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ILEP Meeting on Multidrug Therapy (MDT)

On the Sunday preceding the opening of the Congress, an all-day meeting on MDT was organized by ILEP (The International Federation of Anti-Leprosy Associations, 234 Blythe Road, London W14 0HJ), during which preliminary reports were presented from workers in various parts of the world, who have already implemented MDT. Many of them have already been invited to submit accounts of their experiences in this important area of activity for possible publication in this Journal in 1985.

We are indebted to the Secretary to the Medical Commission, Dr H W Wheate for the following account of the Meeting.

Morning session

The Chairman, Mr A D Askew, opened the Meeting by welcoming all present and asked them to introduce themselves.

He pointed out that MDT offered a great opportunity for advance in leprosy control because it was not only a tool to combat dapsone resistance, but also was necessary only for a defined, limited period of time. It must, however, be applied properly and this Meeting between field workers and members of ILEP had been arranged to discuss the practical problems of implementation of MDT. It was hoped that field workers would explain what they expect from the Voluntary Agencies, which in their turn, would discuss the managerial aspects which are their particular concern.

The result of the Meeting should be practical recommendations.

REPORTS

1 *Ethiopia*—Dr Marijke Becx-Bleumink

The progress achieved in the pilot programme initiated in one area has been affected by several problems. The preparation prior to implementation of MDT had, it was subsequently realized, been inadequate. The technical guidelines for the staff were published only after the programme had started. Previous clinical records had been on the whole poor in quality and smear examinations were generally not done. It had taken time to deal with all these problems, but now they were also ready to start in the area around Addis Ababa.

In the discussion, Professor Pattyn pointed out that it is more important to do skin smears in cases clinically diagnosed as paucibacillary than in those obviously multibacillary. It was also pointed out that after the prescribed period of 6 months' chemotherapy, the skin lesions would still be active in some patients. The fact that chemotherapy is no longer indicated under these circumstances will call for considerable skill in patient management and explanation.

2 *Malawi*—Dr G Boerrigter

Dual therapy with rifampicin and dapsone had been in general use for multibacillary cases since 1981 and the staff capable of giving supervised drugs was therefore available.

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One problem was the backlog of large numbers of paucibacillary patients who no longer needed chemotherapy and in many cases the solution was 'the golden handshake of 6 months' MDT'.

Since 1981, they had experienced no side-effects resulting from the use of rifampicin given in 2 doses of 600 mg on successive days (the first supervised, the second to be taken at home the next day), but there had not been a controlled study.

A system of surveillance had been developed. It was pointed out that this was a vertical programme and that therefore implementation was probably easier than in integrated programmes. A practical recommendation was that a careful check should be made in cases with a BI of around 2+.

In the discussion, it was pointed out that this programme illustrated the value of proper preparation of both staff and patients. One delegate enquired if cases of fainting after rifampicin had been noticed and Dr Gjalt said that such cases had occurred. The occurrence of reactions after completing the 6 months' period of chemotherapy in paucibacillary cases was also noted. It was agreed that 50% of relapses in paucibacillary cases are likely to occur within 3 years and that thereafter surveillance should be limited to asking patients to report back themselves if they notice anything untoward.

3 *Niger*—Dr A Cissé

A pilot project to test the feasibility of the WHO regimens under local conditions is in the course of implementation. There are 500 patients under treatment, 425 paucibacillary and 75 multibacillary. Seminars are held for all health staff of the general health service.

Shortage of trained supervisory staff is however a problem. The programme of health education of the public seems to be effective in increasing public awareness of leprosy and ensuring that patients are welcome to the health centres providing treatment. One interesting feature was a modification of the WHO regimen to take account of local conditions—in the dry season, the monthly supervised drugs are given, whereas in the rainy season when supervisory visits are impossible, dapsone and clofazimine only are dispensed for unsupervised intake at home. Treatment is given on market days. One problem is that most of the population is illiterate and nomadic.

4 *Paraguay*—Dr A E Alvarenga

In this programme, a total of 789 patients had been treated by Isoprodian. Of these, 30 had defaulted and 5 died, leaving 754 on the register, 553 multibacillary and 201 paucibacillary.

To date, 293 multibacillary and 192 paucibacillary cases had been discharged from chemotherapy, and so far there have been no relapses—the period of observation extended to 4 years in some cases. The average duration of treatment in multibacillary leprosy was 1 year 2 months. In the discussion, it was observed that the period of treatment was not fixed, in order to find out the optimum duration of therapy. This involved, however, difficulty in assessing relapse rates. Side-effects had been minimal; 155 patients complained of gastrointestinal disturbances and one with hepatitis had to suspend treatment.

5 *Miraj, Maharashtra, India*—Dr P D Samson

The programme covered a population of 250,000 and was organized through paramedical workers each covering 5–6 villages with a population of about 25,000.

Before introducing MDT, there had been a year of careful preparation, including 1 week's initial training for all the staff, followed by a 'refresher' for 2 days per month, the formulation of 10

key indicators to evaluate operational efficiency, especially as to attendance and case detection. There was also a programme of health education involving firstly the patient and his family, and secondly development officers, group leaders, as well as the news media, village meetings and posters.

The regimens adopted were modifications of the WHO Recommendations. The dapsone intake was monitored by urine testing (the Tile Test) and tablet counts. The plan of operation was based on a routine timetable for the month—1 week of survey, 1 week of pre-clinic preparation and follow-up, 1 week of treatment distribution and 1 week of administrative routine.

The cost amounted to Rupees 343 per patient or approximately Rupee 1 per head of the population covered. There had been no serious side-effects among any of the patients treated who included 191 over the age of 50 years and 101 children.

Two features of this programme particularly noted during the discussion were the importance of health education and the provision for domiciliary rehabilitation.

6 *Tamil Nadu, Uttar Pradesh and West Bengal, India*—Dr Claire Vellut

The regimen adopted is a modification of that recommended by WHO and includes an initial period of intensive therapy with daily rifampicin for multibacillary cases.

It had been found that importing additional staff for the implementation of MDT made for difficulties in subsequent follow-up. Preliminary Health Education had been found to be essential for success—as in Miraj.

The attendance rates were better than with dapsone monotherapy, possibly because patients were impressed by the care taken with their clinical examination before starting treatment and by the emphasis on the initial period of intensive therapy in multibacillary cases.

Afternoon session

The Chairman, Dr D S Chaudhury, explained that this session was to be devoted largely to discussion of the practical implementation of MDT including such matters as preliminary planning, the encouragement of patient compliance, the training of staff, monitoring and evaluation, the identification of the human and social needs of the patients, and cost effectiveness. We were not in a position to discuss the effectiveness of the various drugs used and should preserve an open mind on this issue. He then asked Dr Cap to present his paper, the text of which is given at the end of this article.

Mali—Dr Nebout

The situation was unlike Niger with its Primary Health Care Programme. Coverage by basic health services was inadequate and mobile units were required. The planning of the MDT programme took account of the need for the training of the staff in techniques of clinical and bacteriological examination and their clear job description, the management of drug distribution, criteria for discharge and health education.

Ivory Coast—Dr Serie

Attention was focused on the problem of urban leprosy in cities like Abidjan where stigma seriously affected early self-presentation.

DISCUSSION

The main points covered in a wide ranging discussion were:

1 The fact that the cost of the drugs required for MDT amounted to only 10–20% of the total cost of the programme and that the major expenditure is on operational costs, drug delivery, etc.

2 Whereas Voluntary Agencies are free to choose a particular drug regimen, Governments have to adopt the minimum effective in order to reduce transmission.

Their priority must be to detect and treat all infective cases and they cannot therefore be so concerned about possible relapse rates. There is a need for agreements between Governments and Voluntary Agencies.

3 The phrase 'minimum effective regimen' needs emphasis. This implies the optimum therapy to prevent disability—which is the whole *raison d'être* of leprosy control.

4 Planning must include identifying the problems before MDT is introduced and much money spent. The staff, especially the supervisory staff, need to be trained and prepared (some may fear that the new treatment policy threatens their job). A programme is only as good as the staff it employs.

5 There must be a built-in monitoring procedure based on a well-designed recording and reporting system, with valid operational indicators. In addition, there is need to define the minimum standards of training, of infrastructure, etc., at regional and national level required before MDT should be applied. Voluntary Agencies can then provide funds for countries or projects where minimum standards have been achieved. This will involve support beyond those projects already being financed, and may include assistance to create the essential infrastructure. There is a close link between underdevelopment and leprosy.

The Chairman closed by formulating the following conclusions which were endorsed by the Meeting:

CONCLUSIONS

As multidrug therapy is a very important intervention in our fight against leprosy, it is absolutely imperative that adequate and in-depth planning is made before multidrug therapy is introduced in any area.

2 Such planning must be adapted to the local situation and should ensure minimum effective service which depends upon appropriate information on the disease problem and sufficient and correct documentation. This can be facilitated through visits of experts and meetings between the project manager and senior field workers.

3 Multidrug therapy programmes must have an in-built system of monitoring based upon competent reporting and objective analysis.

4 Correct laboratory control is an essential item to evaluate the programme. The staff should be appropriately trained and updated in this field.

5 Introduction of multidrug therapy in no way precludes our giving full attention to the needs of the individual patient and his family. Discharge from therapy does not mean discharge from care.

6 Health education is extremely important to ensure early diagnosis and maximum compliance by the patients, both in taking the drugs as well as in limb care—including care of the eye. The programme of health education must run parallel to the other activities of the programme.

7 Community participation will promote the success of multidrug therapy and will help in the rehabilitation and social reintegration of the patient. Multidrug therapy programmes must involve the community at all effective levels.

8 Unless all these prerequisites are obtained, multidrug therapy should not be implemented in haste or in a lighthearted manner.

Paper presented by Dr Cap at the XXXth Working Session of ILEP to the Interface Meeting on the Introduction of Multidrug Therapy, Athens, December 1983.

'. . . It is my opinion that we have no choice: MDT has to be introduced because of the constant increase in secondary and primary dapsone resistance. Its application will also shorten the duration of the treatment, with, hopefully, a beneficial effect on patient compliance. Furthermore, it will reduce the period of infectiousness of multibacillary cases, producing a faster decrease in the incidence rate.

Mr Askew's paper[1] is a very valuable and welcome contribution. It emphasizes the need for assessing the possible effect of MDT from a managerial point of view. It is obvious that these managerial aspects will have to be confirmed by medical assessment and a study of suitable parameters for evaluation is being taken up by the Medical Commission. It also points out that the cost of the drugs, though not negligible, does not represent the main obstacle to introducing MDT, the success of which depends upon an adequate medical infrastructure.

As a matter of fact, from a technical point of view, the introduction of MDT is a very difficult exercise, with a number of constraints, some of which have already been stressed in the ILEP booklet[2]. As we all know, in several endemic countries, the situation is not yet sufficiently ripe to introduce MDT on a sound basis, with regard, for example, to basic competence of the staff, operational requirements and so on.

We would like to review the most practical points which could help us to make use of MDT in a proper way, avoiding to do more harm than good.

We should, first of all, be aware of the fact that the number of effective drugs is very limited and that there is no reasonable hope of having additions to the actual list in the foreseeable future. Several specific or other vaccines are in the making, but it will be many years before toxicity and feasibility studies are completed and many more again before their efficacy has been defined and before they can be used safely and widely in endemic areas.

The WHO working group which met in October 1981 has proposed treatment regimens for paucibacillary and multibacillary patients. These regimens are rightly considered as minimal and nothing less should be administered, but they should be applied in the most rigorous way. Even though these regimens are relatively simple, their practical administration will have to be adapted to local circumstances, differing from one country to the other.

These principles are expressed in the WHO[3] and in the ILEP[2] documents, but there is a need for strict, locally acceptable protocols, prepared with the assistance of a leprosy expert, containing detailed, locally adaptable procedures. Such protocols must be very detailed and cover not only the technical aspects, but also take related aspects into consideration, such as geographical constraints, record-keeping systems, administrative implications, requirements for extra staff, cars, etc.

If necessary, the protocol should be supplemented by a local manual for the staff, defining all decisions to be taken and covering all circumstances and doubtful situations which may arise in the particular area. It is encouraging to see that already several of such manuals have been produced, which may serve as a guideline for the elaboration of other manuals adapted to other and different situations.

Before introducing MDT, a thorough training of the staff involved will be essential, and in several areas training alone will not be sufficient. Their total attitude towards the problem of leprosy control has to be changed, and they must be convinced that the introduction of MDT means a revolution in the management of leprosy control programmes. This change of attitude concerns all levels of staff, including, and even more specifically, the medical officers in charge of projects.

In addition, patients must be educated, motivated and encouraged to take the full course of

treatment as prescribed. Preliminary reports from the field indicate that compliance to MDT may sometimes be better than has been the case in general with dapsone-monotherapy, and it must be our constant concern to make sure that this is always the case.

Training must definitely include staff in charge of laboratory examinations. The bacteriological index (BI) has always been of great importance in leprosy control programmes, though it was often rather neglected. With the introduction of MDT, the bacteriological index becomes essential in making extremely important decisions. Strenthening of the laboratory facilities and training of the staff are therefore essential, so that the needs, as defined in the protocol, can be met both quantitatively and qualitatively.

In many areas, it will be necessary to start application of MDT in a selected area where the essential requirements can be met and where the practical, sometimes unexpected, snags and constraints can be identified.

Before introducing MDT, it is important to review all patients still on the register. In many areas, patients, mainly paucibacillary cases, remain on the register for many years for several reasons: partly because in the past the criteria for defining inactivity were unclear, and partly because dapsone was cheap, safe and easy to use, so that it was often continued unnecessarily. Under MDT, the protocol must be strictly observed, as the drugs involved are more expensive and more toxic.

It is obvious that a well-oiled drug supply and distribution system has to be set up. This problem has been a quite simple one during the dapsone monotherapy era. We now have to deal with expensive, relatively toxic drugs with a limited shelf life. Regular supplies and correct distribution at the right time are therefore of the utmost importance.

Finally, it is important to learn from the experience of our colleagues in tuberculosis who have found that the correct managerial handling of diagnosis and treatment presents major difficulties in the control of tuberculosis and we can surely expect that the same will apply in the control of leprosy.'

References

[1] Askew AD. (International Director, The Leprosy Mission—Nov. 1983). *Effects of MDT on Leprosy Programmes.*

[2] *Introduction of Multidrug Therapy for Leprosy.* ILEP—June 1983.

[3] *Chemotherapy of Leprosy for Control Programmes.* Report of WHO Study Group Technical report series 625—WHO 1982.