Ministry of Health & Family Welfare
Government of India

World Health Organization
COUNTRY OFFICE FOR India

Accelerated Plan for **Kala-azar** Elimination 2017

Directorate
National Vector Borne Disease Control Programme

Accelerated Plan for **Kala-azar** Elimination 2017

Directorate
National Vector Borne Disease
Control Programme

Table of Contents

Preamble

The leishmaniases are a group of diseases caused by protozoan parasites from >20 Leishmania species that are transmitted to humans by the bite of infected female phlebotomine sandflies.

There are 4 main forms of the disease: visceral leishmaniasis (VL, also known as kala-azar); Post-Kala-azar Dermal Leishmaniasis (PKDL); Cutaneous Leishmaniasis (CL); and Mucocutaneous leishmaniasis (MCL). While cutaneous leishmaniasis is the most common form of the disease, visceral leishmaniasis or kala-azar is the most serious form and can be fatal if untreated.

In 2012, global estimates[1] of incidence of leishmaniasis from 102 countries were published with 58,227 reported VL cases per year with estimated annual VL incidence of 202,200 to 389,100.

Visceral Leishmaniasis (VL) or Kala-azar (KA) is a parasitic disease with anthroponotic (confined to human only, no animal reservoir) infection in Asian continent. It is a fatal in over 95% patients if it remains untreated. The disease is endemic in the Indian subcontinent in 119 districts in four countries namely Bangladesh, Bhutan, India and Nepal. India is one of the 6 countries which share 90% of global burden of VL: Brazil, Ethiopia, India, Somalia, South Sudan and Sudan. Though KA is one of the most dangerous neglected tropical diseases (NTDs), it is amenable to elimination as a public health problem in South- East Asia Region of WHO. Favourable factors for Kala-azar Elimination are: man is the only reservoir, only one species of sandfly *(Phlebotomus argentipes)* is the vector, availability of rapid diagnostic tests and new and effective treatments are available for use in the programme. The Limited geographical distribution of the disease to 119 Districts and above all there is high political commitment.

VL is endemic in 54 districts in India. Focused activities towards Kala-azar control were intensified in 1990-91, with limited options for prevention and control of the disease. Long treatment schedule with injection Sodium stibogluconate and Indoor Residual Spray (IRS) with DDT 50% were the mainstay of activities. Over a period of time, resistance to the only drug (injection Sodium stibogluconate) led to frequent outbreaks and fatalities.

Memorandum of Understanding signed among Bangladesh, India, Nepal, Bhutan and Thailand calls for elimination of VL from the South-East Asia Region by 2017 or before. The criterion of elimination is attainment of annual incidence of KA to less than one per 10,000 population at upazilla level in Bangladesh, sub-district (block PHC) level in India and district in Bhutan and Nepal.

Since 2003, KA programme activities have been subsumed under the umbrella of National Vector Borne Disease Control Programme (NVBDCP). All the programme activities and operational cost, with 100% central assistance, are being implemented. 'Health Care' being a State subject, endemic states are implementing programme activities through the State Health system under the National Health Mission.

[1]Alvar J et al. Leishmaniasis worldwide and global estimates of its incidence. PLoS One, 2012. 7(5):e35671.

KA elimination activities have received impetus in recent years. Activities and human resources like State and district vector-borne consultants and kala-azar treatment supervisors (KTS) in endemic blocks are being supported from Central domestic budget. Partner organizations are also supporting the efforts of the programme at central, state and district levels with human resource, material and equipment towards elimination.

New technology and advances in diagnosis and treatment like availability of easy to use rapid diagnostic test and availability of effective drugs (Liposomal Amphotericin B) have renewed interest in elimination of KA. Global focus has also been reinvigorated for neglected tropical diseases including Leishmaniasis. The London Declaration in 2012 and World Health Assembly Resolution in 2013 provide opportunities to accelerate the activities towards reducing the impact of neglected tropical diseases and to develop new partnerships.

New Central government after taking over the charge took into cognizance the importance of KA elimination and India's commitment as reflected in National Health Policy, constituted a 'Core Group' at the Ministry of Health & Family Welfare level for guidance and oversight of the progress towards elimination. The accelerated plan and roadmap document is developed for focused efforts at national, state, district and sub-district level. Presently, resources are available, multiple partners are providing support, easy to use diagnostic tests are available, there is drug donation through WHO inter alia high political commitment at all levels. Programme is striving for achieving KA elimination by the target date.

Acronyms

ADR	Adverse drug reaction
AMC	Adverse Drug Reaction Monitoring Centers
ANM	Auxiliary Nurse cum Midwife
ASHA	Accredited Social Health Activist
AWW	Anganwadi worker
BMGF	Bill & Melinda Gates Foundation
BTAST	Bihar Technical Assistance Support Team
CARE	Cooperative for Assistanceand Relief Everywhere
CMHO	Chief Medical and Health Officer
DDT	Dichloro Diphenyl Trichloroethane
DEO	Data Entry Operator
DFID	Department for International Development Foreign Investment and Development
DNDi	Drugs for Neglected Diseases initiative
EDCT	Early Diagnosis and Complete Treatment
ED	Executive Director
HCP	Healthcare Professionals
HIV	Human Immunodeficiency Virus
H-t-h	House to house
ICMR	Indian Council of Medical Research
IDSP	Integrated Disease Surveillance Programme
IEC	Information, Education and Communication
IPC	Indian Pharmacopoeia Commission
IRS	Indoor Residual Spray
ISC	Indian subcontinent
IVM	Integrated Vector Management
KA	Kala-azar

KTS	Kala-azar Technical Supervisor
LAMB	Liposomal Amphotericin B
LD bodies	Leishmania Donovan bodies
MD	Mission Director
MOHFW	Ministry of Health and Family Welfare
MoU	Memorandum of Understanding
MSF	Medecins Sans Frontieres
NCC	National Coordination Center
NCDC	National Centre for Disease Control
NHM	National Health Mission
NRKE	National Roadmap for Kala-azar Elimination
NVBDCP	National Vector Borne Disease Control Programme
PHC	Primary Health Centre
PKDL	Post Kala-azar Dermal Leishmaniasis
Pop	Population
PV	Pharmacovigilance
PvPI	Pharmacovigilance Programme of India
RBSK	Rogi Bal Suraksha Karyakram
RMRI	Rajendra Memorial Research Institute
RDT	Rapid Diagnostic Test
RTAG	Regional Technical Advisory Group
SEAR	South-East Asian region
SHS	State Health Society
SPO	State Programme Officer
SR	Spontaneous Reporting
TSR	Targeted Spontaneous Reporting
VBD	Vector Borne Diseases
VL	Visceral Leishmaniasis
WHO	World Health Organization

Executive Summary

Visceral Leishmaniasis is amenable to elimination in South-East Asia Region of WHO. Memorandum of understanding signed by Bangladesh, Bhutan, India, Nepal and Thailand targets KA elimination by 2017 or before, whichever is earlier.

In recent times, kala azar activities have been intensified in endemic areas. In 2014, National Roadmap for Kala-azar Elimination (NRKE) was developed with clear goal, objectives, strategies, timelines with activities and functions at appropriate level. This document was based on global, regional and local evidences and best practices available in the prevention, control and management of kala-azar disease as well as strategies for vector control. NRKE was prepared in line with National Strategic Plan of National Vector Borne Disease Control Programme for the Twelfth five-year plan period (2012-2017) and at the same time in synchronization with WHO's Regional Strategic Framework for kala-azar elimination from South-East Asia Region (2011-2015), recommendations of WHO Expert Committee on Leishmaniases and WHO Regional Technical Advisory Group of South-East Asia Region.

Roadmap provided strategic directions on reducing the delay between onset of disease and diagnosis and treatment by laying down timelines against each activity. It emphasized on early case detection and complete management (including follow up mechanisms and monitoring for adverse effects). It outlined the introduction and scaling plan of single day, single dose (10 mg/kg) Liposomal Amphotericin B in the treatment of KA. With scanty data currently available on the burden of post Kala-azar dermal leishmaniasis (PKDL), roadmap laid down surveillance needs for PKDL as well as HIV-VL co-infection.

Implementation of NRKE has resulted into significant decline in disease burden with achievement of elimination in 85% of blocks by end-2016. To intensify activities towards remaining period of 2017, an accelerated plan has been prepared. Aims of this document are two folds- to accelerate activities in remaining high burden foci and consolidate gains achieved in rest of the endemic areas.

The population at risk for Kala-azar is among the poorest in the community with limited access to health care due to various socio-economic determinants. Intensive awareness campaigns with the involvement of communities and community health volunteers will address important barriers in utilization of services.

Kala-azar elimination will require effective involvement of health personnel at all levels in the continuum of care, right from the engagement of ASHA at village level to laboratory technicians and medical officers at primary health care to specialists at district hospitals for early identification of a suspected case, and its management (including follow up).

Effective programme management is one of the most important operational aspects of success of KA elimination in India along with supervision, monitoring and surveillance components to ensure that success is not only achieved but sustained also.

Introduction

Kala-azar (KA) also called Visceral Leishmaniasis is a parasitic disease with anthroponotic (confined to human only, no animal reservoir) infection in Asian continent. It is caused by the protozoan Leishmania parasites which are transmitted by the bite of infected female Phlebotomus argentipes (sand fly). Kala-azar is characterized by irregular bouts of high fever, substantial weight loss, enlargement of the spleen and liver, and anaemia. If left untreated, the disease can have a fatality rate as high as 100% within two years.

Kala-azar has been a serious medical and public health problem in some part of India since historical times. Bengal is the oldest known kala-azar endemic area of the world. After the initial success, kala-azar resurged in 70s. Concerned with the increasing problem of kala-azar in the country, the Government of India (GOI) launched a centrally sponsored Kala-azar Control Programme in the endemic states in 1990-91. GoI provided drugs, insecticides and technical support and state governments provided costs involved in implementation. The program was implemented through State/District Malaria Control Offices and the primary health care which brought a significant decline in kala-azar mortality and morbidity, but could not sustain the pace of decline for long.

The National Health Policy-2002 set the goal of kala-azar elimination in India. With focused activities and high political commitment, India signed a Tripartite Memorandum of Understanding (MoU) with Bangladesh and Nepal to achieve Kala-azar elimination from the South-East Asia Region (SEAR). Elimination is defined as reducing the annual incidence of Kala-azar to less than 1 case per 10,000 population at the sub-district (block PHCs) level in Bangladesh and India and at the district level in Nepal.

Transmission in Indian sub-continent generally occurs in rural areas with a heavy annual rainfall, with a mean humidity above 70%, a temperature range of 15–38 °C, abundant vegetation, subsoil water and alluvial soil. The disease is most common in agricultural villages where houses are frequently constructed with mud walls and earthen floors, and cattle and other livestock live close to humans.

Presently all programmatic activities are being implemented through the National Vector Borne Disease Control Programme (NVBDCP) which is an umbrella programme for prevention & control of vector borne diseases and is subsumed under National Health Mission (NHM).

1. The Global Scenario

The leishmaniasis is endemic in ninty-seven countries and territories and 4 countries have previously reported cases. Over 616 million population lives in endemic areas at risk of infection. The global estimate is 300,000 cases annually with over 20,000 deaths each year. In 2015, almost 90% (88.8%) of global VL cases were reported from six countries: Brazil, Ethiopia, India, Somalia South Sudan and Sudan[2]. VL burden in 14 high endemic countries sharing 95% of VL burden reported annual incidence of 30, 758 cases.

There are currently no accurate data on the burden of Post Kala-azar Dermal Leishmaniasis (PKDL). VL–HIV co-infection has also emerged as a serious concern and is reported from 36 countries. There is a strong need to establish surveillance for both the conditions.

1.1 South-East Asia Region (SEAR)

An estimated 147 million people in 119 districts in 4 countries, namely Bangladesh, Bhutan, India and Nepal, are at risk with an estimated 100,000 new cases each year. There is an estimated 400 000 DALYs lost per year. Of the 30,758 VL cases reported from 14 high endemic VL countries for 2014 data, 10,331 (34%) were contributed from the three countries- Bangladesh, Nepal and India from Indian Subcontinent (ISC)[3].

The proportion of unreported cases is yet to be established but estimates range from 0.2 to 4 times of the reported cases.

As per WHO NTD roadmap, kala-azar is slated for elimination in south-East Asia Region. The elimination of kala-azar as a public health problem is defined as annual incidence of less than one case per 10,000 population at upazilla level (Bangladesh), block (India) and district (Nepal). There has been a significant achievement in kala-azar elimination in south-east Asia region that 81% of administrative units (595 out of total 722) have achieved elimination.

1.2 India

Kala-azar is presently endemic in 54 districts in the country of which 33 districts of Bihar, 4 districts of Jharkhand, 11 districts of West Bengal besides occurrence of cases in 6 districts of eastern Uttar Pradesh. Sporadic cases are also reported from Assam, Himanchal Pradesh, Kerala, Madhya Pradesh, Sikkim and Uttarakhand. Imported cases have been reported from Delhi, Gujarat and Punjab. The state of Bihar alone contributes >70% of total KA reported from the four states. There has been significant decline in disease burden from the peak of 80,000 cases in 1992 to less than 9,000 in 2015. Since 2011, the cases have declined by 74%. Mortality has also reduced from 90 deaths in 2011 to 5 in 2015with nil deaths in 2016.

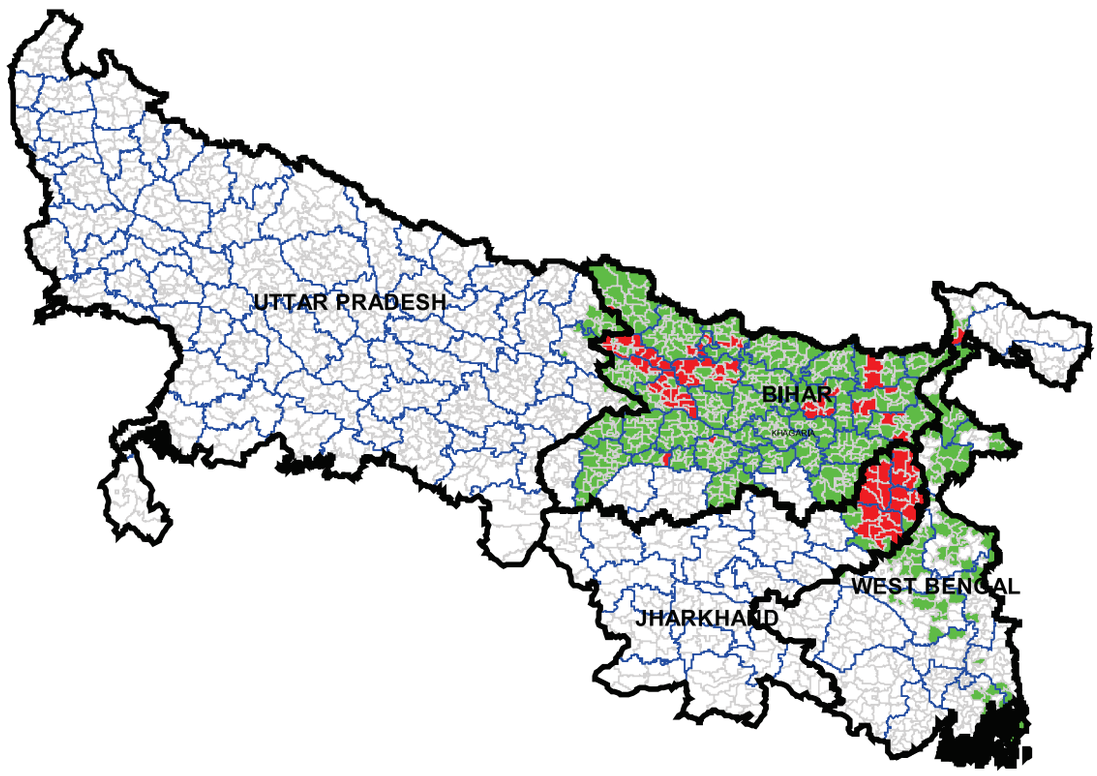
[2]http://www.who.int/gho/neglected_diseases/leishmaniasis/en/, accessed on 8 January 2017
[3]http://www.who.int/wer, No 22, 2016, 91, 285-296, 3 June 2016

Epidemiological information on profile of VL & PKDL cases in 4 States.

PROFILE OF VL & PKDL CASES 2016								
Particulars	**Jharkhand**		**West Bengal**		**Uttar Pradesh**		**Bihar**	
	VL	PKDL	VL	PKDL	VL	PKDL	VL	PKDL
Female proportion	40%	43%	39.7%	40.8%	40%	50%	43%	NA
<15 year (Child proportion)	35%	29%	25%	18%	37%	0	39%	NA

Source: analysis of line list

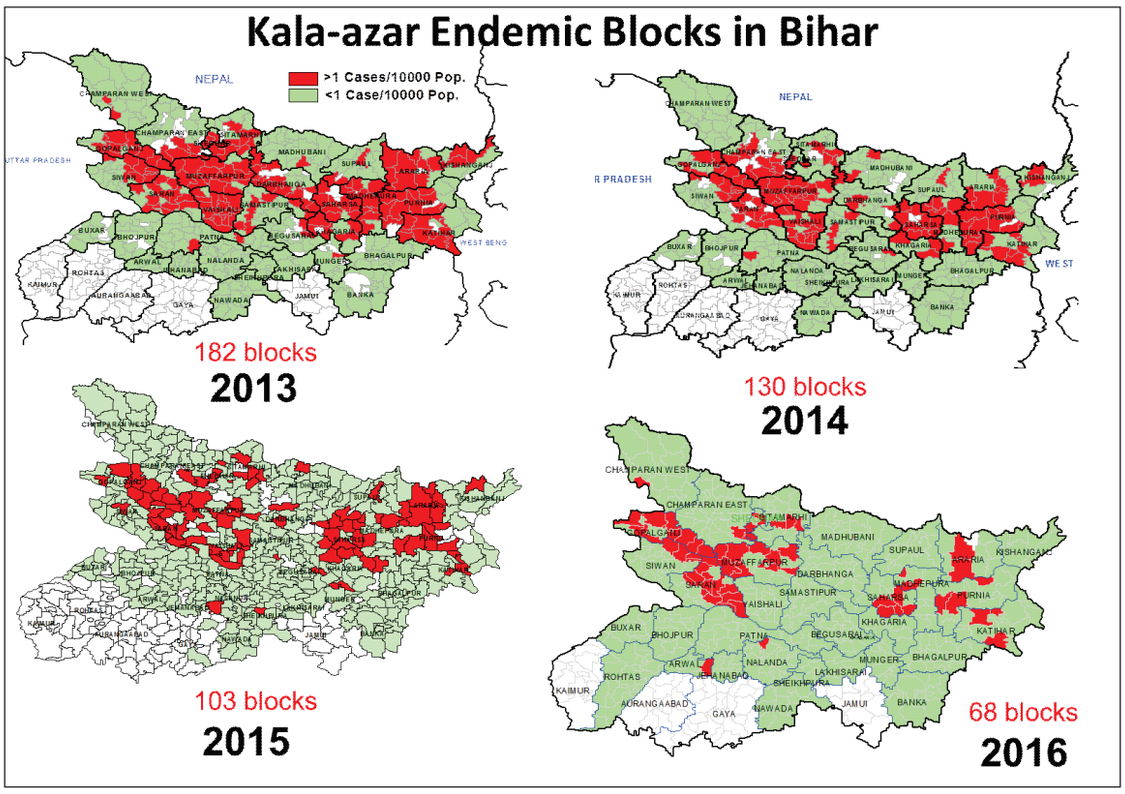
Status of kala-azar incidence rate in the state of Bihar, Jharkhand, Uttar Pradesh and West Bengal (as on November 2016)



1.2.1 Bihar

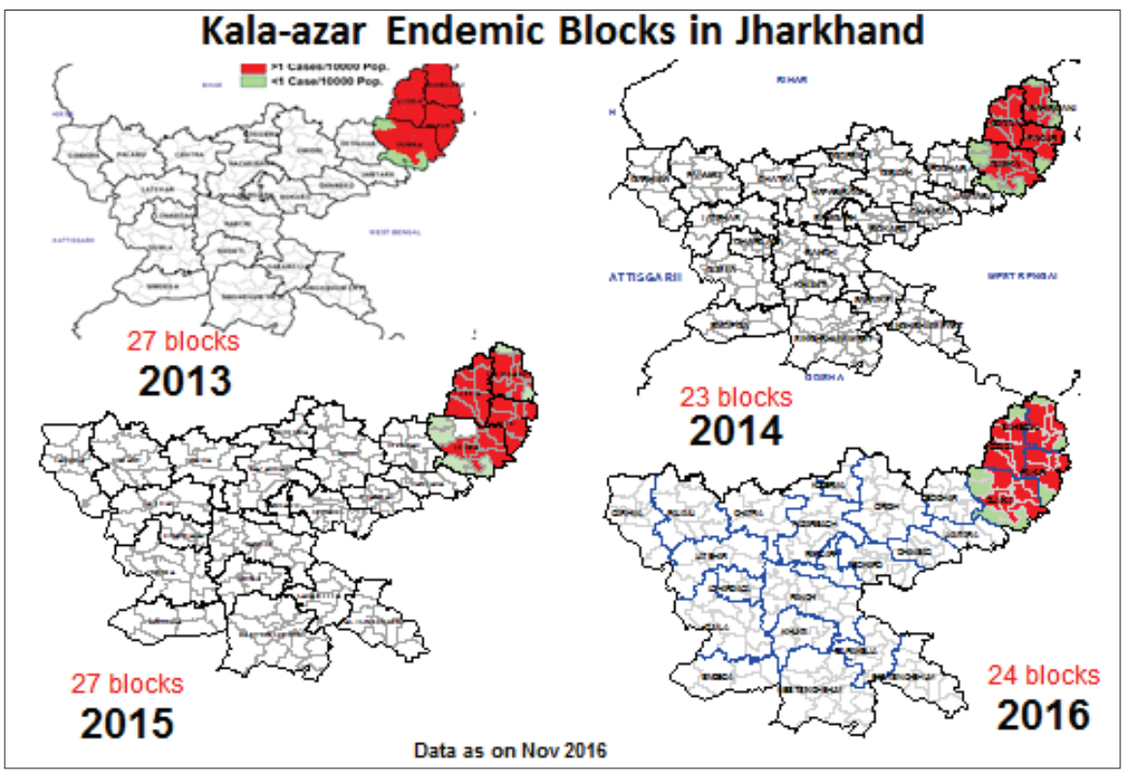
Of the 38 districts of Bihar, 33 are affected. The population at risk is 99 million, in approximately 12,000 villages spread over 458 blocks. 86% of these blocks have achieved level of elimination by end-2016.

10 districts out of 33 affected detect 200 or more cases annually and contribute to about 73% cases of the state. These are Araria, East Champaran, Goplaganj, Muzaffarpur, Purnia, Saharsa, Siwan, Saran, Sitamarhi & Darbhanga.



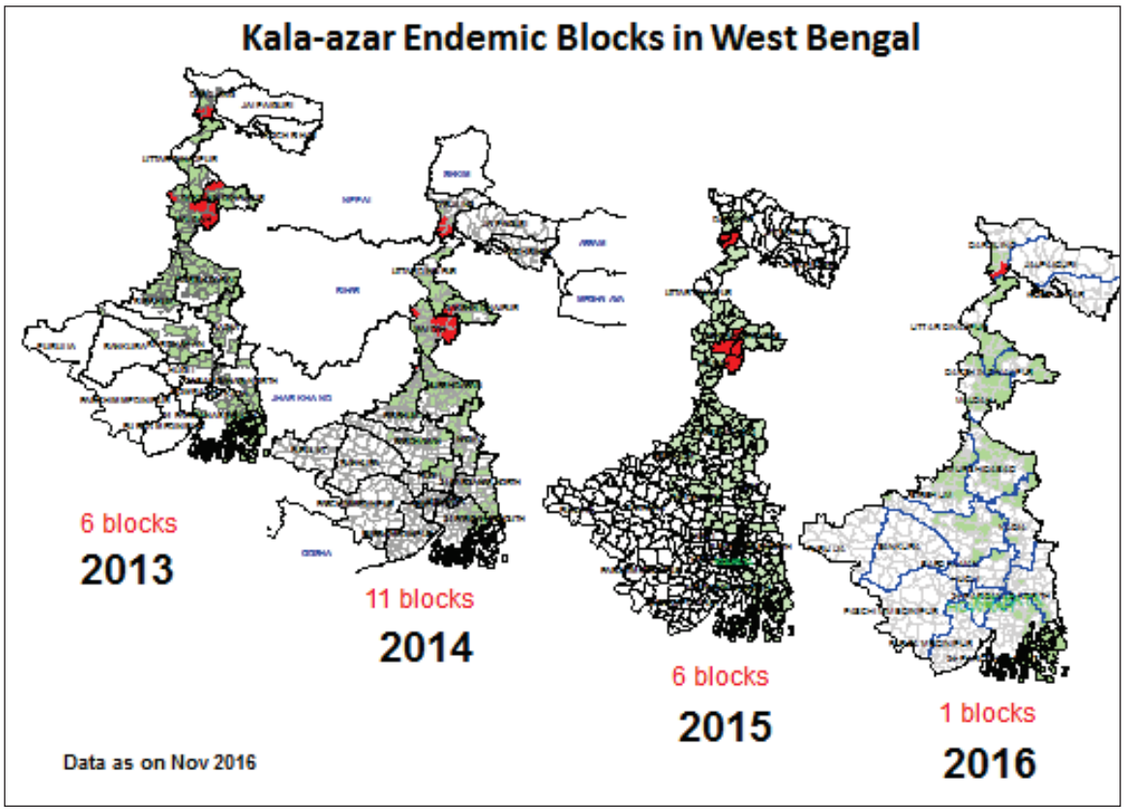
1.2.2 Jharkhand

Out of 24 districts 4 districts namely, Dumka, Godda, Pakur and Sahibganj are endemic for Kala-azar. The population at risk is 5.7 million, approximately 1,336 villages with Kala-azar cases are spread over 33 blocks. Only 27% blocks have achieved elimination.



1.2.3 West Bengal

Out of 20 districts 11 districts namely, Malda, Murshidabad, Darjeeling, 24-Parganas(North), 24-Parganas(South), Nadia, Hooghly, Burdwan, Uttar Dinajpur , Dakshin Dinajpur and Birbhum are endemic for Kala-azar. The population at risk is 28.18 million, in approximately 731 villages spread over 120 blocks. 99% blocks have achieved level of elimination.



1.2.4 Uttar Pradesh

Out of 75 districts, 9 districts in eastern part of the State namely Balia, Deoria, Ghazipur, Gorakhpur, Kushinagar, Jaunpur, Sant Ravidas Nagar, Sultanpur and Varanasi are reporting cases of Kala-azar. The number of cases reported during 2013 was 11 which increased to 131 in 2015 due to increased surveillance. In 2016, 22 blocks across 9 districts reported 107 cases. The population at risk in these blocks is 4.82 million. All the blocks have reached level of elimination.

2. Accelerated Plan for Kala-azar Elimination

2.1 Diagnosis of Kala-azar

Clinical description

An illness with prolonged irregular fever, splenomegaly and weight loss as its main symptoms. In endemic malarious areas, visceral leishmaniasis should be suspected when fever lasts for more than 2 weeks and no response has been achieved with antimalarial medicines (assuming that drug-resistant malaria has also been considered).

Laboratory criteria for diagnosis

- positive parasitology (stained smears from bone marrow, spleen, liver, lymph node, blood or culture of the organism from a biopsy or aspirated material); and
- positive serology (IFAT, ELISA, rK39, direct agglutination test)
- positive PCR and related techniques

Case classification by WHO operational definition

A. A case of visceral leishmaniasis is a person showing clinical signs (mainly prolonged irregular fever, splenomegaly and weight loss) with serological and/or parasitological confirmation.

B. Post-kala-azar dermal leishmaniasis (PKDL) 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. PKDL can be confused with pauci or multibacillary leprosy. The skin lesions may also mimic other skin conditions.

Suspect

A 'kala-azar suspect' case: history of fever of more than 2 weeks and enlarged spleen and liver not responding to anti malaria in a patient from an endemic area.

- All kala-azar suspects should be screened using a standard, quality-assured rapid diagnostic test (RDT) based on the rK39 antigen at the primary health centre (PHC)/ CHC (block) level and if found positive should be treated with an effective drug.

- In cases with past history of Kala-azar or in those with high suspicion of Kala-azar but with negative RDT test result, confirmation of Kala-azar can be done by examination of bone marrow/spleen aspirate for LD bodies at appropriate level (district hospital) equipped with such skills and facilities.

Case

A case of KA is defined as: a person from an endemic area with fever of more than two weeks duration and with splenomegaly, who is confirmed by an RDT or a biopsy.

Probable PKDL

A patient from an area endemic for kala-azar with multiple hypopigmented macules, papules or plaques or nodules with no sensitivity loss and positive with rk39

Confirmed PKDL

A patient from an area endemic for kala-azar with multiple hypopigmented macules, papules, plaques or nodules who are parasite or PCR-positive in a slit skin smear or biopsy.

Cutaneous leishmaniasis

Clinical description

Appearance of one or more lesions, typically on uncovered parts of the body. The face, neck, arms and legs are the commonest sites. At the site of inoculation, a nodule appears, which may enlarge to become an indolent ulcer. The sore remains in this stage for a variable time before healing and typically leaves a depressed scar. Other atypical forms may occur. In some individuals, certain strains can disseminate and cause mucosal lesions. These sequelae involve nasopharyngeal tissues and can be disfiguring.

Laboratory criteria for diagnosis

- positive parasitology (stained smear or culture from the lesion)
- mucocutaneous leishmaniasis only: positive serology (IFAT, ELISA)

Case classification by WHO operational definition

A case of cutaneous leishmaniasis is a person showing clinical signs (skin or mucosal lesions) with parasitological confirmation of the diagnosis (positive smear or culture) and/or, for mucocutaneous leishmaniasis only, serological diagnosis.

2.2 Treatment of Kala-azar

Recommended treatment regimens for visceral leishmaniasis, ranked by preference1
Anthroponotic visceral leishmaniasis caused by L. donovani approved in India

1. Liposomal amphotericin B:

   10 mg/kg as a single dose by infusion (A)

2. Combinations (co-administered) (A)

   • miltefosine plus paromomycin, both daily for 10 days, as below

1. Amphotericin B deoxycholate:

   0.75–1.0 mg/kg per day by infusion, daily or on alternate days for 15–20 doses (A)

2. Miltefosine:

   for children aged 2–11 years, 2.5 mg/kg per day;
   for people aged > 12 years and < 25 kg body weight, 50 mg/day; 25–50 kg body weight, 100 mg/day; > 50 kg body weight, 150 mg/day; orally for 28 days (A) or

3. Pentavalent antimonials: 20 mg Sb5+/kg per day intramuscularly or intravenously for 30 days in areas where they remain effective: in the Indian states of Jharkhand, West Bengal and Uttar Pradesh (A)

Rescue treatment in case of non-response: conventional amphotericin B deoxycholate infusions or liposomal amphotericin B at higher doses

Post-kala-azar dermal leishmaniasis (India

1. Miltefosine orally for 12 weeks at dosage as above (A)

2. Amphotericin B deoxycholate: 1 mg/kg per day by infusion, up to 60–80 doses over 4 months (C)

HIV – VL co infection: LAmB 40 mg/kg b.w as total dose of 3-5 mg/kg bw daily or intermittently for 10 doses, days 1-5,10,17,24, 31 and 38.

*Standard grades adopted from Cochrane reviews.

- A – evidence obtained from at least one properly designed randomized controlled trial;
- B – evidence obtained from well-designed trials without randomization;
- C –evidence obtained from opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees; and
- D –evidence obtained from expert opinion without consistent or conclusive studies.

Treatment outcomes in KA treatment

Treatment outcomes in KA have to be assessed twice: (i) at the last day of drug treatment (initial outcome) and (ii) six months after the last drug was taken (final outcome). The KA elimination initiative has trained health workers to distinguish four main outcomes in KA treatment

Treatment outcomes in KA

1. Cure: a patient is considered clinically cured if he/she has completed full treatment and there are no signs and symptoms of KA

2. Non-response: signs and symptoms persist or recur despite satisfactory treatment for more than two weeks

3. Relapse: any reappearance of KA signs and symptoms within a period of six months after the end of treatment

4. Treatment failure: non-response or relapse

Incubation period: The incubation period ranges from 10 days to over 1 year (average incubation period is 2-4 months)[4]

Peak age of incidence: Early childhood and young adults (in areas where HIV prevalence is high age incidence shifts towards adults) (median age, 13-23 years in various sites in Asia and Africa). In many countries more males than females are reported.[5]

Population at risk: Estimated population of block in 2016 will be based on 2011 census data and growth rate of the district. [Link for Block wise population as per census 2011: http://censusindia.gov.in/pca/cdb_pca_census/cd_block.html

Link for age wise population as per census 2011:
http://www.censusindia.gov.in/2011census/C-series/C-13.html]

2.3 The elimination strategy

The national strategy for elimination of Kala-azar is a multipronged approach which is in line with WHO Regional Strategic Framework for elimination of Kala-azar from the South-East Asia Region (2011-2015) and includes:

i. Early case detection & complete case management
ii. Integrated Vector Management and Vector Surveillance
iii. Supervision, monitoring, surveillance and evaluation
iv. Strengthening capacity of human resource in health
v. Advocacy, communication and social mobilization for behavioral impact and inter-sectoral convergence
vi. Programme management

a. Goal

To improve the health status of vulnerable groups and at-risk population living in Kala-azar endemic areas by the elimination of Kala-azar so that it no longer remains a public health problem.

[4]Control of the leishmaniasis, WHO, Technical Report Series, 949, Page 5
[5]Control of the leishmaniasis, WHO, Technical Report Series, 949, Page 5

b. Target

To reduce the annual incidence of Kala-azar to less than one case per 10,000 populations at block level.

c. Objective

To reduce the annual incidence of Kala-azar to less than one per 10 000 population at block PHC level by the end of 2015 as per NHP 2002* by:

- reducing Kala-azar in the vulnerable, poor and unreached populations in endemic areas;
- reducing case-fatality rates from Kala-azar to negligible level;
- reducing cases of PKDL to interrupt transmission of Kala-azar; and
- preventing the emergence of Kala-azar and HIV/TB co-infections in endemic areas.

[*MOU signed between Bangladesh, Nepal, India with inclusion of Bhutan and Thailand calls for elimination in South-east Asia Region by 2017 or before, whichever is earlier]

2.4 Formulation of accelerated plan for Kala-azar elimination

As per National Health Policy KA was slated for elimination by 2010, which was revised for period from 2011 to 2015. During 2014 Health Ministers of Bangladesh, Nepal, India renewed the memorandum of understanding to achieve KA elimination by 2017 or before.

To guide KA endemic states, the national roadmap was developed and launched in 2014. As per the defined activities mentioned in the roadmap there has been significant progress towards KA elimination (compare the progress). Since 80% of disease burden is now confined to 25% of blocks (geographical area), there is a scope and need for acceleration.

Accelerated plan will build upon the existing National road map and will focus on key strategic areas necessary for achieving KA elimination within defined time frame.

This document focuses on high transmission areas (blocks above elimination level) as well as areas which need consolidation.

For the purpose of acceleration towards elimination and post elimination sustenance, KA endemic areas have been stratified into 4 categories based on annual incidence.

2.4.1 Description of categories

Category 1: Blocks above elimination threshold are grouped together and here efforts have to be accelerated towards steadily achieving elimination (attack phase) Blocks above elimination threshold (annual incidence of more than or equal to 1 case per ten thousand population).

Category 2: Blocks with borderline endemicity (Annual KA incidence varying 0.8[6] to <1).

Category 3: Fluctuations- increasing or decreasing trend of disease either year to year or in a gap of few years. Fluctuation will be state specific. It will depend on population at risk and past status of endemicity. These areas are important from the point of view of KA services and surveillance

Category 4: Silent blocks- areas reporting nil cases annually. Post-elimination sustenance (maintenance phase)

These include areas of zero cases for at least two consecutive years. Generally, these areas are the ones which are not reporting cases though other adjoining blocks are still endemic. Some of the reasons could be flood affected area, hard to reach centres etc. In these areas validation of nil status is required.

Blocks other than these four categories (annual incidence between 0-0.8) should continue case detection activities and sustain surveillance.*as per Regional Kala-azar framework 2011-2015

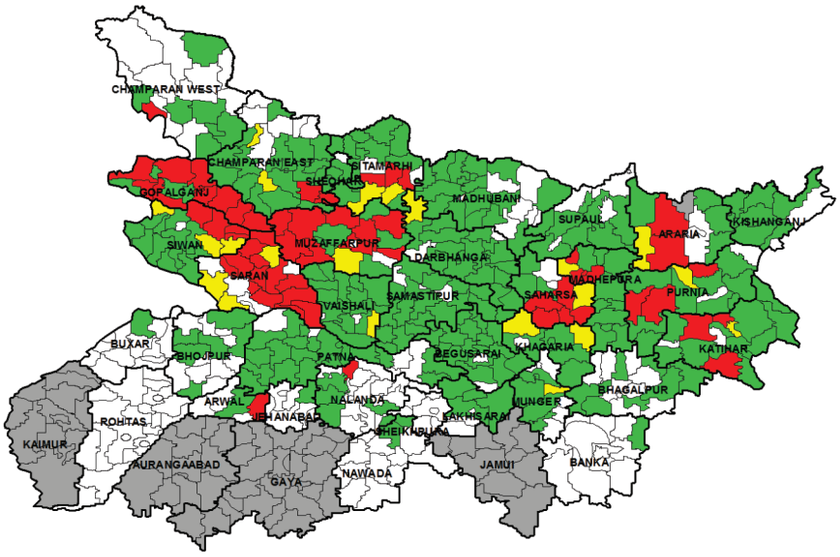
2.4.2 Rationale for categorization

Category I- These blocks are high disease transmission areas requiring intensive case detection and vector control activities to liquidate high transmission foci. Case based surveillance is needed to identify epidemiological linkage.

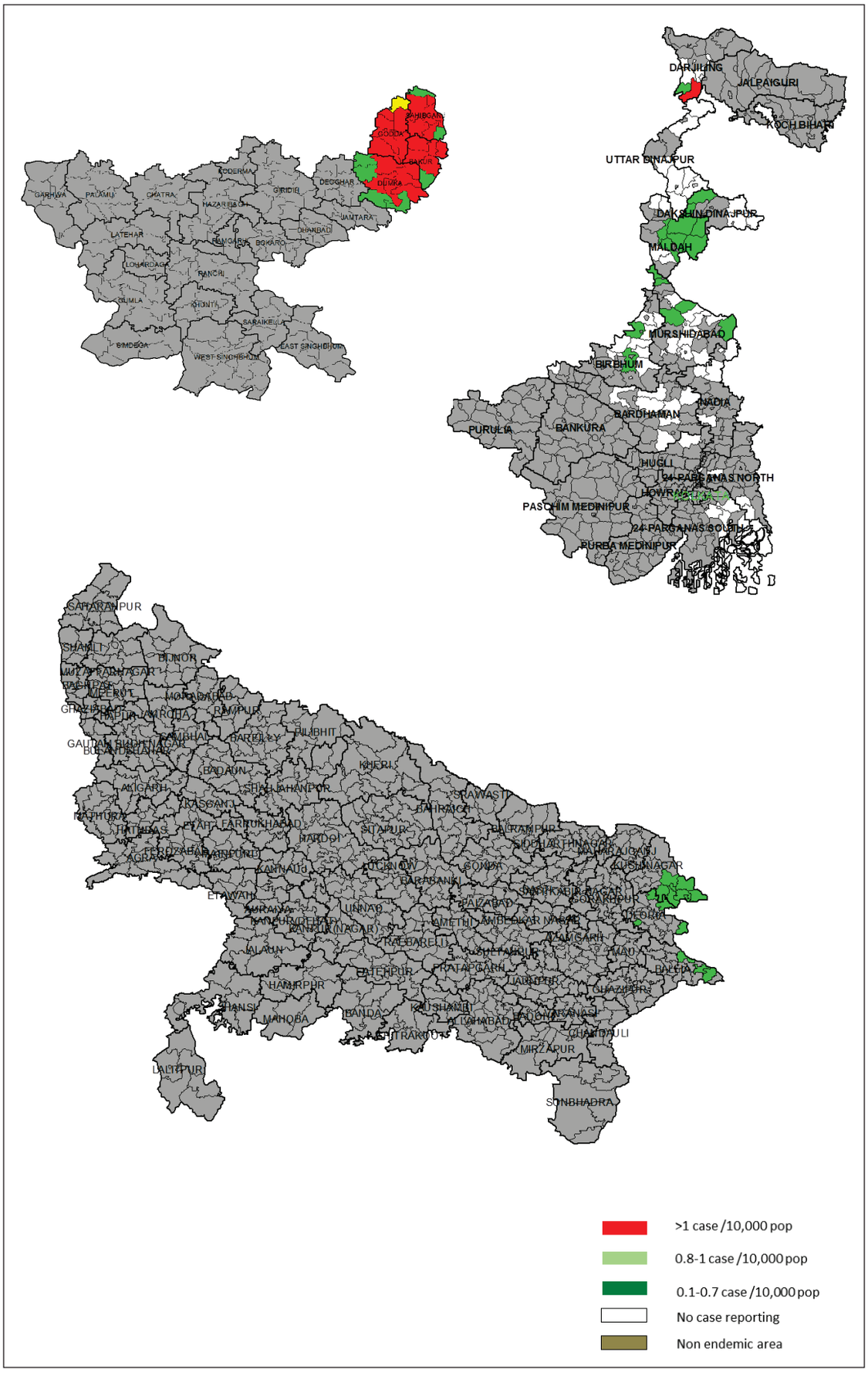
Category II- These blocks are borderline or having hidden pockets (small villages/ hamlets) within low transmission areas and require sustenance with enhanced surveillance.

Category III- Operational factors may be influencing

Category IV- KA is an outbreak prone disease therefore blocks reporting zero confirmed cases or nil suspect cases need to have robust surveillance for validation of the nil status and preparedness for detection if cases occur.



[6]This level is taken arbitrary from elimination point of view



>1 case /10,000 pop

0.8-1 case /10,000 pop

0.1-0.7 case /10,000 pop

No case reporting

Non endemic area

Status of high endemic areas (2016*)

State	Total number of endemic Districts	Total number of Blocks	Total number of cases	Number of districts with blocks >1 case/10,000 pop	Total number of blocks >1 case / 10,000 pop	Total number of villages reporting KA cases (2016)
Bihar	33	458	4773	15	68	NA
Jharkhand	4	33	1132	4	25	1336
UP	9	130	109	0	0	110
West Bengal	11	120	166	1	1	137
Total	57	741	5872	20	89	1573

*as on 31 Dec 2016

Category wise status of blocks

State	Total number of cases	Number of districts with blocks > 1 case / 10,000 pop	Category 1	Category 2	Category 3	Category 4
			Blocks >1 case / 10,000 pop	Blocks 0.8-<1 case / 10,000 pop	Fluctuating from year to year	Nil Status in last 1 year (2016)
Bihar	4496	15	68	20	261	115
Jharkhand	1132	4	25	1	7	0
UP	107	0	0	0	22	13
West Bengal	166	1	1	2	0	79

*Annual KA incidence varying 0.8 to <1

General considerations

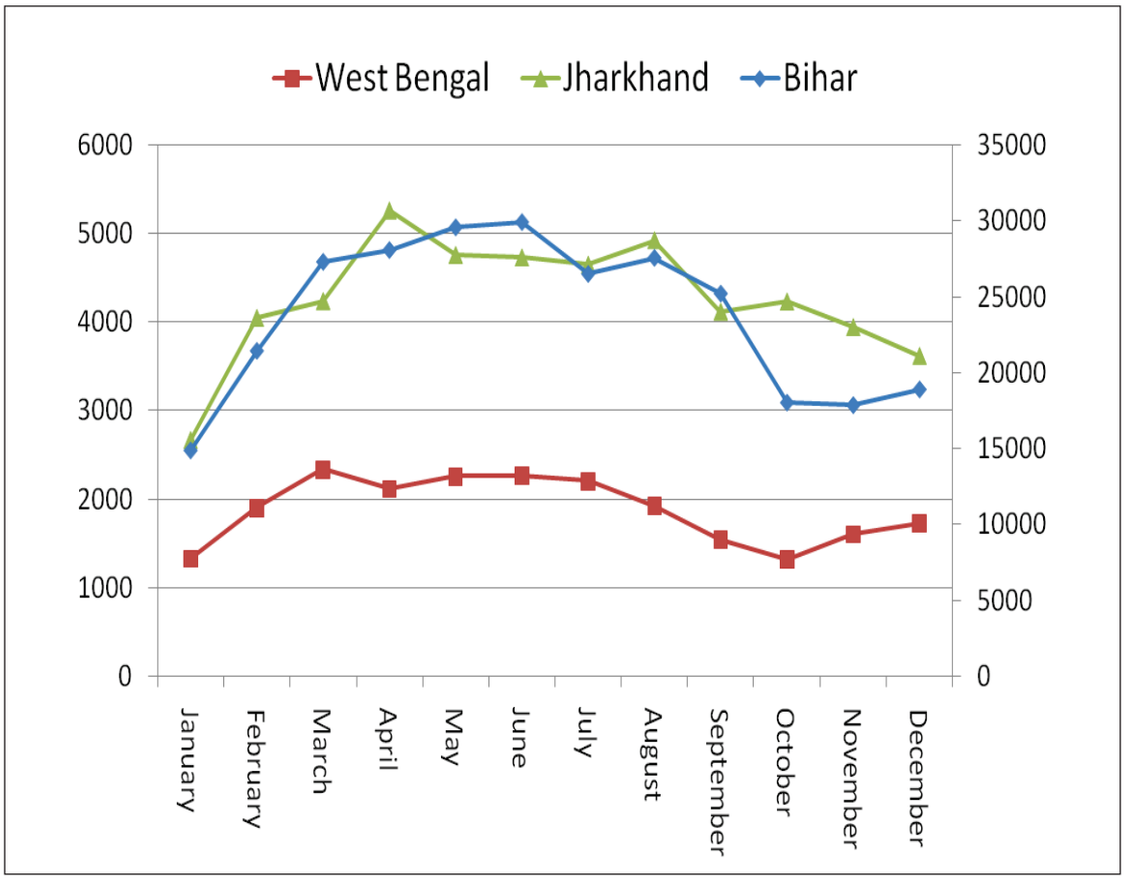
General principles of elimination strategy and challenges

2.5 Early case detection and complete case management

This is done for eliminating the human reservoir of infection through early case detection. An effective case management includes diagnosing a case early along with complete treatment and monitoring of adverse effects. This strategy will reduce case-fatality and will improve utilization of health services by people suspected to be suffering from the disease.

Peak case detection period:

Analysis of monthly case detection in the state of Bihar, Jharkhand and West Bengal from 2000-2014



2.5.1 Challenges in early case detection and complete case management

Disease complex (prolonged fever, loss of appetite, malnutrition, abdominal distention) in Kala azar affecting children and young age group make them vulnerable to frequent infections and morbidity. This results into poor mobility affecting voluntary reporting to health facilities. Hence local contextual experience calls for opting various mechanism (h-t-h, index case, camp approach) for early case detection.

Delayed diagnosis, poor health seeking behaviour, Socio cultural practices , engagement of private practitioners, faith healers are the major challenges inherent with the system. Health care provider attitudes and soft skills need to be improved to ensure maximum uptake and access of services.

Experience of house to house active case detection in Leprosy and Kala azar in the State of Jharkhand and West Bengal has shown good detection of hidden cases. This practice can be followed in other States with their available resources.

To overcome these challenges

a. House to house active case detection: Detection campaign should coincide with the period of peak case detection (between March to August) as depicted in picture of active case detection. The benefit of organizing case detection before IRS round is that newly found villages can be covered under IRS campaign.

b. Index case based: As and when a Kala azar or PKDL case is detected either actively or passively, family contacts, households, and neighborhood will be searched by Village level workers (ASHA, AWW, MPW). In case of HIV-VL/HIV-TB (harbouring high parasite load) and relapse cases co-infected patient in the village, entire village will be screened.

c. Fever camps- fever camps will be organized in most endemic (case reported) villages. Suspects identified need a clinical examination to confirm a case. Integrated Disease Surveillance Programme (IDSP) is the best platform to get the weekly fever surveillance information. Coordination mechanisms between NVBDCP and IDSP exist, but needs further strengthening at all levels. Weekly fever case information will be shared with district VBD officer and block medical officer to screen such cases for KA.

d. IRS spray squads will be oriented to ask for suspect case (as per suspect case definition) during IRS operations

e. Kala-azar fortnight- annual awareness drive in endemic areas during first fortnight of February

f. Leveraging H-t-h campaigns in other national programmes like leprosy case detection campaigns (LCDC), mass drug administration (MDA), national deworming day, VHND and Pulse Polio Programme.

g. Kala-azar largely affects children and young age group. For this vulnerable population existing mechanisms/structures will be leveraged at the village level.

a. Up to five years age group-

   i. Anganwadi workers will screen for suspects (up to 5 years age group) in anganwadi centres. She will closely follow up AWW drop outs and children on poor/delayed growth milestones (as per growth charts maintained at each centre). RBSK teams (mobile units) can also facilitate this in AWC. High risk pregnant women will also be screened

   ii. ANM will screen and follow up high risk children* during her regular visit on Village Health & Nutrition Day (VHND) and during immunization sessions. (high-risk children- a child with family history of kala-azar, a case has been detected in neighbourhood or contacts, vulnerable communities (e.g. Musahar etc)

b. School-aged children-

   i. School health programmes under RBSK will be screened. Kala-azar will be part of 4 Ds theme of RBSK- Disease, Deficiencies, Defects at birth and Developmental delays including disability. Drop-out children will be followed closely particularly KA villages.

c. Adolescent age group- adolescent age group will be screened under Adolescent Reproductive & Sexual Health Programme (ARSH)

d. Other age groups- mechanisms explained above

e. Linkages with local health providers, laboratories, tertiary care centres (medical colleges), non-governmental organizations and other centres (railways, CGHS, ESI etc) will be made for case referrals/reporting. A line list of such providers and labs will be kept at district level.

f. Cross-referrals of KA cases through NACO and TB programme will be promoted. PKDL case detection will be promoted through cross-referrals under national leprosy eradication programme (leprosy and KA is co-endemic in all 54 districts)

g. Village health sanitation committee will be sensitized about Kala-azar elimination and various provisions under the programme (free treatment, single day single dose therapy, patient incentive, ASHA incentive, IRS operation period etc)

h. Existing female self-help groups in highly endemic areas should be sensitized to recognise the signs and symptoms of KA and PKDL

Kala-azar is a notifiable condition in all four states. It will be widely disseminated and its mechanisms for private sector reporting will be developed including from the private lab networks.

Voluntary reporting and suspect referral through ASHA/AWW will be encouraged for consolidating the gains achieved and sustenance. Such mechanisms are expected to find hidden cases and will improve early case detection.

2.5.2 Post- kala azar dermal leishmaniasis (PKDL)

PKDL is considered reservoir for Kala-azar. It is more of a cosmetic condition for patients for which medical consultation is not deemed necessary by patients. Detection of PKDL is important for sustaining Kala azar elimination and also interruption of transmission in future. Since active surveillance for PKDL alone is not cost effective, there is a need to integrate detection of this condition with the existing public health programs like Leprosy control. Kala azar endemic Districts in India are also higly co-endemic for Leprosy, hence any Leprosy case detection campaign should have elements of PKDL. For routine surveillance algorithm of PKDL and Leprosy detection should be displayed in all PHC (Annexure). Additional recommendations and clarifications regarding PKDL have been made in the updated operational guidelines.

Pregnancy testing is mandatory in all females of child bearing age prior to treatment with Miltefosine. The results of the pregnancy test should be noted clearly in the patient records. Additionally, practitioners should ensure that appropriate contraceptives (depot injection which will provide 3 months coverage being first choice) have been administered/provided prior to providing any treatment with miltefosine for PKDL.

In the case where either pregnancy test or contraception cannot be guaranteed, the patient should be offered alternative treatments or treatment postponed until a time where these can be guaranteed.

In the case of pregnant or lactating women, unless there is a clinical indication (eg severe nodular PKDL) the preference should be to wait until the end of pregnancy or lactation before treatment. If treatment is indicated during pregnancy or lactation, expert advice should be sought.

Most patients on the Indian subcontinent have macular monomorphic lesions, however other common presentations are, papular or nodular lesions, with a predilection for the area around the chin and mouth. This presentation can be subdivided into different forms:

- monomorphic (macular papular or nodular)
- polymorphic or mixed (both macules and indurated lesions such as papules are present)
- rare presentations (for example, erythrodermic)

There is no standard system for grading the severity of PKDL on the Indian subcontinent. The severity may be described as:

- mild (very few lesions, usually on the face)
- moderate (lesions easily visible and generalized)
- severe (dense coverage with lesions and little normal skin remains)

2.5.3 HIV-VL coinfection

Both HIV and VL are endemic in the states with kala-zar. Co-infection with both conditions leads to poor patient outcomes, with regular relapses and high mortality. An observational study where over 2,000 consecutive patients aged ≥ 14 years presenting with VL were tested for HIV suggested a point prevalence of 5.6%.

In 2016, out of all 2,346 reported cases of VL aged ≥18 years in Bihar, 119 were co-infected with HIV-VL, suggesting an overall HIV-VL coinfection prevalence of at least 5.1% in the adult VL population of Bihar. Due to sporadic testing of HIV in VL patients (see below), this is likely to be an underestimate. It should also be noted that 4 patients with HIV-VL coinfection died, the only deaths due to VL reported in 2016. Only 3 HIV-VL cases were reported in Jharkhand.

As per the joint meeting between NVBDCP and NACO in 2014, the following recommendations were made:

- All patients presenting with VL should be tested for HIV
- All HIV patients living in VL endemic areas should be regularly screened for VL
- VL is considered an AIDS defining illness and patients should be started on ART irrespective of CD4 count
- Starting ART as soon as patient counselled; not wait until end of VL treatment
- Secondary prophylaxis for VL is not recommended
- Treatment recommendations - use 40mg/kg AmBisome as per WHO guidelines[7]
- Coordination mechanism to be developed between NACO and NVBDCP

As per 2016 reported data, there is a wide range of reported rates across districts. Care needs to be taken to ensure testing is being conducted, with a special focus in those districts with high VL burden but little or no HIV-VL cases. Additionally, ART treatment centre staff need to be sensitized to ensure that they are aware of HIV-VL co-infection and are able to screen patients and refer early. All co-infected patients in Bihar should be referred to the RMRI in Patna, and in West Bengal to the CSTM in Kolkata for specialist care and initiation of ART.

2.6 Integrated vector management

Present tools for vector management include indoor residual spray in affected and endemic areas.

Following factors are important for best results of IRS-

I. What to apply: due consideration should be given on safety, efficacy, cost-effectiveness, acceptability, availability of quality products

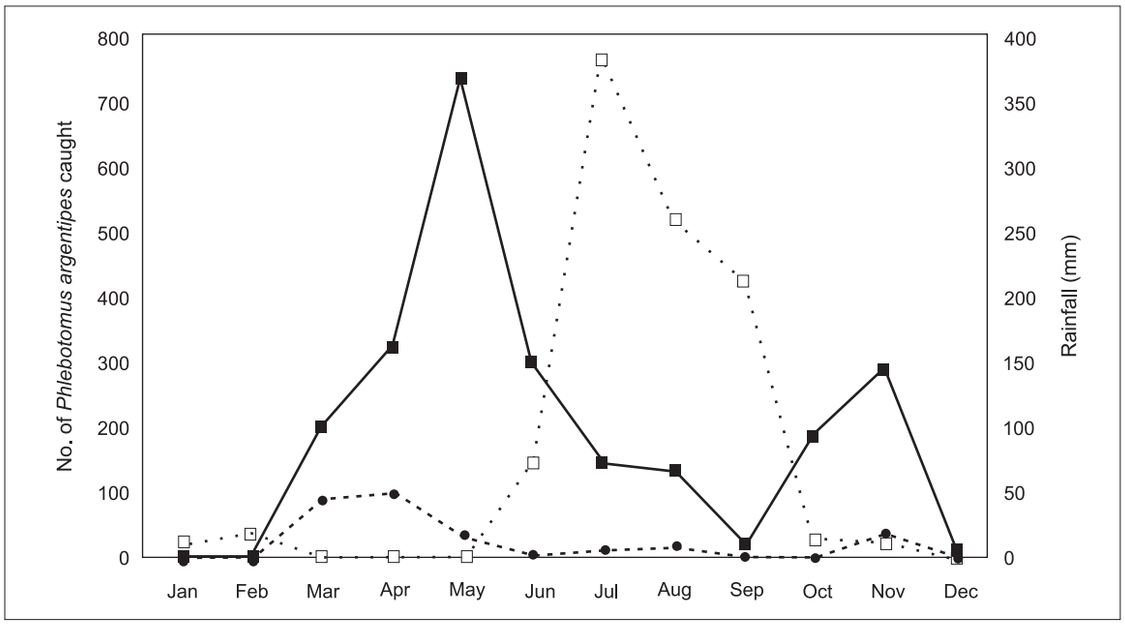
II. Where to apply: due consideration should be given on the coverage, requirements and best targeting

   - o Effective IRS coverage- WHO recommendation is to have minimum of 80% households covered under IRS. Household (including animal shelter) is considered one unit. Patchy and partial coverage is not considered a full unit covered

III. How to apply: focus should be given on personnel skills, right technique, training, equipment, personal protection and individual and community safety [WHO specified and recommended equipment for vector control should be used. Mentioned in annex]

IV. When to apply: consideration on time required for targeted coverage, duration of effect, epidemiological requirements, period of IRS

[7] More evidence needed



Source: Dinesh DS et al. (2001). *Annals of Trop Med Parasitol,* 95(2): 197-202

- Period of IRS

Presently spray operations are organized as below-

State	Present indoor residual spray time line		Proposed indoor residual spray time line	
	First round	Second round	First round	Second round
All four states	February-March	May-June	March-April	August-September

- Things to be ensured for IRS

✍ **Before IRS-**

- Pre-IRS vector density and peak biting rates should be assessed
- Insecticide is checked for physical and chemical properties,
- Micro plan should be prepared and reviewed in advance
- Daily route chart should be shared with monitoring team
- Equipment for vector control are in function with sufficient spare parts (control flow valves, nozzles etc)
- Personal protective equipment are available, micro plan with daily route chart is available, spray squads are sensitized about right preparations, correct calibrations, dosage and correct technique

- Sufficient spares should be procured in advance to conduct spray operations. CFV (red colored) exerting 1.5 bar pressure is ideal.
- Community should be pre-informed about spray timings, benefit of IRS, visit of teams, at least two days in advance. Refusals are generally due to abrupt arrival of teams without prior intimation. It helps in preparing households to shift utensils in advance

- Daily route chart of spray squad should be ready and

✍ **During IRS-**

- Spray squads should enquire about history of fever in the visited household during time of visit

- One person should inform villagers that spray teams have arrived in village

- ASHA/supervisor should accompany spray teams to minimize refusals. A copy of micro plan (route chart) should be available

- All sprayable surfaces should be sprayed uniformly (including sleeping rooms, kitchen, animal shelter and worship rooms). Human exposure to chemicals should be avoided (e.g. avoid spray if some ill person is in room)

- Wall stencil/marking should be in place

✍ **Post IRS-**

- Sprayers should be rinsed and cleaned properly for next day operations

- Residual insecticide at the end of the day should be disposed as per the guidelines

- Post-IRS vector density.

2.6.1 Accelerated actions

Spray area

➢ Focal spray in the 500 meters range of an index case of kala-azar will be undertaken as soon as a case is reported. In small villages, this might as well cover the entire village. For this provision of a spray squad at the block level will be required throughout the year.

➢ Micro plan for IRS-currently, villages reporting a kala-azar case in last three years are included in the plan for spray. Villages where PKDL cases have been reported will also be part of the spray operations. To meet the increased requirement of the logistics (insecticide etc), preference will always be given to the KA reported villages.

Number and timing of spray rounds

- In addition to focal spray, two regular rounds of spray will continue to be applied in targeted endemic villages (a village where one or more cases have been reported in the last 3 years).

- However, if a complete village is covered under focal spray, next round of spray will be avoided for 12 weeks (allowing the residual efficacy of insecticide)

Vector surveillance

- Enhanced spatial and temporal vector surveillance will be carried out through identification of sentinel-site and random sites for monitoring of sand fly vectors in areas (districts/blocks) that are endemic for kala-azar. Sentinel-site will be the most endemic area and will remain fixed throughout the period. Random sites will change to confirm the findings of sentinel sites.

- Monitoring will include information on vector attributes (i.e. vector density, biology, feeding/resting behaviours, insecticide susceptibility, bioassays to monitor residual effect of IRS on sprayed surfaces etc). Entomology component will be strengthened at state level.

Selection of insecticides for IRS

- Use WHO-prequalified insecticides for IRS; this may include wettable powder (WP) (Note: 1st option based on ease of availability of WP products in India) or granule formulations (WG) of synthetic pyrethroids preferably packaged in water-soluble bags (i.e. WP-SB or WG-SB formulations)

- Programme will use or change the insecticide based on the susceptibility data. Presently, all endemic states have switched over from DDT to Synthetic Pyrethroids.

Quality of spray

- IRS applications will be concurrently supervised in general.

- All squad supervisors will be trained on spray techniques and use of equipment.

- Independent assessment and monitoring of spraying by WHO or partners will continue.

Combined use of LLINs and IRS

In areas co-endemic for kala-azar and malaria, requiring the universal coverage of at-risk populations with LLINs, a synthetic pyrethroid insecticide may be used for IRS in 2017 spray rounds. However, the general principles, where universal coverage of at-risk populations with LLINs is achieved, co-endemic areas requiring IRS, different insecticide class (mode of action) should be a preferred option. Supervision of IRS activities:

- IRS spray squads would be made based on case notification rate (case incidence rate) made available at block/CHC level throughout the year with intensified supervision in "problem" areas to enhance quality and coverage of IRS.

- A spray squad may consist of 6 persons: 4 spraymen (hand compression spray operators), one helper and one supervisor (usually a Superior Field Worker)

Quality control

- Quality control will be given utmost priority. As part of the procurement process, pre- and/or post-shipment quality of insecticides will be checked by analyzing samples of insecticide in a quality control laboratory to meet full compliance with the physico-chemical properties rather than insecticide active ingredients of the formulations to ensure compliance with the product specifications.

2.6.2 Risk stratification for IRS:

For the purpose of planning IRS, annual incidence of new cases in a village should be used to stratify at-risk villages. All such villages qualify to receive 2 rounds of IRS

Category I (high endemic)

Action:

a. Case detection activities will be intensified in these blocks. This will be house-to-house in high risk areas e.g. hotspot villages, and will be mixed with camps and all approaches mentioned above under case detection heading.

b. Micro plan will be prepared for assessment of high risk areas (e.g. villages reporting 5 or more cases, brick kiln etc). For this line listing of cases will be done village wise. Each block will have the list of its villages reporting a case in the current and past three years well maintained. Villages will be prioritized based on number of cases reported, high risk-population groups, child cases, IRS coverage, health seeking behavior, housing conditions and other local factors (e.g. flood affected, hard to reach areas). District VBD officer and Block medical officer will mutually decide the high risk villages.

c. Provision of kala-azar Mitra (an identified person from local community, who helps in screening and suspect identification) will be made in high risk areas. KA mitra will visit at-least 60 houses per day for screening of population for KA suspects during high detection period. One village of 1,000 population is expected to be covered in 4-5 days.

d. Upon completion of a village, KA mitra will visit next high risk areas in that order.

e. Patients detected will be treated the same day of diagnosis. Free-referrals will be provided to patients for treatment.

f. Accurate localization of each fresh case will be made and each index case will be traced back to all known and suspected cases related to the index case, within 15 days of diagnosis.

g. Close ongoing surveillance of each affected village for at least 12 months will be done after the last known case to suspect new cases at the earliest (such as fortnightly or monthly reports about suspected cases from the village, to reduce time to diagnosis).

h. Triaging of all PHC/District hospital OPD cases at the point of registration (by OPD Medical Officer or nurse or any other staff) for fever > 15 days will be done, to detect increase staff sensitization to VL.

i. Even within the high endemic blocks, there would be some villages where cases are not occurring. If cases happen and clustering occurs, that can be an indication of impending epidemic. Case based tracking will help in preventing and controlling epidemics.

j. Actions related to vector control will be taken as described under section 'integrated vector management' in response to an index case. Focal spray in response to case occurrence will have to be completed within 15 days.

k. SMS based reporting will be introduced in high burden areas. Kala-azar Mitra will report on daily basis through SMS on houses visited, population screened and suspects identified. Lab technicians at the PHC/district level will notify confirmation of a case through SMS immediately upon diagnosis and medical officers/nurses will notify treatment of a confirmed case. This will track the delay between suspect identification, its confirmation and treatment. Mechanism of non-chargeable SMS will be made.

l. SMS based reporting will be linked with real time data management system through situation room dashboard which will be monitored at central, state and district level as well as by key partners.

m. Contact numbers of all endemic blocks and districts will be registered in the HMIS system and an SMS alert will be sent as soon as soon as a case is confirmed in a particular area.

n. Gradually SMS based system will be scaled in other parts and with other workers.

o. SMS based system will be used for reporting of focal IRS operations as well.

p. Kala-azar is a notifiable condition in all the four states. It will be made sure that private sector health providers and laboratory network are aware and are part of the reporting system including SMS based reporting.

Category II marginal endemicity- These areas need to sustain the gains achieved so far and hence all efforts need to be continued so that the elimination status is maintained.

Action:

a. Early diagnosis and complete treatment to be sustained with focus on co-infections of HIV-VL and TB-VL. Early diagnosis in this category will be mostly through ASHA, kala-azar fortnight and camp approach.

b. Sustain case based surveillance

c. Continue diagnostic and treatment services

d. Maintain more than 80% coverage with IRS in target villages

e. Continue periodic vector surveillance as per guideline

Category 3: fFluctuating endemic blocks

Assess reasons of fluctuation:

i) Village wise line listing of VL/PKDL

ii) Trend analysis of cases

iii) IRS coverage analysis

iv) Any change in quality of service deliveries

v) Any change in housing condition

vi) Recent migration in particular area

Action:

1. A rapid survey to assess hidden cases (KA/PKDL). Such survey should be conducted in places like – sudden increase in fever cases as per IDSP report.

2. Strengthening of IRS

3. Ensuring availability of drug and diagnostics in treatment center

4. Strengthening reporting and cross notification

Category 4: Silent blocks-

Nil status could be due to absence of transmission in an area or due to weak surveillance in an erstwhile endemic area. Assess reasons for nil status:

i. Validation of disease burden/cases of kala-azar and PKDL

ii. Status of provision of diagnostics and treatment services

iii. Access to services (flood area, hard to reach area, health seeking behavior)

iv. Vector surveillance

v. Awareness level in community and service providers

vi. Mechanism of reporting and cross-border notification

vii. Period lapse since last active case search

viii. Status of endemicity in adjoining blocks

Action:

1. If there is an evidence of ongoing transmission, then nil status alerts for improving surveillance. Active house-to-house case search is needed in these areas.

2. Refresher training of health care providers including ASHAs in kala-azar and PKDL. It is widely accepted that PKDL plays an important role as reservoir during inter-epidemic period. All attempts to integrate detection of PKDL cases should be made with other programmes e.g. leprosy.

3. Establish a service delivery point for the underserved and outreach areas –diagnostics facility only at local level and then refer for treatment.

4. Strengthening of reporting and cross notification (by E-mail and phone) if needed.

5. Mapping of the district for water bodies would be useful in limiting spraying operations to those areas where maximum impact is likely to occur. This will help economize on insecticide consumption and help control environmental degradation. Selective IRS would be advisable only when surveillance is geared up and geographic mapping with validation is available; until then, IRS based on incidence reporting may be continued.

6. IDSP will ensure close coordination and notification of fever cases reported from these blocks.

2.7 Surveillance, monitoring and coordination

At Central level:

1. NVBDCP will have a coordination mechanism with all partners supporting the kala-azar elimination programme in India and will convene monthly coordination meetings of partners at State/district level

2. NVBDCP will form a core joint monitoring group of the national programme and major partners, which could meet at regular intervals as appropriate (once in 3 months).

3. NVBDCP in collaboration with partners will develop a common monitoring and correction protocol

4. Data flow pathway for surveillance and monitoring will be as below-

    a. village level case detection activities will be reported through SMS (in high endemic areas) and through existing mechanisms (in rest of the places)

    b. patient confirmation and treatment will be reported through SMS (in high endemic areas) and through existing mechanisms (in rest of the places)

    c. all data will be merged into HMIS at the block and district level

    d. full data set will be linked with the dashboard and situation room at the central level for managerial decisions

5. WHO to create a situation room with a virtual dashboard and undertake joint situation assessment led by the programme fortnightly. The situation room will lead to create critical paths guiding course correction in ongoing activities.

6. Field visits of central level officers will be made on fortnightly basis to assess the progress in the field.

At state level:

1. Formation of state monitoring /supervision cell (State VBD consultants, data quality manager, M&E etc. based on availability) for improved quality of information and timely reporting and action

2. Monthly field visits in high focus areas

3. Periodic review of observations following field visit

4. Action points to be followed and implemented through State Task Force Committee

5. Monthly review of Districts alternately by holding meeting and video conferencing

6. Monthly State Co-ordination Committee meeting with all stakeholders under chairmanship of SPO. (State Coordination Committee may comprise of all partners, research groups under leadership of the programme officer)

7. Dissemination of action points till block level for action.

At district level:

Formation of District monitoring/supervision cell (VBD consultant, data quality manager, M&E etc. based on availability)

1. Weekly field visit in focus areas
2. Review of observations following field visit
3. Action points to be followed and implemented through District Task Force Committee
4. Monthly review of blocks by holding meeting under the chairmanship of District Chief Medical and Health Officer or District VBD Officer
5. Dissemination of action points till the sub-center and village level for action.

At block level:

Formation of Block monitoring/supervision cell (Block in-charge medical officer, Kala-azar Technical Supervisor, VBD consultant, data manager etc. based on availability)

1. Field visit twice a week in focus areas
2. Review of observations following field visit in chairmanship of Medical Officer In-charge
3. Action points to be followed and implemented through Block Task Force Committee
4. Monthly review of Blocks by holding meeting under the chairmanship of Medical Officer In-charge
5. Dissemination of action points till the sub-center level for action.

**** This planning (monitoring and supervision) will be common for categories 1-3.

2.8 Strengthening capacity of human resource in health

Leveraging the existing mechanism (wherever applicable)

1. During monthly meeting of ASHA and MPW at PHC - Orientation of all ASHAs and MPWs at PHC level by ASHA coordinator by taking opportunity of monthly meeting. Ensure MOs, all ANM, MPW, ASHA facilitators/coordinators, ASHA and AWW are well sensitized to identify suspects and refer; maintain record of referrals. Each ASHA should have flash card in hand for field survey.
2. During Monthly meeting of PHC MOs at the district, re-orientation of all MOs to be done by all KA stakeholders at District level.

3. Dedicated training of all MOs and nursing staff

4. Suspects definition to be displayed in private practitioner's clinic or their place of work.

5. Standard Operating Procedure for treatment and algorithm for diagnosis to be shared till Block level with its display in each OPD room.

6. Being a notifiable disease, it is mandatory for all Govt. & non Govt. health facility and practitioner to timely report any suspected cases to the nearest treatment center.

7. Bi-annual sensitization of private practitioners and faith healers for timely notification of suspects/confirmed cases with involvement of IMA, General practitioners' associations

2.9 Advocacy, communication and social mobilization for behavioural impact and inter-sectoral convergence:

Acceleration towards achieving elimination requires strong administrative commitment and field activities by dedicated staff. This can be ensured by holding frequent reviews of progress at all level.

1. State level task force: Monthly meeting under the chairmanship of Principal Secretary/Mission Director for review of Kala-azar program performance and implementations. Action points will be shared with all stakeholders.

2. District level task force: Monthly meeting under the chairmanship of District magistrate/commissioner. Action points will be shared with all stakeholders and State HQ.

3. Block level task force: Monthly meeting under the chairmanship of MOIC and Block Development Officer and co-chair of Chief District Programme Officers for review of Kala-azar program performance with sharing of minutes with district.

4. Monthly partners' coordination meeting to be done at all level (State, District and Block) with their feedback.

Platform of different health program meeting or review can be taken as one of the opportunity to facilitate it.

2.10 Programme management

Activities	Action
Administrative Approval Human Resource	Opportunity of State Task force will be used to clear any activity which is pending due to approval issueBack log of vacancies to be filled on priority. Rationalization of health staffs to be done for all blocks
Funds	Availability of fund at state and District at least 1 month in advance for all activities
Drugs & diagnostics	Indent at least 6 month in advance. Stock position of rK39 in HMIS
Training material, diagnostic & treatment algorithms	Available in all the health facilities
Operational Research	Operational research issues identified by joint monitoring group under the leadership of NVBDCP
Data generation	
Partner	Partners' roles and responsibilities re-affirmed as National Roadmap for Kala-azar Elimination launched in 2014
Plan of action	State wise plan of action exists for all the categories

2.10.1 Stakeholders in the programme

Presently Kala-azar programme is having assistance and support from national and international partners. These stakeholders are-

- State NVBDCP units
- Rajendra Memorial Research Institute (RMRI), an ICMR institute
- WHO
- Regional office of Health & Family Welfare, Patna, Kolkata, and Lucknow
- Patna Branch of National Centre for Disease Control (NCDC)
- State Institute of Health & Family Welfare, Patna, Ranchi, Kolkata and Lucknow
- All India Institute of Hygiene and Public Health (AIIH&PH), Kolkata
- BMGF/CARE
- DFID-KalaCORE (consisting of)
    - o Drugs for Neglected Diseases Initiative (DNDi),

- London School of Hygiene and Tropical Medicine (LSHTM),
- Médecins sans Frontières (MSF) and
- Mott MacDonald (with Mott MacDonald holding the DFID contract)

- DNDi
- MSF (Médecins sans Frontières)
- Through KalaCORE- Public Health Foundation of India, New Concept Information Systems, IPE Global, FRHS, and operational research partners -RMRI and LSTM

S.N.	Stakeholder(s)	Current role/Inputs and responsibilities
1.	RMRI	- Training of District VBD consultants and KA Technical Supervisors (KTS) in KA and spray workers in IRS - Operationalization of sentinel sites (information on efficacy of treatment regimen) - Pharmacovigilence of available KA drugs and quality assurance of RDK - Susceptibility status of vector and validation of insecticide quantification kit (IQK) and data management monitoring system - Undertaking primary and operational research - management of treatment failures
2.	CARE/BMGF	CARE presently supports the planning and implementation of IRS, KA-MIS, case/epidemiological surveillance and entomological surveillance. The VL elimination support team deployed by CARE consists of District Program Managers (about 30) and Block coordinators (about 300) covering all affected areas of Bihar and Jharkhand. The support provided by the team includes: - IRS: microplanning, spray squad training in all aspects of spray operations, concurrent supervision and support during spray operations, concurrent monitoring and support in organizing DTF and BLTF reviews, timely submission of SoEs, independent assessment of household coverage of IRS at the end of each round - KA-MIS: design and establishment of offline and online MIS, training of block, district and state level personnel; basic inventory management and wage-loss and ASHA payments are included in KA-MIS; GIS-ready. - Case/epidemiological surveillance: Index case tracing to ensure completion of treatment, and mopping up suspected cases in the index village, tracking private sector labs and providers in all affected districts and blocks of Bihar and Jharkhand, outbreak investigations, estimation of true annual incidence of VL across affected districts of Bihar and Jharkhand - (yet to be published) - Entomological surveillance: Establishing and managing eight entomological surveillance sites in Bihar (6), Jharkhand (1), and West Bengal (1), with technical oversight from LSTM

3.	KalaCORE	A UK-Aid supported programme (in partnership of DNDi, MSF, Mot MacDonald and London School of Hygiene and Tropical Medicine), and its implementing partners;A consortium of DNDi, MSF and London School of Hygiene and Tropical Medicine (LSHTM); all have long history of working in VL control in India. - Support the programme in scaling up of Liposomal Amphotericin B, upgrading facilities - Strengthening cold chain and logistics - Capacity building of state & district level health staffof IDSP & NVBDCP on strengthening surveillance -Support national programme and state programme in M&E activities through provision of dedicated HR - implementation of pharmacovigilance through WHO - Develop strategy for private sector referral to public sector - Organization of technical meetings wherever needed - Epidemiological surveillance - Support on IEC/BCC materials, printing and dissemination
4.	WHO	- Formulation of policy guidelines, norms and standards - Partnership coordination - Supporting NVBDCP on real time monitoring and establishing linkages with innovative systems of data management - Technical support in KA programme implementation at National and State level (through state coordinators and 9 Zonal Coordinators) - Independent monitoring of IRS activities through NPSP-M&E (through Joint monitoring missions and field visits) - Supplies of Liposomal Amphotericin B - Implementation of Pharmacovigilance for kala-azar
5.	DNDi	- Research into clinical drug trials - Training Medical Officers and Para-medical staff on newer drugs with the help of RMRI and MSF
6.	Regional Branch of NCDC, Patna	- Support on M&E during IRS - Vector surveillance - Operational research
7.	AIIH&PH	- M&E of KA elimination (including IRS)
8.	Regional office of MOHFW	- Coordination with states - Monitoring & supervision

9.	MSF	- Main focus is on the identification, training and improving management of HIV-VL co-infected patients - Providing training to medical officers, BSACs staff and health care providers on HIV-VL coinfection - Monitoring barriers to ensure 2014 recommendations of joint NVBDCP/NACO working group are implemented - Operational research focussed on HIV-VL coinfection
10.	BMGF	Supporting the funding support to CARE for implementation of activities, procurement of hand compression pumps and diagnostics. Supporting VL consortium which is working on to address key questions in epidemiology of VL

3. Time line for Kala-azar Elimination

3.1 National level actions

- Programme management

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Policies	Formation of Core group	Already done in July 2014	MoHFW	
Policies	Revision of guidelines	completed	MoHFW	MoHFW
Policies	strategies of Kala-azar elimination cell at central programme division comprising of public health expert, monitoring and evaluation expert, vector control specialist and statistician cum data manager	completed	MoHFW	MoHFW
Policies	Monitoring of stakeholders	Quarterly	MoHFW	NVBDCP
Policies	Roll out of revised HMIS to all areas	In process	NVBDCP	NVBDCP
Policies	WHO M&E indicators and IRS toolkit	In process	NVBDCP	NVBDCP
Review	Core group meetings	Annually	NVBDCP	NVBDCP
Policies	Upgradation of cold chain	Completed and under expansion	WHO, KalaCORE	NVBDCP, States

- Vector control (indoor residual spray)

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Fund flow	Status assessment of SOE and requirements	Continuing	MoHFW	NVBDCP
Fund flow	Release of funds to state	Continuing	MoHFW	NVBDCP
IRS campaign	Supervisory visits by assigned officers to the field	Throughout the IRS	MoHFW	NVBDCP & Partner
Training	Orientation training for IRS	Before IRS	RMRI	RMRI
Mobilization	Dissemination of IEC prototypes	Completed	NVBDCP & KalaCORE, other development partners	NVBDCP

- Monitoring and evaluation

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Fund flow	Monitoring of fund distribution at national, state, district, block and squad level	Regular	NVBDCP /state	NVBDCP /state
Fund flow	Monitoring of submission of SOE/UC	Regular	state/ NVBDCP	state/ NVBDCP
Cold Chain	Cold chain mapping	ompleted	WHO /KalaCORE	WHO /KalaCORE

- Surveillance/treatment

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Policies	House to house survey (either on polio model or other mechanisms) for active case search & PKDL in villages, BCC and advance information about IRS with monitoring support form stakeholders.	Continuing	NVBDCP /development partners	NVBDCP
Case detection	Revision and disseminate short but effective SOPs/case management flowchart for diagnosis and treatment of Kala-azar for PHCs and private health facilities in view of new treatment policy	Continuing	NVBDCP/KalaCORE, development partners	NVBDCP states
Case detection	Coordination with NACO for HIV-VL treatment guidelines and data sharing	Under process	NACO /NVBDCP	States

3.2 State level actions

- Programme management

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Human Resources	Filling vacant positions on priority	Pending	State Health Society	SHS
Policies	Filling of consultants approved by NVBDCP.	Under process	State Health Society	SHS, Development partner
Review	State Task Force constitution	Completed	State Health Department	PS Health

Review	STF meeting: 1 month prior and on completion of IRS activities. Quarterly meetings for assessing other components.	Continuing	State Health Department	PS Health
Training	Induction/refresher training of District VBD Officer VBD consultants, KTS, Care link workers	Completed	NVBDCP	RMRI
Training	1 day sensitization of District Magistrates at state level	Pending	State Health Deptt.	ED SHS

- Vector control (indoor residual spray)

Components	**Activities**	**Timeline**	**Responsible Organization**	**Responsible Deptt.**
Fund flow	Allocation and release of funds to districts	Two months in advance to IRS	State Health Society	SHS
Fund flow	Submission of SOEs to national level	As per existing instructions	State Health Society	SHS
Supervision	Plan for allocation of state nodal officer for contiguous 4-5 districts by state officers for oversight in microplanning and training & supervision	Continuing	State Health Society	PS Health
Supervision	Supervision plan during IRS	Plan prepared	State Health Society	PS Health
Mobilization	Printing and dissemination of IEC material	Completed	KalaCORE consortium, Development partners	State/ KalaCORE consortium, Developmen t partners
Mobilization	Community sensitization through print & electronic media/IEC/BCC sensitization and use in community mobilization	Completed	KalaCORE , Development partners	State/ KalaCORE , Developmen t partners
Mobilization	Print & electronic media sensitization and use in community mobilization	Continuing	State Health Department	PS Health
IRS campaign	Supervisory visits by assigned officers to the field	Before and during IRS	State Health Department	PS Health

- Monitoring and evaluation

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Review	Feedback to STF on monitoring findings	During IRS	State Health Dept.	PS Health
IRS campaign	Providing monitoring feedback to STF	During IRS	State Health Dept.	PS Health

- Surveillance/treatment

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Training	Up-gradation of district hospitals to undertake parasitological diagnosis	Under process	RMRI DNDi	RMRI DNDi
Case detection	Compile and maintain linelist of all Kala-azar & PKDL cases reported by districts with complete address, treatment details and outcome	Continuing	State Health Society	SPO
Case detection	Sharing the linelist of Kala-azar and PKDL cases with NVBDCP	Continuing	State Health Society	SPO

3.3 District level actions

- Programme management

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Review	DTF meeting: 1 month prior and on completion of IRS activities. Quarterly meetings for assessing other components.	1 month before IRS	District Health Society	District Magistrate
Training	Training of block and district level data operators regarding coverage, transmission, drug and diagnostic kit data entry	Immediate	State	Care/Development partners

- Vector control (indoor residual spray)

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Fund flow	Release of funds to blocks	Continuous	District Health Society	DM
Fund flow	Submission of SOEs to state	Monthly	District Health Society	DM
Microplanning	Compilation and reviews of microplans	As per instructions	District Health Department	Dist VBD Officer

Microplanning	Submission of final microplan to state level with logistic requirement 90 days before IRS	90 days before IRS	District Health Department	Dist VBD Officer
Supervision	Allocation of blocks to district officers for oversight in microplanning and training	90 days before IRS	District Health Society	DM
Supervision	Supervision plan during IRS	90 days before IRS	District Health Society	DM
Training	Supervision of trainings	As per plan	District Health Department	Dist VBD Officer
Training	Training of trainers (TOT)	As per plan	District Health Department	Dist VBD Officer
Mobilization	Display of IEC material	Pre IRS and during campaigns must, wall writing throughout	District Health Department	Dist VBD Officer
Mobilization	Distribution of IEC material to block	As per plan	District Health Department	Dist VBD Officer
Mobilization	Using local news networks for IEC	As per plan	District Health Department	Dist VBD Officer
Mobilization	Assist in display of IEC material	As per plan	Care	Care
Mobilization	Assist in distribution of IEC material to block	As per plan	Care	Care
Mobilization	Coordination with education department in DTF for organization of guru goshtis and rallies prior to IRS campaign	As per plan	District Health Society	DM
IRS campaign	Supervisory visits by assigned officers to the field	During IRS	District Health Society	DM
IRS campaign	Daily compilation of coverage reports and communication to state level	Within a month of IRS	District Health Department	Dist VBD Officer

- Monitoring and evaluation

Components	**Activities**	**Timeline**	**Responsible Organization**	**Responsible Deptt.**
IRS campaign	Providing monitoring feedback to DTF	Pre and post IRS	District task force	District VBD Officer
Review	Feedback to DTF on monitoring findings	Monthly	State Health Society	DM

- Surveillance/treatment

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Case detection	Refresher on Kala-azar detection and notification	Continuing	District Health Department	Dist VBD Officer
Case detection	Enlisting important health facilities in private setup by KTS/Care link workers	Continuing	District Health Department	Dist VBD Officer
Case detection	Allocation of government and private health facilities to KTS/Care link workers for active case searches and sensitization	Continuing	District Health Department	Dist VBD Officer
Case detection	Coordination and dissemination of sensitization through letters and meetings by IMA	Continuing	District Health Department/I MA	Dist VBD Officer
Pharmacovi-gilance	District hospitals to follow national pharmacovigilance protocol	Under process	NVBDCP WHO	NVBDCP WHO

3.4 Block level actions

- Vector control (indoor residual spray)

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Microplanning	Selection of villages based on cases	120 days before IRS	PHC	MOIC
Microplanning	Updation/preparation of microplan as per IRS guideline	120 days before IRS	PHC	MOIC
Microplanning	Submission of microplan to district with logistic requirement 120 days before IRS	120 days before IRS	PHC	MOIC
Microplanning	Facilitating microplanning	120 days before IRS	Care	Care
Fund flow	Distribution of allowance to spray workers	As per plan	PHC	MOIC
Fund flow	Submission of SOEs to district	As per existing instructions	PHC	MOIC
IRS campaign	Conducting campaigns	As per plan	PHC	MOIC
IRS campaign	Daily evening briefing of all supervisors	During IRS	PHC	MOIC
IRS campaign	Daily compilation of coverage reports and communication to district	During IRS	PHC	MOIC
Mobilization	Distribution IEC material to ASHA in monthly meeting for display prior to IRS	Before IRS	PHC	MOIC

Mobilization	ASHA meeting for dissemination of information to beneficiaries prior to IRS campaign and search for cases (meeting 20 days prior to campaign, first visit to family by ASHA 15 days prior, second visit 2 days prior)	As per plan	PHC	MOIC
Mobilization	Meeting of ANMs 15 days prior to campaign for meeting with PRI and local practitioners	15 days before IRS	PHC	MOIC
Supervision	Supervision plan during microplanning, training and IRS	As per plan	PHC	MOIC
Training	Training of IRS workers	As per plan	PHC	MOIC
Training	Submission of training plan to district	As per plan	PHC	MOIC
Training	Facilitation of trainings at block level	As per plan	Care	Care

- Monitoring and evaluation

Components	**Activities**	**Timeline**	**Responsible Organization**	**Responsible Deptt.**
Microplanning	Monitoring the quality and progress of microplanning	As per plan	District	MOIC
Training	Monitoring of trainings	As per plan	WHO/development partners	MOH&FW/district

- Surveillance/treatment

Components	**Activities**	**Timeline**	**Responsible Organization**	**Responsible Deptt.**
Case detection	Active surveillance visits and sensitization of government and private health facilities by KTS/Care link workers. At least one visit to all assigned health facilities in two months.	As per instructions	District Health Department	Dist VBD Officer
Case detection	Screening of fever cases from IDSP weekly linelist	Monthly	PHC	MOIC
Case detection	Sensitization of ASHA/AWW in their monthly meetings for case detection and reporting by MOIC	Monthly	PHC	MOIC
Case detection	Diagnosis and ensuring treatment of suspect cases from any source at designated treatment center	Monthly	PHC	MOIC
Treatment	Follow up of HIV-VL cases	Regular	PHC	KTS
Treatment	Referral of all relapse cases to district hospital	Regular	PHC	MOIC

3.5 Village level actions

- Vector control (indoor residual spray)

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Mobilization	First visit to family by ASHA 15 days prior, second visit 2 days prior (search of cases/BCC/mobilization) Guided Pre IRS orientation and sensitization of ASHA with its monitoring	As per plan of IRS	PHC New Concept (for orientation & supervision)	MOIC
Mobilization	Visit by ANM/other health staff to PRI and local practitioners for BCC and search for cases	As per plan	PHC	MOIC
IRS campaign	IRS spray activities	As planned	PHC	MOIC

- Monitoring and evaluation

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Mobilization	Monitoring of awareness about IRS and visit of ASHA/ANM/other health staff	As planned	District	MOIC
IRS campaign	Monitoring of IRS squads and completed villages	As planned	District	MOIC

- Surveillance/treatment

Components	Activities	Timeline	Responsible Organization	Responsible Deptt.
Case detection	Quarterly active camp search for suspect KA cases & PKDL at the village	As per plan	PHC	MOIC
Case detection	Scanning the village for fever complex of KA suspect cases and reporting to ANM/ASHA cascade	Weekly	PHC	MPHS
Case detection	Active case search in community around index case	Upon detection of cases	PHC	KTS/ Care link worker
Treatment	Follow up of treated VL and PKDL cases at 6 and 12 months respectively	6 and 12 months	PHC	KTS/ Care link worker

4. Roadmap for implementation of Pharmacovigilance for vector-borne diseases

4.1 Introduction

Pharmacovigilance (PV) is the science and activities relating to the detection, monitoring, assessment, understanding and prevention of adverse effects or any other drug-related problem from any pharmaceutical products[1]. The core purpose of pharmacovigilance is to enhance patient care and generate the evidence based information on safety of medicines. It is increasingly gaining significance in pursuit of safe-guarding public health by monitoring and prevention of adverse drug reactions. Adverse drug reactions (ADRs) represent the 3rd leading cause of death after cancer and cardiac disease in USA[2]. In the USA and Canada ADRs account for 4.2-30% of hospital admissions, 5.7-18.8% of admissions in Australia, and 2.5-10.6% of admissions in Europe[3]. A study in India reported overall incidence of 9.8% ADRs including 3.4% of total hospital admissions and 3.7% adverse drug reactions developed during hospital stay[4].

The present roadmap and its implementation at national, state and district levels will provide a crucial opportunity not only in early recognition and management of adverse drug reactions, improved benefit-risk ratio, better patient compliance but also improved treatment outcomes, thus encouraging the safe, rational and more, effective (including cost effective) use of vector borne disease medicines. The Road map has been prepared with clear objectives, outcomes, proposed roles, and responsibilities at national, state and district levels.

Pharmacovigilance of vector-borne disease (VBD) medicines will require effective involvement of state VBD officers, District VBD officers, VBD consultants, medical officers at district and block levels, various partners including PVPI, data entry operators and ASHA at village level for early identification of a suspected adverse drug reaction, reporting the event, assessing causality assessment and uploading the information in the database. Effective management of the data flow will result in success of the pharmacovigilance of vector borne disease programme.

In summary, pharmacovigilance is a branch of patient care and surveillance. It promotes the safe and effective use of medicines, through providing timely information about the safety of medicines to healthcare professionals and patients.

1. *http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/*
2. *Makary Martin A, Daniel Michael. Medical error—the third leading cause of death in the US. BMJ 2016; 353: i2139*
3. *Howard RL, Avery AJ, Slavenburg S, Royal S, Pipe G, Lucassen P, et al. Which drugs cause preventable admissions to hospital? A systematic review. Br J Clin Pharmacol. 2007; 63:136–47.*
4. *Arulmani R, Rajendran SD, Suresh B. Adverse drug reaction monitoring in a secondary care hospital in South India. Br J Clin Pharmacol. 2008; 65:210–6*

4.2 Organizations involved in pharmacovigilance for vector-borne diseases

Indian Pharmacopoeia Commission (IPC)- Pharmacovigilance Programme of India (PvPI)
IPC is an autonomous institution of the Ministry of Health and Family Welfare, Govt. of India. IPC is created to set standards of drugs in the country. Its basic function is to update regularly the standards of drugs commonly required for treatment of diseases prevailing in this region. It publishes official documents for improving Quality of Medicines by way of adding new and updating existing monographs in the form of Indian Pharmacopoeia (IP). It further promotes rational use of generic medicines by publishing National Formulary of India. IPC also provides IP Reference Substances (IPRS) which act as a finger print for identification of an article under test and its purity as prescribed in IP.

IPC is functioning as national coordinating center (NCC) for PvPI since 15th April 2011 to monitor the Adverse Drug Reaction. The mission of PvPI is to safeguard the health and welfare of the Indian population by monitoring drug safety and ensuring the benefits of use of medicine outweigh the risks associated with their use. The vision of PvPI is to improve patient safety and welfare in Indian population by monitoring drug safety and thereby reducing the risk associated with use of medicines.

Organization Committees under NCC

Steering Committee

PvPI Working Group

Core Training Panel

Quality Review Panel

Signal Review Panel

Memorandum of Understanding between NVBDCP, IPC-PvPI

NVBDCP and Pharmacovigilance Programme of India (PvPI) have signed a Memorandum of Understanding (MOU) in New Delhi on 3 August 2016 to monitor drug safety in vector-borne diseases and to initiate and promote the process for reporting adverse drug reactions (ADRs) with WHO as the technical partner.

4.3 Adverse drug reaction monitoring and reporting – Definitions and terminologies

Adverse drug reaction: It is a noxious response to a drug which is unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.

Serious adverse events: A Serious Adverse events (SAE) based on ICH is any toward medical occurrence that any dose:

- results in death;
- is life-threatening; (the subject was at risk of death at the time of the event. It does not refer to an event which hypothetically might have caused death if it were more severe.)
- requires inpatient hospitalization or prolongation of existing hospitalisation;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect;
- is a suspected transmission of any infectious agent via a medicinal product;
- is medically important;

Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should usually be considered serious.

Non-serious adverse drug reactions (ADR) (associated with the use of the drug): Any untoward medical occurrence that does not meet the above criteria to be serious and also is considered associated with the use of the drug.

Life threatening ADR: Any event in which the patient was at risk of death at the time of the even; it does not refer to an event, which hypothetically might have a caused death if it were more severe.

Severity criteria:
The severity of a specific event describes its intensity, and it is the intensity which is graded. Assessment of severity will be made as per the following general categorical descriptors:

Mild: Mild symptoms causing no or minimal interference with usual social & functional activities with intervention not indicated.

Moderate: Moderate symptoms causing greater than minimal interference with usual social & functional activities with intervention indicated.

Severe: Severe symptoms causing inability to perform usual social & functional activities with intervention or hospitalization indicated.

4.4 Road map for pharmacovigilance in vector-borne diseases

4.4.1 Objectives

The main objective of setting up of pharmacovigilance system in programme is, earliest possible recognition of adverse drug reactions, including interactions. It will also include identification of previously unknown adverse drug reactions and interactions, to assess safety in pregnancy and lactation, quality and cost assessment/economic analysis, evaluate the risk factors that could lead to adverse drug reactions with vector borne disease (VBD) medicines. It will also provide evidence for benefit or harm assessment of different regimens or products leading to evidence based regulatory action. The roadmap also aims to provide training to the VBD key functionaries in all the aspects of pharmacovigilance and patient safety for VBD medicines and to enhance their ability to evaluate and address the problems related to adverse drug reactions (ADRs) in the field.

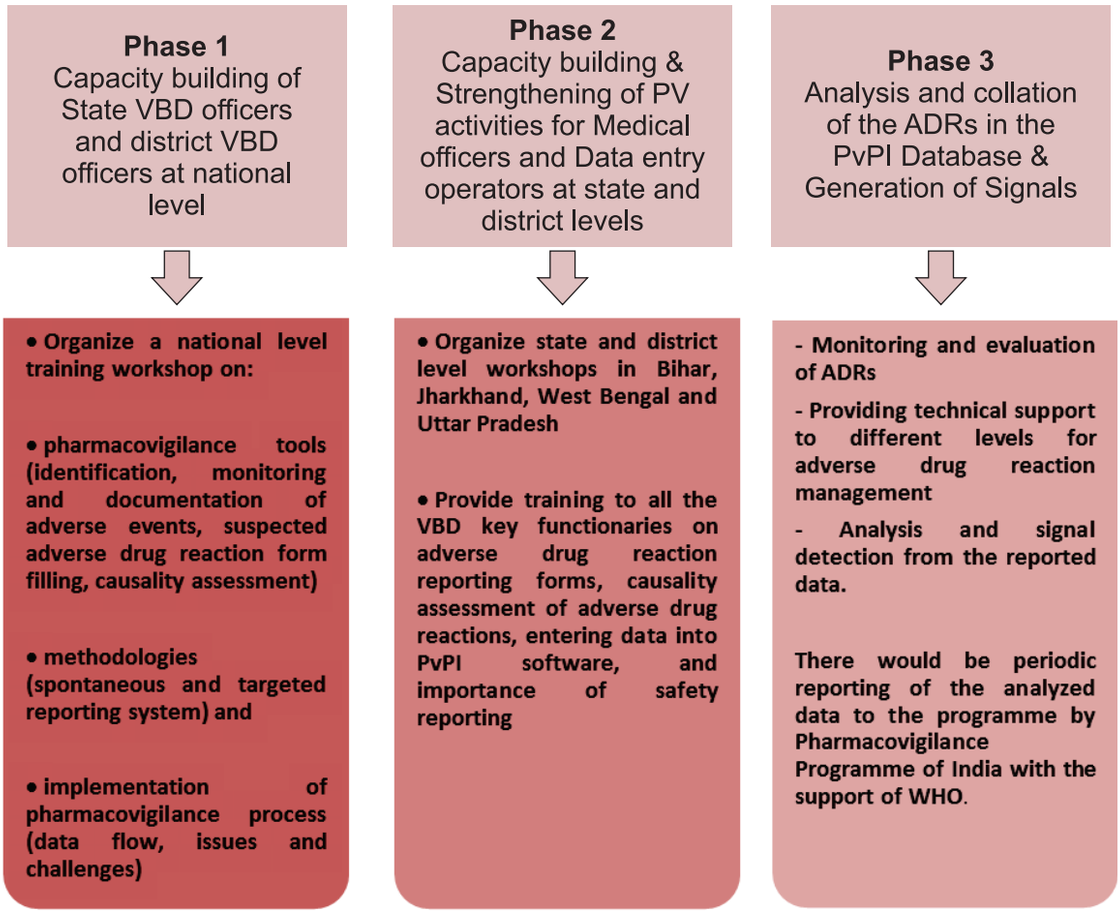
4.4.2 Pharmacovigilance methods

The most common method of pharmacovigilance is 'Spontaneous Reporting'[8]. This method has the potential of early identification of rare & previously unlabeled adverse drug reactions. Targeted spontaneous reporting[9] is useful in focused adverse drug reaction reporting system. It works as an add on to the spontaneous reporting system for a defined medicine and patient group. For the programme, 'Spontaneous reporting' and 'Targeted spontaneous reporting' (for Ambisome) methods will be used.

[8] *WHO. The SAFETY of MEDICINES IN PUBLIC HEALTH PROGRAMMES: Pharmacovigilance an essential tool: WHO; 1997*
[9] *WHO. A practical handbook on the pharmacovigilance of medicines used in the treatment of tuberculosis. Geneva: WHO; 2012.*

4.4.3 Proposed action plan for implementation at national, state and district levels

The road map will be implemented in a phased manner at national, state and district levels



Detailed action plan of implementation of pharmacovigilance systems at national, state and district Levels

4.4.4 Phase 1 of Implementation of PV activities

Roles and responsibilities of key functionaries in the kala-azar programme under NVBDCP

S.No.	Component	Responsibilities
1.	Pharmacovigilance Programme of India	• Provide support in national, state and district level workshops and to train data entry operators on entering data into PvPI software • To evaluate the data uploaded in PvPI Software and prepare monthly reports • Provide reports for early warnings and signals • Communicate regularly with all the stakeholders (NBVDCP, MoHFW and Partners) about the trends of reporting and new findings • Pharmacovigilance Associates who are working in ADR Monitoring Centres will coordinate district level centres/NVBDCP and Zonal Coordinators

		• Provide support in setting up identified additional Adverse Drug Reaction Monitoring Centers (AMCs) for Kala-azar Program (11 medical colleges from the four endemic states) • Facilitate the access to PvPI Software and provide training
2.	WHO India	• Provide technical support for the implementation of pharmacovigilance systems at national, state and district levels • Periodic analysis of the reported ADRs along with PvPI
3.	State Programme Officer	• Monitor the overall pharmacovigilance process in their State • Jointly review the progress of PV activities along with state level review committees • Conduct regular orientations for Medical officers and other staff in public facilities to maintain a high degree of surveillance on finding adverse drug reaction in kala-azar cases
4.	District Vector Borne Disease Officers	• Monitor the overall pharmacovigilance process in their Districts • Jointly review the progress of PV activities in their districts • Conduct regular orientations at district levels
5.	Vector Borne Disease Consultants	• Follow up with medical officers and nurses for reported adverse drug reactions • Communicate with KTS for follow up cases
6.	Medical officers (District/Block level)	• Early detection of any adverse drug reaction during infusion of AmBisome • Identification of adverse drug reactions from any kala-azar medicine during regular checkup • Identification of any drug interaction due to any concomitant drugs (specifically, in case of co-infections) • Filling of suspected Adverse Drug reaction Form for kala-azar Treatment • Causality assessment of ADRs • Evaluate severity and seriousness of the reaction • Encourage patients to report adverse drug reaction voluntarily • Inform patients about toll-free number (1800-180-3024) of Pharmacovigilance Programme of India to report any adverse drug reaction • Counsel patients on reporting of possible adverse drug reactions after discharge from hospital • Entry of data into PvPI software at district level, where required

7.	Data Entry Operators (District/block level)	• Enter the data from adverse drug reaction forms to the PvPI software • Proper documentation of the adverse drug reaction forms at their centre
8.	Nurses	• Early detection of any adverse event during infusion of AmBisome • Identification of any drug interaction due to any concomitant drugs (specifically, in case of co-infections) • Filling of suspected adverse drug reaction form • Encourage and counsel patients to report adverse drug reaction voluntarily • Inform patients about Pharmacovigilance Programme of India toll-free number to report adverse drug reactions and how to report adverse drug reactions after discharge
9.	Partners	• Help in spreading awareness among kala-azar patients for reporting adverse drug reactions • Assist in entering adverse drug reactions data into the PvPI software • Support to Data Entry Operators • Provide support on training of ASHA facilitators and ANMs on pharmacovigilance process • Work with KTS to identify the follow up cases and fill the follow up adverse drug reaction form
10.	Kala-azar technical supervisors (KTS)	• Provide support on training of ASHA facilitators and ANMs on pharmacovigilance process • Work with ASHA facilitators and ANMs to identify the follow up cases • Help in spreading awareness among kala-azar patients for reporting adverse drug reactions
11.	ASHA / Anganwadi staff	• Encourage and counsel patients to report adverse drug reaction • Talk to patients in every village/ block and identify any adverse drug reactions happened to any patient due to Kala-azar treatment at any point • Detection of adverse drug reaction after discharge from hospital following infusion of Ambisome • Follow Up of patients on adverse drug reactions during routine visits and fill Follow Up form, if any ADRs are reported

4.4.5 Phase 2 of Implementation of pharmacovigilance activities

a) Training Plan and Capacity Building Activities for Pharmacovigilance at State Levels

Activities for Pharmacovigilance at State Levels

- Organize workshops and trainings for VBD officers, district medical officers, zonal officers, medical college HCPs (AMC Coordinator and treating physicians)
- Monitor the pharmacovigilance processes and reporting of VBD medicines
- Field visits to district hospitals and medical colleges, block level hospitals, to monitor the activities related to adverse drug reaction reporting and collect feedback
- Analysis of the monthly collected data from all the districts by Pharmacovigilance Programme of India and monthly reporting to programme and other stakeholders
- Monthly meetings at state levels to review the process at various levels, discuss the issues and challenges, take recommendations and feedbacks

b) Training plan and capacity-building activities for pharmacovigilance at district levels

Activities for pharmacovigilance at district levels

- Organize three workshops in Bihar, Jharkhand and West Bengal for block level medical officers, data entry operators and nurses
- Adverse drug reactions will be entered in PvPI software by data entry operators in every district and block level hospitals or by the nearest Pharmacovigilance Programme of India ADR monitoring centers, on monthly basis
- Conduct review meetings periodically at district and block level for healthcare providers to update them on standard process of adverse drug reaction reporting, assess causality, severity of reaction and take their feedbacks on how to improve the existing program
- Training of Field Monitors, ASHA and KTS supervisors for Identification and filling of follow up forms for follow up of the cases
- Spread awareness by regular workshops at district level for medical officers and VBD officers on any updates, sharing data reports
- Expedited reporting of serious and unexpected adverse drug reaction is required as soon as possible, but in no case later than 15 calendar days.
- Death cases should be reported within 24 hours to the Pharmacovigilance Programme of India

Filling of ADR reporting form and data entry into PvPI software: Roles and responsibilities

State	Level	Responsibilities	
		Form filling	Data entry
Bihar	Block level	Block level physicians providing AmBisome treatment to fill the forms and perform causality assessment	Block level data entry operator will enter the data in PvPI software
West Bengal	District/Block level & Treating medical colleges	Block level physicians providing AmBisome treatment to fill the forms and perform causality assessment	District level data entry operators and medical college associates will enter the data in PvPI software
Uttar Pradesh	District level & Treating medical colleges	District hospital physicans & treating physicians of medical colleges providing AmBisome, will fill adverse drug reaction reporting form and perform causality assessment	District level data entry operators and medical college associates will enter the data in PvPI software
Jharkhand	District level	District hospital physicans providing AmBisome will fill adverse drug reaction reporting form and perform causality assessment	District level data entry operators and medical college associates will enter the data in PvPI software

Capacity-building of functionaries: At a glance

Capacity building Timeline			Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Operational Phase	Phase 1	Organise National Level Workshop										
		Situation Analysis: Review the feedback & recommendations from the workshop										
	Phase 2	1st State level training & workshop in Jharkhand along with West bengal and UP										
		1st district level training & workshop in Jharkhand										
		Second state level workshop in Bihar										
		Second district level training & workshop in Bihar										
		Third district level training & workshop in West Bengal										
		Conduct regular meetings to take feedback										
		Follow up forms filled by ASHA, KTS, CARE										
		Spread awareness among KA patients for reporting ADR										
		Organise regular orientations for doctors and other staff										
Outcome Phase	Phase 3	Assessment of the Outcomes										
		Share the reports with participating organizations										
		Periodic reporting of the analysed data to the programme by PvPI										
		Provide Early Warnings & Signal Detection										
		Monitoring and technical support to different levels for ADR management										

Pharmacovigilance reporting: The process

Detection and reporting of adverse drug reaction at district hospitals, medical colleges, or block level by medical officers

↓

Data entry into Pharmacovigilance Programme of India (PvPI) software by district medical officers/data entry operators

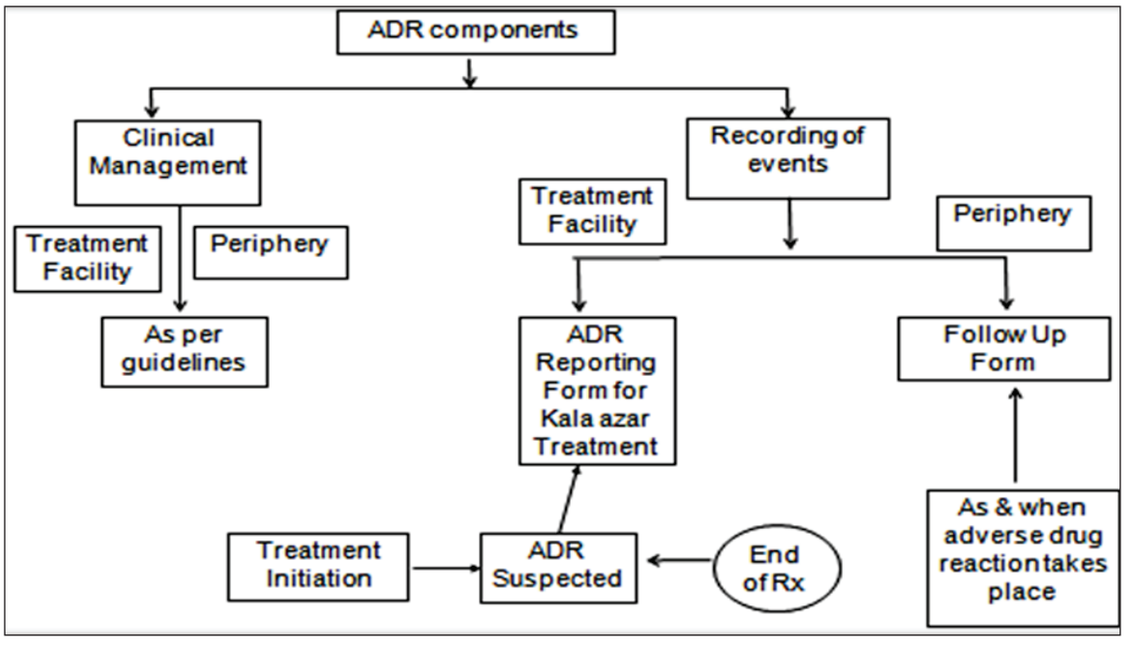
↓

Pharmacovigilance Programme of India will analyse the data with WHO Support

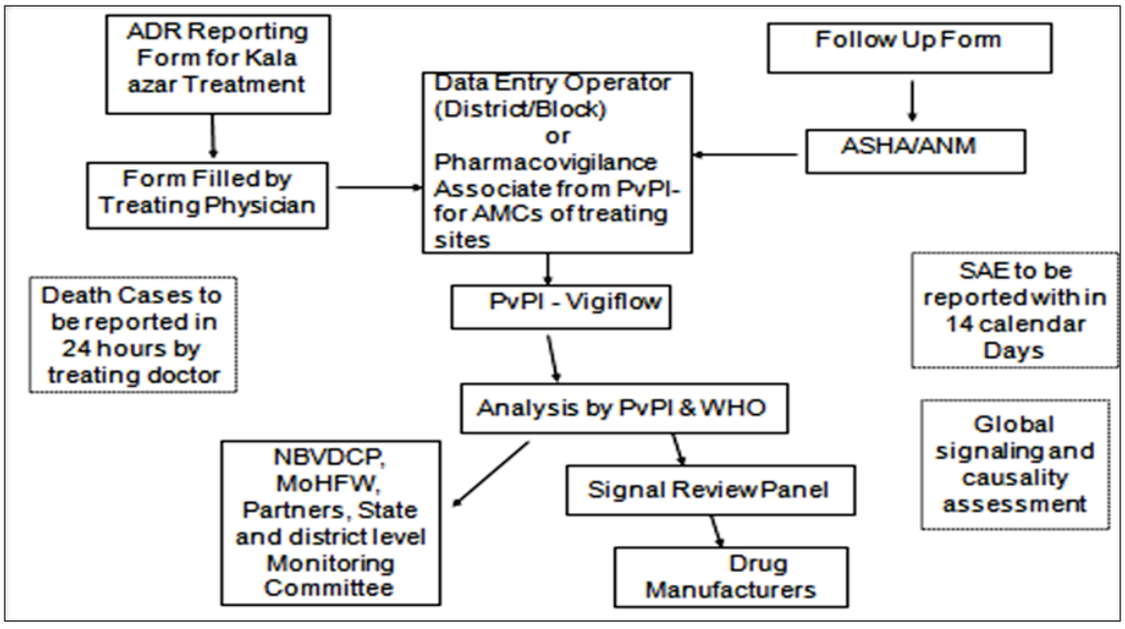
↓

Pharmacovigilance Programme of India will communicate the outcomes (early trends, warnings, signals) to all the stakeholders including NBVDCP, MoHFW, WHO, PvPI, States and Districts

Flowchart 1: ADR management and data capturing related to pharmacovigilance



Flowchart 2: Protocol on data entry, sharing of data and analysis



4.4.6 Phase 3: Outcome phase

Outcome phase will have a major focus on analysis and collation of the ADRs in the PvPI database & generation of signals. There would be periodic reporting of the analyzed data to the programme by Pharmacovigilance Programme of India with the support of WHO.

Technical support will be provided to different levels for:

- Monitoring and evaluation of ADRs
- Analysis and signal detection from the reported data
- Designation of new ADR Monitoring Centres by PVPI to enable scale up PV activities in endemic states
- Facilitate the access to PvPI Software and provide training
- Providing technical support to different levels for adverse drug reaction management

4.5 Frequently asked questions on pharmacovigilance

Q 1. What is Pharmacovigilance?

Pharmacovigilance, as defined by the World Health Organization, is the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions or any other possible drug-related problems. Recent inclusions to this definition are: herbals, traditional and complementary medicines, blood products, biologicals, medical devices and vaccines.

Q 2. What is Pharmacovigilance Programme of India (PvPI)?

The Central Drugs Standard Control Organisation (CDSCO), New Delhi has initiated a nation-wide pharmacovigilance programme under the aegis of Ministry of Health & Family Welfare, Government of India. The programme is coordinated by The Indian Pharmacopoeia Commission (IPC) located at Ghaziabad. The National Coordinating Centre (NCC) is operating under the supervision of Steering Committee to recommend procedures and guidelines for regulatory interventions in India.

Q 3. What is an Adverse Drug Reaction (ADR)?

It is a noxious response to a drug which is unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.

Q 4. What is Serious Adverse Event (SAE)?

A serious adverse event or adverse reaction is any untoward medical occurrence that at any dose:

- Results in death
- Is life-threatening
- Requires in patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity or
- Is a congenital anomaly or birth defect

Q 5. What is the difference between side-effect and Adverse Drug Reaction?

A side effect is any unintended effect of a pharmaceutical product occurring at doses normally used by a patient which is related to the pharmacological properties of the drug.

An adverse drug reactiont or experience is defined as a noxious response to a drug which is unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.

Q 6. Why to report ADR?

As a healthcare professional and citizen of India its moral responsibility to report adverse reaction associated with pharmaceutical products to safeguard public health and help in improving patient safety.

Q 7. Who can report Adverse Drug Reaction?

All healthcare professionals including Clinicians, Dentists, Pharmacists, Nurses and Non-healthcare professionals (patients, consumers) can report ADRs.

Q 8. What type of Adverse Drug Reactions should be reported?

All types of suspected adverse drug reactions irrespective of whether they are known or unknown, serious or non-serious and frequent or rare should be reported.

Q 9. How do we report ADRs through PvPI?

The health care professional attending to the patient, can:

- fill up the suspected ADR form for ADR can report to the nearest ADRs Monitoring Centres (AMCs) under Pharmacovigilance Programme of India (PvPI). The details of AMCs are given in the website of IPC i.e. www.ipc.gov.in
- Toll free helpline (1800-180-3024) number on all working days (Mon-Fri) from 9:00 am-5.30 pm. If a call is not responded then one can drop a voice message on voice recording system.
- Email the form directly to: pvpi@ipcindia.net or ipclab@vsnl.net.
- Android Mobile App: adr (ADR Reporting) PvPI

Q 10. What will happen after submitting the ADR?

There will be monthly reporting for trends of ADRs by PvPI, with technical support of WHO, to NVBDCP and MoHFW. The ADRs will be sent to PvPI software/database for analysis and signal detection. ADRs will be evaluated and the inferences will be used to recommend regulatory body i.e. CDSCO to take necessary regulatory interventions, besides communicating risks to healthcare professionals and the public.

Q11. Terminologies used in ADR Reporting Form

Causality

The evaluation of the likelihood that a particular medicine was the cause of an observed adverse reaction is known as Causality. Causality assessment is done according to established WHO-UMC algorithm (as given below):

Table: WHO-UMC Causality Categories

Causality term	Assessment criteria*
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an bjective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary

Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable / Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified
* All points should be reasonably complied with	

Causal relationship

A relationship between one phenomenon or event (A) and another (B) in which A precedes and causes B. In pharmacovigilance; a medicine causing an adverse reaction.

Congenital anomalies

Morphological, functional and/or biochemical developmental disturbance in the embryo or foetus whether detected at birth or not. The term congenital anomaly is broad and includes congenital abnormalities, foetopathies, genetic diseases with early onset, developmental delay, etc.

Dechallenge

The withdrawal of a drug from a patient; the point at which the continuity, reduction or disappearance of adverse effects may be observed.

Expectedness

Expectedness means the adverse event/ side effect is expected or has been previously documented as adverse drug reaction with the use of the drug as per the reference safety information.

Outcome

An outcome is one of the possible results or effect of an event.

Rechallenge

The point at which a drug is again given to a patient after its previous withdrawal (see dechallenge).

Severity

The severity of a specific event describes its intensity, and it is the intensity which is graded.

Mild	Moderate	Severe
Mild symptoms causing no or minimal interference with usual social & functional activities with intervention not indicated	Moderate symptoms causing greater than minimal interference with usual social & functional activities with intervention indicated	Severe symptoms causing inability to perform usual social & functional activities with intervention or hospitalization indicated

* *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 2.0; Accessed from: http://rsc.tech-res.com/docs/default-source/safety/daids_ae_grading_table_v2_nov2014.pdf*

Seriousness vs. severity

- Severity is the intensity of a specific event (mild, moderate and severe); the event however may be of relatively minor medical significance (eg: severe headache)

- Seriousness is based on patient event/outcome or action criteria which may serve as regulatory reporting obligation[10]

[10]http://ipc.nic.in/index2.asp?slid=466&sublinkid=371&lang=1&EncHid=; https://www.who-umc.org/graphics/25301.pdf

Annexure 1 (adopted from TRS 949)

Performance of the rK39 rapid diagnostic test

The utility of a rapid diagnostic test for visceral leishmaniasis lies in its simplicity.
Several brands of test with rK39 antigen are available. Operators should always read the package insert carefully, and follow the manufacturer's instructions. This is especially important with regard to the type of specimen used: serum or whole blood. Some brands can be used only with serum, while others can be used with whole blood collected by finger prick.

Test procedure

Refer always to the specifications given by the manufacturer.

In general, the test procedure is as follows (Figure A5.1):

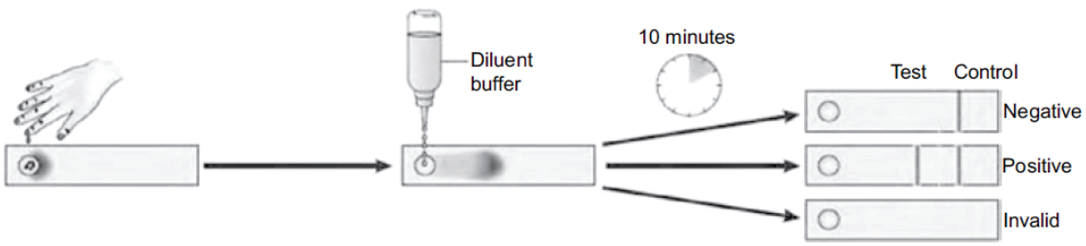
1. Remove the test strip from the pouch and place it on a flat surface
2. Place a specified amount of patient specimen (serum or finger-prick blood) on the absorbent pad on the bottom of the strip
3. Add the specified amount of buffer provided
4. Read the result after 10–20 min, according to the manufacturer's instructions

Figure A5.1.

Some brands require a slightly different procedure, for example:

1. Take a test tube or a U-bottom microtitre plate
2. Add a specified amount of buffer to the tube or well
3. Add a specified amount of specimen (blood or serum) to the tube or well and mix
4. Immerse the test strip into the buffer–specimen mixture
5. Read the result after 10–20 min, according to the manufacturer's instructions

Procedure for performing the rK39 rapid diagnostic test



Points to consider for optimizing use of rapid diagnostic tests:

- Have a clear management plan to deal with·
- positive and negative results
- Follow biosafety standards and precautions for handling blood and other body fluids
- Ensure proper storage conditions
- Do not use damaged or expired tests
- Adhere strictly to the manufacturer's instructions
- Use test kits within 1 h of removal from pouch
- Read the results within the time specified by the manufacturer
- Do not reuse a test

Interpretation of the test

Positive result: When both control and test lines appear, the sample tested has antibodies against recombinant K39 antigen of Leishmania. Even a faint line should be considered positive.

Negative result: When only the control line appears, there are no antibodies against recombinant K39 antigen of Leishmania present in the patient's sample.

Invalid result: When no control line appears, a fresh patient sample should be tested with a new strip.

Advantages and disadvantages of the rK39 test

Advantages

- Simple to perform with minimal training.
- Does not require a laboratory.
- Can be performed with finger-prick whole blood, serum or plasma.
- Kits can be transported and stored at ambient temperature (up to 30°C).
- Results are available within 10–20 min.

Disadvantages

- Cannot distinguish between active cases and relapse in previously treated cases. Therefore, interpretation must always be accompanied by clinical case definition.

In patients with advanced HIV infection, a negative result does not rule out a diagnosis of visceral leishmaniasis.

Annexure 2 (adopted from WHO TRS 949)

Procedures for splenic aspiration and grading of parasites

Splenic aspiration should be performed only if the following conditions are met:

- absence of clinical contraindication(s):
    - o signs of active bleeding (e.g. epistaxis, rectal bleeding, skin bruises)
    - o jaundice (a potential marker of liver dysfunction)
    - o pregnancy
    - o spleen barely palpable
    - o bad general condition (e.g. cardiovascular shock, altered consciousness)
- absence of biological contraindication(s):
    - o severe anaemia (haemoglobin count <5 g/l)
    - o difference in prothrombin time between patient and control > 5 s
    - o platelet count < 40 000/ml
- rapid access to blood transfusion in case of bleeding

The two important prerequisites for the safety of the procedure are rapidity, so that the needle remains within the spleen for less than l s; and precision, so that the entry and exit axes of the aspirating needle are identical to avoid tearing the splenic capsule.

The procedure is as follows:

1. Clean three glass slides and label them with patient´s name, date and the words ‘splenic aspirate’. Have culture medium ready (if available) and labelled in the same way as the slides. Attach a 11/4 -inch × 21-gauge (32 × 0.8-mm) needle to a 5-ml syringe. Place all items on a table at the bedside.

2. Inform the patient about the procedure. Check all clinical and biological contraindications again. Palpate the spleen and outline its margins on the patient´s abdomen with a pen. For safety, the spleen should be palpable at least 3 cm below the costal margin on expiration. Use an alcohol swab to clean the skin at the site of aspiration, and allow the skin to dry.

3. With the 21-gauge (0.8-mm) needle attached to the 5-ml syringe, just penetrate the skin, midway between the edges of the spleen, 2–4 cm below the costal margin. Aim the needle cranially at an angle of 45° to the abdominal wall. The actual aspiration is done as follows: pull the syringe plunger back to approximately the 1- ml mark to apply suction, and with a quick in-and-out movement push the needle into the spleen to the full needle depth and then withdraw it completely, maintaining suction throughout.

4. For young, restless children, have two assistants hold the child (arms folded across the chest, with shirt raised to obstruct the line of vision, and pelvis held firmly). Carry out the aspiration as a single-stage procedure, using the same landmarks, angles and suction as in step 3, all in one quick motion. The insertion should be timed with the patient´s breathing so that the diaphragm is not moving; this should be done during fixed expiration if the child is crying. Only a minute amount of splenic material is obtained, but this is sufficient for culture and smear.

5. If culture is available: slowly pull the plunger back to the 2–3-ml mark, and, using sterile techniques, insert the needle into a tube containing culture medium and briskly push the plunger into the barrel to expel the contents of the needle onto the side walls of the tube. If necessary, repeat once or twice until splenic material is visible in the tube. Replace the cap on the tube and invert to wash splenic material on the side of the tube. Repeat the procedure for the second tube of culture medium. Sterile techniques are essential throughout.

6. Expel material (or additional material if culture is available) gently onto glass slides, holding the needle tip on the surface of the slide. Immediately spread evenly with the needle, using a linear (not circular) motion. The smear should be slightly thinner than a thick blood film for malaria. Remove the needle, and use the end of it to obtain additional material from the tip of the syringe and spread it on slides. Further material found on the end of the plunger may be dabbed directly onto a slide and spread. Allow the slides to dry.

7. Write the time of aspiration on the patient's chart, with the instructions: "Record pulse and blood pressure every half hour for 4 h, then every hour for 6 h. Patient must remain in bed for 12 h." Ensure that the patient understands the instructions. Enter the procedure in the notes, and sign.

8. Take the slides (and medium) to the laboratory. Slides are stained with Giemsa as for a thin malaria film and examined under oil immersion.

The average amastigote density is graded as follows:

6+: > 100 parasites per field (viewed with a 10× eyepiece and 100×oil- immersion lens)

5+: 10–100 parasites per field

4+: 1–10 parasites per field

3+: 1–10 parasites per 10 fields

2+: 1–10 parasites per 100 fields

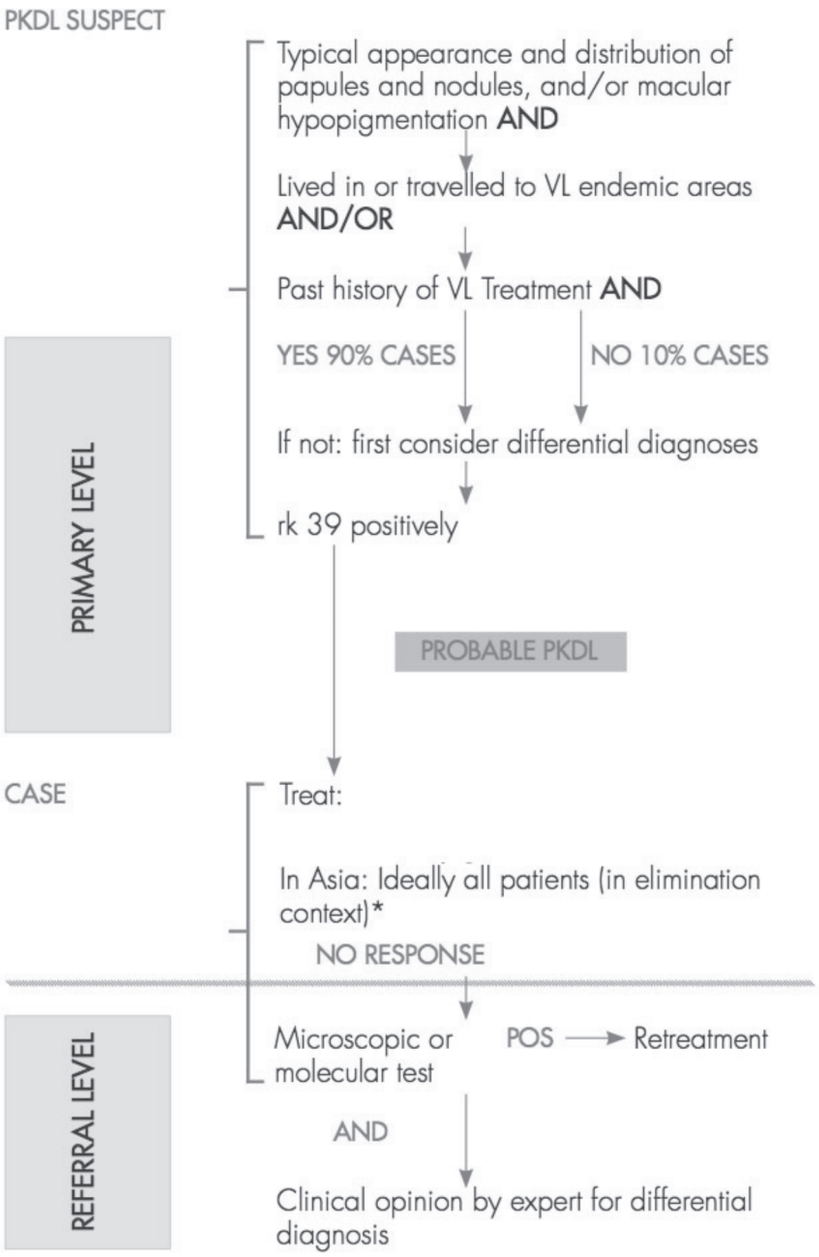
1+: 1–10 parasites per 1000 fields

0: 0 parasite per 1000 fields

Parasite grading has several uses. It increases the sensitivity of parasite detection, provides an objective measure of the speed of response to treatment, distinguishes quickly between slow responders and non responders, and provides an indication of parasite load that is useful in research.

Annexure 3

Algorithm for diagnosing and treating post-kala-azar dermal leishmaniasis (PKDL)



Annexure 4

Dose calculation of insecticide for IRS

Flow rate from a pump (stirrup/hand compression):

Please note that a spray operator should spray a 2 metre (6 ft) high wall with 0.75 m swathe in 5 seconds, i.e. speed = 24 m/min.

Discharge rate:

1. If hand compression pump with CFV is used- 550 mL liquid per minute
2. If hand compression pump without CFV is used- 650-750 mL liquid per minute (average 700 mL)
3. If stirrup pump with CFV is used- 550 mL liquid per minute
4. If stirrup pump without CFV is used- 650-750 mL liquid per minute (average 700 mL)

Example- Taking that nozzle of a compression sprayer with CFV emits a fixed 550 mL liquid per minute, it will deposit 30mL per square metre on wall surface, as calculated under. Following is the formula

$$\textbf{Spray deposit rate} = \frac{\textbf{Volume of suspension (in mL per minute)}}{\textbf{Swath width (in metre) X Operator's speed (in metre per min)}}$$

$$= \frac{505}{0.75 \times 24} = 30\text{mL/m}^2$$

Now, when a stirrup pump is used, normal discharge rate can be 650-750 mL per minute. Taking 700 mL mean value, the discharge from above formula comes to about 40 mL per square metre (actually 38.9mL).

Calculation of dose of insecticide for making solutions: what is happening in different states

Example of dose calculation:
Alphacypermethrin 5% WP applied at 0.025g/m^2 (25 mg/m^2) on walls

(use of CFV with compression sprayers)

Bihar: preparing 7.5 L solution using 125 g 5% (WP) alpha-cypermethrin using hand compression pump with CFV	A	Dose of the insecticide active ingredient to be applied on walls in gram per square metre	0.025
	B	Percentage of the insecticide formulation being used	5
	C	Amount of water in the sprayer tank in milli litre (mL) i.e., 7.5 L = 7500 mL	7500
	D	Amount of liquid suspension applied per m2 of wall using a CFV (i.e. 30 mL/m^2)	30
	E	Surface to be treated with one tank load of 7.5 L = C÷ D = 7500 ÷ 30 = 250 m^2	250
	F	Quantity of active ingredient needed to cover 250 m2 wall area = A x E gram	6.25
	G	Quantity in gram of formulation needed per tank load to cover 250 m^2 area = F x 100/B	125

Example of dose calculation: Alphacypermethrin 5% WP applied at 0.025g/m^2 (25 mg/m^2) on walls

(use of stirrup pump with no CFV with 700mL per minute discharge)

Bihar: preparing 15 L solution in bucket using stirrup pump without CFV with a discharge rate of 700 mL per minute)	A	Dose of the insecticide active ingredient to be applied on walls in gram per square metre	0.025
	B	Percentage of the insecticide formulation being used	5
	C	Amount of water in the sprayer tank (bucket) in milli litre (mL) i.e., 15 L = 15000 mL	15000
	D	Amount of liquid suspension applied per m^2 of wall without using a CFV (i.e. flow rate/m^2)	40
	E	Surface to be treated with one tank load of 15 L = C÷ D (in m^2)	375
	F	Quantity of active ingredient needed to cover 375 m^2 wall area =A x E gram	9
	G	Quantity in gram of formulation needed per 15L bucket load to cover 375 m^2 area = F x 100/B	188

Example of dose calculation: Alphacypermethrin 5% WP applied at 0.025g/m^2 (25 mg/m^2) on walls

(use of stirrup pump with no CFV with 700mL per minute discharge)

Jharkhand: preparing 10 L solution in bucket using stirrup pump without CFV with a discharge rate of 700 mL per minute)	A	Dose of the insecticide active ingredient to be applied on walls in gram per square metre	0.025
	B	Percentage of the insecticide formulation being used	5
	C	Amount of water in the sprayer tank (bucket) in milliliter (mL) i.e., 10 L = 10000 mL	10000
	D	Amount of liquid suspension applied per m2 of wall using a CFV (i.e. flow rate/m^2)	40
	E	Surface to be treated with one tank load of 10 L = C÷ D (in m^2)	250
	F	Quantity of active ingredient needed per tank load to cover 250m^2 area =A x E gram	6.25
	G	Quantity in gram of formulation needed per tank load to cover 250 m2 area = F x 100/B	215

Note: doses in decimal have been rounded off

Note: If the discharge rate is 650mL the WP quantity will be about 140g; if it 750 mL (i.e. when more water is emitted), the WP quantity will be lower, i.e. 120g. Same calculation can be done for DDT as below.

Example of dose calculation: DDT 50% applied at 1g/m2 on walls

A	Dose of the insecticide active ingredient to be applied on walls in gram per square metre	1
B	Percentage of the insecticide formulation being used	50
C	Amount of water in the sprayer tank in milliliter (mL) i.e., 7.5 L = 7500 mL	7500
D	Amount of liquid suspension applied per m2 of wall using a CFV (i.e. 30 mL/m^2)	30
E	Surface to be treated with one tank load of 7.5 L = C÷ D = 7500 ÷ 30 = 250 m^2	250
F	Quantity of active ingredient needed to cover 250 m^2 wall area = A x E = 1 x 250 = 250g	250
G	Quantity of formulation needed per tank load to cover 250 m2 area = F x 100/B = 250 x 100/50 = 500g	500

Annexures 5

WHO Pesticide Evaluation Scheme recommended insecticide formulations

Insecticide compounds and formulations[1]	Class group[2]	Dosage (g a.i./m^2)	Mode of action	Duration of effective action (months)
DDT WP	OC	1-2	contact	>6
Malathion WP	OP	2	contact	2–3
Fenitrothion WP	OP	2	contact & airborne	3–6
Pirimiphos-methyl WP & EC	OP	1-2	contact & airborne	2–3
Pirimiphos-methyl CS	OP	1	contact & airborne	4–6
Bendiocarb WP	C	0.1–0.4	contact & airborne	2–6
Propoxur WP	C	1–2	contact & airborne	3–6
Alpha-cypermethrin WP, SC	PY	0.02–0.03	contact	4–6
Alpha-cypermethrin WG-SB	PY	0.02–0.03	contact	up to 4
Bifenthrin WP	PY	0.025–0.05	contact	3–6
Cyfluthrin WP	PY	0.02–0.05	contact	3–6
Deltamethrin SC-PE	PY	0.02–0.025	contact	6
Deltamethrin WP, WG, WG-SB	PY	0.02–0.025	contact	3–6
Etofenprox WP	PY	0.1–0.3	contact	3–6
Lambda-cyhalothrin WP, CS	PY	0.02–0.03	contact	3–6

Annexure 6

Adverse Drug Reaction Reporting Form For Kala Azar Drugs

Ministry of Health & Family Welfare Government of India

World Health Organization COUNTRY OFFICE FOR India

ADVERSE DRUG REACTION REPORTING FORM FOR KALA-AZAR (KA) TREATMENT

I. PATIENT DETAILS

Patient Initials:	Patient Code No:	Patient Contact No:	AMC report number:
Patient Age: (Yr)		Weight: (Kg)	
Gender: M ☐ F ☐ Others ☐		Breastfeeding an infant: Yes☐ No☐	Worldwide unique number:
Pregnant: Yes ☐ No ☐ Uncertain ☐		If Pregnant, estimated current gestation (weeks):	

II. TREATMENT

A) CONDITION TREATED

Kala Azar (KL) ☐	Post Kala Azar Dermal Leishmaniasis (PKDL) ☐	HIV-VL Co-infection ☐	Others ☐ (Specify)

B) TREATMENT RECEIVED

Mono Therapy ☐ Combination Therapy ☐

Drug Received	Batch No./ Expiry Date	Drug Dose & Unit	Frequency	Route	Start Date (dd/mm/yyyy)	Start Time (Hr:Min)	Stop Date (dd/mm/yyyy)	Stop Time (Hr:min)
Liposomal Amphotericin B								
Miltefosine								
Paromomycin								
Amphotericin B deoxycholate								
SSG/ SAG								
.....								

III. CONCOMITANT DRUGS

S. No.	Name	Indication	Batch Number/ Expiry Date	Drug Dose Unit (if I.V) Infusion rate in ml/hour	Dose & Unit	Frequency	Route	Start Date	Stop date

IV. ADVERSE EVENTS INFORMATION

Reporter's Narrative (Describe the course of events, timing and suspected causes):

Adverse Event/ Reaction Term	Event I	Event II	Event III
Date of Onset	DD/MM/YY	DD/MM/YY	DD/MM/YY
Date Resolved	DD/MM/YY	DD/MM/YY	DD/MM/YY
Severity	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Seriousness	☐ Non-Serious ADR ☐ Serious AE/ADR please specify category ; ☐ Death ☐ Hospitalization/ Prolonged ☐ Life threatening ☐ Permanent disability/disabling ☐ Congenital anomaly/ birth defect ☐ Other medically important condition	☐ Non-Serious ADR ☐ Serious AE/ADR please specify category ; ☐ Death ☐ Hospitalization/ Prolonged ☐ Life threatening ☐ Permanent disability ☐ Congenital anomaly ☐ Other medically important condition	☐ Non-Serious ADR ☐ Serious AE/ADR please specify category ; ☐ Death ☐ Hospitalization/ Prolonged ☐ Life threatening ☐ Permanent disability ☐ Congenital anomaly ☐ Other medically important condition

Ministry of Health & Family Welfare Government of India

World Health Organization COUNTRY OFFICE FOR India

Outcome	☐ Recovered/ resolved ☐ Recovering/resolving ☐ Fatal ☐ Not Recovered/not resolved ☐ Recovered with Sequalae ☐ Unknown	☐ Recovered/ resolved ☐ Recovering/resolving ☐ Fatal ☐ Not Recovered/not resolved ☐ Recovered with Sequalae ☐ Unknown	☐ Recovered/ resolved ☐ Recovering/resolving ☐ Fatal ☐ Not Recovered/not resolved ☐ Recovered with Sequalae ☐ Unknown
Dechallenge/ Action Taken	☐ Drug Withdrawn ☐ Dose Reduced Dose…… ☐ Dose Increased ☐ Dose not changed ☐ Unknown ☐ Not Applicable	☐ Drug Withdrawn ☐ Dose Reduced Dose…… ☐ Dose Increased ☐ Dose not changed ☐ Unknown ☐ Not Applicable	☐ Drug Withdrawn ☐ Dose Reduced Dose…… ☐ Dose Increased ☐ Dose not changed ☐ Unknown ☐ Not Applicable
Rechallenge	☐ No ☐ Yes Dose (if reintroduced)…….. ☐ Unknown	☐ No ☐ Yes Dose (if reintroduced)…….. ☐ Unknown	☐ No ☐ Yes Dose (if reintroduced)…….. ☐ Unknown
Expectedness	☐ Expected (yes) ☐ Unexpected (no)	☐ Expected (yes) ☐ Unexpected (no)	☐ Expected (yes) ☐ Unexpected (no)
For Death	Date of Death…… Primary cause of death (if known): …… Was autopsy performed? ☐ No ☐ Yes Hospital Admission Date …… Hospital Discharge Date……..	Date of Death…… Primary cause of death (if known): …… Was autopsy performed? ☐ No ☐ Yes Hospital Admission Date …… Hospital Discharge Date……	Date of Death…… Primary cause of death (if known): …… Was autopsy performed? ☐ No ☐ Yes Hospital Admission Date…… Hospital Discharge Date……
Causality [-Certain -Probable - Possible - Unlikely - Conditional - Unassessable]	☐ Ambisome…….. ☐ Miltefosine …… ☐ Paromomycin…… ☐ Amphotericin deoxycholate…… ☐ SSG/ SAG…… ☐ Others (……)……	☐ Ambisome…….. ☐ Miltefosine …… ☐ Paromomycin…… ☐ Amphotericin deoxycholate…. ☐ SSG/ SAG…… ☐ Others (……)……	☐ Ambisome…….. ☐ Miltefosine …… ☐ Paromomycin…… ☐ Amphotericin deoxycholate…… ☐ SSG/ SAG…… ☐ Others (……)……

V. MEDICAL HISTORY

Briefly describe diseases and concurrent illness:

VI. RELEVANT LABORATORY TESTS

LABORATORY TESTS					
Test	**Date**	**Result (units)**	**Test**	**Date**	**Result (units)**
Haemoglobin			Creatinine		
ALT (SGPT)			Na^+		
AST (SGOT)			K^+		

VII. OTHER CLINICALLY RELEVANT INFORMATION

Treatment For Managing ADR:

Counseling with Toll Free Number (18001803024): ☐ **Yes** ☐ **No**

VIII. REPORTERS INFORMATION

Name:	**Designation:**	**Signature:**
Email:	**Contact No.:**	
Professional Address:	**PIN Code:**	**Date:**
Name of Paramedical:	**Designation:**	**Signature:**

Annexure 7

Version 1.0
संस्करण 1.0

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

औषधि दुष्प्रभाव सूचना फॉर्म (उपभोक्ताओं के लिए)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.

भारतीय भेषज संहिता आयोग, राष्ट्रीय समन्वय केंद्र – भारतीय फार्माकोविजिलेंस कार्यक्रम, स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार।

1.Patient Details/ रोगी का विवरण

Patient Initials/ रोगी के आद्याक्षर:: ☐☐	Gender/ लिंग (√): Male/ पुरुष ☐ Female/ स्त्री ☐ Other/ अन्य ☐	Age (Year or Month)/ आयु (वर्ष या माह) :

2. Health Information/ स्वास्थ्य संबंधी जानकारी

a. Reason(s) for taking medicine(s)(Disease/Symptoms)/ दवा(दवाएं) लेने का कारण (रोग/लक्षण):

b. Medicines Advised by/ दवाई की सलाह देने वाला (√): Doctor/ डॉक्टर ☐ Pharmacist/ फॉर्मासिस्ट ☐ Friends/Relatives/ मित्र/रिश्तेदार ☐ Self (Past disease experienced/No past disease experienced)/ स्वयं (पूर्व बीमारी का अनुभव/पूर्व बीमारी का कोई अनुभव नहीं) ☐

3. Details of Person Reporting the Side Effect/ दुष्प्रभाव की सूचना देने वाले व्यक्ति का विवरण

Name (Optional)/ नाम (वैकल्पिक):

Address/ पता:

Telephone No/ टेलीफोन नं:	Email/ ईमेल:

4. Details of Medicine Taking/Taken/ ली जा रही है / ली जा चुकी दवाई का विवरण

Name of Medicines/ दवाइयों के नाम	Quantity of Medicines taken (e.g. 250 mg, Two times a day)/ ली गई दवाई की मात्रा (उदाहरण के लिए 250 मिग्रा, एक दिन में दो बार)	Expiry Date of Medicines/ दवा के निष्क्रिय होने की तिथि	Date of Start of Medicines/ दवाइयां आरंभ करने की तिथि	Date of Stop of Medicines/ दवाइयां रोकने की तिथि
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy

Dosage form/खुराक का स्वरूप (√) : Tablet/ गोली (टैबलेट) ☐ Capsule/ कैप्सूल ☐ Injection/ इंजेक्शन ☐ Oral Liquids/ मौखिक तरल ☐ If Others (Please Specify.....)/यदि अन्य (कृपया निर्दिष्ट करें.....)

5. About the Side Effect/ दुष्प्रभाव के बारे में

When did the side effect start?/ दुष्प्रभाव की शुरुआत कब हुई थी? dd/mm/yy Side Effect is still Continuing (Yes/No)/

When did the side effect stop?/ दुष्प्रभाव कब समाप्त हुआ था? dd/mm/yy क्या दुष्प्रभाव जारी हैं (हां/नहीं): dd/mm/yy

6.How bad was the Side Effect? (Please √ the boxes that Apply)/ दुष्प्रभाव कितने हानिकारक थे? (कृपया जो लागू हो, उस पर √ का निशान लगाएं)

☐ Did not affect daily activities/ दैनिक गतिविधियां प्रभावित नहीं हुई थी	☐ Affect daily activities/ दैनिक गतिविधियां प्रभावित हुई
☐ Admitted to hospital/ अस्पताल ले जाना पड़ा	☐ Death/ मृत्यु
☐ Others/ अन्य	

7.Describe the Side Effect (What did you do to manage the side effect?)/ दुष्प्रभाव की व्याख्या करें (आपने दुष्प्रभावों से छुटकारा प्राप्त करने के लिए क्या किया)?

Annexure 8

List of adverse drug reactions from Kala-azar drugs

Medicine	Common ADR	Other ADRs	
Liposome Amphotericin B (LAMB) / Ambisome	• Rigors/chills • Pyrexia • Back pain • Rash • Hypokalemia • Hyponatremia • Hypocalcemia • Hypomagnesaemia • Hyperglycemia • Headache • Tachycardia • Vasodilatation • Flushing • Hypotension • Nausea • Vomiting • Abdominal Pain • Diarrhea • Dyspnea • Liver function tests abnormal • Hyperbilirubinemia • ALP increased • BUN increased • Creatinine increased • Chest pain	• Asthenia • Pruritus • Sepsis • Thrombocytopenia • Anaphylactoid reaction • Anaphylactic reactions • Hypersensitivity • ALT/SGPT increased • AST/SGOT increased • Edema • Hypervolemia • Peripheral edema • Convulsion • Anxiety • Insomnia • Renal insufficiency	• Cardiac arrest • Arrhythmia • Cough increased • Epistaxis • Hypoxia • Lung disorder • Pleural effusion • Rhinitis • Gastrointestinal hemorrhage • Sweating • Rhabdomyolysis (associated with hypokalemia) • musculoskeletal pain (arthralgia or bone pain) • Renal failure • Hypertension • Hematuria
Source: http://www.who.int/neglected_diseases/resources/AmBisomeReport.pdf; https://www.medicines.org.uk/emc/medicine/1236			
Miltefosine	• Abdominal Pain • Diarrhea • Nausea • Vomiting • Malaise • Pyrexia • Headache • Pruritus • Increased billirubin • Pregnancy Category D	• Motion Sickness • Melena • Dyspepsia • Asthenia • Pain at lesion • Dizziness • Somnolence • Seizure • Parasitic Infections • Absent ejaculation • Epistaxis • Jaundice	• Infestations Lymphangitis • Lesion Infection • Generalized edema • Peripheral edema • Decreased Appetite • Thrombocytopenia • Agranulocytosis • Lymphadenopathy • Scrotal pain • Decreased ejaculate volume

http://www.who.int/selection_medicines/committees/expert/18/applications/Miltefosine_application.pdf; https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204684s000lbl.pdf			
Paramomycin	• Mild injection site pain • Nausea • Vomiting • Fever • Rigors • Malaise • Liver toxicity • Ototoxicity • Nephrotoxicity	• Transient AST and ALT elevation • Reversible abnormal audiogram • ALP elevation • Ear buzzing • Blood bilirubin elevation • Albuminuria	• Injection site swelling • Abscess • Conductive deafness • Proteinuria • Hepatotoxic jaundice • Bilateral partial deafness
Source:http://archives.who.int/eml/expcom/expcom15/applications/newmed/paromomycin/paromomycin.pdf			
Amphotericin B deoxycholate	• Diarrhea • Nausea • Vomiting • Abdominal pain • Nephrotoxicity • Rigors/chills • Pyrexia • Hypokalemia • Hyponatremia • Hypocalcemia • Hypomagnesaemia • Hyperglycemia • Myalgia • Headache • Dyspnea • Chest pain • BUN increased • Creatinine increased • Liver enzymes elevated • Back pain • Rashes • Pruritis	• Anxiety • Confusion • Insomnia • Hypoxia • Wheezing • Hypotension • Tachycardia • Edema • Hypertension • Hyperbilirubinemia • Hematuria • ALP increased • ALT (SGPT) increased • AST (SGOT) increased • Bilirubinemia	• Edema • Hypervolemia • Peripheral edema • Anemia • Leukopenia • Thrombocytopenia • Phlebitis • Rhabdomyolysis (associated with hypokalemia) • musculoskeletal pain (arthralgia or bone pain) • Asthenia • Sepsis • Acute infusion reactions • Hypersensitivity reaction
Source: http://www.cdsco.nic.in/writereaddata/NFI_2011%20(1).pdf			
SAG/SSG	• Cardiac toxicity • Arthralgia • Hepato and renal toxicity • Sudden death syndrome	• Anorexia, • Nausea, • Vomiting, • Abdominal pain • ECG changes • Headache • Lethargy • Myalgia • Raised liver enzymes • Renal function impairment • Coughing • Bleeding from nose or gum • Metallic taste in mouth Dizziness	• Substernal pain • Anaphylaxis • Fever • Sweating • Flushing • Vertigo • Jaundice • Thrombosis on intravenous administration • Pain on intramuscular injection • Phlebotoxicity
Source:http://www.cdsco.nic.in/writereaddata/NFI_2011%20(1).pdf			

Annexure 9

List of Adverse Event Reporting Medical Colleges in 4 endemic Kala-azar states[11]

Bihar				
1	Indira Gandhi Institute of Medical Sciences, Bailey Road, Sheikhpura, Patna-800014	Prof. (Dr.) Harihar Dikshit	dikshithariharpatna@yahoo.co.in amcigims2015@gmail.com	0933410638
2	All India Institute of Medical Sciences, Phulwari Sharif, Patna-801505	Prof. P.P. Gupta	drprempgupta@gmail.com	07763800139 09415210579
3	Lord Buddha Koshi Medical College & Hospital, NH 107, Baijnathpur, Saharsa-852201	Dr. Akhilesh Kumar	sykalabs@yahoo.co.in	09431243204
4	Katihar Medical College, post box No. 23, Karimbagh, Katihar, Bihar-854105	Dr. C. B Choudhary	drcb_choudhary@yahoo.co.uk	09431025891
5	M. G memorial medical college, Purabbali, Dinajpur Road, Kishanganj, Bihar-855107	-	-	-
6	Sri Krishna Memorial Medical College & Hospital. Muzaffarpur	In Pipeline		
7	Darbhanga medical College & Hospital, Darbhanga	In Pipeline		
8	Government Medical College & hospital, Betiya, West Champaran	In Pipeline		
9	Narayan Medical College, Rohtas	In Pipeline		
10	Anugrah Narayan Medical College & Hospital, Gaya	In Pipeline		
11	Patna Medical college & Hospital, Patna	In Pipeline		
Jharkhand				
1	Rajendra Institute of Medical Sciences (RIMS), Bariatu, Ranchi-834009	Dr. Janardan Sharma	drsharmaj@gmail.com amcrims@gmail.com	09431175014
2	MGM Medical College, Dimna Roand, Jamshedpur, Jharkhand-831001	In Pipeline		
3	Patliputra Medical College & Hospital (B.C.C.L. Township, Koyla Nagar, Dhanbad - 826005, Jharkhand)	In Pipeline		

[11]http://ipc.nic.in/showfile.asp?lid=514&EncHid=

Uttar Pradesh				
1	B.R.D Medical College & Nehru Hospital, Gorakhpur-273013	Dr. Jamal Haider	jamal001@gmail.com	09839828358
2	GSVM Medical College, Swaroop Nagar, Kanpur-208001	Dr. S.P. Singh	singhdrsp@gmail.com	09415154744
3	Institute of Medical Sciences Banaras Hindu University, Varanasi-221005	Dr. B.L. Pandey	blp53@rediffmail.com	09451964917 09451440039
4	JN Medical College, Aligarh Muslim University, Aligarh-202002	Dr. Mohammad Nasiruddin	naseer_bettiah@yahoo.co.in	09412596898
5	M.L.B. Medical College, Jhansi- 284128	Dr. Sadhna Kaushik	kaushiksadhna55@gmail.com	07897038922
6	M.L.N Medical College, Darbhanga Colony, George Town, Allahabad- 211002	Dr. Rakesh Chandra Chaurasia	drrakesh65@rediffmail.com	09415615064
7	Santosh Medical University, Santosh Nagar, Ghaziabad-201001	Dr. V. S. Chopra	vipen.chopra@gmail.com jjhingran@yahoo.co.in	07838961411 09868579737
8	U.P Rural Institute of Medical Sciences and Research, Safai, Etawah-206130	Dr. Asha Pathak	drasha_pathak@yahoo.co.in	09451021779
9	Muzaffarnagar Medical College & Hospital, opp. Begrajpur Industrial Area, Ghasipur, Muzaffarnagar-251201	Dr. Suman Lata	dr.sumanlata@yahoo.com	09897878728
10	School of Medical Sciences & Research, Sharda University, Greater Noida-201306	Prof. Qazi M. Ahmed Dr. Ashok K Dubey	qma49@yahoo.co.in drakd1105@yahoo.co.in	09313766906
11	Subharati Medical College, Subharti Puram, NH-58, Delhi-Haridwar By Pass Road, Meerut-250005	Dr. Prem Prakash Khosla Dr. Ruchi Choudhary (dy. coordinator)	khoslapp@yahoo.com ruchi.upmanyu@gmail.com	08909654319 09410866646
12	Era's Lucknow Medical College & Hospital, Sarfazganj, Moosa Bagh picnic Spot, Hardoi Road, Lucknow-226003	Dr. Afroz Abidi	afrozabidi@gmail.com	09794979717
13	Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow-226010	Dr. Mukul Mishra	mukul_rk_misra1@yahoo.com	09450959088

14	Sarojini Naidu (S. N) Medical College, Moti Katra, Agra-282002	Dr. Mona Verma	dpsupagr@tbcindia.nic.in dpsupagr@rntcp.org pvpi.snmc@gmail.com	09997024763
15	Teerthanker Mahaveer Medical College and Research Centre, N.H-24,Bagarpur, Delhi Road, Moradabad, U.P-244001	Dr. Farhan Ahmad Khan	dr.farhan.k@gmail.com	09759468300
16	Yashoda Super Speciality Hospital, H-1, Kaushambi, Ghaziabad-201010	Dr. G. J Singh	dr.sunil@yashodahospital.org	09891957745
17	National Drug Dependence treatment centre, sector-19, Kamla Nehru Nagar, C. G. O Complex, Ghaziabad-201002	Dr. Sudhir K. Khandelwal	sudhir_aiims@yahoo.co.uk	011-26593675
West Bengal				
1	School of Tropical Medicine, 108, Medical College Campus Chittaranjan Avenue, Kolkata- 700073	Dr. Santanu Tripathi	stm.pvpi@gmail.com	09230566771
2	R.G. Kar Medical College, 1, Kshudiram Bose Sarani Kolkata-700073	Dr. Anjan Adhikari	adr.rgk.pharma@gmail.com	09831012503
3	Calcutta National Medical College, Dr Sundari Mohan Ave, Beniapukur, Kolkata-700014	Dr. Sushobhan Pramanik	sushobhan.pramanik@gmail.com	09831155886
4	Institute of Postgraduate Medical Education & Research, 244B, A.J.C Bose Road, Kolkata-700020	Dr. Suparna Chatterjee	drsupchat@gmail.com	09831130980 033- 22041428
5	Burdwan Medical college, Baburbag, P.O. Rajbati-Burdwan-713104	Dr. Mithilesh Haldar	amc.pvpibmc@gmail.com	09733106803
6	Bankura Sammilani Medical College, kenduadihi, Bankura 722101	Dr. Ananya Mandal	drananyamandal@gmail.com	09674446226
7	Nilratan Sircar Medical College, Acharya Jagdish Chandra Bose Road, Kolkata-700014	Prof. Nina Das	drninadas@yahoo.com	09433165691
8	College of Medicine & J.N.M. Hospital, Kalyani, Nadia-741235	Dr. Abhishek Ghosh	drghosh.new@gmail.com principal.comjnmh.kalyani@gmail.com	09836557042
9	North Bengal Medical College, PO Sushrutanagar, Siliguri, Distt. Darjeeling-734012	Dr. Anupam Gupta	nathguptadranupam@yahoo.com	09434686320

10	Murshidabad Medical College & Hospital, Berhampore-742101	Dr. Mainak Ghosh	docmainak@gmail.com	09007924708
11	Midnapore Medical College & Hospital, Vidyasagar Road, Paschim Medinipur-721101	Dr. Balaram Ghosh	drbrghosh@gmail.com amc.mmch@gmail.com	09800442964 0322-2222411
12	ICARE institute of medical Sciences & research and Dr. Bidhan chandra roy hospital, Banbishnupur, Balughata, Haldia, Dist.-Purba, Medinipur, W.B-721645	Dr. Sukanta Sen	drsukant@gmail.com	08420532336
13	Malda Medical College, Dist & PO-Malda, PS-English Bazar,Pin-732101	In Pipeline		

Annexure 10

List of villages where five or more than five VL cases have been reported (Nov) in 2016 Jharkhand, West Bengal and Bihar

Name of Villages with 5 or >5 VL Case till Nov 2016				
S.No.	**District**	**CHC**	**Village**	**VL**
1	**Dumka**	Kathikund	Kolha	6
2		Kathikund	Bhandaro	5
3		Kathikund	Nayadih	5
Total				**16**
4	**Godda**	Poraiyahat	Gumma	21
5		Boarijore	Ramkol	8
6		Boarijore	Ithari	5
Total				**34**
7	**Pakur**	Amrapara	Piparjori	9
8		Maheshpur	Barmasia	8
9		Maheshpur	Narayangarh	7
10		Pakur	Shyampur	6
11		Pakur	Dharsundri	7
12		Pakur	Kalidaspur	7
13		Maheshpur	Rolagram	5
14		Maheshpur	Mahadevnagar	5
15		Maheshpur	Datiarpokhar	5
16		Maheshpur	Kutubpur	5
Total				**64**
17	**Sahibganj**	(blank)*	(blank)*	14
18		Barhait	Pahadpur	7
Total				**21**
Grand Total				**135**

* Missing information in line list till Nov 2016. Any mismatch in name of the CHC/village is due to issue in line list entries.

West Bengal Villages with 5 or >5 VL case till Nov 2016	
Darjeeling District – Naxulbari Block – Tirhana Tea Estate	7

Name of villages with 3 or >3 PKDL case till Nov 2016				
S.No.	**District**	**Name of the Block/CHC**	**Village**	**PKDL**
1	**Dumka**	**Gopikander**	Gopikander	3
2		**Kathikund**	Bhitra	4
3			Jangala	4
4			Madhuban	9
5			Pipra	3
6		**Shikaripara**	Balijor	3

Dumka Total				**26**
7	**Godda**	**Boarijore**	Baghmara	4
8			Boarijore	4
9			Dahwa	4
10			Dumariya	4
11			Litti	3
12			Rajabhitta	4
13		**Mahagama**	Bhagan	4
14			Gaurikitta	3
15			Kittapathar	3
16		**Pathargama**	Teteriya Tikar	3
17		**Poraiyahat**	Amuwar	5
18			Bankatti	3
19			Siktia	3
20			Sugabathan	3
21		**Sadar Prakhand**	Dullu	4
22		**Sunderpahari**	Bansjori	3
23		**Thakurgangti**	Budhwachak	4
24			Gajhanda	4
25			Gopalpur	5
26			Navadih	4
27			Raidih	4
Godda Total				**78**
28	**Pakur**	**Amrapara**	Borandiha	3
29			Jamkanali	3
30			Jamugaria	3
31			Pachuwara	5
32			Paderkola	4
33		**Hiranpur**	Binjhamara	3
34			Gamharia	3
35			Hathkathi	4
36		**Maheshpur**	Bhimpur	3
37			Gaibathan	3
38			Kharutola	3
39		**Pakur**	Kalidaspur	3
40			Sonajori	5
41		**Pakuria**	Dholkatta	3
Pakur Total				**48**

42	Sahibganj	Mandrio	Bachha	3
43			Dokuti	3
44			Hatamari	3
45			Randhi	3
46		Pathana	Kesro	4
47			Rangatola	4
48		Rajmahal	Beldharcheak	3
49		Taljhari	(blank)	5
Sahibganj Total				**28**
Grand Total				**180**

West Bengal Villages with 3 or >3 PKDL Case till Nov 2016	
Darjeeling – Phasidewa Block- Paharghumia Tea Estate	7
Malda – Chanchol-II Block - Binodpur	3
Malda – Chanchol-II Block - Gopalpur	3
Malda – Habibpur - Haripur	6
Malda – Habibpur - Kharibari	5
Uttar Dinajpur – Bansihari - Kamardanga	4
Uttar Dinajpur – Kushmandi - Deulabari	4

VL Cases in Bihar

District	Block	Village	2014	2015	Total	Average
Araria	Araria	Araria Basti	8	11	19	10
Araria	Araria	Rampur Mohanpur	4	6	10	5
Araria	Bhargama	Raharia	9	4	13	7
Araria	Forbesganj	Haldiya	13	5	18	9
Araria	Forbesganj	Jhiruwa	8	11	19	10
Araria	Forbesganj	Jhirwa East	6	15	21	11
Araria	Kursakanta	Chikni	6	9	15	8
Araria	Raniganj	Bausi	6	12	18	9
Araria	Raniganj	Gopalpur	6	5	11	6
Araria	Raniganj	Kalabaluwa	4	19	23	12
Araria	Raniganj	Parmanadpur	12		12	6
Darbhanga	Goura Bouraam	Bath mushari tola	7	4	11	6
Darbhanga	Hayaghat	Bilaspur(W)	5	5	10	5
Darbhanga	Kusheshwar Asthan Purbi	Tilkeswar	8	715	8	
East Champaran	Adapur	Nayak Tola	9	3	12	6

East Champaran	Areraj Bajar	Sareya	10	2	12	6
East Champaran	Kalyanpur	Shambhuchak	14	1	15	8
East Champaran	Kesaria	North Hussaini	5	5	10	5
East Champaran	Kesaria	West Sunderapur	7	4	11	6
East Champaran	Kotwa	Bairia	21	1	22	11
East Champaran	Madhuban	Kauriya	9	9	18	9
East Champaran	Turkaulia	Jaisinghpur	26	7	33	17
East Champaran	Turkaulia	Madhopur	5	5	10	5
East Champaran	Turkaulia	Shankar Saraya	6	4	10	5
Gopalganj	Gopalganj Sadar	Hirapaakar		11	11	6
Gopalganj	Manjha	Bathuwa Mauze	9	3	12	6
Katihar	Dandkhora	Kadam Tola	10	1	11	6
Katihar	Sameli	Raksa Rahi	13		13	7
Khagaria	Alauli	Dahma Kharai	8	3	11	6
Khagaria	Alauli	Meghauna	11	3	14	7
Khagaria	Beldaur	Pachath	91	35	126	63
Kishanganj	Bahadurganj	Dhimtola	6	4	10	5
Madhepura	Alamnagar	Bhagipur	2	12	14	7
Madhepura	Ghailar	Bhathrandha	6	7	13	7
Madhepura	Ghailar	Chitty	8	4	12	6
Madhepura	Ghailar	Ghailadh	10	2	12	6
Madhepura	Kumarkhand	Belari	7	7	14	7
Madhepura	Kumarkhand	Gadhiya	13	9	22	11
Madhepura	Madhepura Rural (Murho)	Mathai	6	6	12	6
Madhepura	Madhepura Rural (Murho)	Sahugadh	10	1	11	6
Madhubani	Basopatti	Kauaha	11	2	13	7
Madhubani	Bisfi	Bhataura	4	15	19	10
Madhubani	Khajauli	Chatra	11	6	17	9
Madhubani	Madhepur	Bhargawan	9	1	10	5
Madhubani	Pandaul	Mohanpur	14	2	16	8
Munger	Bariarpur	Hanshu Singh Tola	23	7	30	15
Muzaffarpur	Kurhani	Chajan Dubiyahe	21	10	31	16
Muzaffarpur	Minapur	Minapur	9	3	12	6
Muzaffarpur	Minapur	Tengrari	11	3	14	7
Muzaffarpur	Musahari	Mushari Urf Radhanagar	10	4	14	7

Muzaffarpur	Paroo	Bada Daud	4	13	17	9
Muzaffarpur	Paroo	Deoria	11	5	16	8
Muzaffarpur	Paroo	Dharphari	9	7	16	8
Muzaffarpur	Paroo	Hirapur	11	7	18	9
Muzaffarpur	Paroo	Mohjawa	11	5	16	8
Muzaffarpur	Paroo	Usti	9	1	10	5
Muzaffarpur	Sahebganj	Bangra Nizamat	13	4	17	9
Muzaffarpur	Sahebganj	Madhopur	1	11	12	6
Muzaffarpur	Sahebganj	Madhopur Hazari	14	8	22	11
Nalanda	Islampur	Mohidhin Nagar		20	20	10
Purnea	Dhamdaha	Bishanpur	10	4	14	7
Purnea	Dhamdaha	Jamuniya	8	2	10	5
Purnea	Jalalgarh	Dansar	8	3	11	6
Purnea	Purnea East	Mahrajpur	7	9	16	8
Purnea	Rupauli	Maini Santhal	16	3	19	10
Saharsa	Banma Itahri	Ghourdour	10	2	12	6
Saharsa	Banma Itahri	Murli	7	4	11	6
Saharsa	Banma Itahri	Sarbela	4	6	10	5
Saharsa	Maheshi	Kundah	6	4	10	5
Saharsa	Patarghat	Bishanpur	6	4	10	5
Saharsa	Sattar Katya	Bara	7	5	12	6
Saharsa	Sattar Katya	Bihra	8	6	14	7
Saharsa	Saurbazar	Dhanchhoha	1	11	12	6
Saharsa	Saurbazar	Samada	9	8	17	9
Saharsa	Saurbazar	Saure	17	3	20	10
Saharsa	Simri Bakhtiarpur	Khamothi	11	3	14	7
Saharsa	Simri Bakhtiarpur	Simri	10	7	17	9
Saharsa	Sonbarsa	Sonbarsa	12	2	14	7
Samastipur	Singhia	Akouna	3	7	10	5
Samastipur	Warisnagar	Sathmalpur	16	6	22	11
Saran	Baniapur	Manopali	6	6	12	6
Saran	Dariapur	Banwaripur	7	7	14	7
Saran	Dariapur	Kamalpur	7	13	20	10
Saran	Dariapur	Sutihar	9	5	14	7
Saran	Dighwara	Jhawa	5	6	11	6

Saran	Dighwara	Saidpur	7	4	11	6
Saran	Garkha	Kothia	22	11	33	17
Saran	Garkha	Madanpur	8	5	13	7
Saran	Garkha	Ramgarha	8	2	10	5
Saran	Garkha	Sargatti	10	5	15	8
Saran	Marhaura	Marhaura(Np)	6	5	11	6
Saran	Marhaura	Mothaha	12	4	16	8
Saran	Sonepur	Naya Gaon	5	7	12	6
Sheohar	Dumri Katsari	Rampur Kesho	19	7	26	13
Sheohar	Purnahiya	Adauri	2	16	18	9
Sheohar	Sheohar	Rasidpur	11	2	13	7
Sitamarhi	Bathnaha	Bathnaha	5	5	10	5
Sitamarhi	Bathnaha	Chakwa	8	5	13	7
Sitamarhi	Bathnaha	Godhiya	7	4	11	6
Sitamarhi	Dumra	Khairwa	3	19	22	11
Sitamarhi	Dumra	Punaura	7	9	16	8
Sitamarhi	Parsauni	Parshurampur	10	3	13	7
Sitamarhi	Parsauni	Raja Parsauni	11	4	15	8
Sitamarhi	Pupri	Awapur Utri	7	6	13	7
Sitamarhi	Pupri	Pupri	10	3	13	7
Sitamarhi	Sursand	Sunderpur	11	3	14	7
Siwan	Barharia	Surahiya	4	7	11	6
Siwan	Basantpur	Sipah	18	7	25	13
Siwan	Goriakothi	Agya	9	6	15	8
Supaul	Raghopur	Dhararaha	10	3	13	7
Supaul	Raghopur	Raghopur	11	8	19	10
Supaul	Supaul	Amha	8	9	17	9
Supaul	Supaul	Bairo	9	6	15	8
Vaishali	Patepur	Sakrauli	13	3	16	8
Vaishali	Raghopur	Chandpura Idrak	9	7	16	8
Vaishali	Raghopur	Jurawanpur Barari	9	2	11	6
Vaishali	Raghopur	Paharpur	13	2	15	8
Vaishali	Raghopur	Saidabad	20	8	28	14
Vaishali	Raghopur	Virpur	9	2	11	6
Vaishali	Sahdei Buzurg	Sahdai Buzurg	9	3	12	6

This Accelerated Plan for Kala-azar Elimination 2017 was prepared with the help from WHO Country Office for India, stakeholders and states.