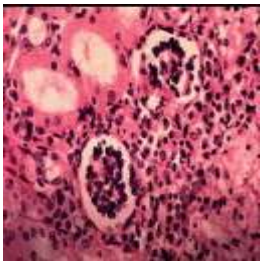
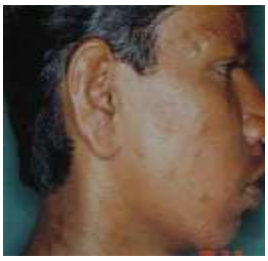
Government of India

OPERATIONAL GUIDELINES ON KALA-AZAR (VISCERAL LEISHMANIASIS) ELIMINATION IN INDIA - 2015








October 2015
NATIONAL VECTOR BORNE DISEASE CONTROL PROGRAMME
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF HEALTH SERVICES
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Kala-azar has been declared as “Notifiable disease” in Bihar and West Bengal

Preface

Visceral Leishmaniasis commonly known as Kala-azar is a parasitic disease prevalent in 4 states with approximately 130 million population living in the endemic areas and at the risk of acquiring infection. Of the four states namely Bihar, Jharkhand, West Bengal and Uttar Pradesh, Bihar alone contributes more than 60% of the cases.

Currently 54 districts in the states of Bihar, Jharkhand, Uttar Pradesh and West Bengal are endemic for Kala-azar. Due to intensified efforts by the centre and the participating states, significant reduction in the number of Kala-azar cases and deaths has been achieved at the end of 2014

It is needless to emphasize that GoI is according top priority towards Kala-azar elimination and the states are also providing ownership to the programme. Kala-azar programme strategies have seen significant changes on account of introduction of newer tools (Diagnostics and drugs) that has necessitated changes in the strategy and development of revised guidelines for use at all levels of implementation.

Based on these developments, it was felt that comprehensive technical guidelines on Kala-azar elimination be developed encompassing all the programme components so that the implementation of the programme strategies becomes user friendly at all levels.

I am sure that these guidelines shall prove to be very useful to all those intensely involved in programme implementation.

Last but not the least, I would like to appreciate NVBDCP officials who devoted their time and energy in preparing these guidelines which I believe shall be widely used in the field.

(Jagdish Prasad)

Acknowledgement

Elimination of Kala-azar is a national priority and is therefore receiving the appropriate attention by GoI. Kala-azar elimination programme has made a significant progress in the endemic states, which are following the programme strategy aimed at elimination of the disease from endemic areas of the country.

Guidelines by NVBDCP in the past have been developed and shared with the states, however since newer tools have been introduced from time to time like introduction of Rapid diagnostic kits, single dose single day treatment regimen of injection Liposomal AmphotericinB, changing insecticide from DDT to Synthetic Pyrethroid in selective districts there was a felt need to develop the newer guidelines in consonance with these developments.

It is a great pleasure for me to share the Kala-azar technical guidelines not only with the participating states but with all the stakeholders who are also working hard for effective programme implementation to realize the national goal of elimination.

I would like to thank NVBDCP officials for preparing these guidelines & making them available for use by the states.

I am sure these guidelines shall emerge as user friendly and will help all those who are working in Kala-azar elimination programme in the field, in appropriate manner.

The support of our development partners like WHO India, RMRI (ICMR) Patna, NCDC, Patna, BMGF/CARE India /DNDi/ KalaCORE/PATH is also acknowledged

(A C Dhariwal)

Contents

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Acronyms

ASHA	Accredited Social Health Activist
AIDS	Acquired Immuno Deficiency Syndrome
ANM	Auxiliary Nurse Midwife
AYUSH	Ayurveda Yoga Unani Siddha Homeopathy
BCC	Behaviour Change Communication
CBO	Community Based Organization
CHC	Community Health Centre
CMO	Chief Medical Officer
DAT	Direct Agglutination test
DBS	Domestic Budget Support
DDT	Dichloro Diphenyl Trichloroethane
DMO	District Malaria Officer
DOT	Directly Observed Treatment
EDCT	Early Diagnosis and Complete Treatment
GoI	Government of India
HIV	Human Immunodeficiency Virus
IEC	Information, Education and Communication
IPC	Interpersonal communication or Counseling
IRS	Indoor Residual Spraying
ITN	Insecticide Treated (bed) Nets
IV	Intra venous
IVM	Integrated Vector Management
LAMB	Liposomal Amphotericn B
LD	*Leishmania donovani*
LLIN	Long lasting Insecticidal Nets
MO	Medical Officer
MO I/C	Medical Officer In-charge
MOHFW	Ministry of Health and Family Welfare
MOU	Memorandum of Understanding
MPO	Modified Plan of Operation
MPW	Multi-Purpose Worker
KA	Kala-azar
KTS	Kala-azar Technical Supervisor
NGO	Non-Governmental Organization
NHP	National Health Policy
NMCP	National Malaria Control Programme
NMEP	National Malaria Eradication Programme
NHM	National Health Mission
NVBDCP	National Vector Borne Disease Control Programme
PHC	Primary Health Centre
PKDL	Post Kala-azar Dermal Leishmaniasis
RCH	Reproductive & Child Health
RDT	Rapid Diagnostic Test
RTAG	Regional Technical Advisory Group
SEAR	South-East Asian Region
SSG	Sodium Stibo- Gluconate
SP	Synthetic Pyrethroid
VBD	Vector Borne Disease
VL	Visceral Leishmaniasis
WHO	World Health Organization

Chapter 1

Introduction

- Kala-azar (KA) or Visceral Leishmaniasis (VL) is caused by *Leishmania donovani* and transmitted by *Phlebotomus argentipes* (Sandy fly).
- Maximum number of 44533 Kala-azar (KA) cases reported in 2007 and minimum 9241 cases reported in 2014 in India.
- Incubation period in KA varies from 10 days to > 2 years in general but from four months to one year in India. Disease found across all age groups. Males are more afflicted than females.

Kala-azar (Visceral Leishmaniasis) is a disease caused by the parasite *Leishmania donovani* and is transmitted in India by the bite of the sand fly vector *Phlebotomus argentipes*. Leishmaniasis in India exists in two forms, namely, Kala-azar (KA) or Visceral Leishmaniasis (VL) and Post Kala-azar Dermal Leishmaniasis (PKDL). The geographical spread of the disease is limited to 54 districts in India. Kala-azar is a chronic and insidious disease which if not treated can be fatal.

With the launching of extensive Indoor Residual Spraying (IRS) with DDT 50% for malaria under the National Malaria Control Programme (NMCP) in 1953 and later National Malaria Eradication Programme (NMEP) in 1958, Kala-azar cases also declined to negligible levels due to collateral insecticidal pressure on sand fly vector and hence resulted in interruption of transmission. However, withdrawal of IRS from erstwhile malaria endemic areas resulted in a gradual build-up of sand fly populations, ultimately leading to resurgence of Kala-azar in the 1970s. The resurgence was initially in four districts of Bihar and slowly spread to entire North Bihar, some parts of Jharkhand and several districts of West Bengal. Sporadic incidence was reported from a few districts of Uttar Pradesh in the 1980s.

Concerned with the increasing incidences of Kala-azar in the country, the Government of India (GoI) launched a Centrally Sponsored Kala-azar Control Programme in the endemic states in 1990-91 with a strategy as under:

(a) Interruption of transmission by reducing vector populations by IRS twice in a year;
(b) Early detection and complete treatment of cases;
(c) Health education programme for community awareness/IEC &BCC

GoI provided drugs, insecticides and technical support and state governments provided costs involved in implementation. The program was implemented through State / District Malaria Control organizations and the Primary Health Care (PHC) system. With above strategies the programme achieved significant decline in Kala-azar cases and mortality, but could not sustain the pace of decline for long. To overcome the situation, GoI further strengthened Kala-azar programme which led to improved case detection through the Primary Health (PHC) Care system resulting in decrease in incidence of Kala-azar cases and deaths. By 1995, there was a 70.7% decline in annual incidence of cases and 80.5% decline in deaths as compared to 1992. By 2003, there was a 76.4% decline in annual incidence and 85.2% decline in deaths as compared to 1992.

The National Health Policy (2002) set the goal of Kala-azar elimination in India by the year 2010 and later revised in 12th Five Year Plan document to 2015. The Kala-azar elimination programme

has the objective of reducing the annual incidence of Kala-azar to less than 1 case per 10,000 population at block PHC level.

Kala-azar Elimination is on top priority under WHO Neglected Tropical Diseases. In 2014, the Penta-lateral MoU signed between Bangladesh, Nepal, Bhutan, and Thailand which also included India as a signatory, the target date for elimination was revised to 2017 or earlier by WHO South East Asia Region at Dhaka. London declaration 2012 also supports to sustain expand and extend drug access programmes to ensure the necessary supply of drugs and other interventions to help control by 2020 including Kala-azar. The declaration also supports advance R&D through partnerships and provision of funding to find next generation treatments and interventions for neglected diseases.

In view of introduction of newer components in the form of drugs and insecticides and other policy decision, it becomes imperative to disseminate the new information to be implemented in a meaningful way. This operational guideline encompasses all the aspects covering Kala-azar Elimination strategy and its use by the concerned health authorities at different levels of intervention shall pave the way for efficient and strengthened implementation of programme components at field level.

Chapter-2

Epidemiology

- Disease is caused by protozoan parasite *Leishmania donovani*. *Phlebetomus argentipes* (sand fly) is the vector transmitting Visceral Leishmaniasis (Kala-azar) in India.
- The symptoms include fever of more than 2 weeks duration, splenomegaly , anaemia, weight loss and loss of appetite. PKDL manifests in the form of hypo pigmentation or erythematous macules on any part of the body which may later become papular or nodular and infiltrative especially on the face.
- 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.
- Kala-azar is reported amongst all age groups, however, in earlier surveys conducted children in the age group of 5-9 years have been most afflicted.
- Male to female ratio is 2:1
- Parasite is mostly confined to Reticulo-endothelial system and may be found in abundance in bone marrow, spleen and liver.

Kala-azar is a visceral infection of reticulo-endothelial system. The disease is associated with high morbidity and may be fatal if not treated promptly and properly.

2.1 Morphology:

The causal agent of VL and PKDL in India is the parasite *Leishmania donovani*. There are two morphologically distinct stages in the life cycle of the parasite, namely:

- Amastigote (aflagellate) or Leishmania stage:occurs in man
- Promastigote (flagellate) or Leptomonad stage: occurs in gut of (a) sandfly and (b) artificial culture.

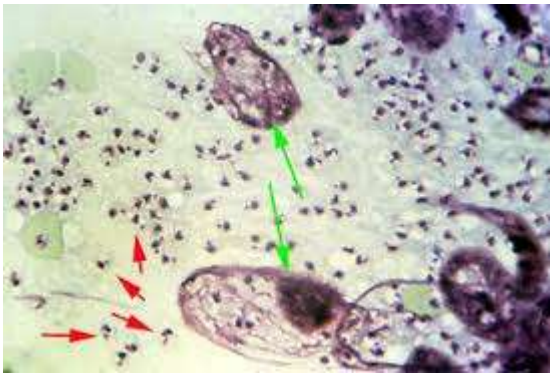


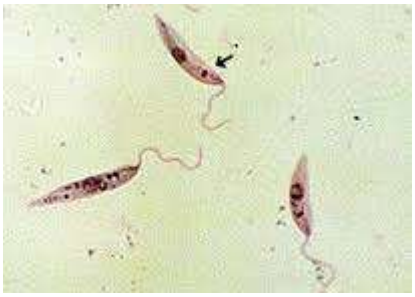
Fig-3.1 Amastigote stage (Source CDC)

2.1.1 Amastigote stage:

The amastigote is the intracellular, non-motile form in the vertebrate host, and it divides by longitudinal binary fission at 37°C.This intracellular stage is found particularly in the reticulo-endothelial system. The amastigote is also called the Leishman-Donovan (LD) body. This stage is represented by round or oval body measuring about 2 to 6 micrometers in length and 1 to 3 micrometers in width. Within cytoplasm, a relative large nucleus, a prominent kinetoplast, and a short axoneme, the last of which consists of a rod like body and a dot like basal body are present. Both nucleus and kinetoplast contain deoxyribonucleic acid. The parasite prefers to stay in macrophages like monocytes, lymphocytes and the cell of bone-marrow, spleen and liver.

2.1.2 Promastigote stage or Leptomonad Stage:

These forms are found in culture medium as well as digestive tract of sand fly. The promastigote has a single free flagellum arising close to kinetoplast at the anterior end and possesses marked motility. The average length is 15-20 µm and 1.5-3.5 µm in width. The flagellum measures 15-28 µm. In old culture, these promastigote tend to form rosettes with their flagella centrally directed. Short, board and rounded forms may be seen in these old cultures.



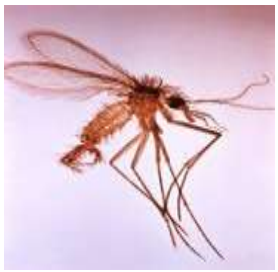
Promastigote Stage

Man is the only known host of *Leishmania donovani* in India. People of all ages are susceptible to the disease but it occurs mainly in older children (between 5-14 years of age) and young adults. Sub-clinical cases of Kala-azar have been reported from Bihar. The disease is widely prevalent among individuals with low socio-economic status, poor standard of living; malnutrition etc. Susceptibility of the host appears to be a critical factor in determining infection and the disease. The way of acquiring the infection is however, not well understood.

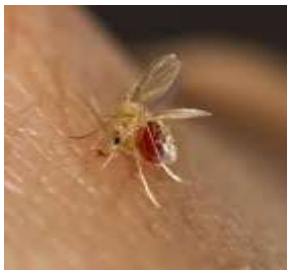
2.2 Vector

Visceral Leishmaniasis or Kala-azar is transmitted by the bite of infected sandflies. *Phlebotomus argentipes* is the only known vector of Kala-azar in India. The seasonal prevalence of this species varies from area to area depending upon the ecological conditions. Disease transmission is highest in the rainy season. The vector breeds in humid soil rich in organic matter and near cattle

sheds and mud- houses. It rests most commonly in cracks & crevices of thatched mud-houses. The peak biting time of the vector is around midnight.

Adult Sand Flies

Sand flies feeding on the host

Kala-azar in India has a unique epidemiological feature of being anthroponotic, i.e. human beings are the only known reservoirs of infection. The female sandflies pick up the amastigote stage (LD bodies) of the parasite while feeding on an infected human host. The parasites undergo development and multiplication in the gut of sand flies to become numerous flagellates (Promastigote or Leptomonad stage) which migrate to their mouthparts. The cycle in the sand flies is completed in about 8 days. Infection is transmitted to healthy human beings when such infective sand flies bite them.

2.3 Incubation period

Kala-azar being a chronic disease, incubation period significantly varies. Generally it varies from 1-4 months but in reality the range is from 10 days to 2 years, however in India the range varies from 4 months to 1 year.

2.4 Extrinsic incubation period

The extrinsic incubation period in the vector sand flies vary from 4-25 days which is the time required for the vector to become infective after an infective blood meal.

2.5 Age & Sex

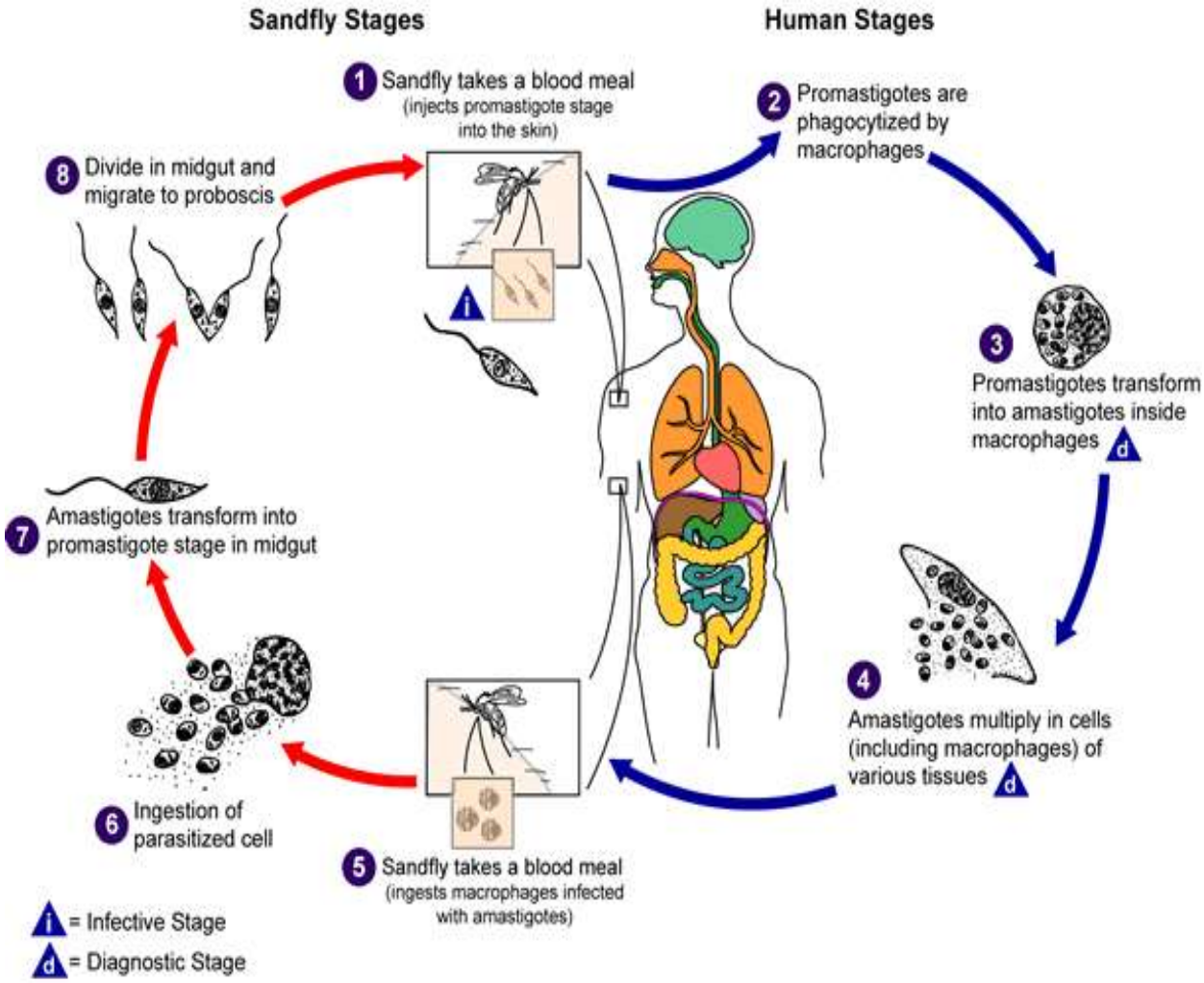
Kala-azar is reported amongst all age groups, however in earlier surveys carried out for the purpose of research children in the age group of 5-9 were most afflicted with male to female ratio of 2:1.

2.6 Environmental and Ecological factors

The prevalence of vector is dependent upon the environmental factors which include humidity, temperature and rainfall. The ecological factors like alluvial soil, kuccha mud-houses and large scale vegetation also influence build up of vector density.

The parasite primarily infects reticulo-endothelial system and may be found in abundance in bone marrow, spleen and liver. Post Kala-azar Dermal Leishmaniasis (PKDL) is a condition in which the *Leishmania donovani* invades cells of skin and develops lesions. This results in skin manifestations of PKDL. Some of the Kala-azar cases manifest PKDL after a few years of treatment. Recently it has been claimed that PKDL may appear without passing through visceral stage.

LIFE CYCLE IN SAND FLY AND HUMAN



Source: Centre for Disease Control website (CDC)

Fig 2. Life cycle of Kala-azar

Chapter-3

Kala-azar Elimination Programme in India

Initial target of Elimination set by NHP (2002) was 2010 which later got extended to 2015 in 12th Financial Plan Document.

- Target for elimination to reduce incidence of the disease to less than one case per 10000 population at block PHC level.
- The elimination strategies include surveillance, case detection and treatment, integrated vector management and cross cutting interventions like capacity building, IEC/BCC, monitoring & evaluation and operational research.
- Altogether 54 districts (33 in Bihar, 11 in West Bengal, 4 in Jharkhand and 6 in Uttar Pradesh are endemic for KA.
- Sporadic case reported from Assam, Himachal Pradsh, Jammu & Kashmir, Kerala and Uttarakhand.

The National Vector Borne Disease Control Programme (NVBDCP) is an umbrella programme for prevention & control of vector borne diseases and an integral part of the India's National Health Mission (NHM). The National Health Policy (NHP) of 2002 has set goal for achieving elimination by the year 2010 which was later extended to 2015 in 12th Financial Year Plan document.

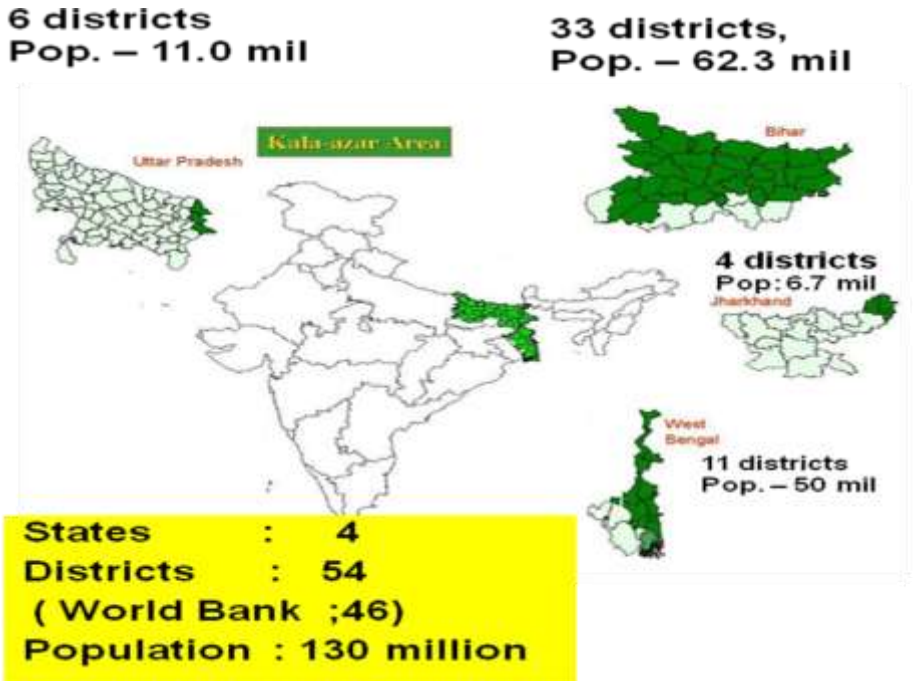


Fig. 1. Kala-azar endemic districts in India

3. The Goal

The national goal is to achieve elimination of KA by 2015. GoI is providing 100% support to endemic states since December 2003 towards attainment of this goal. Kala-azar can be eliminated from the Indian Subcontinent because there is no intermediate host for transmission of the disease and IRS has also been very effective. The disease can be easily recognized and effective methods for diagnosis and treatment are also now available. It is expected that elimination of Kala-azar will reduce poverty, promote equality and lead to socio-economic development in the endemic areas and result in strengthening the capacity of the health system.

3.1 Target

The target of Kala-azar elimination is to reduce the incidence of the disease to less than 1 case per 10,000 population at the Block PHC level in India.

3.2 Objectives

- Reducing the incidence of Kala-azar in the endemic communities including the poor, vulnerable and hard to reach populations.
- Reducing case fatality rate due to Kala-azar.
- Treatment of Post Kala-azar Dermal Leishmaniasis (PKDL) to reduce the parasite reservoir.
- Prevention and treatment of Kala-azar-HIV, TB co-infections.

3.3 Strategy

The Strategy for the Kala-azar Elimination Programme in India is comprised of the following components.

- Early diagnosis & complete treatment (EDCT)
- Integrated Vector Management including Indoor residual spraying (IRS)
- Advocacy, Communication for Behavioural Impact and Inter-sectoral convergence
- Capacity Building
- Supervision, Monitoring and Evaluation

Chapter-4

Disease and Vector Surveillance and Reporting System

- Surveillance in Kala-azar through active and passive case detection by house to house visit or organizing camps.
- Searches usually conducted before or after IRS operations on quarterly basis.
- All the Kala-azar cases detected and given full treatment at district hospital and in identified block PHC level with single dose Liposomal Amphoterecin B (AmBisome) or with other combination drug regimens available at periphery.
- Focus on PKDL cases as they act as reservoirs.
- PKDL cases treated with recommended drugs like Miltefosine, the first drug of choice. Other drugs like Amphotericin B injection also used as per guidelines.
- VL & PKDL cases thus detected being reported and recorded in prescribed formats.
- There is an inbuilt system of information and the flow of such information is from Block PHC to Districts to State and then to NVBDCP.
- HMIS system of information has been developed and is part of the programme.

Surveillance is a continuous and systematic process of collection, analysis, interpretation, and dissemination of descriptive information for monitoring health problems.

4.1 Objectives

Monitoring of disease trends is the primary objective of the Kala-azar surveillance system. The detection of an increase in the disease incidence can alert health programme to the need for further investigation. When outbreaks are suspected, surveillance can provide an historical perspective in assessing the importance of perceived or documented changes in incidence.

4.2 Standard Kala-azar Case definition

- *A 'suspect' case: history of fever of more than 2 weeks with splenomegaly & hepatomegaly not responding to anti malarial and antibiotics in a patient from an endemic area.*

- *Or a patient with above symptoms clinically examined by doctor and found positive on screening with rapid diagnostic test.*

- *Or in cases with past history of Kala-azar or in those with high suspicion of Kala-azar but with negative RDT test result but found (+) by examination of bone marrow/spleen aspirate for LD bodies at appropriate level (district hospital).*

4.3 Surveillance, Case detection and treatment

Surveillance is the mainstay of any disease control programme. In Kala-azar both active and passive case searches are done. Case detection is done through the existing primary health care system supplemented by quarterly active search followed by treatment. Rapid diagnosis has been introduced in the programme for detection of Kala-azar cases at PHC and district hospital levels. Suspected cases as per the Standard Case definition are referred for clinical examination and tested with RDT for confirmation of Kala-azar before initiation of treatment. For treatment, single dose single day treatment with Liposomal Amphotericin B injection is the first drug of choice followed by capsule Miltefosine (28 days) and injection Amphotericin B (15 injections on alternate days) as well as combination of Miltefosine and Paramomycin injection.

Post Kala-azar Dermal Leishmaniasis (PKDL) patients are to be treated with (i) Miltefosine: 100mg orally per day for 12 weeks, or (ii) Amphotericin B deoxycholate: 1mg/kg over 4 months 60-80 doses at what frequency, or (iii) Liposomal Amphotericin B: 5mg/kg per day by infusion two times per week for 3 weeks for a total dose of 30mg/kg *[as per WHO guidelines on diagnosis and management of PKDL, 2012]*

Case management of special conditions like relapse, HIV-VL co-infection and others will follow WHO treatment guidelines described in this document.

4.4 Integrated Vector management:

Integrated Vector Management (IVM) is a rational decision-making process for the optimal use of resources for vector control. The main objective is to reduce longevity of the adult vectors, eliminate the breeding sites, decrease contact of vector with humans and reduce the density of the vector. This approach improves the efficacy, cost-effectiveness, ecological soundness and sustainability of disease-vector control. The five key elements of IVM include capacity building and training, advocacy, collaboration, evidence-based decision-making and integrated approach.

Vector control is carried out by undertaking two rounds of spray annually with 50% DDT at a dose of 1g/m2 of wall surface inside walls of rooms up to a height of 6 feet and full coverage in cattle sheds. Recently on account of published results reporting tolerance of sand flies to DDT 50%, it was decided to use Synthetic Pyrethroid (SP) in seven districts reporting DDT tolerance as well as high KA endemicity during 2015. The Synthetic Pyrethroid areas shall be expanded in phased manner in other areas after obtaining the results on DDT tolerance by research agencies.

4.5 Surveillance

Kala-azar surveillance under the national programme is of two types, i.e. passive and through active case search. Beside disease surveillance, vector surveillance is also carried out. Disease surveillance includes reporting of all cases of Kala-azar and PKDL. Disease surveillance is useful in planning IRS through mapping of areas to be sprayed and in monitoring trends of Kala-azar incidence.

4.5.1 Passive surveillance

Passive surveillance is the mainstay of the programme. This means regular, timely and accurate reporting of Kala-azar cases who seek diagnosis and treatment from all levels of health facilities in the Government, Private or NGO sector. Passive surveillance is done on the format approved by the programme authorities. The patient card, a copy of which rests with the patient and another with the concerned officer/staff at BPHC level is the starting point of passive surveillance. Information on numbers of cases being reported is extracted from records at each level. The following information is elicited from records:

- Cases diagnosed by 'Rapid Diagnostic test'.
- Cases diagnosed by parasitological method.
- Cases currently on treatment categorized according to Kala-azar drug regimen.
- Cases completed treatment.
- Cases dropped out before completing treatment.
- Cases who did not respond to treatment, categorized according to drug regimen.
- Cases admitted to hospital.
- Cases died in hospital.
- Cases died at home.
- Cases developed major side effects of medicine.

In addition to above, information on the age group and sex is to be collected. PKDL case history should be maintained regularly for a regular follow up.

4.5.2 Active surveillance

Active surveillance implies active search of Kala-azar and PKDL cases. Active surveillance in India at present is being done on quarterly basis. When health workers and volunteers visit households to find individuals with fever of more than 2 weeks duration and screen them with 'Rapid Diagnostic test'. The cases found positive are treated with an appropriate regimen of treatment. The health worker / volunteer may have to search about 300-400 households to detect a single case of Kala-azar. Active case search should be started at village level (start with those villages with high number of KA cases) to trace the suspected KA patients.

For the success of active surveillance, it is necessary to ensure that diagnostics and treatment facilities are provided. Arrangements are made for transport for referral of patients, organize timely follow up for feed-back and provide services to patients who may not be suffering from Kala-azar. Development partners/ stakeholders services can be utilized for camp search.

4.6 Surveillance of Post Kala azar Dermal Leishmaniasis (PKDL)

Surveillance of PKDL is important as PKDL cases serve as a reservoir for disease transmission during the inter-epidemic period. Reporting of PKDL cases is an integral part of the programme. Special efforts are needed for surveillance of PKDL for the following reasons:

- PKDL patients have only skin manifestations and therefore often consult skin specialists.
- PKDL may be confused with leprosy and other skin diseases.
- Since PKDL patients do not have other manifestations or any discomfort, they do not seek treatment readily.
- Treatment of PKDL is prolonged and usually associated with side effects. Therefore, patient requires strong motivation to complete treatment.

4.7 Recording and Reporting

A good system of record keeping is essential for smooth running of the programme. It should include the following elements:

- Number of persons treated
- Identification or persons treated and relapse
- Drug inventory
- Movement of personnel and vehicles

Recording forms are the nerve centre of information system. The forms should be filled regularly and accurately. The recording tools in Kala-azar programme are treatment cards, laboratory registers, Kala-azar registers and patient identity cards. **The reporting forms are placed at Annexures from 1-4.**

To make Kala-azar surveillance effective, it is necessary to organize a system of regular reporting, analysis, review and feedback of information on Kala-azar and PKDL cases. Programme with the help of development partners are in the process of developing uniform HMIS system for online feeding and registeration. State may use this facility immediately after its launching on online.

4.7.1 Reporting System

The reporting system comprises of following activities:

- Mapping and identification of reporting units(district level)
- Regular sharing of reports from each unit (district level)
- Compilation (district as well as state level)
- Analysis, Interpretation and presentation of surveillance data (state level)
- Review and feedback (district as well as state level)

4.7.2 Reporting units

The district focal point in-charge of the Kala-azar programme should identify the reporting units in the district from the government, NGO and private sector. At present, reporting of cases is done only by the public sector facilities.

The reporting units at various levels are as follows:
Level - I: Sub-centers and Additional PHCs

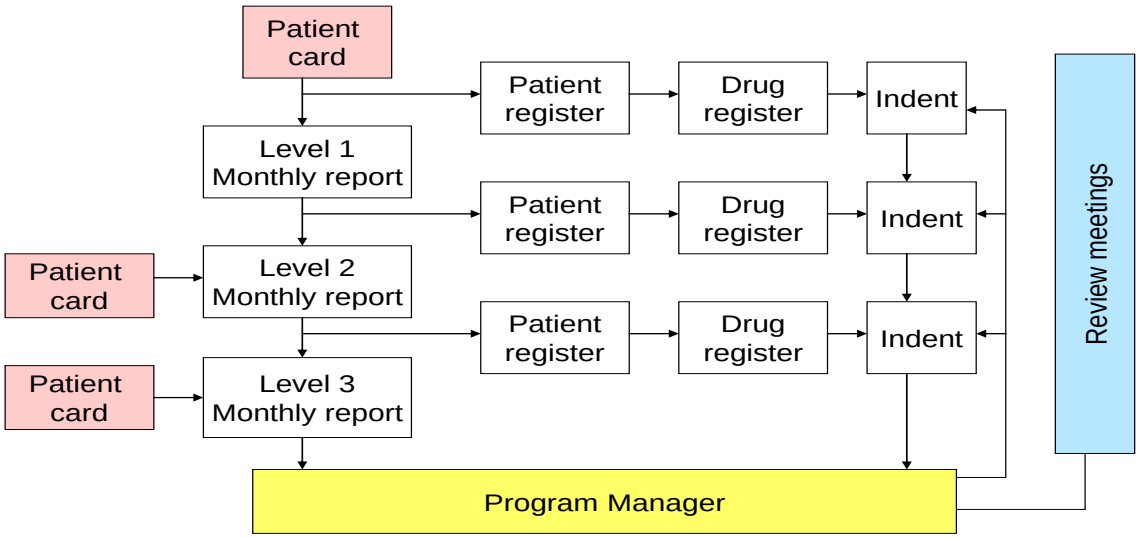
Level- II: Block PHCs
Level- III: Sub-divisional hospitals, District hospitals, specialized hospitals and Medical College.

4.7.3 Reporting of information/ dissemination

Dte. NVBDCP is in process to develop HMIS system for recording of cases. Though HMIS is being made functional, the data is entered manually at level - I but data at level - II and level - III should be entered through computer wherever this facility is available otherwise manually. If there are no cases then it should be a zero report.

The reports from level – 1 facility should be submitted to the supervisor at level II facility. All level - II supervisors are expected to compile information from all level - I facilities from the government, private and NGO facilities and add their own. The consolidated report should be sent to the district. Level - III facilities should compile the data for indoor and outdoor facility separately and send it to the district before the first Wednesday each month as suggested under the national programme. In the district, the information from each reporting facility should be entered on the computer and mapping done to identify the hot spots of Kala-azar in the district. The information flow is summarized in the illustration.

Information flow



The reporting format includes the following information:

- Number of cases of Kala-azar diagnosed on the basis of clinical case definition and positive 'Rapid Diagnostic test'.
- Number of cases of PKDL diagnosed on the basis of clinical case definition and positive Rapid Diagnostic test.
- Number of cases of Kala-azar diagnosed by a parasitic diagnosis (bone marrow / splenic aspirate examination).

- Number of cases of PKDL diagnosed by parasitological diagnosis from a skin biopsy or scrapings.

The reporting format for treatment of Kala-azar / PKDL separately includes the following:

- Number of cases treated with drug
- Number of cases completing treatment
- Number of cases where treatment with drug was discontinued

Treatment cards and registers are recommended for reporting of treatment. The basic information required to be compiled from the treatment card are:

- Age, sex, address, marital status, pregnancy and its outcome
- Drug used for treatment of Kala-azar / PKDL
- Number of days of treatment provided
- Treatment complete/incomplete
- Side effects of drugs
- Treatment provider (public, private, NGO)
- Number of cases where treatment failed, separately for each drug used

It is recommended that line-listing of cases should be done and reported to supplement existing reporting system. If line-listing is difficult to organize widely, then the same should be at least done at sentinel sites to begin with.

4.7.4 Reporting of hospitalized cases

Separate reports are needed for indoor patients of Kala-azar. This should include number of total admissions, number of Kala-azar cases admitted, and number of deaths due to Kala-azar. Cases should be segregated into age groups < 5 years, 5-14 years and 15years &above and sex-wise. Information on pregnant women should be included separately in monthly reports. Outcome should be categorized as cured, worsened and died. The report should also include number of patients who were referred. The monthly report should indicate number of cases who completed treatment and number of cases who are being treated but have not completed treatment.

4.7.5 Report review and feedback

The district focal point and the supervisors have the responsibility to provide a regular feedback to providers in level - I and level - II facilities (government, private and NGO) on a regular basis verbally and follow up with written advice. Review and feedback are important at all level - II facilities. The level - II staff should review with staff in level - I facilities as a part of supportive supervision regularly. All reviews and supervisory visits should be summarized and reports submitted to district focal point.

The monthly reports along with comments of district focal point have to be sent to state focal point by the 10th of each month. The district authorities and regional/zonal/ state authorities,

after compilation of the report and its review should write their comments on the monthly report and send it to the national authorities by the 15th of each month where these are reviewed and follow up action taken. The Directorate of NVBDCP compiles monthly reports from each state. A national review of the elimination programme will be done once in a year.

4.7.6 Review and feedback of Kala-azar

Review of the programme need to be undertaken as follows:

Level	Participating staff	Frequency
Level II	All level - I staff, partner NGO and private sector	Once a month
District	All level - II and concerned level - III staff, partner NGO and private sector	Once a month
State	All district focal points, sentinel surveillance sites and specialized units	Once in 3 months
National programme	All state focal points	Once in 6 months
Inter-country review	National Focal points	Once in an year

4.7.7 Role & responsibility at different levels

Surveillance is the mainstay of the KAE programme hence proactive roles have to be taken at each & every level of implementation

i) At State level

The State Programme Officer must make an action plan in consultation with development partners for carrying out active case searches by the peripheral staff or other identified personnel. Manpower, logistics and other requirements like community mobilization need to be worked out well in advance. Funds required have to be released well in advance for this activity .Time line for the above activities has to be circulated to district levels on schedule.

ii) At district level

At district level the directions of the state need to be implemented on time for successful conduction of active case search. The following aspects to be focused on:

Perfect Coordination with development partners like WHO, BMGF/CARE, KalaCORE and RMRI (ICMR), NCDC for better programme implementation.

District Vector Borne Disease Officer must ensure participation of all Block Medical officers.

District administration to be sensitized for seeking their help during search operations.

Training of all the peripheral staff involved in the search.

Community mobilization.

Availability of funds, drugs & diagnostics

Liaison with Physicians at district hospitals
Reporting of the results in the prescribed reporting format

iii) At Block Level

Block Medical officer to initiate all the prior activities like Social mobilization, Training of the personnel, availability of drugs & diagnostics, preparing the supervision schedule etc.,

Involvement of Block Development Officer (BDO) be ensured for strengthening the activities

Sensitization of KTS & Block Coordinators (CARE) for their supervision and technical support

Special emphasis on detection of PKDL cases (Needs specialized training as sometimes PKDL cases may mimic KA cases or vice-versa).

4.7.8 Role of other Institutions

For the benefit of the programme it would be essential to seek the help of NGOs, PRIs and other development agencies like Rural Development, Irrigation Dept., Human Resource (School Education) for increasing social awareness and also helping in Kala-azar surveillance.

Chapter-5

Vector Surveillance and Entomological Techniques

- Phlebotomus *argentipes* (sand fly) only vector of VL in India. Adult sand fly small, fuzzy, delicately proportioned, 1/4th the size of mosquito. Length ranges from 1.5 to 3.5 mm.
- Favorable ecological conditions proliferating the density of sand flies include (i) alluvial soil (ii) high sub-soil water, (iii) monthly mean maximum temperature below 37° C (iv) Annual rainfall of 1250 mm or more (v) mean annual RH of 70% or more with 80% for at least 3 months (vi) altitude below 600 meters.
- In India distribution mostly on the eastern half of the country though reports of its prevalence have also emerged from other parts as well.
- *Ph. argentipes* found throughout the year in majority of areas of prevalence with complete absence in winter months. In Bihar a minor peak observed in March/April and major peak in August/September.
- Opportunistic feeder, mostly zoophilic, poor flies, hops covering a distance of less than than ½ metre. Resting sites include cracks and crevices, burrows, tree holes, termite hills, earthen mounds, under stone and foliage etc.
- Longevity under lab conditions ranges from 23-27 days but in field conditions from 16-20 days.
- Life cycle in four stages, egg, four instars of larva, pupa and adults, total time taken from egg to adult reported to be 20-36 days with average 26.75 days in laboratory.
- Sampling Techniques include (i) Hand collection, (ii) light trap collection and (iii) sticky traps.

Leishmaniases are the vector borne diseases which exist either as zoonosis (in most of the endemic areas of the world) or anthroponosis (Indian sub-continent i.e. India, Bangladesh, Nepal). The vectors of various Leishmaniasis worldwide over belong to Order Diptera of class Insecta (Phylum Anthropoda).

Sand flies are grouped in two sub-families namely Psychodinae and Phlebotominae. Only the members belonging to family Phlebotominae are transmitting agents for different types of Leishmaniasis.

In India, so far three sand flies species have been incriminated as vectors of leishmaniases, they are:
Phlebotomus argentipes as only known vector of Visceral Leishmaniasis.
Phlebotomus papatasi as the vector of anthroponotic or urban Cutaneous leishmaniasis.
Phlebotomus salehi as the vector of rural (zoonotic) Cutaneous leishmaniasis.

The adult sand fly is a small, fuzzy, delicately proportioned fly, usually 1/4th of the size of the mosquito. The length of sand fly body ranges from 1.5 to 3.5 mm. The males and unfed females can pass through mosquito net easily. The elongated wings are hairy, held erect on the abdomen and are bigger than the size of the body. The body, wings and legs are heavily

covered with long hairs. The sand fly could be spotted easily because of the posture of the wings which are always held vertically erect when at rest.

5.1 Biology and Bionomics

The sand flies are associated with warm climate and could be grouped into two categories namely species associated with wet zone and the species associated with arid zone and this association further delimits the distribution of different types of Leishmaniasis. Napier (1926) suggested ecological factors favorable for transmission of Visceral Leishmaniasis or Kala-azar as:

Sand fly feeding on host

Alluvial soil
High sub-soil water
Monthly mean maximum temperature below 37°C
Monthly mean minimum temperature about 7.2°C
Annual rainfall 1250mm or more
Mean Annual Relative Humidity of 70% or more with more than 80% for at least 3 months
Abundant vegetation
Altitude below 600 meter

These factors inter-alia favour *Phlebotomus argentipes*, the only known vector of visceral leishmaniases in India, to survive with high prevalence through greater part of the year facilitating transmission.

Adults

5.1.1 Distribution

P. argentipes is one of the widely distributed sand flies and is essentially the species of wet zone. It is widely distributed along side of the equator and in India, its distribution could be seen on the eastern half of the country and western limits could be marked by joining a line from Bombay to Delhi. Though commonly the sand flies are not found at the altitude above 600 meters, sporadic occurrence in India has been recorded in Kasauli at a height of 1200 meters and at 1300 meters in Pauri Garhwal in Himalayas. The species is predominantly distributed all along the eastern coast from West Bengal to Kanyakumari.

5.1.2 Seasonal prevalence

As already mentioned, high relative humidity, warm temperature, high sub-soil water and abundance of vegetation favors proliferation of *P. argentipes* and accordingly, depending on this condition seasonal prevalence varies from area to area. In India the species is found throughout the year in majority of areas of prevalence with complete absence in winter months in areas with extremes of temperatures like Assam. With the onset of warm weather coupled with humidity, the density increases till June with sudden decline due to high temperature. It is again followed by increasing trend reaching the maximum during and just after the monsoon rain. A similar trend has been reported in Bihar with a minor peak in March/ April and a major peak in August/ September in densities of *P. argentipes.*

5.1.3 Feeding Behavior

All species of sand flies feed on plant sugar and the females often feed on vertebrate host including man. The females of genus Phlebotomus feed on mammals. Though *P. argentipes* are commonly known as zoophilic, it has been observed by various workers that the anthropohilic index largely depends on the sampling. For example, the samples collected from human habitation showed 69.6% anthropophilic index whereas the samples collected from cowshed in the same area showed only 21.6% anthropophily. The same was true in the case of bovid blood index which was 96% in the cowshed and 44% in the human dwellings. This indicates clearly that *P. argentipes* are primarily indiscriminate (opportunistic) feeder and the type of blood meal largely depends on availability of host in its immediate vicinity. However, studies undertaken in Nilgiri hills indicate a high level of zoophilly to the extent of even 100%.

5.1.4 Flight Range

Sand flies are not capable of flying very long distances. Their usual mode of flight pattern is a series of short erratic hopping in which the fly usually covers a distance less than ½ meter. Further, the dependence of the most of the vectors of humidity for their survival limits their movements.

5.1.5 Resting Sites

The most favored resting sites for sand flies include soil cracks and crevices, burrows (rodent burrows), tree holes, termite hills, caves, bird tunnel, in earthern mounds, under stone and foliage, etc. In eastern parts of India like Bihar & West Bengal, *P. argentipes* prefers to rest indoors, about 9-10 times higher in cattle dwellings than the human dwellings. In western India sand flies rest outdoor also in considerable numbers. As could be seen, all these resting places provide them dark and damp shelter where the microclimatic humidity is very high. They usually leave these shelters at dusk and are active in open in the evening and night. Usually sand flies remain active throughout the night but they are sensitive to decreasing temperature and air currents. Even a gently breeze of 1.5-2 metre/ second may greatly reduce their activity.

5.1.6 Longevity

In India, *P. argentipes* have been reported to undergo 5 gonotropic cycles under laboratory conditions, duration each cycle being 4 to 5 days at 26+ 2ºC i.e a minimum longevity up to 23-27 days under laboratory conditions. Field studies conducted on parity have also shown presence of triparous and "four parous" females in nature indicating probability of longevity under field conditions to be upto 16-20 days in a proportion of natural population. However, longevity in field is directly dependent on ecological factors.

5.2 Immature Stages

5.2.1 Egg

The freshly laid eggs are creamy white in colour which later becomes dark. The eggs are usually deposited in cracks and crevices with high organic content, humidity and darkness. Sometimes eggs are also found in loose soil. The eggs are [glued to the surface through flattened while the convex side faces upwards. The egg shell has sculptors and their size varies from 0.336 – 0.432 mmx0.096-0.160 mm. A wide range has been observed for total number of eggs laid per female (5-68). The eggs hatch in 3-4 days at 26+ 2oC in laboratory.

5.2.2 Larva

The creamy white larva with distinct head, thorax and abdomen has numerous hairs on its body. The larva feeds on organic matter available in the soil. There are four larval stages:

I instar: The delicate larva is whitish with a brown head capsule lacking eyes. A pair of black caudal bristles and presence of egg breaker on the posterior portion of head are the characteristic features of I instar. The average life is 2-4 days.

II instar: Presence of 2 pairs of caudal bristles, round 3rd antennal segment and absence of egg breaker are the features of II instar which lives for about 2-5 days.

III instar: Presence of 2 caudal bristles on completely dark last abdominal segment, partically elongated 3rd antennal segment and yellowish body hairs on a well developed larva help in identifying III instar which lasts for about 3-4 days.

IV instar: It is a well developed brown larva with dark brown head capsule, elongated, oval 3rd antennal segment with a pointed seta. Two pairs of spiracles and two pairs of well developed caudal bristles are conspicuous. The stage lasts for 4-7 days and transforms into pupa. The total larval period may vary from 11-29 days.

5.2.3 Pupa

The elongated comma shaped pupa is milky white in the beginning and turns brown. It is a non feeding stage lasting for about 6-10 days. The sexes are differentiated in this stage. The total life cycle from egg to adult is reported to take about 20-36 days with average 26.75 days in *Ph.argentipes* in laboratory.

5.4 Processing & Mounting

Each field caught specimen of sandlfy is to be kept in 5% KOH solution or soap solution for 24 hours. Alternatively, the specimen may be kept in 5% KOH and gently heated for about 4-5 minutes. This helps in removing the hairs, cuticular wax layer and viscera. The alkali/ soap in then removed by thorough washing with ordinary water at least thrice. The specimen is then dissected in mounting media, the head is oriented ventral side up to expose buccal cavity. The 8th abdominal pleura are stretched gently to expose spermethecae in females. In males, terminalia is properly oriented for examination.

Mounting Media

Hoyer's media is the most commonly used medium for sandfly mounting. It consists of following constituents:

Distilled water	- 100cc
Gum Arabic	- 60gm
Chloral hydrate	- 400gm
Glycerine	- 20cc

After mounting the specimen, it is left for 48-72 hours in an incubator/room temperature for making the cuticular structures clearer.

5.5 Entomological Techniques

5.5.1 Adult sampling techniques

Of the various methods available for adult sampling, the selection depends on the objective of the sampling, biotope selected for sampling and the limitations of particular techniques. Most commonly used techniques are summarized below:

5.5.1.1 Hand collection

This is the most common method wherein sandfly sitting on a surface are caught with the help of an aspirator or test tube and a torch light. This method is particularly useful for longitudinal monitoring of man-hour densities. However, sin sandfly collection the ordinary mosquito barrier netting between glass tube and rubber tubing of the aspirator must be replaced by a muslin cloth as the smaller size of sandflies enable them to escape through ordinary mosquito net.

5.5.1.2 Trap collection

Usually 4 types of traps are used:

(a) Sticky trap

This is the most extensively used trapping devise wherein sandflies are trapped in a layer of castor oil. Suspended arched sticky papers/foils of standard size (20 x 30 cms) are placed at a height of about 4-5 cms from ground with convex sticky side towards ground. Traps are usually laid in the evening and collected on following morning. Sandfly density per trap is calculated for comparisons. Sticky traps are particularly useful in collecting sandflies from hidden shelters like burrows, cracks, tree holes, etc.

For some species showing repellency to castor oil, other vegetable oils are required to be used. However, in Indian these can be safely used against Ph.argentipes.

(b) Illuminated Sticky traps

Box shaped batteries are hung on the walls facing sticky traps to make them illuminated. In some studies, these traps have provided higher catch as compared to ordinary traps.

(c) Light traps

CDC miniature light traps are often used for sandfly collections. However, nylon mesh cage suspended in a rigid frame are better than the collapsible cages provided with the traps. Further, for sandflies they are modified to give UV light or white light.

(d) Funnel traps

These are particularly useful in collecting flies from rodent burrows. Traps are placed just at the mouth of the burrow to catch the flies emerging out of burrows. The inner side is provided with sticky paper or foil.'

Other traps used in mosquito collection like double bed net, stable net, malaise trap, magoon trap, etc. can also be used but the effectiveness is not yet well demonstrated.

5.5.1.3 Bait collections

Both human and animal baits can be used. However, the fact that sandflies are well known for their patchy distribution must be kept in mind while designing bait sampling. Due to clustering habit of sand flies, bait sampling must be extended to cover all parts of a village.

5.6 Age Determination

Usual method of age determination of sand flies is the examination of ovariole relics. The ovaries are dissected in sterile saline and the ovarian follicles are examined for dilatations. Each relic represents one gonotropic cycle.

The examination of accessory glands for secretary granules also provides criteria for determination of age (parity).

5.7 Host Preference

The blood meal of a freshly fed sand fly is sampled on a filter paper which may be subjected to precipitin test, Gel-diffusion technique or ELISA to determine the source of blood meal.

5.8 Vector incrimination

After dissecting a sand fly in sterile saline, midgut is examined for presence of flagellates. If found positive, head should also be dissected for examination of cibarium, pharynx and proboscis. The promastigotes must be spread on a slide, fixed with methanol and stained with Giema or Leishman stain. The presence and promastigote, however does not confirm the species of the parasite as all promastigotes are morphologically indistinguishable. For

confirmation, samples should either be subjected to xenodiagnosis or to biochemical characterization of parasite.

5.9 Determination of susceptibility to insecticide

The conventional WHO susceptibility test kit must be used. Freshly fed *Ph. argentipes* can be subjected to preliminary screening on the basis of silvery white legs. However, after recording the data, all sandflies, subjected to test must be examined under microscope after mounting and due corrections be made in the observations before interpreting the results.

5.10 Sampling of immature stages

Sand flies breed in cracks, crevices and other places with soils rich in organic contents. The resemblance in soil and larval coloration makes it difficult to detect larvae visually in their habitat. The soil is collected, kept in a Petri dish and then examined under microscope (40 x magnification). To facilitate screening of larger soil samples, a floatation technique is often practiced. The soil samples are immersed in a saturated sugar solution i.e. 3 parts sugar + 5 parts water. Larvae and pupae float in this solution. These are then passed through a series of sieves and finally the residues are examined under the microscope.

Chapter-6

Integrated Vector Management (IVM)

- IVM is the choicest approach as it comprises the interventions like IRS, Personal prophylaxis, micro-environmental management etc.
- Currently Indoor Residual spray with DDT 50% being carried out in all the Kala-azar districts except 7 districts in Bihar where Synthetic Pyrethroid has been introduced during 2015.
- High degree of supervision and monitoring required for obtaining quality spray.
- Reorientation training to spray men for each round.
- Preparation of micro action plans at Block PHCs/ district level – key to the success of IRS operations.
- A prior inspection of the spray equipment to be made mandatory to ascertain the proper function of spray pumps.
- Proper storage of insecticide, availability of spares like nozzle tip etc. to be ensured in advance.
- 1 kg of DDT to be added to 10 litres of water for making paste.

6.1 Vector control options

IVM for elimination of Kala-azar comprises the following:

- Insecticidal Residual Spray (IRS)
- Personal protection to prevent human vector contact by use of ITMN / LLIN
- Microenvironment management (Pucca houses and living conditions)
- Environmental code of practices (ECoP) to reduce sand fly to breed in conducive atmosphere, ECoP documents are available in NVBDCP website.

6.2 Insecticidal Residual Spray (IRS)

Insecticidal Residual Spray is one of the most cost-effective control measures for Kala-azar in India. To maximize the impact of IRS, it should be synchronized with case detection. The objective of IRS is to ensure safe and correct application of the insecticide to indoor surfaces of houses and animal shelters so as to obtain a marked reduction in vector populations and consequently a significant reduction of Kala-azar transmission in the target area. Susceptibility tests have shown that the sand fly continues to be susceptible to DDT 50 % insecticide. However, report of RMRI, Patna through longitudinal studies indicates vector resistance to

DDT in some areas in Bihar, Jharkhand and West Bengal. Further studies with documented data on susceptibility status may advice Programme to switch over to next insecticide.

The success of IRS operations depends on the planning and implementation. IRS plans should be developed before end of the year so that there is no last minute rush during implementation.

IRS planning should be made, based on the capacity for achieving complete and uniform coverage. When there is resource constraints it is preferable to limit the size of the operation and achieve quality coverage. The entire village needs to be covered if selected for IRS. Once micro planning is well developed for endemic areas, efforts should be made to utilize Geographic Information System (GIS) and Remote Sensing (RS) for improving the plan. Following criteria are applied while selecting areas for IRS:

- All villages within a Block PHC which reported Kala-azar cases in the past three years;
- New villages which reported cases during year of spray;
- Villages free of Kala-azar, but on search were found to have cases conforming to the case definition.

It is important that while making micro action plan for IRS by district add 10% enhanced budget in action plan to cover any new village(s) reported KA case during the spray round.

Two rounds of IRS with DDT 50 % at a dose of 1gm/sq meter are carried out in a year. Spraying should be started before onset of Kala-azar transmission season which coincides with time of build-up of vector populations. The build-up in vector population starts in March and peak Kala-azar transmission season is from June to October. The effectiveness of DDT lasts for about 10 weeks. Therefore, two rounds of DDT are done, the first in February - March and the second in May - June, to control the vector population and for providing protection during entire transmission season. This schedule may be modified in consultation with meteorological department based on local weather conditions. As it is difficult to conduct spray operations during monsoon, it may sometimes be necessary to delay the 2nd round till the monsoon subsides.

For Kala-azar elimination, the insecticidal spray is done up to a height of 6 feet only as the sand fly vector cannot hop above this height. Cattle sheds are also to be covered for interrupting transmission of Kala-azar. The varanda and areas with full sun light should be avoided for spray. Kala- azar vector prefers dark humid areas, ill ventilated rooms for resting. Therefore, special attention with good quality spray needs to be undertaken to cover these dark humid areas. The average requirement of DDT is 150 grams per house in the rural areas and the average surface area for spray per house is 75 square meters. For one million population the

requirement of DDT is 75 metric ton (MT) for both the round ie 37.5 MT for each round of spray.

Stirrup pumps are at present used mostly for IRS in India. Programme has introduced Hand Compression pumps as pilot under Kala-azar elimination programme in district Vaishali in Bihar through RMRI, Patna to see the advantage of Hand compression pumps v/s Stirrup pumps. The RMRI results have shown hand compression pumps with control flow valve are superior in comparison with stirrup pumps. Spray pumps are decentralized items and at such states are encouraged to procure WHO approved hand compression pumps. At present five international companies are under the approved list of WHO. Hand compression pumps have advantage over stirrup pumps as in stirrup pumps, two workers are required to cover area with insecticide where as in the case of compression pump only one person required to cover the area. The requirement of equipment per squad is as follows:

- Stirrup pumps (2) OR Hand Compression pumps (3)
- Spray nozzle tips for spray pumps (2)
- Bucket 10 liters (4)
- Asbestos thread (3 meters)
- Measuring mug (1)
- Straining cloth (1 meter)
- Pump washers (2)
- Spare nozzle (3-5)
- Plastic sheet 3X3 meters (1)
- Register for records (1)
- Writing material to identify households covered by IRS
- Tools for minor repairs
- Personal protection equipment (PPE) for each member of the squad including a pair of gloves

6.3 Use of Synthetic Pyrethroid (SP)

Though *P. argentipes* is still susceptible to DDT spray in majority of the areas, however, RMRI, NCDC and CARE India have reported resistance of the vector to DDT spray in districts Vaishali, Muzaffarpur, Sitamadhi, Samastipur and Patna. In view of this and considering high endemicity and insecticide (SP) availability, seven high endemic districts in Bihar were identified to be brought under IRS with Alphacypermethrin 5% during 2015. It has been proposed to extend Synthetic Pyrethroid spray in 21 districts (Bihar-15, Jharkhand-4 and West Bengal-2) during 2016.

6.4. Manpower requirements

The spray operations of one round should be completed in 45 – 60 days. This requires thorough planning and proper deployment of staff. Prolonging the duration of 1st round will create problems in carrying out the 2nd round in time, particularly with monsoon period closely following the originally planned schedule. The spray squads should be supervised well to ensure quality (correct dose, uniformity and completeness of application) of the IRS. The training of spray personnel should also be good. The supervisor of the spray teams should be a regular staff member of spray squad team. A spray squad comprises 5 field workers and one superior field worker. The number of houses to be sprayed is determined by terrain in which the team is operating. The population to be covered should be divided by 5 since each household has an average of about 5 members. Calculate the number of spray teams that would be required in each district based on the number of houses to be sprayed. Each spray squad should be supervised by a suitably trained health worker/supervisor. This individual is different from the spray squad supervisor. The task of supervision of the spray squads should not be assigned to health workers who are expected to provide general health services. This is because the quality of services will suffer if the health workers are taken away from their work to supervise IRS. One supervisor would be required to be responsible for adequacy of work of no more than 5 teams.

6.5 Training of spraying squads and supervisors

The training of IRS team comprises of training of the health workers who are responsible for supervising the spray operations, and training of the spray teams. District focal point for Kala-azar is responsible for organizing the training. The training components are:

- Importance of uniform and complete spraying
- Obtaining cooperation from the community
- Safe storage of the insecticide
- Preparation of insecticide suspension
- Correct use of the equipment
- Maintenance of the equipment
- Safety precautions and personal protection measures to be observed during the spraying operations
- Safe disposal of insecticide waste.

The training should be at least 3 days duration and include hands on training on the correct use of spray equipment and the observance of all the steps needed from the preparation of the suspension to safe disposal of left over insecticide suspension.

The training of the supervisors should include community involvement for ensuring community acceptance and participation, which in turn is expected to achieve the completeness of

coverage in all the targeted dwellings and the cattle sheds. The training of the supervisors should also include supportive supervision, which includes the use of a standard checklist and problem solving. The person responsible for solving the day to day problems of spray men is the spray squad supervisor. Each district proposed to be covered by IRS should develop a training plan. The training should be completed one week before the first spraying operations. Avoid a long interval between the spray operations and the training. It should be an integral part of the district work plan for elimination of Kala-azar. Each district should prepare a report on training of the supervisors and the spraying teams in the following format.

Report on training for IRS- District				
	Total number	Training courses (No.)	Dates	Venue
Supervisors and malaria workers				
Spray team members				
Spray supervisors				

6.6 Transportation, storage and safe handling of the insecticides

The bags/containers in which the insecticide is transported should be well sealed and properly labeled. The insecticide transportation should not be done along with transportation of the food items. In consultation with the community, the insecticides should be stored in a safe place where the chances of contact with humans are minimal. Make sure that the insecticide is properly labeled with the name of the insecticide, the name of the manufacturer, date of manufacture, the date of expiry and the danger sign that it is a poison. There should be written guidelines with each container/sachet what to do in case there is exposure to the insecticide. The insecticide should be stored in a well-ventilated room, not exposed directly to sunlight away from the walls. The place where the insecticide is stored should be away from the reach of children and animals. It is important to be sure that no food items are stored in the vicinity of the place where the insecticide is stored.

The stocks that arrive first are to be used first and make sure that the expiry date has not been exceeded prior to its use. It is necessary that insecticide should be tested for quality before use. Date expired insecticide can be used provided that the active ingredient tested conforms to the minimum specifications. Stock registers should be carefully maintained to keep a track of the use. The storeroom where the insecticide is stored should be kept locked and the danger sign should be displayed to indicate that this is a location where hazardous material has been stored. Eating, drinking and smoking are not permitted in the place where the insecticide is stored.

6.7 Spray Programme

The district plan should include a plan for IRS developed on the basis of endemic areas identified for spraying. The plan should include identification of dates when the selected villages are proposed to be sprayed. Each supervisor should then develop a plan for each spray team. This plan should be used to calculate the requirement of the insecticide, which should be supplied and safely stored at least one week before the spray. A prototype framework is summarized below.

PHC	Sub centers	Village (for sub center 1)	Date of spray	Spray team members
Name 1	Name 1	Village 1		
	Name 2	Village 2		
	Name 3	Village 3		
	Name 4	Village 4		
	Name 5	Village 5		
	Name 6			

6.8 Spray operations

Spray operations comprises of estimation of needs for each squad, correct use of spraying technique, full coverage of all the targeted households, proper maintenance of the spraying equipment and preparing daily reports with stock checking. DDT for spraying is provided in sacks and Synthetic Pyrethroid in drums by the national programme. The estimated amounts of insecticide based on the requirements should be given to each spray squad. This should be distributed to the spray team and the team supervisor should be asked to maintain an account. Based on the plan for IRS, a village wise programme should be developed by the supervisors with indication of the number of households to be covered in each village. A copy of the spray schedule should be kept by the supervisor. This would facilitate the supervision of the operations.

6.9 Spraying Technique

It is extremely important that the technique of preparation of the suspension and of spraying meets the recommended procedures.

6.10 Preparation and Spraying Methods

The suspension of DDT for spraying or other insecticide should be prepared when the team is ready to start the spraying. The suspension should be prepared correctly so that sufficient quantities of the insecticide are sprayed to be effective. Prepare 10 liters of the suspension at a time. This is enough for covering 500 meters square surface area. Therefore this will be sufficient for 6-8 households for Kala-azar. In case of Synthetic Pyrethroid (programme at present used Alphacypemethrine 5%) where 250 gm of Alphacypemethrine 5% to mix with 10 lts of waters. Table indicating the quantity of the insecticide (DDT or SP) to be used for making appropriate suspension as well as the requirement per annum of the insecticide is at **Annexure 11.**

The following steps need to be taken;

- Place the required quantities of DDT wettable powder or other insecticide in a 15-liter bucket
- Add volume of water with a mug that is considered adequate to make a paste of DDT or other insecticide as appropriate.
- Do not put too much water at this stage.
- Once the paste is made then pour water on the paste and keep mixing vigorously to make a uniform suspension and add measured volume of water i.e. 10 liters.
- After this procedure filter the solution through a clean cloth to remove any particulate matter. The barrel of the spray pump is placed in the bucket containing the spray suspension.
- One person operates the pump and the other is responsible for the spray. If a compression pump is used it can be operated by one person.
- The spray lance should be kept 45 cms away from the surface to be sprayed. The swath should be parallel.
- It is applied in a vertical swath about 53 cms wide.
- There should be an overlap of about 7.5 cms between two swaths.
- Spraying should be done from the top downwards.
- The top should be about 6 feet from the ground. The spray should not drip on to the floor.
- The discharge rate should be 740-850 ml per minute.
- The person who is responsible for pumping the material should give 20-26 strokes per minute with 10-15cms plunger movement at a pressure of 10 pounds per square inch.
- Spraying into a bucket for one minute and measuring the discharge rate per minute helps to ensure that the discharge rate is satisfactory.

If the discharge rate exceeds 850 ml minute then the nozzle should be rejected. A blockage in the nozzle is a frequent problem. The nozzle cap should be removed by unscrewing it and replaced by a new nozzle. The blocked nozzle should be kept immersed in water for a few hours and then cleaned off blockage. Do not use fine wire etc to remove blockage as this will widen the hole size of nozzle and the discharge rate will more. The unused insecticide should be disposed off safely as per the guidance of ECoP (environmental code of Practices) developed by NVBDCP. The buckets that were used should be cleaned properly ensuring safe disposal of the waste to ensure that it does not contaminate the environment. The deposits on

the wall should be uniform and no areas should be skipped. This is an indication of good spray. The supervisor should check the quality of the spray. This is easy to do in the case of DDT since DDT leaves white deposits after the spraying has been done. In case of Synthetic Pyrethroid which leaves no stain on the wall therefore, it is difficult to assess whether spray has been done or not. To overcome this problem supervisory staff may be suggested to use torch light which after flashing on the wall shows bright star like deposit of Synthetic Pyrethroid. The other way to check is to place your palm on with pressure on the wall and check whether some insecticide have deposited in the palm. It takes about 3 minutes to spray about 150 sq meters area. This is the average size of a dwelling in rural areas of India. The size of the house to be sprayed can vary from country to country. There are always some households that are not covered in the first round. These should be covered under subsequent mopping up round on the same day or on a pre-decided different day.

6.10.2 Routine maintenance of the equipment

The spray equipment is subject to normal wear and tear since the insecticides are corrosive. To reduce the deterioration the following actions should be undertaken at the end of each day:

- The discharge line should be disconnected at the delivery outlet at the end of spraying.
- The bucket and the discharge line should be emptied.
- The spray pump should be thoroughly rinsed with clean water
- The filter assembly should be rinsed and cleaned. Filter should be removed from the valve by grasping it at its screen and slightly twisted on pulling it out.
- Reassemble all the clean parts except the nozzle. Put clean water in the tank, seal the tank and pump air into it. Open the control valve and let the water flow from the lance to flush the hose, filters, control valve and lance. Remove the tank cover and dry the inside of the tank.
- Clean the nozzle tip by washing thoroughly with water. Remove any dirt from the orifice with a fine bristle/a brush. Never use a wire or nails to clean the nozzle.

Supervisory staff is to ensure that all the pumps after spray has washed thoroughly with water before closing of the spray activities on each day.

6.10.3 Minor Repair of the spraying equipment

Minor repairs can be done in the field. Some examples are as follows:

- Cleaning the nozzle
- Cleaning of the discharge line
- Tightening of the hose clamp
- Tightening of the gasket
- Tightening of the nut and compression of the cut off valve

- Replacement of the nozzle.

6.10.4 Instructions for the spray squad members

- A simple flyer should be provided to each member of the spray squad. This should be in simple local language with appropriate illustrations.
- Wash your hands thoroughly with soap and water after preparing the insecticide spray. This is to be repeated every time the spray operation is stopped. Washing of hands thoroughly with soap and water is advised when the team takes a lunch or tea break.
- The personal protection comprising of apron, gloves, mask and goggles should be worn during the insecticide spray.
- Avoid direct contact of the insecticides with eyes or skin. If this happens wash the skin coming in contact and adjacent skin thoroughly with soap and water. Eyes should be flushed repeatedly with clean water for a period of at least 5 minutes or 10 times to protect you against any harmful effects of the insecticides.
- If irritation persists even after thorough washing, seek medical advice.
- If any member of the spray team suffers from any symptoms while the spraying operations are ongoing, medical attention should be sought without any delay.

6.10.5 Information about use of hand compression pump

A hand-compression sprayer consists of a tank for holding a liquid insecticide formulation, which can be pressurized by means of a hand pump attached to it. The compressed air forces the liquid from the tank via a hose with a cut-off valve, a lance and a nozzle. barrel of the sprayer should be capable of withstanding an internal pressure of 14 kg/cm^2 and for this purpose the metal walls should not be less than 0.63 mm thick. The diameter of the plunger shaft should not be less than 12 mm. The plunger bucket of the pump should be made from nitrile rubber or chrome-tanned leather. The plunger assembly should be easily removable for cleaning and repair in the field. The handle may be shaped D or T. The handle grip should be about 30 mm in diameter. Further, the length in the case of T-type handle should not be less than 20 cm.

6.10.6 Actions ensured by the operators/supervisors

- The compression sprayer is pressurized before commencing spraying, and not continuously pumped. The pump is filled to levels usually at about ¾ liquid to ¼ air. A smaller air volume in relation to liquid volume would not retain sufficient pressure for long periods.
- When the tank is not in use, the spray lance is held in a bracket and nozzle cup, which protects the nozzle from damage.
- The nozzle tip is the most important part of the sprayer. It should deliver a precise amount of spray suspension per minute (740-850 ml) at a certain pressure (40 PSI or 2.8

kg/cm^2) in the tank, and maintain a uniform spray pattern and swath width (53 cm or 21").

6.10.7 Post spray activities

The post spray activities include stock taking of the work completed, preparing a report, disposal of the material which could not be used and maintenance of the equipment, estimating the requirements for the next day and planning spraying in the villages that have not been covered.

6.10.8 Disposal of the insecticides and the containers/sacs in which the insecticide is stored

- The unused insecticides or the washings should be disposed off safely to ensure that it does not mix with water or food.
- Prepare only the required quantity of insecticide suspension, which is likely to be consumed in one day. Do not carry over any unused insecticide the next day.
- Never put any leftover insecticide into a river, pond, well or source of drinking water.
- Any spilled insecticide in solid or liquid form, the washings from the spraying, should all be emptied into a pit which is dug away from the source of drinking water and covered with mud.
- Do not use the empty sacs or containers in which the insecticide was stored for any other purpose. These must be buried safely away from the drinking water source.
- All empty containers/ sacs should be returned to the supervisor. The supervisor must check carefully that all empty sacs/containers have been received.

The environmental Code of Practices (ECoP) for safe disposal of insecticide is uploaded on NVBDCP web site. States are requested to disseminate the ECoP to districts.

6.10.9 Daily Summary, reporting of information

At the end of each day, the spray squads should prepare the summary of day's work. This includes information on the households targeted, households sprayed, insecticide consumed, insecticide left, and the problems encountered in the work. A daily summary of spray operations and daily consumption record of insecticide should be maintained in the perform annexed at Annexure12.

The daily report should be sent to the supervisor by all the spray squads for review and feedback by the supervisor in order to take corrective actions if required. The supervisors in turn should send the consolidated report to the focal point in the district once every week.

6.10.9.1 Informing and involving the community

The supervisors should inform the community leaders and key persons in the villages about the plans for the spraying at least a week before the spraying is done. The spray team members should remind them at least one day before the operation. During the first visit discuss the following issues with the community leaders and key persons in the community.

- Distribution of a simple flyer explaining the purpose of the spraying and including the common do's and don'ts developed in local language. Simple illustrations should be included to facilitate easy understanding of the people. This should be a part of BCC. The flyer should be left with several key persons in the village for distribution and briefing amongst the sections/segments they represent or influence. Tell the key persons to share the contents of the flyer to others in the community.
- What is proposed to be done and why. Explain that this is the most effective way of eliminating a dreaded disease Kala-azar. Their cooperation will be a key to success of the efforts.
- Inform the proposed date for spraying the village
- Discuss what specific role the community leaders and key persons can play to ensure that the spraying is complete and thorough. This would require that no household is missed and the spraying done must be complete.
- Explain that if all surfaces are not sprayed the sand fly would fly to the uncovered areas and the desired effect of spraying will not be obtained.
- The insecticide is harmful for the food items. Foods must not be exposed to the insecticides.
- The households must not do any mud plastering of the walls and the sprayed surfaces for 3 months after the spraying.
- One day prior to the spraying audio announcement for masses might be a useful way of informing and reminding the villagers. Other suitable options may be taken up in place of above source if that is not available.

6.10.9.2 Supervision of IRS

Supervision is an essential and integral part of IRS to ensure its efficacy and safety. This should be thorough to produce an impact and ensure that there are no ill effects. To be effective, supervision should be carried out at all levels. There should be a written plan for supervision and supervisory checklists are to be developed and used. Supervision will be effective if problems are identified and they are solved by the supervisors as soon as they are detected. Any unsolved problems should be referred to district authorities for resolution. All supervisory reports should be sent to the district to facilitate follow up action. The supervisory reports should be kept safely in the district and referred to whenever needed.

- Availability of plan with the spray squad. Review of the plan to ensure that the plan is being followed.
- Ensure that all members of the spray squad are present and are doing the job.
- Checking that the spraying is being done correctly according to the norms prescribed in the work manual of the spray squad.
- Examination of the spray equipment to ensure that it is in working condition and is being properly maintained as per the guidelines provided.
- Going with the squad to the households where there is refusal or reluctance for spraying
- Checking the records of the spray squads
- Discussions of plans for mopping up to cover the households where there was refusal or the houses were locked.
- Assessing the consumption of insecticides and making arrangements for additional supplies if required.
- Review of time schedule for the following week
- Visit randomly selected households and ask whether the house was sprayed or not.
- If the house was sprayed, then check for grey white deposits as evidence for spray.
- Check whether the deposits are uniform or not. Uniform deposits indicate that the spraying was satisfactory.
- Check to see if any portions of the dwelling or the cattle shed were skipped.
- Check whether the walls have been plastered with mud. If the walls have been plastered then determine when this was done to determine the time interval between the IRS and the plastering.
- Visit the households that were not covered and find out the reasons for non-coverage. Try to convince them to get their houses sprayed as a part of special mop up drive.
- Prepare a written report along with recommendations and share with the spray squads to ensure that the mistakes are corrected as soon as possible.

In case of Synthetic Pyrethroid, it is difficult to see the deposits on the wall during concurrent supervision. The droplets may be seen on the wooden structures in the rooms/ cattle sheds where insecticide has been sprayed or by flashing torch light on sprayed surface which will exhibit star like twinkling/shining.

Chapter-7

Diagnosis of Kala-azar and PKDL

- Diagnosis of Kala-azar cases is done by using Rapid Diagnosis test Kits in the field. The results can be read in 10 minutes. These kits show > 90% specificity and sensitivity.
- RD test kits are user friendly.
- Interpretation of the test is also simple as two red lines indicate a positive result and only a single red strand – negative result.
- Parasitological diagnosis includes spleen, bone marrow and lymph node aspiration procedures; however each of the procedures must be measured against the potential risks and gains for the patients.
- In PKDL cases confirmation of infection either through PCR or by a slit skin biopsy.

The rapid dipstick 'Rapid Diagnostic test' has become the mainstay in the serological diagnosis of Kala-azar and is the method of choice for diagnosis of Kala-azar. The test kit comprises of test strip (Usually 25 pouched test strips per kit box) Chase Buffer solution (Usually 2 vials per kit)

The Rapid Diagnostic test rapid test for Kala-azar is membrane based immunoassay for detection of antibodies to Kala-azar. The membrane is pre-coated with a recombinant VL antigen (Rapid Diagnostic test) in the test line region and chicken anti-protein A in the control line region. The membrane is coated with the dye conjugate (protein A colloidal gold conjugate). Whole blood or serum sample may be used for testing

During testing, the sample reacts with dye and the mixture migrates upward on the membrane by capillary action to react with the recombinant VL antigen in the test region and generates a red line presenting as a positive result. Regardless of the presence of the antibody to VL in the sample, the mixture continues to migrate across the membrane to the control region and reacts with chicken anti-protein A of the control line region and generates a red line indicating verification for sufficient sample volume, proper flow and control of the reagents.

Requirements: Cotton, Rectified spirit, Disposable needle/Lancet, Rapid Diagnostic test strip, Chase Buffer solution, and Test tube

How to perform

Remove the test strip from the pouch or the vial
With a new lancet to prick the fingertip of the patient suspected to be suffering from Kala-azar.
Let the blood come out on its own without applying pressure or squeezing.
Place one drop of blood on the absorbent pad of the bottom of the strip.
Place the test strip into a test tube so that the end of the strip is facing downwards. This would encourage the blood to migrate upwards by capillary action.

Add 2-3 drops of buffer solution provided with the kit to the pad.
Read the results in 10 minutes. Do not read the results before or after 10 minutes as there are chances of mistakes if correct time is not adhered to.

7.1 Positive result

A red line appears in the control line where the blood was placed and another red line appears where the blood has migrated through capillary action. There should be two red lines for the test to be positive. A faint red line also is to be considered positive.

7.2 Negative result

There is a red line where the drop of blood was placed but there is no red line where the blood has migrated by capillary action.

Fig. 3. Rapid test negative **Rapid test positive (showing two distinct red lines)**

7.3 Invalid test

There is no red line at the place where the drop of blood was placed or in the test area where the blood is to migrate by capillary action. The test is also invalid if there is a red line in the test area but no red line in the control area where the blood was initially placed. If the test is invalid it should be repeated.

7.4 Recording of results and action thereon

The test result should be mentioned as 'Positive' or 'Negative' on the test slip. No recording of 'partially positive' should be made. There should be a separate register for Rapid Diagnostic test having the columns for Serial No., Patient No, if any, Complete address, Date of test done, Test result, Balance of 'Rapid Diagnostic test' strip and signature of the official performing the test. The register should be updated after each test and countersigned as the higher authority should be obtained preferably at the end of the day or at the earliest. The test report should be communicated to the treating physician for treatment advice accordingly. In case of invalid test, it should be repeated by following the correct procedure and should be mentioned in the test slip as well as in the register and the Serial No. should be marked with Red Ink Pen. For repeat test entry in the register, just the earlier Serial No. may be written in the Patient No. and

Address column. If the cause of invalid test is faulty test strip, it should be immediately reported to the concerned authority and earliest replacement should be done and in the meantime the testing should be stopped.

7.5 Storage and supply

The test strips and the buffer should be stored safely at room temperature between 20-30 degrees Celsius. Temperature in excess of 30 degrees can reduce the quality of the test. The test strips and the buffer should not be frozen since freezing deteriorates the quality of the reagent. The strip should be taken out from the vial or the pouch only at the time of performing the 'Rapid Diagnostic test

7.6 Where should 'Rapid Diagnostic test be done

The test is easy to perform and can be done at Block PHC level by medical officer and lab technician. For the success of the elimination programme, it is necessary that 'Rapid Diagnostic test' is available at the minimum at all PHCs and District hospitals. It is recommended that it should be kept at place where;

the health workers can detect enlarged spleen;
the facilities where treatment of Kala-azar is available;
the distance of the facility from the community is less.

Note: All patients in the private sector(s) should be encouraged to be treated in the government sector.

7.7 Supply chain management

A proper supply chain management system should be enforced to ensure regular availability of the test kits at the site with buffer stock in hand. The monthly updated stock position and the requisition for kit and other required items should be sent to the upper level and the upper level should ensure timely reach of the requisite supply at the site.

7.8 Advantages and limitations

The advantage & limitations of Rapid Diagnostic test' in the diagnosis of Kala-azar are as under.

False positives: To exclude suspected hepatitis and TB cases as they may lead to false positives; and in situations where the clinical case definition is not followed.

False negatives: test can be negative in HIV patients where immune response is limited, and other cases.

The RDT can remain positive for months or years after treatment of VL. For this reason this test is not useful in the diagnosis of relapse cases. In PKDL it can be used only to rule out the disease if negative but not for confirmation. In these cases, parasitological diagnosis should be done, by bone aspirate or splenic aspirate.

7.9 Parasitological diagnosis

A clinically suspect case can be confirmed using spleen, bone marrow or lymph-node aspirate. However, use of such invasive diagnostics must be measured against the potential risks and gains for the patient. Splenic aspirates are more sensitive (96%) than are aspirates of bone marrow (70%) or lymph nodes (58%). When a relapse is suspected parasitological confirmation is the gold standard. Procedures for spleen, bone marrow & lymph node aspirations and staining are annexed at Annexure 5.

Detect parasites in amastigote or promastigote stage during diagnosis:
•Amastigote with smear of tissue aspirate (stained with Romanoawsky, Giemsa, Wright or Leishman stains).
•Promastigote with culture using an Novy-Mac Neal-Nicolle (NNN) medium.

Remark:

PCR assays with primers which amplify kinetoplast DNA (kDNA) have been evaluated for the diagnosis of VL and have been shown to have excellent sensitivity (99%) and specificity (100%), and they may prove to be useful for correlation of the findings at the time of diagnosis and for follow up. However further work/ comparative studies with verification against the gold standard (parasitological search) need to be done for use in the field setting.

7.9.1 Diagnosis of Post Kala-azar Dermal Leishmaniasis (PKDL)

Cases of PKDL usually do not have any signs of Kala-azar like fever, splenomegaly, or anaemia because 85-90% of them appear after the cure of Kala-azar. However, it shall be highlighted that 5-6% of cases of PKDL cases occur (RMRI study) without the preceding history of Kala-azar. They have only skin lesions that are varied. The lesions may be macular, papular nodular or mixed. Sometimes the lesions of PKDL are extensive. In PKDL cases sensation over the lesions is preserved in contrast to leprosy where similar lesions have no sensations.

In the Indian subcontinent, the skin lesions of PKDL do not ulcerate and self healing of the lesions is not reported. Suspected patients of PKDL should be screened by 'Rapid Diagnostic test'. In cases of PKDL with only macular lesions, the 'Rapid Diagnostic test' may be negative. These cases should be referred to a laboratory where PCR test can be done to detect the presence of the parasite. If PCR test cannot be done, then the confirmatory diagnosis of PKDL can be made by demonstration of the parasite in the skin lesions by a slit skin biopsy. Skin scrapings can be obtained from the suspected lesions by a needle. It is important to observe all safety precautions to prevent HIV/AIDS, Hepatitis B and C and other blood borne infections while doing the scraping of the skin for the test.) The nodules or the erythematous lesions is scraped and placed on a slide. The slide is then stained the same way as the bone marrow or splenic puncture aspirate. It is then examined for LD bodies under the microscope, or fixed for transfer to a higher center for examination by a pathologist.

Chapter-8

Treatment of Kala-azar, PKDL and HIV/VL co-infection

- Within Indian programme following drugs are used for treatment of Kala-azar
- Liposomal Amphotericin B injection intravenously across all age groups @ 10mg/kg bw including pediatric, pregnant & elderly patients.
- Miltefosine capsules of 10 mg (Pediatric) and 50 mg (Adults) in the age group between 2-65 years. Not to be given to pregnant and lactating women and women who refuse contraception during treatment with Miltefosine. Dosages are: Adults > 12 years weight > 25 kgs 100 mg daily in two doses of 50 mg each after meals for 28 days and adult >12, year weight < 25 kg, only one capsule of 50 mg daily X 28 days. Children 2-11 years milteforsine to be given at 2.5 mg/kg once daily after meals x 28 days.
- Amphotericin B deoxycholate injection intravenously at a dose of 1 mg/kg b.w. on alternate days x 15 doses.
- Combination of Paramomycin injection intramascular & Miltefosine @ a dose of 11/mg/kg b.w x 10 days together with Miltefosine for 10 days. Not to be given to chronic kidney patients, pregnant and lactating women and those not inclined to contraception during treatment
- HIV – coinfected patients – LAMB 40 mg/kg b.w as total dose of 3-5 mg/kg bw daily or intermittently for 10 doses, days 1-5,10,17,24, 31 and 38
- PKDL – In order of preference: First drug of choice, miltefosine 100 mg orally per day x 12 weeks.
- Amphotericin 'B' deoxycholate injection 1 mg/kg bw over 4 months in 60-80 doses.

WHO Expert Committee on Leishmaniasis, and subsequently the Regional Technical Advisory Group (RTAG) of WHO South-East Asia Region (SEAR) recommended Liposomal Amphotericin B (LAMB) in a single dose of 10 mg/kg bw as the first line treatment regimen for the Indian Subcontinent (ISC) within the current elimination strategy, given its high efficacy, safety, ease of use and assured compliance. The decision to use Liposomal Amphotericin B for Kala-azar was taken by the Technical Advisory Committee based on the available evidences and approved by Ministry of Health and Family Welfare, Govt. of India besides combination treatment with Miltefosine and Paromomycin inj of 10 days duration. The other proven drugs like Miltefosine and Amphoterecin B deoxycolate injection are under Kala- azar drug policy.

Amphotericin B emulsion has also been approved to be used on pilot basis in two districts under strict supervision of ICMR.

Within the Indian National Programme, assuming availability of drugs, appropriate training of health personnel, infrastructure and indication, the following drugs will thus be used in order of preference at all levels:

Liposomal Amphotericin B IV (LAMB) Single Dose 10mg/kg.bw
Combination regimens (e.g. Miltefosine capsules plus Paramomycin inj IM)
Amphotericin B emulsion
Miltefosine capsule
Amphotericin B deoxycholate inj in multiple doses
Amphoterecin B emulsion inj in selected districts on pilot

8.1 Single dose of Liposomal Amphotericin- B (LAMB)

The liposome is a spherical vesicle which contains the drug. This presentation is less toxic than the conventional Amphotericin B formulations allowing for higher doses to be given. The single infusion treatment with Liposomal Amphoterecin B requires a total quantity of 10 mg/kg for all ages. . Liposomal Amphotericin B dosage sheet is attached at Annexure 6.

8.1.1 Liposomal Amphoterecin B deoxycolate

Liposomal Amphoterecin B deoxycolate is reconstituted in the vial with sterile water for injection (12 ml). Immediately after the addition of water, shake the vial vigorously for 30 seconds to completely disperse the Liposomal Amphoterecin B (Liposomal Amphoterecin B (AmBisome))

8.1.2 Filtration and Dilution

After reconstitution, Liposomal Amphotericin B vial (containing 50 mg of liposomal Amphotericin B), to yield a preparation containing 4 mg/ml Amphotericin. Visually inspect the vial for particulate matter and continue shaking until complete dispersion is obtained. Withdraw the calculated volume of reconstituted Liposomal Amphotericin B as per the weight of the patient into sterile syringe (Refer Dose calculation form). Using the filter provided, instill the Liposomal Amphotericin B preparation in to a sterile container with the correct volume of 5% dextrose injection.

8.1.3 Mode of Administration of Liposomal Amphotericin B

A test dose must be given prior to giving the full dose. For test dose, start the infusion very slowly at 2 drops per minute for a period of 10 minutes and observe the patient.
If the patient tolerates the test dose well, then infuse the rest of the dose over a period of 2 hour or more.

8.1.4 Pediatric Use

Pediatric patients, aged 1 month to 16 years, with VL have been successfully treated with Liposomal Amphoterecin B (Liposomal Amphoterecin B (AmBisome). There is no evidence of any differences in efficacy or safety of Liposomal Amphoterecin B compared to adults. Since pediatric patients have received Liposomal Amphotericin B at doses comparable to those used in adults on a per kilogram body weight basis, no dosage adjustment is required in this population. Safety and effectiveness in pediatric patients below the age of one month have not been established.

8.1.5 Elderly Patients

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

8.1.6 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 but a special precaution is needed during treating pregnant women.

8.1.7 Infusion related reactions

Infusion related reactions are usually not serious. Anaphylaxis has been reported rarely in association with Liposomal Amphotericin B infusion. Precautionary measures should be taken for prevention and treatment of these reactions. Vital signs should be taken every 30 minute and patient asked for any subjective complaints. In mild reactions including low back pain, the infusion can be slowed down and the patient closely monitored. Symptoms usually quickly disappear. If not, then stop the infusion. In severe reactions (including dyspnoea and tachycardia) stop the infusion and follow emergency SOPs. Consider alternative VL treatment option.

8.1.8 Storage of Liposomal Amphoterecin B

Liposomal Amphotericin B should be kept in cool and dry place (2 to 25oC at all times). Liposomal Amphotericin B is not destroyed by freezing but is recommended by the manufacturers not to be frozen. The reconstituted vial can be kept refrigerated for 48 hours. When a patient needs only a part of a vial, reconstitute the vial, use the part needed and save the other part for the dose for no more than 48 hours. If reconstituted in a vial, store this vial in the carton in order to protect from light, and ideally in a fridge. Unused vials must be kept in the carton away from light.

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

8.2 Treatment with Miltefosine

Miltefosine is a relatively safe oral drug for the treatment of Kala-azar.

8.2.1 Mode of Treatment:

The treatment is provided as Directly Observed Treatment (DOT) with patient coding system being followed for each patient registered at the treatment centre.

8.2.2 Inclusion criteria

A clinical diagnosis of active VL or PKDL with consistent signs and symptoms (e.g., fever for more than two weeks, splenomegaly, anaemia)
Confirmed diagnosis with rapid diagnostic or with splenic/bone marrow smear examination.
Male or female of ages 2 to 65 years

8.2.3 Exclusion criteria

Women during pregnancy
Women who are breast-feeding their babies
Married women of child-bearing age who refuse to give an undertaking of refraining from pregnancy during the treatment period and two months after completion of treatment with miltefosine
HIV positive serology
Infants < 2 years

8.2.4 Dosages

After enrolment oral miltefosine treatment is administered as per following dosage schedule:

Adults (>12 years) weighing more than 25 kg:
100 mg miltefosine daily as one capsule (50 mg) in the morning and one capsule in the evening, after meals for 28 days (56 capsules).

Adults (>12 years) weighing (less than 25 kg):
50 mg miltefosine daily as one capsule (50 mg) in the morning, after meals for 28 days (28 capsules)

Children (2-11 years):
Miltefosine will be given at 2.5 mg/kg once daily after meals for 28 days (needs to calculated as per body weight)

The drug is not to be used in the case of children below 2 years of age and pregnant women/child bearing women. Miltefosine 10 mg and 50 mg capsules are supplied under the programme. Miltefosine dosage guide is at Annexure 7.

8.2.5 Monitoring

At district level monitoring of the use of miltefosine would be carried out by
Chief Medical Officers & District Programme Officers as per operational details under DOT treatment schedule. Medical Officer In-charge in respective PHCs will bear overall responsibility for ensuring compliance among the patients Independent monitoring will be carried out by RMRIMS, Patna on a selected sample basis

8.3. Treatment with Amphotericin B deoxycholate injection

This drug is recommended in the following cases:

Patient not responding to the first-line of drug or the drug was discontinued due to toxic effect
Women during pregnancy
Women who are breast-feeding their babies
Children less than two years of age.

8.3.1 Dosage: 1 mg per kg. body weight on alternate days for fifteen doses.

8.3.2 Route: Through intravenous infusion in 5 per cent dextrose after mixing the drug in water for injection, very slowly in 6 to 8 hours.

8.3.3 Precautions: Stop the drug when signs of renal failure and those of hypokalaemia appear. Make available emergency drugs to guard against hypersensitivity reactions. Amphotericin B causes renal and cardiac toxicity. Therefore, the treatment of the patients under strict supervision and on indoor basis should be undertaken.

8.4 Combination of Miltefosine and Paramomycin (10 days treatment)

The combination treatment can be used in areas with low endemicity or in Block PHCs where infrastructure has not been developed. In such cases Block Medical officer can start treatment with combination till such time Block develops its capacity for single dose treatment with Liposomal Amphoterecin B (Liposomal Amphoterecin B (AmBisome)).

Combination Paramomycin and Miltefosine	10 days of intramuscular paromomycin11mg per kg body weight together with 10 days of oral Miltefosine.
Routes	Intramuscular injection (PM) and oral (MF).
Criteria for cure	Clinical cure till six months after complete treatment
Contra-indication	Kidney disease, pregnancy, lactation, unable to take oral treatment
Precautions	Renal function tests must first be conducted in acute cases as well as elderly

8.4.1 Calculation of the dose for the drug Paramomycin

Patient's weight (kg) × 11 (mg/kg) = Patient's dosage (mg)
Patient's dosage (mg) ÷ 375 (mg/mL) = Patient's dose volume (mL)

The drug Paramomycin must be given as intramuscular injection. Paramomycin dosage guide for patients with normal renal function is at Annexure 8.

8.4.2 Contra-indications

It is a nephrotoxic drug, so, must not to be given to a patient with impaired renal function. It should not be given to patients receiving treatment with other aminoglycosides eg. gentamicin, tobramycin, amikacin.

Treatment card with Kala-azar treatment schedule is at Annexures 9A-9C.

8.5 Treatment with Liposomal Amphotericin B emulsion (Amphomul)

The treatment with Liposomal Amphotericin B emulsion has been included in programme on pilot basis under the strict supervision of ICMR. The dosage shall be 15 mg /kg body weight for single infusion. The use of this drug shall be limited to one low endemic district each in Bihar (Gopalganj) and Jharkhand (Pakur). Programme will revisit for its expansion in future on the basis of its efficacy and other parameter.

8.6 Discharge and follow up

All patients who have completed the treatment with Liposomal Amphoterecin B and had a good clinical response can be sent home. The patients should come back for a follow-up visit 6 months (+/- 2 weeks) after end of treatment to ensure definite cure. Defaulters to treatment should be actively traced. Discharged VL patients should also be encouraged to report to the health facility upon recurrence of symptoms or appearance of skin rash mimicking PKDL.

8.6.1 Discharge

Ensure that examination and laboratory investigations are completed, and findings documented on the VL treatment card.
Advise patient to return for follow-up after six months or before, if the symptoms return and seek medical advice. Patients who come from outside the area need to know to inform their doctor that they have been treated for VL, in case of relapse going undetected by physicians not familiar with the disease.
Give the discharge paper and drugs that patients would need to be continued at home.

8.7 HIV Co-Infected Patients

WHO KA technical experts classify VL as a stage 4 AIDS defining illness. With liposomal Amphotericin B, relapses typically occur in up to 5% of the patients. In contrast, HIV +ve patients demonstrate relapse rates with higher doses of upto 30%, with most relapses occur

within 6 months of initial cure. Relapses tend to have a higher parasite load and are difficult to treat. PICT (Provider Initiated Counseling and Testing) should be routinely offered to patients of all age groups testing positive for KA. It is imperative that these patients after receiving treatment for the KA infection are referred to appropriate facilities to receive ART treatment for their HIV infection.

8.7.1 HIV Diagnosis

HIV should be confirmed by at least three different tests-Two rapid tests, and one ELISA test. All three tests should be positive for declaring the result as positive (refer NACO guidelines for details), and in such cases, CD4 count should be done before initiation of ART.

8.7.2 Primary VL treatment in HIV/VL patients

There is limited evidence for treatment of HIV-KA co-infected patients in the Indian subcontinent. However, it was decided to adopt WHO guidelines on treatment of HIV-VL co-infected patients (LAMB 40 mg/kg body weights as total dose, 3-5 mg/kg daily or intermittently for 10 doses, days 1-5, 10, 17,24, 31 and 38). FAQ regarding HIV-VL co-infection is at Annexure 10.

8.8 Post Kala-azar Dermal Leishmaniasis (PKDL):

Following the 2012 WHO manual for management and control of PKDL, the following treatment options were suggested for the Indian subcontinent:

In order of preference:

Miltefosine: 100mg orally per day for 12 weeks
Amphotericin B deoxycholate :1mg/kg over 4 months 60-80 doses
Liposomal amphotericin B: 5mg/kg per day by infusion two times per week for 3 weeks for a total dose of 30mg/kg

8.9 Pharmaco-vigilance

Pharmaco vigilance is important to ensure the safety of the medicines used in the treatment of Kala-azar. It should be the joint responsibility of selected sentinel sites and of the national programme. Pharmaco vigilance by sentinel sites only will provide limited data at a high cost but the quality is likely to be very good. In contrast, the programme can provide very useful information but unless protocols are appropriate and the supervision is strong the quality of information may be compromised.

Each medicine has got some side effects. The following measures will help to recognize early appearance of side effects.

Monitor the patient regularly for signs and symptoms (indicative of side effects of drugs) as advised by the programme. These signs and symptoms should be classified as major and minor. Perform the tests as recommended in sentinel sites and monitor the results. This can help to take timely measures even before the signs appear.

Periodic meetings should be organized by the programme to review the reports of major and minor side effects obtained from the different levels and take into consideration the findings of the sentinel sites. This will help guide the programme in recommending the tests that should be done to monitor the patients on treatment.

Regularly report the side effects on the reporting formats to higher levels once in a month for a review and feedback

Chapter- 9

Training of Human Resources

- Induction training to the staff like state/district Consultant, Medical officers of BPHCs, KTS, Personnel of development partners, Malaria Inspectors, Basic Health Workers, ASHAs, AWWs to be ensured.
- On the job training of the above staff for acquiring skills and knowledge while performing field duties.
- Re-orientation training to all the levels of staff like ASHAs, Village Volunteers, AWWs, spray workers etc. so that the knowledge acquired remains intact.

NVBDCP is a constantly evolving programme with updating of strategies and revision of policies, which require training and re-training of staff at different levels.

There is a requirement of training of a variety of health care staff involved in service delivery at all levels. These are personnel who have years of work experience and established work patterns. During the training, it is important to ensure their participation and active involvement. Interactive tools like modular trainings, case studies, field exercises etc. should be used instead of monotonous lectures. The trainers should act as facilitators, guiding participants using their own knowledge rather than supplying them with facts.

Training is designed to impart the necessary knowledge and develop the required skills while on the job to change the performance of people assigned the jobs. The training should be an ongoing programme with an inbuilt provision to update knowledge and skills in the light of scientific and technical advances.

The participants should be treated with respect and should be allowed to provide inputs regarding schedules, activities and other events. Discussions should be encouraged. Hands-on work, group and individual projects, and classroom activities should be planned. Audiovisual aids, role plays and case studies should be used.

9.1 Types of Training

9.1.1 Induction training. Induction training is meant to enable newly recruited staff to become productive as quickly as possible. In NVBDCP recruited staff such as District VBD Consultants and KTS will need induction training soon after they join. The following areas may be included in induction training:

9.1.2 On-the-job training. On the job training occurs when workers learn skills whilst working alongside experienced workers at their place of work.

9.1.3 Off-the-job training. This occurs when workers are taken away from their place of work to be trained during a short period. This may take place at a training academy, at a PHC, if class room facilities are available, or at school premises during weekends.

9.2 Personnel involved in Kala-azar control and / or case management.

The following are staff involved in Kala-azar control and / or case management and require training at the time of joining and reorientation trainings.

- District VBD officer(previously designated as DMO) and DVBD consultant
- Assistant DMO / VBD Consultant
- MO-CHC / PHC / hospitals
- KTS
- Multi Purpose Health Supervisor (Male)
- Multi Purpose Health Supervisor (Female)
- MPW (Male)
- MPW (Female)
- LT
- Pharmacist
- IRS teams
- AWWs
- ASHAs / Village link worker / NGO volunteer

The matrix on training needs of different categories of staff for introducing new norms presented is presented at **Annexure 13**.The trainings are to be tailored to the job responsibilities of the health functionaries. Certain categories can be trained together, for example DVBDCOs and VBDs.

9.3 Planning process of training in a district

The training of MO-PHCs, MPWs and ASHAs are integrated with NHM trainings. However, additional programme specific trainings are needed to be planned and imparted separately.

The estimation of training load is to be done at the beginning of the year. This should consider the number of personnel sanctioned and working at different levels in the district. The existing training status of the personnel is to be noted. This would give the requirement of the number to be trained and batches of trainings to be conducted.

9.4 Monitoring and Evaluation of training

It is very essential to monitor the quality of trainings. Concurrent evaluation of the trainings could be done by independent observers. Pre- and post-training evaluation should be conducted. Feedback on quality of training, as well suggestions for improvement should be obtained from the participants at the end of each session. SPOs would be required to submit quarterly progress reports on training as per formats given in the M & E framework. The report should reach the Directorate of NVBDCP on or before 20th of the succeeding month of the quarter.

Chapter-10

Behavior Change Communication (BCC)

- For successful implementation of any disease control programme, community mobilization for seeking their support is as important as developing new tools.
- Communication experts to be roped in for developing the IEC/BCC plans in consultation with community.
- Media research to unravel the perception and use of media by the community which is of paramount importance.
- Focus on printing material display of banners to be significantly minimized and emphasis on IPC, Group discussion etc to be made.
- Simpler messages to be developed for awareness on causation & prevention of the disease.

10.1 Introduction

Kala-azar elimination is currently focused on increasing the awareness about the problem and possible solutions. The strategy used comprises of IEC. In addition, campaigns are organized in India as Kala- azar fortnights. In these campaigns, the health care workers and volunteers visit house to house for case search.

10.2 Interventions Available

Three interventions of proven value are now being introduced at large scale into the programme, each of which has benefits tangible even to the lay person, and thus having high likelihood of acceptability and utilization.

10.3 Diagnosis

In the place of other tests which involve delay in getting results, rapid diagnostic tests etc are now available for diagnosis of Kala-azar. These tests can be conducted at the Block level. Like malaria where ASHAs have been authorized to do the rapid test. In case of Kala- azar, it is different because here the Clinician/ Medical officer is to apply clinical judgment. Moreover, the Rapid test under Kala-azar is antibody based where as in malaria it is antigen based. Antibody based test can give false results from six months to one year after complete cure. In such case the best method of diagnosis is through splenic/ bone marrow investigation.

10.4 Treatment

Kala-azar drug Miltefosine and Amphoterecin B injection are used for the treatment of Kala-azar which is nearly 100% effective and is not associated with any major side effects. However, miltefosine long duration of treatment is one of the barriers for treatment compliance.

Moreover, this drug can't be used among pregnant women, child bearing age women and children less than two years of age.

In view of this, programme has introduced single day treatment with Liposomal Amphoterecin B injection from 2014 through WHO. This drug has more than 98% efficacy as per WHO report with no side effect. Introducing this in the programme will improve treatment compliance. Other drugs, like combination treatment (miltefosine+ paromomycin) of 10 days duration, Amphoterecin B deoxycholate injection, Liposomal Amphoterecin B emulsion form (15mg/kg bw) are also available in programme to choose besides Miltefosine.

10.5 Incentive details.

10.5.1 Wage compensation for Kala-azar patients:
Rupees 500/- for completion of treatment irrespective of any drug regimen.

10.5.2 Wage compensation for PKDL Patients:
Rupees 2000/- after complete treatment irrespective of drug regimen.

10.5.3 ASHA

1. Rupees 300/-for reffering and ensuring full treatment of Kala-azar patients.
2. Rupees 100/- per IRS round for community motivation (Rs. 200/- for two rounds).

Key message for early diagnosis and complete treatment

1. Kala-azar is a curable disease. It should be recognized as early as possible and completely treated as soon as it is diagnosed.
2. Diagnosis and treatment of Kala-azar and PKDL are free of cost.
3. Government will compensate for loss of wages and for travel cost.
4. For admitted patients, the patient and attendant will get food without any charge.
5. There are few side effects of the medicines and even if they occur, the side effects can be treated.
6. The patient should continue treatment as advised and must not stop the treatment even when he/she is feeling better.
7. A cure will help the patient to become normal and it would prevent the spread of the disease to others in the neighborhood.

Key message for effective coverage with IRS

1. All the households should know the schedule for spraying of the households so that they are ready to get their house sprayed after removing their belongings.
2. All the surfaces to be sprayed should be cleared for complete coverage.
3. The cattle sheds should be sprayed thoroughly.
4. Do not wash or mud plasters the sprayed surface for a period of 3 months after the spray. This will ensure maximum effect of the insecticide.
5. Keep the household and the surrounding clean especially the areas where there is dampness.
6. Keep foods and food products covered and make sure that these are not sprayed with insecticide.

10.6 Referral Services

Ensuring early transport of patients of severe Kala-azar cases to the correct referral institution

Helping the family to avail government schemes supporting costs of transportation and treatment.

10.7 Behavior Change Communication (BCC)

Behavior Change Communication has been defined as a process of learning that empowers people to take rational and informed decisions through appropriate knowledge; inculcates necessary skills and optimism; facilitates, stimulates pertinent action through changed mindsets, modified behavior and reinforces the same.

- The analysis of values, beliefs and practices will tell us what the most relevant barriers to behavior change are, and what messages and approaches are likely to be most effective, for which segment of the potential audience.
- Simplicity, brevity, do-ability and relevance are the cornerstones for effective communication for behavior change.
- Interpersonal communication or counseling (IPC) is the preferred primary approach, particularly when introducing new practices that people are not familiar with, since this permits adaptation to a specific context and set of circumstances, but less intensive methods may suffice to sustain change.
- There are no guaranteed success formulae. Every intervention must be periodically evaluated for effect and reasons for success or failure. This should lead to minor or major revisions to strategies and plans. Thus, BCC is an evidence-based process involving continuous learning. Besides these developmental partners are also helping for dissemination of IEC/BCC messages.

10.8 Behavior change for impact

Strategic communication for behavior impact is needed for behavior change to occur. To create an impact it should be an integral part of social mobilization. A BCC strategy is needed for the following reasons:

- To influence planners, policy makers, other stakeholders for inter-sectoral involvement
- To mobilize additional resources and optimally use existing resources
- To use 'influencers' in the community for the empowerment of the community
- To empower and motivate community with information for appropriate behavior
- To get maximum output vis-à-vis the inputs
- To get behavior impact
- To monitor and measure the impact

10.9 Advocacy for behavior change

Advocacy is a strategy to develop an enabling environment to influence political leaders, elected representatives, planners, policy makers, corporate sector, media, organized sectors,

professional bodies, academia, and the media. The objective is to enlist their commitment on a sustainable basis to become ADVOCATES for the programme.

Advocacy is needed to create policies or reform existing policies, and ensure that policies are implemented. There are a variety of advocacy strategies, such as discussing problems with policy makers, contacting political representatives, delivering messages through the media, writing letters to the editor/articles, or strengthening the ability of local organizations to advocate, organizing community meetings, distributing educational materials or other means to communicate one's views.

10.10 Identify preliminary behavior objectives

These are no final objectives hence the following need to be addressed during formative research.

a) People suspected to be suffering from Kala-azar/PKDL utilize the services early in the disease for diagnosis and treatment from trained health care providers
b) Cases of Kala-azar/PKDL complete treatment
c) Household members ensure that the spraying is complete
d) Personal protection measures are practiced to reduce human vector contact

10.10.1 Segment the target audience

It is necessary to segment the target audience to identify the key audience that share similar characteristics and are most likely to respond to similar stimuli for bringing about a change. There are certain segments more in need of the behavior interventions than others. Within this segment there are more willing groups and others who are not quite ready. The willing groups should be targeted first. The segment chosen should be large enough and reachable. The size of the target group should be manageable and the resources should be adequate to be able to reach the segment.

10.10.2 Increase the capacity in BCC

Strengthen the capacity of the staff, health workers and volunteers at the district and sub district level to plan manage and implement social mobilization and behavior change strategies. The sustainability and impact of interventions would depend on the capacity of the providers. Motivation of the person who is responsible for communication is a very important factor that determines the impact on the audience. The non-verbal communication and the timeliness of communication determine the effect that communication has on the audience.

10.10.3 Key to success in BCC

- Elaborate plans for communication and sharing of knowledge and information, which should be an integral part of the strategy.
- Behavior change communication should be implemented only when the facilities are accessible, available and affordable to the target beneficiaries.
- The strategic plan for communication should be implemented in a pilot situation. It should be revised based on the pilot experience.

- Involvement of the community is important for the success of Kala-azar elimination programme. The poor communities need to be involved maximally in the elimination programme.

10.10.4 Reduce the human vector contact

This is the responsibility of all the individuals in the affected areas. People living in Kala-azar endemic areas should adopt suitable measures that reduce or eliminate human vector contact. Key messages should be developed with the following content.

- The contact with the vector most often occurs between dusk and dawn. Therefore protect them from a bite especially between dusk and dawn.
- Wear long sleeved clothes to prevent the sand fly from biting.
- Use mosquito repellents to keep the sand fly away.
- Sleep under bed nets that are treated with insecticides and have the appropriate mesh size to prevent the sand flies from entering the nets.

10.10.5 Micro environmental Control

Micro-environmental control and management is the responsibility of each household, which can be achieved through their participation. Keeping the households and the surroundings clean will help to reduce the breeding sites for the sand flies. This should be done as a regular drill once a week. Guidance should be provided by the health workers and health volunteers and supervised by staff responsible for the elimination of Kala-azar.

10.10.6 BCC in the Kala-azar control program: the goals and a practical approach

The communication strategy of Kala-azar control program is expected to serve the larger goal of the program: the reduction in morbidity and mortality from Kala-azar. Specifically, effective communication is expected to lead to the following:

A. People and their representatives, particularly in high-burden districts, become aware of their entitlements under the Kala-azar control program, and actively demand and monitor the realization of these entitlements.
B. Services offered by the program are widely and correctly utilized by affected families and communities.

10.10.7 Simple mass communication before IRS

This can consist of recruitment of local folk media, NGOs and CBO's to explain the benefits and use of IRS spraying to communities.

10.10.8 Simple information on entitlements provided to people's representatives and CBO's

Existing functional forums of the NHM in the district (Missions and committees) can be addressed by the Kala-azar program staff in the district, explaining the changes being brought into the Kala-azar elimination program, and the expected benefits. Such communication should highlight the specifics of services such as habitation-level availability of diagnostic and treatment facilities, and the large-scale availability of bed nets, as well as the terms of availability (time, cost, quality, etc).

Patients (young or adult who have received treatment with Kala-azar drug and cured fully can act as "**Kala-azar Mitra** (Friend)' who may be made responsible in his /her village to act as a communicator for informing any new Kala-azar resembling patient to the nearest health facilities /Kala-azar Technical Supervisor (KTS) /Block Co-ordinator.

Information

Some of the information that may be delivered for BCC is given below

To community at large

1. Fever more than 14 days could be Kala-azar.
2. Kala-azar can be fatal, so should be treated in time.
3. Kala-azar can be diagnosed easily at nearest government health facilities.
4. Free medicines for Kala-azar treatments are available at PHCs.
5. Make sure that your household should be sprayed with insecticide (DDT)/ SP (WDP)

Before and during the IRS round

1. Make sure you are available when the spray teams come on (date)
2. The actual spraying will take only a few minutes if everything is ready before hand.
3. The sprayed insecticide will not harm you, but it is best to wash utensils before use for cooking or eating
4. Make sure all rooms are sprayed including cattle sheds
5. Do not mud plaster for three months.

Chapter-11

Supervision and Monitoring

- Monitoring and supervision of all the programme components by the identified officials/staff to be made mandatory
- Both direct and indirect supervisions to be planned
- Supervisory visit of the officials to be ensured.
- Monitoring indictors to be analysed before and after the visits.
- Medical officers of BPHCs to be made accountable for the successful implementation of the national programmes.
- Motivational level of all the concerned officials/staff to be raised.
- Monitoring and supervisory formats to be used for a feed back to the concerned officials.
- On the sport instructions depending upon the observation to be given for better results.

11.1 Supervision

Supervision and monitoring are the key elements of a successful programme that has components operating in the field. Supervision and monitoring are two separate entities, but in reality they work hand in hand. Supervision is in fact the continuous evaluation that provides guidance to ensure that a series of tasks are carried out by the concerned staff within a particular unit/ organization and is concerned with operational running. This should be part of the regular management activities. In supervision the most important activity is the visit by the supervisor. Visits by the supervisor enable them (health worker) to learn about the actual implementation whether carried out properly, supervisory visits assure the healthy workers of continuous and positive support by the programme. Supervision should be done in such a way that it motivates the staff working for Kala-azar. It should be done in very supportive manner. The health worker should feel that he is being assisted and his work facilitated and should not get the feeling that he is being audited or inspected.

Needs for Supervision

- It confirms that the job is being done as per the guideline.
- It enables to make minor but necessary correction to working methods of the health worker.
- It should indicate whether the health worker need training/retraining.

11.2 Types of Supervision

There are two basic types of supervision; direct and indirect

11.2.1 Direct Supervision

In case of direct supervision you are able to be in constant touch with the health worker and hence you are able to see what the worker is doing.

11.2.2 Indirect Supervision

In case of indirect supervision the judgment is done from the records which they submit regularly.
Ensure that all forms, records and reports which are submitted should be well organized, complete and up-to-date.

Benefits of Supervision

- Strengthening of the programme implementation as per guideline.
- Impart field training of the staff, if it is felt that they are lacking skill in the specific task.
- Assist in solving problem faced by the health worker are affecting the outcome of the programme.
- Be well informed about activity to provide appropriate feedback.
- The supervisory visit should take place at a time when different work has been accomplished and not at a time when data is collected for compilation. Data collection should be separate activity when both parties have done their homework for forwarding the monthly/quarterly report to the higher authorities.

11.3 Monitoring Indicators used for supervision

The data collected through the system of HMIS consists of volumes of information and is used to assess the performance of the programme at the local level. The monitoring indicators that are used in the programme are case finding, disease burden, programme management etc. The requirement of indicators, at each level of health care delivery, is very specific. At the lower levels like PHC's and Districts indicators are utilized for local decision making while at the National level they are more relevant for policy making and assessing the overall progress. Therefore when visiting a health facility the KTS should assess the situation based on the prescribed indicator at each level. Such an analysis should also be discussed with the health care providers at the respective level to objectively show to them the performance evaluation. For example an ASHA can be shown that the No of Kala-azar cases are rising or more No. of deaths is being reported than the previous year. Therefore she should focus more on timely

case detection. One of the suggestions given to her by KTS could be increased advocacy in the community to improve its health seeking behavior for fever.

11.4 How to Establish Supportive Supervision

11.4.1 Improve performance

- Use a protocol/standard operating procedure including a supervisory checklist for each type of unit supervised.
- Conduct supportive supervisory visits also within health care facilities.
- Provide staff with updates on policies or new recommended practices. Undertake on-the-job training and see guidelines, manuals, visual aids.
- Plan supervision schedule in advance and communicate it to all those, who need to know. Lesser performing health facilities should receive strict vigil for better performance.
- Plan these visits as much as possible, when it is possible to observe the staff and interview patients. Talk to patients about the quality of services, preferably away from the health facility.
- Plan to spend sufficient time (from several hours, to a full day or more) to conduct the supervisory visit to each unit. Rushed visit with no time for dialogue does not bring desired outcome.
- Follow up on recommendations made during previous visits. Discuss progress with the health facility
- Check the stocks and the condition of equipment. Compare stocks with records.
- Review health facility records and provide feedback to the staff as well as MO in charge.
- Analyze programme indicators for the health facility to make the performance objective and measurable.
- Involve the community in the evaluation process. Ask community members how they are treated when they visit the facility. Talk to community leaders during the visit to get their feedback and identify jointly, what the community can do.
- Relationship between community and health workers should congenial.
- Discuss strengths and weaknesses, and actions to be taken (by whom and by when).
- Identify gaps and solve problems in positive ways
- Praise health workers in public for good performance and for practices that meet quality. Correct performance only through person-to-person contacts.
- Work with other health programmes to coordinate supervisory activities in a spirit of mutual support.
- Schedule a return visit before leaving the site.

11.4.2 Maintain and enhance motivation

- Give praise and recognition to health workers for what they are doing right.
- Act on feedback from the health workers, health workers will feel valued that they have an impact. Show that you trust them (as much as you actually do)

- Attend monthly meetings in all health facilities within the Block. This provides an opportunity for health workers to learn new approaches and strategies used in different health facilities and to receive continuing education. It can also be a forum to acknowledge their achievements.

11.4.3 Build sustainability

- Collect data on positive results gained from supportive supervision, such improved performance of health workers, improved coverage of IRS, better treatment etc.
- Develop a team approach involving Health supervisors & MPWs to increase supportive supervision at the health facility and make it a routine procedure, with or without frequent visits from the central or district level.
- Maintain supervisory register, tour diary, Vehicle log Book and route maps.
- Ensure rational use of RD Kits as per the program guidelines.

11.4.4 Monitoring

Monitoring means to watch keep track or check usually for a special purpose. In the case of Kala-azar it relates to maintaining and improving the Kala-azar care delivery so that it meets our aspirations to discover how and why we may have failed and to take appropriate action to improve performance. It is an ongoing process carried out by the programme implementers. The monitoring visits should ensure that work is being carried out along the Kala-azar control guidelines, so that at the end of the reporting period data can be gathered which is easy to interpret.

11.4.5 Characteristics of good monitoring activities

- Monitoring involves the selection of control indicators that reflect the permissible range of performance.
- It involves the gathering of information on how implementation is actually performed and comparing it against the desired standards.
- If needed taking corrective actions if deviations occur and provide timely feed back.
- It is the key to the quality assurance programme.
- A good monitoring system should provide answers to the following questions;
    A) Why should we do it?
    B) What should be monitored or evaluated?
    C) By whom?
    D) Where?
    E) When?
    F) How should it be done?

11.4.6 Important ways of monitoring

- KTS should monitor and ensure rational use of RD Kits as per the program guidelines.
- KTS should monitor and ensure the consumption and collection of anti Kala-azar drugs by the patient.

- KTS should monitor and ensure the intensive supervision of spray activities to its quality, coverage and implementation of IRS rounds.

11.5 ASHA

Every village/large habitat will have a female Accredited Social Health Activist (ASHA) chosen by and accountable to the panchayat, to act as the interface between the community and the public health system.

ASHA acts as a bridge between the ANM and the village and be accountable to the Panchayat. She is an honorary volunteer, receiving performance-based incentives for promoting universal immunization, referral and escort services for RCH, construction of household toilets, and other healthcare delivery programmes.

11.6 Role of Kala-azar Technical Supervisors (KTS)

He/She will be responsible for supportive supervision and micro-monitoring for Kala-azar prevention and control at sub district/block level in Kala-azar endemic districts. The module and standard operating procedures will help the KTS in discharge of his duties as well supervising the programme on issues like:

1. Kala-azar prevention and control operations in the designated blocks.
2. Promoting early care seeking if Kala-azar is suspected.
3. Convincing the patients suffering from Kala-azar to complete the treatment.
4. Rationalizing use of RD Kits (Rapid Diagnostic test) as per the program guidelines.
5. Undertaking advocacy with the community for participation in ensuring complete and uniform coverage of their households with insecticides (IRS).
6. Behavior change communication (BCC).
7. Checking up to date maintenance of records and timely submission of reports.

11.7 Role of Development Partners

BMGF /CARE is supporting the programme by providing human resource like District Prgramme Officer (DPO), Block Coordinators in endemic blocks & state level experts who monitor the proramme as per NVBDCP guidelines.

Chapter-12

Kala-azar Logistics

- For successful implementation of the programme strategies, availability of the material and equipment should be ensured.
- Inventories to be made of the drugs, diagnostic kits, Insecticides, spray equipments, monitoring formats etc.
- Supply chain management at the state/district/Block PHC level to be monitored & strengthened.\
- Any shortfall to be conveyed in advance so that timely logistic supplies are made wherever, necessary.

12.1 Logistic of anti-Kala-azar drugs

12.1.1 Drug management cycle of anti-Kala-azar drugs

The management cycle of anti-Kala-azar drugs comprises many multiple drugs including single day treatment with Liposomal Amphoterecin B (LAMB) There are five elements which are involved in the management of drug cycle:

- drug selection
- quantitative assessment of drug requirements
- management of procurement and distribution
- assurance of drug quality
- ensuring rational drug use

A number of factors must be considered when selecting Kala-azar drug, including the efficacy of the drugs, success of the treatment regimen, adherence, the treatment strategy, possible side effects, and the cost of the treatment. Accurate demand forecasting of Kala-azar drugs, i.e. correct quantification of the drug needs for a specific period of time, is one of the elements that guarantees an uninterrupted drug supply. There are two main approaches for demand forecasting:

Usually, the most precise method for demand forecasting is the consumption-based approach, consisting of projection of future needs based on records of past consumption of individual drugs. This method assumes that the data are complete, accurate, and properly adjusted for stock-outs and anticipated changes in demand and use. This method is recommended once KA-DOT activities have been established for a period of time.

The morbidity-based approach method is recommended for the initial phase of KA-DOT activities. In this method, the standardized treatment regimen and the number of patients to be treated are taken into account. Several other key factors must also be considered, including the existing stock, lead time for delivery, safety stock needed and the shelf lives of the drugs.

Availability of drugs and diagnostics should be available in all the health facilities round the year.

The details with regard to the position of insecticide, drug and diagnostics and stock report on spray equipment are to be provided in the format placed at **Annexures 14, 15 & 16** respectively.

Chapter 13

Process of verification for elimination of Kala-azar as a public health problem- Constitution National Commission on Kala-azar Elimination

13.1 As discussed in Chapter 3, the goal of elimination has been set by National Health Policy (NHP) (2002) to be achieved by 2015. In order to realize this national objective, GoI and the endemic states are providing the requisite inputs with all the zest and fervour as a result of which the country is left with only 26% of blocks which are still showing more than 1 case per 10,000 population, however, further studies and subsequent analysis done by NVBDCP and its partners have identified 49 blocks (43 in Bihar, 2 in Jharkhand and 4 in West Bengal) which need special focus and intensified intervention to fall in line with national objective of elimination.

Kala -azar is targeted for elimination by 2015 for which endemic countries needs verification of the elimination by WHO independent verification team. For attaining the verification, few steps have been described below for states. These will also serve as check list for attaining elimination.

The expected impact of elimination initiative includes (i) reducing KA in the vulnerable, poor and unreached populations in endemic areas; (ii) to reduce case-fatality rates from KA to a negligible level; (iii) to reduce cases of Post Kala-azar Dermal Leishmaniasis (PKDL) to interrupt transmission of KA; and (iv) to prevent the emergence of KA/HIV/TB co-infections in endemic areas.

CARE has done one study on disease burden in 8 endemic districts of Bihar and their unpublished document says that approx. 96% cases are reporting to public sector facilities and 4% cases are going to private practionears and others. Since the study has not been published the true burden of the disease is not known exactly. Moreover, cases of Post Kala-azar Dermal Leishmaniasis (PKDL) are considered to be potential reservoirs particularly during the inter-epidemic periods. There has been an increase in cases of PKDL reported in Jharkhand and West Bengal in 2014.

The process of verification of KA elimination will commence subsequent to achieving the target of elimination by the country, however, there is a need to monitor sustained elimination after that point. There is a need for a standardized approach on an objective basis and according to agreed criteria. WHO will facilitate national preparations for verification of the elimination by providing technical support or consultants to the country to support the activities as per country need.

13.2 Criteria for verification

13.2.1 Need for standard criteria for verification of elimination:

There is a need for standard criteria for the following reasons:

1. The elimination initiative is an international, trans-border effort, and countries voluntarily adopt a common approach.
2. To ensure international credibility for the expected future claim that KA has been eliminated in a given country.
3. To have standard and consistent criteria and a mechanism to assess the achievement of elimination in a country.

13.3 Criteria for reaching elimination target at country level

A country has reached the Kala-azar elimination target when the following criteria have been met:

I. All the preconditions in the national elimination programme are present
II. The country programme is in the consolidation phase
III. Annual incidence of Kala-azar below one per 10,000 populations, at block PHC for a minimum of 3 consecutive years.

13.4 Criteria for sustained elimination

Throughout the maintenance phase, an annual incidence rate of Kala-azar below one per 10,000 populations, at block PHC level.

13.5 Process of verification of reaching the Kala-azar elimination target:

13.5.1 National preparations for verification

All the following preconditions need to be fulfilled by endemic states:

I. Presence of an updated comprehensive national strategic guideline for Kala-azar elimination along with:
    a) SOP for all key activities.
    b) Innovative IEC/BCC strategy and action plan adjusted to individual state situation.
    c) Comprehensive M&E strategy for KA as a whole along with specific guidelines
II. Adequate health services for early detection and effective treatment and follow-up of all KA and PKDL cases
III. Existence of a high quality epidemiological surveillance system with full coverage of all endemic areas. This includes:

a) Kala-azar to be a reportable disease (compulsory notification), this should include case reporting by the private health sector. Bihar and West Bengal states have notified. Jharkhand and Uttar Pradesh still not notified.
b) A national Kala-azar case register and HMIS system to collect information on key variables.
c) Routine and minimum once yearly conduction of active case finding for KA and PKDL.
d) Robust and representative estimates of the under reporting ratio following the standard methodology.
e) Presence of sentinel surveillance for HIV-VL co-infection in the Kala-azar endemic countries.

IV Integrated vector management in the endemic areas in place with proper quality assurance mechanisms which includes
1) Regular IRS spraying in the endemic areas along with monitoring with tool kits
2) Use of insecticide treated nets as per the national policy guidelines and recommendations
3) Environmental management.
4) Entomological surveillance (Pre and post spraying) and monitoring of insecticide resistance in areas.

V. Existence of an effective supply chain management for all commodities (drugs, diagnostics, vector control tools) that is benchmarked on key processes of quality assurance and timeliness in procurement

VI A functional cross- border coordination system, wherever relevant.

13.5.2 Adequate access to diagnosis and treatment of Kala-azar

i. Availability of high-quality laboratory services to diagnose Kala-azar and PKDL, based on rapid diagnostic test (RDT) at Primary Health centre (PHC) level and microscopy of tissue aspirates at district hospital level should be established in the endemic areas.
ii. Availability of 1st and 2nd line drugs for treatment at all the levels of health facilities should be ensured.
iii. Quality control systems and regular training of health staff on diagnosis and treatment should be present including
iv. The quality of the treatment, in terms of dosage, regimen, completeness, supervision and follow-up, in accordance with current established guidelines.
v. The quality of the laboratory examination meets the accepted norms and the presence of an organized quality-control/quality-assurance system

vi. Timely detection and reporting of the cases.
vii. A functioning referral system for Kala-azar patients from a lower to higher level health facility should be established.
viii. Adequate pharmacovigilance.

13.5.3 High-quality epidemiological surveillance of Kala-azar

A quality assured epidemiological surveillance system with full coverage of all endemic areas needs to be in place. This requires exhaustive, sensitive, specific, complete and timely reporting by all implementing units. The reported figure should reflect as closely as possible the true incidence rate. Therefore, the information has to be based on both passive surveillance and regular active case finding in each unit. As several cases of Kala-azar are being treated outside the public health facilities, the country epidemiological surveillance system should make sure information from private sector is captured. The endemic states should document on a regular basis the proportion of unreported cases. This under reporting ratio can be estimated through operational research studies.

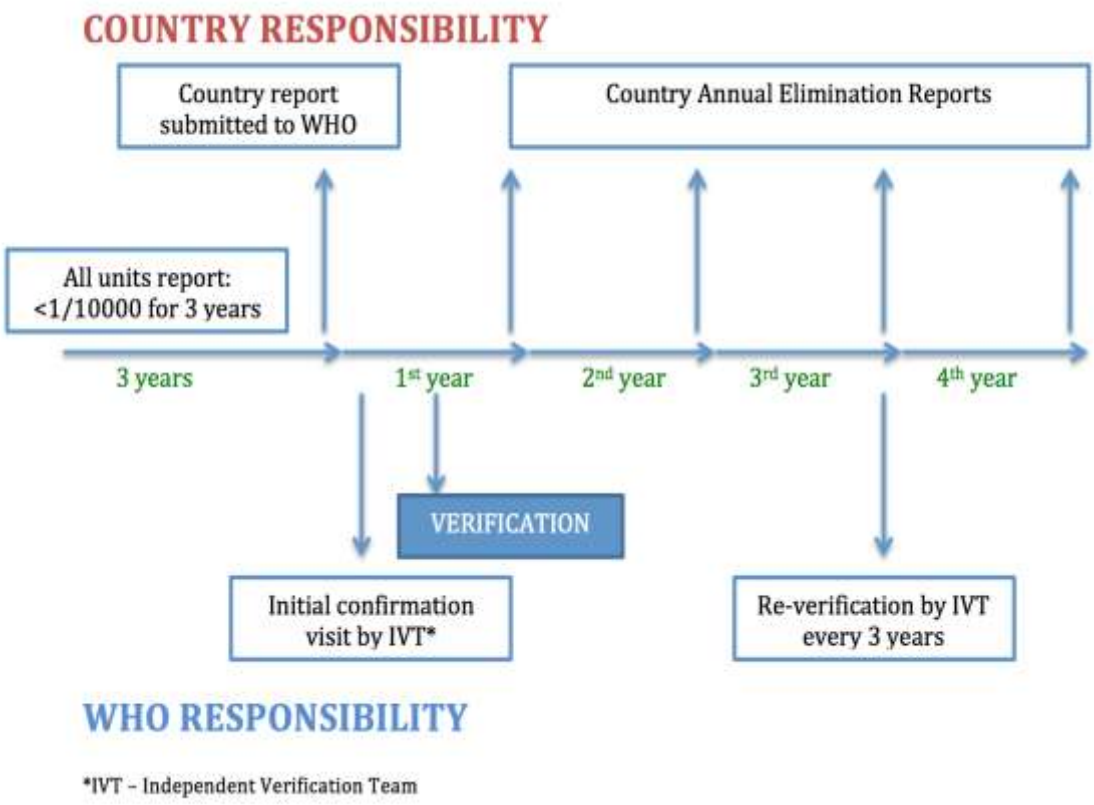
13.5.3.1 The following are essential for the surveillance:

I. Kala –azar should be a notifiable disease by the state. States should have a mechanism for receiving reports of Kala-azar cases from the private health providers in the endemic areas and these cases should be included when calculating incidence rates.
II. Cases should be reported according to their implementation unit of origin to avoid double counting of cases. A unique "Patient Identification Code" should be introduced at each health facility including the privately sector.
III. Active case finding activities for KA and PKDL need to be conducted as a regular activity (quarterly) in each of the implementing units (block PHC). The strategy for active case finding would depend on the level of endemicity
IV. A comprehensive information system should be established with collation of data at each of the reporting unit (block PHC) including data collation from private sectors. Incidence of Kala-azar should be reported as number of cases per 10,000 populations per year, at block PHC level.
V. Regular use and analysis of surveillance data with appropriate and regular feedback mechanism to reporting units.

13.5.4. When to ask for verification:

When all above preconditions have been fulfilled and the reported incidence rate for each of the implementing units observed to be below 1 in 10,000 for **at least 3**

consecutive years, the country may start the process of verification of target and re-verification. Figure below indicates the flow chart of elimination.



13.6 Preparation of country report about reaching the target

If required the country may seek the support from WHO for technical support to prepare such a report. The content of the report needs to be shared with WHO which should include the following:

I. Documents supporting all pre-conditions have been fulfilled.
II. Detailed account of the historical perspective and epidemiology of Kala-azar in the country
III. Description of the elimination programme strategy.
IV. Description of the surveillance system including active case finding strategies, collection of data from private health facilities, information system and
V. Robust and representative estimates of the proportion of unreported cases according to the standard methodology
VI. Diagnostic and treatment strategy for Kala-azar.
VII. Quality control and monitoring system for the activities within the programme.
VIII. Report by year on the following :

a. No of endemic units, population at risk.
b. Annual incidence rate of KA (new and relapse) in each unit.
c. Annual incidence rate prevalence of PKDL should be calculated in each unit
d. Report on number of active case finding conducted in each endemic unit
e. Proportion of targeted private health facilities reporting Kala-azar cases.
f. Proportion of health facilities having adequate diagnostic facilities
g. Operation research conducted to detect proportion of unreported cases.

Before validation by WHO independent Team, MOHFW, GoI will constitute **Kala-azar Commission** which will guide the central and state prgramme managers on the following to declare country free from Kala-azar:

a) Ensure that the endemic areas in all the four states are free from Kala-azar before inviting a WHO sponsored certification team for endorsing the positive report of national commission.
b) The states now need to prepare themselves in order to meet the requirement of this commission. The commission while visiting the states shall focus on process and impact assessment. The states therefore need to take a proactive role in the preparation of the following:
    (a) Documentation of all the communications in a chronological order regarding the relevant aspects of Kala-azar elimination programme. These documents should include minutes of the meetings held at the state level, Action taken report etc.
    (b) Trainings conducted with dates, lists of participants and a follow up at district /block level.
    (c) Human Resource (posts in position against sanctioned)
    (d) Details of the expenditure (Allocation and release).
    (e) Detailed procurement documentation, made if any.
    (f) Details of video conference and other related measures.

c) In addition, a computerized documentation of all the parameters like Demographic profile, Health Infrastructure, epidemiological data for last 5-10 years, Intervention measures including IRS, Innovations by the state, logistic position, problems and constraints etc. have to be prepared and filed. Besides this documentation, electronic availability of weekly/monthly data year wise in a chronological order has also to be ensured. The above documentation is a pre-requisite for all the states. Similarly District Vector Borne Disease Officers need to be communicated to make above preparations at district and block levels.

d) At block levels all the registers like resident and non-resident case registers, treatment cards, inventories of drugs and diagnostics, insecticides used, spray equipment etc has to

be kept in full readiness. Details of IEC activities carried out during the past 5-10 years have also to be documented. Details of patients especially the addresses have to be verified so that the teams coming to evaluate the programme reach correct addresses for case verification. A definite time line (preferably by December 2015) needs to be fixed so that all the data are collected, collated, analyzed and presented in the above format within the prescribed time limit.

Annexure-1

Reporting Format

Block/PHC wise & Month wise Kala-azar Report

S. No.	Name of the District	Name of the Block/PHC	Population	Jan		Feb		Mar		Apr		May		Jun		Jul		Aug		Sep		Oct		Nov		Dec		Total	
				C	D	C	D	C	D	C	D	C	D	C	D	C	D	C	D	C	D	C	D	C	D	C	D	C	D

Annexure-2

Reporting Format
Statewise, Districtwise and Monthwise statement showing the Cases & Deaths due to Kala-azar

Sl. No.	Name of the District	Jan		Feb		Mar		Apr		May		Jun		Jul		Aug		Sep		Oct		Nov		Dec		Total	
		C	D	C	D	C	D	C	D	C	D	C	D	C	D	C	D	C	D	C	D	C	D	C	D	C	D
	Name of the State																										

Annexure-3

State reporting format

STATE : ……. **MONTH : ……. YEAR: ……..**

Sl. No.	Name of the District	No. of PHCs		Population of affected PHCs	Report up to Previous Month			Reported during the Month			Progressive Total			Cases under treatment	Untreated Cases	Resistant Cases	PKDL Cases	Remarks
		Total	Affected		Cases	Deaths	Treated	Cases	Deaths	Treated	Cases	Deaths	Treated					
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19

Annexure-4

Reporting Format

National Vector Borne Disease Control Programme

Line List of Kala-azar Cases

State : _____

Districts : _____

S.No.	Name of Block/ PHC	Population of Block/PHC	Name of Village	Population of Village	Patient's Name	Age	Sex	Date of Diagnosis	Name of Drug	Date of Completion of treatment	Whether Patient has been followed for 6 Months Yes/No	Death	Remarks
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*

(District Malaria Officer)

Note: ASHA/KTS/ VBD Consultant may ensure the follow up of confirmed cases after full treatment for six months period for any other complication.

Annexure 5

Spleen aspiration procedures

Materials needed

- 5 ml syringes and needle (1¼-inch x 21-gauge/32 x 0.8 mm)
- Clean microscope slides
- Wooden applicator or tooth picks
- Spirit lamp with sufficient flame
- Drapes
- Sterile gloves
- Sterile cotton and gauze
- Plaster
- Labels
- Pen and pencil/marker

Pre-operative procedures

Patient is physically examined and the following contraindications excluded:

- Hgb level is not less than 3.0 gm/dl
- Patient has no bleeding tendency and is not jaundiced
- Patient is not at an advanced stage of pregnancy
- Prothrombin time is not more than 5 seconds longer than control or platelet count is not less than 40,000/mm^3
- Patient (in case of children) cannot lie still
- The spleen should be palpable at least 3 cms below the costal margin on expiration
- Vital signs (BP and pulse) are not prohibitive for performing the procedure (splenic aspiration)

Aspiration procedures

1. Put on sterile gloves and cover the aspiration site with sterile drapes
2. Palpate the spleen and outline its margins on the patient's abdomen. A pencil may be used to mark the margins.
3. Clean the skin at site of aspiration with alcohol swab and allow to dry [site of aspiration is 2 – 4 cms below the costal margin at the mid-line of the spleen on the anterior surface)

4. With the needle attached to the syringe, penetrate the skin mid-way between the edges of the spleen
5. Aim the needle cranially at an angle of 45° to the abdominal wall
6. While in the skin, create a vacuum up to 1.0 cc mark of the syringe by pulling the plunger
7. While maintaining a 1.0 cc vacuum, push the needle to its full length (3 cms) into the spleen and pull out completely with a quick in-and-out movement (less than 1 second)

N.B. Carry out the procedure using the same landmarks, angles and suction

- The axes of entry and exit of the aspirating needle should be identical
- Maintain suction throughout the procedure
- Carry the aspiration in a single-step procedure all in one quick motion (about 1 second)

- In restless children, arms should be folded across chest and held with an assistant in addition to the pelvis, which should also be held firmly by a second assistant
- The insertion of the needle should be timed with the patient's breathing so that the diaphragm is not moving, i.e., during fixed expiration in a crying child

Once the aspirating needle is withdrawn, pull the plunger slowly to the 2 – 3 cc mark [Note that only minute amounts of splenic material is visible in the syringe, lumen of the needle or end of the plunger]

8. The material can then be expelled on to clean slides and inoculated into appropriate culture medium (NNN medium preferably)

   For smears, expel any remaining material gently on clean glass slides holding tip of needle on the surface of slide, and spread evenly into a smear immediately using a linear motion.

   More material can be obtained at the end of the plunger or the top end of the needle (or tip of syringe) after removing the plunger and needle. Tooth picks or wooden applicators may be used

9. Slides can be stained with Leishman, Giemsa or Wright's stain.

Post-operative procedures:

1. Record time of aspiration on the patient's chart.
2. Record pulse and blood pressure ½ hourly for 4 hours and hourly for 6 hours.
3. Patient should remain in bed for 12 hours and observed.

N.B. - Facilities for blood transfusion and surgical intervention may be needed during splenic aspiration procedures.

- Experience shows that risk of mortality from aspiration procedure may happen 1 in 1000 cases aspirated

4.7.2 Lymph node (LN) aspiration procedures

Materials needed

- 5 ml syringes and needle (1¼-inch x 21-gauge/32 x 0.8 mm)
- Clean microscope slides
- Wooden applicator or tooth picks
- Spirit lamp with sufficient flame
- Drapes
- Sterile gloves
- Sterile cotton and gauze
- Plaster
- Labels
- Pen and pencil/marker

Pre-operative procedures

No specific procedures are needed, except that inguinal or epitrochlear lymph nodes should be palpable.

Aspiration sites

The inguinal and epitrochlear lymph nodes are most convenient for the procedure.

Aspiration procedures

1. Label a slide with the patients' reference number using a diamond pencil and clean the slide with gauze or dry cotton wool.
2. Rest the patient on the back with the legs stretched out. Another person can hold down the patient if he/she is restless. If it is a small child, the mother can hold him/her in her lap.
3. Put on sterile gloves, cover the aspiration site with sterile drapes, and disinfect the skin over the lymph node with cotton wool soaked in 70% alcohol or iodine and allow drying.
4. Grasp the lymph node between the thumb and index finger of the left hand and insert a sterile 21-gauge needle attached with a 5 ml syringe into the centre of the gland at right angles to the skin. Avoid adjacent blood vessels.
5. Gently squeeze the node with the left hand and twirl the needle in the right hand, at the same time pushing the needle in and out, and pull the plunger to maintain

suction [This may be done for a few minutes, until some tissue is visible at the end of the lumen of the needle]

N. B. The procedure may be painful, but tolerable (no anaesthesia is needed)

- Big LNs may fill the needle with lymph and dilute the tissue; and so smaller but palpable LNs are preferred.
- Lymph nodes might be difficult to grasp by two fingers, hence caution should be made not to sample the surrounding fatty tissues. Palpable lymph nodes (size more than 1x1 cm) are usually felt in the inguinal, femoral and epitrochlear regions.

6. The material can then be expelled on to clean slides and also inoculated aseptically into appropriate culture medium (preferably NNN medium).

For smears, expel any remaining material gently on clean glass slides holding tip of needle on the surface of slide, and spread evenly into a smear immediately using a linear motion. More material can be obtained at the end of the plunger or the needle (or tip of syringe) after removing the plunger and needle. Tooth picks or wooden applicators may be used for this purpose.

N.B. For cultures, insert needle into a tube containing culture medium and push the plunger into the barrel to expel contents of the needle on to the side walls of the tube or directly into the liquid phase of the medium. You may repeat this once or twice until the LN material is visible in the tube. For safety purposes, inoculate 2 culture tubes.

4.7.3 Bone Marrow aspiration procedures

Materials needed

- Sterile Bone Marrow needle
- 10 ml syringe
- Clean microscope slides
- NNN or any other suitable culture medium
- Wooden applicator or tooth picks
- Spirit lamp with sufficient flame
- Drapes
- Sterile gloves
- Sterile cotton and gauze
- Plaster
- Labels
- Pen and pencil/marker

Biopsy aspiration needles (recommended sizes):

Regular/Adults:	4-inch, 11-gauge
Adults:	4-inch, 8-gauge
Orthopaedic:	6-inch, 10/11-gauge
Paediatric:	3 ½ -inch, 13-gauge
Infant:	2-inch, 13-gauge

Aspiration procedures

1. Place the patient in a right or left lateral decubitus position with the back comfortably flexed and the top knee drawn towards the chest.
2. Locate the posterior iliac spine and mark with ink or thumb nail pressure
3. Using sterile technique, prepare the skin with anti-septics and drape
4. Using sterile syringe, apply/infiltrate the marked area with anesthesia especially in the peritoneum
5. Make a 3-mm skin incision with a scalpel blade over the marked area.
6. Hold the needle with the proximal end in the palm and the index finger against the shaft near the tip.
7. With the stylet locked in place, introduce the needle through the incision pointing towards the anterior superior iliac spine and bring it into contact with the posterior iliac spine.
8. Using gentle but firm pressure, advance the needle to bore through the iliac spine.
9. Rotate the needle in an alternating clock-wise and counter-clockwise motion. Entrance into the marrow cavity is generally detected by decreased resistance.
10. Remove the stylet, and check for presence/absence of marrow material. If not, proceed to bore until marrow is found in the tips of the stylet.
11. With a syringe locked into the proximal portion, apply a negative pressure.
12. The material can then be expelled on to clean slides and also inoculated into appropriate culture medium (preferably NNN medium)

    For smears, expel any remaining material gently on clean glass slides holding tip of needle on the surface of slide, and spread evenly into a smear immediately using a linear motion. More material can be obtained at the end of the plunger or the needle (or tip of syringe) after removing the plunger and needle. Tooth picks or wooden applicators may be used for this purpose.

    It is important that culture tubes are not over loaded by large amounts of inoculum, which is not uncommon with BM aspirates.

13. Slides can be stained with Leishman, Giemsa or Wright's stain. NNN cultures should be incubated at 25^0C for up to 2 weeks.

4.7.4 Preparation and staining of aspirates

Materials needed
Slides rack, staining rack or staining trough, 100% methanol, filtered stock of Giemsa stain

Fixation

- Place the slides horizontally on the slide rack and leave to air dry.
- Fix the slides by dipping them in 100% methanol for 1minute. The methanol must be stored in a tightly closed bottle to prevent absorption of water.

Staining

- Stain the slides with Giemsa stain 1: 10 concentration; 1ml of stock Giemsa stain to 9ml buffer solution pH 7.2. In the absence of buffer solution, tap water or filtered water can be used provided the pH is 7.2. The slides can either be stained in a staining trough or on a staining rack. When the stain concentration is 1:10, the staining time is 10 minutes.
- At the end of the staining, rinse the slides briefly with tap water or filtered water and place them in vertical position on a slides rack to dry.

Reading Slides:

Examine at least 300 microscope fields for amastigotes using 100 ^{x} oil immersion lens. An artefact is more likely to be taken for a parasite if the microscopists are overloaded (more than 4 hours of microscopy per day), have poor light for the microscopes, or if dirty (unfiltered) Giemsa is used. It takes at least 20 minutes or 300 microscope fields of reading to label a slide as negative.

Annexure 6

Liposomal Amphotericin B dosage sheet

10 mg/Kg Liposomal Amphoterecin B - doses							
Hospital level use							
Weight in kg	Liposomal Amphoterecin B doses (10 mg/kg)	No. of Vials	mls Diluted Liposomal Amphoterecin B in 12 ml water	Minimum Volume (2mg/ml)	Maximum volume (0.2 mg/ml)	Suggested volume in ml	Drops/min infusion 15-120 min
5	50	1	12.5		250	100	15
6	60	2	15.0	30	300	100	15
7	70	2	17.5	35	350		
8	80	2	20.0	40	400		
9	90	2	22.5	45	450		
10	100	2	25.0	50	500	300	60
11	110	3	27.5	55	550		
12	120	3	30.0	60	600		
13	130	3	32.5	65	650		
14	140	3	35.0	70	700		
15	150	3	37.5	75	750		
16	160	4	40.0	80	800	400	90
17	170	4	42.5	85	850		
18	180	4	45.0	90	900		
19	190	4	47.5	95	950		
20	200	4	50.0	100	1000		
21	210	5	52.5	105	1050	500	90
22	220	5	55.0	110	1100		
23	230	5	57.5	115	1150		
24	240	5	60.0	120	1200		
25	250	5	62.5	125	1250		
26	260	6	65.0	130	1300		
27	270	6	67.5	135	1350		
28	280	6	70.0	140	1400		
29	290	6	72.5	145	1450		
30	300	6	75.0	150	1500		
31	310	7	77.5	155	1550		
32	320	7	80.0	160	1600		
33	330	7	82.5	165	1650		
34	340	7	85.0	170	1700		

35	350	7	87.5	175	1750		
36	360	8	90.0	180	1800		
37	370	8	92.5	185	1850		
38	380	8	95.0	190	1900		
39	390	8	97.5	195	1950		
40	400	8	100.0	200	2000		
41	410	9	102.5	205	2050		
42	420	9	105.0	210	2100		
43	430	9	107.5	215	2150		
44	440	9	110.0	220	2200	500	90
45	450	9	112.5	225	2250		
46	460	10	115.0	230	2300		
47	470	10	117.5	235	2350		
48	480	10	120.0	240	2400		
49	490	10	122.5	245	2450		
50	500	10	125.0	250	2500		
51	510	11	127.5	255	2550		
52	520	11	130.0	260	2600		
53	530	11	132.5	265	2650		
54	540	11	135.0	270	2700		
55	550	11	137.5	275	2750		
56	560	12	140.0	280	2800		
57	570	12	142.5	285	2850		
58	580	12	145.0	290	2900		
59	590	12	147.5	295	2950		
60	600	12	150.0	300	3000		
61	610	13	152.5	305	3050		
62	620	13	155.0	310	3100		
63	630	13	157.5	315	3150		
64	640	13	160.0	320	3200		
65	650	13	162.5	325	3250		
66	660	14	165.0	330	3300		
67	670	14	167.5	335	3350		
68	680	14	170.0	340	3400		
69	690	14	172.5	345	3450		
70	700	14	175.0	350	3500		
71	710	15	177.5	355	3550		
72	720	15	180.0	360	3600		
73	730	15	182.5	365	3650		
74	740	15	185.0	370	3700		
75	750	15	187.5	375	3750		
76	760	16	190.0	380	3800	1000	90

77	770	16	192.5	385	3850		
78	780	16	195.0	390	3900		
79	790	16	197.5	395	3950		
80	800	16	200.0	400	4000		
81	810	17	202.5	405	4050		
82	820	17	205.0	410	4100		
83	830	17	207.5	415	4150		
84	840	17	210.0	420	4200		
85	850	17	212.5	425	4250		
86	860	18	215.0	430	4300		
87	870	18	217.5	435	4350		
88	880	18	220.0	440	4400		
89	890	18	222.5	445	4450		
90	900	18	225.0	450	4500		
91	910	19	227.5	455	4550		
92	920	19	230.0	460	4600		
93	930	19	232.5	465	4650		
94	940	19	235.0	470	4700		
95	950	19	237.5	475	4750		
96	960	20	240.0	480	4800		
97	970	20	242.5	485	4850		
98	980	20	245.0	490	4900		
99	990	20	247.5	495	4950		
100	1000	20	250.0	500	5000		
101	1010	21	252.5	505	5050		
102	1020	21	255.0	510	5100		
103	1030	21	257.5	515	5150		
104	1040	21	260.0	520	5200		
105	1050	21	262.5	525	5250		
106	1060	22	265.0	530	5300		
107	1070	22	267.5	535	5350		
108	1080	22	270.0	540	5400		
109	1090	22	272.5	545	5450		
110	1100	22	275.0	550	5500		
111	1110	23	277.5	555	5550		
112	1120	23	280.0	560	5600		
113	1130	23	282.5	565	5650		
114	1140	23	285.0	570	5700		
115	1150	23	287.5	575	5750		

Annexure 7

Miltefosine dosage Guide for Adults (>12 year)

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 year)

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

Annexure 8

Paramomycin dosage guide for patients with normal renal function

For Patient Weighing (Kg)	Dose Volume (ml)	For Patient Weighing (Kg)	Dose Volume (ml)	For Patient Weighing (Kg)	Dose Volume (ml)
5	0.1	32	0.9	59	1.7
6	0.2	33	1.0	60	1.8
7	0.2	34	1.0	61	1.8
8	0.2	35	1.0	62	1.8
9	0.3	36	1.1	63	1.8
10	0.3	37	1.1	64	1.9
11	0.3	38	1.1	65	1.9
12	0.4	39	1.1	66	1.9
13	0.4	40	1.2	67	2.0
14	0.4	41	1.2	68	2.0
15	0.4	42	1.2	69	2.0
16	0.5	43	1.3	70	2.1
17	0.5	44	1.3	71	2.1
18	0.5	45	1.3	72	2.1
19	0.6	46	1.3	73	2.1
20	0.6	47	1.4	74	2.2
21	0.6	48	1.4	75	2.2
22	0.6	49	1.4	76	2.2
23	0.7	50	1.5	77	2.3
24	0.7	51	1.5	78	2.3
25	0.7	52	1.5	79	2.3
26	0.8	53	1.6	80	2.3
27	0.8	54	1.6	81	2.4
28	0.8	55	1.6	82	2.4
29	0.9	56	1.6	83	2.4
30	0.9	57	1.7	84	2.5
31	0.9	58	1.7	85	2.5

Annexure 9A

TREATMENT CARD

NATIONAL VECTOR BORNE DISEASE CONTROL PROGRAMME

STATE_____ CODE No: IND_____

DISTRICT_____ PHC_____ SUBCENTRE_____

KALA-AZAR TREATMENT CARD

Name : _____ Reg. No. _____ S/o, D/o, W/o: _____

Age : _____Sex : Male/Female

Address : _____

_____

Diagnosis with RDT: Positive / Negative Date of Diagnosis/ Confirmation: _____

Date of start of treatment: _____Date of completion of treatment: _____

Ensuring usage of contraceptives by MO (female patients): Yes/ No.

CLINICAL MONITORING (Every week to be recorded by the doctor)

I. Clinical: I II III IV

a) Weight

b) Loss of appetite

c) Fever

d) Anaemia

e) Spleenomegaly

f) Hepatomegaly

g) Any other

II. Lab :

a) TLC b). DLC c). Hb

d). Urine : Sugar Albumen

` **Yes**

No

Side reactions:

Minor .. Nausea
Vomiting
Diarrhoea

Major.. Jaundice
Decreased urine
Oedema

Prescription:

Doctor's Name, Designation & Signature

Annexure 9B

KALA-AZAR: TREATMENT SCHEDULE

Drug	Dosage
Liposomal Amphotericin B	10mg/kg bw intravenous infusion over 2 hours
Paramomycin/Miltefosine combination	Combination of Miltefosine given orally for 10 days (day 1-10) at 100 mg daily for adults over 25 kg, 50 mg daily for adults under 25 kg, and 2.5 mg/kg daily for children plus Paromomycin 11 mg/kg base given intramuscularly for 10 days (day 1-10)
Miltefosine	100 mg miltefosine daily as one capsule (50 mg) in the morning and one capsule in the evening, after meals for 28 days Adults (>12 years) weighing (less than 25 kg): 50 mg miltefosine daily as one capsule (50 mg) in the morning, after meals for 28 days Children (2-11 years): Miltefosine will be given at 2.5 mg/kg once daily after meals for 28 days The drug is not to be used in the case of children below 2 years of age and pregnant women/child bearing women
Amphotericin B injection deoxycholate injection	1 mg per kg. body weight on alternate days for fifteen doses.

***Separate Treatment Cards should be used for each course of treatment**

Annexure 9C

TREATMENT SCHEDULE

DRUG REGIMEN: INJ. Liposomal Amphotericin B or PM/MF/Ampho. B deoxycholate inj.
(Course details):

	1	2	3	4	5	6	7	8	9	10
Date										
Sig.of M.O.										

OUTCOME:

COMPLETE TREATMENT ☐

INCOMPLETE TREATMENT ☐

REASON'S FOR INCOMPLETE TREATMENT :

1. DEFAULT
2. SIDE EFFECTS
3. NON AVAIL ABILITY OF DRUGS
4. NON AVAI ABILITY OF MO/PARA MEDICAL STAFF
5. ANY OTHER, SPECIFY

IN CASE OF DEFAULT, MO INCHARGE UNDERTAKE DEFAULT RETRIEVAL

REMEMBER :

- Complete course of treatment is a must to cure Kala-azar.
- Incomplete treatment may require repeated courses of treatment for a prolonged period.
- Irregular treatment may cause drug resistance leading to severe complications.
- Ensure complete treatment of all Kala-azar patients in the family.
- In case of any side effects of treatment, report to the nearest health worker/health centre.
- Ensure your house and cattle shed are sprayed with DDT.
- Advise the community to get their houses and cattle sheds with DDT.
- Sleep away from cattle.
- Sleep on cots.

CASE DEFINITION

Person with fever of more than 15 days duration, not responding to anti-malarials and antibiotics with splenomegaly may be a suspected case of Kala-azar. Diagnosis and treatment for Kala-azar is available free of cost at your nearest health centre.

Annexure 10

Question 1. ***Testing for HIV in VL patients?***

Answer Considering that 2-5.6% of VL patients may be co-infected with HIV, it was recommended that all patients who are diagnosed with VL. (rk-39 positive (RDT for VL or otherwise) should be "offered" HIV testing with appropriate linkage to ICTC/F-ICTC where counseling and testing for HIV should be done with formed consent as per national guidelines. These will be done across the country but initial focus will be on four states viz. Bihar, West Bengal, Jharkhand and UP.

Question 2. ***Look up for VL in HIV infected patients?***

Answer The medical officers at ART centers in endemic states should be sensitized and trained to suspect for VL in all HIV positive individuals having fever >2 weeks duration, hepatosplenomegaly and pancytopenia from an endemic area. Such patients should be referred for VL testing with rk-39 (RDT). Those with rk-39 positivity should be immediately linked to facility where VL treatment is available. Those with rk-39 negative but high clinical suspicion for VL should undergo Bone marrow aspiration for confirmation of diagnosis as per algorithm.

Question 3. ***Can we treat all HN-VL co-infected persons with ART irrespective of CD+ counts?***

Answer Though, VL is not an AIDS defining illness the group felt that considering the fact that 79 to 97% of VL patients will relapse, If not started on ART, it was recommended that all HIV-VL co-infected persons to be put on ART irrespective of CD4 counts.

Question 4. ***Is there any need for secondary prophylaxis?***

Answer At the moment there is insufficient evidence to recommend secondary prophylaxis. Moreover, there were concerns about resistance in case secondary prophylaxis because of low dosages used.

Question 5. ***When to start ART-after VL treatment or simultaneously?***

Answer It was decided to start VL treatment immediately and ART to be started after 7-10 days once the patients has been adequately counseled and prepared for life-long ART.

Question 6. ***What would be the coordination mechanism between NACP and NVBDCP programme for of HIV-VL co-infected patients?***

Answer It was recommended that strong coordination mechanism be established

between NACP and NVBDCP at national level as well as at state level in these 4 states. For proper coordination M & E tools be developed for tracking of HIV-VL co-infected patients and regular reporting (on the lines of HIV-TB coordination mechanism). The state VBD officer should be involved in review meeting of ART centre at SACS level. It was also decided that of HIV-VL co-infected patients should be immediately tracked by outreach workers of CARE India and Support Centres (NACO) and brought back for adequate treatment.

Question 7. ***How to treat patients presenting with a relapse to 40mg/kg Liposomal Amphoterecin B (Liposomal Amphoterecin B (AmBisome))?***

Answer Since these patients are going to have multiple relapses even after HAART, best opt ion is to retreat them with Liposomal Amphoterecin B (Liposomal Amphoterecin B (Liposomal Amphoterecin B (AmBisome)))(40 mg/kg), Presently there is no recommendation for combination therapy and further evidence is needed.

1.5 Test of cure (TOC)

The test of cure is a splenic or bone marrow aspirate whereas the latter is less sensitive. If necessary, material can also be obtained from affected lymph nodes. With a therapeutic regime like Liposomal Amphoterecin B (Liposomal Amphoterecin B (AmBisome)), it is not essential to do TOC systematically to all patients, but in some cases it is important to evaluate if there is parasitological cure. See annexes for the procedures.
TOC may be necessary in:

i) Patients without a satisfactory clinical recovery.
ii) Patient who had previous treatment and have signs of clinical relapse.
iii) Those who interrupted the treatment (e.g. defaulted more than 2 weeks ago) and still have signs of disease.

- If negative aspirate and clinical recovery $\Rightarrow$ discharge.
- If negative aspirate in a patient who did not clinically recover $\Rightarrow$ do further investigations related to other diseases (especially HIV, TB) and repeat TOC after one week.

1.5.1 First relapse

A definitive cure is defined as an absence of signs and symptoms 6 months after initial cure (which was at the time of discharge). Therefore, to establish definite cure, active follow up should be done as part of the treatment centre activities. For definitive cure one looks at the clinical picture. No aspirate is necessary at follow up unless relapse is clinically suspected. Patients should be instructed to return for follow up.

If a person returns with symptoms, after having been treated and discharged well, the patient could have a relapse. It is impossible to differentiate a relapse from a re-infection. The later could occur in theory, but in practice it is improbable within the six-month period from treatment (e.g. transmission season, incubation period). Therefore, all are considered relapses and treated as such.

Annexure 11

Table- below indicates the quantity of the insecticide (DDT or SP) to be used for making appropriate suspension as well as the requirement per annum of the insecticide

INSECTICIDAL FORMULATIONS AND THEIR DOSAGES FOR INDOOR RESIDUAL SPRAY IN KALA-AZAR

Sl. No.	Name of the Insecticide	Preparation of suspension in water	Dosage per sq. metre of active ingredient	Residual effect in weeks	No. of spray rounds per annum	Requirement per million population		Area to be covered by 10 lit of suspension to get correct dosage
1	2	3	4	5	6	7	8	9
1.	DDT 50% wp	1 kg / 10 Lit	1 gm	10 - 12	2	37.5 MT	75 MT	500 sq. m
2.	Deltamethrin 2.5% wp (K-Othrine)	400 gm / 10 Lit	20 mg	10 - 12	2	15 MT	30 MT	500 sq. m
3.	Cyfluthrin 10% wp (Solfac)	125 gm / 10 Lit	25 mg	10 - 12	2	4.69 MT	9.38 MT	500 sq. m
4.	Lambdacyhalothrin 10 % wp (ICON)	125 gm / 10 Lit	25 mg	10 - 12	2	4.69 MT	9.38 MT	500 sq. m
5.	Alphacypermethrin 5%	250 gm/ 10 Lit	25 mg	10 - 12	2	18.75 MT	37.50 MT	500 sq. m

Annexure 12

Spray Operations at Village, Sub-centre, Health post (Name) _____ or /_____					
Village	Targeted		Sprayed		
	Houses	Rooms	Houses	Rooms	Locked/ Refused

Spray Operations At Village,S ub-center /Health Post(Name)_____/ on/ _____ _____

Insecticide Issued (Qty. wp)	Balance insecticide available from previous day	Number of buckets (10 liters)	
		Prepared	Consumed

Annexure 13

Training norms of different categories of functionaries

Whom	Location	Duration	No. per Batch	Responsibility
District level				
ASHA / AWW / CHV	Sector/ Block	2days (No night stay)	25	MO in charge assisted by KTS
MPHS/ MPW (M&F)	Block	3days	25	MO in charge assisted by KTS
MO (PHC)	District	3 days	25	Medical College
Physicians from district and other hospitals including private/NGO	Regional	2 day	25	Designated Medical College
State level				
Private Doctors	District	½ day	10	DMO/ IMA/ Pvt Sector/ SPO
National level				
Entomologists	Sub-National/ State	4 weeks	15	RMRI
DMOs	National / Sub-national	5 days	25	RMRI
VBD consultants	National / Sub-national	3 months	25	RMRI
State Program Managers/ Regional Directorate/ Entomologists/ VBD /State consultants	National	5 days	20	National VBDCP in collaboration with management experts

Annexure-14

STOCK REPORT ON DDT/SP/DRUGS

State _____ PHC _____

District _____ No. of sub-centres _____

Sl. No		Balance from previous year			Quantity received in (KTS) during the year			Total quantity (MT)	Qty. used In (M.Tons)		Qty. Balance (MT)
		Qty. (MT)	Date. of Manufacture	Date of Expiry	Qty. (MT)	Manufacture date	Expiry date		1st round		
1.	DDT 50% w.p.										
2	SP										
3	LAMB										
4	Miltefosine 10mg										
5	Miltefosine 50mg										
6	Paramomycin Inj.										
7	Amphotericin B Inj.										
8	Any other										

Annexure-15

NATIONAL VECTOR BORNE DISEASES CONTROL PROGRAMME

MONTHLY PROGRESS REPORT OF THE UTILIZATION OF rK39 DIP-STICKS (KALA-AZAR ELIMINATION PROGRAMME)

State ..... **District** ..... **Month** .....

MONTHLY PROGRESS										PROGRESSIVE TOTAL					
Name of PHC	Balance of rK39 test available as on Ist day of the month	No. of rK39 tests received from state during the month	Total stock of rK39 tests during the month	No. of suspected cases detected during the month		No. of rK39 tests (sample) conducted	**No. of cases confirmed with rK39**		Balance of rk39 tests available at the end of the month	Total No. of rK39 tests available upto reporting month	Total No. of rK39 tests used upto reporting month	No. of suspected cases detected upto reporting month		**No. of cases confirmed with rK39 tests upto reporting month**	
				Kala-azar	PKDL		**Kala-azar**	**PKDL**				Kala-azar	PKDL	**Kala-azar**	**PKDL**

Chief Medical Officer
District _____

Annexure-16

STOCK REPORT ON SPRAY EQUIPMENT

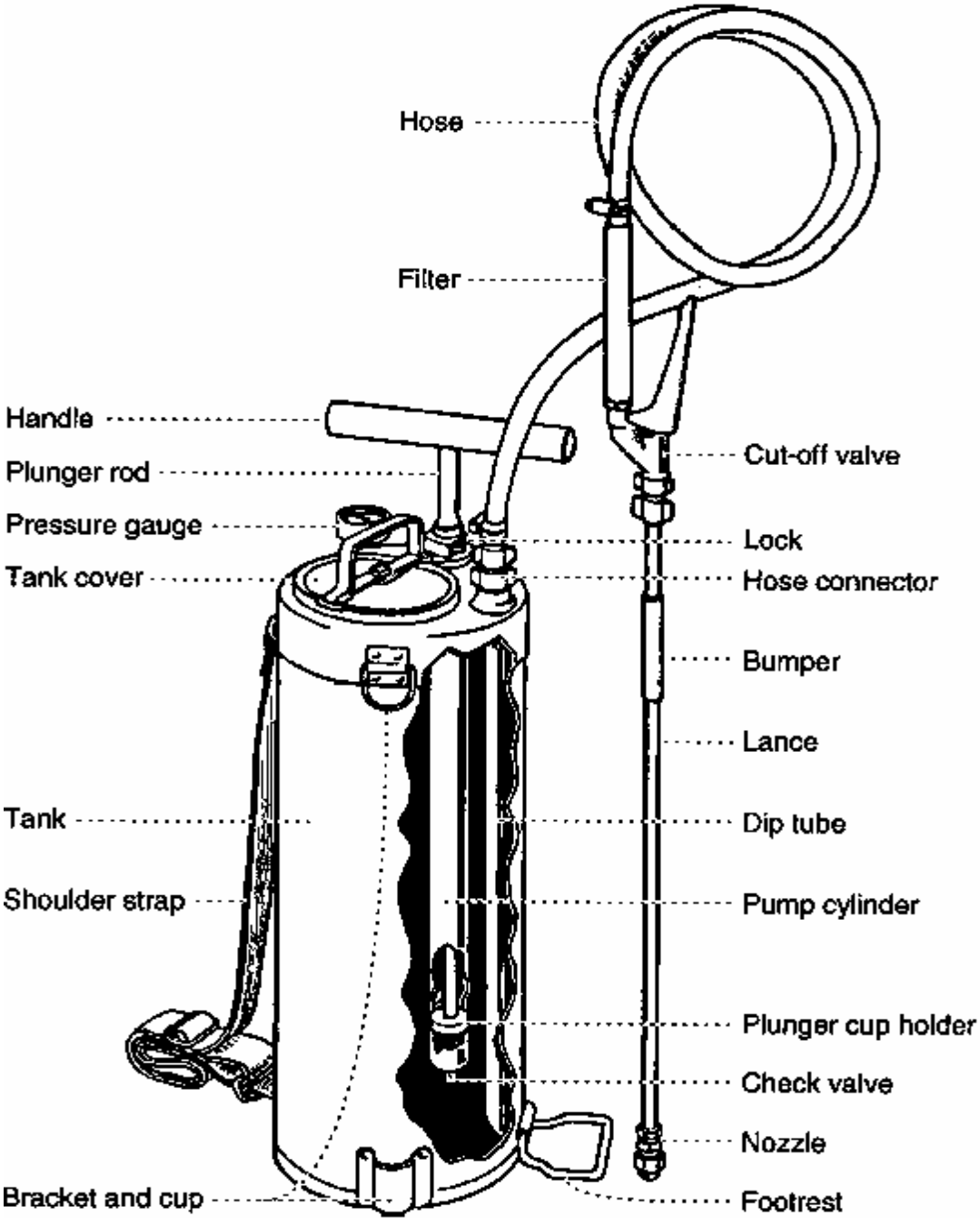
State _____PHC selected for spray_____

District _____No. of sub-centres _____

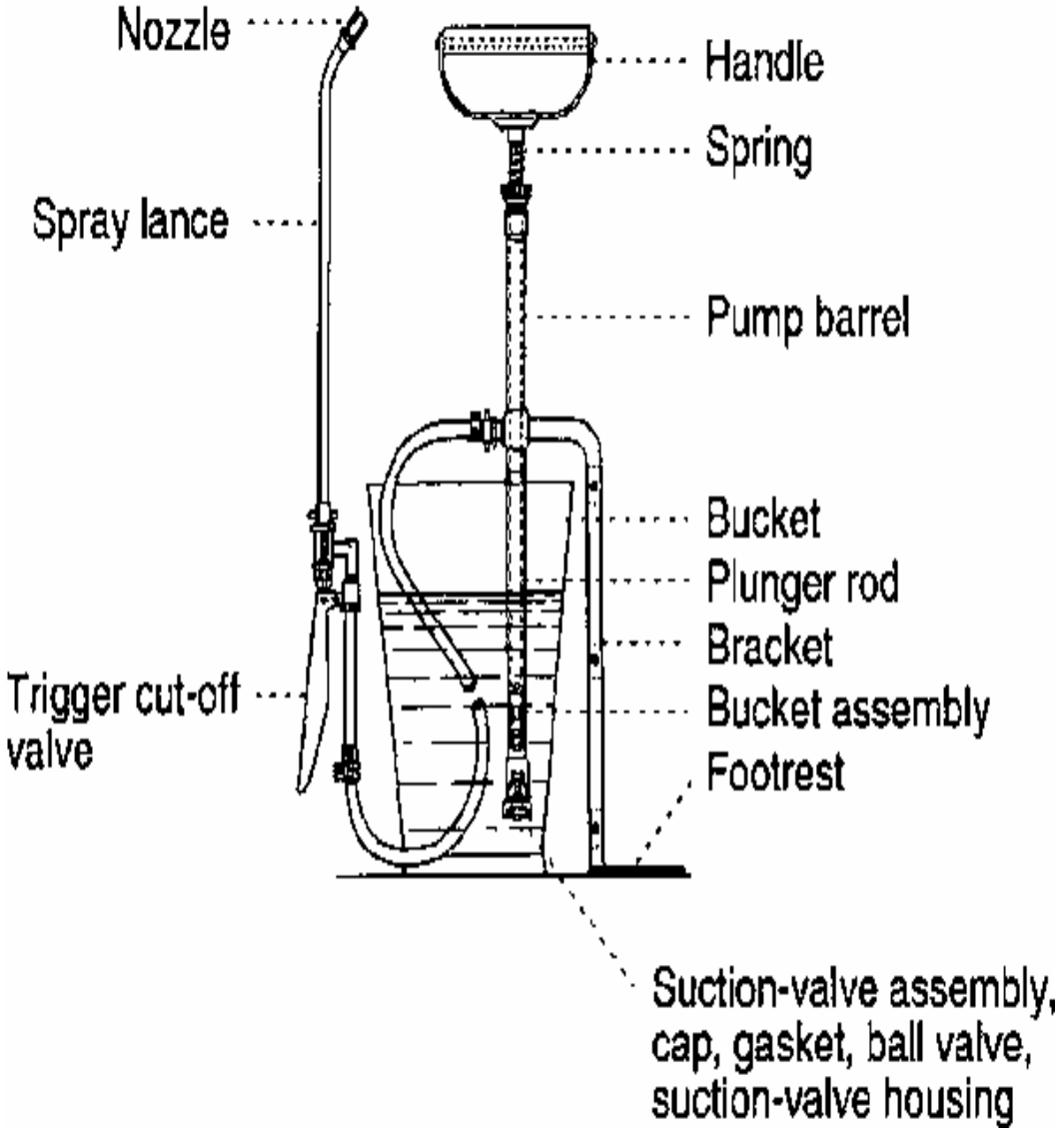
Name of Supervisor _____ Population _____

Sr. No.	Type of Sprayers	Balance in the beginning of the year	Received during the year	In working Order	Repairable	Unrepairable	Remarks

HAND COMPRESSION SPRAYER



STIRRUP PUMP SPRAYER



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