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Ten years' leprosy control work in Malawi (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 Malawi (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 Malawi, 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 Malawi 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

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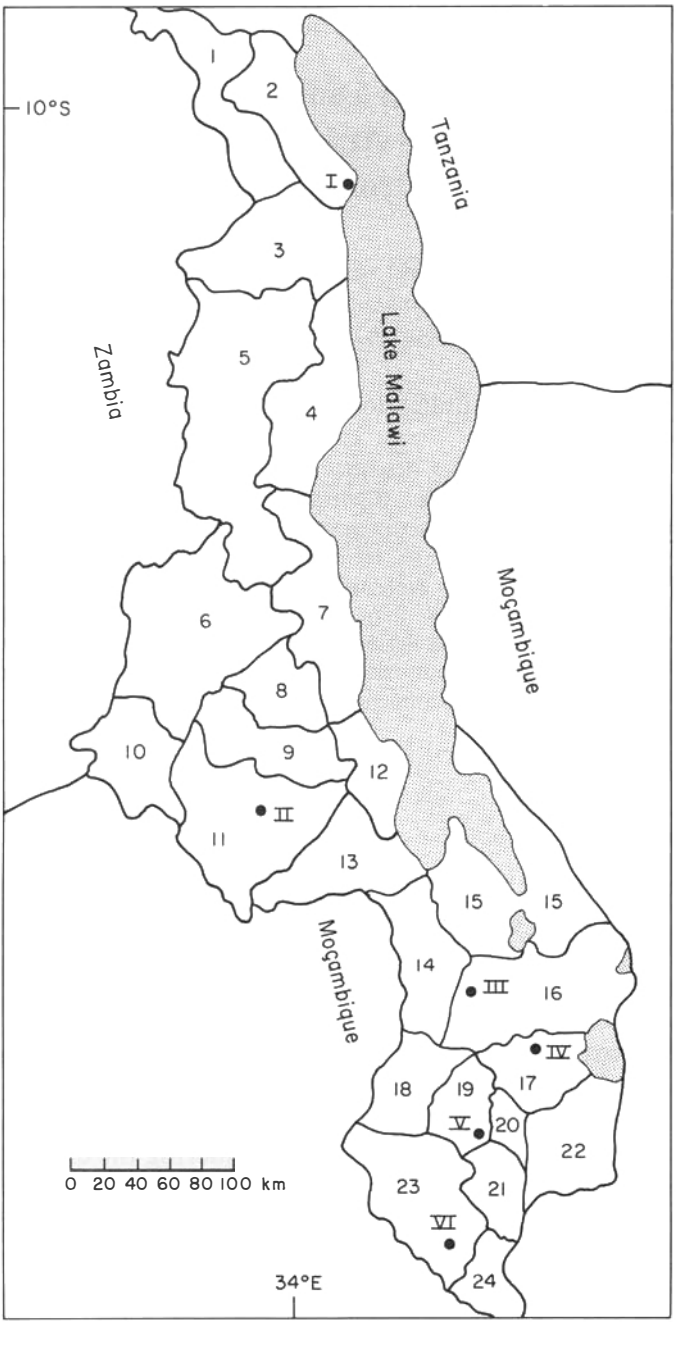
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Figure 1.

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, LEPRA 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 LEPRA.

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

Historical background

Malawi 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%.

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

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Figure 1. Districts of the Republic of Malawi and LEPRA 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 Malawi), 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, Malawi belongs to the southern edge of the tropical belt. The rainy season is from the end of November until the end of April.[i]

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 Malawi (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 LEPRA's 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 LEPRA's 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 LEPRA 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 $\leqslant 3$; 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 LEPRA 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))
	50%	52·6%	64·7%	50%	70%	50%	81·8%	75%	100%	87·5%	
New patients registered as BL/LL with an average BI 1–3	4	3	4	1	3	6	1	2	0	1	% correctly diagnosed + wrongly classified (includes (b))
	40%	31·6%	29·4%	37·5%	30%	50%	9·1%	25%	Nil	12·5%	
New patients registered as BL/LL with an average BI < 1 (a) on review by the authors the diagnosis was considered very doubtful	1	3	1	1	0	0	1	0	0	0	% wrongly diagnosed 'over-diagnosed'
	10%	15·8%	5·9%	12·5%	Nil	Nil	9·1%	Nil	Nil	Nil	
(b) diagnosis was considered correct but the classification was considered wrong	0	3	1	2	0	0	0	0	0	0	
(c) clinically burnt-out LL cases	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 LEPRA 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 LEPRA. It is probable that these patients were misclassified at registration by LEPRA.

(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 LEPRA's 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 Malaŵi. As early as

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

(a) Laboratory superintendent

Microscopist Northern Region Project BI	BI 0	1	2	3	4	5	6
0	12						
1	8	3	1				
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

Microscopist Balaka Project BI	BI 0	1	2	3	4	5	6
0	3						
1	1	1	1				
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 Malawi, 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 Malawi. 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 WHO[8] 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		39 unknown whereabouts	11 (4%) incomplete review notes	
	10 correctly on treatment		23 left for outside Malawi	121† (44%) no evidence of leprosy at time of discharge	
			19 left for inside Malawi (might have reported for treatment elsewhere in Malawi)	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	
	(b) reactivations during treatment: 3*			7* (2·5%) disabilities worse than at registration	
				8† (2·9%) disabilities less than at registration	

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		110 unknown whereabouts	20 (7·1%) incomplete review notes	
	31 correctly on treatment		8 left for outside Malawi	142† (50·4%) no evidence of leprosy at time of discharge	
			22 left for inside Malawi (might have reported for treatment elsewhere in Malawi)	61† (21·6%) inactive lesion(s) only. No disabilities	
	Out of those correctly on treatment				
	(a) relapses after removal or discharge: Nil		1 refused further treatment	33 (11·7%) with same disabilities as at registration	
	(b) reactivations during treatment: 8*			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 therapy[8] 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 Malawi 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 LEPRA 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 LEPRA 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 Malawi, 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 Malawi. 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.

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