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Editorial

HISTORICAL BACKGROUND TO THE DEVELOPMENT OF LEPROSY CONTROL IN MALAWI

Introduction to the LEPRO Control Project

During the meeting of the Executive Committee of BELRA (The British Empire Leprosy Relief Association, later to become LEPRO) on 22 January 1963, the Chairman, Sir George Seal, discussed possible arrangements for a special fundraising appeal in 1964, BELRA's Ruby Anniversary. The possibility of setting up a BELRA Eradication Project to commemorate the occasion was being considered and this was referred to the then Medical Committee.

The Medical Committee considered this major proposal at their meeting held on 26 February 1963 (the first meeting attended by Dr R J W Rees) as proposed by James Ross Innes, then Medical Secretary of the Committee, which included such famous leprologists as Ernest Muir, Frank Davey and Robert Cochrane. Dr Muir had considered the project particularly feasible while stressing the importance of personnel. The final recommendation to the Executive Committee was that the idea of a BELRA Pilot Eradication Unit was enthusiastically approved as being entirely feasible provided modern methods and well-chosen personnel were used. Africa was considered the place of choice to include a Unit with two Medical Officers (one a surgeon), two nurses, one laboratory technician, one physiotherapist and one BELRA worker. The project should be based on 8,000–10,000 patients rather than on a given area, and with suitable facilities for two 5-year periods should be sufficient to make a considerable impact on leprosy prevalence in the area. It is interesting to note that at a meeting of the Medical Committee held on 12 November 1963, under the Chairmanship of Dr Rees, and attended by Mr G F Harris, Dr Lewthwaite raised a point in the protocol on the Pilot Eradication Unit and suggested that the following should be included: '... there is hope of using BCG to prevent leprosy in young contacts or to use other vaccines if justified by trials.' (Based on preliminary and suggestive evidence for the prevention of leprosy by BCG from the trial in Uganda commenced in 1962.)

Time sequences in the negotiations, assessments in the selection of Malaŵi for the Leprosy Control Project and its subsequent establishment

Following the backing by the Medical Committee in February 1983, a letter giving the broad outline of BELRA's project was sent out by the Chairman of the Executive Committee to all Commonwealth countries in Africa, India, and Pakistan, inviting their views and interest.

By June 1963 the most interested replies had been received from Nyasaland and Kenya. It was noted by the Executive Committee that Nyasaland '... appeared the most promising area for the Pilot Eradication Scheme. The success of such a scheme in Nyasaland would depend on the personal support of Dr Banda, the Prime Minister.'

Advantage was taken of the Commonwealth Conference meeting in London in September 1963 for preliminary discussions with Dr Banda and with the Minister of Health from Kenya by Air Vice-Marshal Crisham, Dr Rees and Mr Harris.

After negotiations, WHO accepted Dr Rees' proposal for backing LEpra's (formerly BELRA) Pilot Leprosy Control Unit and this backing was received by mid-March 1964. This was followed by an on-site assessment by Air Vice-Marshal Crisham, General Secretary of LEpra, together with Dr Rees, the Chairman of the Medical Committee. Their report unanimously favoured Nyasaland and this was accepted by both the Executive and Medical Committees of LEpra.

In July of that year Malaŵi declared its independence and Dr Banda was informed that his country had been selected and he accepted LEpra's offer wholeheartedly. He even requested that the headquarters for the Project should be placed in the grounds of the Queen Elizabeth Hospital, Blantyre—a most far-reaching and advanced decision at that time—breaking with the tradition and prejudices against leprosy. Dr Banda also made available the Malaŵi Government's Leprosy Officer, Dr Gordon Currie, to be seconded to LEpra as Project Director.

In September building plans at the Queen Elizabeth Hospital were agreed and Dr Currie came to the United Kingdom for detailed discussions at the beginning of 1965.

Financial and administrative implications

Originally, capital expenditure of some £65,000 was envisaged with annual expenditure of £50,000 for a period of 7–10 years. This was a considerable undertaking for the Association when its total revenue in 1963 was only £170,924. The Executive Committee had also decreed that LEpra's other work should not be jeopardized by the introduction of this project.

OXFAM had shown an interest in supporting the project and it was agreed that half LEPRO's invested reserves could be used towards the capital cost and half the estimated recurrent expenditure. OXFAM were accordingly informed of this.

Mr Kirkly, the Director of OXFAM at the time, was concerned about the practicability of eradication and the effectiveness of new drugs. This was, to an extent, due to using the word 'eradication' in the title of the project, a word deliberately used from the point of fundraising within the United Kingdom. Support was finally approved by OXFAM following negotiation with the Trustees of the Brown Memorial Fund, a fund available in Malaŵi for leprosy work. Once again, Dr Banda's support was essential in getting a favourable response from the Trustees of the Brown Memorial Fund.

Following further negotiations and periods of uncertainty, OXFAM approved a grant in March 1965 of £10,000 per annum for the following three years. The Leverhulme Trust also supported the work and all the problems in setting up the project were resolved.

The Pilot Leprosy Control Project became operative in the Southern Region of Malaŵi on 25 May 1965 and the Agreement with the Government of Malaŵi was signed at the 42nd Annual Meeting of the Association in London on 22nd June 1965 by His Excellency, the High Commissioner for Malaŵi, Mr M W Mbekeani and Viscount Boyd of Merton CH, President of the Association.

On 1 January 1966, Dr Molesworth, formerly Government Leprologist, Ghana, was appointed as Project Director to replace Dr Currie who was returning to the United Kingdom, and Mr John Eldon was appointed Project Administrator.

The first few years

The broad plan for this project was based on the widely accepted principle that the best method of controlling leprosy is to find and treat all patients with leprosy at the earliest stage, thus preventing the spread of infection and reducing deformity. The initial planning worked out between Drs Currie and Rees had been very detailed and based on domiciliary treatment for the majority of cases, with a small administrative centre in Blantyre with laboratory facilities and a hospital unit providing 36 beds for short-stay patients.

The work was to be organized and directed by LEPRO with the leprologist on the spot taking instructions, where necessary, from LEPRO's Medical Advisory Board (MAB) with the Project Director attending MAB meetings when on UK leave. The project ran in parallel with the Government Health Services and the closest collaboration with the Government, as envisaged in the remarks made by the High Commissioner when signing the agreement that his Prime Minister (Dr Banda), assured the meeting that LEPRO could go to Malaŵi and expect all the

cooperation they wanted from the Government, the medical authorities and the people of Malaŵi who 'will do everything they can to make the project a success'. The Prime Minister's message went on to say '... I hope that the time will come—it may not be in our time: it could be in the time of our children's children, when they will sit back and look at this day and say, well, those people were far sighted, the last leprosy case has gone from Malaŵi.'

Planning and the build-up of staff and accommodation were carried out in 1965 under Dr Currie, so that active outpatient control could start at the beginning of January 1966 with the arrival of Dr Molesworth. Already there were some 5,000 leprosy cases registered at government clinics within the area, but less than half of these were traced for detailed recording.

Following an initial intention to carry out widescale case-finding exercises, it was decided to put in landrover circuits based on centres within the control area. By the end of 1966 three such circuits were in operation with 4,000 cases under active treatment of whom 2800 were covered by mobile treatment units. Three thousand five hundred cases had been recorded in detail and contacts examined with a 2.5% leprosy prevalence. Considerable effort was put into training Malaŵian staff and the build-up took place with determination and energy, not only from those in the field, but also those responsible for financing and administering the project.

The aim was to provide treatment within three miles of every patient's home and by the end of 1967 it was estimated that such treatment was available to 8/11ths of the population. By the end of that year the caseload had risen to 6,200. The small hospital had become fully operational and the fourth mobile unit planned.

By the end of 1970 11,000 patients had been registered during the life of the project and already 220 patients had been discharged cured. It now became a project designed to improve its coverage. The main need was for supervision at all levels and on a sustained basis so that the quality of the work did not suffer through repetition and boredom.

In 1972 LEPRAs started to plan extension work in Malaŵi following a feasibility study carried out by its Clinical Consultant, Dr Colin McDougall. Because of his confidence in LEPRAs, its staff and methods of working, the President, Dr Banda, in 1973 invited LEPRAs to assume responsibility for leprosy supervision throughout the whole of Malaŵi. This meant that the work expanded to the north under the direction of Dr Gjalt Boerrigter and LEPRAs assumed overall co-ordination of the tuberculosis/leprosy control scheme run by Dr Warndorff in the Central Region. This project was fully financed by the German Leprosy Relief Association with whom LEPRAs had the closest co-operation.

Dr Molesworth became adviser to the Malaŵian Government for leprosy control thus ensuring LEPRAs's nationwide influence. The original Pilot Project based on Blantyre was handed over to the Government in 1975 but the work elsewhere was gradually being extended. In the original Pilot Area during the 10

years of its life, 13700 cases were registered of whom 8000 were new cases and only 3500 remained under treatment and were transferred to the Malaŵi Government. The overall caseload in 1975 was 19000 and this figure was maintained until multidrug therapy and short-term treatment were able to reduce the average caseload dramatically.

In view of the cooperation with leprosy control in Malaŵi with the German Leprosy Relief Association and others, LEPRAs was advised to join the International Federation of Anti-Leprosy Organisations (ILEP) and became a member in March 1976. Straight away LEPRAs was entrusted with the responsibility of co-ordinating the work throughout the whole of Malaŵi. The strain on LEPRAs's finances was relieved and LEPRAs was able to share its expertise with colleagues working throughout the leprosy endemic world.

Broad lessons learned

The original intention was to provide domiciliary treatment within three miles of every potential patient's home. Initially Landrovers were used combined with bicycle circuits. But following the increase in basic costs of the vehicles and also of fuel in the mid-1970s, and in addition the lack of personal contact via the Landrover circuit LEPRAs was encouraged to re-think its field organizational structure. This became based on the clinic attendant supervised on a 3:1 basis by the leprosy control assistant, supervised again by the field officer or assistant field officer. The success of the project to date has been due to five features:

- 1 The encouragement, support and cooperation from the President, Government and people of Malaŵi.
- 2 The calibre of staff, both ex-patriate and indigenous.
- 3 The insistence on advanced planning and supervision at all stages.
- 4 The on-going training of field and laboratory staff together with follow-ups to ensure that the training is followed and is adequate.
- 5 The enthusiasm of staff at Headquarters to support and encourage those in the field with sustained expertise available from the Medical Advisory Board.

So far as the control project is concerned, it has been based on parallel working with the Government Health Authorities and this has undoubtedly led to greater efficiency and a lack of frustration, but provides a major problem when the final handover becomes a realistic possibility. In the initial Pilot Area this was not satisfactory and showed that with dapsone monotherapy continuous supervised treatment by an outside agency was required for more than 10 years. With multidrug therapy and more experience LEPRAs is now experimenting with handing over districts in which the incidence of leprosy has fallen to less than 20 new cases per annum. Only time will tell whether this is the correct number and how much outside supervision is necessary.

There is little doubt in our minds that leprosy control for those living in the

majority of leprosy-endemic countries will require a considerable input of money, and personnel from the richer countries for many years to come if the disease is ever to be controlled. One of the major problems to be faced is how to justify maintaining adequate supervision and control when the caseload falls dramatically but when there is still an appreciable incidence rate.

Developments from the original pilot project

Following the success of the nationwide coordinated leprosy control project and the financial and other support given by ILEP members and others, consideration was given to the possibility of carrying out extended epidemiological and chemotherapeutic studies in the field in cooperation with the Medical Research Council and WHO. Initial discussions took place towards the end of 1973 but it was not until after a feasibility study was completed successfully in 1979 that the major longitudinal epidemiological research project involving an entire population survey of the Karonga District (more than 100,000) was begun. The main objectives of the study are to determine the risk factors associated with leprosy and transmission of *Mycobacterium leprae*. It will not be before the end of 1989, when the second total population survey started in January 1986 is completed, that data contributing to our better understanding of the disease will become available.

On to the second survey of this project, which has just started, a vaccine trial using a killed *M. leprae* preparation introduced by WHO has now been added, from which it is hoped a more effective vaccine than BCG will result, thus ultimately controlling leprosy by preventing new cases developing.

Conclusions

In 1964 it was a major step in LEPRO's history to undertake a leprosy control project in an area with 10,000 untreated patients. It was not envisaged that such a comparatively modest start should develop into a nationwide control scheme, a major epidemiological study and the first trial in Africa, using a new *M. leprae* vaccine for leprosy. This latter study is of particular interest since it was also in Africa (Uganda) that the first control trial of BCG started in 1972 against leprosy proved effective.

It is hoped that the scientific papers now being written will be of value and interest to those dedicated to the control of leprosy throughout the world. There is no doubt that the effort put in by so many people, be they scientists, administrators, fundraisers or field workers, has been of immense benefit to the people of Malawi and it is hoped that through the lessons learned and lessons to be learned from continuing the work in that country, information will become available universally to help in the fight against leprosy.

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Ten years' leprosy control work in Malaŵi (Central Africa)—I Methods and outcome after treatment

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Summary This paper describes the organizational structure of the LEPRA Control Project in Malaŵi (Central Africa) as it has evolved since 1973. It is meant to serve as a background to a series of publications, which will describe the pattern of endemicity in Malaŵi, relapse rates, pattern of disabilities and duration of treatment required to achieve slit-skin smear negativity.

In addition to describing the methods employed by the LEPRA Control Project, some data are presented on the outcome after treatment in a cohort of patients. It would seem that probably only 3–5% of this cohort did not benefit appreciably from the antileprosy treatment offered.

Introduction

Having operated a Pilot Project in 5 districts around Blantyre in the Southern Region of Malaŵi since 1966, the British Leprosy Relief Association (LEPRA) extended its leprosy control activities from 1973 onwards to the whole of the Northern Region, the Central Region and the northern part of the Southern Region.

This paper (Part I) describes the methodology used in these control activities since 1973 and shows the outcome after treatment of a cohort of leprosy patients. The extended programme was conceived as a vertical programme from the very beginning. This was felt to be appropriate, considering the experience gained in the Pilot Project, the anticipated prevalence rate of clinical leprosy in the areas to which the programme was to be extended, and the paucity of other health services in some of those areas at the time. It seemed unlikely that at that time the existing health services would have been able to cope with yet another demand on their resources.

A second major decision made was that antileprosy treatment would be given on a weekly or fortnightly basis as near to the homes of patients as feasible. Thus

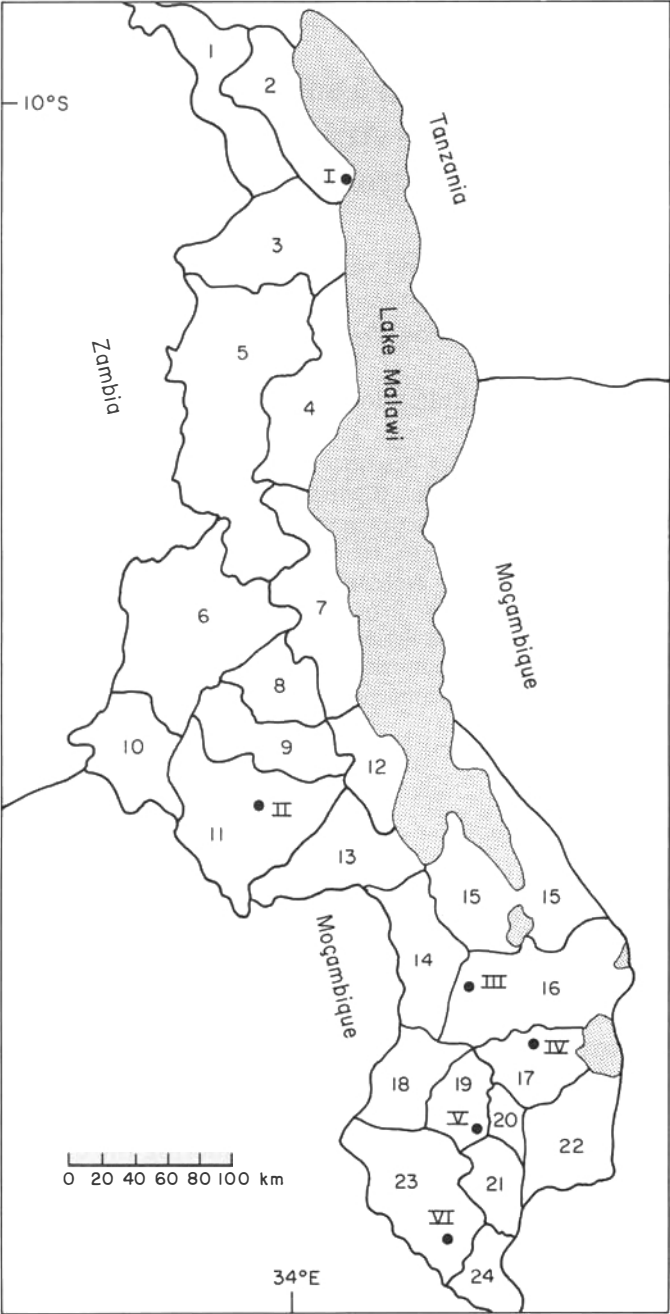


Figure 1.

most 'treatment points' or 'clinics' were at schools, markets, residences of Village Headmen, road junctions, stores and dispensaries where extant. The admission of leprosy patients to hospitals was to be avoided unless other concurrent diseases or complications made admission necessary.

Since not enough Medical Assistants could be spared by the Ministry of Health for this field work, LEPRAs decided to train their own staff for this control programme. It was hoped that in due course, once control had been achieved, the Ministry would take these trained staff into the General Health Services to continue the work at the level required by then.

From the very beginning emphasis was placed on establishing a reliable slit-skin-smear-service for the dual purpose of assisting in the diagnosis of multibacillary leprosy and of monitoring the progress or otherwise during treatment. To reduce transmission of *Mycobacterium leprae* and to achieve control it was felt that priority needed to be given to the early diagnosis and treatment of multibacilliferous leprosy patients. Histopathology services were not built up.

The methodology described has to be seen in the light of these policy decisions. An alternative strategy would have been to provide broad support to the General Health Services to such an extent that they would have been able to deal with the leprosy endemic situation with the required thoroughness. However, this was never felt to be within the scope of a voluntary organization like LEPRAs.

In the following paper (Part II), data will be presented and discussed on evolving patterns of endemicity in Malaŵi since 1973.

Historical background

Malaŵi covers a land area of 94,276 sq km stretching from 9° 45' South to 17° 16' South and 33° East to 36° East. The total population in 1977 was 5,547,460 with a national (since 1966) natural annual growth rate of 2.6%.

Malaŵi has 24 administrative districts (see Figure 1). Of these, 5 border on Lake Malaŵi (elevation 474 m): Karonga, Nkhata Bay, Nkhotakota, Salima and

Figure 1. Districts of the Republic of Malaŵi and LEPRAs Project Centres. Districts:
Northern Region: 1 Chitipa, 2 Karonga—I, 3 Rumphi, 4 Nkhata Bay, 5 Mzimba.
Central Region: 6 Kasungu, 7 Nkhotakota, 8 Ntchisi, 9 Dowa, 10 Mchinji, 11 Lilongwe—II, 12 Salima, 13 Dedza, 14 Ntcheu.
Southern Region: 15 Mangochi, 16 Machinga—III, 17 Zomba—IV, 18 Mwanza, 19 Blantyre—V, 20 Chiradzulu, 21 Thyole, 22 Mulanje, 23 Chikwawa—VI, 24 Nsanje.
Project Centres: I Chilumba, II Lilongwe, III Balaka, IV Likwenu, V Blantyre (Pilot/Govt), VI Ngabu (Shire Valley).

Mangochi. In contrast, 11 districts lie on the western plateaux at elevations from 900 to 1400 m: Chitipa, Rumphi (here the plateau reaches Lake Malaŵi), Mzimba, Kasungu, Ntchisi, Dowa, Lilongwe, Mchinji, Dedza, Ntcheu, and Mwanza. Machinga and part of Zomba district straddle the Upper Shire river, the only outflow of the lake.

Climatically, Malaŵi belongs to the southern edge of the tropical belt. The rainy season is from the end of November until the end of April.¹

During the first half of this century leprosy patients were cared for in a number of leprosaria situated throughout the country. When dapsone became available, the Government established in the mid-1950's a large leprosarium at Kochirira in Mchinji District. In 1964 the newly independent Government invited the British Leprosy Relief Association (LEPRA) to establish a mobile service for the treatment of leprosy patients in Blantyre, Chiradzulu, Mulanje and Thyolo districts and in part of Zomba district. From the end of 1973 onwards, this mobile service was extended by LEPRA to cover the whole of Malaŵi (with the exception of the Lower Shire Valley, where a Seventh Day Adventist Leprosy Control Project had started). Organizationally, this mobile service was split into the Leprosy Control Project North (Chilumba), Central (Lilongwe), Balaka and Likwenu, while the area initially covered by LEPRA (the 'Pilot Project' area) was handed over to the Government Medical Services at the end of 1975.

Organizational structure of LEPRA's control projects since January 1974

(a) Clinic Attendants (CAs)

Treatment is given to registered leprosy patients by CAs. These CAs have usually completed primary school education and are trained to keep treatment records, but they are not in any way trained to examine patients or to diagnose leprosy. The CAs reach their patients weekly or fortnightly at treatment points which are usually within a short walking distance of their patients' homes. The CAs do their treatment circuits on bicycle or, in some particularly hilly areas, on foot. On average 3 CAs work in each district.

For 1 week every month CAs are accompanied by a Leprosy Control Assistant.

(b) Leprosy Control Assistants (LCAs)

These staff have usually completed 2 years of secondary school education although on occasion a particularly outstanding CA has been offered the opportunity to become an LCA. During a 2-year period LCAs are trained to examine people, to diagnose and classify leprosy, to register patients and to prescribe appropriate treatment. During their supervisory visits LCAs should

examine, at the treatment points, individuals who have self-reported to the CAs during the preceding weeks.

The LCAs are also trained to recognize complications (in particular Type-I and Type-II reactions and drug allergies) and to initiate treatment, while at the same time informing their supervisors.

In addition to supervising the CAs, LCAs take slit-skin smears, do mass examinations of school children and complete monthly statistical returns.

On average, 1 LCA is employed per district.

(c) Assistant Field Officers (AFOs)

Assistant Field Officers (AFOs) are either promoted from the level of LCA, or are Medical Assistants seconded by the Government. An AFO supervises 2 or 3 LCAs, visiting each one for 1 week per month.

In the early stages of the projects, LCAs and AFOs travelled with four-wheel drive vehicles but were later equipped with motorcycles to reduce costs and to increase their mobility. In particular AFOs are expected to check on the quality of diagnosis, classification and treatment by LCAs. They also advise LCAs on the treatment of complications. AFOs are encouraged to make suggestions for the improvement of treatment circuits and coverage to the Field Officer/Medical Officer of the Project.

(d) Field Officers/Medical Officers

Initially projects were headed by expatriate Field Officers (Likwenu and Balaka) or by Medical Officers (North and Central). Later Malaŵian Field Officers were appointed (usually promoted from AFOs) in all projects, though the Central Region and the Balaka Project have remained under a Medical Officer.

(e) Medical Director

The different control projects are guided by a Medical Director on diagnostic, laboratory and treatment policies and by a National Manager on logistic and administrative matters. Changes in treatment policy are usually discussed with and suggested to the Medical Director (G Boerrigter) by LEPRAs' Medical Advisory Board (UK). The Medical Director then seeks approval from the Ministry of Health before implementation.

(f) Microscopists

An experienced expatriate has been employed in Malaŵi as laboratory superintendent for all LEPRAs' projects. In addition, one or two microscopists are based at each project headquarters. These staff are trained initially for a year by

LEPRA's Laboratory Superintendent in the taking, staining and examination of slit-skin smears. Usually the microscopists have been employed after completing 2 years' secondary school education.

(g) *The LEPRA Evaluation Project (LEP)*

This project was set up in 1979 in addition to, and organizationally separate from, the control projects. It is a longitudinal epidemiological research project covering the entire population of Karonga District, and aims to study risk factors for clinical leprosy and the transmission of *M. leprae*. The LEP is based at Chilumba and headed by a Project Director (J M Ponnighaus).

Records and flow of information

The LCA, on registration of a leprosy patient, completes a clinic chart with basic information such as name, year of birth, sex and address of patient. He records whether or not he found any nerve enlargement and/or any disabilities. A detailed description of skin lesions is also made by him. He has to classify patients clinically as Indeterminate, TT, BT, BB, BL, or LL leprosy and to indicate the activity on clinical grounds. The clinic chart is then sent to the project's headquarters and is copied onto an office chart by a record clerk.

Until 1983, LCAs were expected to take slit-skin smears only if they suspected multibacillary leprosy and from BB, BL and LL patients. Since then they have been requested to take slit-skin smears of all newly registered patients, 1 smear from each earlobe and 2 smears from the most active lesion(s).

As a matter of routine, LCAs have been taking repeat slit-skin smears at 6-monthly intervals of all patients whose slit-skin smears were previously positive until 2 consecutive slit-skin smears were negative. After that slit-skin smears were repeated every 2-years. Routine sites for slit-skin smears were: until May 1977, earlobes, centre of forehead and the edge of an originally active lesion; from June 1977 onwards routine smears were no longer taken from the forehead. Since 1981 the emphasis has been placed on the importance of taking the repeat slit-skin smears from previously positive sites or from new active lesions.

On registration, the LCA gives a 'treatment ticket' to the patient with an exact prescription of the treatment to be given weekly or fortnightly by the clinic attendant thereafter. He also allocates a unique clinic number to the patient and enters the patient's particulars and clinic number into the CA's treatment register. Each issue of drugs to the patient is entered by the CA in both the treatment register and the patient's treatment ticket. Each patient, in addition to a clinic number (which might change if the patient changes his or her residence), is given a unique registration number which is never changed. Office charts are kept at the projects headquarters in registration number order while the clinic chart is sent

back to the LCA. Different blocks of 5-digit registration numbers are allocated to each project to avoid multiple use of numbers in the country.

If a patient no longer reports at a treatment point, the CA and/or the LCA goes to the patient's home and tries to encourage the patient to attend regularly for treatment. Should the patient have left the area, the CA/LCA will try to gather as much information as is available about the patient's new residence and he will ask the LCA of that new area to try to locate the patient (if the patient hasn't already contacted the LCA or CA of the new area himself.)

If the patient can be found at his new residence the LCA responsible for that area requests the clinic chart and gives a new clinic number to the patient. If a patient, after changing his residence, neither self-reports nor can be found by the CA/LCA, his name is removed from the treatment register as 'disappeared/lost'. Nonlepromatous patients and lepromatous patients who have become smear negative have in practice been removed from the register as 'disappeared/lost' after nonattendance for 6 consecutive months, during which period two efforts of tracing the patient should have been made. Removal of smear positive patients from the treatment registers has been discouraged.

Case-finding activities

The active component in the case-finding efforts of the control projects has been school surveys. These have also been used to spread knowledge about leprosy and about treatment facilities into the communities. The policy of school surveys has not been the same in all projects, but most children attending school have been examined at least once since 1974. Examination of household contacts of leprosy patients has not been carried out routinely. It was always hoped that the dense network of treatment circuits and the regular and unfailing appearance of CAs at specific points at specific times would make it easy enough for anyone to contact LEPRO staff for examination. Preliminary findings of the LEP suggest that at least two-thirds of all leprosy patients and most lepromatous patients do ultimately self-report.² People in whom it was difficult to make a firm diagnosis on first examination have been 'put on observation' and the LCA should have reviewed such people after 3–6 months. However, regular reviews of suspects have proved difficult and have not always been carried out. Biopsies for diagnostic purposes were not taken until 1979 and from then onwards only within the framework of the LEP.

Diagnostic aspects

Quality of diagnosis

Over- and under-diagnosing. In the early years of the individual projects, there

was probably a tendency to overdiagnose leprosy, primarily because of the enthusiasm of new and inexperienced staff. Also it seemed more appropriate to use a wide rather than a narrow definition of the disease at the beginning of a leprosy control project.³ In this context, it should be emphasized that in Malaŵi no appreciable stigma is attached to leprosy.

The authors have tried to investigate the problem of over- and under-diagnosing within control projects in Malaŵi by comparing the degree of clinical 'certainty' with histopathological results.⁴ It is recognized that the methodology used is not entirely satisfactory in so far as it is not known to what extent the histopathological examination of 4-mm punch biopsy specimens by one histopathologist yields false negative results. Nevertheless it seemed likely that the diagnosis of paucibacillary leprosy was missed in at least 15% of all 'true' leprosy patients on first clinical examination. Similarly in 17% of all patients registered on clinical grounds on first examination in this series a negative histopathological result threw some doubt on the clinical diagnosis of paucibacillary leprosy.

The tendency to over-diagnose was probably greater in the earlier years and the under-diagnosing may well have been less. Table 1 gives an indication of the extent over-diagnosing of lepromatous leprosy and wrong classifications have occurred.

(b) Quality of classification

Initially no clear or consistent distinction was made between TT and BT or between BL and LL. Newly registered patients have been classified as BB (mid-borderline), as distinct from TT-BT under the following conditions: (i) if any dome-shaped or raised lesions with immune centres were found; (ii) if numerous symmetrical lesions of otherwise TT-BT appearance were found, or (iii) if there was widespread symmetrical nerve involvement. Patients were classified as 'BB cases', as distinct from BL-LL; (i) if slit-skin smears from apparently normal earlobes had a BI of < 2 and the BI of slit-skin smears from lesions was ≤ 3 ; and (ii) in the absence of any lepromatous macules or nodules.

Of 122 male and 141 female patients who were registered as 'new TT-BT' patients in Karonga District in 1975, only 1 male so far has relapsed after being discharged from treatment. This individual was diagnosed in 1984 with LL leprosy (slit-skin smear: BI: 5, solids 4%, fragments 67%; nasal discharge smear: BI: 6, solids 4%, fragments 89%). This patient was probably misclassified at the original registration in 1975. Of all patients registered since 1976 in Karonga District as 'new TT-BT' patients, none has thus far relapsed with lepromatous leprosy.

The classification 'indeterminate leprosy' has very rarely been used.

The diagnosis and even more so the classification of patients who claimed to have received antileprosy treatment before being registered by LEPRO was often very difficult. There was probably a tendency to classify such patients too far

Table 1. Trends in the possible overdiagnosis of multibacillary leprosy in the northern region of Malawi

	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	
New patients registered as BL/LL with an average BI at registration > 3	4	9	11	4	7	6	9	6	8	7	% correctly diagnosed + correctly classified (includes (c))
New patients registered as BL/LL with an average BI 1–3	50%	52·6%	64·7%	50%	70%	50%	81·8%	75%	100%	87·5%	% correctly diagnosed + wrongly classified (includes (b))
New patients registered as BL/LL with an average BI < 1	4	3	4	1	3	6	1	2	0	1	
(a) on review by the authors the diagnosis was considered very doubtful	40%	31·6%	29·4%	37·5%	30%	50%	9·1%	25%	Nil	12·5%	
(b) diagnosis was considered correct but the classification was considered wrong	1	3	1	1	0	0	1	0	0	0	% wrongly diagnosed 'over-diagnosed'
(c) clinically burnt-out LL cases	10%	15·8%	5·9%	12·5%	Nil	Nil	9·1%	Nil	Nil	Nil	
	0	3	1	2	0	0	0	0	0	0	
	1	1	—	—	—	—	—	—	—	—	
Total number of patients registered with the diagnosis BL/LL leprosy	10	19	17	8	10	12	11	8	8	8	

Table 2. Occurrence of Type-I reactions in the cohort of new smear negative BB patients registered in 1981 and 1982, by project area

	No. of new BB smear negative patients registered 1981 + 1982		No. in Type-I reaction at registration		No. with insufficient review notes to draw conclusions		No. of patients with Type-I reaction within 6 months of registration		No. of patients with Type-I reaction after 6 months of registration		Total No. with Type-I reaction at any time		No. of deaths while on treatment	
North	29	*6.74%	2	6.9%	1	3.4%	Nil		1	3.4%	3	10.3%	4	13.8%
Central	105	*12.44%	7	6.7%	26	24.8%	6	5.7%	6	5.7%	19	18.11%	Nil	
Balaka	19	*5.43%	3	15.8%	3	15.8%	3	15.8%	Nil		6	31.6%	Nil	
Likwenu	27	*6.18%	6	22.2%	Nil		3	11.1%	2	7.4%	11	40.7%	Nil	
Total	180		18	10.0%	30	16.7%	12	6.7%	9	5.0%	39	21.6%	4	2.2%

* Percentage of the total number of new patients registered in 1981 and 1982.

towards the lepromatous end of the spectrum, in particular if there were residual disabilities.

Lepromin tests carried out recently in the Likwenu Project provide an example of this classification bias.⁵ Of 45 previously treated patients who at registration by LEPRO had negative slit-skin smears, but were classified as LL, 10 (22%) had a Mitsuda induration of more than 3 mm, 7–9 years after registration by LEPRO. It is probable that these patients were misclassified at registration by LEPRO.

(c) Occurrence of Type-I reactions

Acting on the advice of the then Government Dermatologist (V Gooskens), staff were encouraged, as of May 1980 to look more actively for early signs of Type-I reactions and to institute treatment without delay. Table 2 shows incidence figures of Type-I reactions in a cohort of slit-skin smear negative new BB patients registered in 1981 and 1982, as borderline patients should be particularly prone to develop Type-I reactions. Smear negative BB patients were singled out, as their true classification might well have been nearer to BT than BB. We thought that this group would provide the best locally available data to evaluate at some future date, whether or not treatment with rifampicin, in addition to dapsone, influenced the incidence of Type-I reactions, in comparison with patients clinically classified at BT, who received dapsone monotherapy.

However as can be seen from Table 2 the incidence of Type-I reactions as diagnosed by paramedical workers varies widely from Project area to Project area. Whether this reflects genuine differences in the occurrence of Type-I reactions, or is due to different ascertainment or diagnostic criteria for Type-I reactions and/or due to excessive zeal amongst the staff in the more southern projects, we do not know. It is also possible that the diagnostic criteria for BB leprosy were more loosely applied in the Northern and Central Region Projects than in the Balaka and Likwenu Projects. On the other hand, such an explanation is not supported by differences between projects in the percentage this BB group constitutes of the total number of new patients registered in 1981 and 1982. The variation in the incidence of Type-I reactions would seem to make it unlikely that any possible influence of rifampicin, in addition to dapsone, on the incidence of Type-I reactions will be recognizable in these areas. On the other hand, the figures suggest that generally half of all diagnosed Type-I reactions were already present at registration. A dramatic difference in this distribution of reactions overtime between smear negative BB patients and patients classified as BT, might indicate an influence that rifampicin might have had on the incidence of Type-I reactions.

(d) Quality of slit-skin smears

Slit-skin smears, generally from 4 sites per patient or suspect, were examined by normal light microscopy for any Acid Fast Bacilli (AFB). Degrees of positivity

were expressed as Bacterial Index (BI) in accordance with the logarithmic scale suggested by Ridley.⁶ In addition microscopists reported on the proportion of solid staining (S), fragmented (F), and granulated (G) AFB (SFG%). Until 1981 the average BI and the average SFG% of all smears were entered on the patients' records, later the highest single BI and its SFG% were recorded.

Since 1981, regular checks have been made for interobserver variation of BI and SFG readings between the projects' microscopists and the Laboratory Superintendent. Before that, standardization relied upon periodic refresher courses. Table 3(a) illustrates the interobserver variation for the first quarter of 1984, between the Laboratory Superintendent and the microscopist of the Northern Region Project (employed since 1977). There was complete agreement concerning the BI in 51.4% of individual slit-skin smears re-examined. In 37.1% the variation was 1 BI only.

Table 3(b) presents the interobserver variation during the first quarter of 1984 between a microscopist (with 15 years' experience) in the Balaka Project, and the Laboratory Superintendent. The Table 3(b) shows that there was complete agreement in BIs in 72.3% of smears, whereas in 24.6% the variation was 1 BI only.

Figures for interobserver variation between the other microscopists and the Laboratory Superintendent are similar.

(e) *Relapses*

Criteria for diagnosing relapses have not been applied consistently throughout the country. The number of relapses re-admitted for treatment cannot be presented in a meaningful way because of the absence of a surveillance system after discharge from treatment. However we hope to present relapse rates for Karonga District in due course, as in this particular area all leprosy patients ever registered are being re-examined periodically by the LEP, as far as they are still alive and resident in the district.

Routine treatment schedules for adults

The routine treatment schedule initially consisted of 25-mg dapsone daily for all adult leprosy patients irrespective of classification. The dosage was changed to 100-mg dapsone daily in 1978. One tablet HT3 (150 mg thiacetazone plus 300 mg isoniazid) daily was added to the routine treatment schedule of all patients with positive slit-skin smears as early as 1975. This addition was recommended by LEPRAs' Medical Advisory Board (chairman Dr R J W Rees) in the light of reports from several countries on the emergence of resistance of *M. leprae* to dapsone.⁷ Although thiacetazone was known to be only mildly bacteriostatic to *M. leprae*, HT3 was chosen because of its easy availability in Malawi. As early as

Table 3. Interobserver-variation in the reading of slit-skin smears, between the laboratory superintendent and project microscopists

		(a) Laboratory superintendent						
		BI						
		0	1	2	3	4	5	6
Microscopist Northern Region Project	0	12						
	1	8	3	1				
BI	2	5	6	14	1			
	3	1	3	9	13	6		
	4		2	1	3	8	1	
	5					2	4	2
	6							
								105
		(b) Laboratory superintendent						
		BI						
		0	1	2	3	4	5	6
Microscopist Balaka Project	0	3						
	1	1	1	1				
BI	2	1	2	4	2			
	3			2	10	1		
	4	1			2	3		
	5					1	11	2
	6						2	15
								65

Table 4. Routine antileprosy treatment schedules for adults by classification and over time in Malaŵi, as implemented by the British Leprosy Relief Association (LEPRA)

	1969–Oct 1974	Nov 74–Aug 75	Sept 75–Dec 77	Jan 78–Dec 80	Jan 81–Apr 83	May 83
TT/BT	25 mg dapsone daily	25 mg dapsone daily	*50 mg dapsone daily	100 mg dapsone daily	100 mg dapsone daily	100 mg dapsone daily plus 600 mg rifampicin supervised monthly until patient has taken 6 doses of rifampicin within a period of 9 months.
BB smear negative	“	“	“	100 mg dapsone daily (+ HT3 daily for 18 months)	100 mg dapsone daily (+ 600 mg rifampicin on 2 consecutive days monthly for 18 months)	As above for BB smear negative or 1+ at registration.
BB smear positive	“	25 mg dapsone daily (+ HT3† daily if MI positive)	50 mg dapsone daily (+ HT3 daily until 2 consec. smears were negative, but for at least 18 months	100 mg dapsone daily (+ HT3 daily until 2 consec. smears were negative, but for at least 18 months)	100 mg dapsone daily (+ 600 mg rifampicin on 2 consecutive days monthly until 2 consecutive smears were negative but for at least 18 months)	100 mg dapsone daily + 600 mg rifampicin supervised monthly + 50 mg clofazimine daily and 300 mg once a month supervised until 2 consecutive negative smears but for not less than 24 months during which period at least 18 doses rifampicin must have been taken.
BL/LL	“	“	“	“	“	“

* For a transition period. † 150 mg thiacetazone plus 300 mg isoniazid.

January 1981 rifampicin (600 mg on 2 consecutive days once a month) was given, instead of HT3, to all multibacilliferous patients as well as to all active new BB patients with negative slit-skin smears. Details of the schedule are shown in Table 4. Until the end of 1977 treatment with dapsone was temporarily reduced or stopped during Type-I and Type-II reactions. Similarly, until the end of 1980, newly registered TT to BL patients with very active lesions on the face were only slowly (over a period of 3 months) introduced to the standard dosage of dapsone.

The definition of 'adults' was changed on the 1 January 1981 from 'aged 12 years or more' to 'aged 15 years or more'. Treatment of Type-I and Type-II reactions: From 1975 onwards the standard treatment of Type-I reactions was a 3-months' course of prednisolone, starting with 30 mg daily (for adults). This treatment was given by the LCAs in the field. It was never a policy to admit a patient to hospital because of Type-I reaction alone.

Patients with Type-II reaction were treated with Aspirin and Chloroquine 300 mg daily for 7–14 days. If there was no improvement, a 12-day course of prednisolone was given. Recurrence of the Type-II reaction within a month was an indication for an 18-months course of clofazimine, 300 mg daily for 6 months, 200 mg daily for 6 months and 100 mg daily for 6 months. On occasion Thalidomide (starting with 100 mg 3 times daily) was used in treatment of Type-II reactions, but only in hospitalized patients. Neuropathic ulcers were, wherever possible, treated in the field by LCAs. Rehabilitation and reconstructive surgery have never been aspects of LEPRA's work in Malaŵi. Emphasis has been placed on establishing and maintaining a reliable and trustworthy mobile treatment service within easy reach of most people in order to encourage early self-reporting and regular treatment. Only occasionally has reconstructive surgery for footdrop been done in the leprosy hospital in Balaka.

Discharges

There was no active policy of discharging or releasing patients from control until the late 1970's. The criterion for stopping treatment of tuberculoid patients was a period of at least 2 years of clinical quiescence of the disease. Borderline patients were not discharged until 5 years after clinical quiescence was achieved. Lepromatous patients were not discharged between 1973 and 1983. Until 1979 there was a tendency not to discharge women of child-bearing age. Discharged patients were not kept under any form of surveillance.

Prior to the implementation (1983) of multidrug therapy as recommended by WHO⁸ in 1982, a concerted effort was made to complete the discharge, in particular, of all tuberculoid patients who qualified for discharge according to the above criteria.

Outcome after treatment

1975 cohort analysis. We have analysed the outcome of the patients newly

Table 5. Outcome after treatment of the 1975 cohort of newly registered patients in the Northern Region (Chilumba).

	Still on treatment	Dead	Removed from register	Discharged	Total
Total	15 (3.7%)	22 (5.5%)	89 (22.2%)	275 (68.6%)	401
	5 (1.2%) should have been discharged 10 correctly on treatment		39 unknown whereabouts 23 left for outside Malaŵi 19 left for inside Malaŵi (might have reported for treatment elsewhere in Malawi)	11 (4%) incomplete review notes 121† (44%) no evidence of leprosy at time of discharge 111† (40.4%) inactive lesion(s) only. No disabilities	
	Out of those correctly on treatment: (a) relapses after removal or discharge: 3*		8 refused further treatment	17 (6.2%) with same disabilities as at registration 7* (2.5%) disabilities worse than at registration 8† (2.9%) disabilities less than at registration	
	(b) reactivations during treatment: 3*				

In 13 patients (3* + 3* + 7*) was the outcome unsatisfactory (= 3.2%) while 240 patients (121† + 111† + 8†) probably benefited from the treatment (= 60%).

Table 6. Outcome after treatment in the 1975 cohort of newly registered patients in the Central Region (Lilongwe).

	Still on treatment	Dead	Removed from register	Discharged	Total
Total	68 (13%)	19 (3.7%)	141 (27.6%)	282 (55.3%)	510
	37 (7.3%) should have been discharged 31 correctly on treatment		110 unknown whereabouts 8 left for outside Malawi 22 left for inside Malawi (might have reported for treatment elsewhere in Malawi)	20 (7.1%) incomplete review notes 142† (50.4%) no evidence of leprosy at time of discharge 61† (21.6%) inactive lesion(s) only. No disabilities	
	Out of those correctly on treatment (a) relapses after removal or discharge: Nil (b) reactivations during treatment: 8*		1 refused further treatment	33 (11.7%) with same disabilities as at registration 16* (5.7%) disabilities worse than at registration 10† (3.5%) disabilities less than at registration	

In 24 patients (8* + 16*) was the outcome unsatisfactory (=4.7%) while 213 patients (142† + 61† + 10†) probably benefited from the treatment (=41.8%).

registered in 1975 in the Northern and Central Region Projects. Data for the Balaka and Likwenu projects are not presented but their trends are essentially similar.

(i) Table 5 shows that out of 401 patients in the Northern Region at least 60% appear to have benefited from the treatment. Only for 3.2% was the outcome known to be unsatisfactory. On the other hand, 22.2% of the 1975 cohort removed themselves from treatment before official completion and we do not know the outcome in this group.

(ii) In the Central Region (Table 6) the case-holding problem seems to have been slightly greater than in the North and also the percentage of patients who should have been, but were not yet discharged by January 1984 was higher than in the North. Thus for the Central Region we can only say that at least 41.8% out of 510 patients, probably benefited from the treatment. The outcome was unsatisfactory in 4.7% of the 1975 cohort.

We are not aware of similar cohort analyses and can therefore not conclude whether this outcome compares favourably with other similar projects or not. However, it would appear to us that the percentage of patients who removed themselves from treatment leaves something to be desired. With the introduction of the WHO recommended multidrug therapy⁸ for pauci- and multi-bacillary leprosy, the problem will, at least as far as pauci-bacilliferous patients are concerned, largely disappear. However, 9 of the 141 patients who removed themselves from treatment in the Central Region Project had positive slit-skin smears (average BI > 1) when last seen.

Secondary resistance

Secondary resistance of *M. leprae* to dapsone in multibacilliferous leprosy patients was first suspected in Malaŵi in 1978. Since then 5 such cases have been proven through mouse footpad testing by Dr R J W Rees (North: 1 low level resistance, 1 low/middle level resistance; Central: 1 middle level resistance and 2 full resistance). In addition, 15 (North 6, Central 3, Balaka 1, Likwenu 5) multibacilliferous patients did not show a shift in the SFG% of AFB in slit-skin smears during 3 months supervised intake of 100 mg dapsone daily and were therefore thought to harbour dapsone resistant *M. leprae*. In another 13 patients such resistance was strongly suspected.

Discussion

As is frequently the case with control programmes, a component of evaluation was not built into the programme. Thus we do not know to what extent the mobile treatment service really achieved its initial objective of encouraging all

leprosy patients to self-report early in the course of the disease. Systematic community surveys were not carried out until the establishment of the LEPRO Evaluation Project in Karonga District.

How far the second operational objective of the mobile service, to give treatment regularly and to attain a high attendance rate by having treatment points near the homes of patients, was achieved will be analysed on the basis of attendance registers and urine analysis results in Karonga District.²

The above two operational objectives are of course only means to achieve the ultimate objectives of a leprosy control programme. These main objectives can be stated as being: (a) to reduce the incidence and prevalence of the disease in the community; and (b) to prevent the development of disabilities in leprosy patients.⁹ Whether a reduction of incidence and prevalence has been achieved and to what extent the control project has been successful in preventing disabilities will be the subjects of further papers. This publication is meant to provide the necessary background information about the methods used in the LEPRO Control Project (LCP).

Within the structure of the LCP as described the least essential of the staff might, to the reader, appear to be the CAs. The main reason for their introduction was the large and increasing workload resulting from the long duration of treatment for all patients. It was also felt that the CAs, being employed locally, would link the leprosy control programme closer to the community than LCAs could, who frequently did not originate from the district in which they were based. In addition the rationale behind the deployment of CAs was to free LCAs from the largely repetitive and undemanding task of giving routine treatment so that they could concentrate on examinations and reviews. A disadvantage in practice of the CAs was that undoubtedly some individuals reporting to them were not referred to the LCA, because the CA hastily and erroneously judged the condition to be certainly not leprosy. Also occasionally, though probably very rarely, complications like drug allergy and reactions were not referred to LCAs as swiftly as one would have wished, on account of a lack of understanding by the CA.

The long tradition of a well established and supervised slit-skin-smear service proved to be very useful and greatly facilitated the introduction of multidrug therapy,⁸ as the allocation to a regimen is largely dependent on the single highest BI. With a BI of 2 now being the critical value for the allocation to a regimen, it is planned to concentrate training and supervision on the reading of smears in this range.

The main problem in our data on the outcome after treatment is obviously the proportion of patients who were lost from control before completion of treatment. If it is assumed that most such patients defaulted because their lesions had disappeared or they were otherwise satisfied with their progress, the percentage of satisfactory outcomes after treatment would be much higher than we were able to demonstrate (see Tables 5 and 6). However unless at least a

random sample of such defaulted patients could be traced and reviewed it remains only speculative to make such an assumption.

On the whole however, it would seem that since only 3–5% of patients deteriorated in their condition before the end of treatment the results can be considered to be reasonably satisfactory.

Conclusion

Given the socioeconomic context and endemic situation in Malaŵi, it would seem that, at the time, a vertically organized leprosy control programme was appropriate and helpful to the country and the leprosy patients. The early introduction of multidrug treatment (since 1975) might well have contributed to preventing drug resistance of *M. leprae* becoming a major problem in Malaŵi. Disabilities worsened or new disabilities developed in only 3–5% of all newly registered leprosy patients, who were usually self-reporting, after initiation of antileprosy treatment.

Acknowledgments

As the LEPRO Control Project developed over time, many people contributed ideas and suggestions to its eventual structure. We would particularly like to mention: the previous Medical Director, B D Molesworth, the previous Manager, J H Eldon, the present Manager, P Garland, and the chairman of LEPRO's Medical Advisory Board, R J W Rees. A driving force behind the establishment and extension of the LCP was the Director of LEPRO, G F Harris. Basic funding was provided by the British Leprosy Relief Association and its donors. Additional funds came from other members of the International Federation of Leprosy Relief Associations (ILEP) and special grants were made available by Mme Monnier, OXFAM, the British High Commission in Malaŵi and many others. We would like to express our sincere gratitude to the Government of the Republic of Malaŵi which has always been encouraging and supportive of LEPRO's efforts.

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Ten years' leprosy control work in Malaŵi (Central Africa)—II Patterns of endemicity since 1973

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Summary The British Leprosy Relief Association (LEPRA) has been operating a vertically structured mobile leprosy control service in 5 districts in the Southern Region of Malaŵi (Central Africa) since 1966. This service was extended from 1973 onwards to the whole country with the exception of the two most southern districts.

Data concerning the patterns of endemicity of leprosy from 1974 to 1983 have been extracted from the available records of the LEPRA Control Project. It would seem that there are at least two distinctly different endemic situations in Malaŵi: districts on the Central African Plateau are characterized by a low level of endemicity of leprosy, while the districts in the Rift Valley along the shore of Lake Malaŵi have a level of endemicity that is five times higher. In both areas a parallel decline in detection rates has been observed since 1978–79.

The authors consider this decline in detection rates to be a reflection of a genuine decline in incidence rates. This decline is accompanied by a trend towards higher lepromatous rates and shifts in the relative age distribution of new leprosy patients towards older age groups.

Projections are given concerning the expected numbers of new leprosy patients to be detected annually from 1984 to 1988.

Introduction

The British Leprosy Relief Association (LEPRA) started operating a leprosy control service (LCP) in 5 districts in the Southern Region of Malaŵi (Central Africa) in 1966. From 1973 onwards LEPRA extended its mobile services to the rest of the country with the exclusion of the Lower Shire Valley in the far south. It is the intention of this paper to analyse data collected in conjunction with this programme in order to study the patterns and recent trends of leprosy in Malaŵi.

It is notoriously difficult to analyse and interpret correctly data routinely collected in leprosy control projects.¹ A major problem arises from the fact that

such data tend to reflect the activity of the control services rather than the activity of the disease in the community. Any absence of information tends to be ambiguous as it might mean that something was not recorded because it was in fact absent, or it might mean that something was present but not recorded, or it might mean it was not even looked for. Even the presence of information tends to be problematic in so far as there is rarely any indication of the quality of the information recorded.

Finally the terms used on routine records are often undefined or unstandardized and thus their meaning may have shifted over time.

When looking at the available data from the LCP in Malaŵi we hope to overcome some of these difficulties by comparing different areas, assuming that the LCP was equally active in all the areas covered. Although we can present no evidence to support this assumption we feel it is a reasonable one given the vertical structure of the LCP as described in Part I².

We are aware that there have been shifts in the use of certain terms during the 10 years' work on which this paper is based. But it would seem reasonable to presume that these shifts occurred more or less simultaneously in all areas covered by the LCP.

Methods

(a) Numerators

Data on previously untreated, newly registered leprosy patients were extracted from each District in Malaŵi. These were taken from individual patients' records. Data are included from the first full year that the LCP was present in that District.

(b) Denominators

The denominators used are based on the 1977 population census.³ Corrected estimates for other years were provided by the National Statistical Office. We chose mid-year population figures for our calculations. The age/sex distribution of the total population of Malaŵi for 1977 is shown in Figure 1. The total population in 1977 was 5,547,460.³

(c) Areas

The districts were divided into three groups for analysis purposes. Group A consists of highland districts, 900–1400 m above sea level. These include Chitipa (since 1975), Rumphi (since 1976), Mzimba (since 1977), Kasungu (since 1975), Ntchisi (since 1978), Dowa (since 1975), Mchinji (since 1975) and Mwanza (since 1978). Group B consists of lowland districts, 472–900 m above sea level. These

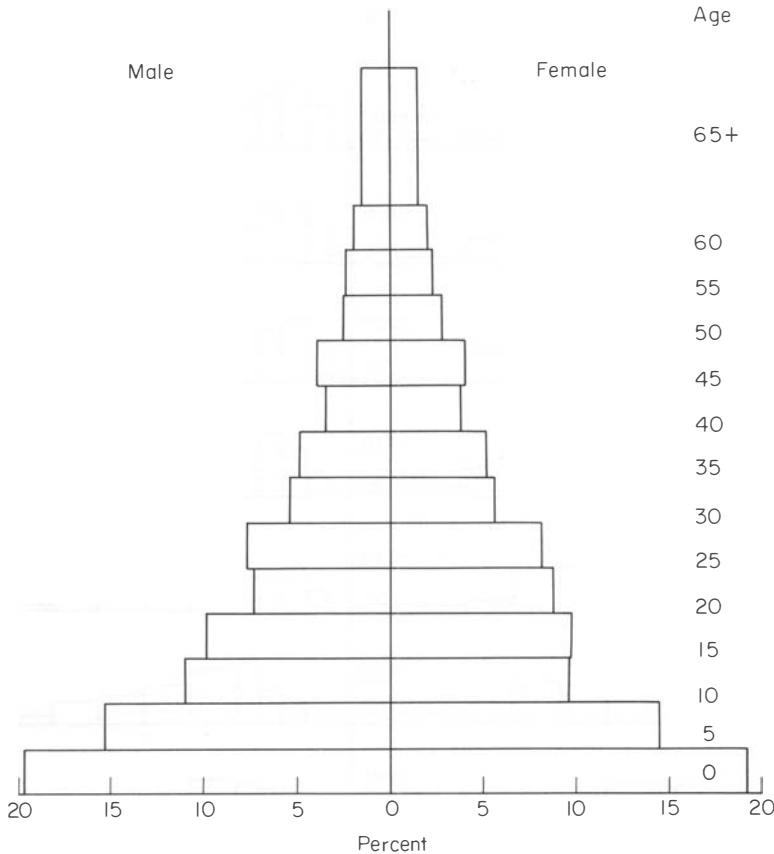


Figure 1. The age-sex distribution of the population of Malaŵi, 1977.

include Nkhata Bay (since 1976), Nkhotakota (since 1977), Salima (since 1975), Mangochi (since 1975), Machinga (since 1975) and part of the Zomba District (since 1975). This grouping into A and B groups first suggested itself to us on the basis of clear differences in the 1983 detection rates, which in the highland districts ranged from 0.04 to 0.12 (Mwanza 0.19) per thousand, compared with the lowland districts where the 1983 detection rates ranged from 0.35 to 0.49 (Machinga 0.28) per thousand.

Data for the Karonga District (since 1974) are shown separately, because of the total population survey conducted by the LEPRO Evaluation Project (LEP) since 1980.⁴ Lilongwe District, although on the highlands, was left out because of dramatic changes in the population structure related to the establishment of the capital city in that district. Dedza and Ntcheu Districts were left out because, although mostly on the plateau, they do include areas on the lowland towards the lake (see Paper I, Figure 1).

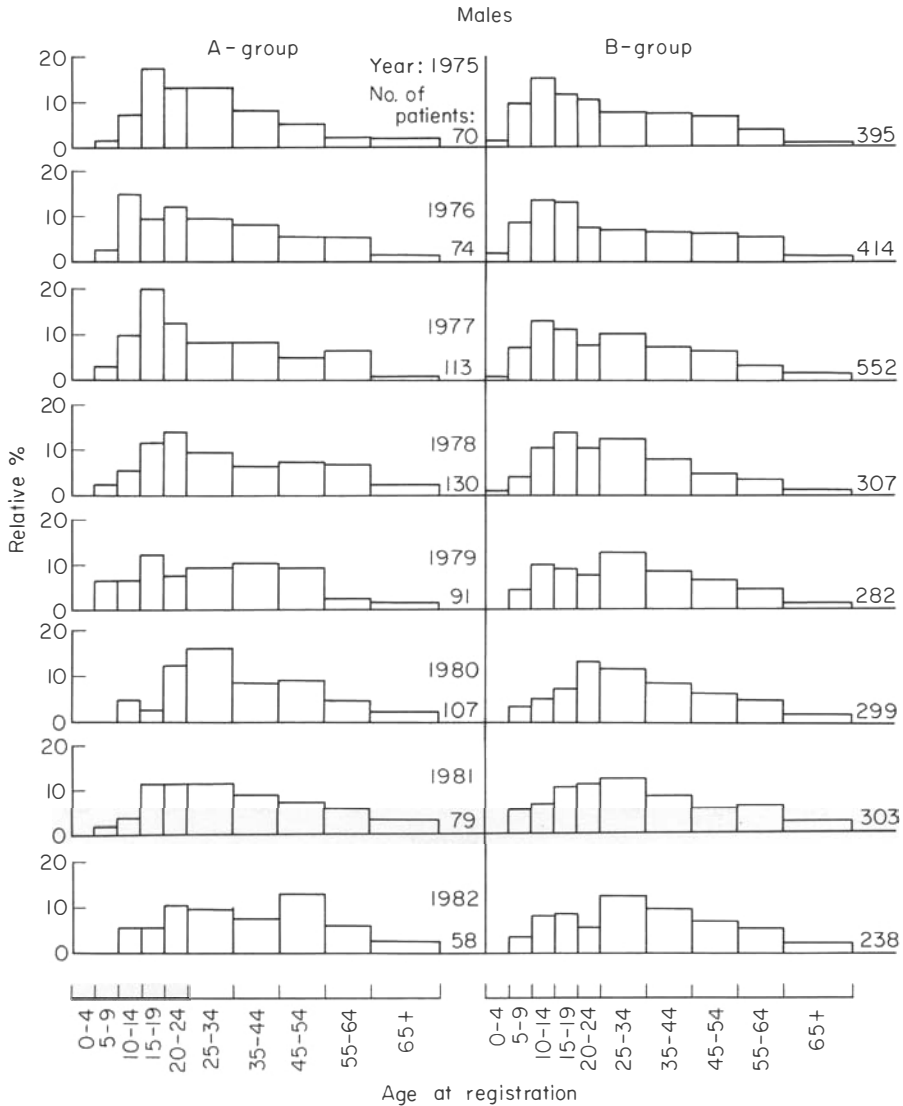


Figure 2. Number and relative age distribution of newly registered male leprosy patients, 1975–82, in highland (group A) and lowland (group B) districts in Malawi.

(d) Years of birth and onset of disease

Although years of birth often had to be guessed by the LCAs and the patients, we believe it is reasonable to present data in 5-year age-groups for patients under 25 years and in 10-year age-groups for patients of 25 years or more. Since we observed that LCAs frequently used the activity and the extent of clinical disease to decide on the time of onset, we do not wish to use the data on the onset of disease for any analysis.

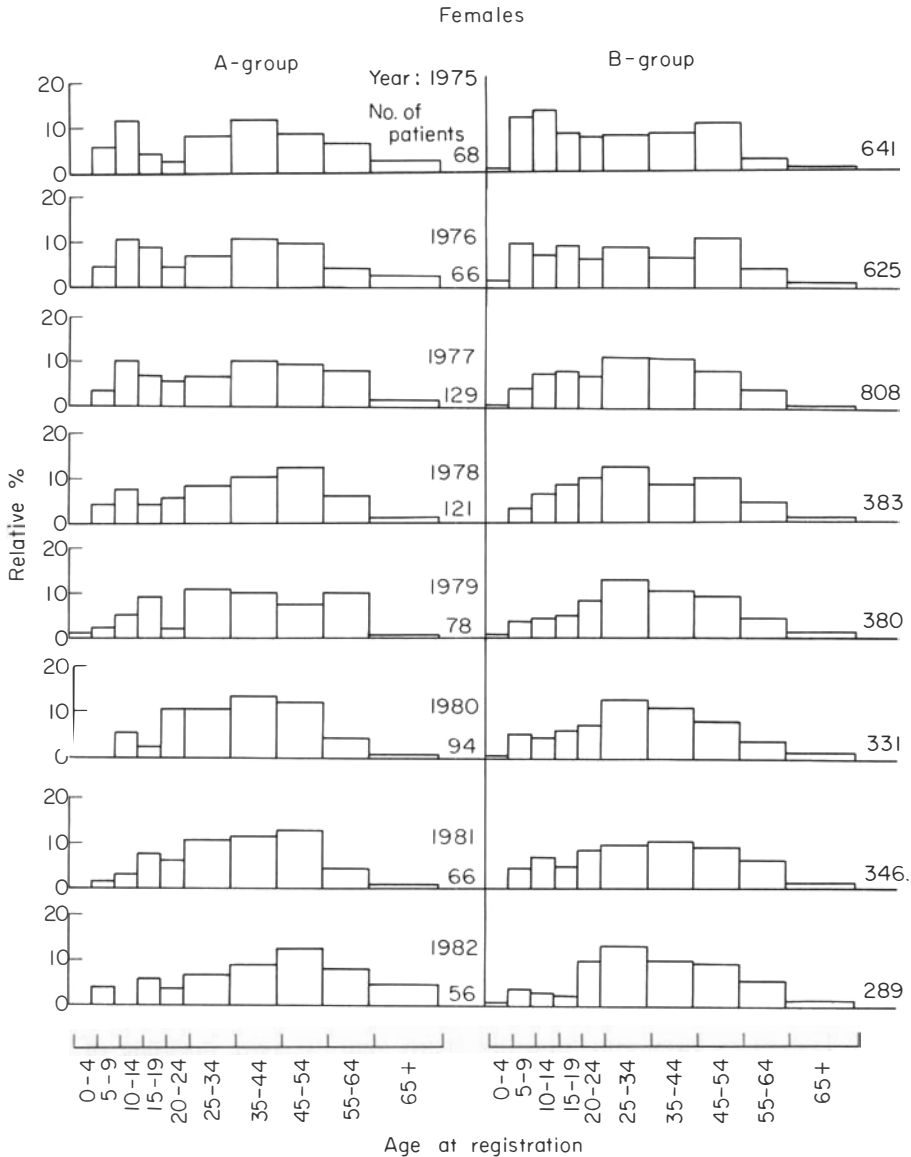


Figure 3. Number and relative age distribution of newly registered female leprosy patients, 1975–82, in highland (group A) and lowland (group B) districts in Malawi.

(e) Ascertainment of cases

Case detection methods, diagnostic facilities, and the quality of diagnosis and classification have been described in Part I.² Therefore it may suffice to say that case detection was largely dependent on leprosy patients self-reporting to Clinical Attendants and Leprosy Control Assistants (LCAs). In addition there was

limited active case detection in the context of school surveys and contact examinations. Cases were classified routinely by the LCAs as TT/BT, midborder-line (BB) or BL/LL.² There was, at least initially, a tendency to over-diagnose rather than to under-diagnose clinical leprosy. The help of histopathology for diagnosis and/or classification was not sought, but extensive use was made of the closely supervised slit-skin-smear service.

Results

(a) Age/sex distribution

Several differences become apparent when we compare the age distributions of newly registered leprosy patients in high altitude areas with those in low altitude areas (Figures 2–4). In all areas and for both sexes there is a shift towards older age groups in successive years since 1975. The proportion of young cases was particularly high in Karonga District for both males and females prior to 1978, and for males in both highland and lowland areas prior to 1979. Most of the distributions appear unimodal, with the possible exception of those for females in the highland areas prior to 1978 and for both males and females in Karonga District since 1980.

We do not think that the tendency towards older age groups is owing to changes in the methods of establishing ages.

(b) Lepromatous rates

Table 1 shows lepromatous rates for new male and female patients for groups A, B and Karonga District. A lepromatous patient is defined for this purpose as anyone registered as a new BB case with positive slit-skin smears or as a new BL/LL case with a positive slit-skin-smear result within 6 months of registration or else with no slit-skin-smear result but clinical findings typical for lepromatous leprosy. The rates vary considerably from year to year because of the small numbers of lepromatous patients detected per year. This makes it difficult to reach firm conclusions on trends over the years. However it is evident that the lepromatous rates are consistently higher for males than for females. In addition, the lepromatous rates appear to have risen since 1975 for both sexes in both the highland and lowland areas. On the other hand, these rates have remained relatively constant in Karonga District.

(c) Male-female ratios

A consistent difference between highland (group A) and lowland districts (group B) in the proportion of males among new leprosy patients is shown in Table 2. There has been a preponderance of male patients in the highland districts and a

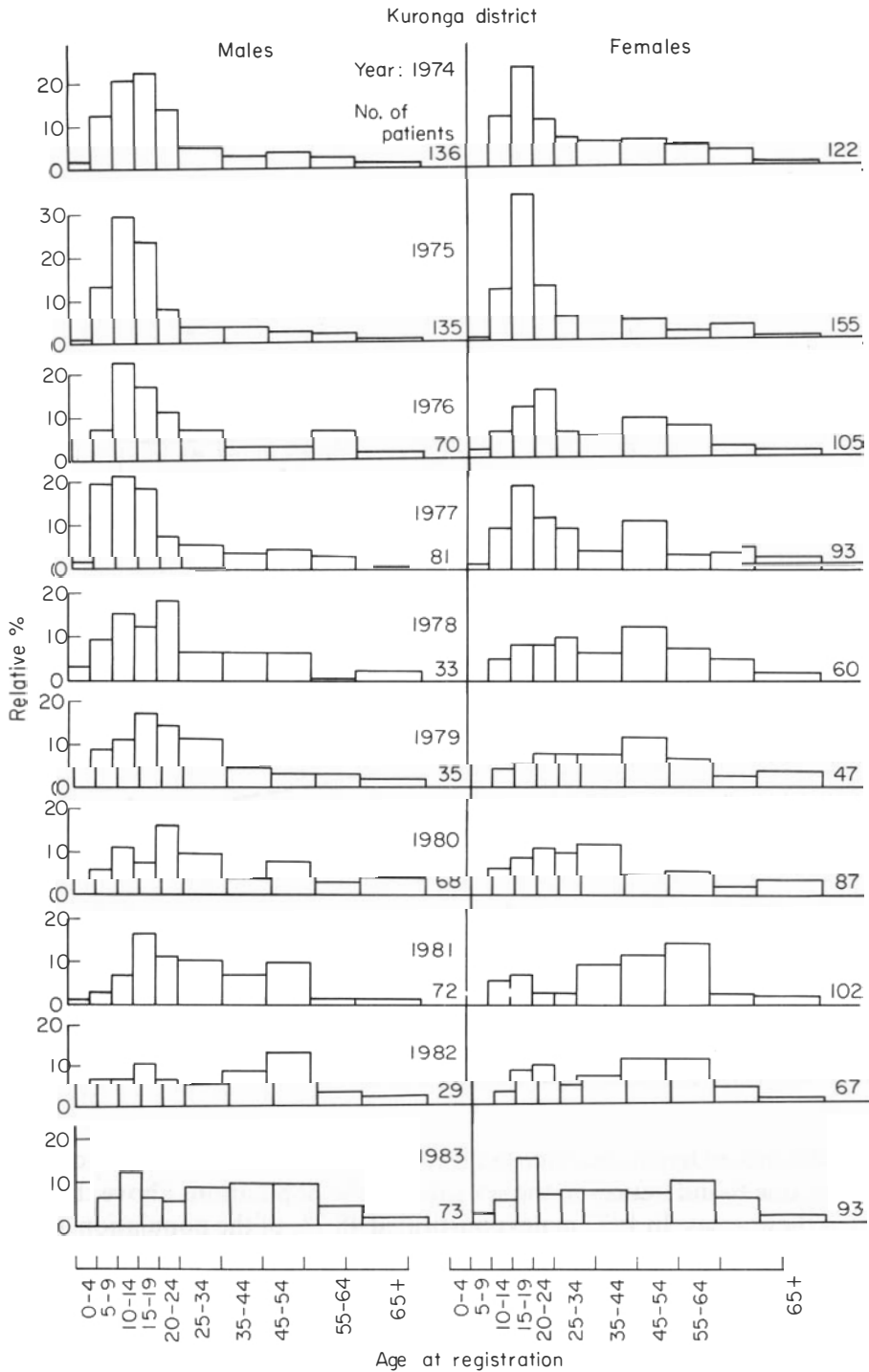


Figure 4. Number and relative age distribution of newly registered male and female leprosy patients, 1974-83 in Karonga District in Malawi.

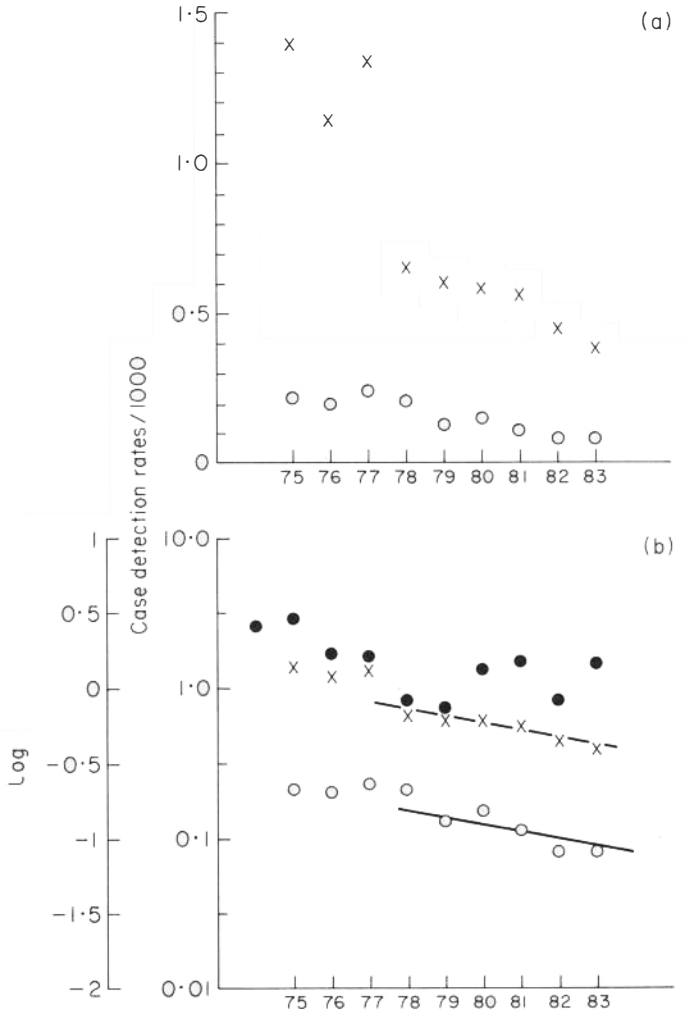


Figure 5. (a) Leprosy detection rates in lowland and highland districts in Malaŵi per 1000 population. Arithmetic scale. (b) Leprosy detection rates in Karonga District, lowland and highland districts in Malaŵi per 1000 population. Logarithmic scale. O, highland districts (group A); x, lowland districts (group B); ●, Karonga District.

preponderance of female patients in the lowland districts. This difference can only partly be due to differences in the sex ratio of the populations above the age of 9 years in these areas. In 1977 males constituted 48.7% of the population above the age of 9 years in the highland districts but only 45.3% of the population above the age of 9 years in the B-group districts.³ In Karonga District males constituted (in 1977) 46.1% of the population above the age of 9 years. The proportion of males among leprosy patients in Karonga District, exceeded 50% only in 1974 (which was the first year that the district was completely covered by the LEPR mobile

Table 1. Lepromatous rates among new patients detected by year and area. (Percentages)

	Karonga District		Highland districts (group A)		Lowland districts (group B)	
	Males	Females	Males	Females	Males	Females
1974	11.0	4.1				
1975	8.8	5.2	25.7	2.9	11.6	4.5
1976	10.0	4.7	14.8	15.2	18.4	6.7
1977	3.7	1.1	10.6	7.0	14.7	6.8
1978	12.1	9.1	22.3	13.3	19.2	8.3
1979	11.4	4.2	20.8	11.5	20.9	7.6
1980	5.8	1.1	29.9	8.5	21.7	8.8
1981	13.8	1.0	21.5	16.6	24.4	4.9
1982	10.3	1.5	32.7	25.0	26.4	10.3
1983	5.5	3.2				

Table 2. Male–female ratio among new patients detected by year and area.

	Karonga District	Highland districts (group A)	Lowland districts (group B)
1974	52.7		
1975	46.6	50.7	38.1
1976	40.0	52.9	39.8
1977	46.6	46.7	40.6
1978	37.5	51.8	44.5
1979	42.7	53.8	42.6
1980	43.9	53.2	47.5
1981	41.4	54.5	46.7
1982	30.2	50.9	45.2
1983	44.0		

service). Since then the majority of cases have been females as in all other lowland districts. Table 2 and Figure 4 also show that the proportion of males in Karonga District among newly registered cases dropped slightly with the institution of widespread active case detection by the LEPRa Evaluation Project (LEP). This suggests that, at least in Karonga District, new male patients were marginally more likely to self-report than new female patients.

The slightly higher lepromatous rates in the highland districts are not likely to account for the differences in the proportion of males among new leprosy patients as observed between the lowland and the highland districts.

(d) Detection rates

Since the leprosy control projects have included some active case-finding (school surveys and contact surveys), detection rates are slightly higher than pure self-reporting rates but lower than true incidence rates. Data from the LEP indicate that the case detection rates are about two thirds of the true incidence rates at least in Karonga District.⁴

Not all districts were completely covered upon introduction of a mobile service to that district. Nonetheless we have consistently used total district populations as denominators. Thus in some districts the detection rate might be artificially low for the 'first year'. The first year in this context means the first year when mobile services were operational by the first of January in that district.

From the rates shown in Table 3 and in Figure 5 we can conclude: (i) That most of the backlog of new leprosy patients, without a history of having received antileprosy treatment before, had self-reported (or been detected) by the end of 1978 in Group A (highland) districts and by the end of 1977 in Group B districts along the lakeshore because of the sharp drop in detection rates in 1979 and 1978 respectively. One can probably also conclude from the Karonga District figures, that a small part of the backlog of patients remained unregistered, because the beginning of the main survey by the LEP in 1980 was characterized by a sharp increase in the detection rate; and (ii) that in the lowland districts (Group B) the endemic situation would appear to be different from the endemic situation in the highland districts (group A) because, although the decline in detection rates is similar to the one in Group A districts, the detection rates are still 5 times higher along the shore of Lake Malaŵi than on the western plateau.

(e) Projections

Annual case detection rates per 1000 population are shown separately for highland and lowland areas in Figure 5. Figure 5(a) shows the rates on an arithmetic scale, revealing a dramatic fall in both regions over the past 10 years. Figure 5(b) shows the rates on a logarithmic scale which reveals that the proportional fall has been very similar in the two areas. The similarity of these trends and their linearity on the logarithmic scale encourages us to predict future detection rates by extrapolating these (loglinear) trends. For group A districts expected detection rates for 1984–1988 were calculated by linear regression of the logarithms of the detection rates for 1979–1983, and for group B districts by linear regression of the logarithms of the detection rates for 1978–1983. Results of these projections are shown in Table 4(a). Multiplication of detection rates with

Table 3. Detection rates per calendar year per thousand.

	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983
Group A		0.22	0.20	0.24	0.21	0.13	0.15	0.11	0.08	0.08
Group B*		1.39	1.14	1.33	0.65	0.60	0.58	0.56	0.44	0.38
Karonga District	2.61	2.87	1.69	1.64	0.81	0.73	1.35	1.49	0.80	1.46

* Excluding Zomba district because the denominator for the area covered by LEPRO/Likwenu is not exactly known.

Table 4(a). Expected number of new patients 1984–1988 by highland districts (group A) and lowland districts (group B). (95% confidence limits in brackets.)

	1984	1985	1986	1987	1988
Group A					
Detection rate per 1000	0.066 (.040–0.108)	0.056 (.030–0.106)	0.048 (.022–0.104)	0.041 (.016–0.102)	0.035 (.012–0.101)
Expected population (× 1000)*	1483.1	1533.4	1582.7	1632.0	1689.2
Expected number of new patients	98 (60–160)	86 (46–162)	76 (35–165)	67 (27–167)	59 (20–170)
Group B					
Detection rate per 1000	0.365 (.292–0.457)	0.329 (.249–0.434)	0.296 (.213–0.413)	0.267 (.181–0.393)	0.241 (.155–0.375)
Expected population (× 1000)*	1193.3	1230.4	1267.3	1303.9	1346.9
Expected number of new patients	436 (348–545)	405 (307–534)	376 (270–523)	348 (237–513)	324 (208–505)

* Mid-year figure.

Table 4(b). Expected number of new patients 1984–1988 in the whole of Malawi.

	1984	1985	1986	1987	1988
	1334	1234	1237	1203	1181

mid-year population estimates, taken from a recent publication of the National Statistical Office on Zomba, Malaŵi,⁵ leads to the numbers of patients expected to be found annually in the years 1984–1988.

If we try to project the numbers of new leprosy patients to be detected annually from 1984 to 1988 for the whole of Malaŵi we have to add another 100 patients per year expected in Karonga District, where the incidence rate is probably about 1 per thousand and does not seem to be declining at present.⁴ For Lilongwe and Dedza Districts we feel justified in applying the detection rates projected for the A group (highland) districts, since the detection rates for 1983 in Lilongwe and Dedza Districts were 0·06 and 0·08 per thousand, respectively. This gives an expected number of new leprosy patients in Lilongwe and Dedza Districts (together) of 84 in 1984, 74 in 1985, 66 in 1986, 57 in 1987 and 50 in 1988. For Ntcheu District, which had a detection rate of 0·17 per thousand in 1983, we performed the same regression analysis as for groups A and B districts. This gives an expected number of new leprosy patients in Ntcheu District of 46 in 1984, 42 in 1985, 38 in 1986, 34 in 1987 and 31 in 1988.

Projections for the Pilot Project Area² and the Lower Shire Valley are considerably more hazardous due to the lack of entirely comparable data and are not presented in detail. The expected number of new leprosy patients in the Pilot Project Area is 294 in 1984, 303 in 1985, 311 in 1986, 320 in 1987 and 330 in 1988. For the Lower Shire Valley we estimate the expected number of new leprosy patients to be 256 in 1984, 264 in 1985, 271 in 1986, 279 in 1987 and 288 in 1988.

The total number of new leprosy patients which we would expect to be detected in the whole of Malaŵi, on the basis of the above assumptions, is shown in Table 4(b).

Discussion

When discussing the data presented in this paper and, in general, data which have been routinely collected, it would seem prudent to discuss first of all whether there is any indication that the data may be distorted by operational circumstances.

It would seem that one of our main findings is the decline in detection rates in the lowland districts (group B) at least since 1978 and in the highland districts (group A) at least since 1979. Two factors could cause this decline in detection rates NOT to reflect a decline in incidence rates of clinical leprosy in the communities.

One factor could be that LEPRA's mobile service and presence in these districts has declined since 1978–79 and the other factor could be that, as time went on, people in general lost interest in self-reporting with signs of clinical leprosy. There is, to our knowledge, no evidence for either.

Thus we think we can assume that the incidence rates of clinical leprosy have also declined, at least since 1978–79, parallel to the decline in the detection rates,

as it would appear that the main backlog of leprosy patients prior to the presence of LEPROA's mobile service in these areas had come forward for examination and registration by 1977–78 (Table 3 and Figure 5).

A decline in incidence rates could in turn explain the trends observed both in a shift towards higher lepromatous rates in recent years and in shifts in the relative age distribution of new patients towards higher age groups. The first could be due to the longer incubation period of lepromatous leprosy,⁶ and the second could be due to breakdowns in immunity in older individuals infected some time in the past, events independent of current transmission of *Mycobacterium leprae*. On the other hand, if school surveys were carried out more frequently in the earlier years than in the later years of the period 1973–1983, it is possible that this might have exaggerated the apparent shift to higher age groups.

It has been suggested that increases in the lepromatous rate and shifts in the relative age distribution of new leprosy patients towards higher age groups are indicators of a decline in incidence rates of leprosy.⁷ However the rise in lepromatous rates could also, at least partly, be due to a selective drop in self-reporting among paucibacilliferous patients in highland and lowland areas.

Several factors might be at the root of the decline in incidence rates of clinical leprosy:

(i) BCG: BCG has been widely used in Malaŵi since 1972, when it was first introduced in mass campaigns aimed at individuals under 15 years of age. After the initial mass campaigns, BCG vaccination was left to the Under Five Clinics. As a result, a high proportion (over 50%)⁴ of Malaŵians born since 1958 have a BCG scar. Though the extent of protection imparted by BCG against leprosy in Malaŵi is still being analysed, it must be recognized that BCG has shown some degree of protection in every circumstance where this has been assessed.^{8–10} Thus the decline in incidence rates and the trends towards older age groups revealed in Figures 2–4 could reflect, in part, the ageing cohort of BCG protected individuals.

(ii) Secular trends: Improving living conditions since Malaŵi's independence (1964) under the leadership of His Excellency the Life President Ngwazi Dr H Kamuzu Banda, may have contributed to the decline in incidence rates.

(iii) Effects of leprosy control activities: In theory, the introduction of chemotherapy against leprosy on a wide scale in Malaŵi, by the British Leprosy Relief Association (LEPROA) may have exerted some influence on trends of transmission of *M. leprae*, and thus have influenced the trends seen in our data. On the other hand, there is no strong evidence either here or in the literature¹¹ which would lead us to attribute these trends to chemotherapy-based control.

Another main finding presented in this paper is the difference in endemicity between highland and lowland areas. Again, although this finding inevitably also reflects the method and intensity of case-finding activities in addition to the true incidence rate of leprosy in the community, we believe that the fivefold difference in detection rates between highland and lowland areas reflects a real difference

and is not merely an artefact of case detection methods. The difference is unlikely to be spurious for the following reasons:

(i) If the boundary between high altitude and low altitude areas, which runs north to south, coincided with individual project boundaries, it would be difficult to know whether or not the observed difference in endemicity was real or owing to differences between the projects. However, the difference between highland and lowland areas is also observed within individual projects whose boundaries run from east to west.

(ii) Leprosy Control Assistants (LCAs) are transferred from one district to another within each project frequently enough to make it unlikely that the difference in endemicity observed is owing to individual activity and capacity of the staff (the less proficient LCAs are not as a matter of policy sequestered on the plateau).

(iii) The Field Officer/Medical Officer of a project is in frequent contact with his Assistant Field Officers and LCAs and we are confident that this has prevented the formation of different diagnostic practices within one project.

We therefore conclude that the difference in endemicity is real and not an artefact. The difference could be a function of a number of climatic, ecological, social and physiological differences between populations living in highland and lowland areas. In particular the relative distribution of species of 'environmental' mycobacteria in the soil might be different in the highland areas on the western plateau from the one in the lowland areas along the shore of Lake Malaŵi. It has been suggested that contact with certain environmental mycobacteria might enhance or decrease the immune response to an infection with *M. leprae*.¹²

Alternatively the higher humidity in the lowland areas¹³ might favour the survival of *M. leprae* outside the human body¹⁴ and thus facilitate transmission of *M. leprae* along the shore of Lake Malaŵi rather than on the Western Plateau.

On the other hand, ultraviolet light, which might reduce the immune response to *M. leprae*¹⁵ should be received in greater amounts on the skin in highland districts than along the shore of Lake Malaŵi.

A further obvious difference between A and B group districts is the population density in those parts of the districts where the land is cultivated and where people live. In B group districts the thus defined population density ranges from 129 in Salima district to 251 in Nkhotakota district, inhabitants per square kilometre, with an average of 197 per sq km. In the A group districts the average is 113 per sq km, with a range of 81 in Mzimba district to 183 in Dowa district, of inhabitants per square kilometre of cultivated land. The figures given are for 1966¹³ (recalculated from Table 4, page 210), later figures were not available to us, but we do not expect a substantial relative change in these population densities.

The third main finding seems to be the difference in sex ratios of new leprosy patients between the highland and lowland districts. The higher proportion of male patients in highland areas might be due in part to the relative excess of males

in the highlands and in part to poorer access in highland areas. But we doubt that this could wholly explain the observed difference. Furthermore, given the well documented observation of a male excess among leprosy patients in most countries, it is the relative excess of female patients in the lowland areas of Malaŵi which is the most striking. This difference is borne out by the total population survey results of the LEP.⁴

Our projections for the next five years (1984–1988) have naturally wide confidence limits as indicated in Table 4(a). According to Figure 5, the annual decline is in the order of 12%. This might be an exaggeration of the true rates of decline for two reasons. First, it is recognized that the backlog of new patients had not all self-reported by 1977–78. However the proportion of backlog cases should have further decreased over the period. The effect of this should have magnified the apparent fall in incidence over the period. Second, it is recognized that more school surveys were carried out in the early years than the later years of the LCP in most districts. Thus the active case detection may have been more intense during the early years, again with the effect of exaggerating the fall in incidence over the period. In opposition to these trends, there may have been an increased tendency to self-report in recent years as the LCP activities became better established and more widely known. Taken together we suspect that the rates of decline as shown in Figure 5 may be an exaggeration of the true trend, but that nevertheless the incidence of leprosy is indeed falling throughout much of the country. And if so, the numbers of patients actually detected during 1984–1988 should, at least in the A and B group districts, not greatly exceed the numbers expected. If on the other hand, the numbers of patients actually detected fall far short of the numbers expected, one should not hesitate to look closely into operational changes introduced in the LEPRO Control Project after 1983.

Conclusion

Data presented in this paper indicate that there are at least two distinctly different leprosy endemic situations in Malaŵi (Central Africa). In the districts on the Central African Plateau (highland districts, or Western Plateau districts, altitude 900–1400 m above sea level) the level of endemicity is low and detection rates had fallen to 0.08 per thousand by 1983. In the districts in the Rift Valley (lowland districts or lakeshore districts, altitude 472–900 m above sea level) the level of endemicity is still five times higher than in the highland districts and the detection rates had only declined to 0.38 per thousand by 1983.

The decline in detection rates in both areas has been observed since at least 1978–1979 and there is no evidence that this decline, which is similar in both areas, has been due to operational changes within the LEPRO Control Project.

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The detection of subclinical leprosy using a monoclonal antibody based radioimmunoassay

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Summary The monoclonal antibody based competition radioimmunoassay test was used to examine sera from 100 healthy household contacts of known leprosy patients. Only 6 out of 100 contacts had detectable specific antibodies.

It remains conjectural that this small fraction of contact subjects may be at much higher risk of developing disease than those without antibodies. Contacts who are antibody positive and lepromin negative (as were 4 of the 6), would best qualify for being offered chemoprophylaxis.

Introduction

Populations in endemic areas are exposed to the risk of developing leprosy because of delayed presentation of cases and prolonged infectivity before treatment is commenced. A large proportion, probably over 90%¹ of those exposed will develop subclinical infection but only a much smaller proportion will subsequently develop clinical leprosy;² the majority of subclinical infections are eradicated by an effective cell-mediated immune response to *Mycobacterium leprae*. A screening test, specific and predictive for leprosy is needed in order to reduce the large at-risk population to a small high-risk population which would be feasible to follow up with chemoprophylactic treatment.

Tests based on the cell-mediated response to *M. leprae* are not sufficiently specific because of cross-reactivity with *M. tuberculosis* and environmental mycobacteria.³ However, a new serological test for leprosy has been developed following the production of a monoclonal antibody, ML04, to the 35 K protein

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antigen of *M. leprae*. This was found to be fully specific for leprosy when tested against patients with active pulmonary tuberculosis, autoimmune diseases, carcinoma and healthy controls.⁵ Because of this high specificity this test was used to screen a population of healthy contacts of known leprosy source cases.

Materials and methods

One hundred household contacts of leprosy patients were studied. The contacts consisted of 84 relatives of patients attending the Central JALMA Institute for Leprosy, Agra and 16 relatives of patients attending the rural health centre at Deeg, Rajasthan. The contacts were all examined and excluded from the trial if they had any definite or probable clinical signs of leprosy. Each contact had a lepromin test performed and blood was taken for antibody titre determination. The diagnosis of leprosy and classification according to the Ridley–Jopling scale⁶ was made for each patient on the basis of clinical features, slit-skin smear and lepromin test in all cases and in addition histology of the skin lesion in 12 cases.

LEPROMIN TEST

Dharmendra lepromin⁷ was used to assess the skin delayed hypersensitivity to *M. leprae* in each contact. A positive early reaction (Fernandez reaction) was recorded after 48 hours if there was erythema and induration of 5 mm or more in diameter; a positive late reaction (Mitsuda reaction) was recorded at 4 weeks if there was a papule of 4 mm or more in diameter.

SERUM ANTIBODY COMPETITION TEST (SACT)

Antibodies to the 35K antigen (MY2a epitope) of *M. leprae* were detected by radioimmunoassay. The principle of the test is competition between ¹²⁵I labelled *M. leprae* specific ML04 antibodies and homologous human antibodies present in the test serum for antigen binding. The technique followed was as described by Sinha *et al.*⁵ Results were expressed as the reciprocal of the serum dilution needed to inhibit 50% (ID₅₀ value) of ¹²⁵I-ML04 binding to the antigen.

Results

Six out of 100 household contacts of leprosy patients had antibodies to the MY2a epitope of *M. leprae* as determined by the SACT assay. All 6 SACT positive cases had low titres of antibody with an ID₅₀ value of 5. Figure 1 shows the pattern of inhibition of ¹²⁵I-ML04 binding by the dilutions of the antibody positive sera. The hatched area indicates the range of inhibition by various control sera including those of tuberculosis patients.

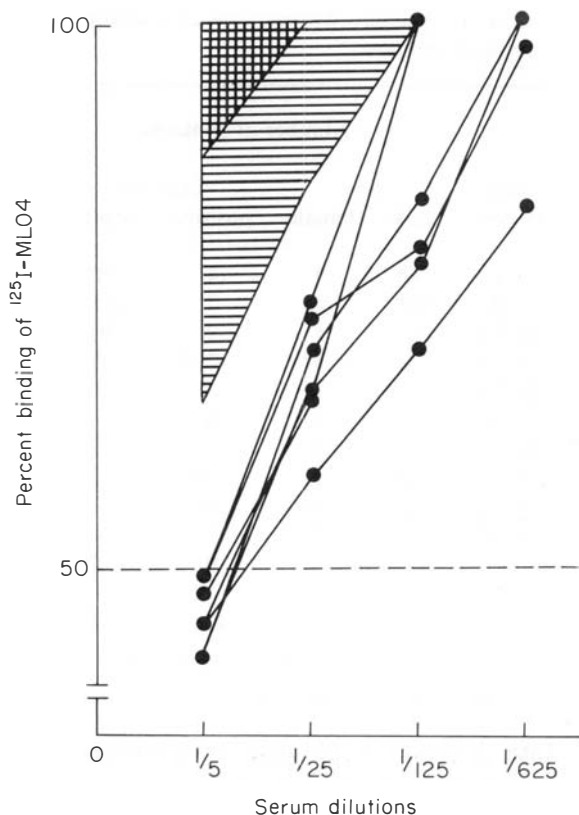


Figure 1. ¹²⁵I-ML04 binding of diluted sera from the six positive contacts and from six healthy controls and six tuberculous patients. ▨, healthy controls from endemic areas; ▩, tuberculosis patients; ●—●, contacts.

The age and sex distribution of the patients studied is shown in Table 1. Two of the 54 (4%) contacts under 15 years old were antibody positive and 4 of 46 (9%) contacts of 15 years and over were antibody positive. The early lepromin reaction was read in 91 cases and 21 of these returned after one month for reading of the late reaction. Nine cases were lost to follow up. Of the 6 SACT positive contacts 4 had a negative lepromin test (all Fernandez reaction) and 2 a positive test (one Fernandez reaction and one Mitsuda reaction) (Table 1). The duration that each contact was exposed to the source case is shown in Table 2. Only one out of the 31 (3%) contacts exposed to LL cases was antibody positive whereas 4 out of 37 (11%) contacts of BT cases were antibody positive. There was thus no positive correlation between the antibody positivity of contacts and exposure to a multibacillary source case. Only 2 out of the 24 (8%) contacts exposed to a source case for 10 or more years was antibody positive whereas 4 of the 76 (5%) contacts exposed for less than 10 years and 2 of the 42 (5%) exposed for less than 5 years

Table 1. Age/Sex distribution and lepromin status of contacts

Age (years)	Number of contacts			
	Sex		Lepromin	
	male	female	positive	negative
0-4	6*	9	4	10*
5-9	16*	4	7	13*
10-14	14	5	9	10
15-19	7	3*	7	1*
20-24	6	3	3	5
25-29	4	1	0	3
30-34	2	3	3	2
35-39	4*	1	2*	3
40-44	2	2*	3*	1
45-49	2	2	2	0
50+	3*	1	0	3*
Total	66	34	40	51

* One SACT positive contact

Table 2. Survey of the duration of exposure of contacts & classification of source cases

Duration of exposure (years)	Number of tested contacts				
	TT†	BT	BB	BL	LL
0-4	2	20*	7	6	7*
5-9	—	10**	5	7	12
10-14	—	3	1	3*	8
15-19	—	4*	—	—	1
20-24	—	—	—	1	3

* One SACT positive contact

† Classification of the source case.

were antibody positive. There was thus no positive correlation between antibody positivity and duration of exposure to a source case.

Discussion

Only a small proportion of those exposed to leprosy will go on to develop disease:

the incidence of leprosy in a marriage partner of a patient is in the order of 5%.⁸ It is therefore impractical to follow up and/or prophylactically treat all contacts of leprosy patients. However, preventative treatment could be considered if a small high-risk group could be identified. Only 6 out of 100 household contacts of leprosy patients were SACT positive. Antibodies detected by the fluorescence test were observed in a much larger proportion of contacts: one study⁹ found them in 81% (21 out of 26) in a similar local population to that of this study and another¹ found them in 92% (57 out of 62) of contacts in Japan. The MAB competition test thus defines a much smaller sub-group of all those with a subclinical infection.

Assuming that antibody positive contacts have a higher risk of subsequently developing leprosy than antibody negative contacts, this small fraction of all contacts could be carefully followed up. In this study 4 of the 6 antibody positive contacts had a negative lepromin test. It is accepted that cell-mediated immunity rather than antibodies can eliminate a subclinical infection.³ Thus the antibody positive contacts who lack a cell-mediated immune response to *M. leprae* as judged by a negative lepromin test would seem to carry the highest risk and could be considered for chemoprophylaxis.

It has been generally assumed that contacts exposed for prolonged periods to a multibacillary case and childhood contacts probably carry the highest risk. Although our study contained only 6 antibody positive contacts the obtained results did not support such trends. Two of the antibody positive contacts were relatives, husband and son, of a 39-year-old paucibacillary case (BT) and they had only been exposed to the overt disease for 3 years. The possibility remains that these two contacts were also exposed to another source as they lived in an area of moderate endemicity; the leprosy prevalence rate in the catchment area of this study is 8 per 1000 head of population. Childhood contacts were not more likely to be SACT positive than adults: 4% (2 out of 54) of those under 15 and 6% (1 out of 15) of those under 5 were seropositive. One study¹ found fluorescent antibodies in higher titres in those under 5 years of age; the only positive contact under 5 in our study had a low titre of antibody as had all the other seropositive contacts.

In the previous study⁵ a higher overall antibody positivity (30%) was reported among the contacts of leprosy patients. However, no information about the age and sex of these contacts as well as the endemicity of the area to which they belonged was recorded. It is possible that most of those contacts belonged to hyperendemic areas and were an older group with prolonged contact with the source cases. In the present study, only 9% positivity among the contacts above 15 years and 4% in those below 15 years of age was found.

Only a longitudinal prospective study could define the significance of antibody positivity by assessing the clinical outcome in the positive contacts and evaluating the predictive value of the MAB competition test. Preliminary results from a prospective study¹⁰ indicated that 6 out of 16 SACT positive contacts developed overt leprosy manifesting as multiple lesions of the BT/BB type within

6 months of the serum being positive. Some of the contacts who were initially SACT positive became negative and developed a positive Mitsuda reaction. This ongoing survey suggests that those contacts who are ML04-SACT positive may be at a greater risk of developing clinical leprosy.

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Mass screening in leprosy endemic areas of Turkey: preliminary report

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Summary A multipurpose programme was devised to enable a research team of university personnel to cooperate with local health units with the following objects: 1, to find registered leprosy patients in selected areas and provide them with curative and rehabilitative services; 2, to locate people known to have been in close contact with registered patients and keep them under surveillance; 3, to screen the whole population in selected areas in order to find new cases; 4, to undertake periodic examination of suspected cases; and 5, to provide on-the-spot training for health personnel in the control of leprosy. Because of a known high prevalence, the province of Van, situated in the eastern part of Turkey, on the Iranian border, was chosen, and in the first year of this project, two regions of this province were covered, with the examination of over 15,000 people. This report describes the methodology and preliminary findings and discusses some of the difficulties in the interpretation of results with regard to the total population coverage achieved by such a screening programme in 1984, and the previously recorded, official census figures. It is planned to continue and expand this research and to analyse results in a future publication.

Introduction

Data related to the epidemiology of leprosy is limited in Turkey, as in other parts of the world, when compared with other communicable diseases. The bacteriological characteristics of *Mycobacterium leprae*, the persistence of the disease in underdeveloped and developing countries, and the behaviour of the patients limit the success of leprosy control methods. The number of newly diagnosed leprosy cases is increasing considerably in countries where the disease is endemic or endemosporic.^{1,2}

In Turkey, the fight against leprosy began in the early 1960s and within a few years the registered cases reached 3454, and the general prevalence rate was calculated as 0·11 per thousand in 1964. The method used for screening could not

be considered as mass screening, because only two millions out of the 10·5 millions population were examined in the leprosy endemic areas, whereas for an effective leprosy control programme, it is necessary to examine everybody in the endemic area by house-to-house visits. As a matter of fact, Dr Dominguez, a WHO consultant in leprosy, prepared a report in 1966 in which he recognized the attempts at leprosy control in Turkey but criticized the method of screening used.³ Gradually, haphazard screening has been replaced by dispensary control. According to the official records, the number of the registered patients were 4140 with a prevalance of 0·09 per thousand in 1981.⁴ Figures are almost the same between 1964 and 1981.

Health units (health centres without beds) are the basis of the governmental public health services in Turkey. According to the characteristics of the area, health units were established per 5,000–10,000 population in order to provide polyvalent health services. Each health unit has one doctor, with nurses, midwives and health technicians as necessary. The duties of the health units include finding new cases and notifying them to the Directorate of Health, treatment of registered cases, and referral of those needing further treatment and rehabilitation⁵. The health units also inform the patients of possible local aid provided by the voluntary people or agencies. The staff of the leprosy dispensaries in the city centres supervise the services given by the health units.

Although the functional structure of the health units was organized to realize this kind of health service, some studies on diagnosis and the registration of new cases and the reliability of the leprosy prevalence (which was static during the last 20 years) gave the impression that the health units were not able to provide satisfactory services for leprosy control.⁶ Because, firstly, the problem of leprosy is underrated compared to the other health problems (e.g. MCH, tuberculosis and environmental health) in Turkey. Secondly, the training of health personnel is not suitable to the needs of the country. In our opinion it is however possible to achieve success in leprosy control with the present health service system in Turkey without adding additional expensive programmes, provided that shortcomings in the training of health personnel as well as the administration of health services for leprosy control are corrected.⁷

Objectives

Investigators prepared a multipurpose research programme considering the functional structure of the health units and the situation of leprosy in Turkey. According to this programme, a research team was organized from the university personnel to cooperate with the local health personnel of the chosen areas to perform mass screening. The following objectives are the aim of the screening programmes:

- 1 To find registered patients in selected areas, and if necessary to provide them with all the available curative and rehabilitative services.
- 2 To locate people known to have been in close contact with registered patients and keep them under surveillance for a period of 5 years.
- 3 To screen the whole population in selected areas in order to detect unknown cases and to find out whether they have ever been in contact with any leprosy patients, and to arrange a suitable treatment programme for such cases.
- 4 To undertake periodical examination and observation of the suspected cases who are not known contacts.
- 5 Last but not least, to provide on-the-job training for health units' personnel about the control of leprosy, so that they do not consider themselves only as drug distributors but as qualified people interested in the problems of leprosy patients and keeping the close family contacts under surveillance.

Materials and methods

According to the data in hand the highest prevalence of leprosy in Turkey is in the province of Van which is 1.0 per thousand. A pilot study carried out in 1983 gave an impression that the prevalence of the disease could be even higher. In order not to miss any leprosy cases or suspected ones, it was decided to undertake mass screening in the province of Van.

This province is situated in the east of Turkey right on the Iranian border and covers 19,062 km². Total population of the province is almost 500,000 of which 312,000 (62.5%) live in rural areas and 93.0% of rural settlers are spread around 560 villages with less than 2000 people each. Considering such factors as the vastness of the area, scattered settlement of the population, inefficient manpower, potential of the working group and the necessary quality of the research work, it has been decided to spread the work over a number of years instead of applying a programme that would cover the whole area of the province. In this preliminary report the results of the first study carried out in 1984 are given.

In the first year two regions of the Van province, namely Bahçesaray and Çaldıran, were chosen as study areas. There were 12,165 persons spread over 66 villages in Bahçesaray and 15,323 persons spread over 47 villages in Çaldıran. The first area is situated in the mountainous south-west part of Van and the second one is located on a high plateau in the north-east part of the province.

The study teams had prepared a working plan based on data obtained from the Directorate of Health of the Province and marked all the known cases on detailed maps of the regions. Before going to Van, study teams were organized. Each team consisted of 4 persons, mainly medical students who had volunteered to work on this investigation and had had one week's training on the clinical diagnosis of leprosy at the Leprosy Hospital.

Generally these groups reached the study areas by car and sometimes on foot

where roads were unsuitable for cars. Mass screening and therapy are accepted as principal methods for the control of leprosy.⁸ Therefore, all the available people in each settlement were submitted to medical examination. In order to secure success in screening and to draw the people's interest to this end, one member of each team was assigned to deal with the other diseases and complaints of the people, and if possible to treat them. To enable effective services, the teams carried with them sufficient amounts of essential drugs, and distributed them free of charge to the patients in both areas. The people of two settlements (5610 persons) which have health units were left out of screening operations because screening would be carried out by the health unit personnel.

Considering field working conditions, and expected functions of health units' personnel on leprosy, clinical examination is the accepted method in this study. As Browne mentioned,⁹ this method is sufficient to diagnose most of the new cases as well as to confirm the type of leprosy of the old registered cases. However, for suspected cases, biopsy and smear examinations were undertaken by specialists.

Results

The screening was completed within 11 days at Bahçesaray, and within 10 days at Çaldıran. In both study areas, all the villages were reached and 6841 people at Bahçesaray, and 9007 at Çaldıran were examined. When these figures are compared with those of census results undertaken in the region 4 years ago, it will be noted that the numbers cover 68·5% of population in the first area and 76·2% of population in the second one. It has not been possible to reach higher figures. The team members have tried to find the reasons for this discrepancy and concluded that either the census figures did not reflect the truth, or that perhaps an inland emigration had taken place during the four years, or some people were temporarily away from their villages. But those who were willing to undergo medical examination remained there at the time. With the help of the health personnel who knew the areas sufficiently well, and the cooperation of the respected elderly villagers, house-to-house screening was conducted. The screening was not considered completed until the teams were sure every individual had been examined. It has therefore been concluded that the difference between the number of people examined and the census figures can only be explained by the census figures being incorrect. It is estimated that the proportion of the people who were absent during the screening and of those who did not accept the examination could not exceed 10–15% of the population registered by the previous census.

It may be concluded that the results of the screening could represent the communities within 95% confidence interval and 3 per 10,000 reliability limits for those examined in Bahçesaray and 4 per 10,000 reliability limits for those

examined in Çaldıran. Findings of the screening activities are summarized in Tables 1 and 2. Age and sex distribution of new cases are given in Table 3.

Since the old registered cases had previously only DDS monotherapy all of these cases together with the newly registered ones have been taken under the MDT programme according to the type of their disease.¹⁰

Time-Effectiveness

The screening was completed within a period of 21 days. An average of 622 individuals were examined in a day at Bahçesaray where working conditions were extremely unfavourable, whereas in the area of Çaldıran the figure reached was up to 901 because of better working conditions there. The screening teams worked net 7·2 h per day at Bahçesaray and 6·0 h at Çaldıran. One team (4 persons) performed a total of 21·5 examinations per hour in the first area and 37·5 examinations per hour in the second area.

Table 1. Findings related to the registered leprosy patients in Bahçesaray and Çaldıran.

Findings	Research areas		Total	
	Bahçesaray	Çaldıran	Number	%
No. of patients previously registered	14	35	49	100·0
No. of previously registered patients examined	8	24	32	65·3
Reasons of not being examined of the remaining previously registered cases:				
Died	4	3	7	14·3
Left area	1	5	6	12·2
Unknown*	1	3	4	8·2
Off registered because of false diagnosis	—	1	1	2·0
No. of previously registered cases after screening*	9	26	35	71·5

* Unknown cases are not excluded from the lists.

Table 2. Registered leprosy patients at the end of screening in Bahçesaray and Çaldıran (October 1984).

Findings	Research areas		Total	
	Bahçesaray	Çaldıran	Number	%
No. of previously registered cases after screening	9	26	35	66.1
No. of new cases found through screening	7	11	18	33.9
Total cases	16	37	53	100.0
History of close contact among the newly found cases	1	5	6	
No. of close contacts examined*	55	89	144	
No. of suspected cases under surveillance†	23	32	56	

* These contacts will be periodically examined once a year for five years.

† Cases in this group include those who had uncertain leprosy case(s) among their distant relatives or in their villages, and had rare enlarged solitary peripheral nerves or slightly impaired sensation but did not have skin signs or loss of sensation.

Table 3. Distribution of newly found patients by age and sex.

Age groups (in years)	No. of patients		
	Male	Female	Total
9 and less	2	1	3
10-19	—	—	—
20-29	6	1	7
30-39	3	1	4
40 and more	2	2	4
Total	13	5	18

The distribution of these patients according to the clinical forms is as follows:

TT: 1 BT: 4 BB: 1 BL: 4 LL: 3 I: 5

Cost-Effectiveness

The project was financed by the Van and Environs Development Foundation. Transport and local health personnel were provided by the Ministry of Health and Social Assistance. For the purpose of cost estimations, the exact values of new materials to be used in operations have been fully taken into account, but the cost of used materials has been omitted. No extra wages have been paid either to the team members or to the health personnel. They were only provided with food, lodging and transportation, the latter consuming the greater portion of the limited budget (US\$ 1877). Food expenses amounted to US\$ 612 and the total expenditure reached to US\$ 2850 averaging US\$ 137.70 per day and US\$ 0.18 per screened person.

Though a more extensive discussion of our findings in respect of this mass screening project could be expected, the diversified nature of the population examined has at this stage prevented us from making generalizations. It is planned to continue and expand these studies in the future and to report our findings and conclusions in the medical press.

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Disability assessment as a measure of progress in leprosy control

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Summary Leprosy control programmes using methods of secondary prevention are in widespread use throughout the world. It is suggested that the most relevant method of assessing progress is by measuring the prevalence and incidence of disability. Disability assessment (WHO criteria) has been carried out in a control programme in India at baseline and now 4 years later. There has been little change in the prevalence of leprosy over this period but the prevalence of disability has fallen from 91.4 to 62.3 per 100,000. It is likely that this fall is the result of the control programme since there is no evidence of a secular trend of reduced disability in leprosy in India. The mechanism of this fall is thought to be the loss of disabled patients through death and migration; these are not being replaced by new disabled patients.

Introduction

Leprosy control programmes using methods of secondary prevention are conducted throughout the world. These programmes are based on early detection of disease using a variety of methods and on early, regular, and adequate chemotherapy. It is well recognized that such methods are unlikely to eradicate leprosy^{1,2} and apart from a few exceptions³ control programmes have had little effect on the incidence of leprosy.⁴ This being so, it is therefore important to evaluate leprosy control programmes using a more realistic objective.

The strategy of leprosy control programmes is unlikely to have any significant effect on disease incidence but is more likely to affect disease severity and the level of disability caused by leprosy. A more realistic objective by which to measure the effect of a leprosy control programme would be to ask whether or not it is affecting the disability caused by leprosy. Since the problem of leprosy to the

individual and society is disability, disability is an appropriate measure of a programme's effectiveness.

This ongoing study examines the effectiveness of one leprosy control programme in India using the point prevalence of disability as the criterion in a defined community. The baseline disability prevalence results have been reported⁵ and we report here the disability prevalence using the same methodology in the same community 4 years later.

Methods

The defined population for the study was resident in 126 villages in two talukas of Belgaum District in Karnataka State, India with a population of 233,581 at the 1971 census. The leprosy control programme was carried out according to the guidelines of the National Leprosy Control Programme of the Government of India⁶ and staffed to the appropriate level. The programme was carried out by population enumeration and examination by households, schools and contact surveillance. Health education was provided as part of the programme at a variety of levels from schools to village leaders.

Patient management was aimed at maintaining the patient within the community. Treatment was based on oral dapsone, although multidrug therapy has now been introduced, disability management and treatment of reactional states as and when they arose. Patients with anaesthetic limbs were taught preventive care, microcellular rubber chappels were offered and walking plasters were used for plantar ulcers when appropriate. Patients who developed acute disability were hospitalized and given appropriate treatment including physiotherapy and practical health education.

Disability assessment was performed at detection and then at regular intervals usually by the physiotherapy technician. The assessment used was that proposed in 1971 for use in epidemiological surveys,⁷ the assessment being summarized in the Disability Index 2 (DI-2). The prevalence of leprosy and its resultant disability had been calculated in 1979 at the end of the first survey and this is compared with the similar findings at the end of the second survey in 1983.

The calculation of the prevalence rate in 1979 is based on the cases detected and the population examined. However, the calculation of prevalence in 1983 is based on existing cases as at the end of December 1983 and therefore includes cases detected during both surveys but excludes those dying, migrating or disease-arrested; this is the true point prevalence rate and not the second survey case detection rate. The denominator in the calculation of the 1983 prevalence is all those examined in either survey. Point prevalence in 1979 is compared with the point prevalence in 1983. Incidence rates can be calculated between 1979 and 1983 but not the change in incidence rates; this can be examined following the third survey. The definition of a case of leprosy includes both active and inactive cases

but excludes those whose disease is arrested; however the definition of disability includes all those with disability due to leprosy irrespective of whether or not the disease is arrested.

Results

The population of the defined project area increased by 5.9% between the two surveys (Table 1). The increase in the number of children (8.8%) was much higher than that for adults (4.1%). The percentage of the population examined at each survey was 80% with the rates being higher in children than adults and higher in women than in men (Table 2).

In the first survey 931 cases were detected and a further 703 new cases in the second survey. The classification of cases detected in both surveys is shown in Table 3, the distribution of cases by classification was statistically different in the second survey compared with the first. In the second survey 76% of cases were at the tuberculoid end of the spectrum compared with 61% in the first survey. The

Table 1. Age and sex structure of population enumerated at first and second surveys.

Survey	Males		Females		Total
	0-14 yr	15 yr +	0-14 yr	15 yr +	
First	47844 (19.9%)	78658 (32.8%)	42767 (17.8%)	70630 (29.4%)	239899
Second	51363 (20.2%)	81106 (31.9%)	47180 (18.6%)	74296 (29.3%)	253945
% age change	+7.4	+3.1	+10.3	+5.2	+5.9

() Figures in brackets are percentages of the totals.

Table 2. Percentage of the population examined in the two surveys by age and sex.

Percentage examined	Males		Females		Total
	Children 0-14 yr	Adults 15 yr +	Children 0-14 yr	Adults 15 yr +	
First survey	87.8	67.3	89.9	82.1	79.8
Second survey	87.4	70.1	89.1	83.5	81.1

Table 3. Leprosy cases detected in the two surveys by classification (Ridley-Jopling).

Type of leprosy	Number in 1st survey	Number in 2nd survey
I	172 (18.5%)	115 (16.4%)
TT	391 (41.9%)	379 (53.9%)
BT	178 (19.1%)	153 (21.8%)
BL	51 (5.5%)	30 (4.3%)
LL	139 (14.9%)	26 (3.7%)
Total	931	703

$$\chi^2 = 64.29; P < 0.001$$

relative importance of the various methods of case detection were very different between the surveys as is shown in Table 4; with both school survey and contact surveillance being more important. The proportion of disabled cases in the second survey was only 5.5% compared with 18.8% in the first survey. Many (19 out of 39) of the disabled patients detected in the second survey had not been previously examined. In the first survey 175 patients with disability were detected. Of these 118 remained within the control programme while the rest, 57, had either died or migrated.

Prevalence of leprosy

The prevalence of leprosy after the first survey in 1979 was 4.86 per 1000, and the prevalence of leprosy in 1983 at the end of the second survey was 4.3 per 1000. The

Table 4. Number of leprosy cases detected using different methods in the two surveys.

Detection method	First survey number	First survey (%)	Second survey number	Second survey (%)
General survey	630	(67.7)	404	(57.5)
School survey	19	(2.0)	65	(9.2)
Contact survey	26	(2.8)	76	(10.8)
Voluntary	256	(27.5)	158	(22.5)
Total	931		703	

$$\chi^2 = 92.28; P < 0.001$$

prevalence of leprosy in 1983 is not the case detection rate at the second survey but includes patients detected during the first survey who were still under treatment in 1983. There were 931 cases detected during the first survey but, by 1983, 72 had died, 349 were disease arrested and 165 had emigrated.

The prevalence of the different classifications of leprosy in 1979 and 1983 are shown in Table 5. There is a fall in the prevalence of indeterminate and lepromatous leprosy but little change in the other types.

The prevalence of leprosy in the age and sex groups is shown in Table 6. Both adult prevalence rates show a fall while the prevalence rates in children of both sexes have risen.

Table 5. Prevalence of leprosy by classification in 1979 and 1983.

Classification	1979		1983	
	Number of cases	Prevalence per 1000	Number of cases	Prevalence per 1000
I	172	0.90	155	0.64
TT	391	2.04	483	1.98
BT	178	0.93	227	0.93
BL	51	0.27	63	0.26
LL	139	0.73	120	0.49
Total	931	4.86	1048	4.30
Population at risk	191,444		243,787	

Table 6. Age and sex specific prevalence rates per 1000 in 1979 and 1983

Age and sex group	Prevalence rate per 1000	
	1979	1983
Male children	2.86	3.34
Male adults	8.89	6.52
Female children	2.26	2.70
Female adults	4.36	3.83
Total	4.86	4.30

Prevalence of disability

Disability was assessed using the WHO criteria⁷ and for these analyses patients with only anaesthesia were excluded. At the end of the first survey there were 175 disabled cases giving a prevalence rate of 91.4 per 100,000. The number of disabled cases in 1983 was calculated by adding those with disability detected during both surveys and then subtracting those who had died or emigrated (those whose disease was arrested but still had disability were not excluded). On this basis there were 153 disabled patients in the project area in 1983 giving a prevalence of 62.3 per 100,000. The percentage of disabled cases in each classification is shown in Table 7 with the mean DI-2 values. The BL group have the highest percentage with disability and the highest mean DI-2 level but show little change between 1979 and 1983. The other types show a fall in the percentage disabled but little change in the mean DI-2 values.

Table 7. The percentage of patients with disability by classification.

Classification	1979			1983		
	Number	Disabled (%)	Mean DI	Number	Disabled (%)	Mean DI
I	0	—	—	0	—	—
TT	42	10.7	1.15	30	6.2	1.17
BT	59	33.1	1.68	58	25.6	1.52
BL	22	43.1	1.72	28	44.4	2.03
LL	52	37.4	1.59	37	30.8	1.62
Total	175	18.8	1.53	153	14.6	1.57

Discussion

Leprosy control programmes using techniques of secondary prevention are employed throughout the world and although the details of the methodology may vary from place to place, they are similar in principle. It is important that such programmes are evaluated in terms of their outcome and not merely by measurements of input such as case detection rates. The objective of evaluation should be realistic to the methods used and an appropriate objective has been set out as the reduction progressively over a period of many years of the morbidity of leprosy to a level at which it no longer presents an important public health problem.⁸ Disability assessment is proposed as a relevant measure of leprosy morbidity. Thus a standard method of disability assessment⁷ has been used to evaluate a leprosy control programme. This evaluation required no additional resources other than that required to carry out the control programme.

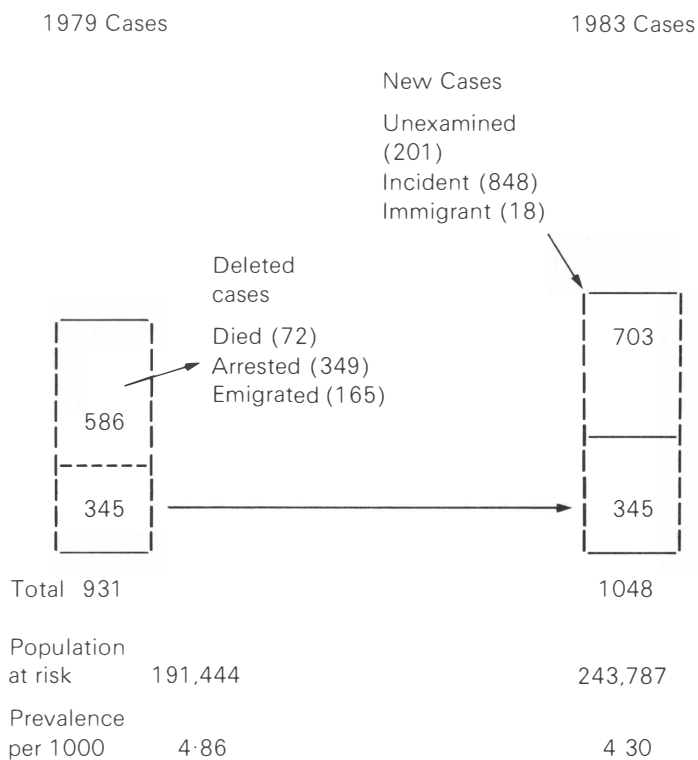
The advantages of this method of evaluation are that it is inexpensive, utilizes standardized methods and requires no additional staffing. The weakness of this method is that there is no control population with which to compare any changes in prevalence. The estimated population size required to have 90% power to detect a difference in prevalence at the 5% level is as large as the study population. The only feasible control for purposes of comparison is the general trend in leprosy and its disability in the neighbouring areas.

The demographic changes between the surveys are interesting and suggest that population growth is the result of births rather than migration or reduction in death rates. The examination rates were similar in both surveys although an improvement might have been expected as the programme became more established. The examination rates were highest in children and higher in women than men in both surveys.

The new cases detected in the second survey differed in type from those detected in the first survey. General house-to-house survey produced the majority of cases in both surveys but both school survey and contact surveillance became more valuable. The prevalence of leprosy in 1983 was very similar to that in 1979, there were more cases but the population examined had also increased. The prevalence of the various types of leprosy (Table 5) is interesting in that the prevalence of indeterminate (I) and lepromatous (LL) leprosy both fell between 1979 and 1983. The I group probably fell due to patients completing their chemotherapy and becoming disease-arrested while the LL prevalence mainly fell through emigration and death. It is also interesting to note that the prevalence of leprosy in adults fell while that in children rose (Table 6). This may be explained by the fact that few children would complete their chemotherapy before the age of 15 years, or die, so that the number of cases increases with the increasing completeness of the survey; whereas the adult rates fell because of becoming disease-arrested, emigrating or dying. Most new cases in subsequent surveys will be in children since leprosy usually starts in childhood.⁹

Between 1979 and 1983 both the number of disabled leprosy cases fell and their prevalence rate despite the increase in total cases and the increase in the completeness of the examinations. The mean DI-2 values show little change between 1979 and 1983 in the severity of the disabilities.

Thus in the 4 years between 1979 and 1983 in a defined population, in which a leprosy control programme has been in action, there has been an increase in the total number of cases and little change in the disease prevalence. However, a fall in the number and the prevalence of disabled cases has been demonstrated. It is suggested that this decline in disabilities is an effect of the programme although without a suitable untreated control it is impossible to say whether this decline is part of a secular trend in leprosy. There is no evidence for such a secular trend of reduced disability in India. The mechanism of effect of the leprosy control programme on disease prevalence and disability prevalence is worth considering. Figure 1 demonstrates the changes in the prevalence of leprosy and suggests that



Incident cases are new cases in individuals previously examined and found to be unaffected.

Figure 1. Change in the number of leprosy cases between 1979 and 1983.

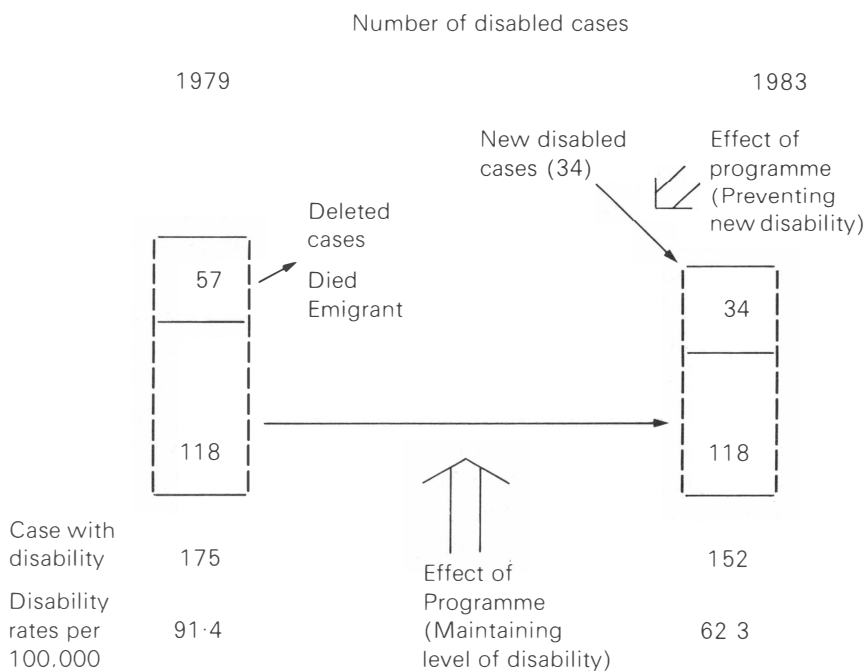


Figure 2. Change in the numbers of disabled cases between 1979 and 1983

there has been little change in prevalence. Figure 2 shows, in a similar way, the changes in patients with disability due to leprosy. It is suggested that the main effects of the programme have been to slow the deterioration in those with existing disability and the prevention of new disability in patients with leprosy and no disability.

This form of evaluation is relevant and simple to incorporate into a control programme. It is proposed to re-examine the population in the same way at the end of the third survey.

Acknowledgments

We would like to thank all the staff of the Belgaum Leprosy Hospital and Leprosy Control Programme for their contribution to this ongoing work.

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Plantar sensory threshold in the ulcerative foot

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Summary Pressure threshold measurements were made using a set of three Semmes–Weinstein monofilaments on 132 plantar ulcer sites in 72 leprosy patients and 45 plantar ulcer sites in 28 diabetic patients. The most common sites of ulceration were the great toe and first metatarsal head. No patient could feel monofilaments smaller than 6·10 (75 g). The next smallest filament, 5·07 (10 g), was identified as the level of protective sensation in leprosy patients who customarily use footwear. Similar results were shown in a small group of diabetic patients.

Introduction

Plantar foot ulcers are well recognized as a major cause of disability in leprosy and diabetes mellitus. Residual neuropathy may result in episodes of ulceration and progressive deformity even when leprosy is cured and diabetes is controlled. Sensory loss and local pressure have been shown to be the cause of plantar ulceration in leprosy and the most common cause in diabetes.^{1–5} Reliable clinical methods of measuring sensation are extremely important in the prevention of foot ulcers.

The relationship between sensory loss and the risk of plantar ulceration has been studied by several investigators. One study found a significant association between the presence of an ulcer and the degree of sensation to pinprick in the feet of leprosy patients.⁴ Another study using Von Frey aesthesiometers found higher pressure thresholds in the feet of diabetic patients compared to normal controls.⁶ A further study using vibration perception found elevated sensory thresholds were associated with a history of plantar ulceration in diabetic patients.⁷ There is general agreement among these investigators that impaired sensation may lead to frequent foot injuries but the degree of sensory loss required for a patient to be at risk of plantar ulceration has not been determined.

Protective sensation is a well accepted term in recent literature.^{1,8-10} Despite common use of this term, few investigators have provided a precise definition of protective sensation. Von Prince identified a level of protective sensation in the hand using Semmes-Weinstein monofilaments based on concomitant loss of the ability to feel heat or pinprick. The World Health Organization (WHO) Expert Committee on Leprosy in 1970 recommended testing for loss of protective sensation by touching the point of a pencil to the patient's skin with enough force to cause dimpling. Blindfolded, the patient must localize the point touched within 2 cm. This method is limited by the inability to standardize the stress applied to the skin by a pencil point. Brand recommended that protective sensation be defined by an individual's actual susceptibility to injury rather than arbitrary criteria. No investigators have established a level of protective sensation based on incidence of injury in the foot for a group of patients with leprosy.

Pressure threshold assessment is an ideal modality for testing patients at risk of ulceration, since unperceived pressure is the mechanism of injury in the foot,³ and nylon monofilaments can be manufactured inexpensively for use by field workers in developing countries. Graded, pressure sensitive filaments have been recommended for objectively evaluating sensory function in leprosy.¹¹⁻¹³ This method was first described by Von Frey and later Semmes and Weinstein developed a set of 20 nylon monofilaments of standardized lengths and thicknesses.¹⁴ These filaments buckle at a reproducible stress and may be identified by the manufacturer's numbers ranging from 1.65 to 6.65 (common logarithm of 10 times the monofilament buckling force in milligrams) or the measured force in grams. We have previously identified the Semmes-Weinstein 4.17 filament as the mean plantar threshold plus two standard deviations for normals and found filaments 4.17 (1 g), 5.07 (10 g) and 6.10 (75 g) to be a reliable set of test instruments at the 95% confidence interval (study submitted for publication).

Several investigators have compared the sensitivity of vibrometry, Semmes-Weinstein filaments, 256 hz tuning fork, two point discrimination, pinprick, and light touch. Vibrometry and Semmes-Weinstein monofilaments were found to be the most effective methods of measuring sensory deficits in the hand and foot.^{15,16} Threshold tests (vibrometry and Semmes-Weinstein filaments) are more likely to show gradual and progressive change seen in chronic neuropathy and compression syndromes as compared to innervation density tests (two-point and moving two-point discrimination).^{15,17} Innervation density tests require greater cortical integration which results in these tests being less sensitive to loss of sensory axons.

Purpose

There is an absence of data to identify a threshold of protective sensation on the plantar surface of the foot. Such data would enable preventative foot pro-

grammes to focus on those patients at highest risk of foot ulceration. The purpose of this study was to determine sensory thresholds for the feet of patients with a history of plantar ulceration and identify a level of protective sensation for the foot in leprosy.

Method

Testing was performed on all leprosy and diabetic patients seen by the Physical Therapy Department at the National Hansen's Disease Center with the presence or history of plantar ulceration during a one-year period, 1984–85. Seventy-two leprosy and 28 diabetic male and female patients were included in this study. Sites of ulceration were determined by physical examination, medical records and patient interview. Questionable sites were not included in the study. Semmes–Weinstein filaments* 4·17, 5·07 and 6·10 were used for pressure threshold measurements. All filaments were calibrated on an Arbor 107 analytical balance.† The sensory testing technique used was similar to that described by Bell.¹⁸ Patients were tested in a quiet area and filaments were applied in ascending order perpendicular to the skin at an approximate rate of 1 s touch, 1 s hold and 1 s lift. The patient responded yes when a touch was perceived. Testing was performed on the skin along the perimeter of the ulcer site to avoid testing of scar, callous or necrotic tissue. The site of ulceration and sensory level perceived was recorded on a foot screening form. Additional preselected areas of the foot were also tested and recorded on the form. An integer scale was used to code pressure thresholds in order to simplify the recording method (Table 1).

Results

LEPROSY PATIENTS

The mean age of the Hansen's disease patients was 57·4 ($\pm 17\cdot2$) years. Pressure thresholds were determined on a total of 132 ulcer areas (Table 2). No area received a rating less than three. Fourteen per cent were rated three, and the

Table 1. Pressure threshold scale.

1	4·17 (1 g force)
2	5·07 (10 g force)
3	6·10 (75 g force)
4	No perception of 6·10

Suppliers

* Nylon filament material, Irving Reicht, D Ontario Street, Philadelphia, PA 19134.

† Arbor 107 Analytical Balance, Arbor Laboratories, 3784 Fabian Way, Palo Alto, CA 94303.

Table 2. Ulcer frequency and pressure thresholds: leprosy patients.

Total subjects	Total ulcers	Subjects > 1 ulcer	Pressure threshold		
			< 6·10	6·10	> 6·10
72	132	33	0	19	113

remaining 86% were rated four. Figure 1 shows the distribution of ulcers by anatomical site in the leprosy patients. The plantar surface of the great toe was the most common area of ulceration and the first metatarsal head was the second most common site.

DIABETIC PATIENTS

The mean age of the diabetic subjects was 51·1 (\pm 11·1) years. Pressure thresholds were determined on 45 ulcer areas (Table 3). No area received a rating less than

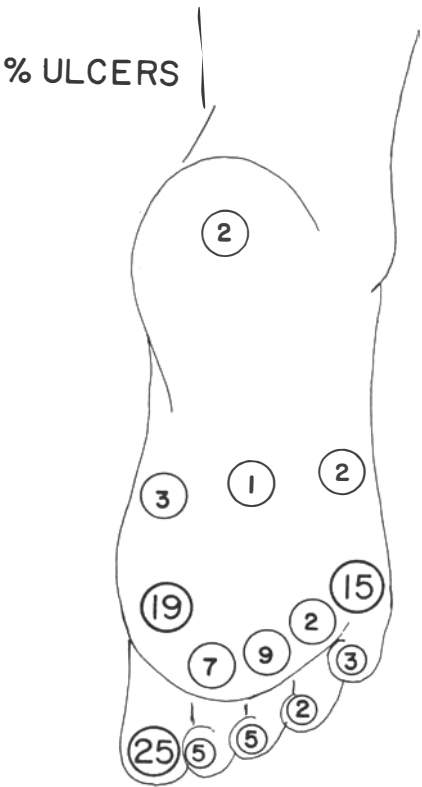


Figure 1. Plantar ulcer distribution in leprosy.

Table 3. Ulcer frequency and pressure thresholds: diabetic patients.

Total subjects	Total ulcers	Subjects > 1 ulcer	Pressure threshold		
			< 6·10	6·10	> 6·10
28	45	15	0	4	41

three. Nine per cent were rated three, and the remaining 91% were rated four. The most common area of ulceration was the first metatarsal head (35%) and the second most common site was the great toe (24%).

Discussion

The distribution of plantar ulcer sites in this study was similar to that found by Ctercteko⁵ and Sabato.⁴ They found the most common sites of ulceration to be the first metatarsal head and great toe. In this study the great toe was the most frequently ulcerated area in the leprosy group, and the first metatarsal head was the most common site in the diabetic group.

Plantar sensory thresholds were measured in this investigation in a group of patients with known foot injuries (ulcerations). Pressure testing instruments used in this study were previously shown to be sensitive and reliable in evaluating chronic neuropathy in the hand and foot. The lowest threshold of pressure sensation surrounding an ulcer area was found to be the Semmes–Weinstein 6·10 filament. A logical choice for testing protective sensation was the next lowest filament, 5·07. We believe that patients who can perceive this level of pressure sensation are unlikely to sustain major foot injuries. A prospective study is planned to investigate further the validity of this definition of protective sensation.

The possibility that sensory loss is a result rather than a cause of ulceration must be considered in this investigation. If nerve damage were to occur secondary to ulceration the distribution of sensory loss would be limited to the area of the ulcer. Patients tested in this study had diffuse patterns of sensory loss on the bottom of the foot indicative of tibial nerve trunk involvement. This evidence suggested that the sensory loss preceded plantar ulceration.

All patients in this study were accustomed to wearing footwear on a regular basis during walking. Barefoot walking results in hypertrophy of the plantar soft tissues and may alter the threshold of pressure sensation. Patients in countries where barefoot walking is common practice may demonstrate higher normal and protective thresholds when tested with similar instruments.¹⁹ Evaluation of our procedures is needed by leprosy control programmes in other countries.

The sample of diabetic ulcers presented is from a small group of patients referred to the centre with severe foot problems and may not be representative of diabetic plantar foot ulcers in the general population. Further study is needed to determine if a similar protective sensory level is found in a large population of diabetic patients.

Conclusions

Within the limitations of this study it is possible to conclude the following:

- 1 The lowest pressure threshold of leprosy patients and a small sample of diabetic patients with a history of plantar ulceration was Semmes-Weinstein filament 6.10.
- 2 Semmes-Weinstein filament 5.07 was identified as the level of protective sensation in leprosy patients who customarily use footwear.

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Letters to the Editor

LEPROMATOUS LEPROSY: FOLLOW-UP RATE IN 84 PATIENTS

Sir,

Many may recall the research into nasal involvement in lepromatous leprosy at Victoria Hospital, Dichpalli, Andhra Pradesh, India initiated by the late Dr Frank Davey in the 1970s. Several other distinguished doctors took part in what was essentially a team effort, including Drs Dick Rees, Colin McDougall, Professor Graham Weddell and Drs Gordon Ellard and Lykle Hogerzeil. As a young ENT Surgeon I was privileged to be involved examining noses, interpreting clinical findings and taking biopsies and smears for further investigations. As a result of these investigations many papers were published.

Material

In April 1985 I was fortunate to revisit Victoria Hospital and took the opportunity to review, from the outpatient records, how the patients who had been studied had fared. Several hundred patients had been examined but two particular groups had been extensively investigated. Thirty-four patients, previously untreated, all with early lepromatous leprosy ('Bergen' Series) of whom 33 had obvious clinical involvement of the nasal mucosa¹ and a further 50 patients ('RR' Series) seen in 1978 all with lepromatous leprosy and having already had dapsone monotherapy for 3 months to 8 years with varying regularity.²

Results

Table 1. Bergen series.

Period of follow-up after initial consultation	Number	(%)
Less than 2 years	12	(35%)
2–5 years	12*	(35%)
5–10 years	7	(21%)
10–12 years	3†	(9%)
	34	(100%)

*Artificially high as 6 (50%) of this group responded to a letter and financial inducement and returned in February 1978.

†All three patients regular attenders over whole period.

Table 2. RR series.

Period of follow-up after initial consultation	Number	(%)
Less than 2 years	7	(14%)
2–5 years	14	(28%)
5–10 years	14	(28%)
10–15 years	5	(10%)
Follow-up elsewhere	3	(6%)
Patients & notes 'lost'	7	(14%)
	50	(100%)

Discussion

At first glance the follow-up rate appears good and certainly every effort is made at Victoria Hospital to maintain a high return rate even though the need for such long-term follow-up may have been reduced now by the introduction of multidrug therapy. All the patients referred to in this article were treated, at least initially, with dapsone monotherapy. Although a 30% (Bergen series) and 38% (RR series) follow-up for 5 years or more may appear encouraging, when the records are examined with reference to regularity of treatment a different picture emerges. For example in the Bergen series only 3 (6%) had attended completely regularly—this being arbitrarily defined as having not been more than 3 months late for an appointment on more than one occasion. In the RR series 5 (10%) patients failed ever to return following evidence of a positive 'nose blow' on the last attendance, despite having started Lamprone or multidrug therapy and having been counselled adequately regarding further treatment. Looking through the records it is possible to read with depressing regularity statements such as, 'Returns after four year gap', or 'absconded from inpatient treatment'. Only 2 (4%) of the patients in the RR series had been entirely regular through to 1985.

There are, of course, many reasons for non-attendance in rural India and it is not suggested that the figures here show an entirely accurate picture. Patients will have died from other causes, moved to other areas, obtained treatment elsewhere or have been cured despite theoretically inadequate treatment.

However, with the introduction of multidrug regimes and the possibility of vaccines in the future all hospitals and institutions treating leprosy should be looking more carefully into the importance of detection and then of ensuring adequate follow-up of patients undergoing treatment.

Acknowledgment

I wish to thank Mr Devedanam and his staff in the out-patient department for providing the patients' records most efficiently and my son, Thomas, for his help in reviewing them. I am also grateful to Lt Col LD Ponnaiya, Officiating Director, for permission to review the records of patients at Victoria Hospital.

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A POSSIBLE 'FLU' SYNDROME ON ONCE-MONTHLY RIFAMPICIN

Sir,

Recently, changes have occurred in the management of leprosy with rifampicin becoming the mainstay of modern treatment, alongside the traditional dapsone.

In countries which can afford daily rifampicin, this is seen to produce few side-effects, except occasional gastrointestinal or cutaneous complaints and, in a few cases, drug-induced hepatitis, especially when given in combination with ethionamide or prothionamide (Pattijn 1983, personal communication).²

In the WHO recommendation for leprosy control, once-monthly rifampicin is advised. From tuberculosis treatment it was known that intermittent rifampicin administration given once or twice weekly could lead to a potentially dangerous reaction called the 'flu' syndrome.¹ It was considered unlikely that such reaction could occur when rifampicin was given only once monthly.

We would like to report a patient who presented with features of 'flu' syndrome on the once-monthly rifampicin regimen.

The patient, a 55-year-old caucasian woman with subpolar lepromatous leprosy, had started multiple drug treatment (MDT) 9 months previously (rifampicin 600 mg once monthly, clofazimine 300 mg once monthly, clofazimine 50 mg daily and dapsone 100 mg daily). She took her monthly dose of rifampicin in the morning and a little over half-an-hour later she felt a sharp pain from her midthorax extending downwards into her lower limbs. She found it very difficult to stand and walk. One hour after taking the drug she felt cold, nauseous and developed a headache. After 2 h she was shivering severely, which was extremely painful due to muscle-ache. Five hours after taking the tablets, the shivering subsided but she felt pyrexial and started sweating. During the afternoon she started feeling better. The next morning the fever and pain had abated but she remained slightly nauseous and exhausted. She recovered completely later that day. There was no evidence of malaria or erythema nodosum leprosum which could have produced similar symptoms. The patient reported that on previous occasions she had experienced slight discomfort after taking rifampicin and this had gradually become worse but not severe enough to report.

Although the diagnosis of 'flu' syndrome was not definite (provocation was considered unethical under local circumstances) her treatment was changed to ethionamide, isoniazid, dapsone and clofazimine, in daily dosage and a similar 'reaction' has not occurred again.

Over 3000 patients are taking or have been taking rifampicin once-monthly within our programme and until now we have not encountered any serious side-effects. If our patient was indeed suffering from the 'flu' syndrome, which we think very likely, it indicates that this reaction with its unknown mechanism can also occur when rifampicin 600 mg is given once monthly.

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SCAR LEPROSY FOLLOWING NEEDLE INOCULATION

Sir,

Although inoculation leprosy following mechanical trauma such as tattooing^{1–3} vaccination,⁴ dog bite,^{5–6} or roadside injury^{7,8} is well documented, it is as yet sparingly reported. The case reported here is of a 12-year-old boy who presented with numbness and tingling of 5 years' duration over the outer aspect of the left arm. He had been given an intradermal injection of smallpox vaccine on this site a few days after birth. He started experiencing numbness, tingling and heaviness over the scar mark 7 years later. Subsequently, his mother noticed a peculiar change in the colour of the skin. It was fainter than the surrounding skin. Ever since it has continued to progress and erythema and scaling appeared over it. At present, the patch is prominent and completely numb.

Cutaneous examination revealed a single, conspicuous hypopigmented plaque of the size of 7 × 5 cm. Its margins were serrated and clearly defined. The periphery of the lesion was indurated, while its centre had a scar mark of 1 × 1 cm size. The lesion was erythematous, dry, scaly and showed loss of sweat. The plaque had impairment of temperature touch and pain sensation. The nerves supplying the plaque were greatly thickened and tender.

A haematoxylin-eosin stained section revealed a compact granuloma formed by epithelioid cells, lymphocytes and attempted giant cells. The granuloma was situated in the upper dermis. The nerves were infiltrated and identifiable. No acid-fast bacilli could, however, be seen in the Zeihl–Neelsons stained section.

Ordinary skin slit smear examination revealed no acid-fast rods. A lepromin test (early-Fernandez reaction) was 15 mm (+ +).

Laboratory investigations were Hb 12·5 g%, TLC 4800/Cmm; DLC, P56% L34% M2% E8%, RBCs, normochromic, normocytic, platelets adequate, total T-lymphocytes 34%, Tpan 55% B, cells 26%, T-4 subsets, 26%, T8 subsets 22%, IgG 1980 mg/dl, IgA 340 mg/dl, IgM 162 mg/dl and complement C₃ 67·5 mg/dl.

Based on the preceding parameters, the diagnosis of borderline–tuberculoid leprosy was formed.

It is, indeed, intriguing to note that most of the cases of inoculation leprosy reported thus far have manifested either as tuberculoid (TT) borderline–tuberculoid (BT) or indeterminate (I), that too, affecting the uncovered areas.⁹ This is a salient observation and may explain that some known or unknown mechanical factors which cause discontinuity or abrasion of the skin serve as the nidus for implantation of *Mycobacterium leprae*. It is likely that the very lodgement of the organisms in the tissue subserves as a microvaccine causing resultant localized phenomenon.

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SUPPLIES OF THALIDOMIDE FOR USE IN LEPROSY

Sir,

We are glad to read the letter written by A Loretto and E Barchi (*Lepr Rev* **57**: 76–7).

Our experience with thalidomide for Type II lepra reaction during the last 6 years has been most gratifying. We had excellent results with thalidomide in bringing down Type II reactions quickly.

Now, since Chemie Grunenthal has stopped supplying the drug, we have to go back to the use of corticosteroids, which in our hands are not the answer due to their inefficacy or side-effects. Some patients cannot tolerate corticosteroids due to peptic ulcer, steroid psychosis, severe osteoporosis, non-healing plantar ulcers etc. Clofazimine for various reasons is by no means widely acceptable.

We have also observed that the compliance to chemotherapy is much better if the lepra reactions are treated promptly and not allowed to recur. Also we never had any serious side-effects with thalidomide among our patients.

Being a teaching hospital, good management of leprosy patients creates a positive attitude in the medical students and other staff towards leprosy and leprosy patients. This is important in our hospital since the leprosy is integrated in both inpatient and outpatient departments.

According to the suggestion made by Chemie Grunenthal, we wrote to the Director General of Health Services, Govt. of India about the thalidomide supplies. We are waiting for a reply. We support the plea of Loretto and Barchi that the matter of supplies of thalidomide is taken up in earnest and a solution found soon.

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P NEELAMKAVIL

RIFAMPICIN IN PREGNANCY

Sir,

Rifampicin has been widely used for a number of years in the treatment of tuberculosis and it is now given to virtually every leprosy patient on multiple drug therapy. It is therefore disconcerting to read in a recent *British National Formulary* that 'Rifampicin should be avoided in pregnancy'.¹ The data sheets of both main manufacturers of the drug offer similar advice, with additional warning about its use during breast-feeding.

Evidence regarding teratogenicity of rifampicin in humans is inconclusive.² Animal studies (whose potential for extrapolation to humans is, of course, limited) do, however, indicate that suspicion is warranted. High doses (150 mg/kg and over) produce in rats neural tube defects and limb malformations, in mice cleft palate and other mesodermal defects, but in rabbits no ill-effects.³ In humans, rifampicin crosses the placenta to foetal circulation and amniotic fluid but published data on the use of the drug in pregnant women neither prove nor disprove teratogenicity. The data are drawn from small, mainly uncontrolled studies of the use of rifampicin in the treatment of tuberculosis under a variety of circumstances.^(3, 5, 6) They reveal a small though nonsignificant increase in the rate of limb-reduction deformities, but no overall increase in congenital malformations.

Current consensus is that rifampicin is probably not teratogenic and that any increased risk to the foetus must be small compared to risks from other sources. Is its use justified under all circumstances? It is important to assess the possible risks in the context of leprosy. My own view, in the light of current evidence, is that I would not be happy to expose an unborn child of my own to even small possible risks if it were merely for the sake of beginning chemotherapy for *non-lepromatous* leprosy a few months earlier. With *lepromatous* leprosy however, the risks of transmitting the disease to others would seem to favour a decision to use rifampicin.

However, in many leprosy-endemic areas and under field conditions, the decision is far from easy to make. For example, in some communities, advice to avoid rifampicin in pregnancy might initiate unwarranted suspicion about leprosy treatment in general and in some leprosy treatment programmes additional complications in the treatment regimens may cause unacceptable difficulties for staff. For some patients, advice to delay starting treatment may mean they are in fact not seen again until the disease has caused severe and perhaps, irremediable problems. However, it is in just these situations that an increased incidence of congenital malformations would easily go unnoticed.

Administered in later pregnancy, rifampicin can in an unknown proportion of cases, give rise to a haemorrhagic tendency in the newborn baby.^(2, 6, 7) This risk is easier to accept in situations where a baby with a bleeding problem is assured of appropriate treatment than it is in the circumstances of the majority of leprosy patients.

Prescribing rifampicin during lactation is less worrying. There have been no reports of adverse effects on breast-feeding babies whose mothers were taking this drug. Such babies will ingest less than 1% of the normal therapeutic dose for infants and less than 0.1% of the dose taken by the mother.⁴ The recommendation that the breast-fed infant should be checked regularly for signs of toxicity may be impossible to follow and the suggestion of minimizing the infant's ingestion by giving rifampicin immediately after a feed and then not feeding again for several hours may be quite inappropriate in developing countries. In most leprosy endemic areas, the very real risks of artificial feeding must far outweigh any small theoretical risk from rifampicin in breast milk.

Doubts about the safety of rifampicin during pregnancy have not been completely resolved and deserve further assessment. This is clearly more important now that MDT is being used so widely. Clinicians, obstetricians, midwives and paediatricians should be encouraged to report all malformations possibly associated with this drug.

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ALISON SUMMERS

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RISK OF EXPOSURE TO LEPROSY IN HYPERENDEMIC SLUMS OF BOMBAY

Sir,

The hazard posed by abnormal multibacillary leprosy cases in metropolitan cities situated in hyperendemic zones of India has been well established by a series of epidemiological studies carried out in Bombay over the past decade. Dharmendra & Ganapati¹ have recently reviewed these studies. Possible effect of transmission of leprosy to susceptible population hailing from areas of low endemicity through migration was indicated in a slum study in Bombay.² This study revealed that the prevalence rate (PR) of leprosy among slum dwellers hailing from Ratnagiri, a low endemic district of Maharashtra State, and settling down in Bombay slums was almost 10 times the estimated PR of 1·67 per thousand in the district proper. It was considered necessary to investigate the possible factors responsible for subjects acquiring the disease in this particular district. The investigators visited Ratnagiri and confirmed the low PR of leprosy in different villages through scrutiny of records. Adult enumeration was found to be low as most of the male population had migrated to Bombay and many returned to Ratnagiri for varying periods.

Children in 4 schools in a rural set up in this district were surveyed. Out of 772 children examined 2 cases with tuberculoid leprosy were detected (PR 2·6 per thousand). Both cases gave history of having stayed in hyperendemic slum pockets of Bombay for the purpose of schooling and returning to Ratnagiri. The families of both children were examined for evidence of leprosy and no intra familial cases were detected.

It is not possible to imagine these children to have acquired infection by any means other than migration to a hyperendemic slum pocket and exposure to a high quantum of infection therein.

The above observation indicates the importance of considering leprosy transmission as due to exposure to a pool readily available in urban slum communities and point to the need for reducing the pool with vigorous chemotherapy.

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Society for Research, Rehabilitation and Education in Leprosy,
Wadala, Bombay 400 031, India

R GANAPATI,
R R REVANKAR &
S S NAIK

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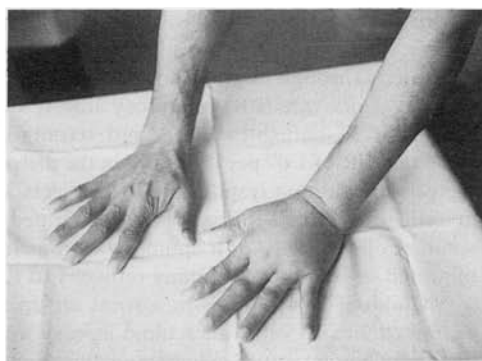
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UNILATERAL OEDEMA OF REVERSAL REACTION (RR) IN BORDERLINE LEPROSY
Sir,

Oedema is a well recognized feature in leprosy, especially during reactions. But oedema in only one extremity or on one side of the face is a rare, though documented occurrence.

In 1983 while I was a volunteer doctor at the Nonsombun Leprosy Hospital in Khon Kaen, Thailand, I had 2 patients in whom I observed this interesting feature of oedema in only 1 limb. One was a 26-year-old male patient with BL leprosy (BI 3+), who after 5 months of combined antileprosy treatment with dapsone, clofazimine and rifampicin developed signs of RR. He had associated swelling of only 1 foot (left) which subsided along with other signs of reaction when treated with a course of prednisolone. The other was a 29-year-old male patient who also had BL leprosy with a BI of 4+. After 3 months of combined therapy, he developed RR associated with oedema of the right foot only. He too received a course of prednisolone following which the reaction as well as the oedema subsided.

The occurrence of unilateral oedema, though rare, has been documented by Dr Jopling in his *Handbook of Leprosy*.¹ I have further discussed the subject with him through personal communication.² He recalls that in the 1960s he had a male Bangladeshi patient who developed oedema of the face and one hand during upgrading from BB to BT (Figures 1 and 2).



Dr Harold Wheate also has observed this feature in his patients—2 cases with unilateral oedema of the hands and one case with unilateral oedema of the eyelids—in association with RR in borderline leprosy in 1958.³ Histopathology in one of them supported the diagnosis of reaction.

Although oedema of face, hands and feet is often observed in both types of leprosy reaction (RR and ENL reaction), oedema confined to one extremity is a phenomenon which has been reported only in RR, and this fact may supply a clue as to the aetiology of oedema in reactional leprosy. I suggest that nerve damage from oedema may be the principal cause, even though clinical evidence of nerve damage may not be present in all cases. Intraneural oedema causes pressure on autonomic nerve fibres controlling capillary permeability, thus allowing leakage of fluid into the tissues. The difference in distribution of oedema may reflect the difference in nerve involvement in lepromatous leprosy compared with borderline leprosy; in the former, nerve involvement tends to be bilateral and symmetrical, whereas in the latter it is either bilateral and a symmetrical, or unilateral. One effect of steroids in treating reactions is to reduce intraneural oedema, hence prednisolone plays an important role in relieving nerve pain due to pressure on axons, and in stopping leakage of fluid from capillaries resulting from pressure on autonomic fibres.

Acknowledgment

I am very grateful to Dr Jopling for his help and support, especially for providing additional information on the subject and kindly supplying me with the photographs of his patient.

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MARY S JOSEPH

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Leprosy Control and Field Work

Implementation of multidrug therapy; WHO document

WHO/LEP/85.1 is a report of a consultation on the above subject held in Geneva in October 1985, which is of considerable importance to all concerned with the drug treatment of patients with leprosy. It brought together 17 people from the field, all with direct personal experience of MDT, and it considered the WHO regimens (*Chemotherapy of leprosy for control programmes*; Report of a WHO Study Group; Technical Report Series, 675, WHO, Geneva, 1982) and reported under the following headings: Background; objectives; newer knowledge obtained on multidrug therapy since the WHO Study Group recommendations in 1981; overview of the present situation in implementation of multidrug therapy; specific projects; conclusions and recommendations. Some difficulties and constraints were reported and discussed, but the general impression is that the advised regimens, for both pauci- and multi-bacillary cases, are acceptable to patients and staff, not attended by an undue risk of adverse reactions or toxic effects and—at this relatively early stage—apparently successful at the clinical level. This is vital—and extremely encouraging—reading for all concerned with the drug treatment of leprosy.

National Leprosy Eradication Programme, India, 1985

The Leprosy Division, Directorate General of Health Services, Nirman Bhavan, New Delhi, 110011, India, has published *Guidelines on case detection, treatment, follow up and reporting* in the context of the National Leprosy Eradication Programme in India. In view of the enormous numbers of leprosy patients both registered and estimated for India, this document is of outstanding interest and it describes in detail some differences in the Indian multidrug regimens, as opposed to those advised by WHO. (Their division into 'intensive' and 'continuation' phases (page 10) is of particular interest and may pose problems for any agency which is attempting to 'compare' MDT in India with the conventional WHO regimens used in other parts of the world).

Leprosy control programme in West Nepal

We are most grateful to Dr Paul Kist for a copy of this booklet, which describes activities in a joint project led by the Government of Nepal (HMG/N) and the International Nepal Fellowship (INF). The very considerable area covered by this project is described, with emphasis on the efforts which have been made, in this difficult terrain, to provide leprosy treatment which is reasonably close to the patient's home. Plans are under discussion to extend this programme into new areas. Further enquiries to: International Nepal Fellowship, P.O. Box 5, Pokhara, Nepal 33701.

Isoprodian and Isoprodian–RMP

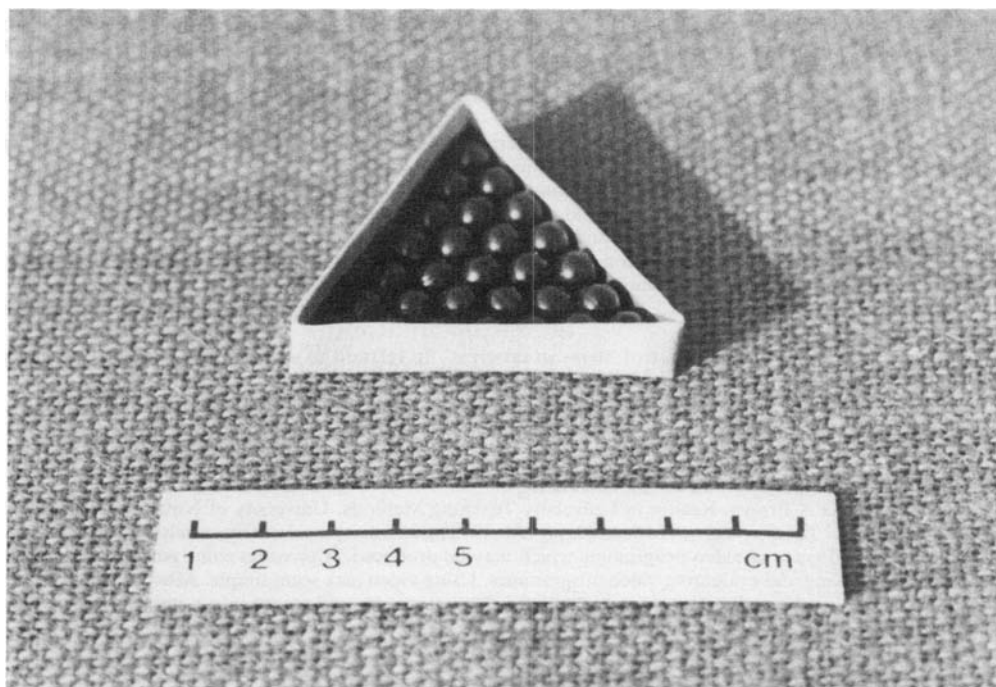
We are grateful to Dr H Frank of the German Leprosy Relief Association for a copy of the booklet *Information for multidrug therapy with Isoprodian and Isoprodian–RMP*, which describes the development and use of these combinations. Isoprodian contains isoniazid, prothionamide and dapsone; the composition, dosage, method of intake, minimal therapy duration, side-effects/contraindications and possible interactions are all described and the final pages deal with 'Basic requirements for the introduction of multidrug therapy'.

Leprosy drugs for Third World countries

In addition to the arrangements which have already been made with CIBA–GEIGY for the purchase of antileprosy drugs by ILEP members at advantageous prices, we have previously drawn attention to other companies which specialize in the stocking, sale and distribution of antileprosy drugs for Third World countries. One of these, in attendance at the recent meeting on MDT organized by the German Leprosy Relief Association in Würzburg (to be reported in full in this Journal at a later date), is Sanavita, Gesundheitsmittel GmbH, Postfach 220, D-4712, Werne, West Germany, which lists dapsone (50 and 100 mg), clofazimine (50 and 100 mg) and rifampicin (150 and 300 mg) in section 19 of its drug list. They offer a wide range of other drugs including many of value in tuberculosis, dermatology and tropical diseases generally.

Triangular container for the counting and dispensing of clofazimine

Dr G Boerrigter, Medical Director, LEPROA-MALAWI: PO Box 148, Lilongwê, Malawi, Africa, Has very kindly submitted information on a metal container which has been devised in Malawi for the purpose of counting out exactly 28 round capsules of clofazimine, each of 50 mg (4 weeks' supply for daily, unsupervised ingestion in multibacillary leprosy). As elsewhere, the staff in Malawi have found that these small round capsules run about like marbles on a flat surface and are also difficult to pick up, one by one, in the fingers. A triangular container, as illustrated below, has therefore been made from soft metal, the sharp edges being covered with tape. The internal measurements of this container are important; the equal laterals should be 5.8 cm (6.0 cm would be equally suitable) and the depth should be at least $1\frac{1}{2}$ times the diameter of the capsules, so that they do not fall out. The prototype shown here had an internal depth of 1.2 cm, which was very satisfactory. Capsules, once loaded into this device and allowed to 'settle' out flat, can easily be tipped into the palm of the hand or directly into a container. This metal version has been examined by technicians working with plastics (in Oxford) and there would be no difficulty in mass-producing it if there is a need. Meanwhile, provided careful attention is given to the measurements above, satisfactory containers can easily be made from metal sheet or old tin covering the edges with tape.



Ciba-Geigy; plastic containers for Lamprene (clofazimine)

Mr Peter Friedli of Ciba-Geigy Basal, Pharma International, CH 4002, Basel, Switzerland, has drawn attention to the development of a small plastic container with a screw top by this company. It is designed to accommodate 30 capsules of 50 mg or 15 capsules of 100 mg clofazimine to cover the usual monthly amount dispensed, for self-administration by the patient. These useful containers are entirely free of charge on application to the above address.

Teaching Materials and Services

TALMILEP; teaching and learning materials, ILEP

We shall continue to use the pages of this section to keep readers up to date on new items of teaching–learning material and to remind them of the very considerable amount which has been produced and printed. It should however be remembered that TALMILEP is now the central point for this subject, certainly as far as ILEP members are concerned, and that it has already coordinated efforts from various parts of the world with regard to: preparation and production; assessment; printing and publication; distribution. The aims of TALMILEP are:

To coordinate efforts for providing all categories of health workers involved in leprosy control and patient care, worldwide, with teaching and learning materials.

To promote the development of high quality materials by ILEP member associations, adequately covering all relevant subject aspects, and avoiding unnecessary duplication of work.

To encourage the local production of teaching and learning materials by people in their own countries.

To set up active distribution networks and thus ensure worldwide availability of materials.

To make information about teaching and learning materials generally available.

Most of the work of TALMILEP is done by correspondence. In addition, the group meets four times a year: working meetings are held in Europe during April and September.

Meetings are also held during ILEP Working Sessions in June and December, and these meetings are open to all ILEP delegates.

The agenda centres around a list of 'items in progress'. In relation to each individual item of teaching material, survey, assessment, production and distribution aspects are discussed.

Further enquiries: Ms K. Rossler, German Leprosy Relief Association, D-8700, Wurzburg 11, Dominikanerplatz 4, W. Germany.

How to make and use video in teaching

This article is by G A Brown, Reader in University Teaching Methods, University of Nottingham, UK and appears in *Medical Teacher*, Vol 7, No 2, 1985, pp 139–49. The summary reads: 'This article outlines the uses, characteristics and types of video programme which may be produced. It provides some guidelines for using video and for making and evaluating video programmes. Using video may seem simple. After all, any fool can switch on a videorecorder. It takes a good teacher to convert images and sound into a meaningful learning resource for students.'

WHO/UNDP Health Learning Materials Programme

The following is extracted from Information, Number 1, 1986, published by BLAT Centre for Health and Medical Education, BMA House, Tavistock Square, London:

'Much of the disease and ill health in developing countries stems from conditions that can be prevented or readily treated. But while 80 percent of the people in these countries live in rural areas, 80 percent of the doctors and hospitals are in urban centres. In 1978, an international conference by the World Health Organization and UNICEF focused attention on this situation. Since then countries throughout the world have adopted Primary Health Care (PHC) as a means of achieving health for all. Primary Health Care: stresses preventive rather than curative care; relies on self-help, community participation and appropriate technology, for the delivery of health care; is broad-based, mobilizing human and material resources in all sectors and at all levels. Training all those involved in delivering PHC is essential for success—doctors, village health assistants, midwives, school teachers, community leaders, rural development officers. To be effective, this training must be supported by quality teaching and learning materials such as reference books, instruction manuals, and audio-visual aids. Such materials need to be tailored to the local situation. They must meet the needs of teachers, students and health care staff, as well as the communities they serve. Unfortunately, there is a severe shortage of such learning materials for health workers throughout the developing world. To address this need, in 1981 the Health Learning Materials (HLM) Programme was set up by the World Health Organization and the United Nations

Development Programme, with UNICEF support at the country level. It aims to: help developing countries achieve self-reliance in the production of teaching and learning materials to support Primary Health Care; encourage countries to pool their resources and experience and build up a network of collaboration in producing health learning materials. The programme began as a pilot research scheme to explore the best ways of developing self-reliance in materials production. Initially, the idea was put forward to a small group of countries where major languages were in use (Arabic, English, French and Portuguese). By mid-1985, projects were well underway in nine developing countries: Benin, Ethiopia, Kenya, Morocco, Mozambique, Nepal, Rwanda, Sudan and Tanzania.'

Gandhi Memorial Leprosy Foundation, India

We gratefully acknowledge receipt of the following documents from Mr S P Tare, Director:

1 *'Eradication of leprosy through mass awareness, health education and community participation'; a master plan.* This is a strongly bound paperback of 75 pages, outlining in some detail the GMLF approach to eradication based on the above main pursuits, emphasizing the extremely complex nature of leprosy and the need to consider not only purely medical, but also sociological aspects in the broadest sense.

2 *Training schedule for 1986-7.* This covers the projected training activities at Chilakalapalli and Wardha, giving the dates for the courses for paramedical workers (6 months), health education workers (2 months) and medical officers (6 weeks).

3 *Centre for Social Research on Leprosy.* The potential importance of this new centre at Wardha is such that we quote in full from Mr Tare's letter:

'The Centre has taken up the following research projects: (a) Evaluation of impact of health education with 3 educational interventions: A prospective study in a highly endemic area of Purulia district (West Bengal); (b) Evaluation of the component of "Education" in Survey-Education-Treatment work under National Leprosy Eradication Programme in 2 Governmental Centres, Orissa and Andhra Pradesh. This is a retrospective study sponsored by ICMR; and (c) Evaluation of impact of comprehensive Health Project in a district near Bombay undertaken by the Foundation for Research in Community Health for the last 10 years.

The Centre will shortly initiate the following 3 projects: (a) Leprosy Control in Primary Health Care: an experiment to develop methodology for integration of leprosy with primary health care. To be undertaken in a tribal district in Maharashtra; (b) Comparative Research in the functioning of the Health Services and impact on perception of people about leprosy in multidrug therapy and monotherapy areas; and (c) Study of people's perception and reaction to leprosy vaccine trials.

Another major activity of the Centre would be to undertake short-term training of health and social scientists in social science research methodology pertaining to leprosy research and to conduct workshops, seminars, symposia etc. as training exercises for participants.'

WHO Health Literature Services Programme Newsletter

Mrs Beryl Ruff, Chief, Office of Library and Health Literature Services, WHO, 1211 Geneva 27, Switzerland, has recently published in the *WHO Chronicle*, 39(6): 212-218 (1985) on national policies for health library networks and at the same time drawn attention to this *Newsletter*, which is issued 3 times a year from WHO. It monitors health literature activities at regional level. Her article also contains a valuable list of 'focal points', which are in fact mainly libraries in Africa, the Americas, Eastern Mediterranean, South East Asia and the Western Pacific.

News and Notes

Dr Tore Godal appointed as New Director of TDR

On 6 June 1986, Halfdan Mahler announced the appointment of Dr Tore Godal as the new Director of UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases. WHO Press Release WHO/12 of the above date reads as follows:

‘Born in the valley of Rauland in Telemark, Norway, Dr Godal graduated with a medical degree from the University of Oslo Medical School in 1966 and in the following year became, at the age of 28, one of the youngest Norwegians to be awarded a Ph.D in a medical discipline.

He can be considered as one of the “founding fathers” of TDR and immunology has always been his chief professional interest. Early on in his career, he chose leprosy as a specific field of interest. From 1970 to 1973, as Director of the Armauer Hansen Research Institute in Addis Ababa, Ethiopia, Dr Godal and his colleagues studied host defences against leprosy. They discovered, among other things, that some of the damage caused by the disease results from the patient’s own immune defences.

Such research findings suggested to Dr Godal that a vaccine against leprosy could be developed and new hope to the 11 million actually suffering from the disease and many millions more living in leprosy-endemic countries.

With support from the Norwegian Development Agency, a network came into being in 1975 in the form of a “Steering Committee on the Immunology of Leprosy” (IMMLEP). A kind of “laboratory without walls”, IMMLEP, under the guidance of Dr Godal as its first Chairman, enlisted the expertise of research groups from many countries including India, Japan, the United Kingdom, the United States, Venezuela and Norway. Ten years later, Dr Godal is being given the reins of a much larger “laboratory without walls”, dealing with more tropical diseases and extending to over 130 countries.’

We wish Dr Godal every possible success and good fortune in this new appointment. *Editor.*

Second National Leprosy Seminar in Turkey, June 1986

This was held in the Medical Faculty, Istanbul, and attended by a large number of medical students, postgraduates, university staff and teachers. Professor Turkan Saylan of the Department of Dermatology also invited a number of guest speakers from abroad (Dr and Mrs D S Ridley; Miss Jean Watson; Dr J A Warndorff; Dr S K Noordeen; Dr A C McDougall) and the Seminar included not only lectures and discussions, but also a visit to the Istanbul Leprosy Hospital and the opportunity to examine patients. It is the opinion of Professor Saylan and her colleagues that very considerable progress should now be possible, not only in the treatment of the known 4000 cases in Turkey, but in the detection of others and the implementation of multiple drug therapy. The *Technical Guide for Smear Examination for Leprosy* was translated into Turkish and distributed at this Seminar. A particularly striking element in the current approach to leprosy in this country is the extent to which Professor Saylan has been able to involve medical students and graduates in case-detection, diagnosis, treatment, epidemiology, eye complications, disability, footwear, surgery and histopathology—all of which were covered during the course of this important meeting.

Ciba–Geigy Leprosy Fund

This fund was recently established in Basle to support the control and eradication of leprosy. Three million Swiss francs are available for this purpose, to be administered by a committee with representatives from the International Federation of Anti-Leprosy Associations (ILEP) and CIBA–GEIGY, Ltd. It is intended that only a limited proportion of the money should be used for drugs and it is our understanding at this stage that some interest has been expressed in work based in Sierra Leone. The Basle representatives are Mr E Decosterd, Mr P Friedli, Dr K M Leisinger and Professor S J Yawalkar.

Joint Chemotherapy Trials in Lepromatous Leprosy: SMHF, Tokyo, Japan

We are grateful to the Sasakawa Memorial Health Foundation, Tokyo, Japan, for a copy of *The Joint Chemotherapy Trials in Lepromatous Leprosy*, conducted in Korea, the Philippines and Thailand; an interim report as of March 1985. This has been compiled by Dr Roland V Cellona, Chief, Epidemiology Branch, Leonard Wood Memorial, Cebu, Philippines and it covers no less than 5½ years of this important study from 1979 to 31 March 1985. The main body of the report is 25 pages long and there are detailed appendices. Although considerable caution is expressed in the conclusions, all who have been concerned with these trials through the years are unanimous in acknowledging their value in the training and familiarization of medical officers, laboratory technicians, nurses and paramedical workers with the concept of multiple drug therapy, thus going a long way to preparing the way for the implementation of WHO and similar regimens in the countries concerned. To those interested in drug trials and MDT, the document is well worth consulting in the original. (Sasakawa Memorial Health Foundation, The Sasakawa Hall, 6F, 3-12-12 Mita, Minato-ku, Tokyo 108, Japan.)

Essential Drugs Monitor

The Essential Drugs Monitor is a newsletter produced and distributed by the WHO Action Programme on Essential Drugs and Vaccines. Since the Action Programme was launched in 1981, more than 80 countries have either drawn up essential drugs lists or started projects in support of primary health care, providing reliable essential drugs and vaccines which: meet real medical needs; have significant therapeutic value; are acceptably safe; and offer satisfactory value for money. All correspondence should be addressed to the Editor, Essential Drugs Monitor, World Health Organization, CH-1211 Geneva 27, Switzerland.

Aspects of leprosy neuritis; a thesis in French from Dakar, Senegal

We are most grateful to Dr J Millan, Institut de Léprologie Appliquée, B.P. 11.023 CD Annexe, Dakar, Senegal, Africa, for a copy of this impressive thesis written by Dr Francois Boillot, based on experience gained during a 13-month period of study at the above Institute in Dakar. It has been presented to the Scientific and Medical University of Grenoble for the degree of 'Docteur en Médecine—Diplôme d'Etat'. The thesis combines a review of the literature, including an extensive bibliography, together with personal experiences and an analysis of the medical treatment of leprosy neuritis as seen in this Centre.

Dermatological journal from Portugal

We have received a copy of *Anais Brasileiros de Dermatologia*, the official organ of the Brazilian Society of Dermatology, Caixa Postal 389, 20000 Rio de Janeiro, RJ, Brazil, which, though mainly concerned with dermatology, also carries articles on leprosy. Those listed in the index of Volume 60, Number 6 of 1985 include contributions on subclinical infection, treatment, dermatoglyphics and the possible role of *Culex fatigans* in transmission. The language is Portuguese.

Training in leprosy; WHO publication

This valuable document (WHO/CDS/LEP/86.2) in English deals with the subject of training in leprosy under the following main headings: Introduction; training health personnel in leprosy; teaching and training considerations; teaching-learning materials on leprosy; references. This is virtually essential reading and study for all concerned with clinical management and leprosy control and represents the combined experience of Miss P J Neville, Education and Training Secretary of The Leprosy Mission International, Dr Felton Ross, Medical Adviser, American Leprosy Missions, USA and the Leprosy Unit, Division of Communicable Diseases, WHO, Geneva.

Vaccination trials against leprosy; WHO publication

In February 1985, at a '... meeting of the Epidemiology Sub-group of the Scientific Working Group on the Immunology of Leprosy', vaccination trials against leprosy were discussed in considerable detail and the subject matter has now been published in this WHO document: WHO/IMMLEP/EPD/85.3 The headings cover: vaccine trial designs; skin tests; sensitization and acceptability studies; serological tests.

Sample surveys in leprosy; WHO publication

Sample surveys in leprosy; an introductory manual (WHO/CDS/LEP/86.1) is written by T K Sundaresan, WHO Consultant in collaboration with Dr H Sansarricq (former Medical Officer, Leprosy), and Dr S K Noordeen, Chief Medical Officer, Leprosy, Division of Communicable Diseases, WHO, Geneva. It covers rationale; choice of sample design; sampling techniques; essential concepts in sampling; a table of random numbers; experience of the Leprosy Advisory Team; practical considerations; organization of a sample survey; procedures and criteria for diagnosis; nonsampling errors; periodic surveys for evaluation.

Health Policy and Planning; a new journal

Health Policy and Planning, A Journal on Health in Development, is concerned with issues in health policy, planning, management and evaluation, and focuses on these issues in the developing world. The journal is intended for people working in health care and in such organizations as ministries of health and planning centres, universities, faculties of medicine and schools of public health, and multilateral, bilateral and non-governmental international agencies. The journal is particularly relevant to those working in international health planning, medical care and community medicine, but it will also have appeal for readers outside the health sector in such fields as social policy and community development.

Articles will have an international perspective and there will be a good balance between theoretical content and practical approaches. They will cover current issues and debates in health policy as well as analyses on political, economic and social factors affecting health. There will be more specific reviews or research on the inter-relationship between health and health programmes, with an emphasis on evaluation studies and critical appraisals of current health programmes being implemented in countries. Articles will thus represent broad analytical approaches as well as the specific applications of such disciplines as epidemiology, economics, social anthropology and sociology to health related policy and planning issues. Provocative papers that explore and question conventional wisdom will be welcomed. Substantive review articles will be a regular feature, as will book reviews and information on forthcoming conferences and training courses.

Editors: Patrick Vaughan and Gill Walt, The London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT

Course in ocular leprosy, Karigiri, India, February 1986

A four-day ophthalmic module was held during the spring teaching course at Karigiri from 25 to 28 February 1986. It was designed to give instruction to leprologists and ophthalmologists on the detection and management of the ocular complications of leprosy by means of a series of formal lectures and clinical and surgical demonstrations. Dr Margaret Brand from Carville, USA, and Mr Timothy ffytche from St Thomas' Hospital, London were invited to run the course. Lectures included

presentations on the anatomy and physiology of the eye with special relationship to leprosy, lagophthalmos, corneal ulcers and intra-ocular inflammation and there were contributions from the Karigiri staff on pathology and rehabilitation. The clinical sessions concentrated on the practical aspects of eye care, and teaching was supplemented by several videos. Dr Brand conducted a demonstration on various aspects of lid surgery.

There were seven participants from other centres and many of the leprologists on the general course attended the lectures. The module proved to be a great success and it is hoped that it will be repeated next year with an increased number of participants.

The Leprosy Mission and LEPROA are to be congratulated on their support for this important contribution to teaching.

International Federation of Medical Students' Associations

We are indebted to the Secretary General of IFMSA, the General Secretariat, Liechtenseinstr. 13, A-1090, Vienna, Austria, for information about this Federation, which is '... a professional organization concerned with the betterment of people's health throughout the world. It represents the medical students from more than 100 countries and is in official relationship with WHO, UNICEF and other UN agencies besides many international non-governmental organizations.' They have recently organized a seminar on 'Health needs and student actions in developing countries' (August 1986).

Heralds of Health—The Saga of Christian Medical Initiatives

Edited by Stanley G Browne, Frank Davey and William A R Thomson. Published by Christian Medical Fellowship, 56 Kingsway, London WC2. Price £4.95. We are indebted to Dr Harold Wheate for the following review:

"In his Foreword to this book, Lord Porritt says 'This is a very remarkable book—it could justly be described, in the truest sense of the word, as 'extra-ordinary'. Based on the ancient historical connection between religion and medicine it is indeed a saga (again an apt description) of medical missionaries and missionary hospitals during the last century and a half.'

The 20 chapters cover a wide spectrum, from surgery to medical education, from the pioneer curative work of the early missionaries to the role of the Christian Medical Commission of the World Council of Churches in propagating the concept of Primary Health Care.

The contributors all have a high reputation in their respective fields and, as one would expect, write lucidly on their subject. Although there is inevitably some overlap there is remarkably little repetition and the style throughout is factual and free from sentimentality. Two statements are worth quoting, as illustrating the motivation of the authors and their purpose in writing not merely for those interested in medical missions but for all concerned with health care delivery in the Third World:

'Christian medical work does not begin in the crowded out-patient department: it begins in research directed to the prevention of disease.' (p. 89)

'The people who need rehabilitation are not merely patients who have specific physical disabilities; they are human beings who feel that they are failures. . . . In this situation they need faith and hope.' (p. 269).

In the later chapters, the gradual development of increasing cooperation between different Christian missions and between them and national Governments and international bodies, notably WHO, is emphasized, especially as to medical education and the contribution of national and international coworkers.

This book is a fitting tribute not only to all those whose exploits it records but also to the three editors, who were themselves fine examples of devoted Christian service to their fellow-men."

The Grants Register 1985–6

The following is taken from the Editor's Note: *The Grants Register* is primarily intended for students at or above the graduate level and for all who require further professional or advanced vocational training. The following kinds of assistance—from government agencies, and international, national or private organizations—are listed: 1. Scholarships, Fellowships and Research Grants. 2. Exchange Opportunities, Vacation Study Awards and Travel Grants. 3. Grants-in-Aid—including equipment, publication and translation grants, and funds for attending seminars, courses, conferences, etc. 4. Grants for all kinds of artistic or scientific projects. 5. Competitions, Prizes and Honoraria—including awards in recognition or support of creative work. 6. Professional and Vocational Awards—including opportunities for academic and administrative staff of educational institutions. 7. Special Awards—for refugees, minority groups, etc., and funds for students in unexpected financial difficulties.

No attempt is made to list awards that are solely sponsored by a particular university or college as such awards are already well publicized.

The Grants Register aims to provide full, current information on awards for nationals of the United States and Canada, the United Kingdom and Ireland, Australia and New Zealand, South Africa and the developing countries. However, as many of the awards listed are international in scope, the book is also useful to students from other countries who are seeking exchange opportunities or international scholarships."

There are over 1600 entries, many of which have information on up to 10 grants. Medicine and science are dealt with in full and there are numerous opportunities under: immunology, pathology, microbiology, tuberculosis, leprosy, community and primary health care. Published by Macmillan Publishers Ltd, London. Distributed by Globe Book Services Ltd, Brunel Road, Houndmills, Basingstoke, Hampshire, RG21 2XS, England. Price: £32.00 sterling.

WHO Catalogue of New Books, Spring/Summer 1986

Pages 12 and 13 of this recently issued catalogue contain the following information which may be of interest to our readers:

WHO publications on special terms of purchase. Many WHO publications, especially in the areas of communicable diseases, education and training, and national health management, are intended to support the improvement of public health in the developing world. Individuals, institutions, universities, and libraries, located in developing areas and in need of a WHO publication, are encouraged to write to WHO for information on special terms of purchase.

Meetings. If you are planning or organizing a meeting on any topic covered in this catalogue, WHO will be happy to supply participants with a list of new, forthcoming, and classic reference works in the appropriate area of interest. Write to: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland.

Symposium on multidrug therapy in leprosy; DAHW, Würzburg, April 1986

The German Leprosy Relief Association recently organized a meeting of international participants in Würzburg, Germany, to consider progress in the use of multiple drug therapy for leprosy. Under the main headings of clinical reports, test models for effectiveness control of chemotherapy, developments and future aspects, reports were given from the USA, Europe and many of the leprosy-endemic countries, with emphasis on experience to date on acceptability, side-effects, clinical results and follow up after various regimens including those using Isoprodian and the combinations recommended by WHO.

All papers, together with discussion and some of the opening speeches, will be printed in this Journal as a full supplement in the near future.

XVI General Assembly of ILEP, Edinburgh, July 1986

The following press release was issued by LEPRa on the occasion of this meeting in Edinburgh:

'Seventeen major voluntary agencies, all Members of the International Federation of Anti-Leprosy Associations (ILEP), met in Edinburgh from 1 to 6 July 1986 for their XVIth General Assembly.

The meetings were to ensure continuing co-operation between the agencies in leprosy work in more than 100 developing countries, and to enable the best use of resources by avoiding competition and duplication.

1986 is also the 20th anniversary of the founding of the Federation. During this time ILEP Members have spent 350 million US dollars, treating about 1½ million leprosy patients every year; 1 million have been cured and 2–3 million new cases detected. ILEP helps at least a third of all those under treatment in the world.

The lion's share of support (70%) goes to treatment projects, but ILEP Members are increasingly turning their attention to research (3.9 million US dollars in 1985). The 20th anniversary has been used as an occasion to launch a series of research projects in areas identified by the ILEP Medical Commission as vital for the future of leprosy control. The first of these, a vaccine trial, is already under way in Malawi under the leadership of LEPRa.

In the realm of treatment, the most important breakthrough in recent years was the introduction of multidrug therapy (MDT), to combat the risk of drug resistance and shorten the length of treatment. The majority of ILEP-supported projects are already implementing MDT in some form.

The General Assembly invested as President, Mr André Récipon, President of the Raoul Follereau Association in France, for the period 1986 to 1988, in place of the outgoing President, Mr G F Harris of LEPRa (UK).'

LEPRa's London Office; change of address

Please note that as from 12 July 1986, LEPRa's London Office will be at 105–107 Farringdon Road, London EC1R 3BT. Telephone 01-833-3491. This is also the 'Registered Office' of the British Leprosy Relief Association.

Leprosy for medical practitioners and paramedical workers; Ciba-Geigy, 1986

This 92 pp booklet by Giba-Geigy, written by Dr R H Thangaraj and Professor S J Yawalkar, has just been published and will no doubt fill a continuing need for accurate up-to-date information. As always with publications from this source, the quality of production is very high and there are over 80 colour prints, including both clinical and histopathological aspects. Medical Department, Giba-Geigy Ltd, Basle, Switzerland.

AHRTAG, London: drug packaging

Following the distribution of a recent questionnaire, Mr K Ritchie, Executive Director of AHRTAG, 85 Marylebone High Street, London W1M 3DE, has written to say that information on drug packaging will now be analysed and probably published in the near future. He adds that a partner organization in Bangladesh is helping AHRTAG by field-testing equipment for the production of small paper envelopes, cardboard boxes and small canisters from scrap plastic. Enquiries to the above address.

XIII International Leprosy Congress, 1988; the Hague

This will take place in the Hague, 11–17 September 1988 and those wishing to receive a registration form and abstract form (for poster and/or an oral presentation) should apply to Congress Bureau, QLT Convention Services, Alton House, Keizersgracht 792, 1017 EC, Amsterdam, the Netherlands. The scientific sessions and scope of the Congress are as follows:

Congress Subjects

Twelve congress subjects are planned, namely: I Immunology; II Clinical Aspects; III Experimental leprosy; IV Microbiology; V Epidemiology and control; VI Treatment; VII Nerve damage; VIII Surgery and rehabilitation; IX Ophthalmology; X Soci aspects; XI Experimental therapy and XII Pathology.

Poster Sessions

Special attention will be given to poster presentations in order to maximize the personal discussions and explanations of your research. The organizing committee will provide a well-planned schedule of poster presentations during the congress days in connection with, and completing the 12 congress themes. The organization will provide professional graphical assistance to participants for the preparation of their posters. This service is provided to present your scientific results in the most perceptive manner.

State of the Art

Every morning a one-hour session will cover all the recent progresses in the main fields of research. The 'Starters of the day' will be given by 5 experts on: A Immunological tools for leprosy control; B Recent developments in molecular biology; C Operational aspects of multidrug chemotherapy; D Nerve damage and E Social aspects in primary health care.

Teaching and Training Sessions

During the congress continuous teaching and training sessions will be held. Video films, continuous slide presentations and films will cover the following subjects: 1 Immunology; 2 Pathology of early leprosy; 3 Reactive phenomena; 4 Epidemiology; 5 Case

taking; 6 Information systems; 7 Deformity; 8 Disability assessment; 9 Vocational rehabilitation and 10 Health education.

After each presentation a question and answer period is planned.

Workshops

The workshops will be held in the week preceding the congress. The summaries made by the chairmen will be made available by the end of the congress. Subjects to be covered are: Immunology, Epidemiology, Chemotherapy, Control, Information systems, Diagnosis and clinical aspects, Training, Prevention and management of impairment rehabilitation, Vaccine trials, Social aspects and Health education.

Proceedings of the XII International Leprosy Congress

The above volume is now available from The Leprosy Mission, 5 Amrita Shergill Marg, New Delhi 100 003, India. The cost including postal charges (this volume weighs nearly 1½ kg) is: air mail, US \$30.00; surface mail, US \$20.00.

The Dr Ragavendra Row Memorial Teaching Programme in Leprosy 1986

The 1 day programme (28 February 1986) was this year devoted to the teaching of pathology of leprosy to a small group (4 from each medical college) of pathology postgraduate students. It was held at the Department of Pathology, Grant Medical College, with the whole-hearted cooperation of Professor U L Waghlikar and the ready assent of the Professors of Pathology from 3 other medical colleges.

Dr K V Desikan, Director, Central JALMA Institute for Leprosy, Agra was the invited teacher and he was assisted by Dr B Narayanan, Immunopathologist at the same Institute.

A special feature of the programme is that each participant is presented with a set of histology slides of skin and nerve for individual study and evaluation, after being introduced to the basis of the immunopathologic classification of leprosy. After individual study of the slides, the teachers demonstrated features of note and answered several questions.

Dr C V Bapat spoke briefly about recent knowledge on the microbiology of the leprosy bacillus.

The participants were asked to evaluate (anonymously) the day's programme after the session was over. All of them expressed their satisfaction with the plan of teaching and said they had benefited from the histology teaching.

The participants and teachers were asked to suggest ways on improving the content and conduct of the programme. The important suggestions were:

- 1 More time to be given for individual study of the slides.
- 2 The histopathology material to be prepared well in advance and to be representative of the leprosy spectrum.
- 3 The students themselves should do the Fite Faraco stain in advance.
- 4 There should be a postprogramme spot test.

CONTENTS

Editorial

- Historical background to the development of leprosy control in Malawi. G. F. HARRIS & R. J. W. REES 193

Original Articles

- Ten years' leprosy control work in Malawi (Central Africa)—I. Methods and outcome after treatment. G. BOERRIGTER and J. M. PONNIGHAUS 199
- Ten years' leprosy control work in Malawi (Central Africa)—II. Patterns of endemicity since 1973. J. M. PONNIGHAUS and G. BOERRIGTER 221
- The detection of subclinical leprosy using a monoclonal antibody based radioimmunoassay. M. ASHWORTH, S. SINHA, S. A. PATIL, G. RAMU and U. SENGUPTA 237
- Mass screening in leprosy endemic areas of Turkey: preliminary report. T. SAYLAN and A. H. AYTEKI 243
- Disability assessment as a measure of progress in leprosy control. W. C. S. SMITH and S. M. PARKHE 251
- Plantar sensory threshold in the ulcerative foot. J. A. BIRKE and D. S. SI 261

Letters to the Editor

- Lepromatous leprosy: follow-up rate in 84 patients. R. P. E. BARTON 269
- A possible 'flu' syndrome on once-monthly rifampicin. B. NAAFS and B. O. MATEMERA 271
- Scar leprosy following needle inoculation. V. N. SEHGAL 272
- Supplies of thalidomide for use in leprosy. P. NEELAMKAVIL 273
- Rifampicin in pregnancy. ALISON SUMMERS 274
- Risk of exposure to leprosy in hyperendemic slums of Bombay. R. GANAPATI, R. R. REVANKAR and S. S. NAIK 275
- Unilateral oedema of reversal reaction (RR) in borderline leprosy. MARY S. JOSEPH 276

Leprosy Control and Field Work 278

- Implementation of multidrug therapy; WHO • National Leprosy Eradication Programme, India 1985 • Leprosy control programme in West Nepal • Isoprodian and Isoprodian-RMP • Leprosy drugs for Third World countries • Triangular container for the counting and dispensing of clofazimine • Plastic containers for clofazimine

Teaching Materials and Services 280

- TALMILEP; teaching and learning materials, ILEP • How to make and use video in teaching • WHO/UNDP Health Learning Materials Programme • Gandhi Memorial Leprosy Foundation, India • WHO Health Literature Services Programme Newsletter

News and Notes 282

- Dr Tore Godal appointed as new Director of TDR • Second National Leprosy Seminar in Turkey, June 1986 • Ciba-Geigy Leprosy Fund • Joint Chemotherapy Trials in Lepromatous Leprosy • *Essential drugs monitor* • Aspects of leprosy neuritis, Senegal • Dermatological journal from Portugal • WHO publications: *Training in leprosy*; *Vaccination trials against leprosy*; *Sample surveys in leprosy* • *Health Policy and Planning*; a new journal • Course in ocular leprosy, Karigiri 1986 • International Federation of Medical Students' Associations • *Heralds of Health—the Saga of Christian Medical Initiatives* • The Grants Register 1985–6 • WHO Catalogue of New Books, Spring/Summer 1986 • Symposium on multidrug therapy in leprosy; DAHW, Würzburg, April 1986 • XVIth General Assembly of ILEP, Edinburgh, July 1986 • LEPROA's London Office, change of address • Leprosy for medical practitioners and paramedical workers • AHRTAG, London; drug packaging • XIII International Leprosy Congress, The Hague, 1988 • *Proceedings of XII Leprosy International Congress* • Dr Raghavendra Row Memorial Teaching Programme in Leprosy, 1986 • Vacancy for a pathologist at ALERT/AHRI