed as a secondary outcome. Patients were followed up for 180 days post-thermotherapy with a final follow-up in February 2020. Intention-to-treat cure rates were calculated at day 90 (initial cure rate) and at day 180 (final cure rate) post-treatment. In the RFHT group: the initial cure rate was 100% (20/20) and the final cure rate was 95% (19/20), with one patient relapsing. The HECT-CL group: both the initial and final cure rates were 80% (16/20), with no relapses and one excluded from the trial. However, in the RFHT group 65% suffered second-degree burns with blistering and rupture of blisters within the first week after treatment while the HECT-CL group only 15% had second- degree burns (Silva et al., 2021b).

Radiofrequency–induced heat therapy consumed less time and required only a single hospital visit. Handheld exothermic crystallization thermotherapy for CL is potentially usable at community settings with both being less costly (HECT: less than 2 USDs) than IL-SSG (Silva et al., 2021b). This study recommended thermotherapy as an efficacious and safe treatment for CL patients in Sri Lanka, complicated by treatment failure to IL-SSG (Silva et al., 2021b).

12.2.1.1 Evidence on Treatment Failure

Newer concerns regarding management of CL cases have now emerged. Persistent CL lesions (i.e. lesions that have not completely healed following at least 10 injections of weekly IL- SSG) or re-occurrence of a lesion (relapse) after previously completing a weekly injection course of

IL-SSG treatment and achieving complete cure, have been reported from disease hotspots in the North and South of the country, particularly from the Anuradhapura and Hambantota districts indicating the possibility of poor response or treatment failure (Refai et al., 2016; Silva et al., 2021b).

Refai et al., 2016 followed up the clinical records of 396 patients who presented to the Anuradhapura Teaching Hospital, Dermatology Clinic, from April 2013 to February 2014. Out of the 396 patients, eight patients continued to attend the clinic due to poor response to treatment. "Delayed or lack of response to therapy" was defined as <50% reduction of the size of the lesion or degree of re-epithelialization of the lesion in the case of ulcers, or persistence of inflammation and swelling at the borders of the lesion in spite of several sessions of IL- SSG or IM-SSG and/or cryotherapy administered over a period of 10 weeks to 6 months (Refai et al., 2016). The presence of treatment failure to IL- SSG was further confirmed by Silva et al., (2021b) in a study carried out in 201 laboratory-confirmed CL patients who attended the District General Hospital Hambantota and Base Hospital Tangalle in southern Sri Lanka between 2016 and 2018. Following IL- SSG therapy these patients were followed up for three months to assess treatment response. Treatment failure was reported amongst 75.1% (Silva et al., 2021b).

Further studies reported that atypical cutaneous lesions (ACL) due to *L. donovani* diagnosed in Sri Lanka demonstrate a delayed response to the first-line anti-leishmanial treatment (Siriwardana et al., 2019a). An average of 18 doses of weekly SSG and 16.7 months were taken by the patients with ACL to achieve a complete clinical cure of the lesions while an average of 10 doses over 12 weeks was required for a typical cutaneous lesion to complete clinical cure as evidenced by epithelialization.

As local *L. donovani* variants may undergo genetic changes which could result in changes to the already known clinical manifestations, epidemiological distribution and treatment response may also vary (Siriwardana et al., 2019b).

12.2.2 Treatment of visceral leishmaniasis in Sri Lanka

Two of the confirmed symptomatic VL cases were successfully treated with intravenous SSG (IV-SSG) 20mg/kg body weight for 28 days with complete cure (Abeygunasekera et al., 2007; Ranasinghe et al., 2012) while one out of six patients reported by Siriwardana et al. (2017) who

in spite of being treated with 3 cycles of liposomal amphotericin (brand Fungizone) 3mg/kg body weight for 14 days (1 cycle) passed away. This patient also had a co-morbidity of a diffuse large B cell lymphoma. Another patient was treated with IV-SSG 800 mg, daily for 26 days followed by oral miltefosine 100 mg daily for another 24 days with an outcome of complete cure; the last case was treated with IV-SSG for 28 days with an outcome of complete cure. None of the other 3 patients reported by Siriwardana et al. (2017) were treated with anti-leishmanial treatment.

12.2.3 Treatment of mucosal leishmaniasis

Only very few cases of mucocutaneous leishmaniasis is reported in Sri Lanka to date (Rajapaksa et al. 2005; Rathnayake et al., 2010, Sujanitha et al., 2018), although lesions inside the lip are observed and treated by many dermatologists (personal communication). SLCD (2013) recommends IM-SSG for treatment of mucosal leishmaniasis.

12.3 Drugs available in Sri Lanka

IL-SSG [Stibovita^{TM}, Vital Healthcare Pvt. Ltd., India], each 1ml containing sodium stibogluconate BP 330mg (which is equivalent to 100mg of pentavalent Antimony)] is available in Sri Lanka.

Observations and findings

- ➢ Different treatment regimens are being used despite clear guidelines been given by SLCD (2013).
- ➢ Dermatologists have observed that the drugs currently being used are less effective than previously used drugs.
- ➢ There is a shortage of drugs. Emergency stocks may have to be obtained from WHO on request.

12.4 Recommendations

- ✓ Develop National Treatment Guidelines – upgrade guidelines developed by SLCD and adopt them as the National Treatment Guidelines.
- ✓ Ensure access to treatment – conduct satellite clinics to cover peripheral villages.
- ✓ Provide counselling sessions.
- ✓ Conduct mobile diagnostic and treatment clinics with methods that can be used in the field.

13.Vector control

There are no specific guidelines developed for vector control nor is there a coordinated vector control programme is in place. The General circular dated 14/11/2019 issued by the Director General of Health services states that "Based on the entomological investigation findings both RMO and District Entomologist need to take appropriate vector control measures in collaboration with RE and the relevant MOH".

There are key health messages which should be given during case investigation; some having made reference to vector control measures. These include:

- To minimize indoor resting of sandflies: keep the houses clean regularly and allow sunlight to come in and facilitate air circulation in the premises.
- Old buildings, animal shelters and huts made with mud thatched walls with cracks and holes provide conducive environment for breeding sites of sandflies. Plastering the walls and floors with cracks and holes evenly with a suitable plastering material will avoid establishing breeding sites.
- Breeding sites and outdoor resting places of the sand fly can be eliminated by keeping the outdoor environment clean. Therefore,
  - Avoid unnecessary vegetation. Allow sunlight to fall and adequate air movement by removing unnecessary items like shady tree branches, broken parts/ debris near houses.
  - Avoid garbage dumping and decaying items near houses and control rodent habitats.
  - Avoid growing shady trees, bushes close to animal shelters. Clean the animal shelters by removing animal waste regularly and keep the shelters dry.
- Exposure to sand fly bites can be prevented by minimizing the vector/ human contact. Therefore,
  - Avoid outdoor activities as much as possible, especially from dusk to dawn and avoid outdoor sleeping.
    - Wear protective clothing (long sleeved shirts, ankle length pants) that cover the whole body when working outdoors, in animal shelters and during outdoor play.
    - Apply insect repellent to uncovered skin and under the sleeves and pant legs. Re-application of repellents needs to be done as they are effective only for 4- 6 hours

- Use other insect repellent methods available.
- Use bed nets impregnated with pyrethroid-containing insecticides if available. Untreated bed nets do not prevent sand fly entry due to small size of the insects.

Observations and Findings

- ➢ No vector control programmes were carried out in the areas visited.
- ➢ There was a general lack of awareness regarding the measures stated above.
- ➢ There is no monitoring mechanism to determine if the above information regarding vector control is provided during case investigations.

13.1Recommendations

- ✓ Continue with dissemination of above messages which will ensure good vector control practices that are already recommended.
- ✓ Develop an integrated vector surveillance strategy and implementation plan after vector bionomics are characterized from entomological surveillance monitoring.
- ✓ Adopt the General circular dated 14/11/2019 issued by the Director General of Health services that states that "Based on the entomological investigation findings both RMO and District Entomologist need to take appropriate vector control measures in collaboration with RE and the relevant MOH" (Annexure 1).
- ✓ Training of all categories of staff engaged in vector control.

14. Human Resources

Many categories of personnel are engaged in the diagnosis, treatment, prevention and control of leishmaniasis. Dermatologists play a key role in diagnosis and treatment of leishmaniasis in Sri Lanka. The distribution of Dermatologists in the country as of 1st July 2023 is shown in Table 1. As seen in this table, the distribution is not equitable. Some Dermatologists conduct satellite clinics in institutions that do have a Consultant Dermatologist.

Table 1. Distribution of Dermatologists in Sri Lanka as of 1st July 2023

Province	District	Number of Dermatologists
Western	Colombo	13
	Gampaha	5
	Kalutara	4
Southern	Galle	5
	Matara	2
	Hambantota	2
Sabaragamuwa	Ratnapura	4
	Kegalle	4
North Western	Kurunegala	4
	Puttalam	3
North Central	Anuradhapura	2
	Polonnaruwa	1
Central	Kandy	7
	Nuwara Eliya	0
	Matale	1
Uva	Badulla	3
	Monaragala	0
Eastern	Batticaloa	1
	Ampara	1
	Trincomalee	1
Northern	Jaffna	3
	Mannar	0
	Vavuniya	1
	Kilinochchi	0
	Mullaitivu	0

In addition to Dermatologists, PHLTs and MLTs are involved in diagnosis of CL by SSS. Although these officers report on SSS, they have not been formally trained. There is also no quality assurance programme in place.

Consultant Histopathologists and Haematologists are also involved in diagnosis of leishmaniasis.

The field health staff involved in preventive and control measures are primarily the PHIs. Although there are guidelines that they should follow, there is no monitoring system. Some of them have not been even trained.

Although Medical Officers in outpatient departments are expected to have the knowledge and skills in diagnosing leishmaniasis, most of them may not have seen CL patients. No information such as bench aids to diagnosis are available.

The preventive and control activities are conducted under the purview of MOHs, REs and the RMOs. Most of these cadres have not had any formal training in leishmaniasis prevention or control.

Although the AMC has been designated the focal point for leishmaniasis in Sri Lanka, even the staff of the AMC have no expertise in leishmaniasis prevention or control.

Observations and findings

- There is a dearth of expertise on leishmaniasis prevention and control in the country.
- Staff cadres have had no formal training on leishmaniasis except for some *ad hoc* programmes conducted by some Universities to selected categories.
- There are no guidelines and teaching-learning materials for staff cadres to follow.

14.1 Recommendations

- ✓ Identify all cadres of staff that need training.
- ✓ Develop training material for different cadres of staff.
- ✓ Develop a training schedule.
- ✓ Organize specialized training for the AMC HQ staff that need specialized training.
- ✓ Include leishmaniasis prevention and control in allied health training programmes and undergraduate medical curricula.
- ✓ Have Continuing Professional Development programmes.

15. Supply Chain Management

The process of purchasing drugs for the national annual requirement is managed by the Medical Supplies Division (MSD), National Medicines Regulatory Authority (NMRA), and the State Pharmaceuticals Corporation (SPC) of Sri Lanka adhering to Cosmetics Devices and Drugs (CDD) Act (Ministry of Healthcare & Nutrition, Sri Lanka, 2008).

The Policy Framework is well-defined explaining each step in the "Manual on Management of Drugs" published by said Ministry of Health Sri Lanka (Ministry of Healthcare & Nutrition, Sri Lanka, 2008).

The supply chain of drugs is managed through the "Management cycle of pharmaceuticals". A password-protected SWASTHA database (Ministry of Health, Sri Lanka, n.d) is used to prepare the estimation of annual requirements of drugs using the data uploaded from each hospital pharmacy in the country.

The Manual on Management of Drugs (Ministry of Healthcare & Nutrition, Sri Lanka, 2008) describes "Stock Control" which addresses the Indenting (receipts) and Issues and Maintenance of specified buffer stocks. The MSD would maintain the buffer stock of 3 months while each institution would maintain for 1-2 months. The normal Lead Time of procurement by SPC varies from 11-15 months or more depending on the type of Tender Board that the drug falls into (Ministry of Healthcare & Nutrition, Sri Lanka, 2008).

There is a procedure for local purchase of drugs for individual indoor patients. The National List of Vital, Essential and Non-Essential (VEN) drugs was published jointly by the Ministry of Healthcare & Nutrition and the Faculty of Medicine Colombo (Ministry of Healthcare & Nutrition, Sri Lanka & Department of Pharmacology, Faculty of Medicine, Colombo, 2009). The medicines not listed in the Essential Medicines list could be purchased as a "Named Patient Item" (State Pharmaceuticals Corporation of Sri Lanka, 2023). There is also a list of "Red Light Antibiotics" which need the authorization of a Consultant Microbiologist prior to prescribing as a strategy to combat antimicrobial resistance under the antibiotic stewardship programme (Ministry of Healthcare, nutrition & Indigenous Medicine, 2016).

It is essential to register every drug with the NMRA, before it is imported or manufactured locally (Ministry of Healthcare & Nutrition, Sri Lanka, 2008). However, the registration of a new chemical costs LKR 50,000 LKR +VAT for a new drug while a re-registration costs LKR 10,000 (NMRA, 2023a) and the process is time-consuming. Before registering the drug, quality assurance is carried out adhering to the CDD Quality Assurance Act. Good Manufacturing Process and other important aspects will be assessed during this process (Ministry of Healthcare & Nutrition, Sri Lanka, 2008); the Office of Director Medical Technology & Supplies and National Drug Quality Assurance Laboratory (NDQAL) are the principal institutions responsible for implementing the activities of the national drug quality assurance system (Ministry of Healthcare & Nutrition, Sri Lanka, 2008). Drugs indicated for rare diseases and drugs designated as "orphan" to Sri Lanka by the NMRA and medicines that are submitted through the WHO Collaborative Registration Procedure are subjected to expedited review (NMRA, 2021).

Distribution and logistics of drugs are managed through the MSD. For the medicines and vaccines that require the cold chain, maintenance of the cold chain will be strictly monitored throughout the storage and distribution process until it is administered to the patient (Ministry of Healthcare & Nutrition, Sri Lanka, 2008). The MSD, Regional MSDs, hospital pharmacies, wards and clinics are adequately equipped with cold rooms, fridges etc (Ministry of Healthcare & Nutrition, Sri Lanka, 2008).

There is a process of "Monitoring of Annual Consumption of Drugs" as well as the "Disposal of Expired/Spoilt Drugs and methods to Minimize Wastage" within the Ministry of Healthcare and Nutrition (Ministry of Healthcare & Nutrition, Sri Lanka, 2008).

Anti-Leishmaniasis Medicines

Sodium Stibogluconate 10g/100ml vial and Amphotericin B 50mg Vial are the only stock items listed in the Priority list for Pharmaceuticals approved by the Ministry of Health Sri Lanka for 2023 (Ministry of Health, Sri Lanka, 2023).

Sodium Stibogluconate (SSG): SSG was not registered at NMRA in 2023 but included in the List of Essential drugs (Ministry of Healthcare & Nutrition, 2009) and Priority Pharmaceuticals 2023 in the Ministry of Health (Ministry of Health, Sri Lanka, 2023). This requires cold chain (2-8° C) maintenance.

Stock availability for 2023: **Out of stock**

(Previously available brands in Sri Lanka were: PENTOSTAM, GSK, UK (no more in production), STIBOVITA; Vital Healthcare (Pvt) Ltd, India., Generic Brand: Mercury Laboratories, India, GUFISOME: Gufic Biosciences Pvt Ltd, India)

Cost: Unit cost without VAT (100ml Vial): LKR: 51,000. Annual requirement 1000 Vials: LKR 5.1 million (average US$ 15,000).

Reason for going "out of stock" situation:
Stockout of SSG is known to be due to the lack of registered suppliers due to the high cost of registration and low profit margin, and due to withholding of Waiver of Registration (WoR) by the Ministry of Health at present. Furthermore, non- compliance by the supplier and changing of the manufacturer after approval by NMRA, resulted in calling of new tenders (personal communication with H.M.D.M. Bandara, Pharmacist, Medical Supplies Division).

Liposomal Amphotericin B (LAmB): This is a Red-Light antibiotic. The WHO recommended AmBisome which is suitable to treat VL is neither registered nor available in Sri Lanka. The LAmB products registered at NMRA Sri Lanka in 2023 include AMPHOLIP®; Bharat Serums & Vaccine Ltd, India., AMPHONEX®; Bharat Serums & Vaccine Ltd, India., GUFISOME; Gufic Biosciences Pvt Ltd, India). None of the LAmB products available in Sri Lanka has been shown to be effective for treatment of VL in clinical trials (Adler-Moore, et al., 2016). LAmB requires cold chain (2-8° C) maintenance.

However, one of the VL patients in Sri Lanka was once treated with FUNGIZONE® successfully. This was purchased as a Named Patient item (Siriwardhana, et al., 2017). FUNGIZONE® has clinical trial evidence for treatment of VL (Adler-Moore, et al., 2016).

Stock availability of LAmB for 2023: The products mentioned above are currently available (personal communication with H.M.D.M Bandara, Pharmacist, Medical Supplies Division).

Amphotericin B deoxycholate: Amphotericin B 50 mg is in the Priority Registration list 2023 at NMRA (NMRA, 2023b).

Stock availability for 2023: Currently available (personal communication with the Pharmacist MSD).

Unit Cost (without VAT)

The unit costs of LAmB products are around 10 times more than Amphotericin B deoxycholate. Therefore, when ordering stocks 25% are ordered from LAmB while 75% are ordered from Amphotericin B deoxycholate, and the latter is recommended for use in spite of the known higher risk of nephrotoxicity (Personal communication with the Pharmacist MSD).

Unit cost: Amphotericin B deoxycholate: LKR 5.000. LAmB: LKR 51,000/- (Personal communication with the Pharmacist MSD).

Miltefosine: Neither registered nor available in Sri Lanka. However, one of the VL patients in Sri Lanka was treated successfully, purchasing as a Named Patient item (Siriwardana, et al., 2017).

Paromomycin: is neither registered nor available in Sri Lanka

Pentamidine: is neither registered nor available in Sri Lanka

Itraconazole*: Available; Capsule: 100 mg (Ministry of Health Care & Nutrition, 2009), included in the Priority List for Pharmaceutical 2023 (Ministry of Health, 2023)

Fluconazole*: Available; Fluconazole lnj. 200mg in100mL Vial, included in the Priority List for Pharmaceutical 2023 (Ministry of Health, 2023), Capsule: 50 mg listed in the Essential Drug list 2009 (Ministry of Health Care & Nutrition, 2009)

*None of these compounds have been tested for efficacy in clinical trials in the treatment of *L. donovani* Sri Lankan strain. These compounds are listed as treatment options for cutaneous leishmaniasis (WHO, 2014).

Process of obtaining drugs to other control programmes; Review of other Parallel Healthcare systems.

Anti Leprosy Campaign-WHO donation
Anti Malaria Campaign- WHO donation
Anti Filariasis Campaign-Purchase through the Ministry of Health & WHO
Anti TB campaign- Purchase through the Ministry of Health

Observations and findings

- Forecasting of anti-leishmanials needs to be done well ahead; a continuous supply of Sodium stibogluconate needs to be guaranteed along with a few doses of AmBisome and Miltefosine that is adequate to treat a few patients of VL.

- Need to explore the possibility of obtaining SSG, Glucantime (Meglumine antimoniate), AmBisome, and Miltefosine through the WHO as is done for some other diseases.

- Need to explore the possibility of purchasing paromomycin ointment for children with CL through MSD or getting it donated through the WHO.

- Need to seek the possibility to categorize the above drugs as "Orphan" drugs with concessions given to suppliers so that the compounds will be registered at the NMRA.

15.1. Recommendations

- ✓ Strengthen procurement and supply chain management system.
- ✓ Ensure no stockout of medicines.

Part B
National Strategic plan for the prevention and Control of Leishmaniasis in Sri Lanka 2024-2028

1. Goal and objectives

Goal

To control cutaneous leishmaniasis for possible elimination as a public health problem in the future and prevention of VL and MCL.

Objectives

- To reduce the annual incidence of cutaneous leishmaniasis < 5 per 10,000 population by 2028 (approximately 6600 cases based on estimates).
- To ensure zero mortality due to visceral leishmaniasis.

1.1 Strategic interventions and priorities

The goal of the National Strategic Plan is to control cutaneous leishmaniasis for possible elimination as a public health problem in the future. This will be attained through the strategic aim:

"To **optimize, integrate and sustain** the three **strategic interventions** towards control of cutaneous leishmaniasis and for possible elimination as a public health problem in the future."

The National Strategic Plan for the control of Leishmaniasis in Sri Lanka 2024-2028 is adapted from the Regional Strategic Framework for Accelerating and Sustaining Elimination of Kala-Azar in the South-East Asia Region 2022-2026.

The plan comprises three strategic interventions and 5 supporting areas: The strategic interventions are the following:

Strategic intervention 1: Leishmaniasis surveillance including cutaneous leishmaniasis, visceral leishmaniasis and muco-cutaneous leishmaniasis;
Strategic intervention 2: Case diagnosis and management; and
Strategic intervention 3: Integrated vector management.

Implementation of the three strategic interventions is supported by the following supporting areas:

Supporting area 1: Leadership, programme governance and management;

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

Supporting area 3: Quality assurance;

Supporting area 4: Capacity building; and

Supporting area 5: Operations research.

2. Strategic intervention 1: Leishmaniasis surveillance

2.1 Parasitological surveillance

Although a system was established and implemented, currently the system functions only through the Communicable Disease Surveillance Programme which is initiated by notification with the H544. Since the AMC was appointed as the focal point, the submission of the special Leishmaniasis Surveillance – Case Investigation Form to the Epidemiology Unit has ceased.

After the AMC was appointed as the focal point for leishmaniasis, the AMC has been getting some data through the PHLTs via the RMOs but the data is incomplete. There is a major discrepancy in the numbers and, based on observations during field visits, there appears to be a gross underestimate of the actual burden of CL in the country.

2.1.2 Proposed activities

Development of a parasitological surveillance plan

A comprehensive parasitological surveillance plan will be developed such that the existing surveillance system will be modified and additional activities included to enhance the scope of work of the AMC, the focal point for leishmaniasis in the country. The plan shall be such that information generated from the existing system is accessible to the AMC for further action. The process involved may be similar to that of malaria which also comes under the Communicable Disease Surveillance programme but data are reported after verification and confirmation by the AMC. Besides, leprosy, tuberculosis and STDs/HIV are reported through another vertical system that does not involve notification through the general Communicable Disease Surveillance Programme.

The parasitological surveillance plan shall describe in detail the following:

- What data will be captured;
- How data will be captured;
- Sources of data collection;
- Formats for data collection;
- Frequency of reporting;
- Data flow;
- Reporting mechanisms; and
- Dissemination of findings.

The parasitological surveillance plan shall describe the coordination between passive and active surveillance, including the private sector and sentinel sites applicable. The surveillance plan should also clearly designate responsible personnel for its implementation and specify the authorities responsible for its implementation. The purpose of the plan should be to take necessary action to prevent further spread of the disease and eventually reduce the burden of leishmaniasis in the country.

It is proposed that a paper-based format is adopted at first and implemented. With fine tuning of the system a digital platform may be created using the District Health Information System 2 (DHIS2) platform with a mapping function.

Notification in Passive Case Detection

Notification should be based on suspicion from all institutions providing health care in both the public and private sectors. In institutions having PHLTs, MLTs and where biopsies are done, test results should be notified to the AMC.

Where PHLTs and MLTs are not available all suspected patients should be referred to a Dermatology clinic. This may result in duplication of data which can be resolved by using a unique health identification number.

For PCD, the personnel for reporting should be specified. The mechanism for reporting data from notification of a case to case investigation and reporting the findings of case investigations should be clearly stated. It also has to be mentioned whether the case investigated is a confirmed case.

The notification of cases may have to be tailor-made for different scenarios that have Dermatology clinics and those that do not have such clinics.

The system should also be designed to capture and report accurate and reliable data with no duplication of incidence data such that the figures reported to the AMC and the routine Communicable Disease Surveillance Programme tally. To facilitate this process some forms may have to be filled in duplicate or triplicate and sent to the different institutions.

It is proposed that a separate notification system be established to obtain information of confirmed cases reported and treated from Dermatology clinics.

Active case detection

For CL, ACD will be carried out as follows:

a) During case investigations the PHIs will enquire from household contacts and from residents of households in close proximity to the index case for persons having similar lesions. If any are found, they will be referred to the nearest Dermatology clinic.
b) By conducting mobile clinics in hotspot areas as determined by the RMOs and the AMC with the assistance of the MOH and range PHI. These mobile services may be combined with other disease surveillance programmes and integrated clinics.

For VL, active case detection will be carried out using rK39 RDT. The rK39 RDT has the ability to detect 95%- 100% of patients who have kala-azar, irrespective of the geographic region. The following activities will be carried out:

a) Identify sentinel sites for active surveillance of VL. It is proposed that initially institutions in high-risk areas will be selected (Anuradhapura, Polonnaruwa, Hambantota, Kurunegala, Matara, Matale and Ratnapura), preferably the larger hospitals, and later on to extend to other institutions depending on the geographic distribution of the disease. Inclusion criteria for screening will be patients having clinical features of simple continuous fever, weight loss, fatigue, anemia, enlargement of liver and spleen and involvement of bone marrow.

b) AMC HQ and Regional Malaria Offices will have rK39 RDTs for emergency testing. The AMC may be contacted if there is a suspicious case.
c) Screen all HIV patients.
d) Screen 10% of positives for CL.

Active surveillance to identify animal hosts

The dog is considered the main reservoir of leishmaniasis, but other animals such as hares and rabbits, goats, rodents, cats, and even birds may be effective reservoirs, and may be involved in transmission. With the assistance of the Public Health Veterinary Services and the Department of Animal Production and Health, a screening programme to identify potential animal hosts will be established in hotspots initially and extended further if necessary.

2.2 Entomological surveillance

One of the four pillars of action in the Global vector control response 2017–2030 is enhancement of vector surveillance and monitoring and evaluation of interventions (Kroeger et al., 2002; WHO, 2022b; WHO, 2023). In Sri Lanka, there are no guidelines for entomological surveillance of *Leishmania* vectors. A draft guideline for some entomological techniques have been developed by the AMC. An entomological surveillance programme for leishmaniasis should be established to achieve the following objectives:

- To ascertain the geographic distribution of sand fly species and trends.
- To determine the vector bionomics in diverse eco-epidemiological settings (seasonal prevalence, resting patterns (indoors or outdoors), feeding habits, and host preferences (humans or animals).
- To incriminate vector species responsible for transmission of the disease.
- To determine infection and infectivity rates.
- To determine and monitor insecticide resistance.

2.2.1 Proposed activities

Development of an entomological surveillance plan

A comprehensive entomological surveillance plan will be developed to achieve the objectives mentioned above. The entomological plan shall describe in detail the following:

- Identification of sentinel sites for entomological surveillance;
- Criteria for identifying sites for spot surveys;
- What techniques will be used with details on how they should be carried out;
- What data will be captured;
- Formats for data collection;
- How will data be reported;
- Data flow; and
- Dissemination of findings.

The entomological surveillance plan shall also include special surveillance to determine and monitor vector resistance to insecticides, clearly designate responsible personnel for its implementation and specify the authorities responsible for its implementation. The purpose of the plan should be to take necessary action to prevent further spread of the disease and eventually reduce the burden of leishmaniasis in the country.

It is proposed that a paper-based format is adopted at first and implemented. With fine tuning of the system a digital platform may be created using the DHIS2 platform with a mapping function.

Training of personnel

Most of the personnel have not been formally trained. In order to implement an entomological surveillance plan, basic and advanced training will have to be given to all engaged in entomological surveillance. Details of the training required are given under the section on training.

3. Strategic intervention 2: Case diagnosis and management

Diagnosis and case management plays an important role in leishmaniasis prevention and control.

3.1 Proposed activities for diagnosis

To provide a quality assured diagnostic service the following activities are proposed:

Develop training material for diagnosis of leishmaniasis

Training material to diagnose leishmaniasis will be developed with the assistance of academic institutions that have special interests in leishmaniasis and international experts with the assistance of the WHO targeting PHLTs and MLTs. Bench Aids will also be developed for quick reference. These will be distributed widely.

In addition, a pictorial guide for the detection of CL will be developed to be distributed in outpatients' departments for easy reference of medical officers to suspect leishmaniasis and refer for investigations or Dermatology clinics.

Conduct Training Programmes

With the aid of the training material that is developed, training programmes will be conducted by the AMC in a staggered manner. The effectiveness of the training programmes will be assessed.

Establish a monitoring system for quality assurance

A monitoring for quality assurance will be established. This will involve cross checking all positive slides and 10% of negative slides. An appraisal system will be developed. Based on the results, PHLTs and MLTs requiring further training will be given in-service training. If possible, an accreditation system will be developed.

Establish a reference laboratory for leishmaniasis

It is proposed that a national reference laboratory for the diagnosis of leishmaniasis be established at the AMC. Adequate funding will be needed for establishing and maintaining the reference laboratory and training of trainers who will be in-charge.

Ensure availability of RDT to screen for VL

It is proposed that rK-39 RDTs be used for screening of VL patients. Adequate numbers of RDTs will have to be procured and personnel using them will be trained.

Ensure availability of commodities for diagnosis of leishmaniasis

Currently, commodities for PHLTs performing leishmaniasis diagnostic testsare being provided by the AMC. This will have to be continued with additional funds for services provided by MLTs and for purchase of RDTs.

3.2. Proposed activities for treatment

Develop national treatment guidelines

Treatment guidelines that are currently being used were developed by the Sri Lanka College of Dermatologists in 2013. The guidelines are not always followed, partly due to shortages of anti-leishmanial medicines. It is proposed that the AMC collaborates with the Sri Lanka College of Dermatologists to upgrade the guidelines (this process has already been started) and the updated guidelines be used as the National Treatment Guidelines. The guidelines should be widely distributed among Dermatologists who will be managing these patients.

Ensure adequate supply of quality assured medicines

There have been many instances of shortages of medicines to treat leishmaniasis patients. Estimating the requirements of needed medicines should be done in collaboration with Dermatologists. All medicines procured should be WHO pre-qualified products.

Ensure access to treatment

The following activities are proposed to facilitate access to treatment.

a) Dermatologists will be provided with facilities and resources by the Ministry of Health to conduct satellite clinics in Divisional hospitals and above that do not have Dermatologists. It is proposed that such clinics will be conducted once in 2 weeks. Initially, high burden districts will be targeted and later expanded to other districts with the increase in the number of Dermatologists in the country.
b) Currently, the time taken for diagnosis is quite long and very often the patient is missed as some patients do not come back to collect the reports for various reasons including cost of travel. It is proposed that results of SSS will be provided on the same day, if

possible. Other methods for informing the results of investigations such as use of short message services (SMS) services will be used to reduce the burden of the patient in having to come a second time to collect the report.

c) A system will be established to monitor referrals to ensure that diagnosed patients are referred and treated. This will be done with the development of a laboratory and Dermatology clinic surveillance plan that will be established.

Provide counselling service

It is proposed to introduce counselling services to patients that have lesions in exposed parts of the body as there may be scarring. A manual and guidelines for counselling patients will be developed. Healthcare personnel including field staff coming into contact with patients will be identified and provided a short training programme.

Conduct mobile diagnostic and treatment clinics

It is proposed to conduct mobile diagnostic and treatment clinics in hotspots to reduce the reservoir of infection. AMC will collaborate with the Dermatologists and conduct such clinics. In addition to a Dermatologist, other staff, equipment, consumables and vehicles will be required. These mobile clinics may be provided along with other mobile healthcare services that are routinely conducted to minimize costs and improve efficiency of the health system.

4. Strategic intervention 3: Integrated vector management

Although Sri Lanka has totally eliminated indigenous malaria transmission and filariasis as a public health problem, dengue has been a persistent problem for several years while CL transmission has also increased in the recent past. The following activities are proposed to develop an integrated vector management plan.

4.1 Proposed activities

Continue with health messages already developed and recommended

The Ministry of Health, Nutrition and Indigenous Medicine has provided guidelines on advice to be given and vector control activities in the General Circular dated 14/11/2019. The circular has specific instructions to be followed at different levels. It specifically states that appropriate vector control measures should be taken by the RMO and District Entomologist in collaboration with the RE and MOH of the area based on entomological investigations.

It is proposed that these measures be continued until an integrated vector control strategy and plan can be developed after the vector bionomics and insecticide susceptibility status have been characterized. Once the required information is obtained, a mid-term review of the findings will be done to develop a suitable integrated vector management plan.

Develop an integrated vector management plan

As mentioned in section 10.2, the development of the entomological surveillance plan will be extended to cover other vector borne diseases after vector bionomics are characterized following entomological surveillance monitoring. This will help in developing an integrated vector management plan by end of 2026.

Training of all categories of staff engaged in vector control

Once the integrated vector control plan has been developed, all categories of staff involved will be trained in vector surveillance and control methods to be used. This will involve task shifting of some personnel and providing additional training to others in other disease control programmes. Training material will be developed and a training of trainers programme conducted so that district training programmes will be conducted by Regional Malaria Officers, District Entomologists and Regional Epidemiologists.

Procurement of equipment and supplies for integrated vector management

Additional equipment and supplies will be required. An inventory of available equipment and supplies available in health regions, including in other disease control programmes, will be taken and an estimate of the requirements based on the proposed integrated vector management plan will be made. WHO pre-qualified equipment and supplies will be procured wherever possible.

5. Supporting area 1: Leadership, programme governance and management

Leadership, programme governance and management are essential for developing and implementing a disease control programme for leishmaniasis in Sri Lanka as there was no organized programme before. Based on observation and evidence, it appears that leishmaniasis in Sri Lanka, reported in the early 20th Century benefitted from malaria control which depended largely on indoor residual spraying even till the 1990's. Leadership, programme governance

and management in establishing a new disease prevention and control strategy requires acceptance of the programme and commitment to implement the programme with adequate political and financial commitment. This becomes more difficult given that CL seen in Sri Lanka is not a fatal disease as compared to diseases such as dengue, but has the potential to do so with visceralisation.

5.1 Proposed activities

Advocacy to policy makers and health administrators

Policy makers and health administrators will be lobbied to consider leishmaniasis control an important preventive health measure as the increase in visceral leishmaniasis case will increase the disease burden in terms of morbidity and mortality. An advocacy brief will be prepared and updated highlighting the feasibility of incorporating leishmaniasis control activities with other routinely conducted activities and the possibility of doing so with increased intra- and inter-sectoral collaboration.

Political and financial commitment will be sought for additional work including training of staff.

Develop an integrated programme structure

The AMC is structured to prevent re-establishment of malaria in the country. The additional activities that will be required for the control of leishmaniasis will have to be incorporated in to the existing administrative structure and implementation plan with involvement of a wider stakeholder base including Dermatologists, Parasitologists, other clinicians, Public Health specialists and Entomologists. This will be done initially and approval sought from the Ministry of Health.

Ensure supervision and oversight

As additional work will be required during the early stages of setting up of necessary structures and activities, regular supervision and oversight will be provided by AMC HQ and Regional Malaria Officers.

Monthly meetings to discuss leishmaniasis control activities will be conducted either separately or in combination with monthly meetings of RMOs for malaria.

Establish an independent Technical Support Group

In order to ensure that the proposed activities will be carried as planned and in a timely manner, it is proposed to appoint an independent Technical Support Group (TSG) for this purpose. The TSG should meet every 2 months. The experience of the TSG for prevention of re-establishment of malaria provides evidence that such a TSG will monitor and provide oversight to leishmaniasis control activities.

The TSG shall be appointed by the Director General of Health Services who will chair the meetings. The TSG shall comprise

- Staff of the AMC (to be decided)
- Parasitologists
- A Dermatologist
- A clinician (Physician and/or Paeditrician)
- A public health specialist
- An entomologist
- Other co-opted members as necessary.

Develop a monitoring and evaluation plan

A monitoring and evaluation plan will be developed to ensure that all proposed activities are carried out in a timely manner, and if changes need to be made to existing plans. The plan should identify indicators and designate responsible personnel.

As there is sparse literature on CL control programmes, the following indicators are proposed:

1. Number of months between onset of symptoms and diagnosis (median):
2. Treatment rate (monthly) - Number of cases treated according to guidelines/total number of patients treated:
3. Number of patients treated with antimonials systemically/total number of patients diagnosed (monthly):
4. Number of lupoid (recidivans) cases (monthly):
5. Size of lesion: Number of patients with lesion size ≥ 4cm/total number of patients
6. Number of lesions: Number of patients with 4 or more lesions/ total number of patients
7. Location of lesions: Number of patients with lesions on face or ears/ total number of patients
8. Cure rate (follow-up 12 months) - Number of cases cured/ total number of cases treated

9. Compliance rate (for each type of treatment): Number of patients treated according to National Treatment Guidelines/ Number of patients eligible for treatment
10. Treatment failure rate (follow-up 12 months) - Number of cases with treatment failure/ total number of cases treated:
11. Relapse rate (follow-up 12 months) - Number of cases relapsed/total number of cases treated:
12. Percentage of serious adverse events cases (monthly) in patients treated with systemic/ intralesional antimonials, LAmB or Miltefosine and other anti-leishmanials - Number of cases with serious adverse effects/ total number of cases treated:
13. Parasitological confirmation: Number of patients with parasitological confirmation/ total number of patients
14. Health care system performance - Number of health facilities where diagnosis and treatment regimens are available (first-line regime) in endemic areas/total number of health facilities in endemic areas:
15. Rate of cutaneous leishmaniasis health facilities with stock-out of medicines - Number of cutaneous leishmaniasis facilities having faced stock-out of medicines (country level)/total number of cutaneous leishmaniasis health facilities:
16. Number of new cases diagnosed monthly (for each type of leishmaniasis):
17. Rate of new foci investigated - Number of new foci investigated/ total number of new foci in the country:
18. Is cutaneous leishmaniasis reporting integrated into the national surveillance system (including private sector, nongovernment organization, etc.)?
19. Is there a national budget line for the cutaneous leishmaniasis control programme?
20. Number of operational research projects completed:
21. Percentage of leishmaniasis personnel trained: Number of personnel trained/total number of personnel

Additional indicator may include

- Number of slides examined for cutaneous leishmaniasis
- Number of slides cross checked
- Number of entomological surveillance days conducted
- Number of community awareness programmes conducted
- Number of vector control programmes conducted
- Number of susceptibility tests conducted

- Vector infectivity status
- Reduction of vector density after implementation of control programme
- Number of meetings on leishmaniasis held per year

Due to the paucity of baseline data for some indicators, estimated targets will have to be derived and these will have to be revised with time. However, targets can be provided for process indicators.

Strengthen procurement and supply chain management

There have been many reports of stock outs of anti-leishmanial medicines. Estimation of required medicines should be done in consultation with Dermatologists. A online database for medicines and their distribution should be included in the existing procurement and supply chain monitoring system.

Where manufacturers are few and quantity of medicines needed are small, processes to obtain same from international sources directly or through WHO should be explored.

Mid-term review of the programme

It is proposed to conduct a mid-term of the programme in mid-2026. At this review, information generated from surveillance (both parasitological and entomological) and progress of the implementation of the National Strategic Plan for the prevention and control of leishmaniasis in Sri Lanka will be reviewed. Based on the findings, changes needed to the National Strategic Plan will be made, if necessary.

6. Supporting area 2: Community awareness and engagement on prevention and care;

Community awareness and engagement will play a key role in augmenting community support for leishmaniasis control activities. The objectives will be to increase awareness on CL and to seek early diagnosis and treatment and harness community participation in vector control activities.

6.1 Proposed activities

Continue with the messages given during case investigation

Continue with messages to be given during case investigation as outlined in the General Circular dated 14/11/2019 issued by the Director General of Health Services until a communication strategy that identifies target groups and key messages are developed. Additional awareness raising key messages and information sources will be developed, or already available messages will be modified to suit the local setting. Additional funding for this activity will be required.

Develop a communication strategy and plan

A communication strategy and plan identifying target groups, key messages and modes of communication will be developed within the first two years. If possible, the strategy will be aligned to cover all vector borne diseases in relation to vector control.

Develop suitable IEC material and training of staff

Based on the identified key messages, target audiences and modes of communications in the communication strategy and plan, suitable IEC material will be developed. Once the IEC materials are developed, staff will be trained on how to deliver them.

Engage school children in the programme

Engagement of school children has the potential of taking awareness raising messages beyond the school to individual homes. Programmes will be developed by Public Health Inspectors focusing on vector control through school health clubs as part of the School Health Programme. Assistance for this activity will be sought from the Zonal Directors of the Ministry of Education and school principals.

7. Supporting area 3: Quality assurance

Quality assurance of all activities will be maintained. The activities will include surveillance, diagnosis, case management and vector control.

7.1 Proposed activities

Develop Standard Operating Procedures (SOPs)

Standard operating procedures will be developed for surveillance, diagnosis, case management and vector control and approved by the Ministry of Health.

Establish a quality assurance programme for diagnosis

A quality assurance programme will be developed for diagnosis. The competencies of all PHLTs and MLTs in diagnosis of CL by SSS will be assessed on a regular basis. Based on the results, PHLTs and MLTs whose performance is not satisfactory will be given refresher training at the reference laboratory established at AMC HQ.

Cross checking of all positive smears and 10% of negative smears will be done at the AMC HQ Reference Laboratory.

Procure WHO pre-qualified medicines and other commodities

WHO pre-qualified medicines, diagnostic test kits and insecticides used for vector control will be procured, where available.

8. Supporting area 4: Capacity building

The review of the current practices adopted for control of leishmaniasis in Sri Lanka revealed that all categories of staff, except Dermatologists, involved in the diagnosis, treatment and control of leishmaniasis have not been formally trained. Training will be a major part in the initiation of leishmaniasis control activities.

8.1 Proposed activities

Develop training material

Training material for different categories of staff (PHLTs, MLTs and PHIs) will be developed for diagnosis and vector control. Bench aids and online material will be developed or adapted from material already available in the public domain.

Develop a training schedule

A training schedule for different categories of staff will be developed. It will be mandatory for all targeted officers to follow the training programmes. This training schedule will also include regular in-service training programmes for different categories of staff.

Include modules on leishmaniasis prevention and control in allied health training programmes and undergraduate medical curricula

At present, undergraduate medical training programmes in the country have a basic curriculum on leishmaniasis. This will be given more importance in collaboration with academia of medical faculties, as the case load of CL is increasing in the country.

Modules on leishmaniasis will also be included in allied health training programmes. The modules will be specific for different training programmes (for example, a module on diagnosis of leishmaniasis will be included in PHLT and MLT training programmes; a module on sandflies and vector control will be included in PHI training programmes).

Conduct Continuing Professional Development programmes

Continuing professional development programmes will be conducted for clinicians in collaboration with professional colleges and medical associations. Areas with a high burden of CL will be targeted initially and then expanded to the rest of the country.

Specialised training

As there is a dearth of personnel with specialized training in leishmaniasis and its control, it is proposed that 5 professional staff be provided with specialized training at a centre of excellence. Ideally AMC staff should be given the training as the AMC is the focal point and will be responsible for all aspects of leishmaniasis management and control. Once trained, the trained personnel can be local trainers for others in the programme.

9. Supporting area 5: Operational research

The paucity of information regarding strategic plans to control CL makes operational research an important supporting area.

The results of operational research will play a key role in adapting the strategic plan as new information will become available. Some priority areas for research include

- Parasite related studies; drug resistance, identification of aetiological agent of MCL
- Vector bionomics
- Vector infectivity studies
- Vector susceptibility studies
- Animal hosts
- Comparison of different control approaches
- Clinical trials of different treatment modalities

It is proposed to have a research colloquium in early 2026 to present findings that may be used to review the national strategic plan for the control of leishmaniasis in Sri Lanka during the mid-term review scheduled in the middle of 2026.

10. Activity plan

The detailed activity plan is given in Table 2.

Table 2. Activity plan

Activity	Sub-activity	2024				2025				2026				2027				2028			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
National Strategic Plan	Finalisation and adoption	√																			
Surveillance																					
Parasitological surveillance																					
Parasitological Surveillance plan	Select team to develop the surveillance plan		√																		
	Develop the surveillance plan		√	√																	
Conduct parasitological surveillance		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Active case detection for CL & MCL	Develop plan		√	√																	
	Carry out ACD				√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Active case detection for VL	Procure RDTs		√			√				√				√				√			
	Identify sentinel sites and carry out ACD for VL			√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Active surveillance to identify animal hosts	Develop plan and proposals			√	√																
	Conduct studies					√	√	√	√	√											

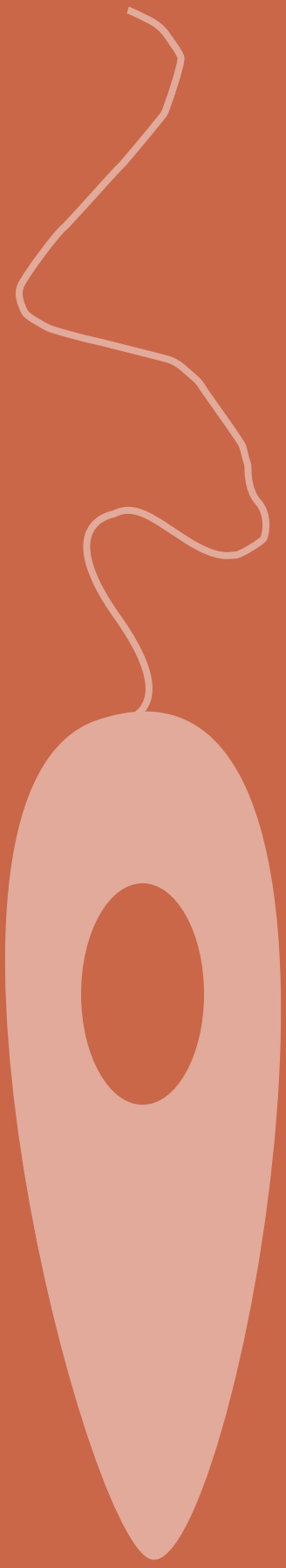
Activity	Sub-activity	2024				2025				2026				2027				2028			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Entomological surveillance																					
Entomological surveillance plan	Select team to develop the surveillance plan		√																		
	Develop the surveillance plan		√	√																	
Case diagnosis and management																					
Develop training materials	Select team to develop training material		√																		
	Develop the training material		√	√																	
Conduct training programmes	Prepare a training schedule				√																
	Conduct training programmes					√	√	√	√	√	√	√	√				√				√
Establish quality assurance monitoring system for diagnosis	Develop plan		√	√																	
	Implement plan				√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Establish Reference laboratory	Identify requirements			√																	
	Procure necessary equipment and supplies				√	√	√														
	Train staff				√	√	√														
Develop National treatment guidelines	Develop guidelines		√	√																	

Activity	Sub-activity	2024				2025				2026				2027				2028			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
	Raise awareness among clinicians				√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Provide counselling service	Develop training material		√	√																	
	Train staff				√	√	√	√	√				√				√				√
	Conduct counselling services				√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Conduct mobile/outreach programmes	Develop a programme		√	√																	
	Procure necessary equipment and supplies			√	√	√	√	√	√												
	Implement programme					√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Integrated vector management	Continue current with vector control activities	√	√	√	√	√	√	√	√	√	√	√	√								
Develop health education messages	Develop health education message	√	√	√	√																
Develop integrated vector management strategy	Develop integrated vector management plan											√	√								
	Implement revised plan													√	√	√	√	√	√	√	√
Training of staff	Develop training material and schedule					√	√	√													
	Conduct training programmes								√	√	√	√	√								

Activity	Sub-activity	2024				2025				2026				2027				2028			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Procurement of equipment	Procurement of equipment and supplies				√	√	√	√													
Leadership, programme governance and management																					
Conduct advocacy sessions for policy makers and administrators	Develop advocacy material		√	√																	
	Conduct programmes				√	√				√				√				√			
Develop and establish integrated programme structure	Programme structure endorsed by Ministry of Health		√																		
Supervision and oversight		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Establish Technical Support Group	Establish Technical Support Group		√																		
	TSG meetings		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Develop Monitoring and Evaluation plan	Develop M&E plan		√	√																	
	Review progress at monthly meetings		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Strengthen Procurement and Supply chain management			√	√	√																

Activity	Sub-activity	2024				2025				2026				2027				2028			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Conduct mid-term review											√										
Community awareness and engagement																					
Develop suitable messages			√	√																	
Develop a communication strategy			√	√																	
Develop suitable IEC material				√	√	√	√														
Training of staff						√	√	√	√			√	√			√	√			√	√
Engage school children in prevention	Develop a programme		√	√																	
	Implement programme				√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Quality Assurance																					
Develop Standard Operating Procedures	Identify procedures requiring QA		√																		
	Develop SOPs		√	√	√	√															
Establish quality assurance programmes					√	√	√	√	√												
Procurement of WHO pre-qualified commodities			√	√				√	√					√	√			√	√		
Capacity building																					
Develop training material	Identify training needs		√																		

Activity	Sub-activity	2024				2025				2026				2027				2028			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
	Develop training materials		√	√	√	√															
	Conduct training programmes					√	√	√	√			√	√			√	√			√	√
Introduce modules in health-related courses and training programmes	Discussions with heads of training institutes and universities	√	√																		
	Develop training material		√	√	√	√															
	Introduce and implement modules				√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Conduct CPD activities				√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Specialised training	Identify personnel requiring specialised training		√																		
	Identify training institutions			√																	
	Provide training				√	√	√														
Operational research	Develop proposals			√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
	Conduct research			√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√



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Annexure

Annexure 1: General Circular

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சுகாதார, போசணை மற்றும் சுதேச வைத்திய அமைச்சு
Ministry of Health, Nutrition & Indigenous Medicine

General Circular No:

All Provincial Directors of Health Services
All Regional Directors of Health Services
All Directors of Provincial General and District General Hospital
All Medical Superintendents of Base Hospitals
All Heads of Medical Institutions
Directors of Special Campaigns/Units
Chief Medical Officer, Colombo Municipal Council
All Medical Officers of Health

Guidelines on Prevention and Control of Leishmaniasis

Leishmaniasis is a vector-borne parasitic disease which is estimated to cause the ninth largest disease burden among individual infectious diseases in the world. Three hundred and fifty million people are at risk of getting the disease with an annual incidence of two million cases. It is endemic in 97 countries, which are mostly in tropical and subtropical regions. Leishmaniasis is an endemic disease in the South-East Asian Region. It is evident that the disease is increasing in the world with a wider geographical distribution.

Three main clinical manifestations of leishmaniasis are Visceral Leishmaniasis (VL), Muco Cutaneous Leishmaniasis (MCL) and Cutaneous Leishmaniasis (CL). Cutaneous leishmaniasis (CL) is the most common form of leishmaniasis which causes skin lesions, mainly ulcers, on exposed parts of the body, leaving life-long scars and disability which may cause stigma.

Cutaneous Leishmaniasis is an emerging public health problem in many countries including Sri Lanka. CL has been established as an endemic disease within a short period of time in the country despite the first local case reported from the Ambalanthota

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MOH area in Hambantota District in 1992. Number of reported leishmaniasis cases have increased gradually after the disease became notifiable in 2008. More than three thousand cases have been reported during 2018 alone. Five districts namely, **Anuradhapura, Hambantota, Polonnaruwa, Kurunegala and Matara** are contributing to approximately 90% of the total annual caseload. Cutaneous Leishmaniasis is the predominantly reporting form of leishmaniasis in Sri Lanka though there were few sporadic cases of visceral and mucosal leishmaniasis reported in the past.

Leishmaniasis is caused by several different species of genus *Leishmania*. The causative organism of leishmaniasis prevailing in Sri Lanka was identified as *Leishmania donovani* (zymodeme MON 37). The parasite undergoes part of its developmental cycle in the body of the sand fly which is essential for transmission of disease to the humans.

Sand flies are the known vector for leishmaniasis. The disease is transmitted through a bite of an infected female sand fly of subfamily Phlebotominae. *Phlebotomus argentipes* is the most likely vector of *L.* donovani in Sri Lanka. Sand flies are widely prevalent in some parts of the country are locally known as "weli massa" or "hohaputuwa" in different parts of the country.

Sand flies are small insects with two to three millimeters in body length. Body colour varies from light brown to black with hairy appearance and having large black eyes and long, stilt-like legs. They keep their wings in a characteristic "V" shape while at rest. Sand flies are weak and silent flyers with characteristic hopping movements. They tend to remain closer to the breeding sites, moving around hundred meter radius. Most sand-fly species tend to fly horizontally and close to the ground level. Sand flies are most active from dusk to dawn and less active during the warmer times of the day. Even though both female and male sand flies feed on plant juices, females take blood meal to mature the eggs. Their feeding activity is influenced by climatic factors such as temperature, humidity and flow of wind. The common resting sites of adult sand flies are cracks and holes in rocks, caves, and rodent burrows, cool, dark and humid corners of animal shelters or human dwellings in peri-domestic settings.

People may expose to sand fly bites during dusk to dawn whilest staying indoors. However, day time biting can occur in darkened rooms, among shaded vegetation specially when disturbed by human activities. Therefore, those who are working outdoors such as agricultural workers are at higher risk.

Sand flies predominantly make their habitat in warm, humid and tropical climates. They have four- stages in their life cycle (egg, larva, pupa and adult). They require microclimate with high humidity to develop their eggs and moist soil with decaying organic matter for the development of larvae. The common breeding places include bark and buttress roots in old trees, animal shelters, cracks and holes in floors and walls, household garbage dumps which are rich in moisture and humus. The exact duration of the life cycle depends mainly on environmental factors, however the approximate

duration is 20- 30 days. Adverse environmental conditions such as heat, cold, droughts may prolong the life cycle.

Reservoir host for leishmania is mammals including humans. Disease can transmit to the human either by infected human (anthroponotic transmission) or an animal (zoonotic transmission). Humans have been identified as the main reservoir for L. donavani. There is some evidence suggestive of possible reservoir status of domestic dogs in Sri Lanka.

Clinical picture varies according to the causative species and host factors.

- Cutaneous leishmaniasis (CL) – This is the commonest form of leishmaniasis. Skin lesion starts with the appearance of a small papule after one to two weeks to several months of a sand fly bite. The papular lesion could developed into a nodular lesion that may enlarge and could become a chronic ulcer. These lesions usually develop in exposed areas of the body such as face, neck, arms and legs in single or multiple lesions. However it can appear in other areas of the body where bite of the sand fly has occurred. Lesions are usually painless and non-itchy and some may heal spontaneously over many months.

- Mucosal leishmaniasis (ML) – This is a less common variant of the disease. Some types of the parasite might spread from the skin and cause sores in the mucous membranes of the nose, mouth or throat.

- Visceral leishmaniasis (VL) – This variant of leishmaniasis is also known as Kala-azar. The illness typically develops within months following a sand fly bite. However, the incubation period can vary from months to several years. Clinical features include simple continuous fever, weight loss, fatigue, anemia, enlargement of liver and spleen and involvement of bone marrow. VL is a fatal condition if untreated.

Prevention and control measures

Ministry of Health has identified the Epidemiology Unit as the national focal point for control and prevention of Leishmaniasis in Sri Lanka.

At health care institutional level,

- All medical officers should be able to identify patients with suspected leishmaniasis (refer case definition below).

Surveillance case definition of Leishmaniasis
An illness with one or more localized skin lesions (nodules, papules or ulcers) that commonly appear on the exposed areas of the body (face, neck, arms, legs) or rare involvement of viscera (liver, spleen) or the mucosal tissue in mouth /nose (*Surveillance case definitions for notifiable diseases in Sri Lanka, Second Edition,2011, Epidemiology Unit, Ministry of Health*).

- **Refer all** suspected patients of cutaneous & mucocutaneous leishmaniasis to a **Dermatologist** /dermatology clinic for early diagnosis and management.
- Refer any suspected case of visceral leishmaniasis (although rare) to the Physician/ Paediatrician for further investigations and management.
- All suspected / confirmed cases of leishmaniasis should be notified to the Medical Officer of Health of patient's area of residence at earliest (By filling the Notification of a Communicable Diseases form - Health 544).
- All clinically or laboratory confirmed leishmaniasis patients should be treated adequately.
- Patients should be educated on the importance of continuing treatment and they should be followed up until complete cure.
- Make aware the patient / guardian about the disease and on preventive measures for the rest of the households

At Medical Officer of Health (MOH) level

- All the notified cases should be entered in the MOH Office Communicable Disease Notification Register and followed by field investigation within seven (7) days of the receipt of notification by the relevant range Public Health Inspector (PHI).

  The following aspects should be looked at during the field investigation:

  - Past history of similar illness
  - Any history of interruption of treatment, If so reasons thereof.
  - Any family member /close contact /neighbour having similar lesion.
  - Occupational and travel history.
  - Favourable environmental conditions for transmission of the disease, if any i.e. animal shelters, shrub areas

  If the PHI has identified any favourable conditions for disease transmission during his field investigations, he should provide advice /take measures to prevent further spread of the disease in the area. (refer key health messages)

  A follow up plan should be prepared for each patient by the PHI and should make sure that it is implemented.

- All clinically / laboratory confirmed cases should be entered into the Infectious Diseases Register (ID register, H 700) and should be sent to the Epidemiology Unit by filling Communicable Disease Part II form (H – 411a)
- A duly filled special investigation form for each confirmed case of leishmaniasis (entered in the ID register) should also be sent to the Epidemiology Unit.
- All confirmed cases should be followed up by the area PHI to ensure the continuity of treatment until complete cure.
- Outcome of the patient (complete cure / treatment default /non-response to treatment etc.) should be mentioned in the remarks column of the ID register.
- If a patient changes, his place of residence during the treatment period, patient's details should be notified to the relevant MOH for follow up.
- All household contacts of confirmed leishmaniasis patients should be screened for symptoms and signs by the area PHI. Households with suspected lesions of leishmaniasis need to be referred to the nearest dermatology clinic without delay.
- Required information on leishmaniosis surveillance should be notified weekly through "e-surveillance" (Weekly Return of Communicable Diseases - H 399) to the Epidemiology unit and to the respective Regional Epidemiologist.
- **If the area is endemic for leishmaniasis,**
  - It should be an agenda item and a discussion point in monthly MOH conference.
  - A spot map for leishmaniasis needs to be maintained at the MOH/PHI office.
- In the event of clustering of cases observed in the area,
  - MOH should organize an active surveillance in the area, with a view to identifying and early referral of suspected leishmaniasis cases.
  - Arrange entomological surveillance with the assistance of district entomological teams.
  - MOOH should carry out integrated vector control approaches and encourage personal protection methods.
  - Chemicals should be used with caution: decision on indoor residual spraying should be taken after careful evaluation of entomological findings and with the consultation with the Regional Epidemiologist and Regional Malaria Officer/ District Entomologist

- There is no proven evidence for outdoor fogging as a preventive measure for leishmaniasis.
- MOH should organize community awareness programmes

At District Level

Regional Epidemiologist (RE) should ensure that

- All suspected cases of leishmaniasis are being notified to the MOH from health institutions in the area.
- All notified cases are investigated, followed up and timely informed to the Epidemiology Unit.
- Analyzed and review of all information on leishmaniasis are received by the RE from the MOOH on regular basis.
- Based on the analysis, predict and intervene early in the outbreaks
- District situation of leishmaniasis is reviewed regularly and discussed at the District MOH reviews, Institutional heads meetings and other forums.

Health Entomological Officer (HEO)

HEO should carry out entomological surveillance for leishmaniasis based on the need of the district. HEO should submit a detailed report following entomological surveillance to the respective MOOH with copy to the Regional Epidemiologist. Once the reportis received, the Regional Epidemiologist should refer the report to the District Entomologist/Regional Malaria Officer/ Regional Filaria Officer for necessary action.

Regional Malaria Officer and District Entomologist

Based on the entomological investigation findings both RMO and District Entamologist need to take appropriate vector control measures in collaboration with RE and relevant MOOH.

At central level

Epidemiology Unit should ensure that,

- The timely and complete receipt of all Weekly Return of Communicable Diseases Returns (H 399) from all the MOOH areas
- Analyse all the special surveillance forms of the confirmed Leishmaniasis cases
- Predict and intervene early in the outbreaks of the disease
- Analyzed and review of all information on leishmaniasis and discuss during the quarterly REE reviews and other relevant forums

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Key Health messages to be given during field investigations/community awareness programmes

- Appearing a papule or nodule following a sand fly bite is an early sign of Leishmaniasis. When left untreated this skin lesion will developed into an ulcer which takes longer time to heal.
- It is important to get yourself examined by a dermatologist or a qualified medical officer to confirm the diagnosis and start early treatments. Therefore if you are having symptoms and signs suggestive of Leishmaniasis, seek medical advice from the nearest hospital.
- It is important to complete the full course of treatment to ensure complete cure.
- Leishmaniasis skin ulcer contains lot of parasites. Covering the wound with clean piece of gauze / cloth will prevent sand fly bite and further spread of the disease.
- To minimize indoor resting of sandflies, keep the houses clean regularly and allow sunlight to come in and facilitate air circulation in the premises.
- Old buildings, animal shelters and huts made with mud thatched walls with cracks and holes will provide conducive environment for breeding sites to the sand flies. Plastering the walls and floors with cracks and holes evenly with a suitable plastering material will avoid breeding sites.
- Breeding sites and outdoor resting places of the sand fly can be eliminated by keeping the outdoor environment clean. Therefore,
    - Avoid unnecessary vegetation. Allow sunlight to fall and adequate air movement by removing unnecessary items like shady tree branches, broken parts/ debris near houses.
    - Avoid garbage dumping and decaying items near houses and control rodent habitats.
    - Avoid growing shady trees, bushes closer to the animal shelters. Clean the animal shelters by removing animal waste regularly and keep shelters dry.
- Exposure to sand fly bites can be prevented by minimizing the vector/ human contact. Therefore,
    - Avoid outdoor activities as much as possible, especially from dusk to dawn and avoid outdoor sleeping.

- Wear protective clothing (long sleeved shirts, ankle length pants) that cover the whole body when working outdoors, in animal shelters and during play outdoor.
- Apply insect repellent to uncovered skin and under the sleeves and pant legs. Re application of repellants need to be done as they are effective only for 4-6 hours.
- Use other insect repellent methods available
- Use bed nets impregnated with pyrethroid-containing insecticides if available. Untreated bed nets do not prevent sand fly entry due to small size of the insects.

Please bring the contents of this circular to the notice of all relevant officers in your district or institution.

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Director General of Health Services

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