

Indicators for monitoring and evaluation of the kala-azar elimination programme

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Kala-azar elimination in Bangladesh, India and Nepal

August 2010

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Abbreviations

ACD	active case detection
ECG	electrocardiogram
HH	household
IEC	information, education and communication
IRS	indoor residual spraying
ITN	insecticide-treated net
IVM	integrated vector management
KA	kala-azar
LN	long-lasting insecticide-treated net
M&E	monitoring and evaluation
OR	operational research
PCD	passive case detection
PHC	primary health centre
PKDL	post kala-azar dermal leishmaniasis
PP	private practitioner
RDT	rapid diagnostic test
rK39	rK39 antigen
rK39RDT	rK39 antigen-based rapid diagnostic test
SAG	sodium antimony gluconate
SSS	slit-skin smear
UHC	upazila health centre
VL	visceral leishmaniasis

Introduction

This document contains the WHO Regional Office for South-East Asia's and The Special Programme for Research and Training in Tropical Diseases' (TDR) recommended indicators for monitoring and evaluation of the kala-azar elimination programme.

The document is presented in two parts:

- **Part 1** covers case detection and management.
- **Part 2** covers vector management.

The indicators outlined in this document were developed by representatives from Bangladesh, India and Nepal at a WHO-TDR sponsored workshop on kala-azar held in Dhaka, Bangladesh 8–16 June 2009 and were endorsed by the regional technical advisory committee (RTAG) in Dhaka, Bangladesh 7–10 December 2009.

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PART 1. CASE DETECTION AND MANAGEMENT

Kala-azar (KA), also known as visceral leishmaniasis (VL), is an infectious disease caused by the *Leishmania* parasite when it is transmitted by the bite of an infected sandfly. KA is fatal when untreated. There are approximately 500 000 new cases every year worldwide, the majority of which occur in Bihar, India, followed by the border regions of Bangladesh and Nepal. These figures do not reflect the true social impact of this disease because KA has a focal distribution that affects primarily the poorest communities.

Although no vaccine is available, important recent advances have made it possible to eliminate KA from the Indian subcontinent. This document provides definitions and indicators that will be useful for those involved in KA elimination.

1.1 Case definitions

1.1.1 Case definition of KA

A person from an endemic area with a fever of more than two weeks duration and with splenomegaly should be tested for KA:

- using a standard, quality-assured rapid diagnostic test (RDT) based on the rK39 antigen at the primary health centre (PHC)/upazila health centre (UHC) level
- or
- by biopsy for parasitology at hospitals with appropriate training.

These are the case definitions presented in the country guidelines of Bangladesh, India and Nepal; the elimination initiative documents use only one case definition for KA (see Box 1).

Box 1. Case definition of KA

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

1.1.2 Treatment outcomes in KA

Treatment outcomes in KA have to be assessed twice:

- (i) at the last day of drug treatment (initial outcome)
- and
- (ii) six months after the last drug was taken (final outcome).

The KA elimination initiative has trained health workers to distinguish four main outcomes in KA treatment (see Box 2).

Box 2. Treatment outcomes in KA

1. **Cure:** *a patient is considered clinically cured if he/she has completed full treatment and there are no signs and symptoms of KA*
2. **Non-response:** *signs and symptoms persist or recur despite satisfactory treatment for more than two weeks*
3. **Relapse:** *any reappearance of KA signs and symptoms within a period of six months after the end of treatment*
4. **Treatment failure:** *non-response or relapse*

There are more possible outcomes at each time point. These are listed below.

At initial assessment, at the last day of drug treatment

- **Initial cure:** a full course of drugs has been completed AND the patient has clinically improved. Clinical criteria for cure should be assessed as no fever + regression of enlarged spleen + return of appetite and/or gain in body weight.
- **Non-response:** signs and symptoms persist or recur. Switch to a second-line drug because of no response to the first-line drug.
- **Side-effects related switch:** side-effects necessitate a change of treatment.
- **Death:** any death, whether or not related to KA.
- **Default:** the patient does not complete treatment and/or does not present for assessment after treatment.

At final assessment, six months after the last drug taken

- **Final cure:** an initial cure patient who is symptom-free at six months after the end of treatment.
- **Relapse:** any reappearance of KA symptoms within a period of six months after the end of treatment.
- **Death:** any death, whether or not related to KA.
- **Loss to follow-up:** patient does not present for assessment at six months.

1.1.3 Case definition of post kala-azar dermal leishmaniasis (PKDL)

Surveillance of PKDL is important since such cases can serve as reservoirs for disease transmission during the interepidemic period.

The programme will include the search for PKDL in active case-detection strategies. The reporting of cases of PKDL should be an integral part of the surveillance and monitoring system. It is essential to make special efforts to trace these cases in the community because patients with PKDL have only skin manifestations and therefore often consult only skin specialists. PKDL can be confused with paucibacillary or multibacillary leprosy and the skin lesions may also mimic other skin conditions (see Appendix 1. Pictorial for PKDL screening). Box 3 shows the recommended case definitions for reporting.

Box 3. Case definitions for PKDKL

Probable PKDL: *a patient from a KA-endemic area with multiple hypopigmented macules, papules, plaques or nodules, who is RDT positive*

Confirmed PKDL: *a patient from a KA-endemic area with multiple hypopigmented macules, papules, plaques or nodules, who is parasite positive in slit-skin smear (SSS) or biopsy*

1.1.4 Treatment outcomes in PKDL

Treatment outcomes in PKDL are also clinically assessed at PHC/UHC level and are not so well-standardized. A drastic improvement can mean, for example, at least 80% resolution in the number of macules and/or a decrease in erythema and flattening of lesions. Box 4 gives the suggested definitions.

Box 4. Treatment outcome in PKDL

Initial cure: *clinical improvement at the end of treatment – defined as a considerable reduction in the number and size of skin lesions*

Final cure: *clinical cure 12 months after the end of treatment – defined as a complete resolution of macules, papules, plaques and nodules*

1.2 Definitions of KA case-detection activities

Passive case detection (PCD): patients are detected through regular health service activities in health centres and clinics. Health providers then manage the cases and notify authorities at district level.

Active case detection (ACD)/active case search: health-care personnel go to the community and screen the population to find cases of KA. ACD is an essential component of the elimination strategy. Several possible approaches are defined below.

- *House-to-house search (or blanket screening):* a medical team visits every house in a community in an endemic area and screens every household member for KA/PKDL.
- *Index-case approach (also called snowballing):* an index case is defined as a person who is currently suffering or has suffered from KA or PKDL during the past 12 months. A focused search in which all households in a certain perimeter around an index case are visited and screened for KA/PKDL.

- *Camp-based approach*: a medical camp is organized in a central place in an endemic village and the community is actively encouraged to participate. It is particularly important that patients with fever of more than two weeks duration or with skin lesions after past KA treatment present for a simple medical check-up that screens for KA/PDKL.
- *Incentive-based approach*: a financial or other incentive/award is provided to health volunteers or village health workers who detect suspected cases of KA and motivate these cases to report to health facilities where they are then diagnosed with KA/PKDL.

1.3 Key indicators for the KA elimination initiative

The target of KA elimination is to reduce KA incidence below 1 per 10 000 persons per year at (sub)district and upazila level by 2015. Box 5 shows three key indicators that each district and subdistrict should monitor closely and compute on an annual basis.

The first indicator is the **detection rate** – tracking all new cases of KA in an area within a given year. Many KA cases are not recorded in the surveillance system and therefore the programme will make efforts to involve the private sector and obtain reports of relevant cases.

The second indicator is the **treatment completion rate**. Without adherence to treatment, patients will not benefit from it but will continue to spread the disease with the risk that the parasites may become resistant to the drugs. The target for treatment completion rate in any district should be above 90%.

The third indicator includes vector control for **coverage rate** by indoor residual spraying (IRS) (see Part 2 on vector management).

Box 5. Key indicators in the KA elimination initiative

Detection rate (%):

$\frac{\text{Number of new cases of KA detected per year in the district, UHC or subdistrict}}{\text{Total population in the same area}} \times 100$

Treatment completion rate (%):

$\frac{\text{Number of patients that took a full course of first-line drugs}}{\text{All new KA cases that started treatment in a given period}} \times 100$

Coverage rate of vector control (%):

$\frac{\text{Number of households protected}}{\text{All households at risk}} \times 100$

1.4 Monitoring clinical outcomes

Monitoring the final clinical outcomes of KA treatment is complex and not retained as a key indicator. It requires an assessment six months after the last day of treatment and few patients return for such a late follow-up visit. Moreover, either the data need to be organized in cohorts, or groups of patients must be recruited in a given time period and patient registers examined at an appropriate time, i.e. AT LEAST six months after the cohort finishes treatment. Such an approach is known as retrospective cohort monitoring and is applied by tuberculosis control programmes. If done correctly, it allows computing of the:

- **final cure rate (%)**:

$$\frac{\text{Number of patients with final cure}}{\text{Total number who started treatment}} \times 100$$

- **treatment failure rate (%)**:

$$\frac{\text{Total number of non-responses + relapses + KA-related deaths}}{\text{Total number who started treatment}} \times 100$$

- **loss to follow-up rate (%)**:

$$\frac{\text{Number of defaulters + number of losses to follow-up}}{\text{Total number who started treatment}} \times 100$$

- **mortality (%)**:

$$\frac{\text{Number of deaths}}{\text{Total number who started treatment}} \times 100$$

In the district programmes it is easier and recommended to keep track of **the initial cure rate**, computed as a percentage:

$$\frac{\text{Number with initial cure}}{\text{Total number who started treatment}} \times 100$$

1.5 Pharmacovigilance

The purpose of pharmacovigilance is to detect, assess, understand and prevent any adverse effects or other medicine-related problems and to monitor drug unresponsiveness/resistance.

Pharmacovigilance is important to ensure the safety of the medicines used in the treatment of KA. It should be the responsibility of the national programme to ensure pharmacovigilance. This can provide very useful information but requires appropriate protocols and strong supervision to avoid any compromise in quality.

Each medicine used in the programme has some side-effects. These may be looked for in the form of signs and symptoms. Laboratory tests can help with early recognition of the occurrence of the side-effects. For example, haemograms, liver and kidney function tests, tests for electrolytes and electrocardiograms (ECGs) are recommended for monitoring a patient but it can be difficult to include such tests in the programme. This information can be complemented by regular reporting of major and minor adverse events.

The following measures will help with early recognition of the occurrence of adverse events:

- Monitor patient regularly for signs and symptoms indicative of adverse events of drugs. Any signs and symptoms should be classified as major or minor.
- If possible, perform tests in treatment sites and monitor the results. This can facilitate timely measures even before any signs appear.
- Organize periodic meetings to review reports of major and minor adverse events submitted from the different levels. This will help guide the programme in recommending the tests necessary to monitor patients that are on treatment.
- Use reporting forms to report any adverse events to higher levels once a month for review and feedback.

For miltefosine, special attention should be given in cases of PREGNANCY and in cases of HIV/KA or tuberculosis/KA coinfection.

Table 1 shows the known side-effects of KA drugs that should be monitored. Each reporting form used by national services should also allow unanticipated effects to be recorded. Other drugs (e.g. paromomycin) can be added to the list according to national drug policies and approval by technical advisory committees.

Table 1. Known side-effects of KA drugs and how to recognize them

Medicine	Side-effects	Symptoms and clinical signs	Laboratory tests and ECG
Miltefosine	Gastrointestinal effects	Abdominal pain, vomiting, diarrhoea	Creatinine Bilirubin, liver enzymes
	Nephrotoxicity	Dehydration, oedema, decreased urine output	
	Hepatotoxicity	Jaundice	
	Any other, unanticipated		
Sodium antimony gluconate (SAG)	Cardiotoxicity	Arrhythmia, heart failure	ECG Creatinine Bilirubin, liver enzymes
	Osteomuscular effects	Arthralgia, myalgia	
	Nephrotoxicity	Oedema, decreased urine output	
	Hepatotoxicity	Jaundice	
Amphotericin B	Drug reaction	Fever with chills and rigors	
	Nephrotoxicity	Oedema, decreased urine output	Check renal function, electrolytes, hypokalaemia
	Cardiotoxicity	Arrhythmias	
	Ototoxicity	Hearing loss, vertigo	
	Any other, unanticipated		

Based on Table 1, the following checklist is proposed for pharmacovigilance of miltefosine in a district (Table 2). Such a checklist should be part of the patient's clinical chart and adapted if other drugs are used.

Table 2. Checklist for adverse events reported during outpatient miltefosine treatment

Adverse events	First visit		Second visit		Third visit		Fourth visit		Last visit	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Vomiting										
Diarrhoea										
Abdominal pain										
Rash										
Jaundice										
Suspected renal failure										
Other (add brief notes here)										
Hospitalization? If yes, give reason for admission (add brief notes here)										

1.6 Framework of indicators for monitoring and evaluation (M&E) of the KA elimination initiative

This section shows a larger toolbox with indicators that programmes can use to monitor and evaluate KA elimination activities at district (Table 3) and country level (Table 4). They are organized within the input-process-output-outcome framework.

- **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 behavioural change and health outcomes (impact).

It is not necessary to measure every single cell in this framework table (Table 3). The purpose of district-level monitoring is to improve the quality of KA elimination operations at that level; indicators should therefore be computed and analysed at district level. Country-level monitoring has a similar purpose and indicators should therefore be computed and analysed at country level (Table 4).

The overview table suggests a number of relevant indicators, the most important of which are shown in bold. Most indicators are expressed as percentages. Those that show numbers only are intended for trend analysis (i.e. examining their evolution over time).

Table 3. Indicators for monitoring KA elimination activities at district level

Service delivery area	Input	Process	Output	Outcome	Source of data
Passive case detection (PCD)		<p>Number of facilities providing KA and PKDL diagnostic services/number of all facilities</p> <p>Number of providers trained in KA and PKDL diagnosis/total number of providers</p>	Number of KA and PKDL cases registered by PCD	<p>KA detection rate: number of KA cases detected by health facility per 10 000 population in (sub)district or UHC</p> <p>PKDL detection rate: number of PKDL cases detected by health facility per 10 000 population in (sub)district or UHC</p> <p>% KA cases treated/all cases diagnosed by health facility</p>	Monthly reports by PHC/UHC to district level
Active case detection (ACD)	Number of screening teams trained and deployed for ACD/number of screening teams planned	<p>Number of ACD training sessions done/number of training sessions planned</p> <p>Number of screening sessions (camps, index-case search) done/number of screening sessions planned</p> <p>Number of villages screened by any method/planned number of villages for screening</p>	<p>Number of KA cases diagnosed by ACD</p> <p>Number of PKDL cases diagnosed by ACD</p> <p>Coverage: % of target population screened</p> <p>Yield: average number of KA cases detected by ACD/number of all KA cases detected</p>	<p>% KA cases treated/all those confirmed in screening</p> <p>% PKDL cases treated/all those confirmed in screening</p>	Screening register and report

Service delivery area	Input	Process	Output	Outcome	Source of data
Diagnosis	Number of rK39RDT kits supplied to PHC level/number of rK39 RDT kits required for the month	<p>Number of facilities with uninterrupted rK39RDT supply (not a single day of stockout in the past month)/number of all facilities with diagnostic services</p> <p>Number of rK39RDTs done per month</p> <p>Number of PHCs doing rK39RDTs/all PHCs</p> <p>Number of lab technicians trained to use rK39RDTs/number of all lab technicians</p> <p>Number of EQA sessions on rK39RDTs done/number of EQA sessions planned</p>	Number of rK39 positive RDTs/total number of rK39 RDTs per month		<p>Laboratory register at PHC/UHC and monthly report to district level</p> <p>Immediate phone alert to programme manager if there are any stockouts in district</p> <p>Requisition form sent on time.</p>
Treatment 1. Starting treatment	<p>Number of miltefosine or other drug courses supplied to PHC or UHC level/number of drug courses requested</p> <p>Number of pregnancy-test kits supplied to PHC level</p>	<p>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</p> <p>Number of pregnancy tests done/number of women of childbearing age starting miltefosine treatment</p>		Number of treated KA cases/number of all confirmed KA cases	<p>Patient register</p> <p>Laboratory register</p>

Service delivery area	Input	Process	Output	Outcome	Source of data
2. Evaluating treatment results Safety		Number of patients treated per month	Treatment completion rate	Initial outcomes: <ul style="list-style-type: none"> initial cure rate (%): number with initial cure/total number who started treatment defaulter rate (%): number of defaulters/total number who started treatment case fatality rate (%) Final outcomes (six months) <ul style="list-style-type: none"> % final cure % treatment failure % serious adverse events reported by type of drug 	Patient register
Social mobilization	Total amount of information, education and communication (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	Behavioural change: acceptance rate of preventive measures (vector control and others)	Behavioural survey

Table 4. Indicators for monitoring KA elimination activities at country-level (additional)*

Service delivery area	Input	Process	Output	Outcome	Source of data
Strategy formulation	<p>Policy and strategy guideline published</p> <p>Advocacy plans available</p> <p>Coordination mechanisms in place</p>		<p>Number of health facilities offering standard KA diagnosis and treatment/number of all facilities</p> <p>% at-high-risk population covered by active case search</p>	% of subdistricts/UHCs/districts reaching elimination target ¹	<p>Guidelines</p> <p>Meeting reports</p> <p>Monthly and annual reports</p> <p>Community surveys</p>
Epidemiological surveillance	<p>Case definitions made available</p> <p>Teams employed for investigation of any alerts on KA cases in new areas provided by health service, newspapers, politicians</p> <p>Response mechanisms defined</p>	<p>Number of public sector units notifying KA regularly/all units</p> <p>Number of investigations done for KA in previously non-endemic areas</p>	Number of new endemic areas reported		Surveillance reports

* Additional to the district level indicators as they also will be aggregated at the country level

¹ To reduce KA incidence below 1 per 10 000 per year in all (sub)districts and UHCs by 2015

Service delivery area	Input	Process	Output	Outcome	Source of data
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
Human resources	Number of dedicated staff for programme/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 Decision-support 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	WHO Regional Office for South-East Asia/WHO documents

PART 2. VECTOR MANAGEMENT

2.1 Definitions and sources of information

2.1.1 Definitions/ acronyms

Environmental management for vector control (EVM): the planning, organization, execution and monitoring of activities for the modification and/or manipulation of environmental factors or their interaction with humans with a view to preventing or minimizing vector propagation and reducing human-vector-pathogen contact.

Integrated vector management (IVM): a rational decision-making process for the optimal use of resources for vector control. IVM seeks to improve the efficacy, cost-effectiveness, ecological soundness and sustainability of disease vector control.

Indoor residual spraying (IRS): application of insecticides by spraying

Long-lasting insecticide-treated net (LN): net treated with slow release chemicals

2.1.2 Sources of information²

- WHO Regional Office for South-East Asia documents on IVM.
- WHO Pesticides Evaluation Scheme (WHOPES) documents on:
 - Guidelines for testing mosquito adulticides
 - Guidelines for testing LNs
 - Manual for IRS.

2.2 Key indicators for vector management

The use of coverage of vector control operations (mainly IRS and/or LNs) as a key indicator in the elimination strategy is mentioned in Section 1.3 above. However, reduction of vector densities depends not only on the coverage of houses or structures (rooms) but also on the quality of treatment.

Quality indicators include:

- performance of spray persons (or dippers, where nets are dipped in slow-release chemicals)
- accuracy of spraying: % of chemical concentration achieved on treated materials out of the target concentration – filter paper technique for IRS; analysis of net samples for insecticide-treated nets (ITNs).

² For details see bibliography.

2.3 Framework of indicators for vector management

The indicators for monitoring vector management at national, district and operational level are presented below (Tables 5–7).

National-level information is generally the aggregation of information from the operational level received via district level activities. For this reason, the national (Table 5) and district (Table 6) tables show only those additional indicators that are to be collected for each level.

The list of indicators to be used for IRS at the operational (i.e. spraying squad) level is presented in Table 7. These indicators (as well as the check list information presented in Appendix 2) are more detailed as they form the basis for the overall information system and will be aggregated initially at district level and subsequently at national level. The electronic information system will facilitate information flow and the construction of indicators at district and national level.

Table 5. Country-level indicators for vector management

Service delivery area	Input	Process	Output	Out-come	Source of data
Strategy formulation	<p>Annual national action plan developed</p> <p>Risk stratification of KA-affected areas completed</p> <p>Choice of insecticides completed</p> <p>Documentation on efficacy of insecticide obtained from manufacturer</p> <p>Human resource plans established</p>				
M&E	<p>Number of endemic districts with plans for vector management & resistance monitoring/number of all endemic districts</p> <p>Number of endemic districts with M&E tool kit/number of all endemic districts</p> <p>Number of endemic districts with risk stratification/number of all endemic districts</p>	<p>Number of endemic districts using M&E tool kit/number of all endemic districts</p>	<p>Number of endemic districts responding to problems identified/number of all endemic districts</p>		M&E reporting system
IRS (see detailed operational M&E tool kit)	<p>Number of endemic districts with annual action plan/number of all endemic districts</p>	<p>Number of endemic districts implementing annual action plan/number of all endemic districts</p>	<p>Number of districts with spraying cycles completed/number of districts with spraying cycles planned</p> <p>Number of districts with M&E tool kit completed/number of districts with spraying cycles</p> <p>Number of districts with household (HH) coverage above 80% in spray areas/number of districts with spraying cycles</p>		M&E reporting system
LN	<p>Number of endemic districts with stratification plan for LN implementation/number of endemic districts</p>		<p>Number of endemic districts with LNs distributed/number of districts with LN plan.</p> <p>Number of districts with LN coverage above 80% in LN areas/number of districts with LN activities</p>		M&E reporting system

Table 6. District-level indicators for IRS¹

Service delivery area	Input	Process	Output	Outcome	Source of data
Supplies (guidelines/action plans; insecticides; spraying pumps; IEC materials)*	<p>Availability of guidelines and action plans in subdistricts/number of endemic subdistricts</p> <p>Logistics of insecticide distribution in place? (descriptive)</p> <p>Insecticides in stock/insecticides requested</p> <p>Protective clothing to operational level distributed/protective clothing needed</p> <p>Number of pumps available/number of pumps needed</p> <p>Number of IEC materials distributed/number of IEC materials planned</p>	Number of functional pumps/number of existing pumps			M&E reporting system
Human resources (spraypersons; supervisors; managers)	<p>Number of available spraypersons/number of spraypersons required</p> <p>Number of supervisors needed/number of supervisors planned</p>	<p>Number of training sessions done/number of training sessions planned</p> <p>Number of supervisions conducted/number of supervisions planned</p>	<p>Number of teams with correct performance/total number of spray teams</p> <p>Average concentration of insecticide on wall/target concentration</p> <p>Number of houses sprayed/number of houses targeted (coverage**)</p> <p>g/m² insecticide compared to expected</p>	Sandfly density (before, one month and six months after IRS)	M&E reporting system

			value		
M&E (use of M&E tool kit; performance monitoring; output/outcome monitoring)	<p>M&E tool kit available in subdistricts/number of endemic subdistricts</p> <p>Bioassay testing in place (descriptive)</p> <p>Bioassays available (contracted out?)</p> <p>Light trapping available (contracted out?)</p> <p>Chemical analysis of filter papers organized? (descriptive)</p>	<p>Number of subdistricts applying M&E tool kit/number of subdistricts with IRS</p> <p>Number of houses sprayed/number of houses targeted (coverage)*</p> <p>Number of bioassays done/number of bioassays planned</p> <p>Number of HHs with light traps done/number of HHs with traps planned</p>	Responses to issues identified by tool kit (descriptive)	Sandfly density (before, one month and six months after IRS)	M&E reporting system
<p>¹ For a number of indicators, information will be collected at operational level and then aggregated at district level.</p> <p>* Other supplies are related to "storage facilities for insecticides", "people's satisfaction with IRS", IRS coverage reported in HH surveys as compared to coverage reported by sprayers.</p> <p>** Coverage can also be expressed as number of HHs sprayed/population.</p>					

Table 7 Operational indicators to be used at IRS operational level
(corresponds to FORM 3.3 in the M&E toolkit; see bibliography)

Identity

Name of country:

Name of district (state)/PHC/upazila/VDC:.....

State/regional code: /___/___/(00 for Bangladesh)

Spray year:.....Spray cycle: /___/ (1= 1st cycle, 2 = 2nd)

Date dd /mm/yyyy:.....

Name of responsible officer:

No	Component	Indicator	Construction of indicator
A. Information below will be collected before IRS			
3301	Functional pumps available	% of functional pumps available	$\frac{\text{No. functional pumps}}{\text{No. all pumps}} \times 100 =$
3302	Insecticides	% available quantity	$\frac{\text{Kg or tonnes available}}{\text{Kg or tonnes needed}} \times 100 =$
3303	Spare parts for pumps	% available spare parts (by type) e.g. nozzle tips, leather cups, washer spring	$\frac{\text{No. spare parts available}}{\text{No. spare parts needed}} \times 100 =$
3304	Personal protective equipment (PPE)	% available of PPE required e.g. caps, goggle masks, overalls, full sleeve shirts and pants, gloves, boots	$\frac{\text{No. PPE available}}{\text{No. PPE needed}} \times 100 =$
3305	Spraying squad	% available squads	$\frac{\text{No. squads available}}{\text{No. squads needed}} \times 100 =$
3306	Training for spray squads before start of IRS cycle	% training sessions Number of training days	$\frac{\text{No. sessions done}}{\text{No. sessions planned}} \times 100 =$ No. training days/session

B. Information collected <i>after</i> IRS			
3307	IRS supervision	% IRS villages supervised	$\frac{\text{No. villages supervised}}{\text{No. villages sprayed}} \times 100 =$
3308	How many monitoring visits have been made?	% visit for monitoring	$\frac{\text{No. visits made}}{\text{No. visits planned}} \times 100 =$
3309	Filter papers analysed for chemical concentration	Number of filter papers sent for analysis	$\frac{\text{No. papers sent for analysis}}{\text{No. papers installed}} \times 100 =$
3310	HHs covered by IRS (reported by spraying squads)	% targeted HHs with IRS according to reports	$\frac{\text{No. HHs sprayed (reported)}}{\text{No. HHs targeted}} \times 100 =$
3311	HHs covered by IRS (according to HH survey)	% targeted HHs with IRS according to HH survey	$\frac{\text{No. HHs sprayed (HH survey)}}{\text{No. HHs targeted}} \times 100 =$
3312	Performance of squads (see Form 4.1)	% squads with overall acceptable quality score	$\frac{\text{No. squads with quality score}}{\text{No. squads observed}} \times 100 =$
3313	Personal protection (see Form 4.1)	% squads with adequate protective clothing	$\frac{\text{No. squads with protection}}{\text{No. squads}} \times 100 =$
3314	Information for HHs	% HHs that received adequate information	$\frac{\text{No. HHs informed}}{\text{No. HH surveyed}} \times 100 =$
3315	HHs satisfied with IRS (per survey)	% satisfied HHs	$\frac{\text{No. HHs satisfied}}{\text{No. HH surveyed}} \times 100 =$
3316	Insecticide susceptibility	Vector mortality above 70 %	% mortality in exposure test =
3317	Reduction of vector density	Reduction percentage	$\frac{(\text{No. before}) - (\text{No. after})}{\text{No. vectors before}} \times 100 =$
3318	Adequate bio-efficacy	% mortality and knock-down in bioassays >80%	Bioassay mortality and knock-down

Note: the numerator and denominator values can be noted in the indicator column and the percentage calculated later.

Verified by: _____ Date: _____

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Glossary

Note: all terms refer to KA unless specified otherwise

Active case detection (or active case search, sometimes also called active surveillance): health-care personnel go to the community to and screen the population to find cases of KA. Several methods possible – house-to-house search; index-case based (also called snowballing), camp-based and incentive-based approaches.

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

Coverage rate of vector control (%): number of households protected/ all households at risk.

Defaulter: patient who does not present for assessment at end of treatment.

Defaulter rate (%): number of defaulters/total number who started treatment.

Detection rate (%): number of new cases detected per year in the district, UHC or subdistrict/total population in the same area.

Elimination target: to reduce KA incidence below 1 per 10 000 per year in all (sub)districts and UHCs by 2015.

External quality assurance (EQA): process by which an independent laboratory certifies the quality of laboratory tests.

Final cure: when patient exhibits no signs and symptoms at six months after the last drug was taken.

Final cure rate (%): number of patients with final cure/total number who started treatment.

Final cure in PKDL: clinical cure 12 months after end of treatment – defined as complete resolution of macules, papules, plaques and nodules.

Final outcome: outcome of treatment six months after the last drug taken. Can be final cure, relapse, loss to follow-up, death.

Hotspot for KA: community with at least five cases over the past year.

Incentive-based approach: active case detection strategy in which a financial or other incentive/award is provided to health volunteers or village health workers who take suspected cases of KA to health facilities

Index case: person currently suffering or who has suffered from KA or PKDL During the last 12 months. Used as the starting point for index-case based active search.

Index-case approach: active case detection strategy in which all households in a certain perimeter around an index case are visited and screened for KA or PKDL.

Initial cure: when a patient has completed the full drug course and has clinically improved, i.e. exhibits no signs and symptoms of KA at last day of treatment.

Initial cure in PKDL: clinical improvement at end of treatment – defined as a considerable reduction in the number and size of skin lesions (e.g. at least 80% resolution of macules and/or decrease in erythema and flattening of lesions).

Initial cure rate (%): number with initial cure/total number who started treatment.

Initial outcome: outcome of treatment on last day of drug course. Can be initial cure, non-response, default, treatment switch because of side-effects, death.

Input: resources allocated to an activity.

KA: chronic fatal disease caused by a parasite – *Leishmania donovani*. Causes fever, splenomegaly, wasting and anaemia. Also known as visceral leishmaniasis (VL).

KA death: death related to KA.

KA death rate (%): number of KA-related deaths/total number who started treatment.

Loss to follow-up: patient who does not present for assessment at six months.

Non-response: when, at the assessment at the end of treatment, signs and symptoms persist or recur despite satisfactory treatment for more than two weeks.

Output: measures what a health programme produces (deliverables) – services, products, etc.

Outcome: the effect that programme activities have on a problem.

Passive case detection: patients are detected through regular health service activities in health centres and clinics.

Pharmacovigilance: surveillance of side-effects of a drug when used in routine practice.

PKDL, probable: patient from KA-endemic area with multiple hypopigmented macules, papules, plaques or nodules, who is RDT positive.

PKDL, confirmed: patient from KA-endemic area with multiple hypopigmented macules, papules, plaques or nodules, who is parasite positive in SSS or biopsy.

Process: activities of the programme.

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

Treatment completion rate (%): number of patients who took a full course of first-line drugs/all new cases who started treatment in a given period.

Treatment failure: non-response or relapse cases or death.

Treatment failure rate: (numbers non-response + numbers relapse + numbers KA-related deaths)/total number who started treatment.

Treatment switch: patient changed from first- to second-line treatment because of non-response or side-effects.

Appendix 1. Pictorial for PKDL screening
(macular and papular forms)



Pictures kindly provided by S Uranw, A Rijal, J Alvar.

Appendix 2. M&E tool kit for vector control

Example of checklists taken from the M&E tool kit for the IRS programme at district level (to be applied once per spraying cycle or per year)

District: Reviewer:
Date:

DISTRICT LEVEL	Yes	No	Comments
Input			
Guidelines/action plan			
Guidelines available to all users?			
Need for update?			
Annual action plan in place?			
Insecticides			
Authorized certificate for chemical quality received from national level?			
Insecticide requirements calculated/requested for one cycle?			
Insecticide in stock/insecticide requested (kg)?	___/___	___ %	
District/upazila storage in place?			
Protective clothing supplied to operational level? (cap, shirt, pants, rubber shoes, goggles)			
Spray pumps			
Number of functional pumps/number of existing pumps	___/___	___ %	
Number of new pumps required			
Number of and type(s) of spares required			
Spraypersons			
Number of persons available/number of persons needed	___/___	___ %	
Last training/retraining			date
Is payment timely?			
For how many days?			days
IEC material/communications			
IEC material developed (poster, leaflet, others)?			
Other promotional activities developed?			

Process			
Supervision			
Supervision of spraying activities in subdistrict?			
<i>At end of cycle:</i> Number of supervisions conducted/number of supervisions planned	___/___	___ %	
Level of supervisors <ul style="list-style-type: none"> • district health officers • vector control officers • malaria inspectors • others (specify) 			Comments about performance
Logistics of insecticide distribution to operational level in place? (description of limitations)			
Output			
Achievements/coverage			
Number of HH sprayed/number of HH targeted	___/___	___ %	
Bioassays			
Number of bioassays done			
Number of bioassays below threshold/total number of bioassays	___/___	___ %	
Chemical concentration achieved			
Number of filter papers analysed			
Results of chemical analysis (average concentration of insecticide: mg/m ² and standard deviation)			
Acceptance of IRS			
Number of HHs accepting IRS/number of HHs interviewed			
Outcome/impact			
<i>Sandfly density</i> (measured through light traps): number of sandflies/100 houses: <ul style="list-style-type: none"> • in sprayed houses • in sentinel houses • in control houses 			
Before spraying			
After spraying			
Six months later			
Annual KA incidence (% reduction or increase)			

M&E tool kit for the IRS programme at PHC/UHC and operational level (to be applied once per spraying cycle or per year)

PHC/UHC: Reviewer:

Date:

OPERATIONAL LEVEL (PHC, UHC, etc)	Yes	No	Comments
Input			
Guidelines/action plan			
Guidelines available to all users?			
Need for update?			
Annual action plan available?			
Insecticides			
Insecticide requirements calculated/requested?			
Insecticide in stock/insecticide requested (kgs)	___/___	___ %	
Insecticide storage in place?			
Protective clothing supplied to operational level? (cap, shirt, pants, rubber shoes, goggles)			
Spray pumps			
Number of functional pumps/number of existing pumps	___/___	___ %	
Number of new pumps required			
Number of and type(s) of spares required			
Spraypersons			
Number of persons available/number of persons needed	___/___	___ %	
Last training/retraining			date
For how many days?			days
IEC material/communications			
IEC material (printed, radio, TV) released or applied?			
Other promotional activities developed?			
Process			
Supervision			
Supervision of spraying activities in subdistrict?			

<i>At end of cycle:</i> Number of supervisions conducted/number of supervisions planned	__/__	__ %	
Level of supervisors <ul style="list-style-type: none"> • district health officers • vector control officers • malaria inspectors • others (specify) 			Comments about performance
Logistics of insecticide distribution to operational level in place?			Description of limitations
Output			
Achievements/coverage			
Number of HHs sprayed/number of HHs targeted	__/__	__ %	
Bioassays			
Number of bioassays done			
Number of bioassays below threshold/total number of bioassays	__/__	__ %	
Chemical concentration achieved			
Number of filter papers analysed			
Results of chemical analysis (average concentration of insecticide: mg/m ² and standard deviation)			
Acceptance of IRS			
Number of HHs accepting IRS/number of HHs interviewed			
Outcome/impact			
<i>Sandfly density</i> (measured through light traps): number of sandflies/100 houses: <ul style="list-style-type: none"> • in sprayed houses • in sentinel houses • in control houses 			
Before spraying			
After spraying			
Six months later			
Annual KA incidence (% reduction or increase)			



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