



THE INTERPRETATION OF EPIDEMIOLOGICAL INDICATORS IN LEPROSY



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The International Federation of Anti-Leprosy Association (ILEP)
234 Blythe Road, London W14 OHJ, Great Britain
e-mail: ilep@ilep.org.uk Web site: www.ilep.org.uk

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EXECUTIVE SUMMARY

This paper reviews the following indicators:

- *Prevalence and prevalence rate* give some measure of the workload, but their epidemiological significance is limited.
- *Case detection and case detection rate* are proxy indicators of incidence (rate), and are the most useful indicators for estimating the magnitude of the problem and the ongoing transmission. Case detection is also essential for calculating drugs needs.
- *MB proportion* can help in estimating the magnitude of the potential source of transmission. It too is important for calculating drugs needs.
- *Child proportion* gives an insight into recent transmission, and is important for calculating drug needs.
- *Disability assessment proportion* is one of the basic indicators for measuring the effectiveness of prevention of disability activities.
- *Disability proportions* are another basic indicator for measuring the effectiveness of prevention of disability. It also gives an indication of the delay between the onset of the disease and diagnosis, and helps to interpret trends in case detection.
- *MDT completion rates* are very important for assessing the quality of patient management.
- *Relapses* are important for monitoring the effectiveness of MDT.

Other useful indicators are mentioned:

- *Proportion of people developing new disabilities during treatment* measures the effectiveness of prevention of disability during MDT.
- *Proportion of people who started corticosteroids* indicates the effectiveness of the management of reactions.
- *Corticosteroid completion rate* shows the quality of the follow-up of people presenting with a reaction.
- *Female proportion* may give some indication of the accessibility of leprosy services for females.
- *Proportion of health centres with MDT blister packs* gives an idea of how far leprosy services are integrated into general health services, and of how accessible the services are to people with leprosy.

INTRODUCTION

The main objectives of leprosy control programmes are usually to cure people with leprosy, to stop the transmission of the disease and to prevent disabilities. It is essential to measure progress towards the achievement of these objectives. That is why indicators are used.

The aim of this paper is to review the indicators that ILEP recommends on its B1 questionnaire – which deals with detection, MDT and the prevention of disabilities – and to discuss their interpretation.

Interpretation of the B2 (care/hospital/non-leprosy) and B3 (socio-economic activities of the programme) questionnaires – which mostly concern activities or whether people take advantages of the benefits offered to them – is much less problematic, and therefore these two questionnaires are not dealt with in this paper.

If used correctly, indicators are powerful tools. They help with the monitoring of programmes, so that adjustments can be made and overall objectives met. They also influence how programme staff spend their time; for example, staff may focus on factors that will be measured and ignore those that they know will not.

Indicators also have their limitations: the conclusions to be drawn from them will not always be correct. Section I outlines some general principles that should be kept in mind when interpreting the data collected. Section II examines the ILEP indicators and Section III discusses some additional indicators that are not currently requested by ILEP. To help clarify the issues at stake, examples drawn from actual programmes are given in Section IV. This is followed by a glossary of terms and the ILEP B1 forms and explanatory notes in Annex 1.

We hope that this paper will give the managers and field staff of leprosy control programmes a better understanding of the current situation in various settings. This should help them to make the adaptations needed to improve the performance of their programmes.

I. GENERAL PRINCIPLES

An indicator is a simple tool for monitoring the progress of a programme. In an ideal world, the indicator would be easy to measure and would directly show how far an important objective is being achieved. Unfortunately, this is rarely the case in the real world. Here are some of the problems:

1. Reliability of data

Was the basic information collected properly from the person with leprosy or the medical records? This is the most basic question to ask about an indicator, and it must be asked *before* trying to interpret the data. If not, there is a risk of misinterpretation, with potentially damaging consequences for the management of the programme. The reliability of the data depends upon the staff who manage the people being treated and record the findings, as well as upon the staff who collect the data from clinic records and registers. Here are some examples of behaviour that might make the data unreliable:

- If people are not examined carefully, some skin patches may be missed, resulting in the diagnosis of leprosy being rejected, or in people suffering from MB leprosy being misclassified as having PB leprosy.
- Testing suspect skin patches for anaesthesia might be done incorrectly, leading to over- or under-diagnosis.
- The collection and copying of data may be inaccurate, so that the findings reported do not reflect the true situation.

Reliability can be maintained through regular and thorough supervision, and by verifying the data. This can be done by:

- Doing the calculations in several different ways.
- Comparing the results with related information: there might, for instance, be some inaccuracy present if the proportion of MB cases is higher among children than among adults, or if the rate of treatment completion is better for people with MB leprosy than for those with PB leprosy.
- Comparing the results with those for other geographical areas: if the proportion of new patients showing disability is much lower in one area than in others offering apparently the

same services, it might be that the people concerned have not been examined thoroughly enough for disabilities.

- Comparing the results with historical data: any sudden and major trend upward or downward in an indicator should initially be treated with caution – is it a mistake?

2. The denominator

An important part of any rate or proportion is the *denominator*, the population from which the cases are drawn. In the child proportion, for example, the denominator is the total number of newly detected cases and the numerator is the number of children aged 0–14 years among them. The process of arriving at the correct denominator is fraught with potential problems; for example, in some areas there might be major differences between the population targeted by the leprosy control programme and the population actually covered. Whether the population effectively covered or the population targeted is chosen as denominator will give a completely different impression of the size of the problem:

Table 1: Bandundu province of DR Congo, 1998

People registered for treatment		<i>'Prevalence' rate (per 10 000)</i>
at end of year	646	
Total population	5,303,599	→ 1.22
Population covered	2,675,196	→ 2.41

In a proportion or a rate, the *numerator* should be a sub-group of people contained within the denominator. In practice, this is not always the case: some people with leprosy are treated in an area other than that in which they live. There may be several reasons for this: the absence of leprosy services in the person's own area; the person's fear of being recognised in their own area as having leprosy; the better reputation of the leprosy services in an adjacent area; the fact

that the people concerned are seasonal workers. Although it is important to include these people in the statistics to give a more accurate picture of the leprosy workload in a particular area, we should be aware of their special status when attempting to analyse an epidemiological situation.

3. Validity of the measures

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:

Difficulties in measuring important statistics

Although we would like to measure real situations, in practice what we measure is what we see of those situations. As a result, our view will often be merely partial, or even biased.

The most obvious example concerns the prevalence of leprosy. Prevalence relates to all cases in need of chemotherapy. It is unfortunately very difficult to measure this accurately, since undetected cases cannot be counted without carrying out a total population survey. It is much easier to count the number of people registered for treatment; however, this is usually an underestimate of the prevalence (see below).

Link between indicators and operational factors

The distinction made above between true prevalence and registered prevalence applies to most other indicators: their interpretation is only possible on the basis of the activities carried out. For instance, a high percentage of children among new cases may be the result of a particularly high rate of transmission or of energetic case detection campaigns among schoolchildren.

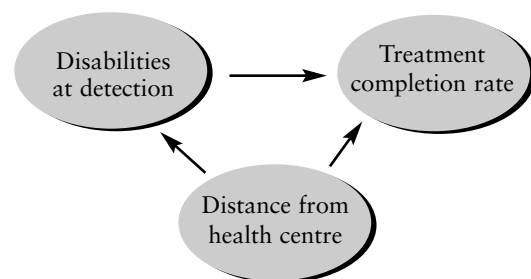
Changes of definition

The meaning of some of the concepts used in leprosy work has changed over time. Prior to 1988 the definition of a leprosy 'case' included people in need of treatment or under treatment, people under surveillance after treatment and people in need of care for old disabilities. Since 1988, however, a leprosy case has been considered to be a person showing the clinical signs of leprosy, with or

without bacteriological confirmation, and in need of chemotherapy. This change of definition has significantly reduced the prevalence of leprosy. Similarly, the definition of a multibacillary (MB) case has widened over the years, resulting in more people being classified as MB.

Presence of confounding factors

A confounding factor prevents the accurate measurement of the association between another factor, such as the exposure to leprosy, and the outcome under study. A factor can only be confounding when it is linked to both the exposure and the outcome. For example, statistics may show that people with disabilities at the time of diagnosis have in general a lower treatment completion rate. In this case, a confounding factor might be how far the people with leprosy live from the nearest health centre: if they live far away, they are more likely to be detected late. They may also be more likely to be irregular in attending for treatment. The real cause of their low rate of treatment completion is thus the distance they live from the health centre, not the fact that they already presented with disabilities at the time of their detection.



4. Trends versus one-off analyses

The trend that most indicators show over a long period – such as several years – is much more informative than a single reading. Observing trends over time is also a way of validating the data. When operational conditions change, however, trends must be interpreted cautiously.

5. Presentation of the data

The way the data is presented can greatly influence how it is perceived. For instance, figures, though usually much easier to understand than tables, can sometimes give an erroneous impression because of the scale of the axes.

II. ILEP INDICATORS

1. Prevalence and prevalence rate

Definitions: Prevalence is the total number of leprosy cases registered for chemotherapy at the end of the reporting year. The prevalence rate is the total number of leprosy cases registered for chemotherapy at the end of the reporting year divided by the total population of the area; usually expressed as a rate per 10 000 population.

Validity: Although prevalence should deal with the actual number of people in need of or receiving chemotherapy, in practice it only refers to those people who are registered for treatment. Undetected people with leprosy, or those who abandoned their treatment some time ago, are not taken into account. Also, some people are kept too long on the register: for instance, they are not always discharged as soon as they have completed chemotherapy. Registered prevalence can change abruptly if the duration of treatment is modified, as it did when the length of MB MDT was reduced from twenty-four months to twelve. As defined here, this indicator usually gives an underestimate of the true prevalence. It can, however, also produce an overestimate, such as when huge detection campaigns are launched using inexperienced health workers. The real prevalence of leprosy is difficult to measure: valid estimates can only be obtained through random sample surveys, which are difficult, time-consuming and costly to organise.

Relevance: Prevalence does not give a genuine insight into the epidemiology of leprosy. It is more a measure of the treatment workload of the health services at any given time. Hence its relevance is in practice limited to the operational aspects of the programme. Even for that limited purpose, this indicator may be misleading: for example, many cases detected during the year are not included in a prevalence calculated once a year – a PB case detected in the first half of the year is unlikely to be still under treatment by the end of December.

The prevalence rate has one advantage as an indicator compared with prevalence expressed in absolute numbers: it takes into account the size of the population. The magnitude of the problem in different areas can thus be theoretically

compared. However, what is measured is so dependent on activities (case detection) and policies (duration of stay in register) that it is a poor measure of the real leprosy morbidity in a given population.

WHO defines the ‘elimination’ of leprosy as the achievement of a prevalence rate below one case per 10 000 population. This definition has certain problems:

- The rate intended when the elimination strategy was launched was the actual prevalence, not the prevalence of registered cases.
- The rate of one case per 10 000 population is completely arbitrary.
- The whole strategy of leprosy elimination was based on the assumption that the transmission would be reduced once the prevalence fell below a certain threshold. There is no scientific support for such a hypothesis when the fall in prevalence is the result of shortening the duration of treatment rather than of a declining incidence of the disease. Hence the prevalence rate is often irrelevant.

Interpretation: Prevalence and incidence are obviously related. In a stable situation, this relationship can be expressed as:

$$\text{Prevalence} = \text{incidence} \times \text{duration of the disease}$$

Prevalence may thus be high either because the incidence is high or because the disease is of long duration (the disease is considered to start at the onset of symptoms and to finish at the end of treatment). As the indicator mentioned here deals with registered prevalence, this relationship should be adapted to:

$$\text{Registered prevalence} = \text{case detection} \times \text{duration of stay in the register}$$

Another obstacle to the usefulness of prevalence as an indicator concerns the definition of the area or population concerned. The distribution of leprosy is known to be patchy, and an apparently low national rate of prevalence may hide pockets of very high prevalence at local level. An example of this is Nigeria:

Table 2: Registered prevalence rates in some Nigerian states (ILEP Annual Report 1999-2000)

	Prevalence rate (registered cases) Per 10 000 population
Nigeria (whole country)	0.65
Niger State	0.19
Kano State	1.21
Jigawa State	3.16

At global level also, the use of the total population of the world as denominator of the leprosy prevalence rate may be quite confusing, since it is known that leprosy is practically non-existent in a number of countries.

Table 3: Factors influencing the registered prevalence (rate)

Increased by...	Decreased by...
<ul style="list-style-type: none"> • High rate of transmission of the disease. • More energetic case detection. • Treatment of longer duration than standard. • Not discharging people after cure; death; moving out; or lost to follow-up. • Over-diagnosis. 	<ul style="list-style-type: none"> • Low rate of transmission of the disease. • A shift from active to passive case detection. • Shorter duration of treatment. • Cleaning of registers. • Under-diagnosis.

The impressive decline in the rate of prevalence observed in most countries during the past fifteen years is mostly due to a reduction in the duration of treatment. Although this means a decreased workload for health staff, it would be dangerous to give the decline any more significance than that.

2. Case detection and case detection rate

Definitions: Case detection is the total number of new leprosy cases detected during the reporting year. The case detection rate is the total number of new leprosy cases detected during the reporting year divided by the total population of the area; usually expressed as a rate per 10 000 or 100 000 population.

Validity: The best indicator of leprosy transmission would undoubtedly be the rate of incidence. This, however, is almost impossible to measure, as it would require the total population to be surveyed at regular intervals. We thus have to make do with case detection as a proxy indicator of incidence. However, this approach poses problems:

- It is directly influenced by case detection activities.
- A number of newly detected cases may actually be people who had developed leprosy several years before.
- At the same time, some people who develop clinical symptoms will only be detected after a number of years, and will thus not be included in the case detection of the present year.

Some attempt has been made to reconstruct incidence on the basis of case detection and estimated delay before diagnosis. This proved rather laborious. Moreover, the reliability of the estimates of delay is always questionable.

Relevance: In spite of the limitations described, case detection (rate) is probably the most useful indicator for estimating the leprosy transmission in an area. It should also provide the basis for calculating the requirement for drugs.

Interpretation: As already mentioned, the number of cases detected in a population depends principally upon the detection activities. It thus reflects the performance of the leprosy control programme. Active case-finding campaigns, whether directed towards the total population of an area or towards specific groups (such as school children), will lead to the detection of more cases than if a programme depends upon self-reporting by people who suspect they may have the disease. It has also been shown that the number of cases detected increases with the frequency of examinations: very frequent examinations will identify a number of self-healing cases that would otherwise never have come forward (and would never have developed any disability).

Case detection is affected by the awareness of leprosy among the population and the health staff.

Table 4: Factors influencing case detection (rate)

Increased by...	Decreased by...
<ul style="list-style-type: none"> • Greater transmission of the disease. • More effective case detection. • Finding cases in untouched 'leprosy pockets'. • Greater awareness among health staff and/or community. • Over-diagnosis. 	<ul style="list-style-type: none"> • Declining transmission of the disease. • Shift from active to passive case detection. • Decreasing awareness among health staff and/or the community. • Under-diagnosis.

In a given population, trends in case detection can be considered as genuinely reflecting trends in incidence if the proportion of newly detected patients who present grade 2 disabilities remains stable (see below).

3. MB proportion

Definition: The percentage of MB cases among the total number of new leprosy cases detected during the reporting year.

Validity: The definition of an MB case has changed considerably over time. In 1981, when a WHO study group recommended the use of multidrug therapy (MDT), the MB category included lepromatous (L) and borderline (B) leprosy according to the Madrid classification and LL, BL and BB leprosy according to the Ridley and Jopling classification. It also included all people with a bacteriological index (BI) of ≥ 2 at any site. In 1988 the sixth WHO expert committee recommended that all people with a positive BI should also be considered as MB cases. Since 1995, the recommendation has been to consider as MB cases everyone who shows more than five anaesthetic skin patches, in addition to those who have positive skin smears. As a result of these changes of definition, the proportion of MB cases among new cases detected has risen.

Relevance: As people with MB leprosy are considered to be more infectious and thus more likely to be responsible for leprosy transmission, it is important to know how many of the newly detected cases fall into this category. It is also necessary for calculating drugs requirements.

Interpretation: The MB proportion can vary considerably from one country to another. It is therefore impossible to state what a 'normal' value should be. However, some general trends can be described that are observable at different stages of a leprosy control programme. The proportion of MB cases among newly detected people with leprosy is usually high at the beginning of a programme or in a population only recently covered by leprosy control services. This is because MB cases will have accumulated over the years, whereas a proportion of the PB cases will have self-healed and thus will no longer present any sign of active disease when the programme starts. Thereafter, the MB proportion usually stabilises at a lower level.

It has also been observed that, in comparison with self-reporting cases, people whose leprosy has been detected as part of an active campaign are more likely to be PB; some of them would otherwise self-heal, while others would shift towards MB disease.

Since MB leprosy is usually less frequent among women and children, its proportion will be affected by the age and sex of the population targeted for case detection (schoolchildren, for instance).

Table 5: Factors influencing the MB proportion

Increased by...	Decreased by...
<ul style="list-style-type: none"> • The start of a new leprosy control programme. • Wide definition of an MB case. • A shift from active to passive case detection. 	<ul style="list-style-type: none"> • A shift from initial phase to intermediate phase of leprosy control. • Narrow definition of an MB case. • Active case detection, including school surveys.

The MB proportion can thus be a useful epidemiological indicator for validating trends in case detection, but it depends upon a stable definition of what an MB case is – and the lack of such a definition greatly limits its usefulness as an indicator.

4. Child proportion

Definition: The percentage of children among all new cases detected during the reporting year.

Validity: Since the definition of a leprosy case and that of a child are both reasonably clear, there are few factors that might reduce the validity.

Relevance: As children will by definition have been infected only relatively recently, a high child proportion may be a sign of active and recent transmission of the disease. It is thus an important epidemiological indicator. The child proportion (or rather the number of new PB and MB children) is also valuable for calculating drugs requirements.

Interpretation: It is usually assumed that, at the beginning of a leprosy control programme, an accumulated backlog of elderly people with leprosy, containing a high proportion of disabled and MB cases, will be detected. By contrast, the child proportion is usually low at the beginning of a programme; subsequently, it tends to stabilise

at a higher level. When transmission is decreasing among the general population, it is to be expected that fewer and fewer children will develop the disease: the child proportion should therefore decrease. This is, however, a very slow process.

Certain operational factors can also affect the child proportion. Greater thoroughness in case detection (such as in a survey) will increase the proportion, because leprosy is often less visible in children than it is in adults; many children have self-healing PB leprosy that would otherwise not have been detected. Obviously, more frequent school surveys will also increase the child proportion. On the other hand, the proportion will decrease as a result of case detection in previous untouched 'leprosy pockets', as this will reveal a backlog of cases. Finally, increasing immunity among the population as a result of natural factors – such as natural selection or immunity induced by other mycobacterial infections such as tuberculosis – or of BCG vaccination will prevent the infection of children and thus decrease the child proportion.

Table 6: Factors influencing the child proportion

Increased by...	Decreased by...
<ul style="list-style-type: none"> • A shift from the initial phase to the intermediate phase of leprosy control. • Greater thoroughness in case detection. • Active case-finding, including school surveys. 	<ul style="list-style-type: none"> • A shift from the intermediate phase to the elimination phase of leprosy control: decreasing transmission. • Case detection in untouched 'leprosy pockets'. • Increased immunity of the population.

In most programmes, the threshold between a high and a low child proportion seems to be at around 10 per cent. As with other indicators, the trend of the child proportion over time in one programme is much more revealing than a comparison of one-off measurements from various programmes or countries.

5. Disability assessment proportion

Definition: The percentage of people with leprosy who are assessed for the presence of disability according to WHO grading scale (0, 1, 2) at the time of diagnosis among the new leprosy cases detected during the reporting year.

Validity: As the definitions of a leprosy case and of a performed disability assessment are quite clear, there are few factors that might reduce the validity.

Relevance: In view of the importance of disability prevention for people with leprosy, it is an essential part of ILEP strategy to provide disability assessment for every person identified as having the disease.

Interpretation: Each project should strive for a disability assessment proportion of 100 per cent.

6. Disability proportions

Definition: The percentages of people with WHO disability grade 1 and 2 respectively among the new leprosy cases detected during the reporting year and for whom a disability assessment was carried out.

Validity: The validity of this indicator can be diminished by the following factors:

- If the clinical examination for anaesthetic areas on hands and feet is not conducted carefully.
- If the clinical examination for visible deformities and damage on hands and feet is not conducted carefully.
- If the examination for visual disability (whether eye problems are present, the ability to count fingers at 6 metres distance) is not conducted carefully.
- A variety of different methods for assessing the presence of disabilities are used in different programmes, and these can give different readings.
- If it is not understood that the highest observed grade of disability decides the grading for the whole person: that is, an observed grade 2 disability in hands or feet or eyes is enough to categorise the person as grade 2. On the other hand, a person with grade 1 disabilities only, must be categorised as grade 1, however many limbs are affected.
- If only some of the new patients are assessed for the presence of disabilities, the proportion of those having grade 2 disabilities may be relatively high, since these disabilities are usually easily detectable. At the same time, the proportion of people with grade 1 disabilities may be underestimated, as these disabilities need careful assessment in order to be detected at all.

Relevance: This is a highly relevant indicator, as the prevention of disabilities should be one of the major objectives of a leprosy control programme. It also gives some indication of the delay before diagnosis. Moreover, a stable proportion of new

patients with grade 2 disabilities helps to confirm that the trend in case detection is a good proxy of the trend in incidence.

Interpretation: As with the child proportion, the disability proportion is influenced by the operational phase of leprosy control and by the activities of the control programme. However, by contrast with the child proportion, the disability proportion will be high at the beginning of programme activities, as a result of the accumulated backlog, and will subsequently decrease and stabilise at a lower level. Similarly, more thorough and more frequent active case detection will find people with an earlier stage of the disease and thus decrease the disability proportion.

Case detection in untouched 'leprosy pockets' will reveal backlogs and thus increase the disability proportion. There is also some evidence that the disability proportion might increase during the elimination phase of leprosy control, because most new cases will be coming from the backlogs in isolated pockets rather than from among more recently infected people without disabilities. Another reason for an increase in the disability proportion may be diminishing awareness and skills among health workers when leprosy becomes less frequent.

One of the main reasons for assessing the disability proportion is the fact that a high reading is a sign of late case detection.

Although grade 1 disabilities are potentially as significant (people with anaesthetic hands or feet need to protect themselves from further injuries), the proportion of grade 2 disabilities is used more widely because it can be more reliably measured.

Table 7: Factors influencing the disability proportion

Increased by...	Decreased by...
<ul style="list-style-type: none"> • Long delay before diagnosis. • Shift from intermediate phase to elimination phase of leprosy control. • Case detection in untouched 'leprosy pockets'. • Belated case detection. • Failure to assess all new patients for disabilities (grade 2 disabilities). 	<ul style="list-style-type: none"> • Shorter delay before diagnosis. • Shift from initial phase to intermediate phase of leprosy control. • More thorough case detection. • More frequent case detection. • Better community awareness and health staff training concerning leprosy. • Failure to assess all new patients for disabilities (grade 1 disabilities).

Determining the threshold between a high and a low grade 2 disability proportion is a rather arbitrary exercise; however, most authorities agree that it should be set at around 10 per cent.

7. MDT completion: number of people with single skin lesion who received single-dose ROM

Definition: The number of people with a single skin lesion who received a single dose of ROM.

Validity: In countries where single-dose ROM is used, and under normal circumstances, this number should be equal to the number of cases diagnosed as single-lesion leprosy, as each case should be treated immediately. If the drugs are not available, the people concerned should be given standard PB MDT.

Relevance: This indicator shows how widely single-dose ROM is used and helps with the re-ordering of drugs.

Interpretation: Interpreting this indicator presents no difficulties, as it is simply the number of people given this form of treatment.

8. MDT completion: percentage of PB cases completing six doses of MDT amongst those expected to complete their MDT treatment.

Definition: The percentage of PB cases diagnosed during a given period of time who complete their treatment correctly.

Calculation: This indicator is calculated by means of cohort analysis. A cohort is a group of people who all start their treatment during the same period – the period may be of any length, but this indicator is usually calculated for a one-year period. The records for each person who started treatment during the period in question are examined and it is noted whether or not treatment was completed within the nine-month limit. It is then a straightforward task to work out the percentage who correctly completed their treatment:

$$\text{Completion rate} = \frac{\text{number completing treatment}}{\text{total number in cohort}} \times 100$$

Since people need time to complete their treatment, the cohort analysis and the calculation

of this indicator cannot be done until nine months after the end of the period during which they started treatment. For convenience, the calculation is usually done a year later. Thus, when the ILEP form for the year 2000 is being completed (in early 2001), the completion rate for PB MDT will be calculated for people who started treatment during 1999.

Validity: The validity depends upon:

- Having the correct number of people in the cohort, as this will be the denominator for the percentage. This should be the same as the number of people with PB leprosy patients reported as new cases in an earlier report covering the starting period.
- The adequacy of the treatment records or registers, which can indicate whether people completed their treatment.
- Whether 'accompanied MDT' is used, as this may artificially raise the completion rate: for example, if people are given all six blister packs at the start and immediately recorded as having completed the treatment.

Relevance: This is a very important indicator, as the effectiveness of MDT depends upon it being taken properly. People who do not complete the treatment are more likely to suffer from the complications of leprosy, leading to greater disability and deformity. Therefore every effort should be made to maintain the completion rate at as high a level as possible.

Interpretation: A proportion of 85 per cent is considered to be an acceptable result. Death and defaulting from treatment are some of the reasons why people do not complete courses of MDT. Most programmes attempt to keep the number of defaulters to a minimum. Any programme with a completion rate below 85 per cent should make more effort to reduce defaulters; it is easier to prevent people from defaulting in the first place than to retrieve them after they have stopped attending.

9. MDT completion: percentage of MB cases completing twelve doses of MDT amongst those expected to complete their MDT treatment.

Definition: The percentage of MB cases diagnosed during a given period of time who complete their treatment correctly.

Calculation: As for people with PB leprosy, this indicator is calculated by cohort analysis. The record for each person who started treatment during the period in question is examined and it is noted whether or not they completed their treatment within the eighteen-month limit. It is then a straightforward task to work out the percentage that did complete their treatment correctly:

$$\text{Completion rate} = \frac{\text{number completing treatment}}{\text{total number in cohort}} \times 100$$

Since people need time to complete their treatment, the cohort analysis and the calculation of this indicator cannot be done until eighteen months after the end of the period during which they started treatment. For convenience, this indicator is usually calculated two years later. Thus, when the ILEP form for the year 2000 is being completed (in early 2001), the completion rate for MB MDT will be calculated for people who started treatment during 1998.

Validity, relevance and interpretation are similar to those for people with PB leprosy. A person, particularly an MB case, who does not complete treatment may become infectious again.

In the ILEP Annual Report for 1999–2000, some countries report no figures for the MDT completion rate. This may be due to the fact that the control programme is just getting started again after a period of interruption; there may be no cohorts that have finished treatment; or the information system may not be functioning properly yet. Most programmes with significant numbers of patients report the results of treatment.

The global figures of 79 per cent completion for PB cases and 69 per cent for MB cases could be improved upon. In most situations, a target of 85 per cent completion for both PB and MB cases is reasonable.

10. Relapses: total number of relapses after MDT treatment for MB or PB leprosy during the reporting year.

Definition: The number of cases diagnosed as having relapsed after MB MDT or PB MDT during the reporting year.

Validity: A relapse can only be diagnosed when a person has previously completed a full course of MDT within the correct time frame. Under field conditions, relapses are difficult to diagnose correctly and are probably much less common than reports suggest. In other words, most suspected relapses are probably not genuine, but rather some form of reaction. However, many programmes do not have the resources to investigate supposed relapses fully, and since the treatment is straightforward (the same MDT as for new cases), they usually find it easier to treat the people concerned once again. If, however, the reported number of relapses is very high compared to the number of cases starting treatment (more than 5 per cent), this should be investigated.

Relevance: MDT has a remarkably low relapse rate and is not at present associated with the development of drug resistance. However, this situation may not last for ever, and a rising relapse rate may be the first indication of problems with the current MDT regimens. It is therefore important to monitor this indicator closely. MB relapses after PB MDT suggest that there has been some misclassification of patients – people who are really MB have received inadequate treatment. If such relapses become a common occurrence, care must be taken to classify people correctly before treating them. PB relapses do not pose the same threat as MB relapses, as the people concerned are likely to be much less infectious.

Interpretation: If the number of relapses is higher than 5 per cent of the number of all cases starting treatment, the situation needs to be investigated. First, the administration of MDT must be examined, and second, the relapses must be confirmed. If more than 1 per cent of all cases starting treatment are proved to be genuine relapses after correctly administered MDT, they will need to be investigated for drug resistance. This can only be done for MB cases, as bacilli cannot be recovered and tested from PB cases.

In the ILEP Annual Report for 1999-2000,

twenty-four countries report a level of MB relapses higher than 1 per cent of the total number of new cases. Many of these are countries with very few cases anyway, so misdiagnosis may be a likely explanation for the figures. However, some countries have more than fifty reported relapses, as well as a rate of above 1 per cent, so it would be useful to examine a sample of future relapses more closely, if possible.

III. OTHER USEFUL INDICATORS

Although the indicators in this section are not included in the list recommended by ILEP, they are of some interest and could be calculated locally if felt to be important.

11. Proportion of people developing new disabilities during treatment

Definition: The proportion of people with PB or MB leprosy who have a higher disability score at the end of their treatment than they had at diagnosis.

Calculation: This indicator is also calculated by cohort analysis. It must be calculated separately for people with PB leprosy and for those with MB leprosy. At the beginning of 2002, for example, the cohorts in question will therefore consist of the people with PB leprosy detected in 2000 and the people with MB leprosy detected in 1999. For each person, the disability scores (between 0 and 2) for each eye, hand and foot are added up to give a total individual score of between 0 and 12. This is known as the EHF score. A person is considered to have developed new disabilities if they have a higher score at the end of their treatment than at the time of diagnosis. This is thus a different way of assessing disability from that used in the disability proportion, where only the highest grade is used as an overall indicator of disability.

Validity: The validity of this indicator is limited by the fact that a person could actually develop new disabilities without getting a higher score: an increased score for one limb might be cancelled out by a decreased score for another one (for instance, a healed foot ulcer). Also, a limb that scores 2 will not get a higher score, even if it develops new or more serious disabilities.

Relevance: In spite of such limitations, this indicator enables a reasonably accurate assessment to be made of whether the prevention of disability is effective once the person has been registered for treatment. It becomes less valid and relevant, however, when the treatment duration decreases.

Interpretation: Here again, defining the threshold between a high and a low proportion is rather an

arbitrary exercise. If the prevention of disability is effective, through the correct management of leprosy reactions and neuritis and the proper counselling of people with insensitive extremities, one would not expect more than 5 per cent of people to develop new disabilities during MDT.

12. Proportion of people who started corticosteroids

Definition: The percentage of people diagnosed during a given period of time who started corticosteroid treatment.

Calculation: This indicator is calculated by cohort analysis. It must be calculated separately for people with PB leprosy and for those with MB leprosy. For the sake of simplicity, it is a good idea to use the same cohorts as for the calculation of the MDT completion rates. The record for each person who started MDT treatment during the period in question is examined (thus providing the denominator) and it is noted whether or not a treatment with corticosteroids was started (the numerator).

Validity: This indicator is influenced by three main factors:

- *The frequency of leprosy reactions.* This will be influenced by the relative proportion of people with MB and PB leprosy. That is why this indicator should be calculated for MB and PB cases separately.
- *The ability of staff to detect reactions.*
- *The treatment policy for people presenting a leprosy reaction.* This can vary considerably between countries, thus making inter-country comparisons potentially misleading.

Relevance: This indicator does not measure the frequency of leprosy reactions, but rather how they are dealt with.

Interpretation: A very low (less than 5 per cent)

or very high (more than 40 per cent) proportion could indicate problems in the detection or management of leprosy reactions.

13. Corticosteroids completion rate

Definition: The proportion of people who correctly complete a corticosteroid course out of those who started the course.

Calculation: This indicator is calculated by cohort analysis. The denominator is the numerator of indicator 12 (the proportion of people who started corticosteroids). It must be calculated at the same time as the MDT completion rate, but obviously for a subgroup of people.

Validity: The validity of this indicator depends upon:

- Having the correct number of people in the cohort, which will serve as the denominator for the percentage.
- Having adequate treatment records or registers, so that it is known whether or not people completed their treatment.

Relevance: The value of corticosteroid treatment depends upon it being taken properly.

Interpretation: Like defaulters from MDT, those who do not complete corticosteroid treatment should be kept to a minimum.

14. Female proportion

Definition: The proportion of females among the newly detected cases.

Validity: The validity of this indicator should not pose a problem, although difficulties may arise from defining what is a case of leprosy.

Relevance: The relevance of this indicator is fairly limited, as more males than females seem to be affected by leprosy. This gender imbalance is even higher for the MB type.

Interpretation: A very low proportion of females (under 30 per cent) could indicate that women are having a problem gaining access to leprosy services. It would be interesting to compare this proportion with the one observed in surrounding areas of the same country. If a problem of under-

detection of females is really suspected, it will then be necessary to carry out a more in-depth analysis for males and females separately. This analysis should be based on the other indicators discussed above in relation to case detection, and particularly the proportion of women presenting with grade 2 disabilities at detection.

15. Proportion of health centres with MDT blister packs

Definition: The proportion of health centres having blister packs available at the time of the supervision or evaluation visit.

Validity: This is not a problem, as both the numerator and the denominator are easily identifiable.

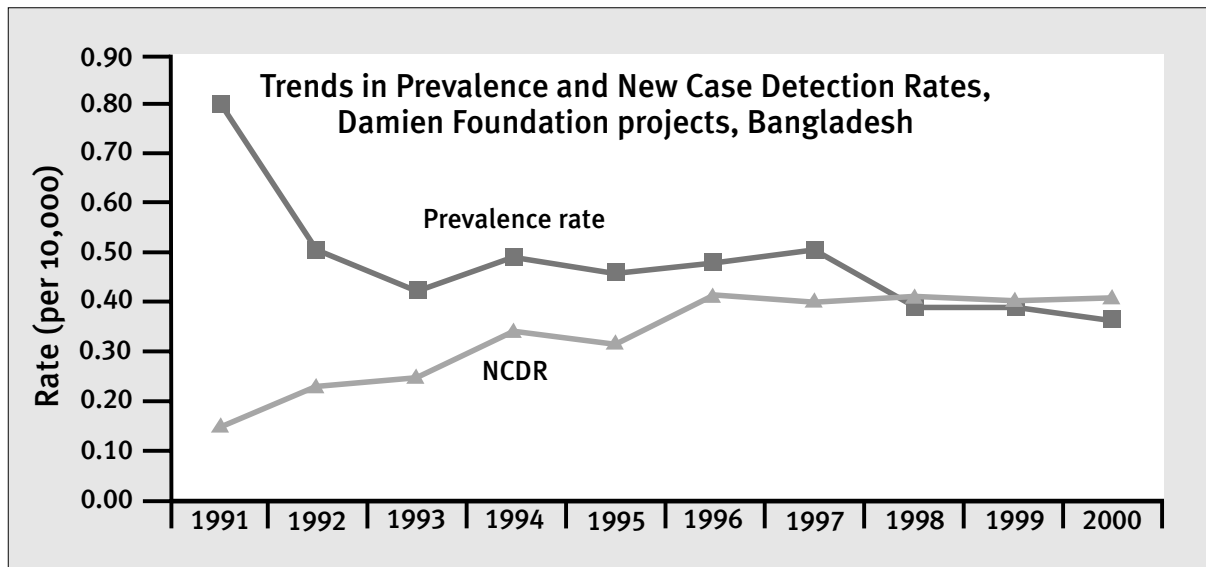
Relevance: This indicator shows how widely MDT is available for all people with leprosy. It measures the accessibility of treatment. The presence of blister packs in a health centre, however, does not mean that these are used properly.

Interpretation: Ideally, MDT blister packs should be available at all health centres. However, in areas with few cases of leprosy, where any diagnosis of the disease must be confirmed by a supervisor, MDT blister packs may only be given to a health centre when a new leprosy case has been diagnosed there. This indicator should thus be interpreted in the light of the local policy for treatment.

IV. EXAMPLES OF INTERPRETATION

Example 1

This example relates to indicators 1 and 2 (prevalence and case detection rates). It shows the importance of being aware of operational factors when interpreting trends:



Although MDT had been progressively introduced during previous years, the decision to use it systematically for everyone who needed chemotherapy was actually made in 1991. The shorter duration of the new treatment compared with that of dapsone monotherapy significantly reduced the prevalence rate, which remained stable, with only minor variations, from 1993 to 1997. In 1998, the shortening of treatment time from twenty-four months to twelve for MB patients and the introduction of ROM for single skin lesion PB patients further reduced prevalence.

Simultaneously, the new case detection rate (NCDR) increased between 1991 and 1996 and then decreased slightly. Although coverage of the population did not officially improve during the period, a number of new clinics were opened in the early 1990s, making leprosy services more widely accessible. Since 1995, these intermittently available leprosy clinics have been

progressively transformed into leprosy and tuberculosis clinics open daily. These changes have boosted the detection rate. Thus the upward trend cannot be interpreted as an increase of incidence – it is due to an improvement in services. The slight decrease in NCDR observed since 1996 could correspond to an actual decrease in the transmission of the disease. This, however, requires further confirmation during the coming years.

It should be mentioned that the decrease in NCDR since 1996 is mainly due to an increase in the denominator (the population); the absolute number of people with leprosy detected during that period remained quite stable.

A consequence of all these changes is that the ratio of prevalence rate to NCDR went down from 4.7 to 0.9 between 1991 and 2000. The prevalence rate is now lower than the NCDR.

Example 2

This example relates to indicator 2 (case detection). Leprosy elimination campaigns (LECs) are good examples of intensified activity leading to increased case detection.

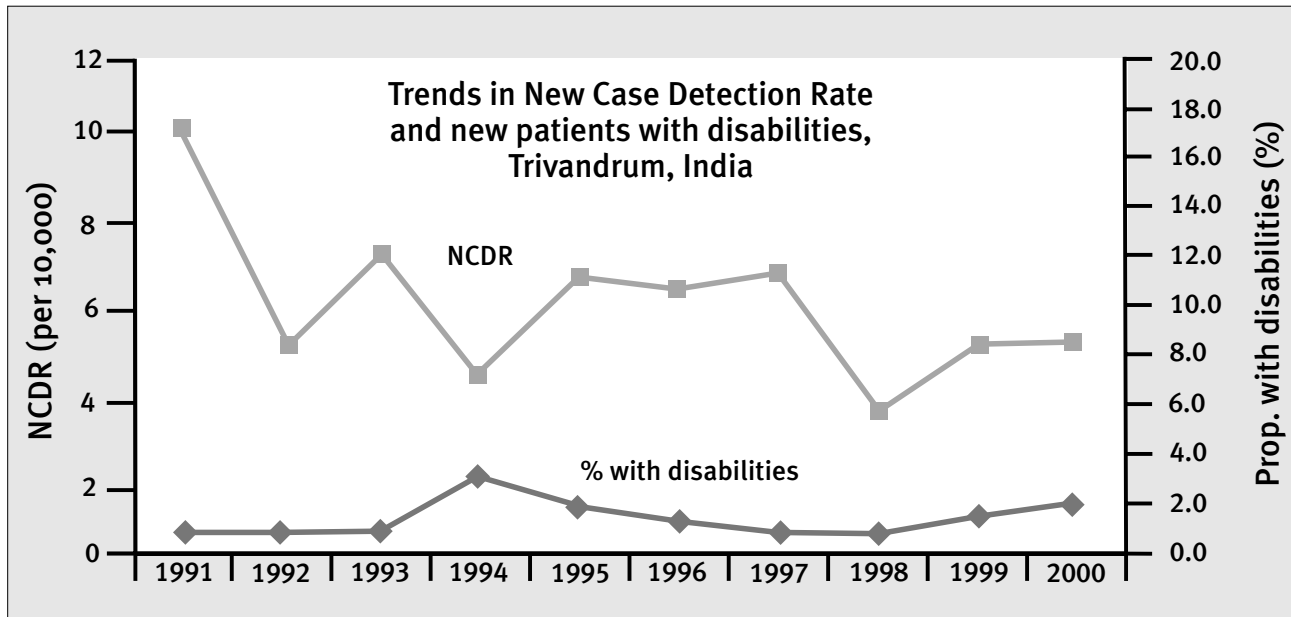
The following table reproduces data published in the *Weekly Epidemiological Record* (10 November 2000, No 45, 2000, 75, 361-368):

Country (area)	Year of LEC	Annual detection during year before LEC	Annual detection during year of LEC	Annual detection during year following LEC
India (Chittoor District)	1996	284	765	341
Myanmar (Shwebo Township)	1998	68	265	169
Nigeria (Ondo State)	1998	91	213	80

Thus LECs have been able to detect large numbers of people with leprosy, some of whom had been ill for several years before the campaign (the so-called "backlog" cases). In several

instances, these campaigns also succeeded in raising awareness of leprosy among the health staff and the population, leading to increased detection in subsequent years as well.

Example 3



This example relates to indicators 2 and 6 (case detection rate and disability proportion.) The figure shows a clear decline in the new case detection rate (NCDR). As the proportion of newly detected patients presenting with grade 2 disabilities is low and remains quite stable throughout the whole period, it seems safe to assume that this trend in case detection reflects a similar trend in incidence of leprosy.

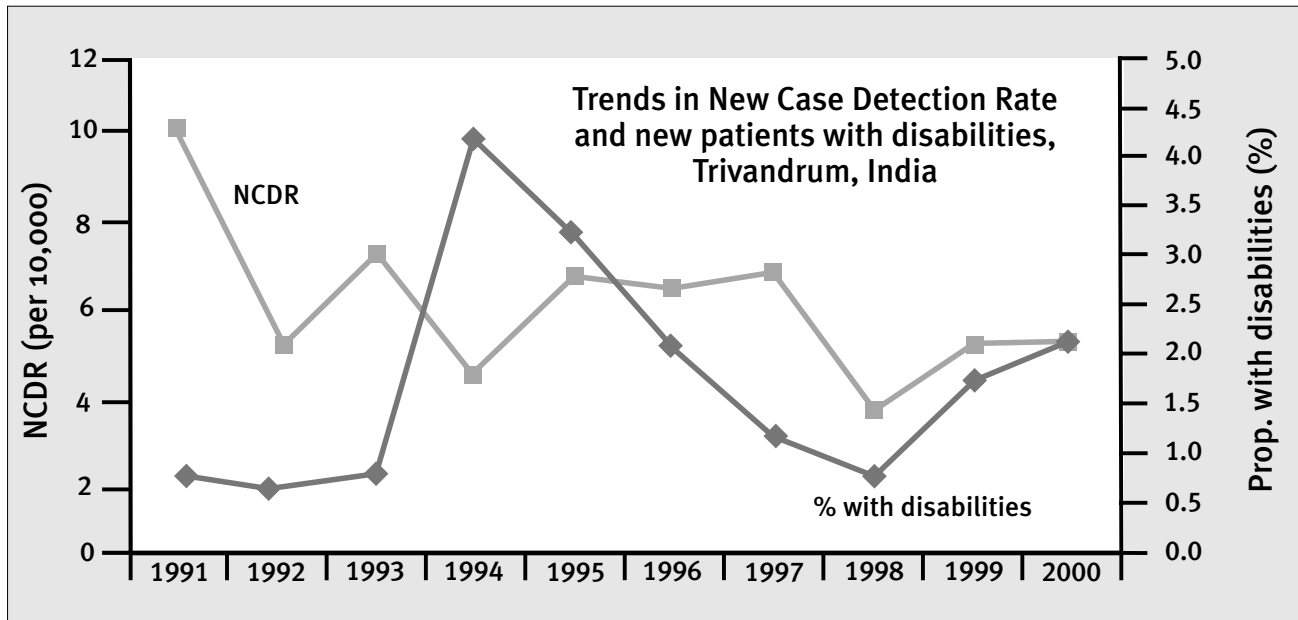
Two other points should be made here:

- In 1994 the proportion of new patients with disabilities reached a peak. This corresponded

with a sudden drop in the NCDR. The assumption must be that detection was less active in 1994, and therefore that fewer very early cases were found during that year.

- Since 1999 the project has extended its leprosy control activities to an additional area. This has, of course, resulted in a greater *number* of people with leprosy detected, but also in an increased detection *rate* and an increased proportion of new patients with disabilities; as expected, there were more "backlog" cases in the new area.

Example 4

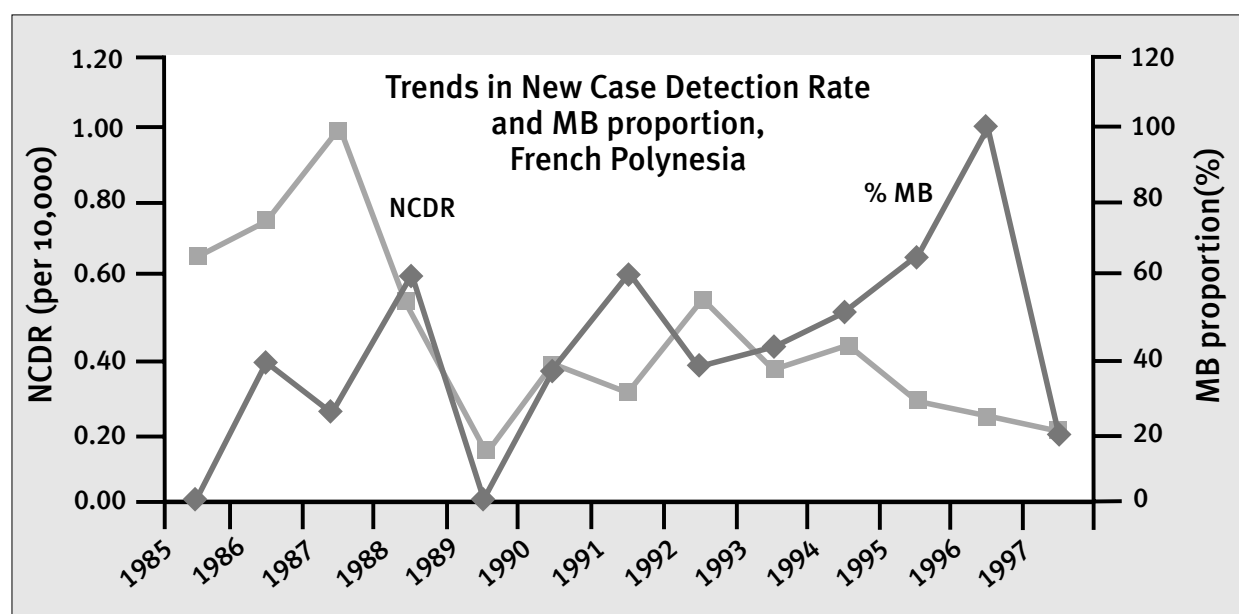


This figure shows the same data as the previous one, the only difference being the scale of the right-hand axis. As a result, it gives a completely different impression of the trend in the proportion of newly detected people with leprosy presenting with disabilities. This underlines the

importance of choosing an appropriate scale for the axes of a figure – it also shows that it is possible to demonstrate almost anything by means of a figure. Therefore all figures must be examined very carefully before coming to any conclusion.

Example 5

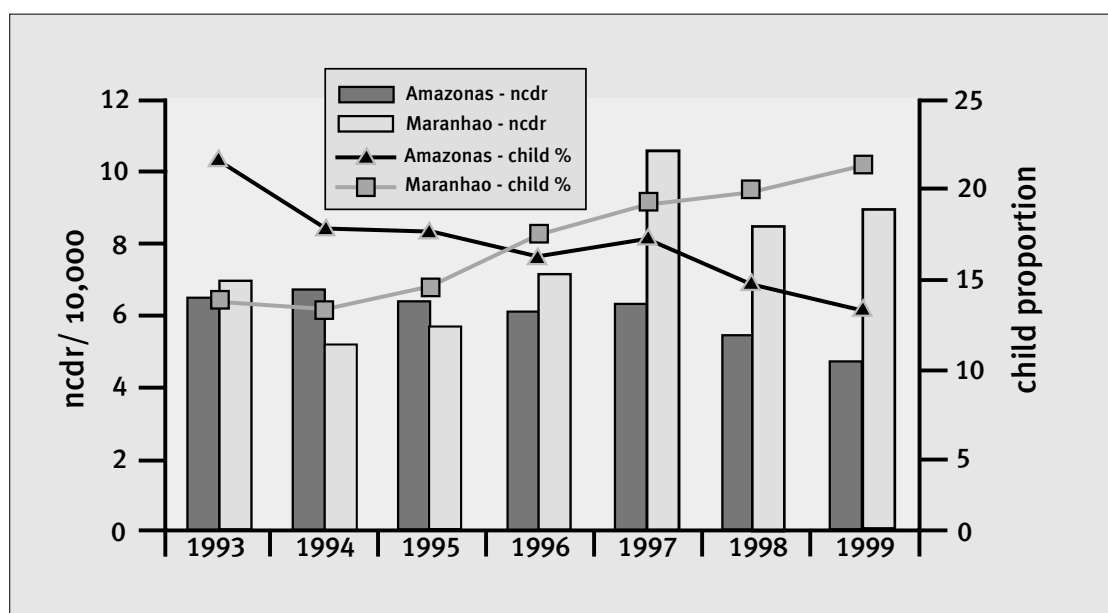
This example relates to indicators 2 and 3 (case detection and MB proportion). The figure shows the trends in new case detection rate and proportion of MB cases among the newly detected patients in French Polynesia (source : *Epidemiological Review of Leprosy in the Western Pacific Region 1983-1997. World Health Organization Regional Office for the Western Pacific, Manila, Philippines, August 1998*). It illustrates how proportions or rates can be dramatically influenced by relatively minor changes in absolute numbers, when the number of patients and/or the population concerned are limited. The absolute numbers are mentioned in the table below.



Year	Population (000)	New cases	Case detection rate (per 10 000)	New MB	% MB
1985	160	11	0,69	0	0
1986	179	14	0,78	6	43
1987	180	19	1,06	5	26
1988	189	10	0,53	6	60
1989	192	3	0,16	0	0
1990	196	8	0,41	3	38
1991	201	5	0,25	3	60
1992	206	12	0,58	4	33
1993	207	7	0,34	3	43
1994	212	9	0,42	5	56
1995	220	6	0,27	4	67
1996	220	6	0,27	6	100
1997	220	5	0,23	1	20

Example 6

This example relates to indicators 2 and 4 (case detection rate and child proportion). The figure shows trends in case detection rate and child proportion in two federal states of Brazil. Although the leprosy control programme in Amazonas has been very active since the 1970s, the state of Maranhão made substantial progress during the 1990s. Hence a slight decline can be seen in new cases in Amazonas and a clear increase in new cases in Maranhão.



New cases detection rate (NCDR) per 10 000 population and child proportion among new cases in two federal states of Brazil (Amazonas and Maranhão) 1993-99

This figure seems to confirm the hypothesis that increased programme activity and the detection of a growing number of cases at the beginning of dynamic leprosy control go hand in hand with

an increasing child proportion. Though confounding factors cannot be excluded, the correlation between the new case detection rate and the child rate is clear. An inverse trend can be observed in a long-running control programme, as in Amazonas: the slow decline of the new case detection rate is associated with a declining child rate.¹

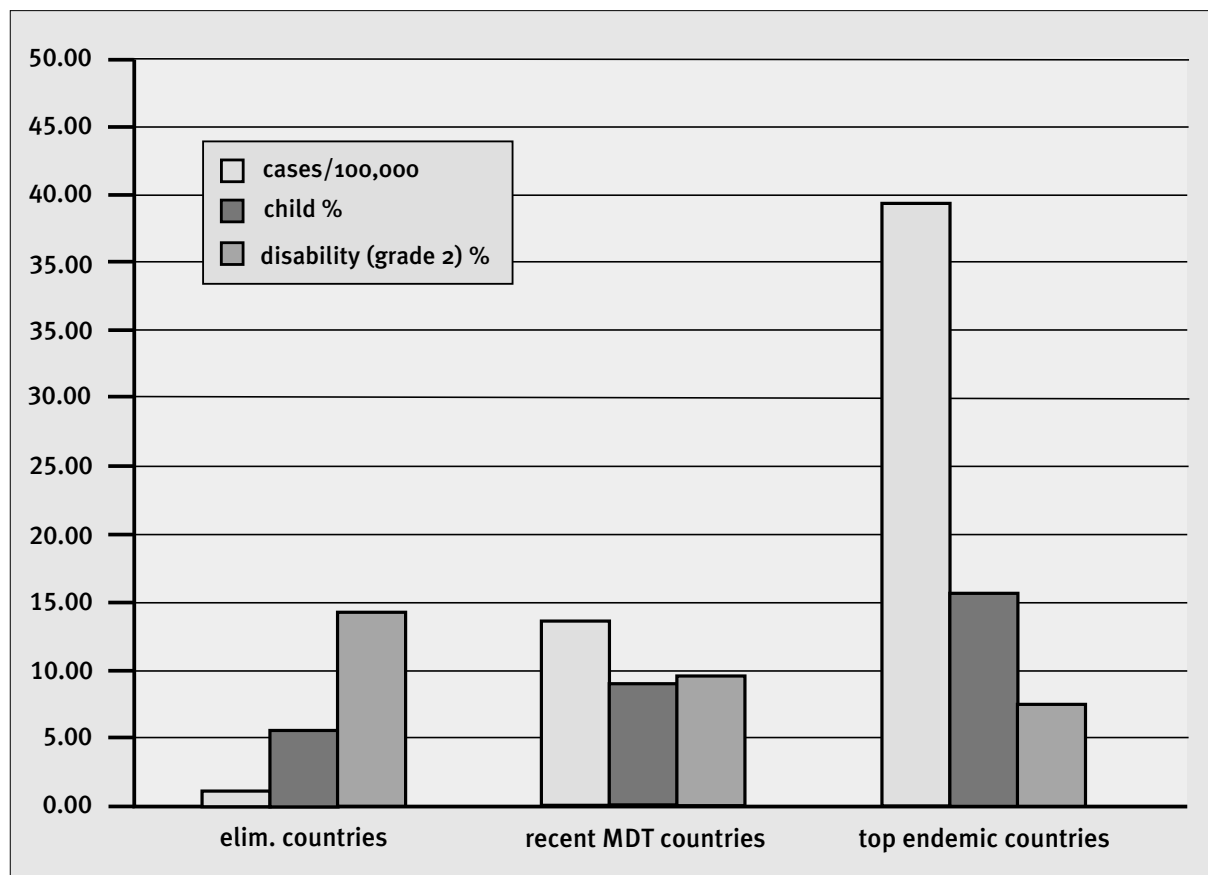
¹For people interested in statistics, the correlation coefficients of 0.67 (Maranhão) and 0.59 (Amazonas) are reasonably high.

Example 7

This example relates to indicators 2, 4 and 6 (case detection rate, child proportion and disability proportion). It is notoriously difficult to make comparisons across countries. Nevertheless, in its *Status Report 1998* WHO identified three groups of countries:

- ‘six countries having reached elimination level recently’ (Benin, Burkina Faso, Mexico, Pakistan, Thailand and Venezuela).
- ‘eight highly endemic countries having implemented MDT recently on a large scale’ (Bangladesh, Cambodia, Chad, Guinea, Madagascar, Mozambique, Myanmar and Nepal).
- ‘top three leprosy endemic countries’ (India, Brazil and Indonesia).

The comparison of new case detection rate, child proportion and disability grade 2 proportion (average 1985-97) reveals some interesting differences:



Average of new case detection rate per 100 000, child proportion and disability grade 1985-97 in three groups of countries as defined by WHO

It is to be expected that countries taking up leprosy control for the first time will have a higher disability proportion and a lower child rate, as they have to deal with the accumulated backlog of older and more disabled people with leprosy; this is clearly illustrated by the figure. It can equally be expected that low levels of transmission in countries having reached the

elimination target lead to the observed low child rate. On the other hand, it is surprising to see that a high disability grade 2 proportion seems to be quite characteristic for such countries; it is seen in all six countries included in this group. The majority of these new patients may have been detected in formerly untouched ‘pockets’. Thus, a high disability rate among the few newly detected cases in countries on the way to elimination seems to be quite a common phenomenon.

GLOSSARY

- *Accompanied MDT*. A strategy proposed by WHO where people with leprosy may, if they wish, receive the whole course of treatment at the time of diagnosis.
- *Backlog*. The accumulated number of people with leprosy who have not been detected during previous years.
- *Cohort*. A group of people who started treatment during the same period (usually a year).
- *Disability grade 1*. Hands and feet: anaesthesia present, but no visible deformity or damage. Eyes: problems caused by leprosy, but vision not severely affected as a result – lagophthalmos, iridocyclitis and corneal opacities must be considered as grade 2.
- *Disability grade 2*. Hands and feet: visible deformity or damage present. Eyes: severe visual impairment (vision worse than 6/60 or inability to count fingers at 6 metres) – as already mentioned, lagophthalmos, iridocyclitis and corneal opacities must be considered as grade 2.
- *Incidence*: The number of new cases of a disease appearing over a given period of time.
- *Incubation period*: For an infectious disease, the period between the infection and the development of clinical signs.
- *MB or multibacillary case*. A leprosy case with more than five skin lesions or at least two enlarged peripheral nerves or positive slit skin smears (if examined).
- *MDT or multidrug therapy*. The WHO MDT consists of two drugs given for six months for PB cases, and three drugs given for 12–24 months for MB cases.
- *PB or paucibacillary case*. A leprosy case with no more than five skin lesions, no more than one enlarged peripheral nerve and no positive slit skin smears (if examined).
- *Prevalence*. The number of cases of a disease existing at a specific time. In practice, what is available is the registered prevalence.
- *Reaction*. An inflammatory episode that might occur during the course of leprosy.
- *Reliability*. The correctness of the method of measuring.
- *Relevance*. The usefulness of the results of measuring.
- *ROM*. A combination of rifampicin, ofloxacin and minocycline administered in a single dose in some countries to treat people with leprosy who present with a single skin lesion.
- *Validity*. The ability of a method or a test to find what the investigator is looking for.

ANNEX 1: ILEP B1 FORMS



Questionnaire B1a MDT and Prevention of disabilities

Projects using the new short drug regimen recommended by WHO *

Project No.	Project name	Reporting year

Population covered (Pop)

Patients registered for MDT

MB	PB	TOTAL
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One dose MDT treatment = 4 week or a month medication

101	Number of new cases detected during the reporting year and never treated before			
101a	Amongst 101, number of cases with single skin lesion who received single dose ROM			
102	Amongst 101, number of children (0-14 years)			
103	Amongst 101, number of cases who have undergone disability assessment at diagnosis			
104	Amongst 103, number of cases with WHO disability grade 1			
105	Amongst 103, number of cases with WHO disability grade 2			
106	Number of PB cases who started MDT treatment during the period 1 January – 31 December, one year previously			
107	Amongst 106, number of cases who completed 6 doses of MDT within 9 months			
108	Number of MB cases who started MDT treatment during the period 1 January – 31 December, two years previously			
109	Amongst 108, number of cases who completed 12 doses of MDT within 18 months			
110	Number of patients registered for MDT at the end of the reporting year			

Relapses after MDT

111	Number of relapses after MDT recorded during the year			
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* See list of definitions

QUESTIONNAIRE B1a: List of definitions

PB	Paucibacillary Leprosy	Leprosy patients with a maximum of 5 skin lesions and not more than one nerve trunk damaged. If slit-skin smears are examined, they must be negative.
MB	Multibacillary Leprosy	Leprosy patients with more than 5 skin lesions or more than one nerve trunk damaged or with positive slit-skin smears.
Pop	Total population in the area covered by the programme	Population in which leprosy cases occur. Please report the most recent reliable figure. If you treat patients from outside your official project area, please specify this in an explanatory note.
101-110	Patients registered for MDT	Patients who are receiving MDT (multidrug therapy) that is treatment with any authorised combination of anti-leprosy drugs: e.g Dapsone, Rifampicin, Clofazimine, Ofloxacin, Minocycline.
101	New case of leprosy	A case of leprosy is a person showing clinical signs of leprosy, with or without bacteriological confirmation of the diagnosis, and requiring MDT. A new case of leprosy is a person fulfilling the above criteria who has never been treated previously with anti-leprosy chemotherapy.
101a	Single dose ROM	Single dose of a combination of Rifampicin, Ofloxacin and Minocycline. This combination is recommended in some countries for the treatment of single skin lesion PB leprosy
103	New cases who have undergone a disability assessment	Only report those cases who were assessed for disability in their eyes, hands and feet at diagnosis
104	New cases with WHO disability grade 1	Hands and feet: anaesthesia present, no visible deformity or damage present. Eyes: eye problems due to leprosy present but vision not severely affected as a result. (vision 6/60 or better; ability to count fingers at 6 metres).
105	New cases with WHO disability grade 2	Hands and feet: visible deformity or damage present. Eyes: severe visual impairment. (vision worse than 6/60; inability to count fingers at 6 metres).
106-109	Patients completing MDT	Patients who have stopped their MDT treatment after successfully completing the prescribed course of treatment. For PB patients, adequate treatment with the WHO recommended MDT regimen is completion of 6 doses of MDT within 9 months. For MB patients, adequate treatment with the WHO recommended MDT regimen is the completion of 12 doses of MDT within 18 months. If in a country or project, some MB patients are treated with a 12-month MDT regimen and some others with a 24-month regimen, all patients should be considered as having completed MDT once they have received at least 12 doses of MDT in 18 months, and this even if, individually some patients receive additional treatment. (One dose = 4 week medication)
111	Relapses after MDT	Patients who had previously completed a course of MDT as prescribed but have now relapsed and are registered for Chemotherapy. Relapses should be reported according to the original classification of the disease.

References WHO Expert Committee on Leprosy, Seventh report. Technical report Series 874, 1997.

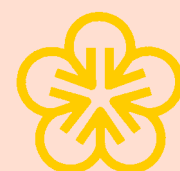
ILEP Medical Bulletin N°14 Operational Guidelines for the Introduction of new MDT Regimens for the Treatment of Leprosy , 1998.

QUESTIONNAIRE B1a: List of indicators
Tot = total
Div = divided by

Indicators		Formulas	Calculations
Prevalence			
1	Total number of leprosy cases registered for chemotherapy at the end of the reporting year	110 Tot	
2	Prevalence rate of leprosy cases registered for chemotherapy at the end of the reporting year per 10 000 population	(110 Tot div Pop) X 10 000	
Case detection			
3	Total number of new leprosy cases detected during the reporting year	101 Tot	
4	Percentage of new MB leprosy cases amongst the total new leprosy cases detected during the reporting year	(101 MB div 101 Tot) X 100	
5	Case detection rate during the reporting year per 10 000 population	(101 Tot div Pop) X 10 000	
6	Percentage of children among the new leprosy cases detected during the reporting year	(102 Tot div 101 Tot) X 100	
Disability assessment			
7	Percentage of new cases who have undergone a disability assessment	(103 Tot div 101 Tot) X 100	
8	Percentage of new cases with WHO disability grade 1	(104 Tot div 103 Tot) X 100	
9	Percentage of new cases with WHO disability grade 2	(105 Tot div 103 Tot) X 100	
MDT completion			
10	Number of cases with single skin lesion who received single dose ROM	101a PB	
11	Percentage of PB patients completing 6 doses of MDT amongst those expected to complete their MDT treatment. To be calculated for a one year cohort intake.	(107 PB div 106 PB) X 100	
12	Percentage of MB patients completing 12 doses of MDT amongst those expected to complete their MDT treatment. To be calculated for a one year cohort intake.	(109 MB div 108 MB) X 100	
Relapses			
13	Total number of relapses after MDT treatment for MB leprosy recorded during the year	111 MB	
14	Total number of relapses after MDT treatment for PB leprosy recorded during the year	111 PB	

ILEP - the International Federation of Anti-Leprosy Associations is a federation of 17 non-governmental organisations. ILEP supports medical, scientific, social and humanitarian activities for the relief and rehabilitation of people affected by leprosy. Through its member associations, ILEP works in almost every country where leprosy is endemic.

The ILEP Medico-Social Commission provides technical advice to ILEP Members in order to improve treatment, to prevent disability and to promote acceptance of those affected by leprosy. ILEP also supplies a range of materials for health professionals on leprosy.



ILEP