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EDITORIAL

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MDT for All; Target Oriented Leprosy Control Program in the 1990s*

For over 40 years, leprosy workers have been saying that "leprosy is curable" and "deformities are preventable" without actually curing many patients or preventing development of deformities. These slogans remained as mere dreams to most of the leprosy patients all over the world. Now, with the World Health Organization-recommended multiple drug therapy (WHO MDT), we have a practical means of realizing these slogans. It is therefore the duty of everyone involved in leprosy to make these slogans a reality for every leprosy patient now in existence and for those who will come in the future. "MDT for all" must be our topmost priority.

So, the question before us should no longer be "whether to implement MDT" but "how to implement MDT?" In the last decade of the 20th century, within 10 years of reaching our overall goal of "health for all by the year 2000," it must be regarded as a basic right of every leprosy patient to receive MDT. Therefore, not giving MDT must be considered as a "grave medical negligence," a 100% failure of a leprosy program or of a national health service. Without MDT, there is no cure. With any sort of MDT, even a very poor one, there is a possibility of some cure. This means that almost any form of MDT is better than no MDT at all.

When planning an action, especially a new one such as an implementation of MDT, our natural instinct advocates caution in order to avoid a possible failure, totally forgetting or ignoring the important fact that true failure often is in taking no action at all. Poorly executed MDT with 50% relapse will be commonly regarded as an unacceptable level of failure, especially from an administrative point of view. However, 50% failure at the same time means 50% success and, from the point of view of so many leprosy patients, that must be incomparably better than no MDT.

Let us remember that the essential part of MDT is nothing more than delivering certain drugs to the patents and helping them to ingest those drugs as prescribed. All of the planning, training, supervising, monitoring, laboratory examinations, record

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keeping, and reporting are, apart from being bureaucratic necessities, only to make sure that the essential actions of drug intake will take place in as many patients and as regularly as possible. In a meeting such as ours today, we sometimes become more concerned with creating an ideal MDT implementation system as such, by adding more and more requirements and refinements, calling for more resources and more time for preparation as well as implementation, forgetting the sad reality in which leprosy is not, and cannot be, a top priority in the long list of health problems in many leprosy-endemic countries, and the resources available for MDT therefore are rather limited.

It is well for us to remember, when we are planning for MDT, what is expected of us by the leprosy patient somewhere in the world who is not yet receiving any treatment at the moment. All he is saying now, I am sure, is "Give me drugs and quickly." Our first job therefore is to start him on MDT, and to give MDT to all of the existing patients without any more delay. To do that, we must be flexible to do our utmost in fitting our plan to the existing situation, rather than trying to change the current conditions to fit into our ideal plan, which often is a near impossibility or at least too time consuming to justify our neglect in meeting the needs of currently existing leprosy patients, said to number up to 10–12 million globally.

Another basic consideration which must be behind our planning for MDT is the question of equity which must form a firm basis for any policy of a government. When we talk of equality in relationship with leprosy patients, we tend to assume that they are the victims of inequality, that they are getting less than others. Perhaps in an unconscious effort to overcome our guilty feelings, we sometimes tend to overcompensate by demanding much more care for leprosy patients, because of their disease, then people normally expect from health services.

It is hard to imagine any government of a developing nation providing a regular rehabilitation program for the victims of polio with physical disability or sufferers of onchocerciasis with blindness. Yet when we deal with leprosy, even in such a purely public health program as MDT implementation, someone always tries to bring up the question of rehabilitation, as if its absence means that the MDT program itself is incomplete. Let us remember that even though equality certainly means "no less than others," it also means "no more than others." Our basic good intention of trying to do the best for leprosy patients could, as a result, be a main cause of making leprosy and its patients different from all the rest, thus resulting in discrimination and prejudice and creating the most dificult leprosy problem ourselves.

GENERAL CONSIDERATIONS

Leprosy control program and the place of MDT in it

In order to discuss "What is leprosy control?," it is necessary to agree on "What is leprosy?" For our discussion, it should probably suffice to define "leprosy" as a disease having two quite distinctive natures, namely: a) *An infectious disease:* thus a legitimate target of public health concern and amenable to the regular control measures of any infectious disease, which is early case detection and effective chemotherapy for all of the cases. b) *A deformity- and disability-producing disease:* effective early chemotherapy could prevent most of this problem arising but not all. Besides, there are already several millions of leprosy sufferers in this category, with or without active disease.

From a public health point of view, leprosy control first of all means dealing with leprosy as an infectious disease and, therefore, our primary aim should be to make all the clinically active patients noninfectious by chemotherapy. Ideally, we should aim at the noninfectivity of all the patients, but this could be too expensive or too difficult technically to be feasible in many leprosy-endemic countries, which means that we must make allowance for some failures, the magnitude of which is related to the general state of available health services in a given country.

Whether handling leprosy as a deformity- and disability-producing disease should come under the concern of public health is a debatable issue closely linked to the degree of social and economic development of the country concerned. Generally speaking, as far as leprosy-endemic countries belonging to the Third World are concerned, this aspect of leprosy is likely to be outside of the current responsibilities of public health authorities. If they have a separate agency to look after the physical and social welfare of their citizens, then leprosy sufferers with deformities and disabilities certainly should become its legitimate concern. But as far as the public health authorities are concerned this aspect of leprosy, at present in any case, has, in all probability, to be ouside of their responsibility.

I consider this distinction and its implications very important, because traditionally these two aspects of leprosy have never been consciously separated. Many existing leprosy control programs have tried and are still trying to address the mixture of these two, with the notable result of not doing an adequate job for either. In the days when the technology of controlling leprosy as an infectious disease was either lacking or inadequate, perhaps that kind of ineffectual dealing with both of these aspects simultaneously was inevitable, or at least understandable. But now we do have the means to control leprosy infection quite effectively. Therefore, it seems imperative that we concentrate our total effort on controlling leprosy as an infectious disease at this stage, since this task alone is likely to fully tax our global resources for quite some time, perhaps the next 5 if not 10 years until the year 2000.

From the foregoing it should now be clear that a leprosy control program, as far as we are concerned, should be defined as a public health measure to tackle leprosy as an infectious disease. Thus the implementation of WHO-recommended MDT, which has already proved itself to be effective in controlling *Mycobacterium leprae* infection, is the main, if not the sole, activity of a leprosy control program run by the public health authority of a leprosy-endemic country. I stress this last point because the objectives of nongovernmental organizations (NGOs), particularly of voluntary agencies, could be different. By the very nature of these organizations they are, unlike any government, not directly responsible or accountable for the public health aspects of leprosy work nor the welfare of the entire population of a country. However, it is strongly hoped that these NGOs will see the importance of and the need for a public health approach to leprosy and will contribute substantially to strengthen and to support the health authorities of leprosy-endemic countries in their efforts to implement MDT, even if that means that the NGOs concerned must sacrifice some of their traditional care of their own patients.

Which MDT, and what is involved in its implementation?

At this point, it is important that when we talk about MDT we can agree that it means the WHO-recommended MDT as spelled out in the WHO Technical Report Series No. 675, entitled "Chemotherapy of Leprosy for Control Programmes." However, there is one very important point which should be clarified before we proceed any further. It is the duration of the multibacillary (MB) leprosy regimen which, according to the WHO recommendation on page 23 of this publication, section 3.1.3., "Duration of treatment," is ". . . that the combined therapy be given for at least two years and be continued, *whenever possible,* up to smear negativity." This statement is probably a correct one as far as WHO is concerned, especially in 1982 when it was made public. But the expression "whenever possible" is causing more confusion and resulting in a delay of MDT program expansion in the field because the intended meaning of "whenever possible" is not defined. The clinicians who are responsible for the treatment of individual leprosy patients take this expression to mean that they must do their utmost to have their MB patients treated until their bacterial index (BI) reaches negativity, often citing ethical responsibility. What they fail to understand is that the MDT program is formulated for the "Chemotherapy of Leprosy for Control Programmes," which, in the majority of instances, is synonymous with a public health program. It is meant to advise a planner or manager of a MDT program in the field where, as the terminology implies, the first consideration is "the health of the public," as against the concern of clinical medicine which is the "illness of an individual patient." Surely there must be an ethical question from a public health point of view as against a clinical point of view. As far as our meeting is concerned, in which MDT is discussed as a national health program within the global context, it should be quite clear to all of us that "whenever possible" should mean only one thing: that when all the existing clinically active leprosy patients are given the basic 2-year MB treatment, then one should be allowed to consider a possibility of extending the treatment beyond this period provided resources are available which, in the case of most of leprosy-endemic countries, is rather doubtful. It makes no sense at all to keep some patients waiting to receive MDT, thus being allowed to have their clinical conditions deteriorate and keep infecting their contacts, while others who are already on MDT, thus no longer infective and in most instances clinically inactive, to be kept on MDT simply because their BI is still positive.

It is not easy to estimate the cost of MDT implementation. From actual experiences, US$100 per case seems to be a fair estimate for many countries, which means that if there are 10,000 cases in a given country, US$1,000,000 is required to complete MDT implementation for all of these patients, probably spread over 3 to 5 years of the program. This estimate assumes that the PB/MB ratio is near 50/50, and this results in roughly 40% of the budget being required for the purchase of MDT drugs. The remaining 60% is roughly divided equally between training and implementation, the significant portion of the latter for the monitoring of the program and whatever remedial actions are needed. The purchase of equipment including transport facilities, production of work manuals, guidelines and others for the training of health workers and health education of the patients and the public are included.

However, the significant exclusion from this costing is the regular salaries of all the health workers involved in MDT, since it is assumed that these people are already in the field and being paid regardless of whether they are involved in MDT or not. It should not be forgotten that the above calculation is based on the implementation of basic MDT, which is the fixed time treatment of 6 months for paucibacillary (PB) leprosy and 24 months for MB. Any extension of these periods could substantially increase the total cost. One should also remember that the above is for the implementation of MDT as such. A leprosy control program, even if we agree that MDT is its main component, is likely to involve some additional activities which will add up to more cost. From a global point of view, if we agree on "MDT for all by the year 2000" as our common goal, probably the total available resources are all required for the implementation of basic MDT and very little else. (US$100 per case was the actual expenditure of the pilot study of MDT conducted in The Philippines covering somewhat over 2500 cases in two provinces over 3 years, and her national leprosy control program currently covering something like 40,000 cases over a 5-year period also has a total budget of US$4,000,000. Even though Vietnam has a totally different health structure as well as control methods, support given to them by one NGO is based on the same unit cost and the program seems to be progressing satisfactorily.)

In order to implement MDT properly, a series of activities are involved as follows:

1) Case finding (will be discussed later).

2) Updating of the existing registry of leprosy patients by tracing individuals whose names are on the registry.

3) Clinical, and possibly bacteriological, examination of each patient to determine current clinical status and to decide whether the patient requires MDT. (As a result of 2) and 3) above, the actual number of patients requiring MDT may be as low as 50% of those on the original register.)

4) Give fixed period basic MDT with whatever support the service can give to the patient to assure regularity of the monthly clinic attendance and compliance of unsupervised daily drug taking.

5) Dealing with any lepra reaction or drug side effects.

6) Prevention of deformities by health education (HE), and teaching of self care of insensitive eyes, hands or feet which should be a regular part of MDT implementation, even by general health services. This aspect is very weak at the moment.

7) Termination of MDT and release from treatment (RFT) after clinical and, if possible, bacteriological assessment. (Any such

examination during the course of MDT is most likely to be unwarranted.)

8) Some kind of post-MDT surveillance.

One additional activity normally considered essential is a clinical survey (at least once but possibly annually) of the members of the household contacts of each MDT patient. True, the yield of new cases is not that high but to protect the family members of the known cases a survey is usually accepted as an ethical duty regardless of the cost effectiveness.

Case finding is mentioned at the top of the above list, but it is most doubtful that any active case finding effort—apart from the just mentioned "household contact survey"—is useful, especially at the start of a MDT program designated as Stage I in the following discussions. A school survey or any other survey, including the so-called "chase survey," done for the purpose of finding leprosy alone is most probably not cost effective. The only feasible case-finding method in every leprosy control program is the so-called "passive case finding" which depends heavily on public awareness of the disease itself and the availability of its cure so that the patient himself or his family recognizes, or at least suspects, the symptoms or signs of the disease and comes forward voluntarily to be treated. It also depends on the alertness of the health worker who has a chance to do a physical examination for whatever reason. If signs suggesting leprosy are found on an unsuspecting patient immediate referral to the appropriate person is mandatory.

What else should be part of basic MDT implementation? Probably very little, apart from general health education of the public on leprosy itself and on MDT to assist "passive case finding" just mentioned, and the teaching of self care of insensitive eyes, hands and feet in order to prevent either new deformities developing or existing ones getting worse. The active care of established deformities, including a treatment of trophic ulcers, may or may not be considered a part of the care provided by existing health services and, even though it is a desirable service, it cannot be considered an integral part of a basic MDT program. Any further care, such as surgical intervention and physical and social rehabilitation, is certainly outside of MDT, if not altogether outside of the public health concern.

What to do with other leprosy sufferers not included in MDT program?

The current WHO definition of a leprosy patient is "a person with active clinical leprosy requiring chemotherapy." By this, any current or past leprosy sufferer who does not require MDT is no longer considered a case of leprosy and therefore is not registered as such. If such a person requires some care, he will be categorized as an "ex-leprosy patient requiring care," and is outside of our consideration for MDT. The previous discussion limited our scope of leprosy control to an implementation of MDT, excluding any care other than chemotherapy against *M. leprae,* with one or two minor additions as mentioned immediately above.

It is most important not only to agree on this, but also that this fact be publicly acknowledged by the health authorities. There is too much loose talk about "total care of leprosy patients" which often is no more than lip service to the activities most governments of leprosy-endemic countries are capable of rendering. A much more constructive way is for the health authority to acknowledge that "rehabilitation" is an important aspect of the care of leprosy patients, but to admit that their resources will not permit them to tackle the problem themselves. They should encourage participation of any interested parties, especially national and international NGOs. At the same time, they must be sure that if there is any rehabilitation program for the physically handicapped, ex-leprosy patients who need such help are not excluded.

Who should implement MDT?

Who should implement? This is a very crucial consideration, and the success or otherwise of global MDT is likely to hinge on getting the right answer to this question. If we accept MDT as a public health program of an infectious disease control in order, first of all, to protect the public from getting *M. leprae* infection which only comes from a clinically active case of leprosy, then the following should be apparent: a) The service which handles MDT must have wide enough coverage to reach every part of the country wherever a case of leprosy is found, and b) the service must be able to maintain regular and frequent contact with the patients, so that not only the monthly clinic is assured but, when necessary, it is possible to reach the patient as quickly as needed for defaulter tracing, handling of lepra reactions or drug side effects, and for compliance check by a pill count at unannounced home visits.

In addition to the above, for long-term care of these patients over 6 months or 2 years, an existence of a rapport between the patient and the health care provider becomes more useful. Such a rapport is more likely to be present if the health worker concerned is: a) in residence in the same area with the patient; b) already providing care to the patient concerning nonleprosy health problems; and c) giving some health care to other members of the patient's family.

The service which can meet the above-mentioned conditions in any country is, by definition as well as in reality, the general health services (GHS). However extensive or well developed, a vertical leprosy service anywhere in the world cannot meet all of these conditions. Therefore, MDT implementation is best handled by the GHS.

There have been many talks of and several attempts, some serious and others not so serious, to integrate leprosy service with the GHS. The results so far are not always encouraging. What are the difficulties? The main problems are said to be: a) The GHS is already overloaded with many tasks, therefore the peripheral health workers (PHW) have no time to do new extra work, such as MDT. b) Leprosy control work is too complicated. c) Health workers do not like to be involved in leprosy work due to their fear of the disease.

It is useful to remember what is exactly involved in MDT implementation by a PHW who actually treats the patient. The situation is different from county to country, but for the sake of our discussion we can think of the PHW as a person working, probably alone, at a village health station (VHS) not far from her own home, meeting the basic health needs of the people in her catchment area with a population of 2000–5000. She is responsible for the basic communicable disease control (CDC) work in addition to maternal and child health (MCH), epidemiology (EPI), nutrition, and hygiene as well. For that work she will be at the station two or three mornings a week, but otherwise she will be making regular rounds of homes in her area constantly. Probably once a week she will go to a main health center in a nearby town for reporting and recording of activities, receiving of supplies (including medicine), and getting any professional advice she needs. Supposing the prevalence rate of leprosy in her area is around 1/1000, she will have up to five MDT cases to start with. Is it going to be a lot of extra work? No, it is most unlikely.

Each MDT patient will come to the clinic once a month, half of them for 6 months only and the rest for up to 24 months. At the clinic, where she spends several mornings a week, it is likely to take no more than 5 minutes per case per month to ask a few simple questions about the health of the patient, give the monthly dose of drugs and watch the patient consume them, hand over other drugs for unsupervised daily taking at home, and make a simple recording of the visit. If the patient does not come on time, she has to visit the patient at home, either to give drugs there or to tell the patient to come to the clinic soon. She is normally expected to make at least one unannounced visit a month to the patient's home to do the pill count in order to check the patient's compliance. How much time do all of these require? It is not easy to get a precise figure, but one must remember that she can do all this work while she is at the clinic and when she is making the regular rounds in the village, thus no extra stay at the clinic nor extra trip from the clinic is likely to be required. In The Philippines, where the above-mentioned conditions generally prevail, it is estimated that no more than 1%–2% of their working time per month is required for MDT as long as the case load per PHW is not more than five. And this is only 2 or 3 years after the start of MDT. Once known cases complete the treatment, new cases requiring MDT will appear only once in 3 or 4 years or even less because, on average, the incidence rate is only 1/10th of the prevalence rate.

In The Philippines, their work was made even simpler and less time consuming by the utilization of the monthly calendar blister pack of MDT drugs devised specifically for their program. Similar packs are now available commercially. This device avoids the chance of giving the wrong kind and amount of drugs. There is no wasting of valuable time counting out tablets from bottles, and the pill count at home visits requires only a simple glance at the pack. Other advantages of using the blister packs are no less significant. They are:

1) Safeguard rifampin against diversion or misuse, providing a better chance for the drug to reach the intended leprosy patient. (This aspect was considered so important that the use of blister packs was one of the conditions by which the Philippine government agreed to involve the GHS, which has never participated in leprosy work in the past, for MDT implementation.)

2) In addition to simpler handling at the village health station by a busy PHW, inventory taking at every level from the Ministry of Health on down to the field is made much simpler.

3) Missing of one or two component drugs of the MDT regimen is avoided, which often causes a serious problem in the field.

4) Safeguard drugs from damage due to adverse weather conditions or insects.

5) Facilitates the patient or his family to remember not only daily drug taking but also the date of the next monthly clinic.

6) The medication in pack form looks more expensive, often suggesting more potency to both the health workers and the patients. This perception often leads them to take MDT much more seriously.

There are some disadvantages in using blister packs, the most apparent one being an extra cost. However, if compliance is improved by the packs, then the cost effectiveness must shift in favor of the pack. The bulk resulting in putting drugs into the calendar packs is another disadvantage, cited usually in terms of storage as well as transportation. Returning to the question of the utilization of the GHS for MDT implementation, there are overwhelming advantages of using the blister packs over the loose drugs out of bottles, and often this could be used to persuade reluctant health authorities to accept MDT as a routine of the GHS activities.

As to the idea of leprosy control being too complicated, the publication of the WHO recommendation on MDT and its global acceptance has, or should have, changed the whole picture. Leprosy work in the past was indeed complicated in addition to being too long. But MDT now being advocated is not complicated at all. In fact, it is very simple both in concept and operation; only two classifications of patients and one standard regimen for each, regardless of whether the patient is new, old or relapsed. This simplicity of MDT is definitely being undersold by many who, instead, try to put so many preconditions or requirements before starting MDT, such as the existence of a reliable laboratory service, which tends to dissuade many potential users of MDT from even trying. As long as we clarify what is involved and perhaps, more importantly, what is not involved, it is not that difficult for the health authority to see that MDT could indeed be undertaken by the GHS.

It is most important, at this stage, to recognize that MDT can be and should be implemented by the "existing" GHS. Having so many constraints, it is almost useless to consider improving the existing GHS for the sake of MDT implementation. If we accept the basic principle of equality to the leprosy patients, as discussed previously, we should not expect MDT implementation to be any better or any worse than the level of health care the existing GHS can provide, on a par with any other service they are providing to nonleprosy patients now. It may be very much less than we hope to see, but accepting the idea that any MDT is better than no MDT, we must be prepared at least to start MDT at whatever level the existing GHS can provide, hoping at the same time that the situation will get better gradually as the level of the GHS improves.

The reluctance of the GHS staff to get involved in leprosy work for fear of the disease is probably more apparent than real. Of course, the stigma attached to leprosy is real and varies from country to country, and health workers' attitudes are certainly influenced by the general belief prevalent in that community. However, because ignorance of the true nature of the disease is often the reason behind the fear, it is amenable to proper health education to a degree. Furthermore, the existing reluctance on the part of the health workers to get involved in leprosy is often due to a total lack of training as well as to the absence of the means to help the patient. Many PHWs who are responsible for the health of the people in their areas, which include leprosy patients and their families, in fact are often kept inactive toward leprosy sufferers not so much by their fears but more by their powerlessness due to the lack of training and provisions. At least in The Philippines, there was hardly any refusal by a health worker to do MDT once a few days of training were given and an uninterrupted supply of drugs as well as technical support were assured. In fact, in my observation at least, many of these ladies become so interested in MDT, I had some guilty feeling of the possibility of these people neglecting other more mundane duties. In any case, MDT implementation as such does not require physical contact with the patient, and even those workers with an intractable fear of the disease should be able to manage MDT work if adequate administrative pressure is put on.

Should a functioning vertical leprosy service be dissolved and absorbed into GHS?

The answer to this question should be considered within a certain time frame and depends very much on the level of the existing GHS. Implementation of MDT in any form at present is more important than doing it in a certain set formula, even if that is theoretically a better one, as far as our goal of Stage I is concerned (discussed later). Under certain circumstances, especially if the level of the existing GHS is much poorer than that of the vertical leprosy service, it might be permissible and certainly more logical to keep utilizing the functioning vertical leprosy service to initiate MDT. If the total known case load is not too great, and the existing leprosy service is reasonably efficient, then they may be able to finish Stage I by themselves within a few years. If that is the case, it is obviously foolish not to employ them for the sake of the principle that MDT is better implemented by the GHS.

However, such situations are not likely to be very common, and whatever exception we do find is likely to be a vertical service provided by a NGO and, in that case, their coverage in terms of both area and case load is likely to be rather limited compared to the total needs within the country. In the majority of cases, the existing national vertical service is far from meeting the total needs. However, it is possible to think of a situation where the existing vertical service tries to provide as much MDT as possible within its means while the GHS is being prepared to take over eventually for nationwide coverage.

But if the existing GHS is reasonably good, in terms of area coverage as well as level of functioning, it seems far better to start MDT with the GHS while utilizing the personnel of an existing vertical leprosy service for the planning of the program as well as the training of the GHS personnel on MDT. Once the implementation is started, make use of them as specialists stationed at various levels of the health structure from the central ministry on down to the second level health station, such as the main health centers, for supervision and monitoring of activities by the GHS staff. Some lab technicians and senior paramedical workers of the leprosy service could actually take supporting roles to strengthen and improve the level of performance of MDT implementation through the GHS.

It should be clearly understood and remembered that the total integration of leprosy service, or any other vertical service, into the GHS does not mean the disappearance of the specialists. Rather, it is a change in function. Instead of doing the work by themselves, they are now taking a supporting role for the GHS which will do the work they have been doing. As will be discussed in the next section, a fair number of leprosy specialists are required in any GHS, so that the prospect of a present member of a vertical leprosy service losing a job or being shifted to entirely different work is most unlikely, as long as the government intends to do a credible MDT implementation. As the total case load diminishes, quite drastically in Stage II, they may have to undertake additional duties, such as TB control work. But as long as leprosy remains the concern of the government, leprosy specialists are likely to be required at all levels.

What to do with a localized MDT program run by a NGO requires very careful handling. Absorption into the national program by the GHS is probably the final goal as far as MDT implementation is concerned. But we must remember that those patients under the care of NGOs are likely to have much higher expectations than any government can provide. It is probably better to leave such NGO programs for the time being but, where appropriate, request an enlargement of the area of coverage to include more cases on MDT by shifting emphasis more to MDT and less to other care. When Stage II is reached in that area, then the GHS should take over responsibility for MDT asking the NGO, if it wishes to remain there, to be responsible for care beyond MDT which is unlikely to be taken up by most governments. Hastily taking over MDT patients from NGOs by government services, either the GHS or even a vertical leprosy service, is likely to invite rather unfortunate consequences.

MDT IMPLEMENTATION: STAGE I AND STAGE II WHEN, WHAT AND HOW?

In every leprosy-endemic country, there is a large pool of leprosy patients who have developed the clinical disease some time ago but, because of either the absence of treatment or ineffective treatment, still remain clinically active thus requiring MDT. This fact is indicated by a relatively large prevalence rate (PR) compared to the incidence rate (IR). It is not uncommon to find the PR (or, more accurately, the Case Registration Rate) to be ten times higher than the IR (or, in reality, the Case Detection Rate), even though in some countries such as India, where MDT is widely implemented and those completing MDT are actively removed from the registry, this ratio is coming down to 5:1 or even smaller. When MDT is in full operation on a nation-wide scale, the PR/IR ratio should be near 2:1, and in terms of case load it should be less than 20% of what it is now.

It is, therefore, proposed to consider a nation-wide implementation of MDT in two stages. Stage I is to tackle this large backlog of patients in order to reduce the accumulated case load and bring the PR much closer to the IR, say no higher than 3:1. Stage II will then take over and continue until the leprosy problem is firmly under control and eventually solved, or achieving the "elimination of leprosy" as a public health problem if not altogether as a health problem.

Stage I

General situation. Due to the large backlog of untreated or insufficiently treated patients, the ratio between the PR and the IR is greater than 3:1, often reaching 10:1 or even higher. In many countries, the national mean PR is greater than 0.6/1000. Leprosy work is often done by a vertical leprosy service, managing to cover only a portion of existing patients effectively. There may be a number of expatriate voluntary agencies doing some leprosy work, including MDT, but their activities are not fully coordinated with the national effort and their coverage is even more limited. On the other hand, their leprosy work is likely to involve much wider activities beyond MDT, including what is now officially termed as "care for the ex-leprosy patients."

Objectives. The overriding importance of Stage I is to put all known active leprosy cases on MDT as quickly as possible. This is the basic principle of a public health approach to an infectious disease control. For this purpose, the field must be prepared to do proper case holding, which aims at the high completion rate of MDT, in order to demonstrate both that "leprosy is curable by MDT" and the "existing health services can deliver the MDT" to earn the trust and confidence of the so far rather skeptical patients and the public and to obtain their full cooperation.

Since the demonstration of "cure" is the main objective and since there are already a large number of known cases waiting for MDT, the handling of which is likely to tax the existing resources, case finding should not be emphasized in Stage I. Also restructuring of the leprosy service, such as complete integration into the GHS, must be done carefully, sometimes postponing the process if the existing vertical service can manage to do substantial MDT work for the known cases.

Even though from the very start, careful long-range planning is necessary to cover both the Stage I and Stage II implementation of MDT. Stage I needs much more flexibility. And any structural change which is likely to be necessary in Stage II must be introduced rather carefully, always remembering that MDT implementation itself in terms of the numbers of patients covered is much more important than the establishment of a "proper" leprosy control structure as such. MDT in Stage I is rather an expensive undertaking requiring a substantial amount of financial support mostly from international donor agencies which calls for an effective coordination among all agencies concerned, including the WHO in most instances, with the initiative coming from the Ministry of Health of the country concerned.

To sum up, the main objective in Stage I is to give MDT to all of the known active cases as soon as possible by establishing a reliable case-holding system. Case finding should not be emphasized at this stage, and restructuring of the leprosy service should be done only if that will strengthen the MDT implementation. An effective coordination of all the agencies involved is mandatory since a large amount of external resources are likely to be required at this stage. Training also needs careful long-term planning because Stage I lasts only several years, and when Stage II is reached, both the amount and the nature of leprosy work required are likely to change in step with a drastic reduction of the case load.

Strategies. Because of the large scale of the undertaking, Stage I is best tackled as a special national project of 3 to 5 years' duration, with a specifically estabished central (national) structure together with a national budget.

Organization/Structure

Central (national/federal) level:

a) National MDT Steering Committee (NSC): Composed of a senior administrator, such as a vice minister, as the chairman and other senior officials, like director generals of various divisions and including the head of finance and personnel, as members. They will meet perhaps quarterly to oversee the progress of Stage I until it is completed.

b) National MDT Task Force (NTF): They function as the effective arm of the NSC mentioned above. This group of a dozen or so members may be headed by the person to whom leprosy service belongs, such as the Director General of Communicable Disease Control (DG/CDC). The majority of the other members should be composed of leprosy specialists in the Ministry but a training and a health education expert should be included, if available. The group's function is to draw up the plan for Stages I and II, then monitor and evaluate the activities starting with training and then implementation itself of Stage I. Each member, perhaps with the exception of the chairman if he is DG/CDC, must be able to go to the field frequently, say once a month for up to 2 weeks, for monitoring purposes. There should be a monthly NTF meeting for the evaluation of MDT at the Ministry with all members attending, and they should present a quarterly report to the NSC. Since this kind of careful monitoring is so important, an adequate budgetary provision must be made for this activity.

One member of NTF should be in charge of the data collection and analysis of the MDT activities, while the other person must be specifically designated to be responsible for the logistics, which need both constant monitoring and long-range planning because drug supply from the manufacturer often takes 6 months or more to reach the peripheral health stations where the drugs are actually needed.

The following two levels may not need a special structure, if MDT is to be handled by an existing vertical leprosy service.

Provincial (or state in case of a federal system) level:

Health activities with its budget and personnel are often controlled at this level rather than directly from the national government. Therefore, even though Stage I is a national project, there must be a structure specifically set up for MDT at this level, if it is handled by the GHS. A provincial task force (PTF) should be composed of the provincial health officer (PHO) as chairman and one medical officer (MO) as the provincial MDT coordinator together with several others, probably public health nurses (PHN) or senior paramedical workers (SPMW). One of them must be specifically designated to look after the logistics while another monitors data collection, although a single person may be able to do both. These people also must be quite mobile within the province for regular and frequent rounds of monitoring.

Peripheral level:

Village health station/post/clinic: Actual implementation of MDT by giving drugs to the patient is best done at the most peripheral or primary health care level, say a village health station (VHS) of the area where both the patient and the multipurpose village health worker (VHW) reside and perhaps know each other. A monthly clinic is held at the VHS.

Main health center: Often several of such VHSs are under the control of a main health center (MHC) in a nearby town with at least one MO, a few PHNs or SPNWs, possibly with a lab technician (LT). One of the PHNs or SPMWs should be designated as the MDT coordinator responsible for both the supervision and the monitoring of VHWs in the area, although the activities as the MDT coordinator are already likely to be done within her normal duty.

The MO at this level must be primarily responsible for the verification and clinical assessment of the known cases, diagnosis and classification of new patients, if any, and initiating and terminating MDT, giving outpatient care for lepra reactions and drug side effects or referring the case for inpatient care at the next higher level. The LT may be responsible for the BI examination, even though it is probably better to restrict this task to taking the smears and fixing the slide only, leaving the job of staining and reading to the LT at the next higher level who is likely to be based at a hospital. The clinical records of the MDT patients are likely to be kept at the MHC.

District hospital: In most countries, there is likely to be another level of the health services structure, most probably based at a hospital. If so, at least one MO should receive special training on clinical leprosy so that proper inpatient care can be given to a patient in case of a severe lepra reaction or a drug side effect. That MO also should be competent in the diagnosis as well as the classification of leprosy when a doubtful case is referred from MHC below. One competent LT at this level should be assigned to do the BI examinations of the slides from the whole district, ideally taking the smears himself. Someone at this level may have to be assigned for data collection and logistics as the MDT coordinator, but this will depend upon the general health structure and the case load.

Financing and logistics

National budget. Since Stage I is a national project, it is essential that the Ministry of Health (MOH) should have adequate funding to conduct all of the activities of this stage, except the regular salaries of all staff involved which should come out of a normal budget (both national and provincial) unless some persons are specifically recruited from outside the MOH. Most of the MOH of leprosy-endemic countries are likely to require substantial support from outside to complete Stage I, partly in kind, such as drugs, equipment and printed material, and partly in cash. (It is often necessary and/or prudent for NGOs in case their contribution is very substantial to insist on a counter budget from the MOH for the project itself, excluding salaries, in order to make sure, both symbolically and in reality, that the MDT is a national project of the MOH and not of a funding agency. This arrangement is essential if Stage II is to succeed Stage I smoothly, because Stage II is meant to be a regular MOH program without large-scale external support, as far as MDT is concerned.)

The national budget should cover: a) activities of NSC and NTF (planning and monitoring); b) may be requested to cover the cost of PTF (monitoring); c) activity cost of planning, training, implementation, monitoring, data collection and evaluation at various levels; d) purchase of drugs; e) acquisition of necessary equipment, including cars; and f) production of material for training, health education, and working manuals.

Provincial budget. Apart from the cost of PTF, mostly for per diem allowances and the transport cost of its members, not much is required since at this stage the drugs and other supplies are provided by the MOH.

Key points in Stage I

1) Political commitments at the highest level of the national health authorities, reflected in a) public announcement on MDT implementation as a national project; b) establishment of special structures within the MOH, such as NSC and NTF, with specific designations of personnel involved; c) al-

location of a national budget; and d) issuing of administrative orders to all personnel in health services on MDT implementation.

2) Detailed planning of Stage I with careful anticipation of the requirements of Stage II. The plan thus decided must be amenable for improvement by alterations if such become necessary as a result of monitoring by the NTF.

3) Production and distribution of the plan of operation and a manual of operation in sufficient quantity to make them available to everyone directly involved in the field.

4) Training should be task oriented to meet the need of assigned job performance. Not much theoretical teaching is needed. Since large numbers are likely to be involved, "self teaching material" should be utilized in full to cut down on time and expense required for teaching sessions. Ample provision should be made for the expected amount of remedial or refresher training, because the training given originally is bound to be inadequate to some of the people. If the training was found to be adequate to every participant, it probably means an overtraining and wasting of time to some of the participants.

5) Establishment of clear lines of authority with a strong central command and an efficient local organization. At every level from the MOH down to the VHS, the person/persons responsible for MDT should be so designated and made known to everyone.

6) The primary objective of Stage I is the establishment of a reliable case-holding system to implement all the known cases and this should be demonstrated. Do not attempt any active case finding, except for a household contact survey. Experience amply shows that if the fact that an effective treatment is being given at the VHS is known, most of those missed or so-called "hiding" nonregistered patients will come forward by themselves. It is a well known fact that many leprosy patients present themselves to a clinic when some early symptoms, such as a skin patch or nerve disturbances, appear but the true nature of the disease is missed by the health worker. Subsequently, as the symptoms become more pronounced and the patients themselves become aware of the diagnosis, their mistrust of the health services prevents them from coming forward. Intensive health education on MDT is no doubt useful but only if the local health service can actually deliver reliable MDT.

Stage II

General situation. Stage II starts when Stage I is completed, but without a break in between. Most of the backlog of clinically active cases should have received MDT during Stage I, so that the total case load in most of the leprosy-endemic countries should have dropped to ⅕ or less of the original number. The true IR may have started dropping somewhat by now, but even if it has not the ratio of PR to IR should become 3:1, or perhaps less, because at this stage we should be dealing mostly with genuine new cases as well as a small number of relapsed cases.

Unlike Stage I, case finding will be as important as case holding in Stage II, although this does not indicate employment of extensive active case finding.

If a vertical service had much to do in Stage I, there is no longer any scope left for them as a separate service as far as MDT implementation is concerned, but if the government is willing to provide some care to the leprosy patients beyond MDT, then there could be room for a vertical leprosy service to stay on. Under most circumstances, such extra care in the leprosy-endemic countries in the Third World is best left in the hands of voluntary agencies, because it seems to be extremely difficult to justify the use of the rather limited public funds available which are most probably needed to deal with other pressing public health problems.

The MDT program now, in which case finding is as important as case holding, must be conducted by the GHS for the reasons already discussed. If an efficient Stage II follows a successful Stage I, leprosy should no longer be a serious public health problem within 10 years or less from the start of the MDT program.

Stage II should be conducted as a routine program of the MOH, without a special national budget and national structure, even though it might be a wise precaution for the national government to procure MDT drugs and distribute them to the provinces. This should act both as a reminder and an incentive to the health authorities of the provincial governments to continue MDT programs under their own responsibility. Only a very few countries have either reached or are approaching Stage II so far. Therefore there is not much point in discussing the matter in too much detail at present, and only some brief statements will be made.

Objectives. By establishing an efficient case-finding system as well as maintaining a reliable case-holding system through the GHS, any new case in any part of the country, together with cases of relapse, will be diagnosed without delay and put on effective MDT, which, with the addition of or substitution by more potent drugs, could well be shorter than what is now recommended as the minimum.

Our main objective in Stage II is to make leprosy no longer a major public problem within 5 years or less of implementation, coming closer to an eventual elimination of the disease, with something like true IR of $< 1/1,000,000$ per annum.

Strategies. Even in Stage II, where case finding is as important as case holding, there probably is very little scope for active case finding, except household contact surveys. Instead, it will heavily depend on efficient passive case finding based on three factors: a) knowledge of the signs and symptoms of leprosy, and what to do when the disease is suspected, by the general public. This will be done by extensive and often repeated and sustained public health education using all available media and opportunities. b) keen awareness of the possibility of encountering a case of leprosy by every person involved in medical and health work, including doctors in private practice, PHNs in schools or factories, etc. They should at least be able to suspect, if not actually to diagnose, leprosy and know where to refer such a case for proper handling. c) readiness by leprosy specialists to deal with the case, including initiation of MDT. This means that a certain number of leprosy specialists must be within the structure of the GHS. Because the majority of peripheral workers are unlikely to face a case of leprosy to handle, there is not much point in giving specific training on MDT to everyone as a routine. It should be given only when a VHW actually has a case in the form of "on-the-job training." However, all GHS personnel should be made to maintain a keen awareness of the possibility of leprosy in the community.

Structure/Organization

Central (national)—no longer any NSC or NTF. The head of the national leprosy service within the CDC division should take full responsibility to run Stage II, together with his staff in the Ministry, through the regular administrative structure of the GHS. A few leprosy specialists (MOs) may be designated as MDT advisers to assist the head of the leprosy service.

It is important to continue reliable data collection from the field within the normal structure of data collection of the Ministry, and to maintain a central registry of patients on MDT and those of the post-MDT surveillance.

Leprosy must be a regular component of any national health activities, such as health education of the population, training of health officers, epidemiological surveys, etc.

In medical schools and schools for nurses or paramedical workers, leprosy must be a subject within the regular curriculum, and part of any practicums, to make sure that all those who enter the medical profession will regard leprosy as part of their responsibility, and will have a basic understanding of the disease and the methodology of its control.

Provincial and lower level. A group of leprosy specialists (MO, PHN, SPM, and LT), who constitute the provincial task force, has to be maintained but since their workload with MDT is likely to be small, they should have other responsibilities as a group or individually. In many countries, the PTF for leprosy is likely to be responsible also for the control of other diseases, such as tuberculosis.

No longer are specialists at the district level required, except one MO and one LT, both based at a hospital, who should be able to function as leprosy specialists whenever the need arises.

Any handling of MDT should be one of the routine activities of the GHS but, as already mentioned, a VHW who has to give MDT must have a short on-site training, most probably by a PHS who is acting as a provincial MDT coordinator. The coordinator must make sure of the regular drug supply as well as the data collection, while the LT at the district level must be able to do a BI examination, although in fact it may be better to have it done by a LT at the provincial level. (Since the LT needs constant practice to keep up his skill, as the case load comes down, it is better to have one competent LT at the provincial level rather than several not so reliable ones in various districts.)

Financing

National—a special budget for MDT is no longer required, except: a) national government may keep purchasing MDT drugs and distribute them to provinces; b) special budget for monitoring of MDT and for an epidemiological survey, especially toward the end of Stage II; c) nationwide health education of the public and health workers is better done by the MOH with its own national budget.

Provincial—no special budget is required for MDT because any activities involved should form a legitimate part of the routine work within the GHS with a regular operational budget.

Key Points in Stage II

1) Even though MDT is no longer a special national program,"MDT for all" or even "elimination of leprosy" should be kept as a national goal, and that should be made public frequently.

2) In conjunction with the above, a high level of health education must be maintained to keep both the public and health and medical personnel aware of how to deal with it.

3) Retain some competent leprosy specialists within the GHS structure, so that their expertise will be available whenever needed.

4) Case finding which is now as important as case holding primarily depends on "passive case finding" or voluntary presentation by the patient as a result of the above-mentioned effective health education. Even though "active case finding" for leprosy alone should not be encouraged because of poor cost effectiveness, every opportunity for physical examination (at clinics, hospitals, schools, factories, etc.) for any purposes should be utilized to look for possible signs of leprosy.

5) Since a major part of MDT is over by the end of Stage I, a possibility of further care of leprosy patients, especially those with physical disabilities, should be seriously considered within the total context of the health care of the nation.

It is not recommended to utilize the public health budget of the MOH for rehabilitation of leprosy patients, unless rehabilitation of those physically handicapped by any cause is already a part of its work. However, it is definitely a responsibility of the MOH to make sure that whatever rehabilitation program exists in the country should be made available to leprosy sufferers, and at the same time, to encourage NGOs (both national and international) to give assistance in this area, again making sure that it is not exclusively for leprosy. If there is a pre-existing specialized rehabilitation program for leprosy, it should be encouraged to open the door to the needs of other nonleprosy sufferers.

CONCLUSIONS

1. In the last decade of the 20th century when we are all striving for "health for all by the year 2000," what is most important is to recognize and accept the basic principle that every leprosy patient has a right to expect MDT to be given, wherever he lives. To give MDT is the top priority; therefore even poorly implemented MDT is better than no MDT.

2. "MDT for all," therefore, should be a national goal of the health authority of every leprosy-endemic country. In order to make this goal attainable, the MDT program must be made simple so that any leprosy-endemic country, with whatever the current state of health services, can adopt it.

3. The above goal may be reached in two stages. Stage I is to tackle all of the accumulated known cases, concentrating on proper case holding. This should be a special national project with a national budget covering 3 to 5 years. Stage II is to establish and maintain an effective case-finding as well as a case-holding system through the general health services so as to cover all existing and newly emerging cases in any part of the country. This stage may also last up to 5 years, at the end of which leprosy should no longer be a public health problem.

4. Even though Stage I, by necessity, has to be a special project for leprosy only with

a separate national budget, every effort must be made, especially in Stage II, to see that leprosy is no longer separated from all other diseases, either in thought or practice by health workers and, hopefully, by the public.

5. It is necessary to recognize that even though MDT is capable of controlling leprosy as an infectious disease, it cannot fully control leprosy as a deformity- and disability-producing disease. This aspect of leprosy, at present, is likely to be outside the concern of public health authorities of leprosy-endemic countries, and, as such, provides a large scope for interested NGOs to make useful contributions in this area.

We should not rest until the day when every leprosy patient all over the world can say that "leprosy is curable" and "deformities are preventable," not as a dream but as a reality from their own personal experience.

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