

## 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.

### Acknowledgments

I thank Mr Neil Alldred, Dr Pieter Feenstra, Dr Guido Groenen, Ms June Nash and Dr Ad de Rijk for their helpful comments.

*Leprosy/TB Control Division*  
ALERT  
PO Box 165  
Addis Ababa  
Ethiopia

PAUL SAUNDERSON

### References

- <sup>1</sup> WHO. Tuberculosis: a global emergency. *World Health Forum*, 1993; **14** (4): 438.
- <sup>2</sup> de Rijk A. Combining tuberculosis and leprosy services in one programme. *Ethiop J Hlth Dev*, 1984; **1** (2): 37–43.
- <sup>3</sup> Feenstra P. Leprosy control through general health services and/or combined programmes. *Lepr Rev*, 1993; **64**: 89–96.
- <sup>4</sup> Saunderson PR. The 20th Kellersberger Memorial Lecture, 1994. Leprosy and tuberculosis combined programmes: an uneasy partnership? *Ethiop Med J*, 1994; **32**: 269–280.
- <sup>5</sup> Lockwood DNJ, Saunderson PR. Harnessing the strengths of the leprosy programme to control tuberculosis. *Brit Med J*, 1995; **311**: 862–3.
- <sup>6</sup> van Wijnen A. 1996, personal communication.
- <sup>7</sup> Karonga Prevention Trial Group. Randomised controlled trial of single BCG, repeated BCG, or combined BCG and killed *Mycobacterium leprae* vaccine for prevention of leprosy and tuberculosis in Malawi. *Lancet*, 1996; **348**: 17–24.
- <sup>8</sup> Rieder HL. Commentary: Repercussions of the Karonga prevention trial for tuberculosis control. *Lancet*, 1996; **348**: 4.
- <sup>9</sup> Lockwood DNJ, Pasvol G. Recent advances in tropical medicine. *Brit Med J*, 1994; **308**: 1559–62.
- <sup>10</sup> Becx M. 1996, personal communication.
- <sup>11</sup> Mbambo JJM. 1996, personal communication.
- <sup>12</sup> Vranken P. 1996, personal communication.
- <sup>13</sup> Enarson D. The IUATLD model National Tuberculosis Programmes. *Tubercle Lung Dis*, 1995; **76**: 95–99.
- <sup>14</sup> Lever P. 1996, personal communication.
- <sup>15</sup> Feenstra P., 1996, personal communication.

- <sup>16</sup> Smith WCS. Prevention of Disability in leprosy—ILEP Medical Bulletin. *Lepr Rev*, 1996; **67**: 68–72.
- <sup>17</sup> Davies HTO, Crombie IK. Assessing the quality of care: measuring well supported processes may be more enlightening than monitoring outcomes. *Brit Med J*, 1995; **311**: 766.
- <sup>18</sup> Sudre P, ten Dam G, Kochi A. Tuberculosis: a global overview of the situation today. *Bulletin of WHO*, 1992; **70**: 149–59.
- <sup>19</sup> Gangadharam PRJ. Chemotherapy of TB under programme conditions. *Tubercle Lung Dis*, 1994; **75**: 241–244.
- <sup>20</sup> WHO. Report of an informal consultation on integration of leprosy elimination activities into general health services. 1996; WHO/LEP/96.1. Geneva.
- <sup>21</sup> Feenstra P. Sustainability of leprosy control services in low-endemic situations. *Int J Lepr*, 1994; **62**: 599–608.
- <sup>22</sup> WHO. Tuberculosis control and research strategies for the 1990s: Memorandum from a WHO meeting. *Bulletin of WHO*, 1992; **70**: 17–21.
- <sup>23</sup> Raviglione MC, Snider DE, Kochi A. Global epidemiology of tuberculosis. *JAMA*, 1995; **273**: 220–26.
- <sup>24</sup> Zielhuis L. 1996, personal communication.
- <sup>25</sup> Nordeen SK. Eliminating Leprosy as a public health problem: why the optimism is justified. *Int J Lepr*, 1995; **63**(4): 559–66.
- <sup>26</sup> Feenstra P. Will there be a need for leprosy control in the 21<sup>st</sup> century? *Lepr Rev*. 1994; **65**: 297–99.
- <sup>27</sup> Hellberg H. Tuberculosis programmes: fragmentation or integration? *Tubercle Lung Dis*, 1995; **76**: 1–3.
- <sup>28</sup> Warndorff JA. Attempts at integrating the training in leprosy and tuberculosis: experience, problems and prospects. *Ethiop J Hlth Dev*, 1984; **1** (2): 45–47.
- <sup>29</sup> Groenen G, Alldred N, Nash J. Comment: Training in leprosy: the training needs for Africa and the role of large training institutions. *Lepr Rev*, 1996; **67**: 148–50.
- <sup>30</sup> Styblo K. The Kellersberger Memorial Lecture, 1982. Tuberculosis and its control: Lessons to be learned from past experience and implications for leprosy control programmes. *Ethiop Med J*, 1983; **21**: 101–22.