Leprosy/Hansen Disease Elimination Dossier

Tool accompanying the WHO Technical guidance on interruption of transmission and elimination of leprosy disease

World Health Organization

Leprosy/Hansen Disease Elimination Dossier: Tool accompanying the Technical guidance on interruption of transmission and elimination of leprosy

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Abbreviations and acronyms

BCG	Bacillus Calmette-Guerin
DHIS-2	District Health Information System-2
EHR	electronic health record
EPHP	elimination of leprosy as a public health problem
G2D	grade-2 disability
HAT	Human African Trypanosomiasis
HIS	Health Information System
ILEP	International Federation of Anti-Leprosy Associations
LEMT	Leprosy Elimination Monitoring Tool
LPTA	Leprosy Programme and Transmission Assessment (tool)
MB	multibacillary
MDT	multidrug therapy
MoH	Ministry of Health
M. leprae	Mycobacterium leprae
NTD	Neglected Tropical Disease
OPD	outpatient department
PB	paucibacillary
PEP	post-exposure prophylaxis
SDGs	Sustainable Development Goals
SDR	single-dose rifampicin
SOP	standard operating procedure
WHA	World Health Assembly
WHO	World Health Organization

Glossary

Child case of leprosy: A case of leprosy in individuals under 15 years of age.

Contact: A person having close proximity to a leprosy patient for a prolonged duration. Such persons are considered "exposed" to leprosy and may or may not have been infected.

Elimination of leprosy as a public health problem: Reducing the registered prevalence of leprosy to less than one case per 10 000 population.

Grade-2 disability (G2D): A visible impairment in the eyes, hands or feet.

Leprosy case: A patient having one or more of the following: (i) hypo-pigmented skin lesion with definite loss of sensation; (ii) thickening or enlargement of peripheral nerve (impairment) or involvement of the peripheral nerve, as demonstrated by (a) definite loss of sensation or (b) weakness of muscles in hands/feet or face or (c) autonomic function disorders such as anhidrosis (dry skin); or (d) presence of visible impairments; (iii) signs of the disease with demonstrated presence of acid-fast bacilli in slit-skin smear or histopathological confirmation; AND in need of leprosy treatment as decided by a clinician.

Lepra reactions: Reactions in leprosy/Hansen disease are acute inflammatory episodes superimposed on the relatively uneventful usual course of the disease. Reactions reflect the clinical manifestations of alterations in the immunological balance between host and the infective organism.

Multibacillary (MB) leprosy: Multibacillary leprosy is a case of leprosy with more than five skin lesions; or with nerve involvement; or with demonstrated presence of bacilli in a slit-skin smear irrespective of the number of skin lesions.

Multidrug therapy in leprosy: Standardized treatment (WHO standard of care for treatment) consisting of dapsone, rifampicin and clofazimine is called multidrug therapy (MDT). The combination of drugs generally prevents drug resistance. MDT is highly effective to treat leprosy disease.

Paucibacillary (PB) leprosy: PB leprosy is a case of leprosy with one to five skin lesions and without demonstrated presence of bacilli in a skin smear.

Post-exposure prophylaxis (PEP): Administration of drugs (e.g. rifampicin) to prevent disease in a person who is or has been exposed to *Mycobacterium leprae (M. leprae)* infection through close contact with a leprosy patient.

Second level subnational administrative unit: A health facility or entity that functions at the subnational level and includes districts/municipalities/islands, depending on the country's administrative structure.

It is important to note that the terminology and administrative units can vary significantly from one country to another country. For specific and accurate information, it is advisable to refer to the administrative and political structure of the particular country in question.

- *Districts are often used as second level administrative units.*
- *In certain countries, second level subnational administrative units can be different, e.g. municipalities, islands.*

Standard operating procedures (SOPs): SOPs in the context of health programmes refer to documented, step-by-step guidance that describes the routine procedures, processes and activities to be followed in various aspects of health-care delivery. They serve as a reference for health-care professionals, administrators, and other staff involved in the programme to carry out tasks in a standardized and systematic manner.

Surveillance: Surveillance in public health involves the systematic collection, analysis, interpretation, and dissemination of health-related data to inform public health action. The purpose is to monitor and assess the health status of population, detect and investigate health problems and provide the foundation for evidence-based decision-making and interventions.

Sentinel surveillance: Sentinel surveillance is a form of surveillance used in public health to monitor the occurrence of specific diseases or health conditions within a population. In sentinel surveillance, a selected group of strategically placed reporting sites, known as sentinel sites or centres, systematically collect and report data on particular diseases or conditions of interest.

Definitions

Autochthonous case

A case of leprosy presumed to have acquired the infection following local transmission in the reporting area. The concept behind this definition is that the case resulted from a locally acquired infection. The definition accommodates within-country situations of cases detected who are not residents of the district or state/province where they are detected. At the subnational level, the term "autochthonous" would mean "locally acquired".

Non-autochthonous case

A new case of leprosy whose infection is assumed to have occurred in another country or area than where she/he was diagnosed to have leprosy. She/he may have moved or migrated temporarily to the current country or area from a leprosy-endemic country or area. Alternatively, a resident of a country or area may be classified as "non-autochthonous" if they have visited/resided in a leprosy-endemic country or area for 6 months or more in the past 15 years. If the person moved to the current country or area more than 15 years ago, they may be assumed to have acquired the infection locally, so can be classified as an autochthonous case. Epidemiologically, non-autochthonous cases are not considered part of the local chain of transmission.

Sporadic case

"Sporadic" refers to a disease that occurs infrequently and irregularly. For leprosy, this is defined as "occasional new cases of leprosy occurring during elimination phase 2 (child cases only) or phase 3 in a given area in a particular year". Sporadic cases are unrelated, i.e. they are not contacts of the same index case, part of the same transmission cluster or part of a possible re-emergence of leprosy (which should be considered in case of "occurrence of three or more child cases on average in three consecutive years in one area during phase 2 (after interruption of transmission), or three or more cases (any age) on average in three consecutive years in one area phase 3 (post-elimination surveillance phase)"). In an area that is already in the post-elimination phase, every new case needs to be investigated to ensure that the diagnosis is confirmed and the case is treated as per the national guidelines. Additionally, it is important to establish whether the new case is autochthonous or is likely to have been infected elsewhere. In case more than one autochthonous case occurs in one district or municipality, a possible relationship between these should be investigated.

Key concepts – control, EPHP, interruption of transmission, and elimination of leprosy disease

Control

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 leprosy as a public health problem (EPHP), a term related to both infection and disease

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 EPHP is called validation. In the case of leprosy, a target for 'elimination as a public problem' was endorsed by the World Health Assembly Resolution WHA 44.9 in May 1991. The target was to reduce the registered prevalence of leprosy to less than 1 per 10 000 population at the global level by the year 2000. Globally and in most endemic countries, this goal has been achieved.

Elimination of transmission (also referred to as interruption of transmission)

Reduction to zero of the incidences 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.

Elimination of leprosy disease

Zero new autochthonous leprosy cases occur in a given area or country for at least three consecutive years.

Executive summary

Leprosy/Hansen disease is a chronic infectious disease primarily impacting the skin and peripheral nerves. If left untreated, leprosy can have long-term consequences, including deformities and disabilities, which are associated with stigma. Leprosy is one of the 21 neglected tropical diseases (NTDs), a group of conditions prevalent in tropical regions. In the "WHO Roadmap for Neglected Tropical Diseases 2021–2030", leprosy, human African trypanosomiasis (HAT) and onchocerciasis are targeted for interruption of transmission. Acknowledging the growing necessity for establishing a process to verify the absence of new autochthonous leprosy cases, a technical guidance has been developed outlining a clear pathway, demarcating phases with indicators and milestones leading towards the elimination of leprosy disease. Each country or subnational unit must progress through three phases before achieving zero leprosy: phase 1 involves interruption of transmission, followed by phase 2, which focuses on elimination of leprosy disease. After successfully reaching the elimination phase, the country must undergo a third phase of post-elimination surveillance.

Elimination of leprosy disease is a bottom-up process, and the milestones should be reached at all second level subnational administrative units. Only after achieving this across all second subnational units can a country be deemed eligible for the verification of leprosy elimination.

Upon achieving the goal of leprosy disease elimination, countries will compile a comprehensive dossier and submit to WHO to verify the successful elimination of leprosy disease. The primary purpose of this dossier is to systematically and meticulously document the actions taken by the country in the process of elimination of leprosy disease. It serves as a detailed chronicle of the interventions implemented and the outcomes achieved throughout the journey of eliminating the disease.

Following the submission of the dossier, WHO responds by organizing a verification process conducted by an external independent committee of experts. This committee reviews the dossier, scrutinizes the evidence presented by the country and assesses the implementation of interventions and services in alignment with the national strategic plan including through on-site visits to observe the service delivery process. The objective is to confirm that the country has indeed reached the goal of elimination of leprosy as a disease. Upon completion of the appraisal, the committee recommends to WHO to officially acknowledge the country's achievement in eliminating leprosy disease.

The tools employed in the verification process are the leprosy programme and transmission assessment (LPTA) tool and leprosy elimination monitoring tool (LEMT). The LPTA encompasses a range of interventions/services carried out within the leprosy programme, spanning three distinct domains: political commitment, programme implementation, and surveillance. A report on the interruption of transmission and elimination of leprosy disease achieved at the second subnational level will be included in support of the dossier claiming the elimination of leprosy disease.

The technical document provides details of the dossier for the elimination of leprosy disease serving as a comprehensive guide for countries, offering systematic assistance in the preparation process. It provides essential guidance to ensure a methodical and organized approach when compiling the dossier. By following the guidance outlined in this document, countries can ensure a thorough and accurate representation of their efforts in achieving the elimination of leprosy disease.

1. Introduction

1.1. About Leprosy

Leprosy/Hansen disease is a chronic infectious disease that predominantly affects the skin and peripheral nerves. If left untreated, leprosy can have long-term consequences, including deformities and disabilities, which are associated with stigma. The causative agent is *Mycobacterium leprae* (*M. leprae*) in most cases, and recent evidence suggests that a genetically similar pathogen, *Mycobacterium lepromatosis* (*M. lepromatosis*) has been found to be causing the disease with similar signs and symptoms. Hereinafter the causative agent is referred to as *M. leprae* in the document.

Diagnosis is done mostly based on clinical signs – anaesthetic skin lesions, enlarged nerves and in a small proportion of cases through laboratory support New leprosy cases are grouped into paucibacillary (PB) and multibacillary (MB) for treatment purposes. Multidrug therapy (MDT) with rifampicin, dapsone and clofazimine as constituents was introduced as treatment for leprosy by WHO.[1]

A significant decrease in registered prevalence was observed worldwide by 1990 after using MDT. Encouraged by the significant reductio n, the 44th meeting of World Health Assembly (WHA) in May 1991 passed a resolution urging countries to accelerate leprosy case detection campaigns to reach a target for "elimination of leprosy as a public health problem" globally by 2000.[2] The target of reduction of registered prevalence of leprosy to less than one case per 10 000 population was achieved at a global level by 2000 and a majority of high-endemic countries reached the milestone by 2005.[3]

1.2. Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021–2030

Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021−2030[4] establishes global targets and milestones aimed at preventing, controlling, eliminating or eradicating NTDs along with cross-cutting targets aligned with the Sustainable Development Goals (SDGs).

The roadmap delineates specific, measurable targets for 2030, accompanied by interim milestones for 2023 and 2025, for the eradication, elimination and control of each of the NTDs. In the NTD Roadmap, leprosy, human African trypanosomiasis (HAT) and onchocerciasis are targeted for interruption of transmission.

1 World Health Organization. (1982). Chemotherapy of leprosy for control programmes: Report of a WHO Study Group [WHO Technical Report Series, No. 675]. WHO. https://apps.who.int/iris/handle/10665/38984
2 World Health Organization. (1991). Elimination of leprosy: Resolution WHA44.9. In: Forty-fourth World Health Assembly, Geneva, 6-16 May 1991. Resolutions and decisions, annexes. WHO. https://apps.who.int/iris/handle/10665/173010 (accessed 16 June 2023).
3 World Health Organization. (2006). Report of the global forum on elimination of leprosy as a public health problem. WHO. https://apps.who.int/iris/handle/10665/43638
4 World Health Organization. (2020). Ending the neglect to attain the Sustainable Development Goals: A road map for neglected tropical diseases 2021–2030. WHO. https://apps.who.int/iris/handle/10665/338565 (accessed 16 June 2023).

1.3. Towards zero leprosy: Global Leprosy (Hansen's disease) Strategy 2021–2030

The Global Leprosy Strategy 2021–2030: Towards zero leprosy [5] aims to contribute to achieving the SDGs and is one of the disease-specific strategies underpinning the WHO Road map for NTDs 2021–2030.

The Global Leprosy Strategy 2021–2030 presents the fundamental direction, goals and strategic pillars at a global level. It is structured along four pillars: (I) implement integrated, country-owned zero leprosy roadmaps in all endemic countries; (ii) scale up leprosy prevention alongside integrated active case detection; (iii) manage leprosy and its complications and prevent new disability; and (iv) combat stigma and ensure human rights are respected.

Interruption of transmission and elimination of disease are at the core of the strategy. The global targets are 120 countries with zero new autochthonous cases; 70% reduction in annual number of new cases detected; 90% reduction in rate of new cases with grade-2 disability (G2D) per million population; 90% reduction in rate of new child cases per million children.

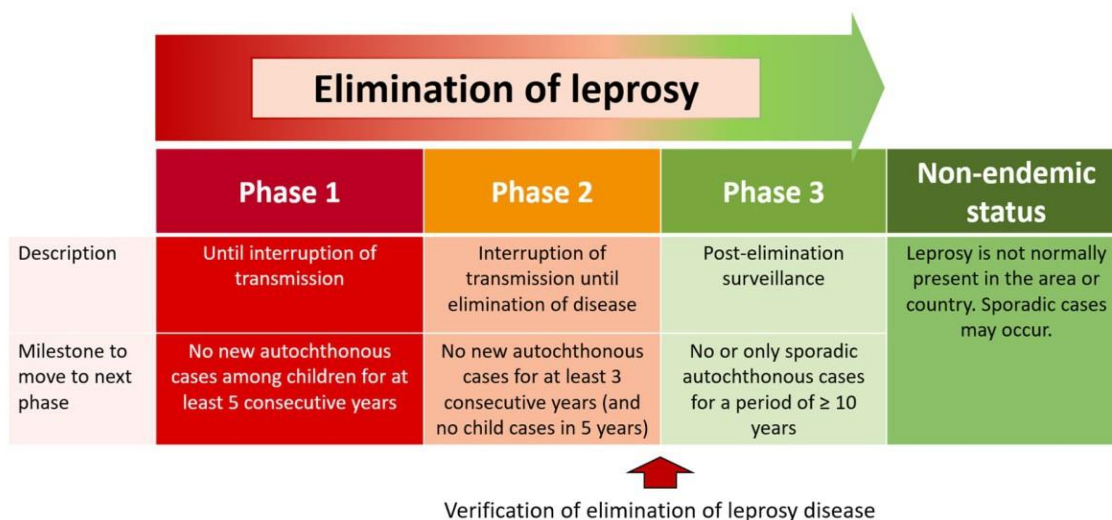
5 Towards Zero Leprosy. Global Leprosy (Hansen's disease) Strategy 2021–2030. New Delhi:World Health Organization, Regional Office for South-East Asia; 2021

2. Elimination of leprosy disease

2.1. Leprosy Elimination Framework

A technical guidance was developed by WHO to support countries seeking verification of interruption of transmission and elimination of leprosy disease. The Leprosy Elimination Framework provides a clear pathway distinguishing phases with indicators and milestones (Fig. 1).

Fig. 1. Leprosy Elimination Framework showing the phases in the elimination of leprosy disease



Every country or a subnational administrative unit before reaching the non-endemic status, has to pass through three phases, i.e. phase 1: until interruption of transmission, followed by phase 2: interruption of transmission until elimination of leprosy disease, and phase 3: post-elimination surveillance.

2.1.1. Phase 1 – Until interruption of transmission

Interruption of transmission is defined as "An epidemiological state in a leprosy-endemic country or area where there is no more local transmission of *M. leprae*", evidenced by zero new autochthonous cases among children <15 years of age for at least 5 years.

2.1.2. Phase 2 – From interruption of transmission until elimination of leprosy disease

Elimination of leprosy disease is defined as "zero new autochthonous leprosy cases for at least three consecutive years".

2.1.3. Phase 3 – Post-elimination surveillance

Once the elimination of leprosy disease has been verified by WHO, the country enters the post-elimination surveillance phase. It is important to note that, due to the long incubation period of leprosy, occasional new cases are still expected to emerge. These occasional cases are referred to as "sporadic cases". Each sporadic case needs to be investigated to determine whether the infection is likely to have been acquired locally or elsewhere. It is therefore crucial to have a robust surveillance and response system in place.

2.1.4. Non-endemic status

If no or only sporadic new autochthonous cases have been detected for at least 10 years in a given country or administrative area, the country or area can be considered non-endemic. Non-autochthonous cases may still be reported, and if this is the case, appropriate surveillance and response facilities need to be in place, including services related to the management of complications, prevention of secondary impairments, and disability management, rehabilitation, and mental health. These services would be provided through general health facilities that also assist individuals with similar issues arising from other causes.

3. Verification process for elimination of leprosy disease

It is imperative for national health care system to deliver services to the persons affected by leprosy that adhere to specific standards in terms of quality and quantity. Verification will be done based on the information and data provided by the country as evidence to in dicate reaching the epidemiological cut-off, continuation of services to the persons with disabilities due to leprosy and sustaining surveillance, which is sensitive enough to detect a case of leprosy both among autochthonous and non-autochthonous populations. The dossier reflects systematic representation of the interventions/ services of the programme with indicators to show evidence of achievement.

Elimination of leprosy disease is a bottom-up process, and the milestones should be reached at all second level subnational administrative units. Only then the country can be considered for verification of elimination of leprosy disease. Countries will prepare a dossier after reaching the goal of elimination of leprosy disease at all subnational administrative levels and submit it to the WHO for verification. The dossier meticulously organizes the data, ensuring its accuracy and reliability.

WHO in response to the submission of the leprosy elimination dossier, organizes verification by a committee of external experts. The "external verification committee" reviews the dossier, examines the evidence provided by the country, makes field visits to observe the service delivery process, as required and recommends to WHO for acknowledging elimination of leprosy disease.

The tools used during the verification process, i.e. the leprosy programme and transmission assessment (LPTA) tool and leprosy elimination monitoring tool (LEMT), are described below.

3.1. Leprosy programme and transmission assessment tool (LPTA)[6]

The LPTA is administered by internal teams at the completion of phase 1 when a subnational administrative unit achieves the milestone of interrupting transmission. This milestone is marked by the absence of any autochthonous child case for a continuous period of 5 years. Additionally, the LPTA is performed at the conclusion of phase 2, when the second milestone of eliminating leprosy disease has been attained. The purpose of LPTA is to systematically document the fulfilment of all pertinent programme criteria and scrutinize epidemiological trends within that area to confirm achievement of the milestone. The LPTA encompasses a comprehensive review of epidemiological data, verification of programme criteria and assessment of health facilities through on-site observations and field visits. The evidence collected at second level subnational administrative units is then collated in a leprosy elimination dossier.

An excel-based tool is developed based upon the WHO technical guidance for verification of interruption of transmission and elimination of leprosy disease (Annex 1). The tool has three main elements: LPTA tool; health facility assessment and trend of epidemiological indicators. The tool will be used by the internal verification team for conducting verification of "interruption of transmission" and "elimination of leprosy disease" at all second level subnational administrative units. The observations, findings and conclusions from internal verification will contribute to drafting the dossier.

6 Leprosy Programme and Transmission Assessment: Tool accompanying the Technical guidance on interruption of transmission and elimination of leprosy. New Delhi: World Health Organization, Regional Office for South-East Asia; 2023.

The dossier submitted by the country to the WHO will be the basic reference document for external verification. The external verification team will use the same tool to verify the claim of the country presented in the dossier for "Elimination of leprosy disease" at the national level and at second level subnational administrative units.

3.2. Leprosy elimination monitoring tool (LEMT)[7]

The LEMT has been developed in alignment with the Leprosy Elimination Framework to establish a standardized method for closely tracking the progress towards interruption of transmission and elimination of leprosy disease.

The LEMT, designed in Microsoft Excel (Annex 2) necessitates the input or import of data on an annual basis, categorizing it by second level subnational administrative units. This data should be segregated into autochthonous child cases and autochthonous adult cases accompanied by the second level subnational administrative units name s and unique area codes. If available, data on non-autochthonous cases can also be included. The spreadsheet utilizes a straightforward legend to apply colour coding (traffic light colours) to cells in accordance with predefined phase-transition criteria.

Typically, the LEMT encompasses a time span of 20 years, commencing from 2000, for most countries studied. However, the tool can be adapted for use in any area where a minimum of 10 years of data are available. The data can be used to create sequential maps. These tools together serve the purpose of recording, reporting, monitoring and presenting the historical progress of areas and countries in their journey towards interrupting transmission and eliminating leprosy disease while documenting the attainment of associated milestones. Second level subnational administrative units still in phase 1 or 2 should be identified by programme managers as requiring additional resources to help them reach the designated milestones.

3.3. National level committees as oversight group for verification of elimination of leprosy disease

Countries are encouraged to constitute a national level committee as per their national policy, which can be referred to as task force for elimination of leprosy disease/steering committee/programme review group for elimination of leprosy. The committee consists of a group of experts from health programmes, partners, academic institutions, and other relevant stakeholders. The committee reviews the national plan, implementation, and progress in reaching the milestone of elimination of leprosy disease. It also plays an advisory role and provides oversight to the Ministry of Health (MoH) on developing the dossier. The committee will review the dossier and make recommendations to the MoH for submission to WHO.

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7 Leprosy Elimination Monitoring Tool: The LEMT is a tool accompanying the Technical guidance on interruption of transmission and elimination of leprosy. New Delhi: World Health Organization, Regional Office for South-East Asia; 2023.

4. Dossier

The main purpose of the dossier is to systematically and thoroughly document the initiatives taken by the country to eliminate leprosy disease. It presents a detailed record of the interventions implemented, and outcomes realized throughout the journey of disease elimination by all stakeholders collectively. The dossier plays a crucial role in the verification process and functions as a repository of evidence, data and insights that substantiate the claim of leprosy disease elimination.

The contents of the dossier are described below:

i. Introduction
ii. Health situation and general indicators of health and development
iii. Health-care delivery system
iv. Progress in eliminating leprosy disease
v. Political commitment
vi. Programme Implementation
vii. Surveillance
viii. Additional information, and
ix. Information to be presented in the dossier as annexes.

4.1. Introduction

The country will give a brief account of the following aspects:

- Geographical features describing borders, coastline along with maps as illustrations highlighting difficult to reach areas.
- Information about first (e.g. provinces/states/atolls) and second level subnational administrative units (e.g. districts/municipalities/islands) will be described with the help of maps. Details may be provided as annexes.
- Governance, political system, language, economy, culture and social practices can be presented briefly with reference to the influence on the leprosy programme.
- Brief description of education and literacy levels among different population segments, e.g. women, children and total population.
- Additional information about specific population groups such as indigenous/ethnic groups, migrants, refugees, and internally displaced people may be presented. Population ratios like urban vs rural may be presented.
- Current population data disaggregated by age (<15 years as children and by adults) at the second subnational administrative level to be presented in the suggested format

4.2. Health situation and general indicators of health and development

- Information on the health situation describing average life expectancy, health indicators such as mortality rates (infant mortality rate, maternal mortality rate, child mortality rate).
- Social determinants that influence the general health condition of the population.
- Vaccination coverage with reference to BCG vaccination.

4.3. Health-care delivery system

Provide a comprehensive overview of the health-care system in terms of its structure and functions highlighting the delivery of health-care services at the primary, secondary and tertiary levels under the following headings:

- **Health-care governance:** The existing health policies governing health systems and a summary of the national health plan to be provided with emphasis on key health interventions under universal health coverage, with specific reference to leprosy and disability care services.
- **Primary, secondary and tertiary health-care services:** Brief information to be provided about preventive and curative health-care services available at the primary, secondary and tertiary levels, with particular reference to leprosy. The description needs to cover referral mechanism operating at the three levels. An organogram of health structure with reference to the general health-care system and with specific reference to leprosy services to be presented.
- **Public and private sectors:** A brief description of roles and contributions of the public (government-funded) and private health-care sectors, including private hospitals, clinics and health insurance providers in general health care and with specific reference to leprosy needs to be presented to understand the linkages and coordination between the public and private sectors.
- **Health information systems:** A summary of leprosy health information systems (paper-based and web-based systems) need to be described. Examples of health information technology products, electronic health records (EHRs), and data management and reports in the health-care system to be presented.
- **Collaborations:** Collaborations or partnerships with national and international organizations in providing health care, with reference to leprosy can be presented briefly.

4.4. Progress in eliminating leprosy disease

The country will provide a brief history of leprosy programme with information about old leprosarium, evolution of MDT and leprosy services across the country, highlighting the contribution of stakeholders.

Reference should be made on the implementation of the leprosy programme, which may vary across countries, as part of general health-care services, or integrated into other disease control programmes such as NTDs, tuberculosis and communicable diseases.

The presentation should preferably cover a period of 10 years before reaching the goal of elimination of leprosy disease. Corresponding epidemiological data for the period should be presented in tables and graphs.

Activities planned during the post-elimination surveillance should be reflected. Reference to the national health plan in the narrative is essential. The intervention or services provided in leprosy programme should be presented as per the criteria laid down in the LPTA tool. The tool covers diverse activities implemented in leprosy programme under three main domains, i.e. political commitment, programme implementation and surveillance. The dossier will present the findings, observations and conclusions from the LPTA as the basic reference for the verification.

Table 1. Programme criteria to be assessed during a leprosy programme and transmission assessment at the end of phase 2

Leprosy programme and transmission assessment tool – national level (end of phase 2)			
Interventions/services	**Indicators/milestones and target (where relevant)**	**Sources of information**	**Level of achievement**
Country assessed:			
Political commitment			
Country-owned national strategic plan adapting global leprosy strategy 2021–2030/NTD roadmap 2030	National strategic plan/national health plan to achieve interruption of transmission and elimination of leprosy disease available with resource allocation	Perusal of national strategic plan,	Yes/No
	A health plan providing for an integrated leprosy case detection and treatment services is available	Multi-stakeholder consultation	Yes/No
	Availability of algorithms/standard operating procedures (SOPs) for diagnosis, management, prevention, rehabilitation including care of disabilities		Yes/No
	National health plan with focus on training to sustain expertise in leprosy and programme management		Yes/No
	A well-defined referral system from community to a sentinel centre/centre of excellence/ referral unit is in place[8]		Yes/No
	Drug procurement and supply chain management are in place (relevant to leprosy)		Yes/No
	Advocacy materials (e.g. investment case for elimination of leprosy disease; information booklets, infographics and videos) are available for sensitizing policy-makers at the national and subnational levels	Review of advocacy materials available	Yes/No
Enabling environment for persons affected by leprosy	Existing laws/policies/traditional practices/regulations that allow discrimination against persons affected by leprosy	Report on existing laws that allow discrimination against persons affected by leprosy	Yes/No/ work in progress
	Number of instances of discrimination reported		Number reported
	Social support, e.g. entitlements, pension/welfare schemes for persons with disability include persons affected by leprosy		Yes/No
	UN Principles and Guidelines[9] are available in the national language (for signatory countries)		Yes/No
	Positive norms or regulations exist to facilitate social inclusion of persons affected by leprosy		Yes/No

8 An institution where facilities such as for training, surveillance, provision of specialized care for leprosy are available at suitable level (at least one per country).

9 United Nations. Principles and Guidelines for the elimination of discrimination against persons affected by leprosy and their family members. UN Digital Library (https://digitallibrary.un.org/record/684458?ln=en, accessed 16 June 2023)

Leprosy programme and transmission assessment tool – national level (end of phase 2)			
Interventions/services	**Indicators/milestones and target (where relevant)**	**Sources of information**	**Level of achievement**
Programme implementation			
Integration of leprosy into general health services	Integrated case-finding, leprosy care package and prevention activities implemented	Programme reports, HIS, facility-based assessment	Yes/No
Training of health staff (leprosy-specific or integrated with NTDs or other programmes)	Training status of health workers (target: at least one leprosy-trained health worker in each designated facility)	Certificate/evidence of training from self-learning/national/ WHO accredited courses	Yes/No
Leprosy care package[10] for treatment and management of complications is implemented	Diagnosis, WHO recommended standard of care for treatment of patients, management of reactions and prevention and care of disabilities practices in line with SOPs	Availability of care package and SOPs	Yes/No
	Drugs required to manage leprosy are available	Observation, discussions, health facility assessment	Yes/No
Referral mechanism	Referral mechanism with designated levels from community to apex/sentinel/referral unit to be verified	Observation, discussions, health facility assessment	Yes/No
Contact tracing	Proportion of cases for whom contact examination (for patients registered for the past five years) was undertaken (target >80%)	Patient cards, registers, HIS	Percentage
	Proportion of contacts of patients examined (target: >80%)		
Administration of single-dose rifampicin (SDR) to eligible contacts as post-exposure prophylaxis (PEP)	Adoption of SDR-PEP in guidelines	Health plan	Yes/No
	Proportion of eligible contacts who received SDR-PEP (target: 95%)	Records, registers, HIS	Percentage
Awareness about leprosy	Awareness campaigns – media	Information circulars and/or communication materials	Yes/No
	Level of awareness in the general community and among traditional healers and opinion leaders	Discussion with general community	Good/ moderate/ poor

10 Implementation of leprosy package of care – verifying adoption of standard operating procedures and observation during health facility assessment.

Leprosy programme and transmission assessment tool – national level (end of phase 2)			
Interventions/services	**Indicators/milestones and target (where relevant)**	**Sources of information**	**Level of achievement**
Surveillance			
Sentinel surveillance and passive surveillance	Sentinel centre/apex centre/centre of excellence/referral unit[11] with staff trained to diagnose and manage leprosy is available at an appropriate level (district/municipality or state/province)	Observation, records and reports, discussion	Leprosy cases (child/adult; autochtho-nous/non-autochtho-nous)
Screening of persons with suggestive signs of leprosy in skin OPD/health centres and skin camps	Persons not found to have leprosy among persons screened with suggestive signs of leprosy Leprosy screening is included as one of the diseases in migrant or displaced persons health screening and care programmes	Records and reports, HIS system	Number
Management of sporadic cases	Mapping of sporadic cases Critical instance investigation of sporadic cases is done	Records and reports	Yes/No
Involvement of private providers	Private practitioners are involved in treating leprosy complications and disabilities of eyes, hands and feet	Reports from private practitioners, discussion	Yes/No
Surveillance through involvement of pharmacists and chemists	Availability of over-the-counter leprosy drugs used in treatment of leprosy	Reports, discussions, observations	Yes/No
Data management system	Reporting is done at the subnational level (including zero case reports)	Reports	Yes/No

11 An institution where facilities such as for training, surveillance, provision of specialized care for leprosy are available at suitable level (at least one per country).

4.5. Political commitment

4.5.1. Country-owned national strategic plan adapting global leprosy strategy 2021–2030/ NTD roadmap 2021–2030

The country should provide a summary of the national health plan highlighting allocation of resources for different interventions and training plan for enhancing skills of health staff on management of leprosy. Formal approval of the national plan by the MoH if available should be presented in the dossier.

The SOPs for diagnosis, referral system, management and prevention (contact examination and post-exposure prophylaxis [PEP] with single-dose rifampicin [SDR]), rehabilitation including care of disabilities should be mentioned in the dossier and make the SOP available for perusal by verification committee. SOPs to be included as annexes to the dossier.

Materials for advocacy to sensitize policy-makers and materials for raising awareness in the community should be presented in the dossier. The national strategic plan or zero leprosy roadmap with activities up to elimination of leprosy disease with budgetary allocations to provinces/states and districts/islands and the information provided in the dossier should be available for perusal of the verification committee.

4.5.2. Enabling environment for persons affected by leprosy

Social entitlements, welfare schemes for persons with disabilities due to leprosy should be described as applicable in their respective country situations under this section of dossier. Wherever available, official government notifications on these entitlements should be provided as reference. Other steps taken to address discrimination on the basis of leprosy, e.g. implementation of UN principles and guidelines can be highlighted if applicable.

In counties where networks of persons affected by leprosy are actively partnering with the government in implementing leprosy services, examples of collaborative activities should be presented. Efforts put in by the national programme to facilitate participation of the primary stakeholders, the persons affected by leprosy and other relevant stakeholders in the community. Efforts made in repealing or amending legislations, statutory provisions which allow discrimination on the basis of leprosy should be presented.

Reference in the national strategic plan to these activities will demonstrate a systematic approach of participation of persons affected by leprosy and other stakeholders.

4.6. Programme implementation

4.6.1. Integration of leprosy into general health services (suspect, diagnose and treat leprosy at subnational units and/or referral centres)

The country should present activities carried out in the area of integrated case-finding to detect a person with suggestive signs of leprosy, diagnose and treat the confirmed patients with MDT.

4.6.2. Training of health staff (leprosy-specific or integrated with NTDs or other programmes)

Information on planning and organization of the trainings with reports indicating number of health staff and community stakeholders trained should be provided in the dossier. If *Open WHO* training programmes are used, details of training can be presented with certificates received by the registered trainees. Training certificates from in-country training programmes also can be included as evidence.

4.6.3. Leprosy care package for treatment and management of complications

SOPs for activities providing treatment, management of lepra reactions and disability care services should be listed in the dossier. Reports on drug stock management (requests for drugs and reports on drug usage) should be described mentioning available drug stocks at the time of the report. Details of leprosy care package provided for management of patients and preventive initiatives such as screening of contacts and administering SDR as PEP should be described.

4.6.4. Referral mechanism for diagnosis, treatment of leprosy and rehabilitation for persons with leprosy-related disabilities and for mental health care

Information about existing referral pathways for a suspected case to get diagnosis and treatment including management of complications such as lepra reactions should be presented. Presentation of referral system through flowcharts will depict a well-defined referral system.

4.6.5. Contact tracing

Information about contact tracing and examination should be provided for the past five years. SOPs for registering contacts, i.e. family, social and neighbourhood contact, should be summarized for information.

4.6.6. Administration of single dose rifampicin (SDR) to eligible contacts as post-exposure prophylaxis (PEP)

As per the national policy and in accordance with recommendations of WHO guidelines for the diagnosis, treatment and prevention of leprosy (2018), eligible contacts[12] should be provided with SDR for preventing leprosy as part of PEP. SOPs for the PEP should be presented briefly as applicable.

4.6.7. Awareness about leprosy

Information campaigns to raise awareness about leprosy and elimination of stigma should be presented. Infographics and communication materials used in the country to be presented if available.

4.7. Surveillance

4.7.1. Data management system

The existing health data management system that is operational in the national programme should be presented with indicators measuring progress in reaching the goal of elimination of leprosy disease. The details of data collection process, data flow from periphery, i.e. primary health care, to the central level should be explained in the dossier. Examples of reports generated from the system at the subnational and national levels should be presented to inform effectiveness of the system.

Zero leprosy case reports from all second level subnational administrative units need to be attached as a claim using LEMT with serial maps showing new autochthonous cases and progress in achieving zero autochthonous leprosy cases over the past 10–20 years.

Salient observations and conclusions from LEMT should be discussed in the dossier.

4.7.2. Screening of persons with suggestive signs of leprosy in skin outpatient department (OPD)/health centres and skin camps

Leprosy should be included in health screening of all population groups particularly covering migrants, internally displaced people and special population groups with limited access to universal health coverage, e.g. refugees. Countries should present the SOP for screening of population at OPDs in hospitals and skin camps. Available data from similar campaigns should be presented to substantiate availability of health screening services.

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12 Leprosy/Hansen disease: Contact tracing and post-exposure prophylaxis. Technical guidance. New Delhi: World Health Organization, Regional Office for South-East Asia; 2020.

4.7.3. Sentinel surveillance (wherever applicable) and/or passive surveillance

The country should give information about the presence of trained staff to diagnose leprosy either at sentinel surveillance centres, apex health facilities or centres of excellence/referral units to provide evidence for availability of the post-elimination surveillance systems in the country.

4.7.4. Management of sporadic cases

The processes involved in registering and treating any sporadic cases can be explained. Sporadic new cases among children and adults should be documented and treated with MDT after confirming the diagnosis. In management of sporadic cases, identifying the source or index case and establishing surveillance for all contacts becomes mandatory. Every sporadic case should be investigated using critical instance investigation protocol. Record of critical instanceinvestigation should be presented in the dossier, if available.

4.7.5. Involvement of private practitioners

Public–private collaborations established by the national programme to provide MDT and specialized care for persons with disabilities due to leprosy should be presented to ensure continuum of care for persons with disabilities and new sporadic cases.

4.7.6. Surveillance through involvement of pharmacists and chemists

In countries where anti-leprosy drugs are available over the counter, surveillance should be encouraged through pharmacists and chemists dispensing antibiotics. Reports, if any from the surveillance should be included in the dossier.

4.8. Additional information

4.8.1. Research carried out on leprosy and relevant publications in the country (optional)

Countries are encouraged to provide information on research projects carried out along with a list of relevant publications.

4.9. Information to be presented in the dossier as accompanying documents

A provisional list of accompanying documents to substantiate the claim for elimination of leprosy disease is provided for reference. Countries can select relevant annexes for inclusion in the dossier.

i. Health structure including organogram/description
ii. National strategic plans (health and highlighting leprosy reference)
iii. National level steering committees and review groups – minutes of meetings
iv. Political commitment, e.g. call by country heads/decree by MoH
v. SOPs for the leprosy programme
vi. Annual reports submitted to WHO–DHIS-2 forms for the past 5 years
vii. Trends of autochthonous new adult cases, new child cases, new cases with G2Ds
viii. Trends of non-autochthonous new cases
ix. Maps – subnational distribution of cases over 10–20 years (serial maps)
x. Data table of sporadic cases detected, and action taken (critical instance investigation – details of report on the last sporadic case)
xi. Report on verification for interruption of transmission and elimination of leprosy disease from all second level subnational administrative units- A summary report on interruption of transmission and elimination of leprosy disease achieved at second level subnational administrative units should be included in the report with data sheets appended as annexes in support of the dossier claiming elimination of leprosy disease.

5. Annexes

Annex 1	Dossier – Excel work sheets – Leprosy programme and transmission assessment tool
Annex 2	Dossier – Excel work sheets – Leprosy eliminating monitoring tool
Annex 3	Terms of reference for internal verification team
Annex 4	Terms of reference for external (independent) verification team and format for a report on “Verification of elimination of leprosy disease” by the team

Annex 1

Leprosy programme and transmission assessment tool (Excel-based)

General Instructions

The information collected and report prepared are for verification of elimination of leprosy disease and should not be used for any other purpose.

1. The purpose of the visit and expectation is to be explained at each data collection level and active cooperation of subnational unit (district) health staff is to be sought. While using data collection tools, the team should explain the purpose, assure the health staff and other key informants that the information would be used for verification of elimination of leprosy disease only and kept confidential.

2. The team should carry with them enough data collecting instruments, pen-drive, pencil, pen, note pad, file folder etc. One of the team members should have a laptop and knowledge of applications such as Word, Excel and Powerpoint. Handwriting should be legible, wherever hand-written notes are included in the report.

3. Photographs of patients, health workers and other informants should not be taken without written consent of the individuals. Photographs of health centre premises, offices, general surroundings in the field and meeting halls should be taken only with permission from the concerned head of the institution or community members.

4. At each level of data collection, the team will verify from the tool whether all the tasks have been accomplished before leaving the site to ensure completeness of information. In case if the information is not available, reason should be mentioned or a mention made in the corresponding cell: "Not Available". No relevant item in the data collection instrument is to be left blank.

5. The team should reach a consensus on the findings from observations and conclusions from discussions before finalizing the column "level of achievement". A team meeting at the end of the day, for completion, compilation, reflection and discussions is important to get the best out of the effort.

6. Debriefing should be done at every level, e.g. head of health facility and with health authorities of district. Each team is expected to prepare and submit a final report (as per the reporting template) during debriefing.

Name of district (second subnational unit)

Name of governorate/state (first subnational unit)

Name of person filling the form along with designation and contact details (email and mobile number)

All the filled data collection forms and the verification team report should be handed over to …............................. (Name and email ID)

Instructions for filing LPTA tool

The tool has three main elements: leprosy programme and transmission assessment (LPTA) tool; health facility assessment and trend of epidemiological indicators. This Excel-based tool is developed using the WHO technical guidance for verification of interruption of transmission and elimination of leprosy disease. The tool will be used by the internal verification team for conducting verification of “interruption of transmission” and “elimination of leprosy disease” at “all second level subnational level administrative units”, e.g. districts. The observations, findings and conclusions from internal verification will contribute to drafting the dossier claiming elimination of leprosy disease. The dossier submitted by the country to WHO will be the basic reference document for external verification. The external verification team will use the same tool to verify the claim of the country presented in the dossier for “elimination of leprosy disease” at the national level and at second level subnational administrative units, e.g. districts.

The LPTA tool is presented in three worksheets covering three different domains for verification, i.e. “Political commitment, Programme implementation and Surveillance”. Each worksheet is presented in nine columns, i.e. from column A to column I.

Column A – Serial number: it provides a serial number for documentation and reference in the report by the verification team.

Column B – Intervention/services: both at the national and subnational levels (as applicable) are mentioned in the column. Progress under each intervention/service need to verified using the suggested indicators as presented in column C.

Column C – Indicators: are identified against each of the intervention/services for which the level of achievement is to be ascertained.

Column D – Source of information: describes the source for obtaining information such as key informants, programme reports, publications and relevant documents. Any other documents used by the verification team as source of information can be mentioned under this column.

Column E – Key information to be collected: describes the specific information to be sought in relation to the intervention/services being verified. These are through perusal of documents and discussion with key informants. Any additional action taken to verify information or progress needs to be mentioned under this column.

Column F – Findings from observations/perusal of documnet: the verification team will note their findings for each action taken with reference to intervention/service being verified. Findings related to reaching the milestones specified for each phasoef elimination in leprosy elimination framework, i.e. “interruption of transmission”, “elimination of leprosy disease” and “post-elimination surveillance” should be mentioned under this column.

Column G – Conclusions from discussion: conclusions from actions taken, observations, findings drawn from discussions with key informants should be mentioned with specific reference to implementation and achievement of targets for each intervention/service.

Column H – Level of achievement/availability: options with a drop-down menu is provided for recording the level of achievement or availability of intervention/service in terms of the indicators being verified. This will help in obtaining uniform reports from different verification teams. The details of the drop-down menu options are provided in a separate worksheet, i.e. options for

political commitment, options for programme implementation and options for surveillance. These separate sheets are for information and reference ONLY.

Column I – Remarks: the verification team may make a few remarks which could not otherwise be entered in other columns of the tool and should pertain to elimination of leprosy disease. Additional suggestions can be made for consideration of the programme to strengthen post-elimination surveillance and continuum of disability care.

Health facility assessment: A separate worksheet is enclosed for health facility assessment. Two health facilities for each second subnational unit/district (all districts should be covered) should be selected in consultation with the MoH and visited by internal verification team (preferably a major hospital, if available in the district and at least one peripheral health facility).

Instructions: Assessment will be conducted at the facility selected by the verification team to verify the fulfilment of facility-linked criteria. This includes assessing the availability of diagnostic services, evaluating the knowledge and skill of staff, ensuring treatment with MDT, and reviewing the effectiveness of the data management system. Additionally, the assessment will encompass services related to di sability prevention and management, as well as initiatives to reduce stigma and address mental health. The availability of a mechanism for referring patients with complications or disabilities beyond the peripheral level will also be evaluated.

Epidemiological data for 10 years: To assess trends in relevant indicators including new autochthonous child and adult leprosy cases and review and validate the colour coding in LEMT. The epidemiological data should be collected at the national and second subnational level (district) by the verification team.

The excel tool will be made available upon request to glp@who.int

Leprosy Elimination Monitoring Tool – Data on new autochthonous adult and child case (Excel-based)

Colour	Legend
Red	Phase 1 – Until interruption of transmission (5 years no autochthonous child cases)
Orange	Phase 2 – Until elimination of leprosy disease (3 years no autochthonous cases)
Light green	Phase 3 – Post-elimination phase (10 years no autochthonous cases)
Green	Non-endemic status
Magenta	Sporadic autochthonous adult case
Pink	Sporadic autochthonous child case

Number	First level subnational administrative units	Second level subnational administrative units		2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
1			**Children**																							
			Adults																							
			Total new cases																							

Data on new child and adult cases among autochthonous population should be filled in for all second subnational level units in line with the LEMT.
The LEMT tool should be updated by the programme staff at second subnational staff.

Annex 3

Terms of reference for internal verification team

Introduction

The "Global Leprosy Strategy 2021–2030: Towards Zero Leprosy" is one of the disease-specific strategies integral to the WHO Roadmap for NTDs 2021–2030 and seeks to contribute to the realization of the Sustainable Development Goals (SDGs). This strategy delineates the fundamental direction, goals and strategic pillars on a global scale, with a primary focus on interrupting transmission and eliminating the disease.

In the provision of leprosy services, it is imperative for national health-care systems to adhere to specific standards in terms of both quality and quantity. Verification will be conducted based on information and data provided by the country, serving as evidence of achieving the epidemiological cut-off, sustaining services for individuals affected by disabilities due to leprosy, and maintaining effective surveillance.

The process of elimination is inherently bottom-up, requiring milestones to be reached at all second subnational administrative units. Besides achieving the epidemiological cut-off, it is crucial that all interventions and services align with the national strategic plan. The suggested indicators will be verified to ensure progress in the implementation of services or the outcome of activities. The reports generated by the internal verification teams in all districts play an essential role in claiming the elimination of leprosy disease in the country. Only after achieving the elimination of leprosy disease across all second subnational units can a country be deemed eligible for the verification of leprosy disease elimination.

The country will prepare a dossier, submitting it to WHO to officially claim the elimination of leprosy disease. The reports from the internal verification teams in all districts are crucial documents of this dossier.

Each team consists of two or three members. Team members should have expertise in public health/community health with experience in disease programme management. The selection of team members will be conducted by the Ministry of Health (MoH) of the respective country.

It must be ensured that team members do not review their own districts where they are currently working.

Purpose of the internal verification team in the context of elimination of leprosy disease

Ensure that second level subnational administrative units (e.g. districts) have effectively reached the milestone of elimination of leprosy disease. This milestone is defined by having "zero new autochthonous leprosy case for at least three consecutive years and no child case in the past five years".

Specific objectives for internal verification team

a. **Verification of milestone achievement:** Validate and confirm the achievement of the elimination of leprosy disease milestone in second level subnational administrative units.
b. **Compliance assessment:** Assess the second subnational units' adherence to the national strategic plan/national health plan and the leprosy programme and transmission assessment (LPTA) tool within the three domains: political commitment, programme implementation, and surveillance. This involves evaluating compliance with established interventions, services, and the attainment of targets.

c. **Data accuracy and reliability:** Review and validate the accuracy and reliability of leprosy-related data collected and reported by the second subnational unit.
d. **Documentation review:** Assess the completeness and accuracy of documentation related to leprosy elimination efforts within the unit.
e. **Identification of challenges and success factors:** Identify and assess challenges faced by the units in achieving and sustaining leprosy elimination. Recognize and document success factors and best practices contributing to the successful elimination of leprosy disease in the respective areas.
f. **Recommendations for improvement:** Provide constructive feedback and recommendations for areas of improvement in surveillance and other aspects related to leprosy elimination. Recommend steps to improve preparedness for management of sporadic cases and strengthening surveillance during post-elimination surveillance phase.
g. **Preparation of verification report:** Compile a comprehensive verification report summarizing findings, conclusions and recommendations. This report serves as an official document attesting to the successful elimination of leprosy disease in the districts, offering valuable insights for future public health initiatives and programme enhancements. The report also contributes to developing dossier for claiming elimination of leprosy disease by the country.

Methodology

Internal verification is carried out by multiple teams at the national level and at second subnational health administration units. One team will be assigned to review information at the national level using the LPTA tool and LEMT to compile a verification report and make recommendation for elimination of leprosy disease.
Each second subnational health administrative unit (e.g. district) will be assigned one internal verification team. The internal verification team reviews implementation and achievements of interventions/services in each domain (political commitment, programme implementation, and surveillance). The team also reviews epidemiological data using the LPTA tool provided in Excel. The team engages in discussions with key informants at the district and health facilities, as indicated in the "Source of information" column of the Excel tool. Information is collected through the examination of documents and conversations with key informants. The team documents findings for each action taken, referencing the specific intervention/service being verified. Conclusions are drawn based on the actions taken, observations made, and findings gathered. To record the level of achievement, inte rnal verification teams utilize a provided drop-down box.
While using data collection tools, the team should explain the purpose, assure the members of the health staff and other key informants that the information would be used for verification of elimination of leprosy disease only and would be kept confidential.

The internal verification team will debrief the findings and conclusions with the respective district and health facility officials.

Deliverables

a. Completed Excel data sheets and relevant documents collected in the unit.
b. Verification report: A comprehensive report on the achievement of the elimination of leprosy disease at the second subnational administrative levels, summarizing findings, conclusions, and recommendations.

Number of days required for internal verification

The number of days required for internal verification depends on the logistics and accessibility of the selected health facilities, with a maximum of five working days allocated for the assignment including preparation of the report.

Annex 4

Terms of reference for external (independent) verification team

Introduction

The Global Leprosy Strategy 2021–2030: Towards Zero Leprosy, is a responsive approach to address the impact of leprosy and contribute to the realization of the Sustainable Development Goals (SDGs). As a key component of disease-specific strategies, the Global Leprosy Strategy holds a central position within the WHO Roadmap for NTDs 2021–2030.

This strategy outlines the fundamental direction, goals and strategic pillars on a global scale, with a primary emphasis on interrupting transmission and eliminating the disease. The elimination process operates from the bottom-up, necessitating the achievement of milestones at all second level subnational administrative units. Beyond reaching the epidemiological cut-off, it is imperative that all interventions and services align with the national strategic plan. Only upon successfully eliminating leprosy across all second subnational units can a country be considered eligible for the verification of leprosy elimination. The reports produced by internal verification teams for all second subnational units are pivotal in claiming the elimination of leprosy disease within the country.

Upon reaching the elimination goal, the country prepares a dossier and submits it to WHO.

External (Independent) verification team

Following the country's submission of the dossier for elimination of leprosy disease, WHO initiates the process of recruiting an external (independent) verification team to review the dossier and conduct field visits within the country.

- Members of the external verification team comprise four or five experts identified from a panel of experts selected by WHO GLP in consultation with respective WHO regional offices for countries in different WHO regions. The number of experts can vary depending on the number of second level subnational administrative units selected for verification.

  Criteria for selection of experts:
  - *Experts in the fields of public health, community health, dermatology with a minimum experience of 10 years in their respective fields of expertise and with effective documentation and reporting skills.*
  - *One of the members would be a person affected by leprosy.*
  - *Experts should be selected from countries other than the one being considered for verification to make the committee independent and ensure objectivity.*
- Members should understand the phases of leprosy disease elimination, including knowledge of the LEMT and LPTA tool and post-elimination phase activities.
- Members should maintain confidentiality of the data collected and should be independent of any affiliations that could create conflicts of interest, ensuring impartiality and objectivity in the verification process.

Purpose of the external verification team in the context of the elimination of leprosy disease

The overall purpose of external verification is to meticulously assess and verify the claims of leprosy disease elimination made by a country. This process is initiated upon the country's submission of a comprehensive dossier to the WHO following the achievement of elimination of leprosy disease at all the second level subnational administrative units.

The team will review information using the LPTA and LEMT to compile a verification report and make recommendation for elimination of leprosy disease.

Methodology

a. Conduct a comprehensive desk review: Conduct a thorough examination and analysis of the dossier, national strategic health/leprosy plan, LPTA, LEMT and other relevant information at the national level and for all second level subnational administrative units.
b. Validate achievement of elimination milestone: Validate and confirm the achievement of the elimination of leprosy disease milestone at second level subnational administrative units by reviewing reports from internal verification teams.
c. Conduct a compliance assessment: In randomly selected second level subnational administrative units (e.g. districts) and health facilities, assess adherence to the national strategic plan/national health plan and the LPTA tool within the three domains: political commitment, programme implementation and surveillance. This involves evaluating compliance with established interventions, services, and the attainment of targets.

Deliverables

Desk review report: A comprehensive report summarizing the findings and analyses from the desk review of the dossier, existing documents, and relevant information.

Verification report for elimination milestone: A report confirming the achievement of the elimination of leprosy disease milestone in all second level subnational administrative units, based on the review of internal verification team reports.

Compliance assessment report: A detailed report on the compliance assessment, outlining the adherence of randomly selected districts and health facilities to the national strategic plan/national health plan and the LPTA tool within the domains of political commitment, programme implementation, and surveillance. This report should include evaluations of compliance with established interventions, services, and the attainment of targets.

The Final External verification team report (Annex 4.1)**:** A comprehensive final report consolidating all findings, conclusions and recommendations from the external verification process including a set of recommendations from the external verification team based on their assessments and observations, aimed at guiding further actions. This report must be signed by all the members before submitting to WHO. Once agreed and the report is signed the WHO Secretariat (GLP) will submit it to WHO HQ for endorsement. This report serves as an official document attesting to the verification of elimination of leprosy disease.

Annex 4.1

Format for reporting on verification of elimination of leprosy disease by external (Independent) verification team

Country:
Date:

The Verification team:

Name	Nationality	Expertise	Team membership (Chair/Member/Representative of persons affected by leprosy)

Summary

Summarize the report with the main conclusions and recommendations.

Narrative Report

Please provide a brief narrative report of your evaluation of the information documented in the dossier.

1. General comments

Please provide a general comment indicating if the dossier covered all the components as per the "WHO Template for the dossier documenting the elimination of leprosy disease" and "WHO Process of verification of elimination of leprosy disease" with all the relevant data to support evidence.

Mention additional data, if required for evidence of elimination of leprosy disease.

-

2. Review of the dossier

2.1. Description of the country (general information)

- Geographical features describing borders, Information about first (e.g. provinces/states/atolls) and second level subnational administrative units (e.g. districts/municipalities/islands), governance, political system, language, economy, culture and social practices
- Brief description of literacy levels among different population segments, e.g. women, children and total population, current population data disaggregated by age (<15 years as children and by adults)

2.2. Health situation and general indicators of health and development

- Information on the health situation in the country. Health indicators such as life expectancy, mortality rates (infant mortality rate, maternal mortality rate, child mortality rate), and social determinants which influence general health condition of the population.

2.3. Healthcare delivery system

Please provide a comprehensive overview of the healthcare system in terms of its structure and functions highlighting the delivery of healthcare services at primary, secondary and tertiary levels.

2.4. Leprosy epidemiological data

Please comment on the main findings in relation to the leprosy epidemiological situation, taking into account the information included in the LEMT.

2.5. Intervention or services provided in leprosy programme:

The intervention or services provided in leprosy programme should be presented as per the criteria laid down in the LPTA tool.

Mention the interventions and their level of achievements under each of the following domain

- Political commitment:
- Programme implementation
- Surveillance

2.6. Plan for post-elimination surveillance

Please comment on the preparedness of the surveillance system to detect and manage sporadic cases and management of non-autochthonous leprosy cases.

3. Conclusions and recommendations

Please state conclusions highlighting the reasons that led to the recommendations, considering the evidence provided and the arrangements for post-elimination surveillance of leprosy. Capacity of health system to sustain disability care basing on information collected through interview with key informants need to be presented as part of conclusions.

Recommendation to the World Health Organization	

The recommendation has to be addressed in two possible ways, to either "verifying the claim of elimination of leprosy disease" or "defer the decision until further information sought by the team is provided".

Verification team members' signature

	Title and name	Signature and dates
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The “Leprosy Elimination Dossier” is an accompanying document of the WHO technical guidance on interruption of transmission and elimination of leprosy disease. Eligible countries are required to put together a comprehensive dossier for submission to WHO to be verified for elimination of leprosy disease.

This dossier is designed to systematically and meticulously document the actions taken by each country throughout the leprosy elimination process.

For further information, please contact:
World Health Organization
Website: www.who.int/southeastasia

World Health Organization
REGIONAL OFFICE FOR South-East Asia

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