

# LEPROSY CONTROL

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## 1. OBJECTIVES OF LEPROSY CONTROL

The objective of leprosy control is three-fold:

- a) The main objective is in the long run to decrease incidence (that is the annual number of new cases as related to the total population) to an acceptable level. This level should be set arbitrarily according to what is considered in each country as an acceptable reduction of the problem, taking into consideration other health needs and availability of resources. Except in very exceptional circumstances, it seems unreasonable to aim at the eradication of the disease.
- b) Second, control should efficiently prevent deformities. Control measures such as chemotherapy will prevent deformities only to the extent that the patients are treated at an early stage.
- c) Beyond these public health oriented objectives, the treatment, cure, and rehabilitation of the individual patients are part and parcel of control.

## 2. EPIDEMIOLOGICAL BASIS OF LEPROSY CONTROL

The epidemiological determinants of leprosy which are relevant to control are the following:

- (1) man is the single (or at least the only) significant reservoir;

- (2) transmission is assumed to be direct from infected to susceptible individuals;
- (3) specific environmental factors regulating transmission have not been identified.

Under such conditions, there are only three possible approaches to control:

- (1) elimination or removal of the reservoir (segregation);
- (2) elimination of the agent in the reservoir (chemotherapy);
- (3) protection of the susceptible population (chemoprophylaxis, vaccination).

### 3. STRATEGIES OF LEPROSY CONTROL

Segregation has been practiced on a large scale as long as no specific medicaments were available. With the discovery of the sulfone-drugs in 1941, chemotherapy became available. For the last thirty years, it has been the keystone of leprosy control.

Chemoprophylaxis, which has been recognized as relatively effective in population trials, is not applicable on a large scale.

Active research is carried out in order to develop a specific leprosy vaccine. Possible availability of a vaccine in the future would overturn the approach to control of the disease.

Since at present control is universally based on chemotherapy, only this method will be considered.

### 4. CHEMOTHERAPY

The aim of control through chemotherapy is to sterilize the agent (*M. leprae*) in the reservoir (man), through treatment of all infectious cases.

The basic requirements are therefore:

- (1) the availability of a potent drug efficient in all cases of the disease;
- (2) early diagnosis;
- (3) complete, or as complete as possible, treatment coverage.

#### 4.1 Available drugs

Until recently, the only drugs active against *M. leprae* were the sulfones, principally the parent-compound, dapsone. Synthesized around 1908, the sulfones were first used in leprosy by Faget, at the Carville leprosarium, in the U.S.A., in 1941. This is a major example of how the lack of laboratory models has hindered leprosy control. It strongly illustrates the need for research. If a laboratory animal or a growth medium had been available at the time of discovery of the sulfones, the patients would have benefited 30 years earlier from a specific medicament.

The availability of the sulfones made possible the large-scale development of ambulatory treatment. Patients, at least the tuberculoid patients, and soon all the patients, were treated in their community. Mobile teams were organized where no basic medical facilities were available. The sulfones were particularly adapted to this mode of treatment. They were cheap, the cost of treatment for one patient was estimated at some 2 dollars per year. They were given by mouth, which makes in-the-field administration easy and requires no special equipment. Their toxicity is low at the usual dosage, which calls for a minimal medical supervision. They are effective when administered weekly, which makes organization of control convenient and allows treating a large number of patients with a relatively modest staff. They have a long shelf-life, which reduces the possibility of logistic difficulties.

Millions of patients were treated on an ambulatory basis, especially in Africa and Southeast Asia. When the footpad model became available (Shepard, 1960), it was shown that the sulfones make a lepromatous patient non-infective in a couple of months. This strengthens the argument to leave all patients in the community and make do without isolation.

This observation was confirmed by epidemiological observations in Hong-Kong and in Venezuela. Attack-rates for leprosy in children of untreated, or not yet treated, lepromatous parents on one hand, and parents under treatment on the other, showed considerable differences.

Over the last decade, however, sulfone-resistance of *M. leprae* has been recognized in an increasing number of patients. Resistance, both primary and secondary, is now widespread worldwide. This has required the addition of new drugs, namely rifampicine, clofazimine, and ethionamide or prothionamide.

#### 4.2. *Early diagnosis*

In order to reduce the period of dissemination of bacilli by untreated patients, it is necessary to detect and treat patients as soon as the first manifestations of the disease are apparent. This requirement, however, raises a number of difficulties, both theoretical and practical.

From a theoretical point of view, it is not known whether some persons in the latency stage, before the onset of overt clinical manifestations, constitute a source of infection. Studies conducted in highly endemic areas have demonstrated bacilli in the skin in a significant proportion (up to 10%) of apparently normal contacts.

Practically, due to the conditions prevailing in countries with high prevalence, there is always a delay between the onset of disease and treatment. This delay may reach years. A detection of 75 per cent of the cases within one year after onset is often the best one can expect.

The importance of early detection has increased with the emergence of primary resistance. Besides its importance for control, early detection is essential to prevent deformities.

Modes of detection of leprosy patients can be classified in several categories: systematic population survey, voluntary reporting, surveys of specific population groups, surveillance of high-risk groups, combined multi-disease detection, consultation at health services, such as skin clinics, health centers, etc. ...

It should be stressed that there is no leprosy control without organized detection. Haphazard referral of casually diagnosed cases has no part in leprosy control.

Systematic population surveys were an essential part of leprosy campaigns in many countries, mostly in Africa in the pre-independence days. Whole villages were examined at periodic intervals for a number of diseases, such as sleeping sickness, yaws, and leprosy. Although there is no doubt that such a method, compulsorily enforced, was highly effective to detect cases, it is most questionable that it could still be implemented today. Such systematic examinations of whole villages, however, still have their place in prevalence epidemiological surveys.

Voluntary reporting covers a whole range of types of detection, from the isolated cases seeking treatment from some specialists to the systematic organization of a surveillance system integrated into primary health care. Its efficiency depends on the motivation and education of the population and the degree of development of health services. It can

be integrated into a structure for primary health care (horizontal), or specially organized in the framework of a specific leprosy service (vertical) including treatment and case-management.

Surveys of specific population groups are often recommended: school children, workers in factories or plantations, army, etc... Sometimes this mode of detection can be applied at a specific time in life (school entrance, recruitment in the army, new employment). The efficiency and effectiveness of such surveys depends very much on the relative prevalence found in such groups as compared to the general population. Furthermore, some population groups, such as army conscripts or workers, are deliberately or implicitly selected for good health. In some countries, schooling is unequally available, attendance at school being associated with a higher socio-economic level.

Contacts, and especially household contacts of multi-bacillary cases, constitute an exposed group of persons, characterized by attack-rates higher than the general population, as demonstrated in studies conducted in the Philippines (Doull *et al.*). In many countries, detection is mainly based on contact examination, with as a result a high yield of cases at relatively low cost. The efficiency and effectiveness of detection through contact examination depend, however, on the prevalence of leprosy.

Detection of leprosy in skin-clinics (called "*dispensarios de dermatología sanitaria*" in Latin America) has been widely practiced in a number of countries having a large problem of public health dermatology together with a significant leprosy prevalence. It is especially worth considering in countries where a psychological stigma is still attached to leprosy, for patients can then receive specialized services without drawing attention.

#### 4.3. Coverage and drug-delivery

Chemotherapy will be efficient to the extent that the largest part of the reservoir of infection is rendered negative, i.e., an adequate coverage of effective treatment.

However, coverage is seldom satisfactory. In many countries, the estimated prevalence may considerably exceed the apparent prevalence; in other words, the number of undetected patients is much greater than the number registered. This is due not only to delay in detection, but also to many patients absconding from the health services. That fact is

confirmed by the high number of old cases with extensive deformities among the newly detected patients.

Poor attendance to treatment is another drawback. Since sulfone-monotherapy must be continued for years (even for life in multibacillary patients) in order to achieve bacterial negativation and prevent relapse, the rate of defaulting is high, and it may happen that a majority of patients are abandoning after a few years.

## 5. DRUG-RESISTANCE

Since the inception of sulfone-based mass treatment campaigns, a major problem has appeared; that is, the resistance of *M. leprae* to the drug. Curiously enough, the possibility of resistance emerging with prolonged sulfone-treatment has been overlooked for a long time. The first WHO Expert Committee on Leprosy, held in 1952, mentioned that there was no clinical indication of resistance. Clearly, after a couple of years of treatment, it was too early to judge. The Second and Third Expert Committee, respectively in 1960 and 1965, recommended initiating sulfone treatment with very low doses and a very gradual increase before reaching full dosages. It was conjectured that this could reduce the incidence of reactional episodes in lepromatous patients at the beginning of the treatment. The existence of resistance as a problem was negated. It is only in 1970 that the possibility of selecting strains of *M. leprae* resistant to sulfones was mentioned, in relationship with recent recommendations then made for a decrease in the usual dosages.

Meanwhile, the techniques of footpad inoculation made it possible to investigate a number of pharmacological aspects of leprosy treatment, such as the minimal inhibiting concentration of drugs, the effectiveness of drugs, and resistance.

Dapsone-resistance has come to be today the major problem of leprosy control. Secondary resistance to dapsone has now been reported from more than 25 countries and its prevalence is steadily increasing. Primary resistance is also being reported with increasing frequency from several countries. In some areas, primary resistance affects 30 per cent of the new multibacillary patients. It has been observed that the prevalence of primary resistance was particularly high in those areas where control activities were conducted intensively and for a long time, which is only normal because under such

circumstances, with a large coverage of early detection, patients treated for long and having developed secondary resistance will constitute the main source of infection.

If adequate measures are not taken, namely multiple drug therapy, the emergence of drug-resistance could jeopardize in many countries the results obtained by leprosy control over the last decades.

Simulation of resistance using epidemiometric models (Lechat *et al.*, 1985) has shown that, with a 3 percent annual incidence of secondary resistance, the prevalence of total resistance among the total of surviving multibacillary patients reaches some 34 per cent after 15 years; with a 2% annual incidence it reaches 26%, and with a 1% annual incidence it reaches 15%.

Conversely, the effect on incidence of an increasing reservoir of infective resistant patients can be calculated for different rates of secondary resistance. Whereas with current control measures, the decline in incidence is markedly reduced, occurrence of secondary resistance at a rate of 1 per cent per year leads to a stabilization in the number of new cases after 32 years. With a 3 per cent rate, the declining trend of incidence is reversed after 11 years, and after 16 years with 2 per cent.

The answer to resistance is multiple drug therapy, based on the following drugs in addition to dapsone: rifampicine, clofazimine, and ethionamide/prothionamide. However, resistance to rifampicine and, exceptionally, clofazimine, has now been reported.

The emergence of resistance has changed the face of leprosy control. Replacement of monotherapy by multiple therapy is much more, however, than a shift in the type of tablets. It implies a complete change in the management of the patients. Drug-delivery has to be modified. Rifampicine, for one, has to be administered under strict supervision and under tight schedule. Adverse reactions are not infrequent and call for prompt diagnosis and referral to specialized care. Bacteriological follow-up is necessary to evaluate the improvement of the disease. Where sulfone monotherapy is still practiced, careful assessment of the bacteriological status is required to detect the emergence of resistance.

Due to drug resistance and to its necessary corollary, multiple chemotherapy, the treatment of leprosy, which for long was an easy matter, has become a very delicate affair indeed. The more hopeful side of the change is that, while sulfone-monotherapy of multibacillary patients was to be prolonged for life, multiple therapy permits to envisage a discharge after two years.

## 6. EVALUATION

It is now more than 30 years that large-scale campaigns based on systematic case-finding and mass sulfone treatment are carried out in a number of countries.

At the beginning of these campaigns, great expectations were entertained. The eradication of leprosy was even contemplated. That was the time when eradication was still a fashionable word. It seemed that all that was needed to achieve it was dedication and money.

Today, by contrast, it is commonplace to hear people question the results of the whole leprosy control as it has been conducted for three decades. Initial expectations have not been fulfilled. Leprosy is still with us, and each year brings its crop of new cases. Governments are raising doubts about the soundness and feasibility of the present strategy, the more so since there are many other health priorities in countries where leprosy is endemic.

There are no doubts that leprosy control based on monotherapy as practiced for some 30 years has totally changed the face of leprosy. Severely mutilated patients and burnt-out cases, a common sight before the sulfone, are exceptionally found any more. Still, there is much question about reduction of transmission.

The truth is that no proper evaluation mechanism had been incorporated in the leprosy control schemes from the beginning. Activities were mostly evaluated from a purely operational point of view. The questions asked were how many patients were put under treatment, how many discharged, how many people were examined for leprosy in the population.

The process of continuous evaluation requires the use of a method for collecting, processing and analysing information on the clinical, epidemiological and operational aspects of programs or projects. Moreover, it is generally recognized that the available information on leprosy in the majority of countries is poor or unsatisfactory. Also, owing to lack of uniformity in the definition of terms and concepts, the data obtained from different countries, and sometimes even from different areas in the same country, are hardly comparable; they consequently have little epidemiological value.

It results that a suitable system for collecting and recording data is essential for the planning, programming and monitoring of leprosy control programs, as well as to evaluate the outcome. Such a system is



also needed to gain knowledge on the epidemiology of leprosy, and judge the respective efficacy of preventive and curative strategies.

In order to permit comparisons of data, such an information system needs the definition of standardized technical terms. An information system must also be seen in a decision-making context. It should be simple in nature so that the necessary data can be collected by health service personnel at any level.

The OMSLEP Recording and Reporting System for Leprosy Patients (Lechat *et al*, 1981) represents an attempt at developing such a system. It is especially designed to facilitate the collection of data and the periodical retrieval of indices.

The system has also been adapted to make possible the use of microcomputers.

## 7. TYPES OF SERVICES

The implementation of leprosy control activities supposes three levels of services: (a) detection and case-management at the interface between health services and the population; (b) supervision; (c) referral.

It can be viewed as a pyramid, from the periphery to the more central, or from the less specialized to the more specialized levels.

These services can be arranged along two axes. At one extreme, there is a specialized leprosy service, dealing only with leprosy patients, with its own personnel and facilities (so-called vertical services). At the other extreme, the leprosy control activities are completely integrated into the general health services (horizontal services). There are many intermediate situations between these two. Each type of services has its advantages and disadvantages.

In the ideal situation of a well-organized extensive primary health care structure, there is no doubt that integration of leprosy control into it will assure its efficiency and decrease the cost. Moreover, it has the advantage that leprosy will not be singled out as a special disease, requiring special services, which can only add to the psychological and social stigma.

When basic health services are not so well developed, specialized services for leprosy control or activities, or part thereof, might remain the only way to actually deliver care to the patients. It is however costly, since it might require special personnel whose only

responsibility is leprosy control, together with its own transportation, proper supervision mechanism, and even particularized health facilities.

In a number of instances, the change from specialized services to integration has resulted in a collapse of all leprosy services, of no avail to general health.

Two remarks should be made regarding the (admittedly most desirable) progressive integration of leprosy services into the basic health services:

- (1) when the leprosy service is well organized and has a wide coverage, and basic health services are poor or even inexistent, rather than integrating existing services into nothing, primary health care should be integrated into the leprosy services. That is to say: leprosy can be used as a catalyst and a nucleus to develop basic health services;
- (2) integration should only be attempted when there is a reasonable expectation that it will not result in the downgrading or even collapsing of leprosy control.

Integration is a matter of good sense. It should be adapted to the local context, taking into account the local cultural patterns (psychological attitude of the population, acceptability), the level of training of the health personnel, the development of basic health services, and also history (in some countries, specialized services have a long tradition).

## 8. THE ROLE OF VOLUNTARY AGENCIES

It should be clearly stated that the responsibility for leprosy control rests with national governments. It should also be honestly recognized that, while in a number of countries governments have made great efforts to fight the disease, in a number of others they have shown little or no concern.

The role of voluntary agencies, either national or international, as well as for foreign official agencies, has been determinant in stimulating interest, raising funds, promoting leprosy activities, implementing leprosy control and alleviating the suffering of patients throughout the world.

To quote the World Health Organization,

“With their flexibility and initiative, voluntary agencies are able to introduce new approaches in leprosy treatment and control in the light of their concern for the social components of the disease. Full advantage could be taken of their training experience, literature, and in-patient facilities both in general hospitals and in hospitals specially catering to leprosy sufferers. They can provide a valuable contribution to the development of the general health services, especially in the early stages of development of rural and urban health facilities.

“Voluntary agencies can also frequently initiate and develop certain aspects of an antileprosy service, e.g., specialized physiotherapy units, workshops for prosthesis, and re-education centres for handicapped patients — which some governments cannot fully provide at present. These, however, should: (1) be developed as part of the facilities for all suitable patients, (2) not become so elaborate or expensive that they cannot be incorporated into the government’s programme if and when desirable, and (3) serve as training centres wherever possible”.

## 9. LEGAL MEASURES

The only desirable compulsory measures toward leprosy patients is medical examination and treatment. It is also the right of the patient.

Leprosy should be reported like other communicable diseases according to the requirements for an efficient implementation of control.

Special legislation should be repealed. Indiscriminate compulsory segregation is an anachronism and must be abolished. Discretionary authority could, however, be given to health authorities to require the hospitalization of presumably infectious patients or their temporary exclusion from work in those instances in which the prescribed therapy is neglected or ineffective.

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