

Meetings of programme managers and the RTAG for the kala-azar elimination programme

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Conclusions

1. 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 it since 2017, was commended.
2. Despite remarkable progress towards reduction in the incidence of visceral leishmaniasis (VL), transmission continues and current tools and case-finding strategies are not optimal to move towards elimination of transmission of *L. donovani*. Several new tools are in the pipeline but their validation and operationalization needs to be accelerated.
3. Contributions of Member States, with support from partners, towards eliminating visceral leishmaniasis and strengthening of the the health system and primary health care (PHC) capacity, particularly over active disease surveillance, case management and vector control, and achievement of universal health coverage (UHC) and the health-related Sustainable Development Goal (SDG) 3 in endemic countries in the Region should be acknowledged more widely.
4. 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 into other public health programmes and routine work of PHC workers and frontline health workers, along with sustained linkages with endemic communities and private sector health-care providers (both qualified and informal) is key for sustainability in the post-validation phase. These should be a core principle of the new Regional Strategy.
5. As the number of reported VL cases dwindles, the political commitment for sustainability should be a priority, creating an appropriate set of tools to communicate on this with the key important stakeholders.

Recommendations for WHO

6. 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.
7. Convene **a sub-group of RTAG** to agree on the standardized endemicity criteria which is feasible for programmes in the elimination context, given the fact that new VL/PKDL (post-kala-azar dermal leishmaniasis) cases continue to be reported from geographical areas which have never reported new cases before, and that such patients/areas remain without access to necessary diagnosis, treatment and care until the area is formerly classified as endemic.

8. Work with Member States and partners to establish a mechanism to ensure that there is no interruption in quality-assured supplies, including drugs, RDT 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 reduces, particularly in the post-validation phase. Examples of strategic revolving funds in the WHO Region of the Americas can be studied, which is 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 quantities and to meet supply needs.
9. Finalize the WHO dossier template for validation of elimination of VL as a public health problem and orient and support national programmes over the requirements and preconditions to be met for the validation process.
10. 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.
11. 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.
12. 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, 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 similar diagnostic test requirements for emerging leishmaniasis situation in Sri Lanka.
13. 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 seek for prompt response by WHO and Member States.
14. 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 WHO's quality, norms and standards to assess the evidence and make recommendations for the South-East Asia Region.
15. Disseminate the new WHO guidelines for treatment of VL-HIV coinfecting patients and operationalize in all relevant programmes (VL, HIV and TB programmes).

- Given the fact that a high proportion of VL-HIV coinfecting patients is also coinfecting with TB, and the mortality rate of VL-HIV-TB coinfection is much higher than in VL-HIV coinfection, all patients with VL-HIV coinfection should be screened for TB following the national HIV/AIDS programme guidelines.
16. Advocate further research to generate evidence on secondary prophylaxis following treatment of the first episode of VL in VL-HIV coinfecting patients, and on how to treat patients with multiple relapses.
- There are scant studies and data on reliable secondary prophylaxis treatments to make recommendations. Patients who have multiple relapses (e.g. 3 or more) should be seen by experts (e.g. centres of excellence such as medical colleges and others) 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 recent information concerning resistance to available drugs is also taken into account.
17. Convene **a sub-group of RTAG** to agree on vector interventions that are feasible for programmes in the elimination context and make a regional adaptation of the new WHO Global Manual on leishmaniasis vector control, surveillance and M&E in the South-East Asia Region, with a guidance on several key areas including when to stop IRS, approach to follow in areas reporting sporadic cases, and detailing available evidence 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.
18. 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 integrated approach, such as skin NTDs and fever syndromes.
 - A multiplex tool for detecting circulation of vector-borne pathogens in vectors could also be considered.

19. 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, that 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 was recently considered endemic for VL.

Recommendations for Member States

20. Contribute to, endorse and operationalize the new Regional Strategy for VL elimination in the South-East Asia Region.
21. Complete classification of 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.
22. Bangladesh may draft the dossier as per WHO guidance and submit to WHO for validation of elimination of VL as a public health problem.
23. Ensure uninterrupted supplies, including drugs, RDT, and WHO insecticide susceptibility test-kits throughout endemic areas in coordination and collaboration with WHO and partners.
24. 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.
25. 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.
26. 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 coinfection of VL, HIV and TB, with support of partners.
27. 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 social determinants of continuing VL transmission is required.
28. Strengthen pharmacovigilance and antimicrobial resistance surveillance systems focusing on VL and CL drugs in collaboration and coordination with national pharmacovigilance programmes and AMR surveillance platforms.
29. Develop, disseminate and include in the curricula, training/orientation programmes on VL elimination strategies (e.g. vector control, case management, social mobilization, integrated disease control approaches and other relevant areas).
30. OpenWHO platform, which is available to all stakeholders, has already published relevant courses and can be disseminated and utilized.