An Information System for Leprosy Control (OMSLEP Recording and Reporting System)[1]

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Leprosy control activities require the collection, analysis, and processing of various kinds of information. A relevant information system should therefore permit the following:

a) evaluation of the efficiency of programs within the context of established strategies and norms;

b) evaluation of the effectiveness of leprosy control methods with regard to the reduction of the problem from the epidemiological viewpoint and, if appropriate, from the social and economic viewpoints;

c) evaluation of the efficacy and productivity of certain program components.

The information collected should be simple. It should be regarded in a decision-making context, i.e., it is justified to collect a piece of information only if it leads to a decision. The information must be sufficiently elementary in nature so that it can be collected directly by the staff, possibly not specialized in leprosy, who are responsible for health activities at the most local level.

The information currently collected in the course of leprosy control activities is often complicated, copious, and at times redundant. Although some systems are well adapted locally, the diversity of information collected in the various systems and their lack of standardization effectively prevent comparisons. There is therefore a need to develop some kind of standard information system which will enable comparisons to be made between different services in different areas. Such a system would also be useful to collect the baseline data for specific field research projects related to the possible development of new strategies for leprosy control such as vaccination.

This study reports the various steps involved in the recent development of such a simplified information system for leprosy (the OMSLEP Recording and Reporting System).

METHODS

The study proceeded in two major steps:

1) The identification of the major components of a relevant information system for leprosy on the basis of objectives, program components, and local practice. This includes: a) an analysis of the types of information collected in leprosy control programs on the basis of the objectives of leprosy control; b) a description of the operational program components required to fulfill the objectives; c) the choice of indices for evaluating the efficiency of the program (operational evaluation); d) the choice of indices for evaluating the effectiveness of the program (epidemiological evaluation).

2) The design and testing of an appropriate system. This includes: a) a preliminary survey of existing information systems for leprosy; b) the design of an appropriate registration and follow-up model for individual patients based on the choice of relevant information and assembled in a logical time sequence consistent with current operational procedures; c) the design of a system for aggregation of the individual data into consolidated population summaries; d) field testing of the system for relevance, validity, and acceptability.

TYPES AND USES OF INFORMATION

The final reason for collecting information is to better achieve the double objective of leprosy control, i.e.:

1) curing, or at least minimizing the effect of the disease on the individual patient;
2) interrupting transmission in the population.

The final goal from a public health point of view is the reduction of incidence, i.e., the appearance of new cases, to zero or to an acceptably insignificant level.

The information collected can be divided into three groups depending on the use to which it is put:

1) Individual information;
2) Operational information;
3) Epidemiological information.

Individual information is concerned only with the specific patient and is not related to a population denominator. This information, which is generally qualitative, may be clinical (distribution of skin lesions, eye complications, development of paralysis, etc.), administrative (food rations, allowances, family situation, etc.), social, economic, or other types. The purpose of collecting such information is to insure that the patient receives the appropriate treatment and care and to adjust that care to the development of the disease in the individual concerned.

Information of an operational nature (development of programs) is a composite made up from individual observations. It is quantified information in the form of parameters such as frequencies (rates) or means. It is used to measure program performance (detection rate, average interval between the onset of the disease and its detection, treatment, coverage, treatment attendance rate, relapse rate, etc.). It is a measure of the efficiency of programs but not a measure of their effectiveness. A program may be conducted highly efficiently (e.g., treatment of patients using a drug dosage that is too low), but its effectiveness in solving the long term problem of leprosy may still be low or zero. It implies the definition of an appropriate denominator.

Epidemiological information (surveillance of the problem) is also a composite of individual data. Its purpose is to measure the size of the problem from appropriate indices (incidence, prevalence) and to assess the impact of the action taken (reduction of incidence, reduction of prevalence). It permits the assessment of the magnitude of the problem in relation to other health problems (determination of priorities), the surveillance of the way the problem develops if no action is taken (surveillance of natural incidence trends), the definition of intervention strategies (choice of methods), the assessment of program impact (effectiveness), and the resulting modification of the measures implemented. It also requires the definition of a denominator.

CHOICE OF OPERATIONAL INDICES

The strategy for leprosy control, as recommended by WHO expert committees and International Leprosy Congresses ever since the Seventh Congress (Tokyo, 1958), may be summarized as follows:

a) earliest possible detection of the largest possible number of patients;
b) proper treatment (early, regular, adequate, and of sufficient duration) of the greatest possible number of patients.

Patients with the lepromatous form of leprosy, who have a higher transmission potential, were regarded as the priority target group for the application of these procedures. The emergence of drug-resistant strains of *M. leprae* and the discovery of persisters has led to a reinforced emphasis on the appropriate management of lepromatous and borderline cases.

Program evaluation, based on information of an operational type, makes it possible to check constantly that activities are being carried out in conformity with the standards laid down for the strategy that has been selected as most appropriate. It is assumed that if the initial hypotheses that determine the choice of control procedures and the definition of the standards are correct, strict adherence to these specifications will produce an epidemiological effect.

The following indices have been selected in regard to the objectives defined in the introduction:

1) At the time of detection:
   a) *The proportion of lepromatous subjects among the total number of patients detected* is interesting to follow over the years. During the first few years of a leprosy control campaign, this proportion is generally high, and then it falls gradually as the activities proceed. Comparison over time or between different areas requires that the diagnosis of leprosy and the type of classification be made according to uniform criteria.
   b) *Coverage and intensity of detection (early detection).* The extent (completeness) of case-finding involves two factors: the proportion of the population actually reached by case-finding activities (*coverage rate*) and the intensity of case-finding within this segment of the population (*detection rate*). These two indices require population denominators.

   In order to compare the yield of the different case-finding methods, it is useful if each patient detected is identified in regard to the detection method (routine examination of the entire population, passive case-finding, examination of contacts, examinations in schools, dermatology clinics, etc.). This makes it possible to work out ratios showing the yield of the different case-finding methods: *percentage of patients found per case-finding method.*
   c) *Age at detection.* Uninterrupted observation of new infections in children is of great epidemiological significance since it indicates recent persistence of transmission. In such cases, it is useful to separate the incidence rates for children and adults.
   d) The *annual bacteriological reversal rate* reflects the number of bacteriologically positive patients who have become bacteriologically negative according to specific criteria (simple bacteriological examination, morphological index, number of sites examined, number of samples).
   e) The *ratio of disability among new cases* permits an indirect assessment of the delay in case detection by providing a measure of the number of

old cases that have escaped earlier case-finding. When leprosy control activities are initiated, this proportion is high, corresponding to the "backlog" of old cases, and subsequently it falls as case-finding is intensified. When the program is conducted efficiently, no new case with irreversible disabilities should be detected, i.e., the norm should be zero disabled cases among the new cases.

2) In subsequent years:
   a) The *treatment attendance rate* indicates the regularity of patients' attendance at treatment sessions. It calls for the definition of criteria of regularity based on a minimum number of times of attendance at treatment sessions. Calculation of this rate requires the systematic recording of attendance at treatment administration sessions or of the date of attendance for self-treatment (issue of tablets to the patient for a specific period).
   b) The *annual treatment defaulting rate* indicates the number of patients who default from treatment each year in relation to the number of patients under treatment. This rate requires the definition of defaulting from treatment in terms of the number of sessions missed, whether consecutive or not.
   c) The *annual inactivation rate* relates to the number of treated patients who become clinically inactive each year according to criteria fixed in advance and applied in a standard manner.
   d) The *annual rate of release from treatment* relates the number of patients released from treatment to the number of patients under treatment.
   e) The *annual relapse rate* indicates the proportion of cured patients who have suffered a relapse (defined according to given criteria).

In addition to their value for program evaluation, these two last indices, i.e., the annual rates of release and the annual relapse rate, are of great importance in lepromatous and borderline patients. Drug resistance of *M. leprae* has become a major problem for the control of the disease. Pro-

vided treatment management is appropriate regarding dosage, regularity, intake, etc., these indices may serve to monitor the effectiveness of treatment regimens.

With the exception of the coverage rate for detection and the detection rate, all other rates or ratios provide their own denominator, be it of patients treated, number of new patients, number of bacteriologically positive patients, etc.

The coverage rate and the detection rate require, respectively, information on the total population covered by control activities and the number of persons actually examined. This can be gathered independently from census or other population statistics and from operational records. With respect to relapse rate, the denominator may often be inaccurate because many patients whose treatment is discontinued are lost sight of, and it is often not known how many among them have died.

To permit valid comparisons, some of these operational indices concerning treatment should be calculated by cohort, i.e., according to the length of time since treatment was started. This applies to the defaulting rate, the inactivation rate, the bacteriological reversal rate, and the rate of release from treatment. Moreover, these rates should be calculated separately for each type of leprosy.

EPIDEMIOLOGICAL EVALUATION OF LEPROSY PROGRAMS

Incidence, or the number of new cases occurring during a given period (generally one year) in relation to the population, is the only index for measuring the efficacy of the measures taken, i.e., the reduction of transmission. It is generally not possible to calculate actual incidence rates during routine activities in view of the delay occurring between the onset of symptoms and detection. Nevertheless, when leprosy control activities have been under way for several years using the same methods and procedures, the detection rate may be taken as a reliable indicator of incidence if one assumes that the delay in detection is short and remains constant.

Prevalence is not an index of epidemiological efficacy. However, the total number of patients to be treated needs to be known

for planning and organizational purposes in order to arrange for the size of services.

Incidence as well as prevalence must be referred to a population denominator. This should be obtained independently from census data or other vital statistics.

SURVEY OF EXISTING SYSTEMS

It was first decided to review the information systems currently in use in a number of leprosy control programs. This was intended: a) to provide an insight into the types of data which can actually be collected under field conditions; and b) to give a general baseline as to the types of information which are considered suitable.

With the cooperation of governments and voluntary agencies as well as WHO/HQ in Geneva and WHO Regional Offices, relevant documents were collected from a number of countries. An analysis was made of the forms, records, and cards used by 78 leprosy control services in 45 countries (26 services and centers in Africa, 37 in Asia, and 15 in the Americas, Oceania, and the Philippines). A total of 623 documents was received. The documents studied were of many types: registration cards, treatment cards, cards for examination of contacts, physiotherapy records, cards for ulcers, statements of disabilities, hospital admission cards, laboratory findings, certificates of termination of treatment, transfer cards, social questionnaires, clinical records, etc.

In a very large number of cases, the headings were not designed for the explicit recording of information already coded but for the recording of a task that generates information: entry of a date, diagrams for recording thickened nerve trunks or sensitivity disorders, boxes for recording the results of the bacteriological examination of a series of sites, columns for marking attendance for treatment, etc. The elementary tasks to which these headings correspond have been translated into terms of the information that could be derived from them, e.g., calculation of the interval between two dates, the total of times of attendance for treatment during a given period, the presence of neurological disorders, bacteriological reversal (by juxtaposition of a series of results), etc.

For each system the extent to which the

TABLE 1. *Number of centers able to calculate given indices from information collected in the documents analyzed.*

Index	Asia: 26 centers	Africa: 37 centers	Americas, Oceania, Philippines: 15 centers	Total: 78 centers
Detection rate	15	3	0	18
Onset/detection interval	21	33	11	65
Disability rate (new cases)	a	a	a	52
Monomacular leprosy rate[b]	20	20	14	54
L/L + T ratio	a	a	a	76
Delay between registration and treatment	11	26	6	43
Treatment attendance rate	17	33	6	56
Treatment defaulting rate	17	33	6	56
Reversal rate	16	17	5	38
Treatment resumption rate	a	a	a	35
Relapse rate	26	37	15	78
Type of leprosy	a	a	a	76
Age	26	37	15	78

[a] No breakdown by region.
[b] Monomacular = single macule. Incidence rate of tuberculoid single macule cases.

information could correspond to operational and epidemiological indices was studied. Table 1 gives, as an example, the number of systems in which the information being recorded permits the calculation of some selected operational indices. The main conclusion from this review was that the use of a new system does not preclude the use of traditional forms for recording individual clinical data, day-to-day observations, or information regarding specific activities. This is imperative since, in order to make any proposed information system acceptable, it has to respect cultural patterns, administrative constraints, and local needs for specific information. Therefore, the new information systems should consist of an annual summary of those data considered relevant for the evaluation. It should also be used for the registration of the patient when first seen.

Local information systems should be adapted and fitted to provide these data, whenever and wherever necessary. A more complete modification should be left to the decision of local authorities.

CHOICE OF RELEVANT INFORMATION

As a first step, a list was established of the items of information necessary to calculate selected operational and epidemiological indices. This list was discussed at various meetings of experts involved in leprosy control and submitted to individuals with local responsibility for leprosy control and to fieldworkers.

The final list with their corresponding indices is given in Table 2. The individual record form is given in Fig. 1.

It should be noted that in addition to the information required to calculate the indices selected, another two have been retained at the specific request of a number of experts, i.e., whether or not the diagnosis has been confirmed by histopathology and the results of lepromin reaction, including post-lepromin scar.

The individual form requires being filled:

1) when the patient is first seen for registration; and

2) at the end of the first year and every subsequent year of follow-up. The format of the form, with a first line for information taken at registration and one line for each of the subsequent years, makes it possible to carry out cohort studies such as, for example, the probability of achieving bacteriological negativity according to the duration of treatment or the rate of inactivation according to attendance for treatment.

TABLE 2. *Operational indices for the evaluation of leprosy control programs.*

Operational objective	Indices	Information
Complete case-finding	Case-finding coverage rate	Population served/population concerned
	Annual detection rate	Patients detected/population served
Early case-finding	Disability rate (new cases)	No. with disabilities/No. detected
	Monomacular[a] leprosy rate	No. of monomacular[a] subjects/No. detected
	L/L + T ratio	No. lepromatous subjects detected/total detected
Early treatment	Average interval before treatment	Detection-treatment interval
Complete treatment	Treatment coverage rate	Patients treated/patients registered
Regular treatment	Treatment attendance rate	Patients attending regularly/patients treated
	Annual treatment defaulting rate	Patients defaulting from treatment/patients under treatment (annually)
	Treatment resumption rate	No. of defaulters resuming treatment/defaulting patients
Adequate treatment	Treatment compliance	No. of doses taken/No. of doses prescribed
	Annual inactivation rate	No. of cases made inactive/No. treated
	Annual bacteriological reversal rate	No. bacteriologically inactive/No. positive (annually)
	Drug resistance rate	No. of strains resistant to sulfones/No. of strains examined
	Annual rate of release from treatment	No. released from treatment/No. treated (annually)
	Annual relapse rate	No. of relapsing patients/No. of patients released from treatment and kept under surveillance (annually)

[a] Monomacular = single macule. Tuberculoid single macule cases.

GLOBAL REPORTS

Individual data has to be consolidated at the end of each year in the form of summary reports for the calculation of population indices. The flowgraph of the system, including the local non-standardized clinical records, is given in Tables 3 and 4.

Since it is necessary to distinguish between data for new patients (which is important for case-finding indices and provides the baselines for subsequent information) and data for old patients (follow-up), two types of consolidated reports have been proposed. These are given in Figs. 2 and 3. It is clear that computation of rates requires, in addition to the numerators, provided by the globalization of individual data, population denominators. These, such as total population for incidence rates, or the number of persons examined in surveys, should be obtained from other sources.
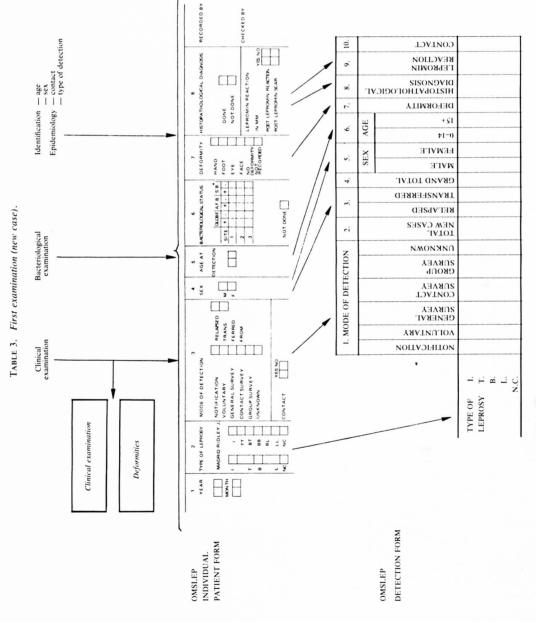
TESTING FORM

Instructions for filling in the Individual Patient Form (Fig. 1), the Detection Form (Fig. 2), and the Annual Statistics Form (Fig. 3), containing precise definitions and recommendations for practical procedures, have been published elsewhere ([1]). Forms and instructions have been translated into 4 languages other than English (French, Indonesian, Portuguese, and Spanish). The proposed system is presently being tested in some 15 areas or leprosy control schemes for registration of new patients and follow-up of patients diagnosed over the last two years.
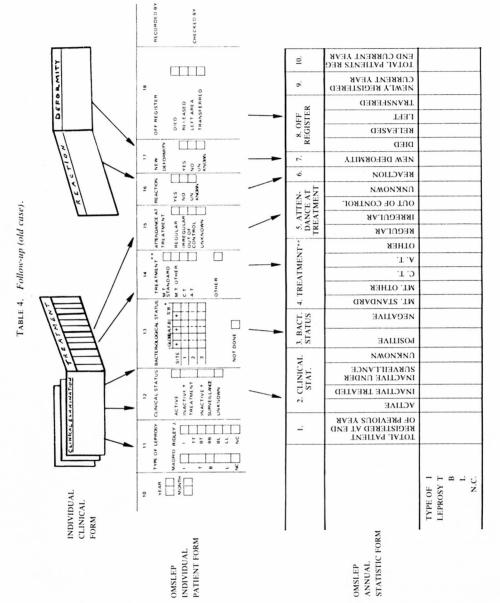
SUMMARY

This study reports the various steps involved in the design of a simplified information system for leprosy (OMSLEP), developed in cooperation between the Unit of

INDIVIDUAL PATIENT FORM

NAME ....

ADRESS ....

IDENTIFICATION N°

DATE OF REGISTRATION

1 YEAR — MONTH

2 TYPE OF LEPROSY — MADRID RIDLEY J.
I, TT, BT, BB, BL, LL, NC
T, B, L, NC

3 MODE OF DETECTION — NOTIFICATION, VOLUNTARY, GENERAL SURVEY, CONTACT SURVEY, GROUP SURVEY, UNKNOWN, RELAPSED, TRANSFERRED FROM
CONTACT YES NO

4 SEX — M, F

5 AGE AT DETECTION

6 BACTERIOLOGICAL STATUS — GLOBE AFB | S'B.*
SITE + | - | + | + ; 1, 2, 3
NOT DONE

7 DEFORMITY — HAND, FOOT, EYE, FACE, NO DEFORMITY, NOT RECORDED

8 HISTOPATHOLOGICAL DIAGNOSIS — DONE, NOT DONE
LEPROMIN REACTION — IN MM, POST LEPROMIN REACTION, POST LEPROMIN SCAR — YES NO

RECORDED BY

CHECKED BY

10 YEAR — MONTH

11 TYPE OF LEPROSY — MADRID RIDLEY J.
I, TT, BT, BB, BL, LL, NC
T, B, L, NC

12 CLINICAL STATUS — ACTIVE, INACTIVE + TREATMENT, INACTIVE + SURVEILLANCE, UNKNOWN

13 BACTERIOLOGICAL STATUS — GLOBE AFB | S'B.*
SITE + | + | + ; 1, 2, 3
NOT DONE

14 TREATMENT** — M.T. STANDARD, M.T. OTHER, C.T., A.T., OTHER

15 ATTENDANCE AT TREATMENT — REGULAR, IRREGULAR, OUT OF CONTROL, UNKNOWN

16 REACTION — YES, NO, UN KNOWN

17 NEW DEFORMITY — YES, NO, UN KNOWN

18 OFF REGISTER — DIED, RELEASED, LEFT AREA, TRANSFERRED

RECORDED BY

CHECKED BY

20 YEAR — MONTH

21 TYPE OF LEPROSY — MADRID RIDLEY J.
I, TT, BT, BB, BL, LL, NC
T, B, L, NC

22 CLINICAL STATUS — ACTIVE, INACTIVE + TREATMENT, INACTIVE + SURVEILLANCE, UNKNOWN

23 BACTERIOLOGICAL STATUS — GLOBE AFB | S'B.*
SITE + | + | + ; 1, 2, 3
NOT DONE

24 TREATMENT** — M.T. STANDARD, M.T. OTHER, C.T., A.T., OTHER

25 ATTENDANCE AT TREATMENT — REGULAR, IRREGULAR, OUT OF CONTROL, UNKNOWN

26 REACTION — YES, NO, UN KNOWN

27 NEW DEFORMITY — YES, NO, UN KNOWN

28 OFF REGISTER — DIED, RELEASED, LEFT AREA, TRANSFERRED

RECORDED BY

CHECKED BY

* S. B. = solidly staining bacilli.

** MT standard = monotherapy standard (dapsone).

MT other = monotherapy (other drugs).

CT = combined therapy (dapsone plus one or several other drugs, e.g., clofazimine and/or rifampin).

AT = alternate therapy (one or several other drugs but no dapsone).

FIG. 1.

TABLE 3. *First examination (new case).*

* S.'B. = solidly staining bacilli.

TABLE 4. *Follow-up (old case).*

* S.'B. = solidly staining bacilli.
** *MT standard* = monotherapy standard (dapsone).
　MT other = monotherapy (other drugs).
　CT = combined therapy (dapsone plus one or several other drugs, e.g., clofazimine and/or rifampin).
　AT = alternate therapy (one or several other drugs but no dapsone).

FIG. 2. Detection form (total new cases registered). Year 19 . .

	1. MODE OF DETECTION						2.	3.	4.	5. SEX		6. AGE		7.	8.	9.	10.
	NOTIFICATION	VOLUNTARY	GENERAL SURVEY	CONTACT SURVEY	GROUP SURVEY	UNKNOWN	TOTAL NEW CASES	RELAPSED	TRANSFERRED	GRAND TOTAL	MALE	FEMALE	0–14	15+	DEFORMITY	HISTOPATHOLOGICAL DIAGNOSIS	LEPROMIN REACTION	CONTACT
INDETERMINATE I																	
TUBERCULOID TT + BT																	
BORDERLINE BB																	
LEPROMATOUS BL + LL																	
NOT CLASSIFIED NC																	
TOTAL																	

FIG. 3. Annual Statistics form (total registered cases). Year 19 . .

	1.	2. CLINICAL STATUS			3. BACTE-RIO-LOGICAL STATUS			4. TREATMENT[a]					5. ATTENDANCE AT TREATMENT				6.	7.	8. OFF REGISTER			9.	10.
	TOTAL PATIENTS REGISTERED AT END OF PREVIOUS YEAR	ACTIVE	INACTIVE TREATED	INACTIVE UNDER SURVEILLANCE	UNKNOWN	POSITIVE	NEGATIVE	MT. STANDARD	MT. OTHER	C. T.	A. T.	OTHER	REGULAR	IRREGULAR	OUT OF CONTROL	UNKNOWN	REACTION	NEW DEFORMITY	DIED	RELEASED	LEFT	TRANSFERRED	NEWLY REGISTERED CURRENT YEAR	TOTAL PATIENTS REG END CURRENT YEAR
INDETERMINATE I																							
TUBERCULOID TT + BT																							
BORDERLINE BB																							
LEPROMATOUS BL + LL																							
NOT CLASSIFIED NC																							
TOTAL																							

[a] MT standard = monotherapy standard (dapsone). MT other = monotherapy (other drugs). CT = combined therapy (dapsone plus one or several other drugs, e.g., clofazimine and/or rifampin). AT = alternate therapy (one or several other drugs but no dapsone).

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The objective of the system is to permit the evaluation of a) the efficiency of programs within the context of established strategies and norms; b) the effectiveness of leprosy control methods from an epidemiological point of view; c) the efficacy and productivity of certain program components.

Prior to designing the system, the relevant epidemiological and operational indices have been reviewed. A survey was also made of the forms used by some 78 leprosy control schemes throughout the world in order to analyze the current information now being collected. The proposed system is described. It includes an individual record form to be filled at registration and once yearly in subsequent years of follow-up, a detection form, and an annual statistics form for the tabulation of total patients. The system is presently being tested in some 15 countries.

RESÚMEN

En este trabajo se presentan los diferentes pasos seguidos en el diseño de un sistema simplificado de información para la lepra (OMSLEP). El sistema fue elaborado conjuntamente por la Unidad de Epidemiología de la Universidad de Louvain, Bélgica, y la Organización Mundial de la Salúd (WHO).

El sistema tiene como objetivo el permitir la evaluación de a) la eficacia de los programas de control dentro del contexto de las normas y estratégias establecidas; b) la efectividad de los métodos de control de la lepra, desde un punto de vista epidemiológico y c) la eficacia y productividad de ciertos componentes de los programas de control.

Antes del diseño del sistema, se revisaron y analizaron los índices epidemiológicos y operacionales relevantes. También se hizo una revisión de las formas usadas en 78 esquemas para el control de la lepra en el mundo, con el fin de analizar la información que esta siendo recopilada actualmente. Se describe el sistema propuesto el cual incluye un cuestionario individual que tiene que ser llenado en el momento del registro y una vez por año en los años subsecuentes del estudio, un cuestionario de detección, y una forma estadística anual para la tabulación del total de los pacientes. El sistema esta siendo actualmente probado en aproximadamente 15 países.

RÉSUMÉ

Cette étude relate les différentes étapes qui ont été suivies pour mettre au point un système d'information simplifié pour la lèpre (OMSLEP), dans le cadre d'un projet mené en collaboration entre l'Unité d'Epidémiologie de l'Université Catholique de Louvain en Belique, et l'OMS.

Le but de ce système est de permettre l'évaluation de l'efficience des programmes actuellement menés dans le cadre des principes présidant à la lutte contre la lèpre. Il doit aussi permettre de mesurer l'efficacité des méthodes de lutte contre la lèpre sur le plan épidémiologique, de même que la pertinence et le rendement de certaines composantes des programmes.

Au préalable, on a dressé la liste des indices dont l'emploi est indiqué pour suivre les résultats des campagnes contre la lèpre, tant sur le plan épidémiologique qu'opérationnel. Une enquête a également été menée auprès de 78 centres de traitement de la lèpre dans le monde, afin d'analyser le type d'informations statistiques, qui sont actuellement recueillies. Le système proposé est décrit. Il comprend une fiche individuelle du malade, qui doit être remplie lors de la détection, et ensuite une fois par an, lors du suivi de même que des tables reprenant le total des malades au moment de la détection, et le total des malades par an. Le système est actuellement mis à l'épreuve dans 15 pays.

REFERENCE

1. WORLD HEALTH ORGANIZATION. Recording and reporting: OMSLEP system. *In: A Guide to Leprosy Control*, doc. WHO/LEP/19.7, Geneva: 1979, p. 45 and pp. 74–82.