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Kala-azar elimination in India: reflections on success and sustainability

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The incidence and mortality of kala-azar (KA, visceral leishmaniasis) in India have fallen drastically in the past few years, and in 2023 the reported KA incidence reached the threshold for elimination as a public health problem (<1 case/10 000 of population at subdistrict level). One of the strategies adopted by India's kala-azar elimination program (KAEP) was the regular independent assessment of the program implementation by teams of experts. We present the findings of assessments undertaken in 2019, 2021 and 2023, when the KAEP was in the last mile of elimination. Factors that contributed to its success were political commitment, intensified implementation, a strong network of KA partners and committed donors. Bottlenecks were observed in disease surveillance, data utilization, vector-control operations and program management at implementation. To sustain the gains and achieve validation of elimination, the KAEP should continue the following minimal essential services: optimized active and passive case detection and management of KA, post-KA dermal leishmaniasis, KA-HIV coinfection and relapse supported by vector-control interventions. Long-term measures that will sustain elimination are overall socioeconomic development, including improved living conditions, parallel with efficient surveillance and operational research that is aligned with the changing epidemiology of the disease.

Keywords: communicable disease control, India, leishmaniasis visceral, national health programs, neglected diseases, parasitic diseases.

Introduction

Kala-azar (KA), also known as visceral leishmaniasis, is a parasitic neglected tropical disease (NTD), transmitted through bites of infected female sandflies and fatal when not treated. In 2023, 80 countries were considered endemic for KA.[1] It is mostly prevalent in marginalized populations who do not benefit from socioeconomic developments. Due to a low economic return there is little attention to research and development for new drugs and diagnostics.[2]

In India, KA is endemic in Bihar, Jharkhand, West Bengal and Uttar Pradesh states, with an at-risk population of 165.4 million and a known established endemicity in 54 districts (information as per January 2025). More than 90% of KA cases are contributed by Bihar and Jharkhand. The disease is endemic in 633 blocks (implementation units) of the 54 districts, out of which 458 blocks (72%) belong to only Bihar (information as per January 2025).[3,4] In 2005, India signed a Memorandum of Understanding with Bangladesh and Nepal to eliminate KA as a public health problem by 2015,[5] a commitment that has been renewed several times since. KA elimination in India was defined as fewer than one primary or relapse case per 10 000 people at the block (third subnational administrative) level, aiming for KA to cease being a public health problem, but without the need for total elimination of new cases and transmission.

The elimination initiatives undertaken by the countries were highly successful and resulted in a drastic drop in cases. South-East Asia represented 67% of the world's KA burden in 2006; in 2023 this was only 6%.[1] In India, KA declined from 77 102 cases in 1992 to 599 cases in 2023.[6] Deaths also dropped from 1419 in 1992 to 58 in 2018, with further drops to 28 in 2021 and four in 2023.[4] There were 324 post-KA dermal leishmaniasis (PKDL) cases in 2023,[4] signifying a gradual decline. The number of KA-HIV coinfections (new and relapse cases) remained stable, with 81 cases in 2022, 71 in 2022 and 75 in 2023.[4] In December 2023, India reached the WHO-defined KA incidence threshold for elimination as a public health problem (<1 case/10 000 of population at the subdistrict level) and has transitioned into the

consolidation phase of sustaining elimination for a minimum of three consecutive years before submitting a dossier to the WHO for validation.[1] According to recent data, all the affected blocks except one still meet the elimination threshold, even surpassing it to <0.5/10 000 population. It is now critical to sustain the elimination threshold in all blocks for at least three consecutive years for India to qualify for the next steps of validation for KA elimination as a public health problem.

In the early years of the program (2009–2013), through support of the World Bank, consultants and KA technical supervisors helped to implement the kala-azar elimination program (KAEP). After the World Bank project ended in 2013, the government absorbed these workers under the overarching umbrella of its National Health Mission.[7] This resulted in sufficient resources for program roll-out with flexible, updated, science-driven policies and regular monitoring and evaluation. Additionally, a staff network working under the WHO's leadership along with involvement of other global health agencies supported program implementation. The Indian government provided the majority of funding and other resources for the implementation of the program; international donors included the World Bank, the Bill and Melinda Gates Foundation and the UK Department for International Development (now the Foreign and Commonwealth office), which provided significant funding for program implementation from 2014 to 2019. Further operational, normative and scientific support was provided by a network of national and international organizations. To avoid overlap in activities, an annual joint work plan with monthly reporting and coordination meetings proved crucial to success.

One of the strategies adopted by the KAEP was the independent assessment of the program implementation, undertaken by teams of experts, organized by the WHO. In this paper, we present the findings of assessments undertaken in 2019, 2021 and then 2023, when KA was in the last mile of elimination.[8]

Strategies of the KAEP in India

Early detection and treatment of KA

The most important strategy of the KAEP to reduce KA mortality and transmission was early case detection and treatment of KA. This was made possible by primary diagnosis by a rapid serological antibody-detecting test that detects up to 97% of cases. Treatment initially involved long courses of intramuscular sodium stibogluconate (28 d), then, since 2006, oral miltefosine[9] (28 d), but a turning point was reached in 2011, when it was shown that one infusion of 10 mg/kg liposomal amphotericin B (L-AMB, AmBisome, Gilead Sciences) cured 96% of patients with KA and had an excellent safety profile[10] (Figure 1). This single-dose regimen ensured complete adherence to treatment and short hospitalization periods. In 2012, the WHO negotiated a donation of AmBisome for all patients with KA in South-East Asia, an agreement that has been renewed subsequently.[11] This donation has been one of the milestones to the success of the KAEP and enabled the Indian government to provide the majority of funding and other resources for program implementation.

A remaining challenge is that an estimated 2–7% of reported patients with KA are coinfected with HIV in the highly endemic

Figure 1. Kala-azar patient receiving AmBisome single-dose treatment, RMRMIS Patna, Bihar, India, 11 June 2022. Photo by Dhruv Pandey / © WHO India.

state of Bihar, with reported numbers of up to 20% in districts with reliable HIV screening.[12] These patients have high parasite loads and are considered KA super-spreaders.[10,13] A focus on their detection and treatment is therefore of paramount importance for the KAEP. They are often severely ill, have low cure rates and require complex clinical management. In 2014, it was estimated that in one-half of KA-HIV coinfected patients, HIV remained undiagnosed due to a lack of integration of KA and HIV services.[14] Since then this situation has significantly improved and, in 2023, national program data showed that >90% of KA cases are screened for HIV. A new approach to treat these patients is extended treatment combining L-AMB and miltefosine, which achieves a cure rate of 91% and is now recommended by the WHO.[15]

Early detection and treatment of PKDL

PKDL is a cutaneous sequela of KA occurring in 5–10% of otherwise-cured patients with KA in South-East Asia up to 2–7 y after treatment completion.[16] In 1994, a single patient with PKDL is thought to have caused an outbreak in 24-Parganas, a district of West Bengal, India, where KA had never been seen before.[17] In 2023, 314 PKDL cases were reported. This is of concern to the elimination efforts, especially because recent research showed that these lesions are surprisingly infectious, with 35–80% of patients with PKDL capable of infecting sandflies with only 400 parasites per µg of skin (normally several thousands are present).[18] For these reasons, all patients with PKDL in the Indian subcontinent are recommended to receive treatment.

PKDL often presents as depigmented macular lesions[19] (Figure 2) that do not pose a clinical problem for patients. Detection is challenging as diagnosis is primarily based on clinical observation and is complicated by the similarity to other skin conditions. Many patients with PKDL do not actively seek care; in one area of India, more than three-quarters of reported PKDL cases were detected through active case search.[20] The first-line treatment, a 3-mo regimen of daily oral miltefosine, is lengthy and associated with serious side effects. Treatment interruption has been seen in around one-fifth of patients with PKDL, although

Figure 2. Child with post kala-azar dermal leishmaniasis. Indra Deo Kishku/©, Medical officer, Jharkhand, India, 10 May 2023.

overall compliance and adherence to treatment was 86%.[21] Eye disorders, sometimes serious, have been reported in patients using miltefosine and the WHO has confirmed causality.[22] A way forward is a much shorter and safer treatment combining liposomal amphotericin B and miltefosine, which has recently shown to be highly efficacious at 12 mo follow-up, including a repigmentation rate of 85%.[23]

The contribution of vector control to elimination

Most KA cases occur in communities with poor sanitation and in people living in close proximity to domestic animal shelters that provide breeding and resting sites for sandflies (Figure 3). Integrated vector management (IVM) is therefore key to KA control. The KAEP focused on indoor residual spraying (IRS) as *Phlebotomus argentipes*, the vector, is thought to bite mainly indoors.[24] Due to its scale and complexity, IRS was a costly and labor-intensive intervention, which absorbed around 80% of the KAEP's total budget (487.5 million INR, which is 80% of the total budget allocated by the central government—609.4 million INR for vector control—from the WHO financial review paper by an external reviewer, commissioned before the independent assessment of 2019–2020). A breakthrough was achieved in transitioning from DDT to the synthetic pyrethroid alpha cypermethrin (5%) and switching from stirrup pumps to the technically superior hand compression pumps in 2014–2015. However, major issues in spraying coverage and technique, equipment maintenance and

Figure 3. Typical sandfly habitat in a village, Bihar, India. Photo by Jorge Alvar, December 2019.

vector surveillance remained. Measures were recommended to improve the quality of IRS, including regular systematic monitoring of operations and the evaluation of insecticidal efficacy and community effectiveness.[25] Vector surveillance has failed to show a consistent decrease in sandfly densities inside sprayed vs unsprayed houses,[24] and KA cases continue to be reported to KA Management Information System (KAMIS) from sprayed villages. Sleeping outdoors was a strong risk factor in the current analysis, suggesting outdoor transmission was unlikely to be controlled by IRS.[25] It was also observed that IRS is not sufficient for tribal mud houses, which offer highly favorable conditions for sandfly breeding and need minor engineering to allow for more air and light inside. The provision of concrete 'pucca' houses to replace mud housing for patients with KA is in progress,[6] but these also need additional improvements such as plastering of the floor and filling of crevices in the wall to fully prevent indoor transmission.

A shift in the approach from IRS to IVM is required to achieve the last mile of elimination; specific IVM approaches and integrated vector surveillance could be developed for districts where several vector-borne diseases are co-endemic (malaria, KA, lymphatic filariasis [LF], dengue). Another factor that needs to be taken into account is that recent entomological and epidemiological data indicate that a large proportion of transmission likely occurs outdoors.[26,27] The provision of long-lasting insecticidal nets (LLINs) to patients with KA and PKDL to prevent transmission should be considered for reducing case numbers within communities with persistent transmission, and where clustering of KA, PKDL or HIV/KA cases occurs.

Challenges in surveillance

Epidemiological surveillance is a critical pillar of the KAEP. KA used to be very substantially under-reported.[28] This improved drastically after the KAEP introduced a case-based surveillance system, largely supported by the non-profit organization CARE, which deployed surveillance teams in all highly endemic blocks. Government-provided cash incentives to female health workers who receive 500 Indian rupees (US$6.91) for each suspect KA case they find, refer and follow-up after treatment had an added value to strengthen KA surveillance. The use of KAMIS enabled

real-time data reporting and allowed for accurate planning and decision-making.

To further improve case detection, in 2023, a national policy of a quarterly active case search for KA and PKDL was implemented, but overall, most cases are found via passive case detection (KA: 48 221/50 536, 95.4% and PKDL: 7087/8369, 84.7%, KAMIS, accessed 12 July 2023, for the debriefing meeting of the joint WHO/MoH assessment of the KAEP in 2023, Nirman Bhawan, New Delhi). Passive KA case detection can be further improved with integrated and innovative context-specific approaches such as fever surveillance. For PKDL, integrating detection into the surveillance and management of skin NTDs could serve as a way forward.[29]

The KA surveillance workforce in India has now decreased considerably and strategies to continue active case detection need to be developed, for example, using case-based analysis to identify villages with a clustering of cases, villages reporting cases for the first time and villages with KA-HIV coinfected cases, relapse cases or KA deaths, where focal active case detection could take place. Integration of active case detection activities should be promoted. At state level, specific integrated approaches for early detection of KA and PKDL are already in use, for example in Jharkand, where KA and PKDL detection is integrated with active case finding for TB, malaria, leprosy and LF.

Access to care

Access to KA diagnosis and treatment was considered a priority by the KAEP. This was achieved by decentralizing services to lower-level health facilities, providing diagnosis and treatment free of charge, as well as providing cash assistance to patients. Patients receive INR 500 (US$6) in all four endemic states; in Bihar and Jharkhand, they receive INR 6600 (US$89) upon completing treatment, while those completing 12 wk of treatment for PKDL receive INR 4000 (US$54).[30] However, despite these measures the first preference for patients seeking care is the informal healthcare provider, who is more accessible and available to their community.[31] This often results in unnecessary expenses, misdiagnoses and delayed referral and treatment. More recently, informal healthcare practitioners have become involved in ensuring earlier identification and referral of suspected cases to public health facilities. This had a positive influence, but in 2023, delays between symptoms and diagnosis of several months were still observed for a significant number of patients. Follow-up of patients after cure, crucial to detect relapse and PKDL, has been implemented (at 2 wk, 1 mo, 6 mo and 1 year and thereafter once for 2 y) and during the 2023 assessment, 100% of patients visited had been followed up 2–3 times during the course of a year.

Although treatment for primary KA in India has been decentralized, PKDL, relapse and KA-HIV patients are often referred to higher-level treatment centers, resulting in delays to care, significant out-of-pocket expenses and longer periods of transmissibility.[6] In 2023, in Bihar state all KA-HIV cases were managed in only two centers. Provision of services to these patients as close as possible to their community is a priority.

An indicator for access to treatment and quality of care is the case fatality rate (CFR). In India, the reported CFR was 3% in 2023.[1] This includes all deaths in KA, relapse KA and KA/HIV coinfections. No published information is available on the type of death and its further analysis. The WHO's NTD roadmap for 2021–2030 has proposed <1% CFR due to primary KA as part of its global targets for eliminating KA as a public health problem and the KAEP should align its strategy to reduce the percentage of mortality accordingly, although this will become more challenging as the number of cases reduces.[32]

The COVID-19 pandemic

The first independent assessment of the KAEP was done in December 2019, before the COVID-19 pandemic. The next assessment was carried out in 2021, and it was found that the COVID-19 pandemic had directly impacted program implementation varying from state to state, resulting in postponement of, or missed IRS rounds, cancellation or postponement of active surveillance activities and delays in case management. The KAEP adopted all feasible mitigation measures to overcome the effects of the COVID-19 pandemic and continued activities such as active case-finding by telephone, case-finding integrated with COVID-19 fever surveillance and IRS in hotspots and persistent villages. However, the quality of implementation was affected. A systematic investigation to examine and measure the impact of COVID-19 on the KAEP was not undertaken at this time.

The last mile of the KAEP in India: leaving no one behind

The KAEP in India has moved on to include intersectoral coordination and poverty-alleviating schemes for patients with KA as strategies to achieve and sustain elimination. Because the lowest socioeconomic groups remain disproportionally affected by KA,[25,33] the program aims to ensure that interventions are prioritized in the most marginalized communities.[34] A model for coordination between village governments, housing, sanitation, rural/tribal development and education has been developed with clearly defined tasks and responsibilities, although in 2023, this was still assessed as needing further strengthening.

Work should also be done to minimize the social bias sometimes exhibited by health workers. The KAEP itself could actively engage with excluded groups, by offering employment or incentives to support program implementation activities such as social mobilization, case-finding and vector-control activities. The 2019 assessment found that in remote locations in the highly endemic states of Jharkhand and Bihar, >40% of positions for medical officers, paramedics and auxiliary nursing staff were unfilled, and that there was a high turnover of human resources for key government positions. In 2023, there were still significant human resource shortages. Staff award mechanisms are already in place in other parts of the country and may need to be adopted for these locations.[35]

The NTD Road Map 2021–2030 has added new targets for elimination of KA, namely, 100% of PKDL cases detected (KA post-treatment followed for 3 y and treated), and <1% CFR due to KA. A further target of achieving zero cases may become possible. However, because many infections are asymptomatic, the parasite may remain in circulation. As KA incidence decreases, the pool of susceptible individuals will grow.[36] Postvalidation, it will be crucial to monitor infection levels in communities even where there are no cases, to inform future outbreak risk. Learning from

the historical trends re-emergence has occurred several times in South-East Asia when surveillance was abandoned.[37]

Operational research

The strategies implemented by the KAEP are evidence-based, and continued operational research is critical. The assessment expert group suggested a list of key operational research priorities (Box 1), which are essential for India and other regions attempting KA elimination.

Box 1. Priority research areas proposed by the assessment expert group in 2019

	Research need
Diagnosis	• An antigen-based point-of-care rapid diagnostic test that can diagnose and ascertain cure of KA (primary and relapse) and PKDL
Treatment	• New, safe and efficacious short-course oral treatments for KA and PKDL • Evaluation should include quantitative estimation of parasite loads during treatment and follow-up to ascertain the period of infectivity in PKDL cases
Surveillance	• Determine the rate of under-reporting. • Follow KA incidence at block level long-term and perform operational research to understand the reasons for increases in cases that surpass the elimination threshold • Relapse and PKDL rates should be established by follow-up of cohorts of treated KA cases
Vector control	• Impact of climate change on vector bionomics KA:

kala-azar; PKDL: post-KA dermal leishmaniasis.

Considerations for the future: What next?

The KAEP is now moving to the phase of validation of elimination after attaining and sustaining the elimination threshold for three consecutive years.

The aspects of the program that need attention in this prevalidation phase include:

- Micro-stratification in high-risk areas and continued case-based surveillance activities in villages reporting one KA/PKDL case in the last year, with an index-based case search for each reported KA/PKDL case
- Increased involvement of formal and informal private healthcare providers
- Continued use of real-time data for planning and decision-making
- Build strategies for the postelimination phase for surveillance, treatment and vector control. These should include the new elimination goals for PKDL and the CFR that are added in the WHO NTD Road Map 2021–2030
- Enhance nationwide surveillance through an integrated and multisectoral approach.
- Strengthen cross-border KA surveillance and collaborate with bordering countries to optimize resources, synchronize action and harmonize efforts
- Sustain the ongoing community awareness/education programs by integration with other health programs. All four endemic states are at varying levels of endemicity and program implementation. Therefore, the strategies adopted at the state level should be guided by the situation on the ground and the health system performance in place
- Sustain the capacity and motivation of frontline health workers
- Strengthen pharmacovigilance (during the 2023 assessment, adverse events were found to be monitored but often not recorded) and drug resistance surveillance systems for KA and PKDL drugs
- Better coverage of marginalized populations through social protection schemes
- Strengthen collaboration with other programs or schemes and integrate roles of intersectoral departments to address developmental issues like housing standards/environmental management, nutrition and sanitation
- Ensure uninterrupted supplies of drugs, diagnostics and spraying equipment by securing domestic budget and procurement
- Gradual engagement of tertiary medical institutions for sustained KA program support
- Partners and donors to share clear transitioning plans with national stakeholders such as the MoH and the National Center for Vector Borne Diseases Control (NCVBDC)

Limitations

Several limitations should be acknowledged, stemming from the methodological constraints of relative short field assessments. Findings on IRS coverage and median delays in treatment were based on field-level observations rather than systematic data collection or published evidence. Additionally, last-minute changes in field visit plans and the unforeseen dropout of a few experts could not be avoided and impacted the ability to visit all the initially planned administrative and health units. Furthermore, areas not known to be endemic for KA but reporting sporadic cases were not included in the assessments and thus, recommendations for non-endemic areas could not be included in the manuscript. The KA assessments were holistic in nature, covering all key aspects of the KA program, but their limited time frame restricted the ability to conduct in-depth investigations into certain areas of concern. Consequently, the findings offer a cross-sectional or 'snapshot' view of program implementation during the assessment period, rather than an exhaustive evaluation.

Concluding points

The factors that contributed most to the success of the KAEP included a strong political commitment, an extensive stakeholder network supporting the elimination strategies in the highly endemic foci and evidence-based program implementation. The reduction in cases was achieved due to early case detection, treatment and vector control, even although many patients still present ≥1 mo after symptom onset, and vector-control activities were lacking in quality and coverage.[28]

With a drastic decline in the number of cases, elimination program fatigue is bound to happen. Sustaining political commitment to provide continued resources will be crucial. Surveillance and case management should be further strengthened, and a rationalized approach to vector control and investment into operational research is needed. With the validation of KA elimination in sight, the support from non-governmental agencies may gradually decline. Therefore, a transition plan must be developed and enacted in a phased manner, with program activities taken over by the government to sustain elimination.

The experiences and lessons learnt from the KAEP in India can serve other regions that are initiating KA-elimination programs, such as eastern Africa.[38]

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