

# INDEPENDENT ASSESSMENT OF KALA-AZAR ELIMINATION PROGRAMME INDIA

9-20 December 2019, India







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# LIST OF ABBREVIATIONS

ACD	active case detection
ADR	adverse drug reaction
API	annual parasite incidence
ARSH	Adolescent Reproductive and Sexual Health
ASHA	social health activist
AWW	Anganwadi worker
BCC	behaviour change communication
BCM	Block Community Mobilization Officer
BHEO	Block Health Education Officer
BPM	Block Programme Manager
CBO	community-based organization
CFW	control flow valve
CMS	central medical store
CMSO	Central Medical Stores Organization
CMSS	Central Medical Service Society
COMBI	communications for behavioural impact
DC	District Collector
DDT	Dichloro diphenyl trichloroethane
DM	District Magistrate
DMO	District Malaria officer
Dte NVBDCP	Directorate of National Vector Borne Disease Control
DGHS	Directorate General of Health Services
DHS	Director of Health Services
DVBDO	District Vector Borne Disease Officer
FEFO	first expiry first out
FGD	focus group discussion
FLW	frontline health worker
FW	field-worker
Gol	Government of India
H-t-H	house-to-house

ICMR	Indian Council of Medical Research
IDR	In-depth review
IEC	information, education and communication
IDSP	Infectious Disease Surveillance Project
IMA	Indian Medical Association
IRS	indoor residual spraying
ITN	insecticide treated (bed) net
JMM	Joint Monitoring Mission
JSBY	Janani Suraksha Bal Yojana
JSSK	Janani Shishu Suraksha Karyakaram
KA	Kala-azar
KAMRC	Kala-azar Medical Research Centre
KTS	Kala-azar Technical Supervisor
LAmB	Liposomal Amphotericin B
LLIN	long-lasting insecticidal net
LSTM	Liverpool School of Tropical Medicine
MF	Miltefosine
MIS	management information system
MO	Medical Officer
MoH	Ministry of Health
MoH&FW	Ministry of Health & Family Welfare
MTS	Malaria Technical Supervisor
MPW	multipurpose worker
NCDC	National center for disease control
NGO	non-government organization
NHM	National Health Mission
NHM FMR	National Health Mission Financial Management Report
NHP	National Health Policy
NHRM	National Rural Health Mission
NIMR	National Institute of Malaria Research
NKEP	National Kala-azar Elimination Programme
NMA	non-medical assistant
NMCP	National Malaria Control Programme
NRL	National Reference Laboratory



NTD	Neglected Tropical Disease
NVBDCP	National Vector Borne Disease Control Programme
PCD	passive case detection
PHC	primary health centre
PIP	programme implementation plan
PKDL	Post kala-azar dermal leishmaniasis
PM	Paromomycin
PMAY	Pradhan Mantri Awas Yojana
PPE	personal protective equipment
PPP	public private partnership
QAS	quality assurance system
QC	quality control
RBSK	Rashtriya Bal Swasthya Karyakram
RDT	rapid diagnostic test
RHP	rural health practitioner
RMRI	Rajendra Memorial Research Institute of Medical Sciences
SAG	sodium antimony gluconate
SC	subcentre
SFW	Superior Field Worker
SKMCH	Shrikrishna Medical College & Hospital
SoP	standard operating procedure
SPO	State Programme Officer
UP	Uttar Pradesh
VBD	vector-borne disease
VBDC	vector-borne disease consultant
VBDS	vector-borne disease technical consultant
VL	Visceral leishmaniasis
WCO	WHO Country Office for India
WHO	World Health Organization





# EXECUTIVE SUMMARY

The National Vector Borne Disease Control Programme (NVBDCP) is an umbrella programme for the prevention and control of vector-borne diseases, including Visceral leishmaniasis, known as kala-azar (KA) in India. The NVBDCP develops evidence-based policies, strategies and financial assistance to the states which are responsible for implementing the programme.

Kala-azar is endemic in a geographically confined area of 54 districts across four states of Bihar, Jharkhand, West Bengal and Uttar Pradesh, with an approximately 140 million population at risk of infection. As per the WHO Neglected Tropical Disease (NTD) roadmap (2012–2020), KA was slated for elimination as a public health problem in India by 2020. In the last decade, several major policy changes have taken place to achieve its elimination. Now, only 37 blocks (6%) remain to achieve the elimination target by 2020.

An independent assessment of the national Visceral Leishmaniasis Elimination Programme was organized by the MoH&FW with the following broader objectives:

- to identify any bottlenecks or challenges in the last mile of elimination and recommend solution/s to overcome them; and
- to assess the national KA elimination programme and recommend measures for strengthening, especially with respect to elimination and sustaining elimination.

The mission was coordinated by WHO from 9-20 December, 2019. The assessment team comprised of 61 experts with diverse backgrounds in clinical and public health, programme management evaluation, vector control, medical entomology and communication.

## Review process

The programme was reviewed from the perspective of disease control as well as functionality of the health system, within the context of the Kala-azar Elimination Programme (KAEP). The assessment was carried out in four steps, namely development of background desk review papers, field visits to endemic areas, and post field visit discussions and formulation of recommendations.

Five desk reviews were conducted on the themes of surveillance, case management and organization of services; vector control strategy; stewardship role of NVBDCP; financial management; and procurement and stock management. Additional areas of assessment included programme management and partner's role, patients and community participation, Information, education and communication (IEC), behaviour change communication (BCC) and research needs.

For field visits, a total of eight teams were formed to undertake visits to the four states of Bihar, Jharkhand, Sikkim and Uttar Pradesh. Another endemic state of West Bengal could not be visited owing to lack of approval from the state government.

A thorough assessment included visits to the central NVBDCP level as also the state, district, block, villages and communities. Data was collected through verification of records and reports, as well as structured interviews from a wide variety of national, state and district stakeholders. These included medical doctors, community members and patients. Demonstration of spray activities by spray-men was organized at the community level to check the technical component of the insecticide residual spraying (IRS) operation, stock checking, laboratory visits, cold chain assessment, treatment ward visit, data entry room as well as focused group discussions (FGD).

## Progress towards elimination and overcoming last mile challenges

### Key findings

- India has observed a steep decline in disease burden, since the KA elimination initiative was launched in the year 2005. In 2019, only 3128 cases were reported, which was all-time low. This represented a 90% decline in disease incidence since 2005 (32 803 cases);
- High incidence areas, also known as hotspots are reducing every year and the current pace of reduction is approximately 10-15% cases annually. However, some challenges persist towards achieving elimination; and
- Notable challenges include continued high endemicity in hotspot areas, significant delays between onset of symptoms to treatment, complacency and fatigue at implementation level, as well as lack of targeted and coordinated approach.

### Observations and recommendations

- Epidemiological trend of the disease and remaining challenges in high endemic pockets suggest probability of achieving elimination in all implementation units by 2023. It is expected that as activities get intensified, several blocks will cross the elimination threshold. However, elimination status will gradually stabilize with maintenance of activities in high endemic pockets;
- The new WHO NTD roadmap has proposed a new target for elimination of KA (VL) as a public health problem. It is defined as achieving less than 1% case fatality rate due to primary KA. It has two more sub-targets for South East-Asia region (SEAR), namely:
  - ◆ Number of countries in SEAR validated for elimination <1 case (new and relapses) per 10 000 population at block level in India at 100% by 2030; and
  - ◆ PKDL cases detected (VL post-treatment follow-up for three years) and treated 100% by 2030.
- To overcome last mile challenges, an independent evaluation mission recommended an intensification of all programme strategies in Mission Mode. This would be from the national to the implementation level with active involvement and coordination of departments within and outside health. A revised strategy for accelerated effort in the form of a mission document needs to be prepared to align with newer strategies. This must then be widely disseminated and implemented;
- The elimination target deadlines were missed on previous occasions and the biggest roadblock was the absence of a coordinated approach and mechanism that could take mid-course corrections, uniformly across all endemic states. To overcome this gap, there is urgent need to



create or reconstitute a high level multisectoral National Task Force to monitor progress and provide governance for last mile challenges. This entity would also help build an accountability framework among stakeholders and programme implementers. Further, it would be empowered to take important policy and programme decisions;

- A risk-based stratified approach needs to be formulated with clear activities and responsibilities that come with measurable monitoring indicators;
- A significant recommendation would be to enforce KA as a nationally notifiable disease in both public and private settings, across endemic and non-endemic areas; and
- The lowest socio-economic castes had poor access to services. This was evident by seeing that their houses were not sprayed often or visited by the Accredited Social Health Activist (ASHA). Moreover, they could not apply for pucca (concrete) houses since they did not own land. Available evidence pointed to these groups being most affected by KA. It was therefore of crucial importance to:
  - ♦ Develop a specific 'plan for the unreached poorest' or underprivileged sections of society in endemic areas;
  - ♦ Leveraging kala-azar elimination programme with POSHAN Abhiyaan (National Nutrition Mission, a flagship programme of the Ministry of Women and Child Development) for the maximum benefit at the community level.
  - ♦ Explore the opportunity of providing improved housing as a flagship programme of the Prime Minister.

## Sustaining elimination

A key recommendation would be to sustain surveillance and intensify case detection activities, in order to identify and address focal outbreaks, emergence of new foci (cases from newer and non-endemic areas), increased relapse rates, persistent high proportion of human immune deficiency virus (HIV)/VL, and continued burden of PKDL.

Kala-azar is an outbreak-prone disease and new cases are expected to occur in the foreseeable future. Therefore, achieving KA elimination as a public health problem is only a milestone on this path and sustaining gains is the most crucial aspect in preventing its re-emergence. Following recommendations are being made to sustain the achievements that have been seen so far:

- Intensify case-based surveillance activities and later sustain them through a syndromic approach (fever and skin lesions) at the health facility for KA and PKDL.
- Systematically introduce suspect register and monitor, number of suspects and RDTs performed vs positives (cases).

## Case management

### Key findings

Although single dose AmBisome treatment is available in all endemic areas and satisfactory cure and relapse rates are reported (>95%) including HIV/VL coinfections, significant delays between onset of symptoms and treatment were noted in Bihar and Jharkhand, due to the lack of diagnostic capacity at facility and case management. For HIV-KA coinfections, it was noticed that except in the Rajendra Memorial Research Institute (RMRI) of Medical Sciences in Bihar, and a few centres in Jharkhand,

district hospitals (DH) and medical colleges do not treat such patients. This results in a delay of out-of-pocket expenses and the added risk of losing patients for follow-up.

None of the interviewed patients were counselled about the disease, its complications and possible side effects of drugs by either the physicians or other staff during admission in the hospital.

The case fatality rate remains high at 2-3%. This is more a matter of concern since these deaths have not been reported by the programme since 2016. Therefore, in the current circumstances there is no scope for identification of cause-specific mortality and of taking measures for preventing deaths, especially in cases where they can be easily avoidable.

Diagnosis and treatment of PKDL with three months of miltefosine (MF) are highly problematic in terms of serious side effects, treatment adherence and use of contraceptives in women of child bearing age. Medical officers (MO) at the primary health facilities have the capacity to clinically diagnose PKDL, but they often refer such patients to higher centres for treatment.

One of the drawbacks of the programme related to pharmacovigilance. Although pharmacovigilance was systematically introduced in the national KA elimination programme in 2017, reporting was observed to be poor and inconsistent, based on the discussion in the treatment centres.

The average incidence of HIV/KA coinfection in India is 5%, which is of concern and all efforts must be made to maximize the detection and management capacity of this condition. In this regard, the following recommendations were made:

- Update and consolidate all guiding documents (diagnosis, treatment, counselling techniques, key definitions, case detection methods, outbreak, reporting forms and measurable indicators) into a simplified practical guide. The definition of death due to KA must be incorporated in the guidelines. The programme must ensure these documents reach the implementation level (districts and blocks) with appropriate orientation and dissemination;
- Access to treatment is the most important component and no patient should have to travel more than one hour or a similar distance in kilometers to seek treatment. An in-depth assessment and indentation of such areas is needed and special provisions made (free ambulance or travel allowance), for patients hailing from these areas;
- The national programme should develop discharge criteria after the treatment and discharge summary on the patient file/card must be made mandatory;
- The second treatment option with paramomycin (PM)/miltefosine (MF) should be made available at the district level for those cases which do not respond to, or do not tolerate AmBisome and provide clear guidelines for its use;
- Ensure compliance of three months of MF for PKDL patients and replace MF for female PKDL patients with multiple dose AmBisome therapy when pregnancy tests and contraception cannot be guaranteed;
- Strengthen the adverse drug reaction reporting system, both for kala-azar and PKDL with special focus on PKDL cases with eye complications;
- Compensate all categories of patients including VL-HIV and relapse cases for wage loss and travel costs for follow-up visits to the clinic and link all category of patients with the national health insurance scheme (Ayushman Bharat);





- Assess patients clinically during follow-up. Ensure all KA patients are followed up for three years for early detection of PKDL cases; institutionalize management of KA/HIV cases at the district level;
- Build capacities of DHs so that they can confirm KA relapse and PKDL diagnosis using microscopy;
- Implement a national/regional/state level quality control (QC) plan for microscopy; and
- Ensure surveillance for resistance to MF, AmBisome and Paromomycin.

## Surveillance

### Key findings

Significant progress has been made in surveillance of KA and PKDL, notably in Bihar and Jharkhand, however, there is a lack of understanding about key terminologies like endemicity, relapse, new foci etc. In the absence of these, correct application of elimination criteria of calculating annual incidence (new cases and relapses) is not done in practice.

KAEP requires a highly performant surveillance system. Towards this end, a wide range of recommendations was made by the independent assessment IA to this effect.

- Set up a real time online platform which is dynamic and has scope to integrate all databases of the programme and further link them to MoHFW's Integrated health information platform (IHIP);
- Adopt an integrated skin-NTDs approach to strengthen detection of PKDL. As far as possible, include PKDL in active case detection in parallel to active case detection (ACD) for KA;
- Fully involve private practitioners (formal and informal) in suspect referrals;
- Assess surveillance in blocks which are consistently reporting zero cases while their adjacent blocks are highly endemic;
- Strengthen passive case detection (PCD) in non-endemic areas and provide guidance on where to refer suspect cases for diagnosis and treatment; and
- Update operational surveillance guidelines and harmonise all surveillance definitions and indicators while also orienting them at the implementation level.

### Vector control

Integrated vector management (IVM), including indoor residual spraying (IRS), long-lasting insecticidal nets (LLIN) and environmental management are crucial for the KAEP to succeed, yet, the current approach relies on IRS only. Serious challenges were encountered in the quality of IRS operations, which will require substantial changes and investments. In both 2018 and 2019, rounds of IRS were missed (2018) or not done as per schedule (2019). The following recommendations were made in this regard:

- Review effectiveness of all vector control measures and develop a more holistic approach;
- Follow these measures for IRS operations:
  - ◆ review the criteria for inclusion of at-risk villages for IRS;
  - ◆ reduce IRS operations from 45 days to as short as possible by pooling spray teams and vector control equipment;

- ◆ rigorously follow timing of spray period;
- ◆ provide water soluble sachets of the currently used synthetic pyrethroid (alphacypermethrin) containing exactly 125 grams of insecticide to spray operators;
- ◆ supply personal protective equipment (PPE) for spray-men and ensure its use and provide proper training, if required;
- ◆ create equipment repair and maintenance teams at the district/state level; and
- ◆ replace spares or non-functional pumps.
- Ensure that all quality assurance measures are adopted, such as
  - ◆ regular monitoring of the quality of IRS operations by programme and partners;
  - ◆ stringent (pre-and-post dispatch) quality control checks of each batch of insecticide following international standards by good laboratory practices (GLP) accredited independent laboratories; and
  - ◆ use the findings for timely decision making by the programme.

#### **For entomological surveillance:**

- Institute a dedicated vector control working group, representing all stakeholders, at national/state level to organize regular systematic monitoring of IRS operations;
- Evaluate the efficacy of applied IRS (bioassays for residual effect); and ensure regular supply of insecticide resistance monitoring kits; and
- Utilise available entomological data for planning of IRS implementation at the district level.

### **Community engagement and mobilization**

There is an ethical issue concerning denial of services to the lowest socio-economic strata of workers. Some houses of the lowest caste are neither sprayed nor visited by the ASHAs. They also cannot apply for pucca (brick and mortar houses since they do not own land. These constitute a general problem for the KAEP that deserves a corrective-specific 'plan for the poorest'. Rural health practitioners (RHPs) are often used as the first point-of-care, hence, it is advisable to involve them in the KA programme. Recommendations include:

- work with the rural development department and engage with Panchayati Raj functionaries for awareness, community engagement, environment management and social empowerment;
- develop a systematic approach to involve RHP's in referral, surveillance and IEC;
- focus IEC messages on prolonged fever, associated symptoms and free access to diagnosis and treatment, proper use of ITN/LLINs, and compensations/incentives; and
- conduct research to understand barriers for seeking care in the public sector and develop culturally appropriate IEC/BCC interventions.

### **Human resources**

It was observed that the programme suffers from a crippling lack of human resources at different levels. Recommendations include:



- make all efforts to fill staff vacancies in district hospitals, community health centres (CHC) and primary health centres (PHC);
- fill all state government positions with respect to male multipurpose workers and entomologists; and
- have the KAEP team reinforced by NVBDCP at the state level and for the high priority districts and blocks.

## **Stock management**

Stock management was found to be mostly in order, although, drugs and diagnostics with a short remaining shelf life were discovered in several locations and there were reports of recent stock-outs due to expiry. Stock expiry should be anticipated and acted upon at an earlier stage. It was recommended that constant inventory monitoring must become a district responsibility and the KAMIS module for inventory management adopted.

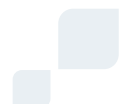
## **Operational research**

In general, the programme will benefit from more operational and implementation research to address knowledge gaps and improved coordination between partners. Short and long term operational research are outlined in the main documents focusing on the evaluation of diagnostics, treatment outcomes and role of newer interventions in the KA elimination programme.

## **Conclusions**

The assessment exercise was undertaken with a broad view that implementation needs to be regularly monitored and readjustments should be made after periodic reviews and evaluations. Concurrently, evidence generation is essential, and also sharing of good practices, so that they may be adopted widely. To ensure smooth progress and to make mid-course corrections, periodical evaluations have a critical role to play.

A revised elimination strategy with focused attention (mission mode), adequate resources, oversight and accountability should result in elimination of KA in India by 2023 and thereafter, move towards fresh targets by 2030 as per the new NTD roadmap.



# 1. INTRODUCTION

Kala-azar (KA) also known as visceral leishmaniasis (VL) is a fatal parasitic disease if untreated, transmitted by sandflies with anthroponotic (confined to human only, no animal reservoir) infection in the Asian continent. The disease is endemic in 79 countries in the world. In 2004, Bangladesh, India and Nepal harboured 67% of the global burden with 42 000 reported new cases every year, and an estimated number of cases ranging from 160 000 to 320 000<sup>2</sup>.

It is also noted that upto 20% of KA patients who are correctly treated and cured, develop a skin condition called post-kala-azar dermal leishmaniasis (PKDL). This is seen in East Africa and up to 9% in the Indian subcontinent. It surfaces within months to years after treatment. These patients can contain large amounts of parasites in their skin lesions, making them an important source of transmission.

KA remains a public health problem in India with established endemicity in 54 districts across the four states of Bihar (33 out of 38 districts), Jharkhand (four out of 24 districts), Uttar Pradesh (six out of 75 districts) and West Bengal (11 out of 24 districts). In these four states, there are 633 endemic blocks. As of 2019, India alone accounted for 20% of the global burden of KA. Sporadic cases appear from other states like Assam, Gujarat, Himachal Pradesh, Jammu and Kashmir, Kerala, Madhya Pradesh, Haryana, Puducherry, Sikkim, Tamil Nadu, and Uttaranchal. (Figure 1).<sup>3</sup>

KA is slated for elimination in India by 2020 as per the WHO NTD roadmap.<sup>4</sup> The National Health Policy (2002) envisaged its elimination which took regional scope by signing KA Memorandum of Understanding (MoU) in 2005 with Bangladesh and Nepal, the other two Asian endemic countries. Later, in 2014, an extension of this MoU included Bhutan and Thailand, as new signatories. India's efforts saw a boost when this MoU was signed and a resolve seen to achieve KA elimination by 2015 (later extended to 2017).<sup>5</sup>

KA elimination is defined as the annual incidence of less than one case per 10 000 population at the sub-district level in India (block), Bangladesh (upazila) and district level in Nepal. Currently, South Asia is the only region where KA is slated for elimination as a public health problem due to its following unique features which include:

- high political commitment in the endemic countries of the Southeast Asia region;
- the disease is confined to limited geographic areas (54 districts with around 650 blocks);
- transmission is anthroponotic in nature (human-vector-human) and humans are the only reservoir; and
- the disease can be readily diagnosed with rapid tests and effective treatments that are currently available.

<sup>1</sup>Peter J. Hotez, Jan H. F. Remme, Paulo Buss, George Alleyne, Carlos Morel and Joel G. Breman. Combating Tropical Infectious Diseases: Report of the Disease Control Priorities in Developing Countries Project. *Clinical Infectious Diseases*. 2004, Vol. 38, No. 6, pp. 871-878.

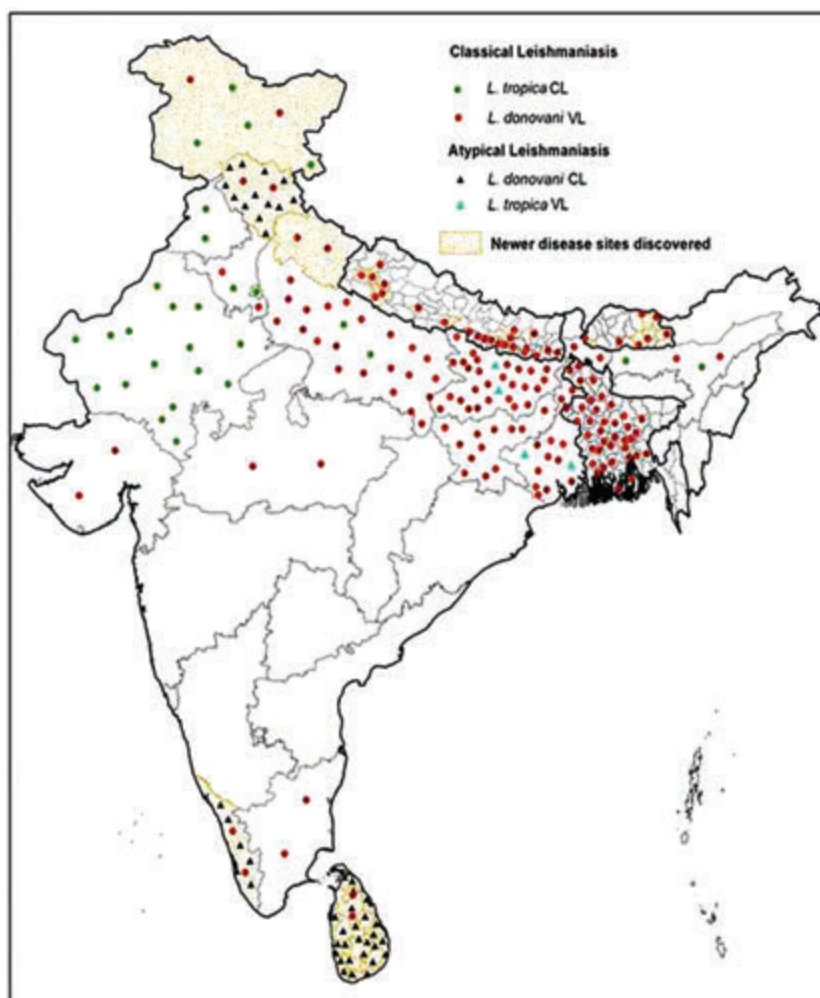
<sup>2</sup>Alvar J, Velez ID, Bern C, Herrero M, Desjeux P, Cano J, Jannin J, den Boer M. Leishmaniasis Worldwide and Global Estimates of Its Incidence. *PLoS One*; 2012;7(5):e35671. doi:10.1371/journal.pone.0035671.

<sup>3</sup>Atypical leishmaniasis: A global perspective with emphasis on the Indian subcontinent, Lovlesh Thakur et al, *Plos Neglected Tropical Diseases*, 2018.

<sup>4</sup>Accelerating work to overcome the global impact of neglected tropical diseases a roadmap for implementation. Page no. 19. 2012-2020. WHO.

<sup>5</sup>National road map for kala-azar elimination August 2014, Directorate of National Vector Borne Disease Control Programme (NVBDCP). Govt. of India.

**Fig: 1. Kala-azar in South Asia 2017-18, including new foci and sporadic cases**



*Source: Surveillance desk review paper for the mission by Dr Rajan Patil, SRM, Chennai*

The main strategies for achieving the target are early diagnosis and complete treatment; integrated vector management; effective disease and vector surveillance; social mobilization and partnerships; and clinical and operational research.

By 2017, Bangladesh and Nepal had claimed achieving KA elimination in 100% of the targeted areas, pending for independent WHO validation. In India, the case-load has declined substantially from 32 803 reported cases in 2005 to 3128 in 2019, with 94% blocks below the elimination threshold (Table 1). Why elimination has not been reached completely is the subject matter of this mission.

The Directorate of NVBDCP organized a joint monitoring mission (JMM) in 2014 with inclusion of all VBDs that served as comparators. Given the past history of intermittent peaks in 1978, 1992 and 2007 (Figure 1), there appeared a possibility of a new peak forming in cases around 2022. Given this oscillating trend, it would be prudent to wait for the final figures in 2022 and examine the challenges.

<sup>6</sup>Accelerated plan for kala-azar elimination programme, NVBDCP, Govt of India, 2017.

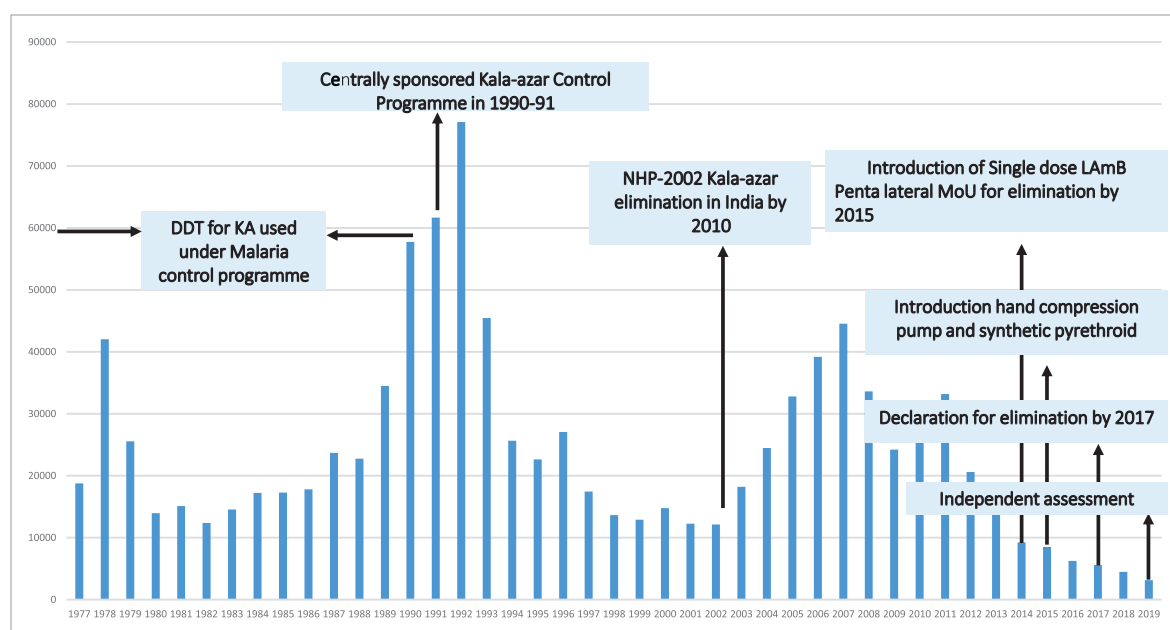
**Table 1: Status of kala-azar, PKDL and kala-azar-HIV cases in 2019**

State	Total No. of districts	Total No. of blocks	Total No. of endemic blocks	No. of villages in all KA endemic districts	No. of new KA cases	No. of KA relapse cases	No. of PKDL cases	No. of KA-HIV cases	No. of blocks reported with incidence of > 1 case (new and relapses)/10,000
Bihar	33	458	458	35233	2416	Data not available	439	121	21 (4.5%)
Jharkhand	4	33	33	8307	539		281	6	16 (48.4%)
West Bengal	11	301	120	19993	87		51	0	0 (0%)
Uttar Pradesh	6	81	22	24933	86		46	0	0 (0%)
<b>Total</b>	<b>54</b>	<b>873</b>	<b>633</b>	<b>88466</b>	<b>3128</b>		<b>817</b>	<b>127</b>	<b>37 (5.8%)</b>

Source: Annual report NVBDCP, 2019

An exclusive review of the KA programme would be required to provide specific recommendations when only a few blocks were found to be lagging and above the elimination threshold. There is need to ascertain whether non-endemic areas reporting cases should be included as newly endemic blocks or whether cases reported in those areas should be assigned to historical endemic blocks to recalculate the disease rate per 10 000 population.

**Fig. 2. Transmission dynamic and breakthrough in kala-azar elimination programme**



Source: Annual reports of NVBDCP. Information updated by WH

<sup>7</sup>Joint monitoring mission VBDs. 2014. Directorate of National Vector Borne Disease Control Programme (NVBDCP). Govt. of India.



## 2. SITUATIONAL ANALYSIS

Although most of the kala-azar primary cases were from blocks which had achieved elimination, the major foci of the disease above threshold was limited to 37 blocks (Fig. 3). These blocks were reporting more than one case per 10 000 population, as of end December 2019. However, micro-stratification showed there were still few blocks that had an annual incidence of more than 4/10 000, such as, Amrapara block of Pakur district in Jharkhand.

Of all the endemic districts in Bihar, Muzaffarpur district contributed the highest number of cases. Gopalganj, Saran and Siwan were also endemic with many blocks still having an endemicity  $>1/10\ 000$  and in some cases as high as  $2.9/10\ 000$ . It is expected that in some districts, all blocks were likely to achieve the incidence of  $<1/10\ 000$  population by 2021. However, in other districts this was unlikely to happen before 2022 given the current spray rates (less than 50% in Kishanganj, between 60 and 70% in Gopalganj and Patna), endemicity ( $>2/10\ 000$ ) and delays in treatment around 60 days.

Across the four states and 54 endemic districts, out of a total of 873 blocks, as many as 547 blocks had reported an incidence of less than  $1/10\ 000$  of population continuously for the last three years, i.e. in 2016, 2017 and 2018 (Table 2). These 547 blocks which were consistently reporting an incidence below the elimination threshold needs to be examined and verified for the quality of the surveillance system and KA services. Interestingly, in some areas, blocks with no cases were found adjacent to blocks with cases which raised suspicion of poor case detection or managerial factors like incomplete reporting, insecticide spraying, etc.

**Table 2: Number of districts and blocks reporting incidence of  $<1/10\ 000$  of population in 2016, 2017 and 2018**

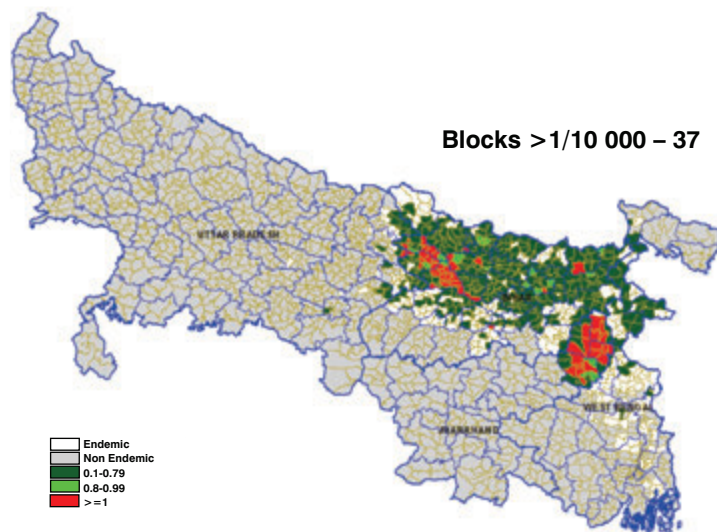
State	Count of districts	Total no. of endemic districts with all blocks having $<1$ incidence in 2016-18	Count of blocks $<1$ incidence in 2016-18
Bihar	33	15	383
Jharkhand	4	0	7
U.P.	6	8	38
Bengal	11	10	119
<b>Grand Total</b>	<b>54</b>	<b>33</b>	<b>547</b>

Source: Annual report of NVBDCP





**Fig. 3 Map showing block-wise status of kala-azar in 2019**



**Deaths:** A substantial decline of KA cases can be observed from the trend-line of cases from 77 102 in 1992 to 328 in 2019 (Figure 4). Since 1992, cases declined by 95%. Similarly, deaths observed among KA cases were around 1415 in 1992 which reduced to 90 deaths in 2011 and then five in 2015. Thereafter, status of death reporting was found to be nil till date and although deaths were observed in the field, none were reported after 2015.

In May 2017, a National Advisory Committee (NAC) was constituted by MoHFW, GoI to review the progress made by the KAEP. It was tasked with advising the Ministry and States/ union territories (UT) on immediate remedial and corrective measure for realizing the goal of elimination and making recommendations. The NAC had reported deaths in Bihar in 2017 but these were not investigated and reported.<sup>8</sup> The report mentioned that, “two deaths have been reported within some days after the patients were treated with single dose AmBisome in Bihar and the causes of death are yet to be investigated.”

Death occurs in almost all KA patients if untreated, and mortality is associated with various factors like age of the patient, late healthcare seeking, immunological status, and the drug used. Prior to 2010, KA caused an estimated over 20 000 deaths annually, a rate surpassed among parasitic diseases only by malaria, and 23 57 000 disability-adjusted life years lost, placing KA ninth in a global analysis of infectious diseases.<sup>1</sup> The mortality trend due to KA in India declined sharply over the last years to nil (Fig. 4) although field observations and analysis shows the existence of a number of deaths as explained below.

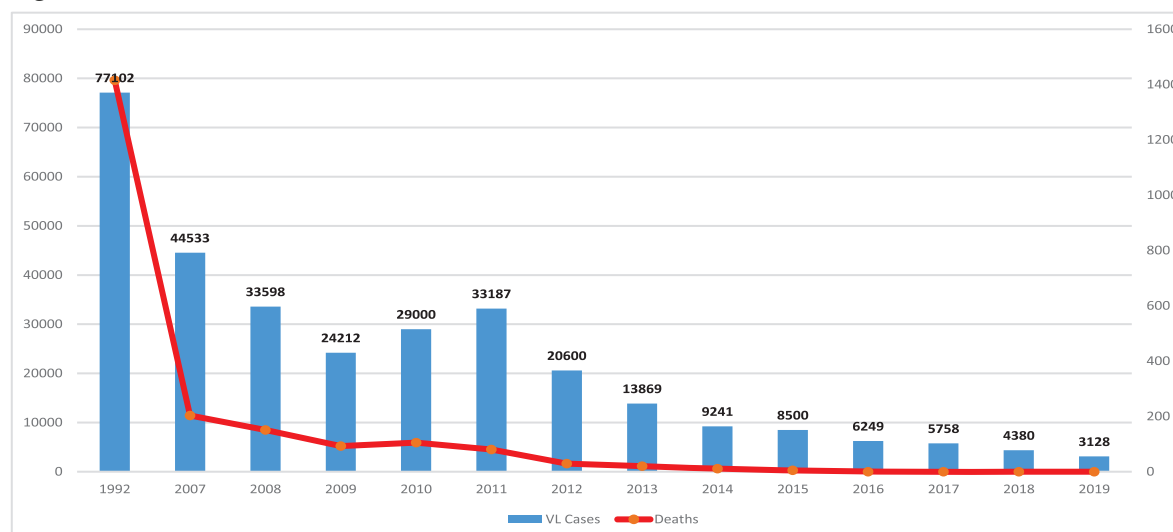
The NVBDCP issued a directive to all states and partners in June 2019 to prepare a list of deaths observed among KA cases. CARE teams in the field shared a list of 269 deaths (2017- August, 2019) from Bihar and Jharkhand and a report of 13 deaths which was shared from Uttar Pradesh and West Bengal during the same period. State and district VBD programme officers, WHO and CARE officers conducted a survey of reported deaths among KA patients during the period 2017 and August, 2019. Preliminary analysis of verbal autopsies of 180 deaths reported during 2017–2019 from the four states are given in Table 3.

<sup>8</sup>Report of national advisory committee (NAC). NVBDCP, MoHFW to review progress of the national kala-azar elimination programme, 2017, Page no – 3.

<sup>1</sup>Control of the leishmaniases, Report of a meeting of the WHO Expert Committee on the Control of Leishmaniases, Geneva, WHO TRS 949. 2010.



**Fig. 4 Trend of kala-azar cases and deaths, 1992, 2007–2019**



Source: NVBDCP

**Table 3. Analysis of deaths among kala-azar cases 2017–2019**

State	Reported deaths	Deaths (n- 180)		
		Female	Male	Total
Bihar	195	37	75	112
Jharkhand	74	14	42	56
Uttar Pradesh	8	0	8	8
West Bengal	5	2	2	4
<b>Total</b>	<b>282</b>	<b>53 (29%)</b>	<b>127 (70%)</b>	<b>180</b>

Source: NVBDCP, Govt. of India, CARE and WHO

Further analysis was done to see if these deaths fitted into the definition of mortality among KA cases. It was found that 84% (152 out of 180) deaths were observed within six months of the onset of disease and diagnosis (Table 4).

**Table 4. Death analysis. Time elapsed between onset of symptoms and presentation to a health centre**

State	4	1-2 month	3-4 month	5-6 month	>6 month	Grand total
Bihar	40	18	4	7	17	86
Jharkhand	20	15	7	5	8	55
Uttar Pradesh	0	1	0	0	0	1
West Bengal	2	1	1	0	0	4
<b>Total</b>	<b>62 (43%)</b>	<b>33 (23%)</b>	<b>12 (8%)</b>	<b>12 (8%)</b>	<b>25 (17%)</b>	<b>144</b>

Source: Analysis of verbal autopsy by WHO. 2019

**Table 5. Concurrent illness in death cases**

State	Anemia	Tuberculosis	Diarrhea	Unknown	no illness	others	Total
Bihar	39	20	0	16	28	10	113
Jharkhand	26		1	5	2	8	42
Uttar Pradesh	1						1
West Bengal	2	1		1			4
<b>Grand Total</b>	<b>68 (43%)</b>	<b>20 (12%)</b>	<b>1 (0.6%)</b>	<b>22 (14%)</b>	<b>30 (19%)</b>	<b>17 (10%)</b>	<b>158</b>

Source: Analysis of verbal autopsy by WHO. 2019

**Table 6. Time elapsed between diagnosis and deaths in percentage (n = 180)**

Months	<1 month	1-2 month	3-4 month	5-6 month	>6 months
Bihar	45	8	8	16	22
Jharkhand	35	33	7	22	4
Uttar Pradesh	50	13	0	13	25
West Bengal	50	25	25	0	0
<b>Average</b>	<b>42 (23,3%)</b>	<b>16 (8,9%)</b>	<b>8 (4,4%)</b>	<b>18 (10%)</b>	<b>16 (8,9%)</b>

Source: Analysis of verbal autopsy by WHO. 2019

The age of deceased patients ranged from 1-60 years and majority of the patients were treated in district hospitals (DHs). This required a further assessment by the implementers. The concern was that the non-reporting of deaths could lead to a situation where no one would have a clue on the reason of the deaths and on ways to prevent them.

The new WHO NTD roadmap 2020–2030 proposed a new target for elimination of KA as a public health problem and defined it as achieving less than 1% case fatality rate due to primary VL<sup>10</sup>. It also had two more sub-targets for the South East-Asia region (SEAR):

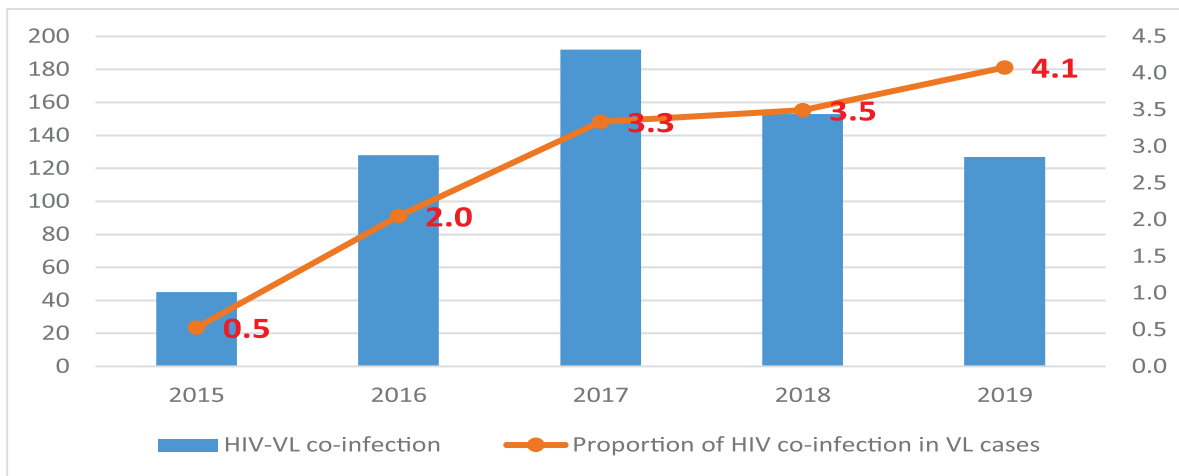
- ♦ With the number of countries in SEAR validated for elimination 1 case (new and relapses) per 10 000 population at district level in Nepal and sub-district level in Bangladesh and India at 100% by 2030; and
- ♦ In SEAR, PKDL cases detected (VL post-treatment follow-up three years) and treated at 100% by 2030, putting the spotlight on the national elimination strategy that would be needed to align to newer strategies.

**HIV-VL co-infection:** In KA patients with comorbid conditions, since the mortality increased, special attention is needed in cases which present with a comorbidity like HIV, tuberculosis or any immunocompromised condition. HIV-VL coinfection is especially of concern and has important immunological implications since it affects the cellular response in charge of parasite control. As a consequence, the parasite multiplies and invades not only the reticuloendothelial system (spleen, bone marrow and liver) but also every organ, like the blood, intestine, lungs and even the central nervous system (CNS). Relapse is very common and occurs recurrently in almost all HIV-VL cases. Reports on relapse in HIV-VL cases represent still an underestimate due to no report, despite the recommendation in the follow-up protocols. Status of HIV-VL cases can be referred from Figure 5.

<sup>10</sup>Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021–2030. World Health Organization. 2020.



**Fig.5 Status of HIV-VL cases and proportion of HIV co-infection among VL cases 2015–2019**



Source: NVBDCP, 2019

**PKDL:** The PKDL is a skin condition that plays a paramount role in disease transmission, especially during inter-epidemic periods. It is considered to be triggered immunologically and follows apparently successful treatment of KA in a proportion ranging from 3 to 9% of patients in the Indian subcontinent.<sup>11</sup> Special efforts should be made to trace PKDL in the community, because patients with PKDL have only skin manifestations and usually do not attend clinics or see skin specialists only.

It can be confused with pauci or multibacillary leprosy. The skin lesions may also mimic other skin conditions. Normally, these patients do not seek treatment unless they feel that it has disfigured their appearance. Therefore, the majority of PKDL cases treated in the public health facility come through active case search efforts in the community. Cohort follow up of 576 PKDL cases in all states showed that 78% treated cases were detected by an active case search. Among the 576 cases, 458 (79%) had a past history of KA and among these, 227 (50%) had an occurrence of KA in the past 1–5 years.<sup>13</sup>

PKDL is a potential reservoir of infection and poses a threat of upsurge of KA cases, especially during inter-epidemic periods. Therefore, early detection, diagnosis and treatment of all PKDL cases is very important from an epidemiological point of view. A special drive and emphasis was given to the programme for detection and treatment of PKDL in 2015 and hence an upsurge of cases was seen from 2016 onwards. However, this trend is declining since 2018 (Fig. 6). Data indicates clearance of a backlog of old undetected cases in the community, although this would have to be correlated and validated with the current follow-up and reporting system.

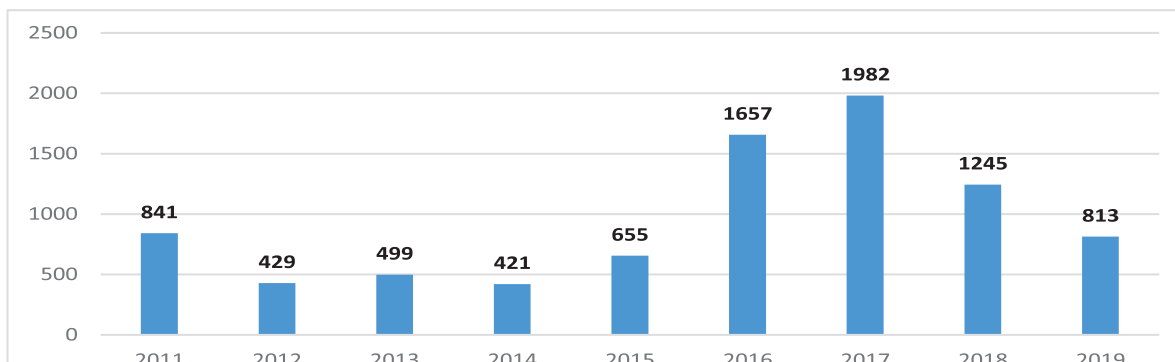
<sup>11</sup>Control of the leishmaniases, Report of a meeting of the WHO Expert Committee on the Control of Leishmaniases, Geneva, Page no. 14. WHO TRS 949. 2010.

<sup>12</sup>Accelerated Plan for Kala-azar elimination. Directorate NVBDCP 2017.

<sup>13</sup>Cohort follow up of PKDL cases. Jan 2017. Report of WHO Country office India.

<sup>14</sup>Siddhivinayak Hirve, et al. Transmission Dynamics of Visceral Leishmaniasis in the Indian Subcontinent – A Systematic Literature Review. PLoS Neglected Tropical Diseases 10(8):e0004896 · August 2016.

**Fig. 6 PKDL case situation 2011–2019**



Source: NVBDCP, 2019

Once the baseline information related to KA and its various clinical conditions is better captured and indicators clarified, the analysis of blocks that still remain above the elimination target would be more accurate. Also, the underlying reasons for not achieving targets would be better understood.

The guiding document on the process of validation of the elimination of KA as a public health problem in South-East Asia has set certain criteria and pre-conditions to be fulfilled by the endemic countries.<sup>15</sup>

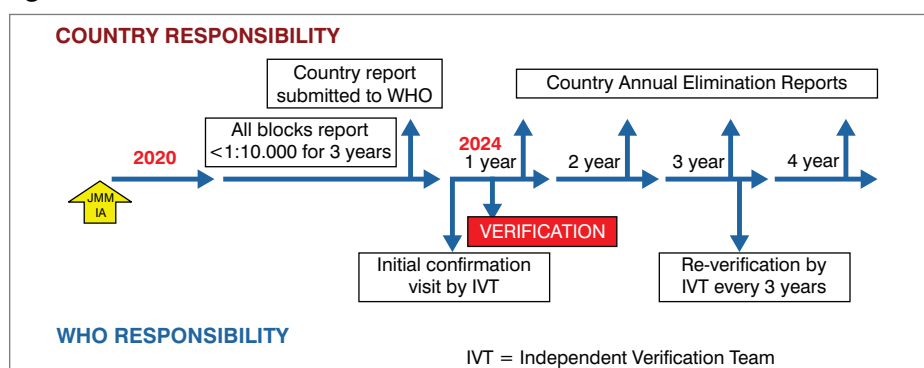
**Rationale for a standard criteria:**

- ◆ Being an international, transborder and voluntary effort;
- ◆ Ensure international credibility to claim elimination; and
- ◆ Have solid criteria and procedures to assess achievements.

**Preconditions to be fulfilled by the endemic country:**

- ◆ National strategic guidelines and SoPs;
- ◆ Adequate health services;
- ◆ High quality epidemiological surveillance system;
- ◆ Integrated vector management;
- ◆ Supply chain management; and
- ◆ Cross-border coordination.

**Fig. 7 Process of validation for the kala-azar elimination in South-East Asia**



<sup>15</sup>Process of validation of elimination of kala-azar as a public health problem in South-East Asia. WHO. 2016.





# 3. GENERAL AND SPECIFIC OBJECTIVES OF THE INDEPENDENT ASSESSMENT OF KALA-AZAR ELIMINATION PROGRAMME

As part of the MoH-Gol commitment to the elimination of KA, an independent assessment was planned with the support of WHO. The following overarching objectives were identified:

## General objectives

- Conduct an independent assessment of the national KAEP and recommend measures for its further strengthening with respect to elimination and sustaining the elimination; and
- Identify any bottlenecks/hurdles/challenges in the last mile of elimination and recommend solutions.

## Specific objectives

- Review progress towards achieving goals and objectives of KA elimination, including analysis of overall programme impact on disease burden (new cases, relapses and mortality). Also, look at programme coverage and outcome in the country with focus on endemicity, vector control situation, risk factors and at-risk population.
- Assess impact of programme strategies on incidence of disease and mortality associated with KA;
- Look into organization of KA related services (specifically preventive vs curative primary health care vis-à-vis specialized care, public vs private, formal- informal). Also consider referral systems and analyze universal health access to case identification, quality early diagnosis and treatment of all KA and PKDL cases;
- Review overall programme stewardship, financial management, procurement of medical supplies, identifying of constraints and facilitating factors;
- Review data quality and data management capacity with recording and reporting system in the programme;
- Assess quality of surveillance, monitoring and robustness of health information system;
- Review vector control policies, strategies and activities under integrated vector management approach and guide for the effective implementation of the strategy;
- Assess role of intersectoral departments and programme partners and collaboration between implementing partners and examine the extent of integration with other programmes;
- Assess community participation, social mobilization and factors affecting health-seeking behaviour;
- Analyze evidence-based policy formulation (operational research/research), contribution of research and regulation; and
- Assess national preparedness and readiness for validation of KA elimination as a public health problem.



## 4. METHODOLOGY

### A. Thematic areas

Five thematic areas were identified which included, surveillance and organization of preventive and curative services; vector control strategies; stewardship and governance role of the national VBDCP; financial and procurement and supply chain management.

Two types of approaches were adopted to conduct the review. One was from the disease control point of view and the other, from the perspective of functioning of the health system, within a given context. The assessment activity attempted to keep a fine balance between both approaches as it embarked on a background desk review that covered all theme areas.

Since the last JMM was organized in 2014, several major policy changes had taken place. This resulted in due priority being given to preparatory activities such as resource mobilization, identification of consultants/experts (in-country and external), seeking prior consent from experts for participation, team formation, desk reviews, and logistical arrangements etc.

### B. Selection of team members and team formation

Due diligence was given for selection of independent experts for the assessment activity. Selection of experts was based on their area of expertise and past experience of such missions. A total of eight teams were formed with experts representing specialized domains such as VBDs, field epidemiologist, vector control, environment, health systems, procurement and supply management, internal medicine, health economics, financing, social sciences, surveillance, data management, monitoring and evaluation, programme administration and management and advocacy, communication and social mobilization.

### C. Selection of field areas for assessment activity

The selection of field areas for the purpose of the assessment was earmarked at four levels, namely state, district, block and village/gram panchayat.

#### **At the State-level**

All known KA endemic states was planned to be covered in the assessment activity. . In addition, the 'non-endemic' state of Sikkim was selected for assessment. Here, local transmission was not proven although sporadic cases were reported in the past. Out of the four KA endemic states of Bihar, Jharkhand, Uttar Pradesh and West Bengal, the assessment exercise could not be conducted in West Bengal as no agreement was granted by the state local government to visit West Bengal. Hence the three KA endemic states of Bihar, Jharkhand, Uttar Pradesh and the non-endemic state of Sikkim were visited for the assessment.

### At the District-level

Two criteria were considered for selecting the districts. These were based on districts which were found to be contributing high number of cases. The other related to districts which had a high case load in 2016 and 2017, but the cases were substantially reduced, and all blocks were reporting incidence less than one.

### At the Block-level

Two criteria were followed for selection of blocks (Fig. 8). They included:

- ◆ Annual incidence > 1 in last 3 years (2016, 2017 and 2018); and
- ◆ Annual incidence < 1 in last 3 years (2016–2018) but > 1 during 2013, 2014 and 2015.

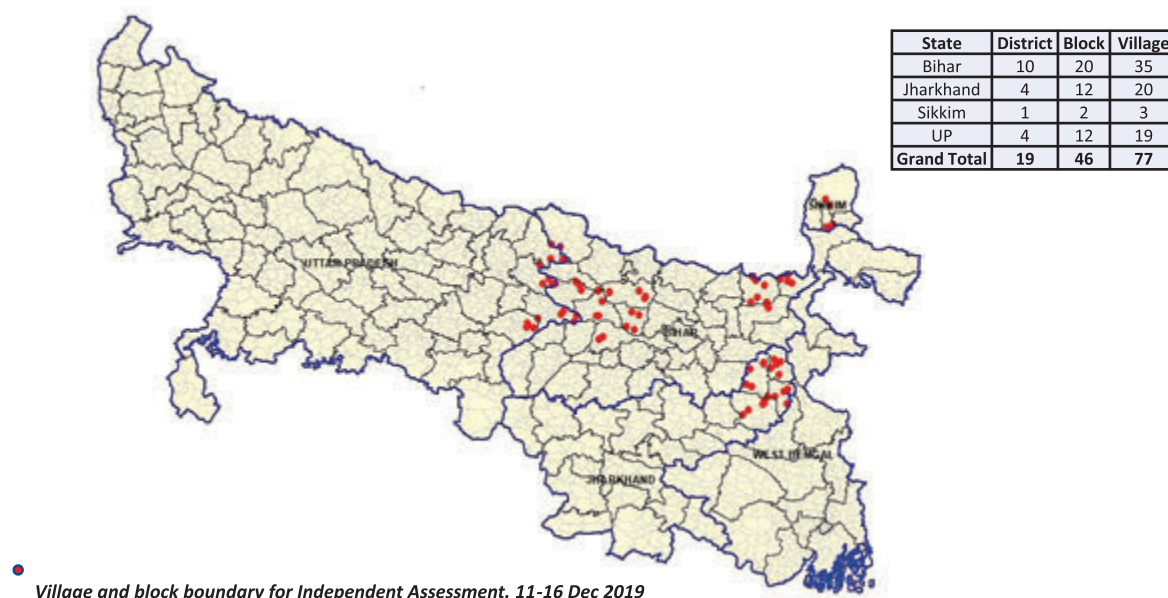
### At the village-level

Two criteria were followed for selecting the blocks. These included:

- ◆ Villages with >3 cases in 2018 and > 1 in 2019; and
- ◆ Villages reported > 3 cases in 2015 and 0 in last three years (2016–2018).

Based on the selection of areas, field visits were done and a total of eight teams were finalized which could covered 19 districts, 46 blocks and 77 villages in four states.

**Fig: 8. Numbers of blocks and villages visited during independent assessment 11–16 Dec 2019.**



Source: Mapping done by WHO. 2019

## D. Data collection at levels and methods

A set of data collection tools were developed for assessment activity at the level (Table 5) of Central>State>District>Block>Village (patients, health workers, private practitioners and community members). Methods adopted for data collection included:

- Verification of records and reports;
- Interview questionnaires covering State and District Programme Officer, MO, lab technicians, stock manager, pharmacist, supervisors, data entry operators, ASHA, spray-men, private practitioners (formal and informal), community members, patients, district and health administrations;
- Demonstration of spray activities, stock checking, lab visit, cold chain assessment, treatment ward visit, data entry room;
- Focus group discussions; and
- Reference from desk review papers.

**Table 5. Quantum of monitoring (total 477 formats filled)**

Form	Level	No of forms filled
National	Centre	1
State	State	4
District office	District Program office	14
District Hospital	District	16
Block/CHC/PHC	Block/CHC/PHC	37
Medical officer/treating physician	Block and District	41
ASHA/ Community health volunteers	Village level	82
Patients (VL, PKDL, VL-HIV)	Village	144
Community interview (6-10 members)	Village	82 x (6/10)
Private practitioners	Billage/Block	52
Medical college/RMRI/KAMRC (tertiary care centres)	Patna, Muzaffarpur, Dumka	5







# 5. OBSERVATIONS AND RECOMMENDATIONS

## A. Surveillance and organization of preventive and curative services

A strong surveillance system is one of the most important pre-requisites for KA elimination as a public health problem. The surveillance system should be:

Sensitive. All cases should be detected as early as possible;

Reactive. Information should flow in order for action to be taken; and

Flexible. It should adapt to local specificities or to changes over time.

So far, tremendous progress has been achieved in the programme, however, the last mile challenges of elimination are confined to few foci. Key observations:

### Key observations:

#### I. Availability of guidelines, use of SoPs, standard uniform terminology and definitions in the programme

- Newly printed copies of guidelines and SoP were found almost in all health facilities that were visited. As part of the preparation for the mission, state and district officials ambitiously printed all possible modules and SoPs and placed them in health facilities prior to the arrival of mission members. Partners on the ground like CARE, PATH and WHO supported these pre-mission preparations in almost all visited health facilities;
- Level of knowledge and awareness on KA guidelines and operational plans varied from very high to low. Although regular trainings took place, their frequency was not aligned with the high turnover of human resources. Not all relevant staff were included in the trainings. It was observed in one location, how a recent training had not included all MOs and nurses. In another location, block programme manager (BPM), block community mobilizer (BCPM), block health education officer (BHEO) and non medical assistant (NMA) had not been trained since they started working. The ASHA's however, were well-trained and conversant with all KA elimination activities;
- Lack of clarity was found for several operational definitions related to relapse, reinfection, treatment failure, endemicity, new foci, outbreak, treatment outcomes, death among KA case, etc. More specifically, major gaps were observed, especially in terms of lack of knowledge of operational definition of elimination of KA as a public health problem. This was calculated as annual incidence of (new cases plus relapses) per 10 000 population at the implementation unit (block).

So far, there has been no mechanism to include relapses in this definition in block reporting up to central level in HMIS. From the elimination perspective, this has been compounded by

uncertainty regarding total number of endemic blocks in the country, due to lack of clarity in ascertaining difference between the terms endemic and affected. All affected blocks not reporting any new case in the current year are classified as non-endemic, the status of which might change the following year in the event of their reporting a new case. Therefore till 2015, the total number of endemic blocks varied between 580 to 650 from one year to another. For reasons not matching the above classification, total number of endemic blocks were fixed at 633 from 2016 onwards;

- Careful assessment of previous records indicated there could be differences in endemic blocks than the designated 633;
- On the same ground, criteria for classifying a new focus is as follows: if a village in an endemic block reports a new KA case after a gap of three years. it is termed as a new focus.

In today's world there is intense population movement within and outside endemic areas which can result in reporting of KA cases from non-endemic areas (never reported a single new KA case before). Such reporting should be encouraged, investigated and included in the report. New foci should not be interpreted as failure of the programme or as a taboo. Proposed recommendations for the short-term, mid-term and long-term:

#### **For the short-term**

- From a surveillance point of view, case definitions must be clear and consistent in all documents and meet international standards, namely definitions of relapse, treatment failure and reinfection. This also applies to the definition of a KA death;
- Update and disseminate key operational and case definitions in official documents;
- Disseminate direction or guidance from NVBDCP and consider the states reporting sporadic cases;
- Ensure guidelines and SoPs are well placed in each health facility and the programme manager and users are clear about the national and state guidance for any activity in the field. For example, if case search activity is planned from the state office, the nodal officer at the district and block must be clear about the steps of preparation, its organization, recording and reporting of the activity. The same applies for follow-up of KA and PKDL cases, outbreak investigation, etc; and
- Encourage reporting of KA cases from non-endemic blocks and affirm this is not interpreted as failure of the programme or taboo.

#### **For the mid-term**

- Conduct regular (annual) refresher training for all staff (doctors, paramedic, KA technical supervisors KTS, ASHA, block communication and mobilization officers etc) involved in their respective areas and integrate them with other VBD trainings where possible;
- Ensure that the new staff that is hired on account of there being high turnover, receives an increased frequency of orientation training; and
- Integrate managerial training (currently missing) in the training plan for SPO, District VBD Officers and block PHC MO's. All induction trainings to take place through partners so that their quality is not compromised.



### For the long -term

- Update the existing operational manual as a reference guide for programme managers and end users at the implementation level.

### ii. Case search activity

- Annual active case detection (ACD) activity in all endemic blocks was not reported. It is understood that endemic areas are vast and they should be organized in a phased manner adopting a risk-based approach. The situation became even more complex since information on active vs passive population screening was not available;
- Inter and intra-state variations were observed in planning and/or organizing ACD search activity, in all the visited states. It was felt that inter-state variations could be understood as they were dependent and decided, based on available human resources within the state. Moreover, ACD activity in Jharkhand was aligned with the national guidance but planning in Bihar was found to be random;
- Programme managers at district and block level, the KA frontline health workforce i.e. malaria technical supervisors (MTS), KTS, BCM etc. were not clear about the procedures of the activity;
- The team observed that field actions (case search, follow up) were relying heavily on a partner. The task of ACD was primarily given to the Block Coordinators of CARE in Bihar and Jharkhand and field volunteers in Uttar Pradesh by PATH. The ACD method was confined to a few informers (index and snowballing) and was largely partner-mediated. The lack of involvement by the state is discussed in the “Stewardship and Governance” section (page 71).
- A good practice of integrated management was observed in Jharkhand by integrating KA and PKDL with leprosy, malaria, tuberculosis and lymphatic filariasis ACD. However, institutionalization and integration of ACD with other national programmes was not found especially in the case of the Leprosy Case Detection Campaign, Integrated Child Development Services (ICDS), Rashtriya Bal Swasthya Karyakram (RBSK), Mass Drug Administration (MDA) for lymphatic filariasis and ACD for tuberculosis fever survey in malaria etc.
- Monitoring visits to the field during ACD suggested that a microplan was usually not prepared and team members were generally absent during the activity. It also found that the assigned and trained team members were not necessarily the ones participating in the activity. Cumulative information about houses covered, population screened, and suspects identified were found at district level, but the same information was not available in many health facilities below the districts. However, in Bihar, this information was also not available at the district level;
- Reporting of ACD depended partly on mobile teams, and partly on ASHA’s and MPW’s who were expected to refer suspected cases (KA, relapses and PKDL). However, reporting could be a difficult task because there were no standardized records and reports of KA suspected/patients at village level. It was not always clear whether PKDL was part of ACD;
- It was observed that in each highly endemic focus district in Bihar, ASHAs avoided visiting areas where the community belong to the lower castes. These areas were at the highest risk of infection due to poor living conditions and low immunity levels owing to malnutrition;

- No incentive mechanism for frontline health workers (FLWs) existed for ACD. An incentive was only given if they found a confirmed case of KA or PKDL, but none for the suspects. For confirming a KA case and its complete treatment, a health worker was paid an incentive of INR 500 (USD 7.14). A similar proposal for PKDL cases was given in the programme planning committee meeting, though this was yet to be implemented;
- ACT was found to be mostly index-case based but this was unlikely to capture the entire endemic village. Any person having fever of two or more weeks was tracked and traced through information from key informants. However, cases of lesser duration of fever (less than two weeks) were neither captured, managed or followed-up later;
- PKDL detection remained a challenge and only micro-approaches were practiced for ACD. What was most striking was that the National Leprosy Eradication Programme organized regular mega campaigns of ACD house-to-house (including KA endemic areas) with no integration for PKDL cases. PKDL was also not on the radar of the health personnel hence there were minimal referrals. Therefore, integration of Leprosy and PKDL case search in KA endemic region would be a cost effective approach with high yield.
- RMRI was engaged in detection activities in certain geographic area. The mechanism of detection could not be verified. RMRI was cross-reporting cases to concerned districts and states though no cross-reporting from block PHC and DH.
- In non-endemic states like Sikkim, officers at district level who attend meetings in the state headquarters tend to have some information on occurrence and reporting of KA but health workers below district level have no clue of KA signs and symptoms;
- Sporadic cases of KA have been documented, some with no travel history. Investigation for assessment of any local transmission therefore needs to be conducted;
- No mechanism of border surveillance and cross border notification was observed in any state;
- Despite KA being a notifiable disease in the four endemic states, implementation of notification (reporting from private health sector), is not observed in any state and no exclusive report of suspects or confirmed cases from private sector were found in any health facility or at any level. Moreover, sporadic cases kept getting reported from different states or so called non-endemic states. Other states reported sporadic cases, namely Assam, Gujarat, Himachal Pradesh, Jammu and Kashmir, Kerala, Madhya Pradesh, Haryana, Puducherry, Sikkim, Tamil Nadu, and Uttaranchal. However, the line-list or epidemiological information of cases from states other than four endemic states did not exist at the central level and there was no clear mechanism of reporting from non-endemic states. Proposed recommendations for the short-term, mid-term and long-term:

#### **For the short-term**

- Disseminate SoPs of ACD at all levels and ensure these are followed. Few states, especially non-endemic states to propose deviation from the SoP as per their resources, though recording and reporting must be ensured in a uniform pattern across the state. Records of field activities must be preserved at the health facility level as one of the essential documents for verification of activity;
- Provide incentives to ASHA's for identifying all KA suspects, not only for confirmed cases but also to better support early case detection;

- Organize ACD in a phased manner adopting a risk-based approach. Strictly follow the suspect and other standard definitions in the field. Fever cases of less than two weeks duration should be followed during repeat visits in the same village. Similarly, all family contacts of a newly detected case must be approached for examination and repeat visits if there are cases of fever less than two weeks duration;
- Strengthen passive case detection (PCD) in non-endemic areas and provide guidance on where to refer suspect cases for diagnosis and treatment;
- Record outcomes from the case search and report in terms of villages, houses and populations targeted/covered/examined, number of KA and PKDL suspects identified, number of RDTs used for KA and PKDL suspects and number of confirmed KA and PKDL cases found;
- Prepare special plans and roll-out for hard-to-reach areas and identify hotspots or villages with persistent cases (village reporting at least one new case for last five consecutive years) to ensure no one is left behind. Select the team members and supervisors for ACD in hard-to-reach areas, hotspots and socially marginalized communities from the same community so that no houses or areas are excluded due to social selection or any kind of social biases.
- Adopt one of two measures, namely to strengthen data recording, reporting and monitoring of ACD and suspected cases referred and incorporate PKDL as part of ACD;
- Ensure ACD by partners, acts as a supplementary activity to the activity planned by the state without replacing the entire state's action plan. There would be a high likelihood of missing suspects and cases if the activity was dependent on the small number of stakeholders on the ground.

#### **For the mid-term**

- Sensitize and train all programme managers on SoPs that are to be followed for ACD.;
- Conduct cascade training of all FLWs including MTS, KTS, BCM, etc. with special emphasis on the microplan, house visits, recording and reporting;
- Strive for better coordination with private health facilities and network and strengthening of case notification from medical colleges/ private practitioners/ other organizations;
- Sensitize private practitioners and informal providers network for notification with display of KA posters in their clinics/working place;
- Undertake extensive community mobilization at all levels (district, block, panchayat and community) for free and best treatment using different IEC media;
- Report from non-endemic areas (in case of sporadic cases) and verify local transmission by conducting rapid case search and outbreak assessment in selected villages;
- Pay incentives to front line health worker (FLW) for identifying suspected cases in ACD; and
- Complete the cross-border surveillance and strengthen inter and -intra state notification

#### **For the long-term**

- Strengthen and explore ACD for KA and PKDL cases by integrating with other disease case search programmes. While planning for integrated ACD consider the daily work-load by integrating other programmes (leprosy, TB, malaria, immunization);

- Declare KA as a notifiable disease at the national level to make the response faster and better standardized in new foci. In addition, if notifiable, advocacy reaches the top of the political pyramid which is the Parliament, it would be important to promote a national approach that converges at the same level with other countries that are cosignatories of KAEP.

### **iii. Strengthen the information system to improve data collection, reporting and data use for action plans.**

- Wide discrepancies observed in ascertaining the number of endemic blocks right from central level up to the district level. The same applies for villages, in the absence of historical data, making it difficult to categorize endemic and non-endemic villages, given that village wise data prior to 2013 was not available;
- Monitoring and oversight at the highest level were seen as essential to maintaining political commitment and providing financial resources. The mission looked deeply into the limitations of the use of KAMIS since it was a proprietary software which was still in its development phase;
- KAMIS is an online data platform for KA which has evolved over time, however, few limitations in its design like lack of dynamicity, not being user-friendly or automated, led to its limited use in the programme. Owing to several limitations, users at the implementation level or decision-makers at state and national level were not utilizing it for any response or decision making. Moreover, KAMIS was not in the national information centre (NIC) portal and the data cloud was owned by a private firm;
- The mission noticed that KAMIS was being used only as a parallel system where paper-based information was transferred to KAMIS without further use of surveillance information for planning and actions in the field. The data entry was done at the block level even though the district level NVBDCP unit did not use it. Same was the case at the state and national level;
- There was no mechanism of monthly report generation in KAMIS that could list out number of KA cases disaggregated by sex, age, type of case- new, relapses, treatment regimen used and treatment outcome. This was a major reason why KAMIS was not considered a reliable source of information by the district, state and central level;
- At the current usage, the role of KAMIS is limited and restricted for the purpose of the programme across all endemic states except for undertaking some analysis like persistent villages and some use by NGOs in Muzaffarpur, Siwan and Saran for active case detection activities. However, it provides extensive patient line-lists which are useful for research and modelling. There is urgent need to customize HMIS where it can generate comprehensive monthly and annual reports and if this is not possible, then to produce hardcopy reports;
- The mission observed in the field that block and district level health coordinators from CARE were filling additional forms for each KA case and taking extensive socio-demographic and household information like type of housing, use of LLIN, sleeping pattern etc;
- The recording and reporting system was functioning for KA, however, duplicity, overlapping and missing of essential variables was quite common in the system. For example, patient information was captured three times, first in the treatment card, then in the treatment register which is also called HMIS register, and finally in KAMIS, which also prepares an excel-based sheet for all patients in some of the states;
- Similarly, line-listing of patients was done at three levels, first in the HMIS register, then in KAMIS



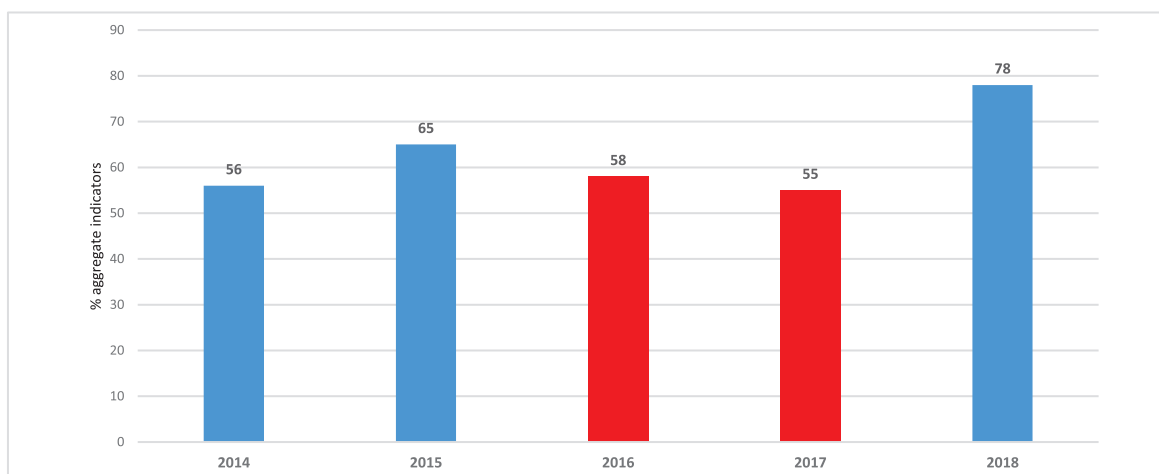
and finally in an excel-based spreadsheet. Due to a parallel line-listing and reporting system, discrepancies were observed in the monthly reports, between treatment cards and HMIS, and between HMIS register and KAMIS;

- The Block data person responsible for managing and using KAMIS had very little knowledge of the utility of entering data in KAMIS. The general statement of data entry operators was, “all data can be stored in one place by using KAMIS, otherwise we do not use it for any other purpose”;
- Important variables like travel history need looking into. There have been cases that have been treated in health facilities that are outside the endemic areas. For instance, a new child KA case was treated in Jaipur, Rajasthan in 2016. Case investigation by Polio teams (local government officials and WHO) revealed this case was not a resident of India and belonged to the KA endemic areas across the border. However, there was no such mechanism in the HMIS to record and report imported cases;
- There were reports of sporadic cases from 10 states, other than the four known endemic states. However, this mission could not see surveillance reports, case-based investigations and action taken (active case search, vector control intervention, treatment regimen provided, treatment outcome) in those areas. Similarly, there were reports of KA cases taking treatment in premier referral health facilities in Delhi, Chandigarh and other non-endemic states. However, there was no information about the place of residence of such patients, treatment regimen used, treatment outcomes and other information. Therefore, the mission recommended introducing an online national registry and taking account of all such cases;
- National documents (active search method) mention the high-risk approach but the criteria for such micro-stratification was not available to the independent mission, except for the use of a term “persistent villages” (villages continuously reporting cases for the past five consecutive years). Therefore, a criterion must be developed by NVBDCP to finalise a high-risk approach (intensity of transmission for programme actions);
- KAMIS has created a repository of block-wise information from 2013 onwards. However, at NVBDCP level, block level information is available from 2009 and before but not shared with KAMIS. All past and historical data needs to be collected at one place and archived;
- Zero cases were reported by a number of endemic blocks in the last three consecutive years. However, it was not clear if cases were not occurring in these areas or there were surveillance issues, or reports of suspects vs diagnostic tests performed. It was therefore suggested that for all such blocks, it should be mandatory to keep a fever suspect register and its surveillance performance to be assessed with the number of RDT tests performed against total number of suspects;
- Missing entries on the treatment card were quite common. Missing information regarding, clinical examination, follow-up, or treatment outcomes were widely observed by all teams.
- Information of last menstrual period was missing in more than 90% treatment cards of female PKLD patients under the reproductive age group;
- Most inpatient records (bed head ticket-BHT) observed in the field had no detail of general examination, vitals and systemic examination and comorbid conditions (pneumonia, diarrhea, TB, etc);
- District profile (table and maps) was visible in several offices, but without any evidence of action taken based on available data;



- Monthly reporting was uniform across all states, although essential information like relapse, comorbidities, deaths etc. were still missing from the reports;
- Historical database of KA and PKDL before 2007 or 2008 was not found in all states.
- Annual country profiles were constantly delayed in their submission to WHO. Profiles for 2016, 2017 and 2018 were updated in 2019 and were still pending for online publication. A huge proportion of aggregate indicators was also missing from the country profile. The percentage of aggregate indicators reported in 2016 and 2017 was 58 and 55% respectively (Fig. 9);
- Deaths due to fever (including situations like deaths at home, before diagnosis and before treatment) in KA endemic areas should be collected and investigated by IDSP; and
- A proposed framework for the KA dashboard was developed in August 2019 but was yet to be made functional.

**Fig. 9 Percentage of aggregate indicators reported in annual report 2014–18**



Source: Published and unpublished annual kala-azar report, India, 2014-2018

#### **iv. Prevention of reestablishment of foci and emergence of new foci. Environmental management**

- In previously endemic areas like Assam, Sikkim and other known places, all DHs should be made designated sentinel surveillance sites to keep KA as one of the differential diagnosis in fever cases of long duration with associated clinical manifestations. Such centres should be equipped with minimal quantities of regular supplies of RDT;
- In the absence of systematic longitudinal data on host and vector, and absence of complete epidemiological information of cases, the team could not establish the occurrence of a local transmission cycle in Sikkim. Areas/states reporting sporadic cases should be provided a template for case-based surveillance and further investigations for travel history. A check-list should be prepared by the national technical advisory committee for actions taken in these areas.





- Any area reporting a new KA case for the first time should be considered an outbreak and steps for outbreak investigation and management should be followed and reported; and there is no doubt that all KA affected areas fall at the marginal position on the social development path. The national roadmap of 2014 had proposed a Block-level task force which was a mechanism to leverage existing government schemes and monitor its implementation (Clean India Movement/Swachh Bharat Abhiyan). Untied funds of health facilities and with the services of the ASHA would be useful in ensuring environmental cleansing in and around endemic villages.

## v. Outbreak

- KA is an outbreak-prone disease. There was an outbreak in Kosra village (Sheikhpura district, Bihar) detecting 70 new KA patients with five deaths (unreported). However, there was no outbreak criteria developed by NVBDCP based on the local epidemiology of the disease. Careful analysis of the available village-wise case details indicated that currently there could be few villages experiencing outbreaks. An important point for consideration was that none of the VBD functionaries under NVBDCP were trained in outbreak investigation and management. Under MoHFW, the IDSP was set up with requisite know-how, orientation and skills to investigate outbreaks. However, KA was not part of the diseases that were included in IDSP and hence no engagement of IDSP programme in KA.
- The capacity for early warning systems (EWARS) to detect outbreaks or new foci requires real time monitoring for early warning reporting and monitoring of an appropriate response. This has been working well in a number of districts. In the remaining, it is either being done irregularly or is not in place yet. During outbreaks, it is essential to understand the progression of the outbreak, especially by using GIS for monitoring spatial patterns over time. Proposed recommendations for the short-term, mid-term and long-term:

### For the short-term

- Institute a standardized recording and reporting system across all states and at all levels and avoid duplication and overlapping of work;
- Use a single line-list from the block till the national level with key variables;
- Make essential variables like relapse, comorbidities and deaths a part of the monthly comprehensive and progressive report. Initiate reporting of deaths among KA (as per the WHO definition) from all levels of the programme. Although directions were released, work-ups were done for some cases, but reporting status of death was still nil from 2016 onwards. Reporting of deaths was important to understand because if these deaths were not being captured, the reasons and complications leading up to them would also not be known. This information could help avert and prevent these deaths with timely response and action.

### For the mid-term

- Train Block data person and programme managers to use the data for programme management, including supervision and monitoring to take adaptive measures as per the situation. Partners must discuss and demonstrate use of data for action on the ground. For example, if any village which was reporting more than three cases in 2018 and nil in 2019 or vice versa, such situations must raise alarm and alert the MO or programme manager. Further, investigations must point towards the cause of reporting/not reporting from such an area/s;

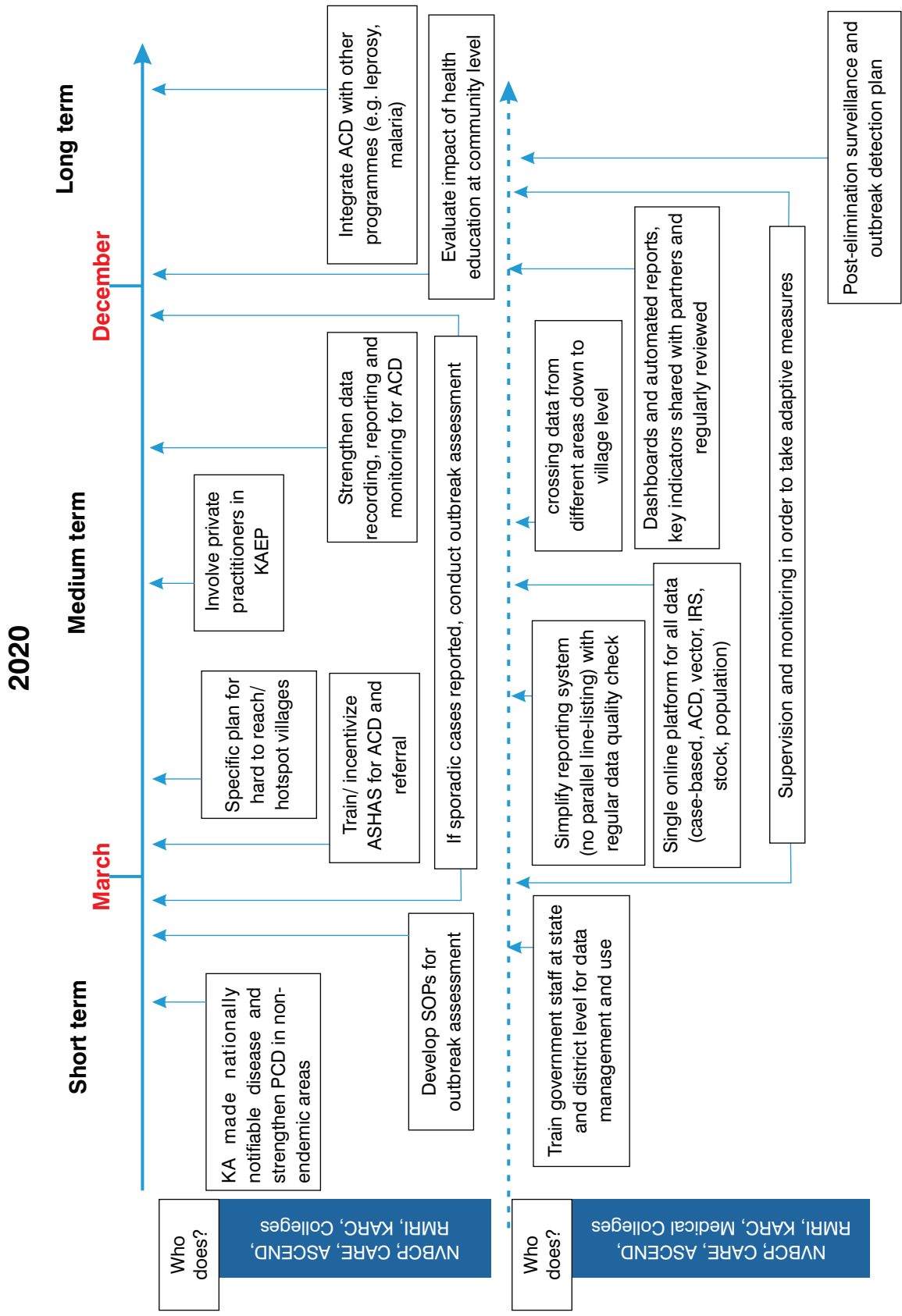
- Review activities during field visits to include analysis of record verifications and actions to rectify it. Monthly KA reports must capture treatment completion, follow-up and treatment outcomes. Special emphasis should be given during the training given to the MO for filling inpatient records (bed head ticket-BHT);
- Count the number of blocks and villages which reported cases in the past ten years (with an established cycle of transmission) in the endemic category. There can be more endemic villages or blocks with time, however, programme impact would always be measured by counting number of blocks or villages which report cases below elimination threshold; and
- Incorporate EWARS in all endemic districts and allow for real-time spatial monitoring of new cases.

#### **For the long -term**

- Adapt and modify treatment cards to include variables on travel history, height of the patient, and adverse drug reaction;
- Improve KAMIS with data analysis crossing data from different areas down to village level, and with dashboards and automated reports, showing key indicators. Access to KAMIS is restricted but it would be of great benefit if shared with partners;
- Transfer urgently cloud of KAMIS to NIC portal and integrate it with the Government data portal;
- Have an online platform which can be dynamic with the scope to integrate the entire database of the programme. The integrated health information platform (IHIP) provides scope to all requirements related to data base management. The dashboard must be used for real-time monitoring of the situation on the ground. Also, automated monthly and annual reports must be modulated as per programme needs at the district, state and national level;
- Develop post-elimination surveillance and outbreak response plans keeping the sustainability lens in mind; and
- Encourage further academic studies in medical colleges seeking inspiration from the enormous information in the KAMIS data base.



Fig. 10 Proposed selected major actions to implement in the last mile related to surveillance



## vi. Diagnosis, case management, comorbidities, treatment and adverse drug reactions

### a) Time elapsed between onset of sign and symptoms and treatment

- IA noticed with concern that the delay between the onset of symptoms to treatment is anywhere between 1-3 months in most cases. The median delay from onset of fever till diagnosis and then diagnosis to treatment observed in the field was unacceptably long. As reported by WHO through a cohort follow-up of 635 cases in December 2018, the interval was of 59 days (Fig. 11).<sup>16</sup> However, cases were observed in the field where substantial delay of four to five months was observed. This is the window of time when the diseased person is in the hands of the informal health sector. It is also the first point of contact for medical care for a majority of the population residing in endemic areas.<sup>17</sup> Median delay from onset of symptoms to treatment among PKDL cases is 3 months<sup>18</sup>. However, many cases with delay of 1-2 years were observed in the field.

#### Several points were noted, namely

- ♦ With introduction of KAMIS, information up to village level was available at the decision makers' level. Analysis by CARE showed that around 60-70% new cases were coming from the same cluster of villages. However, KA related awareness messages (free treatment availability, name of treatment nearest health facility, wage loss compensation scheme etc) were not found in any of the visited villages;
  - ♦ A monitoring finding from WHO revealed that the first point of contact for the community during the first episode of fever illness was the local health practitioner (non-qualified
  - ♦ There was a lack of mechanism/s for systematically collecting information about the suspect and/or availability of a fever register. This was either at the health facility level/with the KA technical supervisor/with the ASHA (village level)/ CARE field coordinators etc. Several instances were found during interview of patients where a significant delay was noted. These patients had visited the health facility for their fever illness and were either sent back or tested negative and never followed up again;
  - ♦ several interviewed patients informed that they first reported about their illness to ASHA but did not receive appropriate information;
  - ♦ It was noted with concern that in some highly endemic blocks, testing and treating facilities do not co-exist, therefore a suspect has to first travel to one health facility (PHC) for diagnosis and then to another (block PHC) within the same endemic block for treatment; and
  - ♦ The delay between diagnosis at the block level and lack of provisions for referral of patients to treatment centres (either another block providing treatment or district hospital) to make sure patients are treated in shortest possible time was another reason for delay.
- In Muzaffarpur, almost 50% new cases were detected through the active case search organized by a non-governmental organization (NGO) through its mobile units. They extended their area of operation to adjacent highly endemic districts and blocks (high risk approach) resulting in almost 58% detection of all new cases in their area of catchment. As soon as a new case appeared in KAMIS, the mobile teams visited locality of the patient and examined all family contacts and

<sup>16</sup>Report on cohort follow up of kala-azar cases. WHO. Dec 2018.

<sup>17</sup>Independent monitoring of indoor residual spraying. Report. WHO. Aug 2018.

<sup>18</sup>Cohort follow up of PKDL cases. Jan 2017. Report of WHO Country office India.

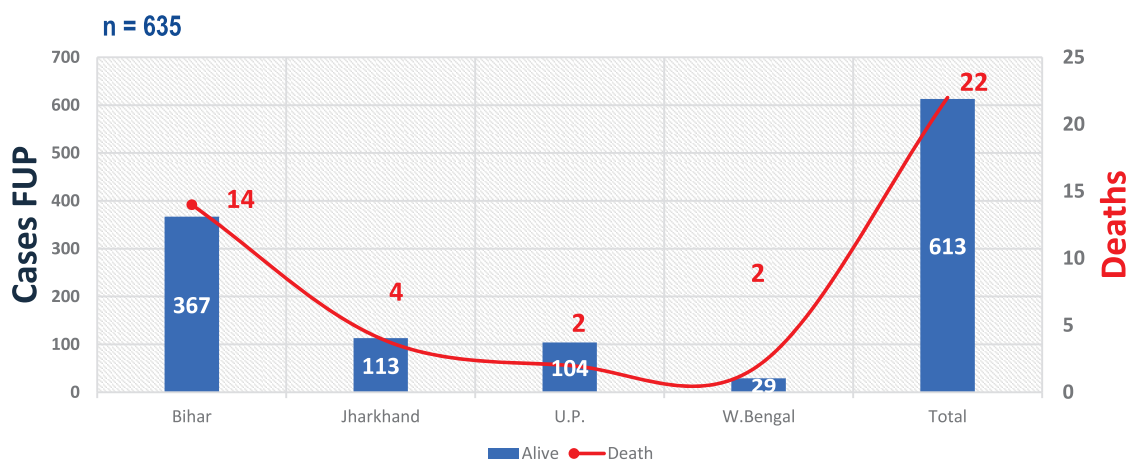


neighbourhood/cluster of houses. They performed rK39 tests at the field level before transporting all positive cases for treatment. Those (fever cases) suspects which did not fit in the standard definition (fever of less than two weeks duration, no palpable spleen and/or loss of weight) were followed again after a two-week interval. This mechanism led to a higher yield;

- A similar mechanism was successfully adopted by the outbreak investigation team (well-trained health personnel) in Kosra village, Sheikhpura district, Bihar (where a big outbreak was detected in 2017) for performing rK39 at the community level along with examination<sup>19</sup>;
- This approach was replicated in Jharkhand and found to suffer from limitations due to non-follow up of standard definition and using of rK39 indiscriminately (in all fever cases irrespective of palpable spleen) at the community level. About 17% of rK39 positives were found without additional clinical confirmatory signs. Such patients were put under observation, and it was noted that about 28% positives developed clinical confirmatory features of KA in few weeks' time and were treated later; and
- The mission observed that examination details including splenomegaly were lacking in patient cards as well as BHT. Therefore, there could be high likelihood at the health facility of relying diagnosis only on positive rK39 RDT and initiating treatment without actually examining patients properly.

Delays have two perspectives with one being from the patient or community side (demand aspect) and the other from the service provider side. A delay of 2-3 days is reported in confirmed cases for their treatment, after being diagnosed at the health facility.

**Figure 11: Delays from onset of symptoms to treatment (in days)**



Source: Cohort follow-up of KA cases. Report of WHO Country office, India. Jan 2019

Another implication of poor health seeking behaviour and lack of confidence towards the public health system is the significant out-of-pocket expenditure (~10 000 INR- 139 USD). In some cases expenditure for treatment quoted by the patient was around 50 000 INR (~693 USD). In addition, most patients were found to have been travelling over 50-60 kilometres to seek care. Every patient who was interviewed was found to have incurred some expenditure relating to fever management spread over a week.

<sup>19</sup>Kumar A, Saurabh S, Jamil S, Kumar V Intensely clustered outbreak of visceral leishmaniasis (kala-azar) in a setting of seasonal migration in a village of Bihar, India, BMC Infect Dis. 2020; 20: 10 <https://www.ncbi.nlm.nih.gov/pubmed/31906924>

This not only drew patients towards “catastrophic expenditure” but also posed great risk for mortality due to complications. It caused more risk of transmission in the community where they lived. Therefore, this delay was likely to seriously impede elimination efforts. It was demonstrated experimentally in Bangladesh, with up to 67% KA patients being unable to infect sandflies. Despite efforts made by the programme, no significant reduction was seen in reducing this period since 2017.

It is well known that KA can be fatal if left untreated for around two years. The most common cause of death relates to complications like severe anaemia, secondary infection, pneumonia and multi-organ failure due to delay in diagnosis and treatment. Recommendations to curtail delay:

- Clarity needed on how to involve private practitioners at the central NVBDCP level, with clear terms of reference (ToR) and incentives that are in line with those of ASHAs. In the last mile, to capture all KA and PKDL patients rapidly implied two actions, namely to involve private practitioners in the elimination strategy, and to carry out ACD in affected villages with and without participation of ASHA;
- Undertake an in-depth assessment and identify areas which are more than one hour away from the health centre to seek treatment. Patients coming from these areas should be provided with free ambulance services;
- Organize a social and community mobilization drive including school teachers, community key members, priests, faith healers, village leaders, PRIs and the formal and informal health sector for all high endemic foci. This will help all community members to be sensitized and clear about the disease, prevention and availability of free diagnosis and treatment. Methods of interpersonal communication must be used for this drive;
- Form mobile teams and train health personnel on standard definitions and procedures (patient examination) followed by diagnosis and confirmation in proportion of cases done reliably at community level. This will reduce delay in highly clustered and intense transmission areas. It comes with a caveat that current diagnostic test is serological and does not differentiate between current and past infections. Also it can be positive in many asymptomatic cases in intense transmission areas. Therefore, it should be assured that the standard clinical case definition before testing is strictly maintained. A mobile team approach can be implemented as part of the high-risk approach;
- Strengthen intersectoral coordination with ICDS, RBSK, Adolescent Reproductive and Sexual Health (ARSH) clinics and use all possible platforms for timely detection of suspects. Do an integrated case search using all options, like house-to-house activity and involving other national health programmes.

## **b) Diagnosis and treatment**

Suspects identified by any means, through active case search or passive case detection are diagnosed and confirmed in the nearest health facility and treatment is provided to all patients. Key observations:

- Lack of clarity about the use of antibody based rK39 was found in almost all centres. This was primarily due to lack of adherence to the standard case definition of clinical suspects (fever and splenomegaly for >2 weeks and no previous history of KA). The current practice was that any person who reports > 2 weeks fever is assigned a rK39 test. Only once the rK39 test is done and found positive, the case is examined by the medical doctor for splenomegaly or hepatomegaly.



However, using rK39 without adhering strictly to the case definition is likely to result in false positives. It is thus, important to consider that the rK39 is a serological test and is only sensitive and specific in patients who meet the clinical case definition;

- Observations from the lab register verification in one state suggested 17% of all rK39 positive tests were not actual cases and were false positives. This was due to rampant use of test kits and not following the standard definition. Further, information of 17% of all rK39 positive people who were found in the lab register but not treated. No further information of such cases could be tracked at the health facility;
- Owing to the high wage loss paid for treated cases of KA (INR 7100 in Bihar and Jharkhand-\$98) and PKDL (INR 4000 or \$55) cases, individual pressure for diagnosis and treatment was reported from few health facilities;
- In few visited health facilities which were designated as diagnostic centres, it was found that rK39 tests were not being done at the same centre, causing inconvenience to patients increasing the risk of losing life;
- In RMRI, all patients were subjected to parasitological diagnosis. Splenic/bone marrow aspiration was performed in RMRI-Patna, KMRC-Muzaffarpur and SKMCH. However, blood transfusion and surgical services for managing complications of splenic aspiration were not available in RMRI and KMRC;
- Previous small-scale external and independent missions (National Advisory Committee, WHO missions) had observed critical gaps in case management for primary KA cases, complicated cases, treatment for special situations e.g. HIV-KA, pregnancy, severe anaemia and PKDL cases. For instance, there was no treatment algorithm available on when not to discharge patients after a single dose infusion of AmBisome. In most of the visited health facilities, patients' BHT were found to have no entries. Some BHTs had instructions to infuse AmBisome without dose calculation/instructions for test dose/ discharge summary;
- Counselling patients as part of case management with information about duration of fever after treatment, regression of spleen, possibility of occurrence of PKDL, relapse, etc. were found missing and not in practice by any treating physician;
- During the visit, select field staff mentioned rumours relating to treating new KA cases as PKDL to maintain elimination level. All such rumours needed to be verified through strong monitoring mechanisms; and
- National KA roadmap and operational manual present lists that outline first to fourth-line treatment regimens. However, the mission observed there was no other treatment regimen available in the programme.

### **Suggested recommendations for the short -term, mid -term and long -term.**

#### **For the short -term**

- Provide urgent direction and SoPs to each health facility for following standard case definition for clinical suspects and ensuring adherence for diagnosis and confirmation of cases before initiating treatment;
- Ensure detailed medical history taking with past history and clinical examination of splenomegaly by all MOs before prescribing lab test with rK39;



- Curtail referral of 100% cases to RMRI for diagnosis by referring these cases to the nearest medical colleges or any other government health facility that provides bone marrow examination facility. RMRI is a referral centre of excellence that has to be used for cases that cannot be managed at lower levels;
- Treating physician to make sure before discharge that patients are not suffering from other comorbid conditions and their general condition allows discharge. Make the discharge summary on the patient file/card mandatory;
- Compensate all categories of patients for wage loss and travel costs for follow-up visits to the clinic. Link all category of patients with the national health insurance scheme (Ayushman Bharat) which has about 150 treatment centres across all endemic states. All treating physicians to receive modular training with demonstration of patients. This can be achieved at RMRI, KMRC, medical colleges and other similar tertiary care/referral facilities; and
- NVBDCP to constitute a group of clinical experts and prepare an algorithm or decision tree when NOT to discharge patients. cal experts and prepare an algorithm or decision tree when NOT to discharge patients.

#### **For the mid -term**

- Include SoPs for all standard definitions in the training curriculum for diagnosis and treatment. Hold training courses regularly for all KA related personnel. Make available simplified guidelines for case management for medical staff. Training to include more content on case recognition and management of PKDL, treatment during pregnancy, definition and treatment of relapse, ADR reporting and cases where referral is needed;
- Involve medical colleges for diagnosis and treatment of KA, PKDL, relapse and comorbid conditions; and
- Conduct entomological, serological and epidemiological surveillance in select two to three villages in south and east Sikkim to document presence/absence of local transmission.

#### **For the long -term**

- Build the capacity of district hospitals for bone marrow examination and integrate services of the internal medicine department of medical colleges for bone marrow, splenic aspiration and other specialized services.

#### **c) Relapse**

- No anti leishmanial treatment provides 100% cure, therefore a proportion of patients are expected to suffer from relapses of symptoms and signs. However, the mission observed little capacity in the health system to effectively detect relapse cases (through parasitological diagnosis). This facility was restricted at RMRI and KAMRC in Bihar and was not available everywhere (available in Jharkhand but not in Uttar Pradesh). Also, the management and reporting of such cases was fragmented;
- The mission observed high relapse rates in several health facilities. However, such relapse cases were not mentioned in the reports. It was also not clear whether they were true relapses or old treated patients tested again with RDTs (serological test);





- Misunderstandings regarding definition and case management of relapse cases were observed on multiple occasions. If a patient relapsed within six months of the treatment, it was recorded as a relapse, and if it was more than six months, it was considered as a reinfection, and recorded as a fresh (new) KA case;
- Several working documents confused relapse and reinfection, but the latter was very unlikely to happen, because protective immunity was lifelong after first episode. It required molecular fingerprinting of strains isolated in the first and second clinical episodes to ensure there were different parasites and a verified new infection (highly unlikely);
- The national roadmap mentioned AmBisome as a first-line treatment option for primary KA and combination therapy as a second option, when AmBisome could not be given. If this was the situation, the combination miltefosine/paromomycin was the best option with a 98% cure rate. However, none of the evidence-based combination treatments for KA happen to be currently in use, partly because PM has not been procured by the national programme even though it is manufactured in India; and
- No incentives were given to relapse cases who presented with re-occurring KA beyond six months after previous KA treatment, only to those who presented within these six months.

### **Recommendations**

- Definition of relapse has to be clarified in all documents as re-appearance of KA signs and symptoms at any time after an apparent initial cure, and not just within six months of finishing treatment ('late relapses');
- Mission recommended identifying of several cohorts and undertaking treatment cohort follow-up to ascertain relapses (through proper confirmatory tests);
- Multiple dose AmBisome was suggested for relapses or, alternatively, combination therapy with MF/PM. Guidelines to be revisited to clarify both options. Of all the combinations studied, the combination MF/PM for 10 days was found to be the most appropriate because it was not cold-chain dependent and its efficacy too was 98%. The recommendation was that, referral treatment centres and DHs should have MF/PM available as a second option, while it should be ensured that both PM and MF are never given as monotherapy to prevent development of resistant strains;
- According to guidelines, DH's should be capable of undertaking Giemsa staining and microscopy to confirm KA relapses and PKDL cases. Further, a regional/state level QC plan for microscopy should be implemented with support of NVBCP; and
- Availability of monetary compensation for wage loss and travel costs for all relapse cases should be ensured.

### **d) Kala-azar and pregnancy**

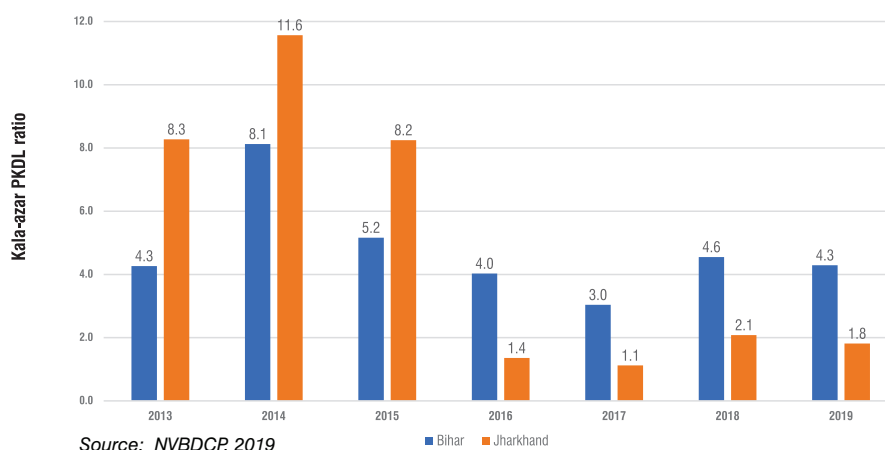
- It was observed that pregnancy testing was not routinely performed in women of child bearing age before initiating treatment; and
- In some blocks, KA treatment was postponed until after pregnancy.

Only one recommendation was suggested for the short-term, namely to strictly follow national guidelines using AmBisome in case of KA during pregnancy.

### e) Post-kala-azar dermal leishmaniasis (PKDL)

- PKDL is not directly included as an indicator for elimination target, and as a result, it is often neglected, not included or missed by the health worker during active case search;
- Diagnosis and confirmation of PKDL was cited as a challenge by the block and DMOs of Bihar. As a result, the general tendency of referring PKDL cases to RMRI was found in the state, irrespective of any indications;
- Three months of MF was the recommended treatment for PKDL but low compliance was recorded in a significant proportion of patients due to frequent gastrointestinal side effects. There was no mechanism in place to verify treatment compliance. A report of cohort follow-up of 576 PKDL cases in all states suggested that 40% cases reported vomiting and 13% reported gastric upset after the treatment;<sup>20</sup>
- Pregnancy screening (test) was not a routine practice (no entries found in treatment card of female PKDL cases, described under section reporting and recording) and could not be verified if contraception during and for five months after treatment was taken seeing that MF was teratogenic;
- Patient interview of a female PKDL case revealed she was treated with sodium stibogluconate in the private sector for her KA illness in 2015 in district Siwan, Bihar.
- PKDL detection was entirely passive in Bihar, although the trend of reporting entirely changed after 2015 (Figure 12) for both Bihar and Jharkhand. An analysis of KA and PKDL cases ratio from the two states suggested that reporting of PKDL was minimal in Jharkhand up to 2015 and then increased exponentially by six times (8.2/1.4) as compared to reporting of KA cases; and

**Fig. 12 Progression of the ratio of reporting kala-azar to PKDL in Bihar and Jharkhand 2013–2019**



### Recommendations

- Follow global guidance of treating probable PKDL cases in the field. The guidance included any case as 'probable' with typical skin lesions, previous history of KA, no sensory loss and positive rK39 test. They recommended a pictorial guide book that could be made available at block level to improve recognition of PKDL of lesions. The Leprosy Control Programme used an eight-fold pictorial flash card that was distributed to field workers mandating PKDL cases to be included for differential diagnosis;

<sup>20</sup> Cohort follow-up of PKDL cases. Jan 2017. Report of WHO Country office India.



- Accord special emphasis during the training programme for inclusion of case search, diagnosis and treatment of PKDL cases;
- Ensure contraception as an absolute necessity during and for five months post therapy, since MF is potentially teratogenic. When pregnancy tests or contraception cannot be guaranteed, the recommended three months of MF for female PKDL patients should be avoided and replaced by multiple dose AmBisome therapy;
- Make extra effort in detecting PKDL cases, the way it has been done in Jharkhand since 2015;
- Conduct two additional studies part of operational research to support PKDL diagnosis. These could be on tele-dermatology at block level, and active case finding via a camp strategy with regular deployment of dermatologists or trained health practitioners at village level. They can validate use of rK39 on skin slit samples at block level. In case both skin and blood are positive for rK39, PKDL could be a more likely diagnosis; and
- Make a provision on the patient card to record the type of lesions (macular, nodular or polymorphic) and extent, including their improvement at follow-up representing healing in subsequent cards.

#### f) Kala-azar-HIV coinfection

- In 2014, NVBDCP constituted an expert committee and developed a treatment and management protocol. However, it never reached lower levels and hence was not implemented. Therefore, patients who required special care and support were managed at limited centres. Special attention needs to be paid to build capacity of tertiary care health facilities to provide all range of services (KA treatment and comorbidity management). The NVBDCP in consultation with the National AIDS Control Organization (NACO) should implement HIV/AIDS (prevention and control) Act 2017<sup>21</sup> strictly. This protects human rights of affected people and penalizes discrimination against them in several fields, including healthcare services and public facilities.
- Although guidance for testing of all KA cases for HIV and all HIV cases for KA in all endemic states is being given by the national programme, testing of all KA cases is almost 90% but clinical screening of HIV positive cases for KA is negligible;
- KA/HIV cases are not treated at the district level and all patients are referred to RMRI Patna from Bihar and Jharkhand. Report from Uttar Pradesh and West Bengal has been constantly nil since the beginning. Referring patients to RMRI Patna posed a huge burden on the patient and family in seeking treatment due to long travel and stay out of their home town. This practice led to a loss of follow-up of few cases from Jharkhand in the past. KA/HIV cases were not included as a new case and therefore they were not taken into account for payment of wage loss and consideration for calculation of annual incidence; and
- RMRI informed that out of all relapse cases received in this centre, 50% were HIV/KA and remaining non-HIV cases. Out of KA/HIV relapse cases, 20% were relapsing within six months of the treatment and rest after six months. Relapse rate in KA cases ranged from 4 to 16 % during the last two years.

<sup>21</sup>The human immunodeficiency virus and acquired immunodeficiency syndrome (prevention and control) act 2017, <https://lms.naco.gov.in/frontend/content/4%20HIV%20AIDS%20Act.pdf>

## Recommendations

- NVBDCP in consultation with NACO to strictly implement HIV/AIDS (prevention and control) act 2017;<sup>22</sup>
- Build the capacity of medical colleges and District Hospitals for treatment of VL/HIV coinfections, particularly in those facilities acting as ART centres;
- Improve acceptability among treating physicians for treatment of VL/HIV treatment by bringing it in their training curriculum and sensitization;
- More screening needed, given that HIV testing in KA is consistently done, but screening for KA at ART centres is not yet considered. Greater interaction with the HIV programme will circumvent this limitation;
- Integrate services of internal medicine departments of medical colleges to provide treatment and follow-up of VL/HIV cases in addition to special conditions/complex cases, including relapse, pregnant women, etc;
- Provide compensation for wage loss and travel to VL/HIV patients like in the case of primary and relapse KA cases;
- Make provision outside endemic areas or states for referral centres/contact persons for diagnosis and treatment of cases of KA, PKDL and VL/HIV;
- Verify estimate of relapse in VL/HIV by cohort community-based data; and
- Take into consideration VL/HIV cases for calculation of annual incidence at block level.

### g) Follow-up of patients

- Clinical follow-up is done for 100% cases for KA and PKDL cases in clinical trials. However, clinical follow-up data is missing from the field as this is mostly dependent on the partners or unskilled field staff;
- None of the followed-up cases in the community are being examined by the MO; and
- CARE staff (BC) is capturing detailed demographic and social information from the patient which is separate from programme surveillance.

### h) Deaths

- The mission observed that case fatality rate remained at 2-3%. Patient cards and interviews with the deceased families revealed considerable delay between onset of symptoms to treatment. The deceased were suffering from additional comorbid conditions warranting further management at the treating facilities; and
- Deaths were observed among KA cases during follow-up but it was not found to be recorded in the health system register at any level. However, the same information was available in the partners' own self maintained register.

<sup>22</sup>The human immunodeficiency virus and acquired immunodeficiency syndrome (prevention and control) act 2017, <https://lms.naco.gov.in/frontend/content/4%20HIV%20AIDS%20Act.pdf>



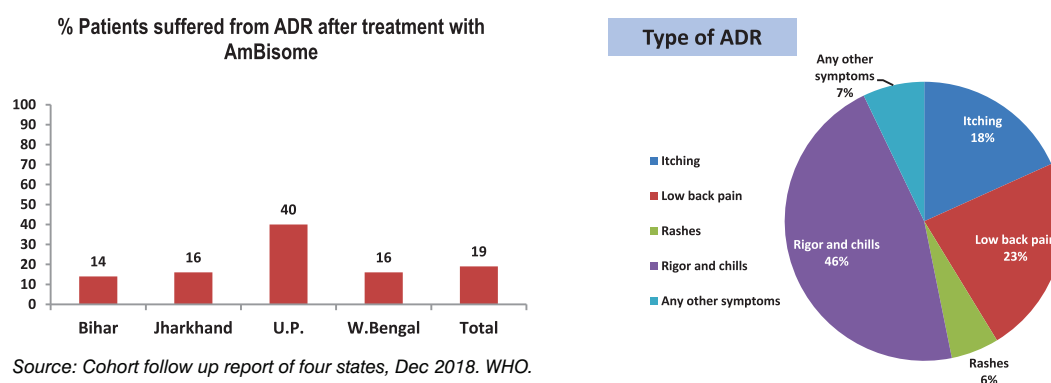
## Recommendations

- Make sure all patients are clinically assessed before discharging and sending them home, according to an algorithm;
- Clarify definition of deaths among KA as per government guidelines;
- Work with MoH to develop a mechanism where death due to fever is reported; including occurrence of such events at home (before seeking healthcare services)
- Ensure IDSP department investigates deaths due to fever (including situations like deaths at home, before diagnosis and treatment) in KA endemic areas;
- Have all patients clinically reassessed during follow-up by MO's, ASHA's and KTS to ensure these patients travel to the treatment centres and their travel reimbursement is provided. In case of critical shortage of medical staff for patient follow-up, a proper and standard checklist must be prepared for patient follow-up by auxiliary health staff. In this case, reports of any relevant condition to be referred to medical staff;
- KA patients should be followed-up to three years to capture majority (>95%) of PKDL patients. Also, ASHA's should proactively look for PKDL improvement/healing during this time;
- Annual follow-up of PKDL patients for at least five years is recommended to document occurrence of PKDL relapses.
- Assess any new drug or regimen for KA for occurrence of PKDL (minimum three years follow-up).

## I) Pharmacovigilance

- In general, adverse drug reactions (ADR) are events that are poorly reported or not reported at all. It is vital to monitor drug safety for KA and PKDL cases undergoing treatment;
- Providing test dose before start of AmBisome treatment and close observation of patients are missing in general and routine care, during treatment. Hence likelihood of missing ADR during initial phase of treatment is always high (Fig. 13);
- Treating physician and staff nurse observe ADR but they do not report, due to poor sensitization and understanding the importance of ADR reporting; and
- Number of adverse drug reactions reported from all four states was 384 centres between Feb 2017 to Dec 2019, from 58 adverse drug reaction monitoring centres. (Table 6). However, field evidence suggested that general occurrence of ADR only in KA cases was around 18% and even more in PKDL cases. This indicated heavy underreporting of the situation from the field.

**Figure 13: % ADR in AmBisome treated patients n= 114**



**Table 6: Status of ADR reporting Feb 2017–Dec 2019**

Bihar	250
Jharkhand	59
Uttar Pradesh	68
West Bengal	7
Total	384

Source: Report from PvPI. 2019.

- Around 36 cases of eye complications were observed in the field among PKDL cases who had either completed their treatment or were on treatment with MF. These cases originated from various areas and the symptoms of manifestations that were reported included, redness of eye, increased lacrimation, photophobia, diminished vision, etc. A few cases of acute uveitis, keratitis, sclerites, corneal infiltration and corneal opacity were also reported. The symptoms were found to be reversible after stopping treatment in some patients while in others, the damage was permanent.

**Suggested recommendations for the short -term, medium -term and long -term.**

**For the short -term**

- Ensure investigation of cases with reported eye complications by a team of experts from PvPI to give further guidance on currently used capsule MF in the country
- Release a directive to the field for maintaining vigilance in PKDL cases which are either on treatment or being treated. Maintain close watch and vigilance for any sign of eye complication like redness, itching, increased lacrimation, diminished vision etc. Undertake counselling for patients and health care workers at all levels about ocular damage and impress upon them, the need for proper reporting of this ADR
- Make use of the toll-free helpline number 1800 180 3024 with SMS feedback facility, initiated by PvPI for all stakeholders. The helpline is manned during working hours and missed calls are followed up the next day. This number can be used by patients, their relatives, ASHA or any stakeholder and informed about the adverse drug event.

**For the mid -term**

- Reinforce implementation, training and monitoring of ADR reporting and adhere to the national pharmacovigilance system/guidelines. Make sure that at the national level, reported ADR's are systematically analysed in-depth and reports prepared; and
- Implement PvPI and strengthen monitoring of ADR for other drugs like Primaquine for malaria, since Jharkhand and Bihar are malaria co-endemic states (high and low endemic respectively) Disseminate causality assessment report and profile of ADR up to implementation level to understand sensitivity and implication of PvPI programme for KA elimination.

**For the long -term**

- Continue the association of PvPI with NVBDCP to maintain a mutually coordinated activity at the implementation level.



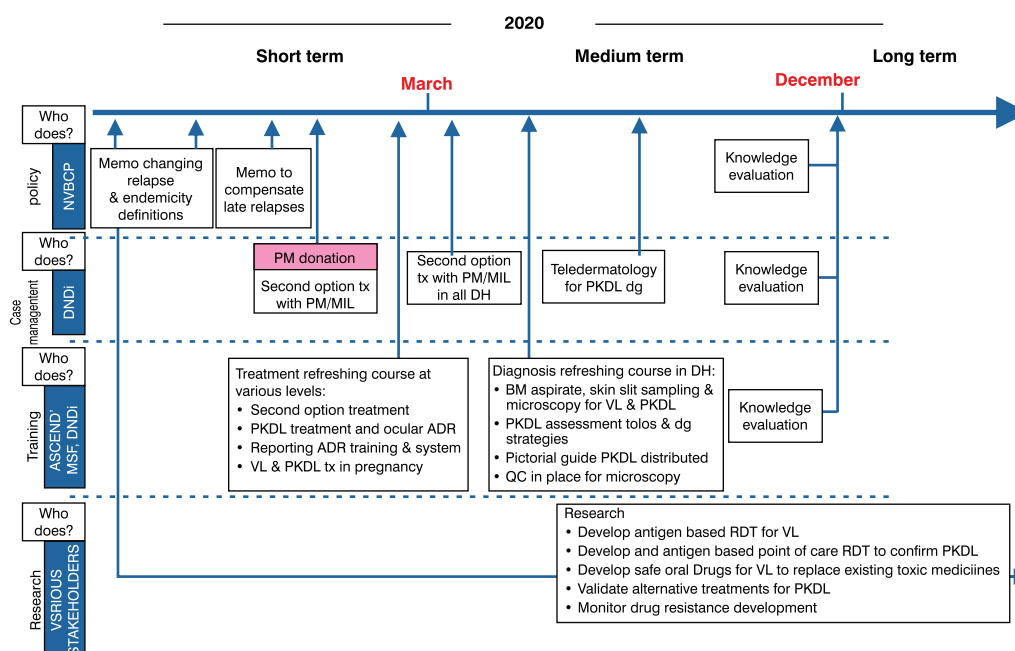
## j) Research areas

This independent assessment understands that research is not the direct responsibility of NVBDCP, although it is important to address knowledge gaps that can jeopardize the programme's future. Key observations:

- AllIMS Patna and other Centres of Excellence must be identified for drug sensitivity surveillance for drugs used in the KA programme with special attention to MF;
- Long-term research goals to improve case management of KA and PKDL require:
  - ♦ To develop an antigen based point-of-care RDT for the diagnosis and test-of-cure of KA (primary and relapse) and safe efficacious oral treatments for KA; and
  - ♦ To develop an antigen based point-of-care RDT for confirmatory diagnosis and test-of-cure of PKDL and to validate alternative treatments for PKDL;
- PKDL is a potential reservoir of infection for KA and hence quantitative estimation of parasitic load in treated PKDL cases is important to ascertain the period of follow-up and understand the period of infectivity. The development of quantitative tools for establishing PKDL cure at follow-up should be considered;
- Real estimation of relapse and cases need to be undertaken by a cohort follow-up study of treated KA cases;
- A new area of research concerns asymptomatic carriers and this is relevant for the last mile of KAEP. In two (unpublished) studies in Spain and India, it was attempted to infect sandflies in laboratory conditions by asymptomatic carriers. None of them was able to infect them. There is however no general agreement on the definition of asymptomatic, as often the asymptomatic period is confused with the pre-symptomatic period, just before first symptoms appear and the immunological response (Ab) is already developed.

In conclusion, since there is no clarity on the role that asymptomatic can play in transmission, nor tools for their detection, the JMM did not consider this topic as part of the assessment.

**Fig. 14 Case management last mile: flowchart of proposed selected-priorities according to implementation**





## B. Vector control

### i. General overview

Integrated Vector Management (IVM) is one of five pillars for the KA elimination. An IVM approach has been advocated by NVBDCP for the optimal use of resources for vector control. The approach is to reduce vector abundance, longevity of adult vectors, eliminate breeding sites, decrease contact of vectors with humans, and interrupt transmission. The spraying area in all houses was up to six feet height on interior walls (except in Jharkhand where it covered entire walls). It had complete coverage of cattle sheds in villages which had a KA case reported in the last three years, supplemented with focused IRS in villages reporting KA cases. IRS was implemented in two rounds every year with the first round in February – April and the second in August – September. This was done to control sandflies populations at their peaks. The second round started in June due to social, cultural and environmental factors.

IRS consumed 80% of the total KAEP budget. It was an area where some serious challenges were encountered and these will require substantial changes and investments. At the district level, vector control is directly dependent on the District Vector Borne Disease Officer (DVBDO) or the District Malaria Officer (DMO). However, it has been noticed that few DVBDO/DMO because of their background and having multiple charges, are much more involved and concerned in case management than in public health aspects of KAEP. Although the NVBDCP advocates for IVM, the current vector control strategy relies only on IRS, using synthetic pyrethroid (SP) (alphacypermethrin 5%).

### General recommendations for IRS

- Adopt a more holistic approach to review evidence of the effectiveness of vector control interventions on KA (IRS, LLIN, environmental management); and
- Divide responsibilities between two different authorities, namely MO's for case management and epidemiological surveillance, and PHO's for public health aspects (vector control, entomological monitoring, vector surveillance, training, IEC).

### ii. Organization of indoor residual spraying (Procedures)

- Operational guidelines on vector control and SoP's were found to be in place, and a micro-plan for IRS was available. However, there were unjustifiable delays in spraying or villages not at-risk that were sprayed. More importantly, the semiannual spraying schedule had not been followed;
- In 2018 there was a problem with the quality of insecticide in the first round, and the second round of IRS in 2018 was missed. The second round of 2019 was delayed due to insufficient number of pumps, and in some locations the first round of 2019 was also missed. This may have had an impact on case numbers seen in 2019;
- The second round of spraying was delayed up to November-December in three blocks of Muzaffarpur in 2019 (Bikaram, Paroo, Motipur) and the second round could not be done in 2018. In the visited areas, IRS was either still continuing at the time of visit (Patna) or was completed in November and early December;
- As there was no actual ongoing IRS during the time of the team visits, spraying operations could not be observed. Therefore, an adhoc spraying operation was arranged and during this demonstration, two of three available pumps were non-functional and the remaining one was





leaking with insecticide flowing down along the lens (photo 12). The person spraying did not wear any PPE and was not aware of its necessity (photo 12). His spraying technique was inadequate and reflected lack of training. When opening the insecticide bag to prepare the solution, the powder had an irregular granular consistency, and did not have the typical 'milk-powder' appearance (Photo 9). An intact bag of the same insecticide batch was requisitioned and deposited at WHO-India for further chemical analysis;

- During demonstration it was observed that the spray-men were provided a measuring pot which did not always give the exact amount of insecticide due to human error. In view of this, it was suggested to provide 125 gm water soluble sachets to avoid such type of error. This could lead to over or under dose of spraying due to variation of insecticide concentration. Field visit reports demonstrated that the quantity of insecticide powder used in IRS was ranging from 85 g to 102 g against the requirement of 125 g powder for 7.5L of water. In some places the quantity was above 125 g as well;
- Till such time water soluble sachets of 125 g were available, a standard (calibrated) measuring container should be made available across all four states with a directive to measure the powder with each batch of insecticide (as density may vary from batch-to-batch);

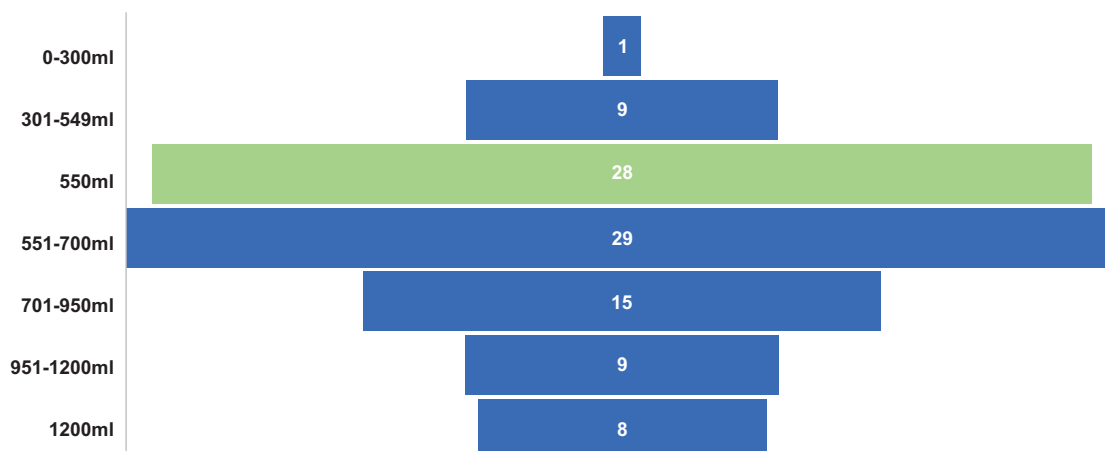
**Photo 1. Insecticide used for mixing (153-51 = 102 g); 52 g – weight of glass**

- This observation was illustrative of the general situation with spraying equipment and insecticide which was often found stored inappropriately (in wet conditions and unsuitable, dirty and defective storage rooms). Also many pumps were found which were dysfunctional. Spare parts such as tool kits, CFV's and nozzles were missing, and in districts where there was usually no local capacity to repair pumps. Usually there was no PPE provided to sprayers, and there was lack of inventory at the PHC;
- NVBDCP should adapt WHO guidelines on PPE and introduce in the system;
- Independent assessment of IRS activity was done in different areas/phases by CARE, WHO and RMRI. Based on monitoring data by WHO, an analysis of discharge rate from 438 hand compression pumps in Jharkhand in June 2018 illustrated that only 28% i.e. 121 hand compression pumps had an adequate discharge rate of 550 ml/min and rest of the pumps either had high discharge rate (62%) or low discharge rate (10%). (Fig: 15 and Photos 3, 4 and 5).
- Other important areas evaluated during independent monitoring of IRS suggested a significant number of areas were missed or not covered by the IRS team due to various reasons (Fig.16). The reason analysis showed majority of such areas were missed was mainly due to negligence of the IRS team (only house marking was done without any actual spray in the house).



Source: WHO field visit in Uttar Pradesh. April 2019

**Figure 15. Spary rate of hand compression pumps, Jharkhand, June 2018 (N= 438)**



Source: IRS monitoring report by WHO. June 2018

**Photos 2, 3 and 4. Insecticide discharge according to the nozzle status**

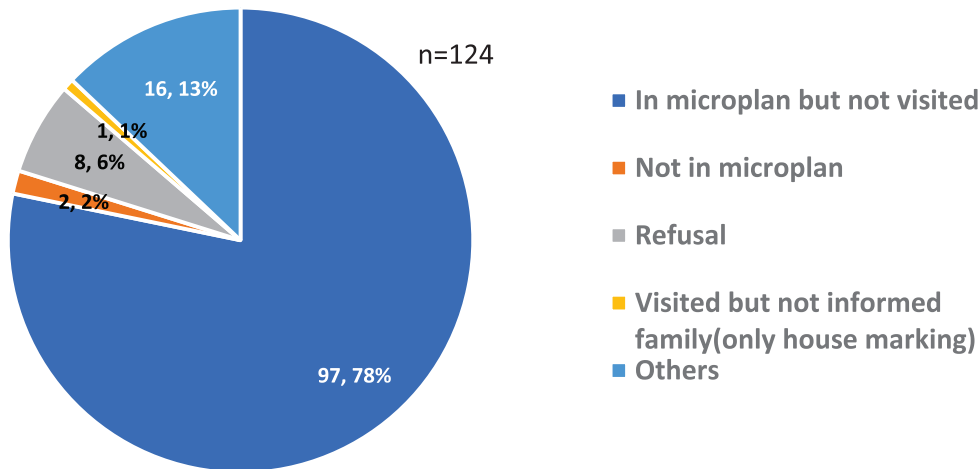


Source: Joint field visit NVBDCP and WHO, Bihar, May 2019

- After visiting endemic communities, it was found that house-arking was not done as guided by the programme and there were intra-and-inter-district variations. Once a house was sprayed, it was marked with a chalk (or geru) and disorganized letterings, making it difficult to trace when and how many times a house was sprayed. Moreover, in Bihar there was no available data on room coverage per house and no records on unsprayed houses, something that needed to be put in place;
- It was also observed that large stockpiles of expired/obsolete insecticides were stored in the proximity of fresh bags of insecticide; and
- The quality of spraying was below standard in a district in Jharkhand. Quality control tests after spraying showed that overall 30% of spraying was below range ( $< 0.02 \text{ g/m}^2$ ) of insecticide deposition in the wall, 10% in target range ( $> 0.02 \text{ g/m}^2$  and  $< 0.03 \text{ g/m}^2$ ) and 50% above target range ( $> 0.03 \text{ g/m}^2$ ) (source: CARE/LSTM 2019).

<sup>23</sup>Guidelines for personal protection when handling and applying pesticides, <https://apps.who.int/iris/bitstream/handle/10665/330917/9789240000223-eng.pdf>

**Fig.16. Reasons for avoiding proper spraying coverage**



Source: WHO IRS monitoring, Bihar, Aug 2019

**Photo**



Source: Team visit to endemic village in Siwan. Dr Jorge Alvar. 2019.

Photo 5. Insecticides storage on the floor, next to a semi-open window

Photo 6. Deteriorated environment where sandflies breed

Photo 7. Spray-men next to a straw house where 5 KA cases occurred in the last two years

Photo 8. House IRS marking with a non-permanent colour and disorganized letterings

Although there is supervision by a team leader, there is little systematic quality monitoring of IRS by government health workers. CARE is enabling quality monitoring of IRS through consequent monitoring by block coordinators (one in each block), as well as independent assessments. Despite other organizations (WHO, RMRI) also monitoring IRS activities, coordination between them is lacking. All these organizations are present in limited areas not covering all endemic districts.

- Training was mostly provided by the PHC/CHC before every round of IRS, however the quality of the training could not be assessed as no spray men were interviewed, and in certain settings it

could not be verified that trainings were organized before each round, as no training modules for assessment and no records of IRS training for the spray men were present. Induction training of ASHA's and ANM's in IRS was not provided and participation of ASHA's and health personnel in review meetings was also considered as trainings;

- In Bihar, newly recruited VBD consultants and KTS were found less aware about IRS operations and MandE activities. Finally, the knowledge of supervisory staff of partners applying IRS was also inadequate;
- A challenge encountered during the IRS rounds related to locked houses due to migration and scarcity of water in villages. During this time it is commonplace for villagers in Bihar and Jharkhand to migrate to West Bengal and neighbouring districts for temporary harvesting activities. Usually, this occurs in June-July and Oct-Nov and in this period, houses may be abandoned, impacting overall coverage of IRS. Records of refusal and locked houses were not always available;
- Although spray coverage was reported and evidenced to be high (almost complete), with low refusal rates, more than 50% houses were found partially sprayed. From community interviews, it could be concluded that spraying seemed to be accepted by communities as a useful intervention, but advance notice of IRS was not always given by ASHA and spray volunteers. House preparation therefore often did not take place, resulting in spraying while items were still placed against walls. Spraying was often refused in house areas where food was stored. Lack of prior information also could result in refusal when head of the household was away as women and children would not give authorization for spraying. Independent monitoring of IRS suggested that advance information to families about the IRS schedule was done at least two days in advance in all states, ranging from 25-30%. This was a consistent trend that was observed over the last four to five years.

## Photos



Source: Team visit to endemic village in Siwan. Dr J. Alvar. 2019

Photo 9. Insecticide in form of granules at the moment of opening the bag

Photo 10. Flies landed on the insecticide bag

Photo 11. Preparation of the insecticide solution

Photo 12. Spraying without PPE. Observe insecticide flowing down along the lens

- In many of the endemic villages people live in close proximity to animals, with animal droppings and rubble providing plenty of breeding sites. Rodent burrows (commensal rats) are found in and around many houses. The houses here are usually made of mud, sticks or un-plastered bricks, with many cracks and crevices on inside walls where sandflies can hide. People often sleep on the floor and the effectiveness of IRS in such cases is questionable;
- There is an ethical issue concerning denial of services to the lowest socio-economic strata of workers. It is not unusual to find houses of few members from lower castes not sprayed or visited by the ASHAs. They unfortunately cannot also apply for pucca (made by brick and



mortar) houses since they do not own land. This is a common problem for KAEP and it deserves a corrective-specific 'plan for the poorest'.

- Presently, IRS is the only strategy followed for vector control in the three states, except for Jharkhand (LLIN's are given by the government for malaria control in KA co-endemic villages). In community interviews it was noticed there was poor knowledge about sandfly vectors and the role of environmental management in protection/prevention. LLIN's, when present, were well accepted, but most households did not have enough of them and purchased additional untreated bed nets at local markets. There was a clear desire expressed for more LLIN's. However, in some villages, in summer months, people slept outside their houses, and were exposed to sandfly bites. In addition, men slept unprotected in the fields during the harvest season. Taking into account the intrinsic limitations to prevent transmission, all measures should be combined to reach a sounding vector control programme under the IVM approach, including larvae control measures and creating of community awareness on environmental management.

### **Suggested recommendations for short-term, mid-term and long-term.**

#### **For the short-term**

- NVBDCP should clarify technical criteria for inclusion of at-risk villages for IRS and the spray schedule must be planned/executed as per guidelines. The IRS period must be decided based on the local evidence of vector abundance data available with the programme and partners and spray timings should be fixed just before the sandfly densities build up;
- Make quality control checks for each batch of insecticide at the pre- and/or post-supply stage mandatory. In addition, analysis for the current batch must be done as soon as possible to ensure the quality of the product in use;
- Provide for the replacement/repair of spray pumps; supply PPEs and put in place a team to repair and ensure equipment maintenance, facilitate proper storage space for insecticide/equipment; and establish inventories at PHC's;
- Use ideally a 125 g insecticide sachet as a uniform measure. If not, do calibrations of insecticide measuring containers before each IRS round. In order to maintain uniformity, district headquarters should distribute the calibrated measuring container to all blocks for spraying squads. States like Jharkhand, Uttar Pradesh and West Bengal having limited number of squads, can ensure distribution of containers right from state headquarters;
- Involve all stakeholders for full coverage of monitoring IRS and other vector control activities.
- move regular M&E for IRS operation from sporadic and patchy to global and daily in all areas and not only where CARE, WHO and RMRI are operating. Monitor spray team leaders ('monitoring of monitors') and develop a joint work plan of all stakeholders at the state headquarters to provide maximum coverage of monitoring and supervision in all areas;
- Get partners to provide monitoring feedback to the programme at each level and ensure follow-up of corrective actions initiated for any concern to maintain quality of the operation. Take into account monitoring data for corrective measures on real-time basis. Take administrative actions for teams not visiting areas and ASHAs not involved in community mobilization activities;
- As an urgent measure, undertake cone bioassays by research institutes in India which have vector control expertise. These could be the Vector Control Research Centre (VCRC), National

Institute of Malaria Research (NIMR), RMRI, Centre for Research in Medical Entomology (CRME) or any other organization that can help assess residual efficacy of insecticide; and

- All the entomological data collected and generated by the National Centre for Disease Control (Patna branch), RMRI, CARE/LSTM and LSHTM to be collected at one place at NVBDCP for further meta-analysis and use.

#### **For the mid-term**

- Undertake further area-wise analysis to determine reasons for locked houses, refusal and absenteeism during spray operations based on the evidence. The studies should formulate recommendations for alternative approaches to protect these population groups;
- Plan refresher training at all levels, from supervisory staff (district/PHC/CHC) to ASHA's, involving them in the planning of regular activities. Training on vector control must cover following topics:
  - ♦ Vector surveillance, M&E of interventions and insecticide resistance monitoring, appropriate IRS application and training of peripheral health workers (ASHA's) to increase community acceptance of IRS;
  - ♦ Data analysis and data management;
  - ♦ Spray men on how to maintain the pumps and establish a spray pump service/repair team at each district headquarter;
  - ♦ Create community awareness on good housing practices (environment), acceptance of IRS and proper use and maintenance of LLINs (distributed for malaria control in Jharkhand);
- Sanction travel allowance to IRS staff (spraying squads, supervisors) who attend training and show greater consideration for those travelling long distance during spraying rounds by reimbursing their travel cost; and
- Ensure maintenance, availability of spare parts and provide repair facility of spray pumps. Constitute a pump repair service at district HQ to overcome challenge of spare parts. Further, NVBDCP should deliberate with Indian Bureau of Standards (IBS) to explore local production of spare parts for specific brand of pumps.

#### **For the long-term**

- Complete the external and internal quality assurance of insecticide (external as well as internal) before dispatch and use in the field;
- Depute a dedicated team to prepare a strategic plan focused on the objective of providing housing to the poorest and most marginalized community in high endemic foci. It should be negotiated at the political level to provide good/improved housing to the poorest through the Prime Minister Housing Scheme (Pradhan Mantri Awas Yojana-Gramin).
- Better housing is key to sustaining elimination. New pucca houses are assigned from state level with an additional 500 from district level. These are prioritized for the poorest villages, but not specifically for KA endemic villages. Tribal populations in endemic districts do not always accept them since they are very different and much smaller than the mud houses they are used to living in. To be allocated a pucca house, they must own land, which is not possible for the poorest of poor. The same (straw) house harboured 3, 4 and even 5 patients within a year or two,



impoverishing the family. The provision of housing under PMAY-G should consider the poorest and KAEP must define an adhoc strategy to rescue them from oblivion;

- communities should be sensitized to seal cracks and crevices and plaster internal walls of the houses, and also not sleep on the floor;
- a shift from IRS to IVM is required in the last mile phase. Education in environmental cleanliness must be initiated without delay because reduction of sandfly breeding sites is essential. Providing LLINs to KA and PKDL cases to prevent KA transmission, in addition to IRS and environmental management will contribute in reducing number of cases in the blocks where reduction is no longer happening; and
- Research areas for consideration:
  - ◆ Research on integrated vector management for its impact on KA and all VBDs;
  - ◆ Longitudinal study to assess vector bionomics with change of climatic and environmental condition to guide the policy of IRS operation;
  - ◆ Assess impact of LLIN in incidence of KA by comparing KA cases in villages with and without intervention (retrospectively and prospectively); and
  - ◆ Mapping of districts where several VBDs are co-endemic (malaria, KA, LF, dengue); an IVM project to be developed for such districts.

### iii. Entomological surveillance

Vector surveillance in the programme is conducted entirely by partners, hence the activities are related only to sentinel surveillance sites. In Jharkhand, the programme has provision for entomological surveillance at state level, however, existing data is not used for implementing decisions at CHC or district levels. The IRS period in the state is primarily decided based on the preparation of state or district. Availability of funds is not based on vector information and transmission pattern. In many instances, IRS is continued in the field when the sandfly density is negligible (November and December).

- LSTM has been subcontracted by CARE and implemented in eight sentinel sites for entomological surveillance in Jharkhand (1), West Bengal (1) and Bihar (6). RMRI and NCDC are also conducting surveillance activities in given sites in Bihar. There was not much clarity on how these sites were chosen and how representative they were of the global endemic areas;
- The team was able to see regular reports from LSTM to NVBCP with information on findings in surveillance in these eight sentinel sites, but there was no feedback by NVBCP for initiating any action based on reports received from LSTM. During a visit to AIIMS, the central laboratory of these eight sites in Patna, mission members were debriefed on research that LSTM and AIIMS were conducting to monitor insecticide resistance. This was seen as an activity of paramount importance for early detection of tolerance/resistance in sandfly populations and to define insecticide rotation.
- There was a shortage of entomological personnel in visited districts of all states. An overview of personnel required to fill vacancies, training needs and forward planning should therefore be prepared.

## **Suggested recommendations for the short -term, mid -term and long -term.**

### **For the short-term**

- Urgently coordinate with all partners to map the situation and understand gaps in surveillance, define functions and develop a homogenous reporting system (ToR) to make use of vector surveillance and M&E data by NVBCP;
- Conduct entomological surveillance before and after IRS, to measure efficacy of IRS; and
- Undertake in-depth study in areas where IRS rounds were missed in 2018 and 2019 to assess impact of missing IRS round on KA incidence, on sandfly densities etc.

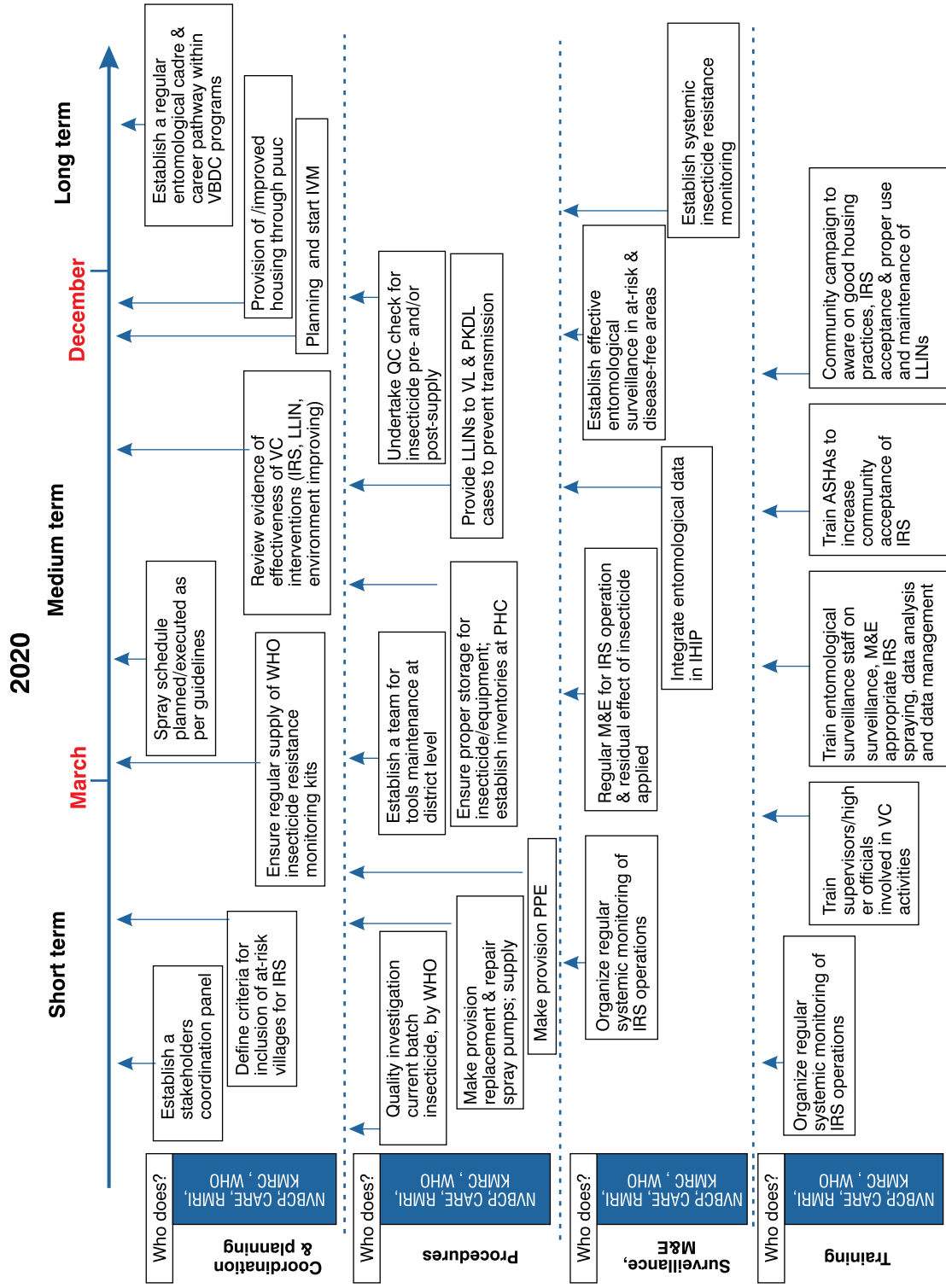
### **For the mid and long term**

- Institute a devoted vector control working group, representing all stakeholders at the national/state level and organize regular systemic monitoring of IRS operations. Also, evaluate efficacy of applied IRS (bioassays for residual effect) using information of all stakeholders, and ensure regular supply of WHO insecticide resistance monitoring kits. Integrate the entire entomological data set in the online data platform (IHIP). In the long-term, this working group should establish effective entomological surveillance in at-risk and disease-free areas.
- Develop a long-term, cross-cutting strategy to establish a regular entomological cadre and career pathway within NVBDCP. This will help address the longstanding problem of lack of entomologists specialized in sandflies in the region





Fig. 17 Vector control last mile: proposed selected-priorities according to implementation period

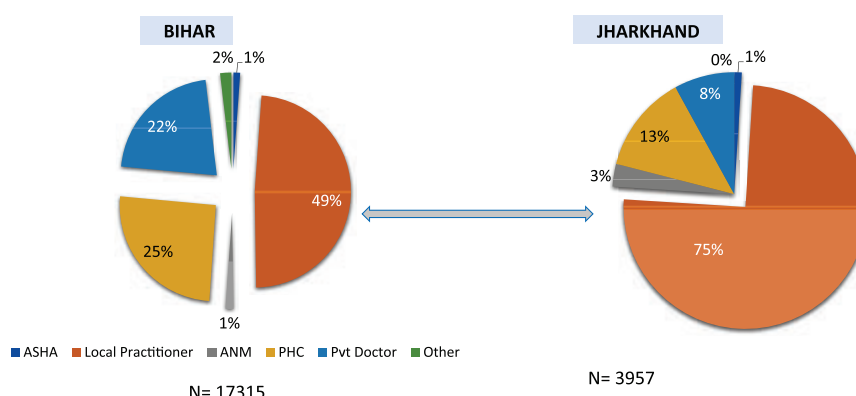


## C. Patient and community participation

### I. Health-seeking behaviour

- Many of the visited villages were remote, poor and had high levels of illiteracy. Sanitation was unsatisfactory, with people living in close proximity to animals (goats, pigs, cows) with many potential outdoor breeding and resting sites for sandflies. Plenty of evidence of clustering of cases within families was seen in the field;
- In most villages, rural health practitioners (RHP) were present. They were either residents or visiting by motorbikes. All patients interviewed mentioned that their first point of contact was the RHP (mostly unqualified; Fig. 18). Typically, the patient contacted the ASHA only if symptoms persisted and it was not the other way round. Efforts were made to sensitize RHP's effectively, as some of them referred patients and were considered 'key informants'. There was generally some awareness of KA and PKDL among RHP's interviewed. In few areas MPWs liaised regularly with RHP's and educated them on KA and PKDL symptoms;
- Interviewed private practitioners informed that they referred patients to ASHAs when patient's condition did not improve (after treating for at least a month). In some cases, they referred patients to public health facilities for KA diagnosis;
- some patients were found to be taking treatment for their fever and illness privately from MOs of PHCs.

**Fig. 18. Health seeking behaviour-first contact of community during illness**



Source: IRS monitoring, WHO. Aug 2019

- Since PKDL was associated with some stigma and discrimination, patients preferred to seek treatment from distant health facilities. Self-inflicted stigma was primarily observed in the case of women. In one of the PKDL cases, a woman who was interviewed narrated her ordeal of social stigma by her own family. Self-inflicted stigma often leads to delay in seeking treatment unless appearance of the person does not disturb them completely. However, this was not the case in tribal communities which are close-knit and tolerant.
- ASHA's were trained and knowledgeable. They were paid on time and were much appreciated in their communities. However, not all could demonstrate registers of their KA activities. Stock-outs were observed in their medicine kits for other diseases (ORS, paracetamol, etc).
- Around 30-35% of kala-azar cases are found among the child age group i.e. below 14 years of age. Malnutrition is one of the most common risk factors in this age group which makes them more vulnerable for kala-azar disease.

### **Recommendations:**

- Reduce time-to-treatment since rural health practitioner (RHP) are often used as first-point-of care and involve these into the KA programme. Develop a systematic approach to involve RHP's in referral, surveillance and IEC. Also suggest periodic training of RHP's and a review mechanism;
- Engage with members of excluded groups and train them as mediators (ensuring social accountability); and consider employing ASHAs from relevant cultures to develop culturally appropriate IEC/BCC interventions; and
- Consider operational research to understand barriers in appropriate health care seeking behaviour and community perceptions /issues for refusal/ non-compliance with special focus on stigma associated with PKDL.
- Leveraging kala-azazr elimination programme with POSHAN Abhiyaan (National Nutrition Mission, a flagship programme of the Ministry of Women and Child Development) for the maximum benefits at the community level.

### **ii. Community awareness and participation**

- Knowledge level on KA, PKDL and prevention methods in communities in Jharkhand was good. Banners and posters, translated into the local language were present in villages, CHC's and district hospitals. ASHA's were involved in IEC and school campaigns. Lot of IEC material is developed as per state IEC plan that caters to district and block level needs. This is given in community and 'drumming' meetings. To assess impact of these IEC materials a systematic monitoring of the same is advised.
- In some communities in Bihar, neither was any IEC material observed nor any IEC activity in KA reported. Majority of people from one community failed to comprehend pictures and read the words of KA IEC material (due to low literacy). ASHAs gave priority to Janani Suraksha Bal Yojana (JSBY) and Immunization programmes with KA acquiring second importance. ACD and Community IEC activities centered around IRS. In Uttar Pradesh there was good awareness of KA, but lack of knowledge/motivation to access PHC. Affected families wanted better housing to prevent sandflies breeding.
- The community was largely unaware about the possible breeding sites and prevention against sandfly vectors. Larger proportion of the general community, including programme managers at implementation level were yet to see sandflies.
- There was no target group oriented standard IEC messaging to promote environmental actions for cleanliness and prevention of breeding of sandflies.
- Community awareness and participation in the case detection and referral was minimal. The Block Community Mobilizer (BCM) and ASHA were weighed down with the load of Janani Suraksha Bal Yojana (JSBY) and immunization programmes. House-to-house visits and monitoring were also prioritized in these areas.
- It was a general observation in each high endemic foci that such foci were primarily located at some distance from main village areas. Residents in these foci were socially marginalized communities with difficult living conditions. They were often rejected by the mainstream community of the village. The ASHA and other health workers avoided visiting them. This was a major reason why cases continued to be reported from these areas.

- Social biases perpetuate and preclude household visits by ASHA in these areas. Hence huge gaps remain in ACD through household visits.

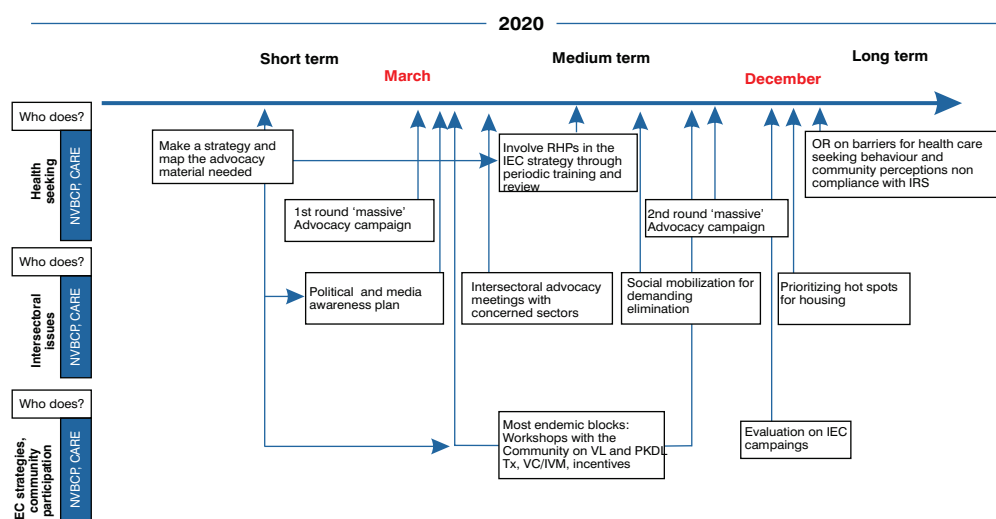
## Recommendations

- More advocacy needed to involve the community (including SHGs) to improve their participation. Better designed IEC interventions, with involvement of a media expert, are needed to achieve the last mile;
- IEC to focus more on immediate treatment seeking behaviour in case of prolonged fever and proper use of LLIN's and not so much on detailed KA information;
- Launch a campaign with a multipronged approach making additional use of posters and banners. This could be similar to the polio or TB campaigns that were tailored to specific village populations, for example, using popular folk media. Also explore use of community TV or mobile team;
- Roll-out the campaign over a limited endemic area and develop district-level plans including impact assessment;
- Define specific plans for hard-to-reach hotspot villages, to ensure no one is left behind, and conduct outbreak assessments in selected villages to verify local transmission;
- Develop an integrated approach towards IEC/BCC in prevention and control of VBDs and ensure that the material that is developed is cultural context-specific and covers all basic messages (timely treatment seeking, proper use of ITN/LLINs, and compensations/incentives). More importantly, plans for the district-level should be evaluated/modified after behavioural surveillance and impact assessment.

## Cross-cutting intersectoral issues

- Step up the political and media advocacy. Undertake intersectoral advocacy meetings with other concerned sectors, along with social mobilization for new initiatives and demand generation for elimination
- Prioritize hotspots for housing and develop culture appropriate housing designs with alternative low-cost materials along with social mobilization efforts to encourage acceptance.

**Fig. 19. Community participation and last mile advocacy: selected-proposed priorities according to implementation period**



## D. Stewardship and governance role of NVBDCP

The stewardship role of NVBDCP and particularly its KAEP component were reviewed as per the framework consisting of core functions central to stewardship.

### Strategies for elimination

- **National Roadmap for KA Elimination:** This was developed and disseminated in August 2014 to all the stakeholders of KA elimination. It contained the goal, target, objective and elimination strategies for its elimination. It laid down work plans and their timelines, broken-down by agencies who were assigned the responsibility to carry them out;
- **Operational guidelines in KA elimination in India – 2015:** A detailed and user-friendly operational guideline, developed by NVBDCP, accompanied the roll-out of the national roadmap for providing guidance for new easy-to-use yet accurate diagnostics (antigen-based rk39 rapid diagnostic test emerging as the standard diagnostic), effective treatment (one day single dose liposomal amphotericin B emerging as the treatment of choice for KA) and effective integrated vector management strategies (synthetic pyrethroids emerging as the mainstay of IRS insecticide);
- **Accelerated plan for KA elimination – 2017:** Publishing the Accelerated Plan in 2017 for the “last big push” towards eliminating KA. Consequently, blocks were categorized into four groups of endemic, borderline endemic, fluctuant endemic and silent blocks, for the purpose of prioritizing and focusing resources based on disease burden of the blocks.
- Exerting influence across all sectors and advocating for elimination;
- **Ensuring 100% funding for elimination activities:** This would come from MoHFW, under the aegis of the National Health Mission (NHM). KA elimination is a 100% centrally sponsored scheme with the state health system implementing the programme at the district/block level;
- **Building access to the Pradhan Mantri Awas Yojna (PMAY):** This is a gram (rural), nation-wide drive to build concrete (pucca) houses in rural areas. The objective being to accelerate building of concrete houses in endemic blocks/villages on priority since mud houses are breeding grounds for sandflies in the KA vector;
- **Developing a partner network:** NVBDCP stewarded the development of a rich and effective network of development partners working specifically for KA elimination, especially in Bihar and Jharkhand, where the maximum burden of the disease lies;
- Ensuring good governance supporting the achievement of elimination goals
- **Financial management:** The mechanism of fund flow for KA elimination is routed through the bottom-up Programme Implementation Planning (PIP) system of NHM, which starts at the block level and goes up to the central NVBDCP;
- **Programme management:** Undertaking regular monitoring and periodic evaluation of various aspects of KA elimination initiatives, by various tiers of NVBDCP along with partners like WHO and other independent external experts. Review meetings of states/districts and meeting with partners are also conducted periodically;
- Aligning system design with elimination goals;
- **KA specific staff deployment:** KA specific supervisors (although many of them in less KA-endemic areas are being repurposed for other VBDs and renamed VBD technical supervisor (VBDTS));

- **Steering partner network:** This is helping develop optimum staff structure comprising BMGF/CARE staff at the district/sub-district level for strengthening the health system;
- **Decentralization of case search, diagnostics and treatment:** Involvement of ASHAs and utilising their new case search strategies (house-to-house, index-based and camp approach) along with decentralization of diagnostic and treatment centres;
- **Making use of legal, regulatory and policy instruments:** These are critical to steer the KA elimination programme and must be part of every strategic effort;
- KA being declared as a notifiable disease in all states;
- **Incentives to KA patients on treatment completion:** The incentive is to the tune of INR 500, from NVBDCP side and INR 6600 from Bihar and Jharkhand state governments in addition to another INR 4000 for treatment of PKDL cases;
- **Guidance for using resident and non-resident registers:** This includes the policy of “transfer” of cases to local registers where the cases originally reside;
- **Information of inventory and supply of diagnostics, drugs and insecticides:** Detailed information is needed to mount a planned response; and

## I. Human resource

- Although overall, it was found that majority of staff involved in KAEP was committed and performed well, vacancies were noted at the state, zonal, district, block and community level. If these positions are not filled and retained, there would be potential risk for effective implementation of the KAEP;
- The team working for KAEP at the NVBDCP central level is clearly understaffed, particularly since there are hardly any entomologists in NVBDCP despite being a central directorate of the national VBD programme;
- At the state level, in Bihar the VBD unit is dependent on consultants appointed by the national and state KA control programme. Regular officer’s positions at the state level and zonal entomological positions remain vacant. In Jharkhand too the state M&E position was vacant when the study team visited;
- At district level, staff situation differs from district to district, but there are significant number of vacancies. This especially applies for medical doctors and nurses in district hospitals, where there is dire need with more than half the sanctioned positions lying vacant. District VBD officers (DVBD) and MDO’s are often assigned additional tasks and hence do not have enough time to devote to the programme;
- At the block level, the situation was similar since most of the assessed blocks had significant understaffing in hospitals as well as other positions. Mostly, there was a lack of MO’s, but also an absence of KTS, laboratory technicians and block coordinators in highly endemic blocks. At the community level, understaffing seemed less of an issue, although a lack of male multipurpose workers was noted;
- Despite efforts being made to improve staffing in Jharkhand, it is difficult to find MO’s and specialists who are willing to work in remote areas; a problem which may also apply to other endemic states. There was dire need for more health personnel in four blocks (Amrara, Hiranpur, Maheshpur and Borio) of Pakur and Sahibganj districts of Jharkhand. These are among the highest endemic blocks of the state;

- The process of relocating block-level staff, such as KTS, from less endemic blocks to places with higher disease burden, often across district borders, has been largely unsuccessful.

### **Suggested recommendations for the short -term, mid -term and long -term**

#### **For the short-term**

- Revisit the real human resource needs at the NVBDCP central level to coordinate all efforts in the last mile;
- Deploy dedicated, competent and motivated staff urgently in all high endemic blocks. Within districts, rationalize posting needs to ensure highly endemic blocks are not vacant. If necessary, make sure there is contractual manpower and additional resources; and
- Depute a dedicated and full time DVBD0 in the four districts of Jharkhand.

#### **For the mid-term**

- Make all efforts to fill staff vacancies in district hospitals, CHC's and PHC's and motivate existing staff; and
- State government to fill posts of at least male multipurpose workers and entomologists.

#### **ii. Planning**

- At national and state levels, planning document is not available and national roadmap which was developed in 2014, followed by Accelerated Plan for KA elimination 2017 has not reached the implementation level;
- At NVBDCP level a costed plan was not available including contributions from all partners'
- A comprehensive monthly activity plan which includes all activities by all partners is not available at the NVBDCP. Nevertheless, activities are planned in advance and happening at the field-level with only ad-hoc information to NVBDCP. This results in lack of information to all stakeholders, duplication of activities and poor participation from key stakeholders;
- It was observed that activities are planned without any objectives and outcomes and mechanisms are not in place to verify if desired outcomes were achieved or not;
- A sample of an objective plan is described below:





Activity	May				June	
	Wk1	Wk2	Wk3	Wk4	Wk1	Wk2
Objective 1 Strengthening data management						
Activity 1- HMIS training of block data entry officer in Vaishali (Bihar)			Through Partner1	Through Partner 1		
Activity 2- HMIS training of block data entry officer in Kushinagar (UP)				Through Partner 2	Through Partner 2	

- Like in the previous JMM, 2014, the mission observed that important communication, letters and notifications did not reach from central to implementation units. Therefore, NVBDCP at central and state level had to either use KA disease-specific KAMIS portal for uploading all circulars and communications or use the main health portal of MoHFW. Alternately, prepare an annual compendium of circulars and circulate as hard copies.

### iii. Programme management

- Programme management skills were found to be weak at all levels from the central NVBDCP to the state and district levels officials. The MoH should identify organizations which can develop and provide professional development courses for central, state and district programme managers. These courses should be made mandatory and part of performance management;
- The mission noticed with concern that at central, state and district level of VBDs, one VBD officer managed all VBDs most of which were not only targeted for elimination (malaria, KA, lymphatic filariasis) but also had outbreak potential (malaria, dengue, chikungunya, KA and Japanese Encephalitis). At district level, district VBD officer was somehow managing the programme along with VBD consultant;
- The KAEP was found to be still running in control mode as KA was yet to be assigned priority at implementation level and was often not discussed and reviewed at the administrator's level. It was also not a priority in review meetings at state and district levels. The content was not KA centered/structured for follow-up and actions. The weak commitment of MOs in the peripheral health facilities, especially in Bihar, remained a challenge to the elimination initiative;
- A large gap was observed in the technical excellence and guidance from central level to implementation units. Weak linkages were observed between state directives and district follow-up. Also, block and district programmes were frequently disconnected from the state or central guidance;
- Medical officers and programme managers were not yet geared for elimination/ mission mode;
- No dedicated independent technical body exists at the central level to oversee progress or to address gaps and guide the programme periodically for adoption of strategies as per the situation. The state task force committee exists at state level but meetings are infrequent and not aligned and connected with central guidance;
- Regular programme review meetings were organized at each level. However, a structure and review framework was missing, which could essentially guide areas that needed to be focused on and which required urgent and immediate action;
- Non-uniformity in action or lack of clarity for required actions was a general observation from state up to the block level. Programme managers were not clear or there was lack of



understanding about roll-out of a uniform strategy for active case search, standardized guidelines for involvement of private healthcare sector (including informal sector) or standardized training modules in KAEP;

- Inter and intra-departmental coordination or integration was completely missing from the programme. No mechanism of linkage with leprosy, RBSK and ARSH programme was seen at the point of implementation. However, this got well captured and described in the accelerated roadmap for KAEP;
- No clear guideline was available on whether cases reported from non-endemic areas should be included as new endemic blocks. It was also not clear if those cases should be assigned to historical endemic blocks to recalculate the disease rate per 10 000 population; and
- Despite the programme taking the decision of reporting deaths among KA in June 2019, reporting system of “deaths” in KAEP remained unclear till date. Status of death has been nil since 2016, although good number of deaths were observed and reported by stakeholders at each level.

### **Suggested recommendations for the short -term, mid -term and long -term**

#### **For the short -term**

- Intensify all programme strategies in mission mode to overcome last mile challenges. The current pace in decline of cases, epidemiological trend of the disease and challenges in remaining high endemic pockets of the country suggests the probable date of elimination for KA as 2023. This must be ensured right from the national to the block level with active involvement and coordination of intersectoral departments urgently converging their activities;
- Establish on urgent basis, a national task force at the central level to oversee the progress of elimination and guide strategic actions for elimination. The task force can build upon the accountability framework among stakeholders and programme implementers. It can include priority neglected tropical disease which are targeted for elimination such as KA, Lymphatic Filariasis and Leprosy. The task force can monitor its progress and identify challenges in achieving elimination before advising MoHFW, Government of India. It can meet twice a year though frequency of meetings can be determined by the status of the disease situation in India. The terms of reference for the national task force are annexed in the report;
- The Mission strongly recommends strengthening at least central and state VBD units and finding sustainable solution for its optimum performance;
- Programme management courses should be made mandatory and part of the curriculum;
- There should be rationalization of staffing based on requirements. For example, district Muzaffarpur (second highest KA endemic in Bihar) is the only district in India having all six VBDs under NVBDCP even though it does not have a data manager to manage programme requirement;
- The programme should convert to ‘Mission-mode’ by strengthening KAEP management, monitoring and evaluation at block and District, along with strong leadership at all levels. Attention should be paid to improving communication and feedback to district and block levels. Active and supportive supervision should be implemented in all levels of the programme. A mechanism should be instituted to ensure communication from central level reaches at the implementation level (block);

- Objective meetings and reviews should be conducted regularly in a structured manner. Action points must be followed up for implementation at the ground level. Partners need to actively support in providing feedback to the programme and in following up implementation of actions; and
- KA disease specific circulars and communication need to reach relevant personnel via suggested pathways mentioned.

#### **For the mid-term**

- Disseminate simplified SoPs for active case search, public-private partnership; and standardized modules for training of different categories of VBDCP and general health staff for all levels;
- Clarify definition of endemicity to programme managers and initiate reported deaths retrospectively and prospectively; and
- Deploy dedicated and competent staff for fixed duration to the highly endemic foci of district. Prompt and responsive relocation of human resources from lower to higher endemic areas would be needed, which the changing epidemiology of KA would demand when the disease is at last mile of elimination. The issue of “relocation allowance” of field staff may be considered and financial resources made available. Repositioning and relocation of partners must be closely followed up by NVBDCP.

#### **For the long-term**

- WHO must continue coordinating independent short-missions with the small group of independent experts at least on a six-monthly basis; and
- Provide neutral and independent findings and review of the programme at the implementation level and as follow-up of actions recommended in this mission.

#### **iv. Award scheme**

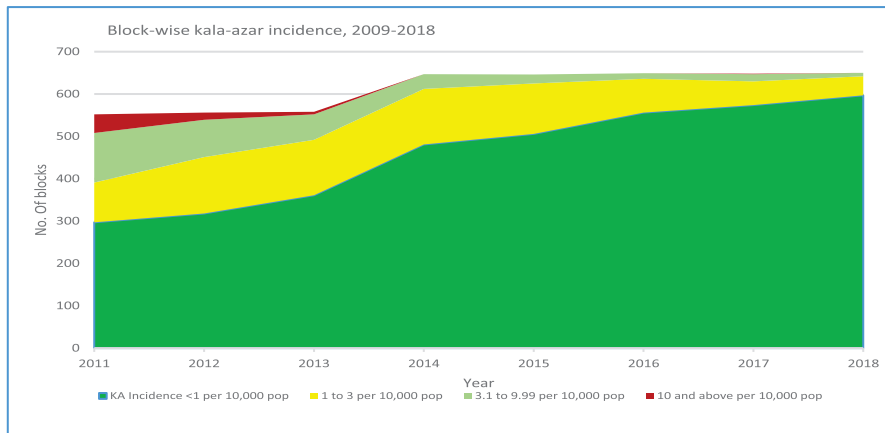
To improve performance, the mission suggests introducing an award scheme for the best performing blocks. Performance indicators should include several inputs (e.g. staff trained, 100% wages paid) and process indicators (no. of suspects identified, no. of RDT performed, 100% KA patients followed-up for three years, etc.) and only one output indicator to encourage early case detection, treatment and follow-up.

#### **v. Sustaining elimination**

KA is an outbreak prone disease and new cases are expected to occur for the foreseeable future. Therefore, achieving KA elimination as a public health problem is only a milestone on this path and sustaining gains is the most critical aspect to prevent re-emergence like in the 1970s. Block-wise KA incidence from 2009–2018, indicates that blocks which have attained elimination are consolidating their achievements. However, this needs to be verified.



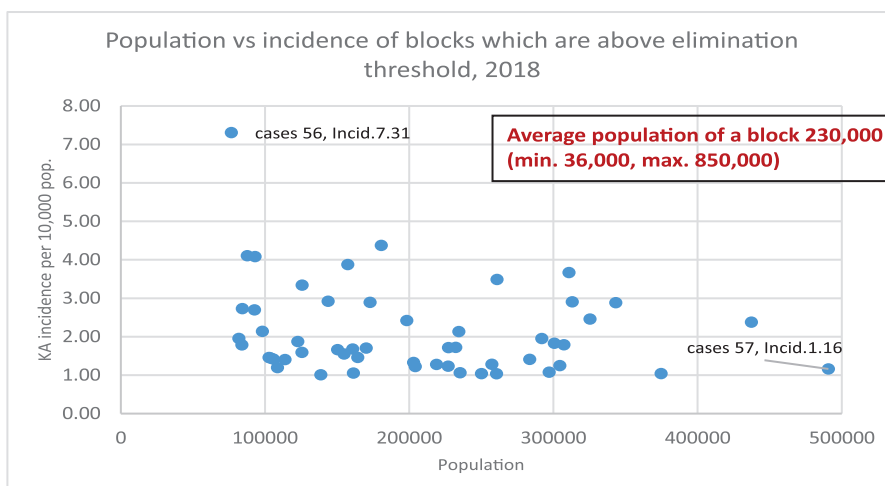
**Fig. 20 Incidence of kala-azar by blocks**



Accelerated plan for KA elimination (2017) has already proposed the following activities which need to be re-emphasized and implemented:

- Syndromic approach (fever and skin lesions) at the health facility level for KA and PKDL;
- Introduction of standard definitions (suspects, probable and confirmed cases);
- Accelerated plan has already described early case detection approaches in under-5, school-aged children, adolescent and young age and others. This plan needs to be disseminated widely;
- A pragmatic way for intensifying PKDL case detection is to introduce skin NTD approach in the country as there is already intense overlap of endemic areas of KA with lymphatic filariasis, leprosy, scabies, and several fungal skin conditions. The MoH should develop a framework and come up with such nationwide approach with strong monitoring mechanisms and reporting systems;
- Following needs to be introduced systematically in all blocks:
  - ◆ Maintenance of a suspect register
  - ◆ Monitoring monthly indicator of no of suspects
  - ◆ Monitoring monthly indicator of no of RDTs performed vs positives.

**Fig. 21 Population versus incidence by blocks**



The graph above indicates that blocks with less population have a higher chance of fluctuation of KA incidence (e.g. one block with 56 cases shows incidence of 7.31 when population is less than 100 000 whereas another block with similar 57 cases shows incidence of 1.16 at the population of around 500 000). These areas require intense case detection and case-based surveillance. Therefore, NVBDCP should ensure that all implementation level functionaries interpret elimination of KA as a public health problem as more and more cases get detected.

#### vi. Collaboration with partners

During interaction with central and state-level VBD functionaries, the mission noticed meagre or lack of involvement of local non-governmental or community-based organizations or public-private partnership mechanisms to strengthen and sustain health systems performance. There is only one self-funded NGO functioning in Muzaffarpur district of Bihar where 50% new cases were detected in the catchment area. Such best practices should be acknowledged, rewarded and promoted through introduction of an NGO scheme that can engage local level organizations which know the context best. Increasing the engagement of community-based and NGOs will be key to sustain KA elimination and further reduce the disease burden.

A coordination mechanism under the leadership of the MoHFW and Directorate of NVBDCP is in place, where partners meet at certain intervals and share information and data. Partners provide key technical support to government activities. Other areas of support include:

- During the mission, partners and stakeholders presented their current roles and functions in the programme. Most functionaries in the field were not clear about their roles and majority stakeholders were found to be monitoring activities rather than providing supportive on-the-job capacity building. In some places, partners were observed to be competing with each other and with the government functionaries;
- In several health facilities, records were incomplete and there was lack of clarity on certain key definitions and terminologies inspite of expert presence of coordinators from CARE, WHO, KTS and others; and
- Mission noticed lack of clarity of role with respect to WHO coordinators and found them disconnected from the field, although they were expected to coordinate with the district health administration.

Major partners at the implementation level are CARE (Bihar and Jharkhand), RMRI (in Bihar), PATH (in UP) and WHO in all four endemic states (Table 7).

**Table 7. Number of personnel employed by stakeholders at various administrative levels per state**

Organization	Presence	National	State	Districts	Block Total
CARE	Bihar and Jharkhand	1	2	27	233263
LSTM (CARE)	Bihar, Jharkhand and WB		1		5657
PATH	Uttar Pradesh	1	1	2	1519
WHO	Bihar, Jharkhand, UP and WB	1	4	12	17
<b>Total</b>	<b>3</b>	<b>8</b>	<b>41</b>	<b>304</b>	<b>356</b>

Source: NVBDCP, Country brief report. 2019.



A workforce of 356 people were found to be on the ground which is without including personnel from RMRI, LSHTM, DNDi, MSF, BMGF etc.

- Despite the presence of many partners, some with considerably large network at the field level, there is lack of clarity about their roles, to both the programme as well as partners themselves. This led to lack of synergy, between the programme and partners, especially at the state, district and sub-district level. Information asymmetry between partners and the programme may be exacerbating this situation;
- Coordination between partners, especially BMGF/CARE, and NVBDCP at the state and district level in Bihar was suboptimal, leading to partners often operating in “parallel” and therefore disharmoniously at times. They tended to not acknowledge the leadership role of NVBDCP in this elimination initiative. On the other hand, the leadership role of different tiers of VBDCP in pulling the partners along towards the common goal of elimination left some room for improvement;
- Several attempts were made in the past to coordinate the work of partners with programme needs, however, the action of partners was independent of the programme decision or programme needs. Lack of coherence and coordination of work existed between programme and partners and between partners, leading to underutilization of resources and required actions on ground;
- The pre-mission preparations like printing of guidelines, SoPs, displaying of banner and posters, filling of treatment card and distribution of new treatment cards to old patients, sensitizing frontline health workers etc. happened just before the arrival of the independent team to the district and block, and was largely supported by partners on the ground like CARE, WHO and PATH. One state that was interviewed was ready with a pre-filled state-level questionnaire. They handed it over to the team lead of mission members. It indicated lack of clarity among implementing partners about their role in the elimination programme;
- Apart from a one-day routine monthly state and district coordination meeting, there was no formal platform or mechanism through which all partners and NVBDCP could interact and initiate synergistic plans and jointly execute them;
- In general, there was a gap in information-sharing by partners with the national programme, and a resulting lack in coordination. At district level, practical orientation and joint planning, decision making and action points were missing in the review meeting. It was currently not possible for all stakeholders to access KAMIS to input information and facilitate joint analysis of data. KAMIS was not fully utilized for real time monitoring and response.
- At the implementation level, ownership of the programme was shared between partners and the national programme. This created a dependency on partners and thus a risk of lack of accountability and continued commitment to KAEP until elimination was achieved. Forward planning was found to be lacking in general. While IRS took up majority of the KAEP budget, there was no exit plan yet developed for this activity.

### **Suggested recommendations for the short -term, mid -term and long -term.**

#### **For the short-term**

- Synchronize stakeholder activities with the action plan and develop it jointly with the programme at the respective level, from the central up to block level. Convergence point between government and partners must be found at the block level;

- Establish more strongly leadership role of the relevant tiers of VBDCP and have this acknowledged unambiguously by partners. Foster greater coordination between NVBDCP and partners working in KA elimination and establish a dedicated National Task Force;
- Examine role of partners and clarify from the central Directorate of NVBDP. Partners to be involved in the programme for value addition and not for substitutions of Government activity;
- Continue monthly meetings with partners, conduct joint field visits and share data in a structured pattern with regularity. Ensure a uniform reporting mechanism to quantify the work with its objectivity and impact of partners to support in the elimination drive;
- Introduce a single standard monitoring framework by the programme for M&E work by all stakeholders. Reports of all field visits must follow a standardized format checklist devised by the NVBDCP;
- Share the PIP of the programme with respect to VBD with partners and also share the partners' programme with the Government; and
- NVBDCP to clarify roles and responsibilities of each stakeholder with one common condition that each field-level functionary ought to undertake on-the job capacity building in his/her area of expertise.

#### **For the mid -term**

- Similar to the action required from the state and district programme division, NVBDCP to closely examine positioning of partners at the implementation level. With the shifting of foci of transmission and epidemiology, repositioning and relocation of partners must be considered immediately. Areas of operation should be divided among partners in order to avoid duplication; and
- WHO NTD coordinators to be more involved in the programme, including training sessions, IRS activities, review meeting to improve quality of training on IRS, disease surveillance and better coordination.

#### **For the long -term**

- Have a well-equipped monitoring and surveillance team that includes one Regional office staff, two research assistants provided through RMRI in Bihar, All India Institute of Hygiene and Public Health (AIIPH) in Kolkata, RLTRI Raipur in Chhattisgarh and a suitable institute in Jharkhand. This team to conduct operation research to guide staff on the spot, identify and address gaps and provide logistics, as required.

#### **vii Transborder collaboration**

The KAEP is a regional voluntary initiative among countries sharing borders in the Indian subcontinent. All of them share a similar epidemiology regarding KA. Among others elements, they share the same sandfly vector, the disease is concentrated in neighbouring areas, and people move across borders for trading, job opportunities, family reasons, etc. Therefore, the whole region is very vulnerable and the risk of reintroduction of the disease is huge where it has been eliminated. There are many examples of imported cases of KA and recent introductions in countries that were previously free of KA, like Bhutan where the first case was detected in 2009.



Although the trans-border issue is recognized systematically in most meetings and documents, in practice few high-level meetings have already happened. As a result of the lack of agreements between countries, there is minimal data sharing of cross-border cases. The KAMIS can record KA and PKDL cases through cross-border information.

A limitation remained as the mission could not observe extensively on cross-border mechanisms, but this no longer exists. Suggested recommendations for the short-term, mid-term and long-term.

#### **For the short-term**

- Since trans-border collaboration is one of the six elements counting for the validation process, WHO SEARO should lead the initiative to institutionalize regular meetings at the decision-maker level among countries aiming for elimination;
- The Mission suggests NVBDCP to request WHO for creating cross-border mechanisms as it is a subject matter of inter-governmental organization.

#### **For the mid-term**

- Surveillance data should be standardized between countries, including information on the origin and recent travels of patients; and
- The HMIS should be strengthened at the national and state levels to share cross border data among the three countries.

### **E. Budgeting and finance**

The KA elimination programme in the country is financed from the funds of Central Government, State Government and External assistance (aid). The GoI is the main source of financing for KA elimination. Central assistance to states is given through the National Health Mission. Annual project implementation plans are prepared by the states in order to apply for funding allocations.

Field visits suggested that adequate funds were available for the programme. There was no indication of additional budgetary requirements for programme implementation from different districts under the assessment. The State project implementation plan approved by the centre and the funds that were requested were released.

- Five-year plan data is available and consolidated for all diseases under the NVBDCP but a costed strategic plan, multi-year plan or country level annual plan for KA elimination activities in India was not available. The state plans are not strategic in nature and they do not present medium-term projections. Hence, it is not possible to ascertain if the investment made for KA elimination was sufficient to meet the resource requirements of the strategies envisaged;
- Bihar and Jharkhand state governments are financing a scheme for supporting loss of wages to KA patients and ASHA incentive from their own resources;
- External aid has been provided mainly by the Department for International Development (DFID), BMGF and WHO. Donors do not have a common expenditure programme and common financial monitoring arrangements. Presently, there is no financial data sharing arrangement between the Directorate of NVBDCP and donors like DFID and BMGF;
- Bihar received the largest budgetary allocation of 86% of the total central allocation in the past six years followed by Jharkhand which received 8% of the total central allocation;



- The IRS activity gets the maximum allocation among all activities. In FY 2019-20 IRS allocation in Bihar was 80% and in Jharkhand it was 72% of the total KA elimination budget. Within the IRS activity, wages of superior field worker (SFW) and field worker (FW) comprised around 91% of the total allocation;
- Cumulative central assistance budget utilization of past five years is 74% in Bihar and 90% in Jharkhand. The reasons for low budget utilization were over budgeting, incorrect posting of expenditure, fund allocation from state received in August-September till 2018-19, payment of committed unspent funds which can be spent done after validation and incorrect quantification of committed unspent;
- The first round of IRS is spread over two financial years. In Bihar, for the year 2019, it started on March 19 due to which payment of approximately 50% of the activity was done in April-May. The payment which was done in the next financial year was committed unspent. This was not an expenditure of the year in which the activity had been started. Committed unspent expenses formed a part of the resource envelope of the state but it needed to be revalidated before it was spent. This presents a challenge in comparability of budget with actual expenditure of the year;
- Case search separate expenditure data was unavailable due to change in budget head after 2016-17. Average budget utilization on case search in Bihar in 2014-15 to 2015-16 was around 31%;
- BMGF awarded grant to six organizations in the past for KA elimination related activities in India over a period of seven years. CARE has been awarded the largest share, namely 73% of the total grant awarded by BMGF for KA in India in the past seven years.
- BMGF through CARE supported KA elimination activities by providing equipment like imported compression pumps, stirrup pumps, buckets, nozzles, rk39 RDT kits, training, squad id cards, booklets etc;
- WHO has been providing in-kind support for the supply of AmBisome to India for treatment of KA. It supplied 221360 number of vials in past five years;
- A large number of human resources are deployed in IRS. The financial guidelines issued by Bihar and Jharkhand in 2019 for IRS do not specify the method of hiring these workers. The system ensures that the workers are trained to do the work;
- As per operational guidelines on KA Elimination, 2015, training should be given for at least three days to spray squads and supervisors. Financial guidelines issued by Bihar in 2019 made budgetary provision for one-day training. Jharkhand also has provision for the same;
- Planned activities for which funds have been approved are not known to the blocks in advance. Budget and financial details/breakdown by activities are difficult to obtain from any district. Internal and external QA being done by the Central Medical Stores Organization (CMSO) but the State Programme Officer (SPO) of one of the states mentioned that he had no role nor he is involved in the process;
- The IRS teams move around during the campaigns on bicycles (supervisors on motorcycles). The distances to remote villages can be considerable and there have been requests for travelling allowances for IRS teams and their supervisors but there are no funds planned for this;
- Relapse cases that occur within six months after finishing treatment for KA do not receive any payments, even though these cases will experience a financial setback from their KA episode, no different from primary KA cases; and





- ASHA's are not paid for identifying suspect cases who are subsequently tested for KA, only for confirmed cases, which means in practice they are performing much unpaid work in villages with low numbers of cases.

### **Suggested recommendations for the short -term, mid -term and long -term:**

#### **For the short-term**

- A mechanism to link identity of SFW and FW working in IRS with a government issued ID and tracking through KAMIS (if possible) would be helpful in strengthening the internal control system in IRS activity. This will ensure that the workers are trained in undertaking IRS work, work history, payment history;
- The first round of IRS needs to be started and completed on time every year to ensure that maximum expenditure is done in the same financial year in which the activity was started. This would help in reducing the committed unspent balance with the states due to spreading of IRS activity over two financial years; and
- Donor coordination mechanism and information sharing about activities being financed by donor grants and actual spending with the Directorate of NVBDCP would bring in more synergy towards KA elimination activities. The Directorate would be able to link cash and commodity assistance with donor support at the time of approval of state PIP.

#### **For the mid -term**

- State-wise budget utilization data for all KA elimination activity budget heads needs to be tracked at the level of Directorate of NVBDCP quarterly by obtaining the data from NHM FMR as basis. At present, the budget utilization is being reviewed at the time of approval of state PIP, meetings and visits;
- Effort should be made to consider allocation of patient payments to all relapse cases. At the moment only relapses that occur after six months receive payments as they are considered reinfections. Payments for all relapse cases will ensure:
  - ♦ They do not suffer from financial setback from their disease episode; and
  - ♦ There will be no risk that these cases will wait six months to report to health facilities, in order to receive payment.
- Additional budget may be required to repair spray pumps and procure new pumps. Consider reimbursement of travel allowance to IRS staff (spraying squads as well as supervisors) as distances travelled; and
- KA case search budget head needs to be separated from the present line item in the NHM FMR budget head, "KA case search/POL/mobility/supervision."

#### **For the long -term**

- A strategic plan for KA elimination with costing needs to be prepared. It must have a financing plan for the target of KA elimination timeline along with a basis for allocation of funds amongst the states. A more flexible approach may be considered for adoption in other states. Lessons can be learnt from the financial guidelines issued by Jharkhand which do not have block-level allocations. Also, in many budget heads, flexibility is given to spend within the overall budget without specifying activity-wise limits;

- Allocation among various KA activities must ensure that sufficient funding is available for each strategy. IRS at present is getting the largest allocation of central assistance funds whereas the KA elimination follows a multipronged approach; and
- Review reimbursals that are made to the ASHAs. The Secretary of Health, Jharkhand has already advised the SPO that they should be reimbursed INR 50 for every suspected case that is identified.

## F. Supply chain and stock management

For successful implementation of elimination strategies, the programme is provided with accurate diagnostics (antigen-based rk39 rapid diagnostic test), effective drugs (one day single dose liposomal amphotericin B and miltefosine) and integrated vector management tools (decompression pumps and synthetic pyrethroids). However, observations from the field suggest that on-time availability of these critical commodities is constrained because of certain procurement and supply chain challenges. For example, though the procurement process is shared responsibility between NVBDCP and Central Medical Services Society (CMSS), there are inadvertent delays in receipt of commodities (MF, k39 test kits and synthetic pyrethroids) at the field-level resulting in stock-outs at facility level. This is primarily because of poor forecasting, procurement and supply chain practices. Key observations:

- As per CMSS guidelines, the expected average time for receipt of supplies from selected L1 bidders is 90 days, but for the year 2018–19, the process took anywhere between 4-8 months depending upon the said commodity;
- There are a limited number of suppliers in the country for majority of these commodities. For example, there was only one supplier for MF to CMSS in the past few years and a shortage of active pharmaceutical ingredient (API) in the country. In addition, there was a shortage of hand compression pumps (HCP) and spare parts;
- Similarly, AmBisome is provided in kind by WHO but the time between the receipt of indents and supply of appropriate stocks to the states was anywhere between 2-3 months on average;
- In terms of buffer capacities and storage space, the state warehouses and facility stores had sufficient space and technology. There was enough storage capacity for AmBisome, MF and rK39 and the time between indents and supplies from state to district was between 3-5 days. However, facility-level stores were poorly managed on account of poor warehousing practices like numerous indents every month and non-maintenance of requisite buffer stocks of drugs and diagnostics;
- Generally, supplies provided were less than demands generated by the facilities and treatment centres and the supply chain operated more as push system than pull system. When sufficient supplies were available, commodities were pushed down the supply chain with zero buffers stock otherwise. It was observed that the stock situation was not maintained properly which could be because of absence of MIS or poor use of the existing MIS system. As a result, there were inadvertent stock-outs at the facility level resulting in masking of patients or referral of KA and PKDL patients to other treatment centres;
- The critical commodities for IVM (synthetic pyrethroids, personal protective equipment and hand compression pumps) had also faced supply constraints in the past years;



- Because of absence of post-dispatch quality checks, major quality issues in IRS were reported in the previous year supplies. This led to the cancellation of second round of IRS (2018), and reform in the post-dispatch quality assurance mechanism at the programme level and a change of suppliers of IRS. As a result, huge stock pile of expired insecticide and nonfunctional equipment was lying at various depots and was occupying storage space;
- A shortage of hand compression pumps and spare parts was reported which resulted in major operational challenges and quality IRS operations in the field. About 50% pumps used in the field were faulty due to lack of supplies and absence of maintenance system in place. These factors have major implications on quality and effectiveness of IRS and its impact on vector transmission and density; and
- There was no systematic inventory management and recording system for KA related supplies. One example being of Godda DH where a total of 342 AmBisome vials were on stock, 162 vials with expiry date in March 2020. On the other hand, in CHCs visited, AmBisome vials had longer expiry date of 2022. Distribution and priority of consumption should be given to supplies with short expiry date.

#### **Suggested recommendations for the short -term, mid -term and long -term:**

##### **For the short -term**

- Availability of essential commodities like rK39 for diagnosis, AmBisome for treatment of KA, MF for treatment of PKDL and synthetic pyrethroids for IRS was critical for the elimination drive;
- Constant updates and monitoring at least once a month must be ensured for consumption of drug and diagnostics, especially for AmBisome; and
- Stock expiry should be anticipated and acted upon at an earlier stage. KAMIS includes a module for inventory management, but this is not used. Continuous inventory monitoring should become a district responsibility and the online platform must take account of the inventory module for constantly generating alerts about expiry, shortage or any critical issues.

##### **For the mid -term**

- Refresher training must take account of finance and logistics supply chain management for capacity building of programme managers at state and district level;
- Surveillance information on KA and PKDL cases should be geographically mapped to provide accurate estimate on demand of commodities; and
- With reports of KA cases being reported from non-endemic states and blocks in the country, not only the scope and scale of the procurement and supply chain must be expanded but at the same time its efficiency and effectiveness must be ensured through capacity building of existing human resources and/or identifying a professional agency.

##### **For the long -term**

- Along with internal, external quality assurance of insecticide must be practiced for ensuring quality assured insecticide in the field; and
- Enhanced fund allocation should be ensured for procurement of quality assured commodities to ensure availability of the same at all levels of implementation from national up to block level.

## G. Best practices

- rK39 has been included in the National In vitro Essential Diagnostic Tests list, thereby, paving the way for procurement of rK39 based tests for the programme. It is well known that there are several poor quality and low cost serological commercial tests are available in the market which, if introduced in the programme, will harm the elimination drive. Similar applies to locally produced liposomal amphotericin B;
- The insecticide quality should be assured in each batch considering the large amount of money that vector control consumes, and the enormous implications for the programme;
- In Jharkhand, a compendium was printed of all circulars/letters/communications for implementation level functionaries. This should be replicated in other areas as well;
- KAMRC like case detection practice should be disseminated in detail and adjusted for the requirement and replicated in all areas. Having a mobile unit is the integral part of it; and
- RMRI, KAMRC and few others are cross-notifying all referred cases to their respective place of residence. This should be encouraged and implemented throughout the state by a standard mechanism.
- Integrated case search approach in Jharkhand is an exemplary practice which needs to be replicated elsewhere.

## H. Operational research

The Mission noticed the limited operational and implementation research in place, which was conducted under the criteria of the stakeholders. A lack of coordination mechanism, i.e. National Task Force, leads to erratic studies, sometimes with no implications for the programme or overlapping between them. There were many ongoing studies such as clinical trials, epidemiological work, studies to optimize vector control and modelling (see Annex) carried out by Indian institutions and partners such as SPEAK India, MSF, DNDi and LSTM. To improve coordination, it was recommended that calls for studies should be open and future study plans published ahead of time.

The Mission encouraged NVBDCP, partners and WHO to invest in operational research in local level institutes and organizations (e.g. supporting MD thesis etc).



## 6. LIMITATIONS OF THE MISSION

- The Independent assessment planned to cover all endemic states vis-à-vis Bihar, Jharkhand, Uttar Pradesh and West Bengal and one non-endemic state that was reporting sporadic cases, i.e. Sikkim. However, due to local administrative issues, the assessment exercise could not be done in West Bengal. Therefore, field visit reports and independent monitoring findings of the past were considered for discussion and description of the local situation of West Bengal. Further, visit by a small group of independent experts must be considered to assess the local situation in the state;
- Methodology of assessment activity described and shared in the concept note was deviated to adapt the last-minute change of field visit plan due to cancellation of visit to West Bengal. Hence the number of administrative and health units planned to be visited could not be fulfilled completely. To adapt with the change of plan, one endemic district of Bihar, i.e. Kishanganj, adjoining to Sikkim border was included for the assessment;
- One non-endemic state reporting sporadic cases was undertaken for assessment of epidemiological situation by one team. In the absence of systematic longitudinal data on sandflies and absence of complete epidemiological information of cases, the team could not establish the occurrence of local transmission. Therefore, the programme must consider conducting an entomological, immunological & epidemiological surveillance in selected 2-3 villages in South and East Sikkim to document presence or absence of local transmission;
- The pre-mission preparations like printing of guidelines, SoPs, displaying of banner and posters, filling of treatment card and even distribution of new treatment cards to the old patients, sensitizing frontline health workers etc. happened just before the arrival of the independent team, largely supported by partners at the implementation level (CARE, WHO and PATH). It would have jeopardized the objectives of the mission. It directly indicated lack of clarity among implementing partners about their role in the elimination programme. Accordingly, all mission members were alerted and informed about this situation and utmost care was taken by the assessment team during the visit;
- Some of the mission members raised their concern about the lengthy appraisal tools which consumed longer time than expected, especially for those experts who had not experienced the implementation of the KA elimination programme closely. This led to missing of few health facility and villages which was planned to cover as per the standard methodology. Designing of tools must be adapted keeping the time constraints and capacities of the team;
- Two objectives of the mission vis-à-vis, to analyze evidence-based policy formulation (operational research/research), contribution of research and regulation and to assess the national preparedness and readiness for validation of KA elimination as a public health problem, could not be discussed and illustrated in detail in the report; and
- Four review papers were commissioned externally to facilitate the JMM task. Although these documents were presented and briefly discussed during the briefing session at the beginning, their quality was found to be variable and they were not peer reviewed by a third party. In preparing the document, these papers were taken into account with due caution.



## 7. CONCLUSION

In the last mile, the KAEP has to make huge investment to fulfil the six preconditions to call for validation of elimination by the end of 2020. Although the national strategic guidelines and supply chain management are generally in place, better use of the high quality epidemiological surveillance system (KAMIS) is mandatory.

Three key preconditions are still far from optimal, namely:

- Adequate health services that can incorporate KA diagnosis and treatment as a routine activity and which are no longer a vertical programme without risk of jeopardizing results achieved so far;
- Revisit entirely the vector control programme under the principle of Integrated Vector Management, examining all steps, from procurement to implementation, from planning to monitoring activities, taking into account that this part consumes over 80% of the total budget of the KAEP; and
- Implement all necessary efforts to coordinate with the countries that signed the KAEP at the regional level in order to have sustainable regional results.

This requires better collaboration between the central level and states, and from the states to the blocks. To incorporate necessary human resources is of paramount importance and to guide the KAEP, from the top to the bottom, and from the bottom to the top, in Mission mode is the only chance to be ready within a year from now to request for validation of KA elimination.

# Annexures

## **Annex 1: Members of the independent assessment mission** (by alphabetical order of family names)

### **List of expert members**

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## Annex 2. Recommendations made in 2014 by the independent kala-azar mission and progress made until 2019

Progress so far from the Joint Monitoring Mission (JMM) 2014 to the independent kala-azar mission 2019. Main recommendations made by 2019 JMM are listed below.

Selected action points suggested by JMM 2014	Selected action points suggested by JMM 2014	Selected action points suggested by JMM 2014
<b>Case management (diagnosis and treatment)</b>		
A comprehensive, updated protocol for KA and PKDL case detection and management is urgently needed. SoPs should be adapted and made accessible at all levels of the health care system. Training of health professionals involved in KA at all levels is required.	Treatment with single dose AmBisome was introduced and rolled out in the programme in late 2015 and significantly scaled up. Guidelines on the use of AmBisome and other drugs were shared (National guidelines on KA elimination 2015 and Accelerated KAEP 2017) and staff have been trained.	<ul style="list-style-type: none"> <li>• Simplified guidelines for case management should be made available to Mo's.</li> <li>• There should be a mechanism in place to train new staff and handover of KA responsibilities and knowledge and it should be ensured that regular refreshment courses are organized for KA related personnel.</li> <li>• The definition of relapse has to be clarified in all documents as the re-appearance of KA signs and symptoms at any time after apparent initial cure.</li> <li>• Incorporate 2nd option treatment based in PM/MF when AmBisome cannot be provided</li> <li>• When pregnancy tests or contraception cannot be guaranteed, the recommended 3 months MF for female PKDL patients should be avoided and replaced by multiple dose AmBisome therapy.</li> <li>• Compliance to 3 months of MF should be ensured.</li> </ul>
Strengthen treatment outcome, monitoring and pharmacovigilance for KA	Pharmacovigilance for KA has been introduced in 2017. MO's have been trained by on data collection and addressing of ADRs. At present data on pharmacovigilance are generated from 58 units.	<ul style="list-style-type: none"> <li>• Reinforce the implementation of ADR reporting. There is need for training in order to increase awareness of medical staff and to improve recording and reporting of ADRs.</li> <li>• Reported ADR's need to be analyzed at state level.</li> <li>• Heightened attention is needed for occurrence of serious eye complications related to 3 months MF therapy for PKDL</li> </ul>



<p>Strengthen follow-up mechanisms through KTSs and ASHAs and include treatment outcome assessment.</p>	<p>There is an in-built system of follow-up of KA and PKDL cases. This is scheduled on monthly, six monthly and yearly basis at present.</p>	<ul style="list-style-type: none"> <li>• Patients are followed up but should always be clinically reassessed by MO's. ASHA's and KTS should be in-charge of bringing the patient to the treatment centre.</li> <li>• Monetary compensation for wage loss and travel costs should be provided for follow-up visits to the patient.</li> <li>• Follow KA patients to document the occurrence of PKDL for at least 3 years after treatment.</li> <li>• Follow PKDL patients for at least 5 years to document occurrence of PKDL relapse</li> </ul>
<p>Develop and strengthen referral systems for counselling and testing for HIV and issue a policy statement to this effect</p>	<p>There is a referral system for HIV-KA co-infected cases at peripheral level. Such patients are either referred to RMRI or designated ART centers for counselling and treatment</p>	<ul style="list-style-type: none"> <li>• It is recommended to generate capacity in more district hospitals to treat HIV/KA so that patients don't have to travel large distances</li> <li>• Medical personnel at ART centres in endemic areas should be sensitized for the possibility of KA in HIV patients and be instructed where to refer</li> <li>• Medical colleges should be capacitated to treat HIV/KA and other complex KA cases.</li> <li>• HIV/KA patients should receive compensation for wage loss and travel just like primary and relapse KA cases</li> </ul>
<p>Elaborate and clear protocols and SoPs for diagnosis are required. The quality control system of lab diagnosis needs to be elaborated and implemented.</p>	<p>SoPs for diagnosis of KA cases have been developed and shared. Capacities of lab technicians are built on regular basis for proper detection.</p>	<ul style="list-style-type: none"> <li>• According to guidelines DH's should be capable of doing Giemsa staining and microscopy to confirm KA relapses and PKDL cases. Next, regional/state level QC plan for microscopy should be implemented with support of NVBCP.</li> </ul>
<p><b>Surveillance</b></p>		
<p>Feasible methods to estimate and validate the levels of underreporting need to be developed so that the correct disease burden can be ascertained.</p>	<p>Surveillance is an ongoing process through ASHAs, KTS block coordinators and key informants. Sporadic cases from non-endemic states are treated.</p>	<ul style="list-style-type: none"> <li>• Recommendation is to make KA a <b>nationally notifiable disease</b> and strengthen passive case detection (PCD) in non-endemic areas.</li> </ul>



Surveillance should be strengthened in emerging and remerging foci where cases are reported from time to time, so that the programme can follow trends, enable early detection, respond to potential outbreaks and prevent establishment of new endemic foci of local transmission.		
Develop a strategy for involvement of the private sector. There should be a clear strategy and activities elaborated for private sector engagement.	Private practitioners are coaxed through meetings and interpersonal communication to participate in programme activities by referring early suspected KA/PKDL cases to the system	<ul style="list-style-type: none"> <li>• A systemic approach should be developed to involve private practitioners in referral, surveillance and IEC. Periodic training and a review mechanism is recommended</li> <li>• How to involve private practitioners must be defined at the state level, with clear ToRs and incentives in line with those of ASHAs</li> </ul>
Develop a strategy to improve PKDL surveillance: Involve ASHAs to detect cases and record /report them. Collaborate with the leprosy programme to improve surveillance	Detection of PKDL cases is a priority. KA staff have been trained and PKDL ACD has been integrated with LCDC with support of state leprosy officials	<ul style="list-style-type: none"> <li>• Incorporate PKDL as part of ACD. Integrating ACD of KA and PKDL with other programmes (leprosy, TB, malaria, immunization etc) should be considered</li> <li>• Better guidance is needed on how to diagnose PKDL on clinical basis</li> </ul>
<b>Last mile challenges to KAEP</b>		
In some areas, improvements in housing, roads and access to safe water need to be made through the rural development department	The government has initiated the construction of pucca houses in high endemic KA villages. In Bihar and Jharkhand more than 25000 pucca houses have been constructed	<ul style="list-style-type: none"> <li>• To move from IRS to IVM is needed. Providing LLINs in addition to IRS and environmental management will contribute to reducing the number of cases</li> <li>• Lowest caste groups are not visited by ASHA's. To address the needs of excluded groups, it is advisable to engage community members as mediators (ensuring social accountability) or employ ASHAs from relevant cultures</li> </ul>



		<ul style="list-style-type: none"> <li>Owning land is a prerequisite to be allocated a pucca house which is not the case for the poorest among the poor. A corrective-specific plan for the poorest should be developed. A dedicated team should prepare a strategic plan focused on this objective</li> </ul>
<b>Last mile challenges to KAEP</b>		
<ul style="list-style-type: none"> <li>Strengthen M&amp;E activities and sharing of data. Ensure continuous monitoring and supervision of IRS activities with appropriate feedback mechanisms in place</li> <li>Conduct entomological surveys to assess IRS efficacy</li> <li>Strengthen entomological surveillance to monitor effectiveness of insecticides</li> </ul>	<ul style="list-style-type: none"> <li>There is continuous monitoring of IRS activities by state/district/block level officials. Besides, regular monitoring is carried out by NVBDCP, CARE, RMRI and WHO. Feedback is provided to the states/districts/blocks for making mid-course corrections and for further improvement in the second round of IRS</li> <li>CARE has set up 8 entomological sites (six in Bihar and one each in Jharkhand and West Bengal). Besides this Jharkhand and West Bengal are regularly collecting data on entomological aspects</li> </ul>	<ul style="list-style-type: none"> <li>A devoted vector control working group, representing all stakeholders, should be instituted at the national/state level and organize regular systemic monitoring of IRS operations, evaluate efficacy of applied IRS (bioassays for residual effect) using information of all stakeholders, and ensure regular supply of WHO insecticide resistance monitoring kits. In the long term, this working group should establish effective entomological surveillance in at-risk and disease-free areas</li> <li>A provision for replacement/repair of spray pumps should be made; PPE supplied, and a team put in place to repair and ensure equipment maintenance, facilitation of proper storage space for insecticide/equipment; and establishing of inventories at PHCs</li> </ul>
<b>Human resources</b>		
<p>There is need for capacity building of existing human resources to improve case detection, management and follow-up</p> <p>Health-care elements such as infrastructure, laboratory equipment and staffing need to be strengthened in collaboration with NHM</p>	<p>Health care systems in KA endemic states have been strengthened, however, infrastructural improvement remains an issue along with deficient human resources at BPHC/CHC levels.</p> <p>The percentage of vacancies of MO's ranges from 40-60% in Bihar and Jharkhand as per the statistics made available by the respective State/ District Health Societies</p>	<p>All efforts must be made to fill staff vacancies in DHs, CHC's and PHC's. If necessary, contractual manpower and additional resources must be ensured. The state government should fill the posts of at least male multipurpose workers and entomologists</p>



<b>Stock management</b>		
Strengthen the procurement system to avoid stockouts by setting up a forecasting system to procure medicines and supplies	The procurement cell at NVBDCP headquarters monitors regularly the use of drugs and diagnostics on monthly basis. Besides this the inventory of drugs and diagnosis is captured through KAMIS	Stock expiries should be anticipated and acted upon in an earlier stage  Constant inventory monitoring should become a district responsibility and the KAMIS module on inventory management should be taken into use
<b>Collaboration with partners</b>		
To achieve the target to elimination by 2015, there is an urgent need for the control programme to intensify proposed interventions (see below). Programme activities should be monitored directly by district magistrates at least once a month	The target for elimination has been shifted to 2020 and efforts have been intensified in all KA endemic states. KA activities are monitored by District Magistrates through District Task Force meetings	<ul style="list-style-type: none"> <li>• A stakeholders meeting organized by the NVBCP should map interests and expertise according to KAEP needs</li> <li>• A general gap in information-sharing by partners with the national programme and a resulting lack in coordination should be addressed. At district level, review meetings need practical orientation and joint planning and decision making</li> </ul>





### **Annex 3. Terms of Reference (ToR) for national task force for neglected tropical diseases**

- Monitor the progress of Kala-azar, Lymphatic Filariasis and Leprosy, which are targeted for elimination as a public health problem and identify challenges in achieving elimination. Additionally, advise MoHFW, GoI on strategies to overcome challenges to achieve the goal of elimination for these diseases.
- Assess and review implementation of five strategies recommended for prevention, control and elimination of NTDs in the disease specific areas of Kala-azar, Lymphatic Filariasis and Leprosy.
  - o intensified case-detection and case management
  - o prevented chemotherapy
  - o vector and intermediate host control
  - o veterinary public health at the human-animal interface
  - o provision of safe water, sanitation and hygiene.
- Review the disease surveillance and monitoring of essential indicators along with results of research studies and provide advice on programme interventions and prioritization of elimination activities.

#### Annex 4. Research conducted by stakeholders and official institutions with implications in the KAEP in India

Institution	Research work done in past (Year)	Ongoing research work	Future plans of research
RMRI	<p>DNDi PKDL study 2 arms                      1st arm Ambisome 20mg/kg total dose                      2nd arm 20mg/kg plus 21 days of miltefosine total sample size 126</p> <p>MSF HIV-VL study sample size 150                      1st arm 40 mg/kg Ambisome                      2nd arm 30mg/kg Ambisome plus 14 days miltefosine                      In both, the combination is better with lesser side effects</p> <p>Fungisome lifecare study                      4 arms sample size 624                      1sr arm fungisome 15 mg/ kg                      2nd arm fungisome 10mg/kg                      3rd arm fungisome 5mg/kg plus 7 days of miltefosine                      4th arm Ambisome 10mg/kv</p> <p>Bioequivalence studies of liposomal amphotericin B 15mg/kg of sun Cipla and Aurobindo Pharma compared to Ambisome as 3 separate studies</p> <p>Pkdl intramural study Ambisome 30mg perkg vs miltefosine for 12 weeks 110is sample size Asymptomatic study in field                      Dr Das</p>	<p style="text-align: center;"><b>ICMR</b></p> <ol style="list-style-type: none"> <li>1. Alternate insecticide</li> <li>2. Combination therapy for PKDL (DNDi)</li> <li>3. Sandfly density monitoring before spray and after spray</li> </ol>	

<b>LSHTM</b>	
<p><b>LSTM</b></p> <ol style="list-style-type: none"> <li>1. Sentinel site monitoring and evaluation: <ul style="list-style-type: none"> <li>• 6 sites in Bihar (Gopalganj, E.Champaran, Samastipur, Muzaffarpur, Katihar, Purnia), 1 site in West Bengal (Darjeeling) and 1 site in Jharkhand (Godda) <ul style="list-style-type: none"> <li>o Entomological indicators: Sand fly abundance and physiological status monitoring using CDC light traps</li> <li>o WHO Tube Bioassay: Susceptibility testing with alpha-cypermethrin, deltamethrin, bendiocarb, DDT, malathion</li> <li>o IRS Quality assurance: WHO gold standard method with pre-spray filter paper attachment, analysed by HPLC</li> </ul> </li> </ul> </li> <li>2. Reactive Focal IRS feasibility study – desk-based exercise <ul style="list-style-type: none"> <li>• Operational feasibility study for introducing focal IRS</li> </ul> </li> <li>3. Quality assurance novel tool development: <ul style="list-style-type: none"> <li>• Field testing and development of a handheld device to provide immediate feedback to IRS teams on whether the target dose has been delivered or not (spray performance -on target, above or below) <ul style="list-style-type: none"> <li>o Developed cypermethrin</li> </ul> </li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. Sentinel site monitoring and evaluation</li> <li>2. Quality assurance novel tool testing and final validation</li> <li>3. With WHO-TDR we are working with RMRI India and ICDDRb Bangladesh to look at diagnostic algorithms in fever patients</li> <li>4. Diagnostic samples were taken from patients entering the health system with fever regardless of duration, as opposed to only VL suspects with long fever &gt;2 weeks and splenomegaly</li> <li>• 1600 patients were enrolled across these two countries and serology and antigen tests evaluated</li> </ol>
<ol style="list-style-type: none"> <li>1. Sentinel site monitoring and evaluation as described ongoing</li> <li>2. Outdoor biting – Determine the optimal method of assessing the outdoor biting behaviour of sand flies – Pilot study <ul style="list-style-type: none"> <li>• Methods for comparison: Human-baited double net trap, sticky traps, CDC light traps, Shannon traps (Black and white)</li> <li>• Study area: East Champaran and Muzaffarpur</li> <li>• Timeframe: 2020 outdoor biting months</li> </ul> </li> <li>3. Optimal method for assessing VL transmission in the vector in hotspot/outbreak areas – Pilot study <ul style="list-style-type: none"> <li>• This work will couple with the LSTM-Speak India field study – study area will be the same</li> <li>• Methods for comparison: Pyrethrum spray catch, CDC light trap and Prokopak Aspirator</li> </ul> </li> <li>4. Integrated vector monitoring - Pilot <ul style="list-style-type: none"> <li>• LSTM will consider all the vector-borne diseases in these sites and site capabilities to develop an achievable framework for integrated entomological monitoring.</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. Sentinel site monitoring and evaluation as described ongoing</li> <li>2. Outdoor biting – Determine the optimal method of assessing the outdoor biting behaviour of sand flies – Pilot study <ul style="list-style-type: none"> <li>• Methods for comparison: Human-baited double net trap, sticky traps, CDC light traps, Shannon traps (Black and white)</li> <li>• Study area: East Champaran and Muzaffarpur</li> <li>• Timeframe: 2020 outdoor biting months</li> </ul> </li> <li>3. Optimal method for assessing VL transmission in the vector in hotspot/outbreak areas – Pilot study <ul style="list-style-type: none"> <li>• This work will couple with the LSTM-Speak India field study – study area will be the same</li> <li>• Methods for comparison: Pyrethrum spray catch, CDC light trap and Prokopak Aspirator</li> </ul> </li> <li>4. Integrated vector monitoring - Pilot <ul style="list-style-type: none"> <li>• LSTM will consider all the vector-borne diseases in these sites and site capabilities to develop an achievable framework for integrated entomological monitoring.</li> </ul> </li> </ol>



		<ol style="list-style-type: none"><li>I. Malaria, lymphatic filariasis and dengue<ul style="list-style-type: none"><li>• Study area: This will be done in a couple of sites (to be determined)</li><li>• This is in alignment with feedback from NVBDCP on monitoring other vectors. The framework will be shared with NVBDCP before implementation</li><li>• Timeframe: October 2019 onwards</li></ul></li><li>5. Sand fly resting behaviour above 6ft – Pilot study<ul style="list-style-type: none"><li>• Requested by NVBDCP</li><li>• In study design phase</li></ul></li><li>6. Outdoor resting in bamboo cluster, banana bushes, litchi, dates, palm and mango trees – Pilot study to determine role in VL transmission<ul style="list-style-type: none"><li>• Requested by NVBDCP</li><li>• In study design phase</li></ul></li><li>7. Insecticidal paints – feasibility in India – Pilot study<ul style="list-style-type: none"><li>• Under discussion</li></ul></li><li>8. Attractive Toxic Sugar Bait (ATSB) for control of VL vectors – Pilot study<ul style="list-style-type: none"><li>• Under discussion</li></ul></li><li>9. Development of novel Antigen tests for VL diagnosis and test of treatment response/cure.<ul style="list-style-type: none"><li>• Working with partners FIND</li></ul></li></ol>
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DNDi	<p>2008 to 2009: A randomised, open-label, parallel-group, safety and efficacy study to evaluate different combination treatment regimens (co-administration), of either AmBisome and paromomycin, AmBisome and Miltefosine, or Paromomycin and Miltefosine compared with Amphotericin B deoxycholate (the standard) therapy for the treatment of acute, symptomatic VL</p> <p>2011 to 2015: A pilot project to evaluate the safety and effectiveness of new treatment modalities for the management of VL in the endemic regions of India</p> <p>2015 to 2018: Cohort observational study to estimate the prevalence of PKDL in VL patients treated with three regimens in Bihar</p>	<p>2018–2021 Open label, non-comparative, randomised, multicentre phase II clinical trial to assess the safety and efficacy of the two regimens AmBisome monotherapy (5 x 4 mg/kg, total dose of 20 mg/kg) and combination of AmBisome (same as arm 1) plus miltefosine (allometric dosing) daily dose for 3 weeks for the treatment of PKDL in India and Bangladesh</p>	
MSF		<p>1. LSTM are working with MSF in Patna on the evaluation of diagnostic tests</p> <ul style="list-style-type: none"> <li>• Diagnosis and test of treatment response/cure <ul style="list-style-type: none"> <li>o Enrolment of 91 HIV/VL coinfection, and regularly sampling through treatment, at the end of treatment and at 6 months post treatment. Evaluation of qPCR, Antigen ELISA, and IgG1 tests</li> </ul> </li> </ul>	





<p>SPEAK- India</p>	<p>1. Pilot study to determine best method for collecting Phlebotomus argentipes females</p> <p>The traditional method for collecting sandflies in the region uses CDC light traps, (CDC LTs) and this was compared with two mechanical aspirating techniques: improved Prokopack aspirators (PVK) and Mechanical Vacuum aspirators (MVA). The field work was required to inform the design of the main xenomonitoring study that will obtain entomological indicators to define endpoints of transmission. A sample size calculation, using the mean and standard deviation of capture rates of female P. argentipes flies collected in CDC LTs during the Kalanet project, was made to determine the number of collections required to detect a difference in effect between collection methods. To detect a difference of one P. argentipes female between collection method, 166 collections are required for each treatment arm (498 in total). 48 households were recruited by SM together with the RMRI team: 12 houses per village, 4 villages (Dhampura, Ruchanpura, Rampur Jagdish and Bishambhapur), and 2 villages per district (Nalanda and Saran). Collections were made in Saran, an endemic</p>	<ul style="list-style-type: none"> <li>Enrolment of 1100 HIV patients who are asymptomatic for VL living in endemic villages of Bihar. Follow any patient who is test positive by qPCR, antigen test, antibody test inc. rK39, and establish conversion rate and appropriate diagnostic algorithm</li> </ul> <p>1. Optimising the metacyclic-specific PCR assay for Leishmania donovani infection</p> <p>We are currently infecting sandflies in the laboratory at LSHM to refine PCR assays, and optimization is ongoing. The methodology to be used is as follows:</p> <p>The methodology for molecular techniques to be used in the xenomonitoring project is shown below (Figure 4):</p> <ul style="list-style-type: none"> <li>female Phlebotomus sandflies will be identified by microscopy. In order to determine infection and infectious rates of female sandflies, the thorax region of each individual female will be dissected</li> <li>the posterior portion will be used to calculate infection rates (sandflies will be pooled, according to household, and DNA extracted) using a PCR;</li> </ul>	<p>LSTM also have a research project that falls under the Speak-India portfolio</p> <p>1. Risk of infection with Visceral Leishmaniasis in an elimination setting using active case detection in Bihar, India</p> <p><b>Research aims below:</b></p> <ul style="list-style-type: none"> <li>to conduct a pilot assessment of the feasibility of undertaking urine and blood tests for detection of recent active transmission of VL;</li> <li>to determine risk of becoming infected within a calculated distance from a VL index household and assess whether the village is the appropriate scale for the focal reactive spraying and active case detection; and</li> <li>to determine if antigen tests can accurately detect recent transmission, and therefore, in the future be used to take villages off the IRS micro-plan earlier than the current 3 years. This work will be modelled first before pilot evaluation if surveillance using antigen is determined to be sufficiently accurate</li> </ul>
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	<p>district for Visceral Leishmaniasis (VL), and Nalanda, which is non-endemic, to explore whether IRS activities affected collection performances. Household surveys examining known risk factors for VL were conducted in June 2018. CDCLTs were placed in the corner of the bedroom overnight, whereas aspirations were standardised at a rate of 30secs/m2. Sandfly sampling, following a randomised Latin Square design balanced for carry-over effects (4 x 12 x 12 = 576 collections - much greater than 498 required), commenced in June 2018 and finished in September 2018. Following collection, all samples were stored in RNA-later and placed in a freezer until molecular analysis performed. In total, 7154 sandflies were caught during the 576 collections; 3682 were female (51.5%) and 3472 were male (48.5%)</p> <p>Statistical analyses were performed. Various models were tested and compared on fit but all yielded the same result that CDC light traps collected more female <i>P. argentipes</i> than the other two trap methods (<math>p &lt; 0.0001</math> after adjusting for month of collection and clustering at the household level)</p>	<ul style="list-style-type: none"> <li>◆ the anterior end (stomodeal valve and head) will be retained for the metacyclic-specific qPCR, that uses RNA extractions. Single sandflies from positive pools will be re-analysed for infectious rates using the metacyclic-specific PCR; and</li> <li>◆ the human bloodmeal index will be calculated for all blood-fed sandflies. Using the infectious rate, and human bloodmeal index, it will then be possible to determine the Entomological Inoculation Rate (EIR) for the first time in sandflies. The EIR has been used as a proxy of human infections in malaria and lymphatic filariasis</li> </ul>	
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	<p>In order to address logistical constraints of CDC LTs, MVAs and PKPs in a field setting, 24 additional collections were performed (8 replicates/trap type) in February 2019. The total time required to carry out collections for each method was recorded to the nearest minute for each household. Additionally, the total time required to sort the samples in each collection pot according to the protocols implemented during the trapping comparison study was recorded to the nearest second. Another important factor to take in to account when selecting an appropriate collection technique for xenomonitoring, particularly when subsequent molecular techniques based on RNA are concerned, is whether parasite RNA is preserved during collection and subsequent transportation prior to storage at -80 degrees C</p>	<p>1. Xenomonitoring project</p> <p>CDC light traps were placed indoors overnight to capture <i>P. argentipes</i> bimonthly in each household. The estimated number of <i>Phlebotomus</i> female sandflies required to detect a significant difference in infectious rate between programme and non-programme villages is 3,745. So far, seven replicates/rounds of collections have been completed for each village, between June-November 2019, and over 2,000 female <i>Phlebotomus</i> sandflies have been collected. All were stored in alcohol at -80 degrees C, at RMRI, in preparation for the molecular analyses described above</p>	
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	<p>To simulate the conditions that infectious sandflies would experience during the different collection methods, sandflies were infected with Leishmania donovani, high and low infection rates, and killed 8 days post-infection</p> <p>Since CDC LTs captured more P. argentipes females, were logistically more feasible for field use, and RNA preservation was not compromised, they were the method of collection selected for the main xenomonitoring study</p> <p><b>Xenomonitoring project</b></p> <p>Household recruitment for the main xenomonitoring project has been completed, and sandfly sampling commenced in June 2019 following a standardized protocol. In total, 120HH have been recruited in 12 villages (6 endemic, 6 non-endemic)</p> <p><b>Surveillance project Objectives</b></p> <p>Develop a surveillance system integrated in the existing PHC system for:</p> <ul style="list-style-type: none"> <li>◆ monitoring of VL transmission</li> <li>◆ monitoring of PKDL incidence</li> <li>◆ monitoring of VL-HIV co-infection</li> <li>◆ develop and pilot a system of improved contact tracing and micro-planning</li> <li>◆ monitor the accuracy of the diagnostic algorithm as VL incidence decreases.</li> </ul>	<p>1. Surveillance project</p> <p>Home visits started in two blocks, Kanti and Dariapur, both in Bihar. By June 27, 2019, 102 former VL patients and 5 new VL patients were interviewed and visited. 750 household members were enumerated (102 (ex)VL patients + 648 household contacts). 549 household contacts and 102 ex-VL patients were screened. One new VL case and three PKDL suspects were identified. Home visits also started in Baira, UP. A total of 1,473 household contacts were screened by 30 September, 2019</p> <p><b>Modelling</b></p> <p>A flexible framework for ordinary differential equation, stochastic and individual-based VL transmission models has been written, which incorporates variable diagnosis rates and dose-dependent transmission, but needs extending to incorporate age-dependence and spatial heterogeneity before publication</p>	
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	<p><b>Modelling</b></p> <p>A framework for spatiotemporal prediction of block-level VL incidence has been developed using the surveillance R package</p> <p>This framework has been applied to historical data from Jharkhand 2009-14 and up-to-date data (2013-June 2018) from the KAMIS case database to predict future block-level VL incidence</p> <p>Two reports on these analyses have been circulated to all stakeholders in July and November 2018 and the results presented at several meetings</p> <p><b>Health Systems</b></p> <p>Workshops and training on the data collection tool</p> <p>A total of 18 interview guides have been developed to conduct in-depth interviews of 17 types of healthcare staff who play a role in service delivery, diagnostics, health-care information, governance and medicine availability for leishmaniasis.</p> <p>One interview guide has specifically been developed to conduct FGD with community. These guides will provide insights into strengths and weaknesses of the health system, in relation to leishmaniasis. The partner organizations have provided timely feedback, piloted the tools to refine them and translated them into the local languages</p>	<p>A simulation version of the model is being developed with which it will be possible to predict the impact of spatially targeted interventions</p> <p><b>Health systems</b></p> <p>A Research Consultant, with a PhD in Social Medicine and Community Health and experience of working in Jharkhand, was appointed to conduct UNION activities in Jharkhand. Ethics approval, in addition to that obtained by IPH, has been obtained from the UNION's ethics advisory board. Training for UNION was scheduled at the end of October 2019. A workshop was planned in November to discuss and finalise the health system assessment framework and analysis plan with all partners by the end of November 2019. This is ongoing</p> <p>PATH, who will be using the tool in Uttar Pradesh, are awaiting ethical approval</p>	
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Two separate quantitative tools have been developed to collect health system related data at block and healthcare facility level; this includes public as well as private facilities

A training manual was developed and translated into local languages by partners. This manual, available in English and Hindi, has been shared with data collectors. Separate modules, a survey checklist (and Secondary Data Extraction Sheet have also been developed in Hindi

The research team at IPH visited RMRI-Patna (11th-13th September 2019) and ran a workshop to train RMRI and CARE staff on how to use the data collection tool. The data collection tool has since been initiated by RMRI in Bihar and CARE in West Bengal. RMRI staff visited Parsa, Saran District, with the IPH team to collect data using the structured questionnaires and visited Chapra district hospital to observe operational aspects relevant to VL





<p>Institute of Postgraduate Medical Education and Research, Kolkata + School of Tropical Medicine, Kolkata</p>	<ol style="list-style-type: none"> <li>1. Diagnosis of PKDL in terms of quantification of parasite DNA</li> <li>2. Development of 'Points of cure' tools for monitoring the effectiveness of treatment in PKDL</li> <li>4. Correlation of immunological and clinical determinants of PKDL to identify potential surrogate markers in PKDL</li> <li>6. Studying the immunopathology of polymorphic vs. macular PKDL</li> <li>7. Altered disease profile of PKDL in West Bengal</li> </ol>	<ol style="list-style-type: none"> <li>1. Diagnosis of PKDL in terms of quantification of parasite DNA</li> <li>2. Development of 'Points of cure' tools for monitoring the effectiveness of treatment in PKDL</li> <li>3. Studying the health seeking behaviour of PKDL cases</li> <li>4. Correlation of immunological and clinical determinants of PKDL to identify potential surrogate markers in PKDL</li> <li>5. Studying the immunopathology of polymorphic vs. macular PKDL for developing chemotherapeutics</li> <li>6. Comparison of molecular pathology of PKDL vs. other forms of dermal Leishmaniasis e.g. Sri Lanka and Brazil</li> </ol>	<p>Pharmacokinetics of antileishmanial drugs using non-invasive microdialysis methods for measuring the drug concentrations of drugs at lesional sites in PKDL</p> <p><b>Prospective of vaccines for:</b></p> <ul style="list-style-type: none"> <li>◆ preventing reduce the infectiousness of infected individuals towards sand flies;</li> <li>◆ reduce risk of developing symptoms after infection;</li> <li>◆ reduce the risk of developing post-kala-azar dermal leishmaniasis (PKDL);</li> <li>◆ Studying the immunological determinants for development of VL to PKDL; and</li> <li>◆ animal model representative of PKDL</li> </ul>
<p><b>VCRC</b></p>			





