

This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization.

WORLD HEALTH ORGANIZATION
TECHNICAL REPORT SERIES

No. 189

**EXPERT COMMITTEE ON
LEPROSY**

Second Report

	Page
1. Infectivity and mode of spread of leprosy	3
2. The lepromin reaction.	5
3. BCG and chemotherapy in leprosy prevention	9
4. Leprosy control	12
5. Therapy	18
6. Rehabilitation of disabled patients	20
7. Teaching and training in leprosy. Health education	24
8. Classification	26
9. Research in leprosy	27
10. Legislation	27

WORLD HEALTH ORGANIZATION

PALAIS DES NATIONS

GENEVA

1960

EXPERT COMMITTEE ON LEPROSY

Geneva, 3-8 August 1959

Members :

Dr J. A. Kinnear Brown, Specialist Leprologist, Ministry of Health and Medical Headquarters, Entebbe, Uganda (*Rapporteur*)

Dr Orestes Diniz, Director do Serviço Nacional de Lepra, Ministério da Saude, Rio de Janeiro, Brazil

Médecin-Colonel de Réserve P. Laviron (former Director of the Institut Marchoux, Bamako, Sudan), Marseille, France (*Vice-Chairman*)

Dr H. W. Wade, Pathologist Emeritus, Leonard Wood Memorial, Culion Sanitarium, Palawan, Philippines (*Chairman*)

Dr R. V. Wardekar, Secretary, Gandhi Memorial Leprosy Foundation, Wardha (Bombay State), India

Secretariat :

Dr W. Bonne, Director, Division of Communicable Diseases, WHO

Dr J. M. M. Fernandez, Rosario, Argentina (*Consultant*)

Dr J. Gay Prieto, Chief Medical Officer, Leprosy, Division of Communicable Diseases, WHO (*Secretary*)

Dr V. Martinez Dominguez, Team Leader, Leprosy Advisory Team, WHO

This report was originally issued as mimeographed document WHO/Leprosy/19.

EXPERT COMMITTEE ON LEPROSY

Second Report *

The Expert Committee on Leprosy met in Geneva from 3 to 8 August 1959.

Dr P. Dorolle, Deputy Director-General, on behalf of the Director-General of the World Health Organization, welcomed the members of the Committee.

The Committee elected Dr H. W. Wade Chairman, Médecin-Colonel de Réserve P. Laviron Vice-Chairman, and Dr J. A. Kinnear Brown Rapporteur.

1. THE INFECTIVITY AND MODE OF SPREAD OF LEPROSY

The Committee considers that primarily three factors are involved, namely:

- (1) the degree to which the individual patient is infectious;
- (2) the susceptibility of persons exposed to infection; and
- (3) the type of contact.

The degree to which the individual patient is infectious

It is generally agreed that lepromatous cases are the most highly infectious. However, the presence of high prevalence rates of leprosy combined with low lepromatous rates in certain countries cannot be explained on the assumption that lepromatous cases are the only sources of infection; the borderline group, reactional tuberculoid and some indeterminate cases evidently have a certain degree of infectiousness.

There is an accumulation of evidence suggesting that truly polar tuberculoid cases are not normally infectious. For example, Fernandez, over

* The Executive Board, at its twenty-fifth session, adopted the following resolution:

The Executive Board

1. NOTES the second report of the Expert Committee on Leprosy;
2. THANKS the members of the Committee for their work; and
3. AUTHORIZES publication of the report.

(Resolution EB25.R7, *Off. Rec. Wld Hlth Org.*, 1960, **99**)

a period of 15 years, was unable to discover a single instance of infection in a large group of child contacts with this type of leprosy. In Brazil, among 40 000 contacts, not a single case of leprosy appeared among those exposed only to the truly polar tuberculoid type. Doull and his colleagues have shown that household contact with this type of leprosy did not involve significantly greater risk than that to which the general population is normally exposed. It is emphasized that these observations refer to contact with truly polar tuberculoid leprosy.

The Committee recommends the careful bacteriological examination of non-lepromatous patients, particularly those of the indeterminate group, some cases of which may be infectious.

The susceptibility of persons exposed to infection

Leprosy, even in the lepromatous form, does not appear to be infectious to the majority of individuals. The rate of conjugal infection is low, as is also that among persons who work for years in close contact with large numbers of patients; and not all the children who are exposed to such cases develop clinical leprosy.

There are on the other hand patients who cannot have had prolonged intimate contact with sources of infection. Moreover, cases have arisen in people who have made only short visits to endemic areas.

For these reasons it is considered that the natural susceptibility of the host plays an important role in deciding whether or not an individual will develop the disease.

In some centres it has been observed that more than 40% of children in close contact with lepromatous parents develop leprosy. Many infected children, however, have a high degree of resistance, and the disease resolves spontaneously in them.

The combination of high susceptibility with a high degree of resistance may explain the pattern of leprosy in Africa and other countries, in which can be observed high prevalence with low lepromatous rates, as exemplified by the Nauru Island epidemic.

Natural susceptibility is greatest in childhood, but in a small proportion of individuals it does not diminish with age. It is in this minority who do not lose their susceptibility that clinical leprosy may develop at any time, often in later life, after exposure to infection.

The type of contact

The type of contact (e.g. household, neighbourhood, etc.) plays an important role in the spread of leprosy. The Committee recommends further studies in rural areas on the infectiousness of different types of contact and the influence of other local factors.

2. THE LEPROMIN REACTION

The lepromin reaction is of established value as a test of the reactivity of the individual to the leprosy bacillus; it provides a criterion in the classification of cases and an indication of the prognosis of the patient and of the relative resistance of contacts.

There still remain, however, various problems in connexion with the lepromin reaction; these include standardization of the antigen, and an increasing scarcity of suitable material for making it which is due to the effects of chemotherapy on the disease.

Antigens

There are three desiderata in the preparation of the antigen. There should be: (1) the maximal possible utilization of the bacillary elements of the lepromas used; (2) simplicity in the technique of preparation; and (3) possibility of standardization.

Types and nomenclature. There is much confusion in the literature because the terminology for the antigens used lacks specificity.

The original or "regular" lepromin of Mitsuda and Hayashi is a suspension of the whole leproma, including such tissue elements as pass the filter. This is sometimes called "integral" lepromin.

"Purified bacillus suspensions" have been made, more or less completely freed from tissue elements without radical modification of the chemical composition of the bacillary bodies. Such preparations are sometimes called "bacillary" lepromin.

Antigens which consist of the soluble proteins of the bacilli, with or without proteins of the leproma not coagulated by heating, elicit only the early reaction. For distinction such antigens should be called "leprolins".

One well-known antigen is the "defatted" bacillary suspension devised by Dharmendra for testing the early reaction; it entails a lessening of the severity of the late reaction. Because of the modification of antigenicity, it should be referred to as the "Dharmendra antigen". This product is neither a lepromin as defined above nor a leprolin.

The fundamental difference between lepromins and leprolins is that the latter elicit only the early (Fernandez) reaction indicative of pre-existing hypersensitivity, and do not themselves sensitize; whereas the former elicit the early reaction, but also induce the late (Mitsuda) reaction and—the test being a form of "micro-vaccination"—affect the immunological status of the individual. One consequence is that persons negative to the first test may give positive reactions to a second or subsequent test.

For routine lepromin testing the Mitsuda-Hayashi type of lepromin is recommended, preferably using the technique introduced by Wade,¹ which permits larger quantities of the antigen to be made from a given quantity of lepromas than does the original technique.

Of major importance in the preparation of lepromin are the selection and preparation of the lepromas used.

(1) One or more smears of each specimen should be examined, preferably before autoclaving, to ensure the presence of an abundance of bacilli. Poor specimens should be discarded.

(2) The specimens should be thoroughly cleansed of all tissue material extraneous to the leproma proper, preferably after autoclaving, because then they can be identified and removed most easily.

(3) Each lot of lepromin should be made of several lepromas from different patients, because bacilli from different cases differ in condition and presumably to some extent in antigenicity. "Pooling" is an attempt to arrive at an average level of uniformity.

Purification

Regular or "integral" lepromin is often spoken of, usually in a derogatory way, as a "crude" product, because of the presence of the tissue elements of the lepromas. Practical experience in the use of lepromin through the years since its introduction suggests that this objection is more theoretical than practical.

Certain methods have been devised for purification of the bacillus suspension, notably by differential specific gravity (Fernandez and Olmos Castro) and by the use of trypsin (Lew and Carpenter), but these methods are laborious and highly wasteful. Extraction of the bacilli from the leproma by chloroform and recovery from a suspension in ether (Dharmendra) removes the lipids and modifies the antigenicity of the bacilli. Products of chloroform extraction without subsequent treatment with ether (Lowe, Wade) have been found to give weaker late reactions than regular lepromin, and have shown no advantage whatever.

Certain workers believe that there is no need to remove the tissue elements, particularly in view of the fact that the lepra cells are impregnated with the products of metabolism of the active bacilli and of disintegration of the old ones. It is, however, recommended that further investigation of this matter be carried out, to arrive at a final conclusion.

In this connexion, it is to be noted that several authors have reported the production of late reactions with suspensions of normal tissues in

¹ *Wld Hlth Org. techn. Rep. Ser.*, 1953, 71

tuberculoid cases but not in lepromatous cases. These results are not understood and should be studied further.

Dilutions

Because of the increasing scarcity of suitable lepromas for making lepromin, there is much interest in the possibility of using higher dilutions than the usual 1/20 suspension of leproma. Experience has shown that high dilutions which may serve for testing actual leprosy cases are not suitable for testing contacts or normal persons in field work. However, several workers have reported that two or three times the normal dilution (i.e. 1/40 or 1/60) may be used. Trials of such a dilution should be extended to large groups of individuals of all classes, with proper controls, to determine an upper limit of dilution which is dependable.

In this connexion, there is the question of the validity of such comparative tests in the same individual, because the reactivity induced by the full dose may enhance the effect of the dilution. An answer should be sought to this question. In the meantime, it is recommended that, for the comparison of the value of a dilution with normal lepromin, separate groups of individuals should be used, strictly comparable in age and other factors and large enough to compensate for individual variability.

There is interesting recent work (Kinneer Brown) in which lepromin was used in various dilutions in a depot vehicle of anhydrous lanolin and paraffin oil, introduced into the skin with the Heaf multipuncture apparatus. This method should be studied in both leprosy cases and in normal individuals, especially young children.

Standardization

Standardization for the Mitsuda reaction depends primarily upon the number of bacillary bodies per test dose.

Fixing the proportion of leproma material and carbol-saline diluent is in no real sense standardization of the product, no matter how standardized the technique of preparation. Biological standardization is not possible with bacterial-body antigens for late reactions, as it is with soluble proteins (e.g. tuberculin, leprolin) for early hypersensitivity reactions. Nephelometry is not applicable because most of the opacity is due to the tissue elements, a very variable factor from batch to batch. Accurate counting of bacilli in regular lepromin is impossible because of the clumping in globi and other aggregates.

The method of standardization by visual comparison under the microscope of comparable smears of a previous batch of lepromin with a new one, introduced by Muir in 1933, is the method in general use, but the results can be only an approximation.

A method of actual counting has been proposed (Hanks), in which a small sample of the lepromin is declumped by chloroform. If this method proves practicable in ordinary laboratories, it may well be the solution of the problem.

In the meantime it is suggested that WHO might arrange with some central laboratory to prepare a standard lot of lepromin so that individual laboratories could send to it samples of their products for comparison with the standard batch by the usual smear-inspection method. By this means it should be possible to lessen the variations that doubtless exist in the lepromins made in various parts of the world.

Reading of the reactions

There is no disagreement with respect to reading the early (Fernandez) reaction between the recommendations of the Expert Committee on leprosy in its first report and those of recent international congresses.

There is disagreement with respect to the lower limit of positivity of the later (Mitsuda) reaction. All open conferences have followed Hayashi in regarding nodulations measuring 3 mm or more in average diameter as positive. On the other hand, the Expert Committee recommended that the lower limit of positivity be more than 4 mm, those measuring 4 mm or less to be regarded as doubtful or negative. Workers in certain countries (Japan, Brazil) advocate still larger measurements as the lower limit. The Committee recommends that this question be left open pending further histological studies of the reaction lesions, as suggested by the Seventh International Congress, Tokyo. Reactions read as doubtful (\pm) should be regarded as negative. Reactions of 1+ grade should be regarded as positive.

In this connexion note is made of recent reports of more or less frequent positive reactions in lepromatous cases, especially in those under sulfone treatment. This matter should be investigated with a view to determining the reason for such reactions. Consideration should be given to the possibility that such reacting cases were previously of a borderline nature, transformed from tuberculoid. Reaction lesions in lepromatous cases should be studied histologically with regard to the possibility that they may represent the Sager "isopathic" phenomenon.

Conditioning for reactivity

Normal persons will give positive Mitsuda reactions to a varying degree according to age and to locality. It is generally recognized that individuals may be "conditioned" to react in larger numbers or to a greater degree by contact (infection) with *Myco. leprae* (specific) and *Myco. tuberculosis*, including BCG (non-specific, cross reaction).

Certain workers have suggested that conditioning may also be produced by the factors which induce low-grade "non-specific naturally acquired" reactivity to larger doses of tuberculin, which has been studied extensively by WHO teams in various countries in recent years. Many observers believe that this effect is produced by mycobacteria in the environment, more abundant in some regions than in others and in rural than in urban areas. It is suggested that students of the lepromin reaction give thought to this possibility.

3. BCG AND CHEMOTHERAPY IN LEPROSY PREVENTION

The Committee recognizes the importance of any method which will help to prevent the contacts of patients from developing the disease. The two principal methods which have been investigated are the use of BCG vaccination and the administration of regular small doses of DDS.

BCG vaccination in prophylaxis

World-wide experience has shown that BCG can induce lepromin positivity in a high proportion of healthy individuals. Lepromin positivity also increases spontaneously with age. In healthy individuals BCG vaccination can accelerate the development of positivity, which may be of benefit to healthy contacts.

It has also been demonstrated that re-testing with lepromin can modify the immunological status and determine lepromin reactivity, but in lower percentages and with less intensity than BCG.

The efficacy of BCG in the prevention of leprosy has not yet been conclusively demonstrated because :

- (a) most the experiments made have been on too small a scale and have been carried out generally without proper statistical planning ;
- (b) many of these experiments have been done too recently to permit assessment of the results.

However, properly conducted BCG vaccination of tuberculin-negative contacts is harmless and confers a certain degree of protection against tuberculosis.

In view of these factors, the Committee considers that there is no objection to BCG vaccination in leprosy campaigns in progress in countries with sufficient resources. In such countries it may be possible to carry out the antileprosy campaign and simultaneous BCG vaccination of tuberculin-negative contacts.

In countries in which there is a shortage of personnel and of financial resources, the attention of the personnel should not be diverted from control work by the inclusion of BCG vaccination of contacts.

Where BCG campaigns are already in progress, it may be that those who are vaccinated will be simultaneously protected against leprosy. Perhaps in the coming years data will become available from work already done or in progress which will indicate whether BCG vaccination is effective in the prophylaxis of leprosy.¹

Chemotherapy in prophylaxis

Similarly, trials have been conducted to ascertain if the regular administration of sulfone in small doses will protect contacts. The results so far obtained are not considered to be sufficiently convincing or significant.

Suggested investigations

If BCG vaccination confers any material degree of protection against leprosy infection, it is to be expected that the mass antituberculosis campaigns now under way in various countries where leprosy is endemic will reduce the incidence of this disease in them.

One plan for the investigation of the effectiveness of BCG vaccination in tuberculosis now being prepared by WHO would give similar information on leprosy if someone trained in the detection of leprosy cases were attached to the tuberculosis team.

This tuberculosis investigation, to be carried out in India, involves a comparison between communities, in only some of which—chosen by random allocation—will vaccination be done. In the region selected there are about 200 community development blocks, and groups of about 10 are to be allocated to different control schemes. By making prevalence surveys in 10 blocks in advance, the overall prevalence of the disease can be estimated. The scheme is then to be started in the chosen blocks. Later, after whatever period is regarded as advisable (e.g., five years), the exact prevalence is to be measured in all the blocks. The prevalence in the treated and control blocks will then be compared, and related to the original estimated prevalence.

It has been calculated by the statisticians that even if 50% of the population should move from a control block the effect of the control measures could still be estimated statistically.

The Committee strongly recommends that the effect of BCG vaccination on leprosy be included in this project.

¹ The Committee notes that up to the end of December 1958 more than 88 million people have been vaccinated in campaigns assisted by WHO and UNICEF.

Most significant and accurate would be the result of a model experiment carried out in two or three rural areas to ascertain the effect of prophylactic measures. It is necessary that both the total prevalence and the lepromatous rate be high. In such an experiment it would be possible to carry out a combined study to compare the effects of both BCG vaccination and chemoprophylaxis. A general outline of such an experiment is as follows :

A group should be taken of household contacts under 9 years of age in close contact with lepromatous or other open cases. The age limit of 9 years is fixed for this group to avoid the change in living conditions which is liable to occur after the age of 15 years and might affect the type of contact.

(1) This group should be previously tested with tuberculin in small dosage (1 T.U.), but not with lepromin. The tuberculin-negative contacts should be divided into three groups :

- (a) a control group which will receive no treatment ;
- (b) a group vaccinated with BCG in accordance with the standards laid down by WHO ;
- (c) a group treated with sulfone at half the therapeutic dosage.

It would be desirable, if feasible, to include a fourth group of tuberculin negatives, to be given both BCG vaccination and sulfone treatment, so as to ascertain the effects of combined measures.

(2) The tuberculin-positive contacts should be divided into two groups :

- (a) a control group to discover the role of natural infection with tuberculosis in protection against leprosy ;
- (b) a group to be treated prophylactically with sulfone in the same way as the tuberculin-negative group 1 (c) above, so as to ascertain the differences in the groups due to chemoprophylaxis alone or associated with tuberculosis infection.

In order to ensure adequate analysis of the collected data, each group should include at least 100 individuals, and records should be carefully planned and maintained, with statistical assistance.

Babies of such families born during the experiment should be properly divided among the experimental groups and added to the original sample.

At the end of the experiment, after the number of years determined (not less than five), all groups should be tested with lepromin.

The question has often been asked if it is possible for leprosy workers to determine, without previous knowledge of the prevalence of leprosy, whether or not a mass BCG campaign in an area has influenced the incidence of leprosy in it. It is not considered possible to do this in an individual area without a reference norm. It is possible, however, to do it by comparing

the findings in a vaccinated area with those in other areas which in all aspects are similar, apart from the vaccination campaign.

4. LEPROSY CONTROL

Definition of terms

Preliminary investigation. A preliminary investigation means an investigation by one or more trained workers to obtain a general picture of the distribution of the disease and the size of the problem in a given territory. The object is to find areas of high prevalence and choose a site for a case-finding programme. All available information should be made use of.

Case-finding programme. A case-finding programme means the detailed search for leprosy cases and contacts with a view to placing every patient under treatment and all household contacts under surveillance.

Epidemiological survey. An epidemiological survey means a study properly planned and carried out with expert statistical advice, and should include the recording of all relevant details (e.g. type and stage of disease, age and sex distribution, diet, and climate), so as to obtain an accurate assessment of the total problem.

Pilot project. A pilot project is a project in a restricted area which serves as a guide to a larger one or to a whole campaign. Its purposes are :

- (a) to train personnel, especially at the beginning of the campaign ;
- (b) to adapt medical, administrative, and field techniques to local conditions.

Pilot projects are carried out by medically qualified personnel assisted by trained nurses, public health workers, medical auxiliaries, and those trained in health education. These projects precede the campaign and may continue during it.

Pilot area. A pilot area is a geographical area in which a pilot project is being carried out. It is also an area in which more detailed investigations may possibly be made.

Mass campaign. A mass campaign consists of a case-finding programme pursued on a large scale in highly endemic areas with treatment of detected cases by standardized methods. In this work paramedical personnel can be utilized under the supervision of doctors. (Mass treatment is dealt with in detail under Therapy.)

Methods of organizing antileprosy campaigns

The methods to be adopted for antileprosy campaigns will differ according to the prevalence rate and economic and social conditions. Each country will adopt the method suited to its own circumstances.

The Committee emphasizes that wherever a campaign is to be undertaken it is essential to establish a central leprosy service. The head of this service should be a leprologist with knowledge of public health administration who should be appointed to the senior grade in the health service of the country.

Where there is a will to deal with the problem of leprosy it is not necessary to wait until there are numerous highly qualified personnel. Field work can be started with a limited paramedical personnel, the staff being augmented as the campaign is extended.

The ultimate trend of the leprosy campaign should be towards its integration within the general health services.

Experience in the various leprosy campaigns suggests that there are usually three phases in their development.

(1) Attack phase

(a) The leprosy campaign should begin with case-finding and treatment. Case-finding will become more successful as the efficacy of sulfone treatment is realized by the public. It is carried out as follows.

(b) Mass examination of the whole population is the best means of detecting leprosy cases, particularly those in the early stages. Gatherings of the whole population can be made use of for leprosy case-finding, as, for example, those which take place in mass campaigns against yaws, trypanosomiasis surveys, smallpox vaccination, etc.

(c) House-to-house case-finding can be carried out in some countries where the circumstances are favourable.

(d) Contact tracing is a more suitable method in countries of medium and low prevalence. In countries with hyperendemic leprosy practically all the population must be regarded as contacts and contact tracing is an expensive method.

(e) Another method that can be used is the examination of previously selected groups of the population, for example, military recruits, factory workers, or schoolchildren.

(2) Consolidation phase

This phase follows the preceding one immediately the ceiling of case-finding has been attained. Leprosy is a chronic disease, and patients have

to be treated for years. Case-holding is the most important part of the consolidation phase.

Means of ensuring the regular treatment of registered cases are :

(a) mobile circuits, e.g., by automobile, bicycle or other means of transport.

(b) out-patient clinics, which should be visited on fixed days by the paramedical personnel in charge of the treatment ;

(c) skin clinics ;

(d) travelling skin clinics (mobile units) ;

(e) leprosy villages in countries of scattered population where the use of mobile circuits is impracticable ;

(f) a unit for survey, health education, and treatment (S.E.T.), which carries out work around a general hospital, dispensary, or health centre (this work may be carried out in difficult situations by paramedical personnel assisted by a doctor) ;

(g) a working group, as established in Brazil, directed by a leprologist who supervises the work of non-specialized physicians and some health workers ;

(h) all existing non-governmental institutions in the country concerned, which should be enlisted in the leprosy campaign if they accept the policy and direction of the health authorities.

The role of special leprosy institutions will be considered later.

(3) *Integration phase*

When health centres have been sufficiently developed, the treatment of leprosy patients should become part of their work.

At the beginning case-finding and re-surveys should be carried out by the specialized leprosy personnel, but when integration is complete these functions should be assumed by the general health services, working from health centres.

When a leprosy campaign has started with a pilot project, extension can be considered when availability of funds and personnel permit.

Functioning of pilot areas and pilot projects

Pilot areas should be established for the evaluation of the results of campaigns in countries which organize mass campaigns covering the whole territory. In many other countries, pilot projects are the only effective way of starting campaigns, the pilot projects being gradually extended until they cover the whole country. In the establishment of a pilot area the following principles should be borne in mind :

(a) It should not be larger than 20 000 sq. km. Larger areas cannot easily be covered by health services which treat all the patients, nor can they be regularly inspected by the chief medical officer of the pilot area.

(b) The population in the area should not exceed 500 000. The pilot area of Khon Kaen in Thailand, with 600 000 inhabitants, represents a maximum already difficult to control. Where there is a dense population, the pilot area must be reduced in size.

(c) The pilot area should be sited where the estimated prevalence rate is higher than the average for the country, never where it is lower.

(d) In the chief centre of the pilot area there should be a hospital or leprosarium with accommodation for acute cases, and a laboratory equipped to carry out bacteriological and, if possible, histopathological examinations.

(e) The medical director of the pilot area must have an adequate knowledge of leprology and public health so as to ensure the efficient operation of the project.

The functions of the pilot area at the beginning of the campaign and during the period of intensive activity may differ from those found necessary in the consolidation phase. The following data should be obtained from the pilot area :

(1) During the initial survey :

(a) a map of the region, with an indication of the population and its distribution in villages, communications, location of treatment centres, and itineraries of mobile teams ;

(b) a census of patients, classified accurately according to the clinical type or group of the disease, sex, age, ethnic group, and distribution in villages ;

(c) a census of disabled leprosy patients, if possible classified by degree of disability ;

(d) information on all the epidemiological factors which may have contributed to the general situation (previous treatment, methods of treatment used, previous vaccination with BCG, etc.).

(2) During operations :

(a) the number of persons examined per annum :

(b) the number of new cases detected, classified as above ;

(c) a census of household contacts of leprosy patients and the results of their periodic examination ;

- (d) the number of cases, classified as above, subjected to each of the treatment schedules adopted (with an indication of the patients receiving regular treatment¹);
 - (e) the progress of treatment as judged by clinical and bacteriological findings; the number of cases discharged as cured; the number of relapses—all these classified in groups as above;
 - (f) the number of deaths and transfers to and from other regions, and cases of whom trace has been lost (it is advisable to make enquiries about the extent to which immigration of patients takes place);
- (3) At the end of the project and at subsequent examination:
- (a) the number of cases remaining under treatment;
 - (b) the number of cases remaining, without treatment, under observation;
 - (c) the percentage of residual disability;
 - (d) the results of re-examination of the population for total prevalence, as before the beginning of the campaign.

Personnel of leprosy campaigns

The national chief of the campaign is responsible for its direction, the training and distribution of personnel, and the obtaining of the statistical data necessary for its evaluation.

There should be a director of each sector who should be a physician with experience in leprology. His responsibilities will include the distribution of medicaments, the collection of statistical data and their transmission to the national chief of the campaign. Sectors will vary in size according to the country concerned; they may be states, provinces, divisions, etc.

In each sector there will be different districts, each under the supervision of a doctor who will assist paramedical workers in difficult situations.

In many countries there are two or more categories of paramedical personnel and at least two kinds of qualification. The better qualified of them should be capable of:

- (a) making a clinical diagnosis of new cases;
- (b) recognizing drug reactions, and the necessity for suspending treatment;

¹ According to the WHO Inter-Regional Conference, Tokyo, and the Conference on Leprosy in Africa, Brazzaville, "regular treatment" is defined as follows: "A patient conforming to at least 75% of the recommended number of attendances should be considered to be attending regularly."

(c) giving intramuscular injections, and taking smears from the nasal mucosa or from skin lesions by the routine scraped-incision method ;

(d) maintaining the register of patients, recording attendances at treatment sessions, reporting periodically the number of patients regularly treated, listing by names those who have failed to follow the treatment, those who have commenced it and those who have resumed it, keeping clinical files of new cases, and recording progress in the patients treated.

The less qualified personnel need only rudimentary training. It is sufficient if they can write, in order to be able to enter patients' names in the register, to note the treatment given, and to recognize drug reactions so as to interrupt treatment when necessary. They will be entrusted with giving treatment and doing dressings. They must have a sufficient sense of responsibility to ensure that they will carry out their task conscientiously.

All these paramedical personnel should be instructed in health education so that they can disseminate any necessary information among patients and their families. Social workers also should participate in the health education of the population regarding leprosy and the antileprosy campaign.

Many persons not specifically attached to the antileprosy campaign can co-operate effectively in the treatment of patients and aid in ensuring their regular attendance. Such persons include :

(a) general practitioners and hospital physicians ;

(b) physicians and health personnel attached to rural units who can administer tablets or give injections ;

(c) non-medical people of sufficient cultural and educational attainments, who can be authorized to distribute tablets.

Assessment of results of leprosy campaigns

Some countries will be able to assess the progress of the campaign themselves, but in others—especially those conducting mass campaigns—circumstances may make it necessary or advisable to get help from WHO in the form of an assessment team.

This team should include a leprologist and a statistician, and be completed by locally engaged staff.

When the team arrives in the country concerned, it should, after analysis of the existing data, determine, in collaboration with the local staff, the most favourable area for evaluating the campaign, select local personnel and instruct them in their tasks.

The team, by some method of random sampling, should examine a section of the total population to assess :

(a) the number of patients discharged as cured and the number of relapses ;

- (b) the extent and type of disability according to the scheme of classification suggested later ;
- (c) the prevalence rate ;
- (d) the number of new cases diagnosed since the commencement or implementation of the project ;
- (e) the results of the periodic examination of contacts ;
- (f) the total number of cases treated and of those treated regularly.

It is necessary carefully to record the data obtained on pre-established punch cards so that a statistical analysis can be made.

5. THERAPY

The Committee recognizes that antileprosy chemotherapy in general is based on drugs belonging to the sulfone group. Of these, the parent sulfone (DDS) has the widest application because of its effectiveness, simplicity of administration, and low cost.

A further advantage of DDS is that it can be used in the treatment of individual patients at such intervals as are desirable or convenient, and also in mass campaigns at relatively longer intervals. Moreover, its low toxicity in proper doses permits of its being entrusted to paramedical personnel.

The Committee recognizes that other drugs have been found active in the treatment of leprosy, as, for example, thiosemicarbazone. Investigations have been carried out, and others are in progress, into the usefulness of thiourea compounds, diaminodiphenylsulfoxide, the mercaptan derivatives, the long-acting sulfonamides and certain antibiotics. Some of the reports on the use of these drugs are very encouraging.

Mass treatment

Mass treatment is the term applied to the treatment of a large number of patients with standardized methods by paramedical personnel under the supervision of doctors.

At the present time DDS is the best drug for mass campaigns. The choice between tablets and injections depends upon local geographical conditions, the qualifications of the staff giving treatment, the financial resources available, and social and psychological factors. The discovery of new medical preparations or better repository media may affect the choice, dosage, and periodicity of the forms of treatment at present being employed.

It is desirable that tablets be swallowed in the presence of the distributor. However, in certain circumstances there may be no alternative but to

entrust the patients with a sufficient quantity to continue treatment at home, but this should be for as short a period as possible. The tablets should be given weekly, beginning with a small dose, generally 50 mg, and increasing progressively to a maximum dose of 600 mg after several weeks.

Repository injections of DDS suspension which have been used generally contain 0.125 g of DDS per ml. They should be given fortnightly, beginning with a dose of 1 ml, and increasing progressively to a maximum dosage of 5 ml. In certain cases, in order to ensure good tolerance, the maximum dosage should be less than this.

Evaluation of progress during treatment

The Committee is of the opinion that where there is regular supervision and examination of patients under treatment by medical personnel as, for example, in leprosia, hospitals and out-patient clinics, i.e., where doctors or nurses are normally in attendance or themselves examine the patients, attention should be paid to certain criteria before deciding that improvement has taken place, to enable a proper or reasonable evaluation to be made and to reduce misleading conclusions to a minimum.

It is suggested that the minimum requirements for evaluation include a careful clinical examination, and that special reference be made to the following features :

- (a) the bacteriological examination ;
- (b) the flattening of raised lesions and a decrease in erythema ;
- (c) the non-appearance of new lesions and non-extension of old ones ;
- (d) the presence or absence of nerve thickening, tenderness, and neuralgic pain, and the non-extension of areas of anaesthesia ;
- (e) the cessation or resolution of any manifestations of reaction ;
- (f) the maintenance and improvement of body weight.

To these criteria should be added, if possible, comparative clinical photographs.

Trials of new drugs

In every trial of a new drug there should be a control group on a treatment of proved value, for example, DDS. Such trials should be planned according to sound statistical principles. They should be continued for a period of not less than two years and should be related to the different types of leprosy, it being understood that any patients who become worse or in whom the pattern of disease is not improved after a reasonable time should be withdrawn from the trial. It is preferable that patients should

have had no previous treatment. However, having had some measure of other treatment should not necessarily exclude patients from being put into either group, as long as the control and trial groups are comparable. Clinical evaluation should include an estimation of the bacteriological picture according to agreed indices. It should be assisted and confirmed by standard serial photographs in monochrome and, if possible, in colour.

The Committee recommends that WHO assist in controlled chemotherapeutic investigations, which should be conducted simultaneously in several centres in various parts of the world.

The Committee also recommends that the policy to be adopted in the trials and the rules to be observed be set forth in a protocol prepared by WHO. This protocol should include all necessary safeguards in the patients' interest, particularly with respect to the toxicity of the drug and tolerance.

6. REHABILITATION OF DISABLED PATIENTS

Definition

By rehabilitation is meant the physical and mental restoration, as far as possible, of all treated patients to normal activity, so that they may be able to resume their place in the home, society, and industry. To achieve this, treatment of the physical disability is obviously necessary, but it must be accompanied by the education of the patient, his family and the public, so that not only can he take his normal place, but society will also be willing to accept him and assist in his complete rehabilitation.

The Committee desires to emphasize that rehabilitation does not mean the creation of asylums for those who are crippled. Indeed, it means the very opposite, although it has to be recognized that there may be a number of patients in institutions (they can, for convenience, be referred to as "residual cases") whom, for various reasons (e.g. blindness, no relatives, no home, etc.), it may not be possible to restore to former spheres.

General principles

The Committee emphasizes that it is desirable that rehabilitation should take place in the environment in which the patient lives. Rehabilitation centres as such should be used for the training of workers, demonstration and research.

The psychological adjustment of the patient should be achieved during treatment by those in whose care he is placed. His restoration to the home and society will be finally prepared by those who are carrying out the leprosy health education programme.

The extent of the problem

From the figures available it is estimated about 25% of all patients have some physical disability. Many of these need physical rehabilitation. Social and psychological rehabilitation may be necessary, however, even for patients who have no physical disability.

It is very desirable that the extent of physical disability be correctly ascertained. This information should be obtained by approaching each country where leprosy is endemic, because it is believed that the extent and type of disability vary from one country to another. It is therefore suggested that such countries be asked to ascertain the number that are disabled and to analyse the deformities according to the scheme of classification recommended later in this section. This analysis will be more helpful if it is related to the type of leprosy, and to the sex and age of the patients, for it is not known which of the polar types of leprosy is the more vulnerable, or to what extent the occupational hazards and the habits of the patients contribute to the type of disability produced.

Methods

The Committee emphasizes that the early treatment of patients, and special attention to anaesthesia of the hands and feet, will without doubt prevent the development of deformities.

At all points the need for education of all patients and employers must be stressed. The educational standards of some of the paramedical personnel may be a limiting factor. Nevertheless, instruction should be given by them to all patients about the care of their hands and feet, the avoidance of the damage which so easily occurs where there is anaesthesia, the care of minor injuries to prevent sepsis, and the reduction of commencing deformity by simple exercises.

When deformities have developed they may be dealt with by physiotherapy and surgery, accompanied by some form of re-education.

Physiotherapy may by itself avoid the need for surgery in the earlier stages of deformity. In others, it will make the work of the surgeon easier and lead to better post-operative results. Physiotherapy after surgery restores mobility to surgically treated hands and feet, and helps in the re-education of muscles that have to assume a different function.

The number of surgeons with the necessary experience and the number of centres at which remedial surgery can be undertaken are limited. It is believed that only surgeons with special experience should undertake this work, and preferably in special units in hospitals, or in hospitals or institutions where physiotherapy is possible before and after operative treatment.

Occupational therapy is necessary for those in whom improvement by surgery or physiotherapy is not possible, and in others after the work of

the surgeon is completed. Special adaptation to local conditions of industry may be necessary, which may include the adjustment of tools for use by patients who, as a result of surgery, may have a different kind of grip. The safety of any measure introduced during occupational therapy must be specially considered, having regard to the fact that the patient's hands remain anaesthetic and therefore liable to injury.

All these methods are complementary, and to them must be added, not only the measures referred to under education to restore the individual to society with some degree of confidence, but also warnings of the increased necessity of care for hands and feet lest they become more seriously damaged by trauma in virtue of the improved mobility and usefulness that have been given to them. Using newly mobilized fingers which are still anaesthetic to lift hot cooking pots is an example of what might occur.

Classification of deformity

For the careful estimation of the extent of deformity in different countries, the following scheme of classification is suggested. The Committee recommends that the information be related as far as possible to disease type, age and sex.

Scheme of classification for grading of physical disability resulting from leprosy

A. *Hands*

- Grade 1 — Anaesthesia to pain.
- „ 2 — Mobile claw hand. Useful thumb.
- „ 3 — Intrinsic paralysis involving fingers and thumb, or fingers only but with contracture.
- „ 4 — Partial absorption of the fingers but with useful length remaining.
- „ 5 — Gross absorption. Stumps only left.

B. *Feet*

- Grade 1 — Anaesthesia.
- „ 2 — Trophic ulceration (present or past).
- „ 3 — Paralysis (foot drop or claw toes).
- „ 4 — Partial absorption of the foot (up to one-third of surface area of the sole lost).
- „ 5 — Gross absorption (more than one-third of the foot lost).

C. Face

- Type 1 — A permanent mark or stigma of leprosy not amounting to ugliness (loss of eyebrows, deformity of the ear).
- „ 2 — Collapse of nose.
- „ 3 — Paralysis of the eyelids, including lagophthalmos or paralysis of the facial nerve.
- „ 4 — Loss of vision in one eye or dimness of vision in both eyes (can count fingers).
- „ 5 — Blindness.

D. Miscellaneous

- Type 1 — Gynaecomastia.
- „ 2 — Involvement of the larynx.

Note : For record purposes it is suggested that it be stated whether conditions under A, B, and D.1 are unilateral or bilateral.

Research

The Committee recommends further study of the possibility, practicability, and methods of preventing and correcting deformities, and suggests that attention be directed to the following subjects :

- (a) the nature of the deforming factors in leprosy ;
- (b) the physical and anatomical factors which are responsible for the distribution of paralysis and deformity in leprosy ;
- (c) the hazards of anaesthesia, and the nature of the particular susceptibility of denervated limbs (trophic changes) ;
- (d) the drawing up of a practical programme for the prevention and correction of mutilation, applicable especially to young children in countries with a high prevalence and limited medical resources ; and
- (e) the role of plastic surgery.

Role of institutions

Leprosy institutions now tend to include three groups of patients : those admitted for active hospital treatment, those admitted for rehabilitation and early discharge, and residual cases whose presence is mainly due to the social effects of their physical condition. The main functions of such institutions should be adapted to deal with and treat active cases needing close supervision or special attention, and to provide measures for the rehabilitation of patients.

Non-governmental institutions should be invited to give special consideration to rehabilitation, particularly as the members of their staffs are well qualified by their sense of vocation for this work.

7. TEACHING AND TRAINING IN LEPROSY. HEALTH EDUCATION

Teaching and training of medical personnel

Undergraduate teaching. Medical students in countries in which leprosy is a problem should receive sufficient instruction in leprology. They should have theoretical and practical training in it during their courses of dermatology and preventive medicine, and at the end of each course should have seen a sufficient number of patients to be able to recognize the various clinical forms of the disease; they should also be instructed in the more simple diagnostic routine methods (test of cutaneous sensitivity, lepromin test, smears, stains, etc.), and in methods of leprosy therapy including the treatment of reactions.

Short refresher courses in leprosy for general practitioners. Such courses should be organized periodically in countries in which leprosy is endemic.

Special courses in leprology for doctors who will participate in the leprosy campaign. The duration of these courses will depend on the participants' previous knowledge of leprosy. The courses can be shorter for dermatologists, public health officers, or general physicians working in countries with high leprosy endemicity. Full-time courses are preferable to part-time courses.

These special courses in leprology can only be organized in institutions having sufficient teaching material, laboratory facilities, and numbers of leprosy patients.

Advanced training of doctors who have already worked in leprosy campaigns. The Committee endorses the recommendations of the WHO Inter-Regional Leprosy Conference, Tokyo, 1958, and the Conference on Leprosy in Africa, Brazzaville, 1959, and strongly recommends that WHO organize, at suitable intervals, courses on an international basis in previously selected leprosy institutions.

Teaching and training of paramedical personnel

The better qualified paramedical personnel are the basic personnel of the mass campaign against leprosy. These personnel should be properly instructed, and it is necessary for them to have the essential lectures on theory and intensive practical training. The duration of the courses will

depend on the previous basic knowledge of the participants, and will vary from one country to another.

Certain countries prefer to recruit general nurses or auxiliary health service personnel, or both, for these courses; others prefer previously untrained people who have sufficient general education.

Less qualified paramedical personnel need only limited instruction on theory, and should be trained in the field as assistants to the better qualified personnel.

In countries with major leprosy problems, the paramedical personnel of health centres (including midwives) should receive some leprosy training.

Teaching and training of social workers

Social workers should be instructed in leprology by the medical personnel of the campaign so as to obtain their efficient co-operation in the health education of the population.

Health education in leprosy

“Health education” is considered a more appropriate designation than “propaganda”. “Propaganda” suggests the imposition of, or the gaining of general acceptance for, an idea without reference to its worthiness; “health education” signifies the awakening of the mind to thinking correctly.

The prejudice against leprosy is deep-rooted, and is associated with the idea that it is incurable, very infectious, and leads invariably to mutilation.

The objectives of health education in leprosy should be :

(a) to convince patients and public of the curability of the disease in the early stages, especially before deformities have developed; and

(b) to demonstrate to society that it will not suffer if it takes up a more liberal attitude to leprosy patients and that the reabsorption of the latter into the community, even if they have deformities, is necessary on the ground of common humanity and in the interests of the more effective prosecution of the campaign.

All those who treat leprosy or deal with leprosy patients in any way should realize that leprosy is a communicable disease, not essentially different from any other. In most circumstances it is actually less contagious, and it is now curable. Doctors should be able to recognize leprosy in its early stages and to treat it or arrange for its treatment. If, however, the work of education is left only to doctors in their normal contacts with patients, the dissemination of knowledge will be very restricted. The chief impact on the public will, of necessity, be made by the paramedical personnel and social workers, for it is they who will go into the homes

of the patients and the general public. Unless these workers really believe themselves that leprosy is not a social disease they will not succeed in educating the patients and the public. It is, therefore, essential that they should be convinced of the truth of these things themselves before they take part in the general programme.

The most convincing way of obtaining the confidence of the public will be by demonstrating the progress that has taken place in the treatment of patients, especially those who have been discovered early enough and cured.

There are certain points that should be emphasized at all stages of the health education programme, namely :

(a) that it is to the advantage of the individual to have any suspicious lesion examined by somebody competent to do so ; and

(b) that it is to the advantage of the patient to follow the advice given about attending regularly for treatment and doing those things which will prevent the development of disability or deformity.

These and other elements in the programme of education can be supplemented by lectures, articles in newspapers, talks on the wireless, the skilful designing and exhibition of posters, pamphlets, booklets, film strips, and all other visual aids, these activities being carried out in conjunction with health education experts familiar with local conditions.

8. CLASSIFICATION

The Committee takes note of the recommendation by the Seventh International Congress on Leprology, held in Tokyo in 1958, that, because of lack of agreement regarding alterations which had been proposed, the formal classification of leprosy cases adopted at the preceding Congress, held in Madrid in 1953, remain unchanged pending further studies designed to correlate clinical features and histopathological findings. The Madrid definitions of the two polar types, lepromatous and tuberculoid, and of the two other recognized groups, indeterminate and borderline (dimorphous), should continue in use.

The Committee agrees emphatically that in classification priority should be given, as in the past, to the clinical criteria (including the bacteriological findings when that examination can be made). It also agrees that radical changes in classification from congress to congress should be avoided. Such action would lead to utter confusion, and neutralize all efforts to arrive at the universal use of the same terminology. On the other hand, it agrees that the classification is susceptible of improvement in detail and perhaps also in respect to the number of forms that should be recognized.

The Committee feels that consideration of the proposal made at Tokyo (namely, that recognition be given to two other subordinate "groups", maculo-anaesthetic and pure polyneuritic—the former involving reconsideration of the position of all simple macular lesions) may have been handicapped by lack of understanding, on the one hand of precisely what those groups would consist, and on the other hand of how their recognition would affect the basic principles of classification. It is recommended that the advocates of those changes publish their views and the reasons for them and their opponents publish their objections in the near future, so as to permit full consideration of the arguments before the Eighth International Congress is held in Brazil in 1963.

The Committee is concerned about the confusion that has arisen in recent years by the application of the terms "dimorphous" and "borderline" to cases, including macular and neuritic, other than those covered by the description of the "borderline (dimorphous)" group in the Madrid classification. It is recommended that the decision of the Tokyo congress in this matter be respected, and that until and unless it is agreed by a leprosy congress that the classification be changed, different and distinctive terms be applied to varieties of leprosy which are believed not to be covered by the Madrid classification.

Note is made of the recommendation of the Tokyo Classification Committee that an appeal be made to WHO to take steps to contribute to the solution of existing problems of classification before the next international congress.

9. RESEARCH IN LEPROSY

Leprosy is one of the diseases in which it is as yet impossible to culture the bacillus or transmit the disease as such to an experimental animal. If either of these objectives can be achieved, there will be a new approach to many problems. There are also other directions in which investigations should be pursued.

This Committee therefore welcomes the interest in leprosy research shown by the Twelfth World Health Assembly.

10. LEGISLATION

The Committee strongly endorses the opinions of recent conferences that leprosy should be placed in the same category as other communicable diseases and dealt with as such by the public health authorities. Special legislation not in conformity with these principles should be abolished.
