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Leprosy Elimination Monitoring (LEM)

Guidelines for monitors

2000

World Health Organization

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Introduction

Background

Multi-drug Therapy (MDT) is recognised as a major technological improvement in leprosy control. It enables leprosy control to have a tremendous impact on disease prevalence and consequently on the disease burden and workload. This impact has led to the concept of eliminating leprosy as a public health problem with the assumption that, below a given level of prevalence, disease transmission will be partially or totally interrupted.

Leprosy control strategies based on MDT and the resolution of the 44th World Health Assembly in 1991 to eliminate leprosy as a public health problem was an impetus for greater priority to be given to leprosy by governments and for strengthened political commitment for leprosy elimination. The cost-effectiveness of MDT and its impact has resulted in increased resources for leprosy control activities, including those from bilateral and international agencies, as well as NGOs, both national and international, in a number of countries where leprosy is a public health problem.

Although it is relatively easy to monitor the prevalence of leprosy, evaluation of its transmission trends is extremely difficult because of the epidemiological characteristics. The general impression among experts is that there were considerable changes in the epidemiological pattern of the disease during the past decade. These changes are reflected by clinical profile of newly detected cases; an increasing proportion of patients diagnosed with few lesions; variations in the proportion of MB patients; and decreasing proportion of patients with irreversible (Grade 2) disabilities. In addition, there are visible changes in the prognosis of the disease during treatment and significant reduction in the risk of becoming disabled. All these changes could be explained by a combination of factors, e.g. the historical trend of the disease; the impact of interventions; the efficacy of chemotherapy and the role of improved health services

The most obvious impact of MDT is the reduction of the risk of transmission from an infected person to others. It is generally believed that a single dose of MDT kills enough bacilli to make both PB and MB patients non-infectious. Leprosy control, based on MDT, is believed to improve the effectiveness of case detection and, in so doing, gives a clearer picture of the overall leprosy problem. The use of standardised and tested procedures to correct detection rates (according to programme coverage), the duration of the programme, indirect indicators (proportion of cases with disabilities among new cases), standardisation according to age and sex and overall cohort analysis, would give valuable information in assessing the level of transmission within the community.

In many programmes, MDT implementation has improved the quality of case-finding and case-holding by improving community awareness and by increasing patients' confidence in health services. However, geographic coverage with MDT services is still very low and many cases are diagnosed very late, or not diagnosed at all. The interval between the onset of the disease and diagnosis are still far too long in many parts of endemic countries, increasing the risk of transmission and the risk of disability.

Purpose of LEM

Assessment of interventions becomes particularly important when considering the leprosy elimination goal. The purpose of monitoring is to assist decision makers and programme managers to assess the progress towards leprosy elimination, to make a plan of action, to implement it and to measure its impact. Monitoring a minimum set of indicators that

describes the MDT services will serve the purpose.

The selection of indicators to be monitored needs to be made carefully, in the light of the epidemiological characteristics of leprosy and the large number of grey areas in our understanding of the disease. Incidence is the most relevant but probably the most difficult indicator. Prevalence varies not only with the level of disease burden but also with the operational component of intervention. The uneven distribution of leprosy, as well as the role of various local factors, calls for caution when extrapolating the results from one place to another.

Monitoring methods should be quick and cost-effective. Routine information system is the principal and essential component in monitoring leprosy situation. It needs to be programme oriented, simple and speedy. Too many indicators to be put on the information flow of routine systems will cause paralysis, and therefore some of the indicators among 'a set of minimum indicators' cannot be collected from routine systems. A monitoring exercise that complements routine information systems is needed to measure specific aspects of leprosy elimination programmes and methods for reviewing elimination programmes.

The techniques for collecting indicators are implemented in a standardised way by >monitors', in collaboration with national programmes and WHO. Monitors collect information which will complement routine leprosy information systems to address specific issues, such as more detailed information on the trend of transmission, cure rates, impact of interventions and changing patterns of leprosy. It is becoming increasingly important to differentiate areas where substantial numbers of backlog cases are included in newly-detected cases from areas where newly-detected cases may be largely made up of single lesion cases. Information on the number of lesions per case, age and sex specific detection, smear positivity, if available and the delay between onset and diagnosis help in better describing indicators used for monitoring leprosy elimination. It is equally important to validate key indicators, such as prevalence and detection, mainly by applying internationally recommended definitions. Wherever possible, trend analysis over the last 5 years will be used to assess the impact of leprosy elimination activities.

Besides all these technical aspects of LEM, past experiences in LEM have shown that it had highly positive effect on field workers and programme managers, who were strongly motivated through discussions on the epidemiological and clinical situations of their areas.

Overview

Indicators collected through LEM exercises are well standardised, have been in use for several years in many countries and are well known to programme managers. All the required information has to be collected from existing patient records, leprosy registers, reporting forms and stock bin cards in selected health facilities as well as interviews of patients. The selected health facilities should reflect the situation prevailing in a specific geographical or administrative area at a given point in time and therefore selection of sample and sample size are essential for extrapolating the findings.

The monitoring will have to be repeated in order to assess the impact of interventions and changes over time. These studies are carried out by independent monitors, responsible for visiting selected units to collect information through standardised methods, and for reporting their findings on compiled data to the national programme managers and the WHO.

The monitoring should be time-limited and the complete cycle (from design to report) should not exceed four weeks. Selected health facilities should be informed in advance of the monitors' visit so that they have time to prepare to get patients available.

Indicators and methodologies described in this document will be adapted/reviewed as and when needed.

Contents of the guidelines

There are two sections in the guidelines.

- The first section explains what to monitor through LEM.
- The second section describes how to monitor.
- Annex provides forms for collecting information, which will also help in understanding the details of information to be collected.

What to monitor

This section describes the procedures for measuring the three groups of indicators. After a brief introduction, pre-requisites and details for the calculation of each indicator are outlined for each group and an example is presented of how the indicators are interpreted. Forms shown in annex will be helpful in better understanding the indicators.

Summary table of key indicators

Indicator group	Key indicators
Group I: Elimination indicators Internal validity of information on prevalence and detection (crude and specific) and analysis of trends. This will be based on the analysis of existing information and review/updating of leprosy registers.	**1. Case finding activities** 1.1 Proportion of new cases with disabilities 1.2 Average delay in diagnosis 1.3 Proportion of children among new cases (or age specific detection) 1.4 Proportion of MB cases among new cases 1.5 Proportion of single lesion among new cases 1.6 Proportion of female among new cases (or sex specific detection) **2. Prevalence: absolute numbers and rate** 2.1 Reported prevalence 2.2 Prevalence after applying standard definitions (case, cure and defaulters) 2.3 Prevalence trend over the last 5 years **3. Detection trend: absolute numbers and rate** 3.1 Detection trend over the last 5 years 3.2 MB detection trend 3.3 Child detection trend
Group II: Integration of MDT services within General Health Services Availability of MDT blister-packs and geographic coverage of MDT services. This will be based on a cross-sectional survey of randomly selected health facilities and interviews of patients.	**1. Proportion of existing health facilities providing MDT** **2. Accessibility to MDT** 2.1 Average distance 2.2 Estimated costs for the patients 2.3 Flexibility in delivering MDT **3. Availability of MDT drugs**
Group III: Quality of MDT services: Diagnosis, case-holding and information. This will be based on a review of individual records, leprosy registers, and interviews of individuals in communities. The quality of MDT services will be reviewed on the basis of cohort analysis.	**1. Proportion of patients treated with MDT** **2. Case holding** 2.1 Cure rate 2.2 Defaulter rate 2.3 Proportion of patients continuing treatment after completing MDT standard regimen **3. Quality of MDT blister-packs**

Group I : Elimination indicators

Group I : 1. Case finding activities

Internal validity of information on prevalence and detection (crude and specific) and analysis of trends. This will be based on the analysis of existing information and review/updating of leprosy registers.

Purpose	**To assess the effectiveness of case-finding activities**
Definition	Case-finding activities will be evaluated through a set of 6 indicators, describing the status of a sample of patients *diagnosed during one year and who have never been treated for leprosy*. One year can be defined as during the past one year from the time of the visit. Should information be unavailable, this can be modified provided it is discussed and agreed before the start of exercise. **1.1 Proportion of newly detected cases with grade 2 disabilities:** The number of patients newly diagnosed with disability grade 2 (see definitions below) divided by the number of newly detected patients *for whom disability status is recorded*. (Minimum sample size 100) **1.2 Average time between recognition of the disease and diagnosis** Based on individual records and/or interviews of a sample of patients, this is the average time (in months) between the first recognition of symptoms and the date of diagnosis. (Minimum sample size 50) **1.3 Proportion of children (age specific detection)** The number of newly diagnosed patients below the age of 15 divided by the number of newly detected patients *for whom age is recorded* (Minimum sample size 100) **1.4 Proportion of MB cases** a) Clinical classification: The number of newly diagnosed patients classified as MB patients divided by the number of newly detected patients *for whom classification is recorded.* (Minimum sample size 100) b) Bacteriological classification1: Wherever possible: the number of newly diagnosed patients showing a positive skin smear examination divided by the number of newly detected patients *for whom skin smear examination results are recorded*. **1.5 Proportion of single lesion** The number of newly diagnosed patients showing a single patch at the time of detection divided by the number of newly detected patients *for whom the number of lesions and/or classification of MB/PB/SSL is recorded.* **1.6 Proportion of female (sex specific detection)** The number of newly diagnosed female patients divided by the number of newly detected