

## Basic Epidemiological Indicators for Monitoring Leprosy

There are several epidemiological and operational indicators for monitoring leprosy control activities. The most important are prevalence, incidence, proportion of new cases presenting grade 2 disability, treatment outcome and the proportion of children among newly detected cases. In simple words:

- **Prevalence and incidence** tell how many patients there are (standard measures of disease occurrence);
- A high **proportion of new cases with grade 2 disability** points to delay in diagnosis;
- **Treatment outcome** tells how many patients have successfully completed treatment among those diagnosed;
- **A high proportion of children among newly detected cases** is considered an indicator for a high transmission of leprosy in a population.

To interpret these indicators, the following must always be specified: the criteria used for diagnosis (for example, adherence to the 3 cardinal signs or whether the diagnosis is only “clinical”; inclusion of indeterminate leprosy or postponing diagnosis until one of the cardinal signs is positive), the definitions of case, cure, and defaulter, the population, and the time period. A case of leprosy is a person presenting clinical signs of leprosy who has yet to complete a full course of treatment. A patient is defined as cured when he has successfully completed his course of treatment. Defaulters are defined as those patients who were not able to complete the course of treatment within the given time.

### Prevalence, Prevalence Rate, True Leprosy Prevalence and Registered Prevalence

**Prevalence** is the number of cases of a particular disease in a defined population at a specified time. This is also called the simple numerical prevalence and provides a useful and straightforward measure of the case load. However, to compare prevalence at different times and places, it is necessary to express the data as proportions, **prevalence rates**, i.e., the number of cases of disease at a specified time divided by the number of the population in which these cases occur. The numerator (cases) and denominator (population) figures refer to the same population. Over the past years, conventionally, the prevalence rate of leprosy has been expressed as the number of cases per 10,000 members of the population.

**True leprosy prevalence** (all leprosy patients in need of treatment) is determined by the patients in the community not yet diagnosed plus those diagnosed and on treatment. Data about the former group are often not available, so statistics commonly refer to the second group only, that is to say, to the number of cases registered for treatment. This is the “registered prevalence” and is conventionally reported at the end of a given year. **Registered prevalence** is the nearest available indicator to true prevalence. Registered Prevalence = the number of leprosy patients registered for treatment on 31 December of a given year (point registered prevalence). It is influenced by factors such as duration of the disease, policies for maintaining registers and case-finding activities.

### **Incidence, Incidence Rate, Detection and Detection Rate**

**Incidence** is the number of new cases (only the new cases) of a particular disease that arise in a defined population over a defined period of time. The time period often used in leprosy statistics is conventionally 1 year. To compare incidence over time and between areas, it should be expressed as a proportion (rate) relative to the population in which the new cases occur. The source of the denominator figure (population) should be stated. Measure of occurrence of new cases of leprosy, expressed as incidence, is the most effective index of transmission of the disease. It reflects the current risk of developing leprosy within a specified population. Since the purpose of control programs is to prevent disease, their aim should be to reduce incidence. Thus, incidence statistics are more useful in monitoring the success of a control program than the prevalence statistics are.

**Detection and Detection Rate.** Despite their value, measures of leprosy incidence are difficult to get. In fact many new cases may not be recognized for some years after clinical onset, and repeated total population surveys are necessary to obtain true incidence. Alternatively the number of newly detected and registered cases is frequently used as an estimate of incidence. This indicator is called **detection** (or case detection or new case detection [NCD]). It is the nearest available indicator to incidence. Detection is the number of cases newly detected and never treated before during a given year. **Detection rate** is the number of cases newly detected during a given year divided by the numbers of the given population. Since detection rate is used, it is important to recognize that it is influenced by the type and intensity of case-finding activities. Detection rates are calculated on an annual

basis. Detection = the number of patients detected from 1 January to 31 December of a given year.

Detection rates can be expressed separately by age groups, for example below 15 years and 15 years or above. It is also useful to group them in a clinical type (paucibacillary [PB] and multibacillary [MB]) and expressed as the proportion of multibacillary; by presence or absence of deformities (proportion of new cases presenting with grade 2 disability); by sex (proportion of female patients), and by child proportion.

### **Proportion of Cases with Grade 2 Disability Among Newly Detected Cases**

This is the proportion of people with W.H.O. disability grade 2 among the newly detected cases during 1 year. It is expressed as a percentage. A high proportion of cases presenting grade 2 disability at the time of diagnosis indicates late diagnosis. This can be due to the patients' delay in reporting to the health service or to the doctors' delay in making the right diagnosis.

A cohort of MB patients has a higher proportion of grade 2 disabilities compared with a cohort of PB patients. The proportion of PB and MB patients differs between areas and over time. As such it is more informative if the proportion of grade 2 disability of a cohort of MB patients is compared with the proportion of grade 2 disability of another (area, time) cohort of MB patients. The number of new patients with grade 2 disabilities is also an indicator of the need for physical and social rehabilitation and at the same time stresses the need for prevention of new and additional disabilities. It would greatly improve the monitoring process if grade 1 disabilities were also recorded and reported, and if the eye–hand–foot (EHF) score for monitoring prevention of disability of patients was introduced.

In many countries the proportion of new cases with grade 2 disabilities is calculated based on “visible deformities” and not on a complete examination including the voluntary muscle test (VMT). There are patients with VMT 0 (no movement at all or depending on the definition 0 and 1), who, however, do not have a visible deformity like for example a claw-hand. During field visits it is often noted that there is a under-reporting of new patients with grade 2 disabilities. Sometimes patients have not been properly examined or the findings have not been recorded, or sometimes not all new patients have been examined, but still in the denominator all new patients are stated.

## Treatment Outcome

It is essential to know the “result of the treatment” of the patients who have been diagnosed and entered in treatment registers. Were they cured? Did they abandon their treatment? If so, in what proportion? Without this information, quality assessment of the case-holding activities, and of the overall performance of leprosy control activities, is difficult. Data about treatment outcome can be obtained by analyzing cohorts of patients having started treatment during a given year. The size of each cohort should be large enough to be meaningful (arbitrarily at least 30). A group of patients with the same diagnosis and classification, paucibacillary (PB) or multibacillary (MB) leprosy, and who were registered in the same period (that is to say, a cohort) is chosen. The results of their treatment in terms of cure, default, etc., are analyzed. Cure rate is the proportion of patients who have been cured among the patients supposed to have been cured in the same cohort. It should be as close to 100% as possible.

In leprosy, patients who have completed their treatment on time are considered “cured”, although we do not have a measurement for being “cured”. As relapses (and we cannot distinguish between a relapse and a re-infection yet) are extremely low after a full course of multi-drug therapy (MDT), for leprosy statistics “complete treatment” or “cured” are used interchangeably. Patients may, however, think differently about this. Those with disabilities and deformities for sure, but even if patients do not have any disability or visible (skin) scars some may still feel they are being stigmatized by the community. Furthermore, late reactions are not uncommon.

Patients who have been transferred out are often no longer included in the cohort total (as of course patients who died). One assumes that patients transferred out continue their anti-leprosy treatment in the other area where they have been referred to (actually one has to receive confirmation of this). However, if there are many “transferred out” one has to be careful: sometimes these are hidden defaulters.

## Proportion of Children Among Newly Detected Cases

This is the number of patients under 15 years old among the newly detected patients over a period of 1 year. It is expressed as a percentage. A high proportion of children among new cases is considered an indication of high transmission of leprosy in the given population.

In some countries not the proportion of children among newly detected cases is reported, but the NCD of the age group 0 -14 years. There is a danger in this. Leprosy is not evenly spread among a population, but comes in clusters. Some areas can be highly endemic and other areas low endemic. In some areas a high transmission may still occur, although the overall national NCD of the age group 0 – 14 years shows a decline.

## Collection of data, calculation and interpretation of indicators

Reliability of leprosy statistics is based on a proper collection of data, calculation and interpretation of indicators. Unfortunately, available global leprosy statistics present problems. In particular, information may be missing about completeness of countries' data, how cure rates or proportions of new patients with W.H.O. disability grade 2 are calculated, and above all, about operational and policy factors that are crucial to trend analysis. The International Federation of the Anti-leprosy Associations (ILEP) suggests the following points:

1. **Reliability of data:** Was the basic information collected properly from the person with leprosy or from the medical records?
2. **The denominator:** An important part of any rate or proportion is the denominator, i.e., the population from which the cases are drawn. In a proportion or a rate, the numerator should be a sub-group of people contained within the denominator.
3. **Validity:** an expression of the degree to which a measurement measures what it is supposed to measure. Even if the individual pieces of information have been collected properly, are we getting an accurate overview of the situation? Validity can be reduced by several factors, including difficulties in ascertaining important statistics, a link between indicators and operational factors, changes of definition and presence of confounding factors, changes in operational factors (for example active versus passive case finding).
4. **Trends versus one-off analyses:** The trend that most indicators show over a long period, for example over many years, is much more informative than a single reading.

5. **Presentation of the data:** For instance, figures, though usually much easier to understand than tables, can sometimes give an erroneous impression because of the scale of the axes.