

## Impact of MDT on leprosy as measured by selective indicators

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*Summary* The impact of multidrug therapy (MDT) on the leprosy situation in endemic districts where MDT has been introduced, is studied, using a hypothetical model.

This analysis indicates that there will be significant falls in prevalence rates during the first 5 years, mainly as a result of discharge of cases during screening and due to shortening of the duration of treatment. These changes have to be interpreted with caution. Already some districts like Wardha in India have shown dramatic falls in prevalence rates from 11.1 in 1981 to 1.8 in 1987.

The impact of MDT on disease transmission as measured by decline in incidence rates and case detection rates will, however, be gradual.

### Introduction

The National Leprosy Control Programme in India was initiated in 1955.<sup>1</sup> After nearly three decades of leprosy control using dapsone monotherapy, the strategy was revised in 1982.<sup>1</sup> The new strategy is based on multidrug therapy (MDT) as recommended by WHO.<sup>2</sup> MDT was introduced in India on recommendations of the Swaminathan committee<sup>1,3</sup> in 1983. As of February 1987, 33 endemic districts in India (prevalence 5 or more/1000) have been put under MDT. There are 412 districts in India and leprosy is endemic in 201 of them. Many areas in India thus have 3–5 years experience with MDT.

The initial optimism continues to grow and there is reasonable hope that the leprosy problem can be considerably reduced by the year 2000. However, it is important to understand the Epi-dynamics of leprosy in an area where MDT has been introduced. The trends in the leprosy situation, as measured by selected indicators currently being used, have to be interpreted with caution. It is crucial that when looking at these indicators, the actual impact of MDT on transmission of *M. leprae* infection, be differentiated from changes brought about by policy decisions, definitions of indicators and secular trends.

This paper seeks to look at an hypothetical area of one leprosy control unit, where MDT is being introduced at time zero (T<sub>0</sub>). It seeks to predict what should happen in 3 to 5 years (T<sub>0</sub> + 3, T<sub>0</sub> + 5). Since there are considerable differences in interpretation of guidelines on MDT,<sup>3</sup> use of actual data

may not be representative. The policy for intake into MDT of paucibacillary and multibacillary patients, criteria for discharge, definitions of indicators and their interpretation vary considerably at the district level.

### Methods and materials

Let us assume the multidrug therapy is introduced in an area of an average leprosy control unit (LCU), with the statistics as follows:

#### POPULATION DETAILS

1 Name of LCU	Leprad
2 Population	500,000
3 Area	1500 sq. km.
4 Estimated prevalence	20/1000 (1981)
5 No. of estimated cases	10,000
6 Estimated incidence rate (annual)	2/1000
7 New case detection rate (annual)	1.5/1000
8 No. of new cases detected each year	750

#### PATIENT PARTICULARS

1 No. of cases	10,000
2 Multibacillary (MB) 25%	2500
3 Paucibacillary (PB) 75%	7500
4 Proportion of active PB and MB cases	25%
5 No. of active MB cases	625
6 No. of active PB cases	1875
7 Total active cases	2500
8 Deformity rate (Grade II and III)	25%
9 No. of cases with deformity	2500
10 No. of child (15 yr and below):	
Cases 30% of total	3000
MB 10%	30
PB 90%	2700

#### NEW CASES PARTICULARS

1 No. of new cases detected per year	750
2 Case detection rate	1.5/1000
3 No. of MB cases (10%)	75
4 No. of PB cases (90%)	675
5 Deformity rate	5%–10%
6 Proportion of child cases (40%)	300 cases

Let us assume that with the above statistics, MDT was introduced in 1981 in the area where dapsone has been used since 1971. If we take 1981 as 'T<sub>0</sub>' let us see what will happen to the following selective epidemiological and operational indicators: 1, prevalence rate; 2, incidence rate; 3, deformity rate; 4, active MB rate, PB rate; 5, positive case rate; 6, child rate; and 7, case detection rate.

## DEFINITIONS

*Prevalence rate*

*Gross prevalence (GPR)*: No. of living cases per 1000 population (including released from control, self-healed cases).

*Operational prevalence (OPR)*: No. of cases requiring treatment or surveillance per 1000 population includes cases under treatment, released from treatment but under surveillance, plus unregistered cases—sometimes the total is called known cases.

*Active prevalence (APR)*: No. of active cases MB and PB/1000 population, based on active cases. (It is total  $2.5 + 2.6$ .) It is assumed that prevalence figures are calculated on population actually examined during surveys.

*Incidence rate (IR)*: No. of new cases of leprosy detected per 1000 population per year. The assumption is that if repeated annual population surveys are done, new cases detected among a population previously examined and declared free of leprosy one year earlier, are considered as incident cases. Cases arising from immigrants, births or unexamined population in the previous year, are not included in calculation of incidence rates.

*Deformity rate (DR)*: Proportion of cases with visible deformity (WHO deformity Grade II and III<sup>4</sup>).

*MB Rate*: Proportion of MB cases (BL and LL) as compared with total cases.

*Active Case Rate (MB and PB)*. MB, the proportion of MB cases clinically active or bacteriologically positive as compared with total cases. PB, the proportion of clinically active PB cases as compared with the total cases.

*Bacteriologically positive rate (BPR)*: PB cases that are skin smear positive in India are grouped along with MB cases that are positive and are put on the WHO regimen of MDT<sup>3</sup> for MB patients. The proportion of cases that are bacteriologically positive as compared with the total cases under treatment constitute this rate.

*Child rate (CR)*: Proportion of cases below 15 years of age.

*Case detection rate (CDR)*: No. of new cases detected in the area per 1000 population (census). It includes cases detected by all sources including surveys and voluntary reporting.

**Results**

## CHANGES THAT WILL OCCUR AT T+1 YEAR—BEFORE MDT IS INTRODUCED

In most LCU an active release from control has not taken place. During the preparatory phase, screening of all cases, PB and MB is done. Intake into MDT is according to the Government of India guidelines.<sup>3,5</sup> PB patients on monotherapy with dapsone are released from control, if: they are classified as indeterminate (Ind), tuberculoid (TT), or borderline tuberculoid (BT), and were skin smears negative at registration; they have completed 3 years of treatment with dapsone; and if they are clinically and bacteriologically inactive as judged by a doctor or a senior non-medical supervisor (NMS).

In patients with MB leprosy, treatment is continued till clinical and bacteriological inactivity and then a further period of 5 years. In many control programmes however PB and MB patients are treated for much longer periods. It is estimated that the screening phase before MDT is introduced will take 1 year. It is essential to train all cadres of staff to enhance their clinical skills, before screening commences.

## CHANGES AT END OF 1 YEAR AFTER SCREENING PERIOD

If one assumes that only a maximum of 25% of PB cases and MB cases are active:

The No. of inactive MB cases will be 2500– 625	1875
The No. of inactive PB cases will be 7500–1875	5625
Total	<u>7500</u>

Assuming that at least 50% of the inactive MB and PB cases would have completed 7 and 3 years of treatment respectively, 50% (i.e. 3750) cases could be straight away released from control, (remaining 938 MB + 2812 PB).

#### IMPACT ON PREVALENCE RATE

If the prevalence rate (OPR) was 20/1000 with 10,000 cases and at screening 3750 cases are released from control, then the prevalence rate would fall to 12.5/1000,  $(10,000 - 3750/500,000 \times 1000)$  before MDT is introduced at T<sub>0</sub>. The prevalence rate would also be considerably influenced by previous definitions of prevalence rates used (see definitions). If the operational prevalence rate was originally used and now the definition is changed to active prevalence rates, and only 25% of cases are active (i.e. 2500), then the active prevalence rate will be 5/1000. This in itself would show a considerable fall in prevalence rates, even before MDT is introduced. The fall would be greater if gross prevalence rates were originally used.

#### IMPACT AT THE END OF 1 YEAR

Cases under treatment at beginning of MDT:

MB, 625 active + 50% (938) inactive	1563
PB, 1875 active + 50% (2812) inactive	4687
Total	<u>6250</u>

#### *PB cases*

Let us assume that all the PB cases are put under MDT. There are 4687 PB cases under treatment with 1875 active cases. These PB cases would have received varying durations of treatment with dapson. However, we will consider that all of them are put under the WHO-PB regimen. At the end of 6 months it is estimated that only 25% of the active cases will continue to be active, i.e. 469 cases. The remaining 4218 cases, who had had previous dapson monotherapy, can be released from treatment but are kept under active surveillance for a period of 2 years.

#### *MB cases*

Let us assume that all MB cases (active and inactive) are put under the WHO-MDT regimen. There were 1563 MB cases under treatment and of them 625 were active (bacteriologically, or clinically). At the end of 2 years, the 938 inactive cases would be ready for release from treatment (RFT). At least  $\frac{1}{3}$  of the active cases, i.e. 208 with initial BI of 1 and 2 would have become negative and ready for RFT. Thus 1146 cases would be released from treatment but kept under active surveillance for a period of 5 years.

#### AT THE END OF 3 YEARS THE STATISTICS WOULD BE AS FOLLOWS

#### *Old cases*

MB cases under treatment at T<sub>0</sub>

1563

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MB cases eligible for RFT at end of 3rd year (938 inactive + 208, i.e. $\frac{1}{3}$ active cases)	1146
MB cases still requiring treatment (625–208)	417
PB cases under treatment at T0	4687
PB cases under surveillance eligible for RFC	4218

*New cases*

Cases detection rate 1.5/1000 population	500,000
New cases detected:	750
MB      75	
PB      675	
PB cases eligible for RFT (1st year cases)	675
PB cases remaining under surveillance (2nd and 3rd year cases) $675 \times 2$	1350
Total PB cases under surveillance (469 + 1350)	1819
MB cases eligible for RFT (10% of 1st year cases)	8
MB cases remaining under treatment (2nd and 3rd year cases) $75 \times 2$	150

*Total*

Total new MB cases under treatment (150 + 68)	218
Total MB cases under surveillance (1146 + 8)	1154
Total cases under treatment at end of 3rd year: (old + new)	
PB (50% of 3rd year new cases $675/2$ )	338
MB (417 + 218)	635
	973
Total	973

*At the end of the 3rd year*

MB cases required treatment/surveillance (1154 + 218)	1372
PB cases required treatment/surveillance	1819
	3191
Total	3191

Operational prevalence rate = $\frac{3191}{500,000} \times 1000$	6.4
Active prevalence rate (635 MB + 338 PB active cases)	
$\frac{973}{500,000} \times 1000$	2

*Apparent impact of MDT, 3rd year*

Prevalence rate (per 1000)	T0	After screening	T + 3 yr
Operational prevalence rate	20	12.5	6.4
Active (APR)	—	5	2

*Incidence rates (IR)*

Based on sample surveys the IR is unlikely to change within 3 yr.

*Case detection rate*

Will be considerably influenced by intensity of case detection. Since the load of MDT work during

the first 2 years is high the case detection usually suffers. Overall, no impact on the case detection rate is likely. It is important to retrain staff to improve case detection by such measures as health education aimed at increasing case detection.

#### *Deformity rate*

Among the total cases under treatment and surveillance the deformity rate may in fact go up. The deformity rate is really ratio (proportion), i.e.

$$\frac{\text{Case with deformity}}{\text{Total case}} \times 100.$$

A large number of PB cases without deformity will be RFCed by the end of the 3rd year, whereas the MB cases with deformity will still be included in the calculation. Depending on the intensity of previous case detection, the deformity rate among new cases will vary. If previous surveys had been done recently deformity rates should fall among new cases.

#### *MB case rate*

The MB rate will in fact increase as this too is a ratio and the numerator (MB cases) will decrease (2500 to 1372), but the total will decrease considerably (10,000 to 3191) as PB cases are released from control. Thus the MB rate will increase from 25% to 43%. However, the positive case rate may fall depending on the new MB cases detected.

#### *Child rate*

Among total cases may fall considerably as most of them would be PB and released from control. But the child rate among new cases is unlikely to fall.

#### STATISTICS AT END OF 5 YEARS

MB cases that required treatment of surveillance at end of 3rd year	1372
PB cases that required treatment of surveillance at end of 3rd year	1819
Total	3191

All the above PB cases can now be released from control as they would have completed 2 years of surveillance. The 938 inactive MB cases at T0 can also be released from control.

#### *New cases*

Cases under treatment at end of 3rd year (PB 338 + MB 635)	973
New cases detected 4th and 5th year:	
MB, $75 \times 2$	150
PB, $675 \times 2$	1350
Total	1500
Total cases requiring treatment or surveillance at end of 5 years:	
PB (4th and 5th year new cases)	1350
MB ( $75 \times 5$ ) + (1372 - 938)	809
Total	2159

Operational prevalence rate:  $\frac{2159}{500,000} \times 1000$  4.3

Active prevalence rate: (33%)  $\frac{713}{500,000} \times 1000$  1.4

(The positive MB cases would become negative at rate of 10–20% per year.)

**Discussions**

The impact of MDT in 5 years of the prevalence rates as calculated is as follows:

Prevalence rate per 1000	After			
	T0	screening	T + 3 Yr	T + 5 Yr
Operational	20	12.5	6.4	4.3
Active	—	5	2	1.4

(P) Prevalence = (I) incidence × (D) duration of the disease. In leprosy the duration of treatment or surveillance is considered the duration a patient is included in prevalence calculations. Then:  $I(2) \times (1-4)D = P(2-8)$ , where 1–4 years, is the mean duration of treatment or surveillance.

Thus the impact on the crude prevalence rate after 5 years merely reflects changes in ‘D’. One could show a fall in prevalence rate from 20 to 4.3 or 20 to 1.4 depending on definitions of prevalence rates used and policy of release from control prior to MDT. These would not be the true MDT effects if one is looking at impact on transmission of *M. leprae* infection and incidence rates of disease.

IMPACT AFTER 5 YEARS OF MDT ON PREVALENCE AND INCIDENCE RATES

After 5 years as mentioned, the case load is going to decrease considerably once old cases are released from control. Usually when arriving at prevalence rates, ‘point prevalence’ is calculated, but when incidence rates are arrived at the period incidence is calculated. In such instances D=duration of disease, if taken as duration of treatment of leprosy (excluding period of surveillance), the incidence rate can turn out higher than the prevalence rates.

At the end of 5 years the figures are as follows for the total number of cases requiring treatment or surveillance:

	Treatment	Surveillance	Total
PB	$675/2 = 338$	$1350 - 338 = 1012$	1350
MB	$75 \times 2 = 150$	$1372 - 938 = 434$	584
Total	488	1446	1934

Approximately 338 PB cases will require treatment. This is because the other 1012 cases are in the 2 years surveillance phase.

Assuming that 675 new PB cases and 75 new MB cases are detected each year, at the beginning of the 6th year the only PB cases under treatment will be those detected in the second half of the previous (5th) year. During the year these cases, plus most of the cases detected during the first half of the 6th year, will be released from treatment. Thus at the end of the year only half the new PB cases detected will be under treatment, plus the 75 new MB cases. During the 6th year closing figures will be:

Old cases under treatment	PB	338
(5 years MB cases)	MB	375
		713
New cases detected 6th year	PB	675
	MB	75
		<hr/> 750

Based on the above figures, the cases under treatment only at end of the 6th year will be: MB 375 + 338 PB cases = 713. The point prevalence rate calculated on cases under treatment only will be:  $713/500,000 \times 1000 = 1.4$ . The active point prevalence will be: (40% of 713 =  $285/500,000 \times 1000 = 0.57$ ). The case detection rate (CDR), however, will be  $750/500,000 \times 1000 = 1.5$ . Thus the CDR will be 2.63 times the prevalence rate!! The incidence rate will still probably be 2/1000.

In Wardha, a MDT district in India, the active prevalence rate (APR) is 1.8/1000 and the case detection rate (CDR) is 2.6 in 1986, similarly in Vijnagaram the APR = 2.8 and the CDR is 2.2.<sup>6</sup>

The calculation  $P = I \times D$  no longer holds good when, in a chronic disease, 'D' becomes less than 1 year. When targets for case detection are calculated this has to be borne in mind. These trends in MDT districts also indicate that the concepts of incidence and prevalence have to be reviewed.

There is, however, a considerable reduction in case load and fall in prevalence rates. In most MDT districts in India this is seen—Wardha, a fall in APR from 11.1 to 1.8, Purulia 19.2 to 7.7, Srikakulam 18 to 2.6.<sup>6</sup> This reduction has to be viewed with caution. There may be a large number of disabled and deformed leprosy patients now removed from the statistics and declared 'cured', who may still need considerable supportive care in the years to come—'Care After Cure'.

Assuming that the incubation period of leprosy is 3–5 years one can begin to see the effects of MDT on transmission, as measured by incidence rates only after 5 years. An early marker, would be measurement of *M. leprae* infection using serological tests. The incidence rate as well as the case detection will probably decline after 5 years.

Changes in the deformity rate, incidence rate among contacts, the child rate and the MB rate will occur among the new cases, assuming intensive case detection continues and the backlog of old cases have been detected and treated.

It was initially suggested<sup>7</sup> that 80% of estimated cases would have to be detected before MDT is to be introduced. This would mean that all the new cases detected would be put on dapsone monotherapy, till MDT was introduced. Hence the current thinking is that MDT be introduced irrespective of what proportion of estimated cases have actually been detected. But during the first 2 years of MDT, the backlog of cases would have to be detected in an intensive case detection programme. The impact of MDT will be considerably influenced by the gap between the estimated cases and actual cases under treatment.

An extremely interesting article on the 'Epidemiology and decline of leprosy in Asia'<sup>8</sup> suggests that, using composite data from East Asia, the decline in new cases had already begun in the 1960s. The fall, however, has been gradual up to the year 1980 prior to MDT. Skinsnes<sup>8</sup> commenting on the East Asia model indicates that it would take 25 years after the peak in the new case detection rate, for leprosy to come down to 25% of its peak.

Assuming that the MDT effect is more pronounced and rapid, one would assume that the declines in the new case detection in MDT districts would be apparent after 5 years of MDT.

The impact of MDT would probably be earlier in low prevalence areas, if a high proportion of estimated cases are put under effective chemotherapy.

At the managerial level, however, one has to keep in mind that:



The impact of MDT will mainly be on reduction in the case load for the first 5 years.

This impact is significant, but interpretation of the falls in prevalence rates cannot imply fall in transmission.

Incidence rates will probably be affected only after 5 years.

Discharge of a large number of cases from statistical formulation should not make one forget patient's long term rehabilitative needs.

Targets based on prevalence rates alone could be misleading.

The fall in prevalence rates is useful managerially in planning resource allocation.

As active case finding is likely to suffer during the initial period after the introduction of MDT, measures to enhance voluntary reporting by means of health education should be encouraged.

It has also got to be understood that the impact on the trends in leprosy, as measured by selected indicators, will be considerably influenced by:

Definitions of indicators and their interpretation.

Efficiency of programme implementation before and after MDT.

Adequacy of population coverage, case detection, case holding and the service delivery components.

Initial prevalence and incidence rates.

When one looks at the possible impact of MDT on the leprosy situation by the year 2000, there is considerable cause for optimism. This optimism, however, should be guided by the knowledge of the Epi-dynamics of leprosy in an MDT area.

### **Acknowledgments**

We wish to thank the Danish International Development Agency, Dr G D Georgiev and the Government of India especially, Dr C K Rao for organizing numerous workshops in the areas of evaluation and monitoring. Participation in these workshops and interaction with colleagues from many MDT districts, helped develop the ideas that have been formulated in this paper. We also wish to thank Mr N Christopher and Mr C Lewis for their secretarial help.

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**NEWS AND NOTES**
**Armadillo survey: Universities of Oxford and Minas Gerais, Brazil 1988**

The explanatory brochure for this project reads as follows:

The Serra da Canastra National Park lies in the province of Minas Gerais, S.E. Brazil. It is a beautiful 71,525 ha area of grassland plateau at 1400 m above sea level, and is a rich source of wildlife, dominated by armadillos and their relatives, the anteaters.

It is hoped that this joint project between the Universities of Oxford and Minas Gerais will enhance Anglo-Brazilian relations. The students of both nationalities should, through shared experience with contemporaries of a different cultural background, gain a greater mutual understanding.

The Survey aims to continue the work of Dr Christiane Encarnaç o who, in her Ph.D. thesis, investigated the social behaviour of the 6 species of armadillo in the Park. A rudimentary population census will be carried out for each species, together with a general study of their behaviour and ecology and an investigation of their ectoparasites. Studies will be centred around the 6-banded armadillo, *Euphractus sexcinctus*.

There are, in all, 20 species of armadillos, which range in length from 10 cm (the pink fairy armadillo, *Chlamyphorus truncatus*, of Argentina) to 1 m (the giant armadillo, *Priodontes maximus*, thinly scattered over most of S. America). They principally feed on ants and live in burrows.

The 6-banded armadillo (*Euphractus sexcinctus*), the main study subject, is about 40 cm long. Unusually, it is largely diurnal. Although not a widely distributed species, and hence little studied, it is the commonest in the Park.

Other species to be seen in the Park are: 'the naked-tailed armadillos (2 species—*Cabassous unicinctus squamicaudis* and *Cadassous tatouay*); the long-nosed armadillos (2 species—*Dasyypus novemcinctus* and *Dasyypus septemcinctus*); and the giant armadillo (*Priodontes maximus*).

Armadillos will be caught in humane traps, as used by Tracy Carter and Christiane Encarnaç o.<sup>1</sup> These may be acquired cheaply in Brazil. The animals will then be tracked by a combination of the following methods.

#### *Spool-and-line tracking*

Spool-and-line tracking devices essentially consist of a fixed spool of thread, with a range of up to 2300 m, enclosed in a plastic sheath. This is attached to the study animal, the thread pays out freely, and the trail may subsequently be followed to the burrow. This technique, developed by Dr M A Miles of the London School of Hygiene and Tropical Medicine<sup>4,5</sup> provides information on distances travelled at night, home, range, size and burrow type and location. It complements radiotracking and is advantageous in that it is inexpensive and allows the tracking of several animals simultaneously and continuously.

#### *Radio-tracking*

*Betalights*—details are available from the address below.

Each armadillo caught will be examined for ectoparasites, which will be identified by an expert at the Federal University of Minas Gerais.

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