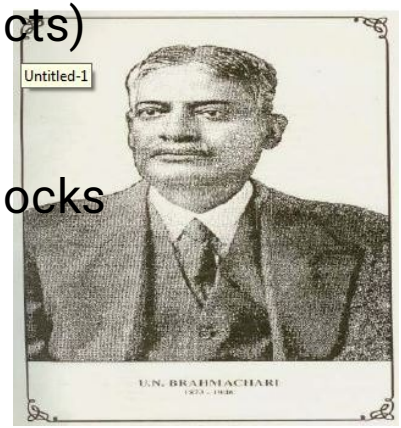
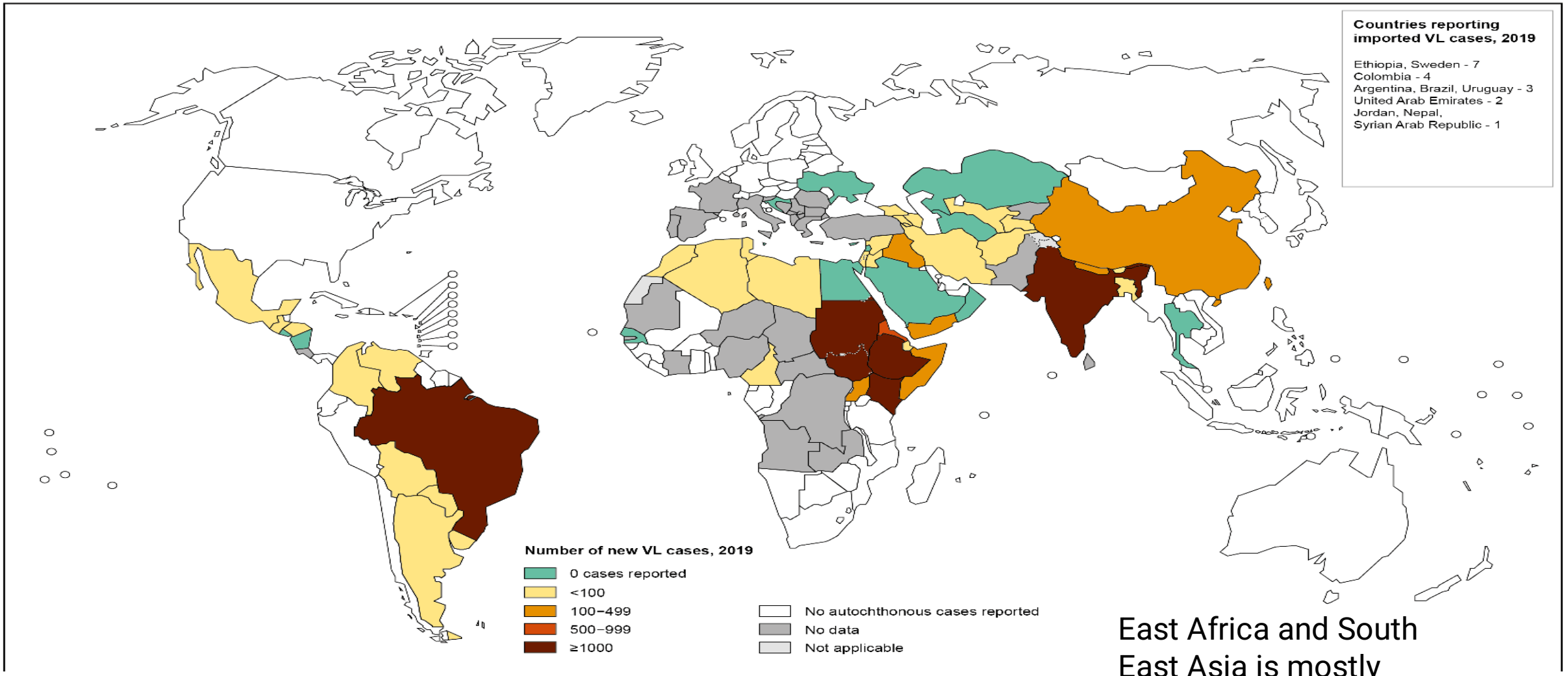
Medical Officer Sensitization for Kala azar in West Bengal

Introduction

- “History of Kala-azar is older than the dated records. In those days malaria was very common and some epidemics of Kala-azar were passed as toxic malaria”. Twining writing in 1835 described a condition that he called “endemic cachexia of the tropical countries that are subject to paludal exhalations”.
- In South Asia, Kala-azar occurs in India, Bangladesh and Nepal, with a small focus reported from Bhutan.
- Nearly, 200 million people are considered to be at risk of contracting Kala-azar in this region.
- In India, Leishmaniasis is endemic in geographically confined area of 54 districts across FOUR states of Bihar (33 districts), West Bengal (11 districts), Uttar Pradesh (6 districts) and Jharkhand (4 districts) with an approximately 140 million population at risk of infection.
- In West Bengal, 11 districts (including health districts) are Kala-azar (KA) endemic. Out of 214 blocks 120 blocks are KA endemic.
- All KA endemic blocks in West Bengal have achieved KA Elimination Target since 2017.



Global VL Situation

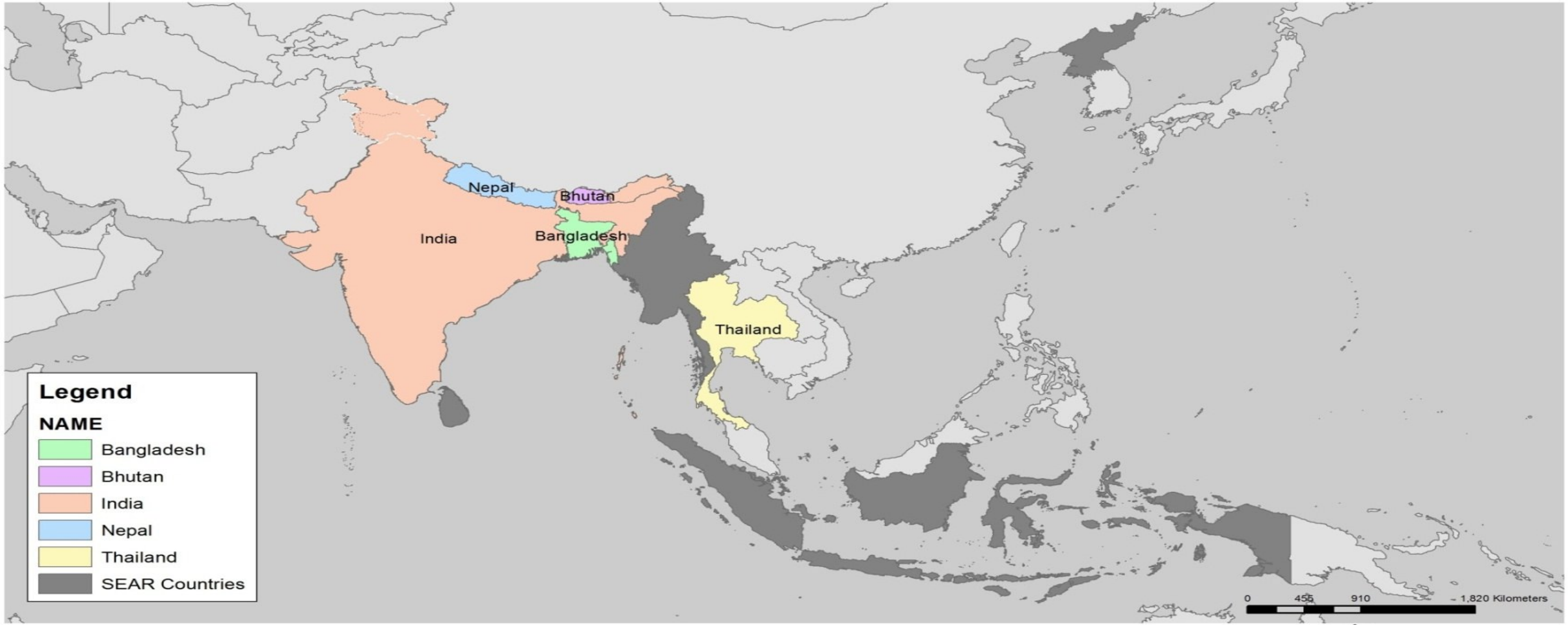


East Africa and South East Asia is mostly endemic.

Data source : WHO annual country reports, 2019

Map production: NTD

Kala-azar in SEA Region



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Production: HSD/HST
Production date : 02/09/2016

World Health Organization

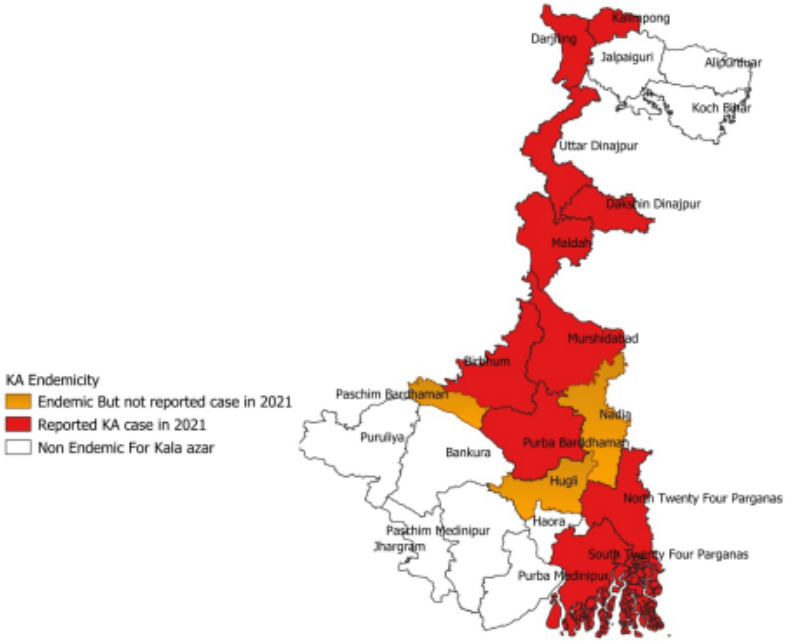
Introduction

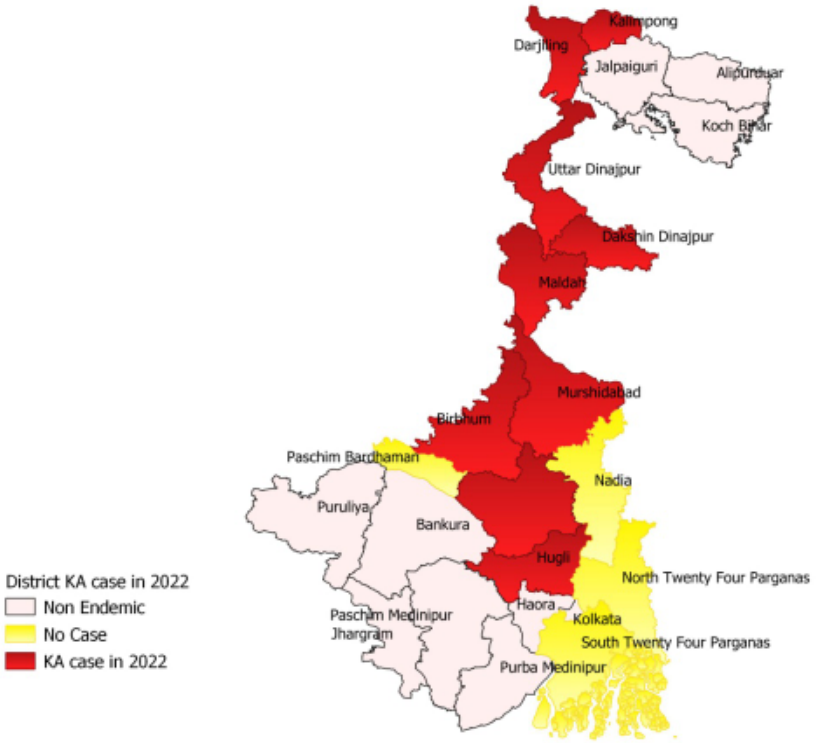
- Kala azar is one of the neglected tropical diseases affecting the most vulnerable communities and is associated with malnutrition and factors affecting population displacement and social determinants of health
- Kala-azar/ Visceral leishmaniasis is a complex of vector-borne diseases caused by protozoan species of the genus Leishmania donovani [1]
- Leishmaniasis is endemic in 94 countries; approx. The World Health Organization (WHO) estimates 700,000 to 1 million new cases of leishmaniasis annually worldwide and 26,000–65,000 deaths[1]
- The visceral form (kala-azar or visceral leishmaniasis) is the second most common parasitic killer disease after malaria and is fatal if it remains untreated. Each year, an estimated 50,000–90,000 new cases occur worldwide out of which only 25-45% are reported .[2]
- Visceral leishmaniasis (VL) also known as Kala-azar, represents the most severe form of disease
- India is one of the 6 countries that account for 90% of the global burden, approx. 100

David M Pigott et.al. 2014; 3: e02851. Published online 2014 Jun 27. doi: 10.7554/eLife.02851; PMCID: PMC4103681- had said 88 countries endemic

[1] NVBDCP 2017. Accelerated Plan for Kala Azar Elimination. New Delhi.

Kala azar Situation in West Bengal





In West Bengal total 11 Districts are known to be endemic for Kala azar, but now due to division of districts the total number of District reported Kala azar cases are 14.

In 2022 - 9 endemic districts and 1 Health District have reported Kala azar cases.

In 2022 – 56 VL cases and 108 PKDL cases ahs been reported.

Kala Azar

- Kala Azar is a slow, progressive indigenous disease caused by a protozoan parasite of genus Leishmania.
- In India Leishmania donovani is the only parasite causing this disease in South Eastern Asia and East Africa
- Parasite primarily infects the reticuloendothelial system and may be found in abundance in bone marrow, spleen and liver.
- VL infection, reticuloendothelial hyperplasia results which affects the spleen, the liver, the mucosa of small intestine, the bone marrow, the lymph nodes, resulting into heavy infiltration with parasites.
- The lifespan of leukocytes and erythrocytes is reduced, causing granulocytopenia and anaemia. Liver functions are altered in later stages leading to hypoalbuminemia and decrease in prothrombin production.
- Depletion of prothrombin along with thrombocytopenia results into severe mucosal haemorrhage. In many cases diarrhoea occurs because of intestinal parasitisation and ulceration or secondary enteritis, which results in loss of fluid and malabsorption.
- Hypoalbuminemia is associated with oedema and other features of malnutrition. In advanced states, intercurrent infections are very common, especially pneumonia, dysentery, and tuberculosis, and are common causes of death.
- Post kala azar dermal leishmaniasis(PKDL) is a condition when Leishmania donovani invades skin cells, resides and develops there and manifests as dermal lesions

How does KA spreads?

- Transmitted to humans by the bite of infected female sandfly Phlebotomus argentipes; KA is fatal if not treated
- Man is only reservoir and there is only 1 vector
- Sandflies must take at least two blood meals to transmit leishmania to man.
- Incubation period ranges from 10 days to 2 years however in India it may range from 4 months to one year. Extrinsic incubation period may vary from 4-25 days[1]
- Sandfly is a poor flier, moving in short hopping flights restricted to about 25 metres.
- Key symptoms of KA include prolonged irregular fever (>2 weeks and not responding to anti malarial drugs in malaria epidemic areas), splenomegaly and weight loss. Post-kala-azar dermal leishmaniasis is a sequelae of KA

[1] NVBDCP & WHO. 2015. OPERATIONAL GUIDELINES ON KALA-AZAR (VISCERAL LEISHMANIASIS) ELIMINATION IN INDIA; https://www.who.int/leishmaniasis/burden/Operational_guidelines_on_kala_azar_elimination_in_India.pdf

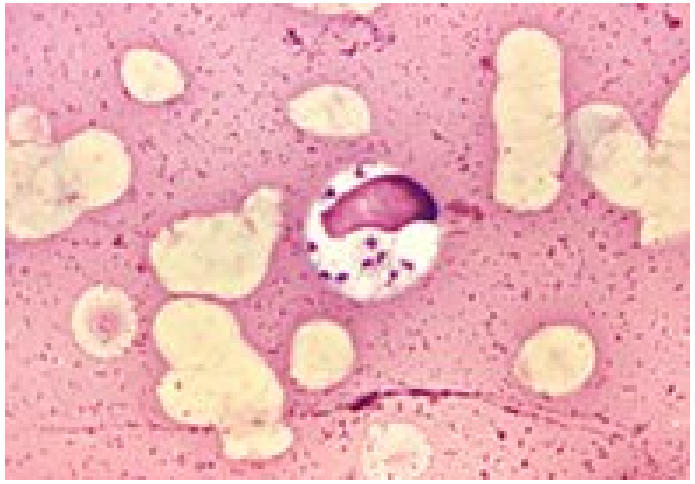
Areas and population most susceptible- India

- P.argentipes is entirely endophilic -(indoor resting and feeding); its active in humidity (75-85%); high densities of sandflies found during monsoon and post monsoon months (June to October)
- Rural areas with a heavy rainfall with mean humidity of 70% and temp. between 15-38%, abundant vegetation, subsoil water and alluvial soil.
- Most common in agricultural villages as most houses are of mud walls and earthen floors and cattle and livestock live close to humans.
- Human behavior viz. sleeping outside/on ground, may increase risk. Malnutrition and diets lacking protein-energy, iron, vitamin A and zinc increase the risk.
- A higher proportion of males than females (approx. 60:40) and close to 40%

Epidemiological Triangle (1)

Host

Human; (No Zoonotic Reservoir)



Parasite:
protozoan Leishmania

Vector- fully fed female sandfly

Vector

Female P. argentipes and Parasite Leishmani

Disease

Environment

*Poor socio-economic condition
*Dark & damp place
*Temperature and humidity condition

Kala-azar Elimination Target

Annual incidence (AI) or Incidence Rate (IR) of kala-azar below one case of VL per 10,000 population at block level in India

$$AI \text{ or } IR = \frac{(\text{number of new cases of VL + relapse of VL in a single year})}{(\text{mid-year population of the implementing unit})} \times 10{,}000$$

For calculation of AI or IR, New case means, case of VL only and not PKDL

Feasibility of Elimination

1. Man is the only reservoir
2. Phlebotomous argentipes sandflies, the only known vector
3. Disease is confined to limited geographical area
4. Rapid diagnostic tests and effective treatments are available
5. High political commitment

The main strategies for achieving the target

1. Early diagnosis and complete treatment;
2. Integrated vector management;
3. Effective disease and vector surveillance;
4. Social mobilization and partnerships;
5. Clinical and operational research

Source: Regional Strategic Framework for Elimination of Kala-azar from the South- East Asia Region (2011–2015) SEA-VBC-85 (Rev.1)

Kala-azar Control

The strategy of kala azar control broadly includes three major activities:

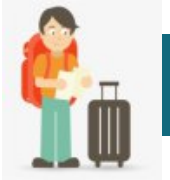
Interruption of transmission for reducing vector population by undertaking indoor insecticidal spray twice in a year

Early diagnosis and treatment of the kala azar cases

Health education for the community awareness

Diagnosis and treatment of Kala-azar & PKDL

Case definition kala-azar case



Suspect kala-azar case:

A person living in or having travel history to a kala-azar endemic area/s showing and having fever of > 2 weeks.

Probable kala-azar case:

A person living in or having travel history to kala-azar endemic areas showing and having clinical signs and symptoms of kala-azar(mainly irregular fever lasting more than two weeks and splenomegaly and/or weight loss), after ruling out malaria in co-endemic areas.

Confirmed kala-azar case:

A confirmed case of kala-azar is when a person from an endemic area with fever of more than two weeks duration and with splenomegaly, is confirmed by a Rapid diagnostic test (RDT) or a biopsy or polymerase chain reaction (PCR). In cases with past history of kala-azar or with high suspicion and with negative RDT results, confirmation can be done by examination of bone marrow/ spleen aspirate for Leishmania donovani (LD) bodies at an appropriate level equipped with such skills and facilities.

Clinical manifestations of kala-azar and relaps

Kala-azar: Patients present with features of persistent systemic infection and parasitic invasion of blood and reticulo-endothelial system.

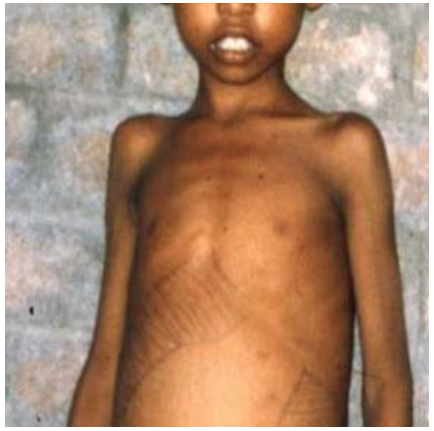
- Irregular fever with chills and rigor; Intermittent (classical)
- Loss of appetite, weight loss & fatigue
- Blackish discoloration of skin
- Enlargement of liver and spleen,
- Anaemia & low blood counts (pancytopenia)

Relapse: A kala-azar case who experiences recurrence of KA symptoms with parasitological confirmation at any point of time after previous initial cure i.e., after 15 days of the treatment when the treatment regimen is less than 5 days.

Photo courtesy: VBD office Godda District, Jharkhand 2017

Clinical kala-azar case

1. Fever T° >100.4° F OR >38° C for two weeks OR more



2. Splenomegaly +/or hepatomegaly

3. Weight Loss

Diagnosis (1)

1. Clinical history & physical assessment (splenomegaly/ Hepatomegaly, Anemia etc.)

2. Rule out common causes of fever

(Malaria, Typhoid etc.)

3. Must enquire history of Kala-azar

4. In non-endemic states/districts explore travel history to

5. Lab tests

- To rule out other common conditions
- Rapid Diagnostic Test for Kala-azar
- If suspected relapse / RDT NEGATIVE with strong clinician suspicion, then REFER to Medical College / District Hospital for confirmation of

Diagnosis (2)

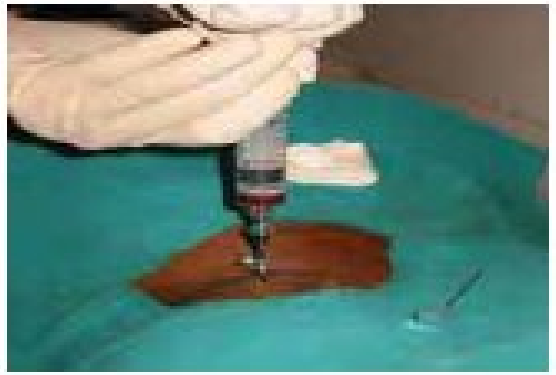
- Currently the diagnosis is done by RDT or Biopsy(Splenic, Bone Marrow or Lymph Node)
- Definitive diagnosis of KA is by culture or microscopic confirmation of parasite[3]

Splenic aspirate

- Reference standard
- Sensitivity ~95%
- Expertise is needed
- Risk of major bleeding (~1/1,000 procedures)

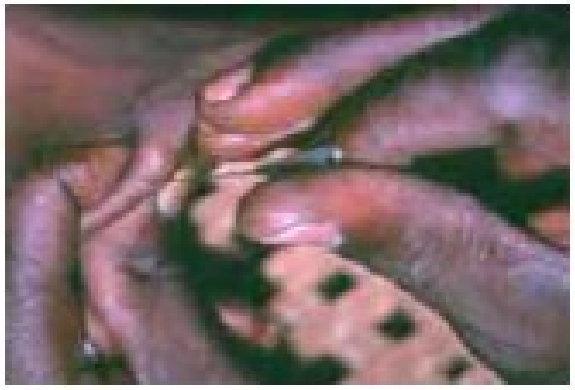
Bone marrow

- Sensitivity 60–85%
- Painful
- Sterilization is required



Lymph node

- Low sensitivity of 58%



1. Sundar S, Rai M. Clin Diagn Lab Immunol 2002; 9(5): 951–8; 2. Savoia D. J Inf Dev Ctries 2015; 9(6): 588–96; 3. The use of visceral leishmaniasis rapid diagnostic testes, World Health Organization http://apps.who.int/iris/bitstream/10665/44012/1/9789241597357_eng.pdf?ua=1 Accessed on 11 May 2017

Diagnosis (3)

Advantages of RDT

- Easy to perform
- Laboratory setting not essential
- Can be performed on finger prick blood, serum or plasma
- Easy to transport and stored at ambient temp. (30^0C)
- Results available in 10–

Disadvantages

- Cannot distinct between current or past infections or in the diagnosis of relapse or as prognostic test

Procedure

Steps to take

Remove the test strip from the foil pouch

Place the test card horizontally on a flat surface

Add 10 µL of the specimen (blood / serum) in the sample area of the card

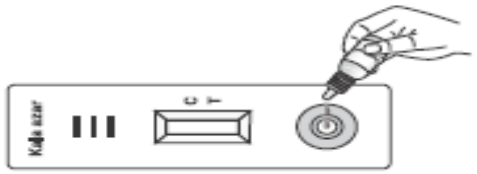
Add 2-3 drop of Chase buffer (150 µL)to the test card

Read the result in 10 -20minutes , do not read beyond 20 minutes

Procedure: How to Do the Test

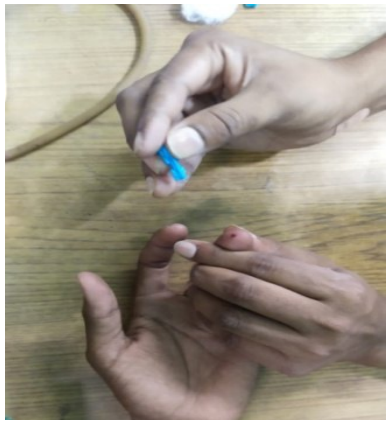
1. Bring the sealed pouch to room temperature, if the pouch of the test card is damaged discard the card and take a new one for the test. Open the pouch and remove the test card.
2. Label the card appropriately with patient identity. Once opened, the card must be used immediately. Refrigerated specimen must be bought to room temperature prior to use.
3. Add 10 µl serum / plasma specimen into the sample well (S) using provided disposable sample dropper.

4. Add 2-3 drops (150 µl) of the Running / Assay Buffer solution provided in the dropper bottle.

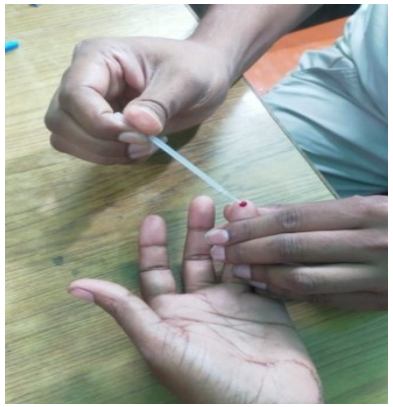


5. Read result within 5-20 minutes. Do not interpret result after 20 minutes.
6. Discard used card in a biomedical waste container after interpreting the results.

Capillary Blood collection by finger prick



Use Micropipette for collection of blood



Collect blood up to 10 µL in Micropipette

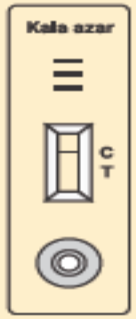
Put blood in Card

Add 150µ L of Chase Buffer

Wait for 10-20 minutes, do not read after 20 minutes

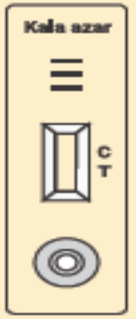
Interpretation: How to Read the Result

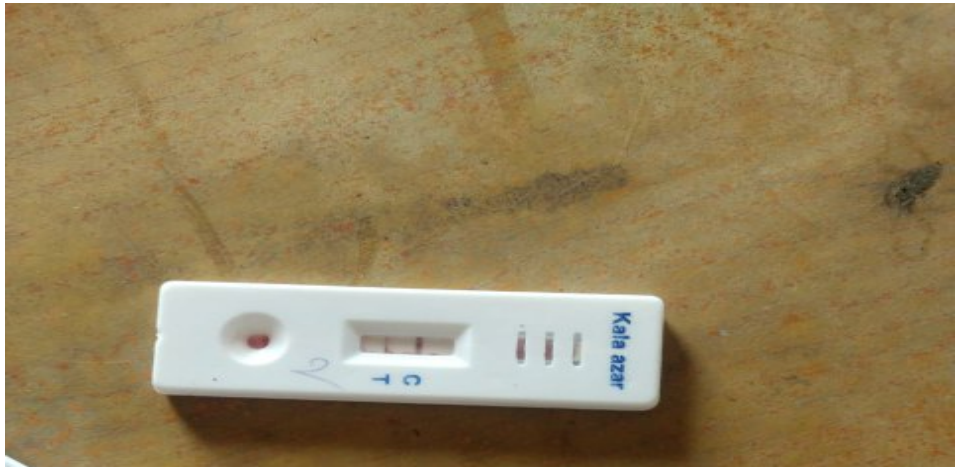
Negative:
Appearance of only one colored band at control line region 'C'. The result should be considered negative.



Positive:
Appearance of two colored bands, one at test region 'T' and other at control line region 'C'. The result should be considered positive.

Invalid:
Appearance of no colored band at the control region C, the result should be considered as invalid. In the absence of sample addition, control band will not appear. Repeat the test with a new test card making sure that the sample was added.





Positive Test

How long RDT test remains positive after treatment

- The Rapid Diagnostic test rapid test for Kala-azar is membrane based immunoassay for detection of antibodies to Kala-azar.
- rK39 tests may remain positive up to 24 months after treatment.
- The earliest documented seronegativity in an immunocompetent individual was at 122 weeks (>2 years) after onset of treatment. One patient even remained ELISA positive for more than 6 years without clinical signs for VL. In contrast to studies performed in endemic areas, where a large proportion of post kala-azar patients remains seropositive (rK39 ELISA) after cure (Srivastava et al. 2013), some for more than 15 years

Video

Treatment of a new KA patient weighing 50 kg (dosage and duration)

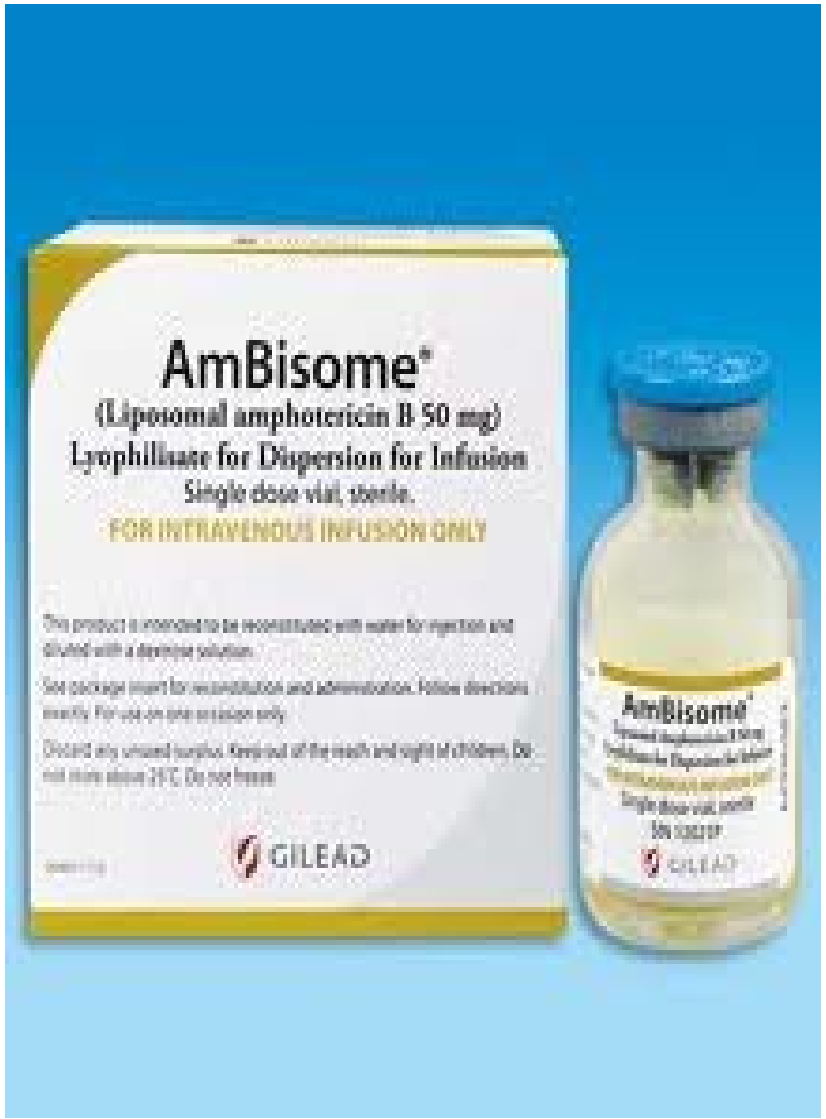
An Immunocompetent and HIV negative patient diagnosed as a case of VL (Diagnosis confirmed by RDT or parasitology)

- Dose of AmBisome: 10 mg/ Kg body weight
- Total dose of AmBisome: 500 mg
- Dose of AmBisome to be given as Single dose: 500mg
- Fluid for reconstitution of AmBisome: Water for Injection (Sterile water)
- Storage of Reconstituted Product Concentrate: The reconstituted product concentrate may be stored for up to 24 hours at 2-8° C (36-46° F)

Storage of AmBisome: Unopened vials of lyophilized material are to be stored at temperatures up to 25° C (77° F).

Reconstituted AmBisome: 5% Dextrose

Reference -AmBisome (amphotericin B) liposome for injection - Gilead ...https://www.gilead.com › pdfs › medicines › other



Liposomal Amphotericin B brand “AmBisome” is provided through the WHO agreement with the Government of India.

Material Required

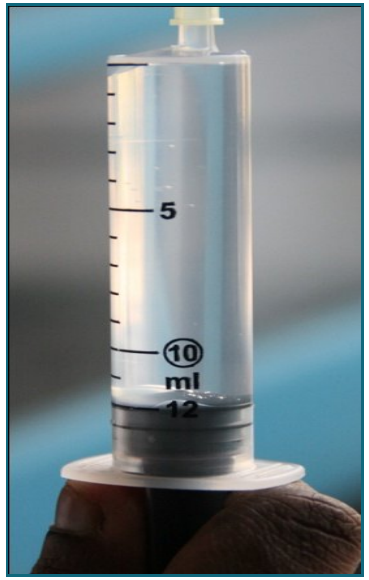
1. Gloves
2. Needle and 10ml, 20 ml syringe
3. 12 ml sterile water for injection
4. Filter (provided with AmBisome vials)
5. Infusion Set (Paediatric / Adult)
6. 5% Dextrose

Steps to be followed during AmBisome preparation administration

Steps to take

- Dose calculation
- Prepare the correct amount of 5% Dextrose
- Reconstitution of AmBisome
- Dispersion
- Aspiration
- Dilution with 5% Dextrose
- Administration of Test Dose

PREPARING AMBISOME



1. Prepare the correct amount of dextrose 5% for the infusion

2. Reconstitute each vial with 12 mL of Sterile water for injection, pressing it slowly

3. Take out 12 mls of air before removing the needle from the vial

Preparing AmBisome infusion

6

Use a 20 ml syringe and enter the same amount of air that you are going to take the AmBisome in the vial, avoiding put the air inside the liquid for preventing make bubbles

5

ALWAYS USE GLOVES AFTER THIS!

4

Shake the vial vigorously for 30 seconds or little more if required

PREPARING AMBISOME

7 Aspirate the reconstituted AmBisome without forcing

8 Enter the AmBisome in a 5% Dextrose solution using a 5 micron filter provided with AmBisome

9 Do not mix AmBisome with saline or with other drugs!

Reconstitution of Ambisome

1 ml of reconstituted solution has 4 mg of

10mg/Kg Ambisome-doses HOSPITAL LEVEL USE

WEIGHT in Kg	AMBISOME DOSES (10mg/kg)	mls DILUTED ambisome in 12 ml water	5% DEXTROSE volume in ml	DROPS/MIN infusion 150-180 min
5	50	12.5	100	15
6	60	15.0	100	15
7	70	17.5		
8	80	20.0		
9	90	22.5		
10	100	25.0	300	40
11	110	27.5		
12	120	30.0		
13	130	32.5		
14	140	35.0		
15	150	37.5		
16	160	40.0	400	50
17	170	42.5		
18	180	45.0		
19	190	47.5		
20	200	50.0		
21	210	52.5	500	60
22	220	55.0		
23	230	57.5		
24	240	60.0		

10mg/Kg Ambisome-doses HOSPITAL LEVEL USE

WEIGHT in Kg	AMBISOME DOSES (10mg/kg)	mls DILUTED ambisome in 12 ml water	5% DEXTROSE volume in ml	DROPS/MIN infusion 150-180 min
25	250	62.5	500	60
26	260	65.0		
27	270	67.5		
28	280	70.0		
29	290	72.5		
30	300	75.0		
31	310	77.5		
32	320	80.0		
33	330	82.5		
34	340	85.0		
35	350	87.5		
36	360	90.0		
37	370	92.5		
38	380	95.0		
39	390	97.5		
40	400	100.0		
41	410	102.5		
42	420	105.0		
43	430	107.5		

Administration of Test dose

For each patient start the infusion with a test-dose for early detection of possible allergic reaction.

Test-Dose: Start the infusion very slowly at 1 to 2 drops per minute for a period of 10 minutes (at slowest possible) and observe the patient (must record the vitals before giving the test dose)

If the patient tolerates the test dose well, then infuse the rest of the dose within 2 - 3 hours.

Infusion Related Reactions

- Usually not serious
- Most common: - Fever, chills
  - Lower back pain
  - Nausea
- Slow down/stop the infusion and closely observe the patient.
- If symptoms do not subside stop the infusion and treat reaction.
- If severe reaction (including angioedema, dyspnea, tachycardia) follow emergency SOPs.
- All adverse events should be recorded and reported in the format already provided as per pharmacovigilance guidelines of the GoI – ADR reporting & VigiFlow!

Anaphylactic Reaction

- Rarely observed (<1 in 2000 patients).
- If a severe anaphylactic reaction occurs, the infusion should be immediately discontinued, and the patient should not receive any further infusions of AmBisome.
- Patient should be referred to Tertiary care Hospital/Medical College for decision on treatment protocol.

Drug Interactions

- Concurrent medication with nephrotoxic drugs may enhance renal toxicity.

- Corticosteroids & Diuretics may potentiate hypokalemia.

Pediatric patients, aged 1 month to 16 years, with VL have been successfully treated with LAmB. Safety and effectiveness in pediatric patients below the age of one month have not been established.

Elderly Patients : It has not been necessary to alter the dose of LAmB for this population.
As with most other drugs, elderly patients receiving Liposomal Amphotericin B should be carefully monitored.

Pregnancy : Liposomal Amphotericin B has not produced any toxicity to the foetus. Dosage of Liposomal Amphotericin B during pregnancy is same as with others patients.

Summary table

Liposomal Amphoterecin B	10mg/kg body weight in a single intravenous infusion
Route	Intravenous
Duration	Single dose over 2 hours
Criteria for cure	Absence of clinical signs and symptoms till six months after complete treatment
Contraindication	Not to be given to those with anaphylaxis or severe renal impairment
Precautions	Monitor side effects, if any.
Pregnancy	Can be given

VL-HIV Co-Infection & its treatmen

Why VL-HIV co-infection is important to address?

- The magnitude of VL-HIV co-infection is ~4 to 5%.
- VL/HIV co-infection has major clinical, diagnostic and epidemiological implications
- The two diseases are mutually reinforcing: HIV and leishmaniasis are mutually reinforcing conditions with a detrimental effect on each other.
- HIV infection has multitude effects on leishmaniasis by increasing the risk of developing VL by 100 to 2,320 times in endemic areas. VL in coinfected patients cannot be cured, and those with CD4+ counts
- Poor treatment outcomes and higher mortality in co-infected patients, regardless of the drug used
- Co-infected patients frequently (>90%) relapse and may act as reservoir for drug resistant parasites
- Co-infective patients are thought to be more ‘infective’
- Poses a new challenge to elimination effort of kala-azar

Earlier Treatment regimens for VL-HIV co-infectio

- NVBDCP recommends 40mg/kg/wt in ten equal doses of 3-5mg/kg/wt over 38 days.

- Days 1-5,10,17,24, 31 and 38th Day

Aug-20						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					
Sep-20						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

Treatment Guideline for VL-HIV

Combination therapy of IV liposomal amphotericin B (up to 30 mg/kg @5 mg/kg on days 1, 3, 5, 7, 9 and 11)

+

Oral Miltefosine (100 mg/day for 14 days) to treat visceral leishmaniasis in HIV positive patients.

Oct-23						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					
Nov-23						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

Points to be noted in BHT

- Diagnosis – date & Method
- HIV test result
- Body weight (after measurement & not by assumption)

- Plan of treatment with dosage as per body weight
- Advice of test dose and necessary instruction
- Post test dose, actual order to start treatment

- Identification & management of ADR (if any)
- Post discharge note

Guidance for discharge of Kala-azar patient

- If patient is stable (as per physician), may be discharged after completing the infusion of AmBisome
- Discharge patient with paracetamol as the fever may persist for a few days.
- Antacid and antiemetic must be given to the patient while on capsule miltefosine
- Counsel patient that all symptoms may take a few days to subside
  - Fever will subside first within a week.
  - This is followed by return of apetite, gain of weight, regression of skin lesion
  - Regression of spleen will be the last at a rate of 1mm per week

- Ask patient to return if any concern is there or condition is deteriorating.
- Re-assurance to patient about the side effects and compliance for the treatment.
- Provide contact deatils of health worker for reporting any adverse reaction or any concern relatad to treatment

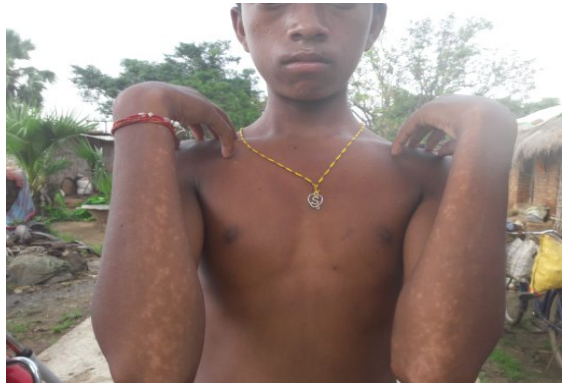
Post Kala-azar Dermal Leishmaniasis (PKDL)

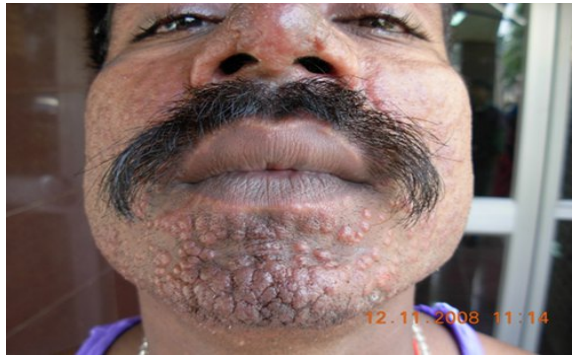
Case definition Post kala-azar dermal leishmania (PKDL)

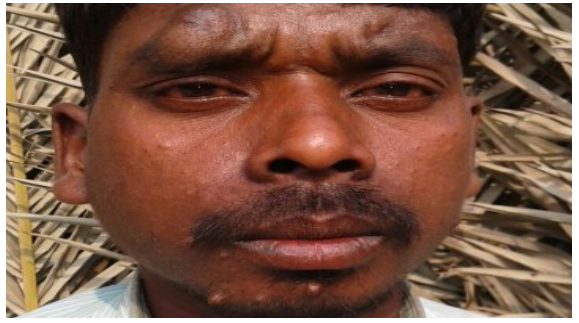
Suspected PKDL: A patient from a Kala-azar endemic area with hypopigmented macules, papules, plaques or nodules with previous history of kala-azar.

Probable PKDL: A patient from a kala-azar endemic area presenting with a typically symmetrical multiple hypopigmented macules, papules, plaques or nodules with or without previous history of visceral leishmaniasis, with no loss of sensation and who is RDT positive. The treatment is started once the probable PKDL case is diagnosed.

Confirmed PKDL: A probable PKDL case confirmed parasitologically by skin-slit smear or biopsy or PCR.



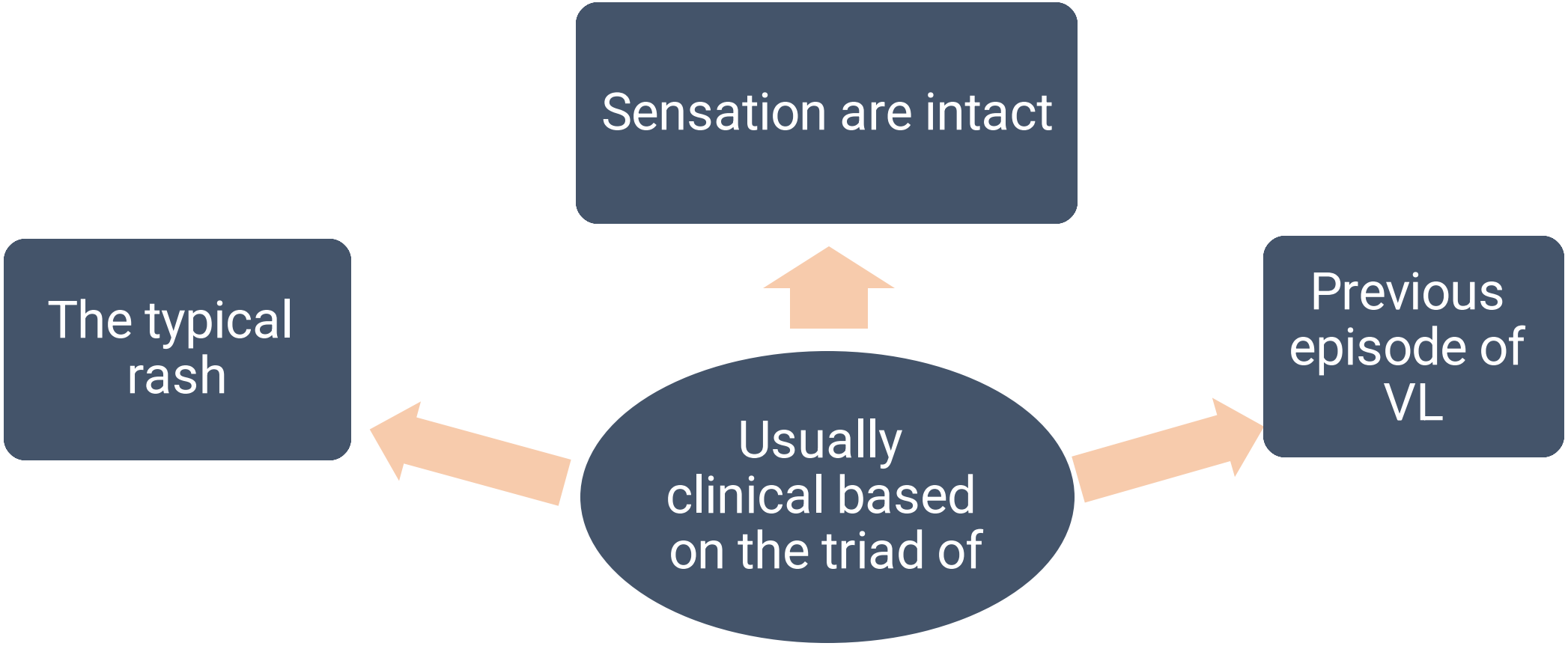




Post Kala-azar Dermal Leishmaniasis (PKDL)

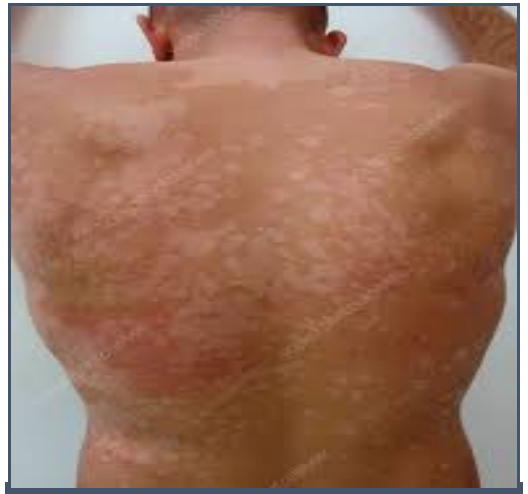
- PKDL Rash/Skin lesions usually first occurs on the face from which it may spread to other parts of the body
- May be mistaken as leprosy and various skin diseases, resulting in delayed diagnosis.
- PKDL has potential role in transmission of VL in the interepidemic period and may act as reservoir of infection.
- Potential threat to success of KA elimination programme.

Diagnosis of PKDL



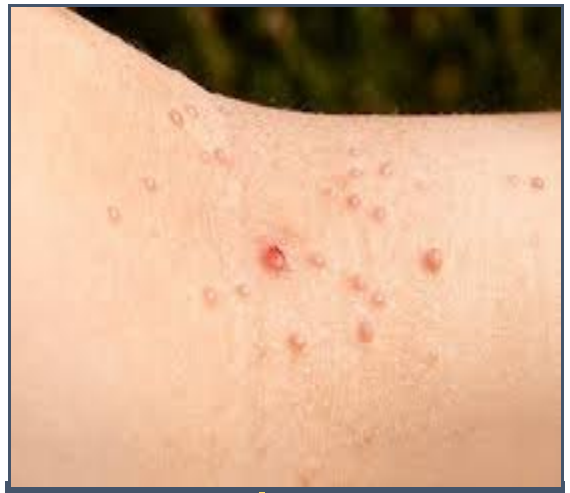
- Diagnosis is confirmed by
  - Demonstration of the parasite (L D body) on skin smear or DNA by PCR

Differential diagnosis of PKDL

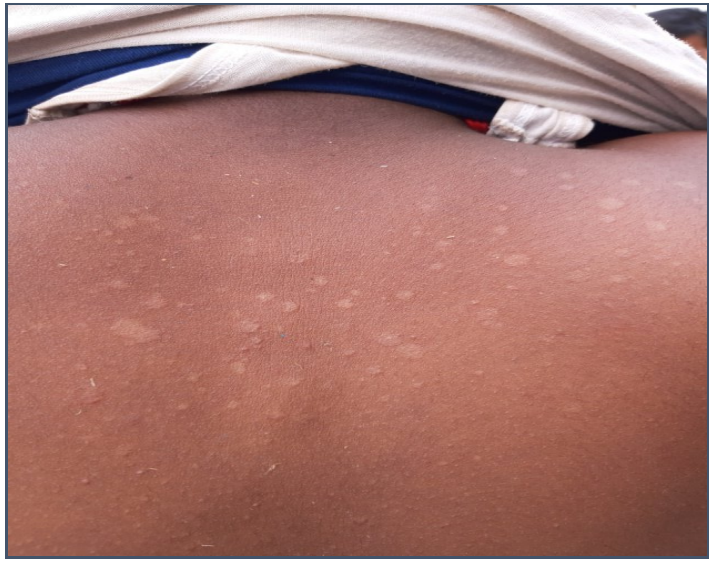


Pityriasis versicolor

Lepros y

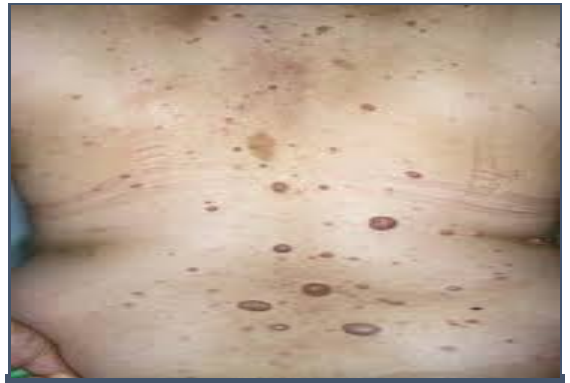


Viral warts

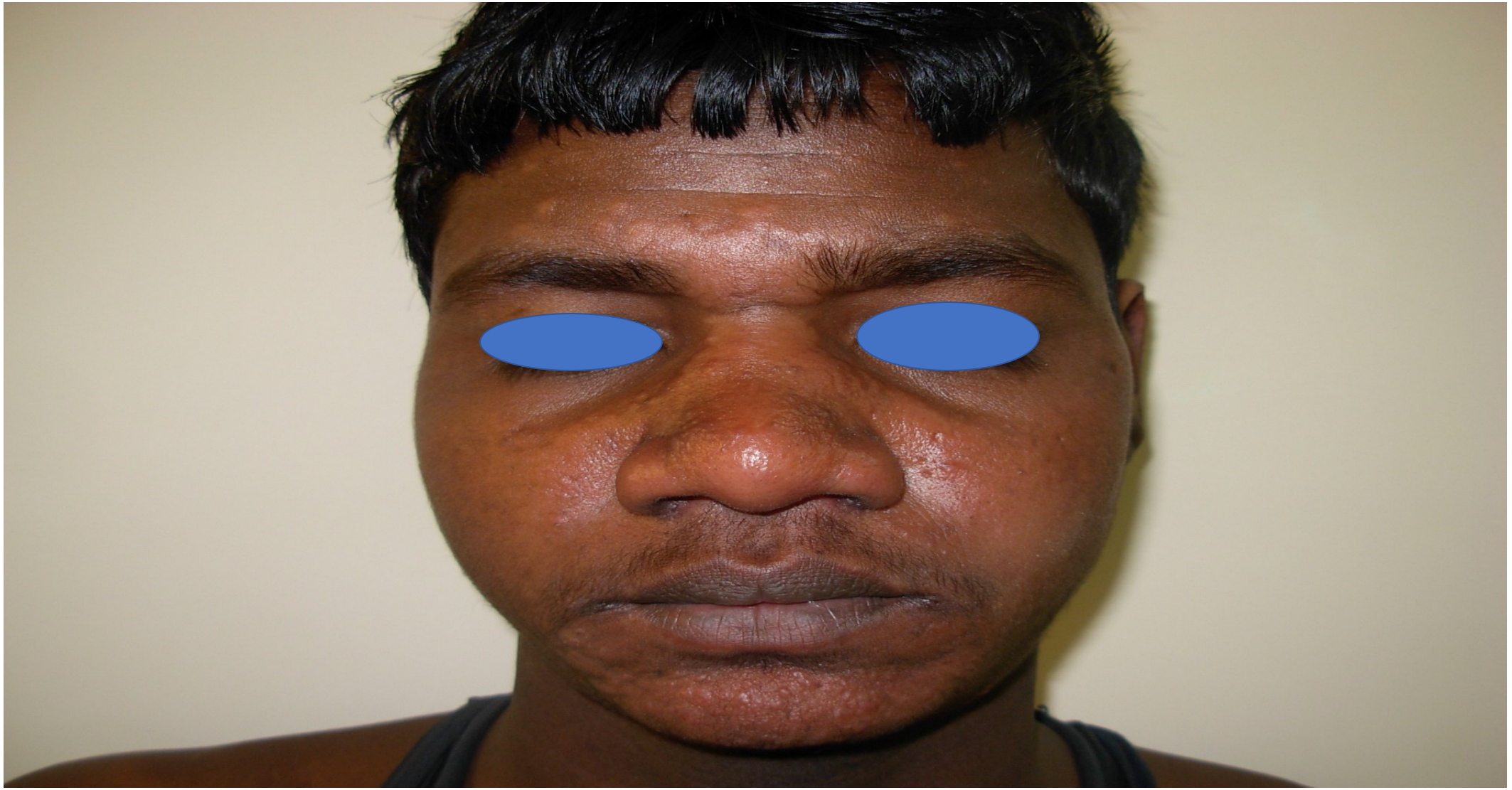


PKDL

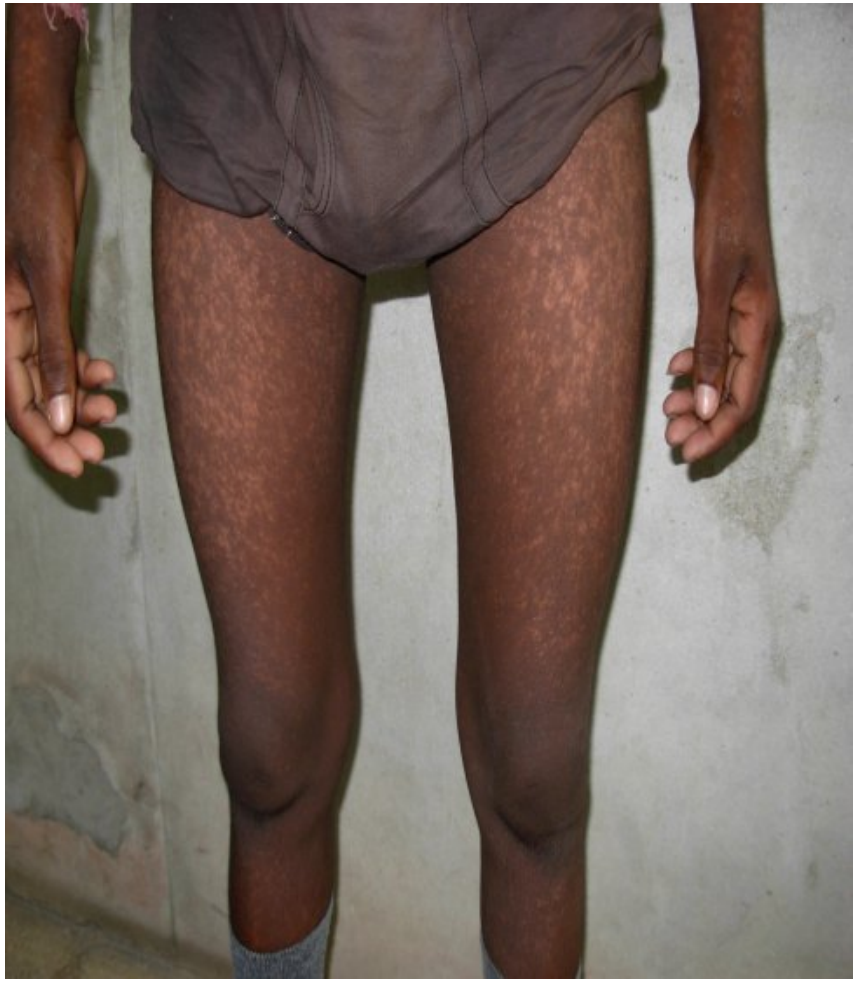
Vitiligo



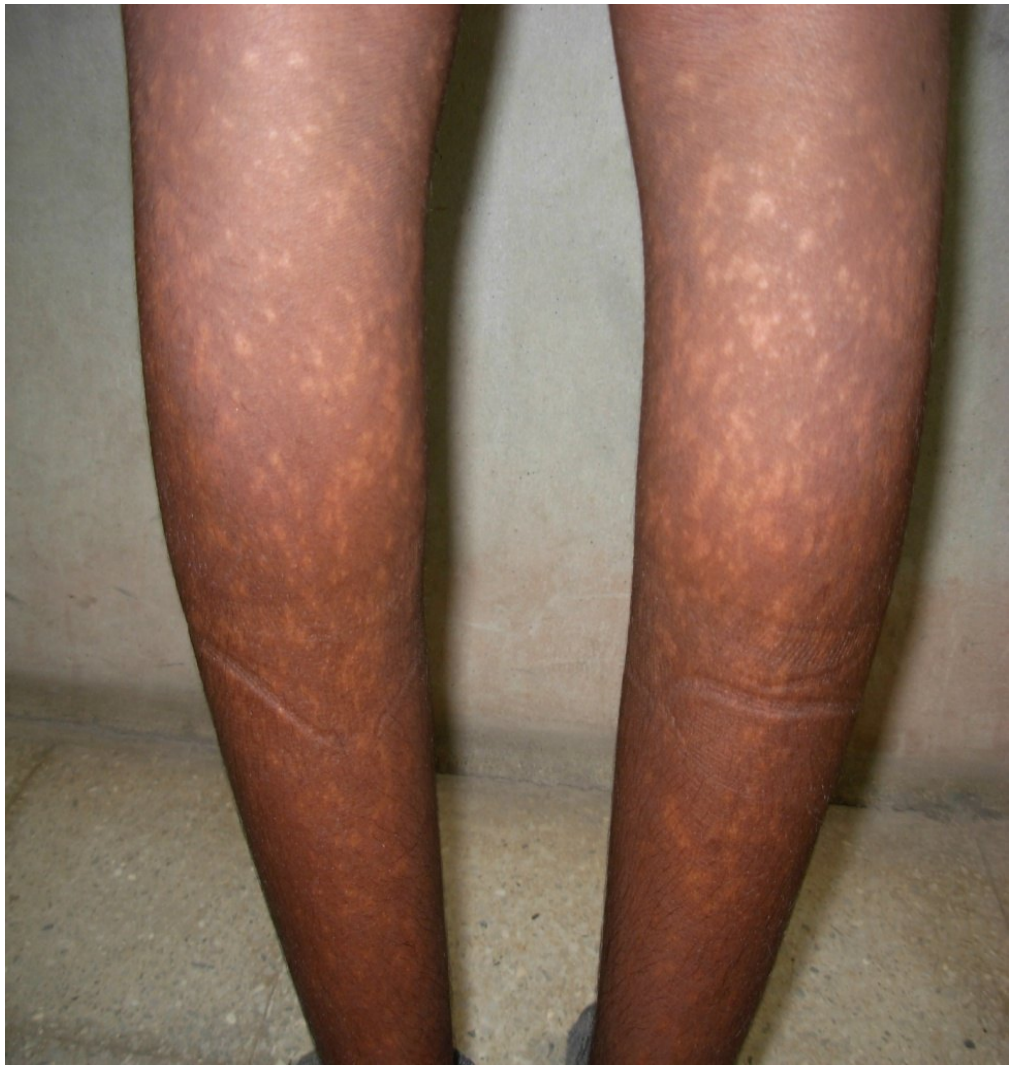
Neurofibromatosis

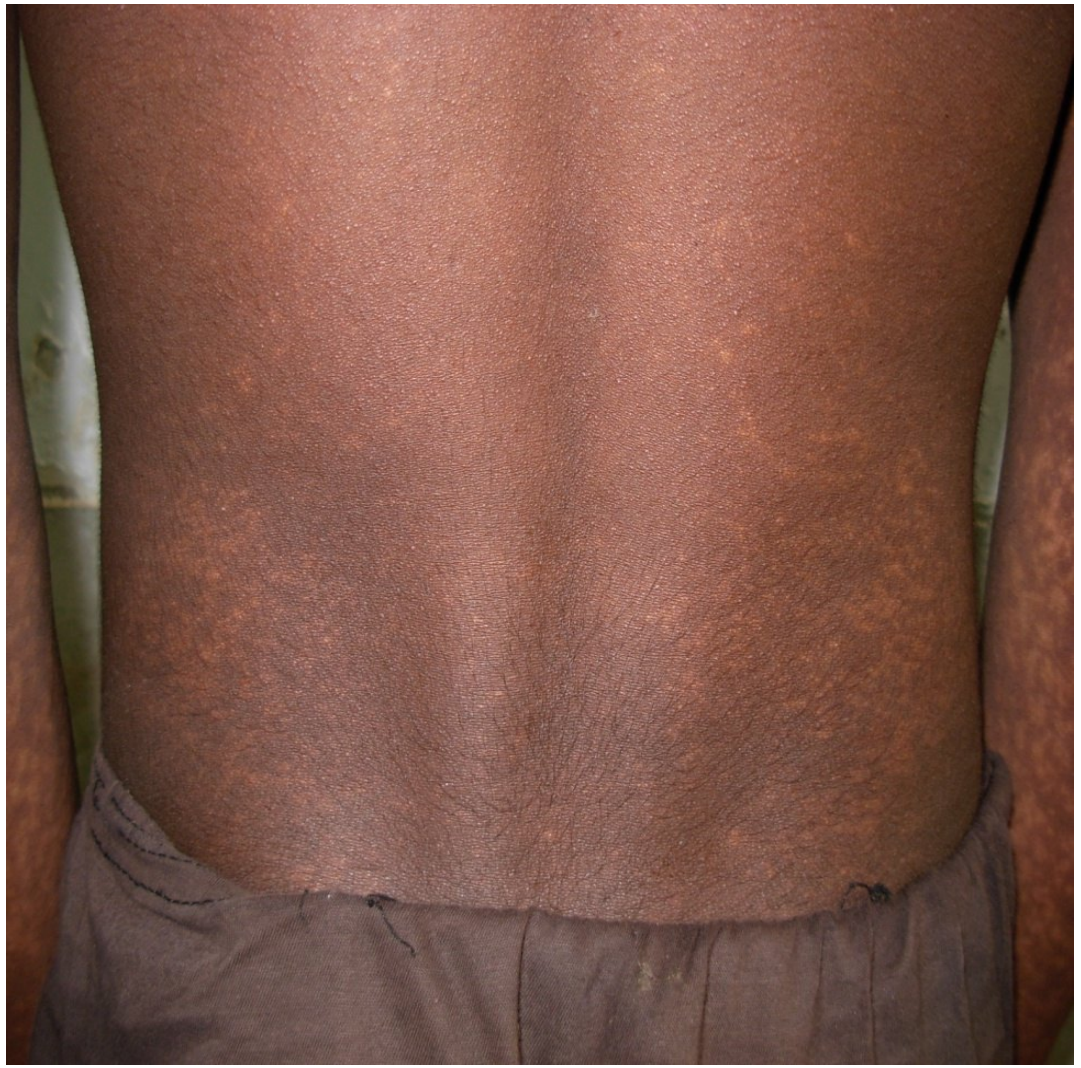


PKDL

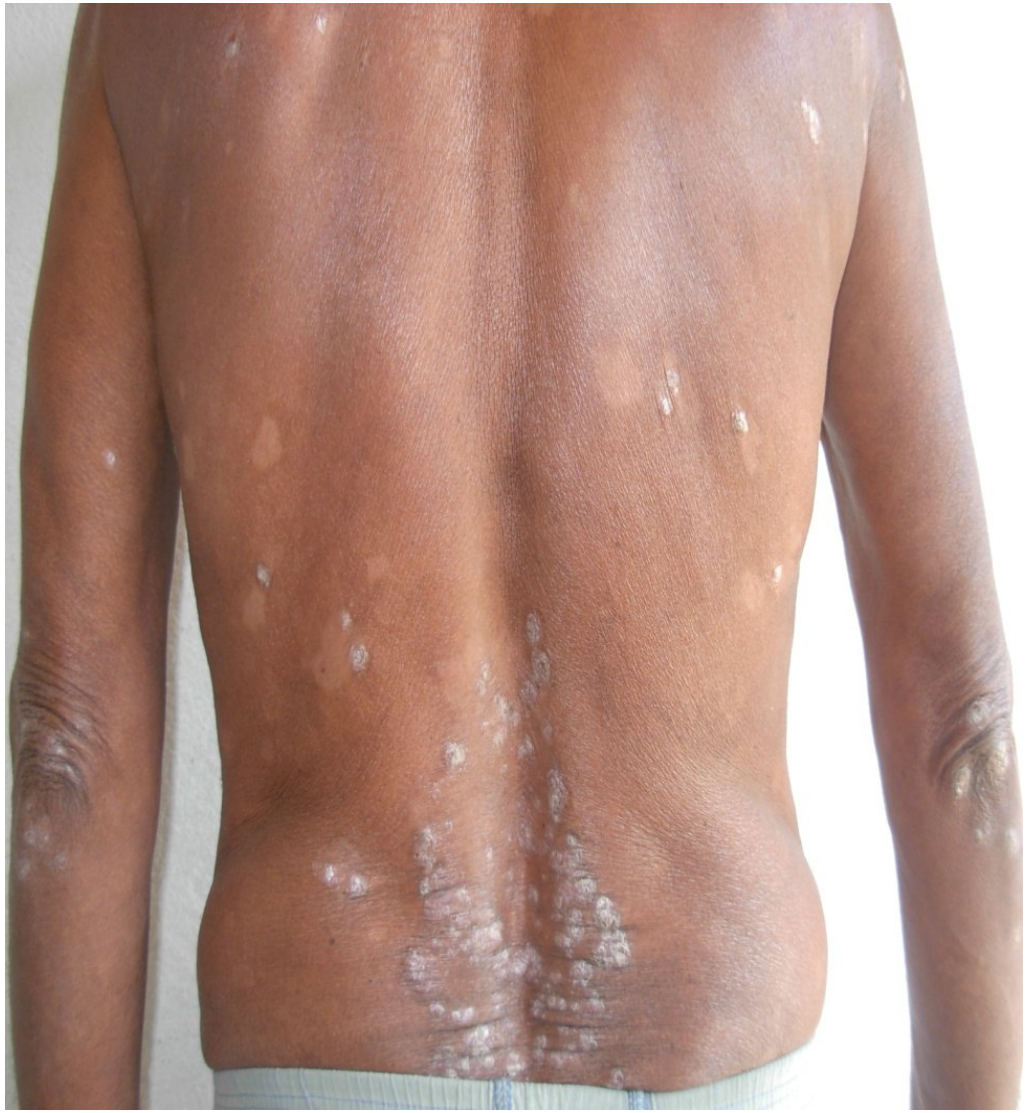


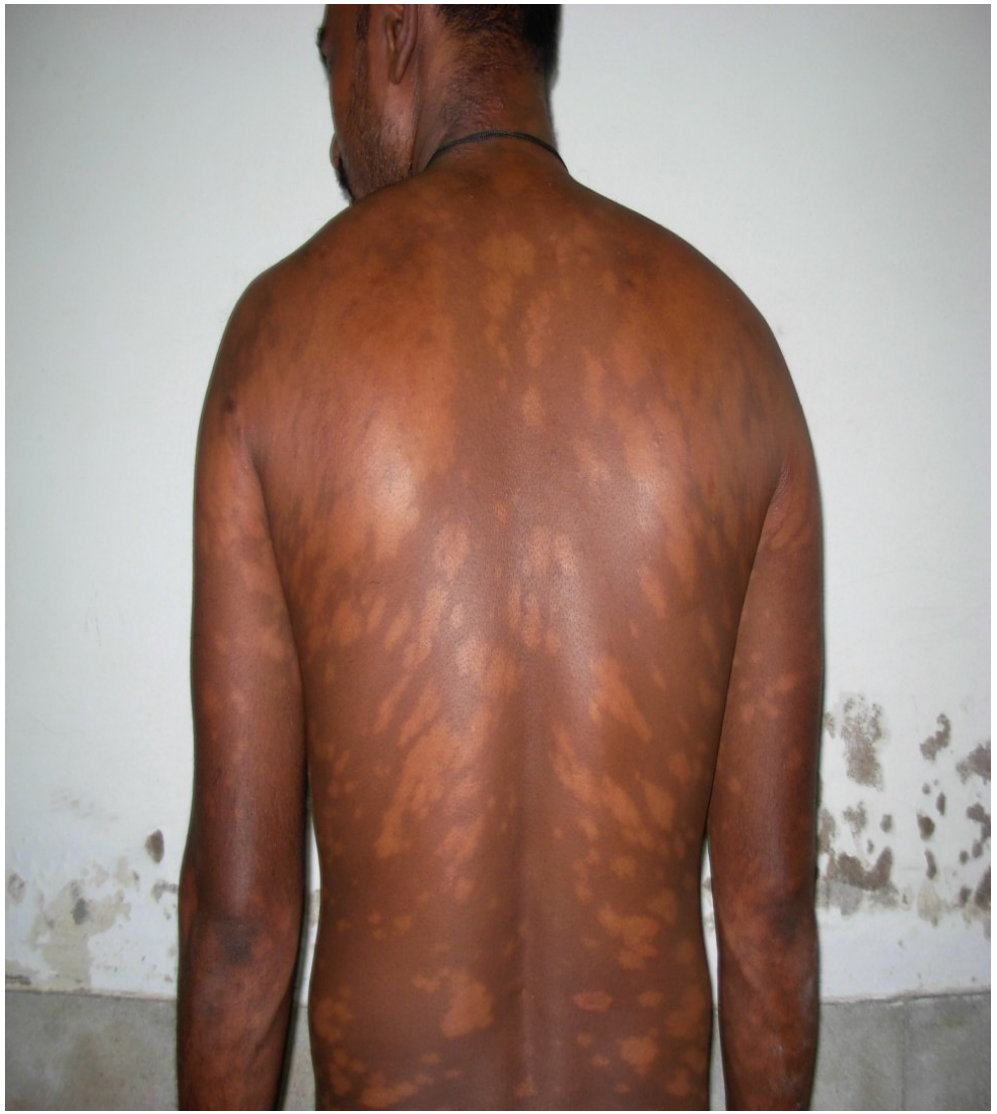
PKDL



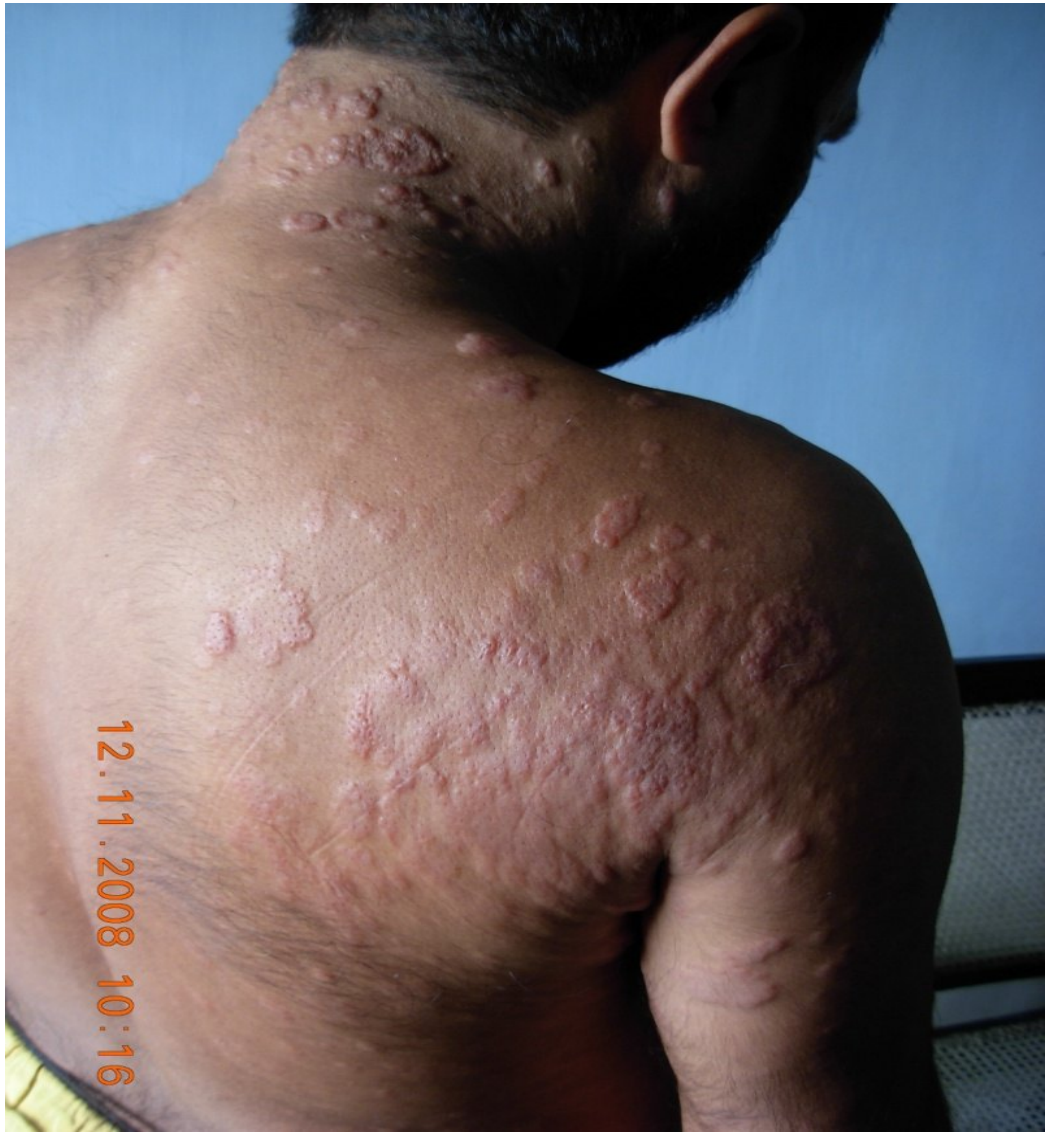


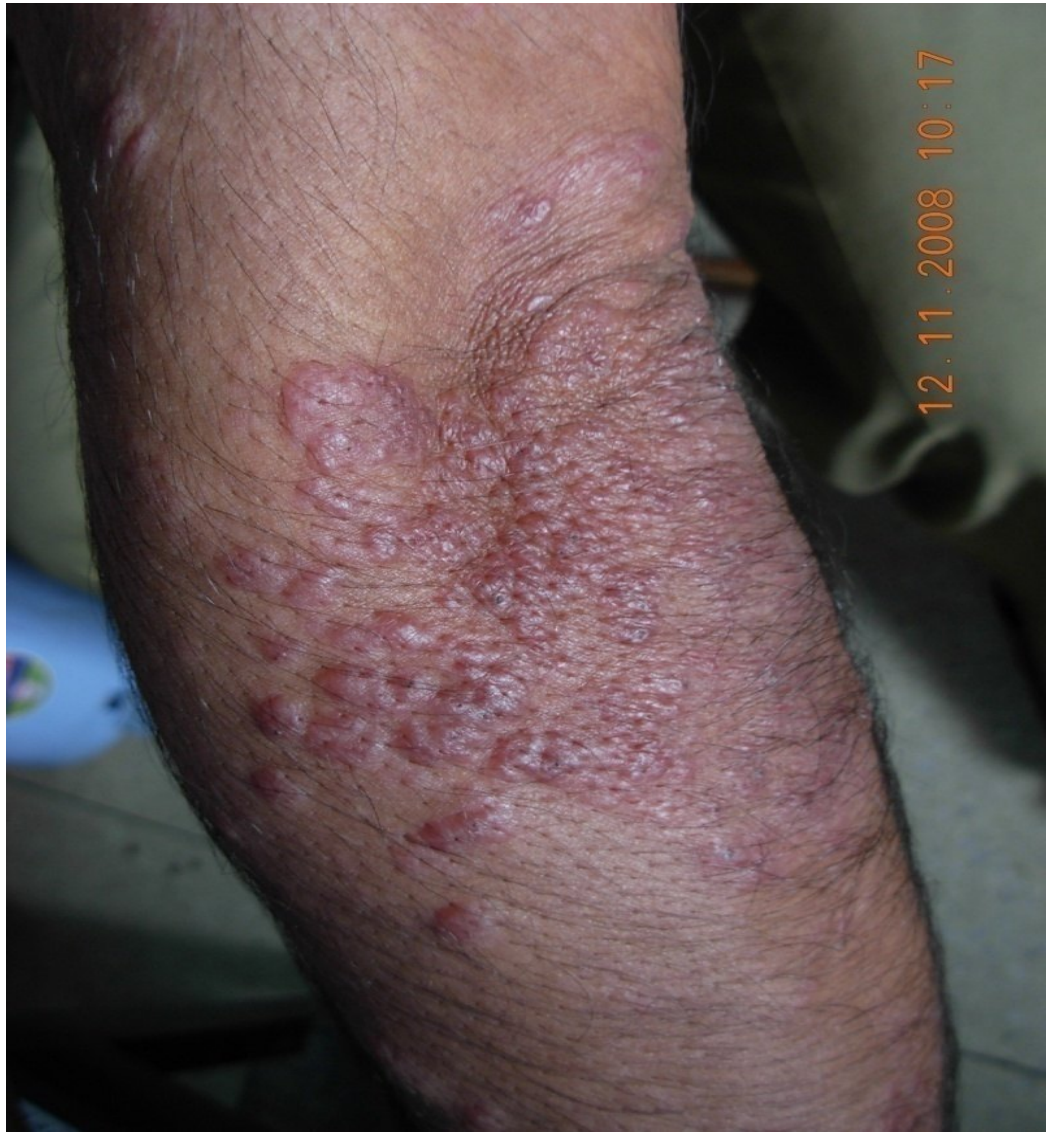
PKDL



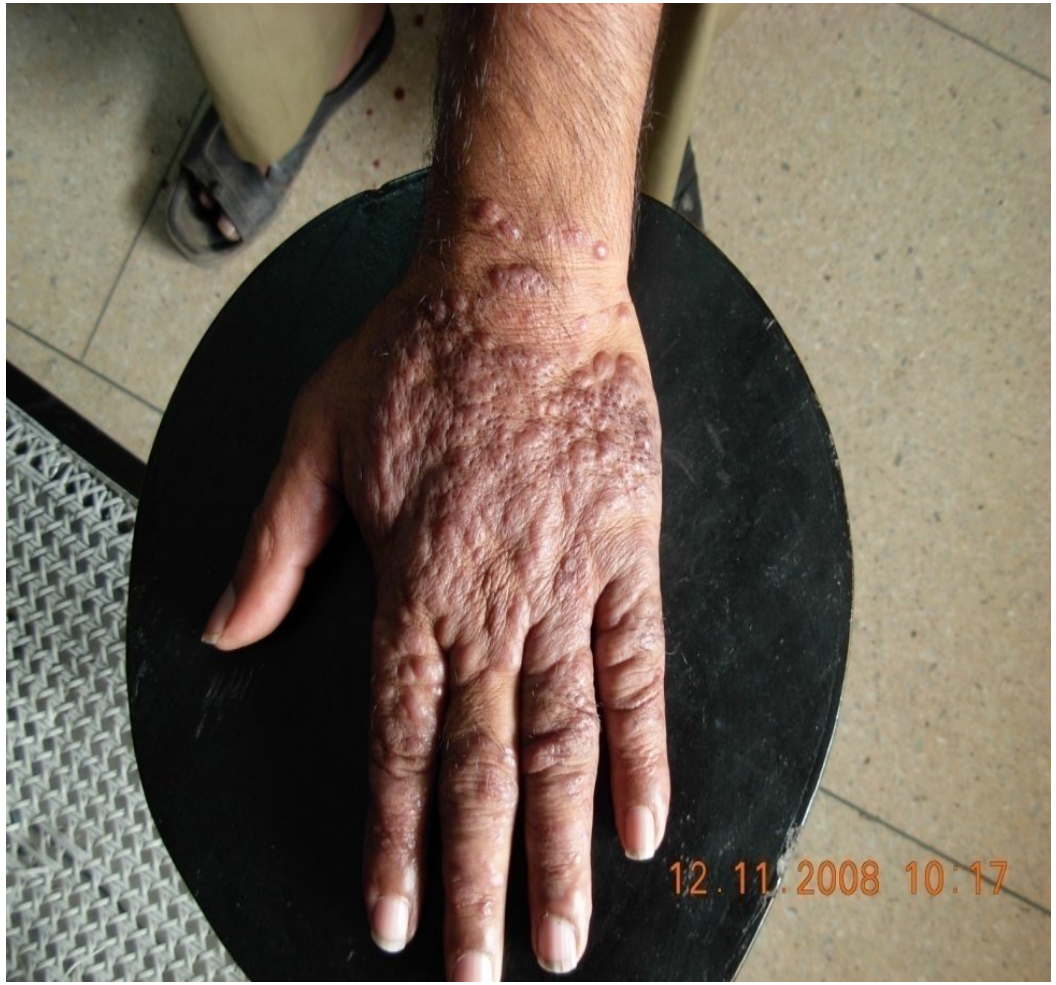


PKDL





PKDL



ost Kala-azar dermal leishmaniasis (PKD

TREATMENT

Treatment: Miltefosine capsule for 12 weeks

Don't use below 2 years of age

Dosage Guide for Adults (>12 years)

Weight	Morning Dose (after meal)	Evening Dose (after meal)
More than 25 kg	1 capsules of Miltefosine 50 mg	1 capsules of Miltefosine 50 mg
Less than 25 kg	1 capsules of Miltefosine 50 mg	Drug not to be given at evening

Dosage Guide for Children (2-11 years)

Body weight	Daily Dosage	Number of Capsules
9-11 kg	20 mg	2 capsules of Miltefosine 10 mg
12-16 kg	30 mg	3 capsules of Miltefosine 10 mg
17-20 kg	40 mg	4 capsules of Miltefosine 10 mg
21-25 kg	50 mg	1 capsules of Miltefosine 50 mg
26-31 kg	60 mg	1 capsules of Miltefosine 50 mg & 1 capsules of Miltefosine 10 mg
32-39 kg	80 mg	1 capsules of Miltefosine 50 mg & 3 capsules of Miltefosine 10 mg
40 kg and above	100 mg	2 capsules of Miltefosine 50 mg

Treatment of KA/PKDL

Miltefosine is the preferred first-line drug. it is a relatively safe oral drug for the treatment of PKDL.

Dosage schedule:

- i. Adults (>12 years) weighing more than 25 kg: Total 100mg- 50 mg morning and evening, after meals for 12 weeks
- ii. Adults (>12 years) weighing (less than 25 kg):

  Total 50 mg- 50 mg morning after meals for 12 weeks
- iii. Children (2-11 years):

  Miltefosine at 2.5mg/ kg once daily after meals for 12 weeks

The drug is not to be used in the case of children below 2 years of age

WHAT IS MILTEFOSINE ?

- Miltefosine is the first oral drug registered for Kala-azar
- Treatment of choice for PKDL cases.

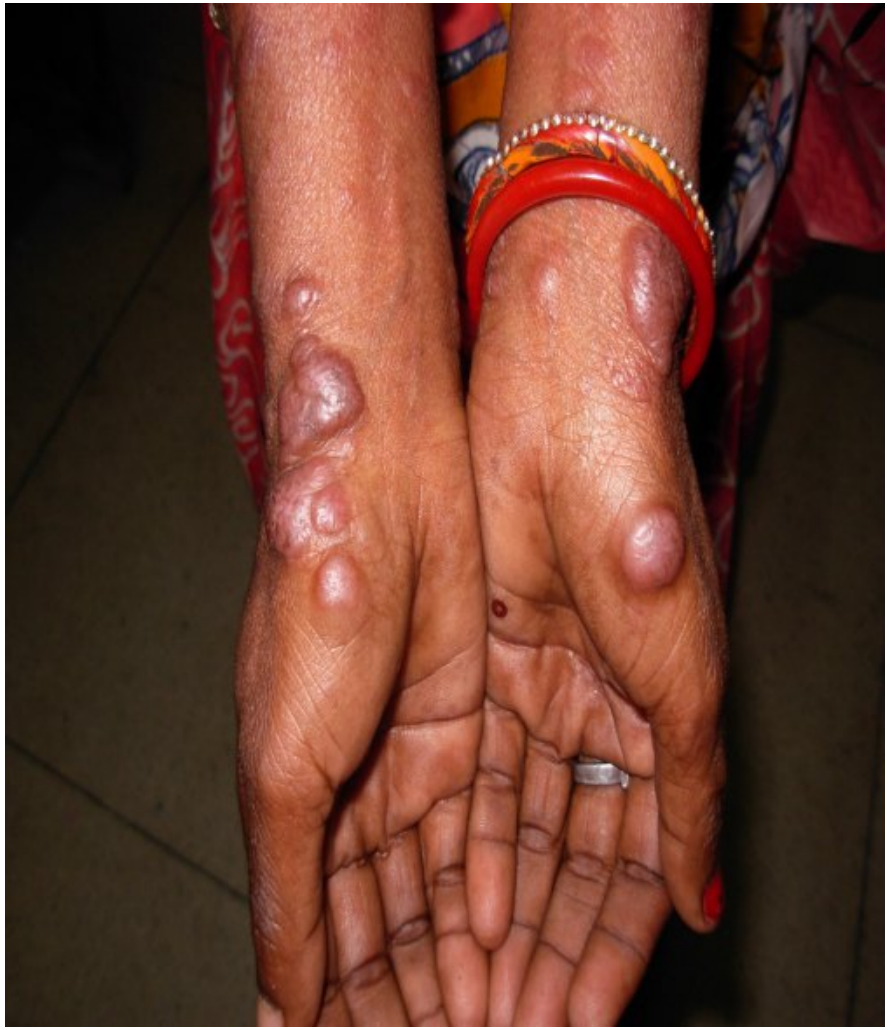
Side effects

Nausea, vomiting, acidity, abdominal pain, malaise
Miltefosine has exhibited teratogenicity (Should not be administered to pregnant women)

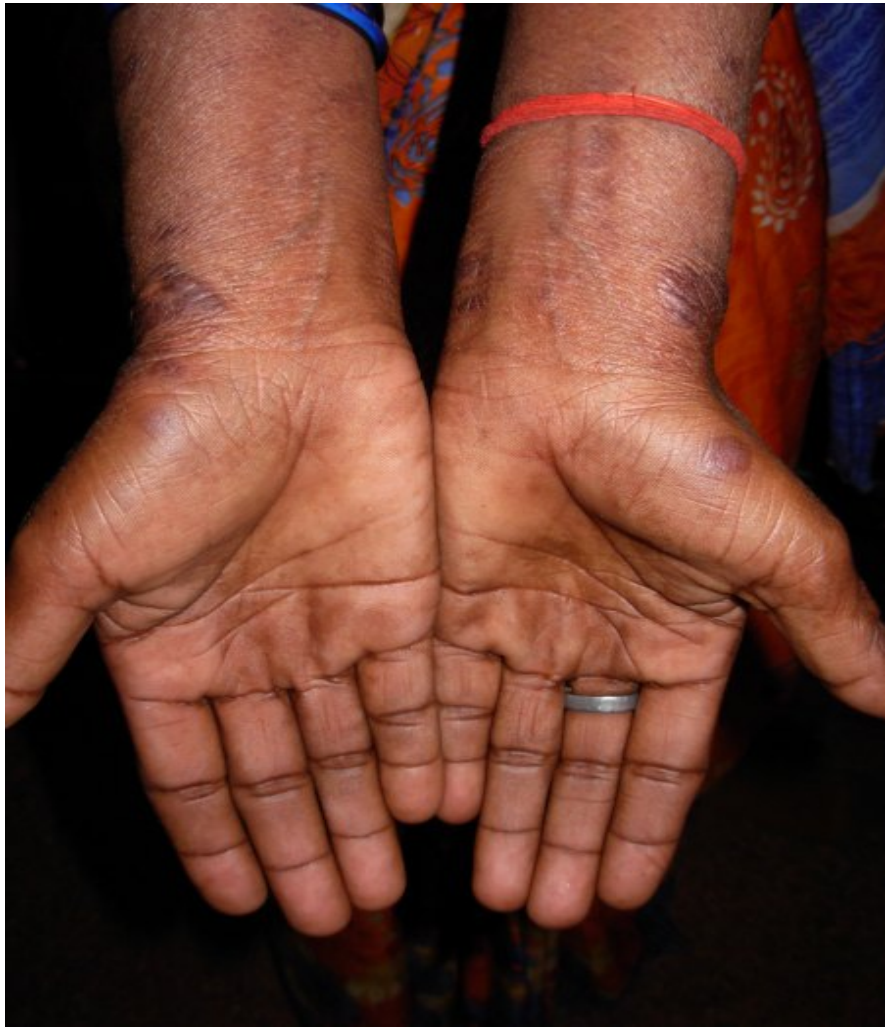
Miltefosine: Important Cautions

- Miltefosine must not be given to female patients who are pregnant or breast feeding. They can be safely treated with AmBisome.
- Contraception must be ensured (in females of reproductive age group) during the treatment period and 03 months after the treatment with Miltefosine.
- Antacid and antiemetic must be given to the patient while on capsule miltefosine
- Re-assurance to patient about the side effects and compliance for the

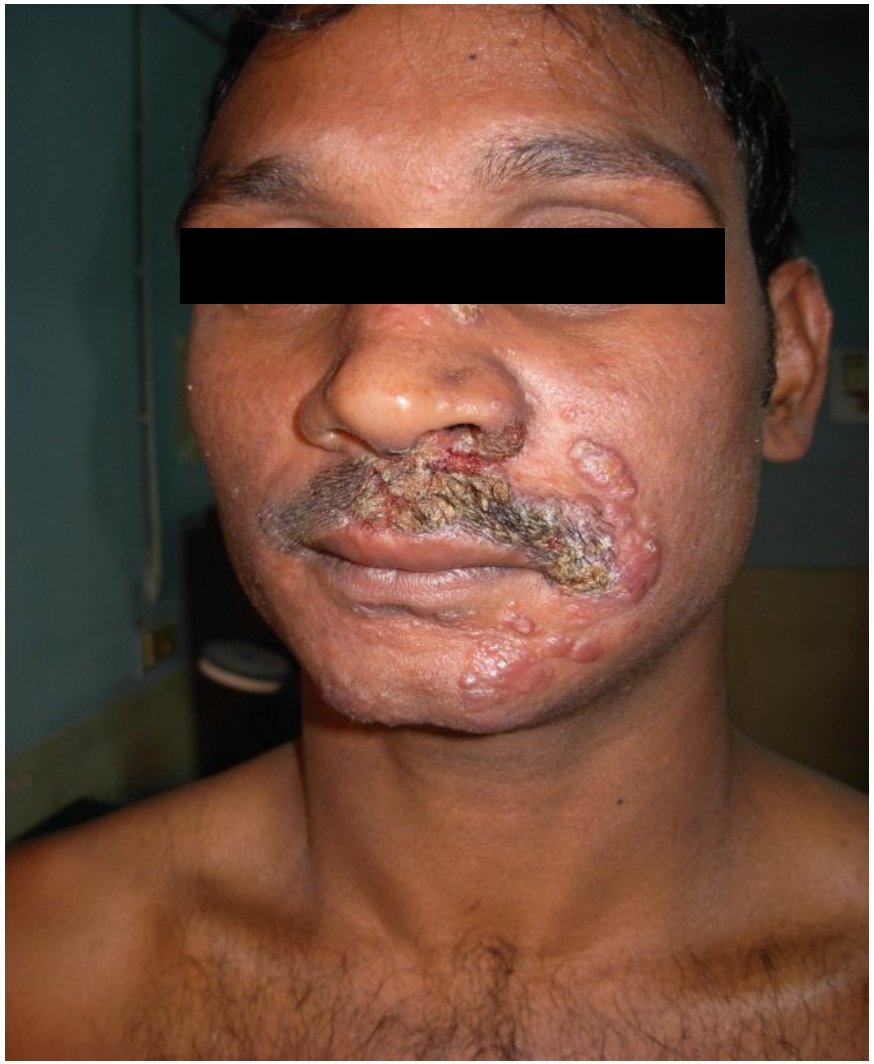
Before Treatment



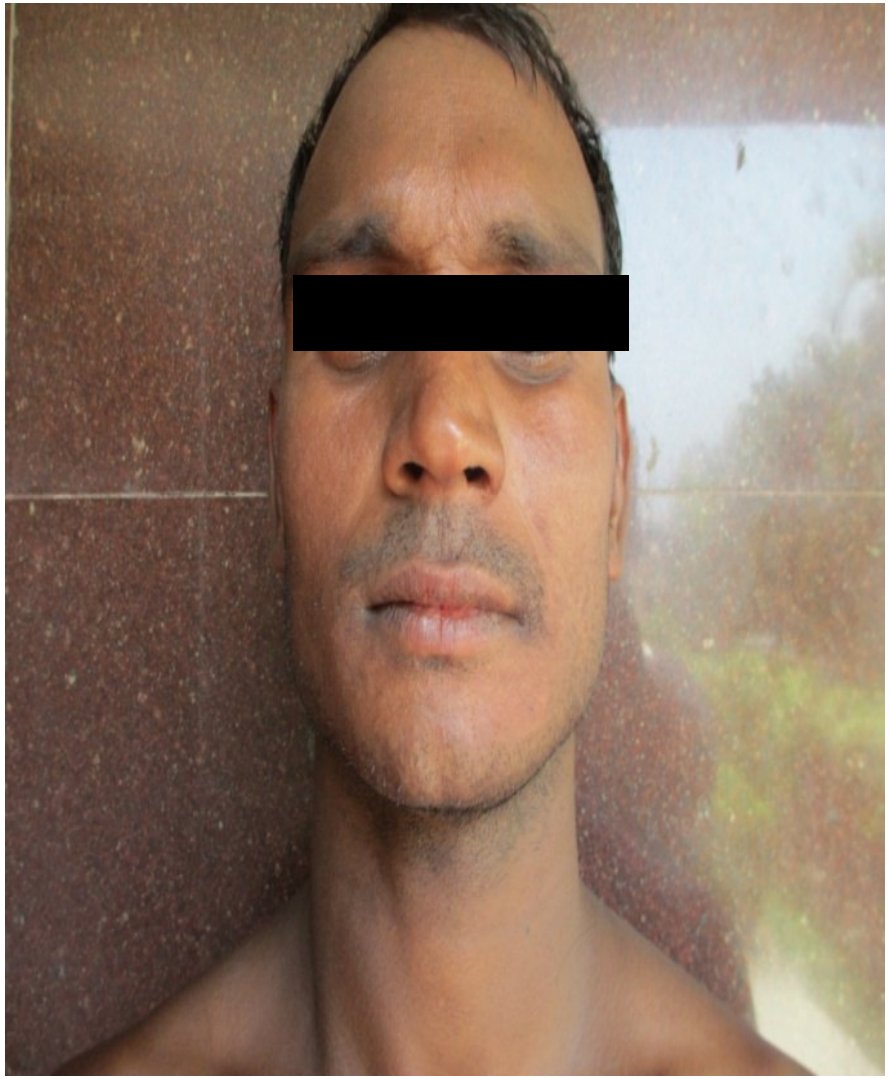
After Treatment



Before Treatment

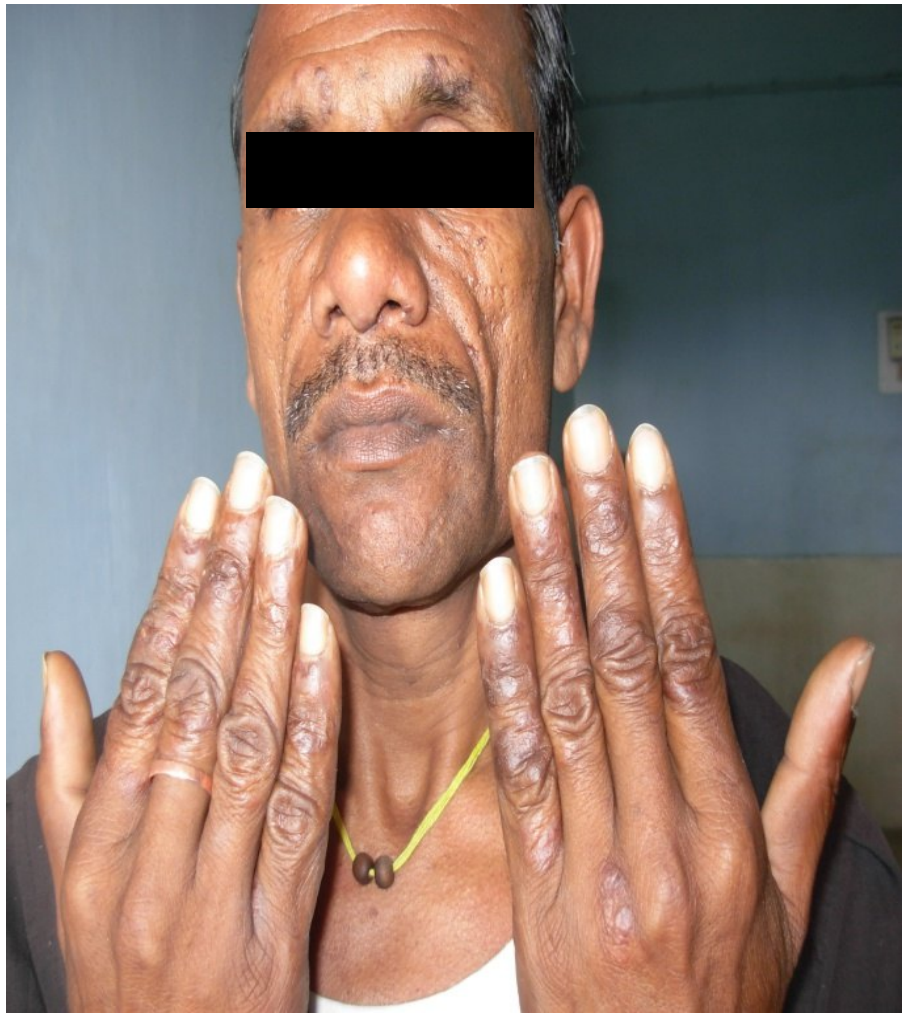


After Treatment

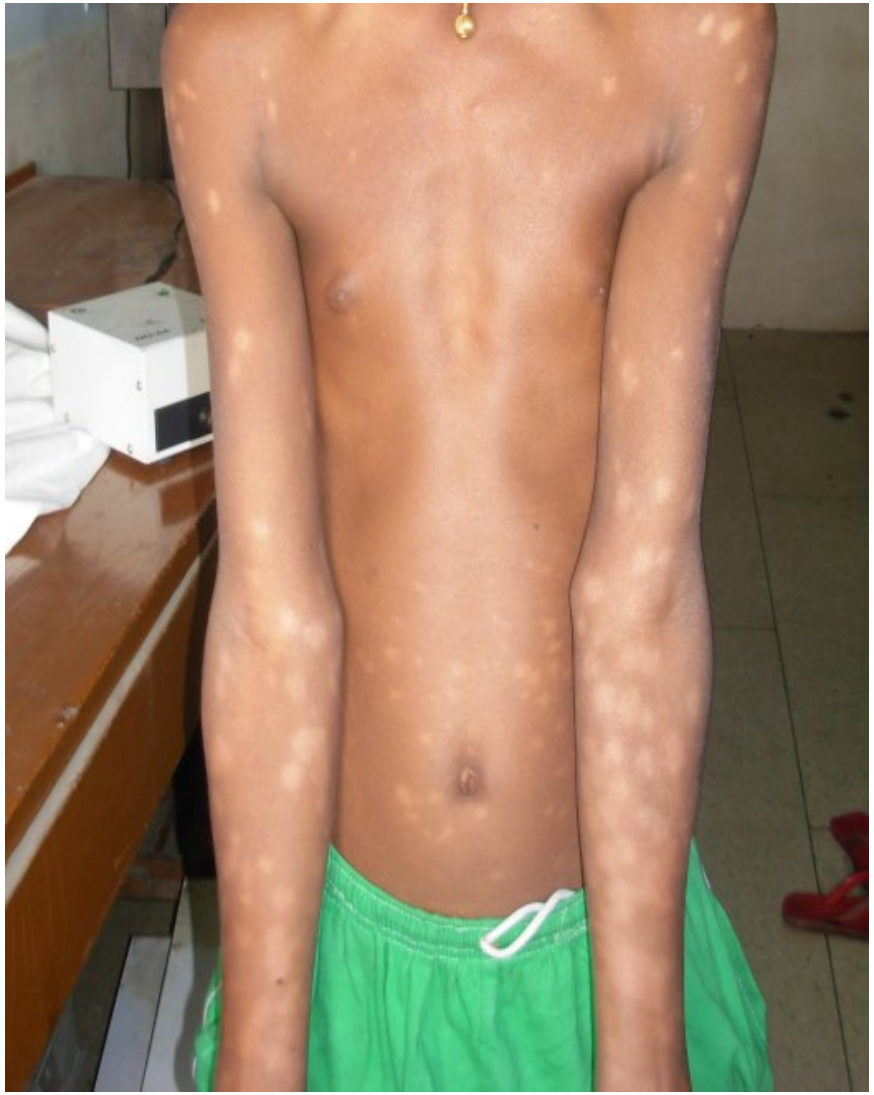


Before Treatment

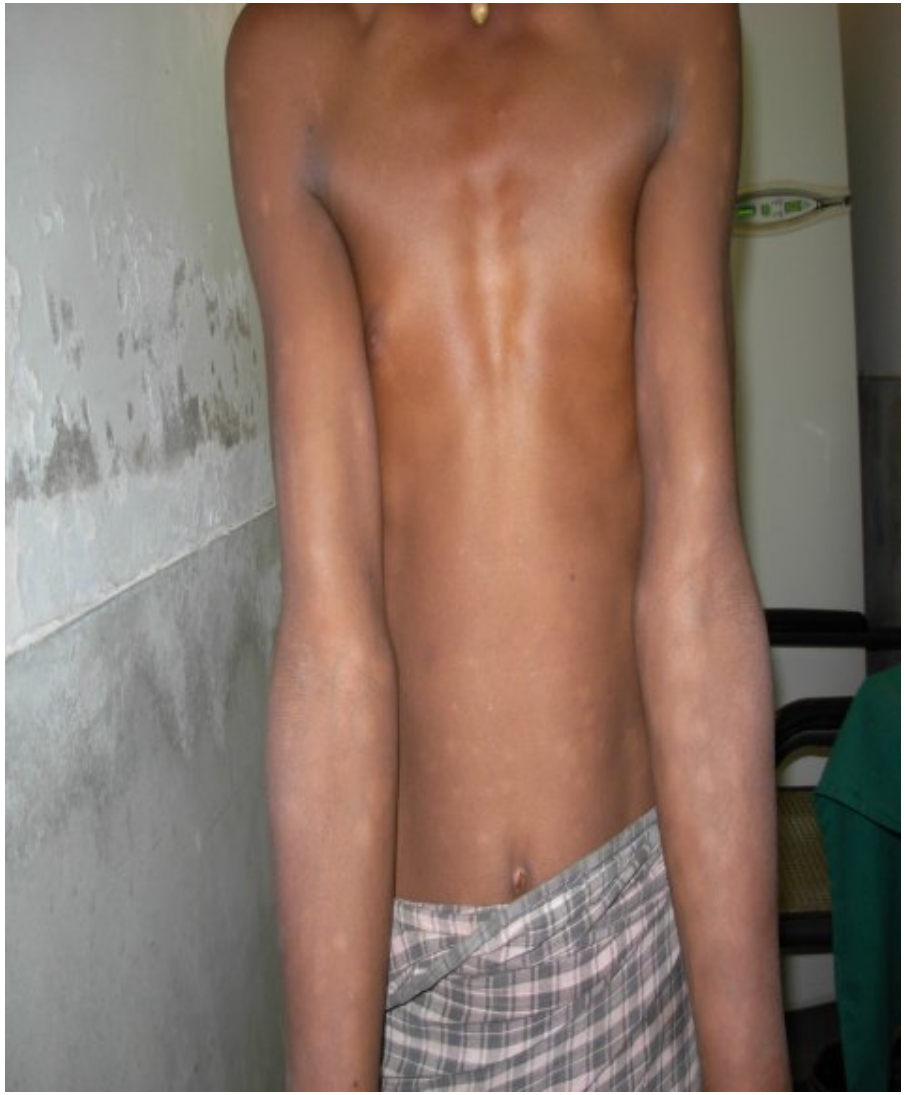
After Treatment



Before Treatment



After Treatment



Treatment Protocol for VL, VL-HIV and PKDL Cases

KALA-AZAR/VISCERAL LEISHMANIASIS (VL)

OPTION- 1

AmBisome infusion in 5% Dextrose solution
10 mg per kg body weight
IV over 2-3 hours
Single Dose

OPTION- 2

Amphotericin B deoxycholate
1 mg per kg body weight
IV
On alternate days for 15 days

OPTION- 3

Miltefosine Capsule, for 28 days, Oral
2-11 years 2.5 mg per kg body weight
>12 years; <25 kg 50 mg
> 12 years;> 25 kg 100 mg

AmBisome can be safely used among pediatric, pregnant and elderly VL patients.

HIV-VL

AmBisome infusion in 5% Dextrose solution
@5 mg per kg body weight
IV over 2-3 hours
6 intermittent doses on 1st ,3rd ,5th, 7th ,9th ,11th days with Miltefosine 100 mg per day for 14 days.

POST KALA-AZAR DERMAL LEISHMANIASIS (PKDL)

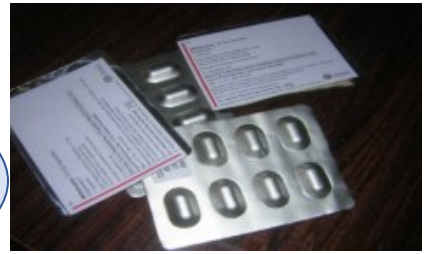
OPTION- 1

Miltefosine capsule, for 84 days, Oral
2-11 years 2.5 mg per kg body weight
>12 years; <25 kg 50 mg
> 12 years;> 25 kg 100 mg

OPTION- 2

AmBisome infusion in 5% Dextrose solution
3-5 mg per kg body weight
IV over 2-3 hours
Twice a week, for 3 weeks

Miltefosine is contradicted in pregnant women, lactating women, women in reproductive age group, who refuse contraception during treatment and 2 months post last dose of Miltefosine and in children < 2 years.



Kala-azar treatment cards

Resident

Kala Azar Patient Treatment Card
कालाज़ार मरीज़ उपचार कार्ड
National Vector Borne Disease Control Program
Kala Azar Elimination Program

RESIDENT / स्थानीय

KAMIS ID: पहचान कोड | OPD No.: ओपीडी संख्या | IPD No.: इंडोर संख्या

Full name of patient: रोगी का पूरा नाम

Father's / Husband's name: पिता या पति का नाम | Age (Years) आयु (वर्ष में) | Male पुरुष | Female महिला | Transgender | Caste जाति | ST अ.जन जाति | SC जन जाति | Mahadalit / PTG महादलित / पीटीजी | Others अन्य

Present address वर्तमान पता (उपचार के दौरान) | Phone number: | Relationship with phone owner: फोन के मलिक से संबंध

Permanent address: State- | District: | Block:

Health Subcenter: | Village:

Name and contact no of ASHA : आशा / स्वास्थ्य कार्यकर्ता का नाम और फोन नम्बर

Clinical Symptoms	Duration (Days)	History of KA/PKDL treatment	Past treatment details
Fever		Yes	(Drug/dosage/duration)
Weight loss		No	
Abdomen enlargement		Year/Month/Date of treatment	
Weakness			
Blackening of skin			

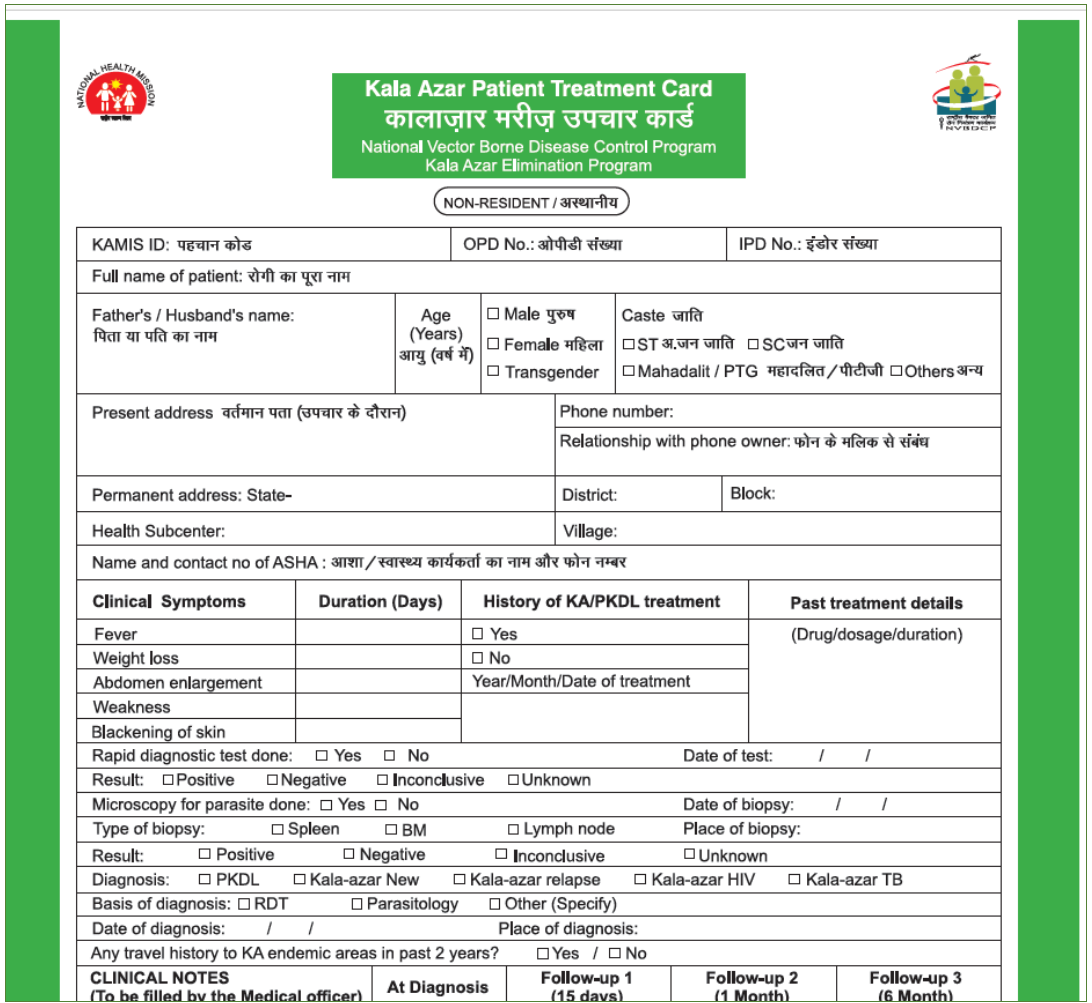
Rapid diagnostic test done: Yes No — Date of test: / /

Result: Positive Negative Inconclusive Unknown

Microscopy for parasite done: Yes No — Date of biopsy: / /

Type of biopsy: Spleen BM Lymph node — Place of biopsy:

Non-Residen



Kala Azar Patient Treatment Card
कालाज़ार मरीज़ उपचार कार्ड
National Vector Borne Disease Control Program
Kala Azar Elimination Program

NON-RESIDENT / अस्थानीय

KAMIS ID: पहचान कोड | OPD No.: ओपीडी संख्या | IPD No.: इंडोर संख्या

Full name of patient: रोगी का पूरा नाम

Father's / Husband's name: पिता या पति का नाम | Age (Years) आयु (वर्ष में) | ☐ Male पुरुष | ☐ Female महिला | ☐ Transgender | Caste जाति | ☐ ST अ.जन जाति | ☐ SC जन जाति | ☐ Mahadalit / PTG महादलित / पीटीजी | ☐ Others अन्य

Present address वर्तमान पता (उपचार के दौरान) | Phone number: | Relationship with phone owner: फोन के मलिक से संबंध

Permanent address: State- | District: | Block:

Health Subcenter: | Village:

Name and contact no of ASHA : आशा / स्वास्थ्य कार्यकर्ता का नाम और फोन नम्बर

Clinical Symptoms	Duration (Days)	History of KA/PKDL treatment	Past treatment details
Fever		☐ Yes	(Drug/dosage/duration)
Weight loss		☐ No	
Abdomen enlargement		Year/Month/Date of treatment	
Weakness			
Blackening of skin			

Rapid diagnostic test done: ☐ Yes ☐ No — Date of test: / /

Result: ☐ Positive ☐ Negative ☐ Inconclusive ☐ Unknown

Microscopy for parasite done: ☐ Yes ☐ No — Date of biopsy: / /

Type of biopsy: ☐ Spleen ☐ BM ☐ Lymph node — Place of biopsy:

Result: ☐ Positive ☐ Negative ☐ Inconclusive ☐ Unknown

Diagnosis: ☐ PKDL ☐ Kala-azar New ☐ Kala-azar relapse ☐ Kala-azar HIV ☐ Kala-azar TB

Basis of diagnosis: ☐ RDT ☐ Parasitology ☐ Other (Specify)

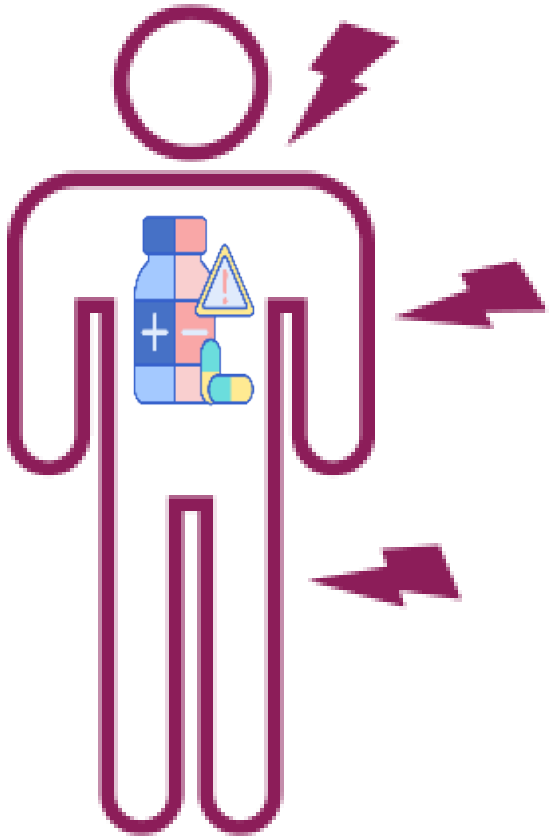
Date of diagnosis: / / — Place of diagnosis:

Any travel history to KA endemic areas in past 2 years? ☐ Yes / ☐ No

CLINICAL NOTES (To be filled by the Medical officer)	At Diagnosis	Follow-up 1 (15 days)	Follow-up 2 (1 Month)	Follow-up 3 (6 Month)

Adverse drug reaction reporting form for Kala-azar elimination programme

Adverse Drug Reactions – Definitions and Terminologies



Side effects: Any unintended effect of a pharmaceutical product occurring at doses normally used by a patient which is related to the pharmacological properties of it.

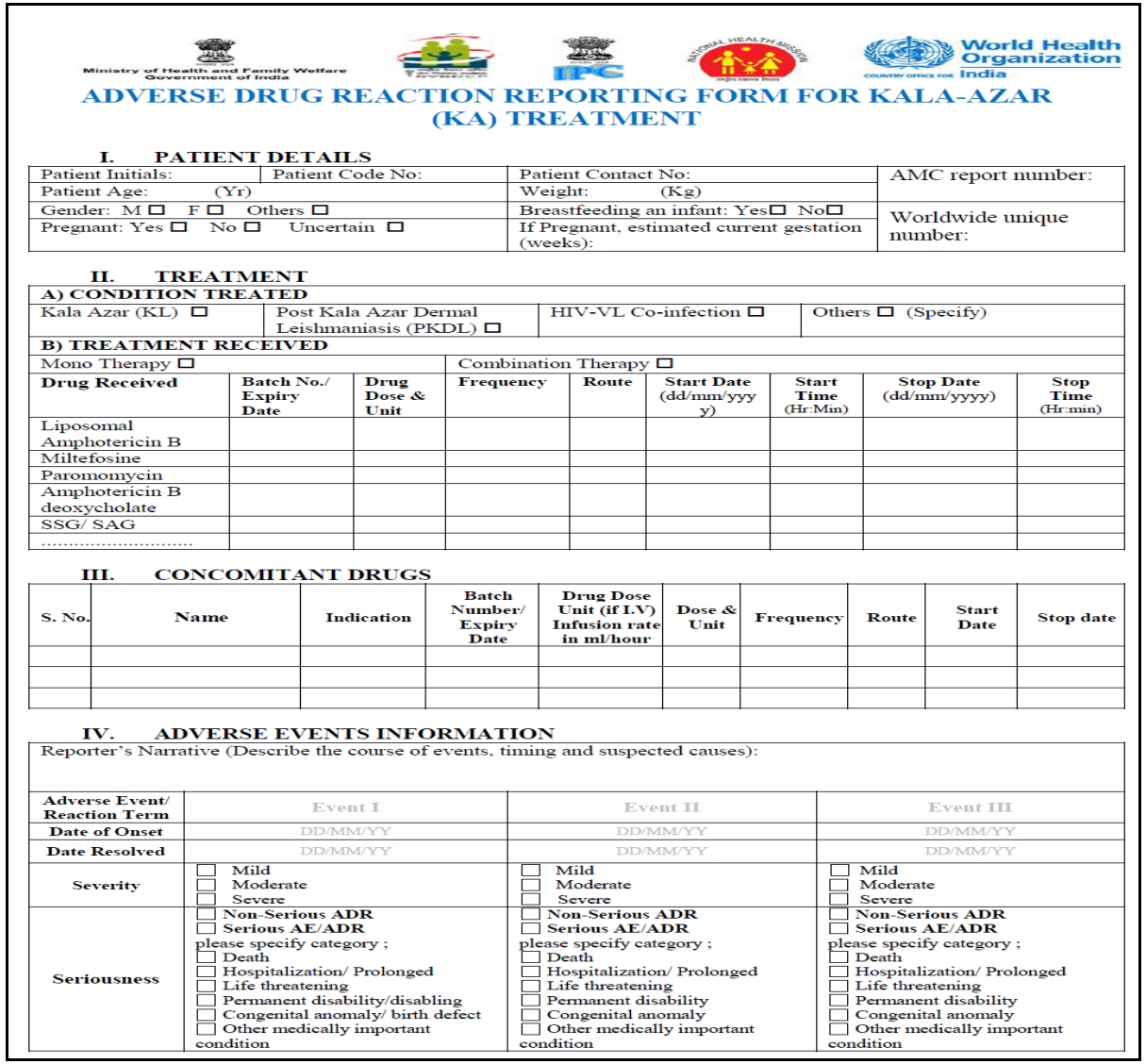
Adverse Drug Reaction : an unwanted response to a drug which is unintended, and which occurs at a doses normally used in man for prophylaxis, diagnosis or therapy of disease or for modification of physiological function.

Severity Grading: the severity of specific events describes its intensity, and it is the intensity which is graded into : Mild, Moderate & Severe

Serious Adverse Reactions: Any medical occurrence that:

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

Adverse Drug Reaction Reporting Form for Kala-azar Treatment



Ministry of Health and 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

ADR reporting under pharmacovigilance programme of India (PvPI)

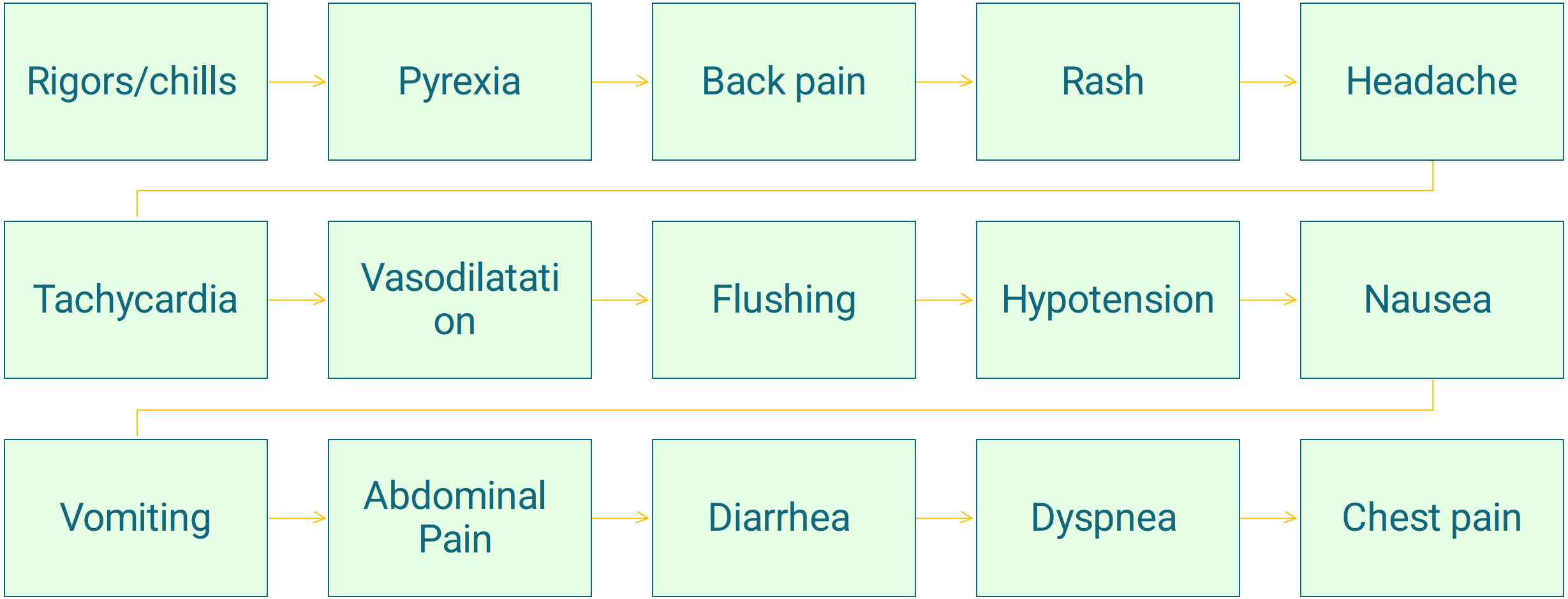
Who can Report?

All healthcare professionals and others including consumers may report a suspected adverse drug reactions (ADRs).

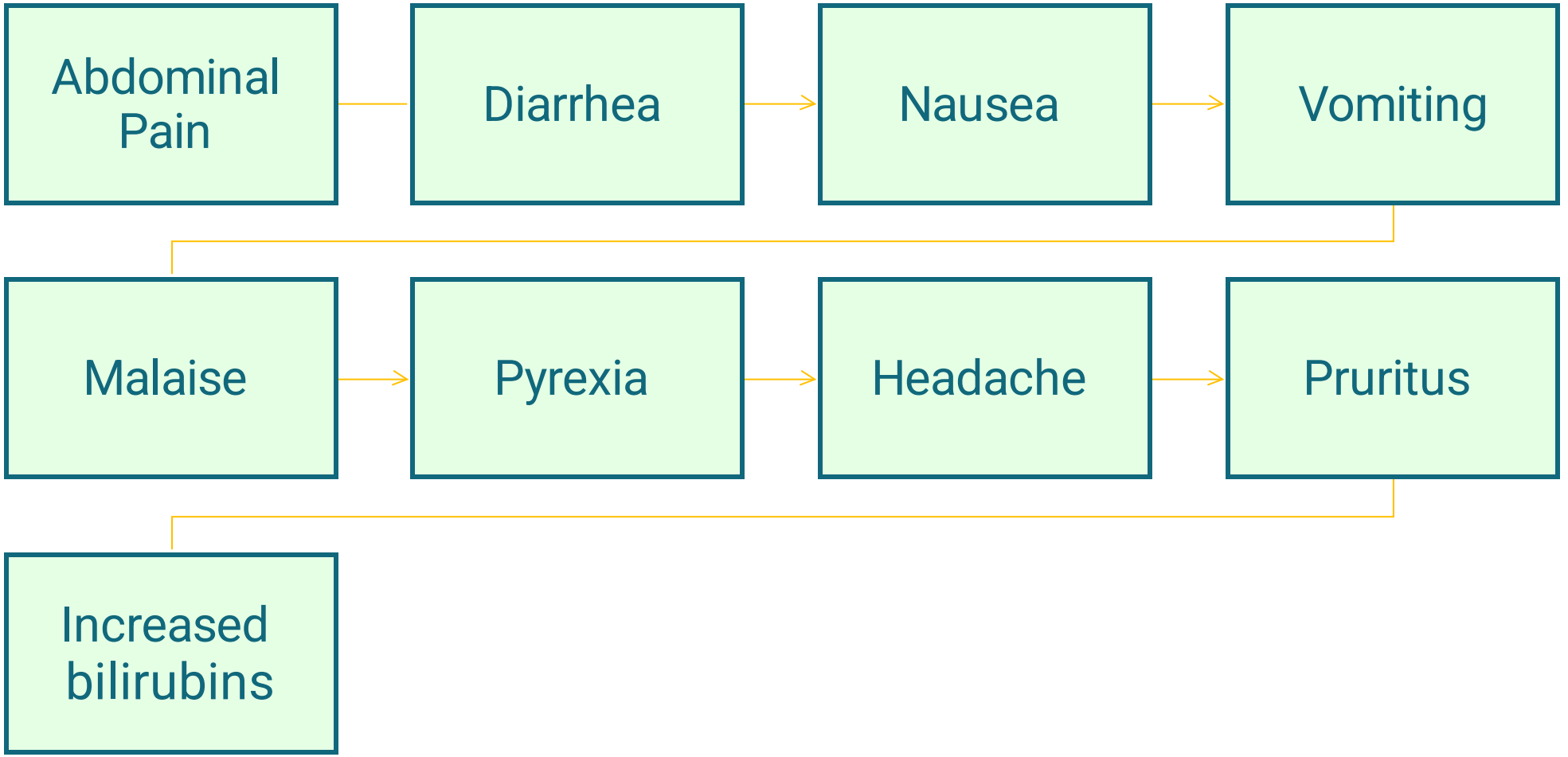
What to Report?

PvPI encourages reporting of all types of suspected ADRs- irrespective of whether they are known or unknown, serious or non-serious, frequent or rare.

Common ADRs to AmBisome



Common ADRs to Miltefosine



PKDL Patient with Eye Complication-

- Eye complication can be directly related to PKDL (uveitis) or it may be adverse drug reaction to Miltefosine , very few cases has been reported.
- Causality is still to confirm relation with Miltefosine.
- A checklist for all PKDL patients undergoing treatment with Miltefosine has been developed to ascertain relation of eye complication with treatment for PKDL.

Format for Eye Examination in PKDL Case

(This form is to be filled by treating physician/ophthalmologist for each PKDL patient being treated with Capsule Miltefosine. Filled form should be attached with the PKDL treatment card)

KAMIS ID:_____ PKDL Diagnosis date:_____

Treatment centre:_____ Age:_____ Gender(M/F/O):_____

Contact no. of Patient/Relative:

KTS/MTS Name:_____ Contact No:_____

KBC: Name:_____ Contact No:_____

A: Pre-prescription Eye Examination details (To be done before the start of PKDL treatment)

A. 1. Details to be filled before treatment of PKDL case:

I.	Is there any current diagnosed/undiagnosed eye problem?	Yes / No
II.	If yes, what kind of eye problem	Painful eye / discharge /redness / intolerance to light (photophobia) / low vision / whitening of black part of eye / loss of vision / any other (specify) _____
III.	No of days since onset of eye problem	_____
IV.	Any Ophthalmic consultation done	Yes / No
V.	Diagnosis as per the Ophthalmologist	_____
VI.	Any treatment for eye problem	Yes / No
VII.	Medications prescribed for eye problem	_____
VIII.	Name and place of eye treatment facility	_____
IX.	Are the symptoms	Persistent / resolved / deteriorating

A. 2. Ophthalmic Examination (Prescription to be attached)

Name of examining doctor:_____

Qualification:_____

Designation:_____

Address of clinic/health facility:_____

Format for Eye Examination in PKDL Case

I.	Involved Eye:	Right / Left
II.	Visual Acuity :	
III.	Colour vision:	
IV.	Any abnormality of lid or eyelashes :	
V.	Congestion of Conjunctiva:	
VI.	Corneal Infiltration :	
VII.	Corneal Ulceration :	
VIII.	Other:	

A.3. Weekly follow up details: (Note: Week may be calculated from the treatment start date.

Follow up may be done either by telephone or home visit. However, home visit must be done every 15 days. In case of any eye complaint, please inform immediately to Medical Officer and DMO/DVBD consultant)

Symptom	Week-1	Week-2	Week-3	Week-4	Week-5	Week-6
Pain	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Redness	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Dry eyes	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Low vision	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Watering	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N

Symptom	Week-7	Week-8	Week-9	Week-10	Week-11	Week-12
Pain	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Redness	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Dry eyes	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Low vision	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Watering	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N

B. Details to be filled in case of ophthalmic complications: (Prescription to be attached)		
I.	Drug used for PKDL:	Miltefosine / Any other
II.	Brand name of drug:	Impavido / Vertefos / Any other (specify)
III.	Batch no. of miltefosine:	
IV.	Date of discontinuation of treatment:	
V.	Date of re-start of treatment, if re-started:	
VI.	Drug dosage (one time/two time a day) 50/100 mg :	one time/two time a day
VII.	Treatment completed	Yes / No
VIII.	Total duration of PKDL treatment in days	
IX.	On any other medication during PKDL treatment:	
X.	Any other co-morbidity	TB/diabetes/ hypertension/ trachoma etc

ADR Reporting form in KAE Programme

Severity

GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 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

To report ADR

All patient receiving treatment (both VL and PKDL), must have ADR form

Even if there is no ADR, please fill below mentioned information and keep a record

Point 1 (patient details);
point 2 (treatment details);
point 3 (concomitant drugs)

If there is any ADR, inform to below mentioned officer/ consultant for reporting & uploading ADR

1. Name, designation & mobile number:

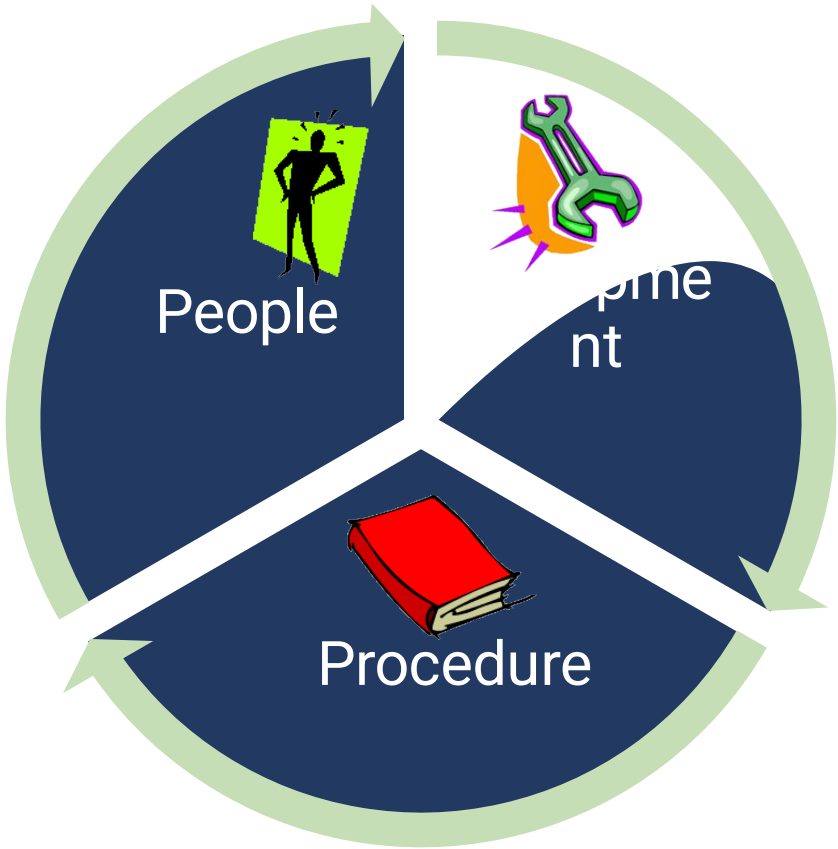
2. Name, designation & mobile number:

Cold Chain Management for AmBisome

What is the Cold Chain?

The Cold Chain is the system of:

that keeps medicine (AmBISOME) at **the right temperature** ($+2^0$ c to $+25^0$ c) during storage and transportation from the point of



Cold Chain System

Thus Cold Chain system

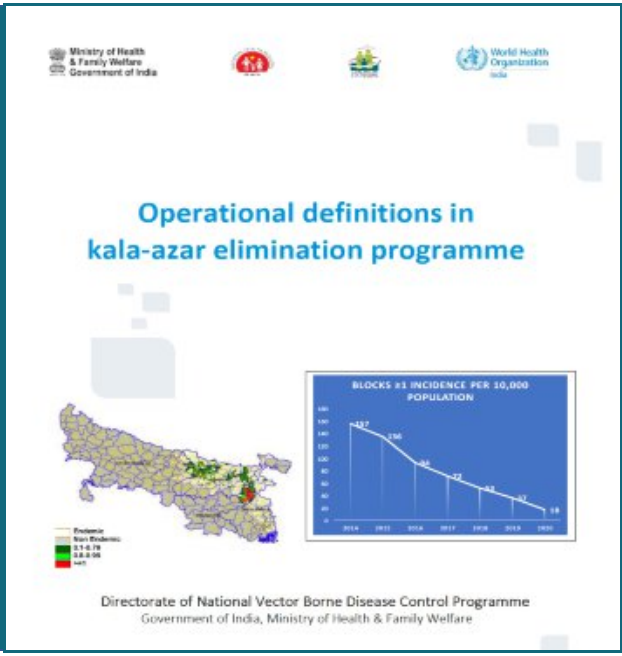
Cold Chain Equipments

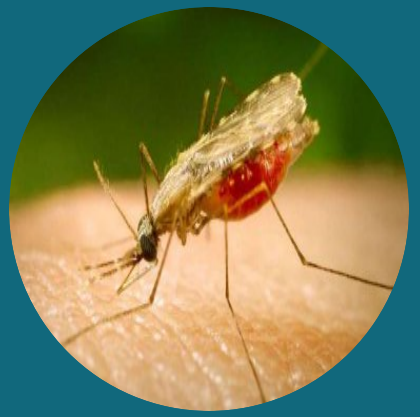
Cold Chain equipments under KA elimination programme

Cold box (20 Litres) with ice packs

Ice Lined Refrigerator(ILR)

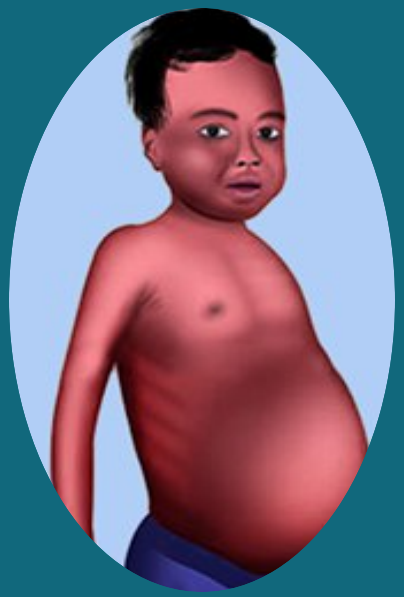
Operational definitions in kala-azar elimination proramme





Kala-azar is a notifiable disease in all kala-azar endemic states of India

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 the block level.



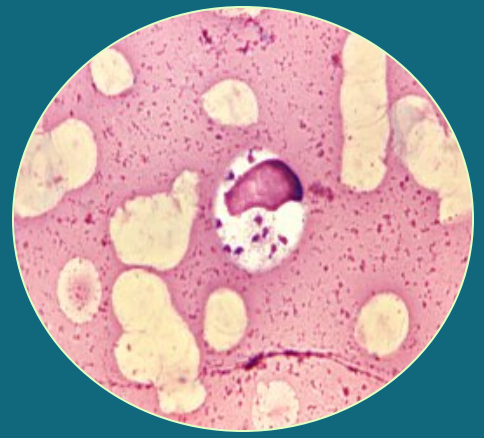
Types of KA cases

New case A confirmed case of KA who has never received treatment before.

Relapse case A KA case who experiences recurrence of KA symptoms with parasitological confirmation at any point of time after previous initial cure i.e., after 15 days of the treatment when the treatment regimen is less than 5 days.

uncommon to see relapses even after 6 months.

- Recurrence of symptoms may occur due to relapse or reinfection.
- Currently the programme does not have tools to differentiate



Origin of Infection

Imported:

- Infection acquired outside the country of reporting.

Autochthonous:

- Locally imported
  - Infection acquired within the country but outside the implementation / administrative unit of reporting.
- Locally infected
  - Infection acquired inside the implementation / administrative unit of reporting.

KA treatment related definitions

Treatment completed: Completed the full course of the treatment as per the guidelines, and the clinician's prescription.

Treatment stopped for medical reasons: Treatment was stopped by the decision of the clinician (e.g., a patient suffering from S/Es, treatment failure or after the death).

Default: The patient does not complete the full course of the treatment due to any reason against medical advice.

Treatment completion unknown: Completion of treatment is unknown (unrecorded).

Treatment failure: Signs and symptoms persist after the initial cure or recur by the end of the treatment (if the treatment duration is 5 days or more) or within 15 days after treatment starts (if treatment lasts for less than 5 days).

Clinical follow up of cases & Assessment of treatment outcome

Clinical follow up of cases

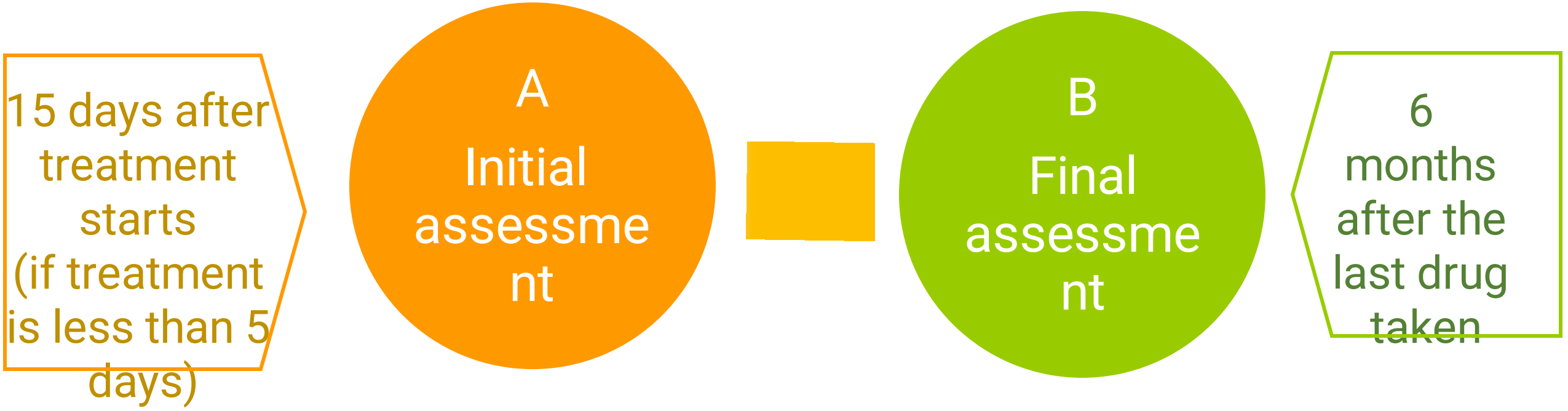
- Patients need to be clinically followed up. If indicated, necessary diagnostic tests to be done
- Schedule:
  - Early: 15 days, 1 month, 6 month
  - Late: 12 month, 18 month, 24 month, 30 month, 36 month

Assessment of treatment outcome

- Treatment outcome needs to be assessed
- Schedule:
  - Initial: 15 days
  - Final: 6 month

Treatment outcomes

Treatment outcomes for KA patients must be assessed twice:



Treatment outcomes - Initial assessment

- **Initial cure:** A full course of drugs has been completed AND the patient has clinically improved. Clinical criteria for initial cure defined as “no fever + return of appetite and/or gain in body weight+ regression of splenomegaly”.
- **Failure (non-response):** Signs and symptoms persist or recur during treatment or up to initial treatment outcome assessment.
- **Lost-to-follow-up /Unknown:** The patient does not present for an initial assessment after completion of treatment, or the patient status was not recorded.
- **Death:** Death of KA diagnosed cases, whether treated or not, due to any reason related to KA or not will be considered.

Treatment outcomes - Final assessment

- Final cure:
  - A patient who after the initial cure remains symptom-free at six months after the end of treatment.
- Relapse:
  - A patient who experiences recurrence of KA symptoms with parasitological confirmation at any time point after initial cure
- Lost-to-follow-up /Unknown:
  - The patient could not be traced for assessment at six months.
- Death:
  - Any death, whether related to KA or not within six months of diagnosis and/or treatment.

Treatment outcomes for PKDL cases

Initial cure

Clinical improvement at the end of treatment – defined as a considerable reduction in the number and size of skin

Final cure

Clinical cure 12 months after the end of treatment – defined as a complete resolution of macules, papules, plaques, and nodules, no new lesion, and near total re-pigmentation of maculae.

Some key epidemiological terms

Endemic

- Full cycle of transmission has been demonstrated at any given time (maintained population of competent vector + parasite reservoir + locally-acquired cases) AND at least 1 locally-acquired case in the last 10 years.

Endemicity doubtful

- Full cycle of transmission has never been demonstrated BUT at least 1 locally-acquired case in the last 10 years OR Full cycle of transmission has been demonstrated at any given time BUT no case has been reported in the last 10 years (0 case or no data).

Non endemic

- A. Previously reported cases: Full cycle of transmission has not been demonstrated AND no locally-acquired case has been reported in the last 10 years BUT locally-acquired case has been reported earlier.
- B. At risk: No locally acquired KA case was reported but epidemiological triangle as risk factors are present (a competent vector population, a reservoir, and appropriate environmental conditions).
- C. No autochthonous cases reported : No locally-acquired case has ever been reported.

Some key epidemiological terms

Focus

- Any circumscribed geographical endemic area

New focus / foci

- A new focus or foci is the reporting unit where kala-azar case has not been reported in the last 10 years.

Outbreak

- 10 or more laboratory confirmed cases reported in a given area or among a specific group of people within six months of the occurrence of the index case (Bihar & Jharkhand)
- 5 or more (UP and West Bengal)
- 1 or more (Non-endemic States/ Non-endemic districts/blocks of an endemic state)

“Let's eliminate kala-azar together”

Thank You

Recording and Reporting system in Kala-azar elimination program

Standard Operation Procedure for Outbreak Investigation and Management

Introduction

Objectives

KA Outbreak detection & Response

i) outbreak criteria,
ii) rapid assessment,
iii) outbreak preparedness,
iv) outbreak response and
v) monitoring, recording and repor..

Role & responsibility of different stakeholder

Prevention & Control measures

Formats

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.

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 outbreak

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

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

3. 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 neighboring villages/blocks

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

i) outbreak criteria

ii) rapid assessment

iii) outbreak preparedness

iv) outbreak response and

v) monitoring, recording and reporting.

According to the WHO, “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.”

Operational definition (Criteria 1 in high burden states i.e Bihar & 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.

Sources of alert

Analysis of web-based portal for kala-azar.

IDSP reports of fever of more than 2 weeks duration in kala-azar endemic areas. (Currently, IDSP does not report such cases but surveillance may improve in future).

Information from any health institutions (public, private, NGOs etc.) or state report.

Whom to communicate a “possible kala-azar outbreak”?

√ Information about the outbreak alert must be passed on from MOIC to the DY CMOH II. DY CMOH II. will take further action in coordination with WHO.

√ DY CMOH II. should communicate about the outbreak alert to the SPO.

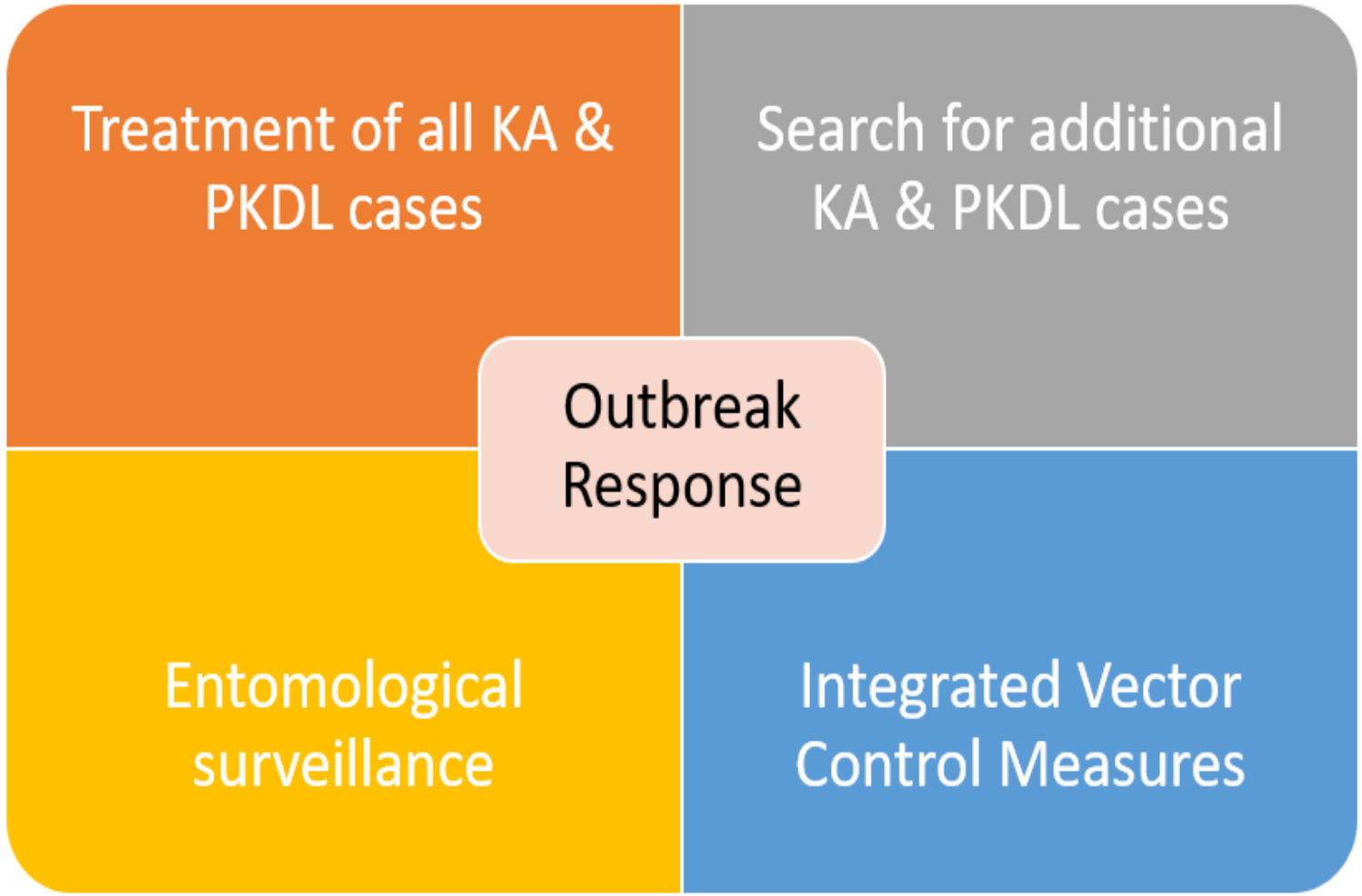
√ SPO should coordinate with NVBDCP, RoHFW, WHO for necessary support and actions.

Once a Kala-azar outbreak is suspected following steps shall be taken by concerned health officials of state/district/block: -

- Confirming the occurrence of outbreak and identifying population at risk.
- Planning and implementing an immediate rapid response; and
- Strengthening system for prevention, early detection and effective management of future outbreaks

- As soon as information of suspected outbreak is received, the first step is to confirm the diagnosis of KA among reported cases. In non-endemic area, parasitological confirmation of first few cases should be done.
- Once diagnosis is confirmed then estimate the extent of the outbreak by systematically collecting epidemiological information about cases.
- Spot map be prepared to see clustering of the cases.

- As soon as the diagnosis is confirmed, treatment of all cases must be ensured (as per national guidelines)
- Detection of additional KA & PKDL cases through house-to-house ACS in at-risk areas or entire village/ hamlet /cluster or 500 metres or 250 houses surrounding the KA Case.
- During ACD 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 Trained MO and tested, if required, within 2 days of identification by escorted referral or medical camp in the affected area.
- In endemic areas, if there has been sudden increase in KA cases, then a review shall be done about ongoing KA activities i.e. IRS, ACD, Diagnosis, and treatment etc. If the activities have been carried out as per guidelines, maintaining the quality, then resistance to IRS shall be investigated


Treatment of all KA & PKDL cases
Search for additional KA & PKDL cases
Outbreak Response
Entomological surveillance
Integrated Vector Control Measures

- Ensuring information about outbreak is communicated to all concerned stakeholders for timely action.
- Ensure availability of adequate fund, logistics supplies, manpower, mobility support
- Dy CMOH II to ensure desired level of support from district & block health programme teams and concerned partners.
- Mobilize a team from the state for monitoring and supervision and ensure response to outbreak as per the SOP using the checklist.

- Details of activities carried out as part of outbreak investigation and management shall be recorded as per the formats guided in respective SOP.
- Data collected should be analyzed with respect to time, place and person.
- Spot maps will be prepared and should be available at the health facility, supervisors and peripheral health workers.
- Reporting of the outbreak investigation and response shall be done by using the KA outbreak reporting format.
- District programme to share report with State programme office and State programme office to share the final report with NVBDCP.

a. Maintaining surveillance: Initiate and maintain regular effective surveillance in affected area. ACD at regular intervals might be required.

b. IVM: IRS should be done in the affected village/ urban as per guidelines. Environmental management through improved housing conditions like pucca house, filling cracks and crevices in walls, plastering, sanitation in the area shall also be focused.

c. IEC/BCC activities

d. Capacity building: Regular capacity building of HCWs, doctors, para medical staff for surveillance, diagnosis, treatment & monitoring of activities. Strengthening of health care services is of utmost importance.

e. Medical supplies: Ensuring availability of adequate drugs, diagnostics, insecticides etc.

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 °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):

Source: Standard Operating Procedure for Outbreak Investigation and Management, Directorate of National Vector Borne Disease Control Programme,2020

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

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 °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):

Achieving Kala-azar elimination is not only achieving physical target of less than 1 incidence of Kala-azar case per 10,000 population at block level.....

But....

To ensure a system where even a single suspect of Kala-azar is timely diagnosed, put on treatment and properly followed up so as to ensure no death or prolonged morbidity.

Outcome of active case detection (2018-2023)

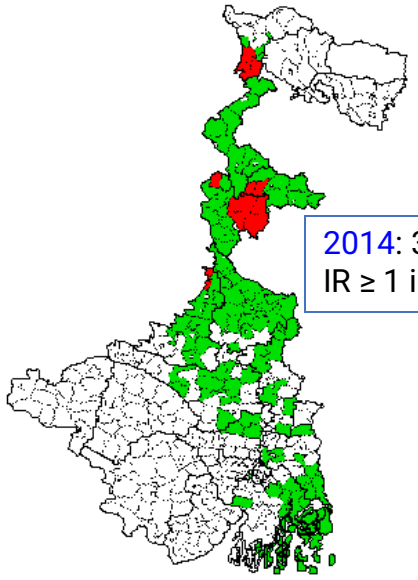
Year	Type	Population covered	Endemic villages covered	Number of KA suspects identified	Number of PKDL suspects identified	New KA cases detected	New PKDL cases detected	Case positivity	
								VL	PKDL
2018	Community screening followed by camp approach	811350	839	1898	475	9	16	0.4%	3.4%
2019		263783	341	972	129	13	13	1.3%	10%
2020		600597	778	1428	371	6	9	0.4%	2.4%
2021		741328	720	2382	649	16	31	0.6%	4.7%
2022		555197	594	1467	481	10	27	0.7%	5.6%
2023 (1st R)		248036	271	602	420	2	5	0.3%	1.2%

Integration with other programmes

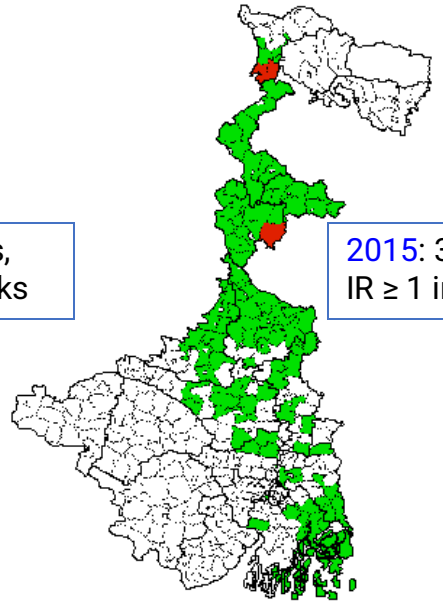
- HIV & Kala-azar for co-management of HIV VL cases
- Kala-azar (for PKDL) & Leprosy in ACS
- Pharmacovigilance Prog of India in reporting adverse drug event for VL and PKDL cases
- RBSK team involved in KA case search activity in Schools and amongst school drop outs for early detection of child cases
- Reporting and investigation of Kala-azar cases/ outbreaks through IDSP
- Integrated Fever Surveillance (VBDs and other PH Progs)
- Kala-azar with COVID for regular fever surveillance
- Integrated Entomological Survey in District
- Using VHND for Kala-azar Social Mobilization activities

- Integration of surveillance activities helped in better programmatic output with holistic approach. This is cost effective and time saving approach.

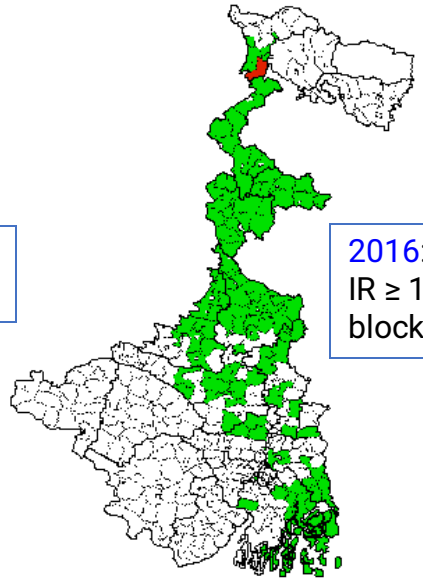
Incidence of VL cases per 10,000 population: 2014-2020



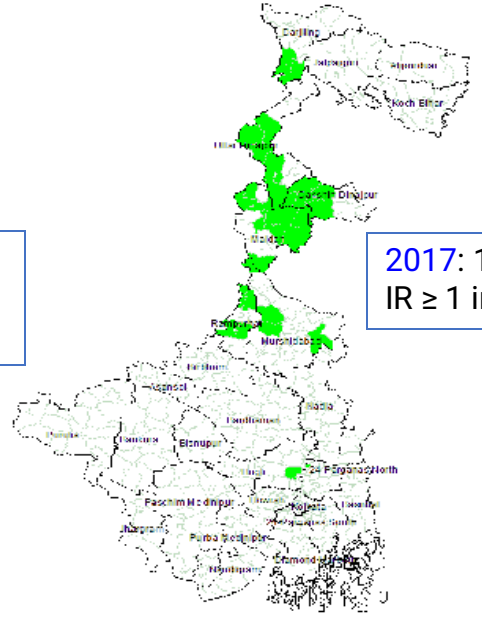
2014: 386 cases,
IR ≥ 1 in 12 blocks



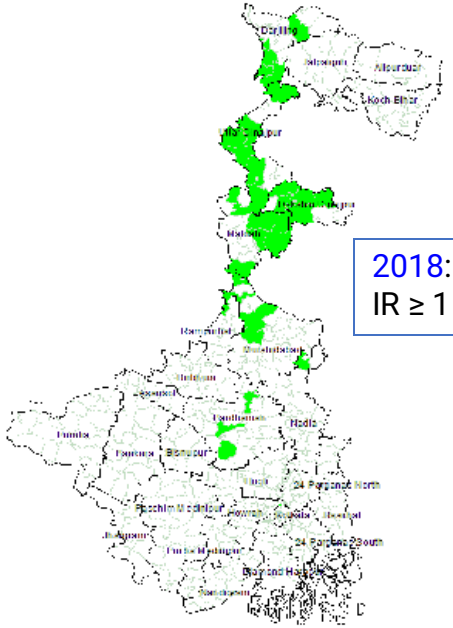
2015: 308 cases,
IR ≥ 1 in 3 blocks



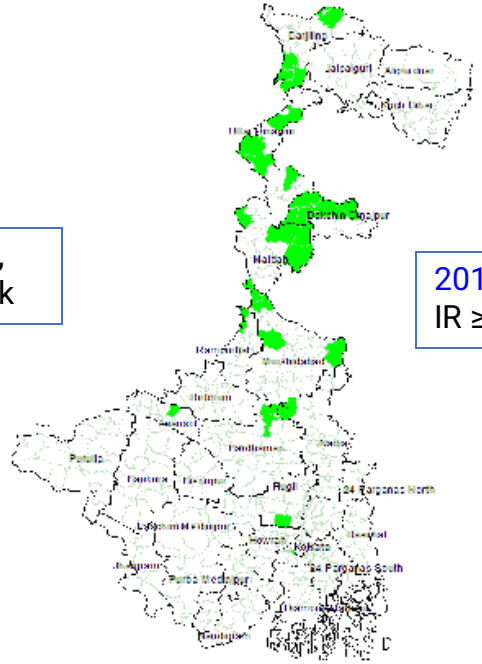
2016: 177 cases,
IR ≥ 1 in 1
block



2017: 142 cases,
IR ≥ 1 in nil block



2018: 90 cases,
IR ≥ 1 in nil block



2019: 82 case,
IR ≥ 1 in nil block

2020: 58 case,
IR ≥ 1 in nil block

	<1 case/10,000 population
	>=1 case/10,000 population
	Non KA- Endemic

Sustaining Kala-azar Elimination

Are my figures correct?

Am I doing enough test?

This is very pertinent when we are talking about sustenance .

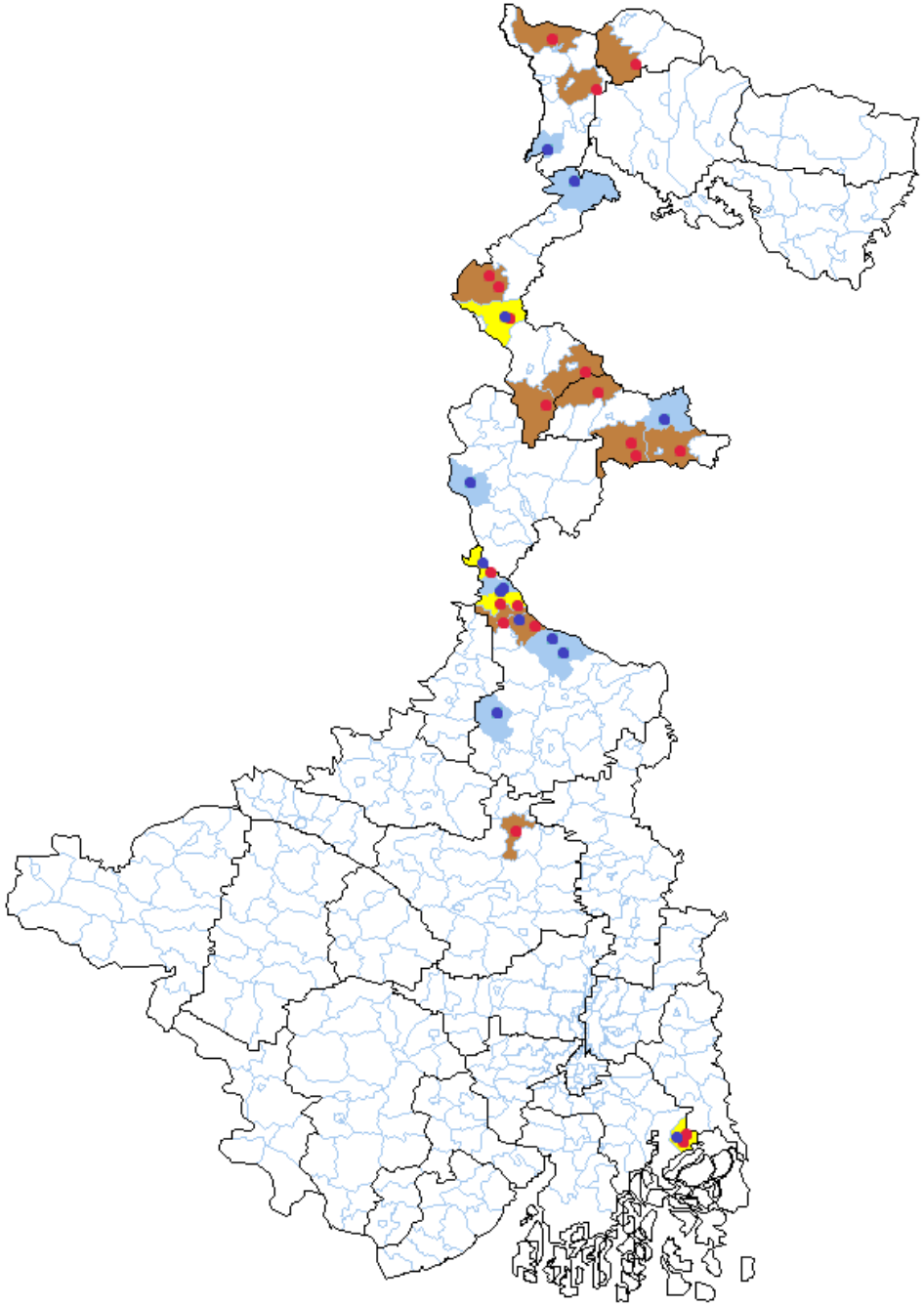
Following recommendations are being made to sustain the achievements that have been seen so far:

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

Major challenges

- Silent villages
- Hot spot villages
- Emergence of new foci (cases from newer and nonendemic areas)
- Climate sensitive
- Address focal outbreaks
- Increased relapse rates
- Animal reservoir
- Continued burden of PKDL. – follow up of VL cases
- CE portal- tracking new cases

SILENT VILLAGES REPORTING CASES : 2020-21



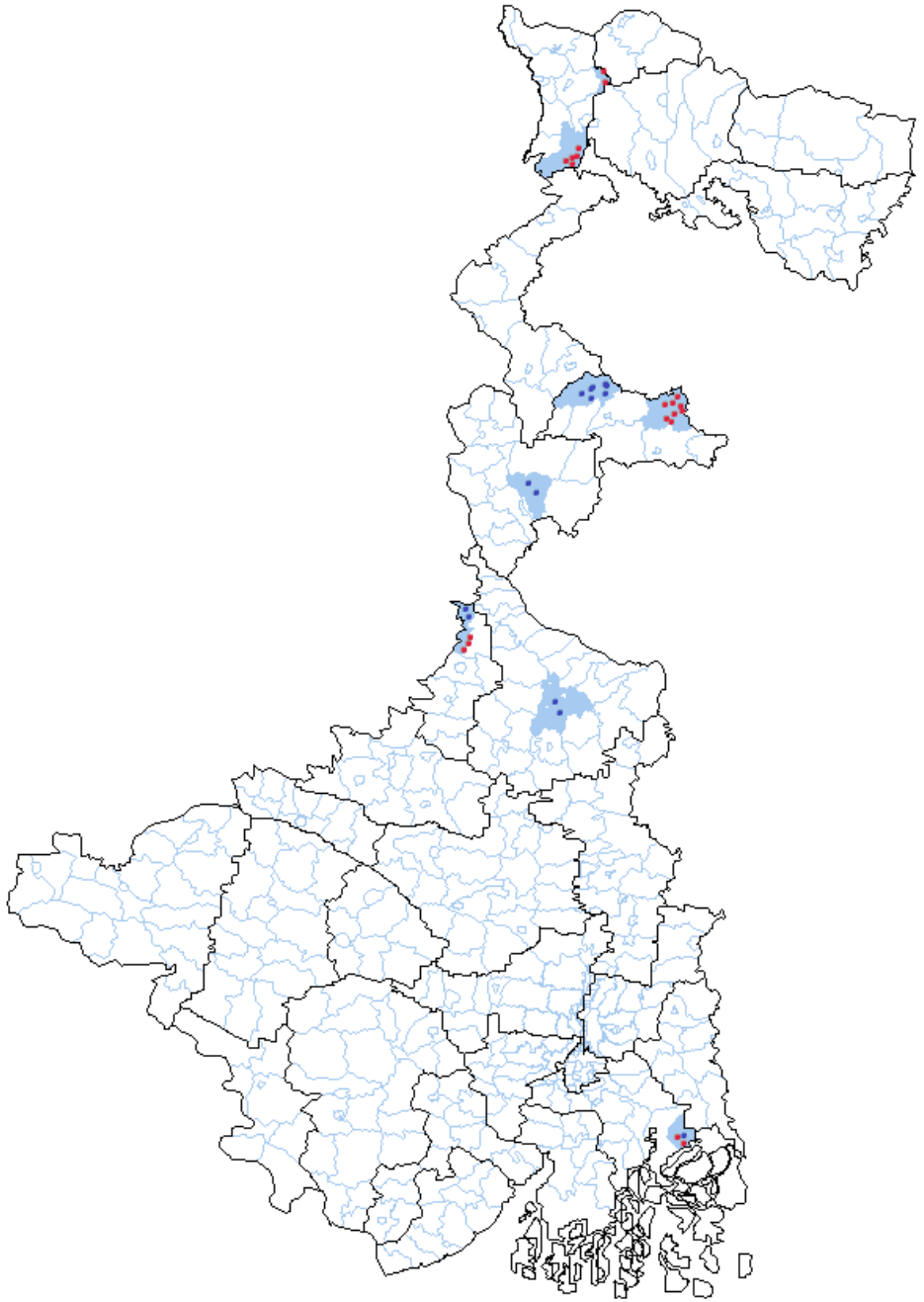
VL Cases	PKDL Cases

Block with New FOCI Village - VL Cases

Block with New FOCI Village - PKDL Cases

Block with New FOCI Village - Mixed (VL+PKDL) Cases

Year	Sl No	District	Block	VL	PKDL
2020	1	Darjeeling	Kharibari		1
2020	2	Kalimpong	Kalimpong-I	1	
2020	3	Uttar Dinajpur	Goalpokhar-II	1	
2020	4	Uttar Dinajpur	Karandighi	1	
2020	5	Dakshin Dinajpur	Kumarganj		3
2020	6	Dakshin Dinajpur	Tapan	1	
2020	7	Maldah	Manikchak		1
2020	8	Murshidabad	Samserganj		1
2020	9	Murshidabad	Suti-I	1	
2020	10	Murshidabad	Farakka	1	
2020	11	Murshidabad	Raghunathgunj II	1	
2020	12	Murshidabad	Suti-II	1	
2020	13	Uttar Dinajpur	CHOPRA		1
2020	14	Uttar Dinajpur	KALIAGANJ	1	
2020	15	Uttar Dinajpur	ITAHAR	1	
2020	16	Dakshin Dinajpur	TAPAN	1	
2020	17	Murshidabad	FARAKKA		1
2020	18	Murshidabad	SUTI-II	1	
2020	19	Murshidabad	SUTI-II		1
2020	20	Murshidabad	LALGOLA		1
2021	1	Darjeeling	Kurseong	1	
2021	2	Darjeeling	Pulbazar Darjeeling	1	
2021	3	Uttar Dinajpur	Kaliyaganj	1	
2021	4	Uttar Dinajpur	Karandighi		1
2021	5	Uttar Dinajpur	Itahar	1	
2021	6	Dakshin Dinajpur	Kushmandi	1	
2021	7	Dakshin Dinajpur	Balurghat	1	
2021	8	Murshidabad	Bhagwangola-I		1
2021	9	Murshidabad	Khargram		1
2021	10	Murshidabad	Farakka		1
2021	11	Murshidabad	Farakka		1
2021	12	Murshidabad	Suti-II		1
2021	13	Purba Bardhman	Katwa-I	1	



NEW HOT SPOT VILLAGE: 2020-21

Block with ≥ 2 KA Cases in a village

Year	SL. No.	Name of the District	Name of the Block	No. of Cases	
				VL	PKDL
2020	1	Kalimpong	Kalimpong-II	2	
2020	2	Dakshin Dinajpur	Kumarganj		3
2020	3	Dakshin Dinajpur	Kushmandi	12	1
2020	4	Murshidabad	Berhampore		3
2020	5	Rampurhat	Murarai-I		2
2020	6	Darjeeling	Phansidewa	2	
2020	7	Darjeeling	Phansidewa	3	
2020	8	Rampurhat	Murarai-I	3	
2021	1	Darjeeling	Phansidewa	3	
2021	2	Kalimpong	Kalimpong-II	1	1
2021	3	Dakshin Dinajpur	Harirampur		2
2021	4	Maldah	Habibpur		2
2021	5	South 24 Parganas	Basanti	1	1
2021	6	Dakshin Dinajpur	Banshihari	3	0
2021	7	Dakshin Dinajpur	Tapan	1	1
2021	8	Dakshin Dinajpur	Kushmandi	2	0

Major challenges

- Address focal outbreaks
- Emergence of new foci (cases from newer and nonendemic areas)
- Climate sensitive
- Increased relapse rates
- Animal reservoir
- Continued burden of PKDL. – follow up of VL cases
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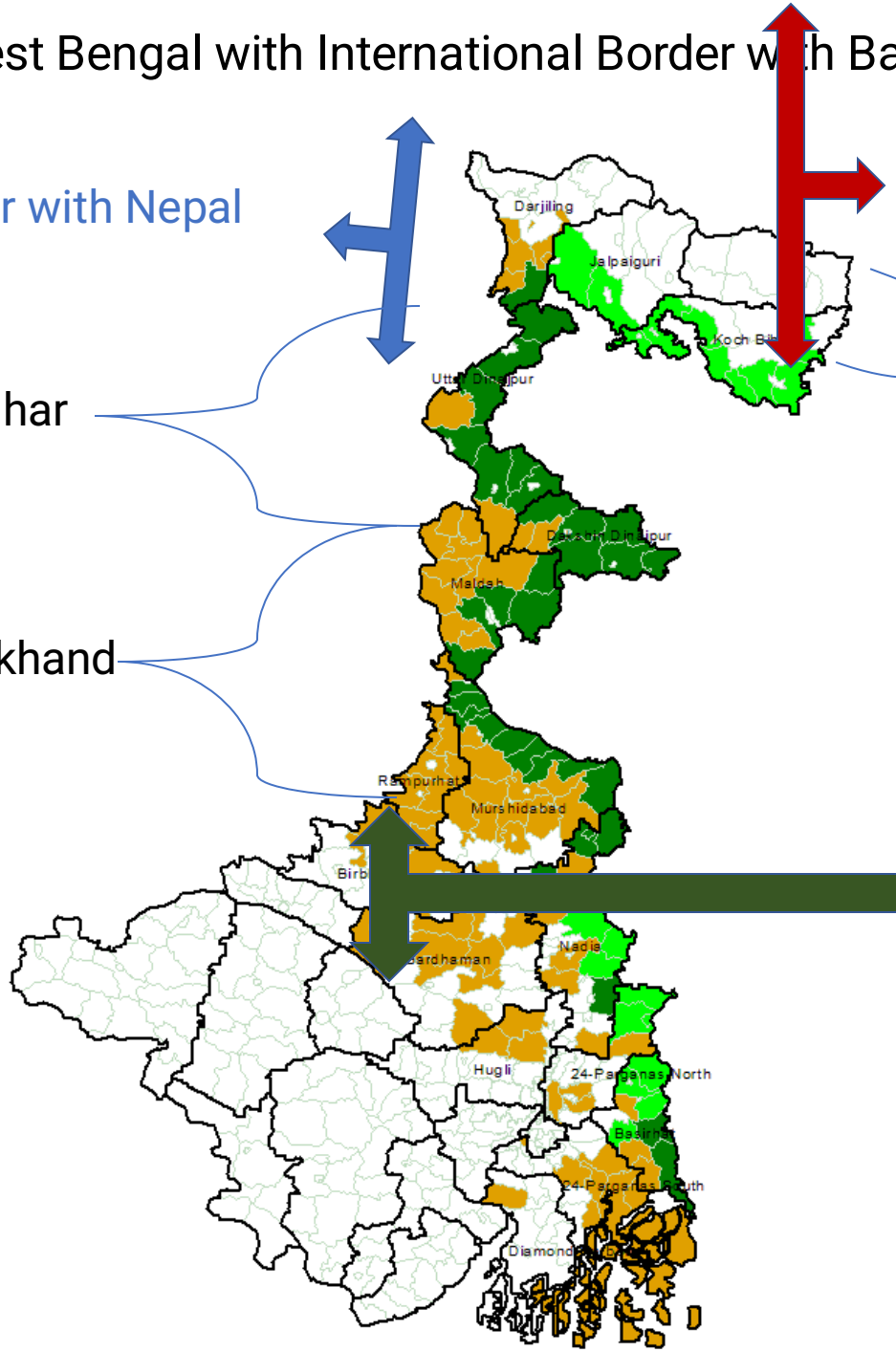
Blocks of West Bengal with International Border with Bangladesh, Nepal & Bhutan (with reference to state border)

Border with Nepal

Bihar

Jharkhand



Border with Bhutan from where one Cutaneous Leishmaniasis case was identified in 2021

Assam (historically VL Endemic State, currently not reporting cases mainly due to lack of surveillance)

Border with Bangladesh

Endemic Blocks Not Linked With Bangladesh Border	86
Endemic Blocks Linked with Bangladesh Border	34
Non-Endemic Blocks Linked With Bangladesh Border	21

Map @ WHO-NTDs

Cross border

- Cross-notifying all referred cases to their respective place of residence.

- This should be encouraged and implemented throughout the state by a standard mechanism.

WHO NTD roadmap 2021-30

- The new WHO NTD roadmap has proposed a new target for elimination of KA (VL) as a public health problem.

- It is defined as achieving
  - less than 1% case fatality rate due to primary KA.

- It has two more sub-targets for South East-Asia region (SEAR), namely:
  - Number of countries in SEAR validated for elimination <1 case (new and relapses) per 10 000 population at block level in India at 100% by 2030; and
  - PKDL cases detected (VL post-treatment follow-up for

Key action points

- Early diagnosis of KA cases , prompt treatment & supportive management
- Assess patients clinically during follow-up. Ensure all KA patients are followed up for three years for early detection of PKDL cases; institutionalize management of KA/HIV cases at the district level;
- Build capacities of DHs so that they can confirm KA relapse and PKDL diagnosis using microscopy;
- Social mobilization for reaching the community

Three key preconditions

- Adequate health services that can incorporate KA diagnosis and treatment as a routine activity and which are no longer a vertical programme without risk of jeopardizing results achieved so far;

- Revisit entirely the vector control programme under the principle of Integrated Vector Management, examining all steps, from procurement to implementation, from planning to monitoring activities,

- Implement all necessary efforts to coordinate with the districts and blocks (use the platform of DTF Meeting & BLTF Meeting)

Way forward…

Target: 01: To maintain Incidence Rate ≤ 0.5 at every KA endemic Blocks

- Individual case-based surveillance followed by 1-3-7 surveillance strategy, i.e., case reporting within one day, case investigation within three days and focus investigation & public health actions within seven days.
- Preparation of block wise list of Rural Health Practitioners (RHPs) and sensitization of RHPs on KAEP.
- Sensitization of all Dy. CMOH-IIs (16 KA endemic Districts), 16 nos. of District Consultant (PH&CD), 139 nos. of BMOH, MO, HO (KA endemic Block & Municipalities), 139 nos. of BPHN, PHN, Public Health Managers, 1960 nos. of LT, Staff Nurse, VBDTS, ANM, MPHW and 1960 nos. of ASHA on Kala-azar Elimination Programme will be performed by May 2023.
- Strengthening of the Pvt. Lab or Pvt. Practitioners reporting through GoWB Health Portal (CE Portal).
- Micro-stratification of high-risk areas based on high endemic boarder area, high vector density, migrant labour, persistent villages, hot spot areas, new foci areas etc.
- District wise tagging of medical colleges have been done and necessary steps will be followed.

#Target: 02: A Mass Survey for all KA Endemic villages since 2010 to till date may be required by June 2023

#Target: 03: KAEP Award claiming documentation submission by 2023

Thanks!

Dr Pritam Roy

MBBS, MD, MPH (Health Economics & Global Policy), FRSPH (London, UK)

Coordinator- Neglected Tropical Diseases, World Health Organization India

proy@who.int

Mobile: 9831846130