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**Leprosy Review**  
**A journal contributing to the better  
understanding of leprosy and its control**

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*Leprosy Review* is published by LEPRA with the main objective of contributing towards the better understanding of leprosy and its control. Original papers on all aspects of leprosy, including research, are welcomed. In addition, *Leprosy Review* seeks to publish information of educational value which is of direct benefit to the control of leprosy under field conditions, and hence to the individual patient. The Journal aims to interpret what is being done in other disciplines, particularly for field workers.

From time to time the Editorial Board invites special articles or editorials from experts in various parts of the world, and gives consideration to the production of a supplement or special number devoted to a particular subject or theme of major importance.

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## Editor's Choice

Starting with this issue of *Leprosy Review* there will be a column from the Editor highlighting papers and articles of particular interest in the current issue. I hope it will stimulate interest and share my excitement for the papers we publish. I see this as an appetizer for the Journal, to whet your appetites for the real thing. It is not intended to be an overview, not every article can be mentioned and please don't take offence if your article isn't mentioned.

This number of *Leprosy Review* has a distinct theme of research on nerve damage in leprosy. From two centres in Nepal there are papers on new ways of measuring nerve impairment. In the first van Brakel *et al.* (pp 25–37) address the difficult problem of assessing impaired stereognosis (the capacity to recognize handheld objects by touch and feeling). You can test the importance of this function by putting your hand in your pocket right now, without stereognosis you will be unable to identify the objects in your pocket. This paper shows that there are no simple tests for this function but most patients unable to perceive a 2 gm monofilament will have loss of stereognosis. Soares *et al.* (pp 55–60) have tested a simple pinch meter made from a neonatal sphygmomanometer which can detect early motor loss at a time when there is no objective loss on VMT testing. Further testing will be needed to determine where this test can be most usefully deployed. The importance of treating nerve damage and of looking for new treatments is shown by the paper from Istanbul reporting that more than 70% of Turkish patients had eye, hand or foot disabilities. The meeting report from Karigiri (pp 50–54) stresses the need for specific objectives and strategies if control programmes are to be effective in the prevention of disabilities.

Thalidomide is the most controversial drug used in the treatment of leprosy and is unavailable in many countries although its use in severe ENL is supported by evidence from high quality randomized controlled trials. In the UK Thalidomide is prescribed on a named patient basis only and guidelines were recently produced for physicians using this drug. We have reprinted these guidelines from the *Postgraduate Medical Journal* (pp 61–66) and hope that readers will find them useful and also comment on their applicability to leprosy patients.

The importance of continuing to look for drug side-effects especially at a time when new drugs are being taken up for use in leprosy is illustrated by the paper from Karigiri (Vijaykumaran *et al.*, pp 10–15) describing definite leucopenia in two patients and a possible third case in three patients in a drug trial involving rifampicin and ofloxacin. This paper is published to highlight this possible problem and to warn other physicians to consider this possibility when patients present with unexplained fevers or infections.

DIANA N.J. LOCKWOOD

## Editorial

### JOINT TUBERCULOSIS/LEPROSY PROGRAMMES

#### Background

The current methodologies for leprosy and tuberculosis (TB) control have been well established for many years, but for both diseases the next few years pose difficult challenges. For leprosy, the possibility of ‘elimination as a public health problem by the year 2000’—adopted as an objective by the World Health Assembly in 1991—has raised questions about the future need for leprosy control activities: these questions are being asked by patients and staff, programme managers and funding agencies, as well as Ministries of Health. Tuberculosis, on the other hand, has been declared a ‘global emergency’<sup>1</sup> and TB control activities are beginning to receive much more attention from health planners, donors, Ministries of Health and even the media.

Several combined TB/leprosy control programmes have been established, especially in Africa, beginning with Tanzania in the late 1970s. Surprisingly, there are few reviews in the literature of this important development in health service provision.<sup>2–5</sup> The diseases have much in common and there are many reasons to advocate joint programmes (Table 1). Initially, the main reasons for linking the programmes related to the available infrastructure and its most efficient utilization. In Tanzania, for example, there was an effective vertical leprosy control programme in the 1970s, serving a large number of patients (the steep decline in prevalence with multiple drug therapy (MDT) was, of course, still to come); a proposal for TB control attracted the funds required for the drugs, but not the money to set up a completely separate infrastructure; the practical solution of using the established leprosy infrastructure was agreed by the parties involved.<sup>6</sup> It is surprising that in the many analyses of the TB control programme in Tanzania, which has become a model for Africa, the specific (and continuing) contribution of the pre-existing leprosy programme has been largely ignored.

These administrative reasons were attractive to Ministries of Health and donors elsewhere, so that now over 20 countries have combined programmes, generally covering the whole country. In recent years research has shown more and more points similarities between leprosy and TB so that this ‘marriage of convenience’ is now important for technical reasons. For example, when examining the effect of BCG, both diseases must now be studied simultaneously,<sup>7,8</sup> while rifampicin resistance has been shown to have an identical genetic basis in the two diseases, with obvious implications for future work.<sup>9</sup>

**Table 1.** Some reasons for advocating joint TB and leprosy programmes

Areas of common ground	Consequences for programme management
Bacteriology	Same laboratory methodology Drugs and treatment regimens are very similar Research findings relevant to both diseases
Epidemiology	Chronic communicable diseases Long and variable incubation period Research findings relevant to both diseases Preventive measures (e.g. BCG, chemoprophylaxis, mass treatment) will affect both diseases
Treatment and control	Shared strategy of case-finding and chemotherapy Cost-effective utilization of infrastructure Ambulatory treatment requires the same support Shared expertise in health education, case-finding, treatment delivery, case-holding, recording and reporting, supervision Complex, but similar, health information systems Sustainability through integration with basic health services Central Unit has similar responsibilities for both diseases
Psychosocial aspects	Fear and stigma attached to both diseases Need for counselling increasingly recognized Both are diseases of poverty Economic problems may affect compliance

**Current issues**

The current position is that many countries have already approved a policy of combining the two programmes and are at various stages of implementation; a process of integration with the general health services is often taking place at the same time, and in a few instances, for example Ethiopia, decentralization as well. It seems reasonable therefore to move on from considerations of whether or not joint programmes are a good idea, to looking at the problems that are being encountered and how those interested in improving leprosy and TB control should respond. Three important and relevant topics will be considered:

- Prevention of disability (POD), care and rehabilitation for people affected by leprosy;
- Coverage and compliance; and
- Integration with the general health services.

**POD, CARE AND REHABILITATION**

The fear of many leprosy health workers is that a combined and/or integrated programme may deliver MDT effectively, but the assessment of nerve function and the prevention and management of impairments and disability may be neglected to a greater or lesser extent. There is some evidence that this has occurred in some programmes<sup>10</sup> while Swaziland, for example, has maintained separate programmes in order to prevent it.<sup>11</sup> There are a number of possible reasons why this neglect could occur:

*Training and supervision*

There may be a lack of training and supervision of general health staff in the relatively complex tasks related to POD, although many of these are not necessarily specific to leprosy. Training is time consuming and expensive, and arbitrary moving of staff may waste these efforts. With decreasing prevalence, individual junior staff members will see very few leprosy patients, making it difficult for them to maintain their skills, a recognized problem in Botswana.<sup>12</sup>

*Indicators*

There are no straightforward and reliable indicators for monitoring POD activities. There is little doubt that the success of chemotherapy for both leprosy and TB in country-wide programmes has been enhanced by the straightforward, standardized reporting mechanisms, from which meaningful indicators can be easily calculated.<sup>13</sup> This deficiency means that the monitoring and evaluation of POD activities are very weak, leading inevitably to vague objectives and poor planning.

*Time*

In a combined or integrated programme, health workers have many different calls on their time. Leprosy patients may be few in number, subject to continuing stigma and unassertive compared with other patients, and may therefore remain as the lowest priority. The chronicity of the disease may also be a discouraging factor for staff.

Each of these issues should be addressed.

*Training and supervision:* There is clearly a need for a basic curriculum for clinic level staff training, which covers the minimum requirements for the provision of an effective service. There may be a need for several different curricula, each with its own manual, for different grades of staff with different responsibilities. Each country would need curricula and manuals suited to its own needs, but perhaps based on a standard format. Good supervision is also required to maintain the quality of the work done.

*Indicators:* Monitoring is an essential element of the management cycle. The ILEP form 'B' for leprosy programmes has been a guide for priorities; it is also a helpful tool in monitoring field activities, allowing the immediate calculation of several indicators, which show how well the programme is doing and how it compares with other programmes or published results. The same is true for the quarterly report forms in TB control ('New cases' and 'Results of treatment'), and it can be argued that the link with TB control activities has brought a more rigorous approach to reporting in leprosy control.<sup>14</sup> Unfortunately, apart from the disability grades of new cases, the ILEP form 'B' does not currently demand any information about POD activities, presumably because these have not been standardised and are not easily reported. Reporting of disability grades at the end of treatment will soon be requested on the ILEP form 'B',<sup>15</sup> but this is not ideal when treatment is of short duration, as many episodes of neuritis will occur after that point.

It is vital therefore that simple methods of reporting POD activities and easily calculated indicators are developed for routine use, as a crucial part of managing the leprosy component of combined programmes; this is already an ILEP recommendation.<sup>16</sup> This monitoring may be related to both process (the activities

carried out by staff in the clinics) and outcome (the results seen in patients over time). Although the effect of POD activities on patients and their well-being is what we are ultimately interested in, it may be very difficult (it is certainly time consuming) to measure in a reliable and reproducible manner. One of the major confounding factors in comparing outcomes achieved by different programmes is the case mix—if the initial status of the patients is very variable (as is usually the situation with a cohort of leprosy patients), the degree of improvement and the final results cannot be easily compared. This is the case in many fields of medical care and so process indicators are often preferable.<sup>17</sup> They are usually much easier to measure and report: they can be useful if they are based on research which clearly links the process to the desired outcomes.

An example which we are trying to validate at ALERT concerns the use of steroids for the field treatment of neuritis. Clearly, nerve function in every patient treated with steroids could be assessed over time and the results, or outcome, calculated in a standardised way for comparison. This is however a large amount of work which could probably not be done routinely by peripheral staff in most integrated, combined programmes. A simpler method of monitoring steroid treatment may be to report the number of patients started on steroids during each quarter, and then report on the completion of steroid treatment in a cohort analysis six months later, an exact analogy with the current methods of reporting on MDT. If the indications for steroids, the regimens and the outcomes are known from research studies, monitoring the process in this way in routine programmes will give valid data regarding that particular POD activity.

The provision of footwear could be similarly monitored, but other aspects of care and rehabilitation are complex and are carried out in different ways in different programmes. It may be unrealistic to demand reports from general staff on these activities; it may be more appropriate to regard some complex tasks as requiring referral of the patient/client to a specialist, as with any other medical or surgical condition, who can then report on the more sophisticated procedures undertaken, whether they be the surgical management of an ulcer or some form of socioeconomic rehabilitation.

*Time:* Time is usually in short supply in the routine health services, but the provision of clear guidelines for staff (typically in a manual), good baseline and continuing education (often through good quality supervision), and a straightforward reporting system with reliable indicators, could all help to avoid the neglect which many fear will occur.

#### COVERAGE AND COMPLIANCE

Although the model programmes managed by the International Union Against Tuberculosis and Lung Disease (IUATLD) have achieved laudable results and have shown what can be done,<sup>13</sup> it remains the case that, in global terms, coverage by and compliance with TB control programmes are problematic, with the development of drug resistance, for example, being a direct consequence of poor compliance.<sup>18,19</sup> Case-holding and compliance have been important measures in leprosy control for many years and this experience and expertise could contribute significantly to TB control. Within a joint programme, dialogue over issues such as structured patient education, treatment delivery, monitoring patient attendance, mechanisms of absentee tracing, management of psychosocial problems, etc., could be very fruitful. As an example, the use of blister

packs in leprosy control has been very successful: similar developments in the field of TB (such as blister packs or combined formulations of four drugs) may offer an alternative to the current 'gold standard' of directly observed therapy (DOT), with significant implications for programme organization and funding.

Coverage (getting the site of treatment delivery as close to every patient's home as possible) is also important in leprosy, in aiming for the target of elimination. In a recent World Health Organization (WHO) consultation in Geneva, it was felt that integration, rather than combination with TB in a vertical setting, would lead to better coverage; the fear being that TB activities would swamp the leprosy work in a combined programme.<sup>20</sup> The mainstay of the elimination strategy is MDT, but after the year 2000, when POD activities constitute a major undertaking, it can be argued that leprosy control can maintain its coverage only by being linked to TB. Leprosy elimination programmes are an important centrally-driven initiative in the short-term; the medium to long-term outlook for leprosy control seems bleak if it remains as a single programme.<sup>21</sup>

Because the combination of the two programmes brings potentially large management-related benefits, such as increased cost-effectiveness, it is surprising that WHO maintains two completely separate programmes, with very little joint activity, at the same time as recognizing the overwhelming need for better management in the field,<sup>22</sup> and that financial constraints are the major obstacle to better control.<sup>23</sup>

A relevant example here would be Kenya, where the Netherlands Leprosy Relief Association (NSL) has sponsored the leprosy control programme since the 1960s. A combined leprosy/TB control programme was then developed, with funding from the Government of the Netherlands. This funding covers all aspects of the programme, including all the infrastructural elements and the management and administration, into which NSL still has an important input. This has meant that the leprosy component is funded by a bilateral donor, releasing the charitable funds available to NSL for work in other countries. NSL continues to be involved, so that the danger of leprosy being pushed to one side is minimized; on the other hand, by being linked to TB, the relatively small leprosy component has a much more secure future with the backing of a bilateral donor.<sup>24</sup>

## INTEGRATION

Integration with the general health services (not to be confused with the combination of leprosy and TB, which could be done in a vertical setting) is probably the best way to maintaining leprosy and/or TB control activities in the longer term.<sup>25-27</sup> It is important that the general health services are functioning effectively before integration takes place. However, because of the stigma attached to leprosy patients, found amongst health workers as well as in the general public, integration may be difficult to achieve in practice. Conversely, it can be argued that managing leprosy patients in a separate, vertical programme contributes to stigmatization. Because TB control activities must be at least partially integrated, combining leprosy with TB may be a convenient route towards the integration of leprosy control activities and ultimately more sustainable programmes, with better coverage of the population.

The best model of integration involves multipurpose workers at the level of patient care, with a specialized, combined component handling donor relations, technical support, supervision, training and research, and providing a mechanism for referral



for specialist opinion.<sup>26,27</sup> This specialized component will be needed at central, regional and district level, to support the activities of general staff at health unit level. In ALERT's experience, personnel matters (changes in job descriptions, places of work, different employing authorities, etc.) are the most difficult and time-consuming issues to deal with when changing programme structures. Clearly these issues are country-specific and therefore general guidelines on combining and integrating programmes, are unlikely to be helpful; planning, discussion, negotiation and compromise will be required during each restructuring process.

Training is a vital element as programmes are integrated. Training for both leprosy and tuberculosis was tentatively begun in 1983 at ALERT,<sup>28</sup> when, incidentally, I was privileged to be amongst the trainees, but the lack of a smoothly functioning TB control programme in Ethiopia prevented this from being firmly established until more recently. It is essential, however, that in an integrated setting, general health workers are well trained and that they are supervised by district and regional staff who are also well trained and kept up-to-date through comprehensive continuing education.<sup>29</sup> The maintenance of such a country-wide training programme, perhaps with assistance from institutions like ALERT and IUATLD, should be a major responsibility of the Central Unit of the National Leprosy/TB Control Programme.

With an integrated programme the Central Unit in the Ministry of Health could become broader than just leprosy and TB. Some programmes also cover AIDS and STD's, and maybe some noninfectious, chronic diseases, such as diabetes or epilepsy would be included in future, as their infrastructural requirements would be very similar.

## Conclusions

A number of issues seem of major importance as joint programmes are developed.

First, there is the challenge to the leprosy community to pursue research and training activities in the field of POD, as a matter of urgency. This is an important public health issue which will require attention for many years, but which could be neglected as leprosy is defined as being 'eliminated as a public health problem,' on the somewhat arbitrary grounds of declining prevalence. Clear guidelines for POD activities and a straightforward mechanism for reporting on (and assessing) the work done, are essential.

Second, combined and integrated programmes can improve the outcome of chemotherapy through better coverage and compliance. There are several recent innovations in the fields of health promotion, treatment delivery, treatment compliance and coverage, which have been developed in either leprosy or TB programmes, but which could profitably be applied to the other. A combined programme allows the utilization of these advances for both diseases: In leprosy, donors will want to see more efficient use of the infrastructure they have helped to establish, while maintaining the quality and coverage of leprosy control activities. In TB, when the traditional services are being swamped by increasing numbers of patients and the majority of the budget is used for drugs, the use of case-management and case-holding methodologies developed in, and run together with, the leprosy control programmes will be the only way to cope financially.

Third, combined and integrated programmes offer the most promising route to sustainability for leprosy control programmes. TB control will become such a large part

of the work of the health services in developing countries that it will demand attention as a single entity, even if the required infrastructure and management skills are lacking. However, if the combined approach is fully supported by ILEP members, as the German Leprosy Relief Association and the Damien Foundation of Belgium are doing at present with the programme in Ethiopia, the leprosy component will have a more secure position as the year 2000 approaches and TB control will gain in terms of programme management. Integration of leprosy work into the general health services, without any formal links to a higher profile, specialized structure at district, regional and national level is a recipe for disaster, as happened with TB control in the 1970s.<sup>30</sup>

Fortunately for leprosy and TB patients in Africa, many countries (especially the larger ones) have adopted the policy of joint TB/Leprosy programmes. It remains for the various international bodies, NGOs and other donors involved in fighting the two diseases to combine their forces and present a united front, rather than defending separate territories.

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## **Leucocytopenia after rifampicin and ofloxacin therapy in leprosy**

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*Summary* New antimycobacterial agents and combined treatment regimens are being introduced for the treatment of leprosy. Ofloxacin is one such broad spectrum antimicrobial agent. In this study rifampicin plus ofloxacin were administered daily for 4 weeks (daily supervised dose). Two patients (and possibly a third patient who refused all investigations) out of 125 patients developed leucocytopenia during the third week of therapy. It was associated with fever, malaise, nausea and loss of appetite. They recovered after cessation of drug treatment. Patients receiving ofloxacin should be monitored for constitutional symptoms suggestive of this complication even though the risk of such complication may be minimal.

### **Introduction**

A large number of leprosy patients have been treated with DDS monotherapy and multidrug therapy (MDT) as recommended by the World Health Organization (WHO). This regimen containing DDS, rifampicin and clofazimine seems to have minimal side-effects. Newer drug regimen<sup>1</sup> containing newer antimycobacterial drugs<sup>2</sup> are being tried for treatment of leprosy. Ofloxacin is one of the antimycobacterial agents that is under investigation as an anti-leprosy<sup>2-7</sup> drug. When a new drug is employed in treatment, possible adverse reactions need to be monitored carefully. In this paper three case reports of adverse reactions to antileprosy drugs (ofloxacin plus rifampicin) are presented.

At S.L.R. & T. Centre, Karigiri short-term chemotherapy trial in paucibacillary (PB) leprosy was initiated as part of a randomized double-blind multicentre field trial, sponsored by the World Health Organization (WHO). A total of 125 (previously untreated) PB leprosy patients were included in the study, of whom 44% were male and 56% were females. All of them were adults, i.e. age 15 years and above. Of these patients 40·8% were in the age group of 15–30 years, 56% were in 31–45 years and 3·2% were in 46–65 years of age.

Baseline investigations done (for all 125) leprosy patients at inclusion in the trial were as follows:

Blood: total WBC count, differential WBC count, haemoglobin %.  
 Blood sugar, urea, liver function tests.  
 Urine: albumin, sugar & microscopic examination.  
 Pregnancy test for all women at inclusion in the trial.

All the patients had normal values before commencement of trial regimen. The study group received daily supervised rifampicin 600 mg and ofloxacin 400 mg for 4 weeks; the control group received WHO-MDT (PB) for 6 months.

The daily dose of rifampicin and ofloxacin was administered by experienced field staff (paramedical worker [leprosy] or non-medical supervisor). All the patients were reviewed by a medical officer once a week during the first 4 weeks of therapy. Apart from this, a patient showing any signs and/or symptoms, e.g. itching, fever, headache, drowsiness, abdominal discomfort, etc. was examined by a medical officer. Hence it was possible to monitor for adverse reactions. Two patients (and possibly a third patient who refused all investigations) were suspected to have developed leucocytopenia. The treatment regimen was decoded and all the three patients were found to have received ofloxacin + rifampicin. All three were females.

**Case report 1**

Patient No. 2186 (female/53 years of age) was diagnosed as having borderline-tuberculoid (BT) leprosy. Baseline investigations were done and a trial regimen was administered. On the fourth day of treatment she had a fever for one day which subsided without any treatment. On

**Table 1.** Laboratory investigations—Patient No. 2186

Date	Total WBC count mm <sup>3</sup>	White blood cell (WBC) counts					Hb g%	PCV %	
		Differential count %							
		N	E	B	L	M			
04.03.94	8300	68	6	—	24	2	11·9	—	
14.04.94	5600	59	5	—	32	4	—	—	
28.04.94	5000	62	5	—	31	2	11·2	—	
29.04.94	4000	56	3	—	39	2	—	—	
02.05.94	6300	46	4	—	46	4	—	—	
23.07.94	6000	69	3	—	28	—	12·1	—	
23.11.94	9700	64	4	—	31	1	11·9	—	
		(on steroid therapy)							
28.01.95	—	—	—	—	—	—	13·9	35	

N, neutrophil; E, eosinophil, B, basophil; L, leucocyte; M, monocyte; PCV, packed-cell volume. Blood sugar within normal limits.

Liver function tests (LFT)

04.03.94	Albumin-globulin reversal	(39 g/Lt & 40 g/Lt)
28.04.94	Globulin level more than albumin.	(30 g/Lt & 35 g/Lt)
	Serum Alk. Phosphatase & SGPT	(49·68 & 48 Units/Lt)
	Serum bilirubin	(3·4 μmol/Lt)
	Serum protein (total)	(65 g/Lt)

the 15th day she had a fever for one day associated with malaise. She was hospitalized and routine investigations (Table 1) were done. The peripheral blood picture revealed that the total WBC count had dropped from 8300 per  $\text{mm}^3$  to 5600 per  $\text{mm}^3$ . The trial regimen was suspended. The WBC dropped to 4000 per  $\text{mm}^3$  on the 14th day after suspension of trial regimen. Further investigations ruled out enteric fever (using the Widal test), malaria and infectious mononucleosis. The constitutional symptoms disappeared within 3 days. Recovery of cell count was noted on the 17th day after suspension of the trial regimen without any specific therapy.

Bone marrow aspiration smears stained by May-Grunwald Giemsa could only be done 10 months after the leucopenic episode (as the patient was not willing to be hospitalized). The smears showed cellular fragments and normoblastic maturation, eosinophilia (7%), plasmocytosis (6%), and a slight increase in reticulum cells. A liver function test revealed normal levels of serum bilirubin, serum alkaline phosphatase and SGPT. There was a tendency for albumin and globulin reversal (serum protein) which reverted to normal after cessation of therapy.

This patient had (at inclusion in the study) a large, erythematous, infiltrated patch with an ill-defined margin, dry surface and loss of pain and touch sensation. Her right ulnar nerve was found to be thick without nerve tenderness or neurological deficit. On the 15th day, i.e. at detection of leucocytopenia, the patch was an ill-defined, hypopigmented macule. Six months later she had an ulnar neuritis (right) which subsided with steroid therapy without residual neurological deficit.

She again had a tingling sensation in the right hand associated with tenderness over the right ulnar nerve 9 months after the leucopenic episode. Surgical decompression of the right ulnar nerve relieved the symptoms.

During the 16th month after the leucopenic episode the patch showed erythema and there was a tingling sensation in the right hand. The right ulnar nerve remained thick but not tender. She was started on WHO-MDT (PB) regimen and steroid therapy.

At the end of MDT (PB) of 6-months duration the patch had become a hypopigmented macule but the ulnar nerve remained thick with a similar tingling sensation recurring frequently. There was no neurological deficit.

## Case report 2

Patient No. 3881 (female/60 years of age) was registered for treatment of BT leprosy. Routine investigations prior to treatment were found to be within normal limits. She had sleeplessness associated with headaches and excessive salivation during the first few days of treatment. During the third week, i.e. 19th day she developed a fever lasting for one day only, and nausea and loss of appetite lasting for 5 days (including 2 days after suspension of the trial regimen). Examination of systems revealed no abnormalities. Routine investigations revealed that there was leucocytopenia. The total WBC count (Table 2) dropped to 2000 per  $\text{mm}^3$  from 10,000 per  $\text{mm}^3$ . The trial regimen was suspended and the patient was hospitalized. Further investigations ruled out malaria and enteric fever (using the Widal blood test). Recovery of WBC count was noted on the 7th day after suspension of the trial regimen without any specific therapy. The bone marrow aspiration smears of this patient could be done only 11 months after the episode of leucopenia. It showed mild megaloblastic changes and eosinophilia (12%) (recovering marrow except for hypocellularity). A liver function test (LFT) revealed normal levels of serum bilirubin, serum alkaline phosphatase and SGPT. But

**Table 2.** Laboratory investigations—Patient No. 3881

White blood cell (WBC) counts								
Date	Total WBC count mm <sup>3</sup>	Differential count %					Hb g%	PCV %
		N	E	B	L	M		
23.10.93	10 000	81	4	—	14	1	12·8	40
02.01.94	2 000	56	11	—	33	—	11·9	—
03.01.94	1 600	44	8	—	36	12	—	—
10.01.94	4 900	40	31	1	27	1	11·6	—
17.01.94	8 700	54	29	—	16	1	11·6	—
26.10.94	9 200	38	40	—	21	1	11·6	—
22.11.94	10 800	73	14	—	10	3	11·9	—

See Table 1 for notation.

Liver function tests (LFT)

23.10.93	Albumin : globulin equal	(45 g/L & 45 g/L)
28.04.94	Globulin more than albumin	(30 g/L & 36 g/L)
22.11.94	Albumin : globulin normal	(42 g/L & 36 g/L)
	Serum alk. phosphatase & SGPT	(43·2 & 14 Units/L)
	Serum bilirubin	(3·4 μmol/L)
	Total proteins	(66 g/L)
	Glucose	(6·9375 μmol/L)

there was a tendency for albumin and globulin reversal (serum protein). These changes reverted to normal after cessation of therapy.

She had three erythematous infiltrated patches with partly ill-defined margins on the right arm without involvement of the peripheral nerves. At the time of the leucopenic episode the lesions were regressing though active. One month later the lesions became vague hypopigmented macules (inactive). As there was no signs of disease activity she had been on surveillance without antileprosy chemotherapy.

### Case report 3

Patient No. 2185 (female of 30 years age) was started on the trial regimen for BT leprosy

**Table 3.** Laboratory investigations—Patient No. 2185

White blood cell (WBC) counts								
Date	Total WBC count mm <sup>3</sup>	Differential count %					Hb g%	PCV %
		N	E	B	L	M		
07.03.94	10 600	63	13	1	18	5	13·6	—

See Table 1 for notation.

Liver function tests (LFT)

07.03.94	Albumin : globulin equal	(38 g/L & 34 g/L)
	Serum alk. phosphatase & SGPT levels normal.	
	Serum bilirubin level normal.	

patch on left arm. Results of baseline investigations were within normal limits (Table 3). She had a bitter taste and nausea on the 3rd day of treatment. She was persuaded to continue treatment. The bitter taste persisted associated with loss of appetite and severe abdominal discomfort. It was so disturbing that she refused to continue the treatment on the 19th day. She even refused to undergo investigations. Hence follow-up investigations could not be done. No abnormality was detected on clinical examination. All the symptoms disappeared after termination of therapy. These symptoms were suggestive of drug-induced side-effects similar to the other two patients.

She had three small erythematous infiltrated patches with ill-defined margins and loss of pain and touch sensation. Peripheral nerves were not involved. At the time of the leucopenic episode the lesions were regressing but active.

## Discussion

Rifampicin has been used widely for treatment of leprosy and tuberculosis in various dosage schedules. It is known to cause skin rashes, hepatorenal impairments, haemolytic anaemia, and 'flu' syndrome.<sup>8-10</sup> When rifampicin was used in combination with thiomide the incidence of hepatitis<sup>11,12</sup> was reported to be high. Rifampicin has been reported to have interactions<sup>8</sup> with many other drugs, e.g. oral contraceptives, anticoagulants and antidiabetics.

Fluoroquinolones have minimal side-effects<sup>13,14</sup> and they are known to cause nausea, vomiting and abdominal discomfort.<sup>2,14,15</sup> Cases have been reported with symptoms related to the central nervous system.<sup>5</sup> Ofloxacin has been widely used as a broad spectrum antibacterial agent.<sup>16</sup> The prescribing information indicates that leucopenia, agranulocytosis, anaemia and thrombocytopenia can occur rarely. Ofloxacin has also been reported as causing leucopenia and eosinophilia which is said to be mild and reversible.<sup>17</sup>

The two patients in this study developed leucopenia during the third week of therapy with a daily dose of ofloxacin and rifampicin. However this seems to be reversible as both these patients recovered completely. These patients with side-effects did not take any other drug or herbal preparations. Viral infections are known to cause leucocytopenia. However no serological test was done to rule out viral infections. Stool examination was not carried out. Serum albumin globulin reversal was observed in two out of the three patients. The significance of this is not clear. Further studies may be required.

There may be two possibilities;

- a, ofloxacin might have caused bone marrow depression; and/or
- b, rifampicin might have enhanced the side-effect of ofloxacin.

Drug challenge was not attempted as leucocytopenia was considered as a serious complication.

This project was a multicentre randomized double-blind controlled (field-based) clinical trial. From our centre 125 PB leprosy patients were included in the trial. Assuming that 50% of the study patients received trial regimen containing ofloxacin and rifampicin, then 3.2% of the patients who might have received this regimen had developed leucocytopenia. However it is more appropriate to compute incidence of complications among the total patients included (from all the participating centres) in this multicentre study. There has been no reports of occurrence of leucopenia after ofloxacin therapy and hence it was not possible to provide an estimate of frequency of side-effects.



Further studies are required on this aspect. However small it may be, one should carefully monitor the patients on ofloxacin therapy to identify any such complications at an early stage to avoid possible serious complications.

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## Release of reactive nitrogen intermediates from the peripheral blood-derived monocytes/macrophages of leprosy patients stimulated *in vitro* by tuftsin

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**Summary** The production of reactive nitrogen intermediates (RNI) by macrophages is critical to host defence, particularly for exerting the bactericidal and tumoricidal properties. Nitric oxide (NO) were measured in the peripheral blood-derived monocytes/macrophages of normal and leprosy patients (BT/TT and BL/LL) in the presence and absence of 'tuftsin' as a function of *in vitro* culture age (on 1, 3, 7 days). Macrophages from both groups of leprosy patients were able to produce NO during the unstimulated state but only BL/LL macrophages could be activated by tuftsin to produce significantly high levels of NO. This increase was highest on day 1, then gradually decreased with *in vitro* culture age. Surprisingly, tuftsin was unable to enhance the NO production in normal macrophages above the basal level. Further, normal and BT/TT macrophages had only Cu–Zn derived superoxide dismutase (SOD) activity whereas BL/LL cultures has Cu–Zn and Mn derived SOD activity. These studies indicate that in BL/LL cultures: a, apart from tuftsin, some additional signal is required to activate nitric oxide synthase (NOS) gene for NO production; and b, Mn–SOD produced by *Mycobacterium leprae* is playing a defensive role against toxic-free radicals. The final outcome of this mechanism is the survival of *M. leprae* inside the macrophages.

### Introduction

Activated macrophages play an important role in host resistance to the development of clinical leprosy and in the limitation of growth of *Mycobacterium leprae*. Tuftsin, a tetrapeptide from immunoglobulin G, is an endogenous molecule and a stimulator of phagocytic and microbicidal properties of macrophages has enormous potential clinical implications.<sup>1–3</sup> This immunomodulator exerts a differential effect for the phagocytic and microbicidal activity in the monocytes/macrophages derived from peripheral blood of leprosy patients.<sup>4,5</sup> It was able to stimulate macrophages of the tuberculoid group for the microbicidal activity but failed to show similar effect(s) in the lepromatous leprosy group. Furthermore, it

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was ineffective in modulating the superoxide anion ( $O_2^-$ ) production, but was effective in enhancing the production of hydrogen peroxide ( $H_2O_2$ ) from the monocyte/macrophages of lepromatous leprosy patients.<sup>6</sup> Studies concerning the mechanism of intracellular killing of pathogens such as leishmania, toxoplasma, *M. leprae*, *M. tuberculosis* and trypanosomes using the murine system *in vivo* and *in vitro* have suggested that production of reactive nitrogen intermediates (RNI) may be the chief pathway of killing by macrophages stimulated with interferon-gamma (IFN- $\gamma$ ) or related cytokines.<sup>7</sup> The activated state of macrophages (as defined by their ability to induce intracellular killing) is related to the release of reactive oxygen as well as nitrogen intermediates and the interaction between them is essential for the final outcome of microbicidal process in the form of lethal radical production. Likewise, the ability of the intracellular pathogens to survive inside the macrophages is related to their levels of scavenging enzymes, amongst them superoxide dismutase (SOD) is one of the key enzymes. Superoxide dismutase is also known to enhance the apparent generation of nitric oxide (NO) from L-Arginine without directly affecting the chemical stability of NO itself.<sup>8</sup> The importance of RNI as a causative agent in the killing mechanism is still not clear in the human blood-derived macrophages. The survey of literature indicates that the production of inducible nitric oxide synthase (NOS) is highly regulated and a delicate functional balance among various microbial stimuli, host-derived cytokines and other factors in the micro-environment is thought to be very important for this regulation.

Modulating the production of reactive intermediates (superoxide anion, hydrogen peroxide, hydroxyl radicals and nitric oxide) and their interaction may contribute to the ability of *M. leprae* either to survive or to be susceptible to these toxic radicals. Hence, the present study is designed to investigate the effect of tuftsin for the RNI production in monocyte/macrophages derived from peripheral blood of normal individuals and leprosy patients as a function of *in vitro* culture age. Furthermore, the present study delineates the mechanism(s) underlying the microbicidal process across the spectrum of leprosy during activation of monocytes/macrophages.

## Materials and methods

### COLLECTION OF BLOOD SAMPLES

Leprosy patients were classified in two groups, i.e. tuberculoid (BT/TT) and lepromatous leprosy (BL/LL) according to their clinical, bacteriological and histological findings.<sup>9</sup> None of the patients had received any previous anti-leprosy treatment. Blood samples were collected in heparinized sterile tubes from these patients and normal healthy individuals, who were taken as a control group and had no previous contact with leprosy patients. A total of 7 normal, 7 BT/TT and 6 BL/LL individuals were assayed for both RNI production and SOD activity.

### ISOLATION AND CULTURING OF MONONUCLEAR CELLS

Peripheral blood mononuclear cells (PBMC) were isolated by density gradient separation on histopaque (density 1.077 g/ml).<sup>6</sup> On an average  $1-2 \times 10^6$  PBMC/ml of whole blood, containing 10-15% adherent macrophages were obtained by the above procedure. The viability (by Trypan blue exclusion dye) and purity of cells (by nonspecific esterase staining) were found to be more than 95%.

## NITRITE PRODUCTION

On the appropriate day of the culture (1, 3 and 7 day),  $1 \times 10^5$  cells/well were plated in a 96-well tissue-culture plate (Linbro, Flow Laboratories) and were stimulated with the optimal concentration of tuftsin ( $0.88 \mu\text{M}$ ) for an optimum time period (24 h) at  $37^\circ\text{C}$ . Another set of culture was kept unstimulated. During the assay period (24 h), cells were kept in HBSS medium containing arginine (2 mM) and glutamine (2 mM). After the incubation, supernatants were transferred to another microtitre plate and kept frozen at  $-20^\circ\text{C}$  for testing later for nitrite production by Griess reagent.<sup>10</sup> The results were expressed as  $\mu\text{M}$  nitrite/ $10^5$  cells/24 h.

## SUPEROXIDE DISMUTASE ACTIVITY

Total SOD, i.e. human macrophages derived (copper–zinc linked) plus mycobacterial derived (manganese linked) and alone Mn-linked SOD activity were measured. Mn-linked SOD activity was measured by inhibiting the Cu–Zn-linked SOD activity using 1 mM potassium cyanide (KCN). On the appropriate day of assay,  $5 \times 10^5$  cells/well were transferred to a 96-well flat-bottom plate. One set of cells were incubated for 30 min with 1 mM KCN and other set of cells were incubated in HBSS media alone. The cells were lysed by adding  $10 \mu\text{l}$  of 0.2% triton X-100. The cell lysates were centrifuged at  $4^\circ\text{C}$  for 20 min at  $1500 \times g$  to remove cellular debris. Supernatants were transferred into another plate and was stored at  $-20^\circ\text{C}$  till further use. Superoxide dismutase (SOD) activity was measured spectrophotometrically by its ability to inhibit the superoxide anion mediated reduction of ferric cytochrome c by the Xanthine-Xanthine Oxidase system.<sup>11</sup>

## STATISTICAL ANALYSIS

All the samples were run in triplicate. Results were expressed as mean  $\pm$  SD of samples. To determine the difference within a group (in unstimulated and stimulated) 'Student's *t* test' was used. To evaluate the intergroup differences in individuals (Normal, BT/TT and BL/LL) and the day of culture (1, 3 and 7 day) one way analysis of variance (ANOVA) was used. 'Multiple range test' was used to calculate pairwise significance between two subgroups.

## Results

A history of each patient for their clinical, histopathological and bacterial index are given in Table 1.

While standardizing the optimal experimental conditions for NO production a requirement of exogenous L-arginine (2 mM) in the HBSS medium was found to be essential. Glutamine (2 mM) was also added in the culture medium to maintain the cell viability for 24 h. Tuftsin at a concentration of  $0.88 \mu\text{M}$  and an incubation period of 24 h was found to be optimum for nitrite production.

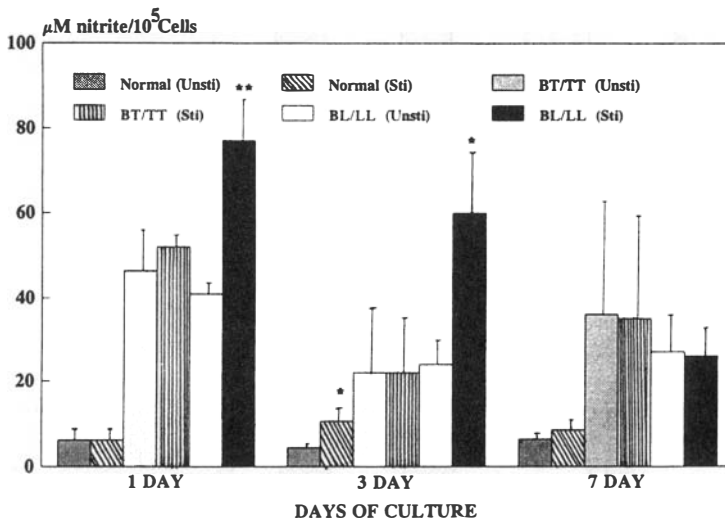
## NITRITE PRODUCTION IN NORMAL HEALTHY INDIVIDUALS AND LEPROSY PATIENTS

The basal levels (unstimulated) of nitrite production in 1-day-old cultures of both the groups of the leprosy patients were found to be significantly ( $p < 0.001$ ) higher than the normal

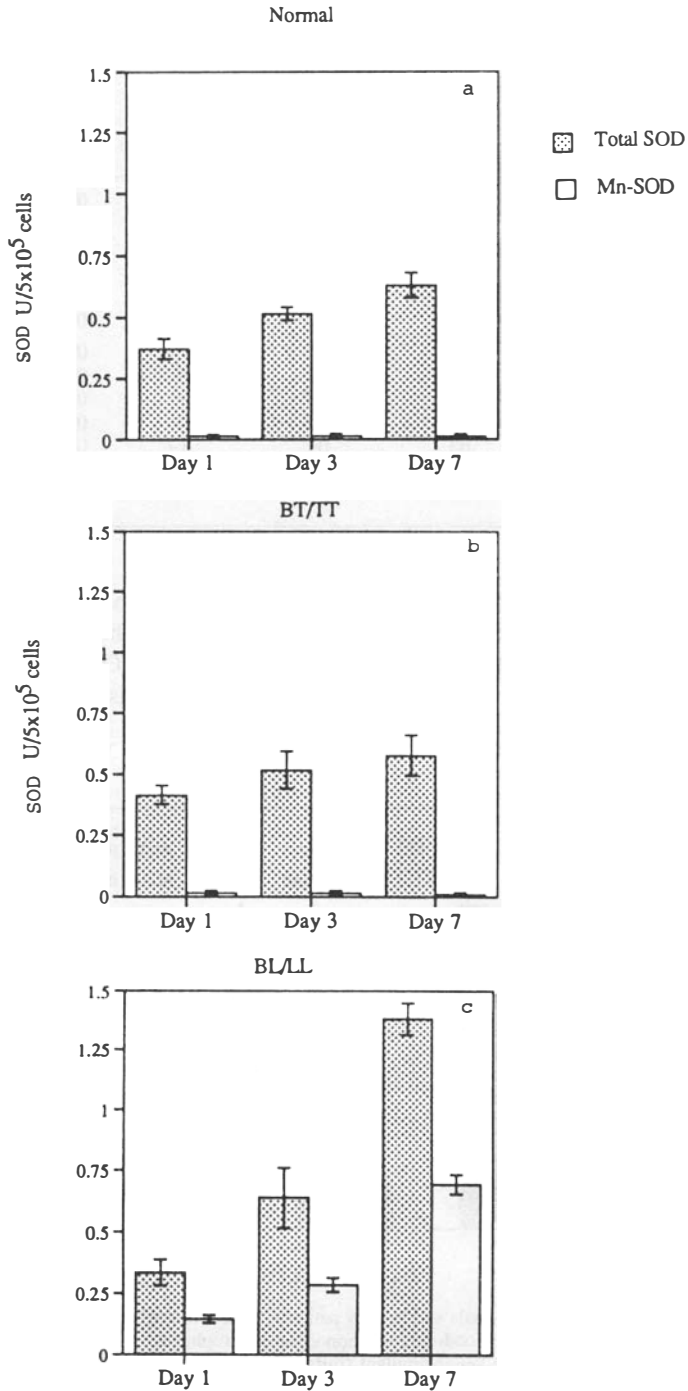
**Table 1.** Detailed history of each patient for clinical, histopathological and bacterial index

Group	S. No.	Patient Code No.	Clinical diagnosis	Histological diagnosis	Bacterial index	Mn-SOD activity (U/ $\times 10^5$ cells)		
						1 day	3 day	7 day
BL/LL	23	L23	BL	BL	4+	0.130	0.268	0.672
	24	L24	BL	-	4+	0.128	0.257	0.661
	25	L25	LL	LL	5+	0.164	0.319	0.770
	26	L26	LL	BL	5+	0.142	0.264	0.660
	27	L27	BL	BL	4+	0.143	0.276	0.677
	28	L28	LL	LL	6+	0.170	0.332	0.720
BT/TT	29	T29	BT	BT	1+	0.021	0.019	0.009
	30	T30	BT	TT	0	0.022	0.031	0.021
	31	T31	BT	BT	0	0.031	0.028	0.019
	32	T32	BT	BT	0	0.019	0.014	0.015
	33	T33	BT	BT	1+	0.017	0.011	0.011
	34	T34	BT	BT	1+	0.000	0.000	0.000
	35	T35	BT	BT	2+	0.007	0.012	0.011

individuals (Figure 1). Upon stimulation with  $0.88 \mu\text{M}$  tuftsin, normal and BT/TT monocytes were unable to undergo any stimulation for nitrite production; whereas BL/LL monocytes showed a significant ( $p < 0.001$ ) increase in nitrite production. On day 3 of culture, the normal macrophages had again significantly ( $p < 0.05$ ) low levels of nitrite production as



**Figure 1.** Nitrite levels in normal individuals and leprosy patients: Levels of nitrite during unstimulated (Unsti) and stimulated (Sti) state in the peripheral blood-derived monocytes/macrophages of normal healthy individuals and leprosy patients, during *in vitro* culture age. Stimulant (tuftsin =  $0.88 \mu\text{M}$ ) was incubated with monocytes/macrophages for 24 h in the presence of HBSS + Arg ( $2 \text{ mM}$ ) and Gln ( $2 \text{ mM}$ ) and then culture supernatant (in triplicate for each sample) were collected. Results are mean  $\pm$  SD of number of samples (normal, BT/TT  $n = 7$  and BL/LL  $n = 6$ ). Values of significance (\*,  $p < 0.01$ ; and \*\*,  $p < 0.001$ ) are of comparison between unstimulated and stimulated state.



**Figure 2.** Activity of superoxide dismutase in monocytes/macrophages of normal healthy individuals (2a) and leprosy patients (2b, 2c) during *in vitro* culture age. Mn-linked SOD was determined by inhibiting Cu–Zn SOD with 1 mM KCN. Each sample was run in triplicate and results expressed as mean  $\pm$  SD of number of samples (normal, BT/TT  $n = 7$  and BL/LL  $n = 6$ ).

compared to both the groups of leprosy patients. On day 3 upon stimulation with tuftsin, normal and BL/LL groups showed a significant ( $p < 0.01$ ) increase in the nitrite production, whereas BT/TT macrophages were unable to show any stimulation for nitrite production. The basal levels of nitrite production on day 7 in normal macrophages were also lower albeit insignificant as compared to BT/TT or BL/LL. Upon stimulation, macrophages from none of the groups showed any increase in the nitrite production on day 7 of culture. In general, while comparing the nitrite production with the *in vitro* culture age, normal and BT/TT monocytes/macrophages do not reveal any statistical changes. However, in the lepromatous leprosy group a gradual significant ( $p < 0.05$ ) decrease was observed.

#### SUPEROXIDE DISMUTASE ACTIVITY

The total SOD enzyme activity (Cu–Zn-linked and Mn-linked) on day 1 was almost comparable in all the three groups (Figure 2). The Mn-linked SOD enzyme activity was detectable in the BL/LL cultures only and it contributed about 44% of the total SOD enzyme activity. Although on day 3, the total SOD enzyme activity was found to be almost comparable in all the three groups but the activity was significantly higher as compared to day 1. Again in BL/LL macrophages about 44.5% of the SOD enzyme activity was Mn-linked. On day 7, the normal and BT/TT macrophage cultures had almost the same total SOD enzyme activity, but the BL/LL cultures had significantly ( $p < 0.01$ ) higher total SOD enzyme activity in which Mn-linked SOD activity was about 50%. A significant increase in the total SOD enzyme activity was observed in the normal ( $p < 0.001$ ), BT/TT ( $p < 0.05$ ) and BL/LL ( $p < 0.001$ ) macrophages as the cell matured. Mn-linked SOD activity was observed in BL/LL monocytes/macrophages only, increased significantly ( $p < 0.001$ ) with the age of the culture.

## Discussion

Under normal circumstances human macrophages do not possess detectable NOS but stimuli such as IFN- $\gamma$  and lipopolysaccharide (LPS) elicit nitric oxide synthesis over a few hours.<sup>12</sup> Since nitrite was measured after 24-h incubation and the existence of L-arginine within the macrophage is short lived an essential requirement for arginine in the HBSS medium was needed in the present study.<sup>13</sup>

At any day of the culture, the normal monocytes/macrophages showed the lowest levels of basal nitrite release as compared to both the groups of leprosy. No significant increase was seen in normal monocytes/macrophages even after stimulation with tuftsin. Thus it appears that apart from tuftsin some additional signal/factor is needed to activate nitric oxide synthase (NOS) gene for nitrite production. Macrophages infected with viable intracellular pathogen alone or in combination with IFN- $\gamma$  or whole killed bacterial particles in the presence of interferon beta (IFN- $\beta$ ) has been shown to produce nitrite.<sup>14,15</sup> Recently it has been reported that NO can also be produced during the infection of macrophages with Gram-positive bacteria.<sup>16</sup> Macrophages activated with bacterial stimuli, can secrete a variety of cytokines, including tumor necrosis factor-alpha (TNF- $\alpha$ ) and IFN- $\beta$ .<sup>17,18</sup> These cytokines function as autocrine or paracrine regulators of macrophage activation in terms of lethal toxic radicals generation.

In the present study both the groups of leprosy patients were able to produce nitrite during

the unstimulated state but only BL/LL monocytes/macrophages could be activated by tuftsin to produce significantly high levels of nitrite. In this connection the most interesting finding in the present study was the high activity of Mn-SOD which was found only in BL/LL monocytes/macrophages. Most of the Mn-SOD is known to be contributed by *M. leprae*.<sup>19,20</sup> We have made an attempt to correlate the bacterial index (BI) and the Mn-SOD activity of the same patient by calculating the correlation coefficient ( $r$ ). As Mn-SOD activity was detectable in BL/LL patients,  $r$  was restricted to these patients only. Mn-SOD activity in 1- and 3-day-old macrophages showed a strong positive correlation with bacterial index ( $r = 0.866, 0.802$  respectively) which was statistically significant ( $p < 0.05$ ). Mn-SOD activity in 7-day-old macrophages showed a weak positive correlation with BI ( $r = 0.544$ ) and is statistically insignificant. The increase in Mn-SOD in the lepromatous leprosy group with age of the culture of the monocytes/macrophages could be due to the multiplication/growth of *M. leprae* inside the monocytes, a similar observation consistent with other workers.<sup>21,22</sup> The paradoxical relationship between the multiplication period of *M. lepra* (11–13 days) and the increase in SOD activity during the *in vitro* culture age (1, 3 and 7 days) of monocyte/macrophages can be explained by the fact that *M. leprae* that are phagocytosed by circulating monocytes/macrophages are not in a synchronous state of multiplication. The present study suggests that a triggering signal provided by bacteria/bacterial particles is necessary for RNI production by the macrophages and we presume that in leprosy patients the monocytes are already primed *in vivo* by *M. leprae*. Tuftsin has been shown to induce NOS gene expression and produce NO in murine macrophages and has been found to replace the effects of LPS in IFN- $\gamma$  induced NOS expression.<sup>23</sup> It has been observed that upon activation with tuftsin, macrophages generally required longer incubation time to synthesize new proteins.<sup>24</sup> It is possible that the effect of tuftsin is to increase cytokine(s) (TNF- $\alpha$  and IL-1 $\beta$ ) secretion which in turn, acts synergistically with the signal provided by bacteria or bacterial products to induce NOS gene.

The highest levels of nitrite was observed in BL/LL monocytes/macrophages on day 1 and then tapered off with the age of culture, this may be due to the inhibition of NO synthase activity by NO itself. This feedback inhibition could account for the rapid decline of the NO synthase activity once high levels of NO are generated. This self-regulatory pathway may be an effective mechanism for avoiding excessive production of NO, which can result in a range of pathological effects including macrophage cytotoxicity. Macrophages which are not initially overstimulated can indeed be repeatedly reactivated to induce the expression of NO synthase gene.<sup>25</sup> Hence, it is likely that this self-regulatory mechanism will enable the macrophages to exert their cytotoxic effect on target cells without damaging themselves in the process and will allow their reactivation, if required.

Despite the fact that BL/LL monocytes/macrophages are able to produce high nitrite levels either during the stimulated or unstimulated state, the earlier findings of our laboratory reporting the failure of tuftsin to inhibit the multiplication of *M. leprae* by BL/LL monocytes/macrophages cannot be neglected.<sup>5</sup> An attempt has been made in the present study to investigate the mechanism of tuftsin action to correlate the interaction amongst the reactive free radicals and the microbicidal responses.

Normal and leprosy macrophages produce similar basal levels of  $O_2^-$  production but only leprosy macrophages produced  $NO_2^-$ . Superoxide dismutase activity (Mn-derived) was found only in BL/LL cultures. Superoxide anion is known to react with NO to form peroxynitrite anion, which decomposes rapidly on protonation to form  $OH^\cdot$  and  $NO_2^-$  and subsequently nitrate and SOD have been shown to increase the stability of this RNI by scavenging  $O_2^-$ .<sup>26</sup>



Therefore, in BL/LL patients it is possible that SOD, by virtue of its ability to scavenge  $O_2^-$ , stabilizes the basal level of NO release. However, upon nonavailability of  $O_2^-$ , nitric oxide is nontoxic by itself; whereas in BT/TT both the toxic ions are present and upon interaction they produce more toxic ions that are lethal to *M. leprae*. The Mn-SOD could function in the defence against macrophage in two ways:

at an early time before the activation of monocytes/macrophages with tuftsin, substantial amounts of nitric oxide is generated, but the Mn-SOD is likely to scavenge superoxide anion production; and

during stimulation of monocyte/macrophage with tuftsin, the nitric oxide flux increases, and the destruction of  $O_2^-$  by the enzyme Mn-SOD may block the formation of intracellular peroxynitrite anion by eliminating one of the reactants.

Thus, the final outcome is survival of *M. leprae* in BL/LL monocytes/macrophages by mitigating the effects of the mixture generated by macrophages rather than the toxicity of any individual component.

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## Functional sensibility of the hand in leprosy patients

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*Summary* The aims of this cross-sectional comparative study was to compare the results of Semmes–Weinstein monofilament testing (SWM) and moving 2-point discrimination (M2PD) with four tests of functional sensibility: recognition of objects, discrimination of size and texture and detection of dots.

Ninety-eight leprosy in- and outpatients at Green Pastures Hospital in Pokhara, Nepal were tested with each of the above tests and the results were compared to see how well they agreed. Using the tests of functional sensibility as reference points, we examined the validity of the SWM and M2PD as predictors of functional sensibility.

There was definite, but only moderate correlation between thresholds of monofilaments and M2PD and functional sensibility of the hand. A normal result with the SWM and/or M2PD had a good predictive value for normal functional sensibility. Sensitivity was reasonable against recognition of objects and discrimination of textures as reference tests (80–90% and 88–93%), but poor against discrimination of size and detection of dots (50–75% and 43–65%). Specificity was high for most combinations of SWM or M2PD with any of the tests of functional sensibility (85–99%). Above a monofilament threshold of 2 g, the predictive value of an abnormal test was 100% for dot detection and 83–92% for textural discrimination. This indicates that impairment of touch sensibility at this level correlates well with loss of dot detection and textural discrimination in patients with leprosy neuropathy. For M2PD the pattern was very similar. Above a threshold of 5 mm, 95–100% of affected hands had loss of dot detection and 73–80% had loss of textural discrimination.

Monofilament testing and M2PD did not seem suitable as proxy measures of functional sensibility of the hand in leprosy patients. However, a normal threshold with monofilaments and/or M2PD had a good predictive value for normal functional sensibility. Above a monofilament threshold of 2 g and/or a M2PD threshold of 5 mm, textural discrimination was abnormal in most hands.

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## Introduction

Impairment of neural function is considered the most serious complication of leprosy.<sup>1-6</sup> Impairment often leads to disability and handicap of the affected person.<sup>3,7,8</sup> These functional aspects of neural damage have received little attention.<sup>7</sup> Different modalities of function have been studied in leprosy patients. These include nerve conduction,<sup>9-12</sup> and autonomic vasoregulation,<sup>13,14</sup> as well as simple methods that are suitable for use in the field, like tests for voluntary muscle power and sensory tests using nylon filaments or a ballpoint pen.<sup>12,15-18</sup> It is claimed that thresholds for touch determined with SWM correlate well with functional sensibility of the hand and with what the patients are still able to do with their hands,<sup>19,20</sup> the latter being the result of treatment of most practical interest to patients. However, data supporting this claim were derived from patients who did not suffer from leprosy.<sup>21</sup>

Normal function of the hand depends on many factors including motor function, tactile sensibility, proprioception and cognition. In practice touch/pressure is often the only modality tested in cases of leprosy.<sup>22,23</sup> We were interested in investigating the extent to which functional sensibility was affected in leprosy patients and to examine the relationship between touch sensibility and functional ability. Therefore, we compared the results of testing with Semmes-Weinstein monofilaments (SWM) and moving two-point discrimination (M2PD) with four tests of functional sensibility adapted for use in Nepal, namely recognition of objects, discrimination of size and of texture and dot detection. The aims of the study were to: 1, examine the validity of using SWM and M2PD as measures of functional sensibility in leprosy patients; and 2, investigate whether SWM and M2PD can be used as screening tests for the presence or absence of impairment of functional sensibility.

## Methods, concepts and definitions

### SELECTION OF PATIENTS

No particular criteria of selection or randomization were used as the objective was to compare tests in the same patient. Those tested included patients admitted to Green Pastures Hospital (GPH) for treatment of leprotic reactions and/or neural impairment (NFI) between March and May 1993 and patients attending outpatient clinics during that period. All had an established diagnosis of leprosy. Impairment of touch sensibility ranged from those in whom no loss was found to those with complete anaesthesia of both hands. If there were severe deformities or missing digits in one hand, only the contralateral one was tested.

### DIAGNOSIS OF LEPROSY

The diagnosis was based on finding at least one of three cardinal clinical signs of the disease; anaesthetic skin lesions, enlarged peripheral nerve trunks or acid-fast bacilli in a split-skin smear.<sup>24</sup> Further details of diagnosis, classification and laboratory tests, including histology have been published.<sup>25</sup>

### DEFINITION OF FUNCTIONAL SENSIBILITY

Stereognosis (stereos = solid; gnosis = knowing) and functional sensibility have very similar meanings. Butterworth's *Medical Dictionary* defined stereognosis, as 'the ability to

recognize the shape and characteristics of an object by means of touch.<sup>26</sup> Collin's *Dictionary of Medicine* qualified characteristics as 'shape, size and texture of an object'.<sup>27</sup> However, the term is used differently in the literature of neurology and hand surgery. In the latter, stereognosis is used to denote the sensory function of the hand. In neurology the term denotes a central function that integrates a variety of sensory impulses into a particular pattern which allows someone to recognize an object.<sup>28,29</sup> Thus, in the neurological sense, it is possible to have intact peripheral sensibility and still suffer from astereognosis.<sup>29</sup> Because of possible confusion about the meaning of stereognosis, Moberg used the term tactile gnosis.<sup>30</sup> In this paper we use the term functional sensibility to denote the ability to recognize and discriminate by touch and we define the term as 'the ability to explore and discriminate between and/or identify objects, including their shape, size and texture by touch'. It is similar to 'active touch' as described by Gibson.<sup>31</sup> Existing tests of functional sensibility were adapted for use in our largely rural population and their validity was tested on healthy volunteers.<sup>32</sup>

#### RECOGNITION OF OBJECTS

A quantified form of this test was introduced by Moberg in 1958.<sup>28</sup> The blindfolded patient was asked to pick up ten objects, identify them and put them in a container. The process was timed and the result expressed in seconds. Dellon modified this test to timed identification, in order to limit the effect of coexisting motor impairment.<sup>33</sup> We introduced a further modification of omission of timing because we considered the ability to recognize objects more important than the speed with which this was achieved. The ten objects selected were similar in texture and in common use in Nepal. These were, a safety pin, small padlock, hair pin, nail, button, marble, coin, ring, bottle top and key. The test was explained, then patients were asked to identify the objects by sight to ensure that they were all familiar. Then with eyes closed, they were given each object once in a random order. The score was the number of items correctly identified.

#### DISCRIMINATION OF SIZE

Two sets of wooden cubes with sides measuring 1 inch, 1½ inches, 2 inches and 2½ inches were shown to the patients. After an explanation of the test they were asked to close their eyes and were presented with each of the cubes in random order and required to match them with the corresponding ones in a duplicate set. To prevent identification by differences in weight, they were not permitted to pick them up. The score was the number correctly matched.

#### DOT DETECTION

Originally we intended to devise a test for graphaesthesia which Butterworth's *Medical Dictionary* defines as 'the ability to recognize letters or figures traced on the skin by blunt pressure'.<sup>26</sup> This is the sensory modality used in reading braille. Because many of our Nepali patients are unfamiliar with letters or geometrical shapes, the traditional test was considered inappropriate. Detection of a small dot on a smooth surface was described by Johansson and LaMotte<sup>34</sup> and LaMotte and Whitehouse considered it 'a means of clinically testing impaired tactile sensitivity in the glabrous skin of the hand'.<sup>35</sup> Since there is no element of recognition such a test is not equivalent to graphaesthesia.

Our test object consisted of a Braille-like dot approximately 0.5 mm high and 0.5 mm wide punched in one corner of a 2 × 2 cm smooth aluminium square which was glued on to a small wooden cube for ease of handling. The examiner held the block between two fingers during the test. With eyes closed, the patient was asked to identify the corner in which the dot was located, using either the index or little finger. The score for each finger was the number of correct responses out of five trials.

#### DISCRIMINATION OF TEXTURE

This is defined as 'the ability to discriminate between surfaces of different texture by touch'. Using their finger tips humans can accurately discriminate small differences in spacing between rows and columns of small dots on a smooth surface.<sup>36</sup> Greenspan & LaMotte suggested that standardized textures in the form of grating patterns could be used clinically to detect impaired sensibility.<sup>37</sup>

We used five familiar materials. Smooth vinyl, 2 grades of sandpaper and 2 different textiles were glued on square wooden blocks measuring 10 × 10 cm. These surfaces differed little in hardness. After the test was explained, the patient closed his eyes and felt one surface with the pad of the index or little finger and then attempted to match this with one in a duplicate set. The five different textures were presented in random order to each of the two fingers. The score was the number of correct matches out of five.

#### SEMMES-WEINSTEIN MONOFILAMENT TEST (SWM)

Touch/pressure sensibility was tested with a standard set of five SWMs as described by Bell-Krotoski.<sup>38</sup> The log numbers of these filaments were 2.83, 3.61, 4.31, 4.56 and 6.65. When applied with a force sufficient to bend the filament, these were respectively equal to application forces of 70 mg, 200 mg, 2 g, 4 g and about 280 g.<sup>39</sup> A score of 5 was given when the thinnest filament was felt and zero if the thickest one was not appreciated. The following sites were tested for the Median nerve: the volar surfaces of the terminal phalanges of the index finger and thumb and skin over the second metacarpophalangeal joint; for the *Ulnar nerve*: the volar surface of the terminal phalanx of the little finger, skin over the fifth metacarpophalangeal joint and proximal part of the hypothenar eminence.

#### MOVING TWO-POINT DISCRIMINATION (M2PD)

Moving touch sensibility for median and ulnar nerves was assessed with M2PD as recommended by Dellon.<sup>40</sup> The test can be done with a paper clip, but we used a Disk-Criminator\*, a plastic disc on which metal prongs are mounted with different interprong distances. Details of the testing technique have been published.<sup>18</sup> Only the index and little fingers were tested at the same sites used for the SWMS.

#### DIAGNOSIS OF NEURAL IMPAIRMENT

A score below that found in the study of normal volunteers<sup>33</sup> was taken as evidence of neural impairment.

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ASSESSMENT OF NEURAL FUNCTION

SWM and M2PD tests were performed by trained physiotherapy technicians. The other tests were carried out by one or other of the authors, (MK, MvL. or IBK).

THE PURPOSES OF THE STUDY

To determine:

- the specificity, sensitivity and predictive value of the results of testing with SWMs and M2PD;
- the correlation between SMM/M2PD and functional sensibility; and
- thresholds of SWM and M2PD tests beyond which functional sensibility is lost.

STATISTICAL METHODS

The differences between proportions was tested using the Standard Normal Deviation (SND) and McNemar's paired Chi-square test for paired sample proportions.<sup>41</sup> The validity of the SWM and M2PD was examined using tests of functional sensibility as reference points. It is realized that these tests are not gold standards, but we consider them to be representative of functional sensibility. For these calculations the data were recoded as binary variables, using the normal level as cut-off for positive/negative. Because the data were often not normally distributed and because most were graded on ordinal, noninterval scales, the strength of association between two measures was examined by a non-parametric method, the Spearman rank correlation coefficient. A *p*-value of less than 5% was used as the level of statistical significance. The 95% confidence interval is given for proportional and correlation coefficients. Analysis was done using Epi Info Software 5.01<sup>42</sup> and SPSS for Windows 6.

**Patients**

Ninety-eight patients were examined of whom 93 (95%) were manual workers and 74 (79%) male. Ages ranged from 15 to 63 years (mean 40 years). The distribution of types of leprosy was as follows:

Tuberculoid	2
Borderline tuberculoid	29
Borderline	6
Borderline lepromatous	32
Lepromatous	20
Pure neuritic	4
Not classified	5

**Controls**

The results of pilot studies on these tests using volunteers from a similar rural population who had no history or evidence of leprosy or any other neurological defects have been published<sup>32,44</sup> and are used as controls for the present investigation.

**Table 1.** Proportion of hands ( $n = 196$ ) with impairment of sensibility as measured with different tests at different sites

Test/Site	Median nerve		Site	Ulnar nerve	
	FI* (%)	95% CI†		FI* (%)	95% CI†
SWM‡					
thumb	3.1	(0.7–5.5)	little finger	29	(23–35)
mcp2§	11	(5.8–14)	mcp5¶	22	(16–28)
index finger	7.7	(4–1)	hypothenar	17	(12–22)
median combined**	12	(7–17)	ulnar combined**	31	(25–37)
M2PD††					
index finger	7.7	(4–11)	little finger	30	(24–36)
Object recognition	5.1	(2–8.2)			
Size discrimination	2.1	(0.09–4.1)			
Dot detection					
index finger	19	(14–24)	little finger	45	(38–52)
Texture discrimination					
index finger	4.1	(1.3–6.9)	little finger	22	(16–28)

\* function impairment, †95% confidence interval, ‡ Semmes-Weinstein monofilament test, § 2nd metacarpophalangeal joint, ¶ 5th metacarpophalangeal joint, \*\* combined score for the 3 sites, which was called abnormal (= impairment) if any of the 3 sites was anaesthetic for the 200 mg filament, † moving 2-point discrimination

**Results**

SCORES AND THRESHOLDS FOUND IN CONTROL SUBJECTS

The number of correctly identified objects	9/10 <sup>32</sup>
Correct discrimination of sizes	4/4 <sup>32</sup>
Dot detection: index finger	4/5 <sup>32</sup>
little finger	3/5 <sup>32</sup>
Discrimination of textures: index finger	4/5 <sup>32</sup>
little finger	3/5 <sup>32</sup>
Threshold for SWM (all areas tested)	200 mg <sup>44</sup>
Threshold for M2PD; index finger	4 mm <sup>44</sup>
little finger	4 mm <sup>44</sup>

FINDINGS IN PATIENTS

Analysis revealed no significant differences between right and left hands for any of the tests. We assumed that presence or absence of an association between functional and touch sensibility would be independent for the right or left hand of each patient, therefore the results are reported on the pooled sample of 196 hands.

The prevalence of neural functional impairment (NFI) by test and site is set out in Table 1. For all tests the ulnar nerve was more frequently affected than the median. There were considerable differences in results of testing with monofilaments. The thumb was affected in 3.1% of hands and the index finger in 7.7% (a difference of 4.6%  $p = 0.007$ , McNemar’s Test). For the ulnar nerve the hypothenar area was affected in 17% of instances as compared with 29% for the little finger (a difference of 12%,  $p < 0.0001$ ).



**Table 2.** Relative validity of SWM testing and M2PD compared with 4 tests of functional sensibility for the median nerve (*n* = 196)

Screening test	Reference test	cut-off level	Predictive value (%)		sensitivity (%)	specificity (%)
			abnormal (positive)	normal (negative)		
	Object recognition					
SWM* thumb		200 mg	5/6§	97	5/10§	99
SWM index finger		200 mg	6/15	98	6/10	95
SWM median†		200 mg	8/24	99	8/10	91
M2PD‡ index finger		4 mm	5/15	97	5/10	94
	Size discrimination					
SWM thumb		200 mg	2/5	99	2/4	98
SWM index finger		200 mg	2/14	99	2/4	94
SWM median		200 mg	2/22	99	2/4	89
M2PD index finger		4 mm	1/15	98	1/4	92
	Dot detection					
SWM index finger		200 mg	11/15	86	11/37	97
SWM median		200 mg	16/24	88	16/37	95
M2PD index finger		4 mm	11/15	86	11/37	96
	Texture discrimination					
SWM index finger		200 mg	6/14	99	6/8	96
SWM median		200 mg	6/13	99	6/8	91
M2PD index finger		4 mm	7/15	99	7/8	95

\* Semmes-Weinstein monofilament test, † 3 sites combined (thumb, 2nd metacarpophalangeal joint and index finger), ‡ moving 2-point discrimination test, § When the denominator is small (<40), the fraction is given instead of the percentage.

**THRESHOLDS FOR PREDICTING FUNCTIONAL STATUS**

With one possible exception, in our sample there was no clinically useful threshold for predicting abnormal discrimination of size and recognition of objects. The exception was the SWM score for the thumb. In six hands with a threshold of more than 200 mg, only one of these had normal ability to recognize objects. Above monofilament thresholds of 2 g (or more) dot detection was abnormal in 6/6 index fingers and 38/38 little fingers and textural discrimination was abnormal in 5/6 index fingers and 34/37 little fingers.

With M2PD thresholds above 5-mm dot detection was abnormal in 10/10 index fingers and 38/48 little fingers and textural discrimination was abnormal in 8/10 index fingers and 35/48 little fingers.

**FUNCTIONAL SENSIBILITY AND THE MEDIAN NERVE**

The agreement between the monofilament thresholds at different sites, M2PD and the tests of functional sensibility is shown in Table 2. The combined score (3 sites) for SWM gave the highest sensitivity for recognition of objects (80%), with a specificity of 91%. Spearman's correlation coefficient for this combination was 0.44 (0.24–0.64). For the index finger the coefficient for the SWM score and dot detection was 0.5 (0.34–0.66) and for M2PD and textural discrimination it was 0.25 (0.10–0.4).

**FUNCTIONAL SENSIBILITY AND THE ULNAR NERVE**

Table 3 shows the agreement between tests for the ulnar nerve. The SWM result for the little

**Table 3.** Relative validity of SWM testing and M2PD compared with 4 tests of functional sensibility for the ulnar nerve ( $n = 196$ )

Screening test	Reference test	cut-off level	Predictive value (%)		sensitivity (%)	specificity (%)
			abnormal (positive)	normal (negative)		
	Object recognition					
SWM* little finger		200 mg	16	99	9/10§	75
SWM ulnar†		200 mg	15	99	9/10	73
M2PD‡ little finger		4 mm	11	97	7/10	72
	Size discrimination					
SWM little finger		200 mg	3.6	99	2/4	72
SWM ulnar		200 mg	3.4	99	2/4	70
M2PD little finger		4 mm	5.1	99	3/4	70
	Dot detection					
SWM little finger		200 mg	96	75	60	98
SWM ulnar		200 mg	97	77	65	98
M2PD little finger		4 mm	84	75	60	92
	Texture discrimination					
SWM little finger		200 mg	70	96	88	89
SWM ulnar		200 mg	69	98	93	88
M2PD little finger		4 mm	60	96	88	85

\* Semmes-Weinstein monofilament test, † 3 sites combined (little finger, 5th metacarpophalangeal joint and hypothenar), ‡ moving 2-point discrimination test, § When the denominator is small (<40), the fraction is given instead of the percentage.

finger agreed well with score for recognition of objects, Spearman's correlation coefficient was 0.35 (0.21–0.49). The correlation coefficients for the combination of the combined SWM score and dot detection and for the little finger and dot detection were both high, being 0.77 (0.7–0.84) and 0.73 (0.66–0.8) respectively. There was good agreement between the ulnar SWM and M2PD scores and textural discrimination. The correlation coefficient for the combination of the SWM score and textural discrimination was 0.69 (0.59–0.79).

## Discussion

Some investigators claim a close correlation between hand function and testing with monofilaments<sup>21,43</sup> whilst this is denied by others.<sup>33,45</sup> According to Moberg and Dellon the tests which correlate best with functional sensibility are static and moving 2PD.<sup>28,33,46</sup> Previously we found a good correlation between the results of SWM and M2PD in sensory assessment of leprosy patients.<sup>18</sup> Although the present study shows no strong correlation between scores for touch sensibility and the result of tests for functional sensibility, there is evidence that critical cutoff thresholds for SWM and M2PD tests can be used as predictors of functional sensibility.

### RECOGNITION OF OBJECTS

This test represents function of the hand more comprehensively than the other ones because it combines graphaesthesia, discrimination of size and texture and motor activity which also

involves receptors in muscles, tendons and joints. Therefore it could be seen as a stand alone test for functional sensibility of the hand. Citon and Taylor considered a timed functional recognition test to be a 'reliable and reproducible test of sensory function' in patients with peripheral nerve injuries.<sup>47</sup> In our study only 10/196 hands had impairment of this complex function, which was not affected earlier than the more simple discrimination of textures and detection of touch. Previously we found that impairment of proprioception was uncommon in leprosy patients.<sup>18</sup>

Surprisingly, sensitivity values for this test were higher for the ulnar than the median nerve, although manipulation was mainly done between the thumb and index finger. However, this finding may not be reliable owing to the small number of hands with abnormal scores. The predictive value of normal thresholds for SWM and M2PD tests was high, indicating that such patients would be likely to have unimpaired ability to recognize objects.

Dellon and Kallman used a timed-object recognition test to measure functional sensibility in 18 patients with lesions due to injury or compression of nerves.<sup>46</sup> M2PD correlated better with the number of objects identified than pressure measured with SWM (Pearson's  $r = 0.87$  vs  $0.45$ ). Novak *et al.* evaluated a test similar to ours (but with 8 objects).<sup>45</sup> Reliability between 2 testers was very high (intraclass correlation coefficient [ICC]= 0.99). Correlation between results of this test and M2PD was close, with a Spearman Correlation coefficient of 0.76. Correlation with monofilament threshold was lower (correlation coefficient 0.69). In the present study correlation was better between functional sensibility and SWM results than between the former and M2PD. Thus it seems that the relationship between impairment of touch sensibility and recognition of objects varies with the nature of the lesion in the nerve. It must be stressed that in leprosy lesions are not necessarily homogeneous throughout the nerves.

#### DOT DETECTION

Johansson & LaMotte showed that humans with intact cutaneous sensibility can detect raised elements of only about  $3 \mu$  high and  $230 \mu$  in diameter on a smooth surface.<sup>34</sup> Movement of the finger tip was essential for detection. Rapidly adapting mechanoreceptors were found to have the lowest thresholds for detection,<sup>35</sup> but when larger dots were used, other mechanoreceptive afferents were also stimulated.<sup>35</sup> In our test a very much larger dot was used. The results were abnormal in most patients with an abnormal SWM or M2PD threshold, but the range of results in those with normal touch thresholds was wide. This might mean that it was a more sensitive test for sensory impairment, but such a conclusion needs confirmation by a battery of tests including one with a controlled stimulus, like vibrometry.

Recently Novak *et al.* reported a 'new measure of fine sensory function, the braille pattern identification test.'<sup>48</sup> Instead of a single dot, as in our test, they used several patterns in matrices of  $3 \times 3$ . This test involves recognition and is a test of graphaesthesia. They found good correlation between it and static and moving 2-point discrimination with an interclass correlation coefficient [ICC] of around 0.75. Correlation with vibration and SWM was slightly less good (ICC around 0.65). Porter found a good correlation between his test of recognition of letters, 2-point discrimination and Moberg's pick-up test.<sup>49</sup> Moving 2-point discrimination seems to correlate well with tests involving an element of recognition such as recognition of objects and classical tests of graphaesthesia. As we removed the element of recognition from our tests, this may explain the lack of correlation we found between M2PD and dot detection.

## DISCRIMINATION OF TEXTURE

The ability to detect differences in roughness is mediated by SAI and RAI cutaneous mechanoreceptors.<sup>36,50</sup> Given normal cognition and intact proximal neural pathways, textural discrimination is a test of the integrity of the thick myelinated afferents. It is therefore not surprising that the results of this test correlated well with SWM thresholds and M2PD. Sensitivity and specificity of the two latter were high. Finding normal touch sensibility was predictive of unimpaired textural discrimination. The results of textural discrimination correlated more closely SWM thresholds than with M2PD (Spearman's correlation coefficient 0.70 vs 0.59).

Novak *et al.*<sup>45</sup> evaluated reliability of textural identification in 30 patients who were asked to order five cards ranging in texture from smooth to rough. Time and order of response were considered. The interclass correlation coefficient between two testers was good (ICC 0.77). They also examined the correlation between textural identification, monofilament testing and M2PD. The Spearman correlation coefficient for textural identification vs monofilament testing was  $-0.31$  or  $-0.44$ , depending on the examiner. For textural identification vs M2PD the coefficients were  $-0.33$  and  $-0.53$ .

## THRESHOLDS FOR PREDICTING ABNORMAL FUNCTIONAL SENSIBILITY

No clinically significant thresholds could be identified as predicting impairment of recognition of objects and discrimination of sizes. This was partly due to the high number of patients scoring normally in these tests. For dot detection and textural discrimination the pattern was consistent. An SWM threshold above 2 g was 100% predictive of an abnormal test for dot detection and 83–93% for discrimination of textures. This monofilament threshold is said to correspond with protective sensibility in the hand.<sup>21</sup> Possibly loss of protective sensation in the hand is associated with defective dot detection and textural discrimination in leprous neuropathy. In most affected hands with a threshold above 5 mm for M2PD, dot detection and textural discrimination were impaired. For this threshold the predictive value of an abnormal test was 73–80%. However, the predictive value of a test is dependent on the prevalence of the condition that is measured.<sup>51</sup> Where the prevalence of neural impairment is lower than in the present study, proportionally more patients will test false positive and therefore the predictive value of a positive (abnormal) test will be lower.

Our results based on testing isolated areas, suggest that in leprous neuropathy, there is only a moderate correlation between monofilament or M2PD test results and functional sensibility. There may be three explanations of our findings.

First, touch/pressure sensibility and M2PD may not be suitable alternative tests for functional sensibility. Actively exploring fingers stimulate all available receptors including mechanoreceptors in muscles and joints which generate impulses providing additional information about the object being touched. Unless all afferent fibres are affected homogeneously, which is not the case in leprosy,<sup>52</sup> a close correlation between thresholds for touch and functional sensibility cannot be expected.

Second, the four tests employed may not be valid and reliable enough as measures of functional sensibility. No reference tests for functional sensibility were available against which ours could be validated. Tests assessing manual function that are in common use in rehabilitation and occupational therapy assessments in developed countries include the Jebsen hand function test, the Williams board test and Moberg's precision sensory tests grips.<sup>53–55</sup> In their present form none of these tests is suitable for use as a reference test in Nepal.

Third, the range of impairment in our sample could be considered inadequate. With a prevalence of median and ulnar sensory impairment of 12% and 31% (SMW) most patients were expected to have normal functional sensibility. Only 1.5% of median nerve and 3.6% of ulnar nerves in our sample of patients had complete loss of touch sensibility. Therefore it could be argued that the number of cases with severe nerve damage was insufficient to fully examine the relationship between SWM, M2PD and tests of functional sensibility. Outside referral centres one usually deals with populations that have a lower prevalence of neuropathy than ours. Therefore our findings may represent the operational relationship between tests.

In our experience, the consequences of impairment of sensibility are inadequately appreciated by many leprosy workers. Our understanding of the sensory neuropathy in leprosy and its epidemiology and treatment is still only partial. Much further work is needed on functional assessment of hands and feet, and prevention and treatment of neuropathy. However limited our knowledge or resources may be, much harm can be prevented if physicians and health workers dealing with leprosy patients made regular use of available methods of assessing neural function and treated neuropathies and their consequences promptly.

## Conclusions

Semmes-Weinstein monofilament testing and moving 2-point discrimination seem to be unsuitable substitutes for testing functional sensibility of hands in leprosy patients.

A normal threshold for SWM and/or M2PD has a good predictive value for normal functional sensibility.

With a monofilament threshold above 2 g and/or a M2PD threshold of 5 mm most hands had abnormal textural discrimination. These results support the validity of the SWM and M2PD as screening tests for impairment of tactile sensibility in leprosy patients.

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## Temporalis muscle transfer in the correction of lagophthalmos due to leprosy

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*Summary* In the correction of lagophthalmos due to leprosy neuritis temporalis muscle transfer (TMT) is used to provide a motor to assist in lid closure. This study of TMT in 51 eyes was carried out to assess the effectiveness of TMT in achieving lid closure and corneal protection. The average lid gap preoperatively on light closure was 7.3 mm which was reduced to 3.2 mm on final follow-up. The average lid gap pre-operatively on tight closure was 5.3 mm which was reduced to 0.4 mm at final follow-up. It is possible to train patients with partial or total anaesthesia of the cornea in a visual THINK-BLINK reflex. The common complications encountered were ectropion in 6 eyes (12%) and ptosis in 3 eyes (6%).

### Introduction

Lagophthalmos due to paralysis of the orbicularis oculi muscle is found in approximately 5% of newly diagnosed leprosy patients.<sup>5,7</sup> This is a result of leprosy neuritis affecting the zygomatic and temporal branches of the facial nerve. Lagophthalmos can lead to exposure keratitis, corneal ulceration, and blindness, especially when there is coexisting corneal anaesthesia.

The main goals of the temporalis muscle transfer (TMT) are to enable the patient to attain closure of the eye, and to prevent loss of vision. This study assesses the degree to which the TMT achieves these goals.

### Methods

Fifty-one TMT operations in 35 patients (27 male and 8 female) were followed up. The operations were performed between 1963 and 1995 (29 since 1992). Sixteen patients had bilateral TMT's, 3 operations were redone due to failure.

Data was collected prospectively on patients operated after 1 January 1994. This consisted of pre-operative, discharge, and follow-up measurements of lid gaps (in mm) on light closure (as in sleep) and tight closure (full voluntary musculature), frequency of blinking (blinks/min during spontaneous conversation), voluntary muscle strength of



orbicularis oculi (graded 0–5), corneal sensation tested with a cottonwool wisp, and visual acuity. Follow-up data for patients operated prior to 1994 was obtained when they presented for review for eye or other problems. Preoperative data for these patients was obtained where available from the physiotherapy assessments.

## Technique

The Johnson<sup>2</sup> procedure was used in 47 eyes and the Gillies<sup>1</sup> method was used in 4 eyes. They were all analysed as one group. Although the major points of technique have been described elsewhere,<sup>1,2</sup> a few salient points need to be made. Usually fascia lata is used as a tendon graft. However if the patient also has a footdrop then a tibialis posterior transfer is also performed at the same session and the plantaris harvested and used as a tendon graft instead.

It is essential that the slips to the lids are tunnelled from about 3 mm above the lateral canthal margin and are tunnelled from the lateral canthus in the lid margin to avoid postoperative ectropion.<sup>4</sup> A 6/0 nylon suture is inserted at the middle of the lid to serve as a sling and hold the slip at the lid margin (see Figure 1). This suture is left about 10 cm long so that at the end of the operation the suture can be taped to the forehead in order to allow the lower eyelid to rest with the lid margin covering the lower third of the cornea.

At the medial canthus the lower slip should be tunnelled around the canthal ligament from above to below (see Figure 2) and attached at maximum tension in order to lift the lower lid as high as possible. The upper slip on the other hand is sutured at low tension so that the upper eyelid at rest sits at the superior edge of the cornea.

The eye is bandaged to prevent excessive swelling for 3 days postoperatively. The sutures at the medial canthus and on the eyelids are removed on day 7 postoperatively and the scalp sutures on day 10. The patient is given a semi-solid diet for 3 weeks and then postoperative physiotherapy and patient education is begun. It is helpful to strengthen the transfer by the use of chewing gum initially and later microcellular rubber. The most important part of postoperative physiotherapy is the development of a THINK-BLINK<sup>8</sup> reflex. This is done by getting the patient to blink regularly whenever a certain visual stimulus is received. In our hospital we also teach the patient to blink whenever they greet another person.

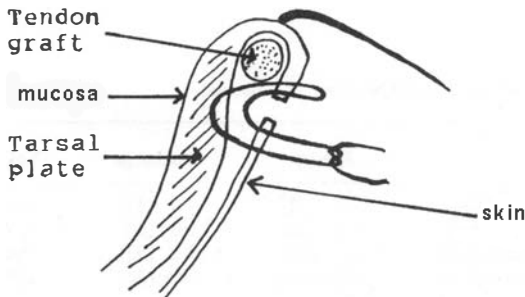


Figure 1. Section through the lid showing a lid suture to prevent ectropion

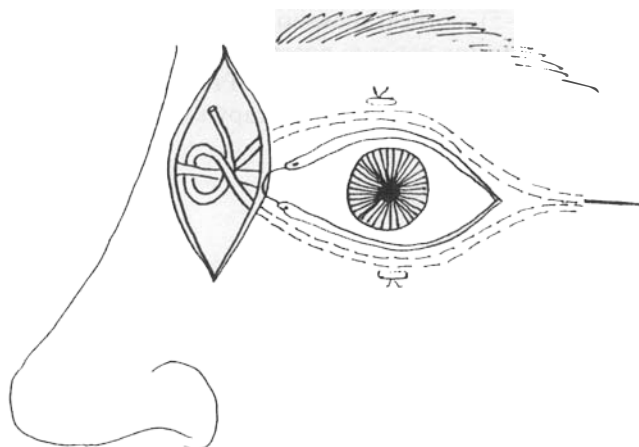


Figure 2. Detail of medial canthus showing attachments of slings.

## RESULTS

The average age was 46.3 years (range 18–78 years). Twenty-eight operations were on the left eye (55%), and 23 were on the right (45%). The average duration of lagophthalmos prior to operation was 8.0 years. The average duration between operation and follow-up was 7 years 3 months (range 101 days–22 years 7 months). The average duration between operation and discharge was 60 days.

There was no significant difference between preoperative and follow-up measurements of orbicularis oculi muscle strength and corneal sensation.

The average reduction in lid gap on light closure at discharge in 27 patients in whom preoperative and discharge data was available was 4.3 mm (range 1–8 mm). The average reduction in lid gap on tight closure at discharge in 20 patients in whom preoperative and discharge data was available was 4.5 mm (range 1–10 mm).

At discharge 16 out of 27 patients had no lid gap on tight closure with another 5 patients having a lid gap of 1 mm and 6 patients having a lid gap of 3 mm or more. At final follow-up 23 out of 30 patients had no lid gap on tight closure with another 4 patients having a lid gap of 1 mm and only 1 patient having a lid gap of 3 mm.

As data on visual acuity has only been collected prospectively since 1993 it is difficult to reach any meaningful conclusions on whether TMT protects against visual loss. When

Table 1. Average values (Number of patients)

	Pre-op	Discharge	Follow-up
Lid gap (light) mm	7.3 (33)	3.0 (33)	3.2 (31)
Lid gap (tight) mm	5.3 (24)	1.0 (33)	0.4 (30)
Blink frequency/min	6.7 (21)	9.2 (27)	7.0 (27)
Corneal anaesthesia	31% (36)	39% (26)	30% (30)

comparing the groups as a whole there was no significant difference in vision when comparing preoperative, discharge and follow-up patients.

## **Complications**

In 3 of the 51 eyes, the upper lid slip was too tight causing the inability to adequately open the eye. When it occurs it is usually seen about 3 months postoperatively. This is treated by dividing or Z-lengthening the upper lid slip.

In 6 eyes ectropion was noted at follow-up—in 4 of these (4/17) the operation was performed before 1990. Since 1991 the technique of creating a suture sling to ensure that the slip remained in the lid margin has been used and the complication has only been seen in 2 out of 33 eyes. In this one patient with bilateral transfers the lower slip was not tunnelled from above the lateral canthus but from below the lateral edge leading to lateral ectropion only. When postoperative ectropion is a problem it is necessary to dissect the slip free from the middle of the lid where it has migrated and attach it in the lid margin with 3 or 4 holding sutures as in Figure 1.

## **Discussion**

Lagophthalmos is a major predisposing factor to loss of vision in people affected by leprosy. When coupled with corneal anaesthesia it has a very poor prognosis.

Correction of lagophthalmos by tarsorrhaphy and/or wedge excision of part of the lid is unsatisfactory. It is cosmetically unacceptable to many patients and often leads to increased irritation of the cornea by the scar on the lid margin. It also fails to provide closure of the eye.

Many workers are fooled into believing a Bell's phenomenon is protective to the eye. The Bell's phenomenon is a voluntary reflex and is lost during sleep thereby causing the cornea to roll forward and be exposed during sleep.

Temporalis muscle transfer provides a good cosmetic result and in the person with corneal sensation provides the effector limb of the reflex arc.

Even in those patients with corneal anaesthesia a THINK-BLINK reflex can be developed with a visual stimulus being the trigger for a voluntary motor action.

Temporalis muscle transfer also serves to reduce the irritation caused to a dry cornea by lagophthalmos. In patients with normal sensation the average blink frequency preoperatively was 20 per minute possibly reflecting corneal irritation. At discharge the blink frequency was 10 per minute. At final follow-up it was 14 per minute.

Training of the patient postoperatively, especially in THINK-BLINK is probably the major determinant of success. In patients with partial or complete corneal anaesthesia blink frequency was much lower preoperatively when compared with patients with normal corneal sensation. However with training in the THINK-BLINK reflex it was possible to improve the spontaneous rate of blinking in these patients (Table 2). This improvement was however lost at final follow-up and suggests the need for ongoing reminders to patients in order to maintain the THINK-BLINK reflex.

In patients with severe lagophthalmos (a lid gap on tight closure of more than 5 mm) the TMT reduces the lid gap while maintaining lid mobility so that on light closure as in

**Table 2.** Average blink frequency per minute (Number of patients)

	Pre-op	Discharge	Follow-up
Corneal sensation			
anaesthetic	2.6 (7)	8.1 (10)	2.9 (9)
partial anaes.	5.6 (11)	9.6 (14)	6.2 (12)
normal sens.	20.1 (3)	10.0 (20)	14.7 (6)

sleep the eye is protected. Some surgeons use TMT only for those patients with sensitive corneas and use tarsorrhaphy for those with anaesthetic corneas. However for the patients with severe lagophthalmos tarsorrhaphy fails to protect the cornea. Even if the patient does a strong blink using the TMT 3 times a minute (average blink frequency at follow-up) then the whole cornea is moistened, whereas with a tarsorrhaphy the inferior aspect of the cornea remains exposed leading to keratitis. It is very difficult to achieve lid closure and protection of the eye using only medial and/or lateral tarsorrhaphy in patients with a lid gap on tight closure exceeding 5 mm. There is a need for long-term follow-up of vision in patients with severe lagophthalmos who have had either TMT or tarsorrhaphy. However in our experience in patients with severe lagophthalmos TMT is the operation of choice.

There is a paucity of long-term follow-up of TMT in the literature. Ranney<sup>3</sup> in 1973 published a series of 54 TMTs performed on 42 patients. In that series 57% of eyes achieved full closure. Weber *et al.*<sup>6</sup> reported 64% of eyes with full closure after TMT. In our series 60% of eyes at discharge and 77% of eyes at final follow-up achieved full closure.

## Conclusion

TMT is useful in the correction of lagophthalmos due to leprosy especially in those patients with a lid gap on tight closure of greater than 5 mm. It should not only be limited to patients with sensitive corneas as it provides some degree of protection even to those with insensitive corneas. In all patients there was a reduction in lid gap on light and tight closure with complete closure in 76% of eyes operated on.

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## The extent of leprosy-related disabilities in Istanbul Leprosy Hospital, Turkey

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**Summary** This study was carried out between January and December 1992 at the Istanbul Leprosy Hospital. Seven hundred and eleven leprosy patients were evaluated according to their age, gender and type of disease and disability according to the WHO disability grading system (1980). There were 527 males (74·2%) and 184 females (25·8%) in the group. The average age was  $50·0 \pm 13·5$  years and the average duration of disease was  $25·9 \pm 13·2$  years. Six hundred and seventy-eight patients (95·4%) were in borderline (BL) and lepromatous (LL) leprosy.

The extent of disabilities was very high in 711 leprosy patients. It was found that 539 of the patients (75·8%) had eye disabilities, 511 of them (71·8%) had hand disabilities, 521 of them (73·3%) had foot disabilities.

The most frequent eye, hand and foot disabilities were a decrease of vision (52·7), acute or chronic iridocyclitis (48·8%), slightly-marked corneal sensory loss (43·2%), mobile claw hand (33·3%), palmar insensitivity (16·3%), plantar ulcer (37·2%) and plantar insensitivity (19·8%).

Eye deformities were the most common of the three affected areas in this study.

### Introduction

Leprosy is a chronic infectious disease caused by *Mycobacterium leprae* and commonly affects the peripheral nerves and the skin. It may produce deformities and disabilities which result in permanent damage for the patients causing stigma.<sup>1</sup>

The Istanbul Leprosy Hospital is run by the Medical Faculty of Istanbul University, The Association for Fight Against Leprosy and the Ministry of Health. Besides 60 beds, there is a laboratory with skin-smear facilities, an operating theatre, a rehabilitation service, a dressing unit, an eye unit, a shoe workshop, a social department, a dental unit and handicraft shops. An ophthalmologist, a surgeon and four dermatologists work in Istanbul Leprosy Hospital. There

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is also an outpatient clinic attached to the hospital. The leprosy dispensary located inside Istanbul Leprosy Hospital gives priority to the routine control of all the patients living in Istanbul and neighbouring cities. These are reviewed at the Dispensary at 6-month intervals if they are under leprosy therapy, and annually if they have completed the therapy. Patients with problems are admitted to the leprosy hospital. The reasons for hospitalization according to the records of 1991 are determined as 25.7% medical control, 29.9% hand or foot care, 18.7% eye problems, 10.5% treatment modulation in newly-diagnosed patients, 5.0% reaction and 9.7% surgical procedure.<sup>2</sup>

In 1991 according to the Ministry of Health Records, of the 3319 leprosy patients 2659 have been seen by the staff of Istanbul Leprosy Hospital, 1058 having come to the hospital for various reasons. Seven hundred and eleven of the 1058 are included in this study.<sup>2,3</sup>

The aim of this study was to detect the percentage of leprosy-related eye, hand and foot disabilities in Istanbul Leprosy Hospital, Turkey.

## Materials and methods

This study in which the patients themselves were questioned about the duration of the disease was carried out in the period January–December 1992. Two hundred and thirteen of 711 leprosy cases were under treatment and 114 were being given multidrug therapy (MDT).

Seven hundred and eleven leprosy patients were evaluated according to their age, gender and type of disease. The diagnosis of leprosy was verified by the case history, clinical and bacteriologic tests done in the Istanbul Leprosy Hospital. These cases were classified by the Ridley–Jopling classification.<sup>4</sup>

Most of the 711 patients were diagnosed previously. Reasons for coming to the hospital were general control, eye, hand and foot disabilities as well as social problems.

### OPHTHALMIC EXAMINATIONS

Ophthalmic examination of all patients were done by experienced nurses under the ophthalmologist's supervision in the Eye Department. The Snellen Chart was used for vision assessment; 2/10 and over were evaluated as mild and moderate visual loss; 1/10 and under as severe visual loss and blindness. Lagophthalmos degrees and ectropium of the patients were recorded. Cochet–Bonnet aesthesiometer was used for corneal sensitivity measurement. The cornea divided into four quadrants and one central area. The examination began with 60 mm of filament and was continued by shortening the filament by 5 mm, until the patient responded that he did not feel the contact of the filament. The average of measurements performed on cornea in 5 different areas by aesthesiometer were calculated; 55 mm and less was evaluated as loss of sensation. Slit lamp (Haag–Streit) was used as the examination for cornea, anterior chamber, iris, pupil and lens.

Eye disability was also assessed according to the WHO disability grading system 1980.<sup>5</sup>

### HAND AND FOOT EXAMINATION

Hand and foot examinations were done by 2 physiotherapists and 3 experienced physiotherapy nurses. WHO disability grading system (1980) was used for assessment.<sup>5</sup>

**Table 1.** Type of leprosy

Type	Female		Male		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
LL	122	66.3	352	66.8	474	66.7
BL	55	29.9	149	28.3	204	28.7
BT	5	2.7	25	4.7	30	4.2
TT	2	1.1	1	0.2	3	0.4
Total	184	100.0	527	100.0	711	100.0

For statistical analysis the statistical programme EPI-Info 5 (Atlanta, Georgia, WHO-CDC) was used.

## Results

The study consisted of 527 males (74.1%) and 184 females (25.9%). The average age of the group was  $50.0 \pm 13.5$  years (females:  $50.3 \pm 14.2$ ; males:  $49.9 \pm 13.2$ ). The average duration of the disease was  $25.9 \pm 13.2$  years (females:  $25.4 \pm 13.2$ ; males:  $26.1 \pm 13.3$ ). The ratio of male to female was 2: 8.

Six hundred and seventy-eight leprosy patients (95.4%) were borderline (BL) and lepromatous leprosy (LL) in our study (Table 1).

Four hundred and eighteen (58.8%) of the leprosy cases were hospitalized once, 245 (34%) twice, 33 (4.6%) three times and 15 (2.2%) four times or more. When the duration of hospitalization was analysed, 312 cases (43.0%) were determined as being hospitalized for 1–30 days, 253 cases (35.6%) for 31–90 days, 83 cases (11.7%) for 91–180 days and 63 cases (8.8%) for more than 181 days.

Table 2 shows the number and percentage of patients with disabilities among the 711 leprosy patients in The Istanbul Leprosy Hospital; 546 (76.8%) of the total number of patients were found to have one or more disabilities, 165 (23.2%) of the total patients did not have any disabilities related to leprosy.

Twenty-five (75.75%) of tuberculoid (TT) and borderline-tuberculoid (BT) leprosy cases, 252 (77.3%) of BL cases, 269 of LL cases (76.4%) had more than one of the eye, hand or foot disabilities.

**Table 2.** Percentage of patients with deformities amongst 711 leprosy patients

Deformity/No. deformity	Female		Male		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Deformity absent	39	21.2	126	23.9	165	23.2
Deformity present	145	78.8	401	76.1	546	76.8
Total	184	100.0	527	100.0	711	100.0

**Table 3.** The total disabilities found in eyes, hand and feet according to sexes

Types of deformity	Female		Male		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Eyes	145	78.8	394	74.8	539	75.8
Hands	127	69.0	384	72.9	511	71.8
Feet	120	65.2	401	76.1	521	73.3

**Table 4.** Eye disability grading (WHO 1980)

Disability grade	Female		Male		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
0	39	21.2	133	25.2	172	24.2
1	35	19.0	91	17.3	126	17.7
2	98	53.3	251	47.6	349	49.1
3	12	6.5	52	9.9	64	9.0
Total	184	100.0	527	100.0	711	100.0

Grade: 0, no eye problem due to leprosy, no evidence of visual loss;  
 1, mild visual loss (7-9/10), mild loss of corneal sensation, orbicularis oculi muscle weakens (not lagophthalmos);  
 2, lagophthalmos, iridocyclitis, keratitis, VA > 6/60; and  
 3, severe visual impairment, blindness.

Table 3 shows the total disabilities found in the eyes, hands and feet according to gender. Among eye, hand and foot disabilities the highest number was found in eyes (75.8%), followed by foot and hand disabilities, respectively (73.3%, 71.8%).

There was no statistically significant difference between the genders in eye, hand and foot disabilities ( $p > 0.05$ ).

**Table 5.** Hand disability grading<sup>5</sup>

Disability grade	Female		Male		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
0	57	31.0	143	27.1	200	28.2
1	28	15.2	88	16.7	116	16.2
2	60	38.0	198	37.6	268	37.7
3	29	15.8	98	18.6	127	17.9
Total	184	100.0	527	100.0	711	100.0

Grade: 0, no anesthesia or visible deformity or damage;  
 1, loss of sensation;  
 2, ulcer, mobile claw hand, visible absorption; and  
 3, drop hand, finger contracture, severe absorption.



**Table 6.** Feet disability grading<sup>5</sup>

Disability grade	Female		Male		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
0	64	34.8	126	23.9	190	26.7
1	34	18.4	107	20.3	141	19.8
2	64	34.8	242	45.9	306	43.1
3	22	12.0	52	9.9	74	10.4
Total	185	100.0	527	100.0	711	100.0

Grade: 0, no anesthesia or visible deformity or damage;  
 1, loss of sensation;  
 2, trophic ulcer, claw finger, drop foot, visible absorption; and  
 3, contracture, severe absorption.

Table 4 shows eye disabilities according to WHO disability system. No eye involvement was found in 172 patients (24.2%), 126 cases (17.7%) had Grade 1, 349 cases (49.1%) had Grade 2, and 64 cases (9.0%) had Grade 3 eye disabilities.

According to the WHO disability system, 200 patients (28.2%) had no hand disabilities;

**Table 7.** Eye, hand and feet disabilities in 711 patients

Disabilities	Female		Male		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
<b>Eye*</b>						
vision 6/6	39	21.2	133	25.2	172	24.2
> 6/60	133	72.3	342	64.9	475	66.8
< 6/60	12	6.5	52	9.9	64	9.0
lagophthalmos	64	34.8	231	43.8	295	41.5
ectropium	53	28.9	231	43.8	284	40.0
corneal sensory loss	56	30.4	251	47.6	307	43.2
keratitis	46	25.0	151	28.7	197	27.7
iritidocyclitis	92	50.0	254	48.2	346	48.7
iris atrophy	74	40.2	174	33.0	248	34.9
pupil deformity	67	36.4	151	28.7	218	30.7
cataract	37	20.1	179	34.0	216	30.4
<b>Hand*</b>						
insensitivity	28	15.2	88	16.7	116	16.3
mobile claw hand	59	32.0	178	33.7	237	33.3
ulcer	11	6.1	20	3.8	31	4.4
drop hand	2	1.1	10	1.8	12	1.7
contracture	15	8.1	46	8.8	61	8.6
severe absorption	12	6.6	42	8.1	54	7.6
<b>Foot*</b>						
insensitivity	34	18.4	107	20.3	141	19.8
ulcer	54	29.3	210	39.9	264	37.2
droop foot	10	5.5	32	6.0	42	5.9
contracture	12	6.5	25	4.8	37	5.2
severe absorption	10	5.5	27	5.1	37	5.2

\* For each patient the most severe deformity of eye, hand or foot is counted in the Table.

116 patients (16.2%) had Grade 1 hand disabilities; 268 patients (37.7%) had Grade 2; and 127 patients (17.9%) had Grade 3 (Table 5).

No foot disabilities were found in 190 patients (26.7%). There were 141 patients (19.8%) with Grade 1 foot disabilities; 306 patients (43.1%) with Grade 2; and 74 patients (10.4%) with Grade 3 (Table 6).

Table 7 shows the deformities of the eyes, hands and feet. The most frequent eye disabilities were a decrease of vision (539 or 75.8%), acute or chronic iridocyclitis (346 or 48.7%), slightly-marked corneal sensory loss (307 or 43.2%), lagophthalmos (295 or 41.5%) and ectropion (284 or 40.0%). Superficial punctate keratitis was seen in 197 leprosy patients (27.7%). There were 218 patients (30.7%) with pupil deformity. Cataract was found in 216 cases (30.4%). Decrease of vision and iridocyclitis was the most common ocular complications encountered in both genders.

The most frequent disabilities of the hands and feet were mobile claw hand (237 or 33.3%), palmar insensitivity (116 or 16.3%), plantar ulcer (264 or 37.2%) and plantar insensitivity (141 or 19.8%).

Statistically there was a very significant relationship between age, and the duration of the disease and disability ( $p < 0.001$ ).

## Discussion

Seven hundred and eleven leprosy patients in our study made up of 21.4% of 3319 registered leprosy patients in Turkey.

In this study, we found that eye, hand and foot disabilities are very high being respectively, 75.8%, 71.8%, 73.3%. Several studies had reported the proportion of the disabilities in leprosy as follows: Guocheng<sup>6</sup> 56.9%, Rao<sup>7</sup> 42.9%, Iyere<sup>8</sup> 38.7%, Zheng<sup>9</sup> 67.5%. Zheng did his study in leprosarium even though his result was lower than our result.

The most frequent disabilities were 75.8% decrease of vision, 48.7% iridocyclitis, 43.2% slightly-marked corneal sensory loss, 41.5% lagophthalmos 40.0% ectropion, 37.2% plantar ulcer, 19.8% claw hand and plantar insensitivity. In our study highly-decreased vision was found to be 9.0%. This rate increases to 9.9% in males. Lagophthalmos, ectropion and decreased vision are higher in males compared to females. However iridocyclitis, iris atrophy and pupillary deformity were found to be higher in females compared to males (Table 7). No statistically significant difference of eye and hand disabilities was found between males and females. Foot disability occurs more in males than females ( $p < 0.05$ ). This difference has been related to the fact that male patients work out of home. Iyere has reported the lagophthalmos rate to be 2.4%, loss of corneal sensation to be 1.3%, palmar insensitivity to be 17.2% and plantar insensitivity to be 17.9%.<sup>8</sup> Sehgal & Srivastava have reported claw hands to be 19.7%.<sup>10</sup> Karacorlu found various degrees of corneal loss of sensitivity in 46.2% of leprosy patients.<sup>11</sup>

The disability rate was high in older age groups in our study ( $p < 0.001$ ). This is similar to the result of Smith,<sup>12</sup> Noordeen,<sup>13,14</sup> Guocheng,<sup>6</sup> Rao,<sup>7</sup> and Zheng.<sup>9</sup> It is considered that the duration of the disease is a more important factor than the age of patients in causing disabilities.

Noordeen reported that deformities were lower in females.<sup>13,14</sup> Srinivasan & Dharmandra said that nerve damage was seen to be lower in females.<sup>15</sup> But, in the present study, there was no statistically difference between males and females ( $p > 0.05$ ).

The percentage of disability among patients is higher in Istanbul Leprosy Hospital, Turkey, than in some parts of the world.<sup>7-9,15</sup> Among the reasons for these are a high percentage of multibacillary disease, prolonged duration of the disease, failure of the local health centre staff to treat patients regularly and insufficient care of patients. Medical personnel in our country are not very familiar with leprosy because of the low prevalence. This could lead to 5–10 years delay in diagnosis.<sup>16</sup> During this time peripheral nerve damage develops leading to disabilities.<sup>1</sup>

## Conclusions

Educating patients and medical personnel in the peripheral nerve disabilities and in the early symptoms of leprosy reactions would help prevent a high proportion of the disabilities and deformities. The organization of leprosy courses about leprosy complications for the health center personnel would also help. The reorganization of living conditions of the severely disabled patients according to their disabilities would prevent the progression of the disease. On this subject, studies are being continued in collaboration with the Ministry of Health, several universities and aid organizations in Turkey.

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## **Alternative approaches for the prevention of disability in leprosy**

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*Summary* Cost-effective programmes for the prevention of disabilities in leprosy require active involvement of the patients and their families as well as an integrated team approach. This paper presents the views and recommendations of a group of 35 experienced leprologists who met at a workshop, reviewed the current scenario and worked out specific objectives, strategies and the reorganization required in the existing infrastructure. Three tiers of workers are suggested: village volunteer; paramedical worker; and the professionals at the base hospital. All three levels should work together at the start of a programme as well as for periodic monitoring and evaluation.

### **Introduction**

Nerve damage in leprosy leading to deformities and disabilities is mainly responsible for the prejudice against leprosy. The effects of these deformities in terms of disability as well as stigma causes great concern among patients who are affected and generates a sense of fear in the minds of general public.<sup>1</sup> Social displacement, vocational loss and destitution perpetuate the above situation.<sup>2</sup> Thus apart from being a medical and a public health problem, leprosy poses issues relating to the social aspects of the patient.

Early diagnosis and early treatment is still the best strategy to primarily prevent the onset of nerve damage and thereby prevent disability. However in many cases the situation is already advanced to the state of established nerve damage and hence the need for other input to prevent the progress of established physical deformities and to protect the individual from suffering social and vocational disadvantages.<sup>3</sup>

At present few leprosy control programmes are structured to carry out disability prevention. This aspect of leprosy urgently needs to be addressed. The programmes should also be designed to cover the multifaceted nature of disabilities in leprosy as described above.

A group of 35 leprologists and related professionals working to prevent disability in leprosy met at the Schieffelin Leprosy Research and Training Centre, Karigiri in June 1996 to discuss how best to give the much needed thrust for disability prevention to be given a multidimensional approach. The main objectives of this workshop were to develop a

prevention of disability programme from its very basic issues, to identify lacunae relating to disability prevention in the existing leprosy programmes, and to suggest new strategies for effective implementation of a programme addressing all components of disability in a multidisciplinary, practical team-oriented approach.

The workshop consisted of group discussion around a set of structured questions followed by a presentation and discussion of each group's findings in a plenary session.

## Terminology

The terminology decided by rehabilitation technologists (WHO) which includes impairment, disability and handicap was accepted by all the participants.<sup>4</sup>

## Evolution of disabilities

Tissue impairments in leprosy lead to physical disabilities which in turn place the patient at social, vocational and psychological disadvantages. Even though physical impairment is the starting point of other disabilities, there is no established pattern of evolution of disabilities. This would largely depend on the patient's socioeconomic status and literacy. The various disabilities due to leprosy can be linked together but it is difficult to prioritize them.

## Existing situation in disability prevention

### PRIORITY

At present, many leprosy programmes do recognize the importance of disability prevention and are making efforts to incorporate prevention of disability policies, objectives and strategies outlined in booklets such as ILEP's *Prevention of Disability Guideline* and WHO's *Guide to Eliminating Leprosy as a Public Health Problem*. All leprosy programmes will be required to incorporate prevention of disability (POD) activities.

### PARAMEDICAL WORKER

At present the paramedical workers' efforts are mainly focused on drug delivery. In some centres paramedical workers are being sensitized to the need for POD activities in the field in addition to drug delivery.

### EARLY RELEASE OF PATIENTS FROM CONTROL

Multidrug therapy (MDT) is very effective in rendering the patients disease free in a short time. Coupled with early diagnosis, MDT is one of the effective tools to prevent disability. However MDT does not help the cause of disability prevention because patients are released earlier from treatment and surveillance after MDT, and it will not be possible to monitor these patients for disability prevention over a longer period, especially those with established impairments.

#### 'EDUCATION' COMPONENT OF MDT

The education component of the 'survey, education and treatment' mandate of the MDT programme has also been restricted mainly to the mere transfer of knowledge, which may or may not result in the much needed behaviour change.

#### TOTAL CARE OF PATIENT

While the health team stresses self-care activities as a priority for patients, patients' more pressing needs may be social or economical or a combination. There is a need to look at the total care of the patient rather than just be concerned about the physical aspects. This is especially true because we believe that leprosy is not only a medical and a public health problem but a human problem affecting relationships in the families and societies.

#### COORDINATION OF EFFORTS

At some large centres there are various professionals working to prevent disability in leprosy, such as doctors, physiotherapists, social workers. These professionals have a tendency to work individually, seeing disability problems through the eyes of their own profession and this has not helped the cause of the total care of the leprosy patient.

#### STANDARDIZATION

Standardized methods of impairment assessment and recording are in practice in many centres and other centres should be encouraged to follow.

#### PARTICIPATORY APPROACH

The main approach has been nonparticipatory with the health team holding the knowledge and technology instead of including the patient and making him responsible for his care. The programmes also have a mass approach to the problem rather than an individualized/personalized care.

#### MOTIVATION

There is lack of motivation for prevention of disability in both the patient and the health team personnel. Family support for preventing disability is often lacking.

### **Suggested changes in the present programmes**

#### HEALTH SYSTEM

Encourage the reorganization of the control programmes from state level downwards; and as a priority to implement the prevention of disability activities.

Standardize procedures, monitoring and records so that there is uniformity and direction to the programmes.

Involve the voluntary and the nongovernmental sector in the prevention of disability.

Enhancing mobile services to seek out patients requiring disability prevention.

HEALTH TEAM

Adopt a multidisciplinary approach in addressing all the disability issues of a leprosy patient.  
Encourage a team-oriented approach.

Include the patient and his family in the programme so that they are participating.

Let the care be for the individual rather than the group.

Retrain all the staff, and particularly those who can be identified as working specifically for disability prevention.

To concentrate on both high risk groups and on the younger age groups.

PATIENT/HIS FAMILY/COMMUNITY

Get patients to accept responsibility for their own care in preventing disability by empowering them with required knowledge and skills.

Motivate them to have a positive outlook towards leprosy and their life.

With the above suggested changes a broad goal for the prevention of disabilities and a set of objectives were worked out.

**Main goal for prevention of disability**

The goal of prevention of disability programme in leprosy would be to prevent development of impairments, to correct or halt progress of established impairments so that they do not develop into disabilities and to address any disadvantages (handicaps) that may have arisen because of impairments or disabilities, thereby helping the integration of the patient into the society psychologically, vocationally, socially and functionally.

**Specific goals**

To prevent the onset of impairments in leprosy patients by early case detection, early diagnosis and treatment of neuritis.

To correct established impairments whenever possible, limit their progress and prevent secondary complications.

To motivate the patient to face the disease and its possible consequences in a positive state of mind and to avoid psychological disturbances.

To help the patient to be accepted socially in his own family and in the community.

To help the patient to be employable by training or by helping to change their vocation.

To make provisions for the patients who are physically and economically dependent.

**Reorganization and constraints in implementation**

The present infrastructure is sufficient to be able to incorporate the changes suggested and to be able to implement the set objectives. Since MDT has reduced the workload on the village-level health worker, it was felt that he could be trained to implement disability prevention activities. Redeployment and redefining jobs may be necessary. The mobility of the village worker also needs to be increased by provision, e.g. of a bicycle.

Since the programme is going to be participatory, it was felt that a volunteer from the village could be selected and trained and be given the responsibility of disability prevention in his village.

As for psychological, social and vocational aspects it was decided that the volunteer from the village can be trained in the basic aspects of identifying problems. These problems then can be referred to professionals based at the base hospital or main centres for appropriate action.

So the programme will have three tiers of POD workers. The first level being the village volunteer, the second level being the paramedical worker and the third level, the professionals at the base hospital. However it will be necessary for all three levels to work together at the beginning of the programme and for monitoring and evaluation from time to time.

## Conclusions

Being a multifaceted disease leprosy needs a multidisciplinary approach. Prevention of disability involves more than one aspect and more than one professional, so for effective implementation of the programme a team approach is needed. Since the success of the programme depends mostly on the patient the programme should be participatory with the patient and his family taking responsibility for preventing disability. Finally the programme should be aimed at an individual level rather than a group.

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## **A simple and inexpensive pinch meter to detect subclinical weakness among leprosy patients**

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*Summary* This paper describes the use of a neonatal sphygmomanometer cuff as a simple, inexpensive pinch meter. Normal values for key pinch, pulp pinch and side pinch in the dominant hand of healthy Nepali people are provided.

The pinch meter was also used to test pinch strength in hands affected by leprosy and normal hands. Some patients with leprosy who have no objective weakness on voluntary muscle testing (VMT) have less pinch strength than people without leprosy. The pinch meter is a useful tool for the early detection of motor function loss.

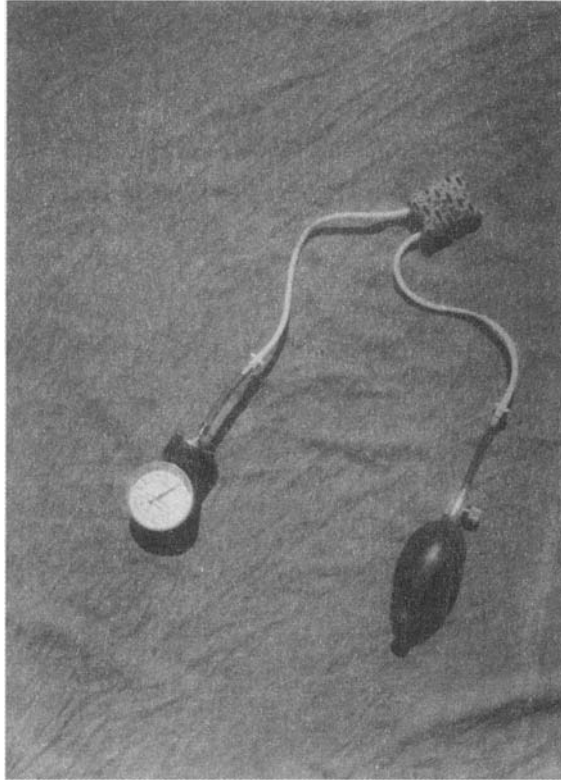
### **Introduction**

Part of the routine assessment of patients with leprosy is an assessment of muscle power in the hand. There are many methods of testing hand function. Voluntary muscle testing (VMT) as described by the Medical Research Council<sup>1</sup> is a detailed and accurate method of assessing hand muscle function.

However even amongst well-trained observers there is significant interobserver variation.<sup>2</sup> Another problem in assessment is that the scale 0–5 is not, in practice, linear, i.e. there is a much greater loss of strength between grade 5–3 than between 3–1. Staff usually modify the VMT scale for testing the intrinsic muscles of the hand as they are not significantly affected by gravity. Thus Grade 3 = full range of movement, Grade 2 = partial range of movement, and Grade 1 = muscle flicker but no movement.

Finger dynamometry is an accurate, reproducible method of testing strength in key and pulp pinches. However pinch meters are expensive and way beyond the budgets of most third world hospital.

At Anandaban Leprosy Hospital, Nepal we designed our own pinch meter using a disposable neonatal sphygmomanometer cuff which we received in a box of donated medical supplies. We tested it on normal, healthy hands of people who presented to our nonleprosy outpatients department as well as on hands of people affected by leprosy.



**Figure 1.** Pinch meter is cloth bag with blood pressure cuff and gauge attached.

## Materials

The sphygmomanometer cuff is a DISPOSA-CUF<sub>TM</sub><sup>3</sup> neonatal size 3 (Figure 1). This was fitted inside a cloth bag (40 mm by 40 mm) so that the volume of the cuff remained relatively constant. The cuff was connected to an ordinary anaeroid sphygmomanometer. The meter was set at zero and the cuff was then inflated to 20 mmHg.

Pulp-to-pulp pinch (between the thumb and each of the fingers) (Figure 2) and key pinch (between the thumb and the side of the index) was measured. Side pinch (Figure 3) between the index and long fingers, long and ring fingers and ring and little fingers was also measured.

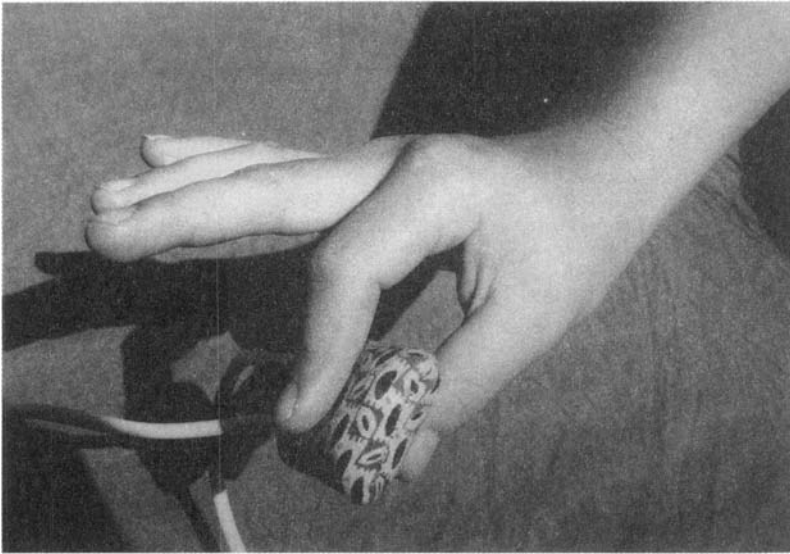
The people tested were classified into 4 groups:

Group 1 normal hands in people not affected by leprosy ( $n = 24$ ).

Group 2 affected hands in people affected by leprosy ( $n = 22$ ).

Group 3 normal hands in people affected by leprosy where the other hand was affected by leprosy ( $n = 17$ ).

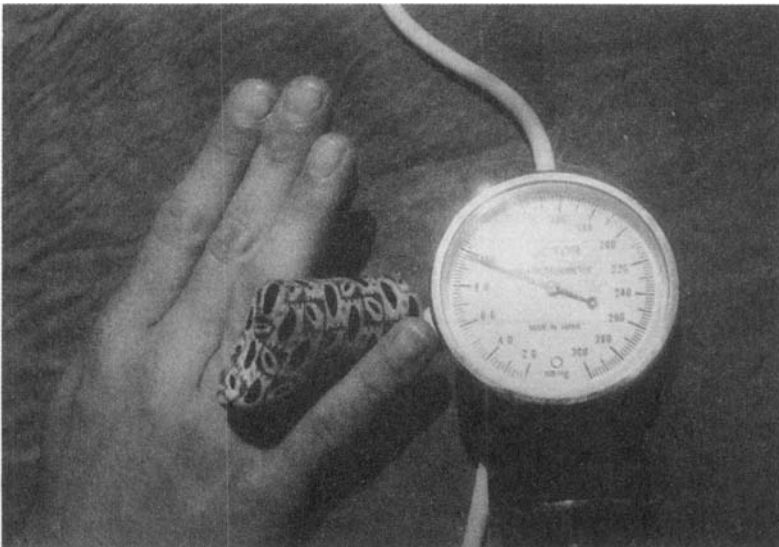
Group 4 normal hands in people affected by leprosy where the other hand was not affected by leprosy ( $n = 15$ ).



**Figure 2.** Pulp pinch.

## **Results**

All measurements listed were made with the cloth bag cover. All strengths were measured in mmHg. These measurements were carried out on 78 hands. People who were tested were aged between 15 and 55 years old.



**Figure 3.** Side pinch.

**Table 1.** All measurements are in mmHg and carried out with the cloth bag cover.

Pulp pinch	Mean	sd	Range
Thumb-Index	237	46	160-360
Thumb-Middle	195	45	130-320
Thumb-Ring	152	54	70-280
Thumb-Little	126	31	70-180
Key pinch	246	41	170-320
Side pinch			
Index-Middle	126	24	85-170
Middle-Ring	87	15	60-110
Ring-Little	71	13	40-95

SD, standard deviation

**Table 2.** Mean pressure in mmHg (% of normal—Group 1)

	Group 1	Group 2	Group 3	Group 4
Pulp pinch				
Index	237	130 (55%)	191 (81%)	221 (93%)
Middle	195	133 (68%)	194 (99%)	199 (102%)
Ring	152	98 (64%)	148 (97%)	148 (97%)
Little	126	64 (51%)	112 (89%)	121 (96%)
Key pinch	246	149 (61%)	209 (85%)	251 (102%)
Side pinch				
Index-Mid.	126	69 (55%)	102 (81%)	121 (96%)
Middle-Ring	87	52 (60%)	73 (84%)	87 (100%)
Ring-Little	71	36 (51%)	59 (83%)	71 (100%)
Grip	234	143 (61%)	187 (80%)	193 (82%)

**Table 3.** Correlation between side pinch between ring and little finger VMT of ring and little finger

Finger intrinsics	Side pinch	
	Normal	Weak
Normal	23	6
Weak	2	15

The mean, standard deviation and range of measurements in healthy people (Group 1) are listed in Table 1.

Among hands of people in Group 2 (leprosy affected hands) there were 15 hands with combined lesions (ulnar and median nerve), 6 hands with only ulnar nerve lesions and one hand with only median nerve damage.

A detailed summary of the results is listed in Table 2. Hands affected by leprosy (group 2) have consistently lower strengths as measured by pressure generated. The

mean pressure in hands affected by leprosy varied from 51% of that produced by normal hands for Thumb–Little pulp pinch to 68% of that produced by normal hands for Thumb–Middle pulp pinch. Normal hands in people where the other hand was affected by leprosy (group 3) were also weaker when compared with normal hands in people not affected by leprosy. The mean pressure produced varied from 81% of that produced by normal hands for Index–Middle side pinch to the same pressure produced by normal hands for Thumb–Middle pulp pinch. In this group the patient pressures could be divided into 2 subgroups—6 hands with pressure equal to normal hands and 11 hands with pressures below that of normal hands. It is possible that these 11 hands represent hands with early motor weakness.

People affected by leprosy but where both hands were normal had similar means to people not affected by leprosy, except for grip strength (82% of normal grip strength).

There was good correlation between VMT and pinch strength in the side pinches. For example if we code the intrinsic function (lumbrical action) of the little and ring fingers together (total VMT = 10 = normal, and if less than 10 = weak) and code the side pinch between these fingers (more than 40 mmHg = normal and less than 40 mmHg = weak) then we arrive at the result given in Table 3. From this there are 6 patients with a normal VMT but with 'weak' side pinch who may represent subclinical weakness.

There was good correlation between ADM weakness and side pinches. Index–Long  $r = 0.74$ ; Long–Ring  $r = 0.66$ , Ring–Little  $r = 0.73$ . There was poorer correlation between weakness of OPP and the pulp pinches. A weakness of FDP or of FDS had poor correlation with all of the pinches.

## **Discussion**

Finger dynamometry is an essential part of the assessment of patients with nerve damage leading to muscle weakness in the hand. The technique of measuring the pinch pressure is simple, reproducible and quick. However as with most medical equipment pinch meters are very expensive. (Prices I have had quoted range from US\$ 500 to 1000, which is beyond the budgets of most hospitals in developing countries). In contrast the disposable neonatal cuffs cost less than \$5 each. So far the first cuff has lasted more than 6 months with no signs of fatigue.

Occasionally, when encased in the cloth bag, the cuff can be pinched by very strong hands beyond the range of the anaeroid sphygmomanometer. To overcome this problem we have tried using a firm plastic cover made from a film container. This requires greater force to compress it and can thus be used for very strong pinches (in particular the key pinch and the Thumb–Index pulp pinch). The soft cloth bag is more sensitive and suited to side pinches. The use of the neonatal sphygmomanometer cuff makes the use of finger dynamometry available to hand therapists and surgeons in developing countries with limited resources.

In the normal hands of people where the other hand is affected by leprosy the mean strength was lower than in normal hands in normal people. This may be due to early motor nerve damage where the VMT is normal but where there is a measurable deficit in pinch strength. These patients are at risk of developing overt motor weakness if they experience further damage due to leprosy neuritis. In these patients finger dynamometry

may be a useful tool to assess early changes in motor strength. This technique may also be useful for assessment of recovery of nerve function after prednisolone or peripheral nerve surgery because it is less liable to assessor bias.

## Conclusion

Finger dynamometry using a neonatal sphygmomanometer cuff is reliable and useful in the assessment of hand function, particularly in situations where resources are limited.

This simple, inexpensive pinch meter is a useful addition to the tools available for the assessment of hand motor function in people affected by leprosy. It may help to identify those at risk of further nerve damage who may later develop overt motor weakness as measured by VMT.

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*SPECIAL ARTICLE*

## **Guideline for the clinical use and dispensing of thalidomide\***

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### **Introduction**

In the 1960s thalidomide virtually disappeared from clinical use after it was demonstrated that it is both a causative agent of severe irreversible peripheral neuropathy<sup>1,2</sup> and a human teratogen.<sup>3,4</sup> Currently in the UK there are no product licences for thalidomide but it can be prescribed on a 'named patient' basis in accordance with Section 9(1) of the Medicines Act 1968,<sup>5</sup> and its subsidiary legislation.<sup>6</sup> It is being prescribed by hospital-based physicians to a small number of patients who have exhausted other therapeutic options. Hospital doctors who prescribe thalidomide should have the necessary expertise in its use and the resources to detect subclinical neuropathy. There is the potential for an increase in its use in conditions such as bone marrow transplantation<sup>7</sup> and HIV-related disease.<sup>8</sup> Even in these new areas, thalidomide should only become an option when all other therapeutic modalities have failed.

This continued, albeit limited, use of thalidomide has been criticized by some clinicians,<sup>9,10</sup> and by individuals affected by thalidomide<sup>11</sup> because of the known serious side effects of the drug. One of their concerns is that there are no legal restrictions or guidelines regulating its clinical use. Its current use is subject to the requirements of the laws governing the supply of a medicine for a 'named patient' prescription.<sup>5,6,12,13</sup> This guideline is designed to promote the safest possible clinical use and dispensing of thalidomide.

These recommendations may require revision and modification as further clinical experience with thalidomide is gained. For that reason it is preferable that its clinical use should be regulated by guidelines rather than by law. However, it cannot be overstated that the risks of teratogenicity and peripheral neuropathy must be recognized, and addressed in each and every patient.

### **(A) Clinical use**

1. Only severe disabling conditions that cause an unacceptable interference with normal life

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- should be treated with thalidomide, and only after other treatments have been tried and failed.
2. Pregnancy should be excluded before instituting therapy with thalidomide, specifically by a negative pregnancy test within 2 weeks prior to starting therapy.
  3. Patients should be specifically excluded from treatment with thalidomide for any of the following reasons:
    - a. Unwilling to sign a consent form.
    - b. Unable to understand the potential risk from the use of thalidomide.
    - c. Unlikely to be able to comply with the prescribing instructions.
    - d. Women who wish to become pregnant.
    - e. Women of childbearing potential:
      - i. who have not practised a reliable form of contraception for 1 year;
      - ii. who are unwilling to take reliable contraceptive precautions;
      - iii. who are considered not capable of complying with the requirements for reliable contraception. Reliable contraceptive methods include the contraceptive pill, an intrauterine device, surgical sterilization of patient or sole partner. Female patients who do not normally practise contraception because of a history of infertility should do so whilst taking thalidomide.
  4. Fully informed consent should be obtained using a written consent form and a signed agreement.
  5. Women of childbearing potential should agree to stop taking thalidomide immediately should they miss a period, and urgently contact their prescribing physician. A pregnancy test should be provided and, if positive, appropriate counselling should be given.
  6. Women of childbearing potential who discontinue treatment with thalidomide should agree to take reliable contraceptive precautions for 3 months after discontinuing thalidomide.
  7. Patients should agree to return any unused supply of thalidomide to the prescribing physician.

## **(B) Monitoring**

1. Appropriate clinical and electrophysiological measurements should be recorded before treatment is commenced. For certain conditions, photographs may be useful to monitor the progress of treatment.
2. The anticipated duration of treatment at which benefits of therapy will be judged should be agreed with the patient and treatment critically reviewed at the end of that period. Treatment failure must be recognized to avoid unnecessarily extended courses of thalidomide.
3. Follow-up visits should be at monthly intervals or less for the first 3 months to enable the clinician to detect side effects/early signs of toxicity. The warnings about the possible toxicity and the need for adequate contraception should be reinforced. Adequate time should be allowed to answer all questions raised by the patient.
4. All adverse events should be recorded and serious events notified to the Clinical Trials Section. Medicines Control Agency.\*

\*Clinical Trial Section, Medicines Control Agency, Room 1418 Market Towers, 1 Nine Elms Lane, London SW8 5NQ, UK. Tel. 0171-273 0327.



5. Electrophysiological measurements (see below) should be repeated after each 10 g increment in total dose or 6 monthly, whichever is the sooner, for the duration of therapy.
6. Patients should be warned, and understand, that they must stop thalidomide immediately if paraesthesiae develop. In some cases the sensory loss may be permanent and adequate diagnosis, management and follow-up for these patients should be arranged.

### **(C) Electrophysiological measurements**

1. Peripheral neuropathy is a common, severe and often irreversible side effect of treatment with thalidomide. Every effort must be made to detect this presymptomatically by electrophysiological techniques. Unfortunately there are no published electrophysiological studies that outline the criteria to predict the development of paraesthesiae. Should paraesthesiae develop, then thalidomide must be stopped immediately to limit further damage.
2. Electrophysiological testing should be performed at a constant temperature, by a consistent technique and by the same neurophysiologist, to provide at least one, preferably two, pretreatment baseline measurements of sensory nerve action potential amplitudes (SNAP). If more than one pretreatment value is available, confidence limits can be calculated for the individual patient.
3. The SNAP amplitudes should be measured in at least three nerves, for example, median,<sup>14</sup> radial<sup>15</sup> and sural.<sup>16</sup> A summated score with equal weighting for each nerve can be used to reduce the dominant contribution from the radial nerve SNAP amplitude. Nerve conduction velocities would not be expected to show significant changes in the early phase of an axonal neuropathy.<sup>17</sup>
4. Based on available data, a fall from the baseline summated score of >40% should be regarded as significant.<sup>18</sup>
5. For those patients with a fall from baseline summated score of between 30% and 40%, the intervals should be reduced between measurements and, therefore, the need to use thalidomide should be reviewed.

### **(D) Patient information**

1. Each patient being treated with thalidomide should be given an information sheet (Figure 1).
2. A doctor prescribing thalidomide on a 'named patient' basis is entirely responsible for the patient's welfare. He must inform the patient of any contraindications, warnings and precautions associated with the use of the drug. To comply with the law,<sup>12</sup> suppliers of a drug for a 'named patient' prescription must provide information about the drug on the containers and packages, but are not required to provide contraindications, warnings and precautions.
3. A sample patient information sheet is provided, which contains information relating to its proposed use and warnings about the potential, severe side effects of thalidomide. It should be updated as required.

**(E) Manufacture and dispensing**

1. Thalidomide does not have a product licence in the UK. Nevertheless, a manufacturer or supplier may supply it to a medical practitioner for a prescription for a particular patient<sup>6</sup> ('named patient' supply) provided that the manufacturer has a manufacturer's licence for 'specials'.<sup>19</sup>
2. Staff and equipment at the manufacturing site should be adequate to ensure that the product is of the nature and quality specified by the doctor or pharmacist. Manufacture should be under proper supervision and adequately controlled.
3. Adequate records should be kept by the manufacturer/supplier. Records should include the amount of thalidomide that has been made, the form of the finished product, the 'named patient', the prescribing doctor and the person to whom it has been supplied.
4. The supplier should satisfy himself beyond doubt that orders are from hospital-based consultants who have knowledge of the use of thalidomide and its side effects.
5. It is recommended that the supplier should require that the order should be made in writing with the name of the patient, the prescribing doctor and the hospital address and telephone number. The letter should include a statement that the doctor is familiar with the use of thalidomide and its side effects, including peripheral neuropathy and teratogenicity. Also, a written assurance should be obtained that the drug will only be dispensed by the hospital pharmacist to the 'named patient' in accordance with the prescription.
6. Orders to provide a stock for a hospital pharmacy should not be accepted. However, an amount to provide for 3 months prescription for a 'named patient' could be supplied to be held in the pharmacy.

**(F) Labelling**

1. The labelling of containers and packages for medicines supplied for 'named patient' prescriptions are regulated by law.<sup>12</sup>
2. All particulars should be clear, legible and readily discernible so that they can be easily read. The particulars to be shown on the container should normally be shown on the body of the container.
3. Every container for thalidomide should be labelled to show the following information:
  - The non-proprietary name or a proprietary designation. In addition the label should show a warning: 'Contains thalidomide'.
  - The quantitative particulars in a conspicuous position. The labelling should distinguish between active and non-active ingredients.
  - The quantity of thalidomide in the container or package.
  - Any special requirements for the handling and storage, and the expiry date.
  - The batch reference number, the number of the manufacturer's licence (preceded by ML), and the name and address of the person who manufactured the product.
  - The container should also show the warnings: 'Do not exceed the stated dose', 'Keep out of the reach of children', 'Thalidomide causes serious damage to babies if taken by women during pregnancy' and 'This drug must not be shared with anyone else.'

### PATIENT INFORMATION SHEET FOR THALIDOMIDE USE

in ..... (patient's name)

Thalidomide is a drug which can have severe side effects. This means it can only be used to treat a few debilitating conditions in which alternative treatments have been tried and failed. Thalidomide must be used with great care by patients and doctors and treatment will involve careful monitoring. Despite these drawbacks, in some patients thalidomide can be of significant benefit.

**Condition being treated** .....

#### How is the treatment given, how often and for how long?

Dr ..... at ..... Hospital

Tel. no. .... has prescribed thalidomide (proprietary name if used) for you.

The dose is ..... mg= ..... tablets and should be taken daily at night for ..... days.

#### Hospital visits

This treatment is monitored in the out-patients clinic, initially with monthly visits. You will be asked to have an electrical nerve test at regular intervals. These nerve tests can cause some discomfort but are an essential aspect of monitoring.

#### Does the drug have side effects?

1. *Morning drowsiness* is the most noticeable problem. This varies in each individual and may require your doctor to reduce the dose. Drowsiness may impair your ability to drive and operate machinery.
2. *Nerve damage*: Pins and needles of hands and feet are early signs of nerve damage and can develop after repeated courses or regular administration of thalidomide. Should you develop pins and needles **you must stop thalidomide immediately** and contact your hospital doctor. This is not uncommon and can be both severe and irreversible.

The aim of the electrical tests is to detect nerve damage before symptoms develop, and these will be a crucial part of your follow-up assessments. Should damage become apparent on the nerve test, thalidomide will be stopped, halting further deterioration in nerve function. Any damage at this stage would be so small it would be unnoticeable, but you would not be given thalidomide again.

3. *Damage to babies*: This is very important for all women considering thalidomide. Thalidomide is toxic to the developing baby, especially in the early months of pregnancy. If you wish to consider thalidomide you must be prepared to use adequate contraception throughout the duration of thalidomide therapy and for 3 months after it has finished. Should contraception fail, any resulting pregnancy may incur damage to the baby and consequently, if you miss a period at any time during treatment, **you must stop thalidomide immediately** and contact the doctor who prescribed the thalidomide. A pregnancy test would then be arranged and appropriate counselling given. Should pregnancy be confirmed, further investigations to assess any damage to the baby would be indicated. Your doctor can advise you about adequate contraception. No effects on male sperm are recognized.
4. *Minor side effects* such as constipation, nausea, dizziness, headaches and rarely skin rashes can occur.

#### Having read this sheet

This treatment involves you in possible risks and benefits. You should not agree to start thalidomide until you clearly understand these. Even if your doctor recommends the treatment you are free to refuse it and this will not in any way influence the rest of your care.

#### Remember

Thalidomide is a potentially dangerous medication. It must be securely stored away from children and *only* taken by the person to whom it is supplied.

Figure 1. Patient information sheet for thalidomide use.

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*SPECIAL ARTICLE*

## **2nd International Conference on the Elimination of Leprosy, New Delhi, India, 11–13 October 1996**

### **Recommendations**

The Second International Conference on the Elimination of Leprosy, convened on the initiative of the World Health Organization in New Delhi, India, from 11 to 13 October 1996, mindful of the commitment of all Member States of WHO, under World Health Assembly Resolution WHA44.9, of 1991, 'to continue to promote the use of all control measures including Multidrug Therapy (MDT) together with case-finding in order to attain the global elimination of leprosy as a public health problem by the year 2000', endorses the updated WHO global strategy and the intensified plan of action, and **RECOMMENDS** that:

- All parties concerned—national governments, nongovernmental organizations and international agencies—should recognize the unprecedented opportunity available now to reach the goal of eliminating leprosy as a public health problem, particularly in the light of the remarkable progress made so far, and that they intensify their political commitment and efforts to reach the remaining patients before the year 2000, bearing in mind that there is no room for complacency if the goal is to be attained.
- The remaining problem of leprosy treatment will be far more difficult as it includes hitherto neglected areas, population groups and communities. It is important that programme managers develop special intensive operations to reach them through such mechanisms as leprosy elimination campaigns (LEC) to detect hidden cases and special action projects (SAPEL) to reach difficult-to-access patients among under-served population groups such as nomads, refugees, migrants, etc.
- Ministries of Health in endemic countries should take immediate steps to further involve health personnel from the general health services in the treatment of leprosy patients, as well as in case-detection, so that these activities are adequately integrated into the general health services. Even as integration within the general health services is achieved, the quality of services provided to patients should be assured.
- As the technology employed to reach the leprosy elimination goal is essentially through the treatment of patients with multidrug therapy (MDT), it is extremely important that the free supply of WHO recommended MDT drugs in blister packs to patients be continued without interruption to ensure every patient has access to MDT.
- In order to ensure that all patients have access to MDT and that the progress being made towards leprosy elimination can be accurately assessed, the special initiative of leprosy monitoring (LEM) should be implemented as soon as possible.
- In view of the continued social problems faced by persons affected by leprosy, it is highly important to further intensify our efforts at creating community awareness of the disease and its curability, and to mobilize community action towards the elimination of leprosy. It is important that persons affected by leprosy be actively involved as partners in this process.

- Even as leprosy patients are being cured of the disease, many of them continue to face problems in rehabilitating and reintegrating themselves within their communities, and consequently every attempt should be made to bring persons disabled due to leprosy and their rehabilitation within the general ambit of all disabled in the community and within existing community-based rehabilitation programmes.
- At this critical stage in the progress being made towards reaching the target, there is an urgent need for all to step up the coordination and mobilization of the resources needed—finance, manpower and planning for the future. This is particularly important for all partners, including governments, international donors and nongovernmental organizations.
- It is important that research activities in leprosy be continued, especially with regard to the operational aspects, chemotherapy and treatment of complications of leprosy. The understanding of the basic biological mechanisms of this disease is important for developing potential tools that may lead to eventual eradication.
- Countries, as they reach the elimination goal at the national level, should focus their attention on the target of elimination at the subnational levels, and sustain leprosy treatment and rehabilitation activities. It is important to ensure that services are capable of continuing to detect and treat new cases, and to respond to physical and social needs faced by individuals who have been affected by the disease. The efforts to ensure elimination as a public health problem will lay the foundation for our ultimate vision of the total eradication of leprosy in the future.

#### **SHORT REPORT ON THE SECOND INTERNATIONAL CONFERENCE ON ELIMINATION OF LEPROSY in New Delhi, India, held in October 1996**

Following the resolution of the World Health Assembly in 1991 that leprosy should be eliminated as a public health problem by AD2000, the WHO launched a global drive to mobilize support and political commitment to achieve this goal. A first International Conference on Leprosy Elimination was held in Hanoi in 1994.

The Second International Conference was held in New Delhi, 1996. Its purpose was to maintain and, where possible, further strengthen the political and technical commitment in the top 24 leprosy-endemic countries to achieve the elimination goal by the turn of the century. To this extent, the Ministers of Health and Leprosy Control Programme Directors of the respective countries were invited to this high profile conference. Among the dignitaries present for some or all of the Conference were the Honourable Prime Minister of India, Mr H. D. Deve Gowda, the President of the Sasakawa Foundation, Japan, Mr Yohei Sasakawa, and the Director General of the WHO, Dr H. Nakajima. Other participants included senior representatives of ILEP member organizations, experts on leprosy and representatives from other organizations active in the field of leprosy, such as the International Leprosy Union (ILU) and IDEA. The latter is an international organization of persons affected by leprosy working on advocacy of the rights and needs of people disadvantaged in any way by the disease.

The theme of the conference was 'Reaching every patient in every village'. Country progress reports were presented by the respective Directors. This showed an invariable decline in the registered prevalence of leprosy, which was quite often not yet matched with a reduction in the case-detection rate. Overall, the MDT coverage of patients on treatment had improved dramatically in the last few years, with several countries having already reached 100%. The main reasons for patients remaining undetected or not having access to MDT included remoteness of villages and difficult terrain, lack of motivation or involvement of

peripheral health workers, migration and civil unrest, and war. Some, but not all of these problems can be overcome by carrying out Special Action Programmes for the Elimination of Leprosy (SAPEL) and/or Leprosy Elimination Campaigns (LEC). Reports on successful SAPEL and LEC campaigns, and lessons learned so far, were presented.

The International Leprosy Association (ILA), ILEP, ILU and World Bank presented their policies and programmes regarding leprosy control. Compared with earlier conferences of this nature, there was a much greater emphasis on what was called 'the human face of leprosy'. The presentations and the final recommendations of the conference highlighted the importance of prevention and treatment of impairments, disabilities and handicaps, 'normalization of lives' of persons affected by the disease through rehabilitation and community awareness and participation. The latter was considered essential to achieve not only a medical but also a 'social elimination of leprosy as a public health problem'.

Four working groups of conference participants outlined priorities in important areas such as acceleration of leprosy elimination efforts at country level, reaching patients under difficult circumstances, monitoring and evaluation, and quality patient care and community action for leprosy elimination and rehabilitation. One highlight in the resulting recommendations was to advocate a global change of terminology when talking or writing about 'leprosy patients'. The use of this term should be restricted to the medical context of a health worker-patient relationship. In all other situations, when referring to a person and when his/her association with leprosy needs mentioning, the preferred term is a 'PERSON AFFECTED BY LEPROSY'. Referring to the association with leprosy is often not necessary: one does not for example talk about 'a gallbladder patient' when referring to a member of staff who has had his gallbladder removed. In many rehabilitation situations, a description such as 'a person with disability' will be sufficient. It was felt that such a change of terminology, if applied consistently, would greatly help to reduce the stigma against persons affected by leprosy and thus help towards the social elimination of leprosy.

While the longer-term benefits of this Conference are still awaited, it seemed very successful in increasing the interest and motivation among the senior country representatives present to work on a national level towards eliminating leprosy. With this increased political will and commitment, overcoming the many hurdles that still lie on the path of leprosy elimination may well be possible.

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### **Statement on behalf of The International Federation of Anti-Leprosy Associations (ILEP)**

Dear Friends and Colleagues

On behalf of the 20 member-associations of ILEP, several of whom are themselves represented here, I welcome this opportunity to outline the current concerns and initiatives of our Federation.

## WHAT IS ILEP?

As most of you know, ILEP brings together all the main non-governmental donor agencies interested in leprosy. For them the meetings and information services of ILEP are the means to co-ordinate the support they are giving to a thousand field and research projects in a hundred and one countries.

Despite the difficult fundraising conditions of recent years, ILEP Members have been able to budget \$65.5 million for support of projects in 1996. Furthermore, at the end of 1995 projects supported by member-associations were providing chemotherapy to 450,000 patients or 49% of the world total of registered patients.

We believe these are impressive achievements for voluntary organizations. There can be few other health areas where the contribution of the non-governmental sector is so significant. And, of course, while I speak for the donor agencies who come together in ILEP, the contribution of local NGOs in endemic countries must also be recognized. It is often their activities which are supported by ILEP Members. They, as well as National Programmes, are our partners in the field.

## A COMMITMENT TO LEPROSY

The other important introductory point I would like to make is that ILEP and its member associations have a long-term commitment to work against leprosy and to respond to the needs of the individuals who have been affected by the disease.

The nature of leprosy work is changing and some of us see linkages with other health programmes such as tuberculosis as an effective way to ensure the continuance of anti-leprosy activity under conditions of low endemicity.

Nonetheless, it is clear from a survey of member-associations last year that the great majority of us are committed to anti-leprosy work as our main concern for the foreseeable future.

ILEP Members expect to be supporting work connected with leprosy well into the next century.

## THE LONG-TERM CHALLENGE

In this Conference we are discussing *Elimination of Leprosy as a Public Health Problem by the Year 2000*. We have today heard encouraging reports of progress. The prevalence target of 1 per 10,000 looks likely to be reached in many countries albeit with some gaps.

ILEP member-associations with our own target of *MDT for All* have long supported and recognized the importance of this achievement. It is a major step on the road. It means that in many areas leprosy will have been brought under control in public health terms.

But, as my predecessor, Tom Frist explained at the Conference in Hanoi in 1994, in ILEP we believe that there is a great deal more to be done.

Effective implementation of multidrug therapy is not the end of the leprosy story. Our eventual aim must be to truly eradicate this disease. But we do not yet have the tools to do it.

Beyond the year 2000 there remains considerable work to be pursued and on which I hope we will all be able to collaborate:

- Responding to the social and physical disadvantages suffered by many who have had the disease.



- Ensuring new cases continue to be detected and treated, and that there is no resurgence of the disease.
- Seeking the tools and strategies which one day will permit us to really eradicate *Mycobacterium leprae*.

With these concerns in mind, ILEP member-associations at their General Assembly in June this year adopted a statement of priorities for our Federation over the next few years. I believe it encompasses much of our view of what is important in leprosy-related activity today; so I want to read it to you in full.

*ILEP and its member-associations are determined to respond to the total and continuing problem of leprosy. The priority of the Federation, therefore, over the next few years is to assist Members as effectively as possible to achieve:*

- *Prevention of Disabilities for all people affected by leprosy.*
- *MDT for All who need it.*
- *Health services capable of sustaining cost-effective anti-leprosy activities under conditions of low endemicity.*
- *Normalization of the lives of all people who are or have been affected by leprosy. Normalization covers both physical and social rehabilitation.*
- *Continuation of essential research into leprosy, especially as regards the development of tools for prevention of the disease, ever more efficient treatment, and the prevention of disability.*

For each of the topics touched on in this statement of priorities, I would like to say some more about what ILEP is doing:

### *1 Prevention of disabilities*

- (a) It has often been said that any good leprosy control programme should include action for the prevention of disabilities. Practice, however, is often more difficult.

So this time last year ILEP undertook a survey of a random sample of projects to find out what they did and what constraints to PoD activity they faced. This was followed up by a workshop of invited experts, leading to the publication in December 1995 by our then Medical Commission of a set of **recommendations for including simple and effective PoD activities in control programmes**. These are available as a Medical Bulletin of ILEP.

I should say that we were not only telling others what they should do. One recommendation was aimed at our own Members because the survey showed we had failed to get our own detailed guide on PoD to 40% of our projects!

- (b) There is a lack of data on the scale of the disability problem in leprosy. The only hard information regularly collected is whether a patient has Grade 2 disability at the point of diagnosis. On the basis of this, WHO estimated a year ago that there are around 2 million people with *severe* disabilities caused through leprosy.

While Grade 2 data is an indicator of the effectiveness of a programme's case detection, Grade I is an indicator of those individuals who are at risk of disability due to loss of sensation. If identified, they can learn self-care and be helped to avoid ever developing serious disability.

Following advice from our Medical Commission and field testing of several possibilities, we are about to **modify the ILEP B Questionnaire and include a new question on Grade**

**1 disability.** We hope this will encourage projects to assess and record patients with Grade 1 disability as a matter of course, and take appropriate action.

## 2 *MDT for All who need it*

- (a) By the end of 1995, **87%** of patients registered in ILEP-supported projects were **receiving MDT**. We had hoped to have reached 100% by now and we are happy that is indeed the case for most projects. The shortfall relates in effect to just a handful of projects and a couple of countries.

Furthermore, the figure of **96.5%** MDT coverage for newly-detected cases shows that for all practical purposes we can say MDT is now used as a matter of course in ILEP-supported projects.

As a result, reference to monotherapy will be removed from the ILEP B questionnaire to avoid any suggestion that it could be an alternative to MDT.

- (b) Our target of *MDT for All*, however, was never intended to relate only to *registered* patients. We are very conscious that there remain many individuals who have leprosy but have not been detected.

Incidentally, we have some hesitation about the WHO estimate of 400,000 undetected cases. This seems to us to be a rather optimistically low figure. None of us can know for sure what is the reality but on the basis of experience and reports from programmes, we consider it more reasonable to think in terms of **around one million undetected cases**.

We do, however, very much welcome the new WHO target of *Treatment for Every Patient in Every Village*. That parallels our concern for **Filling the Gaps**.

We recognise the positive intentions of SAPEL projects—to get to hard-to-reach patients—and LEC campaigns to get to ‘missing’ patients in areas of long-standing leprosy control activity. Indeed, several ILEP member-associations have supported SAPEL and LEC initiatives in countries where they are active. We look forward to exploring further possibilities for collaboration in initiatives of this type.

- (c) I am sure that we all aim to bring down the number of cases of leprosy as far and as rapidly as possible. In ILEP, therefore, **we are especially interested in what is happening to incidence**. The reduction achieved in prevalence is impressive—In ILEP we have seen very near a halving of our caseload in 10 years (1985: 829,000; 1995: 449,000)—but until the number of new cases also falls it is difficult to be sure that MDT has had the impact we all hope for of limiting transmission.

The ILEP figures for newly detected cases in projects supported by member-associations show that we experienced a noticeable *increase* in numbers between 1991 and 1994. This may well have been due to operational reasons but as we have said at previous WHO meetings, it made it difficult for us to assume that incidence is indeed about to decline. However, the figures appear to have levelled out in the last couple of years. This is encouraging but still far from persuasive.

We welcome, therefore, any efforts that can be made to understand in greater depth what exactly is happening to new detections and how far changes in the numbers demonstrate a genuine drop in new infections.

## 3 *Sustaining anti-leprosy activities under conditions of low endemicity*

Even where the 1 per 10,000 target has been reached, new cases will continue to appear for

the foreseeable future. And, of course, 1 per 10,000 of the global population would still mean around 500,000 cases worldwide.

It is thus essential that health services retain the capability to detect, diagnose and treat leprosy both for the individuals affected and to avoid any danger of a resurgence of the disease.

We see this as the next major organizational challenge in leprosy. Thus, only two weeks ago, we convened in Amsterdam with the help of the Royal Tropical Institute an expert workshop to develop guidance on the process of integrating and preparing health services to sustain leprosy-related activities once endemicity is low. I believe some of those who anticipated are here today. Thank you!

We expect that the Guidelines resulting from this exercise will be published early next year. They are aimed in the first instance at ILEP member-associations and the projects they support but I believe will be of particular importance also to those of you who are managers of national programmes.

#### 4 Normalization of the lives of all people affected by leprosy

WHO tells us that some 8 million people have been cured with MDT over the past fourteen years. That is a wonderful success story but we must not forget that many of these individuals suffer social stigma or disability due to leprosy.

Indeed, a recent study by the GLRA/ALES office in Southern India found that out of 50,000 past patients followed up, 18% reported social discrimination against them because of leprosy *even though* they suffered no physical disability. A further 14% suffered *both* disability and discrimination.

As ILEP Members we believe ways must be found to ensure that all who suffer the social or physical affects of leprosy, even after completion of MDT treatment, should have access to appropriate social and medical services whether integrated or specialized. The purpose must be to help people affected by leprosy overcome whatever difficulties they face due to the disease so that their lives return to normal. We have taken a number of relevant steps recently:

- (a) As ILEP member-associations we see a need for more expert advice in the social area. We decided in June, therefore, to expand what was our Medical Commission and turn it into a Medico-Social Commission with a slightly larger membership.

The seven members have had their first meeting and elected Dr Cairns Smith as their Chair. We now look forward to a new impetus in our thinking about both the medical and the social aspects of leprosy.

- (b) I must also recommend to you the book *Don't Treat me like I have Leprosy* written by Tom Frist, my predecessor as President of ILEP, under the auspices of our then Action Group on Social Aspects. It is a very helpful explanation of the social issues faced by people affected by leprosy and of what can be done to overcome them. You can obtain copies from Talmilep at TLMI in London.
- (c) A novel initiative for us is a campaign we are undertaking to explain to other international development NGOs what is happening in leprosy today. We are *not* asking them to support leprosy work. We *do*, however, want them to be aware of the needs of people affected by leprosy so that they will ask if the community and health development programmes they support are conscious of and open to people affected by leprosy.

The leaflet we have prepared for this purpose is available from us here at the Conference, if you are interested.

### 5 *Continuation of essential research*

We have been most concerned at the disappearance of funding for research related to leprosy. Much support for research is inherent in government funding of institutions in Europe and America. That has been tailing off as they begin—we believe much too early—to think that leprosy is no longer a priority. That word ‘elimination’ does not always have a positive effect!

ILEP member-associations plan to spend \$3.7 million on research and scientific activity this year. That is helpful but does not replace the much larger sums involved in the basic salaries and buildings of research institutions.

This problem was discussed last year by both the Forum of medical advisers to ILEP member-associations and by the WHO Leprosy Elimination Advisory Group (LEAG). Since then the ILEP Medical Commission has developed advice for member-associations on what research areas are of particular importance today and seem reasonably feasible. Their advice took on board ideas from a WHO/Sasakawa consultation in Bangkok earlier this year.

In general, we believe it is essential that research continues, especially into the development of tools for:

- Prevention of leprosy.
- Yet simpler and more efficient treatment.
- Prevention of disability.

As regards prevention of leprosy, ILEP member-associations are proud to have been closely associated with the **Karonga Prevention Study** which reported a few months ago. The main source of funding for what is recognised to be one of the most careful vaccine studies ever undertaken, came from ILEP Members, led by LEPRAs.

I leave detailed discussion of the results to others but it is fascinating to see the differential impact of BCG in this population of Northern Malawi as between leprosy and tuberculosis. I look forward to hearing more regarding the implications for leprosy control of the effectiveness shown by the study of a second BCG vaccination.

In closing I want to reiterate the determination of ILEP and its member-associations both to continue work in leprosy and to do so in partnership with WHO, governments and local NGOs. The slogan of my own association, the Damien Foundation Belgium, is *To the End of the Challenge*. The job for all of us is not over until the day, still in the unknown future, when leprosy has been completely eradicated.

DR JEAN-PIERRE SCHENKELAARS  
President of ILEP

*SPECIAL ARTICLE*

## Health education to aid leprosy control in Nepal: Lepra Elective Study\*

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### Introduction

Leprosy is curable, but remains one of the most feared diseases of the Third World. This is not surprising, because the handicaps caused by untreated leprosy reduce sufferers' abilities to perform physical work and thereby to earn enough money to survive in developing countries.

Unfortunately, the potentially disastrous effects of leprosy have increased stigmatization of the disease and isolation of its victims. This means that sufferers in the early stages of the disease, suspicious of the diagnosis but fearing social isolation, are reluctant to seek help. This is a serious problem since effective management of leprosy, using multidrug therapy and techniques to help prevent disability, must be started as early as possible to prevent progression of the disease.<sup>1</sup>

In endemic areas, where the majority of cases are detected by self-reporting, it has been shown that earlier presentation of sufferers is encouraged by raising public awareness about leprosy.<sup>2,3</sup> Such health education schemes are designed to develop a high index of suspicion about leprosy among health workers and the general population and tend to concentrate on leprosy's existence as a transmissible disease, its symptoms, the need for prompt medical treatment and its amenability to cure.

In this report the authors, both final year medical students at Oxford University, have made use of an eight-week period spent on elective in Nepal to study health education and social attitudes towards the leprosy in that country.

Leprosy is a serious public health concern in Nepal and has a prevalence of over 12 per 10,000 in 19 of the country's 75 districts.<sup>4</sup> (WHO target for leprosy elimination is 1 per 10,000 by the year 2000.)

Unfortunately, the combination of tight socioeconomic limitations and unforgiving hilly terrain means that government capital available for effective public health measures and widespread health education is very limited. Resources available for leprosy control are no exception and the disease remains a major public health and social problem.

Numerous international voluntary organizations play a vital role in leprosy work in Nepal and in recent years have worked increasingly in close cooperation with the Nepali Ministry of Health and its Leprosy Control Programme. At present, Nepali policy is aimed at reducing the

\* This study was undertaken during an 8-week period as a Lepra Elective Student.

prevalence of leprosy by training local health workers about the disease and instituting widespread health education about the disease's features and the importance of early treatment.<sup>4</sup>

This report reviews current opinion about the place of health education in the control of leprosy and draws specifically from the authors experiences in Nepal.

### **Information gathering in Nepal**

Information was obtained by interviewing doctors in leprosy mission hospitals, volunteer workers at the headquarters of two leprosy relief charities and health workers in tuberculosis/leprosy health posts in three villages in the Eastern region of the country. Seven interviews were conducted by the two authors and were between 25 and 50 minutes in total duration.

The interviewing style was deliberately informal. The interviewees were asked open questions and encouraged to voice their own opinions. The interviews were designed to allow the respondents to express their ideas and to have as much free speech as possible and not to constrain them to answering set questions. The interviewees opinions on certain issues were sought in each case, as follows; How well does the local population comprehend the disease of leprosy? What are the population's attitudes towards leprosy sufferers? Has health education perceptibly changed local attitudes? and Are any local health education initiatives especially effective?

The interviewees were: Dr Mark McKenzie; Anandaban Leprosy Hospital; Dr Dhundi Raj Paudel, Chainpur Health Centre; Mr Harka Bdr Gurung, BNMT Khandbari; Mr Kirtiman Grl, BNMT Ditel; Mr DK Chapagain; Netherland Leprosy Control Project; Mr Shir Narayan Chaudhary; BNMT Bojpur; and The Director, BNMT Headquarters (East Nepal), Biratnagar.

In an attempt to provide a semiquantitative indication of social attitudes towards leprosy, a questionnaire was used whilst the authors worked with the Gurkha Welfare Trust in the Eastern Region of the country. Subjects were retired Gurkha soldiers and their families who attended Gurkha Area Welfare Centres as patients. The aims of questioning were: to establish the extent of the subjects' contact with the disease either through experience or education; to establish the understanding of leprosy as a transmissible, curable disease; and to explore attitudes towards sufferers of leprosy.

Each patient seen at the health centres was asked to help the authors by answering a few questions when their medical consultation had finished. The eight simple questions were devised in conjunction with Dr Mark MacKenzie of the Anandaban Leprosy Hospital and the authors' Nepali language teacher Mr B. Devkota. Questions were in the Nepali language and were designed to prompt simple 'yes' or 'no' answers (Table 1).

Unfortunately, despite early successes using the questionnaire in a pilot study in Kathmandu, the method did not work well in rural East Nepal where dialects are different. Out of 13 East Nepali subjects that were initially interviewed, only one was able to understand the verbal questions and give answers that the authors could confidently translate. The remaining 12 were only able to complete the questionnaire with assistance from local health workers fluent in Nepali. This requirement is a potential source of bias as there was no way to verify that their translations were accurate. In addition, the authors found that the process of asking patients several questions after their medical appointments was very time consuming and caused the clinics to run unacceptably late. This became a particular

**Table 1.** The interviews with Gurkha Welfare Centre patients proceeded as follows.*Introduction*

ma student doctor hu, mero desh belaayat ho  
[I am a student doctor, I am from the United Kingdom]

ma kustarogko/maharogko baaremaa anusandhaau gardaichhu  
[I am doing some research into leprosy]

ma tapaaillai kehprasua sodhna chaahanchhu  
[I would like to ask you some questions]

tapaaillai kustarog/maharog bhaeko chaina  
[You do not have leprosy]

*Questions*

maharogko/kustarogko baaremaa sunnubhaeko chha?  
[Have you heard of leprosy?]

kasailai maharog/kustarog bhaeko thaahaa paanubhaeko chha? (pariwaar ki saathi)  
[Do you know anybody who has had leprosy? (family or friends)]

kasaila tapaaillai maharogko/kustarogko baaremaa sikaeeeko chha?  
[Had anybody ever taught you about leprosy?]

Maharog/kustarog purnaruple niko huna sakchha?  
[Can people with leprosy be completely cured?]

Maharog/kustarog bhaeko/laageko maanchhelaai aru maanchhebhandaa taadhaa rakhnuparcha?  
[Is it important to keep people with leprosy away from other people?]

Maharog/kustarog bhaeko maanche, baseko gaaumaa, basna khatraa huncha?

Maharog/kustarog bhaeko maanche, baseko gaarmaa, basna khatraa huncha?

Maharog/kustarog bhaeko maanchelaai chhuna khatawaa huncha?

[Is it dangerous to —live in the same house as someone with leprosy?  
—live in the same village as someone with leprosy?  
—touch someone with leprosy?]

Tapaaillai kustarogiko samparkabata kustarog lagchha ki lagdina?  
[Could you catch leprosy from someone with leprosy?]

kustarog sarab ho?  
[Is leprosy a punishment from God?]

problem on days when the welfare centres payed pensions as the medical cells were already busy.

**Discussion**

## THE IMPORTANCE OF HEALTH EDUCATION IN LEPROSY CONTROL

It is now widely recognized that health education is an essential component of leprosy control:

In 1982, the International Federation of Anti-Leprosy Associations (ILEP) summarized the aims of health education as:

- to correct by dissemination of the truth in simple terms popular conceptions about leprosy and the stigma that these engender;
- to increase the index of suspicion about leprosy in first, the patient himself, so that he

seeks advice early, and second, in all medical workers, so that they consider the possibility of leprosy at an early stage in the disease;

- to create public support for leprosy patients in their efforts to obtain treatment for the disease;
- to ensure that leprosy patients maintain their place within the family and the community; and
- to show a realistic appreciation of the benefits of antileprosy treatment in preventing progress of the disease and deformity, so that patients will continue their treatment as long as is necessary.<sup>5</sup>

Lennon has argued that the first step in any successful leprosy control programme should be to overcome the stigma of the disease. He suggests that there should be an emphasis on leprosy case-finding, but that if the problem of stigma has not been addressed before leprosy sufferers are identified then results of any programme might be disastrous:

‘People will often avoid detection until their leprosy has developed into a more advanced stage, making treatment and cure more difficult’.

He suggests that if the social basis of stigma is not tackled then leprosy sufferers may become socially isolated.<sup>6</sup>

This concept is consistent with the authors’ own experiences: It is frequently the case that young Nepali women who are diagnosed as leprosy sufferers have great difficulty in finding a marriage partner. Such a woman may often only be able to marry another sufferer. The problem is made worse in Nepali society because the younger members of the typical extended family are expected not only to become self-sufficient as in the developed world, but also to support the older generations. The potential loss of earning capacity of a daughter diagnosed as having leprosy, who is unable to wed, may place considerable strain on her family. In addition, stigmas such as the misconception that leprosy is hereditary may also cause isolation of the family unit.

Thus, the social and family consequences of the disease are potentially great on the young Nepali woman and her family, and pressures on her to avoid the diagnosis are huge.

This problem is not confined to Nepal. Valencia mentions that the stigma leprosy engenders in Indonesia can result in the loss of job and family, whilst in India, female sufferers are often unable to marry.<sup>7</sup>

Sandhu has suggested that health education should become a high priority against diseases where sufferers have become a prey to social prejudices. Such prejudices are deeply engrained in culture and require education programmes to be sustained indefinitely to have a significant impact.<sup>8</sup>

Health workers interviewed in Nepal also referred to the widespread idea that leprosy is viewed as a curse or punishment from God.

Mr D. K. Chapagain, a health assistant at the Netherland East Nepal Leprosy Control Project (ELCP) in the city of Biratnagar on the Nepali–Indian border, drew a distinction between Indian and Nepali attitudes. He suggested that Hindu Indians passing through the clinic were more likely to regard leprosy as a punishment for evil acts committed in a previous life, whereas an increasing proportion of the Nepali patients regarded the disease as a medical problem. Followers of Hinduism would often avoid social contact with sufferers of leprosy, he said, not through fear of contracting the disease, but because of a belief that it was best to avoid people that had done so much wrong in a previous incarnation.

The perceived low status of leprosy sufferers in the Hindu religion is perhaps exemplified



by the fact that sufferers are not allowed to be cremated on the burning ghats on the River Ganges at Varanasi, the most holy site in the Hindu religion.

This type of religious stigmatization is well documented elsewhere: Bijleveld reports that in Indonesia, leprosy is regarded as a curse from God but points out that when challenged, no one is able to cite a passage from the Bible or Koran to support the notion of leprosy as a curse. He goes on to suggest that, religious teachings may be able to be used, with the help of local spiritual leaders, to overcome notions about health that are unfounded in the respective faith.<sup>9</sup>

Health workers interviewed at BNMT posts in Khadbari and Bojpur, two towns in the rural east of Nepal, reported that leprosy sufferers were still becoming ostracized from the community to some extent, but thought that there had been a perceptible change in attitude, with the extensive education campaign, in the last 5 years.

Their impression was that whilst the more elderly people often still regarded leprosy as a punishment from God, the younger generations had a better concept of the disease as a transmissible and curable condition. This impression is based purely on the health workers' own anecdotal experiences, but is consistent with studies in Nepal that have shown a change in attitudes and an increase in case-finding since the introduction of widespread health education schemes.<sup>10</sup>

Mr Chapagain, suggested that another explanation for what he saw as the recent destigmatization of leprosy was the recent twinning of the medical care of leprosy with tuberculosis, a disease which he feels more widely acknowledged as a medical condition. These two conditions are soon to be managed at district level by the new government employed leprosy/tuberculosis/sexually-transmitted disease (L/TB/STD) assistants supported and trained by supervisors from The Leprosy Mission.<sup>11</sup>

While reducing the stigma attached to leprosy is designed to encourage earlier presentation, education must also inform susceptible individuals about the symptoms of the early stages of the disease.

Studies to establish the level of awareness about the condition should be carried out before health education programmes begin, so that resources can be most efficiently allocated, and should be repeated to help establish the education programmes' efficacy. The vast majority of such studies relate to India, which is better resourced than Nepal, and which has a population of 928 million with the highest national incidence of leprosy of any nation in the world.

In Mangalore, Shetty *et al.*<sup>12</sup> used a survey of community knowledge and attitudes about leprosy as a basis for a health education programme there. When asked the cause of leprosy, only 8% of people (who had never suffered from leprosy) answered correctly, with 15% of those surveyed able to describe the common symptoms. A relatively high proportion (54%) believed that the disease could be spread to others, although only 19% believed that spread was 'due to close proximity with a case'. The authors of the study concluded that there was an overall lack of knowledge in the basic ideas of leprosy and the health education programme was then designed to address these points.<sup>12</sup>

A similar survey of nine villages and six urban slums in Tamil Nadu State, India carried out by the Indian Leprosy Control Programme showed that there was a high lack of knowledge about the cause of leprosy. It found that 81% of the community (non-patients) and 75% of leprosy patients had 'insignificant-to-little awareness of disease causation'. It was also found that 73% of people surveyed were against social contact with leprosy patients.<sup>13</sup>

A study of attitudes of leprosy patients done in Agra, India indicated that over 80% did

not understand the cause of the disease, and believed it to be due to past sin, fate, curse of God or other causes. The authors of the study emphasized the need for health education, saying that the low level of understanding among leprosy patients about their own condition suggested that the community's understanding would be even poorer.<sup>14</sup>

Matthews & Jesudasan surveyed the leprosy knowledge, attitudes and practices (KAP) of a community in South India before and after a leprosy health education project. The evaluation of the project showed a favourable attitude change in both the public and leprosy patient groups with the 'mean attitude score' increasing from 12% to 43% in the public and from 3% to 50% in the leprosy patients.<sup>15</sup>

### **Methods of health education**

The Nepali Leprosy Control Programme has three stated aims. The first is to reduce the incidence of leprosy to below 1 per 10,000 by the year 2000, the second to integrate leprosy care into the existing health setup, and the third to use appropriate health education media to encourage the early detection of cases.<sup>4</sup>

Health education media can be classified into basic and extended types:<sup>16</sup> Basic media are those which communicate ideas from person-to-person and person-to-group, for example, in classroom discussions and meetings. Extended media, on the other hand include books, printed matter, films, radio and the television. In the basic media setting, extended media such as posters, flashcards, pictures etc. may be a useful way of strengthening the impact of the message.

Successful health education borrows many of the principles and techniques used by commercial advertising in which a so-called multimedia approach has been found to be particularly effective. This approach aims to bombard the general public with key messages on billboards, buses, posters, magazines, television and on radio and thereby to pass on information whether the public likes it or not.<sup>17</sup>

An example of an effective multimedia approach to health education in Nepal is the Nun Chini Pani (literally 'salt sugar water') oral rehydration campaign. Radio, television, and practical demonstrations in village squares and schools throughout the country were used. In addition, posters, memory cards and leaflets giving directions on how to make the solution were distributed to households throughout the country.

The potential effectiveness of this type of multimedia approach in Nepal is suggested by the fact that at the end of the 3-year campaign, 85% of the population had heard the message, 57% could repeat the ingredients and 25% had actually used it. Also 60% reported that they had heard the message on the radio. This highly effective health education campaign was thought to be due to the continuous, rather than sporadic repetition of simple messages over a long period of time using all available media.

Crucially, it was based on well-conducted research studies into the local beliefs, attitudes and customs. It was concluded that interpersonal means of communication using practical demonstrations were by far the most effective way of transmitting the message, whilst posters, radio and television were good for creating awareness and lending authority to the health terms.<sup>18</sup>

The success of the Nun Chini Pani programme has provided an excellent model for other health education programmes in Nepal. The Leprosy Control Programme has made much use of the extended media to reach as wide a possible audience and to continuously repeat three

simple messages: leprosy can be caused . . . ; the early signs of leprosy are . . . ; and treatment can be found at . . .

The messages are reinforced by health workers in the field, by street plays performed by travelling drama groups, by printed materials distributed among literate community leaders and by being repeated again and again on the radio. It has been found that leprosy case-finding significantly increases during and after the periods of radio broadcasting of these messages.<sup>19</sup>

Interestingly, the widespread use of printed materials has not proven effective in Nepal. This is thought to be due partly to the difficulty of carrying and distributing the material and partly due to low literacy rates in rural areas. McBean has shown that visual literacy is limited to those who are already literate, thereby limiting the effectiveness of visual aids and posters.<sup>20</sup>

This is an important finding; previously, many education schemes have exclusively relied on the basic media so that a health worker might have felt his educational obligation met by simply sticking a poster on his wall. Friedericks suggests that health workers should be trained in communication skills so that they can effectively pass on information, use initiative to meet the needs of a local population and be able to effectively use extended media.<sup>17</sup>

The ELCP educates volunteer village health workers and holds workshops for village leaders. By using a combination of oral teaching with visual aids, the health workers and village leaders are taught new skills so that they become able to identify new cases and also pass on information about leprosy to village dwellers.

BNMT village health workers interviewed by the authors operate a number of interesting health education schemes at district level. Workers at Bojpur train traditional faith healers to be able to recognize the symptoms and signs of leprosy in the hope that the traditional healers will refer leprosy cases to them. Such an approach is important since traditional healers constitute a vast reservoir of healthcare manpower. In Nepal, the ratio of qualified doctors to population is 1 : 50,000, whilst the ratio of traditional healers to population in India (probably similar to the Nepali figure) is 3550 : 50,000.<sup>21</sup>

The education of traditional healers in Varanasi, India was studied in 1983 by Kaur *et al.*<sup>20</sup> Kaur's team selected 20 traditional healers using defined criteria and subjected them to five days of training about the causation, transmission, cardinal signs and curability of leprosy. In particular, the trainees were told about the misconceptions prevalent in the local community regarding leprosy. They were taught that patients with any one of the cardinal signs should be referred to the nearest leprosy clinic, but were not advised to stop any other form of treatment that they had been practising.

The researchers showed, using questionnaires, that the knowledge level of the traditional healers had significantly increased 3 months after training and that most of the new leprosy cases presenting to the clinics had been referred by the traditional healers.<sup>21</sup>

Another approach at Bojpur and in Diktel BNMT health posts is to spend time in local schools teaching children about leprosy in the expectation that they will subsequently pass on health education information to their parents. The efficacy of such an approach was studied in Tamil Nadu, India by Kumar *et al.* in 1991.<sup>21</sup> They showed that although significant improvement in the knowledge about leprosy was detectable in a leprosy-educated group of children compared to controls, no transmission of information to family members was detected in either group. The authors speculated that this failure may be explained by the fact that in the usual family hierarchy in India, the direction of knowledge flow is from elders to their offspring and not vice versa. Despite their results, they suggest that a potential for

knowledge transfer from schoolchildren to their families does exist and propose that actively encouraging the children to discuss leprosy with their parents may be effective.<sup>21</sup>

## Conclusions

Leprosy remains a serious public health concern in Nepal, where sufferers continue to be victims of social stigmatization and consequently are reluctant to be identified. Effective health education is important to encourage earlier presentation of sufferers, to educate about the disease and to create public support for the patients. Education schemes need to be well planned to suit the particular requirements of the local population and their effectiveness should be checked at intervals. Current policy in Nepal is to use a multimedia approach as well as more basic interpersonal techniques to reinforce the messages at a local level. Local initiatives encountered include interesting techniques such as teaching parents by educating their children and involvement of traditional healers.

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*SPECIAL ARTICLE*

**Leprosy in Guyana, 1990–95: Lepra Elective Study\***

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**Introduction**

Guyana lies on the north-east coast of South America and has an area of 83,000 square miles (215,000 sq km). The population estimate in 1992 was 730,000 and comprised of East Indians (50%), Blacks (36%) Indigenous Ameridian (7%) and 7% comprising Chinese, Portuguese and mixed-race people. While Guyana is geographically located in South America, it is culturally an integral part of the English-speaking Caribbean and politically and economically a member state of the Caribbean Common Market (CARICOM). For administrative and political reasons the country has been divided into 10 regions (see Figure 1), each providing primary health care services.

The last publication on leprosy in Guyana was in 1989 by Patricia Rose<sup>1</sup> and the aim of this paper is to update the situation. Leprosy in Guyana is monitored by the headquarters of the Guyana Hansen's Disease Control Programme (GHDCP) which is located in Brickdam, Georgetown. The programme started in Guyana with the establishment of the Mahaica Asylum, the first in the world, in 1958 as a refuge for poor leprosy patients. Since 1988, GHDCP has been funded by the Netherlands Leprosy Relief Association (NSL).

In 1971, a programme based entirely on domiciliary care was introduced. It is a vertically structured one functioning as an urban and rural dermatological service. Approximately 86% of the population of Guyana live in the coastal region and the clinics are located in this coastal strip except for two clinics in the mining town. There is no special clinic for leprosy control other than the headquarters office situated in the capital Georgetown. The GHDCP has embarked on a programme for the integration of leprosy into the primary health care service and leprosy work has been handed over to the various regions, with the officers at the headquarters acting as consultants.

Currently, the GHDCP has a staff complement of 13 who are well equipped to recognize leprosy (4 of the staff receive salary from NSL project funds). Except for the laboratory technician, the high turn over of staff common to other sections of the health sector in Guyana is not true for the leprosy clinic.

\*This study was undertaken during an 8-week period as a Lepra Elective Student

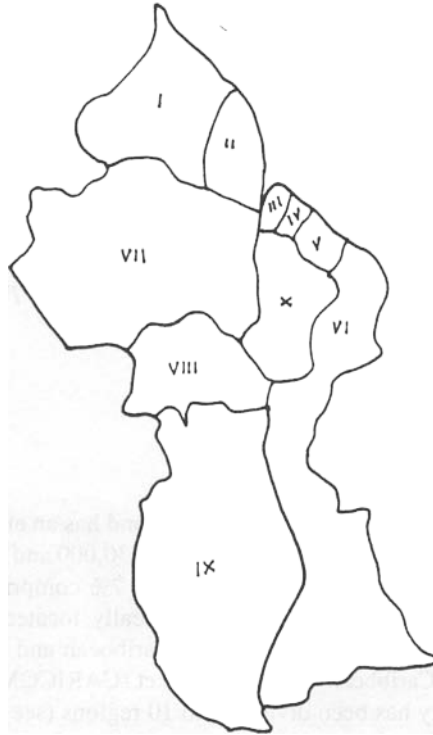


Figure 1. Political-administrative regions of Guyana

Regions	Regional Descriptions	Population (1992)
I	Barima/Waini	18,590
II	Pomeroon	42,769
III	Essequibo/West Demerara	91,328
IV	Demerara/Mahaica	297,162
V	Mahaica/Berbice	49,498
VI	East Berbice/Corentyne	142,839
VII	Cuyuni/Mazaruni	15,342
VIII	Potaro/Siparuni	5,737
IX	Upper Takatu/Upper Essequibo	15,087
X	Upper Demerara/Berbice	39,106
Total		717,458*

\* This excludes the non-household institutional population, floating population (e.g. people without a normal residence) and foreign nationals. The total of these is estimated as 13,000 bringing the total population of the country to about 730,000.

### The leprosy situation in Guyana (1990–95)

The following tables and text highlight the status of leprosy in Guyana over the last 5 years.

The incidence has been fairly constant over the last 5 years; an average of 34 new patients per year were registered with the number of males being approximately equal to that of females. The 48 patients recorded in 1992 may be a reflection of an increase in case detection activity. The higher percentage of PB cases seems to be consistent with the proposal that with an increasing tendency to eradication, more PB than MB cases will be diagnosed.

**Table 1(a).** Epidemiology of leprosy in Guyana, 1990–1995

Year	New cases	%Male	%Female	%Children (0–14)	Race				
					%B	%I	%M	%MB	%PB
1990	34	62	38	29	47	44	9	38	62
1991	36	47	53	27	58	33	9	22	78
1992	48	58	42	31	35	52	13	27	73
1993	23	30	30	30	43	35	22	39	61
1994	27	48	52	15	41	48	11	48	52
1995*	19	58	42	10	26	53	21	26	74

\* Jan–Sept data only.  
 B, black; I, East Indian; M, mixed.  
 MB, multibacillary; PB, paucibacillary.  
 Data from private hospitals and private doctors is not known.

**Table 1(b).** Incidence of leprosy per 10,000

Year	1990	1991	1992	1993	1994	1995
Incidence*	0.4	0.5	0.6	0.3	0.4	0.3

**Table 1(c).** Prevalence of leprosy per 10,000

Year	1990	1991	1992	1993	1994
Prevalence†	0.11	0.6	0.4	0.5	0.6

†The prevalence can be defined as the number of individuals with the disease in a specific time, e.g. 1 year, divided by the population at risk.

The year 1994 was better for children than the previous years as only 15% of the newly-diagnosed patients were under 14, but it is worrying that there is still active transmission in the communities. With malnutrition and poor social condition prevailing among various areas, it is imperative to have total eradication of leprosy.

The data suggest that Black and Indian people are affected equally, and generally these two races appear to be affected more than Mixed race people. These findings may reflex the proportion of the various races in the population but one needs to remember that the data from private hospitals and private doctors are not known.

All patients registered are placed on the standard WHO–MDT regimens: dapsone and rifampicin for PB and dapsone, rifampicin and clofazimine for MB. These have been found to be convenient to the patients and health workers. If patients do not report for treatment, it is

**Table 2.** Registered number of cases on chemotherapy

Years	1990	1991	1992	1993	1994
Cases	84	42	30	38	43

**Table 3.** Registered number of cases on surveillance

Year	1990	1991	1992	1993	1994
Cases	222	165	169	155	144

promptly taken to their homes or workplace. This system has resulted in the situation that many patients, especially those on long duration treatment, received their drugs at home and find it convenient not to visit the clinic.

Since the introduction of MDT in December 1981, the number of patients registered for treatment has decreased considerably. This has been mainly due to the short duration of treatment required for PB cases. Eight percent of patients on treatment live in Regions III and IV, i.e. in the vicinity of Georgetown, where patients with a dermatological (or leprosy) problem would normally attend the special dermatological service either at the Georgetown Hospital or at the Public Health Clinic.

The apparent steep fall of cases in 1991 has been as a result of 42 patients being released from extended treatment. The trend in the Guyana Hansen's Disease Control Programme was to continue to treat patients at least one year after their smears were negative or at least one year after prednisolone therapy was terminated. This was changed in September 1991, in keeping with the recommendations of ILEP (24 monthly doses of MDT for MB patients) and now PB is treated for 6 months and MB for 24 months. An average of 38 patients are now on chemotherapy each year and in 1994 Guyana records a 100% PB compliance and a 95–98% MB compliance so that almost all patients complete their regime within the specified time. The figure for the average number of patients is considered to be small and this resulted in a smaller workload and better manageability.

Patients released from treatment are placed on passive surveillance, 3 years for PB and 5 years for MB.

The surveillance figures are high in ratio to the staff complement of 13. Consequently, a system of passive surveillance was introduced and the staff lost contact with many of the patients. The strategy now is to update regularly the contact examination cards and use the opportunity to remind patients about the surveillance visits.

In 1993 five relapsed cases were recorded of which four were MB. The single PB had not been regular while on treatment. Interestingly there was no relapse when the one extra year regime was used. It is unfortunate that facilities are not available to have patients investigated as to the cause of the relapse or whether it was a re-infection.

There are now 21 residents at the Mahaica Leprosarium which is run by the Ministry of Labour and Social Services and is visited monthly by the medical officer from the Public Health Clinic. Social Impact Amelioration Programme (SIMAP) provides food for about 50 home-based former patients as well as for former residents at the Mahaica Leprosarium.

The "dole" system for a few disabled patients is in place. Some money is available from the Social Welfare Fund to buy commercial shoes for a few patients. The footwear technician

**Table 4.** Number of cases who relapsed after MDT

Years	1990	1991	1992	1993	1994
Patients	0	0	0	5	1



**Table 5.** Number of patients in care\*

Year	1990	1991	1992	1993	1994
Patients	56	56	72	70	68

\* Patients at the Mahaica Leprosarium have been included from 1992.

for the Mahaica Leprosarium died several years ago and since then there has been no provision of special footwear for leprosy patients. Currently, there may be up to 30 patients who desperately require special shoes. There is no footwear workshop in Guyana and no shoemaker from outside the country has yet visited despite numerous correspondences with Trinidad and Tobago.

An ongoing programme of ulcer care including dressing and POP casts/splints is aimed at preventing infections and disabilities.

One disabled girl has had sewing lessons but needs a sewing machine. She and one boy need hand surgery which is not currently available in the Caribbean. The leprosarium is badly in need of a library for its residents.

Most patients are found before developing grade II disability. Denial, hiding and ignorance are some of the reasons for the high proportion of disability reported in 1993. This indicates that there is still a need for education about leprosy. It has been reported that general practitioners have misdiagnosed obvious leprosy and with time the result was deformity for the patient; at least two patients had been seeing a doctor for at least three years and treated for arthritis.

About 70% of the new cases are detected through self-referral or referral from other health personnel. Area and school surveys are only carried out upon indication. For instance, following the detection of a few new patients from Fort Island in the Essequibo River, a survey of the remaining 90 inhabitants was carried out and one further new case was identified.

Generally, the programme achievement regarding case-finding has been satisfactory. More than 90% of the cases are detected before disabilities have occurred. However, some cases could be detected earlier if contact examinations are done systematically.

## Integration

The programme aims to achieve complete integration of all leprosy control activities into the

**Table 6.** Registered new cases and proportion of Grade II disability

Year	New cases	Grade II disability (%)
1990	34	6
1991	36	6
1992	48	0
1993	23	26
1994	27	0
1995*	19	10

\* Jan–Sept data only.

**Table 7.** Methods of detection (expressed as a percentage)

	1990	1991	1992	1993	1994	1995
Self referral	31	36	42	48	48	26
Contact examination	26	6	8	17	11	37
Gen health staff	41	39	27	22	18	16
GHDCP staff	6	3	10	0	15	11
Areas/school surveys	0	9	11	0	4	5
General public	6	8	2	13	4	5

\* Jan–Sept data only.

general health services of Regions II, III, IV, VI and X by the end of 1997. The pilot project in Region II (Pomeroon) was completed in 1993 and considered to be successful. Planned activities for integration in Region III and VI were carried out in 1995. Regions IV and X integration will be carried out in 1996 and 1997. There are no routine dermatology/leprosy clinics run by the leprosy staff from the Public Health Clinic in Region II. In Region III, there are three regular dermatology/leprosy clinics being held and, despite the training exercise, the 11 registered patients are still managed by the specialist visiting staff. There will continue to be regular dermatology/leprosy clinics in Region IV (Georgetown) VI and X and the leprosy clinic staff will probably, therefore, continue to manage the patients in these regions. Complete integration is unlikely to be achieved but awareness amongst health workers has been raised.

### Laboratory services

The leprosy workload in the laboratory is small (130 skin smears were examined in 1994) and the laboratory facilities at the leprosy clinic are reasonably adequate. It may be worth discussing its possible extension to other activities, such as sputum examination. At the same time the number of routine repeat smears can be reduced, in line with the guidelines in the WHO publication.<sup>2</sup> ‘‘A guide to eliminating leprosy as a public health problem’’ (WHO/LEP/95.1, Geneva, First edition 1995). (Currently, it is routine GHDCP practice for PB patients on 6 months of chemotherapy to have a skin smear at the start, at the end and yearly for the 3 years of surveillance. For MB patients the practice is for an annual smear to be taken during treatment and until the completion of 5 years of surveillance.)

The programme has suffered from a frequent change of laboratory technicians. The previous technician was accepted for entry to the medical school and a replacement technician was eventually posted and trained by the project leader. The technician normally goes on the supervision visits and takes smears as well as assisting in patient management. However, the new technician has also been recently selected for entry to the medical school. At one of the author’s time of leaving a replacement technician had not been found.

NB Biopsies are not read in Guyana; the samples are sent to the Caribbean Research Council (CAREC) in Trinidad.

## **Training and health education**

All nursing students and interns from the medical school get 2-week exposure in the leprosy clinic so that they can function in the community. Lectures are given to doctors at general medical association meetings. Patients are asked about the doctors they visited before being diagnosed and those doctors are visited and given information about the disease so that they do not misdiagnose leprosy.

There has been considerable health promotion work about leprosy. A booklet has been produced in addition to handouts, posters and stickers. Photocopies of extracts from *Partners* are occasionally used. It is proposed that a short video clip from Trinidad be shown on local television and there have been discussions regarding a locally made documentary film. Teaching about leprosy in schools is undertaken by GHDCP staff.

## **Conclusions**

We are happy to conclude that the leprosy in Guyana is well controlled and managed and that the GHDCP is well supported and functioning efficiently.

## **Acknowledgments**

This work was supported by the Netherlands Leprosy Relief Association (NSL), Lepra Medical Elective Award and St Francis Leprosy Elective Award.

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## Letters to the Editor

### COMMENT: IMPLEMENTING MULTIDRUG THERAPY IN AREAS NOT COVERED BY THE HEALTH SERVICES—SOME EXPERIENCES FROM CHAD

Sir,

After reading the article by Ahmed & El Tahir<sup>2</sup> in *Leprosy Review* we would like to share our experiences in Chad.

The Guéra Prefecture, located in central Chad, covers a population of 300,000 scattered over an area of 60,000 km<sup>2</sup>. Health services are poor, only 12 out of 32 designated health zones are covered by the health services. Even where health facilities exist, the quality of health care is often poor due to the lack of qualified staff. In addition to poor health service coverage, communications constitute a major problem. Large parts of the Prefecture are inaccessible during the rainy season.

The Guéra Leprosy and Disability Control Project (funded by The Leprosy Mission) has taken an active role in implementing multidrug therapy (MDT) within the framework of the National Leprosy Control Programme of Chad.<sup>1</sup> MDT was introduced in the Guéra in 1992. From 1992 to 1996, 545 patients (233 MB, 312 PB) have been put on MDT.

#### Methods

The introduction of MDT in the zones covered by the health services was completed in 1994. Extension of leprosy control to zones not covered by the health services commenced in 1995. This is done using an approach similar to the one described by Ahmed & El Tahir.<sup>2</sup> All the villages within a health zone are systematically visited on at least two occasions for health education about leprosy by a nonmedical worker who has been specifically trained for the task.

Meetings are held with the village headman and village elders. The following topics are addressed in the form of a guided discussion: signs and symptoms of leprosy, the availability of drugs that can cure the disease, and the importance of early detection and treatment. The village leaders are asked to encourage suspected cases to come forward and a list is established.

On a subsequent visit by the leprosy supervisor, the suspected cases are examined. Where the diagnosis is confirmed, a skin smear is done for classification and patients are put on MDT following the guidelines of the National Leprosy Control Programme.<sup>1</sup> Treatment is given in blister packs. If regular visits by the nonmedical worker are not possible, the village elders designate a person who keeps a small stock of MDT blister packs and is responsible for the monthly distribution. The leprosy supervisor visits the area about once every three months for a review of the patients and to verify that drugs have been taken correctly.

#### Results

In 1995–96 patients were put on treatment in six zones (Abrèche, Djilmi, Gassara, Katalok, Magnam and Mokofi), covering a population of approximately 45,000. A total of 133 villages were visited.

Eighty-one patients (20 MB, 61 PB) were put on MDT. Of these, 56 (69%) were new cases who had never been treated before (Table 1), 70% of all the patients were women (Table 2). Among the new

**Table 1.** Number of cases put on MDT in 1995 and 1996, all cases and new cases

	All cases			New cases			
	MB	PB	Total	MB	PB	Total	% of all
1995	13	39	52	9	24	33	63%
1996	7	22	59	5	18	23	79%
Total	20	61	81	14	42	56	69%

**Table 2.** Distribution of cases by gender

	All cases				New cases			
	MB	PB	Total	%	MB	PB	Total	%
Women	9	48	57	70%	7	36	43	77%
Men	11	13	24	30%	7	6	13	23%
Total	20	61	81		14	42	56	

**Table 3.** WHO disability grade among new cases

	MB	PB	Total	%
Grade 0	4	25	29	52%
Grade 1	0	4	4	7%
Grade 2	10	13	23	41%
Total	14	42	56	

**Table 4.** Duration of disease before diagnosis (new cases),  $n = 56$ 

<1 year	4	7%
1-5 years	21	38%
>5 years	31	55%

**Table 5.** Treatment completion rates (PB) and regularity (MB), 1995

	MB	PB
Put on MDT	13	39
Completed MDT (PB)		35
Regular (MB)	11	
% regular/completed	85%	90%

cases we found 5 children under 15 (2 MB, 3 PB). Twenty-three percent (41%) of the new cases had WHO Grade II disability on diagnosis (Table 3). Four (7%) reported that they had first noticed signs of leprosy less than a year before diagnosis, 21 (38%) had noticed the disease 1–5 years prior to diagnosis and 31 (55%) said they had been ill for more than 5 years (Table 4).

Of the 52 patients (13 MB, 39 PB) put on treatment in 1995, 35 (90%) of the PB cases have completed their treatment and 11 (85%) of the MB cases are regular, i.e. they have taken at least two out of three monthly doses (Table 5).

## Conclusions

Our results support Ahmet and El Tahir's<sup>2</sup> conclusion that involvement of community leaders in the field of leprosy is very important and that with their help MDT can effectively be implemented in areas where there is no health service coverage. This can be seen particularly in the high treatment completion rates and the low defaulter rates. However there are a number of striking differences:

The MB:PB ratios observed differ considerably (20% MB in Chad compared to 74% in Sudan). This may be accounted for in part by the fact that different classification systems (skin smear vs. clinical classification) were used.

There is a marked difference in the male:female ratios observed (44% women in Sudan compared to 70% in Chad). The relatively high proportion of women among our patients has been a constant feature in our programme since the introduction of MDT in 1992. We are not sure whether this reflects the epidemiological situation or must be attributed to other factors.

Disability rates among our patients are very high, with 41% of the new cases presenting WHO Grade II disabilities on diagnosis. This may be due to: the backlog of cases resulting from the unavailability of any treatment for leprosy for nearly two decades which leads to late detection; the fact that visible deformity, i.e. Grade II disability, is impossible to conceal from the community and, in consequence there is higher pressure for these patients to come forward; and the severe environmental conditions leading to the rapid development of secondary disability once nerve damage has occurred. We conclude that we need to intensify case-detection activities.

We are encouraged by the results and will maintain our commitment to making MDT available to all persons suffering from leprosy. However we feel that the approach described above is not without problems. By introducing MDT in areas not adequately covered by the health services we implicitly accept that we will not be able to provide treatment or care that goes beyond delivery of MDT. When complications do arise (in particular reactions and infection of wounds in insensitive hands or feet) they cannot be dealt with adequately. For any health worker who is concerned with the well-being of his patients and not only with drug delivery this experience can be very frustrating.

Considerable efforts must be made to reach these patients who live in isolated areas. At the same time we are effectively verticalizing some of our services. While this may be justified in the initial phase of MDT implementation, where caseloads are relatively high, it is hard to see how these vertical activities can be maintained as caseloads decrease. We are already facing a situation where the number of cases on MDT has halved in comparison to 1993 while the area effectively covered by the programme has more than doubled.

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## COMMENT: TRAINING NEEDS FOR PHYSIOTHERAPY TECHNICIANS

Sir,

This letter makes some additional comments to the Editorial by Dr A. C. McDougall on *Training in Leprosy*,<sup>1</sup> and the subsequent Letter to the Editor regarding this report by Dr G. Groenen *et al.* from ALERT, Addis Ababa, Ethiopia, highlighting the training needs for Africa.<sup>2</sup>

Both these articles no longer see vertical programmes as either necessary or cost-effective. McDougall gave details about the establishment of combined services with tuberculosis, skin or venereal diseases in some countries. In an event of such integration, physiotherapy technicians' skills will be under utilized as they will not be in a position to contribute to other public health problems. Therefore, they will be restricted to handling only leprosy impairments and disabilities.

It is true that leprosy work is an unfinished agenda. However, it is also true that there has been a decline in the quantity of disability. For instance, prevalence of deformities and disabilities among leprosy patients in India was 200/1000 in 1976,<sup>3</sup> and a study published in 1996 showed the prevalence rate of Grade II deformities in hyperendemic districts in India was 0.82/1000 leprosy patients and 0.22/1000 in low endemic districts.<sup>4</sup> With these low levels of caseload, the physiotherapists will handle fewer and fewer cases, despite the possible introduction of newer additional responsibilities in prevention of disabilities (POD) and home-based self-care activities; it is therefore very likely that they will still be under employed.

Needless to say that a steady flow of physiotherapy technicians in small numbers will be required much beyond the year 2000 AD. In order to meet the prevailing needs, the curriculum requires drastic alterations. One suggestion is that the detailed study of the anatomy of the face and limbs and the surgical assessments and therapies should be curtailed. Instead, combining leprosy services with a few other common disabling conditions will make the course more relevant to 'real life' conditions. This will make it easier for physiotherapists to be better prepared for integration. Also many of our leprosy physiotherapy trainees are already being forced to look for employment in small- and medium-sized general hospitals as recruitment opportunities in 'pure' leprosy control programmes have become drastically reduced. Such hospitals will prefer to offer opportunities for employment to physiotherapists with broad-based technical skills.

In India, two courses are available, which provide this kind of multispeciality training. The first offered by the Christian Medical Association of India (CMAD), which commenced in 1994, is a 2-year course entitled 'Multi Rehabilitation Work'. It offers hospital-based exposure using a curriculum that deals with 20 common disabling conditions seen in India, including leprosy.<sup>5</sup> The applied rehabilitation aspects (physio and occupational therapy) for these conditions and basic counselling skills are taught at a low-technical level. Its leprosy content deals only with POD activities. Multirehabilitation workers are trained to work in a hospital environment and their job description involves only assessment–treatment–reassessment. They do not have any managerial or educational role. After qualifying, they could work either in leprosy or at any other medical rehabilitation centres as assistants. In smaller hospitals they are expected to provide medical rehabilitation care, as the first referral.

The second is the WHO's 'Community-Based Rehabilitation Worker's Programme', which commenced in 1992, and which should be an excellent model to train field-based physiotherapy technicians.<sup>6</sup> Here, the worker's job description is: a, impairment/disability case detection; b, referral; c, community education related to disability; and d, first aid.

Our experience has shown that the large leprosy training centres, despite having the facilities and ability, will not be in a position to train multirehabilitation workers, as the number of other impairments treated in their hospitals are negligible.

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R. PREMKUMAR

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**COMMENT: LONG-TERM FOLLOW-UP OF JOINT STABILIZATION PROCEDURES IN THE TREATMENT OF FIXED DEFORMITIES OF FEET IN LEPROSY**

Sir,

We would like to make the following comments on the above article published by M. Ebenezer, S. Parthebarajan and S. Solomon in *Lepr Rev*, **67**: 126–134.

Correction of static deformities of the feet in leprosy by joint stabilization procedures helps the patient to retain his own limb with all its advantages. Yes, may be, but only in certain circumstances. When I was working in Lao PDR, several patients with severe foot deformities were referred to Thailand for ankle arthrodesis and other joint stabilization procedures. After healing they were fitted with orthopaedic footwear. These patients had already been hospitalized for long periods of time, e.g. healing of ulcers, and treatment of neuropathic feet. Together with their stay in Thailand they were often away from home for more than 2 years. Because of the poor living conditions at home the pressure to contribute to their family's upkeep, and the virtual absence of proper medical care, re-ulceration (with further destruction, infection and boneloss) started soon after returning home with inevitable outcome of amputation. Our medical 'heroics' resulted in prolonged suffering with several years of active life lost with nothing to show for it. If such patients live in protected surroundings (and do not have to work in the fields, collect water or firewood) with medical care readily available and are not too far from centres of excellence, then may be a conservative approach is warranted. But in countries with difficult terrain, poor infrastructure and a lack of proper medical services near home patients with severe foot deformities will, in most cases, be better off with an early amputation (and the fitting of an artificial limb). In Lao PDR patients still die from leprosy, may be not from the Mycobacterium, but from septicaemia from chronic infected and ulcerated feet. State of the art procedures, yes, but not in all circumstances.

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PIETER A. M. SCHREUDER

**COMMENT: THE MANAGEMENT OF ENL: CURRENT AND FUTURE OPTIONS**

The above titled Editorial<sup>1</sup> makes reference to a 'Guideline for the clinical use and dispensing of thalidomide' by Powell & Gardner-Medwin, reprinted in this issue.<sup>2</sup>



Given the legitimate and justified concerns of many clinicians and the public generally, it is commendable that such guidelines for the use of thalidomide be drawn up and strictly adhered to. However, I would argue that these guidelines are only appropriate in their current form for use in the European clinical environment where the commitment to follow and closely monitor is likely to be more effective and reliable. In other parts of the world, particularly in Brazil, the evidence in recent years of misuse and abuse of thalidomide would lead me to caution against the unquestioning adoption of such consensual guidelines as a solution per se.

Thalidomide has been shown to be effective in over 90% of Type II leprosy reactions (ENL) and this accounts for most of its current use world-wide.<sup>3</sup> In Brazil in particular there remains widespread use of thalidomide in treating ENL and it appears that guidelines for its safe use have proven ineffective. In 1994 a survey by MORHAN (Movimento de Reintegração do Hanseniano) with the support of the Brazil National Leprosy Programme showed that of 31 cases of thalidomide syndrome, 55% resulted from the prescription of thalidomide to women of child-bearing age despite prohibition of its prescription to such women since the 1980s. The other 45% of cases I assume result from thalidomide either being purchased privately or unwittingly passed on to women from male patients. Either way, guidelines to ensure the patient has full access to information were clearly not enough. In July 1994 the Brazilian Ministry of Health passed a further decree prohibiting the prescription of thalidomide to women of child-bearing age and stating that there would be no exemption from legal sanctions for any medical professional flouting this decree. The effectiveness of this decree and sanctions needs to be continuously evaluated.

R.J. Powell argues that 'it is preferable that (thalidomide's) clinical use should be regulated by guidelines rather than law.' Clearly in the Brazilian context this is not enough. I accept that it is difficult to legislate for good practice when there will always be health professionals whose standards of patient care and provision of information to patients are poor. But by legislating for prescription on a named patient basis only with obligatory written consent, some of the problems of negligent medical practice may be overcome. In any event, such guidelines would need to be adapted for a cultural context in which patients are less likely to question a health professional; or indeed may be illiterate. Much more stringent controls would need to be built in to ensure that good practice becomes the norm.

On a separate but related point concerning thalidomide, Jakeman & Smith<sup>4</sup> refer to an earlier article by Hastings,<sup>5</sup> which states that 'the teratogenic and the anti-inflammatory effects of thalidomide are separable in derivatives of the drug'. To a lay person this would seem to provide the natural solution enabling the prevention of further tragedy. My assumption as to why this option has not been taken up is that such technical development is not profitable to the pharmaceutical companies. Perhaps since thalidomide is becoming increasingly used in the treatment of AIDS-related illness this constraint of nonprofitability might be removed to the eventual benefit of the leprosy world.

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**COMMENT: SURGICAL RECONSTRUCTION OF LEPROTIC FOOT-DROP**

Sir,

It was a great surprise to learn that Bari, Islam & Haque<sup>1,2</sup> employed the two tail tibialis transfer to the toe extensors for the correction of drop foot.

I used this technique many years ago. The immediate results were uniformly good. On follow-up, however, a large proportion of these feet had developed marked, and crippling supination of the foot, while, in addition, a fair proportion of them had developed strong dorsiflexion of the toes with severe plantar depression of the metatarsal heads.

Since then I have consistently used a technique with circumtibial transfer of tibialis posterior in the direction of the insertion of peroneus brevis, while incorporating the toe extensors en route. Lengthening of tendo Achillis is performed in at same time if required.

The results, on long-term follow-up have always been consistently excellent or good.

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## Book Review

### *A Guide on Leprosy.* N. S. Dharmshaktu

The author of this Guide has been working at the National Headquarters of the Ministry of Health and Family Welfare in New Delhi, India, since 1985 and is Assistant Director of Health Services (Leprosy), in which position he has been able to study the development of the national Leprosy Control (later Eradication) Programme through the years and the growth of medical, paramedical and technical services in both government and voluntary sectors. The Guide has been written in an individual capacity and is published by a nongovernment agency, *The Indian Leprosy Foundation*, 11 Hardevi Society, Caves Road, Bombay 400 060, India. The first two pages refer to the magnitude of the leprosy problem in India, but at the same time acknowledge the remarkable success of multiple drug therapy in reducing prevalence; the number of patients on record in 1994 was 0.95 million and dropped to 0.74 million in 1995 (the latest figure from WHO, May 1996, is 0.56 million). The States of West Bengal, Uttar Pradesh, Bihar and Madhya Pradesh have the largest number of patients, followed by Orissa, Andhra Pradesh, Tamil Nadu and Maharashtra. The first six chapters cover basic aspects of leprosy, the situation in India, the role of voluntary agencies, diagnosis, classification, reactions and multiple drug therapy. Chapters 7–10 (66 pages out of a total of 131 in the Guide) are almost entirely devoted to a detailed description of the various agencies available for leprosy patients in India, including: rehabilitation services provided by nongovernment agencies and central institutions, rehabilitation of the handicapped under Ministry of Welfare/Labour, the current status of the handicapped in leprosy, and suggestions for deformity care. This information is not only remarkably up-to-date and comprehensive, but may well prove surprising to many people working in the National Leprosy Eradication Programme (NLEP) of India and voluntary agencies. How many State Leprosy Officers or other programme managers, one wonders, are aware that India has 12 institutions producing micro-cellular rubber chappals (Indian style protective footwear), plus 59 other centres which provide footwear and rehabilitation services to leprosy handicapped, 55 special cells in various states for employment of the handicapped, 23 special employment exchanges for the physically handicapped, 17 vocational rehabilitation centres for the physically handicapped and 287 voluntary organizations engaged in leprosy work?

Dr S. K. Noordeen, *WHO Action Programme for the Elimination of Leprosy*, comments on the back cover: 'I congratulate Dr Dharmshaktu for undertaking the very important task of disseminating information on the availability of services for all leprosy patients in India. This will certainly improve the utilization of such services by needy patients and peripheral workers, who are often unaware of their existence.' This Guide is manifestly of great practical value and should be in the hands, of all who contribute to the control of leprosy in India, including those who wish to pursue the concept of teaching increased responsibility and self-care to patients. The price is Rs 190 and copies are available from the address above. All proceeds go to *The Indian Leprosy Foundation* to support eradication.

A. Colin McDougall

The Indian Leprosy Foundation, Bombay, India, 1995. 132 pp.

## Teaching Materials and Services

### Schieffelin Leprosy Research and Training Centre: Karigiri, Courses for 1997\*

Course	Duration	Commencing Date	Fees		
			India Rs.	Saarc US \$	Other US \$
<b>I COURSES RECOGNIZED BY THE GOVERNMENT OF INDIA</b>					
1 Medical Officers' Course	6 weeks	Jan. 20–Mar. 1 Jul. 28–Sep. 6	1925	250	750
2 Nonmedical Supervisors' Course	3 months	Apr. 1–Jun. 30	1325	150	300
3 Physiotherapy Technicians' course	12 months	Jul. 1–Jun. 30	3000	275	700
4 Laboratory Technicians' Course	12 months	Jul. 1–Jun. 30	6000	300	750
5 Smear Technicians' Course	3 months	Jan. 13–Apr. 12 Sep. 8–Dec. 7	1500	175	350
6 Paramedical Workers' Course	6 months	Jul. 1–Dec. 31	1850	200	450
7 Shoe-Makers' Course	6 months	Jan. 2–Jun. 30 Jul. 1–Dec. 31	800	95	200
8 Diploma in Prosthetic & Orthotic Engineering	30 months	Jul. 1–Dec. 31	7500	600	1500
9 Ophthalmic aspects in leprosy	1 week	Mar. 3–8	700	85	185
10 Eye care in Leprosy	1 week	Sep. 8–13	700	85	185
<b>II OTHER COURSES OFFERED BY THE INSTITUTION</b>					
1 Medical Records Technologist	1 year	Jul. 1–Jun. 30	2575	250	600
2 Condensed Course in Leprosy	1 week	Nov. 3–8 Nov. 24–29	700	85	185
3 Refresher Course in Skin Smears	2 weeks	Apr. 21–May 3 Aug. 18–Aug. 30	1000	90	200
4 Ophthalmic Nursing care in Leprosy	2 weeks	May 19–31	1000	90	200
5 Research Methods in Leprosy	1 week	Nov. 10–15	700	85	185
6 Programme Management issues in Leprosy Control	1 week	Nov. 17–22	700	85	185
7 Training of Trainers	2 weeks	Mar. 17–29	1000	90	200
<b>III IN-SERVICE TRAINING</b>					
a) Inservice training in Med., Surgery Surgical Rehabilitation, Pathology, Lab. Technology, Ophthalmology & Epid. and Lep. Control	3 months	By arrangement	150	25 (per week)	25
		1 time payment for other amenities	100	35	7
b) Medical Record Keepers	2 months	By arrangement		Same as given above	
c) Basics of Physiotherapy in Leprosy	1 week	By arrangement		Same as given above	

\* These courses are run every year, please check dates for 1998.

Course	Duration	Commencing Date	Fees		
			India Rs.	Saarc US \$	Other US \$
d) Medical Students Course	1 week	By arrangement		Same as given above	
e) Psycho-social aspects in Leprosy	1 week	By arrangement		Same as given above	

Facilities: Hostel: 60 men, 16 women & Guest house: Single & Double Rooms.

Courses: English fluency essential. Recognized by WHO and Indian Government (all paramedical technical courses are fully recognized by the Indian Government).

Mailing Address: Director or Registrar, Training Unit, S.L.R. & T. Centre, Karigiri, 632 106, N.A.A. Dist., Tamil Nadu, S. India.

Telephone: (0416) 74227, 74229, 74251; Telegram: 'LEPSEARCH' Vellore-7; Fax: 91-416-74274 or 32103

Contact Institution: Mr T. Jayarajan, Registrar, Schieffelin Leprosy Research & Training Centre, 632 106 Karigiri, Tamil Nadu, South India. Tel.: +91/41674227, +91/41674229, +91/41674221 (Director). Fax: +91/41632103, +91/41671274.

### The London School of Hygiene and Tropical Medicine

In the context of professional partnership with the Special Programme for Research & Training in *Tropical Diseases* (TDR) issue No. 50 (June 1996) describes the main activities as follows:

The London School of Hygiene & Tropical Medicine has been a strong partner of TDR from the beginning, and staff across the School continue to be heavily involved in TDR's steering committees and in TDR projects overseas. Much of the collaboration has involved the School's strengths in laboratory research, clinical medicine, public health, epidemiology and social and economics sciences.

The School was founded in 1899, and now has four academic departments, Public Health & Policy, Epidemiology & Population Sciences, Medical Parasitology, and Clinical Sciences, with a total of 305 academic staff, of whom approximately 50% work on the tropical side. The School's mission is to contribute to the improvement of health worldwide and this is reflected in research which addresses major issues of public health in the UK, Europe and the tropics.

The School collaborates with over 300 institutions worldwide, and raises \$20 million annually through research grants and contracts. The School is keen for its overseas collaborations to result in institution building and capacity strengthening and it therefore maintains and develops long-term partnerships in research and training schemes such as those supported and encouraged by TDR.

Recent collaboration between the School and TDR is illustrated by the large-scale randomized, controlled trials of insecticide-treated nets (ITNs). Following collaborations by members of the Tropical Health Epidemiology Unit in field research in ITNs at the MRC Laboratories, The Gambia in the late 1980s, and preliminary discussions with TDR, a workshop was hosted by the School in 1991 to develop guidelines for the design of trials to assess the effect of the treated nets on child mortality. Draft project protocols were drawn up by six research groups and a further workshop was held in the School in 1992 to standardize the protocols as far as possible and finalize the designs. A coordinator, Dr Christian Lengeler, was appointed to the School for the four studies in Kenya, The Gambia, Ghana and Burkina Faso with financial support from ODA through TDR. The coordinator was initially responsible to the TDR Steering Committee on Applied Field Research in Malaria and later to the Task Force on Insecticide Impregnated Bednets and other Materials. The role of coordinator was crucial not only in assisting with the logistics of getting enough nets and insecticide to the trial sites in time for the initial distribution, but also in keeping the investigators in touch with other sites, implementing standard procedures where appropriate, and organizing football matches! In addition, a statistical epidemiologist from the School was attached to each site, to assist with aspects relating to data collection and management, and data analysis. A key role was also played by economists from the Department of Public Health & Policy in planning and supervising studies of cost-effectiveness and cost-benefit, and by entomologists from the Department of Medical Parasitology in advising on technical aspects of the intervention and monitoring of the vector.

During the progress of the trials, a number of workshops for investigators were held in Africa, covering economic issues, entomology and operational issues, and a final workshop was held in London in May 1995 to discuss strategies and methods for analysts. Since clusters of villagers were randomized to receive treated nets or no nets, the analysis of these trials has been based on the mortality rates in each cluster. The analysis of such community randomized trials presents interesting methodological problems which have been addressed by members of School staff, and which have wider application to trials of other interventions which are delivered to communities, such as improved treatment and diagnosis of sexually transmitted diseases (STD).

The School has a flourishing post-graduate teaching programme and offers Ph.D. training, 23 M.Sc. courses and a growing number of short courses. The M.Sc. programme is taught on a modular system which allows students great flexibility to choose units which reflect their training needs and interests. The student body form a truly international group, representing 89 countries in the current year. A further development to be promoted this summer is the opportunity for external participants to take individual units from the M.Sc. programme, as short courses. TDR has given training awards to many Ph.D. students over the years, and four Ph.D. are based on studies planned within the framework of the ITNs trials.

TDR has, on many occasions, encouraged the School to examine its research priorities and training portfolio. The close relationship between members of School staff and TDR continues to be fruitful and stimulating.

For further information write to: The Secretary, The London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT, UK.

### ***Illustrated history of tropical diseases, The Wellcome Trust, London***

The Wellcome Trust brochure for the above title, edited by Professor F. E. G. Cox, Professor of Parasite Immunology, King's College, London, reads as follows:

'The discovery and investigation of tropical diseases has long fascinated scientists and non-scientists alike. This meticulously researched and richly illustrated book traces the history of humankind's understanding of these diseases from the earliest written records to the most sophisticated findings of today.

Tropical disease was first recognized as a separate branch of medicine at the turn of the century and this book emphasizes the spirit and personality of those individuals who devoted their lives to understanding these diseases and working out how to treat them.

The *Illustrated History of Tropical Diseases* has been published to mark the sixtieth anniversary of the founding of the Wellcome Trust, one of the world's major supporters of research into tropical disease and in the history of medicine.

Each of the book's 41 chapters is written by a scientific expert in the field, presenting a unique historical perspective and a real understanding of the conditions described. Written for a general scientific audience, each chapter includes a brief introduction into the aetiology of the disease and includes information on its current status and treatment. This unique work will appeal to everyone with an interest in tropical diseases and their treatment.'

It is published in hardback, has 454 pp and 488 colour, and black and white images. Copies of the above can be obtained from: Publishing Department, The Wellcome Trust, 210 Euston Road, London NW1 2BE, UK. Price: £35.00 plus postage and packing £5.00 (UK), £11.50 (EU), and £15.00 elsewhere.

### ***New Manual on TB-HIV co-infection, WHO***

Sir John Crofton, Emeritus Professor on Respiratory Diseases and Tuberculosis, University of Edinburgh, Scotland, has reviewed this new Manual:

'This manual provides a pocket-sized guide to the clinical management of tuberculosis, particularly

in patients suffering from co-infection with HIV. Designed for use by busy clinicians, the manual aims to promote the best possible diagnosis and treatment in low-income countries where the prevalence of TB and HIV infection is high, case loads are heavy, and laboratory support may be limited. With these needs in mind, the manual combines the latest scientific knowledge about these diseases with authoritative advice based on extensive field experience in several of the hardest hit countries.

Throughout the manual, tables, flow charts, lists of do's and don'ts, questions and answers, and numerous practical tips are used to facilitate quick reference and correct decisions. Information ranges from advice on how to distinguish TB from other HIV-related pulmonary diseases, through a coloured score chart to aid the diagnosis of TB in children, to the simple reminder that in sub-Saharan Africa, anyone with TB is in a high risk group for HIV. Though primarily addressed to clinicians working at district hospitals in sub-Saharan Africa, the manual is also suitable for use in areas of Asia and South America where the problem of TB and HIV co-infection poses a growing clinical challenge.

The manual has twelve concise chapters presented in a convenient spiral-bound format. Background information is provided in the first chapters, which summarize basic facts about TB, HIV, and HIV-related TB, and outline a framework for effective TB control. Diagnosis is covered in four chapters, which set out detailed principles and procedures for the diagnosis of TB in adults and in children, and for the diagnosis of HIV infection in adults and in children with TB. Chapter seven presents standardized TB case definitions, by site of disease, result of sputum smear, and by previous treatment, and explains how these case definitions allow categorization of patients for treatment purposes.

Extensive treatment guidelines are presented in chapters covering the treatment of TB patients, management of the side-effects of specific anti-TB drugs, and the management of other HIV-related diseases in TB patients. The manual concludes with a discussion of the importance of coordinated care in different settings, followed by advice on the prevention of TB, including the role of BCG, in HIV-infected individuals.'

The main chapter headings are as follows:

- Diagnosis of HIV infection in adults with tuberculosis: Clinical recognition; HIV testing; Counselling.
- Diagnosis of HIV infection in children with tuberculosis: Clinical recognition; HIV testing; Counselling.
- Standardized TB case definitions and treatment categories.
- Treatment of TB patients: Mode of action of anti-TB drugs; TB treatment regimens—new cases, retreatment cases, standard code for TB treatment regimens, recommended treatment regimens, and use of streptomycin and thiacetazone in areas of high HIV prevalence  
TB treatment regimens; Use of anti-TB drugs in special situations: pregnancy, renal failure, liver disease; The role of adjuvant steroid treatment; Monitoring of TB patients during treatment; Response of HIV-positive TB patients to anti-TB treatment.
- Side-effects of anti-TB drugs: Prevention of side-effects; Where to manage drug reactions; When to stop anti-TB drugs; Side-effects of anti-TB drugs; Symptom-based approach to management of drug side-effects; Management of itching/skin rash; Desensitisation; Management of hepatitis.
- Management of other HIV-related diseases in TB patients: Sexually transmitted diseases; Skin and mouth problems; Gastrointestinal problems; Respiratory problems; Neurological problems; Fever; Other HIV-related problems which may occur in TB/HIV patients.
- Coordinated care in different settings.
- Prevention of TB in HIV-infected individuals.

*TB/HIV, A Clinical Manual* by A. D. Harries and D. Maher, with contributions from M. C. Raviglione, P. Chaulet, P. P. Nunn and E. van Praag. 1996, 135 pages (available in English; French and Portuguese in preparation). WHO/TB/96.200; order no. 1930088. Sw.fr. 12.–/US \$10.80. In developing countries: Sw.fr. 8.40.

Apply to: WHO, Distribution & Sales, 1211 Geneva, Switzerland.

### **Dermatologists in the National Leprosy Eradication Programme, India**

In *Leprosy; a glimpse at the changing scenario* published by Acworth Leprosy Hospital for Research, Rehabilitation and Education in Leprosy and Bombay, India, Dr R. Ganapati comments as follows:

'It is interesting to note that inspite of the low endemicity reported in many areas the dermatologists are encountering a large number of leprosy patients. Besides all clinical types, they seem to be dealing with even histoid forms of lepromatous leprosy which have a great transmission potential. The Government of India has done an excellent job under NLEP to make MDT available to almost all identified patients in most parts of the country. They have taken the help of several leading NGOs, both Indian and international, in this massive undertaking. The fact that progressive cases of leprosy are still reporting to the dermatologists calls for more vigorous involvement of the dermatologists of the country in the NLEP. In fact, if one can manage to count all the patients being managed by the dermatologists all over the country, the number will still be phenomenal, justifying the group of dermatologists to be considered as a major NGO. However, this group at present is not cohesive as far as leprosy management is concerned.'

For further information write to: Dr R. Ganapati, Bombay Leprosy Project, Vidnyan Bharan, 11, V.N. Purav Marg, Sion-Chunabhatti, Mumbai 400 022, India.

### **International Federation of Anti-leprosy Associations (ILEP)—membership list**

Here follows the membership list of ILEP, dated December 1996:

ILEP Secretariat and Co-ordinating Bureau, 234 Blythe Road, London W14 0HJ, United Kingdom. Tel.: 44/171-602.69.25. Fax: 44/171-371.16.21. E-mail: 100450.1011@compuserve.com.

AIFO, Associazione Italiana Amici di Raoul Follereau, 4 via Borselli, 40135 Bologna, Italy. Tel.: 39/51-44.34.02 and 39/51-61.45.437. Fax: 39/51-43.40.46. E-mail: aifo@iperbole.bologna.it.

ALES, Aide aux Lépreux Emmaüs-Suisse, 9 Spitalgasse, 3011 Berne, Switzerland. Tel.: 41/31-311.77.97. Fax: 41/31-318.08.41.

ALM, American Leprosy Missions, 1 Alm Way, Greenville SC 29601, USA. Tel.: 1/864-271.70.40 and 1/800-537.76.79. Fax: 1/864-271.70.62. E-mail: amlep@leprosy.org.

CIOMAL, Comit Exécutif International de l'Ordre de Malte pour l'Assistance aux Lépreux, 3 place Claparède, 1205 Geneva, Switzerland. Tel.: 41/22-346.86.87. Fax: 41/22-347.08.61.

DAHW, Deutsches Aussätzigen-Hilfswerk, P.O. Box 9062, 97090 Würzburg, Germany. Tel.: 49/931-79.480. Fax: 49/931-79.48.160.

DFB, Damien Foundation Belgium, Boulevard Léopold-II 263, 1081 Brussels, Belgium. Tel.: 32/2-422.59.11. Fax: 32/2-422.59.00. E-mail: damien@pophost.eunet.be.

FF, Association Française Raoul Follereau, BP No. 79, 75722 Paris Cedex 15, France. Tel.: 33/1-53.68.98.98. Fax: 33/1-48.56.22.22. E-mail: tom75@infonie.fr.

FL, Fondation Luxembourgeoise, Raoul Follereau, 151 avenue du 10 Septembre, 2551 Luxembourg, Luxembourg. Tel.: 352/44.66.06 and 352/45.78.07. Fax: 352/45.96.53.

FO, Foperda, Boulevard Léopold-II 263, 1081 Brussels, Belgium. Tel.: 32/2-422.59.39. Fax: 32/2-422.59.00.

HF, Hartdegen Fund, Reppersgergstrasse 66, 66119 Saarbrücken, Germany. Tel.: 49/681-346.18. Fax: 49/681-374.174.

ICLL, Institut Cardinal Léger Contre la Lèpre, 130 avenue de l'Epée, Montreal H2V 3T2, Canada. Tel.: 1/514-495.2409. Fax: 1/514-495.2059.

LEPRA, British Leprosy Relief Association, Fairfax House, Causton Road, Colchester CO1 1PU, Great Britain. Tel.: 44/1206-56.22.86. Fax: 44/1206-76.21.51. E-mail: 100657.2556@compuserve.com.

LWM, Leonard Wood Memorial, 11600 Nebel Street, Suite 210, Rockville MD 20852, USA. Tel.: 1/301-984.1336. Fax: 1/301-770.0580.



NSL, Nederlandse Stichting voor Leprabestrijding, Postbus 95005, 1090 HA Amsterdam, Netherlands. Tel.: 31/20-59.50.500. Fax: 31/20-668.08.23. E-mail: infolep@antenna.nl.

PLF, Pacific Leprosy Foundation, Private Bag 4730, Christchurch, New Zealand. Tel.: 64/3-3663.685. Fax: 64/3-3667.771.

RD, Red Barnet, Rantzausgade 60, 2200 Copenhagen N, Denmark. Tel.: 45/35-36.55.55. Fax: 45/31-39.11.19. E-mail: redbarn@inet.uni-c.dk.

SF, Santorio San Francisco de Borja, 03791 Fontilles Alicante, Spain. Tel.: 34/63-51.15.83 and 34/65-58.33.50. Fax: 34/65-58.33.76. E-mail: fontilles@dirac.es.

SJ, Sasakawa Memorial Health Foundation, The Sasakawa Hall, 3-12-12 Mita—Minato-ku, Tokyo 108, Japan. Tel.: 81/3-34.52.82.81. Fax: 81/3-34.52.82.83.

SLC, Le Secours aux Léproux, 1275 rue Hodge, Bureau 125, Montreal H4N 3H4, Canada. Tel.: 1/514-744.31.99. Fax: 1/514-744.90.95. E-mail: secours-lepreux@msn.com.

TLMI, The Leprosy Mission International, 80 Windmill Road, Brentford, Middlesex TW8 0QH, Great Britain. Tel.: 44/181-569.72.92. Fax.: 44/181-569.78.08. E-mail: tlmint@cityscape.co.uk.

## News and Notes

### **Global plan of action for the elimination of leprosy, updated 1996, WHO**

The Contents and part of the text of the above document (WHO/LEP/96.8) are reproduced below:

- 1 Introduction
- 2 The global strategy: 2.1 Objective; 2.2 Approach; 2.3 Targets.
- 3 Intensification of global plan for elimination: 3.1 Technical support at the country level; 3.2 Leprosy Elimination Campaigns and Special Action Projects; 3.3 Organizing supplies of MDT drugs; 3.4 Leprosy Elimination Monitoring; 3.5 Simplified disability prevention and management; 3.6 Promotion and development of community action.
- 4 Responsibilities of the national programmes: 4.1 National Leprosy Elimination Committee; 4.2 Monitoring of Leprosy Elimination; 4.3 Organizing supplies of MDT drugs; 4.4 Annual independent evaluation of the elimination programme.
- 5 The role of WHO: 5.1 Promoting the intensified elimination strategy; 5.2 Promoting a technical policy for elimination; 5.3 Implementation of Leprosy Elimination Campaigns; 5.4 Monitoring the implementation of the intensified plan of action; 5.5 MDT drug supply; 5.6 Structure and activities of WHO's Action Programme for the Elimination of Leprosy.
- 6 Additional resources needed for all planned activities
- 7 Conclusions

### ***1 Introduction***

This update to the Global Plan of Action first adopted in Hanoi in 1994 contains no major technical changes, but rather refocuses attention on the main element of that first plan, namely, the need to ensure MDT is within reach of all patients even at village level.

Over the last two years since the Plan of Action was first formulated, enough evidence has been accumulated from endemic countries to show that MDT is the most effective tool now available for eliminating the disease. Progress varies between countries depending on MDT coverage and the overall management of the national elimination programme. Data from well-organized programmes show that where MDT is properly applied, the incidence of the disease can decrease by as much as 5–10% per year. Moreover, leprosy of consequence and the number of new patients showing disabilities attributable to leprosy is also significantly decreasing. However, despite strong political commitment many endemic countries are not yet in a position to provide this very effective technology to all populations in need. This is mainly because geographic coverage of MDT services in some countries is still not wide enough, treatment is inflexible or remains too sophisticated, or is carried out only by specialised workers. What is required is a more simplified approach to treatment, making as much use as possible of general health workers at village level, and making access to MDT for the patient flexible and uncomplicated. We can no longer rely on the simple assumption that a community level 'demand' for MDT will somehow be reflected by an immediate 'supply' response from more central levels.

Rather, the best way to stimulate public awareness of the disease and the effectiveness of its treatment is to have MDT always available at a local level.

Without some new approach of this kind, there is increasing evidence to show that elimination of the disease will be difficult to achieve in some major endemic countries (or significant regions within these countries) by the year 2000. The new approach required needs to remain simple but well-organized and systematic. At its most basic, it involves developing activities to be implemented at national and sub-national levels aimed at decentralizing as much as possible the diagnosis and treatment of the disease.

There are four basic elements to this new approach: firstly, the national Leprosy Elimination Campaigns (LEC) will stimulate public awareness of the disease at the community level and help detect 'hidden' cases of consequence (i.e. MB cases and those patients with multiple lesions); second, ensuring that MDT is available and readily accessible to patients at the community level; third, Special Action Projects (SAPEL) will tackle difficult-to-access areas where normal services cannot be applied; and fourth, monitoring the impact of this approach at the community level and strengthening existing information systems so that the progress being made towards elimination can be evaluated by district, regional and national managers of the programme. This implies looking at the problem at a micro level rather than relying on aggregated data at a regional or national level, which can mask many anomalies. Because of the progress made so far, this is now considered feasible: the eventual aim being to count down the progress being made towards elimination by focusing on the individual leprosy patients themselves.

## 2 *The global strategy*

A global strategy is essential if the envisaged goal is to be achieved. Its time-limited nature warrants constant review of the progress being made and the application of flexible approaches, particularly in areas where special problems are faced. The technical basis of the strategy, as defined in 1991, remains unchanged: elimination is to be achieved by the detection of patients and their treatment with MDT. Disability prevention and rehabilitation are also important, although not directly related to the elimination goal.

### 2.1 OBJECTIVE

The global strategy aims at reducing the prevalence of leprosy below one case per 10,000 population by rapidly curing patients with MDT, reducing the transmission of *Mycobacterium leprae* in the community and thereby reducing the occurrence of physical and social disabilities related to the disease.

### 2.2 APPROACH

The major focus, at the time of first implementing the strategy, was to reach all prevalent cases with MDT and to cure them. By continuously reducing the source of infection, it was expected that transmission of the disease will be significantly reduced over a period of time. In 1996, considering that almost all registered cases have been or are being treated with MDT, the global reduction of the known prevalence pool has reached its maximum limit. Knowing the uneven distribution of leprosy and the variations of leprosy control services, it is now crucial to focus on the most peripheral levels and to plan for reaching elimination at national and sub-national levels. To progress further towards elimination, it is essential to develop new approaches aiming at diagnosing and curing the hidden prevalence. The existence of the hidden prevalence is mainly due to a) poor MDT services coverage, b) too rigid or sophisticated an approach to leprosy control, c) poor accessibility to MDT treatment.

Therefore, it is recommended that endemic countries give high priority to four major activities as follows:

- Organization of national elimination campaigns using simplified procedures for diagnosing leprosy of consequence;
- Decentralization of MDT services to the most peripheral level;
- Innovative approaches to the delivery of MDT drugs that will ensure an equitable distribution to underserved populations;
- Close monitoring and evaluation of elimination at the most peripheral level.

### 2.3 TARGETS

At the beginning of 1996, the global prevalence was about 950,000 and the annual detection around 560,000. Over the next 4 years, it is expected that 2 million patients (1.2 million incident cases and 800,000 backlog cases) have to be diagnosed and cured in order to achieve elimination. Thus, including the patients already on treatment, it is estimated that about 2.9 million patients will need MDT between 1996 and the year 2000.

It is estimated that:

- 1.25 million patients, in addition to the 950,000 already under treatment in 1996, will be treated through already existing health services, assuming that they are maintaining the same level of performance;
- 650,000 patients have to be diagnosed and treated through a campaign approach;
- 100,000 patients have to be diagnosed and treated through a SAPEL approach.

Considering that more than 95% of the patients live in 16 major endemic countries, the global plan of action aims at intensifying elimination activities for diagnosing and curing the patients as follows:

1996–2000	Estimated number of cases to be treated through existing health services	Estimated number of cases to be treated through LEC	Estimated number of cases to be treated through SAPEL	Total
<b>COUNTRY</b>				
India	1,100,000	350,000	50,000	1,500,000
Brazil	15,000	95,000	5,000	115,000
Indonesia	30,000	25,000	3,000	58,000
Bangladesh	20,000	25,000	5,000	50,000
Myanmar	7,000	15,000	2,000	24,000
Nigeria	3,000	25,000	5,000	33,000
Nepal	2,500	20,000	2,000	24,500
Mozambique	2,000	8,000	5,000	15,000
Zaire	4,000	18,000	5,000	27,000
Ethiopia	7,500	8,000	3,000	18,500
Madagascar	4,000	12,000	2,000	18,000
Sudan	5,000	8,000	3,000	16,000
Philippines	5,000	6,000	1,000	12,000
Cambodia	3,500	8,000	2,000	13,500
Guinea	4,500	7,000	1,000	12,500
Tanzania	5,000	3,000	1,000	9,000
<b>Total</b>	<b>1,218,000</b>	<b>633,000</b>	<b>95,000</b>	<b>1,946,000</b>

## 6 Additional resources needed for all planned activities

Budgetary estimates are based on the latest available information on the cost of MDT drugs and transport, and the average cost of detecting new cases through LEC and SAPEL mechanisms in 1995

and 1996. There is a considerable cost advantage to be gained if these major activities are fully funded and implemented within as short a time scale as possible (perhaps in part by a reallocation of some existing resources). This is because they will result in a reduced caseload, fewer chronic or complicated cases, and a consequent reduction in the need to fund the treatment of disabilities and rehabilitation.

Additional resource needs for 1996–2000 (Million US\$)	Country level activities	Activities supported by WHO	Total
MDT Implementation	56	4	60
Leprosy Elimination Campaigns (LEC)	182	8	190
Special Action Projects (SAPEL)	28	2	30
MDT Drug Supply & Management	25	40	65
Leprosy Elimination Monitoring and Geographic Information Systems	6	2	8
Capacity Building and Health Systems Research	2	2	4
Community action & rehabilitation of patients*	10	0	10
<b>Total</b>	<b>309</b>	<b>58</b>	<b>367</b>

\* There is only limited information on the cost of this activity. It may vary considerably from one health system to another.

## 7 Conclusions

WHO's intensified plan of action for elimination goes beyond the basic strategy first formulated in Hanoi in 1994, by aiming to extend MDT services to the community level:

- LEC will create awareness of the disease within communities, and thus accelerate the detection of 'hidden' cases of consequence;
- WHO will encourage national programmes to make MDT available and readily accessible to all patients at the community level;
- SAPEL will tackle difficult-to-access areas where normal services cannot be applied;
- the impact of this new community-based approach will be monitored at district, regional and national levels in order that progress being made towards elimination can be evaluated.

WHO believes that this community-based approach is essential, if the goal of achieving the elimination of leprosy as a public health problem by the year 2000 is to remain within reach.

For further information write to: WHO Action Programme for the Elimination of Leprosy, 1211-Geneva, Switzerland.

## Integration of leprosy elimination activities into general health services—informal consultation, WHO

The above Consultation was held in Geneva, 12–13 April 1996. The participating experts were Dr G. A. Alabi (Nigeria), Dr P. Feenstra (Netherlands), Professor J. Grosset (France), Dr A. C. McDougall (United Kingdom), Dr C. Pirayanvaraporn (Thailand) and Dr C. K. Rao (India).

The Consultation was opened by Dr S. K. Noordeen, Director, Action Programme for the Elimination of Leprosy, who said that this consultation should provide guidelines on the best approaches for involving the general health services in accelerating the progress towards the goal. He concluded by indicating that the outcome of this consultation would be considered at the forthcoming Second International Conference on the Elimination of Leprosy in New Delhi, India, in October 1996 and the ensuing meeting of the 7th Expert Committee on Leprosy, planned in 1997.

The objectives of the consultation were:

- 1 To review experiences in implementing leprosy elimination activities at the most peripheral levels.
- 2 To review the advantages and disadvantages of combined programmes as compared with integrated leprosy elimination programmes.
- 3 To identify the prerequisites, obstacles and constraints to integration of leprosy elimination activities into the general health services.
- 4 To discuss and develop approaches for accelerating the implementation of leprosy elimination activities within general health services.

The Conclusions and Recommendations were as follows:

Because the goal of eliminating leprosy as a public health problem is a feasible one and because MDT (in blister packs) is a robust technology capable of being applied by minimally trained health personnel, the Consultation concluded and recommended that:

- 1 MDT should be available in all health facilities in endemic areas after appropriate preparation, and the general health service personnel should also participate in case detection and treatment activities. They should be supported by referral services at district and regional levels. Technical supervision from upper levels has to be ensured to support health staff. General health supervisors should be involved in technical supervision.
- 2 Technical procedures for diagnosis, classification, treatment delivery, case-holding, recording and reporting have to be simplified. Similarly, monitoring of leprosy elimination activities has to be simplified using only crucial indicators.
- 3 Community demand and pressure should be created and sustained through professional approaches, (e.g., social marketing) and local strategies in order to achieve leprosy-free communities. The patients and general health workers who are also members of the community should be involved in the community action.
- 4 For leprosy elimination to be achieved, the utmost emphasis should be placed on full participation of the general health services. There is, therefore, no need for exclusive vertical or combined vertical (e.g., TB/LEP) programmes.
- 5 The training of general health workers should be brief and task-oriented to ensure acquisition of the specific skills required. On-the-job training by technical supervisors to enhance performance should be emphasized. Training should be supplemented by simple manuals and other education materials.

Document number: WHO/LEP/96.1. For further information write to: Action Programme for the Elimination of Leprosy, WHO 1211-Geneva, Switzerland.

### **Further decline in leprosy prevalence, *LEPNews*, WHO, June 1996**

The following is taken from the opening page of *LEPNews*, Vol. 5, No. 2:

The number of registered leprosy cases in the world has fallen below one million for the first time since global statistics on the disease began to be collected. This suggests convincingly that WHO's strategy for eliminating leprosy as a public health problem is well on track. WHO's Action Programme for the Elimination of Leprosy (LEP) gives the figure for registered cases as 926,259, to make a global prevalence of 1.67 cases per 10,000 population.

In fact, the overall prevalence of leprosy, which declined by 27% between 1994 and 1995, has fallen by a further 28% between 1995 and this year. Over the past ten years, the world's leprosy burden has been reduced by 83%.

Moreover, 91% of the cases now have access to multidrug therapy (MDT), a figure which compares with only 55% of cases in 1994. The cumulative total of leprosy cases so far cured by MDT stands at around eight million. The increased coverage can mainly be attributed to the efficacy and acceptability to patients of this treatment, which is now fully standardized and of fixed duration. The number of

treatment failures or relapses remains very low, and drug resistance to MDT has never been reported. The supply of adequate quantities of drugs at the peripheral level, together with treatment free of charge, can also be credited for the high level of compliance. Better coverage with MDT has in turn led to improved case detection, and the large backlog of leprosy patients waiting for appropriate treatment has been significantly reduced.

Detailed figures for the estimated cases, registered cases and MDT coverage region by region, as well as details for the top 16 endemic countries and for other countries with more than 100 registered cases, were given in WHO's *Weekly Epidemiological Record* (Vol. 71, No. 20) dated 17 May 1996.

Against these encouraging figures must be set the fact that, in a few high-endemic countries, substantial numbers of patients still do not have easy access to diagnosis and treatment. Many live in such remote areas that they may not even be aware that leprosy is a curable disease. This could hamper the attainment of WHO's goal of eliminating leprosy as a public health problem by the end of the year 2000.

Once the prevalence has fallen below 1 case per 10,000 population at a national level, WHO and its partners working in this field will direct their attention to reducing the number of cases at sub-national levels.

Over half a million new cases are being detected each year, and these detection rates are particularly high in some countries or in areas within countries. WHO says that the extent to which this reflects a high level of disease transmission is not clear, but those countries or areas will clearly have difficulty in reaching the elimination target on time and will need special attention.

Leprosy remains a public health problem in 60 countries or areas, but 16 countries contribute to about 90% of the leprosy problem in the world. India heads the list with 560,000 registered cases, far ahead of Brazil with 95,564. Then follow Indonesia, Myanmar, Nigeria, Nepal, Bangladesh, Philippines, Mozambique, Ethiopia, Zaire, Madagascar, Sudan, Tanzania, Guinea and Cambodia.

WHO concludes that the elimination strategy has already had a significant impact in terms of a dramatic and constant reduction in morbidity, increased priority accorded to leprosy control activities in more endemic countries, free supply of MDT drugs through WHO to the countries in need, and focused attention on difficult-to-reach populations. But all these direct benefits of the strategy should not obscure the fact that considerable challenges remain, and continuing resources—both human and financial—are still needed, if the goal is to be attained by the end of the century.

For further information write to: WHO Action Programme for the Elimination of Leprosy, CH-1211 Geneva, Switzerland. Fax 41 22 791 4850.

## **Strategy for the elimination of leprosy from Maharashtra, India by the year 2000, June 1996**

We thank Mr S. S. Naik for supply the following the report:

A seminar on 'Strategy for the elimination of leprosy from Maharashtra by 2000 AD' was organized by Acworth Leprosy Hospital, Society for Research, Rehabilitation and Education in Leprosy and held on 10 June, 1996.

The Seminar was Chaired by Dr J. A. Ponniah, NLEP Consultant, State of Maharashtra and the resource persons included Dr R. Ganapati, Member, Maharashtra State Leprosy Council, and Dr J. T. Kale, JT Director of Health Services Leprosy, State of Maharashtra.

About 45–50 delegates representing State Government, NGOs in leprosy, staff and students from the medical colleges participated in the seminar.

After extensive scientific deliberations the following points were recommended:

1 As the operational experiment in the hilly terrain of Panvel was highly successful, it was recommended that similar strategies may be developed and worth emulating in other parts of the districts of Maharashtra that are difficult to access.

2 It was also recommended that in some of these districts certain community volunteers may be identified and trained in diagnosing leprosy.

3 It was recommended that in urban areas, smear facility provision be started for the city of Greater Bombay with the active assistance of staff from ADHS, to the practising dermatologists. It was decided to set up a pilot scheme in one suburb of Greater Bombay, after identifying a group of practising dermatologists.

4 On involvement of associations like the Indian Medical Association, it was recommended to avail the assistance of the leprosy wing (to be started) of the Indian Medical Association for case detection, referral of cases for research etc.

5 It was recommended to have a separate strategy for certain tribal population of Maharashtra, namely advance dispensing of blister-calendar packs to the patients.

### **Acworth Leprosy Hospital Society, 25th Anniversary**

This 52-page report shows the wide range of activities undertaken in research, rehabilitation and education in leprosy undertaken by the Society from 1970–1995. Copies are available from: Dr S. S. Naik, Acworth Leprosy Hospital, Wadala, Bombay 400 031, India.

### **Tropical Medical Resource, The Wellcome Centre, London**

The August 1996 issue of *Focus*, a bulletin from Tropical Medicine Resource (TMR), describes the development of material on leprosy:

Few diseases have evoked more fear (by its more mention) or despair (by its cruel disfigurement and social rejection) than leprosy. Today, as the worldwide prevalence of this disease declines, 75% of an estimated total of 1.8 million people afflicted with leprosy are benefiting from multidrug therapy. Although many questions about leprosy remain, it provides a good epidemiological model for the elimination of a disease. Indeed, the World Health Organization (WHO) aims to 'eliminate' leprosy as a public health problem by the year 2000 ('elimination' is defined as a prevalence of less than 1 case per 10,000 of the population). However, leprosy will continue to cause significant global concern long after the millennium. Relapse and residual disability are just two considerations.

The TMR Leprosy Information/Training Resource will help maintain professional and public awareness of the disease to assist the elimination process. The Project, with Dr Simon Cathcart as task editor/cataloguer, will offer a comprehensive collection of catalogued images and related interactive tutorials.

The WHO will help appraise the completed materials (estimated production time, 12–18 months). The Project will reflect international interest and collaboration between TMR and specialists working in the UK (including several from the London School of Hygiene and Tropical Medicine) and overseas, for example:

#### THE NETHERLANDS

Ms Helga Dietrich (Nederlands Leprosy Relief Association) and Dr Peter Lever (Dutch Tropical Institute) viewed the TMR leprosy images and CD-ROM in London last October. Simon is collaborating with Dr Lever, to catalogue images gathered by the late Professor Dick Leiker. Appropriate examples will be included, with due credit, in the TMR leprosy archive.

#### INDIA

In January, Simon diverted from a holiday in India to visit the Schiefflin Leprosy Research and Training Centre at Karigiri. The centre—under its Director, Dr P. S. S. Sunder Rao—combines a 200-bed hospital with rehabilitation, research and training facilities. Mr Timothy ffytche (Consultant



Ophthalmic Surgeon) is helping TMR with the leprosy project training courses at Karigiri. The Centre's video unit, managed by Mr Michael Joseph, produces excellent audiovisual materials for a wide range of local and overseas leprosy training programmes.

The WHO is funding new leprosy treatment trials around Karigiri. However, the local population has a poor understanding of both the recognition and transmission of leprosy and of basic healthcare. Dr Kumar Jesudasan (Head of the Department of Epidemiology at the Centre) expressed interest in using TMR materials to help local medical officers and health workers develop community health education/public health programmes. The leprosy project is thus providing opportunities to develop valuable professional networks and address fundamental issues in public health.

For further information write to: Dr Simon Cathcart, TMR, 210 Euston Road, London NW11 2BE, UK. Fax 44 171 611 8270.

## **XV International Leprosy Congress, Beijing, China, September 1998**

Basic concept and framework:

The XV International Leprosy Congress in Beijing, to be held in September 1998, may be termed a '*Centennial Congress*,' signifying the end of the first century of modern leprosy control. This century was initiated by the first Congress in Berlin in 1897 and, hopefully, will achieve the 'Elimination of leprosy as a public health problem.' This achievement will signal the start of the second century of our modern fight against the disease which should culminate in the total eradication of the disease and its consequences. Eradication means elimination of not only the disease itself but, also, of all the adverse effects of the disease, including the social problems faced by 'people affected by leprosy.'

Therefore, the Congress is being organized under the heading of '*Working Toward a World Without Leprosy*,' not just hoping but actually intending to achieve that final goal sometime during the next century.

The Congress will deal with leprosy and its problems from a holistic point of view, and try to come up with some practical, appropriate solutions in a closely-integrated manner.

The whole programme of the Congress, including keynote speeches, open panel discussions, workshops, question-and-answer sessions in plenary, oral presentations of individual papers in separate sessions as well as poster presentations and other exhibits, have been planned with this approach in mind.

The date of the Congress of six working days is currently fixed as from *Monday 7 September to Saturday 12 September 1998*. The venue will be the *Beijing International Convention Centre* with accommodation at the adjacent Continental Grand Hotel. Both are located well within the city on the 4th Ring Road of Beijing, less than half an hour from the airport by direct highway link, and about 20 minutes by car from Tian An Men Square, the centre of the city.

The Congress is being arranged quite differently from previous Congresses. Four main changes are proposed: 1, no more pre-Congress workshops; 2, much less time for oral presentations of individual papers; 3, much more provision for poster presentations; 4, much more time to be spent in plenary sessions. There will be short teaching sessions on 10–12 subjects on three or four evenings. The plan reflects the four main characteristics of the XVth Congress which are: '*Integrated*,' '*Action Oriented*,' '*Interactive*,' and '*Participant Friendly*.'

The *first official announcement of the Congress*, a one-page flier with dates, venue, and a broad outline, will be sent out *later this year* without details such as daily programmes, which will appear only in the *second/final announcement* scheduled to be published in *October 1997*.

In addition to the daily programmes, we have discussed some other relevant matters as follows: The expected number of *Participants*, 800–1000 overseas plus 300 Chinese. The *Registration fee*, US\$250 or less. *Accommodation cost*, with more than 10% annual inflation, the cost of living is increasing rapidly, but we are hoping to settle on US\$100 per twin bedroom for two persons per day. *Language*, English only with Chinese translation as required. *Schedule* of events related to the preparation of the

Congress: Joint consultation with Chinese Organizing Committee in September 1996. Second Organizing Committee meeting in April/May 1997 to decide the details of the programme, selection of people for key roles, such as keynote speakers, moderators and members of open panels and workshops, teachers for short-course sessions, etc. Closing of Abstract submission, end of March 1998. Third Congress Organizing Committee Meeting, June 1998.

### **Robert Cochrane Fund for Leprosy**

The Fund, in memory of the great leprologist Robert Cochrane, is administered by the Royal Society of Tropical Medicine and Hygiene. It is to be used to finance up to three travel Fellowships each year, to a maximum value of £1000 each.

The Fund will support travel for:

Leprosy workers who need to obtain practical training in field work or in research.  
Experienced leprologists to provide practical training in a developing country.

There is no restriction on the country of origin or destination providing the above requirements are fulfilled.

Application forms are available from the Society and completed forms must be received by the Society at least six months ahead of the proposed visit. All applications must be sponsored by a suitable representative of the applicant's employer or study centre, and agreed by the host organization. A two-page report on the travel/study should be submitted to the Society within one month of the recipient's return.

Apply: Robert Cochrane Fund for Leprosy, Manson House, 26 Portland Place, London W1N 4EY, UK. Tel: 44 171 580 2127; fax: 44 171 436 1389.

### **American Lung Association & American Thoracic Society Conference, May 1997, USA**

The above Conference is to be held in San Francisco, USA, 16–21 May 1997. Vital information on the prevention, control and management of lung disease will be presented in a variety of symposia and workshops. For more information write to: 1997 International Conference, ALA/ATS, 1740 Broadway, New York, NY 10019-4374, USA.

### **Where are we in the fight of leprosy approaching 2000? April 1997, Turkey**

The above Conference is to be held 27–30 April 1997 in Istanbul, Turkey. The guest speakers include: J. G. Andersen, J. W. Brandsma, T. ffytche, S. D. Gokhale, M. Kararcorlu, K. U. Kiran, A. C. McDougall, S. K. Noordeen, T. Ozkan, T. J. Ryan and T. Saylan.

All workers who have spent the last 20–30 years in the fight against leprosy and invited to discuss the past, present and the future of the struggle. If you wish to participate contact: Dr Tulay Cakiner, Istanbul Lepra Hastenesi, Bakirkoy, 34747 Istanbul, Turkey. Tel: 90 212 575 25 75; fax: 90 212 583 00 86.

### ***Leprosy Review* posters: Immunology**

The A3 poster enclosed with this issue of *Leprosy Review* is the third in a series of four covering important areas of management and research in leprosy and is distributed free to subscribers to the Journal.

We hope subscribers will find these posters informative and useful. Displayed prominently in clinics, they should serve as a useful teaching resource and aide memoire for all those involved in the treatment of leprosy and its reactions and in prevention of disability work.

We would welcome feedback and comments (to the Editor please) on this series and suggestions for future topics. Additional copies of the poster in this issue and those in future issues will be available from LEPRA, Fairfax House, Causton Road, Colchester CO1 1PU, England.

## Instructions to Authors

Papers submitted for publication in *Leprosy Review* should be sent to the Editor, Dr Diana Lockwood, LEPR, Fairfax House, Causton Road, Colchester CO1 1PU, England. The name(s) of the author(s) and the place where the work was done should be clearly indicated below the title of the paper. Degrees and diplomas are not to be included.

It is understood that the paper is offered to *Leprosy Review* alone, that it will be subject to editorial revision, and that its copyright becomes the property of LEPR. Manuscripts should be typewritten, in double spacing, on one side of A4 (297 × 210 mm) paper, with wide margins (4 cm all round). Contributors must send three complete copies of the text, tables and figures. On a separate sheet give the title, short title, name and postal address of the author, together with the name of the institution where the work was done. Abbreviations of titles of journals should follow the list of journals indexed in *Index Medicus*. References to books should include the editor(s), publisher and place of publication. Once manuscripts have been accepted a copy on disk that matches the hard copies exactly would be very much appreciated.

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*Proofs* are submitted to authors for immediate return by air.

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