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Editorial

MANAGERIAL IMPLICATIONS OF MULTIDRUG THERAPY

Summary The managerial effects of multidrug therapy (MDT) are discussed, using three possible models of leprosy control programmes, and tentative conclusions recorded. The three models may be modified according to local circumstances and local experience in particular control programmes.

Introduction

The widespread use of dapsone monotherapy revolutionized leprosy treatment. Activities focused on the outpatient clinic, and the long-stay leprosy 'home' became a base for the out-patient 'control' work. The base hospital today admits mostly short-term patients from a few days to a few months. Its work includes, or should include: (a) treatment of complications, e.g. reactions, eye problems, plantar ulcers, etc; (b) health education, e.g. orientation and motivation of patients towards regular treatment, the early detection of reactions, and in prevention and care of disability; (c) surgical and vocational rehabilitation, although not at all base hospitals.

In some limited geographical areas, efficient dapsone monotherapy has brought the control of leprosy nearer, as indicated by a change in the local picture of leprosy—fewer new multibacillary cases, and a significant reduction in the number of patients developing nerve damage and resultant disabilities.

In most areas though, dapsone-resistant leprosy has appeared. The aim of multidrug therapy is to prevent and/or overcome dapsone resistance, whether secondary or primary, to prevent the emergence of other drug resistances, and to provide quicker, more effective, and shorter-term treatment than is possible with dapsone alone.

As part of its long-term planning, The Leprosy Mission appointed a study group to assess the possible managerial effects of MDT, using regimens recommended by the World Health Organisation,[1] for the following durations:

(a) *Multibacillary patients* (MB)—at least 2 years treatment, and preferably until skin smears are Bacillary Index (BI) negative.

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(b) *Paucibacillary patients* (PB)—at least 6 months treatment (although there are growing signs that field workers in some areas are reluctant to stop treatment at this point, e.g. some wish to give 12 months continuous treatment).

It is still too early to assess the effectiveness of MDT, particularly in terms of relapse rates, and it will take several years to form a balanced view. The most optimistic forecasts suggest a rapid decrease in total case load where MDT is introduced, particularly through a rapid reduction in the number of PB cases needing treatment.

PB cases form a large majority of all leprosy cases worldwide, although the ratio of PB:MB varies in different areas from 85:15 to 70:30. (For discussion later in this paper an arbitrary ratio of 75:25 will be used.)

Methods

Taking a theoretical population of 100,000 with 1000 known patients, i.e. a prevalence of 10 per 1000, the effects of the introduction and use of MDT over a five-year period were examined. Three different models were used:

A. An 'ideal' programme, assuming 100% regularity of attendance, MDT being administered for the minimum recommended times,[1] no complications, and no new patients.
B. A 'realistic' programme, assuming less than 100% regularity, some patients requiring more than the minimum length of treatment, and new patients continuing to register for treatment during the 5-year time scale.
C. A 'pessimistic' programme based on experiences of average-to-low efficiency control schemes.

(NB—Most of the experience used to identify B and C is based on Asian conditions. Other parts of the world, may require different local modifications.)

CONTROL PROGRAMME A (100,000 population; 1000 registered patients)

This 'ideal' programme is not seriously considered to be a practical proposition. It assumes 100% regularity of attendance, bringing down the caseload to nil in 5 years, and also assumes no new patients join the programme, although it is realized that the prolonged period of incubation of leprosy precludes the last possibility. It is included for comparison with other programmes. A ratio of PB:MB of 75:25 is used throughout. (See Table 1.)

CONTROL PROGRAMME B (100,000 population; 1000 registered patients)

In this programme, the case load drops to approximately 50% within 12 months, but then the number drops only gradually over the next 5 years. (See Table 2.)

Table 1

Time	PB	MB	Total	Comments
Beginning of MDT	750	250	1000	
At 12 months	Nil	250	250	Assumed: all PB treatment concluded : all MB continue treatment
At 24 months	Nil	200	200	50/250 MB patients have concluded treatment without incident
At 60 months	Nil	Nil	Nil	250/250 MB cases have concluded treatment

Table 2

Time	PB	MB	Total	Comments
Beginning of MDT	750	250	1000	
At 12 months	Nil	250		Assumed: 750/750 PB treatment concluded
	+75	+25		
	+75	+25		250/250 MB continue treatment
	150	300	450	
				Add: *100 new patients from project area: 75 PB, 25 MB *100 new patients from outside area: 75 PB, 25 MB
At 24 months	Nil	200		Assumed: 150/150 PB's treatment concluded
	+60	+50		
	+75	+20		200/250 MB's still need treatment
	135	+25		
		295	430	50/50 second batch MB's still need treatment
				Add: †80 new patients from project area: 60 PB, 20 MB *100 new patients from outside area: 75 PB, 25 MB
At 36 months	120	235	355	By similar reasoning
At 60 months	90	195	285	By similar reasoning

* The figure of 100 new patients from inside the project area, and a similar figure from outside the project area, are arbitrary assumptions. In some highly-populated areas of Asia, e.g. a figure of even 200 might reasonably be argued. Conversely, in some areas where treatment for leprosy is widely available, there may be less or even no new patients from outside joining the project.

† The figure of 80 assumes that project area patients will slowly diminish, although in fact this may not happen for 5 years or more. Indeed, initially the number may rise because of early reporting by patients desirous of the new treatment.

Other factors should be remembered though, to obtain a full picture: (i) The number of new patients from inside the project area may not diminish as predicted. The *incidence* may show little change for some years because of the long incubation period for leprosy. (ii) Most patients will need regular check ups for several years. (iii) At the start of MDT, many patients will already have had leprosy for years and a significant number will continue to need help for residual disability and/or social problems. (iv) A number of apparently uncomplicated cases can still develop disability through nerve damage during and after treatment is concluded and, again, will need continuing help, although this number should eventually diminish.

As Wheate[2] says: '. . . discharge from chemotherapy is not to be equated with discharge from care . . .'.

Both A and B programmes assume that MDT will work just as predicted, with all patients 100% regular in attendance and responding according to plan. A rather less favourable picture, based on assumptions which are more pessimistic, but which could reasonably be argued from experience, is shown in Programme C.

CONTROL PROGRAMME C (100,000 population; 1000 registered patients)

From the 24-month point onwards, and assuming a continuation of these trends, the total case load would reduce by only 20–30 per annum, and could *even increase* somewhat if 100 patients per annum continue to come from outside the project area.

At 60 months there would be a fairly stable case load of about 500 with PB and MB's about equal in number. This would continue for some years, reducing only slowly, or until a thorough MDT programme were extended into adjacent areas (with the *added* costs of another, newer programme).

To this should be added annual check ups, help for the disabled, and the socially dislocated.

In theory, non-area patients could be refused. In practice, and in many Third World situations, this is very difficult on humanitarian grounds. We are left then with a picture in which MDT, in Programme C, would reduce the case load in 5 years to 50% but perhaps no less. (See Table 3.)

Discussion

1 COSTS

MDT will certainly increase the cost of individual treatment and, therefore, increase budget demands short term. Costs of medicine vary somewhat, and the comparison of costs of the 3 programmes is based on the following:

Table 3

Time	PB	MB	Total	Comments
Beginning of MDT	750	250	1000	
12 months	250	250		Assumed: 250/750 PB have been irregular, or need further treatment
	+75	+25		250/250 MB still under treatment
	+75	+25		
	400	300	700	
				Add: 100 new patients from project area: 75 PB, 25 MB
				100 new patients from outside project area: 75 PB, 25 MB
				(Collier's[3] statistical analysis suggests equal numbers of patients may come from within or outside project area)
24 months	100	200		Assumed: 100/750 original PB still need care
	+50	+50		50/150 of later PB still need care
	+60	+20		
	+75	+25		
	285	295	580	
				200/250 original MB still need care, because BI still positive and 50/50 later MB still need care
				Add: 80 new patients from project area: 60 PB, 20 MB
				100 new patients from outside: 75 PB, 25 MB
				(The reservoir of new patients in project area begins to decrease, but not that outside the project area)

(i) Dapsone monotherapy, per patient, per annum: US $2.25
(ii) MDT per paucibacillary patient for 6 months treatment, i.e. the minimum recommended by WHO: US $6.00
(iii) MDT per multibacillary patient, per annum: US $26.00

The costs are for medicines only, and do not include the other necessary costs of a control programme, e.g. salaries, transport etc.

It may be argued that although the initial cost is higher, the effective cost in curing one patient, and the effective cost of achieving local control of leprosy, will be lower long term, because of the speed and effectiveness of MDT. Even before

control, medium term costs will also be lowered by a rapid reduction in total case load. (For a modified view see below under 'Case Load'.)

It is noted that costs for medicine may amount only to between 10–20% of the total running costs of a leprosy control programme.

Table 4. Comparative costs in US of Programmes A, B and C. (Medical costs only)

	Dapsone monotherapy	Programme A	Programme B	Cost increase* (%)	Programme C	Cost increase* (%)
1st year	2500	11,000	11,000	(448)	11.000	(448)
2nd year	2500	6500	8700	(386)	10,200	(435)
3rd year	2500	2600	8480	(376)	9380	(416)
After 5th year	±2500	Nil	5610	(249)	8000	(355)

* Percentage cost increase as compared with dapsone monotherapy

2 CASE LOAD

The introduction of MDT should reduce significantly the total case load because: (i) before the local introduction of MDT, all patients will be screened, and many inactive PB cases released from control immediately without further treatment; and (ii) within 6–12 months of introducing MDT many PB cases (PB's being approximately 75% of the total caseload) will require no further treatment other than regular annual check ups. The reduction in the number of MB patients (25% of total) will not begin before 24 months and would be spread over a period of 24–60 months, or longer, because of the longer period of treatment recommended.

However, this 'ideal' view of MDT may be modified, particularly in some countries, by any of the following: (i) A percentage of PB's will need continuing care for complications arising from nerve damage. There will be fewer of these as time goes on, particularly from among new patients treated from the beginning with MDT, but every programme inherits a significant number of patients from earlier, less-effective, treatment. (ii) Few MB patients will be BI negative within 24 months. Most will need 60 months at least, many will need more. (It is understood that, while MDT may speed up changes in the morphological index, MI, it does not alter the rate of change in BI.) (iii) The number of patients requiring MDT in a particular programme will continue to increase for some time, for three reasons: (a) because there will still be undiagnosed and unregistered cases within the area, who will slowly report for treatment; (b) there will be cases already infected but who will only gradually show clinical signs of leprosy over the next ±10 years; and (c) patients may enter the area from outside, attracted by better treatment.

3 WORK LOAD

Case load and work load are not synonymous. The reduction in case load (the number of patients under active treatment) may not reduce proportionately the work load (the amount of work needed to run the treatment programme successfully). The introduction of MDT demands the highest standards of regularity of treatment, recording of treatment, laboratory services, treatment of complications, and staff training, and therefore increases the work load. A diagrammatic interpretation is given below.

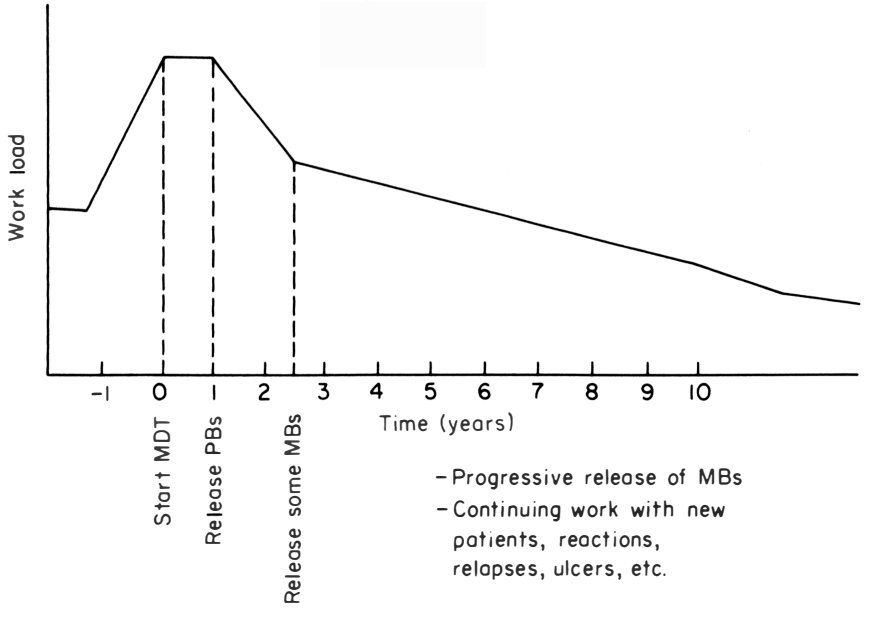

Figure 1. The effect on staff work load of introducing MDT.

4 IMPLICATIONS

Programme A. Cannot be expected to happen.

Programme B. In the Study Group's view, this is the most likely picture. After the initial release from control of old PB cases, and the discharge of many other PB's after 6–12 months MDT, the further reduction in case load will be gradual. Over the first 5 years therefore, clinics will still have to provide a regular service, although it may be possible to cut down the frequency, e.g. from weekly to monthly. A reduction in staff could then take place. Possibly up to 40–50% of paramedical workers (PMW) would no longer do intensive survey work, and the time spent at clinics would be less. In theory, skills could be 'doubled up,' e.g. a PMW could also acquire and use physiotherapy skills, or a physio-technician could take charge of shoe fitting or health education, etc. In practice, cultural

problems and/or trade union objections could slow this down. Travel would, however, be reduced somewhat.

If significant staff reductions are foreseen there are several alternatives: (i) redundancies and natural wastage. The first is unpleasant, the second slow; and (ii) redeployment in other geographical areas. Problems of language, culture and humanity may be involved. Redeployment of some categories *within* a language area is possible if control activities are extended to adjacent areas.

Rather than lose staff, it may be better to use the available time in more effective contact and absentee-tracing, health education, disability prevention, and care for patients' individual social and community needs.

The number of patients needing hospital admission would be reduced, although medical, surgical and physiotherapy services would continue to be needed by many patients for continuing disability. Reducing hospital admissions by, e.g. 50%, would not allow a similar reduction in staff or costs. For example, a ward of 20 beds may need 4 nurses to cover a 24-h day (2 on duty together during the busy day, the others singly in shifts). A 10-bed ward will still need 3 nurses to cover a 24-h day, singly in shifts.

5 GENERAL COMMENTS

(a) *Integration*. The desirability and practical outcome of integrating leprosy care into general medical services is a continuing, and separate debate. The effects of MDT on integrated services is difficult to assess. The hope that leprosy treatment would be limited, over a 24–60 months period, would help; but the need for absolute regularity of treatment with MDT is probably harder to achieve in a general health clinic than within a vertical leprosy programme.

(b) *Mobility*. If Programme A is practical then staff mobility and flexibility are important, either in moving to begin new and similar programmes in adjacent areas where their cultural background, language and experience could immediately be used, or in moving further away to areas of need. Modified movement could also be organized under Programme B although probably only to adjacent areas, rather than wider afield.

(c) *Social Care and Rehabilitation*. Whatever savings of money, time, and staff may be possible, they could well be redirected towards vocational and social rehabilitation for the handicapped.

(d) *Primary Health Care*. If case loads decrease, a widening of activities into other health problems, e.g. water supply, nutrition, immunization, could be considered.

Conclusions

This is an investigatory paper, and conclusions can only be tentative, being based on insufficient evidence of the practical effects of MDT.

(a) MDT is the most effective form of treatment now available, and is likely to be much more effective than dapsone monotherapy, although evidence of relapse rates will only become available in about 10 years time. It is very unlikely that any new, more effective drugs will become available during this time, and it will be at least that long before candidate vaccines, now under test, can be assessed.

(b) MDT will certainly increase medical costs for 5–10 years, with no corresponding reductions in other costs. This may not be dramatic, because the cost of all medicines in a control programme is usually between 10 and 20% of the total running costs.

(c) MDT will not reduce long-term costs generally, partly because of the continuing need to care for complications, and also to give social and vocational help. Also because MDT should be extended progressively to patients in adjacent areas. Budget demands, therefore, will remain high, as well as increasing by inflation.

(d) Laboratory facilities and services need to be improved, because of the importance of accurate diagnosis of MB and PB cases, in order to establish the appropriate treatment regime.

(e) Staffing levels will not be reduced significantly, although there may be significant retraining and redeployment of skilled workers.

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