Conferência / *State of Art*

Eliminação no período pós-eliminação / *Monitorization of post elimination period*

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"Epidemiologists fall into two categories, thosewho cannot predict the future and thosewho know they cannot predict the future."

First let me say how honoured I am to have been invited to take part in this important Congress here in Brazil. Secondly, let me apologize for not being able to cover fully the subject I was to address, namely: 'Monitoring the post-elimination of leprosy'. This is because the definition of eliminating leprosy as a public health problem is not yet clear enough to envisage a 'pos elimination' phase. Of course, it will be theoretically easy to devise a strategy for leprosy 'eradication' and its monitoring but, at this stage, I do not believe that this will be useful. I strongly believe that endemic countries still have a lot to do in implementing and monitoring activities leading to elimination. Countries that have already reached elimination have no need to monitor the pos-elimination phase. Indeed, when leprosy is reaching very low levels, the comunity and public health authorities know by experience that there is no risk of re-emergence and that setting-up a surveillance system for a rare disease that is unlikely lo cause an epidemic is not cost-effective. In this context, the best we can do is to implement a system for monitoring that is likely to continue after elimination. This system will have to be relatively simple, effective and well-integrated into the national information systems.

My presentation is base on five main topics:

(1) The basis of monitoring leprosy elimination;
(2) The issues related to the concept of elimination and its monitoring;
(3) The global monitoring of leprosy elimination;
(4) The basic requirements at the national level for monitoring elimination and beyond, and
(5) The perspectives within the overall context of health services

Introduction

WHO-recommended MDT is recognized as a major technological improvement in leprosy control. In several countries, MDT has provided governments with the opportunity to give greater priority to leprosy and to strengthen their political commitment to its elimination, MDT has made possible the strengthening of health services for leprosy elimination. The cost-effectiveness of MDT and its impact has resulted in an increase in resources for leprosy elimination activities, including those from bilateral and international agencies, as well as NGOs, both national and international, in a number of countries where leprosy is a public health problem.

Leprosy elimination, based on MDT, has had a tremendous impact on disease prevalence and, consequently, on the disease burden and workload. This impact has led to the concept of eliminating leprosy as a public health problem with the assumption that, below a given level of prevalence, disease transmission will be partially or totally interrupted.

Although the prevalence of leprosy is relatively easy to monitor, its epidemiological characteristics have made evaluation of its transmission trends extremely difficult. The general impression among experts is that the epidemiological pattern of the disease has changed considerably during the past decade. These changes are reflected by the clinical

profile of newly detected cases: an increasing proportion of patients diagnosed with a single lesion; variations in the proportion of MB patients; and very few high BI patients. In addition, there are visible changes in the prognosis of the disease during treatment and a significant reduction in the risk of becoming disabled. All these changes could be explained by a combination of factors, e.g. the historical trend of the disease; the impact of interventions; the efficacy of chemotherapy and the role of improved health services. The implementation of MDT has also introduced changes to the description of the disease, case definitions, the perception of leprosy by communities and the status of patients. Available information shows that the cure rate with MDT is more than 99%, even when applied in areas with relatively poor health services.

The most obvious impact of MDT is the reduction in the risk of an infected person transmiting the disease to others. It is generally belived that a single dose of MDT kills enough bacilli to make both PB and MB patients non-infectious. Leprosy elimination, based on MDT, is believed to improve the effectiveness of case detection and, in so doing, gives a clearer picture of the overall leprosy problem. The use of standardized and tested procedures to adjust detection rates (according to programme coverage), the duration of the programme, standardization according to age and sex, the use of indirect indicators (proportion of disabled among new cases), and overall cohort analysis, would give valuable information in assessing the level of disease transmission within the community. In many programmes, MDT implementation has improved the quality of case-finding and case-holding by improving patient and community awareness and by increasing patients' confidence in health services.

A less obvious, but essential impact of MDT, is the use of the public health approach in eliminating the disease. The introduction of standardized definitions and indicators, as well as the implementation of national information systems, has been a tremendous achievement in the history of leprosy. Thanks to visionary leprologists and epidemiologists who have designed (under the umbrella of WHO) the system which is still in use today, Brazilian experts have played, and continue to play, a key role in this.

1. Basis of leprosy elimination monitoring
Definition and measurement
Definitions

To quote Newell: 'there is no definite, finite or absolute test, sign or finding which can be said to divide a person with leprosy infection or leprosy illness from the rest of the population". Clinical, bacteriological, histopa-thological and immunological tools are all unsatisfactory with regard to reaching a high positive predictive value for screening leprosy in the community.

Leprosy is defined as a chronic disease affecting humans, resulting from infection with *Mycobacterium leprae* affecting mainly the nerves and skin. The definition has not changed over time but is of very little use for operations and epidemiological studies. Leprosy is coded as A 30 in the International Classification of Diseases, Edition 10. This classification categorizes leprosy into indeterminate (A30.0), tuberculoid (A30.1), borderline tuberculoid (A30,2), borderline (A30.3), borderline lepromatous (A30,4), lepromatous (A30.5), others forms (A30.8) and unspecified (A30.9). The sequelae of leprosy are coded as B92. In the previous International Classification of Diseases, Edition 9, leprosy was coded 030.0, lepromatous leprosy 030.0, and tuberculoid leprosy 030.1.

The definition of a case of leprosy is not universally accepted. This is because there is no gold standard to identify leprosy infection for the majority of patients. The diagnosis of leprosy is mainly based on clinical grounds and therefore lacks specificity, notwithstanding intra-and inter-observer variations.

In view of the above, WHO proposed an operational definition of a case of leprosy as "a person showing clinical signs of leprosy, with or without bacteriological confirmation of the diagnosis, and requiring chemotherapy". This definition excludes individuals cured of the infection but having residual disabilities due to leprosy.

The classification of various forms of leprosy is also controversial. For operational purposes, WHO proposed classifying patients as either paucibacillary (PB) or mutibacillary (MB) leprosy cases. The paubacillary group

includes smear-negative indeterminate tuberculoid and borderline tuberculoid cases, the multibacillary group includes all smear-positive cases. However, even this simplified classification is not easy to implement, mainly because the majority of endemic countries do not have a good network of laboratory services allowing the classification of cases based on bacteriological criteria. For this reason, WHO has recommended classifying patients according to clinical criteria wherever skin-smear facilities are not available or are unreliable.

Most endemic countries use operational definitions proposed by WHO for the preparation of their annual reports. This has greatly contributed to standardized information, but can make the comparison of time series difficult, particularly with information collected before the 1980's.

With regard to disabilities caused by leprosy, the situation is more complex and several grading systems have been developed. In 1969, WHO proposed a simple classification which was modified in 1988. The WHO three-grade classification (0-1-2 grades) is a simple tool allowing rapid assessment of the problem in the field.

Data sources

In many parts of the world sample surveys, and even total population surveys, were conducted to assess the magnitude of the leprosy problem at the nationl level (Burkina Faso, India, Indonesia, Mayanmar). These surveys were very useful in enabling a better understanding of the distribution of the disease and in standardizing procedures. They were acceptably cost-effective when the prevalence of the disease was about 1%. However, prevalence and incidence of leprosy are decreasing in most endemic countries and surveys have become too expensive, time-consuming and often inadequate. Statistical methods to assess small rates, especially for unevenly distributed events, are less robust. For these reasons, sample surveys are conducted only special situations and in limited places, mainly for research purposes. However, the results of such surveys do not help in estimating the leprosy problem at the national or global levels.

With the implementation of the global strategy for the elimination of leprosy as a public health problem, it was decided to use existing information and to improve existing information systems in order to update estimates annually.

Most the information available on the leprosy burden in the world is based on registrations. Annual reports from most endemic countries provide by type of leprosy point prevalence, annual detection, treatment coverage and the number of patients removed from registers. Some countries provide more details, such as age-group specific detection (below 15 and adults), the proportion of multibacillary patients among new cases, and the proportion of disabled patients (WHO grade 2) among new cases.

Information generated by national information systems is supplemented by:
- Surveys: total population surveys, selected population surveys, random sample surveys, LEM and special monitoring exercises; - WHO questionnaires;
- Regular national programme evaluations; - Reports from consultants and publications; - Prospective studies for research purpose: vaccine trials in India, Malawi, Venezuela and large-scale drug trials.

It is clear that data collected by the majority of programmes are mainly action-oriented and provide limited information on the epidemiological pattern of the disease. However more detailed information is collected through special studies, or through computerized information systems, e.g. Brazil. In addition, epidemiometric modelling, as developed by Profesor Lechat and others, is used for a better understanding of the transmission of the disease and the impact of control measures. A new leprosy simulation model is being developed to enable the best use of existing information, to validate estimates, and to predict future leprosy trends according to various control strategies.

Essential indicators: advantages and disadvantages

I. Prevalence rate

The point prevalance rate is defined as the number of cases registered for chemotherapy at the end of the year divided by the population in which the cases have occurred. This indicator reflects the magnitude of the problem and helps in planning and

evaluating elimination measures. It is useful to express to prevalence using absolute numbers and rate per 10 000. This indicator is well accepted and understood. Some countries and experts prefer to use the period prevalence in order to better reflect the annual workload for planning purposes. However, considering that the elimination target is set as a point prevalence, endemic countries should continue to report it. The main difficulty regarding this indicator is its interpretation at various geographic and population levels. There is a need to propose solutions in defining denominators. In many endemic countries, estimated prevalence is used for planning purposes. This indicator should be interpreted with caution, especially as we come closer to the elimination target. There is a need to:

- refine the definition of elimination at the country level, for example, prevalence below 1 per 10,000 over a period of time, or in all districts, or using absolute numbers at a given level;
- develop new methods for evaluating the leprosy burden at the community level.

II - Detection rate: Newly detected cases

This rate is defined as the number of previously untreated cases detected during a year, divided by the population in which the cases have occurred. This indicator is used for estimating the "true" incidence of the disease in a given population when analysed in conjunction with the proportion of disabled patients (grade 2) among newly detected cases. It should always be related to the prevalence, and be expressed using absolute numbers and rate per 10 000. In the past, this indicator was not always reported by the programmes, making analysis of trends difficult. Detection rates have the same limitations as the prevalence rate, the difficulty being to clearly define denominators. The prevalence/detection ratio is very useful in assessing programme performance, both in terms of detection and duration for which cases are kept in the prevalence. Though it has no epidemiological value, it should continue to be used for assessing case management and planning drug supply needs.

Detection and detection rates need in-depth analysis and it is important to clearly define what it precisely reflects. Detection

should be analysed in conjunction with programme performance and coverage, and information should be collected on the duration of the disease before actual diagnosis. The proportion of MB and the proportion of disabled at the time of detection are not robust enough to extrapolate incidence from detection. In the near future, especially after reaching the elimination target, detection should replace the prevalence as the key indicator for targeting and assessing programmes.

III - Proportion of patients with disabilities grde 2 among new cases

This is defined as the proportion of cases with grade 2 disability among the total number of newly-detected cases during the year. This indicator is supposed to reflect the effectiveness of the programme in terms of delay in detection and the level of awareness about the disease in the community. This proportion is likely to be influenced by the type and age distribution of new cases and by operational aspects of case-finding methods, particularly when programmes reach low levels of case-detection. Moreover, the collection of data to calculate this indicator is difficult, especially for reporting at the national level.

IV - MDT coverage

According to the Technical Report Series (TRS) 716 on Epidemiology of leprosy in relation to control, this is defined as the proportion of cases receiving MDT at any time during the year among the total number of cases appearing on the register during the year. This indicator reflects the programme performance in achieving optimal MDT coverage and helps to set targets.

In practice, most of the programmes report `point' MDT coverage which is the proportion of patients on MDT among registered patients at a given point of time. In some instances, MDT coverage is overestimated by using a "period" numerator and a "point" denominator.

For a number of years, the definition of MDT coverage was not fully standardized, making interpretation difficult. Today, all endemic countries report the "point" MDT coverage. However a number of problems remain, such as disagreement on the definition of what MDT is and whether defaulters should

be included or not in the numerator. Sometimes, MDT coverage is interpreted as geographic coverage.

There is no doubt that MDT coverage is a very useful indicator for targeting purposes and for assessing programme performance. However, one should not overestimate its meaning: too often 100% MDT coverage gives a false "good image" of the programme. It should always be interpreted in conjunction with programme coverage, detection and cure (MDT completion) rate. More information should be collected on geographic coverage of programmes, MDT acessibility, and the "quality" of MDT. There is an urgent need to propose a definition for "defaulters" and to implement methods for assessing cure rates (cohort reporting) at the district and national levels.

V - Cure rate

This rate is defined as the proportion of registered cases cured of leprosy. This indicator is extremely useful in monitoring treatment with MDT at all levels. It can be calculated using cohort reporting, the cohort being defined as a group of patients starting their treatment at the same period of time. This system needs to follow retrospectively 9-month (or 1 year) cohorts of PB patients and 3-year cohorts of MB patients (assuming that the duration of treatment is fixed). While cohort reporting is easy to implement at the peripheral level, the compilation of information at the upper level is difficult. For this reason, the annual absolute number and the cumulative number of cured patients are used to approximate the cure rate. At the global level, it becomes possible to estimate an "average cure rate" if certain fctors are known, e.g. the duration of the programme; the number of patients treated with MDT and whether the duration of treatment is standardized. There is a need to promote the implementation of cohort analysis of treatment outcome, at least in some selected projects, during supervisory visits or evaluations.

VI - Relapse rate/Relapse risk

This rate is defined as the number of individuals who were cured of leprosy and then showed new signs of the disease. It is well known that this rate is very much related to time and its calculation requires the follow-up of cohorts of cured persons. The relapse rate has to be expressed in person/years of follow-up and the relapse risk, as an annual probability for each cured patient to relapse. This type of follow-up is not practicable as a routine measure and for this reason, absolute and cumulative number of relapses are used. At the global level, knowing the number of patients cured of leprosy, the duration of the programme and the number of relapses, it becomes possible to estimate an "average relapse rate".

VII - Additional indicators
1. Treatment outcome indicators

- Cure rate or treatment completion rate;
- Defaulters and defaulter rate: There is a need to standardize this indicator, and to clearly define for how long defaulter patients should be maintained in the registered prevalence. WHO has defined a defaulter as a patient missing treatment for more than 12 months, even several tracing attempts. Defaulters are removed from the register and no longer included in the prevalence;

  Proportion of patients cured without disabilities, or
- Cumulative number of disabled patients.

2. Programme performance indicators

- Case-finding: number of MB cases missed. Age-specific incidence or incidence in children;
- Geographic coverage with MDT services;
- Drug utilization during the year;
- Number of healthy years of life lost due to disabling leprosy or Disability-Adjusted Life Years (DALYs).

2. Issues related to monitoring of elimination

The assessment of impact of interventions becomes particularly important when considering the leprosy elimination goal. Taking into account the epidemiological characteristics of leprosy, and the large number of grey areas in our understanding of the disease, it is important to select carefully the outcome indicators we would like monitored. Incidence is the most relevant, but may be the most difficult indicator. Prevalence, as a composite indicator, varies too much depending on operational components of

interventions. Incidences of disability and of MB cases could be very useful to evaluate the leprosy situation.

The uneven distribution of leprosy, as well as the role of various local factors, call for caution when extrapolating the results from one place to another. In order to use sentinel systems as a decision tool, one should make sure that these factors are taken into account. Finally, there is a clear need to develop a flexible tool to enable programme managers at various levels in an endemic country to analyse the results of their work, increase their motivation to improve the programme and to convince the decision-makers.

The impact of MDT

While the positive impact of MDT on various aspects of leprosy treatment and control is widely recongnized, it is difficult to clearly demonstrate changes in the transmission of the disease. This may be because the epidemiology of leprosy was, and still is, not very well understood. Recently, following the introduction of the concept of eliminating the disease as a public health problem, many questions have been raised about the possibilities for decreasing, or interrupting the transmission of the disease, mainly by implementing chemotherapy in all known cases. It is clear that many aspects have changed, that the leprosy burden has been reduced, and also that the incidence of the disease continues to decrease in many parts of the world. What ramains unclear is what aspects are attributable to the efficacy of MDT, to the efficiency of control based on MDT or to other factors. MDT implementation refers to all activities related to leprosy elimination, including treatment with MDT and, therefore, the potential impact of both operational and technical components should be discussed.

Prevalence of leprosy and disease burden

It is clear that MDT programmes decrease the number of patients in need of chemotherapy and thus decrease prevalence. This reduction is also related to the operational impact of MDT: improved case-finding, case-holding and shorter duration of treatment. Some could argue that such a reduction is artificial or "administrative", but one should consider the efficacy of MDT in

reducing the size of the reservoir, both in quantitative and qualitative terms. Comparated to previous interventions, MDT sterilizes the source of infection and prevents the selection of resistant mutants, this prevents re-entering of patients in the prevalence pool as relapses.

One important indirect impact of the implementation of MDT has been to reduce the disease burden and thus the workload. Health workers can spend more time on activities such as case-finding, creating community awareness and the prevention of disabilities. In some countries, this has helped the integration of leprosy control into general health services.

Another important impact of MDT operations has been to improve early case-finding and to increase opportunities for dianosis. As a result of this, the detection figures in many programmes increased significantly after MDT implementation, but then became stagnant. As a result, the proportion of newly-detected patients with disabilities has been reduced. However, these changes were not observed even in well organized programmes prior to the introduction of MDT.

Incidence of leprosy and transmission

Since 1992, the global detection of leprosy remains stable between 500 000 to 600 000 cases per year. This stability reflects a combination of epidemiological and operational factors, but so far it is impossible to know their relative proportions. In many countries detection and detection rates are constantly decreasing. However, this was observed even before MDT implementation: it is difficult to establish whether or not MDT has accelerated the decline in leprosy incidence. At the local level, where information is available, it is apparent that the incidence of leprosy is declining in many parts of the world. The annual average decline varies from 5% to 20%. In some countries, MDT introduction seems to have accelerated the decline in incidence (French Polynesia, India, Thailand), while in others (Malawi) its impact has not been significant. Many factors are contributing to the reduction of incidence, and many biases have to be considered before any conclusion can be reached.

In addition to detection figures, other changes could give indirect indication of the potential impact of MDT in reducing the transmission of leprosy. Na example of such

indicators are: the incidence of MB cases or the proportion of MB cases among new cases; age-specific incidence, or mean age at onset.

In support of these changes, there is some evidence that the epidemiological pattern of leprosy has been modified in many countries. For instance, an increasing proportion of new cases are single lesion (up to 80% in some districts in India). The classical American, African and Asian profile of leprosy is no longer valid. In Africa, for example, the proportion of MB cases among those that are new has increased significantly (up to 45% in some countries), whereas in America and in Asia PB cases are more frequent than previously. The extent to which this phenomenon reflects operational or epidemiological changes needs to be evaluated further.

Incidence of disabilities

There is some evidence that after starting treatment which MDT the risk of disability (grade 1 or 2) is reduced in a patient, compared to dapsone monotherapy. A cohort study conducted in Malawi indicates that risk is about 6% a year for PB patients. There is also some evidence that patients treated with MDT are less likely to be affected by permanent disabilities. This should be confirmed by long-term cohort studies.

MDT programmes have made a major impact on the incidence of disabilities in the community by facilitating early diagnosis. In many countries, the proportion of disabled patients (grade 2) at the time of diagnosis has decreased significantly. The combination of these two factors (reduction in incidence and earlier diagnosis) has had a definite impact on the overall prevalence of disabilities due to leprosy.

Prevention of relapses and resistance

Information available from special studies, as well as from routine control programmes, shows that:

- the annual risk of relapse, for both PB and MB patients, is about 0.1%;
- the risk to select mutant resistants is negligible (no cases reported).

It is estimated that between 500 000 to 1 000 000 relapses were averted following the introduction of MDT.

3. The global monitoring of leprosy elimination

In order to ensure the efficient implementation of the global strategy for the elimination of leprosy as a public health problem, WHO proposed that essential information on leprosy be collected and that national elimination programmes be assessed with respect to their effectiveness. The information system for monitoring the elimination of leprosy in endemic countries was developed in collaboration with experts and national programme managers. Information generated by the national information system is supplemented by WHO regional and national meetings, site visits by WHO consultants at the national and sub-national levels, reports from other agencies and NGOs, and regular national programme reviews in major endemic countries. Data collected by elimination programmes are mainly action-oriented and provide limited information on the epidemiological pattern of the disease. More detailed information is collected through special studies. Epidemiometric modelling is used to obtain a better understanding of the transmission of the disease and the impact of elimination measures.

Since 1995, WHO has monitored the drug supply process from drug procurement to drug use at the peripheral level. Special methods for this have been developed and implemented since 1996.

The global leprosy information system

A simplified global information system based on six essential indicators has been developed and implemented in all endemic countries. This system is computerized in WHO and in some major endemic countries. Its functions are:

- to report on the occurrence of leprosy and elimination activities;
- to assess the performance of national programmes; and
- to evaluate the impact of elimination programmes on the progress towards elimination.

The information collected is used for setting priorities, for assessing the overall performance of the global strategy, and for modifying plans of action as needed.

Review of national leprosy elimination programmes

WHO has developed guidelines to assist programme managers in determining priorities with regard to the elimination of leprosy, and to suggest what specific actions might be taken. Programme reviews are organized and coordinated by LEP in selected endemic countries. They are based on information which can be collected by health staff under field conditions. Review teams consist of national participants involved in the leprosy elimination programme and - whenever possible - external participants, including international reviewers identified by WHO, and representatives of agencies and NGOs which have direct input in the programme. Every leprosy elimination programme is subjected to a periodic review by its manager and by WHO. In practice, these reviews generally concentrate on operational issues, logistics and resource allocation. Larger national programmes like those in Bangladesh, Brazil, Ethiopia, India and Myanmar are now undertaking what is known as an Independent evaluation of their programmes, involving experts from both inside and outside the country. These independent evaluations are very comprehensive, since the process uses several instruments for collecting data from different levels. Such reviews have produced excellent documentation and recommendations for future plans of action. However, there are some weaknesses such as a lack of standar-dization, difficulties with data analysis and interpretation, limited feedback and high cost.

Monitoring drug supply

WHO has developed an information database for monitoring the whole flow of drugs from the supplier to the recipient country. A strategy for strengthening national capacity in MDT management has also been developed which includes guidelines and workshops on drug supply and technical support to help countries to identify problems of logistics. Following the introduction of basic guidelines in durg management last year, WHO intends to continue strengthening the overall management and administration of the various national MDT supply programmes. As an aid to producing periodic reports, facilitating inventory control, the analysis of drug flows and future drug

requirements, use will be made of spreadsheet and database management systems wherever computer facilities are available at the country level. Athough WHO is responsible only for the procurement and supply at the national level, mechanisms aimed at monitoring the drug flow and drug use within countries have been developed and implemented during the last two years.

Geographic information systems

Of particular interest to LEP is computerized mapping, whereby the distribution of "pockets" of leprosy prevalence not yet fully covered by MDT can be instantly visualized and monitored. Inventories of comparable geographical data such as administrative boundaries and the location of villages can be made available for each selected country, with related databases comprising health infratructure, disease indicators and so forth. The network will, in effect, provide a map of the epidemiology of leprosy which is essential for the accurate monitoring of the progress towards elimination.

LEP is developing a database of all health facilities in those countries where leprosy is endemic. This database will eventually form the core of a geographical information system (GIS) showing all locations where leprosy cases are registered and are being treated with MDT. In a Leprosy Elimination Programme, a GIS system can help to monitor the extent of MDT coverage at the regional, district or even sub-district level. It can also provide a graphic analysis of epidemiological indicators over time, the spatial distribution and the severity of the disease, identify pockets of high endemicity and indicate where there is a need to target extra resources.

Computerized mapping systems such as GIS provide an excellent means of analysing epidemiological data, revealing trends, dependencies and inter-relationships that would otherwise remain hidden in data shown only in tabular format. GIS can therefore be seen as a valuable management tool in the elimination programme, strengthening national, regional and sub-regional capacities in surveillance and monitoring.

Communication through the Internet

The WHO Action Programme for the Elimination of Leprosy has established an Internet "home-page" that gives information on

the disease and displays up-to-date statistics. The Web site address is: http://www.who.ch/programmes/lep/lep_home.htm. Most of the documents and publications published by the Programme are posted on the Internet. A discussion list was opened recently and the use of e-mail is encouraged. To subscribe to the discussion list, one should send the following message to majordomo@who.ch:subscribe leprosy.

Special monitoring and LEM (Leprosy Elimination Monitoring initiative)

The assessment of interventions becomes particularly important when considering the leprosy elimination goal. Taking into account the epidemiological characteristics of leprosy and the large number of grey areas in our understanding of the disease, it is important to select carefully the outcome indicators that we would like monitored. Incidence is the most relevant indicator, but it may be the most difficult one. Prevalence, as a composite indicator, varies considerably, depending on the operational components of interventions. Incidences of disability and of MB cases in the community could be very useful to evaluate the leprosy situation. The uneven distribution of leprosy, as well as the role of various local factors, calls for caution when extrapolating the results from one place to another.

There is a clear need to develop a set of indicators that will enable programme managers in endemic countries to analyse the results of their work, increase their motivation and convince the decision-makers. The main purpose of Special Monitoring is to develop a limited number of indicators that can describe the performance of MDT services at the national, sub-national and peripheral levels of the most endemic countries. The term "MDT services" refers to comprehensive health activities, including: diagnosis, classification, prescription of treatment, delivery of MDT, case- holding and cure of leprosy patients. It is expected that such indicators will help decision-makers and programme managers to assess progress towards the elimination of leprosy at the most peripheral level. This will also assist in planning and implementing appropriate action and measuring its impact. In some situations, these indicators could help in identifying areas where LEC or SAPEL could be implemented. It

is expected that the techniques for collecting indicators could be implemented in a standard way by "monitors", in collaboration with national programmes and WHO.

The principal objective of the special monitoring is to assess the extent and quality of MDT services at the national, regional, district and sub-district levels and to identify potential problems. If major structural problems are uncovered, WHO will assist in making an in-depth evaluation of the system. Details of all findings will be provided to national programme managers, and indicators will be published at least once a year in WHO's internal reports. The design of the monitoring will depend on many factors and may vary from one country to another.

However, the monitors will collect key indicators on the following issues:

- Availability of MDT blister-packs and geograph coverage of MDT services; this will be based on a cross-sectional survey of randomly selected health facilities.
- Quality of patient care: diagnosis and case-holding. This will be based on a review of individuals records and leprosy registers. Quality of MDT services will be reviewed on the basis of cohort analysis.
- Analysis of elimination indicators: internal validity of information on prevalence and detection (crede and specific) and analysis of trends. This will be based on analysis of existing information and review/updating of leprosy registers.

4. Basic requirements at the national level for monitoring elimination and post-elimination

It is becoming increasingly important to improve information systems on leprosy. However, a special information system will become less relevant as the number of cases will be small. National information systems for the surveillance of leprosy could be outlined as follows:

4.1 Data sources

According to the strategy in use (vertical, integrated) the data on cases registered for chemotherapy are available using individual clinical files, patient identification forms or special registers for leprosy patient. This information has to be collected from all health units dealing with leprosy, including specialized

institutions, hospitals and private practitoners. Wherever the elimination programme is integrated or partially integrated, there is a need to simplify recording and to use clear definitions. The timing of recording is continuous.

4.2 Data flow

The flow of data from the peripheral level has to be performed by supervisors (specialized or multipurpose supervisors) and at this stage the use of standardized procedures is essential. Whatever information is collected to manage individual cases, the relevant data will have to be summarized using a simple form. This form should be simple but comprehensive and should meet the needs of the requested information. Calculation of rates should, as much as possible, be avoided at this stage. Quarterly reporting is sufficient at the intermediate level and annual reporting sufficient at the national and global levels. The compilation, analysis and feed-back should be carried out at intermediate and national levels and should be computerized. The necessary compilation, checking, calculation, feed-back, publication and distribution can be undertaken by programme managers at all levels.

4.3 Data to be collected

(I) General information

Name of the geographic location, date of the report and data source. Data on demography are considered as optical because this information is available from other existing databases which could be linked with other databases

(II) Data required for surveillance

Morbidity: absolute number of cases at the beginning and at the end of the period.
Transmission of the disease: absolute number of cases newly detected during the period and the distribution of cases by type of leprosy (Single lesion PB, PB and MB) by age-group and according to disability grading.

(III) Data required for monitoring

• Case detection: Absolute number of cases newly detected during the year, distribution of

cases with or without disabilities at the time of diagnosis and distribution by type of leprosy.
• Cases treated with MDT: Absolute number of cases who received at least one dose of MDT during the year and distribution according to the type of leprosy.

(IV) Data required for evaluation

• Morbidity and transmission as described under (II)
• Cases having completed MDT treatment: Absolute number of cases having completed their MDT treatment as prescribed (who can be considered as cured from leprosy)
• Absolute number of relapses and distribution by type of leprosy

It is clear that this system is still very demanding and should be, as much as possible, part of the existing national health information systems. When prevalence becomes very low at the national level, it is essential to assess the situation at the sub- national level. There can be wide disparities within individual regions of countries. In order to fully interpret and manage both these interregional and intra-regional disparities, the development of an information system focussed at a more micro level than generally used at present is crucial.

4.4 The District level database

The district should be the geograph unit for analysis, as it can be seen as the most peripheral geographical and administrative area of government which maintains power and responsability for carrying out the duties of major ministries, such as health, agriculture and education. Although detailed analysis of sub-district levels would have provided a far more accurate indication of actual trends, this would be more difficult to update on a regular basis However, a few countries, including Brazil, have already started their analysis of the leprosy elimination programme using sub-district level data.
The quality of analysis that the compu-terized database can provide depends entirely on the accuracy of the district level data recor-ded, whether all districts are included, and how regularly the data is update. Provided all the relevant data is recorded, the system can be a very powerful management tool for any disease

elimination programme. Using district level data as the basic "building block" of the information system, national programme managers will be able to:

- rapidly access relevant data such as prevalence, new case detection, grade 2 disability, etc. at a district, regional or national level, presenting the data in tabular format, as a chart, or as a map;
- analyse whether the type and quantities of MDT in stock are adequate for the existing caseload, in a given geographical area;
- identify under-served, difficult to access, or "problem" areas that may benefit from Special Action Projects (SAPEL) or Leprosy Elimination Compaigns (LEC);
- produce easy to undertand graphics presentations for decision-makers and donor agencies;
- monitor the progress being made towards elimination nationally, regionally and at the district level

5 - Perspectives and new issues arising beyond elimination

After reaching the elimination target and in the absence of precise tools for measuring leprosy infection and its transmission, there will be an important need for studying the epidemiological profile of leprosy. This will facilitate the development of new strategies and interventions for diagnosing and treating the very last cases of leprosy. In this context, Geographic Information Systems which are already in use in various sectors (e.g. agriculture, eduction, health) can be a valuable tool in strengthening the national, regional and sub-regional capacities in surveillance and monitoring.

5.1 Epidemiological studies

5.1.1 Population at risk, risk factors and infection

Geographic distribution, Leprosy clusters or foci

In a country where leprosy is endemic, there are large variations in epidemiological indicators in different parts of the country. In certain areas the transmission of the disease may seem very intense, and thus the population is considered at higher risk. However, it is very difficult to know whether this is because of geographic, human or others factors. Additional reservoirs, special modes of transmission, population immunity and behaviour could play a role in these areas. it could be interesting to map "leprosy clusters" and to estimate the environmental risk to contract the disease.

Age/Sex

Age-specific incidence probably varies according to levels of endemicity. In high endemic areas, age groups 10-15 and 40-50 seem to be at a higher risk. In this situation, one should also consider the age cohort effect. Males seems to be at higher risk (2/1) in most parts of the world. However, where prevalence is declining, the risk appears to be equal for both male and female.

Socio-economic factors

It is not yet possible to identify the major components of socio-economic factors that influence trends in leprosy, but such factors are probably of major importance. A composite indicator taking into account housing, household and income should be considered.

Immunity

- Factors stregthening immunity:

The most important factor to consider, despite the large geographic variations, is BCG immunization. Cohort BCG coverage by age group should be integrated in a model.

- Factors decreasing immunity:

While is so far no evidence that HIV infection increases the risk of leprosy, it is important to collect information on this matter.

Population at risk, denominators

Epidemiological data are often analysed for situations in which incidence and prevalence are relatively high and the affected population size is relatively constant. However, this might not be valid in the case of leprosy, where there may be endemicity in communities with rapidly changing populations. Small incidence rates and minor variations might become very difficult to analyse, and would require special methodologies.

5.1.2 Epidemiological trends

- Natural and historical trend of the disease

Time trends of leprosy vary according to the geographic situation. Wherever leprosy is declining, this decline has been associated with clustering of the disease, increased proportion of MB cases, older age at onset and both sexes being equally at risk.

- Detection/incidence

These key indicators pose a number of problems. It is necessary to develop a case-definition (for example clinical certainly scale) and to test its positive predictive value. The difficult problem of differentiating between detection and incidence is only important for programmes based on passive case-finding.

5.2 Geographic Information Systems

There are two basic elements to developing a GIS system for leprosy. The first, geographic element, involves the accurate recording of the location of each health facility in the country. A list must first be compiled of the health facilities with their full address, and if readily available, the geographical coordinates (expressed in terms of latitude and longitude position) of the health facilities. The inclusion of these coordinates uniquely identifies each health facility and enables its position to be digitally "mapped" on a computer with great precision. For developing a GIS system, a list of all health facilities, togheter with their geographical coordinates (where available) needs to be prepared, using a computer spreadsheet or database programme. All health facilities should be included, in both rural and urban areas, whether or not leprosy treatment is currently being carried out.

There are many potential sources for obtaining the geographical coordinates of health facilities: Ministry of Health or Planning, the Central Statistics Office, the Department of Land Suveys, university geographic depar-tments or other institutions. Where coordinates on each individual health facility may be unavailable, the coordinates of the nearest village might well be. Coordinates of the villages would be sufficient to start the development of a GIS database. If geographical coordinates for the health facilities are not available, it may be possible to approximate them by identify their position on existing maps. These maps need to be sufficiently detailed to include village names and positions. They may be obtainable from the relevant ministry or gover-nment department. Using these maps, pro-gramme managers will endeavour to digitise the position of the health facilities on a computer. In some countries, it may be possible for "unma-pped" health facilities (i.e. those Geographic Positioning System (GPS) technology.

The second element in developing a GIS system for leprosy is recording the relevant baseline data for each health facility. The most relevant data required for leprosy are as follows:

Location of the health facilities: this must be in a standardized address format for inclusion in the database. A maximum of five "administrative" levels can be shown (e.g. state, region, district, sub-district, village). The actual definition and names of the various "administrative" units may vary between countries and rural and urban areas. This information is included in the database as a textual equivalent of the geographic coordinates;

Number of Registered Cases: this is the current number of patients attending each health facility for chemotherapy. This data is used by the GIS system to indicate the varying point prevalence levels by geographic area, but when combined with historical data can also show how these levels change over time; Number of New Cases Detected during the Year: when considered together with other essential indicators, this can provide very useful information on the progress of the eliminination programme at various geographic levels;

Type of Leprosy Treatment Available: this information is useful to quantify the extent of MDT coverage at various geographic levels.

Most of the computerized mapping could be done at the national level if both the necessary facilities and trained personnel are available. Any local initiative (either by Government or NGO) should be supported to carry out these mapping procedures, including additional training in the use of GIS software and GPS techniques where considered necessary. The GIS software currently being considered for this

purpose is Maplnfo, wich can read Lotus 123, Excel spreadsheet files, dBase and FoxBase database files and several others. One obvious advantage that a computerized list has over a paper based reporting system is the ease with which data can be updated, revised and analysed. Another is the speed at which it can be transmitted via E-mail or the Internet (where these facilities exist at the national level)and yet still retain its original format.

Conclusions

While satisfactory progress continues to be made towards the elimination of leprosy as a public health problem in the majority of endemic countries, with national targets to reduce the prevalence below 1 case per 10 000 is likely to be reached by the year 2000, we cannot afford to be complacent about the situation prevailing at the sub-national levels.

We should aim to use existing information systems to monitor the elimination of leprosy at the most peripheral levels possible, using the best technology available to us. We should make full use of computerized databases, GIS, and the Internet as modern tools that can assist us in this process.

Once very low prevalence levels are reached, new challenges will emerge. The main one will be to justify the continuation of a sophisticated and demanding information system for leprosy alone. Therefore it is vital that essential information on leprosy is integrated within national health information systems. Finally, one should never forget that the aim of any information system is to assist patients in getting access to the best possible health care.

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