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

August 2010

Bangladesh, India and Nepal

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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.