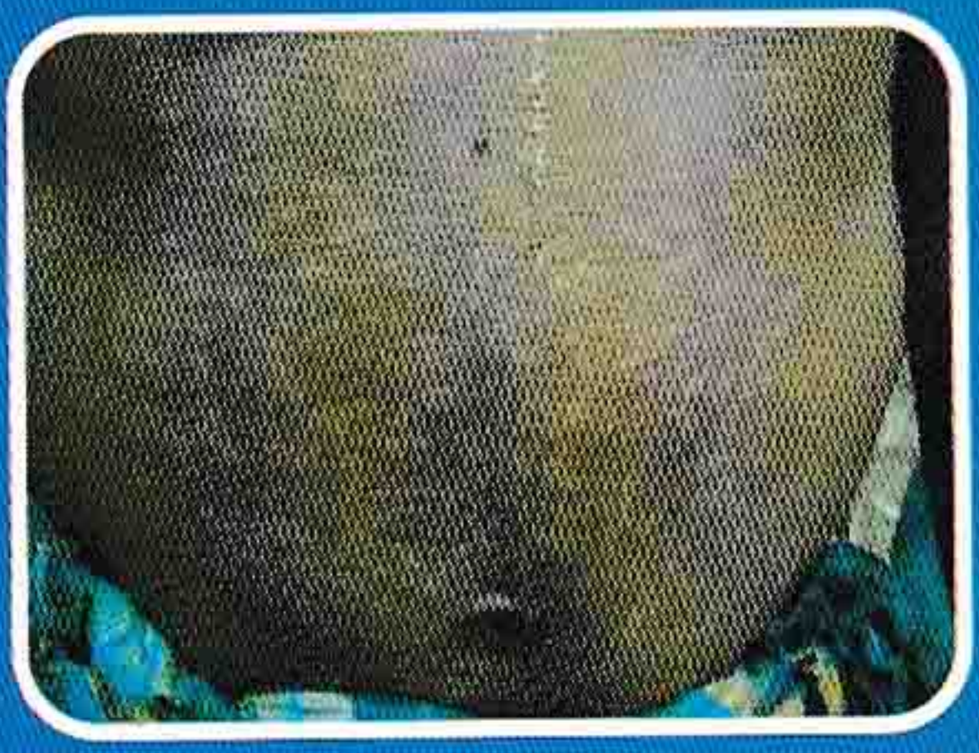
National Guideline
for Kala-azar Case Management

May, 2013



Kala-azar Elimination Program
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of the People's Republic of Bangladesh

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Honorable Minister
Ministry of Health & Family Welfare
Govt. of the People's Republic of Bangladesh

Message

In most of the developing countries communicable disease is as a major public health problem. Among all communicable diseases Kala-azar is one of the most neglected tropical diseases that attract little attention while claiming more than 50,000 lives every year. In Bangladesh Kala-azar is a major public health problem. I am much more delighted that Communicable Disease Control (CDC), DGHS has been publishing 'National guideline for Kala-azar Elimination in Bangladesh'.

The guideline will serve to provide the necessary guidelines, knowledge and strategies for the concerned people who are going to serve the patients of Kala-azar. I congratulate all those experts and resource persons who participated and were involved in every endeavor in developing 'National guideline for Kala-azar Elimination in Bangladesh'.

I wish every success for the initiatives taken by the Disease control unit, Directorate general of Health services (DGHS) for betterment of our health system.

Joy Bangla, Joy Bangabandhu.
Long live Bangladesh!

Professor AFM Ruhal Haque, MP
FRCS, FCPS, FICS

Honorable Advisor of Prime Minister
Ministry of Health & Family Welfare
Govt. of the People's Republic of Bangladesh

Message

It is an excellent news for our gratification that Communicable Disease Control (CDC) Division of DGHS is publishing 'National guideline for Kala-azar Elimination in Bangladesh'. Kala-azar is one of the major neglected tropical public health problems in developing countries including Bangladesh. Recent advancement of health commodities, development of new strategies, drugs and better management has reduced the morbidity and mortality both, but Kala-azar is occupying the disease burden in the resource limited countries like Bangladesh.

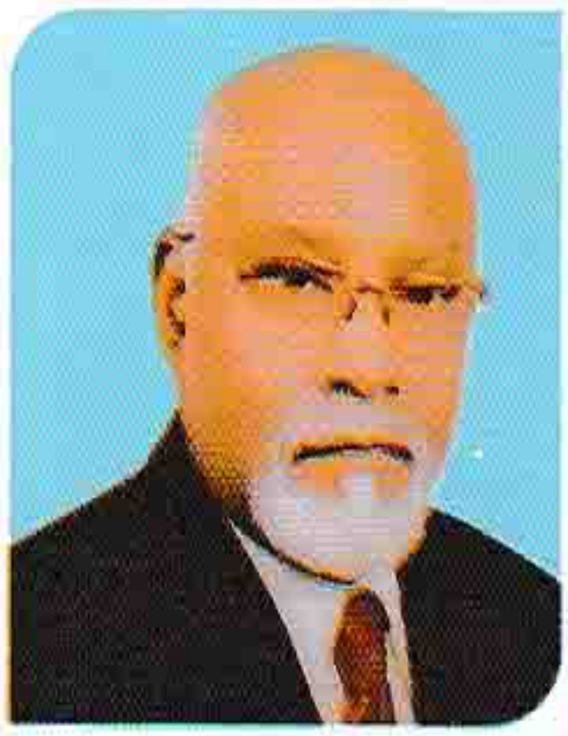
I am glad to know that 'National guideline for Kala-azar Elimination in Bangladesh' represents the national strategies, guidelines for treating the poor population in the community.

I would like to congratulate and express my cordial thanks and gratitude to CDC, Division of DGHS and all those experts and resource persons, who participated and were involved in every endeavor in developing 'National guideline for Kala-azar Elimination in Bangladesh'.

I wish immense success for all initiatives taken by the Disease control unit, Directorate general of Health services (DGHS).

Joy Bangla, Joy Bangabandhu.
Long live Bangladesh!

Prof. Dr. Sayed Modasser Ali
Advisor of Prime Minister MOH & FW



Honorable State Minister
Ministry of Health & Family Welfare
Govt. of the People's Republic of Bangladesh

Message

I am very much glad to know that Communicable Disease Control Division (CDC) of Director General of Health Services (DGHS) is going to publish 'National guideline for Kala-azar Elimination in Bangladesh' which will be a resourceful document for all physicians, researchers and the persons involved with Kala-azar disease in Bangladesh.

In 2005, total number of Kala-azar cases rose to more than 9000 and almost 40 districts became endemic. Like other developing countries, Kala-azar disease nests as a major neglected tropical disease in Bangladesh though recent development in the field of medicine has reduced both morbidity and mortality.

I believe that 'National guideline for Kala-azar Elimination in Bangladesh' will serve as guidelines for all level of health facilities in Bangladesh and could be very much useful for the planners, researchers and physicians.

I like to praise and express my heartiest thanks and gratitude to CDC, DGHS and all those experts and resource persons who were involved in every endeavor in developing for such a nice document.

I wish every success for the initiatives undertaken by the Disease control unit, DGHS for improving communicable disease control and health system in Bangladesh as well.

Joy Bangla, Joy Bangabandhu.
Long live Bangladesh!

Dr. Captain (Rtd.) Mozibur Rahman Fakir
State Minister

Secretary
Ministry of Health & Family Welfare
Govt. of the People's Republic of Bangladesh

Message

I am very much delighted to hear that Communicable Disease Control (CDC) Division of DGHS has published 'National guideline for Kala-azar Elimination in Bangladesh' with latest treatment guideline. Bangladesh Government has taken initiative for eliminating Kala-azar from Bangladesh and the national treatment guideline for Kala-azar will work as a step ahead to accomplish the initiative and also meet the goal set by MDG.

I am much more pleased that 'National guideline for Kala-azar Elimination in Bangladesh' describes the recent and upgraded treatment guidelines and national strategies in prevention and control of Kala-azar. I would like to praise and utter my heartfelt thanks and gratitude to CDC, DGHS for developing 'National guideline for Kala-azar Elimination in Bangladesh'.

I wish enormous success for all necessary steps taken by the CDC unit, DGHS for controlling infectious disease in our country.

M. M. Neazuddin
Secretary
MOH & FW

Director General
Directorate General of Health services (DGHS)
Ministry of Health & Family Welfare
Govt. of the People's Republic of Bangladesh

Message

I would like to express my great appreciation to the Disease control Unit, Communicable Disease Control, DGHS for publishing 'National guideline for Kala-azar Elimination in Bangladesh' to prevent and control of Kala-azar in Bangladesh.

Kala-azar is regarded as one of the most neglected tropical diseases that attract little attraction while claiming more than 50,000 lives every year. The vector borne disease transmitted by sandfly, generally affects the poor communities of the poor countries. In Bangladesh Kala-azar is major public health burden and affects people of a number of districts in Bangladesh. Though the disease was controlled during intensive DDT spraying for Malaria Control, it reemerged in the past decade and took several hundred lives since then.

'National Guideline for Kala-azar Elimination in Bangladesh' will serve to provide the necessary guidelines, knowledge and strategies for the concerned people that will strengthen the ongoing program for Kala-azar elimination.

I would like to express my heartfelt thanks and gratitude to all resource persons, consultants, experts and physicians who gave their valuable time and contributed to the development of this important guideline which will be an advantageous document for the patient and all level of physicians, researchers and the persons involved with Kala-azar of Bangladesh as well.

I like to praise and wish unbound success for all necessary steps taken by the CDC unit, DGHS for betterment of infectious disease control in our country.

Prof. Dr. Khondhaker Md. Shefyetullah
Director General
Directorate General of Health Services

Director
Disease Control & Line Director, CDC
Directorate General of Health services (DGHS)
Ministry of Health & Family Welfare
Govt. of the People's Republic of Bangladesh

Message

It's my immense pleasure that the Communicable Disease Control Unit (CDC) of the Directorate General of Health Services (DGHS) of the Ministry of Health and Family welfare of Bangladesh is publishing 'National guideline for Kala-azar Elimination in Bangladesh' which follows the latest management guideline for Kala-azar. With successful strategies, guidelines, recent advancement in diagnosis, management and preventive health education the morbidity and mortality due to Kala-azar have been reduced in the whole world and Bangladesh as well, but still remains as an important public health problem in Bangladesh.

Kala-azar remains one of the most neglected diseases affecting the poorest of the poor. But the present government and the honorable Health Minister are committed to eliminate the disease by the stipulated 2015 and offer all necessary supports for achieving the goal. The `Indoor residual spraying' is already continued and be strengthened to cover all the Kala-azar endemic districts. The doctors, nurses and all service providers are being trained to combat Kala-azar.

I am expressing my sincere gratitude and thanks to the Director General of Health Services for leading us towards appropriate direction and tremendous assistance for the communicable disease control program and his interest for this 'National guideline for Kalaazar Elimination in Bangladesh'.

I would like to express my heartiest thanks to all the resource persons, consultants, experts and physicians who gave their valuable time, providing technical and financial support and contributing to the development of this important guideline within the shortest possible time.

I hope that the 'National guideline for Kala-azar Elimination in Bangladesh' will be an advantageous document for the planners, researchers, all level of physicians and patients of Bangladesh as well.

Prof. Be-Nazir Ahmed
Director
Disease Control & Line Director, CDC

Deputy Program Manager
Kala-azar Elemination Program
Directorate General of Health services (DGHS)
Ministry of Health & Family Welfare
Govt. of the People's Republic of Bangladesh

Message

Kala-azar is known as a major neglected tropical disease and it is also one of the major public health problems in Bangladesh. The disease commonly affects the poor community of the developing countries and thus addressed as the disease of the `poorest of the poor'. From the historical view Kala-azar has been persisting in the sub-continent for quite a long duration and responsible for a number of deaths each year. As a collateral benefit of blanket DDT spraying during Malaria eradication Program the disease was controlled to some extent in our country. But during the late 80's it re-emerged and was spreading quickly. The total number of cases rose to more than 9000 an almost 40 districts became endemic in 2005.

The introduction of Kala-azar Elimination Program (KEP) with the target of reducing the prevalence of Kala-azar to < I case per 1000 population has been improved. Then early diagnosis and prompt treatment for Primary Kala-azar and PKDL are ensured, the surveillance and monitoring system is strengthened and the all-important Indoor residual (IRS) was instituted. As a consequence, the disease started to decline in the last 2 years and we are hopeful that we can achieve our goal set by MDG even before the scheduled cut-off 20 15.

The recent and upgraded `National Guidelines for Kala-azar Elimination in Bangladesh' is published with aim to provide a handy and quick guideline to diagnose and treat a Kala-azar or PKDL patient as well as effectively handle the IRS Program, ensuring a robust and effective disease and vector surveillance and develop public awareness community participation.

At the end I would like to think from the core of my heart to all individuals who provide their kind support and stressful efforts to publish the `National Guidelines for Kala-azar Elimination in Bangladesh'.

Dr. Shah Golam Nabi
Deputy Program Manager
Communicable disease Control

List of Abbreviations

AIDS	Acquired Immune deficiency Syndrome
ARV	Anti Retroviral Therapy
BCC	Behavior Change Communication
CDC	Communicable Disease Control
CL	Cutaneous Leishmaniasis
DDT	Dichlorodiphenyltrichloroethane
DGHS	Directorate General of Health Services
H&FWC	Health & Family Welfare Centre
HIV	Human Immune Deficiency Virus
ICT	Immune-chromatographic test
IEDCR	Institute of Epidemiology, Disease Control and Research
IPD	Inpatient department
IRS	Indoor Residual Spray
IM	Intramuscular
ITN	Initial Training Network
IV	Intravascular
KA	Kala-azar
KATF	Kala-azar Treatment Failure
LAmB	Liposomal Amphotericin B
MIS	Management Information System
MO	Medical Officer
MOU	Memorandum of Understanding
NGO	Non Government Organization
OPD	Outpatient department
PCR	Polymerase Chain Reaction
PKA	Primary Kala-azar
PKDL	Post Kala-azar Dermal Leishmaniasis
RD	Rural Dispensary
RDT	Rapid Diagnostic Test
RKA	Relapse Kala-azar
rK39	rK39 Antigen
RTAG	Regional Technical Advisory Group
SC	Sub Centre
SEARO	South East Asian Regional Office
SOP	Standard Operation Procedure
SSG	Sodium Stibogluconate
TB	Tubercle Bacillus
UHCs	Upazila Health Complexes
UH&FPO	Upazila Health and Family Planning Officer
WHO	World Health Organization

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Chapter 1

Introduction

1.1 Background

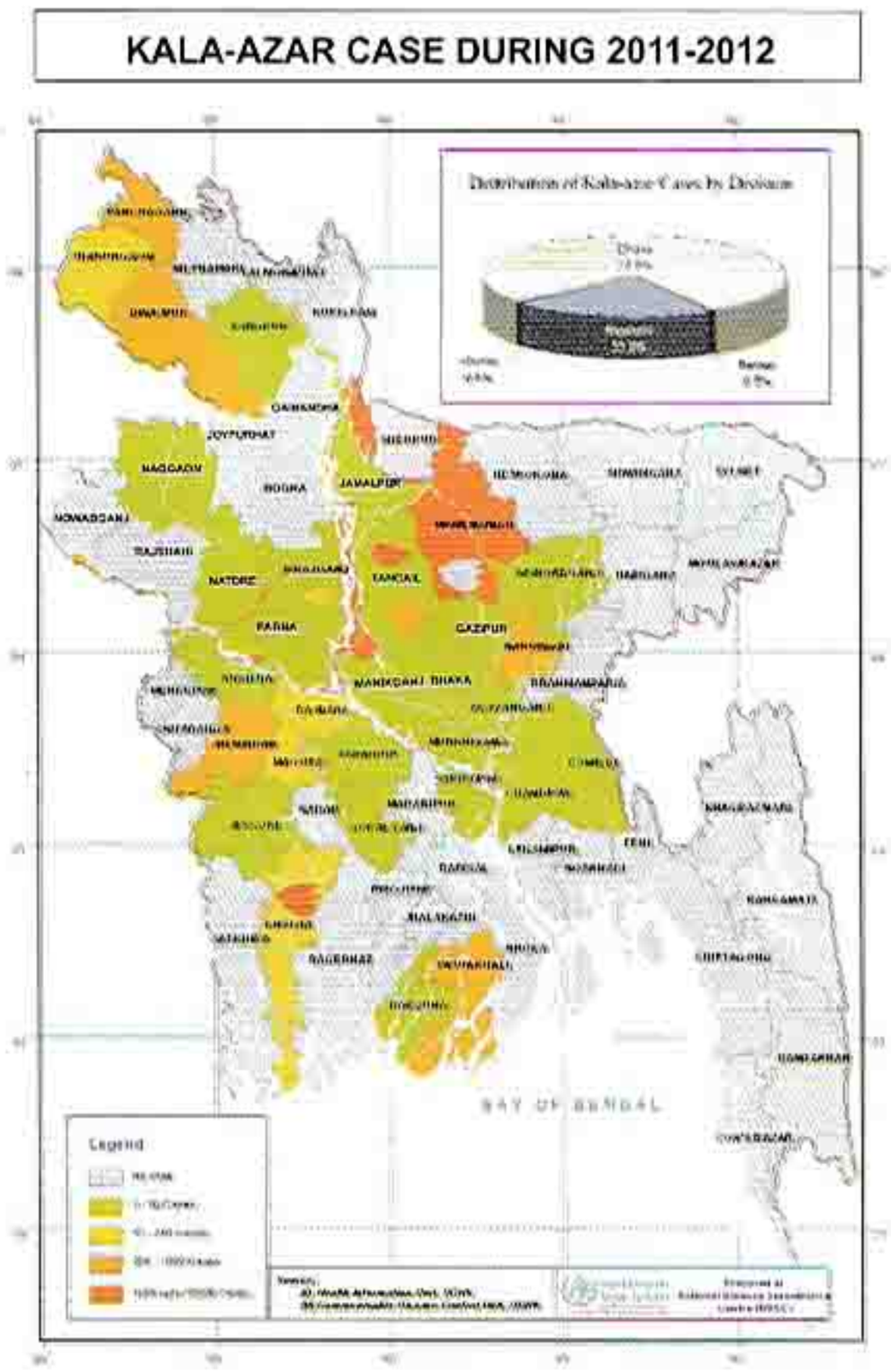
Kala-azar is one of the clinical forms of Leishmaniasis and is caused by the protozoa Leishmania donovani. In Bangladesh it is transmitted by the sand fly named Phlebotomus argentipes. The disease presents as prolonged fever with splenomegaly, anemia, weight loss and darkening of complexion. In endemic areas, children and young adults are its principal victims. Kala-azar is fatal if not treated timely. Kala-azar HIV or TB co-infection has emerged as a health problem in recent years. The disease is seen in several countries of the world with about 500,000 cases annually. India, Sudan, Nepal, Bangladesh and Brazil account for 90% of the total global cases. It affects largely the socially marginalized and the poorest communities.

1.2 Kala-azar situation in Bangladesh

Kala-azar is one of the major public health problems in Bangladesh and the disease is endemic for many decades. During the 'Malaria Eradication Program' blanket DDT spraying controlled Kala-azar transmission. In the late 1970s Kala-azar re-emerged sporadically. During 1981-85 only 8 upazilas (Sub-district) reported Kala-azar, which increased to 105 upazilas in 2004. During the last few years the Kala-azar situations has assumed epidemic proportion with the number of reported cases increasing from 3978 in 1993 to 8505 in 2005. But for the last few years the incidence declined to some extent and reach to (2534+842) = 3376 cases are reported in 2011.

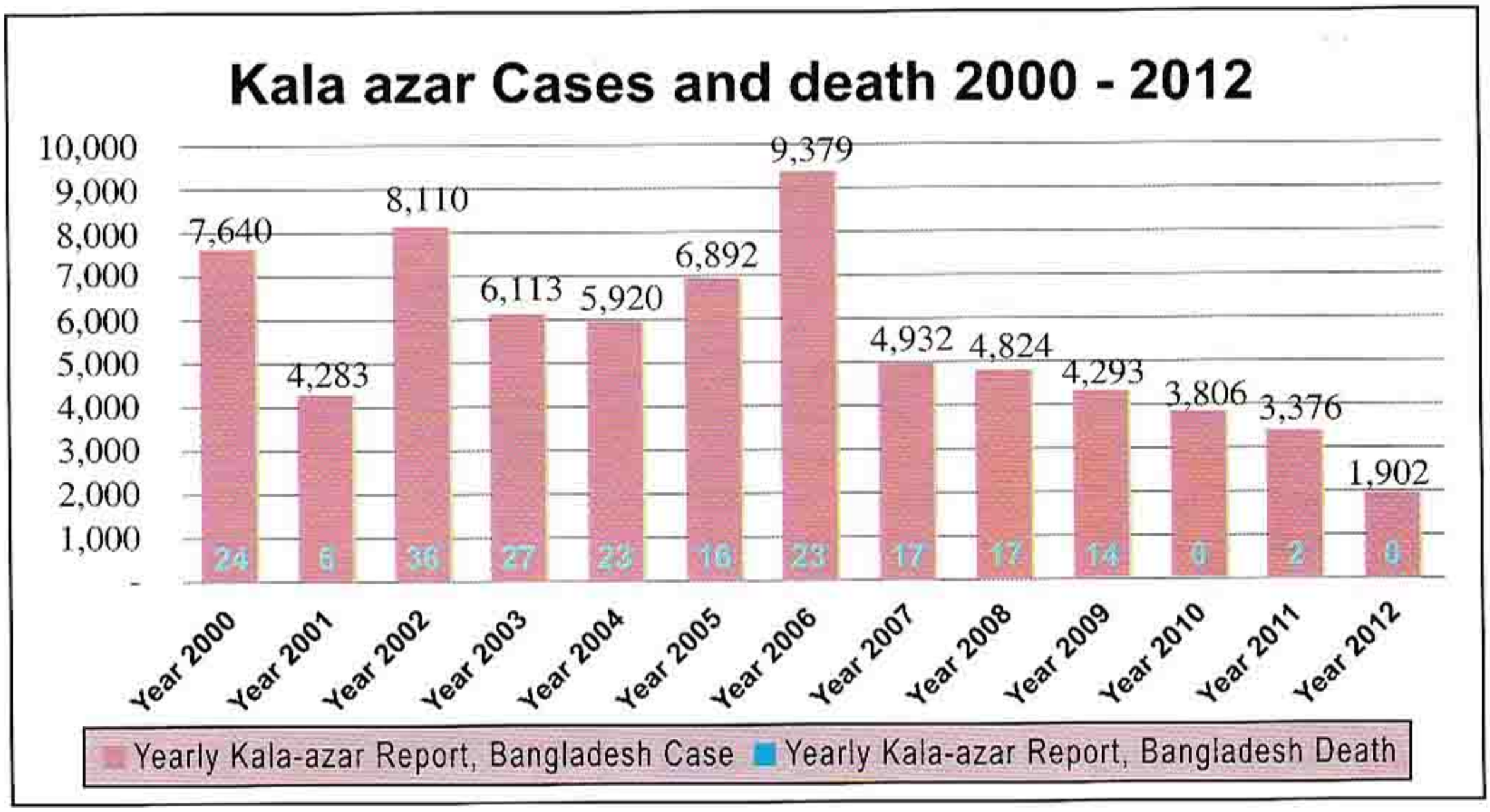
Under the current surveillance system the Upazila Health Complexes (UHCs), District Hospitals and other specialized hospitals report cases to Civil Surgeon Office and the Civil Surgeon Office after compilation report to the Kala-azar Elimination Program, Communicable Disease Control (CDC) Unit in DGHS. This is however is a gross under reporting because the private sector clinics and hospitals, and the cases treated by private practitioners are not included.

Figure 1: Kala-azar cases during 2012



The bar chart below shows the number of Kala-azar cases reported during 2000- 2012. The highest case fatality rate recorded from research on known Kala-azar patients in Mymensingh district has been found 6.4% (Desjeux P., 1991). The prevalence rate in some selected villages in the same district has been found be as high as 6% of the total population (unpublished report, 1993). However, definite data on morbidity and deaths due to Kala-azar are not available from the current reporting system. Age and sex segregated data is not available with the control program at present.Cases are usually clustered in the villages having environmental and related factors for the vectors to grow and proliferate. There is no marked seasonal variation but the pre and post-monsoon rise in number of cases indicates two picks of transmission. Areas in the old Brahmaputra and the Ganges basin show the highest prevalence of the disease.

Figure 2: Kala-azar cases and deaths 2000-2012, Bangladesh.



Cases are usually clustered in the villages having environmental and related factors for the vectors to grow and proliferate. There is no marked seasonal variation but the pre and post-monsoon rise in number of cases indicates two picks of transmission. Areas in the old Brahmaputra and the Ganges basin show the highest prevalence of the disease.

1.3 Target audience for the guidelines

These guidelines will be useful to the-

- Program managers- national/divisional/district/upazila level.
- Doctors and health care providers
- Supervisors at all levels
- Supervisors and health workers engaged in supervising the spraying squads
- The health care providers and volunteers responsible for Behavior Change Communication (BCC) can use the guidelines to (a) promote early care seeking if Kala-azar is suspected, (b) convince the patients suffering from Kala-azar to complete the treatment and (c) undertake advocacy with the community for participation in ensuring complete and uniform coverage of their households with insecticides.

This guideline is adopted according to the SEARO, WHO guidelines. Whenever translation is needed for training of grass root level workers, volunteers, NGO workers for providing training on particular areas of their involvement in Kala-azar elimination program, local managers are encouraged to translate it in 'Bangla'.

Table 1: Level of health facilities in Bangladesh

Level 1	Level 2	Level 3
Public sector - Upazila Health Complex (UHC) - Community clinic - Union Health Facilities (Health & Family Welfare Centre-H&FWC, Rural Dispensary-RD, Sub-centre-SC)	**Public sector** -District Hospitals	**Public sector** - Medical College Hospitals. - Specialized hospitals
Private sector - Qualified private practitioners - Non qualified health care providers including health volunteers - NGOs, private hospitals, private clinics, and private laboratories.	**Private sector** - Qualified private practitioners - NGOs, private hospitals, private clinics, and private laboratories.	**Private sector** - Medical College Hospitals - Qualified private practitioners - NGOs, private hospitals, private clinics, and private laboratories

N.B- *Treatment will be given in upazila health complex in case of level I and other private and public sector of Level I will refer the patient to upazila health complex.*

For the success of the program it is important to develop linkages between the three levels and establish ongoing communication with the private sector. The district focal point should be responsible for sustaining the linkages. The details of collaboration between the public and private sector need to be worked out with the objective of obtaining uniform standards of practices.

1.4 Kala-azar Elimination Program

Kala-azar can be eliminated from the Indian Subcontinent including Bangladesh because there is no intermediate host for transmission of the disease. The Indoor residual spray (IRS) has been very effective. As a collateral benefit of malaria Kala-azar was almost eliminated. The disease can be easily recognized and effective treatment for Kala-azar is available.

1.4.1 Target

The target of Kala-azar elimination is to reduce the incidence of the disease to less than 1 case per 10,000 populations at the upazila level in Bangladesh by the year 2015.

1.4.2 Objectives

The impact objective is to reduce the incidence of Kala-azar to less than 1 case of Kala-azar and Post Kala-azar Dermal Leishmaniasis per 10,000 population upazila level in Bangladesh by:

- Reducing the incidence Kala-azar in the endemic communities including the poor, vulnerable and un-reached populations.
- Reducing case fatality rate from 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.

1.4.3 Elimination strategy

A regional strategy for elimination of Kala-azar has been endorsed by the Regional Technical Advisory Group (RTAG). It comprises of the following components:

a) **Early diagnosis and complete treatment:** All suspected cases of Kala-azar and PKDL would have access to recommended diagnosis and treatment.

b) **Integrated vector management:** The mainstay of vector control is indoor residual spray (IRS) with suitable insecticides. Improvements in housing and personal preventive methods would be promoted through community involvement.

c) **Effective disease surveillance:** A revamped surveillance system should strengthen diagnosis treatment and reporting both in the public and the private sector.

d) **Social mobilization and partnerships:** Behavioral Change Communication (BCC) would aim at achieving early diagnosis and complete treatment, participation of the community in IRS, and adoption of personal preventive methods and micro-environmental management. Partnerships within and outside the health sector are to be forged to promote the goals of Kala-azar elimination.

e) **Operational research:** Operational research to monitor the drug and insecticide resistance, quality of drugs, treatment compliance, pharmacovigilance, ITNs use etc. would be undertaken.

Chapter 2

Diagnosis of Kala-azar & PKDL

2.1. Background

Kala-azar and PKDL are a significant health problem and has been reported from 26 out of 64 districts in Bangladesh. Bangladesh is committed to eliminate Kala-azar by 2015 (Incidence of Kala-azar- less than 1 case in 10,000 population at Upazila level). The political commitment for elimination of Kala-azar is high. In May 2005, the three countries in this region have signed an MOU committing themselves to mutual cooperation towards elimination of Kala-azar from their respective countries. A Regional Strategic Plan has been prepared and endorsed the guidelines and standard operating procedures (SOPs) to ensure the application of interventions in the endemic countries uniformly. The purpose of this guideline is to update the present guideline (incorporated in the training module) published in 2008 based on experience of existing elimination program and available new information and tools.

In our country Kala-azar and PKDL is transmitted by the sandfly, *Phlebotomus argentipes*. The disease generally presents with prolonged fever (more than two weeks) with splenomegaly, anemia and progressive weight loss. In endemic areas, children and young adults are its principal victims. Without in time treatment the disease may cause serious consequences. The health facilities in KA affected areas are classified into different levels for programmatic purpose and by the diagnostic and treatment facilities available. Both the government and the private sector will be guided by the national guidelines, policy and norms. The different levels of health facilities are summarized in the table below. Adjustments of levels are allowed according to the local circumstances.

2.2 Clinical Case definition for Kala-azar and PKDL

The diagnosis of Kala-azar will be based on the following criteria in a symptomatic case.

- History of fever for more than 2 weeks
- Residing/ traveling in endemic areas
- Any one of the following symptoms and signs:
  - Splenomegaly
  - Weight loss
  - Anemia
- And 'rk39' test (+) positive.

PKDL should be considered if all of the following features are present.

- Residing / travelling in the endemic areas
- History of treatment for Kala-azar any time in the past1.
- Suggestive skin lesion without loss of sensation, which may be macular, papular, nodular or mixed.
- Exclusion of other causes of skin disease eg. Leprosy, Vitiligo, Pityriasis, Ring worm etc.
- 'rk39' positive2/ Slit skin smear positive/ PCR positive.

[1] In rare instances h/o treatment of Kala-azar may be absent in PKDL.

[2] In rare instances in PKDL rk39 may be negative and should be diagnosed by slit skin smear.

2.3 Case definition for reporting

Following clinical case definitions will be used for reporting and follow up.

Primary Kala-azar (PKA):

An individual who is diagnosed to have KA with the above mentioned case definition and no history of treatment for KA before will be considered as primary Kala-azar (PKA)

Primary Kala-azar (PKA):

An individual who is diagnosed to have KA with the above mentioned case definition and no history of treatment for KA before will be considered as primary Kala-azar (PKA)

Kala-azar Treatment Failure (KATF):

An individual who is diagnosed to have KA with the above mentioned case definition and history of treatment for KA within last one year, will be reported as KATF. All efforts should be made to diagnose KATF parasitologically by examination of splenic smear or bone marrow or PCR.

Relapse Kala-azar (RKA):

An individual who is diagnosed to have KA with the above mentioned case definition and history of treatment for KA anytime in the past but not within last one year will be reported as RKA. All efforts should be made to diagnose RKA parasitologically by examination of splenic smear or bone marrow or PCR.

Post Kala-azar Dermal Leishmaniasis (PKDL):

An individual who is diagnosed to have PKDL with the above mentioned case definition will be reported as PKDL.

Cutaneous Leishmaniasis (CL):

CL should be suspected in a person or a case of skin ulcer (single or multiple) that travelled an endemic area (Middle East, South America, Africa etc.). CL should always be confirmed by demonstration of parasite from the lesion by slit skin smear or parasite DNA in tissue specimen.

2.4 Diagnosis of Kala-azar in special situations

The diagnosis of Kala-azar can be difficult in special situations. The common special situations are Kala-azar-TB co-infection, Kala-azar-HIV co-infection, Kala-azar in pregnancy etc. All efforts should be made to diagnose KA in special situation by parasitological examination of splenic smear or bone marrow or PCR. In cases of Kala-azar HIV co-infection 'rK39' test may be negative. Patients with Kala-azar in special situations should be referred to the required level of facility as appropriate.

Table 2: Location for PKA, KATF, RKA and PKDL diagnosis.

A) Level 1 (UHC, Union Sub Centre, Community Clinic)
In endemic areas in (union sub centre, community clinic or others) 1. Identify cases of fever of more than 2 weeks duration 2. Identify cases who have macular, papular or nodular skin lesions but no other signs 3. Refer the patients with above problems to Upazila health complex for evaluation, testing and treatment for Kala-azar or PKDL. In endemic areas in upazila health complex 1. Check patients with fever of more than 2 weeks associated with splenomegaly 2. Check patients with macular, nodular or mixed lesions without loss of sensation. Perform 'rK39' test : (a) On all patients with fever of more than 2 weeks and have splenomegaly (b) Patients with macular, papular or nodular or mixed lesions and no loss of sensation. 3. Treat patients of Kala-azar with first line drugs 4. Refer KATF, RKA,PKDL cases whose need tissue biopsy and unresponsive cases of Kala-azar to level III facility.
B) Level II (District Hospital)
1. Check patients with fever of more than 2 weeks associated with splenomegaly. 2. Check patients with macular, nodular or mixed lesions without loss of sensation. Perform 'rK39' test : (a) On all patients with fever of more than 2 weeks and have splenomegaly (b) Patients with macular or nodular or mixed lesions and no loss of sensation. 3. Treat patients of Kala-azar with first line drugs 4. Refer KATF, RKA, PKDL cases to who need tissue biopsy and unresponsive cases of Kala-azar to level III facility.
C) Level III (Tertiary Hospital)
1. Treat unresponsive Kala-azar or KATF cases and refer back of PKDL cases to level I and II for treatment after tissue diagnosis. 2. Perform the slit skin smear/biopsy in suspected cases of PKDL that are 'rK39' test negative 3. Perform bone marrow / splenic aspiration in patients where these are indicated, as a part of drug monitoring studies or as a part of quality assessment 4. Treat any complications associated with bone marrow/ splenic aspirate
D) Level IV (Specialized laboratories)
1. Perform PCR test for establishing the diagnosis of PKDL in cases that are suspected to havethe disease but 'rK39'test is negative 2. Diagnosis of HIV-Kala-azar co-infection may be done by bone marrow/ splenic aspirate

Chapter 3

Treatment of PKA and PKDL

The objective of treatment for Kala-azar is to cure the patient, prevent the complications of the disease and minimize side effects of medicines, restrain drug resistance and reduce the risk of spread of disease. Complications and concomitant disease conditions (if any) should also be diagnosed and treated accordingly.

3.1 Drug treatment of Primary Kala-azar (PKA):

1st line treatment:

Following drugs are recommended as 1st line treatment for KA in Bangladesh:

Drug of choice-
Liposomal Amphotericin B (10 mg/kg single dose)
Alternative 1st line choices- (Depending on availability in our country)
♦ Miltefosine ♦ Paromomycin ♦ Combination treatment: Combination of Miltefosine and Paromomycin will be 1st choice. Other alternative combinations will be Liposomal Amphotericin B* + Miltefosine or Liposomal Amphotericin B* + Paromomycin. * LAmB 5 mg/kg body weight on alternate days for 3 doses.**2nd line treatment:**

The following drug is recommended as 2nd line treatment for PKA patients (if the 1st line drugs are not available or not tolerated):

1. Amphotericin B deoxycholate
2. Sodium Stibogluconate (SSG)

Indications of 2nd line drugs:

3. When the first line drugs are not available or not tolerated.

3.2 Description of the 1st line drugs for PKA

3.2.1 Liposomal Amphotericin B (LAmB):

- To improve the tolerance and widen the narrow therapeutic window, a lipid formulation of Amphotericin B is formulated. Amongst the three formulations liposomal Amphotericin B has the best safety profile.
- Liposomal Amphotericin B should be given in a single intravenous infusion at a dose of 10 mg/kg for a period not less than 2 hours duration. Please see annex for details.
- In special situations like children of less than 5 years, in pregnancy, co-infection with HIV/ AIDS etc would be treated with multiple dose of Liposomal Amphotericin B (5mg/kg body weight on alternate days for 3 doses). Please see annex for details.

3.2.2 Indications for alternative 1st line drugs:

- When Liposomal Amphotericin B is not indicated due to hypersensitivity, intolerance, contraindication
- When Liposomal Amphotericin B is not available.

3.2.3 Miltefosine:

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

Recommended dose schedule:

- Age more than 12 years and weighing? 25kg:
  - 100 mg. (cap 50 mg in morning and 50 mg in evening with meal)
- Age more than 12 years but weighing <25kg:
  - 50 mg. (cap 50 mg in the morning with meal)
- 2 12 years:
  - 2.5mg/kg body weight in two divided doses with meal, not exceeding 50mg/day)

In case of missed doses, the scheduled 28 doses may be taken within a period of 35 days. The daily dose should never exceed the recommended amount.

If an exact dose cannot be administered, the closest 10 mg increment will be chosen at the dose. Rounding will be done as follows:

- If the calculation comes to <5 to round dose down.
- If the calculation comes to >5 to round the dose up.

When to avoid the use of Miltefosine:

Miltefosine is the preferred drug for the treatment of Kala-azar/ PKDL in the elimination program except in the following situations:

- Pregnancy
- Married women of child bearing age who are not using contraceptives regularly.
- Women who are breast feeding.
- Children less than 2 yrs of age

Miltefosine may not be the ideal drug for patients of Kala-azar

- With severe under nutrition
- Severe anemia and
- Patients with known history of kidney or liver disease

Adverse reactions of Miltefosine and their treatment:

Adverse reactions to Miltefosine are mostly mild. Mild to moderate vomiting is seen in 40% patients and mild diarrhea in 15 20% patients. These usually occur during first week of treatment.Adverse reactions of Miltefosine and their treatment:

Adverse reactions to Miltefosine are mostly mild. Mild to moderate vomiting is seen in 40% patients and mild diarrhea in 15 20% patients. These usually occur during first week of treatment.

Duration of treatment of Miltefosine:

Miltefosine should be given daily for 28 days. In case of missed doses treatment up to 35 days is recommended to complete the full course.

3.2.4 Paromomycin:

Paromomycin is a promising effective drug for the treatment of Kala-azar. It has been registered for use in India which is a parenteral aminoglycoside.

Doses and administration:

Paromomycin sulphate should be given at a dose of 15mg/kg/day. Each dose is to be taken from a separate ampoule. It should be given I/M in the gluteal muscle (alternative buttock cheeks) once a day for 21 days.

Combination therapy:

- The 1st choice of combination therapy will be Miltefosine and Paromomycin.
- The alternate choice

Liposomal Amphotericin B
+
Miltefosine
or
Liposomal Amphotericin B
+
Paromomycin.

Dose and administration:

1st choice:

Cap. Miltefosine following the above mentioned dose for 10 days

+

Inj. Paromomycin following the above mentioned dose for 10 days

Alternate choice:

Inj. Liposomal Amphotericin B 5 mg/ kg body weight IV single dose on day 1

+

Cap. Miltefosine following the above mention dose from day 2 to day 8.

Or,

Inj. Liposomal Amphotericin B 5 mg/ kg body weight IV single dose on day 1

+

Inj. Paromomycin following the above mention dose from day 2 to day 11.

Assessment of cure at end of treatment (Initial cure):

- Improvement of all clinical parameters including absence of fever
- Reduction of spleen size.
- Gain in body weight.

Assessment of cure at 6 months (Definitive cure):

- No fever.
- Substantially reduced spleen size or not palpable.
- Feeling of general well being.

3.3 Description of 2nd line treatment for Primary Kala-azar:

3.3.1 Amphotericin B deoxycholate:

Recommended second line drug for treatment of Kala-azar and KATF is Amphotericin B deoxycholate.

- Amphotericin B deoxycholate is also an effective drug. But it has high toxicity profile and thus pushed to second line.
- Amphotericin B deoxycholate 1 mg/kg daily or alternate day is recommended in the form of infusion (in 5% Dextrose solution 500 ml) for 15 doses having a cure rate of >90%. A test dose should be given before administration of Amphotericin B.
- After preparation of solution 5 drops /min for 30 min, then 10 drops/min for another 30 min and if there is no reaction occurs, then the infusion should be given slowly over a period of 4-6 hours.

3.3.2 Sodium Stibogluconate (SSG):

- SSG is an effective and widely used drug for KA and KATF. But the drug is pushed to second line because of its cardiac toxicity and is recommended by WHO to be phased out gradually.
- SSG should be given at a dosage of 20mg/kg body weight, daily IM injection for 30 days.
- It is essential to weigh the patient before starting treatment. Clinical cardiac monitoring should be done throughout the treatment period.

Route of Administration of SSG:

The preferred route of administration recommended is by deep intramuscular (IM) injection. It is better not to give the drug intravenously (IV) to avoid the risk of cardiovascular collapse.

3.4 Treatment for Kala-azar treatment failure (KATF)/ Relapse Kala-azar (RKA)

1. KATF and RKA cases will be treated with alternative 1st line agent (eg. Patient who received LAmB will be treated with Miltefosine or Paromomycin or combination).
2. If alternative 1st line agents are not available, then a 2nd line agent should be used.

3.5 Treatment of PKDL

First line treatment:

Miltefosine

Longer duration of oral Miltefosine is recommended. The treatment will be supervised. Patient will received their drugs monthly after being followed up by the respective physician.

- Adult dose: 100 mg daily for 12 weeks in two divided doses.
- Children: 2.5 mg/kg body weight/ day in two divided doses, not exceeding 50mg/day for 12 weeks.

Second line treatment

Amphotericin B deoxycholate

- Dose: 1 mg/kg body wt daily or alternative days for 15 doses per cycle with 6 cycles followed by 10 days gap after each cycle.
- Route: IV

Sodium Stibogluconate (SSG)

SSG should be given at a dosage of 20 mg/kg/day in intramuscular route. It is essential to weight the patient every time, before starting a new cycle. Total 6 cycles of treatment should be given. Each cycle consists of 20 days of treatment and there should be an interval of 10 days in between two cycles.

3.6 Treatment of Cutaneous Leishmaniasis (CL):

The treatment approach largely depends in part on the Leishmania species/ strain and the geographic area in which infection was acquired. In general, the first sign of a therapeutic response to adequate treatment is decreasing indurations (lesion flattening). The healing process for large, ulcerative lesions often continues after the end of therapy.

First line drugs:

Sodium stibogluconate: The standard daily dose will be 20 mg of SbV per kg/ per dose, administered IV or IM for 20 days (10 days may suffice based on clinical judgment).
Or,
Cap. Miltefosine

The standard duration will be 28 days with the following dose:

i. Age more than 12 years and weighing ?25kg: 100 mg. (cap 50 mg in morning and 50 mg in evening with meals)
ii. Age more than 12 years but weighing <25kg: 50 mg. (cap 50 mg in the morning with meals)
iii. 2 12 years: 2.5 mg/kg body weight. in two divided dose, not exceeding 50mg/day with meals

3.7 Complete Treatment of Kala-azar:

All efforts should be made to ensure the complete treatment. The following measures are recommended to complete the treatment:

- Every patient should be counseled so that the patient/family fully understands the importance of complete treatment and the consequences of the incomplete treatment.
- All treatment should be provided free of cost to eliminate the economic constraint as a reason for discontinuation of treatment
- Each patient should have a separate treatment box at the health facility that contains the full dose of drugs labeled with the name and individual identification of the patient. A treatment card with a unique identification number showing the number of days the treatment taken should be provided to patients.
- It is advisable to follow up the patients during treatment, immediately after completion of treatment and up to 1 year (at 1st, 5th, 9th, 12th month) The treatment should be directly observed as per SOPs.
- There should be coordination amongst the public and private sector providers and a follow up plan should be developed for each patient.

3.8 Pharmacovigilance:

Pharmacovigilance is important to ensure the safety of the medicines used in the treatment of Kala-azar and PKDL. It should be the responsibility of the national program to ensure pharmacovigilance. The program can provide very useful information regarding efficacy of treatment options and related adverse events during follow up of the patients.
The program must encourage health facilities and personals to ensure regular reporting of major and minor adverse events. The following measures will help to recognize early the occurrence of adverse events.

- Monitor the patient regularly for signs and symptoms (indicative of adverse events of drugs) and should be reported as major & minor events (Ref. Training module for Kala-azar elimination program)
- Perform the tests if clinically indicated in treatment sites and monitor the results. This can help to take timely measures even before the signs appear.
- Periodic meetings should be organized to review the reports of major and minor adverse events obtained from the different levels. This will help to guide the program in recommending the tests that should be done to monitor the patients on treatment.
- Regularly report the adverse events on the reporting formats to higher levels once in a month for a review and feedback.

3.9 Treatment of Kala-azar in special situations:

The treatment of Kala-azar in special situations is recommended in centers where appropriate expertise and facilities are available. The following conditions can be considered as special situations:

- **Pregnancy**

  Risk of treatment should be weighed against benefit. Treatment should be prioritized according to the severity. If a pregnant mother is diagnosed as PKA during 1st trimester she should be treated at 2nd trimester or if she diagnosed as PKA during 3rd trimester then she should be treated after delivery. Drug of choice is Liposomal Amphotericin B (5 mg/kg body weight on alternate days for 3 doses). Miltefosine and Sodium stibogluconate is contraindicated in case of pregnancy.

- **Married women of reproductive age who are not using contraceptives regularly**

  The drug of choice is single dose Liposomal Amphotericin B (Miltefosine is contraindicated).

- **Women who are breast feeding their babies**

  The drug of choice is Liposomal Amphotericin B but temporary discontinuation of breast feeding for 2 weeks should be advised.

- **Kala-azar with severe anemia (Hemoglobin less than 5 g/dl)**

  There should be transfusion of whole blood to raise hemoglobin ?6 gm/ dl prior to commencement of treatment.

- **Kala-azar with TB**

  Treatment of both diseases should be continued and KA will be treated as PKA.

- **Kala-azar HIV/AIDS co-infection**

  It will be treated with Liposomal Amphotericin B with multiple doses. ARV should be continued for HIV/AIDS.

- **Kala-azar in a patient suffering from another serious disease**
  All the case of Kala-azar with serious co-morbidities should be treated under specialized supervision. Liposomal Amphotericin B will be the drug of choice and treatment should be given in a tertiary care facility.

Figure 3: Diagnosis and management chart for Kala-azar

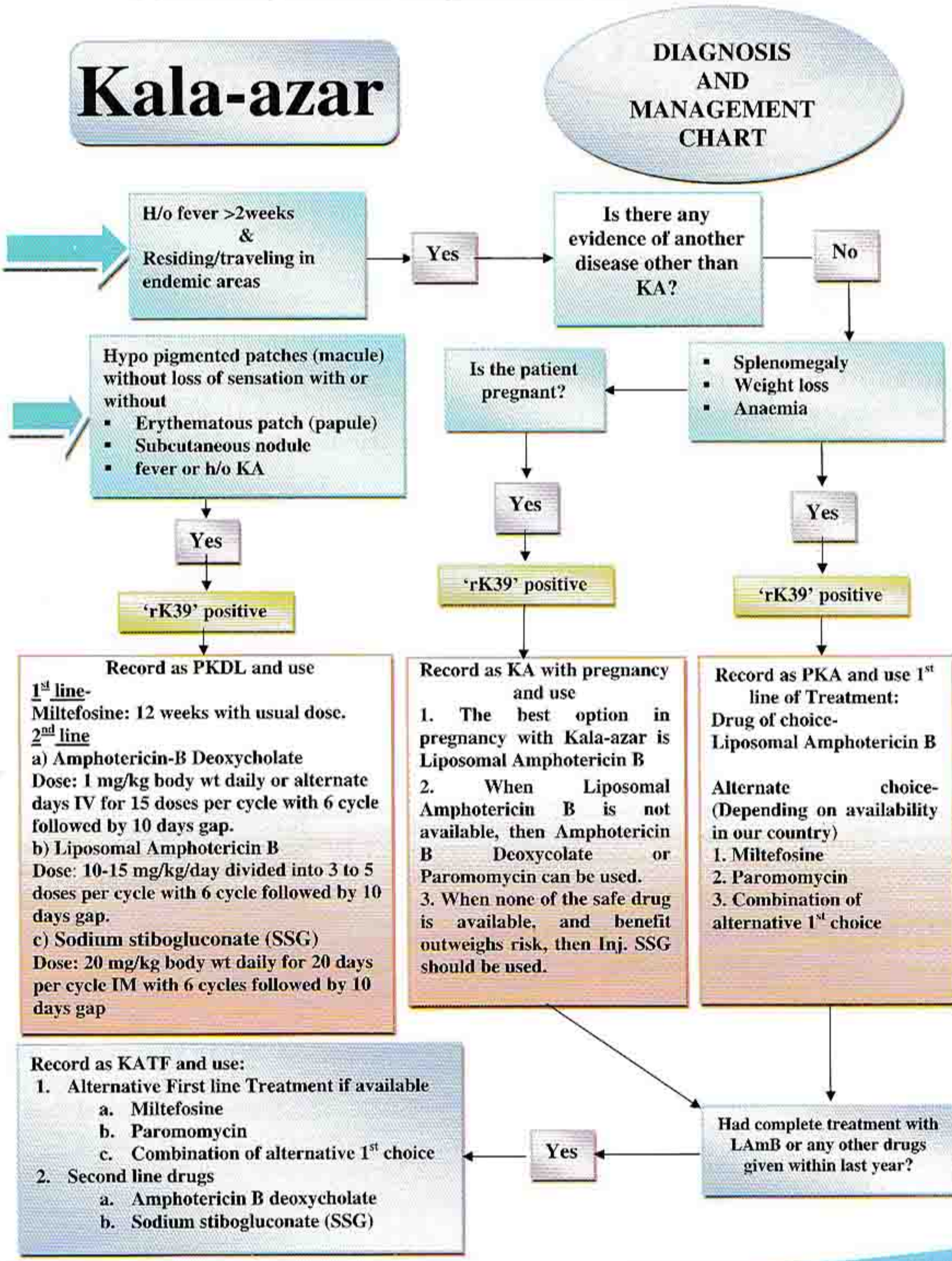


Figure 4: Treatment chart for Kala-azar.

Treatment Chart

Primary Kala-azar (PKA)

1st line treatment for PKA

Drug of choice

1. **Liposomal Amphotericin B (10mg/kg single dose)**

Alternative 1st line choices-(Depending on availability in our country)

- **Miltefosine**
- **Paromomycin**
- **Combination**

treatment: Combination of Miltefosine and Paromomycin will be 1st choice

Other a lternative combinations will be

Liposomal Amphotericin B*
+
Miltefosine
Or,
Liposomal Amphotericin B*
+
Paromomycin.
***LAmB 5 mg/kg body weighton alternate days for 3 doses.**

2nd line treatment for PKA

Amphotericin-B deoxycholate

Dose: 1 mg/kg body wt IV daily or alternate day (in 5%Dextrose solution 500 ml). Duration: 15 doses

Sodium stibogluconate (SSG)
Dose: 20 mg/kg body wt IM daily.
Duration: 30 days

Weight (kg)	SAG (ml)
up to 3	0.6
4-5	0.8-1
6-8	1.2-1.6
9-10	1.8-2
11-13	2.2-2.6
14-15	2.8-3.0
16-18	3.2-3.6
19-20	3.8-4.0
21-23	4.2-4.6
24-25	4.8-5.0
26-28	5.2-5.6
29-30	5.8-6.0
31-35	6.2-7.0
36-40	7.2-8.0
41-45	8.2-9.0
46-50	9.2-10
51-55	10.2-11
56-60	11.2-12

Figure 5: Treatment chart of PKTF, PKDL and RKA.

Treatment Chart

KATF, PKDL& RKA

When LAmB is not available or contraindicatedor in KATF

1st line drugs:

1. Miltefosine 28 days

- **a. Age more than 12 years and weighing? 25kg: 100 mg. (cap. 50 mg in morning and 50 mg in evening with meal)**
- **b. Age more than 12 years but weighing <25kg: 50 mg. (cap 50 mg in the morning with meal)**
- **c. 2 12 years: 2.5 mg/ kg body weight in two divided doses with meal, not exceeding 50mg/day)**

2. Paromomycin: Dose: 15mg/kg/day Paromomycinfor 21 days IM

3. Combination of 1st choice2nd line drugs

- **a. Amphotericin-B deoxycholate (1 mg/kg daily or alternate day in IV for 15 doses)**
- **b. Sodium stibogluconate (SSG should be given at 20mg/kg daily IM for 30 days)**

Rx for RKA

1. Combination 1st line drugs cap. Miltefosine (For Adult dose: 100 mg daily in two divided doses for Children: 2.5 mg/kg body weight/ day in two divided doses for 10 days) plus inj. Paromomycin at a dose 15mg/kg/day for 10 days.2. If fail then choose alternate combination-
Inj. Liposomal Amphotericin B 5 mg/ kg body weight IV single dose on day 1
+
Cap. Miltefosine following the above mention dose from day 2 to day 8.
Or,
Inj. Liposomal Amphotericin B 5 mg/ kg body weight IV single dose on day 1
+
Inj. Paromomycin following the above mention dose from day 2 to day 11.

Rx for PKDL
1st line-
Miltefosine:
Adult dose: 100 mg daily in two divided dose for 12 wks.
Children: 2.5 mg/kg/ day in two divided doses, not exceeding 50mg/day for 12 weeks
2nd line
a. Inj. Amphotericin B Deoxycholate
Dose: 1 mg/kg body wt daily or alternate days IV for 15 doses per cycle with 6 cycle followed by 10 days gap.
b. Inj. Sodium stibogluconate (SSG)
Dose: 20 mg/kg body wt daily for 20 days per cycle IM
Duration: Six cycles with 10 days interval between cycles

Chapter IV
Kala-azar Surveillance System

4.1 Introduction

Disease surveillance is a key component of Kala-azar elimination program. It comprises passive and active surveillance of Kala-azar cases and vector surveillance. Surveillance includes reporting of all cases of Kala-azar and PKDL. To make the disease surveillance effective, it is necessary to organize a system of regular reporting, analysis, review and feedback of information. Regular reporting and exchange information should be organized upwards, downwards and laterally in the system that comprises government, private sector, NGOs and the community as partners. Feedback linked to surveillance system is a critical element of the elimination program. Surveillance should also be used for sharing of reports periodically to higher authorities on a regular basis to facilitate and rationalize the planning of elimination program. Surveillance is useful for planning indoor residual spray through mapping of the areas to be sprayed and in monitoring the trends of Kala-azar.

4.2 Kala-azar Surveillance

Kala-azar surveillance will be a part of web-based national disease surveillance system centrally managed by IEDCR. Kala-azar elimination program-specific indicators will be incorporated in the reporting format. In order to strengthen Kala-azar surveillance, KA surveillance units will be set up at district and upazila level. Kala-azar Elimination Program will have access to surveillance data in real time. The surveillance data will also be fed into the Management Information System (MIS) of DGHS.

4.2.1 Kala-azar Surveillance Units

I. Upazila Kala-azar Surveillance Unit

- Head: UH&FPO
- Focal person: MO (Kala-azar Elimination)
- Statistical Assistant

II. District Kala-azar Surveillance Unit:

- Head: Civil Surgeon
- Focal Person: MO (CS/DC)
- Statistician

III. Government Medical College Hospitals:

- Hospital Director
- Focal Person: to be assigned by the Hospital Director
- Statistician

4.2.2 Surveillance Reporting from UHC

UH&FPO will be responsible for implementation of KA surveillance activities at the Upazila level and below. The activities will include:

1. Community awareness building through advocacy meetings
2. Organizing training for the health personnel
3. Identification of 'suspected cases' of Kala-azar and PKDL at the community level and their referral (as per flow chart given thereof)
4. Confirmation of diagnosis by rK39 based ICT
5. Line listing of the confirmed cases at all levels using a software which should be compatible with the web-based disease surveillance (software to be provided by the program)
6. Reporting of confirmed Kala-azar and PKDL cases including the program monitoring indicators
7. Generation of a unique identification number for each case with confirmation of diagnosis of KA and PKDL at all reporting levels

4.2.3 Flow Chart for KA and PKDL Detection from Community

Identification of 'suspected cases' of KA and PKDL by 'First Contact Points'*

↓

Referral of the suspected cases of KA and PKDL using prescribed referral form

↓

Diagnosis of the cases at UHC

Weekly reporting of incidence of KA and PKDL through the web-based disease surveillance system

*Health and family welfare centre, Union sub-centre, Community clinic, NGO health clinic, Field staff of health and family welfare, Private practitioner, Informal health care providers, IPD of UHC, OPD of UHC

Figure 6: Patient Management and Data management in UHC

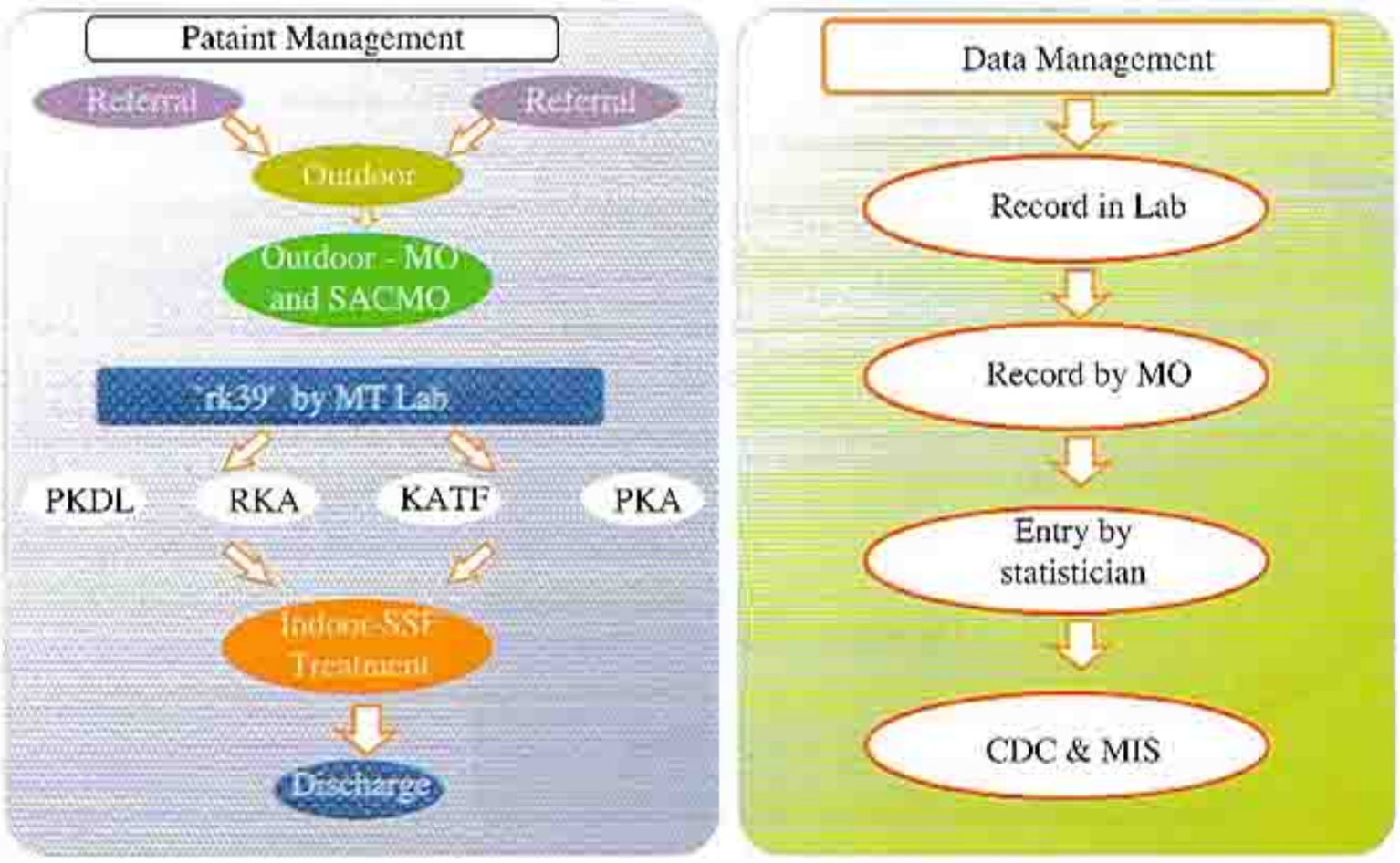
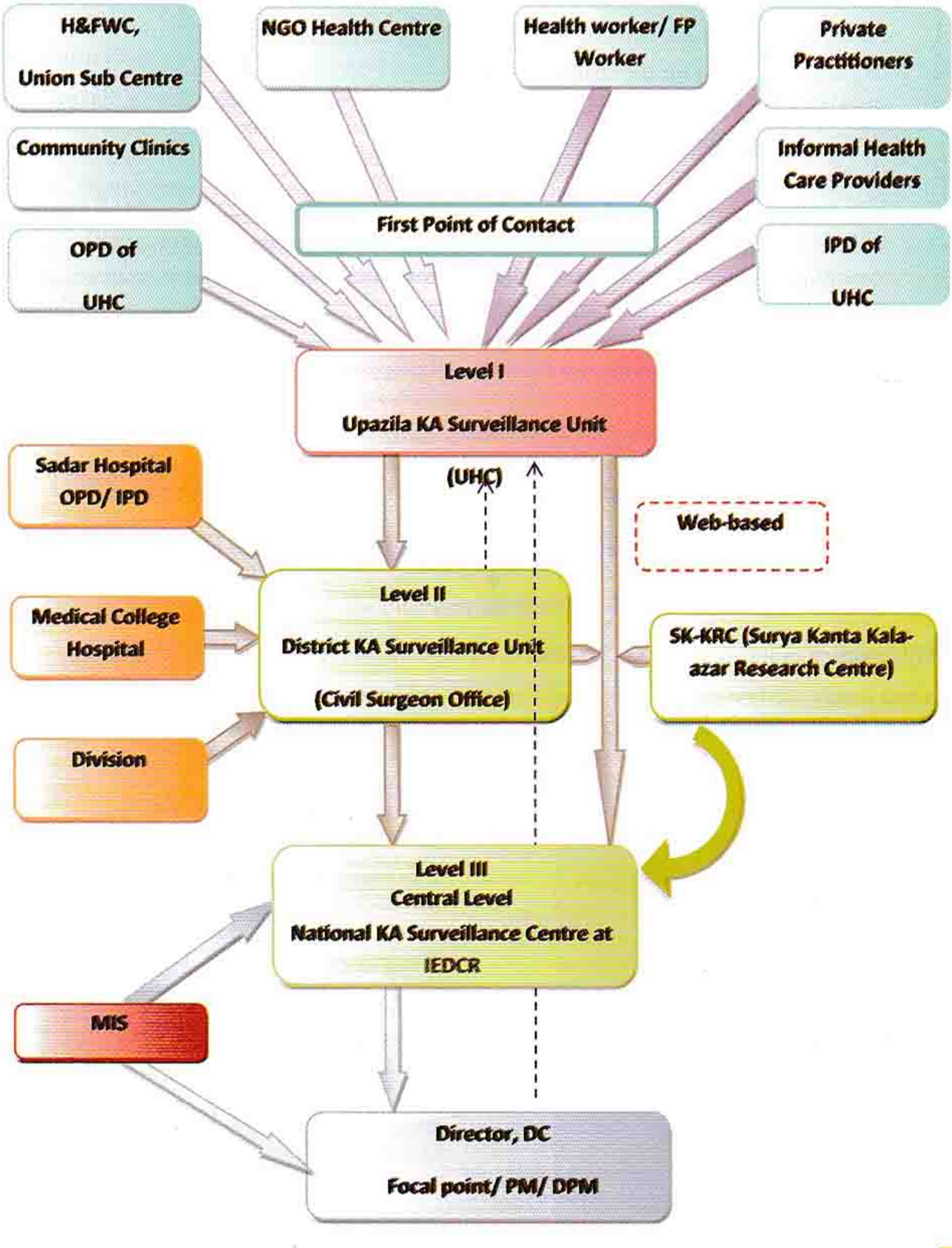


Figure 7: Data flow in Kala-azar Elimination Surveillance



4.2.4 Reporting format for diagnosis of PKA and PKDL

All suspected cases of PKA Kala-azar and PKDL attending UHC should be screened using the check list given below (Table 1 and 2). All reporting units are expected to enter the information using the reporting format mentioned in Tables 3-6. Prototype formats including the check list for identification of cases for reporting are summarized in the Tables below.

Table 3: Screening tool for diagnosis of PKA attending UHC (Check list)

Put a (√) mark on the appropriate area.

	Items	
01	History of fever for 2 weeks or more	
02	Living in endemic area	
03	Palpable spleen	

If all of the above indicators are positive, then do 'rK39'-test.

Results of 'rK39' test: +ve ☐ -ve ☐

- Patients will be labelled as a 'Suspected Kala-azar case' if the three indicators mentioned above are positive.
- Patients will be labelled as 'Probable Kala-azar Case' if 'rk39' test is posotive in a suspected Kala-azar case (All Probable Kala-azar cases must be treated according to national guideline).
- Patients will be labeled as 'Confirmed Kala-azar cases' if they meet the criteria for 'Probable Kala-azar case' and are parasitologically confirmed by spleen or Bone marrow aspiration.
- Only the suspected cases and probable cases are required to be reported for the surveillance system.

Table 4: Screening tool for 'Suspected Cases' of PKDL attending UHC (Check list)

Put a (√) mark on the appropriate area.

	Items	
01	Previous history of Kala-azar	
02	Living in endemic area	
03	Skin manifestations: with macule, papule or nodule without loss of sensation	

If all of the above indicators are positive, then do 'rK39' test.

Results of 'rK39' test: +ve☐ -ve ☐

- Patients will be labeled as a 'Suspected PKDL Case' if the three indicators mentioned above are positive.
- Patients will be labeled as a 'Probable PKDL Case' if 'rk39' test is positive in a 'Suspected PKDL Case'
- Patients will be labeled as 'Confirmed PKDL Case' if skin biopsy is positive for PKDL. Skin biopsy is recommended when the facility is available or in doubtful cases.
- All three categories of PKDL cases should be reported for the surveillance system.

Table 5: Reporting format for diagnosis of Kala-azar and PKDL.

Content	**Name of the Reporting Unit** **Upazila: Code:** **District: Code:**
Number of 'suspected' PKA cases	
Number of 'probable' PKA cases	
Number of 'confirmed' PKA cases	
Number of 'Suspected' KATF cases	
Number of 'Probable' KATF cases	
Number of 'Confirmed' KATF cases	
Number of 'Suspected' RKA cases	
Number of 'Probable' RKA cases	
Number of 'Confirmed' RKA cases	
Number of 'Suspected' PKDL cases	
Number of 'Probable' PKDL cases	
Number of 'Confirmed' PKDL cases	

Table 6: Reporting format for treatment of Kala-azar

Content	Level I (Upazila)	Level II (District)	Level III (National)
Number of patients recruited for treatment with Liposomal Amphotericin B			
Number of patients completing treatment with Liposomal Amphotericin. B			
Number of patients recruited for treatment with Miltefosine			
Number of patients completing treatment with Miltefosine			
Number of patients where treatment with Miltefosine was discontinued			
Number of patients recruited for treatment with Paromomycin			
Number of patients completing treatment with Paromomycin			
Number of patients where treatment with Paromomycin was discontinued			
Number of patients where treatment with Paromomycin was discontinued			
Number of patients recruited for treatment with Amphotericin B			
Number of patients completing treatment with Amphotericin B			
Number of patients where treatment with Amphotericin B was discontinued			

Table 7: Reporting format for treatment of KATF/ RKA

Content	Level I (Upazila)	Level II (District)	Level III (National)
Number of patients recruited for treatment with Miltefosine			
Number of patients completing treatment with Miltefosine			
Number of patients in whom Miltefosine had to be discontinued because of side effects			
Number of patients recruited for treatment with Paromomycin			
Number of patients completing treatment with Paromomycin			
Number of patients in whom Paromomycin had to be discontinued because of side effects			
Number of patients recruited for treatment with combination of Miltefosine & Paromomycin			
Number of patients completing treatment with combination of Miltefosine & Paromomycin			
Number of patients in whom combination of Miltefosine & Paromomycin had to be			
Number of patients in whom combination of Miltefosine & Paromomycin had to be discontinued because of side effects			
Number of patients recruited for treatment with combination of LAmB & Miltefosine			
Number of patients completing treatment with combination of LAmB & Miltefosine			
Number of patients in whom combination of LAmB & Miltefosine had to be discontinued because of side effects			
Number of patients recruited for treatment with combination of LAmB & Paromomycin			
Number of patients completing treatment with combination of LAmB & Paromomycin			
Number of patients in whom combination of LAmB & Paromomycin had to be discontinued because of side effects			
Number of patients in whom combination of LAmB & Paromomycin had to be discontinued because of side effects			
Number of patients recruited for treatment with Amphotericin B			
Number of patients completing treatment with Amphotericin B			
Number of patients in whom Amphotericin B had to be discontinued because of side effects			
Number of patients of PKDL recruited for treatment with SSG			
Number of patients of PKDL who complete treatment with SSG			
Number of patients of PKDL in whom SSG had to be discontinued because of side effects			

Table 8 Reporting format for treatment of PKDL

Content	Level I (Upazila)	Level II (District)	Level III (National)
Number of patients recruited for treatment with Miltefosine			
Number of patients completing treatment with Miltefosine			
Number of patients in whom Miltefosine had to be discontinued because of side effects			
Number of patients recruited for treatment with Amphotericin B			
Number of patients completing treatment with Amphotericin B			
Number of patients in whom Amphotericin B had to be discontinued because of side effects			
Number of patients of PKDL recruited for treatment with SSG			
Number of patients of PKDL who complete treatment with SSG			
Number of patients of PKDL in whom SSG had to be discontinued because of side effects			

Table 9: Reporting format for death associated with PKA, KATF, RKA and PKDL.

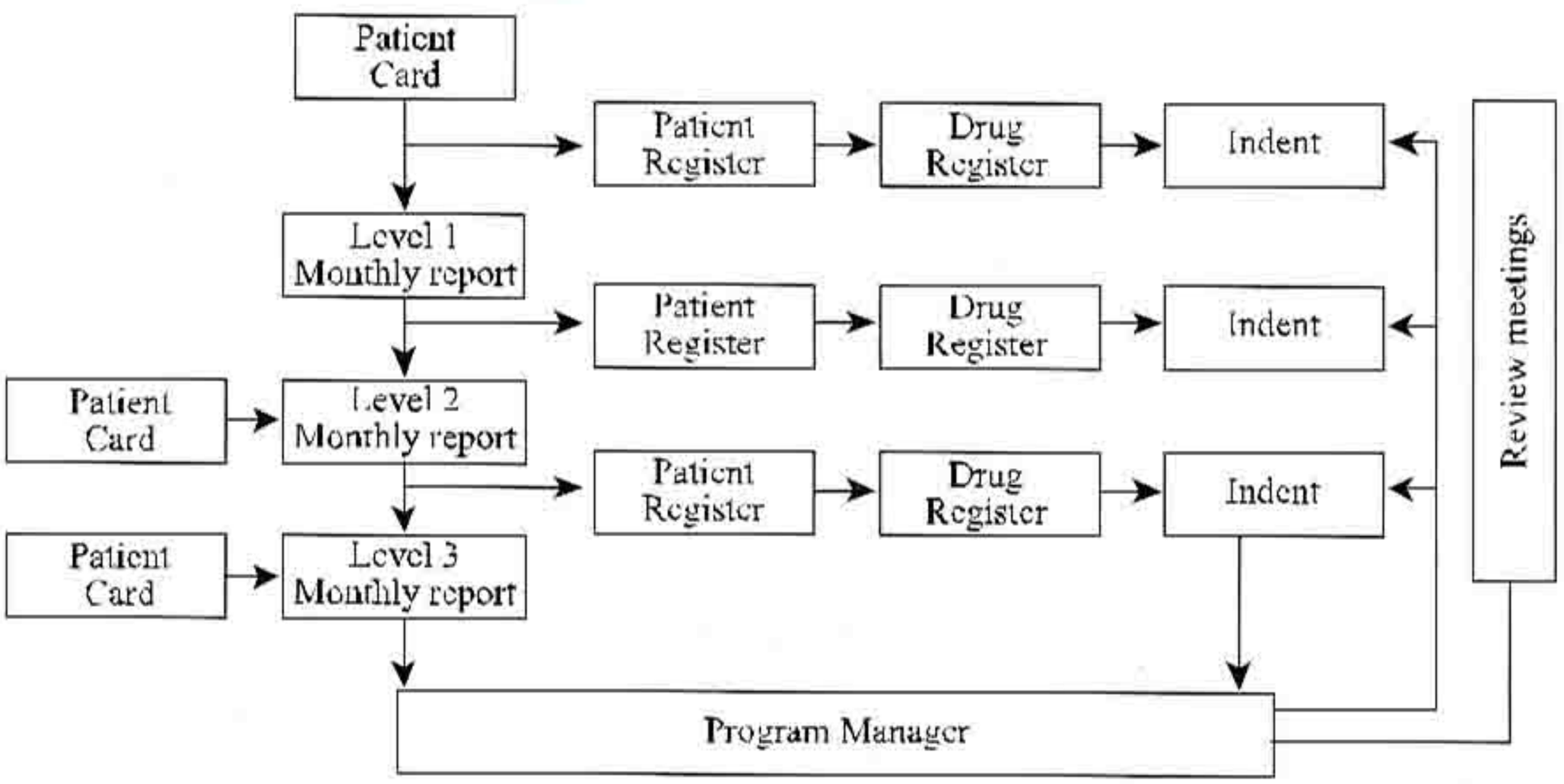
Content	Name of the Reporting Unit Upazila: Code: District: Code:
Number of patients who died after a diagnosis of PKA before starting treatment	
Number of patients who died after a diagnosis of PKA after starting treatment	
Total number of death in PKA patients	
Number of patients who died after a diagnosis of KATF before starting treatment	
Number of patients who died after a diagnosis of KATF after starting treatment	
Total number of death in KATF patients	
Number of patients who died after a diagnosis of RKA before starting treatment	
Number of patients who died after a diagnosis of RKA after starting treatment	
Total number of death in RKA patients	
Number of patients who died after a diagnosis of PKDL before starting treatment	
Number of patients who died after a diagnosis of PKDL after starting treatment	
Total number of death in PKDL patients	

4.2.5 Reporting of information

The data flow for reporting of cases of Kala-azar and PKDL should follow the flow chart shown in Fig 1. Upazila Kala-azar surveillance unit should send complete information on Kala-azar to the district focal point once in a month before the first Wednesday of each month. Once web-based surveillance is in place, surveillance data should be uploaded to the server maintained at IEDCR from all levels. A unique identifier should be used for each case during diagnosis to avoid duplication of reporting. If there are no cases then it should be a zero report. The data should be compiled at each level for the government, private and facilities, and reported mainly at Upazila and District levels in a coordinated way. Data from tertiary level health facilities including the medical college hospitals may be reported through District level or uploaded directly to web-based surveillance system if the facilities are available. There should be a feedback mechanism to make the best use of surveillance data by the government, private and NGO facilities for a common understanding of the problems that will lead to identification of possible solutions. The reports after compilation should be submitted to MO (Kala-azar elimination) of the UHC. The statistical Assistant will compile information from the reporting units from the government, private and NGO facilities and add their own.

A consolidated report should be sent to the district. The data will cover information for the preceding month. 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.

Figure 8: Information flow



4.2.6 Report review and feedback

The focal points at all levels have the responsibility to provide regular written feedback to relevant stakeholders every month. Review and feedback are important at all levels to take appropriate action. The written feedback from upazila and district will have to be copied to the program.

4.2.7 Reporting of treatment

Information available from the Treatment cards provided to patients and registers will be used for preparing treatment report. The basic information recorded include

- Personal information about the patient including address, age, sex, weight, marital status, pregnancy and lactating status
- Drugs used for treatment of Kala-azar
- Number of days treatment provided
- If treatment course has been completed or not
- Side effects of drugs
- Outcome of treatment
- Treatment provider (public, private, NGO)

4.2.8 Reporting of hospitalized cases

Separate reports are needed for indoor patients of Kala-azar. This should include the total number of admissions, the total number of patients admitted for Kala-azar, the total number of deaths and the total number of deaths due to Kala-azar. The report should be categorized according to age (under five, 5 14 and 15 and above) and sex. Information on pregnant women should be included separately in the monthly report. The outcome should be summarized as (a) cured (b) worsened (c) died. To indicate the number of patients who worsened and were referred. The report should indicate the number of patients who used the referral services. The monthly report should indicate the number of patients who completed the treatment and the number of patients who are being treated but have not completed treatment. It is also necessary to indicate the number of patients who were started treatment but have dropped out.

4.2.9 Criteria for cure

The following criteria should be used to assess cure in every patient treated for Kala-azar.

- Return of normal appetite
- Remission of fever
- Regression of spleen size
- Improvement in anemia and a rise in hemoglobin
- The full course of treatment has been taken
- Increase in body weight

4.3 Active and Passive Surveillance of PKA and PKDL

4.3.1 Passive surveillance

This is the mainstay of the program in the beginning. This means timely, regular and accurate reporting of cases who seek diagnosis and treatment of PKA, KATF, RKA and PKDL from any facility.

4.3.2 Sentinel surveillance

If there are inadequacies in the program and valid or regular information cannot be provided, the competent authority will identify sentinel sites at each level in the government, private and NGO sectors. The basic data set should be common for all the sentinel sites. Selected sites can take up additional responsibilities which include the following:

- Monitoring therapeutic efficacy of medicines according to agreed protocols
- Quality assurance of diagnosis and treatment
- PCR testing in selected cases as a part of quality assurance
- Online transmission of data
- Development of capacity of staff

4.3.3 Active surveillance

Active surveillance implies active search of cases of Kala-azar and PKDL. The active surveillance is to be done through Kala-azar week or Kala-azar fortnight by campaigning and 'house to house' visit. Active surveillance through case search will not be undertaken until the program has established adequate services.

Active Case Search:

Now Bangladesh government is trying to treat the PKA and PKDL patients at the primary level health care center with AmBisome and Miltefosine and also attempting to eliminate Kala-azar from Bangladesh. But a large number of patients have been remained undiagnosed and PKDL patients act as reservoir for transmitting disease from one person to another. There are some asymptomatic cases like PKDL who are not attending in the Upazila health complexes due to sense of well being and opportunity cost. So Active case search will be a strategy through which PKA, KATF, RKA and PKDL cases will be detected at the community level through house to house search by Kala-azar Search Volunteer (KSV) following the cases found in Upazila Health complexes.

Goal:

To reduce total Kala-azar cases by interrupting human to human transmission of Kala-azar disease.

Objective:

General objective:

To strengthen the early case detection and prompt treatment by active case search at the community level.

Specific Objectives:

1. To prepare the village wise micro-plan for active case search.
2. To develop capacity of Kala-azar Search Volunteer (KSV) to identify suspected Kala-azar cases.
3. To detect suspected Primary Kala-azar and PKDL in the community level.
4. To refer the patient to UHC or District Sadar Hospital (DSH) for early lab confirmation.
5. To manage the detected cases at UHC or District Sadar Hospital (DSH).
6. To follow up the patients for 1 year for outcome of treatment.

Strategies:

Strategy-1: The active case search team will be formed at the Upazila level consists of field staffs (AHI/HI/ Volunteer). After receiving an index case in Upazila Health Complex the active case search team will work at the community level and perform house to house search in 50 HH surrounding the Index case.

Strategy-2: During IRS the team leader also searches for suspected cases and then the suspected cases are referred to health complexes for proper diagnosis. After confirm diagnosis in Upazila health complex the address of the patient will be collected and then the team will perform house to house search in the same manner.

Strategy-3: The Kala-azar search volunteer (KSV) will search for new cases in 150 HH per day in every village in respective union of hyper-endemic upazilas and will cover all the HH of that village. After indentifying the suspected cases the Kala-azar search volunteer (KSV) will refer the suspected cases to Upazila Health Complex where the Physician will perform clinical examination and lab technician will perform 'rk39' test and after confirmation the patients will be given treatment according to National Guideline of Kala-azar Treatment and the patient will be taken under follow up program. The HI/AHI/SI will supervise the activities of Kala-azar Search Volunteer.

Activities have to be performed:

1. Protocol Development on Active case search (ACS)
2. Development of Micro-plan for Active case search (ACS)
3. Development of budget for all activities
4. Training of Upazila Kala-azar Elimination Team (UKET)
5. Training of Kala-azar Search Volunteer (KSV)
6. Development of IEC materials and it's execution
7. House to house search at the community level
8. Monitoring and supervision
9. Reporting

Activity flow chart during Active Case Search (ACS)

Kala-azar Search Volunteer (KSV) will do house to house search according to Micro-plan by using HH Survey Form (Annex) and will ask the HH members regarding Kala-azar

After finding the suspected case KSV will fill up Suspected Kala-azar case list (Annex).

Then the suspected case will be referred to UHC with a referral form (Annex) including Name and contact number of medical Officer of that UHC and Contact number of Central person

In UHC the Medical officer will check the referral form and perform medical examination and then send the patients to MT Lab for rk39 RDT test. After confirmation MO will fill up the registration and Follow up book (Annex) for the patient and provide him/ her treatment according to National Guideline of Kala-azar treatment.

During discharge the patient will be given a Follow up card (Annex) and a date for the next follow up

AHI/HI will ensure follow up of the patients at the community level

4.3.4 Surveillance of PKDL

The surveillance of PKDL is as important as surveillance of Kala-azar since cases of PKDL serve as a reservoir for disease transmission during the inter-epidemic period. The program should do passive and active surveillance of PKDL

Chapter V
Monitoring and Evaluation

Routine monitoring, periodic assessment and evaluation would be done by the program at all levels to ensure effective implementation of different activities as per plan. A set of objectively verifiable indicators will be used to measure progress and assess the achievement of elimination program in line with national Kala-azar strategy. For regular monitoring a checklist will be used to see any gaps of the ongoing activities. External independent evaluation can be done to assess the progress and thereby indicate necessary modification in strategies of program implementation. World Health Organization or any other competent authority will do external evaluation.

For monitoring and supervision four different teams will be deployed.

1. Central monitoring team- which consists of
   a. Line Director (CDC)
   b. DD, M&PDC, DGHS
   c. DPM- Kala-azar
   d. National Consultant- Kala-azar
   e. Surveillance Medical Officer- Kala-azar
2. District level monitoring team
   a. Civil Surgeon
   b. De
3. Upazila level monitoring team
   a. Upazila Health & Family planning officer
   b. MO (DC)
4. Field Monitoring team
   a. Health Inspector
   b. Assistant Health inspector
   c. Health Assistant

5.1 Framework of indicators for monitoring and evaluation (M&E) of KEP

The tables of indicators stated below explain how the 'Kala-azar Elimination Program' will be monitored and evaluated at upazila (table-3) and country (table-3) level.

The input-process-output-outcome framework is used for monitoring and evaluation.

- Input: describes the resources allocated to an activity.
- Process: describes the activities and performance within the services.
- Output: measures the direct products (deliverables) of an activity.
- Outcome: describes the effect of these activities in terms of behavioral change and health outcomes (impact).

It is not necessary to measure every single cell in this framework table. The Indicators will be calculated and analyzed separately for Upazila and country level to improve the quality of service in both level.

Table 10. Indicators for monitoring KA elimination activities at upazila level

Service Delivery area	Input	Process	Output	Outcome	Source of data
Passive case Search		Number of facilities providing KA and PKDL diagnostic services/number of all facilities Number of providers trained in KA and PKDL diagnosis/total number of providers	Number of KA and PKDL cases registered by passive case search	KA detection rate: number of KA cases detected by health facility per 10 000 population in (sub)district or UHC PKDL detection rate: number of PKDL cases detected by health facility per 10 000 population in (sub)district or UHC % KA cases treated/ all cases diagnosed by health Facility	Monthly reports by PHC/UHC to district Level
Active case Search	Number of screening teams trained and deployed for Active case search teams planned	Number of training sessions done/ number of training sessions planned Number of screening sessions (camps, index-case search) done/number of screening sessions planned Number of villages screened	Number of KA cases diagnosed, Number of PKDL cases diagnosed : % of target population screened Yield: average number of KA cases detected /number of all KA cases detected	% KA cases treated/all those confirmed in screening % PKDL cases treated/all those confirmed in Screening.	Screening register and report
Diagnosis	Number of rK39RDT kits supplied to PHC level/number of rK39 RDT kits required for the month	Number of facilities with uninterrupted rK39RDT supply (not a single day of stockout in ihe past month)/number of all facilities with diagnostic services Number of rK39RDTs done per month Number of PHCs doing rK39RDTs/all PHCs Number of lab technicians trained to use rK39RDTs/number of all lab technicians Number of EQA sessions on rK39RDTs done/number of EQA sessions planned	Number of rK39 positive RDTs/total number of rK39 RDTs per month	Laboratory register at PHC/UHC and monthly report to district level Immediate phone alert to program manager if there are any stockouts in district Requisition form sent on time.	

Service Delivery area	Input	Process	Output	Outcome	Source of data
Treatment 1. Starting treatment	Number of miltefosine or other drug courses supplied to PHC or UHC level/number of drug courses requested Number of pregnancy-test kits supplied to PHC leave	Number of facilities without interruption of miltefosine (or other drug) supply (not a single day of stockout in the past month)/number of facilities with KA treatment Number of pregnancy tests done/number of women of childbearing age starting		Number of treated KA cases/number of all confirmed KA cases	Patient register Laboratory register
2. Evaluating treatment results Safety		Number of patients treated per month	Treatment completion rate	Initial outcomes: o initial cure rate (%): number with initial cure/total number who started treatment o defaulter rate (%): number of defaulters/ total number who started treatment o case fatality rate %) Final outcomes (six months) o % final cure o % treatment failure o % serious adverse events reported by type of drug	Patient register
Social mobilization	Total amount of information, education and communicatio n (IEC) materials - leaflets, posters, videos Number of IEC staff	Number of IEC sessions done/number of sessions planned Amount of IEC materials used/total amount of IEC materials supplied	Coverage: number of population reached with IEC/target population	Behavioral change: acceptance rate of preventive measures (vector control and others)	Behavioural survey

Table 10. Indicators for monitoring KA elimination activities at country-level (additional)*

Service Delivery area	Input	Process	Output	Outcome	Source of data
Strategy formulation	Policy and 3strategy guideline published Advocacy plans available Coordination mechanisms in place		Number of health facilities offering standard KA diagnosis and treatment/ number of all facilities % at-high-risk population covered by active case search	% of subdistricts/UHCs/districts reaching elimination target1	Guidelines Meeting reports Monthly and annual reports Community surveys
Epidemiological surveillance	Case definitions made available Teams employed for investigation of any alerts on KA cases in new areas provided by health service, newspapers, politicians Response mechanisms defined	Number of public sector units notifying KA regularly/all units Number of investigations done for KA in previously non-endemic areas	Number of new endemic areas reported	Surveillance reports	
Private sector involvement through awareness raising	Sessions training private practitioners (PPs) in standard KA care Incentive mechanisms for PPs	Number of sessions training PPs in standard KA care/number of planned sessions	Number of PPs actively involved/all PPs	Number of PPs notifying KA for trend analysis % KA patients accessing quality care with trained PPs	Health-seeking behaviour studies
Drug and diagnostics supply	Supply mechanisms defined Quality assurance mechanisms in place	% health facilities reporting stock status on monthly basis	% health facilities reporting no shortage in rK39RDTs and miltefosine supply	% target population with access to diagnostics	Stock register and physical verification

Service Delivery area	Input	Process	Output	Outcome	Source of data
Human resources	Number of dedicated staff for program/ number of planned staff	Number of training sessions		Number of target areas covered by trained staff	
Funds	Annual budget allocated		Spending Rate		
M&E	Indicator toolbox developed	Annual review meeting Number of WHO Regional Office for South-East Asia independent review missions conducted/number of review missions planned	Response given to M&E information	% subdistricts/upazila/districts reaching elimination target (< 1 cases/10 000 population/year)	Monthly report Annual report Decisionsupport system
Operational research (OR)	Funds allocated to OR	Number of OR studies conducted/number of OR studies planned	Number of OR studies contributing to strategic decisions	Number of OR studies contributing to strategic decisions	Central Level data base/ MIS Data Base