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Teaching Materials and Services

Chemotherapy of leprosy: new recommendations from WHO

KEY RECOMMENDATIONS

The report of the WHO Study Group on Chemotherapy of Leprosy, which met in Geneva on 1–5 November 1993, has now been published in the WHO Technical Report Series (TRS 847, 1994). The group extensively reviewed experiences with WHO/MDT, considered recommendations regarding the use of new anti-leprosy drugs and possible changes in the operational aspects of leprosy chemotherapy, and sought to identify future research needs in order to improve the chemotherapy and control of leprosy. Among its conclusions and recommendations are the following:

DURATION OF TREATMENT:

Multibacillary leprosy:

The WHO-MDT regimen for multibacillary leprosy has been very successful and has been widely implemented as recommended. Most data on the effects of limiting therapy to a 24-month course of WHO-MDT—rather than continuing until skin smears are negative—are favourable. It is therefore recommended that all multibacillary patients be given the standard WHO regimen for 24 months, since such a change is considered safe and will increase the use of the regimen under field conditions.

Paucibacillary leprosy:

The 6-month WHO-MDT regimen for paucibacillary leprosy has yielded excellent results wherever it has been appropriately used, and there is no convincing evidence to suggest that it should be extended beyond six months.

CLASSIFICATION:

Classifying patients through skin smear examinations should be continued. Where reliable facilities for the bacteriological examination of skin smears are not available, approaches based on clinical classification may be required. When classification is in doubt, the patient should be treated as having multibacillary disease.

REGULARITY OF TREATMENT:

Regularity of treatment requires that the multibacillary patients should receive 24 monthly doses of MDT within 36 months and paucibacillary patients six monthly doses within nine months. If

any patients drop out before completion of therapy, they should be re-evaluated when retrieved to determine whether further treatment is needed.

FOLLOW-UP AFTER COMPLETION OF THERAPY:

Because the risk of relapse after completion of the WHO-MDT regimen has been shown to be negligible, it is no longer necessary to continue routine annual surveillance of patients. Instead, patients should be taught, at the time of release from treatment, to recognize the early signs of possible relapse or reaction and to report promptly for treatment.

ALTERNATIVE DRUG REGIMENS FOR PATIENTS FACING SPECIAL PROBLEMS:

Resistance or toxicity to rifampicin:

For multibacillary patients who have rifampicin-resistant *M. leprae* or who have shown toxic effects to rifampicin, the Study Group recommended daily administration of 50 mg of clofazimine, together with two of the following drugs—400 mg of ofloxacin, 100 mg of minocycline, or 500 mg of clarithromycin—for six months; followed by daily administration of 50 mg clofazimine, together with 100 mg minocycline or 400 mg of ofloxacin for an additional period of 18 months. These should be administered under regular supervision in a leprosy referral centre.

Severe dapsone toxicity:

If any patient shows severe toxic effects to dapsone, the drug treatment with dapsone should immediately be stopped. No further modification of the regimen is required for patients with multibacillary disease. However, clofazimine in the dosage employed in the standard MDT regimen for multibacillary disease may be substituted for dapsone in the regimen for paucibacillary disease for a period of six months.

Refusal to accept clofazimine:

When clofazimine is totally unacceptable owing to pigmentation of the skin, 400 mg daily ofloxacin or 100 mg daily minocycline may be substituted for the clofazimine. In view of the severe hepatotoxicity of ethionamide and protionamide, these drugs should no longer be recommended as substitutes for clofazimine. Because of the limited information available, new drugs should be administered only under supervision in a referral centre.

FACILITIES FOR BACTERIOLOGICAL EXAMINATION:

A service for the bacteriological examination of skin smears is not a prerequisite for initiating an MDT programme. In view of the increasing prevalence of human immunodeficiency virus (HIV) infection and hepatitis B infection in many countries where leprosy remains endemic, the number of skin-smear sites and the frequency of smear collection should be kept to a minimum.

Source: *LEP News*, Vol. 3, No. 2, November 1994. WHO Action Programme for the Elimination of Leprosy, 1211 Geneva 27, Switzerland

Risk of relapse in leprosy. WHO/CTD/LEP94.1

The above paper prepared by the Leprosy Unit, WHO, reviews in detail the risk of relapse

following WHO-recommended multiple drug therapy (MDT). The results have been extremely favourable and the main points of the paper are as follows:

(a) The most significant result is that the risk of relapse is very low, both for MB and PB patients, after completion of MDT.

If we assume that all the biases and limitations which could possibly affect the results of this study were also, to a large extent, applicable to studies on relapses occurring after monotherapy with dapsone, then we find that the risk of relapsing with MDT is at least 10 times less than with dapsone monotherapy.

(b) There is strong evidence that in MB patients, 50% of relapses occur within the first three years after stopping MDT, and 75% within 6 years. Among PB patients, 50% of relapses occur within $2\frac{1}{2}$ years and 75% of relapses within 5 years.

Moreover, there are indications that in both MB and PB patients the annual risk of relapse does not increase over time. In other words, if in an individual patient the disease does not relapse within the first 5–6 years, then his/her risk of relapsing is negligible.

(c) With such a low risk for relapse and since the majority occur within a few years after stopping MDT, there is definitely no need to have long-term active post-MDT surveillance of patients for the purpose of detecting relapse. In other words, patients can be declared "cured" after completion of treatment.

(d) The protective effect of MDT in preventing post-treatment relapses as compared to dapsone is more than 90%. In other words, it can be estimated that the introduction of MDT has probably prevented close to half a million relapses during the last decade.

Applied field research, TDR

TDR News, October 1993, describes the new structure of TDR(UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases) and describes the function of its Applied Field Research Unit. Priority topics for TDR-funded applied field research are:

Disease control within existing health care systems

- preventive measures, for individuals and communities, against malaria infection and disease
- optimal combinations of measures to interrupt *Trypanosoma cruzi* transmission in human populations
- cost-effective strategies for the prevention and treatment of schistosomiasis and managerial tools for its control
- strategies for using ivermectin in the control of onchocerciasis (river blindness) in Africa
- malaria case management, particularly in children and women, in hospitals and at the "periphery" of the national health system
- new strategies for improving the organization and management of control programmes
- better detection and treatment of leprosy
- integrated control of visceral leishmaniasis through interventions targeted to children
- feasibility and cost-effectiveness of tools and strategies for the control of lymphatic filariasis
- integration of tropical disease control into primary health care systems and the sustainability of disease control programmes
- improving systems of health care delivery for better control of tropical diseases
- systems of drug delivery for diseases requiring repeated mass treatments
- ivermectin-based strategies for eliminating onchocerciasis in the Americas
- field-testing of new tools for the control of lymphatic filariasis
- feasibility and cost-effectiveness of different drug treatment regimens for leprosy
- optimization of current drug treatment regimens for African trypanosomiasis

- early identification and correct management of impaired nerve function in leprosy with a view to prevention of deformities.

Heath care financing
- impact of changes in financing mechanisms on the availability of funds for the control of tropical diseases, on treatment-seeking behaviour and on prevention of disease
- perceptions, by health care providers and communities, of the impact of changes in financing mechanisms
- the role of the nongovernmental sector in the control of tropical diseases
- improving control of tropical diseases, where possible, through a mix of public and private sector involvement in health care provision and financing.

Gender and tropical diseases
- women's recognition and understanding of disease, including malaria, schistosomiasis, African trypanosomiasis and Chagas disease
- operational research to improve the services and care provided to women by health centres
- cultural obstacles to women's access to and use of treatment facilities
- gender differences that relate to stigma associated with tropical diseases (notably, leprosy, cutaneous leishmaniasis, lymphatic filariasis and schistosomiasis) and that hamper early detection of these diseases.

Environmental and demographic changes
- migration and environmental changes (using, among other things, geographical information systems) and their effects on leishmaniasis
- disease control in situations of rapid socioeconomic, demographic and environmental change
- the effect of ecological changes on the transmission of vector-borne diseases
- agricultural development and rice growing as related to malaria and schistosomiasis.

Information-education-communication (IEC) from the perspectives of communities and policy makers
- IEC strategies for tropical disease control
- community compliance and participation in disease control efforts
- the school as an entry point for tropical disease control
- health promotion, directed to women as key health providers, in the control of leishmaniasis.

Rapid assessment procedures (RAPs)
- development of RAPs to determine the distribution of diseases requiring intervention at the community level
- development to RAPs to monitor and evaluate disease control efforts
- cost-effective strategies for community and individual diagnosis of schistosomiasis.

Surveillance and impact assessment
- local and national surveillance and health information systems, especially for malaria
- epidemiological modelling for disease surveillance and control
- cost-effective surveillance for the control of African trypanosomiasis: methods and managerial tools
- socioeconomic and public health importance of lymphatic filariasis
- epidemiological assessment of schistosomiasis morbidity and the impact of efforts to control it.

Source: TDR Communications, WHO 1211 Geneva 27, Switzerland

All Africa Leprosy and Rehabilitation Training Centre

TRAINING CALENDAR 1996

Jan 29–Mar 8 Prevention and Management of Disabilities
Course aimed at qualified physiotherapists and occupational therapists as well as experienced leprosy workers involved in the prevention and care of disability. Emphasis on POD programme management and disability problem solving.

Mar 11–Apr 12 Management of Combined Leprosy and TB Control Programmes
Course aimed at physicians and senior paramedical staff involved in managing a combined programme at the regional or national level.

Apr 15–Apr 26 Training Methodology
Course aimed at senior staff involved in human resource development. Emphasis on curriculum planning, learner centred teaching methods, appropriate teaching tools and course assessment.

May 6–May 24 Tuberculosis Control for Physicians
Course aimed at physicians newly involved in TB control, especially those working in leprosy programmes recently combined with TB. Emphasis on programme management.

Jun 10–Jun 22 Essentials of Leprosy and TB for Non-Medical Staff
Course aimed at non-medical managers and administrative staff working in Leprosy and TB programmes or donor agencies. Objectives: to gain a better understanding of the two diseases, to communicate more efficiently with the medical staff and to contribute more effectively in decision making and priority setting.

Aug 5–Aug 16 Social Rehabilitation
Course aimed at both general and leprosy workers involved in social rehabilitation. Emphasis on community participation, sustainability and independence.

Aug 26–Sep 6 Tropical Dermatology
Course aimed at physicians with experience and/or special interest in the diagnosis and management of skin diseases in Africa.

Sep 16–Oct 25 Essentials of Leprosy and TB for Physicians
Course aimed at physicians with limited experience in either leprosy or TB. Emphasis on clinical aspects and programme management.

Oct 28–Dec 13 Supervision of a District Leprosy and TB Control Programme
Course aimed at experienced paramedical workers responsible for leprosy and TB control at the district (or equivalent) level. Emphasis on programme management, with special attention on supervision and evaluation.

In-service Training
To be arranged on an individual basis.
Duration and content in function of experience and interest of trainee.
Possible subjects: physiotherapy, surgery, laboratory, dermatology, ophthalmology, etc.

A more detailed training brochure will be sent upon request.

For further information, please contact: The Director of Training, ALERT, P.O. Box 165, Addis Ababa, Ethiopia.