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Editorial

LEPROSY CONTROL AND THE IMPLEMENTATION OF MULTIPLE DRUG THERAPY: TO WHAT EXTENT CAN THE OPERATIONAL STRATEGY BE SIMPLIFIED FOR PRIMARY HEALTH CARE?

Since the publication of the recommendations of the World Health Organisation (WHO) on the use of regimens of multiple drug therapy (MDT) of relatively short duration for all cases of leprosy,[1] remarkable progress has been made, not only in the implementation of such regimens, but also in the development of leprosy control programmes in many parts of the world. In the first few years, the implementation of MDT was slow, reaching a coverage of only 8·8% in 1986, but thereafter increasing rapidly to 55·7% in 1990. From a total of 5·4 million registered cases in 1985, the figure dropped to 3·7 in 1990 (a reduction of about 31%), attributable mainly to the implementation of MDT and the release from treatment (and eventually from surveillance) of very large numbers of patients. Disability and child rates have come down, relapse rates are remarkably low, and the incidence of toxic (drug) reactions or immunological reactions based on either cell-mediated or humoral mechanisms, has been no greater (and possibly less) than with dapsone monotherapy. Given time, it is expected that some early reports of reduction in incidence rates following MDT will be confirmed. By 1987, speaking at a meeting in New Delhi on the evaluation of MDT through Primary Health Care (PHC), Dr SK Noordeen, Chief, Leprosy, Division of Control of Tropical Diseases, WHO, drew attention to the major changes in technology brought about by MDT, the improved outlook, virtually worldwide, towards the disease, and the immense opportunities to reduce leprosy in the next decade.[2] In 1988, a widely circulated WHO publication bore the title *Multidrug therapy for leprosy: an end in sight*,[3] and this was followed by a second in 1991, entitled *Towards elimination of leprosy*,[4] drawing attention to the progress being made in many endemic countries and to the possibility of reducing prevalence to an elimination level of less than 1 case per 10,000 of the population by the year 2000. New estimates by WHO for the number of cases worldwide have recently been published, revising the previously quoted figure of 10–12 million cases to 5·5 million.[5]

The overall pace and extent of MDT implementation worldwide

Despite these encouraging results, concern has been expressed in recent years about the

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overall pace and extent of MDT coverage worldwide. A recent WHO report[6] draws attention to considerable regional variations with regard to prevalence and MDT implementation between 1986 and 1990; the South-East Asia Region (SEARO) and the Western Pacific Region (WPRO) have achieved satisfactory levels, but elsewhere this is not the case. Progress in the development of control programmes and the implementation of MDT has been distinctly weak in Brasil, Nigeria, Myanmar and Indonesia. In Africa (AFRO Region), the overall rate at the end of 1990 was only 18·4% (compared, for example, with 66·2% for South-East Asia), with some notably low figures in Burkina Faso, Cape Verde, Chad, Congo, Côte d'Ivoire, Guinea, Madagascar, Mali, Mozambique, Niger, Reunion, Rwanda, São Tomé, Senegal, Swaziland, Togo and Uganda. Figures for the Americas are also unsatisfactory. The reasons which lie behind this situation vary greatly from one country to another, or even in different regions of the same country, but they include—(1) lack of political commitment and motivation, (2) constant, even increasing pressure to allocate time, money and personnel to health problems other than leprosy (for example, AIDS/HIV infection, tuberculosis, malaria, immunization, population control), (3) poorly developed infrastructure and lack of trained personnel, (4) absence of a proper plan of action, (5) shortage of money, (6) lack of laboratory facilities, notably for slit-skin smears, (7) poor referral facilities for complications and (8) inadequate resources, including regular supplies of dapsone, clofazimine and rifampicin for MDT.

We are now well into 1992 and the goal, whether in terms of 'control', 'elimination', 'eradication' or 'MDT for all' is almost universally directed at the year 2000. Despite the progress described above, it is clearly disconcerting that many leprosy endemic countries, especially in Africa, have barely started to implement MDT, or have achieved only single figure percentage results in their cases on treatment.

Integration with primary health care and the district health programme

Various proposals have been made through the years[7,8,9] to overcome these problems, for the most part based on the wider use of PHC, including the District Health Programme (DHP), the latter being defined as '. . . a geographical area that is small enough for its health and related social and economic problems to be properly understood and for appropriate action to be taken in response, but large enough to permit the deployment of essential technical and managerial skills for planning and management of the health programme.' Writing in 1978, before the development of MDT as we now know it, Buchmann reviewed the entire subject of PHC in relation to leprosy control in great detail,[10] concluding that it was not only advisable, but clearly the most obvious strategy for the full development of leprosy control programmes, including treatment delivery. Since the publication of the Declaration of Alma Ata on PHC in 1978,[11] all Who documents and publications on leprosy (and tuberculosis[12]) have accepted the principle of integrating leprosy control into the general health services wherever possible, whilst at the same time underlining the importance of maintaining a vertical, specialized element at various levels of the programme, for supervision, referral facilities, drug supply and financing. *The International Federation of Anti-Leprosy Associations* (ILEP), representing over 20 independent, voluntary organizations working in the field of leprosy, has also strongly affirmed its commitment to the use of the general health services based on PHC,

whilst at the same time describing the basic, rather than optimal, requirements for implementation[13]—a most valuable step in the direction of simplification. The principle of using PHC/DHP in leprosy control seems to have been accepted by most agencies working in leprosy as the only operational technology likely to have a progressive epidemiological impact, but in practice, its application continues to present problems. These are basically similar to those which have been described for tuberculosis[12]—planning, training, provision of supplies and supervision.

The possibility that the pace and extent of MDT implementation are unsatisfactory and unlikely to improve in the foreseeable future, unless new strategies are introduced, has recently been reviewed in depth by Yuasa in the *International Journal of Leprosy*.[14] He outlines the main problems which have so far been encountered and makes a plea for the involvement of *all* members of the health services, in *all* leprosy-endemic countries, to bring the benefits of MDT to *all* patients in need, without delay. He emphasizes that '. . . the MDT program must be simple, so that any leprosy-endemic country, with whatever the current state of health services, can adopt it'. His approach gives great emphasis to the use of PHC and DHP personnel in detecting, diagnosing and treating leprosy cases (but without any expectation that they will routinely participate in the prevention and management of disability or deformity—a somewhat unconventional view, which is discussed in more detail below). The strategy described seems to have worked well in the Philippines, where it has to a large extent been carried out by 'barangay' midwives, with facilities for supervision and the referral of problem cases, and including the provision of MDT for both pauci- and multi-bacillary cases in blister calendar packs. This account of a successful programme is by no means unique. In 1982 an entire number of this *Journal* was devoted to the subject of leprosy and PHC,[15] with accounts of experiences from Tanzania, the Sudan, Kenya, Indonesia, Sri Lanka and India. Some reservations were expressed, particularly about the timing of integration in relation to the treatment of all known cases, but in general the views recorded were positive and encouraging. In 1986, an important report from WHO[16] described a consultation on leprosy control and PHC, with contributions from the Gambia, Malawi, Vietnam, Malaysia, Ethiopia, Brasil and Thailand. Some failures and a number of problems were reported, but in general it was agreed by participants that the approach had great advantages over the continued use of vertical, specialized systems.

PHC and leprosy control in India

Despite encouraging progress in the implementation of MDT in the National Leprosy Eradication Programme in India, the Leprosy Division recently identified an area of difficulty in extending MDT services to 66 of their endemic districts. The problem had been accentuated by the large numbers of patients in need and the lack of trained personnel, coupled with the impossibility of training them in the foreseeable future. A decision of potentially great interest and importance, not only for India, but for control programmes elsewhere, was therefore taken by the Leprosy Division late in 1990, when *Guidelines for Modified MDT Scheme in Selected Districts* were drawn up and circulated to appropriate regions, accompanied by training manuals for various grades of health staff. This 66-page document is reviewed in greater detail elsewhere in this *Journal*;[17] it describes the administrative and technical steps which must be taken in order to

implement MDT through the general health services, using PHC and DHP (as opposed to using the specialized staff of the NLEP). The 14-day period of intensive therapy at the outset, used hitherto by the NLEP, will be discontinued; the WHO regimen will be used instead. Health education activities are to be intensified and the bacteriological examination of skin smears will be limited to multi-bacillary cases, or suspected multi-bacillary cases. This initiative should clearly be monitored with great care; it represents, at least in concept, a significant simplification of the existing operational strategy in India (estimated to have 3 million cases), thus affording an opportunity for the collection of date and an assessment of feasibility, presumably within a relatively short period of time. Inherent in the modified approach is the continued use of NLEP staff wherever possible and it bears repetition that this is in keeping with the advice which has been given by WHO and other agencies advocating this approach, to the effect that integration with PHC does *not* imply that all specialized elements should disappear from the scene; on the contrary, a specialized element, wherever it is available, should be retained at various levels.

Further simplification

In recent years, either from WHO or ILEP, several modifications which undoubtedly simplify the approach needed at PHC level, have been made. They include the following—(1) for the treatment of multi-bacillary patients, 24 months' treatment (rather than extending, wherever possible, until skin smears are negative, as in the original recommendations of 1982) is acceptable, particularly if there are resource constraints, (2) the supervision of monthly doses of rifampicin (pauci-bacillary cases) or rifampicin and clofazimine (multi-bacillary cases) should ideally be carried out by a health worker, but if this is difficult or impossible, responsibility may be delegated to other members of the community (teacher, village leader, family member, etc.), (3) provided they are reliable, skin smears are valuable and should be made available, but they are no longer regarded as an absolute prerequisite for initiating MDT, since in most cases it is possible to diagnose leprosy and distinguish between multi- and pauci-bacillary cases on clinical grounds. Two further aspects of the subject call for more serious investigation in the context of simplifying MDT at PHC level. The *first* concerns the use of systems which take note of the number of skin, or skin and nerve lesions, or of the number of 'body areas' affected, in order to allocate patients to either pauci- or multi-bacillary groups for treatment. A number of publications recording experience from different parts of the world[18,19,20,21] suggest that this approach may be preferable in certain circumstances to reliance on skin-smear results. The *second* relates to the use of blister-calendar packs for MDT drugs[22] and to the need for an objective assessment of their value, particularly in programmes using the PHC/DHP approach. If found useful and potentially cost-effective, efforts should be made to set up local production thus avoiding the main impediment to their wider use at the present time, which centres on the additional cost of packs manfactured by drug companies. Finally, the proposal by Yuasa, in the editorial referred to above,[14] that disability management should realistically be separated from the public health activities of staff who are engaged in case detection and chemotherapy, giving responsibility to a separate agency, or to non-government organizations, calls for serious consideration. This is partly because current (and past) efforts to combine case detection and

chemotherapy with disability prevention and management have been, in general, unsuccessful and partly because the proposed separation could, if properly planned and executed, very considerably simplify the work of PHC/DHP personnel.

Conclusion

The principle of using PHC/DHP in leprosy control appears to have been widely accepted by WHO and other agencies. Some progress has been made in its application, but in many countries where control programmes and MDT are particularly weak no systematic attempt has so far been made to develop its potential. The success of MDT under a wide range of circumstances, including some which, at least at the outset, had sub-optimal personnel and other resources, suggests that PHC/DHP should be considered more widely. Some important simplifications for this purpose have already been made; others could be developed quite quickly. Particularly for those who have identified the year 2000 for elimination, time may be short, unless new strategies are used. Is this perhaps the moment to look more closely at what is needed and what is possible, and to use PHC/DHP to close the gap, thus bringing the benefits of MDT to a much wider segment of patients?

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