Report of the meeting of programme managers and the Regional Technical Advisory Group for the kala-azar elimination programme

Virtual meeting, 18–20 April 2022
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Summary and recommendations of the meeting

The WHO Regional Office for South-East Asia (WHO-SEARO) hosted a meeting of programme managers and the Regional Technical Advisory Group (RTAG), both in-person and virtual, in New Delhi, India from 18 April to 20 April 2022. It was held over three days to review developments in the national visceral leishmaniasis (VL) programmes of the five VL-endemic Member States and Sri Lanka, scientific community and WHO initiatives since the last RTAG meeting, hosted virtually on 5–8 October 2020. The main purpose of the meeting was to determine how RTAG could support the regional elimination programme in the most effective way.

Following presentations on recent evidence and reports on developments, there were opportunities for extensive discussions leading to the conclusions and recommendations below, which were agreed upon for action with designated responsibilities.

Conclusions

- The effectiveness of the current Regional Strategic Framework for Elimination of Kala-azar from the South-East Asia Region in achieving substantial reduction in the disease incidence in the last decade, including attaining the target of elimination as a public health problem by Bangladesh and maintaining this feat since 2017, was commended.

- Despite remarkable progress towards reduction in the incidence of visceral leishmaniasis, transmission continues and current tools and case-finding strategies are not optimal for moving towards elimination of transmission of *Leishmania donovani*. Several new tools are in the pipeline, but their validation and operationalization need to be accelerated.

- Contributions of Member States, with support from partners, to eliminating visceral leishmaniasis and strengthening of the health system and primary health care (PHC) capacity, particularly with regard to active disease surveillance, case management and vector control, and achievement of universal health coverage (UHC) and health-related Sustainable Development Goal (SDG) 3 in endemic countries in the Region should be acknowledged more widely.

- Continued action is required to maintain the targets after validation of elimination as a public health problem is achieved. Strong government ownership and effective integration of surveillance, clinical management and vector control interventions deployed against VL in other public health programmes and routine work of PHC workers and front-line health workers, along with sustained linkages with endemic communities and private-sector, health-care providers (both qualified and informal), are key for sustainability in the post-validation phase. These should be a core principle of the new Regional Strategy.

- As the number of reported VL cases dwindles, the political commitment to sustainability should be a priority, creating an appropriate set of tools to communicate on this with the key stakeholders.

Recommendations for WHO
Work with Member States, experts and partners to finalize and launch the new Regional Strategy for VL Elimination in the South-East Asia Region 2022–2026.

Convene a subgroup of RTAG to agree on the standardized endemicity criteria, which is feasible for programmes in the elimination context, given the fact that new visceral leishmaniasis/post-kala-azar dermal leishmaniasis (VL/PKDL) cases continue to be reported from geographical areas that have never reported new cases before and the fact that such patients/areas remain without access to necessary diagnosis, treatment and care until the areas are formally classified as endemic.

Work with Member States and partners to establish a mechanism to ensure that there is no interruption in quality-assured supplies, including drugs, rapid diagnostic tests (RDTs) and WHO insecticide susceptibility test kits, in endemic countries.

- It becomes more difficult to procure drugs in small quantities when the number of reported cases gets reduced, particularly in the post-validation phase. Examples of strategic revolving funds in the WHO Region of the Americas can be studied; they are created by pooling of funds from endemic Member States for WHO pooled procurement.

- Suppliers and manufacturers should be engaged for quality control, regulation, better production planning, forecast, minimum ordering of quantities and meeting supply needs.

Finalize the WHO dossier template for validation of elimination of VL as a public health problem and orient and support national programmes for the requirements and preconditions to be met for the validation process.

Support Member States in the harmonization of policies on key interventions, such as treatment regimen for VL and cutaneous leishmaniasis (CL), indoor residual spraying (IRS) application and outbreak response across the Region.

Advocate for and coordinate external validation of the use of loop-mediated isothermal amplification (LAMP) and/or availability of new prototype, based on the target product profiles (TPPs) (for VL and skin-related neglected tropical diseases or skin NTDs), endorsed by the Diagnostic Technical Advisory Group (DTAG) for diagnosing relapse, PKDL and VL-HIV co-infections for potential programmatic use, with the support of partners.

Advocate for continued research and development of point-of-care diagnostics for PKDL, relapse VL and VL-HIV. There is an urgent need to develop new, simple and non-invasive diagnostic tests to accurately differentiate between skin conditions to ensure that PKDL cases have access to appropriate treatment to prevent transmission as well as to similar diagnostic test requirements for the emerging leishmaniasis situation in Sri Lanka.

Ensure implementation of the recommendations of the WHO Advisory Committee on Safety of Medicinal Products (ACSoMP) regarding the potential ocular adverse events in patients with miltefosine for PKDL/other clinical forms. Convene a multidisciplinary expert group to support the assessment of causality and the identification of adequate risk minimization measures and further actions,
as needed, in full collaboration with the authorities of Bangladesh, India and Nepal.

- RTAG expressed its concern on the potential ocular adverse events reported following miltefosine treatment across the Region, and sought prompt response on this from WHO and Member States.

(9) Once the outcome of ongoing clinical trials of a short-course combination therapy for PKDL patients is published, convene a group of independent experts following the quality, norms and standards of WHO to assess the evidence and make recommendations for the WHO South-East (SE) Asia Region.

(10) Disseminate the new WHO guidelines for treatment of VL-HIV co-infected patients and operationalize in all relevant programmes (VL, HIV and TB programmes).

- Given the fact that a high proportion of VL-HIV co-infected patients is also co-infected with TB and the fact that the mortality rate of VL-HIV-TB co-infection is much higher than that for VL-HIV co-infection, all patients with VL-HIV co-infection should be screened for TB following the national HIV/AIDS programme guidelines.

(11) Advocate further research to generate evidence on secondary prophylaxis following the treatment of the first episode of VL in VL-HIV co-infected patients and on how to treat patients with multiple relapses.

- There are scant studies and data available on reliable secondary prophylaxis treatments to make recommendations. Patients, who have multiple relapses (e.g. three or more), should be seen by experts (e.g. centres of excellence, such as medical colleges and other institutions) to receive secondary treatments on a case-to-case basis (e.g. considering other complications, such as advanced HIV, diabetes, TB and other comorbidities). It is important that the recent information concerning resistance to drugs available is also taken into account.

(12) Convene a subgroup of RTAG to agree on vector interventions that are feasible for programmes in the elimination context. Ensure a regional adaptation of the new WHO global manual on leishmaniasis vector control, surveillance and M&E in the South-East Asia Region, with guidance on several key areas, including when to stop IRS, the approach to follow in areas reporting sporadic cases and detailing of the evidence available on the effectiveness of IRS.

- IRS is a resource-intensive intervention, taking up a significant proportion of the budget available to programmes, and the evidence supporting its efficacy and where/when it should be implemented and stopped needs reconsideration. Alternative methods of vector control should also be explored.

- Wherever possible, an integrated approach for vector surveillance following integrated vector management should be attempted.

- Member States and partners should prepare an annual report on vector surveillance and vector control interventions. This is an important aspect in the post-validation phase.
Advocate and promote innovation and research to support national programmes in accelerating VL elimination, including:

- use of serological markers to confirm the presence or absence of subclinical cases;
- use of geospatial mapping to enhance cost-effectiveness of pre- and post-validation surveillance, risk stratification of areas, prediction maps and vector control; Member States and partners can approach WHO for further support;
- enhancement of sustainability of VL surveillance through an integrated approach, such as skin NTDs and fever syndromes; and
- use of a multiplex tool for detecting circulation of vector-borne pathogens in vectors, which could also be considered.

Convene a high-level advocacy meeting to revisit the extension/renewal of the memorandum of understanding (MoU) on regional cooperation to eliminate kala-azar from South-East Asia, which was signed on 9 September 2014 by five endemic Member States, for renewed and continuing political commitment. This should now also include Sri Lanka as the country that was recently considered endemic for VL.

**Recommendations for Member States**

1. Contribute to, endorse and operationalize the new Regional Strategy for VL elimination in the South-East Asia Region.

2. Complete the classification of the endemicity status of non-programme/doubtful areas with reported VL cases in the last few years and initiate full-scale implementation of VL elimination programme in new foci/endemic areas as soon as possible.

3. Bangladesh may draft the dossier, as per WHO guidance, and submit to WHO for validation of elimination of VL as a public health problem.

4. Ensure uninterrupted supplies, including drugs, RDT and WHO insecticide susceptibility test kits, across endemic areas in coordination and collaboration with WHO and partners.

5. Enhance sustainability of surveillance by integrating passive and active case-finding efforts with other disease control programmes.
   - Apply implementation research to test and refine approaches to make integrated surveillance effective and sustainable.

6. Expand the national leishmaniasis surveillance to include CL-endemic areas and establish minimum essential variables/indicators, including case management guidance, with the support of WHO.

7. Continue to establish and strengthen the centres of excellence (CoE) equipped with the capacity for case management of complicated VL and PKDL cases, such as co-infection of VL, HIV and TB, with support of partners.
(8) Strengthen collaboration with other programmes or schemes to enhance housing standards/environmental management in the affected communities and sustain communication and advocacy for the affected population of the poor.

- VL is a disease of poverty. Improved housing, nutrition and targeted communications with such communities to address the social determinants of continuing VL transmission are required.

(9) Strengthen pharmacovigilance and antimicrobial resistance (AMR) surveillance systems, focusing on VL and CL drugs in collaboration and coordination with national pharmacovigilance programmes and AMR surveillance platforms.

(10) Develop and disseminate the curricula and training/orientation programmes on VL elimination strategies (e.g. vector control, case management, social mobilization, integrated disease control approaches and other relevant areas).

- The OpenWHO platform, which is available to all stakeholders, has already published relevant courses and can be disseminated and utilized.
1. Proceedings of Day 1

1.1 Opening session

Welcoming all participants, Dr Suman Rijal, Director, Department of Communicable Diseases, WHO-SEARO, delivered the opening remarks. Dr Rijal congratulated stakeholders and partners contributing to the Regional VL Elimination Programme on their efforts resulting in a 95% reduction in the VL burden in the SE Asia Region.

“By the end of 2021, 10 implementation units were above the target for elimination as a public health problem. This is an unprecedented achievement. Nevertheless, the last mile is always the most challenging in an elimination programme. It is now even more important to mitigate possible fatigue and lack of motivation among staff. Other factors that may threaten the successes gained include management of PKDL and VL-HIV co-infections. It is opportune to develop and implement a new strategy for sustaining VL elimination.”

Dr Aya Yajima, Regional Advisor, Neglected Tropical Disease Control, WHO-SEARO, introduced the objectives of the meeting, which are to:

- review the progress in implementation of the recommendations of the 2020 RTAG meeting and the overall achievements with regard to elimination of VL in the Region;
- discuss existing and emerging challenges and priorities in accelerating and sustaining elimination of VL in the Region and make recommendations to WHO and Member States; and
- discuss and agree on the strategic goal, objectives and key actions for the new Regional Strategy for Elimination of VL in the South-East Asia Region.

1.2 Participants

A full list of those attending is included at the end of this report.

1.3 Nomination of the Chairperson and the Rapporteur

Professor Nirmal Kumar Ganguly was appointed as the Chair and Professor Be-Nazir Ahmed as the Vice-Chair while Professor Mary Cameron accepted her nomination to serve as the Rapporteur. Professor Ganguly welcomed all participants and emphasized the need to retain partnerships with continued investment through funders to sustain efforts.
2. Presentations

2.1 Global and regional updates – Dr Saurabh Jain, Scientist, NTD, WHO-HQ and Dr Aya Yajima, Regional Advisor, NTD, WHO-SEARO

There has been an increase in the number of new countries reporting endemicity of CL and VL. Of the 98 countries reporting it, 79 are endemic with regard to VL and 71 are endemic with regard to both VL and CL. In 2020, there were 12,739 cases of VL globally. Due to the success of the VL elimination programme, the global burden of VL in the SE Asia Region is at an unprecedented low – 18% (it was 70% in 2005). East Africa has the highest burden (57%) now. Brazil has the next highest burden (16%). Globally, around 50%–60% of cases are found among children/young adults and around 50% among men.

The New Global NTD roadmap 2021–2030 was launched in January 2021, which includes the following targets and milestones for VL elimination:

- number of countries validated for elimination as a public health problem (defined as <1% case fatality rate due to primary disease);
- number of countries in the SE Asia Region validated for elimination as a public health problem (defined as <1 case per 10,000 population at the district level in Nepal and at the sub-district level in Bangladesh and India) by 2023; and
- PKDL cases detected (VL post-treatment follow-up three years) and treated in the SE Asia Region by 2030.

Regional

There has been a 95% decline in VL incidence since 2005; 98% of all endemic implementation units have achieved the target for elimination as a public health problem at regional level – all endemic upazilas in Bangladesh, 99% of the blocks in India and 87% of the endemic districts in Nepal. Bangladesh has sustained this status since 2017. However, an increasing number of VL cases has been reported outside programme districts and cases of PKDL, relapse and CL continue to be reported, which may threaten success.

RTAG made several recommendations to WHO during the meeting in October 2020.1 Key progress made and actions taken on the recommendations are the following:

- A draft of the new WHO-SEARO Regional Strategic Framework for kala-azar (KA) elimination had been developed for further discussion at the current meeting.
- The WHO Global Manual on leishmaniasis surveillance, monitoring, evaluation and outbreak management is being finalized by WHO HQ.
- A VL sub-group in the WHO NTD Diagnostic Technical Advisory Group (DTAG) was established in 2021 and the draft target product profile is being finalized.

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1 https://apps.who.int/iris/bitstream/handle/10665/340612/sea-cd-329-eng.pdf?sequence=1&isAllowed=y
WHO Guideline for the treatment of visceral leishmaniasis in HIV co-infected patients in East Africa and South-East Asia is being published by WHO HQ.

A meeting on cross-border collaboration for elimination of kala-azar and malaria along the international border of India with Bangladesh, Bhutan and Nepal was convened on 28–30 September 2021.

A WHO-SEARO meeting on prioritization of operational research areas was conducted on 16–18 November 2021.

Discussion

Substantial progress in reduction of VL incidence in the SE Asia Region was acknowledged. It is important to ensure that success is not interrupted and also to keep in mind the fact that surveillance activities may have been affected by the COVID-19 pandemic; these need to be assessed and built back.

PKDL has declined markedly in the SE Asia Region, but less prominently in East Africa. This drop may apply to the number of cases but is not necessarily in proportion to VL cases.

In East Africa, a biregional (the WHO Regional Office for the Eastern Mediterranean and the WHO Regional Office for Africa) elimination initiative is required, which WHO and TDR, the Special Programme for Research and Training in Tropical Diseases, are jointly supporting.

There are several external global challenges, which could impact the programmes: inflation, food insecurity and climate change, to name a few.

In addition, specific issues relating to the programme include supply of drugs, need for better drugs, how to manage asymptomatic cases and how to improve integrated vector management (IVM).

2.2 Country updates: Bangladesh – Dr Abu Nayeem Mohammad Sobel, Deputy Programme Manager, National Kala-azar Elimination Programme, Bangladesh

Progress

All of the 100 VL-endemic upazilas, where more than 37 million people are estimated to be at risk, reached the elimination target in 2016 and this status has been sustained since then. The number of new VL and PKDL cases since the last RTAG meeting was maintained at low levels (28 and 36 in 2020, 35 and 37 in 2021 respectively). Although no relapses were reported in 2020, 23 were reported in 2021.

Interventions

Vector surveillance: Indoor residual spraying (IRS) was not performed in any upazila in 2021. A vector control survey (in 16 upazilas, 625 households) collected 397 Phlebotomus argentipes sandflies, using mouth aspirators, and calculated the mean density as 0.172 per man hours.
• VL surveillance: Passive surveillance was performed in 100 endemic upazilas and 40 110 people were screened in 149 active case detection sessions.

• Capacity-building: 5215 health-care providers and health managers of 100 upazilas were provided with training as appropriate.

• Advocacy, communication and social mobilization: The World NTD Day was celebrated and 29 advocacy meetings were held at the upazila level, in addition to one national meeting.

• Partner coordination: A cross-border situation analysis was carried out and a roadmap proposed.

• Operational research: Xenodiagnostic transmission studies were performed on VL and PKDL patients, using an axenic colony of P. argentipes.

• Guideline development: This involved 1) kala-azar surveillance, outbreak and M&E, and 2) kala-azar vector control.

**Response to the 2020 RTAG recommendations**

The programme has shown significant improvements in response to the recommendations made at the 2020 RTAG meeting:

<table>
<thead>
<tr>
<th>2020 RTAG recommendations</th>
<th>Implementation progress</th>
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| Align definition of VL cases, new KA, relapse and KA treatment failure, death, endemicity, outbreak and PKDL with WHO terminology. | • It has been incorporated in the updated kala-azar surveillance, outbreak management and M&E guideline.  
• Case management guideline will be updated soon |
| Provide guidance on updating treatment regimens and its continued availability.            | • Case management guideline is aligned with WHO guidance, “Control of the leishmaniases”.  
• Liposomal amphotericin B (LAmB) and miltefosine are available currently |
| Vector surveillance, including regular insecticide resistance monitoring, should be practised routinely to support all VC activities with due consideration accorded to classes of insecticides to use to avoid further development of insecticide resistance. | • Vector surveillance has been carried out, but no insecticide resistance monitoring has been conducted routinely. |
| Ensure a regular supply of WHO insecticide resistance test kits.                           | • This is yet to be implemented.                                                                                                                                 |
| IRS: the spray equipment should be checked regularly to ensure their proper functioning in spray operations; ensure supply of sprays and spare parts and provide refresher training to spray teams, and supervisory visits should be provided to each round of spraying. | • Spray equipment are checked regularly.  
• Refresher training is provided to spray teams and supervisory visits before each round of spraying. |
2020 RTAG recommendations | Implementation progress
--- | ---
The determination of area sprayed around the household of each VL/PKDL case should consider evidence of local transmission scenarios (e.g. use of a 300-m radius in Bangladesh). Where second cycle of IRS is not possible on time, insecticide ensuring long effects should be used to escape second cycle. | • Consider 200–300 m radius or 60–100 households.
• Deltamethrin is used for IRS

Distribution of pyrethroid-LLINs to VL, PKDL and VL/HIV and confirmed cases is recommended; a strategic approach to supplementing vector control, focusing on preventing transmission of L. donovani, is required rather than indiscriminate use of insecticides in households | • This is yet to be implemented

**Challenges and request for support and advice from RTAG:**

- lack of resources to maintain momentum and coverage of implementation, particularly active case detection (ACD) and IRS;
- ensuring uninterrupted supply of drugs and logistics;
- inadequate information on vector bionomics, insecticide resistance and molecular surveillance of vectors;
- cross-border collaboration; and
- validation dossier development and submission.

**The way forward:**

- adequate resource allocation for implementation of the National Strategic Plan;
- continuation of WHO technical and financial support to the national programme for uninterrupted supply of drugs, diagnostics, insecticides and surveillance strengthening;
- strengthening surveillance and outbreak management;
- regular training for health staff;
- re-assessment of endemicity of kala-azar at the upazila level;
- generation of vector bionomics data;
- implementation of cross-border collaboration through Government-to-Government meeting; and
- validation dossier development and submission.
2.3 Country updates: India – Dr Nupur Roy, Additional Director, National Centre for Vector Borne Disease Control, India

**Progress**

In 2019, 37 blocks (21 in Bihar and 16 in Jharkhand) reported >1 VL case per 10 000 population. This has decreased significantly to 16 blocks (four in Bihar and 12 in Jharkhand) in 2020 and eight persistent blocks (two in Bihar and six in Jharkhand) in 2021. But Bihar still has the highest case-load (967 cases in Bihar in 2021 compared with 279 in Jharkhand, 57 in West Bengal and 50 in Uttar Pradesh). The number of deaths associated with VL increased from six in 2019 and six in 2020 to 28 in 2021. Cases of VL-HIV co-infections have fallen steadily from 2019 (124 cases) to 2021 (78 cases), but the trend was not as strong for the number of PKDL cases (821 in 2019 versus 770 in 2021).

In addition to the eight persistent blocks, concerns were raised regarding 94 new foci identified in 2022 in villages, which had no previous VL cases reported between 2019 and 2021.

**Interventions**

- VL surveillance: KA is a notifiable disease and all VL patients are registered at the block level. Line lists are shared by blocks with districts and the Government of India every month. Real-time reporting is conducted, using a Kala-azar Management Information System (KAMIS). In 2021, VL/PKDL cases identified, using different approaches, amounted to 42%/35% for passive case detection, 47%/43% for snowballing/index ACD and 11%/22% for house-to-house ACD.

- Treatment: VL (1st line – inj LAmB 10/mg/kg BW; 2nd line – tab miltefosine 100 mg for 28 days), PKDL (tab miltefosine 100 mg for 12 weeks), VL-HIV (inj LAmB 40/mg/kg BW in 10 doses), relapse (inj LAmB)

- IVM: IRS with synthetic pyrethroid is still being carried out with high coverage rates twice a year in all four endemic states (except in 2019 in West Bengal). This is being monitored at block, district, state and national levels. LLINs are being distributed in blocks, co-endemic to malaria, every 3–5 years, but the added impact on VL is uncertain. Pucca houses have been built in high-endemic blocks of Jharkhand (25 955 houses) and Bihar (1371 houses) under the Pradhan Mantri Awas Yojana initiative.

**Challenges:**

- shortage of vector-borne disease personnel;
- occurrence of new foci/reporting of cases from non-endemic states;
- health-seeking behaviour of tribal populations;
- gap between onset of symptoms and diagnosis;
- VL/HIV co-infections and surveillance of PKDL cases;
- sporadic reports of eye complication in PKDL cases treated with miltefosine;
- involvement of private practitioners, quacks and traditional healers; and
- monitoring of IRS activity and implementation.

**Response to the 2020 RTAG recommendations**

<table>
<thead>
<tr>
<th>2020 RTAG recommendations</th>
<th>Implementation progress</th>
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<tbody>
<tr>
<td>Align definition of VL cases, new KA, relapse and KA treatment failure, death, endemicity, outbreak and PKDL with WHO terminology.</td>
<td>• SOPs have been developed and shared with the states. All endemic districts/blocks were oriented to SOPs and the states are reporting accordingly.</td>
</tr>
<tr>
<td>Ensure guidance on updating treatment regimens and its continued availability.</td>
<td>• The continued availability of drugs and diagnostics is ensured at all treatment facilities at the district/block level. Management of logistics is regularly monitored and tracked through KAMIS/National Centre for Vector Borne Disease Control stock input Google sheet to ensure no stockout of supplies. Currently, there is no change in the treatment regimens.</td>
</tr>
<tr>
<td>Vector surveillance, including regular insecticide resistance monitoring, should be practised routinely to support all VC activities with due consideration accorded to classes of insecticides to use to avoid further development of insecticide resistance.</td>
<td>• NCVBDC with support of CARE/London School of Tropical Medicine regularly monitors vector abundance and the susceptibility status against alphacypermethrin 5% across eight sentinel sites (six in Bihar and one each in West Bengal and Jharkhand). Apart from Jharkhand and West Bengal, states are independently generating the data on vector density and other related aspects of vector surveillance.</td>
</tr>
<tr>
<td>Ensure a regular supply of WHO insecticide resistance test kits.</td>
<td>• A request is made to WHO for supply of susceptibility test kits for testing sandflies. After the receipt from WHO, it will be supplied to the states on demand.</td>
</tr>
<tr>
<td>IRS: the spray equipment should be checked regularly to ensure their proper functioning in spray operations; ensure supply of sprays and spare parts and provide refresher training to spray teams and supervisory visits should be provided to each round of spraying.</td>
<td>• Prior to IRS operations, all spray equipment are adequately checked to ensure proper functioning. The states are provided with sufficient funds for procurement of spares as well as PPE kits. The spray squads are adequately trained prior to the commencement of IRS.</td>
</tr>
</tbody>
</table>
2020 RTAG recommendations | Implementation progress
---|---
The determination of the area sprayed around the household of each VL/PKDL case should consider evidence of local transmission scenarios (e.g. the use of a 300-m radius in Bangladesh). Where second cycle of IRS is not possible on time, insecticides ensuring long effects should be used to escape second cycle. | • The selection of villages is based on three years of epidemiological data. If any of the villages has reported even one case at any point of time in the last three years, it is included in the IRS microplan. • Apart from the above, focal spray is undertaken in new villages reporting cases or endemic villages that report cases after the completion of the IRS round. These villages are also sprayed. Focal spray in the 500-m range of an index case of KA is undertaken.

Distribution of pyrethroid-LLINs to VL, PKDL and VL/HIV and confirmed cases is recommended; a strategic approach to supplementing vector control, focusing on preventing transmission of *L. donovani*, is required rather than indiscriminate use of insecticides in households. | • In the states of Jharkhand and West Bengal, LLINs are distributed in the endemic districts, where malaria is also coexisting with KA.

**Request for support and advice from RTAG:**

- review of the validation requirements and pre-conditions to be met for declaring VL elimination as a public health problem for India;
- support and facilitation of time-to-time evaluation of the programme;
- continuation of drug donation in the post-elimination phase;
- country guidance for the VL programme in line with the NTD roadmap 2021–2030;
- seeking guidance on treatment of sporadic cases of CL reported from non-endemic states (even though CL is not part of Kala-azar Elimination Programme in India); and
- alternative treatment options to avoid adverse reactions (e.g. eye complications with miltefosine for PKDL).

**The way forward:**

- continuation of village-focused intensified plan for all programme components with a high degree of monitoring and supervision;
- strengthening IEC and BCC for creating awareness among communities for early reporting of signs and symptoms of KA and PKDL;
- sustenance of the KA elimination programme in 625 blocks across four states through regular surveillance, early detection and treatment of VL and PKDL cases;
• functioning of a centre of excellence for VL case management to strengthen the capacity by district and block personnel;
• enhanced intersectoral coordination; and
• validation and certification for KA elimination.

2.4 Country updates: Nepal – Dr Gokarna Dahal, Section Chief, NTD/VBD, Epidemiology and Disease Control Division, Nepal

Progress

The total number of authochtonous VL cases has increased from 203 in 2019 to 257 in 2021. Furthermore, the number of endemic districts that have crossed the elimination threshold has increased from 0/18 in 2019 to 3/23 in 2021.

The endemicity status in 2022 has changed as follows:
• endemic districts* (23/77) – five more districts added since 2019;
• endemic doubtful districts** (49/77) – three more districts added since 2019; and
• non-endemic districts (5/77) – 3 districts less since 2019.

*Endemic district – The full cycle of transmission has been demonstrated at any given time (maintained population of competent vector + parasite reservoir + locally acquired cases) AND at least one locally acquired case in the last 10 years.

**Endemic doubtful district – The full cycle of transmission has never been demonstrated BUT at least one locally acquired case in the last 10 years OR the full cycle of transmission has been demonstrated at any given time, BUT no case has been reported in the last 10 years (0 case or no data).

Interventions

The National Guidance for the Kala-azar Elimination Programme was updated in 2019. Key interventions in 2021 include:
• early diagnosis and treatment – free rK39 test and free treatment with LAmB, miltefosine and paramomycin;
• surveillance system strengthening – introduction of DHIS2 reporting;
• IRS activities that are ongoing in 34 districts;
• ACD conducted in 48 districts with support from local levels and partners;
• IEC/BCC conducted by local levels in high-risk districts with (minimal) support from Epidemiology and Disease Control Division;
• training for health workers in vector-borne diseases and a workshop on VL (WHO TDR); and
• operational research – endemicity assessments of two districts conducted in 2021.
### Response to the 2020 RTAG recommendations

<table>
<thead>
<tr>
<th>2020 RTAG recommendations</th>
<th>Implementation progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Align definition of VL cases, new KA, relapse and KA treatment failure, death, endemicity, outbreak and PKDL with WHO terminology</td>
<td>• The 2019 guideline has defined the VL case, new KA case, treatment failure, endemicity, as per WHO terminology.</td>
</tr>
<tr>
<td>Ensure guidance on updating treatment regimens and its continued availability.</td>
<td>• Revised guideline recommends LAmB as the first-line treatment for primary kala-azar.</td>
</tr>
<tr>
<td>Vector surveillance, including regular insecticide resistance monitoring, should be practised routinely to support all VC activities with due consideration accorded to classes of insecticides to use to avoid further development of insecticide resistance.</td>
<td>• Vector surveillance is being conducted, but sparsely. The joint insecticide programme has been conducted by EDCD for all VBD-related disease.</td>
</tr>
<tr>
<td>Ensure a regular supply of WHO insecticide resistance test kits.</td>
<td>• Regular supply of WHO test kits are ensured at the PHC level. However, this needs to be ensured at the PHC level in some districts and at local levels.</td>
</tr>
<tr>
<td>IRS: the spray equipment should be checked regularly to ensure their proper functioning in spray operations; ensure supply of sprays and spare parts and provide refresher training to spray teams and supervisory visits should be provided to each round of spraying.</td>
<td>• ToT on IRS was provided to the provincial focal person for the management of IRS activities with the budget being ensured.</td>
</tr>
<tr>
<td>The determination of the area sprayed around the household of each VL/PKDL case should consider evidence of local transmission scenarios (e.g. the use of a 300-m radius in Bangladesh). Where second cycle of IRS is not possible on time, insecticides ensuring long effects should be used to escape second cycle.</td>
<td>• NA</td>
</tr>
<tr>
<td>Distribution of pyrethroid-LLINs to VL, PKDL and VL/HIV and confirmed cases is recommended; a strategic approach to supplementing vector control, focusing on preventing transmission of L. donovani, is required rather than indiscriminate use of insecticides in households.</td>
<td>• There is no distribution of LLINs among VL, PKDL and VL/HIV cases. However, an integrated approach has been implemented with regard to distribution of LLINs.</td>
</tr>
<tr>
<td>Establish the endemicity status of endemicity doubtful districts.</td>
<td>• The endemicity status is being assessed, assessment of endemicity of all doubtful districts is needed.</td>
</tr>
</tbody>
</table>
Sustain the targeted incidence in districts.

• There is focused response to districts reporting an increasing number of cases, especially from Karnali and Sudurpaschim province.

Emergence of CL and Mucocutaneous leishmaniasis (MCL)

• Training in management of CL and MCL for physicians and medical recorder for reporting.

There is an increase in emergence of relapse VL cases as reported by physicians.

• Verify the number of relapse case, know the causes of relapse and measures to overcome.

There is lack of HR for effective implementation of integrated vector management and monitoring of vector control interventions.

• Focus on the district level to implement the IVM (IRS) with coordination support from the Central level.
• Cases are being reported from new districts, outbreaks are being reported too.

Undisrupted supply chain of drugs to the provincial level

• Paromomycin and miltefosine being provided at provincial stores for management of relapse and emergence of CL cases

**The way forward:**

- verification of the endemicity status of endemic doubtful districts;
- VL strategic intervention intensification in endemic and endemic doubtful districts;
- intensification of active case detection (index case-based approach);
- training in diagnosis, treatment, recording and reporting of kala-azar in line with 2019 revised guidelines;
- implementation of integrated vector management;
- ensuring and maintaining supply chain management of VL commodities at the provincial level and referral hospitals and RDT kits at the PHC level; and
- ensuring that BCC/IEC activities are implemented at high-risk districts for early diagnosis and treatment.

**Discussion on the three country presentations**

Speakers were congratulated on their commendable work and actions and the following points were raised during the discussion:

- VL is a relapsing disease – we need guidance on how to treat and manage relapses and VL-HIV co-infections. Some patients may have more than 10
relapses and the rK39 test cannot be used for diagnosing cases (i.e. diagnoses require parasitological confirmation of bone marrow or spleen samples).

- It is critical that VL-HIV and TB patients are screened and treated at a professional centre (if splenic biopsies are required).
- More attention needs to be paid to treatment of PKDL cases (who should be considered “mobile reservoirs” of transmission).
- The incentive scheme in India should be improved so that patients have better access.
- We need to investigate whether the COVID-19 pandemic has deterred patients from seeking treatment at PHCs.
- The definition of death due to VL needs to be explained, e.g. during the pandemic, deaths may increase but not necessarily due to VL.
- A mechanism is required to ensure adherence to clinical protocols.
- rK39 RDT is a good surveillance tool; LAMP tests to diagnose relapse, PKDL and VL-HIV cases require validation.
- We need biomarkers to differentiate between PKDL and leprosy.
- The definition of “endemicity” may need revisiting post-elimination.
- Programme supplies need to be monitored so that potential gaps are identified and mitigated.
- New guidance for IRS may be required, including how to respond to new outbreaks.

2.5 Country updates: Bhutan – Dr Tenzin Wangdi, Chief Entomologist, Vector-borne Disease Control Programme, Ministry of Health, Bhutan

Progress

Two new VL cases were reported in 2019, four in 2020 and none in 2021. In addition, two cases of mucocutaneous leishmaniasis were reported in 2021.

Interventions

VL and CL are not notifiable diseases in Bhutan. Data (no. of cases and annual incidence) are reported by focal medical officers at three national referral hospitals to the Principal Investigator of a project funded by National Institutes of Health. Once a case is reported, a focus investigation is performed, the case is followed up on and focal IRS implemented.
Response to the 2020 RTAG recommendations

<table>
<thead>
<tr>
<th>2020 RTAG recommendations</th>
<th>Implementation progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harmonize case management protocols in line with WHO recommendations/other countries in the WHO SE Asia Region.</td>
<td>• Revision of integrated clinical management guideline for NTDs has been planned.</td>
</tr>
<tr>
<td>Conduct further research to better understand the epidemiology and transmission dynamics of VL.</td>
<td>• Ongoing; VL elimination roadmap is to be developed in the coming fiscal year, 2023.</td>
</tr>
<tr>
<td>Make miltefosine available</td>
<td>• This has not yet been achieved.</td>
</tr>
</tbody>
</table>

Challenges and advice/support needed from RTAG:

- VL not a notifiable disease;
- sporadic, very low incidence and remoteness of cases;
- limited capacity of the programme with multiple mandates;
- limited diagnostic capacity at health facilities; and
- emergence of PKDL cases.

The way forward:

- Develop guidelines for surveillance and control of leishmaniasis.
- Develop a roadmap for elimination.
- Establish VL surveillance in at least three national referral hospitals.
- Ensure training workshops on early detection and referral for diagnosis for clinicians or make rK39 tests available for health facilities with endemic communities.
- Follow up on all VL cases for detecting relapse/PKDL.
- Delimitate endemicity of each district/sub-district.
- Seek sustainable funding for programme activities.

2.6 Country updates: Sri Lanka – Dr Manjula Kariyawasam, Epidemiology Unit, Ministry of Health, Sri Lanka

Progress

In Sri Lanka, *L. donovani* causes CL, which became a notifiable disease in 2008. The number of CL cases reached a peak of 4066 in 2019 and 2719 cases were reported in 2021. Cases have increased almost throughout the country, with hotspots in the centre and south.
Interventions

Cases are notified from dermatology clinics/wards and outpatient departments to the medical officer of the health office closest to a patient’s residence. A public health inspector visits the patient within seven days of notification, ensures proper treatment and follow-up, refers contacts to the nearest dermatologist/clinic and makes people aware of how to prevent the spread of the disease. Entomology surveys are conducted at the point of need by the district entomology team under the guidance of the regional epidemiologist.

Challenges and advice/support needed from RTAG:

- CL is increasing in the country.
- Disease epidemiology is under-researched.
- There are competing priorities for allocating resources.

Ongoing activities and the way forward

- Continue surveillance activities.
- Share control and prevention guidelines with all stakeholders.
- Continue awareness campaigns through mass media and IEC materials.
- Follow treatment guidelines.
- Ensure separate clinics in high-risk districts.
- Ensure vigilance regarding VL cases.
- Conduct a situational review and develop a strategic plan (2022–2026) supported by WHO.
- Ensure advocacy to mobilize funds for research (particularly for vector bionomics and potential reservoirs).
- Provide staff training both locally and internationally.

2.7 Country updates: Thailand – Ms. Rawadee Kumlert, Public Health Technical Officer, Division of Vector Borne Disease, Ministry of Public Health, Thailand

Progress

Two cases of VL were reported in the Lampang province in 2021.

Interventions

Cases are reported to a situation awareness team via a surveillance database (https://apps-doe.moph.go.th). Cases are confirmed by PCR and provided with treatment (miltefosine) until completely cured. Surveys of vectors/potential reservoir hosts are carried out and IRS conducted. The potential risk of transmission is communicated to communities.
Challenges and advice/support needed from RTAG:

- lack of CL reporting in the surveillance system;
- poor coordination with network systems outside the Department of Disease Control;
- limited knowledge of the disease; and
- no screening of visitors from endemic areas.

The way forward:

- mapping of VL and CL cases and sandfly pathogen screening.

Discussion following the presentations on Bhutan, Sri Lanka and Thailand

- Sodium stibogluconate and cryotherapy are used to treat CL and miltefosine is used for PKDL in Sri Lanka.
- The rK39 RDT test is not suitable for diagnosing cases in Sri Lanka, but rK39 ELISA may be used.
- Bhutan needs provision of miltefosine.
- Access to drugs is a key bottleneck. Drug development takes time. Obtaining pentavalent antimonials is challenging because they are difficult to procure in small quantities.
- Sequencing all strains of *L. donovani*, causing CL, is needed.
- Policies and interventions need to be harmonized.

2.8 Eye disorders during leishmaniasis treatment with miltefosine –
Dr Adrien Inoubli, Regional Advisor, Medical Products Quality and Regulation), WHO-SEARO/Dr Saurabh Jain, Scientist, NTD, WHO-HQ

In the SE Asia Region, miltefosine is administered orally for 12 weeks to treat PKDL patients and it is used in combination therapy for 14 days to treat VL-HIV co-infected patients. Since 2019, 52 cases of eye disorders have been reported, ranging from mild to severe (including keratitis and irreversible loss of vision).

In India, side-effects are mainly observed after four weeks of treatment, but pretreatment ocular conditions of these patients are not known. In Bangladesh, five cases of keratitis were reported in PKDL patients following treatment (four treated with Miltefos®, one with Impavido®).

Keratitis can be found in CL, MCL or PKDL cases, but retinal involvement is reported in VL cases only.

On 10 February 2022, WHO released a statement concerning potential ocular disorders in patients treated with miltefosine. The key points are that miltefosine is an
important drug and ocular disorders are uncommon but should be reported to a national pharmacovigilance centre. Blindness is rare. The data available are insufficient to confirm or rule out a causal association. Ocular conditions at the time of PKDL diagnosis should be noted.

Discussion

- Ocular disorders may be dose-related – combination treatments may prevent retinopathy.
- Eye examinations should be made every two weeks and images kept on file by ophthalmologists.
- Suggestion from programme for PKDL patients not treated in-house is to be followed up on to detect ocular complications, if any, early and provide appropriate care on time.
- Preliminary results of a combination therapy trial (LAmB with miltefosine) show that it is better than LAmB alone. Study at Rajendra Memorial Research Institute of Medical Sciences, India, found only one complication after three weeks and the patient recovered sight after treatment was stopped. Study at Kala-Azar Medical Research Centre, India, reported no eye complications. Full analysis will be performed in 2–3 months and will be presented to policy-makers.

3. Proceedings of Day 2

3.1 Protocol for endemicity assessment: An example from Nepal – Dr Surendra Uranw, Assistant Professor, Department of Internal Medicine, B.P. Koirala Institute of Health Sciences, Nepal

The distribution of VL cases has changed in Nepal during recent years with a rise in the proportion of cases observed in non-programmatic districts. A survey was conducted to determine whether local transmission was occurring. This involved verifying travel history of cases, investigating risk factors associated with transmission, undertaking a seroprevalence survey and vector collections. Inclusion criteria of clusters included VL cases reported in the last two years, accessibility and willingness of the local authority and community to support.

Following a community meeting, a household survey and case-control questionnaires, a venous blood sample was taken from consenting individuals (two years and above) living around an index case. This was tested using a rK39 RDT, DAT and qPCR. Sandflies were captured from households and cattle sheds, using CDC light traps and mouth aspiration, stored in 80% ethanol and kept in a freezer before ID and molecular screening for *L. donovani* DNA.

The survey provided evidence of local transmission in six hilly districts in Western Nepal at a cost of US$ 10 000–US$ 12 000/district (molecular confirmation was a major cost).
A discussion point raised involves what type of evidence is required for declaring endemicity – presence of a new VL case, presence of *P. argentipes* or detecting *L. donovani* DNA in sandflies.

**Discussion**

- Current definition of WHO (presence of a competent vector, one locally acquired case and presence of a reservoir) was considered acceptable, but a heightened level of control may be required when there are few cases.

- A critical density of vector (e.g. similar to malaria) or proportion of infected vectors (e.g. LF xenomonitoring) was considered but not recommended since there is a lack of supportive data from research studies. Furthermore, given the low infection rates at this stage in the elimination programme, the resources involved in molecular screening using qPCR for operational use are too costly. Simple, point-of-need tests need to be developed to make this approach feasible for programmatic use.

### 3.2 WHO guideline for the treatment of VL in HIV co-infected patients in East Africa and the SE Asia Region – Dr Saurabh Jain

The principles behind guideline development and the evidence required in order to make recommendations were described. Evidence needs to be relevant, compliant with ethics, of high quality, publicly available and transparent. A guideline panel and external review group relevant to the scope of the guideline are set up and a GRADE system is used to appraise evidence and formulate recommendations before they are approved by the Secretariat and disseminated.

The global distribution of leishmaniasis countries reporting VL-HIV co-infections was updated in 2021. Between 2014 and 2020, 3070 cases of VL-HIV were reported.

In the SE Asia Region, a conditional recommendation for using a LAmB + miltefosine regimen over LAmB monotherapy was made, based on very low-quality evidence. It is important to consider the following: routine screening of TB, contraception and pregnancy test for women of childbearing potential before administering miltefosine and providing comprehensive support to HIV patients.

Secondary prophylaxis was conditionally recommended over not providing secondary prophylaxis, also based on very low-quality evidence. This may be particularly important for patients with a high risk of relapse. The selection of drug may depend on which drugs were used for the primary VL episode, collateral benefits in other infections and potential drug resistance.

Access to HIV testing for all VL patients should be improved and uninterrupted free access to treatment ensured. Coordination among HIV, VL and related programmes, such as pharmacovigilance and TB, should be improved.
Discussion

Guidelines were gratefully received as being much needed.

The guidelines also took into account the views of patients, which is an important factor as HIV patients are reluctant to take additional drugs when receiving retrovirals.

Severe adverse events (eye complications) may occur more in patients with TB and diabetic patients are also difficult to treat when immunocompromised. For recurrent relapses, it may be better to move away from LAmB + miltefosine to miltefosine and paromomycin, but this is not evidence-based at present.

Consider referring patients with >3 relapses to an expert (centre of excellence). Immunoprofiling may be considered to inform treatment options and secondary prophylaxis. Risks to patients with advanced HIV (low CD count) regarding opportunistic infections should also be taken into account. RMRI may serve as a centre of excellence and provide advice to other Member States.

3.3 Is regional elimination of transmission of *L. donovani* a technically possible, operationally achievable and desirable goal in the SE Asia Region? – Dr Suman Rijal, Director, CDS, WHO-SEARO

In 2018, RTAG explored whether interrupting transmission was technically feasible, given the tools available. At that time, the overall opinion was that it was not feasible, but desirable, and it may now be opportune to revisit the question in the current situation.

IRS has been used extensively since 2011 and from 2018 onwards, focal IRS has been deployed in response to reported VL cases. Since 2005, there has been a 95% decline in VL disease incidence and the proportion of PKDL cases and VL-HIV co-infected patients might be more significantly contributing to transmission. Therefore, new tools should be targeted at these populations, including vector control.

For elimination as a public health problem, continued actions are required to maintain targets. For elimination of transmission, continued actions to prevent re-establishment of transmission may be required.

New challenges have been identified, such as new outbreaks and spread of endemicity (e.g. at altitudes >600 metres in Nepal, migration and cross-border coordination). Gaps still remain, such as diagnosis and treatment of PKDL, relapse VL and VL-HIV co-infections. A post-elimination phase strategy for surveillance, treatment and vector control needs to be integrated and a multisectoral approach (e.g. fever syndrome approach and pooled procurement mechanism for provision of drugs) used. Health systems need to have sufficient capacity to deliver the strategy independently without partner involvement and this will require political and donor support and engagement, particularly concerning the need to continue developing better tools that are fit for purpose.
Discussion

- Two more challenges were identified: need for economic development in the community and for communications for advocacy in the community.
- There needs to be a shift in surveillance, from house-to-house/snowballing approach to integration into primary health care functions to increase the awareness of VL sustainably.
- Retaining staff expertise through continued training is needed.
- Sustainability requires continued funding.

3.4 SPEAK India: Outcomes and recommendations – Professor Mary Cameron, Professor of Medical Entomology, London School of Tropical Medicine

The SPEAK India consortium conducted operational research to address gaps and improve surveillance in the post-elimination era.

To determine whether serological surveys can be used as a tool to monitor (absence of) *L. donovani* transmission, a total of 15,426 samples were screened from people living in currently endemic, previously endemic and non-endemic villages, using rK39, DAT and rK39 ELISA diagnostic tests. All methods distinguished between currently endemic and previously/non-endemic clusters, and the rK39 test was the most sensitive and best suited for most of the age groups. Children reflected recent changes in transmission and represented a good target population for surveys. The total cost of the screening was US$ 49,355.

To improve VL surveillance at the PHC level, PHC staff interviewed former VL patients, registered one, three and five years ago, and screened them and their household members for VL, PKDL and leprosy (integrated active case detection). Data were collected via “ODK collect” on a smartphone. Of the 5,618 householders examined (1,093 former patients and 4,525 contacts), three had VL, 46 PKDL and one leprosy. The total cost per household was US$ 9.30 in Bihar and US$ 22.00 in Uttar Pradesh (UP); the higher cost in UP was due to the lower disease burden requiring extra effort.

The xenomonitoring study showed that CDC light traps remained a more useful method for collecting a higher number of *P. argentipes* females than mechanical aspirators and collections had high incidental captures of female mosquitoes (useful for integrated vector surveillance). *Kdr* mutations were identified in sandflies, which may present a threat to the effectiveness of IRS. Two robust protocols to specifically detect *L. donovani* DNA in sandflies were developed but none of the pools, including those collected from currently endemic villages, was positive. The effort to collect sufficient female *P. argentipes* for *L. donovani* detection using qPCR was challenging and resource-demanding. A simple, point-of-need test to screen multiple pathogens transmitted by vectors is currently under development, which could represent a more viable method of integrated vector surveillance.

Mathematical models suggest that although VL cases are most infectious, as they resolve, PKDL becomes the major source and substantial risk of onward transmission. Using KAMIS case data, a short-term prediction model was developed to forecast outbreaks and
trends in incidence to help efficient use of resources and to anticipate the demand of services at the block level. This could be integrated into routine surveillance. Another model, investigating spatial variation in delayed diagnosis of VL in Bihar, found that cases diagnosed in endemic blocks experienced shorter delays than those in areas affected less recently, implying that incidence-based targeting of ACD alone may not be sufficient going forward.

**Discussion**

- Alternative collection methods, such as cattle-baited traps, were found to collect higher numbers of *P. argentipes* in Sri Lanka.

- Collection methods should be selected according to the research question of the study and in the case of the SPEAK India study, looking at transmission to people in houses, CDC light traps and mechanical aspirators were selected.

### 3.5 Geospatial mapping of VL – a potential use in pre- and post-validation surveillance – Mr Prashant Hedao, GIS Consultant, WHO-HQ

The WHO GIS Centre of Health connects maps, apps, data and people to support countries to make informed public health decisions. Mr Hedao presented an example of geospatial mapping. It was based on the geocoding of VL cases reported since 2013 in India, and land use/land cover as well as human population estimates to demonstrate an example of geospatial mapping to potentially help case-based VL surveillance and response.

To illustrate the application of the approach, the following examples were also presented:

- Mapping where humans and snakes interact can be used to look at the risk of snake-bites in Nigeria.

- Geographical patterns and environmental factors are associated with the presence of human yellow fever in the Americas.

- Risk maps of VL in Ethiopia were developed based on epidemiological and meteorological data.

The GIS Centre of Health supports the following areas: mapping and visualization, geospatial reference data management, field data collection, monitoring, design and planning, geodata and analytics, constituent engagement and sharing and collaboration.

Main projects that benefited from their involvement in 2021–2022 include:

1. Snake-bite Information and Data Platform (SIDP)
2. Training and Capacity Development (TCD)
3. AccessMod, Drive-time Analysis to Health Facilities
4. GIS Software, Server and Baseline Data (SBD)
5. Global Health Facilities Database (GHFD)
(6) COVAX GIS Working Group
(7) COVID-19 ACT-A, Health Systems and Response Connector (HSRC)
(8) COVID-19 Rapid Mortality Survey (RMS)
(9) Adverse Effects Following Immunization (AEFI)/VigiMobile
(10) Field data collection tools (Survey123, ODK and survey solutions)
(11) World Health Data Hub-GIS support.

**Discussion**

- A poverty map and nutritional map are also available in India to add layers to risk maps.
- Reference was made to a research article looking at a VL risk in Vaishali, a district in Bihar, India: [https://doi.org/10.4081/gh.2011.173](https://doi.org/10.4081/gh.2011.173)

### 3.6 Global manual on leishmaniasis vector control, surveillance and M&E, and guidance for insecticide resistance in sandflies – Dr Rajpal S. Yadav, Scientist, Vector Ecology and Management, NTD, WHO-HQ and Dr Saurabh Jain, Scientist, NTD, WHO-HQ

An overview of the global manual, expected to be published in November 2022, was presented. The manual was written and peer-reviewed by experts with representatives from all WHO regions.

The scope of the manual was to:

- present distinct scenarios and dynamics of leishmaniasis transmission and vector control in different eco-epidemiological settings;
- provide practical tools, techniques and procedures for sandfly surveillance;
- describe rationale and primary methods of vector control and IRS;
- discuss monitoring and evaluation of interventions and provide key indicators;
- describe management and reporting approaches;
- provide an update of the status of new or novel vector control tools; and
- identify operational research areas.

The manual comprises the following chapters:

1. Introduction and scope of the manual
2. Sandfly vector bionomics and transmission dynamics in different geographical settings
3. Vector surveillance
(4) Vector control and insecticide resistance management
(5) Monitoring and evaluation of vector control interventions
(6) Data management, repository and reporting
(7) Operational research needs
(8) Annexes
(9) Resources (for further reading).

Operational issues may vary between regions. For example, those previously identified by the SE Asia Region Working Group were:

- Investigate the role of possible alternative vector species in newly/doubtful endemic areas/incrimination of other vector species.
- Investigate the role of exophagic/exophilic vectors in VL transmission.
- Research on new vector control tools to target outdoor transmission.
- Develop strategies for appropriate vector control (e.g., when to stop IRS, use of alternative approaches, implementation of vector surveillance at sentinel sites to detect changes in vector infection and a rapid response of targeted vector control).
- Evaluate the potential of integrated vector management/surveillance.

Discussion

- Insecticidal paints should be included in any decision tree.
- The subject of when to stop IRS has long been debated and a regional meeting is required to review the evidence.

3.7 New Regional Strategy for elimination of kala-azar from the SE Asia Region 2030 – Dr Aya Yajima

A draft framework of the new strategy was tabled for RTAG input. It described the remaining and emerging challenges regarding the current situation and the existing tools available, and programmatic issues in relation to: ACD, passive case detection, data reporting, management and use for action, diagnosis and treatment, vector control and vector surveillance.

The goal of the framework is to achieve and sustain elimination of VL as a public health problem in the SE Asia Region. Two objectives were proposed: 1) ensure early case detection and complete case management, and 2) reduce density of sandfly vectors.

To achieve the objectives, cross-cutting areas of support are required:

- Strengthen governance and programme management.
Report of the meeting of programme managers and the Regional Technical Advisory Group
for the kala-azar elimination programme

- Engage, educate and empower communities at risk on prevention and access to treatment and care.
- Strengthen and sustain health workforce, laboratory capacity and referral system.
- Improve inventory management system and storage conditions.
- Enhance advocacy, regional partnership and cross-border collaboration.
- Continue to catalyse innovation and research.

Participants were invited to join breakout sessions, according to their expertise (case surveillance, case management and vector surveillance/control). They were asked to delete, update or revise any of the suggested key actions following discussion. Nominated rapporteurs from each group were given guidance on how to present the group’s feedback on suggested issues to all participants the following day.

4. Proceedings of Day 3

4.1 RTAG discussion, recommendations and closing

Rapporteurs from each working group presented feedback from their respective groups.

The Chair thanked all presenters and invited additional comments from participants.

All service, including referral, should be free of charge.

Integration of the programme needs a mandate from the Ministry of Health (e.g. Secretary of Health).

Comprehensive understanding of IVM remains a challenge and there is a shortage of entomologists. Many activities are conducted by partners, but the programme needs more entomologists.

All VL-HIV patients need to be screened for TB as a minimum requirement.

To ensure an uninterrupted supply of drugs, the SE Asia Region may consider parking funds (similar to AMR) – WHO strategically revolving fund.

Professor Mary Cameron was invited to present draft recommendations and further discussion followed. The draft recommendations were circulated to RTAG for further comment and revision and the finalized recommendations are provided in the summary above.

The Chair concluded that it had been an excellent, productive meeting and thanked the organizers and everyone involved.
## Annex 1

### Agenda

<table>
<thead>
<tr>
<th>Day 1: Monday 18 April 2022</th>
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<tbody>
<tr>
<td>13:00–13:05</td>
<td>Opening remarks</td>
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<tr>
<td>13:05–13:10</td>
<td>Welcome remarks</td>
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<tr>
<td>13:10–13:15</td>
<td>Meeting objectives</td>
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<td>Appointment of the Vice-Chair and Rapporteur</td>
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<td>Global and regional updates on leishmaniasis</td>
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<td>Discussions</td>
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<td>14:05–14:20</td>
<td>• India</td>
</tr>
<tr>
<td>14:20–14:35</td>
<td>• Nepal</td>
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<tr>
<td>14:35–14:50</td>
<td>Discussions</td>
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<tr>
<td>15:05–15:15</td>
<td>• Bhutan</td>
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<td>15:15–15:25</td>
<td>• Sri Lanka</td>
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<td>15:25–15:35</td>
<td>• Thailand</td>
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<tr>
<td>15:35–15:50</td>
<td>Discussions</td>
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<tr>
<td>15:50–16:05</td>
<td>Ocular disorders after administration of miltefosine</td>
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<tr>
<td>16:05–16:15</td>
<td>Discussions</td>
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<tr>
<td>16:15–16:30</td>
<td>Protocol for endemicity assessment – an example from Nepal</td>
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<tr>
<td>16:30–16:40</td>
<td>Discussions</td>
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<tr>
<td>16:40–16:50</td>
<td>New WHO HIV-VL treatment guideline</td>
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<tr>
<td>16:50–17:00</td>
<td>Discussions</td>
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<td>Day 2: Tuesday 19 April 2022</td>
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<tr>
<td>13:00–13:15</td>
<td>Is regional elimination of transmission of <em>L. donovani</em> a technically possible, operational achievable and desirable goal in the South-East Asia Region?</td>
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<tr>
<td>13:25–13:35</td>
<td>SPEAK India: Outcomes and recommendations for policy-makers</td>
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<tr>
<td>13:35–13:45</td>
<td>Discussions</td>
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<tr>
<td>13:45–13:55</td>
<td>Geospatial mapping of VL – a potential use in pre- and post-validation surveillance</td>
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<tr>
<td>13:55–14:05</td>
<td>Discussions</td>
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<tr>
<td>14:05–14:20</td>
<td>Global manual on leishmaniasis vector control, surveillance and M&amp;E, and guidance for insecticide resistance testing in sandflies for the South-East Asia Region</td>
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<tr>
<td>14:20–14:30</td>
<td>Discussions</td>
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<tr>
<td>14:45–15:00</td>
<td>The new Regional Strategy for elimination of VL from the South-East Asia – a proposed goal and strategic objectives</td>
</tr>
<tr>
<td>15:00–16:15</td>
<td>Breakout discussion to agree on strategic objectives and priority actions</td>
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<tr>
<td>16:15–16:45</td>
<td>Plenary presentations from breakout discussion</td>
</tr>
<tr>
<td>16:45–17:00</td>
<td>Discussions</td>
</tr>
</tbody>
</table>

**Day 3: Wednesday 20 April 2022**

|  |
|-----------------------------|------------------|
| 13:00–14:15 | Breakout discussion to agree on supportive areas and priority actions | |
| 14:15–14:45 | Plenary presentations from breakout discussions | |
| 14:45–15:00 | Discussions | Chair/Vice-Chair |
| 15:15–15:25 | Timeline and next steps for finalization and endorsement of the Regional Strategy for elimination of VL | Dr Aya Yajima |
| 15:25–15:40 | Discussions | Chair/Vice-Chair |
| 15:40–15:55 | Conclusions and recommendations | Chair |
| 15:55–16:10 | Discussions | Chair/Vice-Chair |
| 16:10–16:50 | Remarks from partners – updates on innovation for VL programmes (including vaccines) | |
| 16:50–17:00 | Closing remarks | Dr Rijal Suman |
Annex 2

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Report of the meeting of programme managers and the Regional Technical Advisory Group for the kala-azar elimination programme

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Virtual meeting, 18–20 April 2022