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# Surveillance and monitoring of multidrug therapy using cohort analysis

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## 1 Surveillance of the leprosy situation

The twin goals of leprosy control programmes are to interrupt the transmission of infection by detecting cases as early as possible and treating them in order to achieve complete cure. A leprosy control programme also aims to prevent the development or occurrence of deformities and disabilities among detected patients. Therefore the most relevant indicators are those which reflect the programme's effectiveness and efficiency in the detection and management of leprosy patients.

The main purpose of leprosy surveillance is to assess continuously the epidemiological situation using some selected indicators, in order to enable decision-makers, programme managers and health workers to take public health action at the correct time. At the international and national levels, data should be used to monitor trends, set priorities, allocate resources and raise funds. At district level, the data should be used to target interventions, monitor and evaluate programme effectiveness.

The existence of a leprosy information system at global level is essential. It should be able to give reliable information on selected indicators. Its purpose is not necessarily for research, or evaluation of MDT efficacy, or programme monitoring or assessement at country level. The main purpose is to provide clear data on the epidemiological trends of leprosy at different levels (worldwide, WHO regions, subregions and countries). Considering the elimination purpose, the need for good information on prevalence and incidence becomes a priority and considering that the MDT strategy is the main tool for leprosy control, monitoring of its implementation and coverage is relevant.

Data collected should provide information on 3 different topics:

### 1.1 OCCURRENCE OF THE DISEASE, MAGNITUDE OF THE PROBLEM

- Prevalence of the disease and monitoring changes over time.
- Populations at risk.
- Leprosy morbidity in terms of time, place and population.
- Disabilities.
- Attitudes, practices, behaviours and stigma.


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### 1.2 MANAGEMENT AND MONITORING INFORMATION

- Availability and distribution of resources.
- Distribution and quantity of supplies.
- Coverage.
- Access to the programme, acceptability.
- Quality of the programme.
- Cost-effectiveness.

### 1.3 RESEARCH ON AETIOLOGY, RISK FACTORS, DEVELOPMENT OF NEW INTERVENTIONS AND EVALUATION OF THE EFFICACY OF THE PROGRAMME

This includes clinical, epidemiological, social, economic and operational research. The data needed for such research are many and vary according to the objectives of the study. Therefore this topic will not be discussed in this paper.

All different types of data can be collected separately or in conjunction with:

—routine reporting systems;
—sentinel systems;
—special surveys;
—special studies.

However, it should be kept in mind that the collection and analysis of data have to be relevant, reliable, flexible but standardized and done at the right time. The implementation of a surveillance system should not create additional work for programme managers and health workers.

## 2 Technical issues related to leprosy surveillance

### 2.1 A CASE OF LEPROSY: OPERATIONAL STANDARD CASE DEFINITION

The definition of a case of leprosy as recommended by the 6th Expert Committee on Leprosy is widely used and has dramatically improved the standardization and interpretation of the available information. It would be useful to determine the sensitivity and specificity of this case definition through special studies and/or sentinel systems.

### 2.2 CLASSIFICATION

The 6th Expert Committee on Leprosy recommends classifying patients in control programmes as either having multibacillary (MB) or paucibacillary (PB) leprosy. This classification is mainly based on clinical and bacteriological criteria. However, in most leprosy control programmes the absence of laboratory services, or the poor quality of smears and microscopy, make standardization difficult and increases the risk of misclassification.

### 2.3 PREVALENCE OF LEPROSY

This is the main indicator used worldwide to assess the magnitude of the problem, to monitor trends and to assess the impact of the control measures. In addition to the issues

related to the definition of a case of leprosy, it is very often not easy to define the population under surveillance in a given area due to the lack of updated statistics, weakness of health services coverage, migration, etc. In assessing the magnitude of the problem, the point prevalence has to be reviewed in conjunction with incidence or new case detection over a given period of time if it is to be meaningful. The monitoring of trends requires consistent information in order to detect changes in the disease rate. Assessing the indicators in determining the impact of the control measures, i.e. MDT on the epidemiology of the disease, the decrease in the point prevalence is not sufficiently robust. The temporal changes could be explained by various factors such as the deterioration of the surveillance system, the deterioration of the control programme, the natural trend of the disease, the impact of confounding factors, etc.

The point prevalence is generally used, which is defined as the number of leprosy cases among a given population in a defined area on a specific day. Point prevalence is appropriate for chronic diseases with low incidence. In the past, with the long duration of treatment, a case of leprosy was a 'case' for almost the rest of his/her life. The point prevalence was reflecting an acceptable picture of the leprosy situation.

Nowadays, with the implementation of MDT, leprosy is becoming a short-term disease for a large proportion of patients. Therefore it would be necessary to question the relevance of continuing with point prevalence as a measure of reflecting the magnitude of the problem.

In this respect, the use of period prevalence may be more appropriate, as it offers some advantages and seems to reflect better the magnitude of the problem, the workload and the impact of the control programme.

### 2.4 ELIMINATION OF LEPROSY

Elimination is defined as a prevalence below 1 per 10,000 population. When determining the prevalence target, we have to differentiate point and period prevalence. We have also to define the level of elimination (global, regional, country, district).

In terms of prevalence of registered cases, it will be relatively easy to monitor the elimination using essential indicators based on prevalence, focusing on the surveillance in some selected countries and checking/assessing the results of surveillance with small size sample surveys. However, taking into consideration the 'true prevalence', it would be necessary to conduct surveys to determine the number of estimated cases. For the time being such surveys are not standardized, and are not cost-effective.

## 3 Essential indicators

### 3.1 ESSENTIAL INDICATORS TO ASSESS THE MAGNITUDE OF LEPROSY

The following indicators have to be calculated according to global, regional, country and district levels:

*Prevalence rates: Registered cases*

*Numerator*: The operational case definition recommended by the 6th Expert Committee is appropriate and we should continue to encourage its use.

*Denominator*: The mid-year estimated population during the current year should be utilized, as published by 'World Population Prospects' (UN).

*Detection rates: New cases*

Calculated for the considered period of time and using as the numerator all new cases registered for treatment and for the denominator the population as defined above.

—proportion of PB and proportion of MB among registered cases;
—proportion of PB and proportion of MB among new cases;
—proportion of children among new cases;
—proportion of patients with disabilities rated as grade 2 among new cases.

### 3.2 ESSENTIAL INDICATORS TO MONITOR MDT IMPLEMENTATION

MDT implementation and MDT coverage are discussed below.

*Proportion of registered cases (MB and PB) treated with MDT (MDT coverage)*

This statistic is defined as the number of registered cases (PB or MB) receiving at least 1 month's dose of MDT during the year among the total number of cases (PB or MB) appearing on the register during the year.

Theoretically, data needed to calculate this indicator are easy to collect. However, the numerator and denominator are a type of period information, and this introduces confusion and explains some inconsistencies in the data provided by countries and the poor reliability of this indicator. In addition, MDT coverage does not reflect the quality of the coverage and should be analysed in conjunction with geographical coverage, compliance and the proportion of registered MB and PB cases cured with MDT.

*Proportion of registered cases (MB and PB) cured with MDT*

This indicator would be extemely useful to monitor MDT at district, national and global levels. It can be calculated using cohort reporting, a cohort being defined as a group of persons sharing one or several characteristics at the same period of time.

### 3.3 OTHER INDICATORS

According to the existing situation, the objectives of each leprosy control programme and the standards defined at national level, leprosy control managers can define a set of specific indicators in order to monitor and/or evaluate the various components of the programme. In addition to the essential indicators, additional data can be collected for specific purposes such as special studies, risk factors, health system research, trials, etc.

## 4 Cohort analysis for surveillance in leprosy

In the surveillance of patients with long-term diseases, it is generally admitted that certain characteristics of the patient and his/her disease may be analysed using powerful yet

flexible statistical methods based on regression models and life-tables. These methods were developed to analyse survival data and their use was generalized to all data related to time and trends. The concept is to collect and analyse information on the occurrence, or the non-occurrence, of special events. This approach is used for calculating rates (descriptive epidemiology) or probabilities. With respect to leprosy control, these statistics offer a number of advantages in monitoring and analysing relevant indicators such as MDT coverage, patients cured with MDT, reactions, relapses etc.

## 4.1 DEFINITIONS

The term cohort refers to a group of individuals who are exposed to the same risk at the same time. Analysing cohorts helps to dissociate potential confounding factors such as age, secular trends, etc.

Cohort analysis should involve collecting information on each individual that details:

—the reference date (date of commencement of observation);
—the date of the last examination and the patient's status at that date;
—the surveillance duration (the time between the date of the start of observation and the date of the last examination);
—the point date (the date of the analysis, i.e. when the status of each patient is ascertained);
—lost for follow-up (a patient for whom it is impossible to know the status at the point date).

## 4.2 MDT COVERAGE AND CURE RATE

Cohort reporting of treatment outcomes is the most informative technique for evaluating case-holding and treatment effectiveness. It avoids biases that occur in retrospective and cross-sectional methods. Cohort monitoring could be carried out at district level to provide immediate feedback of the results to staff. It is based on analysis of data obtained from the leprosy patient register, or other forms used to monitor treatment.

Here the cohort is constituted by all patients registered during a given period of time (reference date), say a quarter. The duration of the follow-up period is chosen in such a way that all patients have had the chance to complete the prescribed treatment period, according to the criteria of regularity (2/3 rule), and the final examination. The items (status) will represent the numerator and the number of input-patients will represent the denominator.

The treatment results can be expressed using 2 main indicators calculated with the data collected from the cohort:

### *MDT coverage*

The proportion of patients treated with MDT among patients registered for treatment in the cohort.

### *Cure rate*

The proportion of patients who completed treatment (according to the definition of

completion of treatment), have been examined and declared cured (according to the definition 'cured patient') in the cohort.

Some other indicators can be calculated using the same method/data such as: MDT attendance rate, new disability rate, defaulter rate, fatality, etc. In practice, we need to follow 2 types of cohorts—PB cohort and MB cohort: the PB cohort should be analysed every 9 months and MB cohort should be analysed every 36 months.

### 4.3 RELAPSE RATE

The relapse rate is mainly used to judge the results of clinical trials and the efficacy of new regimens and new combinations. Though it can be estimated using person/years of follow-up as the denominator, the use of cohort life-tables offers a number of advantages in estimation of probability to relapse; computation of the probability taking into account; patients lost to follow-up; comparisons between various groups using non-parametric tests, etc.

The use of cohort life-tables gives a reliable estimation of the evolution of the relapse risk during the time, and authorizes the use of non-parametric tests to compare several cohorts.

### 4.4 SCOPE AND LIMITATIONS OF COHORT ANALYSIS AND SURVIVAL STATISTICS

Current data are generally used to calculate rates at a given time: prevalence, detection, incidence, ratios, etc. This is appropriate in assessing the magnitude of a problem as it is at present and permits a glimpse of the future, if present rates continue. The data needed to calculate such rates are relatively easy to collect. However, these rates are of limited value if they are atypical of the general time period, or if future rates fluctuate greatly.

Cohort analysis and cohort life-tables give us a way of assessing events as they are experienced and related to populations exposed to the same risk at the same time. Their disadvantage is that it may often only be of historical value: to generate cohort and life-tables we need to collect information appropriate to each time period and to perform the results retrospectively. Information collection and summary appears more complicated as they involve the calculation of date intervals. This problem can be solved by the use of appropriate registers and forms, and by the use of microcomputers that are often available these days at intermediate and central levels in monitoring health problems.

The use of cohort reporting to monitor MDT coverge and cure rate is recommended as a control. Cohort analysis for prevalence, detection and incidence should be used only to carry out epidemiological studies, life-tables to follow relapse rate in clinical trials, or in comparing the efficacy of several regimens.

## 5 Conclusions

The information collected in a surveillance system should be the minimum necessary to achieve the objectives of the system. The fewer data collected, the more likelihood there is that these will be collected and reported correctly. For leprosy control, a basic surveillance system might collect data annually on the magnitude of the problem (existing cases and new cases) including information on the type of leprosy, age and disabilities and

on the controi measures (number of patients cured with MDT). The information generated by the system has to be carefully analysed for decision-making, and feedback information should be given to the users.

The quality of the surveillance system should be regularly assessed to ensure that it is based on a good understanding of the epidemiology of leprosy. The surveillance system should facilitate rapid action which in turn leads to a reduction in the prevalence and incidence of the disease.

Information collected routinely at the periphery is usually considered to be of poor quality and inadequate. However, this is often a misconception. Most leprosy control managers are aware of the fact that health workers in the field are faithfully collecting, recording and reporting the data. Unfortunately, this vast amount of painstakingly collected data is neither compiled nor analysed at the intermediate or central level. Moreover, whenever information is required, there is an attempt to conduct fresh surveys or demand the completion of new sets of forms. This has often resulted in an increase in the workload without any potential benefit to the programme. If we study carefully the available data, we can see that it is more than adequate and of a reasonably good quality. If the data are compiled properly and analysed they provide a very powerful tool for decision-making. Cohort analysis will be able to do this efficiently for the various needs of leprosy control, without overburdening the routine activities.