Summary of the report

Introduction

Tremendous progress has been made in the control of leprosy, particularly since the adoption of multi-drug therapy (MDT) as standard treatment policy. However, despite a dramatic reduction of the number of leprosy patients registered for treatment, the number of newly detected cases at the global level has not shown a comparable decline. Moreover, other problems remain to be solved. In recent years, a number of new technical policies aimed at simplifying the diagnosis and treatment of leprosy have been recommended for application in the field. The implications of some of these policies appeared to require further discussion, in the light of evidence from research. To accomplish this, the International Leprosy Association (ILA) organized a Technical Forum, consisting of 16 experts in leprosy from 11 countries, to review critically the strategic issues related to leprosy control and the major technical policies being applied in the field.

Methods

An organizing committee developed a set of questions addressing important issues in the field of leprosy. A systematic search of the literature was carried out, using these questions to define the parameters of the search, and searching four health-related bibliographic databases covering the literature from the year 1966 onwards, as well as the bibliographies of papers already identified and the ‘gray literature’, and contacting key researchers.

Some 7000 titles and abstracts were read, from which more than 800 studies were selected as relevant. The critical studies have been graded in terms of the strength of the evidence, based on an objective assessment of the design and quality of each study, and a subjective judgment of the consistency, clinical relevance and external validity of the entire body of evidence. The Forum has produced evidence-based recommendations for leprosy control activities (graded EB). For those issues for which evidence was found to be lacking, the Forum has produced recommendations based on best practice (graded BP). Finally, the Forum has identified those areas requiring further research (graded R).

Conclusions and recommendations

GLOBAL SITUATION OF LEPROSY

Actual prevalence is likely to differ significantly from available figures, which are based on the patients registered for treatment. In addition, there are many people living with the
consequences of leprosy. Despite a dramatic reduction of the number registered cases, the global new-case detection-rate has not declined. Furthermore, there is no evidence that, once a predefined level of prevalence rate is reached, leprosy will necessarily die out.

It is very likely that significant numbers of new patients will continue to present for many years. Thus, it is essential to ensure that leprosy control activities be sustained, even in countries or areas that have officially reached the elimination target (BP).

**DIAGNOSIS AND CLASSIFICATION**

Approximately 70% of leprosy patients can be diagnosed by means of the single sign of skin patches with sensory loss, and this sign of leprosy should be taught as widely as possible. However, 30% of patients, including many multibacillary (MB) patients, do not present with this sign. Enlargement of one or more nerves is an important additional sign, to be supplemented by skin smears, if these are available and of assured quality. This has implications for training: peripheral health workers should be taught to suspect leprosy, by becoming familiar with the typical appearance of leprosy skin lesions. Patients with suspicious lesions that are not anaesthetic should be referred. Health workers at the first referral level must be able to diagnose almost all cases of leprosy among suspects referred to them (EB).

The skin smear remains the most accurate means of classifying leprosy in the field. In practice, however, classification can be based on counting the number of skin lesions: paucibacillary (PB) ≤5 patches; MB >5 patches (EB).

Further research into easily applicable and cost-effective tests that would be useful for identifying *Mycobacterium leprae* infection and diagnosing leprosy should be continued (R).

**CHEMOTHERAPY**

The 24-month MDT regimen for MB patients and the 6-month regimen for PB patients have been found to be highly effective for routine application in the field (EB). Currently, almost all MB patients are being treated by 12-month MDT; however, very little information is available regarding the rate of relapse among patients treated by this regimen. Therefore, field programmes with adequate facilities should monitor the relapse rates. Surveillance among relapsed patients for the emergence of rifampicin resistance should be carried out by special centres (R).

Although a shorter, common regimen for both PB and MB leprosy is desirable, such a regimen must first be studied in controlled trials, with relapse as the outcome, before it can be implemented (R).

Nerve function should be included as an outcome measure in chemotherapy trials in leprosy (R).

The system for delivery of MDT should be patient-friendly. Flexibility is important, but regular contact between the patient and the health worker should be maintained. Only in exceptional cases, in which the patient cannot be seen monthly, should more than a 1-month supply of MDT blister packs be provided (BP).

Health workers should actively trace absentees and encourage them to complete their treatment as early as possible, instead of passively awaiting their return and removing them from the register as defaulters after an absence of 12 or more consecutive months (BP).
Early diagnosis of leprosy and treatment with MDT reduces the frequency of nerve function impairment (NFI). However, MDT will not prevent all NFI, and the magnitude of the impact of MDT on NFI is dependent on early case-detection and treatment (EB).

During MDT, nerve function should be assessed regularly using standard methods. PB patients with existing NFI and MB patients should be carefully monitored for new NFI, as they are at greatest risk. Steroids are recommended for the treatment of reactions and NFI of recent onset; the expected recovery rate for nerve function is approximately 60% (EB). Relevant training and a supply of steroids should be assured.

Research is recommended to identify the optimal steroid regimen, to develop alternative and more effective treatments for reactions and recent NFI, and to determine indications for treatment. Further research is recommended on the use of prophylactic steroids in preventing NFI (R).

Teaching and empowering patients in self-care is an effective activity, which should be part of all leprosy programmes. The use of locally acceptable, appropriate footwear is a cost-effective intervention for those with loss of plantar sensation (EB).

Socio-economic rehabilitation, which requires participation by client, family and the community, is valuable for selected clients, and is best delivered through general, community-based rehabilitation programmes (BP).

Epidemiology and Organization of Leprosy Services

There is no consistent evidence that the introduction of MDT has accelerated the decline of the incidence of leprosy. Whereas early diagnosis and regular treatment by MDT will remain the cornerstones of leprosy control for the foreseeable future, additional strategies should be developed, based on better understanding of the epidemiology of the disease (R).

Vaccination with BCG as part of childhood immunization must be continued in countries in which leprosy still exists. Repeated BCG might be considered for individual protection of contacts of leprosy patients (EB).

Because chemoprophylaxis with dapsone has been shown to be an effective way to reduce the incidence of leprosy, particularly among household contacts, the possible role of chemoprophylaxis based on bactericidal drugs should be further studied (R).

More research is needed, particularly on transmission of *M. leprae*, the role of subclinical infection, progression from infection to disease, and trends of incidence of the disease, including the impact of MDT (R).

Prevalence alone is of limited value as an indicator of leprosy control. The new-case detection-rate may be a better indicator; this rate should be analysed in conjunction with other indicators. The treatment completion rate is an important indicator of the effectiveness of patient management (BP).

To guarantee sustainable leprosy services, leprosy control programmes should be integrated within the general health services. The process of change from a vertical to an integrated programme should be carefully planned and adapted to the local situation. An uninterrupted supply of anti-leprosy drugs must be guaranteed. Field procedures, including recording and reporting, must be simplified (BP).

Where case-detection rates are low, a focused approach is appropriate, whereby services are provided mainly in selected general health facilities in the areas in which leprosy still
occurs. The skills of health workers will be limited mainly to suspecting leprosy. Referral facilities should confirm the diagnosis and begin treatment. Continuation of treatment could be delegated to the peripheral health facility serving the community in which the patient resides. The resources devoted to leprosy must be in balance with those required for other, often much more serious, public health problems (BP).

Training of all categories of staff involved in leprosy control should be task-oriented. Leprosy should be included in the curricula of medical faculties and paramedical schools. Every major leprosy endemic country should have at least one centre with expertise for training of specialized staff (BP).

Information-education-communication (IEC) activities, especially those employing participatory approaches, result in increased knowledge, change of behaviour, and reduction of stigma (EB). Studies should be carried out to identify the methods that are most cost-effective under different conditions (R). Before IEC activities can be implemented, effective MDT services should be already available in the area. Combining IEC for leprosy with that for other health problems is cost-effective, and does not set leprosy apart (BP).

Leprosy elimination campaigns (LECs) can play an important role in the process of integration. Case-finding in LECs must be based on self-reporting to the general health staff (BP). In leprosy endemic areas in which there is no health infrastructure, innovative, situation-specific strategies for diagnosis and delivery of MDT should be developed. These activities should be combined, wherever possible, with other special initiatives to address other health problems (BP).