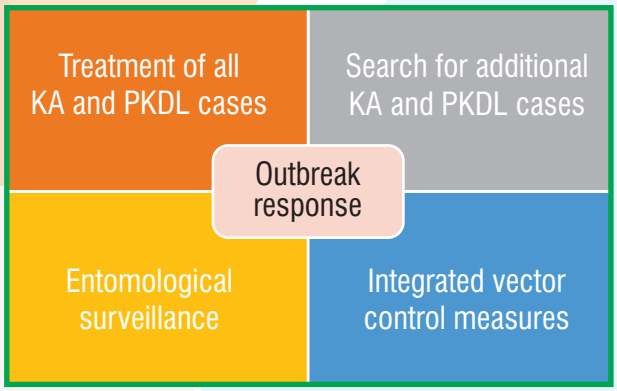
Ministry of Health & Family Welfare
Government of India

World Health Organization
India

STANDARD OPERATING PROCEDURE FOR OUTBREAK INVESTIGATION AND MANAGEMENT



Directorate of National Vector Borne Disease Control Programme
Government of India, Ministry of Health & Family Welfare
Directorate General of Health Services, 22-Sham Nath Marg, Delhi 110054

STANDARD OPERATING PROCEDURE FOR OUTBREAK INVESTIGATION AND MANAGEMENT

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Disclaimer:

This is a consensus document developed by the group of experts under the aegis of the National Vector Borne Disease Control Programme. The document is based on local disease epidemiology, risk factors and health systems contexts and at the same time due cognizance is taken of global best practices and evidences. All precautions have been taken to acknowledge contributions and references. However, contributors or Directorate of NVBDCP will not be responsible for any inadvertent omissions.

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ABBREVIATIONS

ACD	active case detection
ANM	Auxiliary Nurse Midwife
ASHA	accredited social health activist
AWW	Anganwadi Worker
BCC	Behaviour change communication
BCM	Block Communication Manager
BHM	Block Health Manager
BHU	Banaras Hindu University
DVBDCO	District Vector-Borne Control Officer
IDSP	Integrated Disease Surveillance Programme
IEC	information, education and communication
IRS	kala-azar
NVBDCP	National Vector Borne Disease Control Programme
PHC	primary health centre
PKDL	Post-kala-azar dermal leishmaniasis
RMRI	Rajendra Memorial Research Institute of Medical Sciences
SPO	State Programme Officer
VCRC	Vector Control Research Centre
VL	Visceral Leishmaniasis
WHO	World Health Organization

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INTRODUCTION

Kala-azar or Visceral Leishmaniasis (VL) is an outbreak-prone disease with anthroponotic (human to human) mode of transmission in India. The disease presents a constant risk of an outbreak in the long-standing stable endemic area, or new foci can appear where the disease has not been reported previously. If the outbreaks are not investigated and contained during the initial phase, community transmission may go on for long time and may adversely affect the elimination efforts.

Main objectives of a kala-azar outbreak investigation are:

i. To confirm that there is indeed an outbreak of kala-azar (i.e. Temporally, epidemiologically linked with confirmed local transmission)

ii. To prevent morbidities and mortalities by early diagnosis and treatment, and

iii. To determine the most effective and practical means of controlling the outbreak (by adaptation of the outbreak response measures to the local situation) and avoid spreading of the outbreak to neighbouring villages/blocks.

The outbreak investigation shall answer the following questions:[1]

1) Is there actually an outbreak?
   a) Are all reported cases indeed kala-azar?
   b) If yes, are they epidemiologically/temporally linked?

2) What are the characteristics of the outbreak?
   a) Describing KA cases distribution by time, place and person?

3) More specific questions for an outbreak in kala-azar endemic districts:
   a) What may have caused the outbreak? (focus on local conditions i.e. changes in vector population, environment or host/reservoir susceptibility)
   b) Assessment of kala-azar elimination activities

[1] National Guideline on Kala-azar Elimination Program. Nepal. 2019.

4) Specific questions for an outbreak in non-endemic blocks/districts/states:
   a) Is there local transmission of kala-azar?
   b) Assessment of other vector-borne diseases interventions i.e. indoor residual spraying (IRS) for malaria

5) Entomological assessment:
   a) In non-endemic kala-azar districts, the collection and identification of locally captured sand flies is a strong additional argument for local transmission. However, sandfly density may be low or zero at the time of outbreak investigation visit.
   b) In kala-azar endemic districts/blocks/villages, local transmission does not need to be proven and entomological investigations are not necessary to launch the standard outbreak response, including focal case-based IRS. In villages which are already in the routine IRS plan, the quality of IRS shall be checked.

The kala-azar outbreak guideline is intended for the programme managers working at central, state, district, and peripheral level as well as for frontline health workers. It outlines several steps at various levels.

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KALA-AZAR OUTBREAK DETECTION AND RESPONSE

Kala-azar outbreak detection and response can be divided into five parts, namely:

i) Outbreak criteria
ii) Rapid assessment
iii) Outbreak preparedness
iv) Outbreak response
v) Monitoring, recording and reporting

2.1 Outbreak criteria

According to the World Health Organization, "a disease outbreak is the occurrence of cases of a disease in excess of what would normally be expected in a defined community, geographical area or season. An outbreak may occur in a restricted geographical area or may extend over several countries. It may last for a few days or weeks or for several years".

There is no strict definition for a kala-azar outbreak as it depends on the context and epidemiology. Kala-azar outbreak may be suspected in both endemic and non-endemic areas. After several consultations of the National Vector Borne Disease Control Programme (NVBDCP) with stakeholders, it was decided that when the incidence of kala-azar is more in a village compared to the previous year over the same time period, it may amount to an outbreak. However, the quantification of 'more' should be decided based on current epidemiological and practical considerations.

Operational definition. Based on epidemiological situation of disease in India, the following operational criteria are proposed for endemic and non-endemic states to initiate outbreak investigations:

a. Endemic states (Bihar, Jharkhand, West Bengal and Uttar Pradesh)

Criteria 1 in high burden states i.e Bihar and Jharkhand, 10 or more laboratory confirmed cases are reported in a given area (cluster/hamlet/village) or among a specific group of people within six months of occurrence of index case.

Criteria 2 has been seen in low burden states i.e. Uttar Pradesh and West Bengal where occurrence of five or more laboratory confirmed cases warrants an outbreak investigation.

Five or 10 cases "in a given area" may be scattered around the area without any geographical linking. Alternately, the clustering of cases on both sides of an administrative border may lead to a delay in recognizing an existing geographical linking. Therefore, such issues should not hamper the outbreak response and actions.

b. Non-endemic states or non-endemic districts/blocks of an endemic state

Criteria 3 is where there is occurrence of even a single laboratory confirmed case that is reported in a cluster/hamlet/village and it amounts to a kala-azar outbreak.

While declaring an outbreak, some important points must be considered. These have been listed below.

- Confirm the outbreak by comparing current and previous (ideally for the previous five years) incidence of the disease.
- Record potential changes in completeness of reporting due to alterations in local conditions e.g. access to health care facilities, reporting from private cases and active case detection campaign.
- Clinical skills of medical officers may overly inflate or under report an outbreak.
- Use a standard case definition for cases that are suspect, probable and/or confirmed; and
- Document travel history to an endemic area, where kala-azar infection may have occurred and due to long incubation period, the case was diagnosed and reported in the non-endemic area.

Sources that sound an alert

- Analysis of web-based portal for kala-azar.
- Integrated Disease Surveillance Programme (IDSP) reports fever of more than two weeks duration in kala-azar endemic areas.
- Information from any health institution (public, private, non-government organizations or NGOs etc.) or state report.
- Reports from media and community.

Whom to communicate a "possible kala-azar outbreak"

- Information about the outbreak alert must be passed on from the Block Medical Officer incharge to the District Vector-Borne Disease Control Officer (DVBDCO). The DVBDCO will take further action in coordination with the IDSP unit of the district and Civil Surgeon/Chief Medical and Health Officer.
- DVBDCO should communicate about the outbreak alert to the state programme officer(SPO).
- SPO should coordinate with NVBDCP, the Regional Offices of Health and Family Welfare (RoHFW), independent institutions i.e. Rajendra Memorial Research Institute of Medical Sciences (RMRI), Banaras Hindu University (BHU), Vector Control Research Centre (VCRC) and stakeholders such as. WHO, CARE and PATH for necessary support and actions.
- Roles and responsibilities of concerned stakeholders involved in outbreak investigation and management are well defined (Annex 1).

2.2 Rapid assessment

Once a kala-azar outbreak is suspected as per the criteria mentioned above, following steps shall be taken by the concerned health officials of the state/district/block:

- confirming the occurrence of outbreak and identifying population at risk.
- planning and implementing an immediate rapid response.
- strengthening the system for prevention, early detection and effective management of future outbreaks.

1.2.1 Steps of rapid assessment

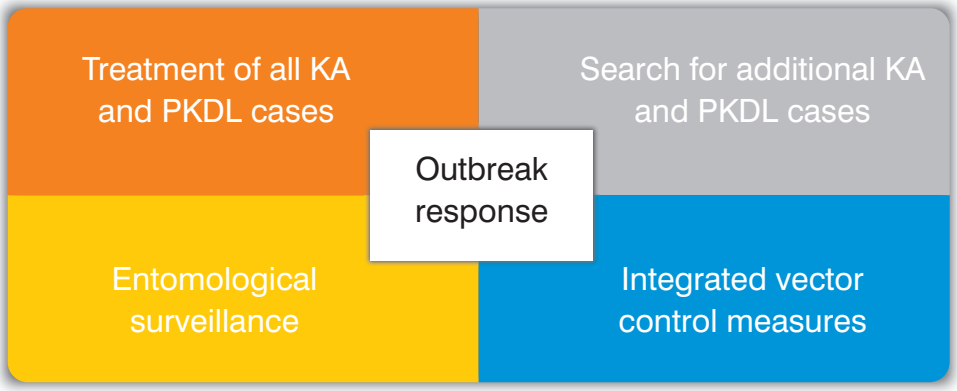
Step 1. As soon as information of the suspected outbreak is received, the first step is to confirm the diagnosis of kala-azar among reported cases. In a non-endemic area, parasitological confirmation of first few cases should be done.

Step 2. Once diagnosis is confirmed, then an estimate of the extent of the outbreak must be done by systematically collecting epidemiological information about cases.

Step 3. A spot to map must be prepared to see a clustering of cases.

2.3 Outbreak response

- As soon as the diagnosis is confirmed, treatment of all diagnosed kala-azar cases must be ensured as per national guidelines.
- Detection of additional KA and PKDL cases through house-to-house active case search[2] in at-risk areas or entire village/hamlet/cluster or 500 metres surrounding the KA case.
- During active case search in all places, all the fever cases of any duration and cases with skin lesions consistent with PKDL shall be line-listed. All the suspected cases shall be examined by a trained medical officer and tested if required, within two days of identification by an escorted referral or medical camp in the affected area.
- The entomological response to the kala-azar outbreak shall depend on whether there has been ongoing transmission in the affected area. In non-endemic states, a team of experts shall visit the affected area for entomological surveillance using a certain format (Annex 2).
- In endemic areas, if there has been a sudden increase in kala-azar cases, then a review shall be done about ongoing kala-azar activities (IRS, ACD, diagnosis, and treatment etc). If the activities have been carried out as per s per guidelines and quality is maintained then vector resistance to insecticide in use shall be investigated.



[2] Follow SoP of kala-azar active case detection, NVBDCP

2.4 Monitoring, recording, and reporting

- Ensure that the information about the outbreak is communicated to all concerned stakeholders for timely action.
- Ensure availability of adequate funds, logistics supplies, manpower and mobility support.
- DVBDCO to make sure that the desired level of support is there from the district and block health programme teams and concerned partners.
- Mobilize team from the state for monitoring and supervising on-ground activities and ensure response to the outbreak as per SoPs using an approved checklist (Annex 3).

Recording and reporting process includes the following:

- Details of activities carried out as part of outbreak investigation and management to be recorded as per formats provided in respective SoPs.
- Data collected to be analyzed with respect to time, place and person.
- Spot maps to be prepared and made available at the health facility.
- Ensure reporting of the outbreak investigation and response is done using the kala-azar outbreak reporting format (Annex 4).
- Ensure that the District VBD officer shares the report with the State Programme Officer who in turn shares it with the NVBDCP.

3

PREVENTION AND CONTROL MEASURES

The following prevention and control measures could be taken for kala-azar outbreak:

a. **Maintaining surveillance** in affected areas by conducting regular active case search.

b. **Integrated vector management.** Conduct IRS in the affected village/urban area as per guidelines. Undertake environmental management through improved housing conditions like having pucca (concrete) houses, filling cracks and crevices in walls, doing plastering and ensuring, sanitation in the area.

c. **Information, education and communication (IEC)/Behaviour change communication (BCC) activities**. These activities are targeted for making communities more aware of kala-azar. Advocacy, communication and social mobilization are important as new cases are likely to occur for longer periods, even after 100% screening of the at-risk population is completed Therefore, improved knowledge of the community about the disease, risk factors, prevention, diagnostic and treatment facilities are important for better community participation.

d. **Capacity building.** Regular and ongoing capacity building of health care workers, doctors and paramedical staff for surveillance, diagnosis, treatment and monitoring of outbreak investigation activities is imperative. Simultaneously, health care services must continue to get strengthened.

e. **Medical supplies**. Ensuring availability of adequate drugs, diagnostics and insecticides, amongst others must remain a priority.

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ANNEXURES

Annex 1: Roles and responsibility for outbreak management

Member	Responsibility
Responsibilities of NVBDCP	• Dissemination of SoP and guidelines to the states. • Including SoP in training curriculum for capacity building of state officers. • Guidance to states from NVBDCP for reporting outbreak to centre on real-time basis. • Guiding states to develop a long-term plan for prevention of kala-azar outbreaks in future. • Supervising KA activities in the field.
Responsibilities of the State Programme Officer	• Ensure necessary advisories and guidance are timely disseminated to districts for desired actions. • Ensure that district health authorities constitute a rapid response team immediately. • Ensure good coordination among government, non-government organization and partners so that resources are utilized optimally during outbreak management. • Ensure availability of adequate funds, logistics supplies, manpower and mobility support that are fundamental for mounting a quality outbreak response. • Monitor and supervise district preparedness and response. • Share progress report with NVBDCP in a time-bound manner.

District Magistrate/ Deputy Commissioner and Civil Surgeon/ Chief Medical Health Officer	• Convene the district task force committee meeting as per need. • Review planning, preparedness, logistics, funds and mobility to ensure rapid and effective response. • Develop a long-term plan to maintain and sustain surveillance.
District Vector-Borne Disease Control Officer	• Ensure that SoP for outbreak investigation and management is followed. • Ensure planning, preparedness, logistics, funds and mobility for rapid and effective response. • Coordinate the role of all concerned stakeholders and assign them specific and non-overlapping tasks in outbreak response. • Ensure complete and timely reporting of information to the district from the block-level for necessary action. • Undertake daily reporting and review of progress of outbreak investigation. • Assign outbreak identification.
District Surveillance Officer	• Ensure formation of outbreak response team at block level. • Facilitate the training and capacity building of outbreak response team members, including lab technician at block-level. • Facilitate report writing and its submission by the district to state outbreak management team.
WHO	• Zonal coordinators to ensure coordination, planning, capacity building, data analysis, supervision and monitoring of the entire outbreak. State coordinator to liaise with state programme officer for desired action. • Monitor the outbreak response using a monitoring checklist.
CARE/PATH	• Support and supervise block-level outbreak response teams for complete enumeration and line-listing of kala-azar cases. • Assist in conducting quality active case search and supervise operational aspects of house-to-house case search. • Support IEC activities in the affected area through effective medium such as video show, miking, drum beating, village meetings etc. • Monitor outbreak response using a monitoring checklist.
Block Medical Officer In-charge/ Block Nodal Officer for kala-azar	• Make a specific plan for outbreak investigation and issue written instructions to all members of the block-level outbreak investigation team. • Coordinate work of all partners at the block-level. • Conduct on-site supervision of house-to-house active case search teams and lab technician. • Carry out clinical and anthropometric examination of confirmed cases.

Lab technician	• To conduct rapid test of all suspects found during the search activity. • Do this either at a designated central point or in a centrally located point where all suspects can be mobilized for rK39 testing. • Record findings and preserve positive test strips to avoid repeat testing at the primary health centres (PHC).
Block Health Manager (BHM)	• Enlisting of all rapid test positive cases in the PHC line-list. • Ensure transportation of newly diagnosed patients to the AmBisome treatment centre. • Ensure availability of all the logistics that are required, like rapid test kits, lancet, cotton, blank formats at the central point.
Block Communication Manager (BCM)	• Ensure participation of the accredited social health activist (ASHA) in the house-to-house case search team. • Coordinate IEC activities and ensure mobilization of materials from the PHC for IEC e.g. (television sets/hand mikes etc).
Malaria Inspector/ Sanitary Inspector/ Male Multipurpose Health Worker/ Basic Health Worker (regular staff) **Kala-azar Technical Supervisors (contractual staff)**	• Supervise and move in the field along with house-to-house case search teams. Complete all operational components such as wall marking, complete enumeration, asking of proper questions in each household to detect kala-azar cases and providing referral slips to kala-azar suspects so that they be closely monitored by them. • Coordinate with the central point for provision of logistics (formats, rapid diagnostic kits) and motivate kala-azar suspect patients for testing. Next, motivate newly diagnosed patients for treatment. Also, plan and monitor the focal spray activity.
Block Coordinator/Staff Nurse/ANM	• Provide referral slips to kala-azar suspects for testing at the central point. • Block Coordinator/Staff Nurse/ANM to ensure testing of all Kala-azar suspects. Ensure counselling of newly diagnosed patients and record the patients in the PHC line list. Also ensure physical examination by medical officer.
ASHA or Anganwadi Worker (AWW)	• ASHA or Anganwadi worker to ensure activity in the field according to the microplan and ensure complete enumeration of the area. • Complete the house marking and explain the reason for house-to-house case search for community members.

Annex 2: Entomological survey format

(Using CDC light trap/ mouth aspirator)

(Using CDC light trap/ mouth aspirator)

Name of the household head:

District name:

Block name:

Village name:

Household no.:

Method of collection (encircle): CDC light trap/Mouth aspirator

Time of collection: ____ (1=1st day, 2= 2nd day)

Date of collection (dd-mm-yyyy):_____

Temperature and humidity of the place of test:

Temperature (in ^{o}C):				Humidity (in %):	
Time spent: (in hours) Per man hour or CDC trap density					
No. of sand fly collected by species and sex:					
Sand fly	**Males**	**Females**			**Total**
		Unfed	**Fed**	**Gravid**	
Phlebotomas argentipes					
Phlebotomas papatasi					
Sergentomyia spp.					
Total					

Any special tests requested: Y/ N
Encircle special tests: Bioassay / Xenodiagnosis / Leishnania Parasite detection in Sand fly?
Name and address of lab where special test is sent:
Expected date of result (of special tests):

Result of special test done (if any): .....

.....

Comments (if any):

.....

Entomologist name:

Signature: Date (dd-mm-yyyy):

Annex 3: Kala-azar outbreak response monitoring checklist

State: ……..... District: ……..…….....

Block: ……..... Village: ……..

Name of monitor: ……..... Designation: …….....

Date of monitoring: dd/mm/yyyy: ……....…….....

1.	Geographical demarcation of outbreak affected area	Yes/No
2.	Mapping of the affected area done	Yes/No
3.	Relevant letter issued by CS/CMHO/MoIC	Yes/No
4.	Telephonic communication done to all manpower a day before (includes MoIC, Lab technician, ANM, ASHA, health staff)	Yes/ No
5.	Case search planning done	Yes/ No
6.	Area of work of outbreak teams demarcated based on maps/microplan	Yes/ No
7.	Adequate number of rK-39 kits made available	Yes/ No
8.	Adequate number of lancets made available	Yes/No
9.	Location for lab testing in the community identified	Yes/No
10.	Other documents such as referral slips/ lab register etc made available	Yes/No
11.	All required documents / formats are arranged and filed in one place	Yes/No

Preventive and treatment services

1.	Whether focal spray in affected area done/ planned	Yes/ No
2.	If yes, date done or planned _____	
3.	Whether IEC activity carried out	Yes/ No
4.	If yes, date done or planned_____	
5.	Whether community leaders and influencers contacted for their support for treatment of suspected cases and help in focal spray	Yes/No
6.	Whether adequate number of vials of AmBisome indented from state to offer quick treatment to all the newly diagnosed cases?	Yes/ No
7.	Whether adequate funds are ready for incentive distribution to patients?	Yes/No
8.	Whether adequate funds are available for payment of focal spray workers?	Yes/ No
9.	Whether treatment card etc are made available at treatment centre?	Yes/No
10.	Whether there is a plan of adequate up of treated cases and detection of new cases after the outbreak investigation?	Yes/ No

Annex 4: Kala-azar outbreak final reporting format

1. Outbreak location:

   State: ……..... District: …….....

   Block…… Village:…….....

2. Outbreak ID allotted: For e.g only
3. Date outbreak was reported to state: dd/mm/yy
4. Source of alert:
5. Criteria of outbreak: 1 / 2 / 3 / 4 (any other)
6. Number of cases reported for outbreak declaration:
7. Response activity undertaken: ACD / vector survey / IRS / any other
8. Output of active case search (in numbers):
   a) Population targeted:
   b) Population screened:
   c) Number of kala-azar suspects identified:
   d) Number of PKDL suspects identified:
   e) Number of RDTs performed for diagnosis of kala-azar:
   f) Number of positive RDTs for confirmation of kala-azar:
   g) Number of RDTs done for diagnosis of probable PKDL:
   h) Number of positive RDTs out of probable PKDL:
   i) Number of confirmed kala-azar case:
   j) Number of confirmed PKDL case:
9. Entomological survey:

Temperature (in ^{o}C):			Humidity (in %):		
Exposure time: (in minutes)					
No. of sand fly collected by species and sex:					
Sand fly	**Males**	**Females**			**Total**
		Unfed	**Fed**	**Gravid**	
Phlebotomas argentipes					
Phlebotomas papatasi					
Sergentomyia spp.					
Total					

10. Outcome of IRS/routine IRS (in numbers):

    a) Population targeted

    b) Population covered

    c) Houses targeted

    d) Houses covered

    e) Rooms targeted

    f) Rooms covered

    g) Partially covered house

    h) Complete coverage

    i) Refusal

11. Probable reason of outbreak: High vector population / no IRS in last year / no case search in last year / service compromised area / migration / travel history / any other (specify)

12. Reason for poor programme implementation:

13. Recommendations for long-term preventive measures:

Reported to	Reported by
(Name, designation and address):	(Name, designation an address):

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