World Health Organization

DEFINING CRITERIA TO DECLARE ELIMINATION OF LEPROSY

Report of an informal consultation

Mexico City, Mexico, 10-12 February 2020

Defining criteria to declare elimination of leprosy: Report of an informal consultation meeting, Mexico City, Mexico, 10-12 February 2020

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Contents

Abbreviations

BCG	*bacille Calmette-Guérin*
G2D	grade-2 disability
GPZL	Global Partnership for Zero Leprosy
HAT	human African trypanosomiasis
ILEP	International Federation of Anti-Leprosy Associations
LEM	leprosy elimination monitoring
MB	multi-bacillary
MDA	mass drug administration
MDT	multidrug therapy
MIP	*Mycobacterium indicum pranii*
NTD	neglected tropical disease
PAHO	Pan-American Health Organization
PEP	post-exposure prophylaxis
SDG	sustainable development goal
SHF	Sasakawa Health Foundation
TAS	transmission assessment survey
TT	trachomatous trichiasis
WHA	World Health Assembly
WHO	World Health Organization

1. Inaugural session

1.1. Introductory messages

Mr Cristian Morales, Pan-American Health Organization (PAHO)/World Health Organization (WHO) Representative to Mexico formally opened the Informal consultation on defining criteria to declare elimination of leprosy.

On behalf of the host country, Dr Ruy López-Ridaura, Director-General of the Disease Control and Prevention Centre, Ministry of Health, welcomed all participants to Mexico. In his opening remarks he highlighted the achievements of Mexico's leprosy control programme. Leprosy was once a very prevalent disease, but new cases have become rather rare and are increasingly confined to fewer geographic areas.

1.2. Statement by partners

Ms Arielle Cavaliero, Global Franchise Lead (Leprosy) of Novartis International AG, reiterated the long-time commitment of Novartis, donating medicines for multidrug therapy (MDT) since 2001. She also mentioned that since 1 May 2019, all activities of the leprosy portfolio (apart from digital health) of the Novartis Foundation are now being coordinated by Novartis. She further summarized that the Leprosy Post-Exposure Prevention programme, funded by the Novartis Foundation, has created a shift in thinking about preventing leprosy beyond treating persons with the disease. As a founding member of the Global Partnership for Zero Leprosy (GPZL), the Novartis Foundation (and now Novartis) emphasizes the need for partners to work in a collective spirit.

Ms Courtenay Dusenbury, Director of the GPZL Secretariat, stated that GPZL is keen to support a joint strategy for zero leprosy, by working together with endemic countries to build national capacity and contributing to broadening the financial resource base for leprosy control. A proposal for US$ 100 million was thereto submitted to the McArthur Foundation and passed already the first iteration. This event already triggers interest from other financial partners.

Mr Geoff Warne, Chief Executive Officer of the International Federation of Anti-Leprosy Associations (ILEP) summarized the work undertaken by the 14 members of ILEP in 60 countries, both high and low burden countries. ILEP is also a founding member of GPZL, subscribing to its ultimate goal of a world free of leprosy, which includes zero new disease but also zero disability due to leprosy and zero stigma and discrimination.

Ms Aya Tobiki, Programme Officer of the Sasakawa Health Foundation (SHF), conveyed a congratulatory message on behalf of both The Nippon Foundation and SHF to WHO and partners for supporting leprosy control and having demonstrated impact in countries. Leprosy is increasingly confined to pockets. Following the achievement of elimination as a public health problem, interruption of transmission is an ambitious new goal. She also conveyed the regards of Mr Yohei Sasakawa, WHO Goodwill Ambassador for Leprosy Elimination, who is showing keen interest in these new developments.

1.3. Introduction of participants

All participants introduced themselves. The list of participants is provided in Annex 1.

1.4. Objectives and expected outcomes

Dr Erwin Cooreman, Team Leader, WHO Global Leprosy Programme, highlighted the objectives of the informal consultation.

The general objectives were:

- To discuss and review the current context, criteria and procedures for validation of elimination of leprosy as a public health problem;
- To discuss, analyze and propose the criteria and procedures for verification of interruption of transmission/elimination of disease.

The specific objectives were:

- Elimination of leprosy as a public health problem:
  - To define the criteria and procedures to validate elimination of leprosy as a public health problem in countries not yet having achieved this goal or in countries eager to properly document it;
- Determine the intermediate steps:
  - To analyze, define and discuss the steps, benefits and challenges of moving from elimination as a public health problem to interruption of transmission/elimination of disease;
- Interruption of transmission/elimination of disease:
  - To establish the conceptual framework needed to understand the basis for interruption of transmission;
  - To identify the (most likely) main strategies to achieve interruption of transmission;
  - To determine criteria for elimination of leprosy;
  - To propose a mechanism to verify the elimination of transmission in time and territory;
  - To explore surveillance and prevention actions for the post-elimination period;
  - To develop a draft protocol and guidelines for piloting.

The programme of the informal consultation is included in Annex 2.

2. Overview of leprosy control

2.1. Current global leprosy situation

Leprosy is one of the neglected tropical diseases (NTDs) with one of the highest record of cases annually when compared to other case management NTDs (e.g. dracunculiasis, Buruli ulcer, human African trypanosomiasis (HAT), visceral leishmaniasis or yaws; only Chagas' Disease reports a higher incidence).

Worldwide, 208 641 new cases were reported for 2018. Most cases occur in only three countries: India, Brazil and Indonesia while another 12 countries reported each more than 1000 cases. The overall trend is a steady decline in new cases, especially in the WHO South-East Asia Region. The decline is however off set by active case detection and a more complete reporting in other regions.

Detailed information was also provided, by WHO region, on the following indicators: prevalence (rate); proportions of multi-bacillary (MB) cases; female cases; children and patients with visible deformities at the time of diagnosis (grade-2 disability or G2D). The last indicator is showing a steady decline (1.5 per million population in 2018). Zero leprosy in children is another key indicator of the Global Leprosy Strategy. Table 1 highlights the achievements versus this indicator.

Table 1: *General aspects of leprosy notification for 2018*

Parameter	Number of countries
Countries reporting zero new leprosy case [A]	32
Countries reporting at least one new case [B]	129
Countries reporting leprosy data [C]={A]+[B]	**161**
Countries reporting zero leprosy in children [D]	40
Countries reporting at least one leprosy child case [E]	81
Countries with leprosy reporting child data [F]=[D]+[E]	**121**
Countries reporting zero G2D in children (including [A]) [G]	37
Countries reporting at least one child case with G2D [H]	33
Countries reporting on the status of G2D in children [I]=(g]+[H]	**70**

Leprosy among foreign-born was a new indicator, collected since the last three years. This indicator provides proxy information on imported disease. An outlier is Nepal which reported 784 foreign-born cases, virtually all of them cross-border patients residing in a neighbouring country. More than 25 such cases were reported by Malaysia, Thailand and Argentina; while small absolute numbers were reported from high income countries (with very high proportions, up to 100%), reflecting likely import cases; as well as from endemic countries (with lower proportions).

He also provided information on the status of discriminatory laws since annulling such laws is also one of the key targets of the Global Leprosy Strategy. Still 21 countries reported having such laws, though they are not necessarily applied. In addition, there are customary (non-codified) laws and practices as well as societal attitudes that continue the discrimination of persons because of having or having had leprosy.

2.2. History of leprosy control

Dr Erwin Cooreman made this presentation on behalf of Dr Vijay Kumar Pannikar, Chair of the WHO Technical and Advisory Group for Leprosy.

The history of leprosy control is linked to many mistakes as well as great advances. Different strategies have been designed for its control, including isolation and various treatments.

In the absence of medical knowledge about the disease and medication to prevent or cure it, ancient communities chose isolation of those affected as the best strategy for control. Many of these practices are now considered as inhumane (e.g. compulsory separation from family, travel ban).

Early treatment – practiced in the middle ages – included drinking blood, snake venom, scorpions, various ointments. In the 19th century chaulmoogra, an oil obtained from *Hydnocarpus wightianus* tree seeds, was used with very limited success. Its application was improved (known as "Ball method") and formed the mainstay of treatment till the advent of antibiotics.

The discovery of the causative agent of leprosy in 1873 gave the basis for a modern treatment. In the 1940s sulphones introduced the antibiotic era, allowing domiciliary treatment (instead of in leprosaria) and in the 1950s it was aspired to gain control of leprosy with dapsone and other interventions, paving the way for leprosy control programmes. However, within less than ten years after introducing dapsone monotherapy, resistance was recognized and increased to more than 50% in the 1970s, rendering control programmes very ineffective.

In the 1980s, MDT became the cornerstone of leprosy treatment and has continued to be so since then. Due to its limitation in time, patients could be declared "cured" and return to normal life. Since its introduction, more than 17 million patients have been cured. Donation of MDT free-of-charge has proven to be a game-changer in leprosy control, prompting the World Health Assembly (WHA) to pass a resolution in 1991 to eliminate leprosy as a public health problem, defined as less than one case per 10 000 population on treatment. The registered leprosy prevalence decreased indeed from over 5 million to less than 200 000.

It is, however, now clear that MDT has reached its maximum potential and that it has now a much lesser impact on further reducing the incidence. The end game in leprosy will necessitate the introduction of prophylactic tools, of which chemoprophylaxis with single-dose rifampin is currently recommended by WHO. With regard to immunoprophylaxis, only vaccination with *bacille Calmette-*