Process of validation of elimination of kala-azar as a public health problem in South-East Asia

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Contents

Page

Annexes

1. Introduction

Worldwide, an estimated 200 000–400 000 new cases of kala-azar (KA) or visceral leishmaniasis (VL) occur annually [1] of which Bangladeh, India, and Nepal, and harbour an estimated 67%. In the South-East Asia Region, kala-azar is predominantly endemic in Bangladesh, India and Nepal. There are also sporadic cases in Bhutan and Thailand. In Thailand, the epidemiology of KA still needs to be clarified. In this Region, the causal parasite species is *Leishmania donovani*, the vector, *Phlebotomus argentipes*, and the transmission cycle is anthroponotic. In 2005, the Governments of Bangladesh, India and Nepal, supported by WHO, launched a regional kala-azar elimination initiative to reduce cases to a level where it is not a public health problem any longer [2]. The target is to maintain the annual incidence rate below 1 KA case per 10 000 population at upazila (Bangladesh), subdistrict/block (India) and district level (Bhutan and Nepal).

The expected impact of this elimination initiative includes (i) reducing KA in the vulnerable, poor and unreached populations in endemic areas; (ii) reducing case-fatality rates from KA to a negligible level; (iii) reducing cases of post-kala-azar dermal leishmaniasis (PKDL) by interrupting transmission of KA; and (iv) preventing the emergence of KA/HIV/TB coinfections in endemic areas [3].

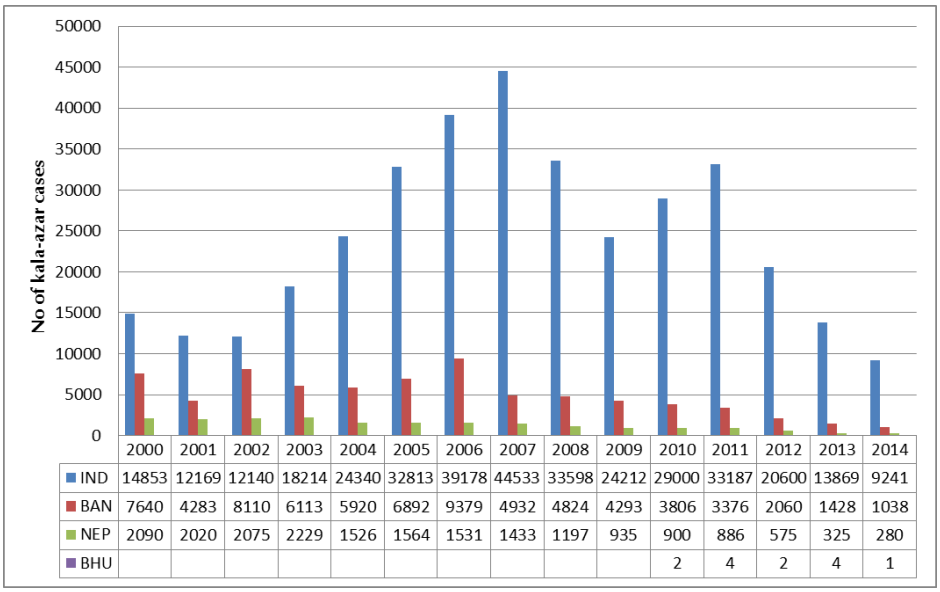
The main strategies in this campaign are (i) early diagnosis and complete treatment; (ii) integrated vector management; (iii) effective disease and vector surveillance; (iv) social mobilization and partnerships; and (v) clinical and operational research [3].

The kala-azar elimination programme consists of four consecutive phases: (i) the **preparatory phase:** This phase begins after the plan has been prepared and approved by individual countries. It includes development/review of national policy, strategic and advocacy plans, operational plans to implement the national plan for elimination, development and adoption of technical guidelines and reporting formats, etc.; (ii) the **attack phase:** This phase begins when the preparatory phase

has been completed and includes implementation and monitoring of the strategies. The main activities include integrated vector management (IVM) with indoor residual spraying (IRS) in all the affected areas for five consecutive years, early diagnosis and complete treatment and active surveillance of cases; (iii) the **consolidation phase:** This phase begins when total coverage by IRS has concluded, i.e., at the end of the attack phase. This phase will end after three years of active surveillance has shown no increase in the incidence rate at district/subdistrict/upazila levels in the endemic countries. The main activities to be carried out during this phase include limited IRS, intensified active case detection (ACD) along with early diagnosis, and complete treatment; (iv) the **maintenance phase:** During this phase, the case incidence at the district/subdistrict or upazila level should be less than 1 per 10 000 population and surveillance against re-emergence of kala-azar will be continued.

Since the launch of the campaign, there has been an augmentation and intensification of the activities in all three countries. This has been reflected in a decrease in case numbers (Fig. 1) and incidence rates. In India, the number of cases decreased from 44 533 cases recorded in 2007 to 9241 in 2014. Similarly, in Bangladesh, in 2006, cases were reduced from 9370 to 1038 in 2014 and in Nepal from 1564 in 2005 to 280 in 2014. This has also been reflected in the proportion of blocks reaching the elimination target of < 1 in 10 000 population (Fig. 2). By 2014, the elimination target was reached in all the endemic districts in Nepal, in 96% of the endemic upazilas in Bangladesh, and 74% of the endemic blocks in India.

Figure1: *Reported kala-azar cases, 2000 to 2014 in Bangladesh, Bhutan, India and Nepal*



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
IND	14853	12169	12140	18214	24340	32813	39178	44533	33598	24212	29000	33187	20600	13869	9241
BAN	7640	4283	8110	6113	5920	6892	9379	4932	4824	4293	3806	3376	2060	1428	1038
NEP	2090	2020	2075	2229	1526	1564	1531	1433	1197	935	900	886	575	325	280
BHU											2	4	2	4	1

Source: WHO-SEARO reported number of cases

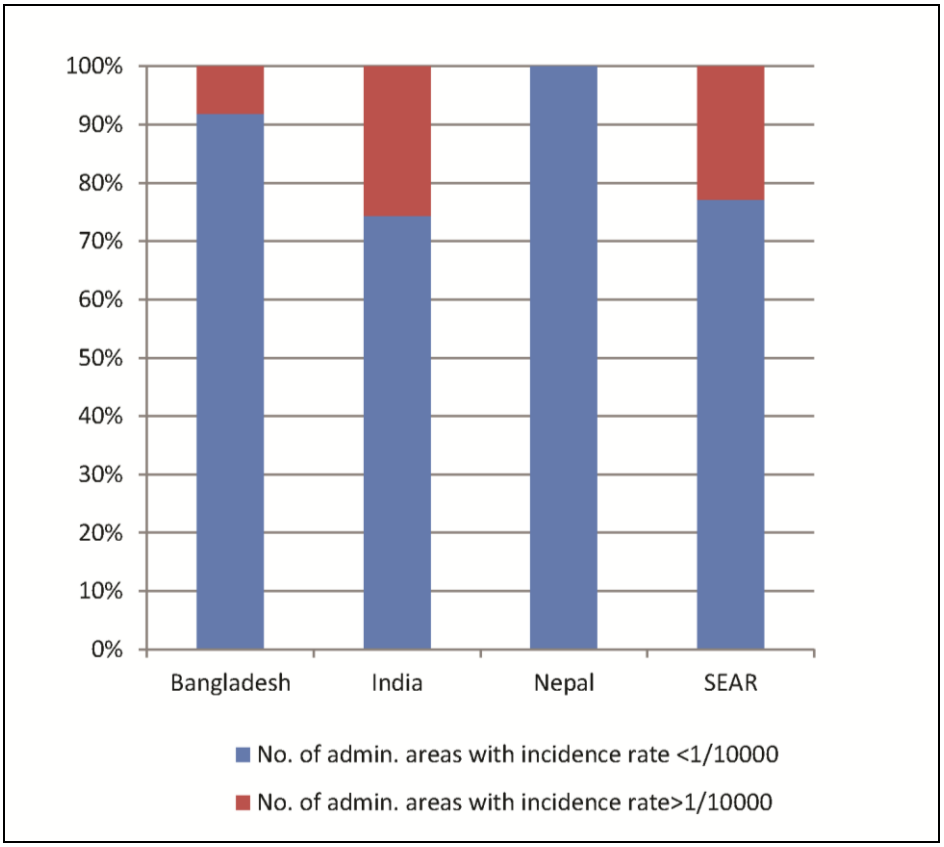
However, the actual number of VL cases is considered to be much higher than what the official records show, as a significant proportion of cases may not be recorded in the surveillance system of the government programme. Variable ratios of underreporting have been described in the Region (Singh 2006) and the true burden of the disease is not exactly known. Moreover, cases of post-kala-azar dermal leishmaniasis (PKDL) are considered to be a potential reservoir particularly during the inter-epidemic periods. There has been an increase in cases of PKDL reported in Bangladesh in the last few years after initiation of active case-finding activities. However, in India and Nepal, where active approaches have not been routinely conducted, very few cases have been recorded. Surveillance of VL and PKDL has not been standardized and active case finding strategies have not been validated within the three countries.

The need for validation of attainment of the target is inherent in any elimination programme. In the case of KA, the goal is not eradication but eliminating KA as a public health problem. A quantitative target has been set (annual incidence rate of KA < 1 case per 10 000 in each implementation unit), and this low level should be maintained on a permanent basis. The process of validation of KA elimination will establish if a country has reached this target, but there is a need to monitor sustained

elimination after that point. There is a need for a standardized approach on an objective basis and according to agreed criteria. The indicators as well as the process to be considered for the validation of the elimination of KA in South-East Asia need to be described. The WHO Regional Office in SEARO will facilitate national preparations for validation of the elimination by providing technical support or consultants to the country to support the activities as per country need.

The aim of this document is to (i) define the specific criteria for the validation of the achievement of elimination of kala-azar and to (ii) describe the process for documentation and validation of elimination of kala-azar in South-East Asia.

Figure 2: *Proportion of administrative units achieving the target of eliminating VL as a public health problem (2014)*



2. Operational case definitions in the kala-azar elimination initiative

Kala-azar elimination target: Annual incidence of kala-azar below 1 case per 10 000 population at upazila in Bangladesh, block in India and district level in Nepal. *Source: Regional Strategic Framework for Elimination of Kala-azar from the South-East Asia Region (2011–2015) SEA-VBC-85 (Rev.1)*

This indicator counts the number of new cases and relapse cases in a single year in the numerator divided by the mid-year population of the implementing unit.

The expert consultation stresses the importance of PKDL and recommends to RTAG to either revise the above target by adding the number of PKDL cases in the numerator or by setting a separate target for the reduction of PKDL below levels of public health importance. The first option has the advantage of being simpler, but it can render the interpretation of trends more difficult. The second option allows for specific attention to PKDL in its own right, does not change current reporting procedures, but requires some empirical threshold.

Kala-azar case: a person from an endemic area suffering from fever of two weeks or more duration and splenomegaly that is confirmed by a rapid diagnostic test (RDT) or a biopsy.[*]

Relapse case: a KA case that has an initial cure but has a recurrence of signs and symptoms, and is parasitologically positive.

PKDL Case[**]

Probable PKDL: a patient from an area where visceral leishmaniasis is endemic – with or without a previous history of visceral leishmaniasis – who has a symmetrical macular, papular or nodular rash often starting on the face with further spread to other parts of the body without loss of sensation and positive rk39 RDT.

Confirmed PKDL: a probable case as described above with parasite infection confirmed by PCR or a slit-skin smear or biopsy.

[*] *Indicators for monitoring and evaluation of the kala-azar elimination programme, August 2010, TDR-WHO.*

[**] *Post-kala-azar dermal leishmaniais: a manual for case management and control, Kolkata, India, 2–3 July 2012. Report of a WHO consultative meeting.*

Population at risk: all inhabitants of endemic areas, i.e., an implementation unit (district, upazila, block) with local transmission.

3. Criteria for validation

3.1 Need for standard criteria for validation of elimination

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

(1) The elimination initiative is an international, trans-border effort, and countries voluntarily adopt a common approach.

(2) To ensure international credibility for the expected future claim that KA has been eliminated in a given country.

(3) To have standard and consistent criteria and a mechanism to assess the achievement of elimination in a country.

3.2 Criteria for reaching elimination target at the country level

A country has reached the VL elimination target when the following criteria have been met:

(1) All the preconditions in the national elimination programme are present (refer to Section 4).

(2) The country programme is in the consolidation phase [3].

(3) Annual incidence of kala-azar is below 1 case per 10 000 population, at upazila in Bangladesh, block in India and districts in Nepal for a minimum of three consecutive years.

3.3 Criteria for sustained elimination

Throughout the maintenance phase, an annual incidence rate of kala-azar is below 1 case per 10 000 population, at upazilla in Bangladesh, block in India and districts in Nepal.

4. Process of validation of reaching the kala-azar elimination target

4.1 National preparations for validation

Preconditions that need to be fulfilled in the endemic country

(1) Presence of an updated comprehensive **national strategic guideline** for kala-azar elimination along with:

- Standard operating procedures for all key activities.
- IEC/BCC strategy/action plan adjusted to individual state situation.
- Comprehensive M&E tool for KA as a whole along with specific guidelines.

(2) **Adequate health services** for early detection and effective treatment and follow-up of all KA and PKDL cases (refer to Section 4.1.1)

(3) Existence of an adequate **epidemiological surveillance system** with full coverage of all endemic areas (refer to Section 4.1.2). This includes:

(a) Kala-azar to be a notifiable or reportable disease including case reporting by the private health sector.

(b) A national kala-azar case register and HMIS system to collect information for key variables.

(c) Conducting routine and minimum once-a-year active case finding for KA and PKDL (refer to Section 4.1.2 and Annex 2 for SOP for active case findings).

(d) Evidence for estimates of the underreporting ratio.

(e) Presence of sentinel surveillance for HIV-VL coinfection in kala-azar endemic countries as applicable.

(4) **Integrated vector management** in the endemic areas in place with proper quality assurance mechanisms that include:

- Regular IRS spraying in the endemic areas along with monitoring with toolkits.
- Use of insecticide-treated nets as per the national policy guidelines and recommendations.
- Environmental management.
- Entomological surveillance (pre- and post-spraying) and monitoring of insecticide resistance in areas.

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

(6) A functional **cross-border coordination** system, wherever relevant.

Adequate access to diagnosis and treatment of kala-azar

- Availability of adequate laboratory services to diagnose kala-azar and PKDL, based on a rapid diagnostic test (RDT) at the primary health centre (PHC) level and microscopy of tissue aspirates at the referral hospital level should be established in the endemic areas.
- Availability of first and second line drugs for treatment at all levels of health facilities should be ensured.
- Quality control systems and regular training of health staff on diagnosis and treatment should be present including:
  - The quality of the treatment, in terms of dosage, regimen, completeness, supervision and follow-up, in accordance with current established guidelines.
  - The quality of the laboratory examination to meet the accepted norms and the presence of an organized quality-control/quality-assurance system.

- Early detection and reporting of the cases.
- A functioning referral system for kala-azar patients from a lower- to higher-level health facility should be established.

Adequate epidemiological surveillance of kala-azar

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

The following are essential for the surveillance:

- Kala-azar should be a notifiable or reportable disease in the country. Programmes should have a mechanism for receiving reports of kala-azar cases from private health care providers in the endemic areas, and these cases should be included when calculating incidence rates.
- Cases should be reported according to their implementation unit of origin to avoid double-counting of cases. A unique "Patient Identification Code" should be introduced at each health facility, including the private sector.
- Active case finding activities for KA and PKDL need to be conducted as a regular activity (at least once a year) in each of the implementing units (block/upazila/district). The strategy for active case finding would depend on the level of endemicity.
- A comprehensive information system should be established with collation of data at each of the reporting units (block/upazila/district), including data collation from the private sector. Incidence of kala-azar should be reported as number of

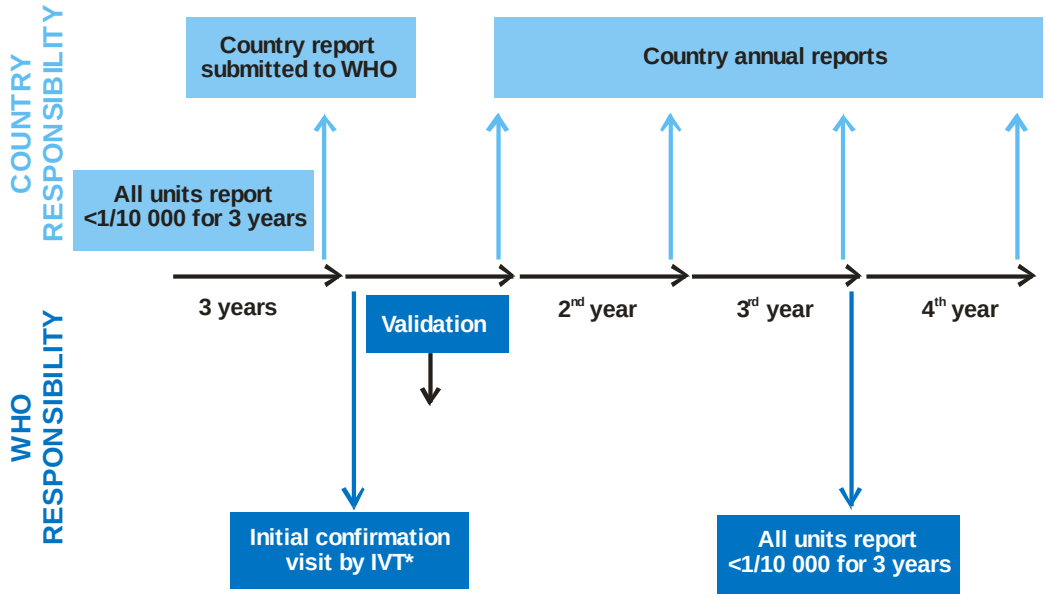
cases per 10 000 population per year, at the upazila level in Bangladesh, block level in India, and district level in Nepal.

- Regular use and analysis of surveillance data with appropriate and regular feedback mechanism to reporting units should be established.

4.2 When to ask for validation of reaching elimination

When all the above preconditions have been fulfilled (see Section 4.1) and the reported incidence rate for each of the implementing units is below 1 case in 10 000 for at least three consecutive years, the country may start the process of validation of target and revalidation (Figure 3).

Figure 3: *Timeline for validation and revalidation of KA elimination*



4.3 Preparation of country report about reaching the target

If required, the country may seek WHO support for technical assistance to prepare such a report (see Template in Annex 2). The content of the report needs to include the following:

(1) Documents supporting fulfilment of all preconditions.

(2) Detailed account of the historical perspective and epidemiology of kala-azar in the country.

(3) Description of the elimination programme strategy.

(4) Description of the surveillance system, including active case-finding strategies, collection of data from private health facilities and information systems.

(5) Robust and representative estimates of the proportion of unreported cases according to the standard methodology.

(6) Diagnostic and treatment strategy for kala-azar.

(7) Quality control and monitoring system for activities within the programme.

(8) Report by year on the following:

- Number of endemic units, population at risk.
- Annual incidence rate of KA (new and relapse) in each unit.
- Annual incidence rate and prevalence of PKDL calculated in each unit.
- Report on number of active case findings conducted in each endemic unit.
- Proportion of targeted private health facilities reporting kala-azar cases.
- Proportion of health facilities having adequate diagnostic facilities.
- Operation research conducted to detect proportion of unreported cases.

4.4 Validation by an independent validation team (IVT) if requested by countries

(1) Selection of expert team: An independent expert team will be constituted by WHO. The members of the team should be chosen from different areas (epidemiology, entomology, etc.) and they should be experts in their field. Persons with potential conflicts of interest should be avoided.

(2) Objective: The principal objective of the IVT will be to evaluate the reliability of the country's report.

(3) Process: The IVT will spend 2–3 weeks in the country depending on the size of the endemic area. Activities to be conducted during the visit will include:

(a) After arrival in the country, the IVT would spend several days with the national programme to review the country report. The country report will be reviewed for completeness and ascertainment of fulfilment of the elimination target.

(b) Visit to endemic sites and health facilities, and interview health personnel and others. To facilitate visits to all epidemiologically important areas, the IVT team would divided into groups. The areas selected for the visit would be those identified as having the least satisfactory documentation or as being at unusual risk of continuing transmission; for example: (i) previous highly endemic areas, (ii) areas where the last cases occurred, (iii) areas with a history of poor surveillance or increasing number of cases. Team members will decide independently which areas, village and health units they wish to visit.

(c) Examining the records at both central and peripheral levels. Records should be compared with reported data in the country report.

(d) Return to the centre and finalize the IVT report. All teams will work together and generate one report for the whole country.

(e) Presentation and feedback to be given to the national programme and WHO by IVT members.

(f) IVTs will be asked to reach one of two possible conclusions: either (i) they are satisfied that elimination has been achieved, or (ii) they are not satisfied. IVT reports will spell out any reason for their decision.

(4) Once it has been verified that the country has reached the elimination target, the monitoring of the sustenance of elimination will be done by (see Fig. 2):

- Annual reports produced by the country
- Joint (national and international experts) monitoring missions every three years.

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Annex 1

General features for different active case-detection methods

Methods for active case detection

Currently, four approaches of active case detection (ACD) have been validated for their utility in KA and PKDL case detection in the Indian subcontinent (Hirve 2010; Singh 2011): blanket approach, camp approach, index case-based approach and incentive-based approach. The *blanket approach* is done by conducting house-to-house visits by trained public/private health workers in the endemic areas for detection of kala-azar (KA) and PKDL cases. The *camp approach* is done by organizing health camps in defined KA endemic communities where screening of KA and PKDL is done by mobile teams of medical officers, nurses, lab technicians and health workers/health volunteers. Inhabitants are preinformed about the team, its purpose, time, date and place of the team's activities. The *index case-based approach* includes the search of new KA and PKDL cases among household members through house-to-house visits around residences (radius of 50 metres or 100 households) of recently diagnosed (usually in the previous six months) KA cases. In the *incentive-based approach,* the search for new KA and PKDL cases is done through health workers who receive an incentive for each newly detected case by him/her. Incentive-based ACD is currently practiced in India, and by some research teams in Bangladesh. *Passive-case detection (PCD)* includes self-reported cases of KA and PKDL in public hospitals and ideally also in private medical services. This method does not require additional efforts and resources as it is currently part of the existing health system but has proven expensive for KA and PKDL patients who are "shopping" for different kind of healers before they finally get diagnosed in the public or private health service.

When to use which approach of ACD (including PCD)?

Recent research has established that all ACD approaches are particularly useful in the KA endemic areas where the community awareness about KA and PKDL is low and the actual programme is weak (Singh 2011; Huda

2012).The *blanket approach* is considered the "gold standard", but due the additional high costs incurred with this method, it is only recommended in outbreak situations. However, in those countries where the health system permits its use by integrating it with other health activities, such as family planning activities, the cost of the method may not be a hurdle.

The *camp approach* is a sensitive tool for the detection of new KA and PKDL cases, particularly in high KA endemic areas. For the moderate-to-low KA endemic areas and in those areas where households are scattered, the *index approach* is the preferred method for ACD. The use of *incentive-based ACD* can be a useful method that can be applied particularly in low KA endemic areas or in combination with the above-mentioned methods. The incentive-based approach of case detection may induct the snowball technique for new KA and PKDL case findings. However, this method needs meticulous supervision and monitoring to prevent misuse of funds.

PCD is otherwise existing in all three countries. It is useful and sensitive for the areas where community awareness about KA and PKDL is high and the health services are actively involved in KA control.

With which frequency has ACD to be conducted?

It has been shown that when conducting the camp approach, twice a year is sufficient to capture a substantial number of new cases of KA and PKDL in a given area. The index case and incentive-based approach have to be organized throughout the year. The blanket approach is recommended for an outbreak situation.

Cost estimates of the different approaches

PCD with all its limitations has the advantage of being integrated into the existing public health system. ACD, which is particularly important during the elimination phase of a disease, is associated with additional costs that have been estimated to be between approximately US$ 20 and US$ 600 per new case detected (Singh 2011). In general, the blanket approach is the most expensive method of all ACD methods followed by the incentive approach, camp approach and index approach.

SOP: Index Case-Based Approach

Purpose

To describe the procedure for active case detection of new KA cases using index case-based (ICB) approach.

Policy/Scope

The SOP is applicable for screening procedures for KA to be used in the ICB approach. This approach is to be implemented in low KA endemic areas (to be defined in each country) on an ongoing basis throughout the year in communities with newly detected KA cases.

General Responsibilities

The Programme Manager (PM) of the KA elimination programme at the district/subdistrict/upazila is responsible for implementing the activity.

Materials Required

(1) Work diary

(2) Patient register

(3) Patient referral slips

(4) Training manual

Procedures

Activity	Responsibility
Preparatory activities (district/upazila level) 1. Identify PHC/villages where the index case approach will be applied. 2. Identify and train public/NGO health workers/health volunteers in identification and referral of chronic fever cases. 3. Identify staff (district/PHC/upazila) responsible for conducting index case search of neighbourhood. 4. Define information sources of index cases – e.g., monthly review meetings at district/upazila, etc.	PM at district/subdistrict/ upazila designee

Activity	Responsibility
5. Ensure availability of drugs, rk39 test kits, fund requirements, IEC material, treatment cards, etc., at the PHCs/district/upazila. 6. Prepare a plan for supervision and M&E of index case-based approach – identify a supervision team for supervision activities on a sample basis. 7. Define reporting system from health post /PHC/upazila to district. **Preparatory activities (PHC/upazila/health post-level)** 8. Identify and train health workers/health volunteers in identification and referral of chronic fever cases and skin lesions cases. 9. Identify staff/health volunteers responsible for conducting index case-based search of neighbourhood.	
Index case-based search activities 1. Monthly review of all KA cases reported by PHC/zonal/district/upazila hospital from the district/upazila. 2. List KA patients – name, age, sex and detailed address of patient, name of PHC/health post responsible for index case search. 3. Health post/PHC/UHC staff visits the community of the index case, traces the home, confirms identity of the patient and alerts the health worker/health volunteer. 4. Organize house-to-house search around index case in the same month of reporting of index case using screening forms or format or register. 5. Screen all individuals for fever ≥ 2 weeks in neighbouring households in the village/hamlet around the house of index case done by PHC/HP/UHC staff and health worker/health volunteer. 6. Fill patient referral form and refer patient to nearest PHC/district /zonal/upazila hospital for confirmation of kala-azar. 7. Maintain a list of patients referred for confirmation of KA diagnosis.	DMO/UHFPO

Activity	Responsibility
8. Inform PHC/district/zonal/upazila hospital staff of patients referred for KA diagnosis. 9. Maintain records and report to district/upazila on index case finding activities conducted.	
Post-index case-based search activities at PHC/district/upazila/zonal hospitals 1. Ascertain diagnosis of all patients referred by health workers after index case-based search. 2. Ensure that all KA patients are started on treatment. 3. Monitor treatment compliance and side effects. 4. Ensure timely payment of wage-loss monies to kala-azar/PKDL patients (India and Nepal). 5. Ensure timely payment of incentives to NGO health worker/health volunteer for patient follow-up (India). 6. Ensure availability of drugs and diagnostics at hospitals based on number of KA cases. **Post-index case-based search activities at the district level** 1. Assess monthly reports from PHC/district/upazila on number of kala-azar cases, drug distribution. 2. Supply of drugs and diagnostics to PHC/district/UHC based on number of KA cases reported. 3. Evaluate index case-finding activities based on supervision/monitoring reports. **Post-index case-based search activities at health post-level** 1. Inform public/NGO health workers of patients diagnosed and started with KA/PKDL treatment to ensure treatment compliance or for any side effects.	MO

SOP: Camp-Based Approach

Purpose

To describe the procedures for active case detection of new KA cases using the camp approach.

Policy/Scope

The SOP is applicable to screening procedures for visceral leishmaniasis (KA, kala-azar) to be used in the camp approach. The camp approach is to be implemented in high KA endemic areas (to be defined by each country). The camp approach ideally is to be implemented twice a year.

General Responsibilities

The Programme Manager of the KA elimination programme at the district/upazila designee is responsible for implementing the camp detection strategies.

Materials Required

(1) Rk39 kits in a cold box for transport

(2) Lancet & lancet disposal box

(3) Cotton

(4) Spirit

(5) Gloves

(6) General medicines – antipyretics, antibiotics, antidiarrhoeal, antimalarial drugs, etc.

(7) Rapid diagnostic kits for malaria (optional in malaria endemic areas) and other diseases, if available

(8) Patient referral form

(9) Lab investigation form

(10) Camp register (register book)

(11) Photo album of PKDL

(12) KA/PKDL patient registration form

(13) IEC materials, banners, posters, pamphlets (local language), pictures of PKDL skin lesions

(14) Mikes

(15) BP apparatus

(16) Thermometer

(17) Stethoscope

(18) Disposable syringes, IV infusion sets, etc. (optional)

(19) Transport box for drugs, supplies, etc.

(20) Emergency drugs – cortisone, anti-histamines, IV fluids, adrenaline

(21) Bio-waste disposal containers

(22) Equipment for starting treatment (optional in areas where treatment will be started in the camp)

Procedures

Activity	Responsibility
Precamp preparatory activities (district/block/upazila level) 1) List the PHC area/villages with high KA incidence (new cases reported). 2) Conduct a meeting with MO of PHCs to prepare a micro-action plan at least one month before initiation of camps. 3) Prepare a time schedule for camps – decide the number of camps, timings, duration of each camp, list name of villages where camps are to be held, etc. 4) Prepare logistics plan – estimate requirement of drugs, rk39 test kits, lancets, gloves, fund requirements, IEC material, etc. 5) Prepare supervision and monitoring plan for camps – identify supervision team, supervision schedule, etc. (on a sample basis).	DMO/UHFPO/designee

Precamp preparatory activities (PHC/district level) 1) PHC staff meeting to plan camp activities at least two weeks before initiation of camps. 2) Identify the PHC team (medical officer, i.e., nurse, lab technician, health inspector, etc.), which will conduct/coordinate camp activities. 3) Define duration of camp (usually one-day camp). 4) Prepare plan for camp logistics – drugs, diagnostics, etc. 5) Provide for refreshments for camp team on the day of camp. 6) Vehicle requirement. 7) Identify and coordinate with village level functionaries/leaders. **Precamp preparatory activities (village level)** 1) One PHC staff (nurse, lab technician, health inspector or other) conducts coordination meeting at least one week before camp with village head/VDC members/Union Chairman and other formal and informal village leaders to inform and solicit community involvement in publicity and conduct of camp activities. 2) Identify venue for camp and determine its suitability for conducting camp. 3) Identify, train and assign roles to village functionaries/volunteers/religious leaders/school teachers for camp publicity activities. 4) Publicity activities to include miking, public announcement through mosques (in Bangladesh), distribution of pamphlets, putting up of banners/posters (at least four) in public places, (announcement on local FM radio stations – Nepal), publicity by mouth of camps by	

health workers, etc. 5) Publicity activities to be conducted at least one day prior to camp and on the day of camp. 6) List and procure locally camp furniture (tables, chairs, bench, examination table, bedside screens), drinking water, etc. 7) Set up camp one day prior or early morning of the camp day (e.g., through local volunteers).	
Camp day activities 1) Camp team: one MO, one lab technician, one nurse, NGO/community volunteers/school teachers, etc. 2) Organize flow of camp activities. 3) Patient registration (name, address, age and sex). 4) Examination of patient for fever ≥ 2 weeks by MO, past history of kala-azar, spleen examination, general examination, examination for skin lesions. 5) rk39 test to be done by lab technician at camp if fever ≥ 2 weeks and splenomegaly. 6) If rk39 test is positive, case referral form to be filled and given to patient. Case referral register to be completed. The patient is referred to PHC/district for treatment and follow-up. 7) For suspected PKDL patients (PKDL-like skin lesions with rk39 test positive and past h/o kala-azar treatment) will be referred to district/appropriate level hospital for confirmation of diagnosis and beginning of treatment. 8) If rk39 test is negative or for all other patients, MO advises appropriate treatment/recommends further diagnostic tests. Particular emphasis may be given to suspected leprosy patients.	MO

9) All patients with severe kala-azar and/or other coinfections to be referred to appropriate level hospital. 10) Proper disposal of bio-waste at the end of the camp.	
Post-camp activities at PHC level 1) Maintain camp records – camp register, treatment cards, referral register, drug distribution register. 2) Manage patient-specific drug box for kala-azar patients. 3) Ensure that patients referred from camp or patients started on KA treatment follow up regularly for further treatment at PHC. 4) Ensure timely payment of wage-loss monies to kala-azar patients. 5) Assessment of camps - number of attendees, number of chronic fever cases, number of rk39 tests done, number of rk39 test positives, number of patients started treatment for kala-azar/PKDL, number of patients referred for KA/PKDL treatment and follow up, drug distribution. 6) Assessment of constraints, difficulties of conducting camp. 7) Submit camp activity reports to district on a monthly basis (web-based reporting in Bangladesh). 8) Ensure timely payment of incentives to NGO health worker for patient follow up (only India). **Post-camp activities at district level** 1) Assess camp reports from PHC - number of kala-azar/PKDL cases, drug distribution.	

2) Supply of drugs and diagnostics to PHC based on number of KA/PKDL cases reported by PHCs. 3) Evaluate camp activities based on supervision/monitoring reports. **Post-camp activities at village level** 1) Inform NGO/health workers of patients diagnosed and started with KA/PKDL treatment to ensure treatment compliance or for any side effects.	

SOP: Incentive-based approach

Purpose

To describe the procedures for active case detection of new KA/PKDL cases using incentive-based approach.

Policy/Scope

The SOP is applicable to screening procedures for KA/PKDL to be used in the incentive approach in Bangladesh, India, and Nepal. The incentive approach is to be implemented in low KA endemic areas (to be defined in each country) and will be implemented on an ongoing basis throughout the year in communities with newly detected KA/PKDL cases.

General Responsibilities

The Programme Manager, KA elimination programme at the district/upazila designee is responsible for implementing the incentive-based case-detection strategies.

Materials Required

(1) Work diary

(2) Patient register

(3) Patient referral slips

(4) Training manual, pictures of PKDL skin lesions

Procedures

Activity	Responsibility
Preparatory activities (district/upazila level) 1) Identify PHC/villages where the incentive approach will be applied based on endemicity. 2) Identify and train health workers/NGO/health volunteers in identification and referral of chronic fever cases. 3) Ensure availability of drugs, rk39 test kits, fund requirements, IEC material, treatment cards, etc., at the PHCs/district. 4) Prepare plan for supervision and M&E of incentive approach – identify a supervision team for supervision activities on a sample basis and based on the report of cases in the district hospital/PHC/upazilla health complex. 5) Define reporting system from health post/PHC to district. 6) Manage fund for providing incentive. **Preparatory activities (PHC/health post-level)** 1) Identify and train health workers/NGO/health volunteers in identification and referral of chronic fever cases, skin lesions cases.	PM at district /upazila designee
Incentive-based search activities 1) Screen individuals for fever ≥ 2 weeks in the village/hamlet. 2) Fill patient referral form and refer patients to nearest PHC/district/zonal hospital/upazila health complex for confirmation of kala-azar.	Trained community-based health workers/ASHA/health volunteers/pharmacists

3) Maintain a list of patients referred for confirmation of KA diagnosis. 4) Inform PHC/health post/upazila health complex staff of patients referred for KA diagnosis.	
Post-incentive-based search activities at PHC/health post-level 1) Ascertain diagnosis of all patients referred by health workers. 2) Ensure that all KA patients are put on treatment. 3) Monitor treatment compliance and side effects. 4) Maintain records and report to district about case finding. 5) Ensure timely payment of incentive to the health worker after confirmatory diagnosis of kala-azar. 6) Ensure timely payment of wage-loss monies to kala-azar patients (India and Nepal). 7) Ensure availability of drugs and diagnostics at PHC based on number of KA/PKDL cases. **Post-incentive-based search activities at district level** 1) Assess monthly reports from PHC - number of kala-azar/PKDL cases, drug distribution. 2) Supply of drugs and diagnostics to PHC based on number of KA/PKDL cases reported by PHCs/VDCs. 3) Evaluate incentive-based case search activities based on passively reported cases in the PHC/district hospital/upazila health complex.	

Post-incentive-based search activities at health post-level 1) Inform NGO/-health workers/health volunteers about the patients diagnosed and started with KA/PKDL treatment to ensure treatment compliance or for any side effects.	

Annex 2

Template for country report for validation of kala-azar elimination

The "Country Report" or "Country Dossier" is a process of documenting all the evidence to support elimination of kala-azar from an entire country. A dossier should include all the historical and current and published and unpublished evidence, country health policies, definitions and indicators followed by the programme, and monitoring, surveillance system, etc.

Writing a country report or dossier would need considerable review of data/reports/published articles from various sources; and interview of earlier health officials/managers responsible for kala-azar elimination.

The following format is suggested for writing a country dossier. Countries may add any additional information and maps if available.

(1) An account of the historical perspective of kala-azar.

(2) Epidemiology of kala-azar in the country:

- Describe the parasite, vector, reservoir, mode of transmission.
- Details on criteria for defining endemic implementation unit.
- Burden of disease including population at risk, and risk factors for transmission.
- Geographic and socioeconomic features of the endemic areas/districts.

(3) Description of the elimination programme strategy:

- Strategies for the control of transmission including IEC.

(4) The public health system and the role and responsibility of different levels within the programme. The role of nongovernment partners in the kala-azar programme.

(5) Description of the surveillance system including:

- System of reporting from private and public health facilities.
- Description of the information and HMIS system, collation, analysis and reporting of data.
- Strategies of active case finding for VL and PKDL and the frequency of ACD.
- Methodology for estimation of underreported cases.
- Methodology used for surveillance for HIV-VL coinfection and PKDL.

(6) Diagnosis and treatment strategy for kala-azar:

- Case definitions of suspect KA, KA and PKDL.
- Diagnostic tests used at different levels of health facility.
- First and second line treatment for KA and PKDL at different levels of health facility.
- Quality control system used for diagnostics.
- Training and capacity-building activities undertaken.

(7) Integrated vector management in endemic areas:

- Guidelines for IRS spraying in endemic areas including insecticide use.
- Monitoring of quality of spraying and quality assurance mechanisms.
- Use of insecticide-treated nets and environmental management in the programme.
- Description of entomological surveillance (pre- and post-spraying) and monitoring of insecticide resistance.

(8) Monitoring, quality control and cross-border collaboration:

- Process followed for monitoring of activities and quality of data.
- Composition and activities of internal and external monitoring committees.
- Cross-border activities undertaken among implementation units, districts, states and countries.

(9) Operational research and publications:

- Description of operational research undertaken and results.
- List of publications on the control/elimination of KA relevant to the endemic country.

(10) Report by year on the following to be generated:

- Number of endemic units, population at risk.
- Annual incidence rate of KA (new and relapse) in each unit.
- Annual incidence rate and prevalence of PKDL should be calculated in each unit.
- Report on number of active case finding conducted in each endemic unit.
- Proportion of targeted private health facilities reporting kala-azar cases.
- Proportion of health facilities having adequate diagnostic facilities.
- Operational research conducted to detect proportion of unreported cases.

(11) Attachment of the following documents in the dossier:

- An updated comprehensive national strategic guideline for kala-azar elimination.
- SOP for all key activities.
- Innovative IEC/BCC strategy and action plan adjusted to individual state situation.
- Comprehensive M&E strategy for KA as a whole along with specific guidelines.

Annex 3

Generic framework for control, elimination and eradication of neglected tropical diseases

1. Introduction

In formulating definitions for control, elimination and eradication of neglected tropical diseases, public health workers need to consider the diversity of their causative pathogens, epidemiology, interactions with humans, ecology and other factors influencing transmission in specific communities. For some chronic diseases, such as soil-transmitted helminthiases, light infections rarely cause disease, and the main aim of interventions, such as preventive chemotherapy, is to reduce heavy infections in a population using regular, large-scale treatment. Conversely, for some acute diseases, such as human rabies, infection invariably leads to severe disease or death, and the main aim of interventions is complete prevention of the infection.

2. Definitions of control, elimination and eradication

The World Health Organization (WHO) Strategic and Technical Advisory Group for Neglected Tropical Diseases has proposed the following definitions for consideration by the WHO Department of Control of Neglected Tropical Diseases.

Control to mean reduction of disease incidence, prevalence, morbidity, and/or mortality to a locally acceptable level as a result of deliberate efforts; continued intervention measures are required to maintain the reduction. Control may or may not be related to global targets set by WHO.

Elimination of transmission (also referred to as interruption of transmission) to mean reduction to zero of the incidence of infection

caused by a specific pathogen in a defined geographical area, with minimal risk of reintroduction, as a result of deliberate efforts; continued actions to prevent re-establishment of transmission may be required. The process of documenting elimination of transmission is called verification.

Elimination as a public health problem is a term related to both infection and disease. It is defined by achievement of measurable global targets set by WHO in relation to a specific disease. When reached, continued actions are required to maintain the targets and/or to advance the interruption of transmission. The process of documenting elimination as a public health problem is called validation.

Eradication to mean permanent reduction to zero of a specific pathogen, as a result of deliberate efforts, with no more risk of reintroduction. The process of documenting eradication is called certification.

Extinction to mean eradication of the specific pathogen so that it no longer exists in nature or the laboratory, which may occur with or without deliberate efforts.

3. Assessment process

The formal process of certification will involve an International Commission that verifies and progressively grants country certification while surveillance is continued until all countries are duly certified. Certification is justified only for diseases that are targeted for eradication, such as smallpox in the past and dracunculiasis, yaws and poliomyelitis in the present.

Validation of elimination as a public health problem or verification of elimination of transmission should be assessed against objective criteria in a country, area or region, and the achievement recorded formally. Elimination (according to these two definitions) is therefore not an end-point but a status that must be sustained. The development and implementation of novel, effective interventions or surveillance and response systems may lead, in the future, to eradication: In this event, countries in which elimination as a public health problem or elimination of transmission has been validated or verified would have to undergo the formal process of certification, under an International Commission.

The WHO Roadmap on neglected tropical diseases has set eradication and elimination targets. Eleven diseases are targeted for elimination at the global, regional or country level in 2015–2020 (Table 1).

4. Process for validating elimination as a public health problem, verifying elimination of transmission and certifying eradication of disease

The WHO Roadmap targets the eradication, elimination of transmission or elimination as a public health problem, at regional or global level, of Chagas disease, human African trypanosomiasis, human dog-mediated rabies, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, trachoma, visceral leishmaniasis and yaws by 2020. These targets are all supported by global political commitment as elaborated in various World Health Assembly or regional resolutions.

The definitions of elimination as a public health problem, elimination of transmission and eradication of disease, as well as the indicators used to assess their achievement, are specific to each disease and were established through a consultative process by WHO and partners.

Table 1. *WHO Roadmap targets for eradicating and eliminating neglected tropical diseases*

Disease	2015				2020			
	Eradication	Global elimination	Regional elimination	Country elimination	Eradication	Global elimination	Regional elimination	Country elimination
Rabies			√ EOT Latin America				√ EOT South-East Asia Region and Western Pacific Region	
Blinding trachoma						√ EPHP		

Disease	2015				2020			
	Eradication	**Global elimination**	**Regional elimination**	**Country elimination**	**Eradication**	**Global elimination**	**Regional elimination**	**Country elimination**
Endemic treponematoses (yaws)					√			
Leprosy						√		
Chagas disease			√ EOT Transmission through blood transfusion interrupted				√ EOT Intra-domiciliary transmission interrupted in the Region of the Americas	
Human African trypanosomiasis				√ EPHP In 80% of foci		√ EPHP		
Visceral leishmanisis							√ EPHP Indian subcontinent	
Dracunculiasis	√							
Lymphatic filariasis						√ EPHP		
Onchocerciasis			√ EOT Latin America					√ EOT Selected countries in Africa
Schistosomiasis			√ EOT Eastern Mediterranean Region, Caribbean, Indonesia and the Mekong River basin				√ EOT Region of the Americas and Western Pacific Region	√ EOT Selected countries in Africa

EOT, elimination of transmission; EPHP, elimination as a public health problem.

*Adapted from *Accelerating work to overcome the global impact of neglected tropical diseases: a roadmap for implementation*. Geneva: World Health Organization; 2012 (WHO/HTM/NTD/2012.1).

4.1 Standard operating procedures

Standard operating procedures for validating elimination as a public health problem or verifying elimination of transmission need to be established and standardized for (i) preparation, review and feedback on dossiers for validation, verification or certification in a Member State; (ii) public acknowledgement by WHO of validation, verification or certification of a Member State; and (iii) activities after validation, verification or certification in a Member State (which may be intended to either sustain the disease burden under the targeted threshold or continue progress towards a more advanced goal). The principles that will regulate those standard operating procedures are given below.

4.2 Preparation of dossiers for validation, verification or certification

- WHO will provide the Member State with a template dossier for each disease.
- The dossier should contain the minimum amount of information necessary to establish whether the Member State has met the requirements for validation, verification or certification.
- Additional optional information may be included at the discretion of individual national programmes, and should be clearly indicated.
- The dossier should be completed and maintained online. If the national programme does not have the capacity or the bandwidth to complete the dossier online, information should be forwarded to WHO for uploading.
- If possible, systems should be established to transfer data already stored in electronic format elsewhere (e.g. baseline trachoma prevalence data, mass drug administration coverage data, atlas of human African trypanosomiasis) to the dossier, in order to maximize efficiencies for national programme staff and maintain the integrity of the data.

- The Member State is responsible for initiating the preparation of the dossiers for its national programme. If requested, WHO will provide technical assistance.
- WHO headquarters is responsible for maintaining the repository of dossiers. Each dossier should be systematically reviewed to ensure that duplicate information is removed.
- If the dossier fulfils the requirements of the validation process, the consent of Member States should be requested to allow either the full or the summary dossier containing the pre-specified core information to be accessible on the Internet via the WHO NTD website.

4.3 Submission and assessment of dossiers for validation, verification or certification

- The Member State should submit the completed dossier to WHO. For each disease, WHO will establish the process for review of the dossier and identify a Reviewing Authority.
- The Reviewing Authority will vary according to whether validation, verification or certification is being assessed (*Table 2*).

Table 2. *Operational definitions for eradication and elimination of neglected tropical diseases*

Status	Applicable term	Geographical area	Reviewing authority	Acknowledged by
Eradication	Certification	Global	International Commission established by World Health Assembly Resolution	WHO Director-General (for individual countries) and World Health Assembly (globally)
Elimination of transmission	Verification	Geographical region and country	Ad hoc international Reviewing Authority	WHO Director-General
Elimination as a public health problem	Validation	Country (sum of subnational units)	Ad hoc regional Reviewing Authority	WHO Director-General

- The Reviewing Authority should collectively discuss each dossier received, via video conference, teleconference or at a face-to-face meeting.
- With the exception of eradication, country visits will not be required unless requested by the Reviewing Authority.
- The Reviewing Authority should decide by consensus and within one year of receipt of the dossier to either: (i) validate the claim of elimination as a public health problem, verify the claim of elimination of transmission or certify the country in the process towards eradication; or (ii) postpone such decisions until more evidence has been provided in the dossier to demonstrate that this has occurred.

4.4 Feedback on dossiers for validation, verification or certification

- WHO will summarize the comments and decision of the Reviewing Authority.
- If the claim of elimination is accepted, the summary will be forwarded to the Director-General of WHO.
- If the claim of elimination is postponed, WHO will request the country to provide any further evidence needed to enable validation, verification or certification by the Reviewing Authority.

4.5 Acknowledgement of validation, verification or certification

- At the discretion of the WHO Director-General, a letter of notification will be provided to the Member State by way of official acknowledgment.
- WHO headquarters will, where indicated, change the endemicity status of the Member State in the Global Health Observatory to "eliminated as a public health problem", "elimination of transmission" or "eradicated", with a note specifying the date of the change in status. For eradication, an Eradication Commission will decide on certification where there is an eradication programme.

- Where indicated, WHO headquarters will also acknowledge the achievement of the Member State in the next annual disease-specific article published in the Weekly Epidemiological Record. WHO will continue to note whether the definition of elimination as a public health problem, elimination of transmission or certification is still met in the Member State, on an annual basis, in the Weekly Epidemiological Record.

4.6 Activities after validation, verification or certification

- The Member State should continue to undertake post-elimination surveillance for the disease according to its epidemiological characteristics. A statement of commitment and a description of the surveillance strategy should be included in the dossier.
- All stakeholders must recognize that the status of validation, verification and certification is potentially reversible, and take this into consideration in their communications at all stages. Where post-elimination surveillance data indicate that the disease or infection has recrudesced above defined thresholds or has reappeared, this change in endemicity status will be noted in the Global Health Observatory and the Weekly Epidemiological Record.
- Member States are responsible for ensuring that surveillance data are made available to WHO.
- For some diseases, Member States that have achieved elimination as a public health problem may, at a later date, request verification of elimination of transmission, if appropriate evidence demonstrates that this has occurred.

In the WHO South-East Asia Region, kala-azar (KA) or visceral leishmaniasis (VL) is predominantly endemic in Bangladesh, India and Nepal with sporadic cases reported from Bhutan and Thailand. In 2005, a programme was launched to eliminate KA as a public health problem, setting a target of 1 KA case per 10 000 at the sub-district levels in Bangladesh and India, and the district level in Nepal. Nepal is maintaining this target for the last three years (since 2014), with other endemic countries in the Region close to achieving the target. In order to assess progress towards the achievement of the elimination target by the Member States, a formal process needs to be put into place to validate the elimination of KA as a public health problem. This document describes the process and steps that will be followed to validate the elimination of kala-azar as public health problem.

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