COMMITTEE 5: WORKSHOP ON EPIDEMIOLOGY AND CONTROL INCLUDING FIELD THERAPY

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EPIDEMIOLOGY

Only a limited amount of additional information on the epidemiology of leprosy has accumulated since the last Congress, and there is a continuing need for more planned studies on various aspects of the problem. One of the important requirements for field studies is clear and comparable terminology, so that geographical comparisons are possible. There is also a need for more information on mortality rates of leprosy patients and also on spontaneous inactivation of the disease in certain types of leprosy.

One of the major handicaps in the study of the epidemiology of leprosy, particularly on transmission, is the lack of a simple and dependable test to identify subclinical infection in the field, despite the considerable progress which has been made in developing immunologic tests. The available information indicates that leprosy is a disease of high infectivity and low pathogenicity. With regard to transmission of the disease, there is more and more evidence of the importance of airborne spread, although other modes of transmission cannot be ruled out. The available evidence on arthropod transmission is inadequate to permit definite conclusions. However, there is less and less justification for insisting on the necessity for direct, prolonged, intimate contact for transmission of the disease. There is also the possibility of a carrier state in leprosy in view of the occurrence of acid-fast-bacilli in the skin and nose of apparently healthy persons, and studies on the occurrence of such bacilli should be repeated in combination with mouse foot pad and serological studies. Regarding possible extra-human reservoirs of infection, it is difficult to evaluate the significance of the occurrence of leprosy or leprosy-like disease in armadillos in certain parts of the USA, and it may be worthwhile to look for similar reservoirs in other parts of the world using modern methods.

The role of genetic predisposition in leprosy is not clear in view of the inadequacy of the available information. Further precise studies on the importance of genetics in leprosy are indicated.

One area of research in leprosy that could be fruitful is "risk factor" studies, where association of leprosy with certain variables related to environment or host could be studied prospectively with the hope that it may be possible to contribute to disease prevention through intervention or manipulation of the risk factors identified.

LEPROSY CONTROL

In leprosy control, program planning is vital for successful control work. Program formulation provides a logical process to ensure a full analysis of the current epidemiological, operational, and managerial problems. Such a formulation requires specially trained staff. A program should include precise objectives, targets, manpower requirements, physical facilities, financial resources,

timings of activities and their interrelations. Programming incorporates implementation and evaluation; the latter should include specification of the subject, verification and analysis of information support, review of original program planning, and review of progress on a) operational efficiency, such as staff competence, case detection activities, case holding, bacteriologic monitoring, etc; and b) epidemiologic effectiveness, such as reduction of prevalence and incidence rates and of deformity rates.

The program planning should lead to a gradual integration of specialized programs into the general and primary health services, which should eventually take full responsibility. This is a task for which the general health workers must be trained and motivated in order to prevent failures.

For the analysis of the leprosy situation and to make the comparison between data from different regions possible, it is recommended that a uniform leprosy information system be developed.

Case detection methods should, among others, include methods to encourage voluntary reporting through health education of the community utilizing, among others, mass media such as radio, TV, etc. In urban areas, motivation of general practitioners could be useful for case detection; they should coordinate with health authorities. Where facilities are available, lepromin testing is useful for identifying early cases which are lepromin negative.

With regard to release of patients from control, the recommendations of the Fifth WHO Expert Committee on Leprosy were considered to be valid. However, further studies on optimal duration of chemotherapy of paucibacillary leprosy were considered necessary.

Regarding treatment delivery, while the mode of treatment delivery will depend upon individual situations, it is necessary to carry out periodic checks on drug intake through urine tests. Every effort should be made to maintain regularity of treatment of patients, particularly of patients with multibacillary leprosy. In this connection it is necessary to ensure high standards in patient care.

Regarding primary prevention, although studies on chemoprophylaxis have established their moderate protective value, the application of chemoprophylaxis on a mass scale will not be practicable. Notwithstanding the difficulties, chemoprophylaxis can still be recommended in individual situations, where the risk of contracting leprosy is considered to be unduly high. Considering the limited prophylactic value of BCG, there is a need to develop a specific antileprosy vaccine.

FIELD THERAPY

The workshop reviewed field therapy of leprosy in the light of the recent advances in the pharmacology of the antileprosy drugs, the increasing incidence of dapsone resistance reported from different parts of the world, and the need for effective, acceptable, practicable, simple, and supervisable therapy, both for infection with *Mycobacterium leprae* and for the treatment of reactions.

The group reviewed the drugs available, and confirmed the importance of using bactericidal drugs, namely dapsone in full dosage, rifampicin, clofazimine and ethionamide or prothionamide.

Dapsone remains the basis of treatment, at a dosage of 6 mg to 10 mg per kg body weight per week. The drug should be commenced in full dosage, without any initial "build-up," and this dosage should be kept unchanged throughout treatment, and should not be interrupted or altered during reactions.

In tuberculoid (TT and BT), borderline (BB), and indeterminate (I) leprosy, monotherapy with dapsone is acceptable. In lepromatous (LL and BL) leprosy, it is recommended that an initial intensive phase of combined therapy should be given.

Recommended adult regimens for the treatment of lepromatous leprosy include:

a. *Rifampicin* 600 mg daily for a minimum of two weeks plus
   dapsone 100 mg daily, indefinitely.
b. *Rifampicin* 1500 mg in a single dose on the first day of treatment, plus
   dapsone 100 mg daily, indefinitely.
c. *Clofazimine* 100 mg daily for two months, then 100 mg three times a week for four months, plus
   dapsone 100 mg daily, indefinitely.
d. *Ethionamide* 375 mg daily for three months, plus
   dapsone 100 mg daily, indefinitely.

Pre-program studies of ethionamide are recommended in any area, before the drug is introduced generally.

Choice of regimen depends upon cost, cul-

tural acceptance and toxicity. If none of the above regimens can be afforded, the alternatives are:

e. *Thiacetazone* 150 mg daily for one year, plus
dapsone 100 mg daily. (Thiacetazone may have an unacceptably high incidence of toxic side-effects, especially in East Asia; its cost over one year equals that of a single dose of rifampicin, and thiacetazone-resistant *M. leprae* show cross resistance with ethionamide.)

f. *Dapsone* 100 mg daily indefinitely, ensuring regularity of treatment.

Dapsone resistance. Secondary dapsone resistance has to date only been reported in lepromatous (LL and BL) leprosy. The diagnosis should be confirmed by a medical officer. It is appreciated that mouse foot pad confirmation is not widely available. However, random specimens of the patient's urine should normally be tested to confirm the presence of dapsone. Further information is needed on the incidence and prevalence of dapsone-resistant leprosy in different geographical areas.

Recommended adult regimens for the treatment of dapsone-resistant patients include:

a. *Rifampicin* 600 mg daily for one month, plus
clofazimine 100 mg daily for six months, then 100 mg three times a week indefinitely.

b. *Rifampicin* 600 mg daily for one month, plus
ethionamide 375 mg daily, indefinitely.

c. *Ethionamide* 375 mg daily for three months, plus
clofazimine 100 mg daily for six months, then 100 mg three times a week indefinitely.

d. *Clofazimine* 100 mg daily for six months, plus
ethionamide 375 mg daily, indefinitely.

Primary dapsone resistance may occur in any type of leprosy, and this possibility should always be kept in mind, especially among contacts of known cases of secondary resistance.

Field therapy of reactions. Effective treatment of reactions is essential for the well being of patients, and to retain their cooperation with drug therapy. This involves improved training of field staff, and the provision of referral centers for the treatment of severe reactions. Mild reactions should be treated in the field, the patient being seen regularly; patients suffering from severe reactions should be sent immediately to the referral center, antileprosy treatment being continued unchanged.

Prevention of deformities. This depends on the early diagnosis of leprosy, effective antileprosy treatment, effective treatment of reactions to prevent (further) nerve damage, and education of the patients in the care of anesthetic limbs.