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Editorial: **Tuberculosis control: did the programme fail or did we fail the programme?**

Introduction

Under pressure of the increasing numbers of tuberculosis (TB) cases in the world, TB control has once again become a major challenge. As such it is the subject of intensive scientific activity, as evidenced by the numerous studies and publications that have been devoted to it over the last few years. *The Lancet* recently published two documents which summarize present concerns: the minutes of the conference organized in Washington DC by *The Lancet*, in September 1995: 'The challenge of tuberculosis: statements on global control and prevention' (Enarson *et al.* 1995) and an article which proposes substantial modifications of activities in the standard tuberculosis control programme (De Cock & Wilkinson 1995). From the most recent literature, two major challenges may be identified (Reichman & Hershfield 1993; Porter & McAdam 1994; De Cock & Wilkinson 1995; Enarson *et al.* 1995): On the one hand there is a call for the development of new diagnostic techniques, especially procedures that are faster and more sensitive than smears or cultures and techniques that would improve or facilitate the diagnosis of smear-negative TB; and a call for new treatments that are effective against multidrug-resistant TB and/or that would shorten length of treatment. On the other hand, the scientific community also acknowledges the importance of some operational aspects of TB, such as problems of drugs delivery and financing, and patient compliance to treatment (Reichman & Hershfield 1993; Porter & McAdam 1994; De Cock & Wilkinson 1995; Enarson *et al.* 1995). This last point is considered a top priority, and WHO is currently promoting DOT (Daily Observed Therapy) as a new strategy to be implemented by each TB control programme (Enarson *et al.* 1995).

However, other aspects linked to the organization and the functioning of health services, or linked to the perception of the illness by both health personnel and patients, are underestimated. In his presidential address, given at the 21st Andhra Pradesh TB and Chest Diseases Conference held in July 1994 in India, Dr Ranga Rao proposed a critical self-evaluation of the state TB control programme which started more than three decades ago (Rao 1994). This physician, who has been working as a TB officer for more than 25 years, identified 17 major weaknesses of the TB control programme. His very impressive list begins with:

> 'We failed in implementing the programme in the health districts.
>
> We failed in providing the services of all the trained medical and paramedical key personnel continuously in some districts, due to frequent transfers or otherwise.
>
> We failed in improving the laboratory services in the primary health centres.
>
> We failed in seeking administrative support of the competent authorities to run the programme ... etc.'

What is striking about this presidential address given by a TB specialist to the members of a tuberculosis association, is that most of the 17 weaknesses identified are related to human or organizational failures and some to lack of political will, but none are directly attributed to a technical problem.

Whether in industrialised or in low-resource countries, our experience points in the same direction: we failed in implementing TB control programmes mainly for operational reasons (human and/or organizational failures linked to the overall functioning of health systems), not because of a problem of diagnostic tools or drug resistance. These operational reasons are due to specific challenges arising from the integration of a TB control programme into general health services and from the quality of the overall functioning of the health services.

An operational model for the analysis of TB control programmes

Piot (1967), who at that time was attached to WHO's TB programme, put forward a model enabling a

comprehensive assessment of all the different technical and operational aspects of a TB control programme. We propose a simplified version of this model focusing on the problems raised by the integration of the TB programme into the general health services.

The model, which is conceptually simple, is based on the passive detection strategy of smear-positive TB cases. It starts from a description of the different steps individuals in the community go through between becoming ill with active TB and getting cured by the TB control programme under consideration. The main steps – the number of which may vary according to the characteristics of the control programme – are summarized below:

Step 1: Motivation:	Patients suffering from symptoms related to TB contact a health care delivery point.
Step 2: Selection:	The health professional suspects TB and requests a sputum examination (smear).
Step 3: Examination:	The sputum test is correctly carried out on the patients thus selected.
Step 4: Sensitivity:	The smear is positive if the patient has bacilli in the sputum.
Step 5: Prescription:	The newly identified case of TB receives the correct treatment prescription.
Step 6: Treatment:	The TB patient obtains the prescribed treatment.
Step 7: Regularity:	The TB patient takes his treatment regularly as prescribed.
Step 8: Effectiveness:	The patient is cured with a certain probability if treatment is taken as prescribed.

In ideal circumstances, all new cases of TB consult without delay, are suspected of suffering of TB and are diagnosed promptly and accurately, receive a correct treatment prescription, obtain the prescribed treatment and take the full treatment regimen regularly to finally be cured. This would lead to a 100% prompt cure rate of new TB cases in the population and to a decrease in the transmission of TB. Of course, real life is different. *At each step* problems and difficulties arise: a suspect individual is not identified, there is no reagent to carry out the sputum smear, a positive sputum is missed by the laboratory technician, drugs are out of stock, the patient does not present at the health centre regularly, and so on ... The probability that a patient does proceed from one step to the next is a measure of the performance of different TB control activities.

Some steps are essentially technical (sensitivity of diagnostic test, theoretical effectiveness of treatment) and depend on the choice made at the central level by the TB programme officers. Their probabilities are theoretically independent of circumstances. Other steps' probabilities are quite variable from one situation to another because they depend in the first place on the quality and performance of the health services where TB control activities are integrated. These so called 'operational steps' depend on the operational quality of the health services such as they are and include: motivation, selection, examination, prescription, treatment and regularity. To illustrate the importance of the problems encountered in the field and the need of a global approach, we briefly discuss two of these operational steps, examination and regularity.

Examination is often the weakest link in the chain of steps that should lead to the cure of TB patients. Many types of problems are encountered in practice. First there is the case of the doctor who failed to properly explain the importance of this examination, and the patient who thus is not inclined to queue up again at the laboratory, especially if he needs to come back two more times in order to complete the required series of three sputum examinations and one more time to hear the result (the whole process often takes more than a week, several days at best (Aluoch *et al.*1984). Secondly, the laboratory technician does not adequately instruct the patient on how to produce sputum or does not allow him the necessary time; the collected specimen is saliva instead of bronchial secretions. We have seen this situation over and over again. Thirdly, the sputum collection may be correct, but the smear not correctly prepared: old slides are used (one of the sources of false positives), the sputum is badly spread out, reagents are either past the expiry date or out of stock, procedure is not followed, the staining is done badly.

Lastly, an adequate sputum sample is correctly prepared, but microscopic examination by the laboratory technician is not reliable due to

incompetence or lack of professional attitude. Another explanation – our own experience in Latin America – has to do with integration of TB programs. In their willingness to detect as soon as possible all new TB cases, TB officers tend to push health professionals to identify more and more suspect patients (the sometimes observed 'rule' that 1% of the new patients at the OPD or curative clinic have to be selected for sputum examination). As a consequence, too many 'suspects' may be referred to the laboratory, the workload becomes too high, the health officer tends to select fewer suspected patients and/or the laboratory technician does not respect the prescribed duration of reading the slide and the result is a false negative. This is an example where maximization could be counterproductive.

The reliability of this step (quality of sputum production and collection, quality of smear preparation, quality of microscopic examination) thus appears to be crucial, all the more so since it depends entirely on factors within the health services, and especially since high quality (in other words, a probability value close to 1.0) is technically and organizationally feasible. As a matter of fact, operational research has shown that decentralization of this step, and the reading of slides by auxiliary personnel with only 6 weeks' training (Toman 1979) and even less (2 weeks in one author's field experience – PM), could be done without any noticeable loss of quality, but requires regular supervision. None of these problems are identified or discussed in recent literature. Knowing the present state of dilapidation of many health services, regular surveillance of the technical quality of this step is absolutely necessary in order to avoid too many false positives as well as false negatives.

Regularity or long-term compliance among TB patients under treatment varies from one programme to another. As for Step 1, *Motivation*, this is highly influenced by geographical accessibility, indirect costs, quality of relationship between health professionals and patients (Nagpaul *et al.* 1970), state of health of the patient, defaulter retrieval procedures implemented by the health services (Rao 1994), capacity of the service to solve social problems, family problems and various other kinds of problems that patients encounter (Anastasio 1995). What is certain is that ensuring a TB patient's treatment regularity is difficult. In fact, we know very little in this field; we do know many of the factors that are associated with irregularity, but very little research has been done to evaluate interventions with a view to improve regularity. For certain authors, admission of patients in the hospital would guarantee better regularity, whereas it has been demonstrated that in a functional health district the health centres can ensure better regularity than can be obtained by admission in the hospital (Kasongo Project Team 1981). In Korea, experimental research showed a significant increase of patients' regularity from 65% to 79% when central level supervision was organized in order to help district health professionals to solve their operational problems (Jin *et al.* 1993).

Direct Observed Therapy (DOT) is very fashionable at the moment and sometimes presented as a panacea (WHO 1995). This strategy guarantees of course a high level of regularity, but also has a number of disadvantages. It is costly in terms of human resources and difficult to implement in sparsely populated regions. The DOT strategy also presents another major problem: the underlying assumption is that the patient is incapable of understanding the importance of what he or she is being asked to do: regular treatment for a sufficiently long time. However, our experience does not support this; if health professionals take the necessary time to explain clearly what is at stake, and if they are able to ensure an empathic follow-up of the patient, the majority of TB patients *can* be regular (Kasongo Project Team 1981; Grange & Festenstein 1993; Jin *et al.* 1993; Anastasio 1995).

Conclusion

The use of an operational model like the one we have proposed allows us to identify the problems that may arise at different steps and can be used as a tool for dialogue between specialists in charge of TB control and public health professionals. This model also allows us to improve the identification of research priorities, especially in the field of operations research.

Of course, technical research on diagnostic tools (to decrease the dependency on qualitative factors such as staining, reading) and on treatment (to decrease the dependency on regularity) may help control some of the operational difficulties. However, new techniques will more often simply displace the problem: if a one-day TB treatment will solve the compliance failure, this operational problem still remains a challenge with the present 'short course' therapy.

To be effective, tuberculosis control needs to be conceived in a comprehensive way, be it before or in the HIV era. The different steps of a TB programme are closely linked, and concentrating all resources on one step, while neglecting the others, will not lead to perceptible improvement. We will neither reduce human suffering nor decrease TB transmission by curing a few patients more with a novel treatment that is even better than the existing ones if, at the same time, the majority of new patients are not identified in a timely way. By the same token, the transmission of TB will not be reduced if we concentrate all resources on the DOT strategy while failing to ensure correct selection and examination of suspect cases, leading to false negatives who continue to contaminate their environment.

There are no miracle solutions in TB control. We feel that present approaches and research priorities are too narrowly focused on technical aspects while ignoring those that have to do with the overall functioning of health services and integrating the TB programme into the general health services. Furthermore, problems related to the perception of TB by both health personnel and patients are underestimated. The different elements of an entire programme need to be improved together. An operational model like the one we propose will help us to reach this comprehensive approach.

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Foreword

This report is the second in the Global TB Programme's "DOTS More Widely" Research Series. The DOTS (Directly Observed Treatment, Short-course) strategy has been shown to transform the outcomes of TB treatment from cure rates of below 50% to over 80%. Cure of infectious TB patients is currently the best form of prevention. Innovation and research to achieve "DOTS More Widely" are among the top priorities for efforts against TB.

This report, authored by Prof. Ravindra Dholakia (Indian Institute of Management, Ahmedabad), was initiated and edited by Dr. Joël Almeida of the WHO's Global TB Programme. Peer reviews were obtained from WHO, the World Bank and other organizations.

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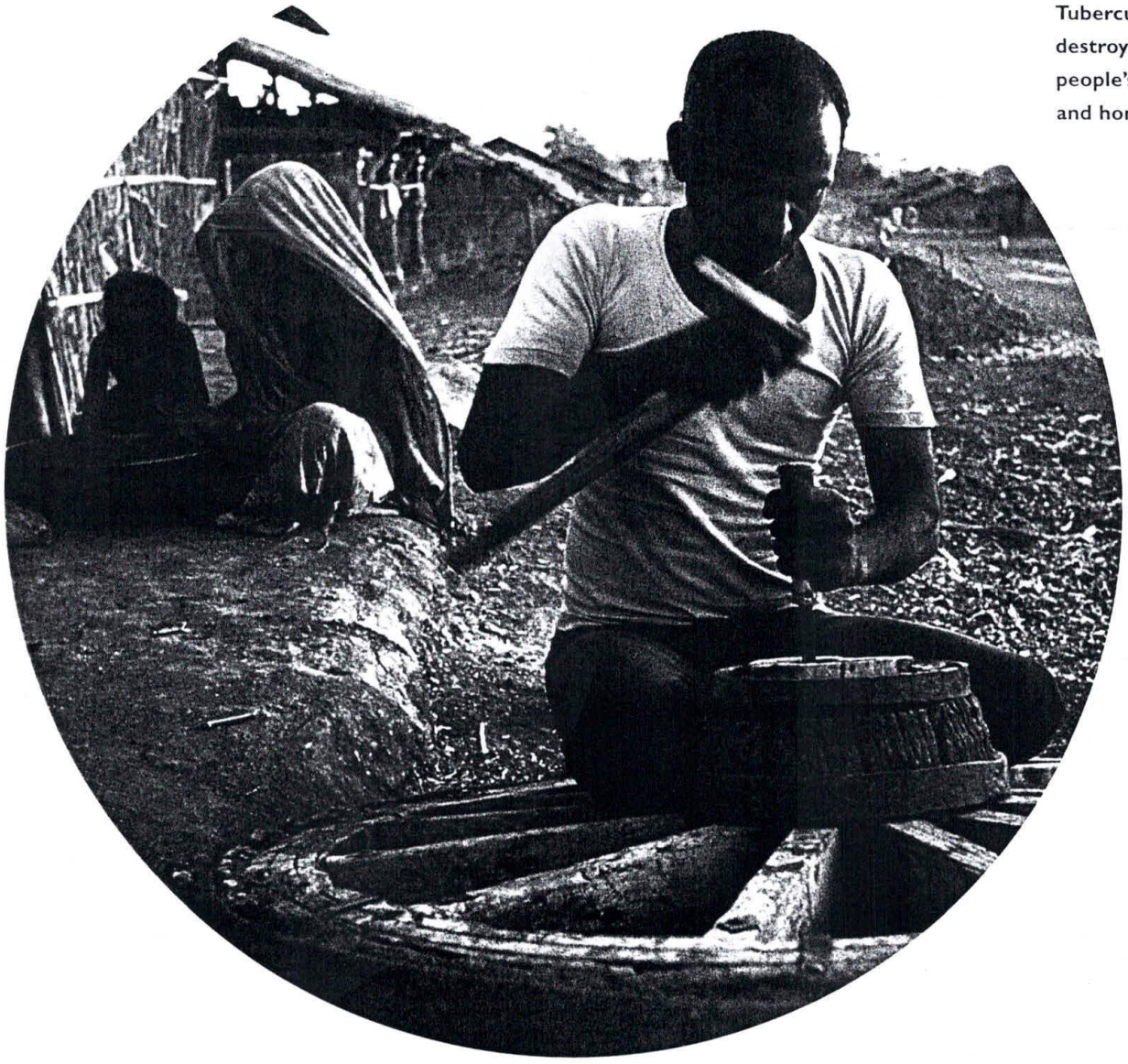

Tuberculosis destroys people's lives and homes.

Preface

Tuberculosis (TB) kills several millions of people each year. Most of these are in the wage-earning age group. The DOTS (Directly Observed Treatment, Short-course) strategy reduces these deaths several-fold, and replaces ineffective treatment with consistent cure.

This report asks a simple question: How much income would be gained by using DOTS, instead of non-DOTS, against TB in India? The question addressed has a direct bearing on the related question: How much investment and effort is worth devoting to the DOTS strategy, to ensure successful TB control?

One approach, taken in this report, is to estimate the lower (most conservative) bound on the magnitude of the tangible economic benefits from successful implementation of the DOTS strategy. If successful DOTS in place of non-DOTS yields tangible economic benefits worth a given present value, then DOTS deserves resources and efforts to at least that value in order to ensure successful operations.

The main contribution of this report is to place a lower bound on the magnitude of the tangible economic benefits to be gained from successful implementation of the DOTS strategy against TB in India.

Reasonably careful efforts have been made to assess how much of the lost income of TB patients could be salvaged by successful DOTS in place of non-DOTS strategies. Being a lower bound, the estimate of benefits carefully excludes all benefits other than the proximate and tangible economic benefits from DOTS.

The anticipated financial cost per cure within DOTS programmes in India may be noted. About 100 million US dollars extra are being invested in DOTS for 30% of India, in anticipation of producing about one million documented cures of infectious TB during the next five years. Should this extra investment prove sufficient to ensure the success of DOTS, the cost per documented cure will have been about USD 100 (at present, virtually no cures are documented). Assuming that successful DOTS will be extended throughout India to cure all the new cases arising each year (roughly two million new cases per year) the incremental cost of successful DOTS in India could turn out to be of the order of 200 million US dollars per year. Within 15 to 20 years, the number of new cases is predicted to start declining and the investments required for successful DOTS should correspondingly decline.

It is also worth stating the obvious. Effective TB control has benefits far beyond gains in income. Reduced suffering and death are of the first importance, whether or not gains in income follow. Multiple drug-resistant TB is a risk whose upper limit can never be fully known, given the unpredictable nature and virulence of newly arising mutant bacteria. DOTS is currently our best bet against multiple drug-resistant TB. In the longer term, the transmission of TB is expected to be reduced by effective DOTS: a delayed benefit whose present economic value is greatly reduced by discounting. All these benefits have been carefully excluded from the present estimate, so as to avoid any overstatement of the economic benefits of DOTS.

These excluded benefits (which might be captured in further studies which assess the Willingness to Pay) merely underline the main message of the report: much depends on the successful implementation of DOTS. Investing the resources and effort required to ensure the success of DOTS is the logical response.

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The tangible economic benefits of successful DOTS are likely to exceed the financial costs by several fold.

Executive Summary

1. Pulmonary TB is among the top killer diseases. According to the official statistics on the survey of causes of death in rural India, the relative importance of pulmonary TB, even among the top killer diseases, has been gradually rising in the country. About four million people in India are estimated to suffer from pulmonary TB. It imposes a cost on the economy in terms of current and future output loss because of premature deaths and ill health.

2. Currently, TB is treated with self-administered chemotherapy lasting 6 to 12 months. Patients often discontinue treatment. This creates several problems such as low cure rates, high relapse rates, high case fatality rates, drug resistance, etc.

The DOTS strategy (Directly Observed Treatment, Short-course) has been demonstrated to overcome most of the short-comings of self-administered chemotherapy.

3. There are several benefits from successful application of the of the DOTS strategy. The constraining factors or the impediments to the success of DOTS are a sub-set of the ones responsible for the current situation with self-administered chemotherapy. Therefore DOTS could well succeed if sufficient effort and resources were invested.

4. In order to ensure that DOTS succeeds in India, several aspects of implementation, organisation and management, need to be geared up. However, it is an important first step to believe that all these efforts can be fruitful, that they can yield good returns, that they are feasible and that these efforts can contribute to the larger social goals of alleviating poverty, raising the productivity of the poorer sections, and improving the quality of life in the society. Thus, we need to have some dimensional idea about the lower bound of the economic benefits of successful DOTS in India.

The main aim of this report is to estimate a lower bound for the magnitude of potential tangible economi benefits of the DOTS strategy in India.

5. There are several potential benefits of successful DOTS in India. They can be divided into two broad categories:

Pure social welfare increasing effects of DOTS which do not generate direct tangible economic benefits. These would include reduced suffering of TB patients, quicker and surer cure from the disease, lives saved and disability reduced for dependents and non-workers suffering from TB, poverty alleviation (since TB hits wage-earning age groups), the psychic benefits of living in a more healthy society, etc.

Direct tangible economic benefits of DOTS, which include the following three types of benefits:

- Reduction in the prevalence of TB due to DOTS which improves the efficiency and productivity of workers by reducing their forced absenteeism on account of ill health;
- TB deaths averted among current and future workers, which adds to the productive capacity of the economy; and
- Release of the hospital beds currently occupied by the TB patients, since successful DOTS averts hospitalization of patients.

6. We have estimated only the direct potential tangible economic benefits of successful DOTS. In order to estimate the economic benefits of DOTS, estimates of population for the base year 1993-94 by age-sex-residence are derived using the latest and most reliable figures available. Similarly, the estimates of workers by age-sex-residence and sectors are obtained.

Further, consistent estimates of average and marginal labour productivity in the country are derived, cross-classified by age-sex-area and three broad sectoral categories of the economy for the base year 1993-94. Aggregative macro economic studies and estimates of productivity differentials are used to calculate the rural/urban incomes by sectors, productivities of child workers vis-a-vis adult workers, productivities of young adults (15-44 years) vis-a-vis old adults (45+ years), productivities of male and female workers in each category. These labour productivities are used to calculate the output gains predicted when the DOTS strategy is successfully implemented. All the calculations are therefore made at 1993-94 prices to account for future inflation and to express the estimates in real terms.

7. TB is largely a disease of adults. Within adults, it is prevalent more among older adults than younger adults and more among males than females. Even the deaths due to TB show a similar pattern. Estimates of labour productivities are therefore needed to estimate the economic benefits of DOTS. Workers with pulmonary TB among the existing TB patients, and the future workers among the TB deaths averted/averted by DOTS are also estimated by age-sex and area.

The estimates of deaths averted and the reduction in prevalence of TB on account of DOTS are estimated by comparing the two scenarios "with DOTS" and "without DOTS" and considering the conservative estimates of improvements likely to occur "with DOTS".

8. Since there are two alternative sets of estimates of mortality due to TB in India, each having some followers/users, two alternative sets of estimates have been generated, of benefits due to deaths averted by DOTS. These estimates are generated by using the marginal productivity of labour and future workers among the deaths averted by DOTS in each age-sex-area category. In order to generate these estimates, the average age at death at present within each age group by sex and area was considered, as was the length of productive life for the future workers among the deaths averted by DOTS.

The present discounted value of the contributions of the future workers among the deaths averted in one year due to DOTS, during the remaining part of their economically active life, is considered as the economic benefits of deaths averted by DOTS.

9. Similarly, the benefits of reduction in prevalence of TB due to DOTS are estimated by using the available information on the disability imposed by the disease on workers. The improvement in the average productivity of workers by age-sex and residence due to successful DOTS is estimated.

10. Since benefits are also available in future from the reduced prevalence and the deaths averted by DOTS, these future benefits are estimated using alternative discount rates.

11. The alternative discount rates used are within the broad range of 5% to 16% since the former represents an estimate of the social time preference rate (STPR) and the latter the social rate of return on capital (SRRC) in India. The labour productivity in India is assumed to grow on an average by 3% per annum, though the current trend suggests 4% to 5% p.a. growth. Similarly, the TB deaths and prevalence of TB in future "without DOTS" are assumed to remain level. If they are taken to grow at the annual rate of 1% to 2% per annum (to allow for population growth), the calculated figures remaining the same, the implied discount rate would become higher by the same number of percentage points.

12. Our estimates of the potential economic benefits of DOTS in India at 1993-94 prices in terms of present value are as shown (Rs. in billion) in the chart below:

13. The main implication of our finding is that DOTS is potentially highly beneficial even at relatively high rates of discount. With the most conservative set of estimates, the potential economic benefits of DOTS to the Indian economy are estimated at about 4% of GDP in real terms or U.S. dollar 8.3 billion in 1993-94. This is the present (1993-94) value of the entire future stream of benefits from DOTS, not the annual benefit. So long as the Indian economy spends a total sum whose present value is less than this amount, the economy gets a return of more than 16% p.a. in real terms. Since the present value of all future costs attributable to to DOTS is likely to be considerably

Economic Benefit	Discount Rates		
	5%	10%	16%
A) Reduction in Prevalence of TB due to DOTS	622	186	106
B) Deaths Averted due to DOTS			
i) Set A	4035	703	259
ii) Set B	2469	422	152
C) Release of Hospital Beds due to DOTS	26	13	8
Total Benefits due to DOTS (P.V.)			
i) With Set A (in Rs. billion)	4683	902	373
(as % of GDP in 1993-94)	(13%)	(5%)	(66%)
ii) With Set B (in Rs. billion)	3117	622	266
(as % of GDP in 1993-94)	(44%)	(9%)	(4%)
Annualized Benefits due to DOTS			
i) Set A	234	156	90
(as % of GDP)	(3.3%)	(2.2%)	(1.3%)
ii) Set B	62	60	43
(as % of GDP)	(0.9%)	(0.8%)	(0.6%)

Note: Set A is based on Murray and Lopez (1996) TB Mortality rates. Set B is based on Survey of Causes of Death TB Mortality estimates.

less than 4% of GDP, DOTS can effectively help step up India's future economic growth.

14. The estimates of potential economic benefits of DOTS in India presented above are essentially based on twin optimistic assumptions: a) DOTS can and will succeed in effectively tackling pulmonary TB in India; and b) DOTS would effectively reach 100% of TB patients with full and instantaneous coverage. In order to be more realistic, we may presume that DOTS will reach about 90% patients in an area where the DOTS strategy is working. Special efforts may be presumed necessary for the 10% of patients who are considered "hard to reach." Similarly, we need to consider some phasing in of DOTS implementation over a few years largely because:

- DOTS requires training of personnel;
- organisational and management inputs require some time;
- drug supply systems take time to set up.

Five alternative phasing-in patterns are considered in this study. They are:

- Instantaneous "full" coverage (i.e., 90% covered);
- 5 years with 18% effective coverage every year;
- 10 years with 9% effective coverage every year;
- 15 years with 6% effective coverage every year;
- 10 years with effective coverage of 5%, 10%, 15%, 15%, 15%, 10%, 5%, 5%, 5%, and 5% in successive years.

15. Our estimates of economic benefits of DOTS in Rs. Billion at 1993-94 prices for all these five alternatives are presented in the chart below:

16. Phasing in of DOTS (TB cure) over time reduces the present value of the economic benefits. The longer the time period for phasing in, the lower is the present discounted value of the benefits. Similarly, the higher the discount rate used, the lower is the present value of benefit with a given pattern. Even with a linear phasing in of the coverage over 10 years with a 16% discount rate, the present discounted value of all the future economic benefits of DOTS turns out to be about 2.1% of GDP (in the year 1993-94). Thus, even if the Indian government spends about USD 0.74 billion per year to ensure the success of the DOTS (TB cure) strategy (the present value of which is about USD 4.6 billion or 2.1% of the GDP) the investment would fetch a return of 16% p.a. in real terms. (Projected incremental costs to the government for successful DOTS implementation throughout India are of the order of USD 200 million per year, compared to the tangible economic benefits of at least USD 750 million per year – *Editor's note*).

Alternative Phasing Patterns for DOTS	Discount Rates		
	5%	10%	16%
1. Instantaneous Coverage	2805 (39.7%)	559 (7.9%)	24 (3.4%)
2. 5 Year Linear Coverage	2697 (38.1%)	490 (6.9%)	191 (2.7%)
3. 10 Year Linear Coverage	2507 (35.5%)	420 (5.9%)	147 (2.1%)
4. 15 Year Linear Coverage	2451 (34.7%)	363 (5.1%)	117 (1.7%)
5. 10 Year Non-Linear Coverage*	2603 (36.8%)	436 (6.2%)	156 (2.2%)

**Effective coverage for successive years are: 5%, 10%, 15%, 15%, 15%, 10%, 5%, 5%, 5% and 5%.*

Notes:
1. All these calculations are based on the assumption that there is a "hard to reach" 10% of patients in any area who require special measures, and only 90% are reachable by routine measures.
2. The benefits are based on the most conservative available estimates, from Survey of Causes of Deaths (1993).
3. Figures in parentheses are percentage of Gross Domestic Product in 1993-94 at current prices.
4. The discounting of benefits is done by assuming real growth of 3% p.a. in the labour productivity in the Indian economy over time, and with no growth of TB patients in the "without DOTS" scenario. These are the most conservative assumptions.

Tuberculosis is the leading infectious killer of adults.

I. Introduction

Infectious TB is one of the most dreaded diseases. In India, pulmonary TB is among the leading killers of adults. The mortality rate on account of TB is so high as to imply that every minute, a death occurs due to TB in the country. Moreover, the high prevalence of TB damages the national economy not only because of deaths, but also because of prolonged illness. Regular and complete treatment is required for cure. At least 75% of prevalent TB cases have been previously treated in India through the traditional system in which regularity and continuity of the treatment were not effectively monitored. Thus, they received palliation, not cure.

This is thought to be the main reason why traditional approaches and strategies to deal with the problem of TB in the country have failed. The DOTS strategy attempts to overcome this limitation. Indian pilot projects where the DOTS strategy is rigorously applied have shown consistent, documented cure of TB patients.

The advantages of the DOTS strategy over the traditional TB treatment programmes include the following which are relevant to our estimate (see Datta, 1995 and National TB Control Programme, 1996).

- DOTS cures the existing TB cases and produces a quick reduction in the prevalence of TB in the population.
- The cure rate with successful DOTS can be taken as 85% as against 30% with traditional treatment.
- The relapse rate is only 1% to 2% with DOTS as compared to 15% to 20% with the conventional therapy.
- The failure rates with DOTS are likely to be less than 2% as compared to about 20% with traditional treatment.
- Case fatality rates are likely to drop from about 14% with conventional treatment to less than 2% with DOTS. In lower income groups, to which most Indian households belong, the TB patient is often the sole wage-earner.
- DOTS averts or shortens major illness from TB, and hence could release in future the 4% to 5% of hospital beds currently occupied by TB patients (World Bank, 1995). As far as other costs go, it is most unlikely that the remaining costs "without DOTS" would exceed the total costs "with DOTS". We have therefore ignored here any other cost-saving "with DOTS" over "without DOTS".

After 15 years or so, the annual incidence of TB is also likely to fall and hence the deaths averted by DOTS would further increase. However:

- the rate of decline in the annual incidence is not very predictable;
- the actual further gain is only marginal (because most of the deaths from TB are already averted even without a fall in incidence);
- the benefits lie at least 15 years or more in future (which implies a relatively low present value).

Considering all these, we have preferred to ignore the fall in annual incidence rate in future (after 15 years) on account of DOTS while estimating the economic benefits of DOTS. To the extent the annual incidence declines in future, our estimates represents an underestimate of the true benefits of DOTS. This is in the spirit of conservatism often practised in the field of social cost benefit exercises.

In short, if the DOTS strategy is implemented on a national scale, there would be probably be substantial economic benefits to the country. The main aim of this report is to estimate a lower bound for the magnitude of potential tangible economic benefits from the DOTS strategy in India.

Based on the available secondary data — both in the published and unpublished forms (including surveys conducted by other organisations) — some preliminary estimates of the potential gains in terms of employment, productivity and output in the national economy are attempted here.

II. Steps followed for estimation

It may be noted that the present study is not based on any fresh primary survey. It is based on the secondary sources of data and information already collected for othe studies in the field. In order to estimate the potential economic benefits of DOTS in India, the following steps are needed:

i. Estimate the population and total work force in India in 1993-94 by age-sex-residence. The most comprehensive single source is used for estimating both these, in the absence of alternative data sources. The sectoral classification of the work force into the standard primary, secondary and tertiary sectors of the economy is also obtained using the same source.

ii. Estimate the gross domestic product (GDP) for 1993-94 at current prices by rural-urban residence and sectoral classification. Moreover, the average labour productivity by sex and age within the rural-urban classification is obtained, by sectors.

iii. Estimate the total deaths due to TB in India in the base year which is taken to be the year 1993-94. There is more than one estimate of the number of deaths due to TB in India. Murray and Lopez (1996) estimate the deaths due to TB in India in excess of 0.75 million. Survey of Causes of Death for 1993 implies TB deaths number 0.45 million. These two alternative sets of estimates provide TB deaths by five age groups among males and females.

iv. Estimate the prevalence (i.e., stock) of pulmonary TB in the population by age-sex-residence. Here again there are several alternative estimates, though many experts use the parameters from the 1955-58 ICMR survey, with

some modifications. About four alternative sets of estimates of the prevalence rates of TB by age-sex-residence have recently been made for India or some Indian states.

v. Estimate the total existing TB patients in 1993-94 by age-sex-residence from the alternative sets of estimates of the TB patients in the country. Also, estimate the number of workers with TB in the base year by age-sex-residence.

vi. DOTS would substantially reduce the number of deaths from pulmonary TB and also the prevalence of TB. Deaths averted among workers lead to a stream of future direct output contribution. Similarly, reduced prevalence of pulmonary TB by DOTS leads to gains in output on account of decreased disability of patients with respect to their economic activity. These latter estimates are based on the productivity differential between workers with TB and other workers.

vii. The benefits accruing in the future are brought to the base year 1993-94 by discounting them at the appropriate rate. Since the benefits are largely in the form of the wastage averted and increased consumption in future by the cured persons and their dependents, the social time preference rate (STPR) for India is considered the best rate of discount to use. In order to take policy decisions, it is relevant to consider some alternative rates of discount. The World Bank as also many other donors/ investors use discount rates varying from 9% to 15% in real terms. We can, therefore, consider some plausible alternative rates of discount.

viii. Finally, an estimate is made of the saving of hospital beds, currently used by the TB patients, from using DOTS.

All these benefits are aggregated to arrive at the estimate of potential economic benefits of DOTS (TB cure) in India with the base year of 1993-94. In the following sections, these steps are discussed and the estimates derived. In the final analysis, we have alternative estimates of the potential economic benefits of DOTS in India using differing estimates of the deaths due to TB and various discount rates.

III. Estimates of population and work force 1993-94

In order to estimate any economic benefits of a TB cure strategy such as DOTS, it is necessary to have a consistent classification of the population by age-sex-residence. The 1991 census estimates with these disaggregations are not yet available in India. The only reliable and comprehensive source of information on this pivotal variable is the latest National Sample Survey. These are available at the required level of disaggregation for the year July 1990 to June 1991 (see, NSSO, 1994). From this source, the age distribution by sex and rural-urban residence for 1993-94 is assumed to be valid for the extrapolated population by sex and rural-urban residence obtained from the 1991 census of India. The age distribution of population by sex and rural-urban residence for the year 1993-94 (mid-year estimate) is presented in Table 3.1.

The estimated distribution of the work force in India by the primary, secondary and tertiary sectors of the economy in 1993-94 is obtained from the NSSO, (1994) taken

TABLE 3.1

Projected population (in '000) as on 1st Oct. 1993 (i.e., 1993-94) in India

	Rural Areas			Urban Areas			All Areas		
Age / Sectors	Males	Females	Persons	Males	Females	Persons	Males	Females	Persons
0 - 4	41920	38081	80001	13581	12959	26540	55501	51040	106541
5 - 14	91818	76702	168520	28968	25641	54609	120786	102343	223129
15 - 44	143076	140559	283635	60193	53583	113776	203269	194142	397411
45 - 59	37740	38707	76447	13665	11097	24762	51405	49804	101209
60 +	21707	20434	42141	6438	6994	13432	28145	27428	55573
All Ages	336261	314483	650744	122845	110274	233119	459106	424757	883863

Source: See the text, Section III.

with the estimates of population presented in Table 3.1 here. It is assumed that the sectoral distribution of workers by age-sex-residence available from the NSSO (1994) is applicable to the estimates of the population in 1993-94. Table 3.2 provides the estimates of the workers for three broad sectors so obtained by sex and rural-urban residence for broad age groups. The primary sector consists of agriculture and allied activities, fishing, and forestry and logging; the secondary sector includes mining and quarrying, manufacturing, construction, and electricity, gas and water supply; and the tertiary sector which is largely a service sector includes the rest of the economy.

IV. Estimates of GDP and labour productivity, 1993-94

The latest data from the Central Statistical Organisation (CSO) on National Accounts Statistics provides estimates of income at current prices by sectors, for the year 1993-94. This is currently the latest year for which confirmed income estimates are officially available. The CSO (1994) also provides official estimates of the Net Domestic Product (NDP) by sectors and rural-urban areas at current prices, for the year 1980-81. This is again the latest year for which official estimates of NDP by rural-urban areas are available. It is possible to derive the

TABLE 3.2

Estimates of workers (in '000) in India in 1993-94 (1st Oct. 1993)

		Rural Areas			Urban Areas			All Areas		
Age / Sectors		Males	Females	Persons	Males	Females	Persons	Males	Females	Persons
5 - 14:	P	8529	4322	12851	89	123	212	8618	4445	13063
	S	407	400	807	533	375	908	940	775	1715
	T	551	180	731	548	159	707	1099	339	1438
Sub Total		9487	4902	14389	1170	657	1827	10657	5559	16216
15 - 44:	P	81231	53777	135008	3554	2557	6111	84785	56334	141119
	S	166684	5416	22100	15549	3575	19124	32233	8991	41224
	T	21880	4432	26312	25952	4778	30730	47832	9210	57042
Sub Total		119795	63625	183320	45055	10910	55965	164850	74535	239385
45 - 59:	P	26744	15713	42457	1154	942	2096	27898	16655	44553
	S	3451	1343	4794	4075	711	4786	7526	2054	9580
	T	5953	1507	7460	7719	1337	9056	13672	2844	16516
Sub Total		36148	18563	54711	12948	2990	15938	49096	21553	70649
60 +:	P	13502	3372	16874	818	175	993	14320	3547	17867
	S	847	347	1194	747	196	943	1594	543	2137
	T	1389	225	1614	1320	350	1670	2709	575	3284
Sub Total		15738	3944	19682	2885	721	3606	18623	4665	23288
All Ages:	P	130006	77184	207190	5615	3797	9412	135621	80981	216602
	S	21389	7506	28895	20904	4857	25761	42293	12363	54656
	T	29773	6344	36117	35539	6624	42163	65312	12968	78280
Grand Total		181168	91034	272202	62058	15278	77336	243226	106312	349538

Source: See the text, Section III.

sectoral average labour productivity by rural and urban areas combining these estimates of income with the estimates of workers from the 1981 Census of India. We assume that the urban-rural productivity differential remains the same in 1993-94 as in 1980-81. Based on this assumption, it is possible to calculate the sectoral average productivities for the urban and the rural areas in 1993-94 consistent with the overall Gross Domestic Product estimates using the break up of the workers given in Table 3.2 (methodology in Appendix 1). The estimates of average labour productivity and GDP at factor cost by rural-urban areas for the year 1993-94, at current prices, are provided in Table 4.1.

In order to estimate the average productivity of the child labour (age 5-14 years) and the adult labour (15+ years) within the urban and the rural areas, we assume that the children's productivity is a third of the average productivity of labour.

Considering the predominantly rural character of the child labour in the primary and low productivity sectors, this assumption seems to be in overall conformity with the B.H. Dholakia study (1974, p.125n) in which similar weights were used based on information then available regarding agricultural labour. Table 4.2 provides the estimates of average labour productivity for the child labour and adult labour by sectors within the rural-urban areas in India in 1993-94. (methodology in Appendix 2).

The labour productivity differential between the young adults (15-44 years) and old adults (45+ years) is obtained from the detailed tabulation of the 1971 Census which provides age-sex distribution of degree holders and technical personnel by salary ranges. Based on this data source, it is estimated that the productivity differential between old adults and young adults is 1.76. Using this productivity differential, the average productivities for the workers belonging to the age groups 15-44 years and 45+

TABLE 4.1

Estimates of labour productivities and GDP, at factor cost, at current prices by rural-urban areas in India, 1993-94.

	Labour Productivity (in Rs.)			GDP at F.C. (Rs. Crores)		
Sectors	Rural	Urban	All Areas	Rural	Urban	All Areas
Primary	9761.67	12884.43	9897.51	202252	12130	214382
Secondary	29115.87	44628.80	36427.11	84130	114966	199096
Tertiary	33244.49	41173.30	37514.95	120069	173598	293667
Total				406451	300694	707145

Source: See the text, Section IV.

TABLE 4.2

Estimates of labour productivity in 1993-94 at current prices of child and adult workers in India (in Rs.)

	Rural Areas			Urban Areas		
Sectors	Child Workers	Adult Workers	All Workers	Child Workers	Adult Workers	All Workers
Primary	3253.89	10192.01	9761.67	4294.81	13082.37	12884.43
Secondary	9705.29	29673.56	29115.87	14876.27	45715.80	44628.80
Tertiary	11081.50	33702.33	33244.49	13724.43	41641.42	41173.30

Source: See the text, Section IV.

years for the three broad sectors are estimated and shown in Table 4.3. (methodology in Appendix 3).

For each sector and age groups in the rural and urban areas, the male-female productivities are estimated with the help of the male-female productivity differential. The 1971 Census, providing the age-sex distribution of the degree holders and technical personnel by the salary ranges, is used to estimate the productivity differentials between male workers and female workers within the age groups 15-44 years and 45+ years to be respectively 1.28 and 1.41. Moreover, it is assumed that among the child labour i.e., in the age group 5-14 years, there is no male-female productivity difference. Based on all these, the male and female average productivities are worked out in

TABLE 4.3

Estimates of labour productivity in 1993-94 at current prices of young and old adult workers in India (in Rs.)

Sectors	Rural Areas			Urban Areas		
	Young Adults	Old Adults	All Adults	Young Adults	Old Adults	All Adults
Primary	8272.57	14559.72	10192.01	10422.72	18343.99	13082.37
Secondary	25536.14	44943.60	29673.56	38900.72	68465.26	45715.80
Tertiary	28205.47	49641.64	33702.33	34798.72	61245.75	41641.42

Source: See the text, Section IV.

TABLE 4.4

Estimates of labour productivity in 1993-94 at current prices of male and female workers by age and area in India (in Rs.)

Sectors and Age Groups	Rural Areas		Urban Areas	
	Males	Females	Males	Females
Primary Sector				
5 - 14	3253.89	3253.89	4294.81	4294.81
15 - 44	9062.19	7079.84	11472.84	8963.15
45 +	16062.09	11391.55	20499.46	14538.63
Secondary Sector				
5 - 14	9705.29	9705.29	14876.27	14876.27
15 - 44	26982.64	21080.19	40559.30	31686.95
45 +	48961.75	34724.65	71769.19	50900.14
Tertiary Sector				
5 - 14	11081.50	11081.50	13724.43	13724.43
15 - 44	29284.50	22878.51	36023.97	28143.72
45 +	52558.79	37275.74	64181.02	45518.46

Source: See the text, Section IV.

each sector, age groups and rural-urban areas in 1993-94 and are presented in Table 4.4. (Appendix 4)

Using productivities as reported in the Table 4.4 along with the estimates of workers given in Table 3.2, we can generate the estimates of Gross Domestic Product at factor cost at current prices in the year 1993-94 cross-classified by the age-sex-sector and area. These estimates are reported in Table 4.5. These estimates are consistent with the available evidence at the macro level and are comparable with the overall GDP estimates available from the CSO. Table 4.5 along with Table 3.2 is useful for calculating the possible contributions of various age-sex-residence categories of workers. The DOTS strategy to cure TB would have a different extent of influence on different categories

TABLE 4.5

Estimates of GDP in India, 1993-94 (Rs. Crores) – classified by age, sex, sector and area

	Rural Areas			Urban Areas			Total of All Areas		
Sector	Male	Female	Persons	Male	Female	Persons	Male	Female	Persons
Primary									
5 - 14	2775	1406	4182	38	53	91	2813	1459	4273
15 - 44	73613	38073	111686	4077	2292	6369	77691	40365	118056
45 - 59	42956	17900	61816	2366	1370	3845	45322	19269	65661
60 +	21687	3841	24568	1677	254	1822	23364	4096	26390
Sub Total	141032	61220	202252	8158	3969	12127	149190	65189	214379
Secondary									
5 - 14	395	388	783	793	558	1351	1188	946	2134
15 - 44	45018	11417	56435	63066	11328	74394	108084	22745	130829
45 - 59	16897	4664	21546	29246	3619	32767	46143	8283	54313
60 +	4147	1205	5366	5361	998	6456	9508	2203	11823
Sub Total	66457	17674	84130	98466	16503	114968	164922	34176	199099
Tertiary									
5 - 14	611	199	810	752	218	970	1363	418	1780
15 - 44	64074	10140	74214	93489	13447	106937	157564	23587	181151
45 - 59	31288	5617	37033	49541	6086	55464	80830	11703	92497
60 +	7300	839	8012	8472	1593	10228	15772	2432	18240
Total Age Wise									
5 - 14	3781	1994	5775	1583	829	2412	5364	2823	8187
15 - 44	182705	59630	242335	160633	27067	187700	343338	86697	430035
45 - 59	91141	28181	120395	81153	11074	92077	172294	39255	212471
60 +	33135	5885	37947	15510	2845	18506	48644	8730	56452
Grand Total	310762	95689	406452	258879	41816	300694	569641	137505	707146

Source: Tables 4.4 and 3.2.

TABLE 5.1

Pulmonary TB importance in mortality in rural India

Year	% of Total Reported Death due to Pulmonary TB	Rank of pulmonary TB Among the Top Killers
1989	5.2%	4th
1990	5.0%	4th
1991	5.3%	3rd
1992	5.9%	2nd
1993	5.7%	2nd

Source: India: Vital Statistics Division: Survey of Causes of Death (Rural) India: Annual Report 1993, Series 3, No.26; p.49.

of workers and hence these estimates provide the basis for further estimates of benefits of DOTS in India.

V. Deaths due to pulmonary TB in India

Pulmonary TB is among the top killer diseases in the country. According to the official statistics on the survey of causes of death in rural India, the relative importance of pulmonary TB, even among the top killer diseases, is gradually rising in the country. (See Table 5.1). In 1993, Pulmonary TB causing about 5.7 percent of the total reported deaths in the country is the second most important cause of death. It is generally stated and believed that TB is widespread and that it is almost equally prevalent across regions in the country as per the one time survey carried out in 1955-58. The death pattern across the regions, however, tells us a different story, particularly in the recent years. The relative importance of TB in the five zones of the country, in the two years 1992 and 1993, in the reported deaths in the rural areas are given in Table 5.2. As it can be seen, in all the five zones in the two years, TB is among the top five killer diseases. However, in the eastern zone, its relative importance is considerably lower as compared to the rest of the zones. On the other hand, in the central and northern zones, TB is considerably more important as a cause of death. Thus, if mortality due to TB is considered an indicator, the disease is not necessarily prevalent equally among different regions of the country. The two tables, however, clearly reveal the magnitude of the problem of Pulmonary TB in the country. In the rural areas it is responsible for five to six percent of the total deaths.

The percentage distribution by age groups for males and females of the reported deaths due to pulmonary TB in rural India is also available (See Table 5.3). As it can b seen from the table, TB deaths as a proportion of total deaths occur relatively more among males than among females. Similarly, the TB deaths are more common among the adults than the children. Even within the adult deaths, it is more common among older adults than the younger adults. Assuming the same percentage distribution by age groups for the deaths due to TB among urban males and females respectively it is possible to derive the estimate of deaths due to TB in India by age-sex and residence. These estimates are reported in Table 5.4. According to this estimate, the TB deaths in the country in 1993-94 were 0.452 million out of the total deaths of 8.090 million. (i.e., about 5.6%). The age pattern of the TB deaths also clearly brings out that children under 15

TABLE 5.2

Pulmonary TB: Relative importance in mortality by regions in (rural) India, 1992 and 1993

Region	1992		1993	
	% of Reported Death	Rank Among Top Killers	% of Reported Death	Rank Among Top Killers
Northern	6.6%	3rd	5.6%	3rd
Central	6.9%	3rd	7.4%	2nd
Western	5.3%	3rd	5.5%	3rd
Southern	5.4%	4th	5.3%	3rd
Eastern	4.0%	5th	4.0%	4th
All India	5.9%	2nd	5.7%	2nd

Source: The same as Table 5.1; p.64.

years account for only 3.8%, the young adults (15-44 years) account for 42% and old adults above the age of 45 years account for 54.1% of total TB deaths in the country.

The other set of estimates for TB deaths in India is reported by Murray and Lopez (1996) in the context of Global Health Statistics for the year 1990. Based on their rates and our projected population in the year 1993-94, the total TB deaths by sex and age groups are given in Table 5.5. According to the Murray and Lopez (1996) estimates, the TB deaths in India in 1993-94 are 0.76 million out of the total deaths of 8.090 million (i.e., 9.04%). The age pattern of their estimate shows that children below 15 years of age account for 5.5%, young adults (15 to 44 years) account for 28.5%, and old adults above the age of 45 years account for 66% of the deaths due to TB in India. Thus, the two estimates of deaths due to TB in India do differ considerably not only in the magnitude but also in terms of the age patterns. However, according to both the sets of estimates, it is clear that TB death is largely a phenomenon among adults and more so among the old adults who are most likely to be productive and also supporting their respective families (World Bank, 1995, p.14).

VI. The prevalence of pulmonary TB in India

Regarding the prevalence of diseases in the population, there have been very few comprehensive studies carried out in India. There have been several piecemeal and district/city/town specific studies carried out on the subject in recent years. The only reasonable comprehensive study on the subject was carried out in India by the ICMR in 1955 to 1958. Prior to this data the First Five Year Plan in India (1952, p.502) estimated the economic loss of 900 to 1,000 million persons days on account of active TB among 2.5 million persons in the country. The draft outline of the First Five Year Plan (July 1951, p.198) estimated that TB accounts for about 0.5 million deaths in the country (as quoted by Visaria et al 1994). Thus, the prevalence

TABLE 5.3

Age-sex distribution of reported deaths due to pulmonary TB, rural India, 1993

Age Groups	Proportion of Deaths Due to pulmonary TB	
	Males	Females
< 1	0.79%	0.55%
1 - 4	1.14%	0.91%
5 - 14	1.06%	4.01%
15 - 24	5.73%	10.56%
25 - 34	11.72%	17.67%
35 - 44	19.12%	23.86%
45 - 59	32.60%	21.86%
60 +	27.84%	20.58%
Total	100.00% (6.96%)	100.00% (4.13%)

Note: Figures in the parentheses are proportions of TB deaths to total deaths in the respective category.

Source: The same as Table 5.1; pp.72-77.

TABLE 5.4

Estimates of deaths due to TB in India by age-sex and residence, 1993-94 (in '000)

Age Groups	Rural Areas		Urban Areas		Total Persons
	Males	Females	Males	Females	
0 - 4	4.5	1.9	1.1	0.4	7.9
5 - 14	2.5	5.3	0.6	1.1	9.5
15 - 44	85.6	68.8	21.2	14.6	190.2
45 - 59	76.3	28.8	18.9	6.1	130.1
60 +	65.1	27.2	16.2	5.8	114.3
Total TB Deaths	234	132	58	28	452
Total Deaths	3363	3208	835	684	8090

Source: Table 5.3 above and our estimates of population for 1993-94.

rate estimated by the Planning Commission was about 694 per 100,000 population and death due to TB was estimated to be of the order of 1.39 per 1,000 population which is about 20% of the prevalence of TB. It can be seen from various surveys of the prevalence of TB in the country, that several experts in the field are of the opinion that the ICMR National Sample Survey of 1955-58 remains valid in terms of some epidemiological characteristics regarding TB in the country. (See for instance, Chakraborty 1996, p.38; Murray and Lopez 1996, p.142; Uplekar and Rangan 1995, A 71-72; ASCI 1996, p.50; Datta 1995, p.1; etc.). The National Tuberculosis Institute Longitudinal Surveys from 1961 to 1977 (Chakraborty 1996) have shown that the proportion of outflow of cases on account of death (20%) and cure (18%) is almost balanced by the inflow of about 36% to 38% annually. The frequency of TB thus remains the same with about two-thirds of it being the continuing or the left-over cases. It thus represents a steady state. The same data sources suggest that about 10% of the crude mortality in the society is due to TB which agrees with the Murray and Lopez (1996) estimate. However, the Sample Registration System (SRS) data estimates around 0.4 million annual deaths from TB in India which is very close to the Survey of Causes of Death estimates. (See Tables 5.4 and 5.5).

Regarding firm estimates of the prevalence of Pulmonary TB in India, there are a few recent estimates with fairly detailed age-sex and sometimes urban-rural classification of the prevalence of TB. We have come across five sets of such estimates. They are:

- Murray and Lopez (1996) estimates for the year 1990,
- National Family Health Survey (NFHS) 1992-93 conducted by International Institute for Population Sciences (IIPS) (1995),
- The Andhra Pradesh estimates made by Dr.Ramana et al of Administrative Staff College of India (ASCI) (1996),
- The estimates obtained through a Household Survey of Health Care Utilization conducted by Sundar Ramamani at the National Council of Applied Economic Research (NCAER) (1995), and
- Visaria et-al (1994) estimates based on analysis of data from five states obtained from the National Sample Survey 42nd Round for the year 1986-87.

TABLE 5.5

Alternative estimates of deaths due to TB in India by age and sex, 1993-94 (in '000)

Age Groups	Males	Females	Persons
0 - 4	13.6	10.0	23.6
5 - 14	11.0	7.7	18.7
15 - 44	140.5	77.0	217.5
45 - 59	164.1	90.5	254.6
60 +	177.5	71.4	248.9
Total TB Deaths	506.7	256.6	763.3
Total Deaths	4198	3892	8090

Source: Murray and Lopez (1996), p.142 Our estimates of population for 1993-94.

We have considered the first three estimates for this study because they have the fewest limitations. The NCAER study (Sundar, 1995) considers a group of diseases which includes Mumps, Measles, Chickenpox and TB, but interprets without justification the prevalence as if it were only for TB (See p.17 and pp.54-55 of the Report). This makes the estimates non-usable for our purposes. Visaria et (1994) covered five states of Gujarat, Maharashtra, Tamil Nadu, Uttar Pradesh and West Bengal accounting for about 383 million or about 45% of India's population. The survey in the chosen five states covered 11,378 rural households and 7,912 urban households; and provided information on 9,086 cases of illness treated in hospitals during the preceding year of the survey and 18,954 cases treated without hospital admission during the preceding 30 days of the survey. Out of all these cases, only 414 (or 4.6%) in hospital treatment and 360 (or 1.9%) in non-hospital treatment were the TB cases. Recall errors could not be excluded.

Tables 6.1, 6.2, 6.3 and 6.4 presents estimates of the prevalence rates by age, sex and rural-urban areas wherever available. Applying these rates to the common population estimates by age-sex-residence for the year 1993-94 reported in Table 3.1 above, we get the corresponding estimates of the prevalence of TB (in terms c number of patients) in India which is also reported in the respective tables. From the tables, it is clear that although there are some differences in the age distribution of the TB cases across the studies, the overall extent of prevalence is very close in three out of the four studies. The implied prevalence of TB in India in 1993-94 according to the ASCI (1996) study of Andhra Pradesh gives an estimate of 4.1 million, whereas NFHS implies an estimate of 4.0 million and Murray and Lopez (1996) study implies an estimate of 3.9 million of prevalence of TB in India. We take the most conservative estimate[1] of Murray and Lopez (1996) out of the three sets of estimates. Moreover, since these three sets of estimates are very close to each other, we estimate the rural-urban break up of the Murray and Lopez

TABLE 6.1

Prevalence of pulmonary TB in India 1993-94 – Murray and Lopez (1996) estimates

Age Groups	Prevalence Rate (Per 100,000)		Prevalence (in '000)		
	Males	Females	Males	Females	Persons
0 - 4	83	66	46.07	33.69	79.76
5 - 14	152	123	183.59	125.88	309.47
15 - 44	513	482	1042.77	935.76	1978.53
45 - 59	983	452	505.31	225.11	730.42
60 +	2247	672	632.42	184.32	816.74
All Ages	539	342	2410.16	1504.76	3914.92

Source: Murray and Lopez (1996) and Table 3.1.

TABLE 6.2

Prevalence of pulmonary TB in India 1993-94 – NFHS estimates

Age Groups	Prevalence Rate (Per 100,000)		Prevalence (in '000)		
	Males	Females	Males	Females	Persons
0 - 4	81	140	64.80	37.16	101.96
5 - 14	117	181	197.17	98.84	296.01
15 - 59	617	368	2221.71	509.82	2731.53
60 +	1771	1019	746.32	136.87	883.19
All Ages	512	344	3230.00	782.696	4012.69

Source: IIPS (1995) p.202 and Table 3.1.

TABLE 6.3

Prevalence of pulmonary TB in India 1993-94 – ASCI (1996) estimates

Age Groups	Prevalence Rate (per 100,000)				Prevalence (in '000)				
	Rural Areas		Urban Areas		Rural Areas		Urban Areas		Total
	Males	Females	Males	Females	Males	Females	Males	Females	Persons
0 - 4	15.2	13.6	12.2	11.1	6.37	5.18	1.66	1.44	14.65
5 - 14	28.0	28.9	20.7	21.7	25.71	22.17	6.00	5.56	59.44
15 - 44	617.8	45.7	470.3	233.1	883.92	64.24	283.09	124.90	1356.15
45 - 59	1846.8	1298.5	1301.3	616.9	696.98	502.61	177.82	68.46	1445.87
60 +	2918.2	2078.4	2683.0	211.5	633.45	424.70	172.73	14.79	1245.67
All Ages	714.7	532.3	498.6	301.7	2246.43	1018.90	641.30	215.15	4121.78

Sources: ASCI (1996) pp.58-59 and Table 3.1.

(1996) estimates by age and sex using the proportions of the number of TB cases implied by the ASCI (1996) estimates. This is partly because the NFHS estimates made by the IIPS (1995) do not have the necessary break up of the rural-urban by sex and age group corresponding to Murray and Lopez (1996). Thus, our estimates of the prevalence of TB using both the Murray and Lopez (1996) estimates and ASCI (1996) estimates are presented in Table 6.5.

VII. Estimates of workers with TB in India

Having estimated the prevalence of pulmonary TB in India, the next step is to estimate the number of workers actively engaged in the economically productive activities among those patients. There are hardly any surveys with reasonably large samples providing useful information on this aspect. A recent book, Uplekar and Rangan (1996) provides some bi-variate tables on occupational status, age, literacy, income groups, etc., of TB patients in rural and urban areas of Pune district of Maharashtra State. Their sample size, however, is very limited —103 for rural areas and 196 for urban areas. Moreover, bi-variate information is not very useful for our purpose here. Similarly, the NCAER study (Sundar, 1995) provides estimates of prevalence rate by broad occupations and rural — urban residence of the household heads for serious communicable diseases which include TB. It is also not considered adequate for our purpose here. The study by Nayyar et al (1989) which is an unpublished study provides estimates of culture positive TB by sex, residence and specific occupations based on the study of the Wardha District in Maharashtra State. However, the occupational classification does not match with our all-India sectoral classifications for productivity calculations. It is, therefore, difficult to use these estimates meaningfully. Moreover, the sample size, concepts used and the methodology are not readily available.

TABLE 6.4

Prevalence of pulmonary TB in India 1993-94 – TRC estimates (based on culture test)

	Prevalence Rate (Per 100,000)		Prevalence (in '000)		
Age Groups	Males	Females	Males	Females	Total
10 - 24	226	124	334	164	498
25 - 44	1934	546	2236	601	2837
45 +	3613	867	2874	670	3544
All Ages		778	5444	1435	6879

Source: P.R. Narayanan (1996) and our estimates of population for 1993-94 by the corresponding age groups based on NSS 42nd Round.

TABLE 6.5

Prevalence of pulmonary TB in India by rural-urban residence, sex and age, 1993-94 (in '000)

	Rural Areas		Urban Areas		All Areas	
Age Groups	Males	Females	Males	Females	Males	Females
0 - 4	36.55	26.36	9.52	7.33	46.07	33.69
5 - 14	148.85	100.64	34.74	25.24	183.59	125.88
15 - 44	789.82	317.82	252.95	617.94	1042.77	935.76
45 - 59	402.6	198.12	102.71	26.99	505.31	225.11
60 +	496.92	178.12	135.5	6.2	632.42	184.32
All Ages	1874.73	821.07	535.43	683.69	2410.16	1504.76

Source: Tables 6.1 and 6.3, see the text, Section VI.

Nevertheless, the estimates from all the three studies indicate higher prevalence of TB among the workers than among the total population. This is obvious, because TB is more prevalent among males than females and among adults than the children. When we consider the age structure, sex and rural-urban residence of the TB patients, however, we have no evidence to assume differential prevalence of TB among workers and non-workers. Thus we assume that within an age-sex-residence specific category of population, pulmonary TB is equally prevalent among workers and non-workers. In other words, we can assume that for each of the age-sex-residence specific category, the worker-population-ratio (WPR) for the population and the TB patients is identical. Table 7.1 presents the worker population ratio by age-sex and residence in India for the base year 1993-94. We may, however, exclude the category of child labourers from this because if a child has pulmonary TB he is most unlikely to be employed for long enough to be called a worker. Thus, among the children aged 5-14 years, the WPR among the TB patients is taken as zero. This makes our eventual estimate of the benefits of DOTS even more conservative.

With these assumptions the workers among the TB patients can be derived from the estimates of the prevalence of TB presented in Table 6.5 above. The estimates of workers with TB in the base year 1993-94 are presented in Table 7.2.

VIII. Benefits of DOTS – Reduction in TB prevalence

The Revised National TB Control Programme targets the cure rate with DOTS to increase substantially from the current level of about 25-30% to 85-90%. Thus, the net improvement in the cure rate is likely to be of the order of 55-65%. We may take 60% as the average improvement in the cure rate when DOTS strategy is successfully implemented. TB kills and also disables. Workers with TB are less productive over the year than the workers without TB. It is estimated by Dr. Ramana of ASCI through several case studies of the TB patients in Andhra Pradesh "that even in urban areas one to two months time is taken for the diagnosis of the disease from the day symptoms start. In case of rural areas this could be as long as six months to one year. Most of the patients stated that they could not perform their routine work for a period of

TABLE 7.1

Estimates of worker population ratio in India, 1993-94

	Rural Areas			Urban Areas			Total of All Areas		
Age Groups	Males	Females	Persons	Males	Females	Persons	Males	Females	Persons
0-4	85	11	96	44	3	47	129	14	143
15+	0.8477	0.4313	0.641	0.7583	0.204	0.4969	0.8223	0.3713	0.6015
45+	0.8728	0.3806	0.6273	0.7876	0.2051	0.5117	0.8513	0.3395	0.5992
60+	0.725	0.193	0.4671	0.4481	0.1031	0.2685	0.6617	0.1701	0.4191

Source: Tables 3.1 and 3.2.

TABLE 7.2

Estimates of workers with pulmonary TB in India, 1993-94 (in '000)

	Rural Areas		Urban Areas	
Age Groups	Males	Females	Males	Females
15 - 44	661.3	143.865	189.337	125.818
45 - 59	385.613	95.016	97.325	7.271
60 +	360.276	34.379	60.721	0.639

Source: Tables 7.1 and 6.5.

three months (urban) to six months (rural)." (Dr. G.N.V. Ramana, personal communication). These estimates are not likely to differ considerably across the country. Our preliminary inquiry with some medical practitioners in rural and urban Gujarat confirms this belief. Thus, one of the major economic benefits of DOTS is through the reduction of prevalence of TB among workers which averts the loss in output. Workers with TB are unable to do their routine economic activity for some part of the year. As per Dr. Ramana's estimate, workers with TB lose about 1/4th of the year in the urban areas and almost half of the year in the rural areas. Thus, on the whole, the workers with TB have no more than 75% of the productivity of the other workers in the urban areas, and 50% of the productivity of the other workers in the rural areas. When the prevalence of TB in the population and thereby among the workers reduces, the overall average productivity of the working force would increase. Since this is a purely short run phenomenon, the reduction in the disability induced forced absenteeism does not require any further investment or new capital equipment for its productive use. In fact, such forced absenteeism involves underutilization and wastage of the existing capital stock. Thus, the improvement in production can be directly measured through increased average productivity of labour. Symbolically, the methodology can be presented as follows:

$$\text{Let National Output} = \sum a_i . W_i \quad (1)$$

Where a_i and W_i represent respectively the average productivity per worker and the total workers in i-th category; and the subscript i denotes the age-sex-area specific category. Moreover,

$$a_i W_i = b_i WT_i + c_i OW_i \quad (2)$$

Where WT_i and OW_i denote the workers with TB and other workers in the i-th category respectively; and b_i and c_i are their respective average productivities. Then,

$$b_i < c_i \text{ for all } i \quad (3)$$

$$\text{Let } \propto_i = WT_i / Wi \quad (4)$$

Thus, $\propto_i$ represents prevalence of TB among workers in the i-th category. It can be seen from the above equations (2) and (4) that

$$a_i = (1 - s_i \propto i) c_i \quad (5)$$

Where s_i is the proportion of the forced absenteeism due to the disease in the i-th category. It can be seen from equation (5) that other things being given, as DOTS succeeds and $\propto_i$ declines, a_i tends to c_i.

In order to estimate the change in the average productivity, a_i when $\propto_i$ declines, we again use equation (2) and introduce the change in $\propto_i$. Thus,

$$\Delta a_i = -b_i \Delta \propto_i + c_i \Delta \propto_i ; (\Delta \propto_i \text{ being positive}) = \Delta \propto_i (c_i - b_i)$$

$$\text{But } b_i = (1 - s_i)\, c_i \text{ by definition.}$$

$$\therefore \phi 0\, \Delta a_i = \Delta \propto_i (s_i c_i) = [(s_i \Delta \propto_i)/(1 - s_i \propto_i)]^* a_i \quad (6)$$

The estimates of s_i, $\propto_i$ and a_i are all derived above for different age-sex-area categories. The $\Delta \propto_i$ representing the decline in the prevalence of TB among workers on account of DOTS can be taken to be 60% (i.e., 0.60) as stated before. Equation (6), thus, makes it possible to estimate the economic impact of DOTS on labour productivity. Table 8.1 presents our estimates of the possible increase in the average productivity of labour in the Indian economy on account of the DOTS strategy. By multiplying these average productivity increases by the total number of workers in respective age-sex-area categories, we can derive the total increase in output on account of reduction in the prevalence of TB due to DOTS. Table 8.2 presents these estimates for the year 1993-94 at current prices.

It is important to recognise that these are the benefits of DOTS in terms of annual additions to the flow of national income during the year when DOTS succeeds in

TABLE 8.1

Increase in APL in India due to DOTS (In Rs.)

	Rural Areas		Urban Areas	
Sectors	**Males**	**Females**	**Males**	**Females**
15 - 44	25.32762	6.364698	22.49732	43.04052
45 - 59	81.12279	23.37125	70.79941	13.51884
60 +	146.2642	39.18964	170.6225	5.250896

Source: See the text, Section VIII.

reducing the prevalence of TB. However, these additions once achieved, would continue in future since the relapse rate with DOTS is almost negligible. If the DOTS strategy continues to be successfully implemented, the percentage addition to the GDP of the country becomes permanent. It almost amounts to shifting the time path of GDP upwards by the same percentage. The present value of these future additions at constant (1993-94) prices should be considered as the benefits of DOTS through reduction of the prevalence of TB in the country. This is because in the scenario without DOTS, the prevalence of TB is likely to be almost stagnant at the present level. Thus, between the two scenarios "with DOTS" and "without DOTS", the percentage increase in GDP due to reduction in the prevalence of TB by DOTS is a permanent annual increase ascribable to DOTS. The question of appropriate rate of discount to be used for the purpose of estimating the present value of these additions to the national income will be considered in the Section X below. We turn to the estimation of another important economic benefit of DOTS, arising from deaths averted.

IX. Benefits of DOTS– Reduction in TB deaths

As stated in Section I, the DOTS strategy is likely to have a very substantial impact on deaths due to TB. The targets of the Revised National TB Control Programme in India (Datta 1995), state that the case fatality rate for TB is expected to be reduced to less than 2% from the current 14%. As we have seen in Section V above, the estimates of the current mortality from pulmonary TB are not confirmed. The Survey of Causes of Death implies a mortality due to TB around 0.45 million per year whereas Murray and Lopez (1996) provide an estimate of around 0.76 million per year. DOTS can save the deaths which would occur in the "without DOTS" case. Moreover, since the Indian situation currently resembles a steady state (See Chakraborty, 1996, P.13), the case "without DOTS" would have the same amount of deaths occurring every year. Sustained successful implementation of DOTS would prevent these additional deaths every year. Moreover, "with DOTS" the prevalence of TB would be substantially reduced and hence the minimum 2% case fatality would also reduce in absolute number.

In order to estimate the economic benefits from the deaths averted by DOTS, we have to estimate the future workers among the deaths averted. These estimates have to be carefully derived. There are no ready made surveys or any empirical findings to go by. It all depends on dynamics of worker participation rates by age and the age pattern of the mortality due to other causes over a fairly long time period. It is difficult to envisage the exact behaviour of these two important parameters. However, the way the Indian economy is shaping particularly with rapid economic reforms introduced in the system, it can be argued that demand for labour is going to increase considerably in future inducing the WPR to rise. The economy is all set to achieve a fairly rapid growth in national income at about 7% p.a. Such a high rate of growth is known to put excessive pressure on the labour market wherever it has occurred. WPR across the age groups in such economies has a tendency to rise. This is clearly borne out by the experience of China, Malaysia, Singapore, Mauritius, etc. On the other hand, age-specific mortality has a depressing effect on the future workers out of the deaths averted by DOTS. The net effect of both these factors would, thus, be largely offsetting. We may, therefore, apply the existing appropriate worker participation rates to the current deaths averted in the particular age-sex-group.

In order to determine the appropriate worker population ratio to apply to the current deaths averted in a particular age group, we need an estimate of the average age of death due to TB in different age-sex groups. Here

TABLE 8.2

Increase in GDP in India due to reduction in prevalence by DOTS in the first year (in Rs. Crores)

	Rural Areas		Urban Areas		All Areas		
Sectors	Male	Female	Male	Female	Male	Female	Persons
15 - 44	303	40	101	47	405	87	492
45 - 59	293	43	92	4	385	47	432
60 +	230	15	49	0.4	279	16	295
Total	827	99	242	51	1069	151	1220

Source: See the text, Section VIII.

TABLE 9.1

Average age at death due to TB in India, 1993-94

Age Groups	Average Age at Onset (in years)		Average Duration (in years)		Average Age at Death (in years)	
	Males	Females	Males	Females	Males	Females
0 - 4	3.0	3.0	2.0	2.4	5	5
5 - 14	10.0	10.0	2.7	2.4	13	12
15 - 44	29.7	29.8	2.5	2.5	32	32
45 - 59	52.2	52.3	2.4	2.2	55	55
60 +	70.0	72.6	2.2	1.8	72	74
All Ages	43.0	37.0	2.4	2.3	45	39

Source: Murray and Lopez (1996), p.142 and Section IX of the text.

TABLE 9.2

Worker population ratio for aggregative age groups by sex and area in India, 1993-94

Sex and Area		15+ years	45+ years	60+ years
Rural	Males	0.8477	0.8728	0.7250
	Females	0.4313	0.3806	0.1930
	Persons	0.6410	0.6273	0.4671
Urban	Males	0.7583	0.7876	0.4481
	Females	0.2040	0.2051	0.1031
	Persons	0.4969	0.5117	0.2685
Total	Males	0.8223	0.8513	0.6617
	Females	0.3713	0.3395	0.1701
	Persons	0.6015	0.5992	0.4191

Source: Table 3.2.

TABLE 9.3

Deaths averted by DOTS in India, 1993-94 – set A (in '000)

Age Groups	Males	Females	Persons
0-4	13	9	22
5-14	7	5	12
15-44	120	58	178
45-59	154	86	240
60+	165	68	233
Total	459	226	685

Source: Set A is based on Murray and Lopez (1996) estimates of deaths due to TB and our estimates (See Section IX of the text).

again, Murray and Lopez (1996) provide estimates of the average age of the onset of the disease and average duration by each of the age-sex group. We may assume that the summation of the two is a reasonably close approximation[2] of the average age of death due to TB for our purposes to determine:

- the appropriate WPR to be used; and
- the duration of economically active life of the worker whose life is saved by DOTS in the current year.

We further assume that the worker on an average works up to the age of 65 years. Similarly, we assume that the earliest he/she starts working is 15 years. Table 9.1 provides these estimates for India.

The estimates given in Table 9.1 are for the population — i.e., for workers and non-workers. In order to obtain the future workers from the deaths averted due to DOTS, we need to apply the average WPR which would cover the relevant age groups and the working life. Table 9.2 provides the estimates for the WPR for these three aggregative age groups by sex in India for the years 1993-94.

At this stage, it is important to note that we have two distinct sets of estimates of deaths due to TB in India with the same population base of 1993-94. We, therefore, prepare two alternative sets of the estimates of benefits due to deaths averted by DOTS. We call them:

1. Set A based on Murray and Lopez (1996) estimates of deaths due to TB; and
2. Set B based on SCD (survey of Causes of Death) estimates of deaths due to TB in 1993-94.

These two sets of estimates of deaths averted by DOTS are presented in Tables 9.3 and 9.4. By applying the WPR's given in Table 9.2 to the estimates of deaths averted by DOTS (given in Tables 9.3 and 9.4) we can generate the two alternative sets of the future workers among those whose lives are saved. These estimates are presented in Tables 9.5 and 9.6.

The marginal productivity of labour is the most appropriate concept to determine the contribution of additional workers in the long run in the economy. The contribution of the additional work force in terms of additional potential output is ideally measured through the marginal value product of labour (Solow, 1958).

The marginal productivity of labour is the most appropriate concept to determine the contribution of additional workers to the economy in the long run. This is very well recognised (see for instance, Dornbusch and Fischer, 1994). When a worker dies, he/she gets substituted by some other person from the labour market. Therefore, when the death of a worker is averted, additional employment is generated in the economy to the same extent. This follows from our basic assumption of the economy in the macroeconomic dynamic long-run equilibrium where the natural rate of unemployment (or long-run or structural unemployment rate) remains constant. The steady state growth of output is then determined by the growth of labour supply as per the widely used neo-classical growth model developed by Solow (1958) which is also extensively used for empirical investigations. Accordingly, the contribution of the additional work force in terms of additional potential output is ideally measured through the marginal value product of labour.

A recent study on the growth accounting by Dr. B.H. Dholakia (1995) estimates the relative share of labour for the entire economy for the period 1991 to 1994. Its average value is estimated to be 0.5842 which is also the estimate for the labour elasticity of output in the long run. The labour elasticity of output is defined to be the ratio of the marginal product of labour and the average product of labour. Assuming that the labour elasticity of output remains the same for different age-sex-area categories of workers, it is possible for us to estimate the marginal productivity of labour for different categories of workers in India. These estimates are presented in Table 9.7. It may be noted here that these represent the estimates of the contribution of additional workers on an average in the respective categories in one year. When the death is averted, the person contributes for several years in future. The average life expectancy is going to increase well beyond 65 years in India for both males and females.

Thus, the present discounted value of the contributions of the future workers among the deaths averted in one year due to DOTS for the remaining part of their economically active life needs to be considered as the economic benefits of deaths averted by DOTS. Once the appropriate discount rate is chosen, we can generate these estimates.

It may also be noted that if DOTS continues to be successfully implemented, it will save the deaths at the same rate per annum in future also as compared to the "without DOTS" scenario. The contribution to the GDP of the additional work force arising out of the deaths averted in future would also have to be considered for estimating the benefits of DOTS. As noted in the beginning of this section, in the "with DOTS" scenario there would be an increasing number of deaths averted in future. These future benefits will however have to be discounted at the appropriate discount rate. We turn to this question in the next section.

TABLE 9.4

Deaths averted by DOTS in India, 1993-94 – set B (in '000)

Age Groups	Rural Areas			Urban Areas			All Areas		
	Males	Females	Persons	Males	Females	Persons	Males	Females	Persons
0 - 4	3.7	1.6	5.3	0.9	0.3	1.2	4.6	1.9	6.5
5 - 14	2.1	4.4	6.5	0.5	0.9	1.4	2.6	5.3	7.9
15 - 44	70.8	56.9	127.8	17.5	12.1	29.6	88.4	69.0	157.4
45 - 59	63.1	23.8	87.0	15.6	5.0	20.7	78.8	28.9	107.6
60 +	53.9	22.5	76.4	13.4	4.8	18.2	67.3	27.3	94.6
Total	193.6	109.2	302.8	48.0	23.2	71.2	241.6	132.4	374.0

Source: Set B is based on Survey of Causes of Death 1993-94 estimates of deaths due to TB and our estimates (See Section IX of the text).

TABLE 9.5

Future workers among the deaths averted by DOTS in India, 1993-94 – set A (in '000)

Age Groups	Males	Females	Persons
0 - 4	10	3	14
5 - 14	6	2	8
15 - 44	98	22	120
45 - 59	131	29	160
60 +	109	12	121
Total	355	68	423

Source: Tables 9.2 and 9.3.

TABLE 9.6

Future workers among the deaths averted by DOTS in India, 1993-94 – set B (in '000)

Age Groups	Rural Areas			Urban Areas			All Areas		
	Males	Females	Persons	Males	Females	Persons	Males	Females	Persons
0 - 4	3.2	0.7	3.8	0.7	0.1	0.8	3.8	0.7	4.6
5 - 14	1.8	1.9	3.6	0.4	0.2	0.6	2.1	2.1	4.2
15 - 44	60.0	24.6	84.6	13.3	2.5	15.8	73.3	27.0	100.4
45 - 59	55.1	9.1	64.2	12.3	1.0	13.3	67.4	10.1	77.5
60 +	39.1	4.3	43.4	6.0	0.5	6.5	45.1	4.8	49.9
Total	159.1	40.5	199.6	32.7	4.2	36.9	191.8	44.8	236.6

Source: Tables 9.2 and 9.4.

X. The rate of discount and future benefits

The benefits in future need to be discounted to bring them to the base year. Since the benefits of DOTS over the existing standard chemotherapy to cure TB in India are largely in terms of deaths averted and increased efficiency of work force due to reduction in the prevalence of TB, the rate of interest at which the future benefits should be discounted must be the consumption rate of interest. It is also called the social time preference rate (STPR). It shows the extra amount of future consumption which the society considers necessary in order to forego a unit of present consumption without becoming worse-off or better-off. Thus, if the society sacrifices one unit of consumption today, it needs (1 + STPR) units of consumption in future to yield the same amount of welfare. Fellner (1967) has provided a framework to estimate STPR for any economy. Tiwari and Pandey (1993) made an attempt to estimate the STPR for India by estimating the fundamental relationships suggested by Fellner (1967). Dholakia and Oza (1996) have considered their estimates removing certain flaws in the estimation procedure. The estimate of the STPR for the Indian economy turns out to be around 5%.

On the other side, the labour productivity in Indian economy is likely to be growing almost at 3-5% p.a. This is because the real GDP in India is expected to grow at the rate of about 5-7% p.a. at least during the 9th Plan period and in future too according to the revised Perspective Plan targets. The population (and working force) is growing at the rate of 2% p.a. at present and is most likely to show a decline in the annual growth rate in near future. Hence the working force may grow at around 2% p.a. in India in future. Thus, the labour productivity growing at 3-5% p.a. is a reasonable assumption. When the real income additions in future are growing at 3-5% p.a. considering only the effect of labour productivity growth, the rate of discount has to be reduced by 3-5% to get the effective rate of discount. If STPR is estimated to be 5% in India, and if labour productivity in India is likely to grow at 3-5% p.a., the effective discount rate in this case would turn out to be zero to 2%.

However, the World Bank, Asian Development Bank and several other financial institutions, donors and investors expect a much higher rate of return on the investments. For international investors, it is the return on capital that matters. These institutions, therefore, often evaluate projects at the discount rates (in real terms) of between 9% to 15%. Given that the labour productivity in the country is likely to grow in real terms at 3% to 5% in future, we may also, therefore, consider the range of effective discount rates of 4% to 12%. We have, therefore, considered five effective rates of discounts, viz. 2%, 4%, 7%, 10% and 13%.[1] We present our estimates by the category-wise disaggregation for both the types of benefits of DOTS viz. deaths averted and reduction in prevalence of TB.

It is important to recognise that we should carefully avoid double counting of benefits. For instance, let us consider that the prevalence of TB is 100 during the given year without DOTS. About 14 will die during the year and about 20 to 25 will be cured during the year. On the other hand, about 35 to 37 will be the new cases of TB added during the year. Thus, the situation is more or less repetitive every year "without DOTS". The situation changes considerably with successful implementation of DOTS. Only 2% out of the prevalence will die during the year and the cure rate will be 85 to 90%. As a conservative estimate, we have taken the improvement due to DOTS in the cure rate to be 60% of prevalence. Now the deaths averted by DOTS are largely included in those who are additionally cured during the year. While calculating the economic benefits of DOTS, we have to be careful in avoiding this double counting. We have assumed that the patients who would have died "without DOTS" remained patients

TABLE 9.7

Estimates of marginal product of labour by age-sex-residence in India, 1993-94 at current prices (in Rupees)

Age Groups	Rural Areas			Urban Areas			All Areas		
	Males	Females	Persons	Males	Females	Persons	Males	Females	Persons
15 +	10446	6355	90796	24687	16377	23078	14174	7809	12250
45 +	13993	8842	12434	35666	21913	33055	19060	10692	16725
60 +	12300	8717	11263	31407	23054	29981	15260	10933	14162

Source: Tables 4.5 and 9.2 above.

TABLE 10.1

Discounted present value of gains out of deaths averted in the first year due to DOTS – set A* (in Rs. Crores)

A) Discount Rate of 5%

Age	Male	Female	Persons
0 - 4	380.8922	69.35341	450.2456
5 - 14	257.7056	44.28677	301.9924
15 - 44	3344.215	405.8955	3750.111
45 - 59	2244.916	280.3681	2525.284
60 +	323.2578	24.43525	347.693
Total	6550.986	824.3391	7375.325

B) Discount Rate of 7%

Age	Male	Female	Persons
0 - 4	214.4337	39.0444	253.4781
5 - 14	169.465	28.56254	198.0275
15 - 44	2529.93	307.0638	2836.994
45 - 59	2027.062	253.1603	2280.222
60 +	314.0176	23.73678	337.7543
Total	5254.908	651.5678	5906.476

C) Discount Rate of 10%

Age	Male	Female	Persons
0 - 4	103.6603	18.87463	122.535
5 - 14	102.8496	16.84878	119.6984
15 - 44	1777.988	215.7988	1993.787
45 - 59	1755.326	219.2231	1974.549
60 +	301.0147	22.75388	323.7685
Total	4040.839	493.4991	4534.338

D) Discount Rate of 13%

Age	Male	Female	Persons
0 - 4	56.48156	10.28424	66.7658
5 - 14	69.91482	11.14094	81.05576
15 - 44	1334.056	161.9176	1495.973
45 - 59	1535.648	191.7874	1727.435
60 +	288.9441	21.84146	310.7856
Total	3285.044	396.9717	3682.016

E) Discount Rate of 16%

Age	Male	Female	Persons
0 - 4	33.40784	6.082948	39.49079
5 - 14	51.28617	7.955592	59.24176
15 - 44	1053.371	127.8502	1181.221
45 - 59	1356.106	169.3645	1525.471
60 +	277.7227	20.99322	298.7159
Total	2771.894	332.2464	3104.14

**Set A is based on the Murray and Lopez (1996) estimates of TB death rates.*

Source: See the text, Sections IX and X. We have assumed the growth of labour productivity to be only 3% and not 5% for being conservative. If we consider higher labour productivity growth or growth in the number of TB deaths "without DOTS", the discount rates have to be accordingly increased with the calculated numbers remaining the same.

TABLE 10.2

Discounted present value of gains out of deaths averted in the second and subsequent years due to DOTS – set A* (in Rs. Crores)

A) Discount Rate of 5%

Age	Male	Female	Persons
0 - 4	19553.31	3560.139	23113.45
5 - 14	16751.35	2859.618	19610.97
15 - 44	182512.4	24044.33	206556.7
45 - 59	114738.1	14211.25	128949.3
60 +	16636.05	1240.213	17876.26
Total	350191.1	45915.55	396106.7

B) Discount Rate of 7%

Age	Male	Female	Persons
0 - 4	5398.19	982.8669	6381.057
5 - 14	5401.856	904.4149	6306.27
15 - 44	67708.54	8919.979	76628.52
45 - 59	50805.57	6292.685	57098.25
60 +	7924.868	590.7966	8515.664
Total	137239	17690.74	154929.8

C) Discount Rate of 10%

Age	Male	Female	Persons
0 - 4	1449.37	263.8918	1713.262
5 - 14	1820.863	296.3131	2117.176
15 - 44	26428.67	3481.735	29910.41
45 - 59	24435.07	3026.483	27461.55
60 +	4219.269	314.5453	4533.815
Total	58353.24	7382.969	65736.21

D) Discount Rate of 13%

Age	Male	Female	Persons
0 - 4	537.7277	97.90593	635.6336
5 - 14	842.8161	133.4115	976.2276
15 - 44	13502.36	1778.812	15281.17
45 - 59	14555.82	1802.857	16358.67
60 +	2757.735	205.5884	2963.324
Total	32196.45	4018.574	36215.03

E) Discount Rate of 16%

Age	Male	Female	Persons
0 - 4	238.1634	43.36323	281.5266
5 - 14	462.9507	71.33702	534.2877
15 - 44	7983.397	1051.739	9035.136
45 - 59	9625.196	1192.159	10817.36
60 +	1984.819	147.9677	2132.787
Total	20294.53	2506.567	22801.09

**Set A is based on the Murray and Lopez (1996) estimates of TB death rates.*

Source: Same as Table 10.1.

TABLE 10.3

Discounted present value of gains out of deaths averted in the first year due to DOTS – set B* (In Rs. Crores)

Age	Rural Areas			Urban Areas			Total of All Areas		
	Male	Female	Persons	Male	Female	Persons	Male	Female	Persons
A) Discount Rate of 5%									
0 - 4	85	11	96	44	3	47	129	14	143
5 - 14	55	36	91	28	9	37	83	45	128
15 - 44	1505	374	1879	788	97	885	2292	471	2763
45 - 59	693	72	765	395	20	415	1087	92	1180
60 +	93	7	101	37	2	39	130	10	139
Total	2431	500	2931	1291	131	1422	3722	632	4353
B) Discount Rate of 7%									
0 - 4	49	6	54	24	2	26	73	8	80
5 - 14	36	23	59	18	6	24	55	29	84
15 - 44	1138	283	1421	596	73	669	1734	356	2091
45 - 59	625	65	690	356	18	375	982	83	1065
60 +	91	7	98	36	2	38	126	9	135
Total	1938	385	2323	1031	101	1132	2969	486	3455
C) Discount Rate of 10%									
0 - 4	23	3	26	12	1	13	35	4	39
5 - 14	22	14	36	11	3	15	33	17	50
15 - 44	800	199	999	419	51	470	1219	250	1469
45 - 59	542	56	598	309	16	324	850	72	922
60 +	88	7	94	34	2	36	121	9	130
Total	1474	28	1752	785	74	858	2258	352	2611

Age	Rural Areas			Urban Areas			Total of All Areas		
	Male	Female	Persons	Male	Female	Persons	Male	Female	Persons
D) Discount Rate of 13%									
0 - 4	13	2	14	7	0.4	7	19	2	21
5 - 14	15	9	24	8	2	10	23	11	34
15 - 44	600	149	750	314	39	353	914	188	1102
45 - 59	474	49	523	270	14	285	744	63	807
60 +	83	7	90	33	2	35	116	9	125
Total	1185	216	1401	631	57	688	1816	273	2089
E) Discount Rate of 16%									
0 - 4	7	1	8	4	0.2	4	11	1	13
5 - 14	11	6	17	6	2	7	17	8	25
15 - 44	474	118	592	248	30	279	722	148	870
45 - 59	418	44	462	238	12	251	657	56	713
60 +	80	6	86	31	2	33	112	8	120
Total	991	175	1166	527	47	574	1518	222	1740

** Set B is based on Survey of Causes of Death Estimates of TB deaths.*

Source: Same as Table 10.1.

TABLE 10.4

Discounted present value of gains out of deaths averted in the second and subsequent years due to DOTS – set B* (in Rs. Crores)

	Rural Areas			Urban Areas			All Areas		
Age	Male	Female	Persons	Male	Female	Persons	Male	Female	Persons
A) Discount Rate of 5%									
0 - 4	4734.6	618.7	5353.4	2446.6	158.7	2605.3	7181.2	777.5	7958.7
5 - 14	3081.8	1982.6	5064.5	1563.6	501.5	2065.1	4645.4	2484.2	7129.1
15 - 44	83810.4	20850.4	104660.9	43879.4	5392.8	49272.2	127689.8	26243.3	153933.2
45 - 59	38580.2	4012.3	42592.6	21980.8	1135.2	23116.0	60561.1	5147.5	65708.7
60 +	5195.2	409.5	5604.7	2040.3	123.3	2163.7	7235.6	532.8	7768.5
Total	135402.5	27873.8	163276.3	71910.8	7311.7	79222.6	207313.3	35185.5	242498.9
B) Discount Rate of 7%									
0 - 4	1307.1	170.8	1477.9	675.4	43.8	719.2	1982.5	214.6	2197.2
5 - 14	993.8	627.0	1620.8	504.2	158.6	662.8	1498.0	785.6	2283.7
15 - 44	31092.0	7735.1	38827.1	16278.4	2000.6	18279.0	47370.4	9735.7	57106.2
45 - 59	17083.2	1776.6	18859.8	9733.0	502.6	10235.7	26816.2	2279.3	29095.5
60 +	2474.8	195.0	2669.9	971.9	58.7	1030.7	3446.8	253.8	3700.6
Total	52951.0	10504.7	63455.7	28163.0	2764.5	30927.6	81114.1	13269.3	94383.4
C) Discount Rate of 10%									
0 - 4	350.9	45.8	396.8	181.3	11.7	193.1	532.3	57.6	589.9
5 - 14	334.9	205.4	540.4	169.9	51.9	221.9	504.9	257.4	762.3
15 - 44	12136.1	3019.2	15155.4	6353.9	780.9	7134.8	18490.1	3800.1	22290.2
45 - 59	8216.2	854.4	9070.7	4681.1	241.7	4922.8	12897.3	1096.2	13993.5
60 +	1317.6	103.8	1421.4	517.4	31.2	548.7	1835.1	135.1	1970.2
Total	22355.9	4228.9	26584.8	11903.8	1117.6	13021.5	34259.8	5346.6	39606.4

Age	Rural Areas			Urban Areas			All Areas		
	Male	Female	Persons	Male	Female	Persons	Male	Female	Persons
D) Discount Rate of 13%									
0 - 4	130.2	17.0	147.2	67.2	4.3	71.6	197.4	21.3	218.8
5 - 14	155.0	92.4	247.5	78.6	23.3	102.0	233.7	115.8	349.6
15 - 44	6200.3	1542.5	7742.8	3246.2	398.9	3645.1	9446.5	1941.4	11388.0
45 - 59	4894.3	509.0	5403.3	2788.5	144.0	2932.5	7682.8	653.0	8335.8
60 +	861.2	67.8	929.0	338.2	20.4	358.6	1199.4	88.3	1287.7
Total	12241.1	2228.9	14470.1	6518.9	591.1	7110.1	18760.0	2820.1	21580.2
E) Discount Rate of 16%									
0 - 4	57.6	7.5	65.2	29.8	1.9	31.7	87.4	9.4	96.9
5 - 14	85.1	49.4	134.6	43.2	12.5	55.7	128.3	61.9	190.3
15 - 44	3666.0	912.0	4578.0	1919.3	235.8	2155.2	5585.3	1147.9	6733.2
45 - 59	3236.4	336.5	3573.0	1843.9	95.2	1939.1	5080.3	431.8	5512.2
60 +	619.8	48.8	668.6	243.4	14.7	258.1	863.2	63.5	926.8
Total	7665.1	1354.4	9019.6	4079.7	360.2	4440.0	11744.8	1714.7	13459.6

** Set B is based on Survey of Causes of Death estimates of TB deaths.*

Source: Same as Table 10.1.

throughout the year with reduced efficiency if they were also workers. Thus, the economic benefits of deaths averted by DOTS during the particular year when the patient is put on DOTS would be the same as any other patient getting cured by DOTS. The benefits of deaths averted are thus only the additional benefits accruing in future and therefore appropriately discounted.

Secondly, we must also consider the future flow of benefits of DOTS due to future deaths averted. As we have already discussed, "without DOTS", the situation is repetitive and therefore the deaths remain the same. On the other hand, with successful DOTS, the prevalence sharply declines to about 33 to 35% of the present level. The number of deaths occurring "with DOTS", therefore, would be 0.7% of initial prevalence as compared to 2% as in the initial year of DOTS. The number of deaths averted during the second year of DOTS is thus 13.3% of initial prevalence as compared to 12% in the initial year of DOTS. After 15 years or so, the annual incidence is also likely to fall and hence the deaths averted by DOTS would further increase. However:

- the rate of decline in the annual incidence is not very predictable;
- the actual further gain is only marginal (because at best it can reach 14% from 13.3% of initial prevalence); and
- the benefits lie at least 15 years or more in future (which implies very low present value).

Considering all these, we have preferred to ignore the fall in annual incidence rate in future (after 15 years) on account of DOTS while estimating the economic benefits of DOTS. To the extent the annual incidence declines in future, our estimates represents an underestimate of the true benefits of DOTS. This is in the spirit of conservatism often practised in the field of social cost benefit exercises.

The estimates of present value of economic benefits of DOTS due to deaths averted in the first year and due to deaths averted in the subsequent years are presented in Tables 10.1 and 10.2 according to the Murray and Lopez (1996) estimates of TB deaths and in Tables 10.3 and 10.4 according to the Survey of Causes of Death estimates of TB deaths. Similarly Table 10.5 provides the present discounted value of the future economic benefits due to reduction in prevalence of TB on account of DOTS in India at different discount rates.

We have so far considered the estimates of the tangible economic benefits of DOTS given in Tables 8.2 and 10.1 to 10.5, from reduced prevalence and deaths averted by DOTS. It is stated that when the prevalence is significantly reduced, the transmission cycle of the infectious TB gets effectively interrupted and the incidence of new TB patients in the distant future also gets reduced. However, these effects usually take a long time because as such about 40-50% of the country's total population is believed to be already infected by the TB bacilli. The disease can become active even years after the initial infection. Thus, even when the annual risk of infection which is currently estimated for India to be around 1.5% as per the World Bank (1995, p.5), starts declining at a rate of 10% as against the current rate of 2-2.5%, it would take more than 25 years to reach the level of 0.1% of the annual risk of the disease. Significant reduction in the annual incidence rate of TB due to intervention through DOTS can, therefore, be expected only after about 15 years. Until then, the annual incidence rate is likely to be about one-third of the prev lence rate in the initial period given the epidemiological situation of TB in India. Under these circumstances, if the prevalence (stock) of TB were rapidly lowered with successful DOTS therapy the cost of tackling TB would fall by two-thirds and remain at that level for about 15 years after which it would again start declining. This feature of the DOTS strategy has implications on the cost "with DOTS" as compared to "without DOTS". As we have already seen, India has reached a steady state which has a tendency to repeat itself in an epidemiological sense with respect to TB. Thus, if things do not change, the present cost (both private and public) would have to be incurred annually just in order to keep the situation from worsening.

XI. Saving of hospital beds due to DOTS

In 1993-94 hardly 1.2 million TB cases out of the probable 3.9 million were detected and put on treatmen (See, Datta, 1995). Moreover, most of these cases receive palliation and not cure. Therefore, it is believed that almost 75% to 80% of the existing TB patients in India have received some treatment for TB at one time or another. The treatment does not result in cure because it is neither complete nor of proper quality. The unit cost incurred for such treatment — both by the patients and the provider institutions — are possibly lower than what would be needed if the treatment was complete and of proper quality. DOTS on the other hand, cures the patients and could cost more particularly because we have to consider all the social costs necessary to ensure that the DOTS strategy succeeds in India.

In the scenario "with DOTS" as compared to "without

TABLE 10.5

Discounted present value of future increase in GDP in India due to reduction in prevalence due to DOTS (in Rs.Crores)

Ages	Rural Areas		Urban Areas		All Areas		
	Males	Females	Males	Females	Males	Females	Persons
A) Discount Rate of 5%							
15 - 44	15170.61	2024.77	5068.083	2347.861	20238.7	4372.63	24611.33
45 - 59	14662.13	2169.203	4583.554	202.1067	19245.69	2371.31	21617
60 +	11509.53	772.8197	2461.229	18.92948	13970.76	791.7491	14762.51
Total	41342.27	4966.792	12112.87	2568.897	53455.14	7535.689	60990.83
B) Discount Rate of 7%							
15 - 44	7585.306	1012.385	2534.041	1173.93	10119.35	2186.315	12305.66
45 - 59	7331.066	1084.601	2291.777	101.0533	9622.843	1185.655	10808.5
60 +	5754.765	386.4098	1230.615	9.464739	6985.379	395.8746	7381.254
Total	20671.14	2483.396	6056.433	1284.448	26727.57	3767.844	30495.41
C) Discount Rate of 10%							
15 - 44	4334.461	578.5056	1448.024	670.8173	5782.484	1249.323	7031.807
45 - 59	4189.181	619.7723	1309.587	57.74476	5498.768	677.517	6176.285
60 +	3288.437	220.8056	703.2084	5.408422	3991.645	226.214	4217.859
Total	11812.08	1419.083	3460.819	733.9705	15272.9	2153.054	17425.95
D) Discount Rate of 13%							
15 - 44	3034.123	404.9539	1013.617	469.5721	4047.739	874.5261	4922.265
45 - 59	2932.427	433.8406	916.7108	40.42133	3849.137	474.2619	4323.399
60 +	2301.906	154.5639	492.2459	3.785896	2794.152	158.3498	2952.501
Total	8268.455	993.3584	2422.573	513.7794	10691.03	1507.138	12198.17
E) Discount Rate of 16%							
15 - 44	2333.94	311.503	779.705	361.2093	3113.645	672.7123	3786.358
45 - 59	2255.713	333.7235	705.1621	31.09333	2960.875	364.8169	3325.692
60 +	1770.697	118.8953	378.6507	2.912227	2149.347	121.8076	2271.155
Total	6360.35	764.1219	1863.518	395.2149	8223.868	1159.337	9383.205

Source: See the text, Sections VIII and X and also the note in Table 10.1.

DOTS" the costs to the society[4] are, therefore, not likely to be saved in spite of the declining costs of the DOTS in the distant future. If there is any net saving of cost to society in the "with DOTS" over "without DOTS" scenario, it can be considered as a net benefit of DOTS. However, when we are using a high rate to discount the future, there may be negligible net saving in terms of social costs "with DOTS" over the situation "without DOTS". This is because successful DOTS might well cost more in the short run.

There is some obvious saving of resources due to DOTS which we have not considered so far. DOTS strategy to cure TB averts hospitalization of the TB patients. If the strategy is properly implemented, it can save the economy the cost of hospital beds currently used for TB patients. This again is not a one time benefit but is a permanent benefit to the society. In order to estimate this benefit of DOTS, we need to know the number of hospital beds and the duration for which they are used by the TB patients in the base year 1993-94 in India. Secondly, we need to estimate the cost of providing a hospital bed per day on an average in India. We are not interested in estimating how much a TB patient has to pay for the hospitalized treatment in the government hospital and the private hospital or how much subsidy he receives from the government or non-government organisation. Our interest is to estimate the amount the society has to spend in order to create the infrastructural facility equivalent to the number of TB beds released by DOTS. In this context, a set of some relevant estimates are derivable from the Gujarat Institute of Development Research, Ahmedabad study about TB from the NSS 42nd round data on five states (see, Visaria et al. 1994).

Table 11.1 presents the proportion of public and private hospital treatment among the selected sample of TB patients in the rural and urban areas of the five states.

TABLE 11.1

Proportion of public and private hospitalization by TB patients, 1986-87 (in %)

States	Rural Areas			Urban Areas		
	Public	Private	All	Public	Private	All
Gujarat	75.7	4.3	100	67.2	32.8	100
Maharashtra	76.9	23.1	100	62.0	38.0	100
Tamil Nadu	63.9	36.1	100	93.5	6.5	100
Uttar Pradesh	70.7	29.3	100	70.7	29.3	100
West Bengal	95.7	4.1	100	95.5	4.5	100

Source: Visaria et al. (1994), pp.34-35.

TABLE 11.2

Average amount per day paid to the private hospital by the TB patient for hospitalization, 1986-87 (in Rs.)

States	Rural Areas	Urban Areas
Gujarat	19.75	94.44
Maharashtra	65.82	61.55*
Tamil Nadu	58.33	100.67
Uttar Pradesh	22.82	11.20*
West Bengal	22.61	241.22*
Average	38	102

** Some error is suspected but Visaria et al. (1994) are silent about it.*

Source: Calculated from Visaria et al. (1994) pp.38 and 40.

Based on these figures, we may take the average proportion of the government to non-government hospital beds used by the TB patients in India to be 75:25. The total TB beds in the government hospitals is reported to be 47,326 by the end of 1991. Assuming the same number of beds in the year 1993-94, and applying the proportion of 75:25 to obtain the beds in the non-government hospitals, the total number of hospital beds in 1993-94 used by the TB patients turns out to be 63,101 or say, 63,000.

In order to estimate the cost of a hospital bed to the provider — whether government or non-government, it is most relevant to consider the market value of the bed. It is, therefore, the private hospital's charges which should provide some guidance. However, in the light of non-availability of precise data, we use whatever rough and ready estimates one can derive from Visaria et al. (1994). Table 11.2 presents the average amount per day spent by TB patient for hospitalized treatment in the five states. Taking a simple average in the rural and urban areas, the overall weighted average amount works out to be Rs.57 per day per bed in 1986-87.[5] Taking 30% of this as the cost of medicine, the profits of the private sector and other incidental service charges, the cost of the hospital bed for TB patient per day would work out at Rs.40 per day in 1986-87. Considering the overall inflation rate of 9.4% per annum (based on GDP deflator), the cost of a hospital bed per day in the economy works out to about Rs.75 per day in 1993-94. Considering the utilization of the bed by the TB patients on an average for 275 days out of 365 days (i.e., at about 75%), the cost saved by DOTS per bed released by the TB patients would be Rs.20.6 thousands per year.

The estimate of the benefit of DOTS in terms of releasing the hospital beds currently used by the TB patients, thus, works out to 63,000 beds * Rs.20,600 per bed = Rs.129.8 crores per annum. Since this is an annuity, its present discounted values at different discount rates are reported in Table 11.3. It may be noted here that the discount rate in this case is not reduced by the labour productivity growth since that is not a factor in the numerator. But the discount rate will get reduced by the growth rate of the hospital beds used by the TB patients in future in the scenario "without DOTS".

XII. Potential economic benefits of DOTS in India

The DOTS strategy is an effective way of tackling TB. The strategy has worked elsewhere and is expected to work in India too. Regular treatment is a major factor in curing TB. DOTS aims to tackle that factor directly. It is important to consider the various aspects of the problem of TB in India to ensure that DOTS succeeds in India. However, it is important to have some dimensional idea about the potential benefits of DOTS in India so that any extra or additional resources required to make the strategy work effectively in the country can be considered in the light of the likely benefits of those interventions. In this context, we have to consider the potential benefits of DOTS and not its actual performance in the pilot projects or any operational constraints on the implementation of DOTS in the country. Identification of such constraints, factors to improve the effectiveness of DOTS, and finding ou management solutions to make DOTS succeed to the desired extent are important studies, the justification and feasibility of which depends critically on some idea about the potential economic benefits the country may derive if DOTS succeeds. In our exercise, therefore, we have assumed that DOTS can and will succeed to the desired extent in India. Another crucial assumption we make to begin with is that of full and instantaneous coverage of the whole population (100%) by the DOTS strategy in India. This assumption is made initially for two reasons: 1) It gives us an idea of the potential benefits of the DOTS strategy in India; and 2) It would serve as a good reference and the base estimate from which we can easily derive the flow of benefits according to the desired pattern of the coverage of the population "with DOTS" in India. Thus, although this assumption may sound unrealistic, it has great utility for considering more realistic scenarios.

Having made these basic assumptions, we have derived the most conservative estimates of the economic benefits of DOTS to the country's economy. Here again we have not considered the pure social welfare increasing effects which do not generate direct tangible economic benefits. Thus, we have not considered here the benefits arising from reduced suffering of TB patients, quicker and surer cure from the disease, increased welfare on account

TABLE 11.3

Present discounted value of the benefit of DOTS in terms of hospital beds released (in Rs. Crores)

Discount Rates	5%	7%	10%	13%	16%
PDV in Rs.Crores	2596	1854	1298	998	811

Source: See the text, Section XI.

of lives saved and disability reduced for the dependents and non-workers suffering from TB, the income distribution gains and poverty alleviation effects because TB is known to be more prevalent among the poor than the rich, the psychic benefits of living in a society where the risk of the infection and the disease is substantially reduced, etc. We have considered here only the obvious and direct potential economic benefits of DOTS succeeding in India. These include mainly the following three benefits:

1. Reduction in the prevalence of TB due to DOTS which improves the efficiency and productivity of workers by reducing their forced absenteeism on account of ill-health;
2. TB deaths averted among the current and the future workers which add to the productive work force in the country;
3. Release of the hospital beds currently occupied by the TB patients since the DOTS strategy averts hospitalization of patients.

These benefits are to be evaluated within the framework of comparing two scenarios — "with DOTS" and "without DOTS". The benefits at 1) and 2) are largely in terms of additions to the national income over the future years. While calculating the present discounted value, therefore, we have to adjust for the expected growth in labour productivity. Although the current growth rate of labour productivity in India is around 5% which is also targeted in the ensuing 9th Plan, we have effectively assumed the growth rate in labour productivity to be only 3% which is more realistic in a very long term perspective. Similarly, we have assumed constant absolute prevalence and incidence rates of TB in the "without DOTS" scenario. Given this, the population growth rate would also apply to the annual benefit flows such as the real labour productivity growth. Thus, if real labour productivity growth is more than 3% p.a. or the number of TB patients without DOTS grow at some positive rate, our calculated figures for potential benefits remaining the same, the corresponding discount rates would be higher to that extent.

All the benefits are estimated considering five alternative discount rates, viz. 5%, 7%, 10%, 13% and 16%.[9] This range should cover any realistic expectations of return on capital since all these calculations are in real terms or at constant base year (1993-94) prices. These discount rates are therefore real rates of interest. If the benefits exceed the costs despite a 16% discount rate, the nominal rate of return on the investment would be (16% + inflation rate). This is likely to exceed 20% to 22% if inflation runs at 4% to 6% per annum. A discount rate as low as 5% is considered here because ideally, these benefits from DOTS should be discounted at the social time preference rate (STPR) which is estimated at 5% for India.

The second parameter where we have preferred to consider alternative sets of estimates is the mortality due to TB. There are two usable sets of estimates of the deaths due to TB in the country — having dimensionally very different estimates. Murray and Lopez (1996) estimates of death rates due to TB provide a very high estimate of TB deaths consistent with the old 1955-58 NSS Survey. As against this, the Survey of Causes of Death in 1993 gives a substantially lower mortality due to TB. Since deaths averted at present and in future are very important components of economic benefits of DOTS, we have considered both the sets of estimates as alternatives. We summarise the potential economic benefits of DOTS in India in Table 12.1.

It can be seen from the table that the DOTS strategy to cure TB in India is beneficial even at higher discount rates. As the discount rates increase, the present value of all future economic benefits falls dramatically from 66% of GDP in 1993-94 at a 5% discount rate to only 5% of GDP in 1993-94 at a 16% discount rate with Murray and Lopez estimates of mortality due to TB. More conservative estimates are obtained when we use the Survey of Causes of Deaths estimates of TB mortality. Even with these most conservative estimates of TB mortality, the present value of all future potential economic benefits of DOTS turns out to be about 4% of GDP in 1993-94 at a 16% discount rate.

DOTS is potentially highly beneficial even when we consider extremely high discount rates such as 16%. Even then and with the most conservative set of estimates, the present value of all future potential economic benefits of DOTS to the Indian economy turns out to be at least 3.8% of its GDP in 1993-94 or about Rs.266 billion or USD 8.3 billion in 1993-94. If the present value of the stream of future costs in successfully implementing DOTS works out to anything less than 3.8% of the GDP at factor cost in the country, the effective rate of return from DOTS would be at least 16% in real terms. Since the budget and other managerial inputs required to successfully implement DOTS in India are most likely to be less than 3.8% of GDP, DOTS represents an opportunity to step up India's economic growth in future. (Rough projected costs for successful DOTS implementation throughout India are of the order of 200 million US dollars per year, lower than the benefits of at least USD 750 million per year — *Editor's note*). Moreover, there can be few better examples of a project which offers accelerated growth with significant social justice because its poverty alleviating and equity promoting effects are known to be substantial.

XIII. Benefits of DOTS with gradual coverage of population

As mentioned in the beginning of the Section XII, the estimates of the potential benefits of DOTS presented so far have been derived on the basis of the following two assumptions:

- DOTS can and will succeed in effectively tackling TB in India; and
- Coverage of the population with DOTS is full and instantaneous.

It can be readily seen that the second one is an extreme assumption primarily made to get an idea about the potential benefits DOTS can offer in India. In a geographically large and relatively densely populated country like India, instantaneous coverage of 100% population by any TB cure programme like DOTS may appear to be almost infeasible. This is not only because trained manpower, organisational and management inputs required for such a task must first be generated, but also because such large investments might exceed readily available finances.

TABLE 12.1

Potential economic benefits of DOTS in India (in Rs. Billion)* at 1993-94 prices

Economic Benefits	Discount Rates 5%	7%	10%	13%	16%
1-A Reduction in Prevalence of TB in First Year of DOTS	12.30	12.20	12.20	12.20	12.20
1-B Reduction in Prevalence of TB in Subsequent Years	609.91	304.95	174.26	121.98	93.83
Sub-Total (1A+1B)	622.11	317.15	186.46	134.18	106.03
2-A Deaths Averted in the First Year of DOTS – Set A	73.75	59.06	45.34	36.82	31.04
2-B Deaths Averted in the Subsequent Years – Set A	3961.07	1549.30	657.36	362.15	228.01
Sub-Total (2A+2B)	4034.82	1608.36	702.70	398.97	259.05
2-C Deaths Averted in the First Year of DOTS – Set B	43.53	34.55	26.11	20.89	17.40
2-D Deaths Averted in the Subsequent years – Set B	2424.99	943.83	396.06	215.80	134.60
Sub-Total (2C+2D)	2468.52	978.38	422.17	236.69	152.00
3 Release of Hospital Beds	25.96	18.54	12.98	9.98	8.11
Total with Set A (1+2+3)	4682.89 (66.2%)	1944.05 (27.5%)	902.14 (12.8%)	543.13 (7.7%)	373.19 (5.3%)
Total with Set B (1+2+3)	3116.59 (44.1%)	1314.07 (18.6%)	621.61 (8.8%)	380.85 (5.4%)	266.14 (3.8%)

**Rs. 1 Billion = Rs. 100 Crores.*

Notes:

1. Figures in parentheses are percentages to the GDP in the base year 1993-94 at current prices.
2. Set A is based on Murray and Lopez (1996) Mortality Rates.
3. Set B is based on Survey of Causes of Death Mortality estimates.

Source: See the text, Tables 8.2, 10.1 to 10.5 and 11.3.

TABLE 13.1

Economic benefits of DOTS (TB Cure) in India with alternative patterns of coverage (Rs. in billion at 1993-94 prices)

Alternative Phasing Patterns for DOTS	Discount Rates 5%	7%	10%	13%	16%
A) Total Present Discounted Value of Benefits					
1. Instantaneous Coverage	2805 (39.7%)	1183 (16.7%)	559 (7.9%)	343 (4.9%)	240 (3.4%)
2. 5 Year Linear Coverage	2697 (38.1%)	1095 (15.5%)	490 (6.9%)	286 (4.0%)	191 (2.7%)
3. 10 Year Linear Coverage	2507 (35.5%)	998 (14.1%)	420 (5.9%)	232 (3.3%)	14 (2.1%)
4. 15 Year Linear Coverage	2451 (34.7%)	912 (12.9%)	363 (5.1%)	191 (2.7%)	11 (1.7%)
5. 10 Year Non-Linear Coverage*	2603 (36.8%)	1022 (14.5%)	436 (6.2%)	243 (3.4%)	156 (2.2%)
B) Annualized Benefits					
1. Instantaneous Coverage	140 (2%)	83 (1.2%)	56 (0.8%)	46 (0.6%)	38 (0.5%)
2. 5 Year Linear Coverage	135 (1.9%)	77 (1.1%)	49 (0.7%)	37 (0.5%)	31 (0.4%)
3. 10 Year Linear Coverage	125 (1.8%)	70 (1%)	42 (0.6%)	30 (0.4%)	24 (0.3%)
4. 15 Year Linear Coverage	123 (1.7%)	64 (0.9%)	36 (0.5%)	25 (0.4%)	19 (0.3%)
5. 10 Year Non-Linear Coverage*	130 (1.8%)	72 (1%)	44 (0.6%)	32 (0.4%)	25 (0.4%)

**Effective coverage for successive years are 5%, 10%, 15%, 15%, 15%, 10%, 5%, 5%, 5% and 5%.*

Notes:

1. All these calculations are based on the assumption of effective total coverage of 90% of population by DOTS.
2. The benefits are based on more conservative survey of causes of deaths estimates of TB deaths.
3. Figures in parentheses are percentage of Gross Domestic Product in 1993-94 at current prices.
4. The discounting of benefits are done by assuming real growth of 3% p.a. in the labour productivity in the Indian economy over time, and with no growth of TB patients in the "without DOTS" scenario. These are most conservative assumptions.

Source: Calculated by taking Table 12.1 as the base.

In order to guard even more carefully against any possible overstatement of the economic benefits of DOTS, the following steps are taken. Assume that the DOTS services may be able to reach effectively 90% of the population in any unit area unless special efforts are made to reach the last 10%. The hard-to-reach (last) 10% in each area unit is likely to be covered by special augmentation of DOTS efforts to overcome hurdles of varying and often unknown difficulty. Therefore, for all practical purposes, the most conservative estimate of the benefits of DOTS should consider no more than 90% effective coverage in any area unit serviced by DOTS.

We may now consider a few alternative phasing in patterns for DOTS implementation eventually to cover the whole population of India. The important considerations in phasing in of coverage by DOTS are:

- training of the personnel;
- organisational and management inputs needed;
- supply of medicines;
- budget allocation for the programme.

All these concerns get finally translated into the number of years required and the exact distribution of the coverage of the total population. We may consider the following options assuming that 90% of a "covered" population gets effective DOTS services.

- Instantaneous full coverage, i.e., 90% effective coverage in the first year.
- 5 years with 18% effective coverage every year.
- 10 years with 9% effective coverage every year.
- 15 years with 6% effective coverage every year.
- 10 years with effective coverage of 5%, 10%, 15%, 15%, 15%, 10%, 5%, 5%, 5%, and 5% respectively in successive years.

The results are presented at the same five alternative discount rates for these five alternative patterns of coverage of DOTS in India in Table 13.1.

It can be readily observed from the table that phasing in reduces the present discounted value of the benefits at any given discount rate. Similarly, the economic benefits also decline for the given type of phasing in of DOTS implementation as the discount rate rises. ■

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Appendix 1:

The methodology can be described through symbols as follows:

Let P_i, U_i and R_i be the average labour productivity in the i-th sector in the whole economy, urban area and rural area respectively; and u_i and r_i be the proportion of workers in the i-th sector in urban and rural areas respectively. Then,

$$P_i = u_i U_i + r_i R_i \text{ and if } U_i / R_i = \propto_i \text{ then,}$$

$$R_i = P_i / (\propto_i u_i + r_i) \text{ and } U_i = \propto_i P_i / (\propto_i u_i + r_i)$$

Estimates of P_i, $\propto_i$, u_i and r_i are available as described in the text. Hence, estimates of U_i and R_i are obtained. Multiplying these productivities with respective workers, we can get the respective income estimates.

Appendix 2:

The methodology for estimating the average labour productivity for child and adult workers by sector and area is as follows: (see Table 4.2).

Let P_i, C_i and A_i be the average productivities of all workers, child workers and adult workers in the i-th sector of the given area respectively; and c_i and a_i be the proportion of workers in the i-th sector of the given area belonging to the age groups 5-14 years and 15+ years respectively. Then,

$$P_i = c_i C_i + a_i A_i \text{ and } C_i = (1/3) P_i \text{ by assumption.}$$

$$\therefore \phi 0 \; A_i = P_i (3 - c_i)/3a_i$$

Estimates of P_i, c_i and a_i are available from Table 4.1 and Table 3.2.

Appendix 3:

The methodology is for calculating the productivity of young and old adult workers (see Table 4.3) as follows:

Let A_i, Y_i and O_i be the average productivities of respectively the adult (15+ age) workers, young adult (15-44 age) workers and old adults (45+ age) workers in the i-th sector of the given area and y_i and o_i be the proportion of workers respectively in the young and old adult workers in the i-th sector of the given area. Then,

$$A_i = y_i Y_i + o_i O_i \text{ and } O_i = 1.76 Y_i;$$

as described in the text.

$$\therefore \phi 0 \; \Psi_i = A_i / (y_i + o_i * 1.76) \text{ and } O_i = 1.76 \; A_i / (y_i + o_i * 1.76)$$

Estimates of A_i, y_i and o_i are available from Table 4.2 and Table 3.2.

Appendix 4:

The methodology used to calculate the productivities by sex, sector, age group and rural/urban residence is as follows:

Let YP_i, YM_i and YF_i be the average productivities of respectively the young adult (15-44 age) workers, young adult male workers and young adult female workers in the i-th sector of the given area; and ym_i and yf_i be the proportion of young male and female workers in the i-th sector of the given area. Then,

$$YP_i = ym_i\, YM_i + yf_i\, YF_i \text{ and } YM_i = 1.28 * YF_i$$

as described in the text.

$$\therefore \phi 0\ \Psi\Phi_i = YP_i/(1.28\, ym_i + yf_i) \text{ and } YM_i = 1.28\, YP_i/$$

$$(1.28\, ym_i + yf_i)$$

Similarly, we get,

$$OP_i = om_i\, OM_i + of_i\, OF_i \text{ and } OM_i = 1.41 * OF_i$$

as described in the text.

$$\therefore \phi 0\ O\Phi_i = OP_i/(1.41 * om_i + of_i) \text{ and } OM_i = 1.41 * OP_i/$$

$$(1.41 * OM_i + of_i)$$

Estimates of YP_i, ym_i, yf_i, OP_i, om_i and of_i are available from Table 4.3 and Table 3.2.

Endnotes

1. Since the higher the prevalence of TB the greater the predicted benefits of the DOTS strategy, the lowest estimate of prevalence of TB is used for the most conservative estimate.

2. Actually the summation of the two would provide an upper limit to the average age of death occurring currently. Thus, this is a conservative assumption to estimate the benefits of DOTS due to deaths averted.

3. We have made calculations at these effective rates of discount. The advantage is that the calculations and the numbers do not change if we change our assumptions about the growth of labour productivity and/or the growth in the TB cases and TB deaths in future. Thus, if it is assumed that labour productivity would grow at 3% p.a. and TB deaths at 1% p.a., the rates of discount corresponding to our effective rates of discount would be 6%, 8%, 11%, 14% and 17%, and so on.

4. The costs of TB cure to the society would include the expenditures incurred by the patients and the expenditures with subsidies by the government and non-government sectors on TB cure. The consistent costing exercise would consider only additional costs "with DOTS" over "without DOTS" scenario just as the benefits of DOTS are estimated in the present study in terms of additional benefits "with DOTS" over "without DOTS".

5. The weights for rural areas and urban areas are taken as 0.7 and 0.3 respectively as per the cases of hospitalization reported by Visaria et al. (1994) pp.4.

6. A discount rate of 16% is taken here because the implied economic rate of return in the VIII Plan estimates for achieving the growth rate of 5.6% during the Plan period was 16%. For details of calculations and implications, see Dholakia, Ravindra H. (1993).

This is essentially the estimate of the "expected" social rate of return on capital in India. Thus, the discount rates considered here are in the range of social time preference rates and social rate of return on capital in India.

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Gender as a determinant of health

The gender concept was first used in the 1970s to describe those characteristics of men and women which are socially constructed, in contrast to those which are biologically determined. Essentially, the distinction between sex and gender aims to emphasize that everything women and men do, and everything expected of them, with the exception of their distinct biological functions (for women, pregnancy, childbirth and breast-feeding) can and does change over time, and according to changing and varied social and cultural factors. But in practically all cultures the role of women is subordinate to that of men. They are taught what the appropriate behaviour and attitudes, roles and activities are for them, and how they should relate to other people. This learned behaviour is what makes up gender identity and determines gender roles.

A gender approach to health moves beyond describing women and women's health in isolation, but rather brings into the analysis how the different social roles, decision-making power and access to resources between women and men affect their health status and their access to health care. It examines how these differences determine, for example, differential exposure to risk, access to the benefits of technology, information and services, and the ability to protect oneself from disease and ill-health.

■ *The world health report 1997 – Conquering suffering*

Round Table

Tuberculosis control – is DOTS the health breakthrough of the 1990s?

Arata Kochi

The resurgence of tuberculosis in recent years has made an effective control strategy indispensable. The strategy exists and is called DOTS – Directly Observed Treatment. Short-course. It has proved its effectiveness and now needs to be used worldwide on a much larger scale.

In the five years since the Directly Observed Treatment, Short course (DOTS) was adopted by WHO as a strategy to combat tuberculosis worldwide, more than 2 million people have received this treatment. Most of them are young and middle-aged adults, and more than 900 000 of them had the infectious, smear-positive form of the disease. If they had access only to the treatment previously available in their countries, many of them would almost certainly have died, and many more would have become chronic cases, spreading the disease in their communities. It is, in fact, these chronic cases resulting from poor or interrupted treatment, that become the main source of the deadly drug-resistant strains of tuberculosis.

Proven effectiveness

In this wide variety of infected populations, the DOTS strategy achieved an overall cure rate of nearly 80%, with a range from 70% to 95%. Most of these cases were found and treated within the past two years, as the mobilization of the DOTS strategy began in earnest. Measured in adult lives already saved as well as the potential to save millions more in the years immediately ahead of us, no other new health intervention of this decade has achieved such significant results or been of such thoroughly proven effectiveness in the field. If backed by the modest investment needed to expand the DOTS strategy and make it available to the millions now infected with tuberculosis, this breakthrough can begin to have a major impact on the global tuberculosis epidemic.

Chronic cases, resulting from poor or interrupted treatment, become the main source of the deadly drug-resistant strains of tuberculosis.

Dr Kochi is the Director of the Global Tuberculosis

DOTS, especially in the 15 countries hardest hit by endemic tuberculosis, could cut the incidence rate of the disease in half in 10–15 years. An estimated 10 million deaths from tuberculosis could be averted in that span of time. In practice, DOTS is still a strategy waiting to be used. In 1993, when the system was first fully defined, no more than 2% of the active tuberculosis cases worldwide were treated by this method. Today, the estimated figure is nearly 12%, which reflects a remarkable rate of expansion, but is far from enough. For millions of people with tuberculosis the system is still inaccessible.

In 1993, when the system was first fully defined, no more than 2% of the active tuberculosis cases worldwide were treated by this method. Today, the estimated figure is nearly 12%.

Preliminary WHO epidemiological studies suggest that, after rising for decades, the rate of increase in the burden of new tuberculosis cases may begin to decline as DOTS expands. Today, the global tuberculosis epidemic remains a leading destroyer of lives. This year, 1997, its death toll will still be between two and three million. But it now appears possible, although not yet certain, that the global epidemic may be peaking.

Deploying DOTS more widely to take advantage of the opportunity it offers in curing patients and preventing the spread of infection is going to require substantial resources and a sustained public policy commitment, particularly in the 15 countries that are host to some 75% of all active cases of tuberculosis (see table). The

Countries suffering the highest incidence of tuberculosis in 1995

Countries	Estimated number of new cases (000s)	Estimated incidence rate (cases per 100000 population)
India	2059	220
China	1038	85
Indonesia	436	220
Philippines	270	400
Bangladesh	265	220
Nigeria	248	222
Pakistan	211	150
Russian Federation	146	99
Zaire	146	333
Brazil	129	80
Viet Nam	124	166
South Africa	104	250
Thailand	102	173
Myanmar	88	189
Ethiopia	85	155

ened immune systems of people with HIV helps tuberculosis to spread more rapidly in the population; in many places, 30%–50% of people with HIV infection also develop tuberculosis.

Unlike some major breakthroughs in health care, DOTS is not the direct outcome of recent basic or clinical research, but of subsequent operational research. The drugs used for treatment in the DOTS system are not new. They have been available for three decades and have been almost 100% effective in curing tuberculosis when used correctly. Prior to the DOTS strategy, the proper use of these drugs was often limited to hospitals, since progress could be carefully monitored. It was this kind of care, coupled with improved methods of case-finding, that enabled western Europe and North America to succeed in minimizing and largely containing tuberculosis as a public health threat during the last 30 years.

But hospitalizing a majority of tuberculosis patients is not an option for the countries in which this disease is now most endemic. Nor is it necessary. The DOTS strategy makes it possible to carry out case-finding, chemotherapy and patient monitoring effectively without hospital care. The 6–8-month course of treatment limits further transmission of the tubercle bacillus by making each case uninfectious, usually within the first two to four weeks of treatment. It is an approach that can be used anywhere. Where there is precise classification of each patient's treatment history, uninterrupted and observed delivery of treatment to each patient, and careful monitoring of each patient's progress, a very high cure rate can be achieved.

In many developing countries the health services have tried to stem the tide of tuberculosis by simply giving patients medication to take at home, without supervision and without determining whether they are dealing with a new case or one that has been treated before. This approach usually fails to cure the patients or to check the spread of the epidemic, and, in fact, actually often makes matters worse. Where cure rates are low, there is a pool of chronic cases which continue to spread infection. Furthermore, a consequence of repeated ineffective treatment is drug resistance, which spreads strains of tuberculosis that are today virtually im-

The DOTS system was designed primarily for use with large, usually poor rural and urban populations. It involves careful definition and application of each component of the treatment regimen and delivery methodology, and close monitoring of each patient's progress. When systematically applied, it results in permanent cures. The strategy was field tested and refined in countries as diverse as Bangladesh, Benin, China, Guinea, Malawi, Morocco, Nicaragua, Peru, the United Republic of Tanzania, the United States of America (New York City) and Viet Nam, and has now been adopted as the national TB control policy in over 70 countries.

Using standardized dosages of a combination of drugs, permanent cure rates in large populations average 85%. In some provinces of China proven cure rates among new cases have been as high as 94%, where methods previously in use had success rates of 30%–40%. In Peru, where DOTS has now been used extensively for three years, the treatment completion rate is 88% and the overall rate of new cases has begun to decline.

The DOTS strategy makes it possible to carry out case-finding, chemotherapy and patient monitoring effectively without hospital care.

The low cost per patient of the DOTS strategy and its effectiveness without hospitalization makes the treatment affordable and accessible in developing countries where the majority of cases occur. The actual cost of curing a patient varies, of course, from country to country, but US$ 100–200 is a fairly reliable bench-

case. The treatment can be administered by health workers and community volunteers after adequate training. This keeps the cost to a minimum, and enables the health system to concentrate on supervising workers, monitoring the progress of patients, keeping accurate records, and ensuring reliable laboratory services. In doing this they not only control tuberculosis but may well improve the health service as a whole.

Another important advantage of the DOTS system is that it makes it possible to set precise and attainable goals for public health services. WHO's worldwide goal is to treat successfully 85% of all new active (smear-positive) TB cases and to detect 70% of such cases by the year 2000. We calculate that, with adequate support, this would be possible for the majority of countries in which tuberculosis is endemic, with some large countries still reluctant to

WHO's worldwide goal is to treat successfully 85% of all new active (smear-positive) TB cases and to detect 70% of such cases by the year 2000.

deploy the DOTS strategy widely, such as Brazil, India, Pakistan and the Russian Federation, requiring another decade to reach this goal. If this is achieved and sustained, the risks of contracting tuberculosis will decline drastically, falling by half every 10–15 years. Thus it would become possible to think in very specific terms about a strategy for eliminating this disease as a public health threat in the next century.

Of equal importance is the fact that the DOTS strategy provides the best known defence against the development of multidrug-resistant strains of *Mycobacterium tuberculosis*. The incidence of such cases, which are the result of repeated incomplete or unsuccessful drug therapy, is still largely undocumented. It is a cause for serious concern in countries with poor control services, and is too much of a danger to ignore in any circumstances, since it is extremely difficult and expensive to treat. In the United States and Western Europe, mortality rates of 30%–50% have been the norm. In developing countries the chances of being cured of it are very small indeed.

Although the effectiveness of the DOTS strategy is unquestionable, we must recognize its limitations. With the diagnostic and treatment tools currently available, tuberculosis cannot be eradicated globally as smallpox was, although elimination may be conceivable in some rich countries. Even in the most optimistic epidemiological scenarios, a significant proportion of the global burden of tuberculosis (perhaps more than 20%) will survive even the most rigorous and complete application of the DOTS strategy. This is partly because sputum microscopy does not detect smear negative cases and no currently available method of screening can reliably detect all TB cases. In addition, infection with mutidrug-resistant strains of the bacillus is becoming more widespread.

While better tools for the strategy are being developed, the current DOTS package needs to be deployed aggressively and globally. Each dollar invested in it will yield a high return both in human health and in increased economic activity. A recent study estimates that phasing in comprehensive coverage of India with the DOTS strategy over the next two decades would yield a net benefit to the economy of US$ 8300 million, equivalent to 1% of India's gross domestic product.

Key components of the DOTS strategy

To launch a successful DOTS programme, the following key components must be put in place.

- ***A network of trained workers able to administer directly observed therapy at least for the first two months.*** They must be supported by health supervisors who can monitor and report patient progress in locations that are readily accessible to those under treatment. With effective supervision, directly observed treatment providers do not need to be trained health professionals and can even be volunteers. However, if the programme is to succeed, the patients must not be faced with too much difficulty in the form of distance, cost, inconvenient times or other obstacles to access. Today, regions in Bangladesh are achieving consistent cure rates of 85% in rural areas with little infrastructure by delivering directly observed therapy through village women. Most of the women doing this work are illiterate, but they are trained, given incentives and closely supervised. Perhaps most importantly they are – unlike the majority of trained health professionals – living near their patients and readily accessible to them, and are thus ideally placed to ensure that the drugs are taken without fail and on schedule, and that treatment is completed.
- ***Laboratories with personnel equipped and trained to recognize tubercle bacilli in sputum smear samples.*** There should be one such laboratory, capable of returning sputum test results within one day, for every 50 000–150 000 people in the population. In addition to detecting new cases of tuberculosis, the laboratories are pivotal in monitoring patients' progress towards cure by examining sputum samples collected at scheduled intervals. No one is assumed to be cured after completing the course of treatment.

Today, regions in Bangladesh are achieving consistent cure rates of 85% in rural areas with little infrastructure by delivering directly observed therapy through village women.

Each patient must be proved by laboratory test to be cured.

- ***A dependable supply of high-quality drugs.*** The drugs required are isoniazid, rifampicin, pyrazinamide, and streptomycin or ethambutol. The primary cause of failed treatment is interruption, which can be caused as easily by a supply failure as by patient non-compliance. Poor quality is also a risk factor. The use of substandard drugs manufactured without proper quality control or dating, or with deficient bioavailability, can also result in treatment failure and drug resistance.
- ***An accurate record-keeping and cohort analysis system for monitoring case-finding, treatment and outcomes.*** Working case by case and district by district, record-keeping is of central importance in providing the information needed to manage the DOTS system in local and national TB control programmes. Cohort analysis tracks the outcome of every TB patient registered for treatment each quarter. This provides an ongoing performance measurement by indicating how many are cured, discontinued treatment, died, etc. It can also raise warning flags. An unexpectedly low number of new TB cases in a new cohort, for instance,

would signal the possibility of a failure in the case detection process. By closely monitoring case and cure rates, programme managers can allocate resources, personnel, training and medication for maximum results at minimum costs. Good records and cohort analyses also show where communities and districts are failing to achieve target cure rates, so that managers can intervene quickly with the necessary support.

> ***The patient's ability to pay should never influence the decision to provide treatment.***

- ***Sustained political commitment and funding.*** This is required to support each key component of the DOTS strategy. Because the benefits of effective treatment accrue not only to the patient but to the local community and society as a whole, it makes no sense to attach conditions to the availability of treatment. The patient's ability to pay should never influence the decision to provide treatment.

The importance of directly observed therapy in the DOTS strategy

Directly observed therapy is only one part of the DOTS strategy, but it is a pivotal part. Curing tuberculosis requires the scrupulous adherence by patients and doctors to a precise schedule of medication for at least the first two months of treatment, and ideally for the complete six to eight month course of therapy. Voluntary compliance by unsupervised patients is, not surprisingly, very often poor. Symptoms usually disappear within the first two to four weeks of treatment, and when patients no longer feel sick they feel no pressure on them to continue treatment. The schedule of medication is daily or every other day, and each dose consists of a combination of drugs. The temptation to stop taking the pills is powerful, particularly for those in developing countries for whom the treatment may be costly, either directly in charges for medication or indirectly in time and travel costs to a public health facility or a private practitioner.

Though non-compliance is highly understandable it must not be tolerated because it can build up multidrug resistance and spread infection to others. Therefore, health workers who administer directly observed therapy also have the responsibility of contacting and convincing any patients who miss an appointment to resume their treatment. Good rapport between the treatment provider and the patient can be an important factor in the success of the treatment.

Strategic questions

DOTS promises to lead us a long way towards defeating the TB epidemic, but not the whole way. Defeating the tuberculosis epidemic demands sustained commitment to operational, basic and clinical research.

Diagnostic tools

The most immediate need is for diagnostic tools that are more sensitive, produce results more quickly and are easier to use. This would help to make DOTS available more widely. The diagnostic method in current use, of examining a sputum smear by microscope for the presence of the tubercle bacillus, was discovered in 1882. Although the technique and equipment have been refined since then, it is still a labour-intensive and time-consuming method, both for health workers and for patients.

Sputum microscopy can only detect cases that are actively disseminating germs at the time of examination, and not always even then. And in many cases it cannot reliably detect the presence of tuberculosis in people with HIV/AIDS. The WHO Tuberculosis Diagnostics Initiative is working with researchers in industry to speed the development of a new, simpler and more user-friendly diagnostic tool. One promising area of enquiry focuses on a clinical specimen test (such as blood or urine) that would reveal the presence of TB bacilli by the generation of antibodies, and the presence of disease by the quantification of specific antigens.

Drugs

Efforts to combine the different drugs used in the DOTS regimen into single tablets of consistent quality may succeed in the near future. This will simplify the ordering, stocking and management of drugs and eliminate the risk of patients failing to take all of the drugs required. It would also make for further improvement by reducing the cost of treatment.

But at this stage, a major difficulty is the sheer physical quantity of medication needed to destroy the TB bacilli. The ideal alternative would be a vaccine to prevent the outbreak of disease among the 2000 million people already infected with TB bacilli. However, this is still only a remote prospect, with a timeline for research and testing that could easily extend to 20 or 25 years or more. In that period, the continued expansion and improvement of DOTS is expected to reduce the global burden of tuberculosis by a quarter, and to continue this progess at a rate which makes the risk of being newly infected with tuberculosis decline by half every 10–15 years.

Expecting the unexpected

Nonetheless, we also need to be aware that unforeseeable events can make such projections invalid. In the past decade we have witnessed the emergence of HIV as an accelerator of new tuberculosis infection, as well as the increasing occurrence of multidrug-resistant strains. The breakdown of health and other services in the former Soviet Union has also led to a sharp increase in both the incidence and the case fatality rate of tuberculosis that would not have been predicted less than a decade ago. With mounting concerns about

> ***At this stage, a major difficulty is the sheer physical quantity of medication needed to destroy the TB bacilli.***

antibiotic resistance, emerging diseases and economic instability, nothing can be taken for granted.

Making the DOTS strategy work effectively worldwide to reduce the morbidity and mortality caused by tuberculosis and to combat the emergence of deadly multidrug-resistant strains is ambitious but certainly feasible. It is a pragmatic approach which does not depend on the potential development of a new "magic bullet" drug or vaccine. Everyone would be glad to see DOTS enhanced or superseded by a quicker and more powerful

drug therapy or a vaccine. But even if such a "new generation" product were now in development, it could take at least 15–25 years to reach the market. What we can anticipate, however, are new tools for the DOTS strategy.

Although DOTS has won recognition as one of the most cost-effective interventions available for protecting and enhancing human health, resistance to it on the part of national health authorities is still common. Sometimes this is because TB patients are seen as a low priority in an environment where resources are desperately scarce. Sometimes, even where the gravity of the problem is recognized, there is the fatalistic feeling that nothing can be done about it. To correct these dangerous misconceptions, two facts must be kept clearly in mind. First, tuberculosis is a disease to which few people are immune, and which spreads quickly, causes great suffering and tends to kill people in their most productive years. Second, it can be brought under control effectively if the necessary steps are taken to implement the DOTS strategy. ■

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Adoption of the DOTS strategy

Over 80 WHO Member States have adopted, or are starting to use, the DOTS strategy, with an increase in cure rates to 90% in some countries. WHO continues to identify ways to facilitate DOTS adoption in different environments. An operational research project in Malawi improved the efficiency of diagnosis and treatment. Studies are under way to show the potential economic benefits of DOTS in India and how good-quality care might be delivered through a network of private providers. Advocacy workshops help translate programme review findings into action, and WHO's new training modules, "Managing tuberculosis at national level", and guidelines aim to reinforce national technical expertise (e.g., tuberculosis control among refugees, and the management of drug-resistant tuberculosis). A new WHO newsletter, the "TB treatment observer", highlights the success of DOTS in many countries.

■ *The world health report 1997 – Conquering suffering, enriching humanity.* Geneva, World Health Organization, 1997: 88.

Discussion

Don't let's wait another 40 years

John Crofton

My main qualification for commenting is that I am old enough to have participated in the first British Medical Research Council (BMRC) trials of streptomycin in 1947–8 and in our subsequent demonstrations in Edinburgh in the 1950s that 100% cure of pulmonary tuberculosis, with no relapse, could be a reasonable aim (even with the drugs then available: streptomycin, isoniazid and para-aminosalicylic acid). I have had subsequent experience of tuberculosis problems in most parts of the world. The BMRC in India demonstrated in the late 1950s that hospital or sanatorium treatment was unnecessary and subsequently in Africa that relapse could be prevented by six to eight months of treatment if it included rifampicin and pyrazinamide. But for many years no national service in a developing country succeeded in achieving anything like the cure rates demonstrated in research projects.

The answer to this sad failure came primarily from the leadership of Dr Karel Styblo, Annik Rouillon and their colleagues at the International Union Against Tuberculosis and Lung Disease (IUATLD). They showed that it was possible to persuade governments of poor countries that tuberculosis was a major problem for their own countries, and that by good organization, good supervision, training and retraining, it could be effectively controlled through their routine health services, using the DOTS method which the IUATLD had pioneered. Such success, of course, depended on good leadership in the country itself. Tuberculosis had often been neglected by the health services and sometimes failed to attract able physicians. But with national government support, international interest, and the ongoing success of pioneer projects, this has started to change, and it has been heartwarming to see the emergence of so many able national leaders who have achieved so much even in the poorest countries.

> ***We demonstrated in Edinburgh in the 1950s that 100% cure of pulmonary tuberculosis, with no relapse, could be a reasonable aim (even with the drugs then available: streptomycin, isoniazid and para-aminocalicylic acid).***

The success of these early programmes supported by IUATLD, and the demonstration of their high cost-effectiveness by the World Bank, has led to the outstanding work being done by Dr Kochi and his team, in cooperation with the World Bank, in progressively extending the DOTS method globally in high-prevalence countries.

Dr Kochi in his article outlines some of the initial successes and the potential for advance towards global control if the

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method can be universally applied. Understandably, the initial successes have resulted in a certain amount of euphoria. It is tempting to extrapolate, to prophesy the relatively quick reversal of the present still escalating global tuberculosis problems resulting from both the explosion of the HIV epidemic and increases in population in poorer countries. I am glad to see that Dr Kochi does emphasize the many difficulties still to be overcome.

On the "supply" side, these difficulties for the main international bodies concerned, WHO and IUATLD, include the shortage of financial resources and the shortage of the skilled international staff needed to support the initiation of national programmes. Fortunately the situation is improving, though still much too slowly.

On the operational side, there is the difficulty of persuading some governments of the importance and feasibility of control. There can be the difficulty of finding

Obstinate individualism is the enemy of cooperative success.

and supporting outstanding national leaders. There are the problems of chaotic treatment by ignorant or unscrupulous doctors, responsible for causing so much multidrug resistance. In some cases such "doctors" may not be qualified in Western medicine although they abuse Western drugs. Unfortunately in some countries medical schools may be using and teaching outdated methods and may fail to cooperate effectively in implementing a national programme instituted along WHO lines. In some countries, certain sections of the commercial drug industry may also be unscrupulous. They may provide unreliable drugs, or their commercial representatives may persuade doctors to use unreliable treatments.

It is often more difficult to implement DOTS in cities, where private practitioners are numerous and there are many vested interests within the government, nongovernmental and academic institutions concerned. It is particularly difficult to coordinate all these into the single organizational plan which is so essential. Obstinate individualism is the enemy of cooperative success.

These are some of the great challenges which remain. But I am deeply encouraged by the challenges which have already been overcome. It gives me hope that these others will in due course be dealt with effectively. I am also immensely encouraged by the quality (but not yet the quantity!) of international expertise now available through WHO and IUATLD, and by the ongoing support of tuberculosis control by the World Bank.

Finally, I do congratulate Dr Kochi on his balanced, yet hopeful, article on progress in attempting to control one of the world outstanding medical challenges. For the last 40 years the problem has been theoretically soluble. Now at last there is some hope that in the next 40 it might actually be solved, or at least be on the way to being solved. How much misery and death, and how much unnecessaary expenditure, could be avoided! ■

A breakthrough in Peru

Hugo Guillermo Suárez A.

The tuberculosis situation can be seen as an indicator of national development. The higher the prevalence of tuberculosis the more evident are the shortcomings of the health care system, which in its turn is a reflection of the cultural and socioeconomic situation of the country. This viewpoint is needed for an understanding of the introduction and use of the DOTS strategy in Peru.

Peru's Tuberculosis Control Programme is based on the following strategic principles:

- sustained political, technical and financial commitment to ensure the viability of the programme;
- combining the approaches of public health and individual care;
- enhanced management capacity at all levels of responsibility;
- integrated activities at all health facilities, from health outposts to hospitals;
- use of scientifically sound and effective technology which is also affordable and acceptable to the population in which it is used;
- community participation in disease surveillance and control activities.

An important consideration for the Programme is that each patient who obtains timely and effective treatment saves up to 15 others from infection. Put negatively, each untreated case produces up to 15 others. The control of this disease is thus recognized as a social investment and a government responsibility for the well-being of individuals and society as a whole.

For these reasons the DOTS strategy was adopted by Peru in 1991. Adapting it to conditions in this country involves taking into account the particular cultural and behavioural characteristics of the patients, and introducing a continuous process of change and improvement in the health facilities. To carry out the necessary case detection activities and provide supervised treatment free of charge, it was necessary to ensure a continuing supply of laboratory equipment and drugs, train and motivate health workers, form multidisciplinary teams, and establish

Each patient who obtains timely and effective treatment saves up to 15 others from infection. Put negatively, each untreated case produces up to 15 others.

good relations with the community. Differences of language, culture and behaviour have presented difficulties in some parts of the country, often in the form of patient resistance to diagnosis and treatment. This obstacle is gradually being overcome in the process of establishing and expanding the programme.

The achievements of implementing the DOTS strategy can be summarized as follows.

- During 1996, diagnosis and treatment were provided free of charge to 47 438 TB patients. In the same year, the TB morbidity rate was 198.1 cases per 100 000 people, which represents a drop of 22.6% since 1992. Of the cases

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detected in 1996, 26 800 were smear-positive, which means a rate of 111.9 per 100 000, which is 30.5% lower than in 1993.

- In 1990, only 25% of the public health facilities carried out TB control activities, whereas by last year 97% offered public access free of charge to diagnosis and treatment.
- The number of laboratories in the country with personnel equipped and trained to recognize tubercle bacilli in sputum smear samples increased by 132%, from 425 in 1991 to 987 in 1996. The number of intermediate laboratories, in which the smear culture is made, more than tripled during the same period. The number of smear samples analysed rose from 211 000 in 1990 to 1 164 198 in 1996.
- In the 1980s, only 50% of the cases detected completed treatment successfully. In 1996 the average cure rate nationally was over 90%.

In conclusion, despite the increased case-finding that has taken place during the last six years, prevalence and incidence rates have declined. The results achieved in Peru show the epidemiological impact that can be achieved with DOTS when it is correctly carried out with sustained political commitment, adequate financing and good management. ■

In Nepal it is the breakthrough of the decade

Dirgh Singh Bam

The question of whether DOTS is truly the major health breakthrough of the 1990s has generated much discussion and comment. The first question that must be answered is: "Is it a breakthrough?", presumably meaning a recent and significant advance. Dr Kochi's summary of the DOTS strategy is very useful, and shows that DOTS is a strong management system which combines two relatively weak technologies – smear microscopy and short-course chemotherapy – in one disease control package. These technologies are not new; it is the management package that is the main advance. Perhaps the reason for the suggestion of a breakthrough arousing such controversy is that a managerial advance is less attractive and newsworthy than a technical one.

The second question is: "Does any other intervention introduced during this decade bring with it a greater potential benefit to health than DOTS?" It is difficult to think of either a managerial or a technical tool of comparable potential benefit in terms of numbers of lives saved, or of money saved. But, as Dr Kochi points out, so far these are only potential gains. The actual benefits of DOTS have yet to be realized because few countries have adopted the strategy widely enough. Perhaps this is a second reason for scepticism – that people want to see more evidence of the benefits of DOTS.

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It is my opinion that DOTS is the major health breakthrough this decade in Nepal. In 1994, WHO and His Majesty's Government conducted a joint review of the National Tuberculosis Programme. At that time we had been using unsupervised short-course chemotherapy for about four years, covering 25 of the 75 districts of Nepal. A further 40 districts used standard 12-month chemotherapy, and 10 remote mountain districts had no TB treatment services. Although some districts were achieving good results (mainly with the assistance of international non-governmental organizations), the majority had poor cure rates or could not show any results of treatment. The national cure rate was only 40%, and we registered only 30% of the patients estimated to be suffering from tuberculosis.

Over the next two years we worked hard to revise our National Tuberculosis Programme. We adopted the policy of using DOTS, established national guidelines for the Programme, introduced a national reporting and recording system, developed a programme of training and supervision for different levels of health workers, and established four model demonstration sites for DOTS.

Results have been spectacular: 86% of the newly diagnosed smear-positive patients registered in the DOTS centres were smear-negative after two months of treatment. We have just seen the first treatment outcome results: 87% cured! This is a very encouraging result and one we are all immensely proud of. This for me is one of the great benefits of DOTS that is perhaps not mentioned often enough: implementing DOTS, especially at the beginning, takes a lot of effort and hard work, but the results are so encouraging. Health workers see that they can make a difference, that their work is of value, and that they can be justifiably proud. For people who are used to working in developing countries, talk of government health workers being proud of their work may sound a little farfetched but it is true.

From a situation characterized two years ago by scepticism and opposition to DOTS, we have moved to one in which

For people who are used to working in developing countries, talk of government health workers being proud of their work may sound a little farfetched but it is true.

everyone wants to do DOTS but we do not have the capacity to train and supervise health workers fast enough to meet the demand. Even so, we have now managed to expand the number of DOTS centres to cover a population of 2.6 million, which is about 12% of the population of Nepal. Overall our national cure rate has risen to 58% with an additional 16% of patients completing treatment. We are now diagnosing about 50% of the estimated new cases occurring each year.

We do face significant challenges though. In our experience the DOTS model is best suited to rural populations of relatively high density with reasonable access to centralized health services provided mainly by the government. We have difficulties in adapting the strategy to urban areas in which the majority of TB patients are treated in the private sector, and to hilly districts where the nearest health service is as least four hours walk away – sometimes even several days – and there are no other means of transport.

In summary, DOTS is the health breakthrough of the 1990s in Nepal. There has been no other single health-related intervention with the potential to produce such an impact on health status so far this decade. However, we are a long way from realizing the full potential benefits of DOTS and there are several significant obstacles to be overcome in the future.

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Over the next few years we will need to find ways of adapting this important strategy to some of the more difficult local conditions in Nepal. ■

The view from World Vision

Milton B. Amayun

World Vision recognizes that tuberculosis today is an old scourge with a known cure. Health workers have known for years that, apart from its being curable, its spread can be contained through a combination of preventive and curative measures. Yet tuberculosis continues to contribute significantly to the disease burden of several countries. Why? Because there are poor people who have no access to the drugs that could cure them, and there are countries whose health systems do not have adequate resources to support a comprehensive TB control programme.

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The most important battle related to DOTS will not be between the drug and the disease, but over resources. Governments must recognize the long-term economic benefits of investing in controlling this disease. International donors must maintain and perhaps expand their current funding of TB control. The political and financial support of the public must be mobilized. Ministries of health must designate and train human resources to pursue case-finding and observe the treatment of individual cases up till the completion of the recommended regimen.

The fact is, to cure tuberculosis is not cheap. A conservative estimate for ensuring that a patient receives the full directly observed treatment short course is US$ 200, an amount beyond the reach of the many countries that allocate less than $5 per capita for all health services per year. In this era of budget cuts the allocation of scarce resources has to be weighed against other development priorities, or even equally deserving health programme

The effective control of tuberculosis will also not take place within the time frame for which most donors normally provide funding. The impact of AIDS, the prevalence of chronic cases and the existence of resistant TB bacilli indicate that it will take a whole generation, maybe more, to achieve worldwide control. Enough donors must be convinced that they need to support DOTS over the long term – perhaps for as long as tuberculosis continues to be a disease of public health significance.

The DOTS strategy is not new. Directly observed treatment was the norm when the hospitalization of patients was still seen as an essential part of TB control. It has been given new life now partly because of the rising prevalence of tuberculosis among the poor and the excluded in Western societies, and the danger this represents for other groups in the form of drug resistance resulting from unsupervised care. DOTS has been effectively "marketed" and the media have been responsive. We must not miss the opportunity this has given us to strike a decisive blow against this killer of children and adults.

World Vision has invested in TB control in many parts of the world. In Haiti we founded the Crusade against Tuberculosis, a nationwide control programme. Our Child Survival programmes around the world target the newborn for immunization with BCG. We are currently exploring a multicountry strategy in Asia to implement DOTS as part of our area development programmes. As an organization we are committed to making the DOTS strategy a long-term effort rather than a passing fad. We join ministries of health, international funding agencies, our private donors, communities and WHO in the current big push to promote it. We plan to be there until the disease can no longer be called a deadly scourge. ■

A good start

Samuel Lieberman

Dr Kochi's article provides a good account of why DOTS has generated interest among those concerned with TB control and prevention, and why this approach has been adopted for additional trials and even large-scale implementation in some countries. DOTS offers a means of bypassing conventional hospital-based treatment which entails high individual and public costs. Furthermore, DOTS tackles the risks of low cure rates, continuing spread of the disease from infectious cases, and the drug resistance associated with the earlier experimental strategies which avoided extended confinement of patients.

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At the same time, Dr Kochi's article hints at how formidable an effort may be required to put in place and sustain DOTS programmes, and what other policy steps may be needed to complement DOTS. His article acknowledges that assembling the key elements of DOTS – namely a network of well-trained and carefully supervised workers in the field, fully equipped laboratories with trained staff, good record-keeping and monitoring, and a dependable and ample supply of high-quality drugs – requires substantial resources and long-term policy commitment. Clearly, a major effort is entailed, which may have to go well beyond the "modest investment" Dr Kochi refers to.

What are some of the obstacles which DOTS programmes must contend with, and what can be done about them? First, there may be problems in fitting DOTS-related activities into existing primary health care programmes, assuming that such delivery "platforms" are available to be used. DOTS may become another unprioritized task added to the burdens of multipurpose workers who were already over-extended. These field staff, and their laboratory-based colleagues, may either resist such additional burdens or divert attention from other key activities; they may also demand incentive or service payments to carry out their assignments.

Careful microanalytic research is needed to see how DOTS is being accommodated in actual situations, what problems and trade-offs are arising, and how these are being resolved. In short, detailed information is needed on how DOTS is actually working in different settings, and the mechanisms which must be established to make this approach effective.

Clearly, a major effort is entailed, which may have to go well beyond the "modest investment" Dr Kochi refers to.

A different set of concerns arises where functioning and well-used primary health care systems are not in place. In these not unusual circumstances drugs may not be widely available, the pay, skills and morale of staff in public facilities may be low, and the quality of care offered by private providers may be substandard. Here the feasibility and affordability of DOTS would be likely to depend on the characteristics of the broad health system reform which may be under way or resorted to eventually. Reform programmes usually involve:

- greater decentralization of health decision-making, financing and delivery;
- rethinking of the roles of public and private providers in health;
- and greater reliance on regulatory mechanisms.

It would be useful to look at the implications for DOTS strategies of the different paths to health system reform being chosen.

A related set of challenges for DOTS arises out of the need to involve private providers. As noted, t[illegible] functioning publicly run care system that is taken for granted in many presentations of the DOTS strategy may be an unreachable ideal. In many if not most developing country settings, patients with tuberculosis typically visit private providers, who also need the skills and incentives to deliver high quality care. Fortunately, Dr Kochi and his colleagues in the Global Tuberculosis Programme have launched ingenious efforts to train and mobilize private providers, including schemes to franchise delivery of DOTS and to license private microscopy laboratories. These initiatives should be pursued and widened because of the likelihood, in view of the health reforms cited above, that the "normal" context for DOTS strategies will be private services with some opportunities for regulation and guidance.

Another issue with DOTS is neglect of demand-side considerations. DOTS has comprised a classic supply-side response to a public health concern, with little attention to how tuberculosis is perceived and conceptualized or to the various determinants of patient compliance. This is changing as the Programme is testing ways of involving communities in providing DOTS. Initiatives, including a World Bank-assisted project in India, are under way to assess stakeholders' views on tuberculosis and on DOTS itself.

Finally, Dr Kochi stresses the importance of political commitment to implementing DOTS. This is a key point. But it is worth noting that such commitment must be strong not only at the senior levels among policy-makers and others concerned with health outcomes, but also at the district level and below. In fact, given the multiplicity of priorities and legitimate needs that health officials have to grapple with, what really counts in the medium term is the extent to which subnational decision-makers are authorized and assisted to recognize and respond to local health priorities. In short, what will make DOTS work is awareness locally that tuberculosis is a huge problem and the conviction that DOTS is an adaptable and sustainable response to it.

Dr Kochi acknowledges the limitations of DOTS and the need to develop better strategies and tools. While large-scale trials of the feasibility and affordability of DOTS go ahead in different countries, it is important that work should continue that will lead to new diagnostic tools, cheaper and less risky drugs, and eventually a vaccine. ■

A great deal more is needed

Anthony Harries

The DOTS strategy for tuberculosis control is one of the most important health breakthroughs in the last 30 years, and from the perspective of sub-Saharan Africa it might well be the most important breakthrough of the 1990s. As the main article explains, DOTS is a strategy which incorporates targets, a control policy package and key operations which should be undertaken by a national tuberculosis programme. DOTS is a catchy name, and many health care workers in sub-Saharan Africa will be familiar with it. However, only 12% of global TB cases are treated by DOTS, which implies that there must be some inherent difficulties preventing its widespread and rapid adoption by all TB programmes in the world. I will discuss some of the difficulties which are encountered in countries with a high prevalence of HIV infection in sub-Saharan Africa.

- The targets for cure rates and detection rates are difficult to hit. Cure rates of 85% in smear-positive TB cases are almost impossible to achieve because of high HIV-related mortality. The detection target of 70% of smear-positive TB cases is also impossible to achieve because a method of estimating the total of such cases has not yet been found.
- The DOTS strategy is vitally dependent on countrywide laboratory services with accurate sputum smear microscopy. In poor countries, laboratories may be deficient in both human and material resources, supervision may be almost non-existent and there is often no systematic form of quality control. Clinicians entrusted with patient care tend to believe any sputum smear result, positive or negative, that appears on the sputum test request form, and order treatment accordingly. If laboratory accuracy is low the TB control programme can be compromised, not least because smear-positive TB cases wrongly diagnosed as smear-negative paucibacillary tuberculosis may receive insufficient treatment.
- A key component of DOTS is the use of short-course chemotherapy, for at least all smear-positive TB cases. Initially it was widely perceived that the high costs of anti-tuberculosis drugs such as rifampicin and pyrazinamide precluded their use in poor countries, unless donor support was available. However, since 1994, the prices of anti-tuberculosis drugs (particularly

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rifampicin and pyrazinamide) on the international market have fallen considerably, and short-course chemotherapy is now cheaper than some standard treatment regimens which use streptomycin, isoniazid and ethambutol.

If laboratory accuracy is low the TB control programme can be compromised, not least because smear-positive TB cases wrongly diagnosed as smear-negative paucibacillary tuberculosis may receive insufficient treatment.

Ministries of Health could therefore take on more responsibility for purchasing these effective drugs, relying less on donor support. However, in many countries there is still the perception that some anti-tuberculosis drugs are too expensive and there is little appreciation of what cost-effective treatment actually means.

- With DOTS, all doses of rifampicin should be directly observed. In the pre-HIV era, TB case-holding was often carried out in hospital wards, and this had the advantage that it was easy to administer rifampicin directly to a large group of patients and to monitor treatment response. With the huge upsurge of TB cases in areas of high HIV prevalence, case-holding in hospital wards is becoming impossible because of overcrowding, and there are moves to decentralize treatment to peripheral health centres and the community. This is a patient-friendly approach. However, the logistics of observed drug administration, supervision, monitoring and recording in the community are daunting (although not impossible), and any scheme of decentralization needs to carefully monitored in case there is loss of control.
- One of the stated benefits of DOTS is the number of adult lives saved. However, HIV-related illness undoubtedly has a negative impact on this benefit. In HIV-positive smear-positive TB patients, high death rates mean that treatment is less cost-effective in terms of years of life saved than previously calculated. Before the advent of HIV, smear-negative paucibacillary tuberculosis was a disease whose treatment had a good outcome, even without chemotherapy. Experience is slowly accumulating in sub-Saharan Africa to show that HIV-positive smear-negative TB patients have a much worse prognosis than those who have smear-positive tuberculosis. Yet these patients are ignored in the DOTS strategy despite the fact that their numbers are high, in some countries exceeding the numbers of smear-positive TB cases. Smear-negative TB cases are not followed up and are often given treatment inferior to that given to smear-positive TB cases.

HIV-related tuberculosis is a major problem in sub-Saharan Africa, and in the next few years will assume similar importance in India and South-East Asia. The DOTS strategy, undoubtedly very effective in predominately HIV-negative environments, must adapt to the challenges posed by the HIV epidemic if it is to maintain credibility in these areas. Ways of determining the TB case rate must be found, so that the 70% detection rate target has some meaning. The issue of smear-negative paucibacillary tuberculosis must be tackled. Community care schemes must be rigorously piloted and evaluated. Ways of ensuring accurate smear microscopy and good quality control must be devised. Attempts must be made to reduce the high rate of mortality during treatment. Above all, the Global Tuberculosis Programme must continue to lead the way in calling for more resources for TB control. Trained and motivated manpower, equipment for diagnosis, uninterrupted drug supplies and transport for supervision do not come cheap, and governments need to be persuaded that these measures are worthwhile.

Good breakthroughs come as a result of innovation, hard work and commitment. These must be maintained from the top to the bottom, from WHO headquarters to the district health centre and community-based guardian entrusted with drug supervision, if DOTS wishes to keep its high position in the hierarchy of effective health care interventions. ■

Success is possible but it has to be fought for

Jaap F. Broekmans

Tuberculosis remains one of the world's major public health challenges with more than two million (mostly young) adult deaths a year. The scale of the problem is such that in 1993 WHO was forced to declare tuberculosis a "global emergency". In the public health community this acted as an eye-opener regarding the magnitude of the problem but did not yet result in the political and professional response needed to deal with the problem.

After the Second World War most industrialized countries successfully moved from high to low tuberculosis prevalence in little more than a generation by effectively treating infectious cases in well-established tuberculosis networks. Most countries in Africa, Asia and Latin America, however, were unable to follow suit. Numerous field studies have shown that the failure to cure infectious cases under the insufficient programme conditions prevailing in most of the world is the most important reason for tuberculosis still being endemic worldwide. In most countries overall treatment success rates do not exceed 30%–50% of detected cases. The world now has to pay a high price for its negligence in controlling the disease over the past decades. In the wake of HIV transmission tuberculosis becomes increasingly epidemic. Poor programme performance has increased drug resistance, and increased migration from countries where prevalence is high has a substantial impact on case rates in those where it is low.

A rigorous application of the DOTS strategy, focusing available manpower and resources on successful treatment delivery makes it possible to cure eight out of 10 detected cases in Africa and nine out of 10 detected cases in Asia. We present evidence from national tuberculosis programmes in three countries in Asia and five countries in Africa that have received support from the Royal Netherlands Tuberculosis Association and other sources over the past decade (see Tables 1 and 2). Table 3 demonstrates that the DOTS strategy is not a dogmatic "one way only" approach, but a flexible system, which is highly adaptable to the health environment of a particular country. Tables 1 and 2 also show that effective programmes are possible despite the low per capita income of the countries

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Table 1

Successful national programmes in Africa up to 1994

Case management (new infectious cases)

	Tanzania (since 1982)	Malawi (since 1984)	Benin (since 1984)	Gambia (since 1988)	Kenya (nomads since 1986) (NTP since 1993)	Total
Number evaluated	97 450	35 893	11 016	4087	11 146	159 5[illegible]
Success (%)	79	78	79	71	86	79
Died (%)	8	12	5	5	5	8
Failure (%)	1	1	2	1	0	1
Absconded (%)	7	4	12	15	6	7
Transferred out (%)	4	4	1	8	2	4
Total (%)	100	100	100	100	100	100

Case management (retreatment cases)

	Tanzania (since 1982)	Malawi (since 1984)	Benin (since 1984)	Gambia (since 1988)	Kenya (since 1986)	Total
Number evaluated	7874	3262	1277	39	364	12 8[illegible]
Success (%)	73	78	73	59	77	74
Died (%)	10	13	7	15	8	10
Failure (%)	3	1	4	0	2	3
Absconded (%)	11	5	14	10	6	9
Transferred out (%)	4	3	3	15	7	3
Total (%)	100	100	100	100	100	100

Source: National tuberculosis programmes

In these countries the DOTS strategy is a major health breakthrough. In our opinion it could become so in most countries, provided DOTS is accepted as the strategy of the national programme. For its effective implementation, directly observed treatment for all infectious cases should be ensured, especially in the initial phase of treatment, and monitored closely by bacteriological examination. Curing infectious cases reduces mortality and at the same time curbs transmission. Few other health interventions possess such a formidable double-edged weapon.

Our experience, however, indicates that success is never guaranteed. It has to be fought for in the context of the national programme itself. Weak political commitment, poor programme management and insufficient capability to carry out directly observed treatment are important limiting factors. Under such conditions, treatment success remains unsatisfactory, and infectious cases become chronic with the danger of systematically introducing drug resistant tuberculosis on a wide scale. In one country this sobering experience made it necessary for us to withdraw our long-term commitment to strengthening the national programme. The poor treatment success rates underlying this decision are presented in Table 4. At a recent technical advisory committee an outside observer

Successful national programmes in Asia up to 1994

Case management (new infectious cases)

	China (since 1991)	Viet Nam (since 1988)	Sulawesi (Indonesia) (since 1993)	Total
[illegible] evaluated	103 686	49 407	2010	155 103
[illegible]ss (%)	94	89	93	93
[illegible] (%)	2	3	2	2
[illegible] (%)	2	2	1	2
[illegible]nded (%)	1	3	1	2
[illegible]rred out (%)	0	2	3	1
[illegible]	100	100	100	100

Case management (retreatment cases)

	China (since 1991)	Viet Nam (since 1988)	Sulawesi (Indonesia) (since 1993)	Total
[illegible]t evaluated	93 992	6941	46	100 979
[illegible]ss (%)	87	79	85	87
[illegible]	4	5	4	4
[illegible] (%)	7	10	4	7
[illegible]ded (%)	2	3	7	2
[illegible]red out (%)	0	4	0	1
[illegible]	100	100	100	100

[illegible]National tuberculosis programmes

[illegible]ked "Why are some societies apparently [illegible]lling to tolerate a high burden of disease [illegible]m tuberculosis?" It is a question that [illegible]ten has to be dealt with before effective [illegible]tion can be taken.

[illegible] countries with well-established pro-[illegible]ammes two developments pose a par-[illegible]ularly tough challenge to maintaining [illegible]ccess. First, HIV transmission pushes [illegible]berculosis incidence upwards, leading, in [illegible]m countries in Africa, to doubling (or [illegible]re) of the case rates. This severely [illegible]retches the capacities of these pro-[illegible]ammes to deal with the increased case-[illegible]nds. Increased staff and resources, to [illegible]nsure strict adherence to the bacteriologi-[illegible]l diagnosis and [illegible]

procedures, is of great importance. It may be expected that when HIV prevalence levels off, tuberculosis incidence will stop increasing and then decrease if an effective control programme remains in place.

> ***Our experience indicates that success is never guaranteed. It has to be fought for in the context of the national programme itself.***

Second, health sector reforms are sometimes dogmatically focused on decentralization and integration. In such cases they

Table 3

Case management of infectious patients in different countries

Africa

Country	Treatment regimen	Supervised intensive phase*	Continuation phase**
Tanzania	2SHRZ/6HT(E)	Rural: hospitalization Urban: supervised ambulatory treatment	Self-administered treatment
Malawi	2SHRZ/6HT(E)	Rural: hospitalization Urban: supervised ambulatory treatment	Self-administered treatment
Benin	2SHRZ/6HT(E)	Hospitalization	Self-administered treatment
Gambia	$2S_3H_3R_3Z_3/4R_3H_3$	Supervised ambulatory treatment at village level	Supervised ambulatory treatment at village level
Kenya (Indian)	2SHRZ/2HRZ/3TH	Self-care unit with extended intensive phase of treatment	Self-administered treatment

Asia

Country	Treatment regimen	Supervised intensive phase*	Continuation phase**
China	2SHRZ/4HR (every other day)	Supervised ambulatory treatment at village level	Supervised ambulatory treatment at village level
Viet Nam	2SHRZ/6HE	Urban: supervised ambulatory treatment Rural: supervised ambulatory treatment or hospitalization	Self-administered treatment
Sulawesi (Indonesia)	2EHRZ/4R$_3$H$_3$	Weekly supervised ambulatory treatment at village level	Self-administered treatment, bi-weekly supervised

* Lasting [illegible] months at 2 months

** Lasting [illegible] months at 4 and 6, or at 5 and 8 months

Table 4

Example of a poor national programme

Year	Total	Case management (new infectious cases)				
		Success	Died	Failure	Absconded	Transferred out
1989–1991	1963	915 (47%)	122 (6%)	5 (0%)	753 (38%)	168 (9%)
1992–1993	1779	790 (44%)	92 (5%)	17 (1%)	763 (43%)	117 (7%)
Total	3742	1705 (46%)	214 (6%)	22 (1%)	1516 (41%)	285 (8%)

[illegible]s of an effective and coherent national [illegible]ramme, such as regular supervision, [illegible]terrupted supply of drugs and a strict [illegible]itoring of programme performance. A [illegible] established control and surveillance [illegible]t at the Ministry of Health, as well as [illegible]ntifiable and accountable staff at inter-[illegible]diate and district level are indispensable [illegible] effective application of the DOTS [illegible]ategy.

[illegible] have witnessed the dire state of tubercu-[illegible]s control in Kenya and the United [illegible]public of Tanzania in the late 1970s, in [illegible] Nam in the mid-1980s, in Indonesia [illegible] late 1980s, and in China in the early [illegible]90s, before the modern tuberculosis [illegible]ntrol policy was introduced. I was [illegible]vileged to witness the way in which the [illegible]OTS strategy subsequently revolution-ized tuberculosis control by successfully curing the great majority of infectious cases in these countries. In China an old proverb about tuberculosis says "ten get it, nine die". The DOTS strategy reversed this truth: now it can be "ten detected, nine cured". In view of the more than two million deaths occurring yearly world-wide, wider application of this strategy would constitute a major public health breakthrough, towards solving one of the most devastating infectious disease prob-lems that remain in the world today. ■

The old proverb "ten get it, nine die" has been replaced by "ten detected, nine cured".

DOTS in the Western Pacific

The notification rate of tuberculosis in the [Western Pacific] Region has increased by 30% over the last decade. This is partly due to the improved reporting system. Tuberculosis control is being strictly implemented through the WHO policy package known as DOTS, already with promising results. For example, at subnational level in Cambodia, a cure rate of more than 80% has been achieved. The plan is now to implement the programme nationwide.

■ *The world health report 1997 – Conquering suffering, enriching humanity.* Geneva, World Health Organi[illegible]

The State of World Health

The World Health Report 1997 – Conquering suffering, enriching humanity

This self-contained, concise and analytical publication is the third in a series of annual reports. It provides an assessment of world health status and needs, and recommends relevant priorities for international health action to meet those needs, as well as reporting on WHO's contribution towards improving the world health situation. ***The world health report 1997*** *focuses on chronic diseases and gives an overview of WHO's work during 1996 (1).*

Dramatic increases in life expectancy, combined with profound changes in lifestyles, will lead to global epidemics of cancer and other chronic diseases in the next two decades. The main result will be a huge increase in human suffering and disability. There is an urgent need to find ways to reduce that coming burden.

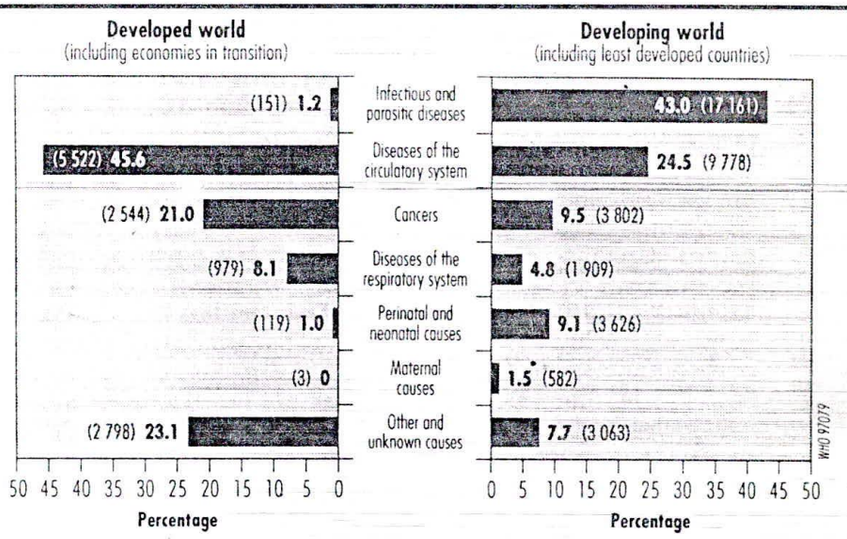
Half a century ago, most people died before the age of 50. Now, the great majority live well beyond that age. Global average life expectancy at birth reached 65 years in 1996. However, while extending our life span is a desirable goal in itself, it is much more so if it can be accompanied by freedom from additional years of suffering poverty, pain or disability. Unfortunately, for many millions of people, there is as yet no such freedom. The quality of human life is at least as important as its quantity. Individuals are entitled to be concerned not so much about their *life expectancy* as their *health*

Health expectancy can be defined as life expectancy in good health, or the average number of years an individual can expect to live without major health problems. Such a concept is needed since longer life in itself can be viewed as a penalty rather than a prize if it is likely to involve a longer time of suffering from a chronic disease.

The health transition

As shown in *The world health report 199* – *fighting disease, fostering development*, infectious diseases kill about 17 million people a year and afflict hundreds of millions of others, particularly in the developing world. In the industrialized world, infectious diseases are well under control. It is noninfectious diseases – particularly cancer, circulatory diseases, mental disorders including dementia, chronic respiratory conditions and musculoskeletal diseases – that now pose the greatest threat to health in developed countries (see Fig. 1). These are essentially

Causes of death, developed and developing world, 1996[1]



[1] Figures in brackets refer to the number of deaths in thousands.

diseases that strike later in life and ch, as life expectancy increases, will me more prevalent.

nic diseases are responsible for more 24 million deaths a year, or almost of the global total. The leading causes circulatory diseases, including heart ease and stroke, cancer and chronic structive pulmonary disease.

life expectancy in developing countries increases, so does the prevalence of eases that are more common among der age groups. Already, the outlook for st individuals in the developing world th t if they do manage to survive the fer infections of infancy, childhood and turity, they will become exposed in ter life to noncommunicable diseases.

This situation is known as the "epidemiological transition" – the changing pattern of health in which poor countries inherit the problems of the rich, including not merely illness but also the harmful effects of tobacco, alcohol and drug use, and of accidents, suicide and violence. It is also referred to as the "double burden", because of the continuing weight of endemic infectious diseases. Increasingly, health is influenced by social and economic circumstances over which the individual has little

> ***As life expectancy increases, so does the prevalence of diseases that are more common among older age groups.***

control, and over which the conventional health sector also has little sway. As a result, many countries are now experiencing a widening gap in health terms between rich and poor.

D18-5.

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Papers

Comparison of cost effectiveness of directly observed treatment (DOT) and conventionally delivered treatment for tuberculosis: experience from rural South Africa

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Abstract

Objective: To conduct an economic evaluation of directly observed treatment (DOT) and conventionally delivered treatment for the management of new cases of tuberculosis in adults.
Design: Community based directly observed treatment, which has been implemented in the Hlabisa district of South Africa since 1991, was compared with a conventional approach to tuberculosis treatment widely used in Africa. Each was assessed in terms of cost, cost

effectiveness, and feasibility of implementation within existing resource constraints.
Setting: Hlabisa Health District, South Africa.
Subjects: Adult patients with new cases of tuberculosis on smear testing; the number of cases increased from 20 per month to over 100 from 1991 to 1996.
Main outcome measures: Cost of case management in 1996, cost effectiveness in terms of the cost per case cured, and bed requirements in comparison with bed availability for the 1990, 1993, and 1996 caseload. Costs are expressed in US dollars at values for 1996.
Results: Directly observed treatment was 2.8 times cheaper overall than conventional treatment ($740.90 compared with $2047.70) to deliver. Directly observed treatment worked out 2.4-4.2 times more cost effective, costing $890.50 per patient cured compared with either $2095.60 (best case) or $3700.40 (worst case) for conventional treatment. The 1996 caseload of tuberculosis required 47 beds to be dedicated to tuberculosis to implement directly observed treatment, whereas conventionally delivered treatment would have required 160 beds; the current number of beds for tuberculosis treatment in Hlabisa is fixed at 56.
Conclusions: Because of the reduced stay in hospital, directly observed treatment is cheaper, more cost effective, and more feasible than conventional treatment in managing tuberculosis in Hlabisa, given the existing hospital bed capacity and the escalating caseload due to the HIV/AIDS epidemic. Such results may hold elsewhere, and wherever conventional tuberculosis management is practised a switch to directly observed treatment will increase hospital capacity to cope with a growing caseload.

Key messages

- Tuberculosis is a problem of global importance, and the number of cases is rising as a consequence of population growth, worsening poverty, and the HIV/AIDS epidemic
- Conventional approaches to management are increasingly difficult to implement, especially when caseloads are rapidly increasing
- This study found that community based directly observed treatment, a novel approach to treating tuberculosis, was considerably cheaper and more cost effective than a conventional approach entailing prolonged admission to hospital
- Because directly observed treatment considerably reduces hospital stay, its implementation will increase the capacity of hospitals to cope with a rising tuberculosis caseload wherever the conventional approach is currently used
- This South African model of directly observed treatment for tuberculosis is worthy of serious consideration by policymakers and programme managers elsewhere

Introduction

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Tuberculosis is a problem of global importance,[1] and population growth, increasing poverty, and the AIDS epidemic mean that the number of reported cases continues to grow.[2 3] Coping with this rising caseload is difficult: delivery of treatment is not straightforward, and successful programmes in Africa have typically relied on lengthy admissions to ensure patient compliance.[4] Given that already constrained resources preclude either the construction of new wards or the hiring of additional staff and that hospitals are already operating at or beyond capacity,[5 6] this approach seems to be increasingly unviable. Other approaches to case management are urgently needed that can achieve high patient compliance while being cheaper per patient and less dependent on hospital care.

Community based directly observed treatment (DOT) is currently the standard approach to care in the United States. Though expensive,[7] it is probably less costly than admission, and high cure rates have been achieved. To evaluate whether directly observed treatment could be an attractive economic option in a resource poor setting, we studied such a programme in Hlabisa district, South Africa—one of the few sites in a developing country where it has been implemented. We have previously reported the costs, cost effectiveness, and feasibility of implementing several strategies within existing resource constraints.[8] In this paper we compared directly observed treatment with the conventional approach that has been widely used elsewhere in Africa.

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Subjects and methods

Hlabisa is a rural district where the tuberculosis caseload has increased from 25 to over 100 per month during 1991-6, largely because of the emergence of the HIV epidemic. In 1993, 35% of adult patients with tuberculosis tested positive for HIV infection[9]; in 1997 the figure was 70% (unpublished data). There are seven clinics and a district hospital, and the yearly income per head is $1730 (£1081).[10]

Strategies

The two strategies were compared after diagnosis of new cases of tuberculosis in patients with positive results on smear testing. Before diagnosis the strategies were similar.

Directly observed treatment has been described in detail elsewhere.[11,12] After diagnosis, the time patients spend in hospital is determined by their clinical condition and the time taken to arrange community care. In 1996 the average length of stay was 17.5 days. While in hospital, patients receive daily treatment with four drugs (isoniazid, rifampicin, pyrazinamide, and ethambutol) and, with the help of field workers, identify someone who can supervise treatment after discharge. The emphasis is on choosing a supervisor who makes accessing directly observed treatment convenient for the patient. In 1995, 56% of patients were supervised by unpaid non-health workers, most of whom were storekeepers; 21% were supervised by health clinic staff; 21% by community health workers; and 2% by staff in tuberculosis wards. On discharge, field workers transport patients to their supervision point in a hospital vehicle. Supervisors are given the prepacked drugs required for completion of the six month treatment course. The drugs used after discharge are the same as those given in hospital, except that they are given at higher dose and are taken on an intermittent basis twice weekly. Patients therefore visit their supervisor twice a week to take their drugs under direct observation, visiting on average 48 times. Field workers visit supervisors monthly to check compliance, collect patient outcome data, and trace absconders. A hospital doctor manages the programme.

Conventional approach—Patients stay in hospital for the first two months of treatment under the conventional management strategy for tuberculosis. This lengthy stay is designed to ensure compliance with treatment during the intensive phase (at least), when patients are most infectious, and with some drug regimens is necessitated by the use of streptomycin. At discharge, patients are given a one month supply of drugs, and they subsequently collect their drugs once a month from their nearest clinic. Drug regimens vary, but we assumed that the six month course recommended by the World Health Organisation would be used. This consists of two months of isoniazid, ethambutol, pyrazinamide, and rifampicin, followed by four months of rifampicin and isoniazid, with exact dosages dependent on body weight. Two sputum smears are examined at 2, 4, and 6 months.

Costing

We assessed both average and marginal costs.[13] We report average costs because they are a better reflection of true variable costs and therefore of greater use for planners and policymakers concerned with national policy for a large number of facilities, such as a country's tuberculosis control strategy.[14] Costs were assessed from a societal perspective in United States dollars at values for 1996.

Health system costs

For each strategy component except drugs, total annual recurrent health system costs for the financial year 1995-6 were calculated using one or more of the following: expenditure files which provided a breakdown for inpatient, outpatient, and health clinic care; the hospital payroll; the rate paid by the ministry of health for vehicle usage; vehicle logbooks; and interviews with staff. Gross salaries were used to calculate staff costs. Average drug costs per patient were established by combining a costing of each regimen by weight category (using the hospital pharmacy price list) with data from the tuberculosis register on the weight of patients.

Total annual capital costs were calculated using quoted 1996 purchase prices, reasonable assumptions concerning expected useful life (5 years for a vehicle, 10 years for equipment, and

30 years for buildings), and a discount rate of 8% (the difference between the interest rate paid on government treasury bonds and the inflation rate).

For hospital costs, 92.5% of the costs of administrative and support staff and of capital costs were allocated to inpatient care and 7.5% to outpatient care, since staff involved in direct outpatient care accounted for 7.5% of the total costs of staff involved in direct patient care. We allocated 4.1% of laboratory costs (staff and equipment not used solely for tuberculosis work) to sputum smear testing since smears comprised 4.1% of the total number of laboratory tests in 1995.

Annual output data were for 1995—that is, the number of days in hospital; the number of visits to outpatient departments, health clinics, and community health workers; the number of patients receiving directly observed treatment for tuberculosis; the total number of patients with tuberculosis; and the number of laboratory tests done. Sources included hospital admission records, the medical superintendent, programme reports, and the regional laboratory manager.

For average cost calculations we assumed that visits to outpatient departments, health clinics, and community health workers by a patient with tuberculosis would cost the same as visits for other health problems. For spending a day as an inpatient we assumed that all costs (except those associated with staff allocated to the tuberculosis ward, drugs, laboratory investigations, and *x* ray examinations) would be the same for a patient with tuberculosis as for any other inpatient. The cost of a visit for directly observed treatment was calculated by combining the cost per visit with the pattern of supervision in 1995 as costs vary according to the site chosen for supervision of treatment.

Patient costs

A questionnaire was administered to all patients eligible for treatment under the directly observed treatment programme at the outset of the study (48 in total). The time and travel costs associated with visits to hospital and health clinics were recorded. When different sites were chosen for directly observed treatment, the time and travel costs incurred to visit them were also noted. Time costs were translated into monetary costs using monthly incomes reported in a second questionnaire (designed one week into the study and administered to the 35 original respondents in the tuberculosis ward at this time). Calculations assumed patients would work 25 days a month and 8 hours a day. Travel and time costs were then summed and average costs associated with visits to hospital and health clinics and for directly observed treatment by specific type of supervisory site calculated. The average costs of directly observed treatment by supervisory site in 1995 were combined to calculate the average cost incurred by a patient per directly observed treatment visit.

Community costs

Time constraints meant that the only data collected on community costs were those incurred when patients were accompanied on hospital visits. These were comparatively small and were included in the patient cost per hospital visit. Costs incurred by non-health worker supervisors were considered to be nil because the time commitment was negligible and supervision creates no additional costs for supervisors (unpublished data).

Effectiveness measure

We chose cure as the measure of effectiveness—the WHO's criterion for measuring a programme's success.[15] To estimate a best and worst case scenario for the likely effectiveness of the conventional strategy, we analysed data on the outcomes of a six month cohort of patients with positive results on smear testing in Tanzania in 1990[16] and annual reports with detailed outcome data from Malawi 1989-93[3] because these programmes used a similar case management approach. For directly observed treatment we used data from the 1991-4 audits of the Hlabisa programme.[12] Cure is not routinely assessed bacteriologically in Hlabisa, but a retrospective analysis of 109 patients found that 95% were cured.[17] In this analysis, the rate of completion of treatment was therefore multiplied by 95% to give an estimated cure rate. For consistency, the same assumption was applied to the data from Malawi and Tanzania for the small number of patients who completed treatment but for whom cure was not confirmed.

Patients who died or left the district during treatment were excluded from the analysis. Differences in the death rate may reflect the varying impact of the AIDS epidemic. The proportion of patients leaving the district during treatment is related to population transience. Neither of these is a direct function of the tuberculosis programme itself, so omitting these categories prevented unnecessary distortion of the analysis.

Calculation of cost effectiveness

Cost effectiveness was calculated in three steps. First, the proportion of patients who completed treatment was multiplied by the cost of managing a patient up to the completion of treatment. Second, the cost of a patient not completing treatment (calculated by assuming that default would occur at hospital discharge) was multiplied by the proportion of patients not completing treatment. Third, the resulting two costs were summed and divided by the cure rate.

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Results

Directly observed treatment was considerably cheaper than the conventional strategy (table 1). It was 2.7 times cheaper for the health system, 3 times cheaper for the patient, and 2.8 times cheaper overall. In both cases, health system costs accounted for 87% of total costs. Admission to hospital was the most costly item. For directly observed treatment it accounted for 75% of health system costs, 76% of patient costs, and 75% of costs overall; for the conventional approach it accounted for 94% of health system costs, 88% of patient costs, and 93% of costs

overall. The only other important cost items were visits for directly observed treatment (14% of the total cost of the directly observed treatment strategy) and organisation of supervision and supervision of supervisors (5% of the total cost of the directly observed treatment strategy). No other item—including drugs—accounted for more than 5% of total costs.

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Table 1 Average health system, patient, and total costs in 1996 $ (percentages of total) for curing one patient of tuberculosis according to management strategy

The data for individual strategy components (tables 2 and 3) showed that a day in hospital was costly ($27.80 per day for the health system and $4 for the patient), as was an outpatient visit ($16.70 for the health system and $9.70 for the patient). In terms of time, a hospital visit cost a patient five hours. Visits to health clinics and community health workers cost less. The different drug regimens cost about the same, and sputum smear examination was a minor cost.

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Table 2 Average health system costs (in 1996 $)

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Table 3 Average patient costs (in 1996 $)

The organisation of supervision and the supervision of supervisors were less expensive than expected, at $38.90 per patient. Visits for directly observed treatment were also notable for their low cost. Visits to non-health workers were cheapest, costing the health system nothing and the

patient just 35 minutes, estimated to equate to $0.30. On average, each visit for directly observed treatment cost the health system $1.70 and the patient $0.45. Overall, the input of non-health workers reduced the total cost of directly observed treatment by 26% from the health system's perspective, by 53% from the patient's perspective, and by 31% overall in comparison with what costs would be if health clinics alone were used for supervision.

Directly observed treatment based in the community was therefore inexpensive. In combination, arrangements for supervision, supervision of supervisors, and 48 visits cost the health system $120.50 per patient (equivalent to 4.3 days spent in hospital receiving treatment for tuberculosis) and the patient $21.60 (equivalent to five days in hospital).

Directly observed treatment also seemed to use resources efficiently (table 4). At $890.50 per patient cured, it was between 2.4 and 4.2 times more cost effective than the conventional approach. Moreover, directly observed treatment was feasible within existing resource constraints (table 5). Both strategies were possible in 1990, but in 1996 the increased caseload meant that directly observed treatment was the only strategy that could be implemented without displacing patients from other wards, reducing the quality of care provided, and needing extra investments in infrastructure (and, probably, staff).

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Table 4 Cost effectiveness of different case management strategies

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Table 5 Numbers of beds available and required to manage patients with tuberculosis in Hlabisa hospital according to management strategy

Discussion

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Directly observed treatment is an attractive economical option in Hlabisa. It is cheap, cost effective, and implementable within existing resource constraints.

This strategy is cheap because treatment based in the community that is supervised by field workers is cheaper than lengthy hospital supervision of care (all other cost items were insignificant in terms of impact on total costs). This is also likely to be true elsewhere in South Africa because the costs of the major inputs—staff, vehicles, and fuel—do not vary much; population densities in most districts are unlikely to fall to the point where the costs of vehicles and fuel would become inordinately expensive; and non-health worker input is considered acceptable by the Department of Health.[18]

Even in very poor African countries, the cost of hospital care is unlikely to fall enough to make directly observed treatment comparatively expensive. In Malawi in 1995, a day in hospital cost $2.09[7] (13.3 times less than in Hlabisa), so 60 days in hospital would cost the health system $125.40. On the assumption that health clinic and community health worker visits and field worker and driver costs would also be 13.3 times less but that vehicle and fuel costs would be the same as those in Hlabisa, 17.5 days in hospital, 48 visits for directly observed treatment, and field worker supervision would cost $64.30 (36.60+6.10+21.60). Since the population density is higher in Malawi than Hlabisa (93 *v* 67 per square kilometre),[19] the cost of field worker supervision might be cheaper still. Furthermore, the low cost of visits for directly observed treatment suggests that if input by non-health workers were unacceptable and the costs of directly observed treatment more than doubled, this strategy would still be cheap from the perspective of the health system.

For the patient, in contrast, the acceptability of non-health worker input is critical. When this is feasible, 48 visits for directly observed treatment will always be cheaper than 42.5 days in hospital because the patient can choose a supervisor who makes access to treatment convenient. Moreover, recent observation in Hlabisa indicates that the increased caseload secondary to the HIV epidemic may be best absorbed through supervision by volunteers.[20] When using non-health workers is not acceptable and access to health facilities is limited, however, 48 visits for directly observed treatment will incur large costs and treatment in hospital could be preferable.

The likely effectiveness of directly observed treatment elsewhere is harder to assess. Nevertheless, a nearby district has found early success in implementing a similar programme (G Dean, personal communication); and the programme in Hlabisa has continued to prove highly effective even after management was no longer the responsibility of the programme innovator. Evidence also suggests that contacts of patients with tuberculosis treated in the community are not at increased risk of infection compared with those managed in hospital.[21 22 23]

Wherever the conventional approach is currently relied on, a switch to directly observed treatment will help to decongest hospitals and increase the capacity to cope with a growing tuberculosis caseload and a more widespread increase in demand for hospital care. Indeed, with the HIV related tuberculosis epidemic across Africa and limited extra resources for tuberculosis control programmes, it may become programme managers' only option.

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Conflict of interest: None.

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(ill opportunity costs of pts. were not properly considered.

Basically the author says that hospital care is costlier than domiciliary care which is nothing new. She also mentions that in America DOT was found to be expensive.

Average costs & not variable costs were taken since it would be more useful for policy makers & planners.

D15-5

A Cost-effectiveness Analysis of Directly Observed Therapy vs Self-administered Therapy for Treatment of Tuberculosis*

William J. Burman, MD; Craig B. Dalton, B Med; David L. Cohn, MD; James R. G. Butler, PhD; and Randall R. Reves, MD

Study objectives: **To compare the costs and effectiveness of directly observed therapy (DOT) vs self-administered therapy (SAT) for the treatment of active tuberculosis.**
Design: **Decision analysis.**
Setting: **We used published rates for failure of therapy, relapse, and acquired multidrug resistance during the initial treatment of drug-susceptible tuberculosis cases using DOT or SAT. We estimated costs of tuberculosis treatment at an urban tuberculosis control program, a municipal hospital, and a hospital specializing in treating drug-resistant tuberculosis.**
Outcome measures: **The average cost per patient to cure drug-susceptible tuberculosis, including the cost of treating failures of initial treatment.**
Results: **The direct costs of initial therapy with DOT and SAT were similar ($1,206 vs $1,221 per patient, respectively), although DOT was more expensive when patient time costs were included. When the costs of relapse and failure were included in the model, DOT was less expensive than SAT, whether considering outpatient costs only ($1,405 vs $2,314 per patient treated), outpatient plus inpatient costs ($2,785 vs $10,529 per patient treated), or outpatient, inpatient, and patients' time costs ($3,999 vs $12,167 per patient treated). Threshold analysis demonstrated that DOT was less expensive than SAT through a wide range of cost estimates and clinical event rates.**
Conclusion: **Despite its greater initial cost, DOT is a more cost-effective strategy than SAT because it achieves a higher cure rate after initial therapy, and thereby decreases treatment costs associated with failure of therapy and acquired drug resistance. This cost-effectiveness analysis supports the widespread implementation of DOT.** ***(CHEST 1997; 112:63-70)***

Key words: cost-effectiveness; decision analysis; directly observed therapy; tuberculosis

Abbreviations: AST=aspartate aminotransferase; CDC=Centers for Disease Control and Prevention; DOT=directly observed therapy; SAT=self-administered therapy

The world is in the midst of a remarkable resurgence of tuberculosis. In the United States, approximately 63,000 excess cases have occurred since 1985;[1] in some developing countries, rates of active tuberculosis have doubled.[2] Factors associated with the increased number of cases of tuberculosis in the United States include the effect of HIV coinfection,[3,4] immigration from areas of endemic tuberculosis,[5,6] and homelessness.[7-9] Another key factor has been the failure to complete tuberculosis therapy, resulting in relapse and ongoing transmission.[8,10] Equally alarming are increases in drug-resistant tuberculosis. Resistance to isoniazid in isolates from previously untreated patients increased from 4% in the late 1970s and early 1980s[11] to 8.2% in 1991.[12] Primary resistance to both isoniazid and rifampin, which markedly decreases the response to treatment, increased from <1%[11] to 3.2% over this time period.[12]

The resurgence of tuberculosis and the rising prevalence of drug resistance have occurred despite the development of highly efficacious regimens for the treatment of active tuberculosis. In clinical trials, short-course (6-month) regimens that include isoniazid, rifampin, and pyrazinamide have cure rates

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exceeding 95% for drug-susceptible tuberculosis.[13-15] In clinical practice, however, short-course chemotherapy has been much less successful than the clinical trials had predicted.[16] This discrepancy has shifted the focus from the efficacy of treatment regimens to the mode of their administration. There is increasing evidence that treatment protocols that use direct observation of each dose of therapy are more effective than those that rely on self-administration. Although there have been no randomized trials (to our knowledge) comparing directly observed therapy (DOT) with self-administered therapy (SAT) in the United States, the recent experience from Tarrant County, Texas[16] and New York City[17,18] strongly suggest that the use of DOT provides a higher cure rate and markedly decreases the emergence of drug resistance.

Based on this evidence, the Centers for Disease Control and Prevention (CDC) has recommended the use of DOT whenever possible.[19] One of the barriers to the widespread adoption of DOT is the perception that it is an expensive form of therapy,[20] beyond the limited financial resources of many tuberculosis control programs. However, because the therapy of treatment failures, particularly drug-resistant treatment failures, is very expensive,[21,22] DOT could be a less expensive form of treatment if the savings from the occurrence of fewer treatment failures offset the higher initial costs of DOT. We performed a cost-effectiveness analysis of DOT compared with SAT for the treatment of active tuberculosis.

Materials and Methods

Decision Analysis Model

The analysis uses a decision analysis model to compare the event rates and costs of DOT and SAT. The model begins with the outpatient treatment of drug-susceptible tuberculosis (Fig 1). The cost of the initial diagnosis of active tuberculosis, which might include hospitalization, is not included in this analysis; this cost was assumed to be equivalent with DOT or SAT. The DOT treatment arm uses the "Denver regimen," a 62-dose, largely intermittent regimen of isoniazid, rifampin, pyrazinamide, and streptomycin.[13] The SAT arm uses the currently recommended regimen for self-administered short-course therapy: daily isoniazid, rifampin, pyrazinamide, and ethambutol for 2 months followed by daily isoniazid and rifampin for 4 months.[15]

Failure to cure tuberculosis can be due to the failure to initially control the disease or to relapse after completion of initial therapy. For this analysis, we combined these two events into an overall failure rate. Failure or relapse can occur with drug-susceptible, single drug-resistant, or multidrug-resistant organisms. Because the treatment of single drug-resistant tuberculosis is generally successful, even with short-course retreatment regimens,[13,23,24] we assumed that single drug-resistant treatment failures could be treated as successfully and inexpensively as drug-susceptible treatment failures, and we combined these two

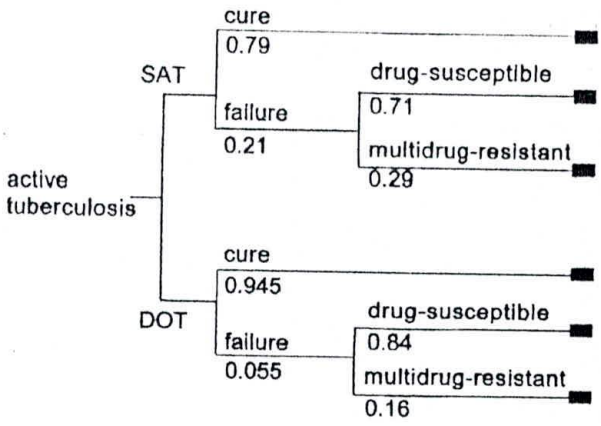

FIGURE 1. Estimated clinical event rates for treatment of drug-susceptible tuberculosis using DOT or SAT, from reference 16. Drug-susceptible failure of initial therapy includes patients whose isolates are resistant to one drug; multidrug-resistant includes all patients whose isolates are resistant to two or more of the first-line antituberculous drugs (isoniazid, rifampin, pyrazinamide, ethambutol, and streptomycin).

rates. Therefore, failures are categorized as either drug susceptible or multidrug resistant (Fig 1). Although some patients with tuberculosis, particularly those with drug-resistant strains, have multiple failures,[25] this analysis considers only the costs associated with first episode of treatment failure. All treatment failures were assumed to be successfully treated with a chemotherapy regimen given as DOT.[26]

We assumed that treatment failures would occur during treatment or within 6 months following the completion of treatment, since most relapses occur within 6 months of the completion of initial therapy.[27] The identification of treatment failures within 12 months of diagnosis obviates the need for discounting of future events for drug-susceptible failures.[28,29] However, treatment of multidrug-resistant tuberculosis continues for 2 years after the failure of initial therapy, so the relevant costs of therapy in later years were discounted.

The model includes both the costs of initial therapy and the costs of treating disease that arises as a result of failure of initial therapy. Although tuberculosis may be transmitted to contacts of a patient who is failing to respond to initial therapy or suffering a relapse,[10,30] it is difficult to estimate the frequency with which this occurs. Therefore, this model does not include the costs of contact investigation, preventive therapy, or treatment of secondary cases of active disease due to transmission from patients who fail to respond to therapy.

We used software programs (Excel 5.0; Microsoft; Renton, Wash; and Data 2.6; TreeAge; Williamstown, Mass) for this analysis.

Event Rates

The event rates for DOT and SAT in Figure 1 were those published from the Tarrant County tuberculosis control program.[16] Because of high rates of failure and acquired drug resistance with the use of SAT, the tuberculosis control program in Tarrant County changed to "near-universal DOT" in November 1986. During the SAT era (January 1980 through October 1986), the use of DOT was limited to treatment failures and cases with acquired drug resistance. In the DOT era (November 1986 through December 1992), 90% of patients were treated with

DOT from the beginning of therapy; 10% received SAT through physicians outside the health department. The event rates used in this analysis were based on the Tarrant County tuberculosis program's "intention-to-treat," meaning that the event rates for DOT were based on all patients treated during the DOT era, including the 10% treated with SAT.

Costs

Estimated Cost of Initial Treatment: The estimated costs incurred for initial treatment with DOT and SAT are given in Table 1. The cost of the initial diagnosis of active tuberculosis, which might include hospitalization, is not included in this analysis, but costs for the treatment of treatment failures (Table 2) include the cost of diagnosis and hospitalization, since the occurrence of these events is directly related to the effectiveness of initial therapy.

Drug costs were calculated by using prices for the Denver Metro Tuberculosis Clinic in September 1994. To estimate the cost of streptomycin (currently available only cost free through the manufacturer), we updated the cost when the drug was last available on the commercial market to 1994 dollars using the Medical Consumer Price Index.[31] Personnel costs were estimated by using the current costs at the Denver Metro Tuberculosis Clinic. Hourly figures include the cost of employee benefits, but not the estimated cost of overhead (*eg*, facility costs, administrative support) as this cost is likely to be equivalent in a DOT and SAT program. To estimate the nursing time necessary to administer DOT, we monitored 107 successive DOT visits at the Denver Metro Tuberculosis Clinic. The average time (mean±SD) of 10.7±6.5 min (range, 3 to 40 min) was increased to 15 min in the model to account for time spent waiting for patients. A 6-month course of SAT was estimated to require eight visits of 20 min each.[15] To account for differences in the amount of nursing time required to administer DOT or the personnel cost for nurses, we included nursing time as a variable in the cost analysis. The cost of physician time was estimated using the salary and benefits for a physician in the Denver Health and Hospitals system ($125,000 for salary and benefits=$60/h).

DOT programs must deliver doses of medications to patients to ensure compliance. We estimated that the delivery of one dose requires 1 h of an outreach worker's time ($13.25), plus the cost of leasing a car ($220/mo apportioned over 4 h use a day, 20 d/mo=$2.75 per dose delivered) and driving it 10 miles ($0.23/

Table 2—*Estimated Costs for Diagnosis and Treatment of a Drug-Susceptible or Multidrug-Resistant Treatment Failure (Undiscounted)*

Expenditure	Drug-Susceptible Failure	Multidrug-Resistant Failure
Diagnosis	$ 354*	$ 687†
Hospitalization		
Duration, d	14	90
Estimated cost per day, $	693	1,286
Percentage of patients hospitalized	80	100
DOT drugs (in hospital), $	58	
Estimated cost of hospitalization, $	7,820	115,740
Outpatient DOT‡		
Drug cost, $	135§	7,834
Nursing cost, $	322§	2,654
Monitoring therapy,‖ $	649	1,901
Delivery of doses,¶ $	211	1,537
Cost of outpatient DOT, $	1,317	13,926
Total diagnosis and treatment cost, $	9,491	130,353
Hours of patient's time		
Hospitalization/respiratory isolation, h	244 (3.5 wk)	1,040 (6 mo)
Outpatient DOT, h	44	400
Total hours of patient's time	288	1,440
Total cost of patient's time at $11.75/h, $	3,384	16,920
Total cost (including patient's time, $)	12,875	147,273

*Includes three mycobacterial cultures, a chest radiograph, CBC count, serum chemistry panel, 1 h of a physician's time ($60/h), and 2 h of nurse's time ($25.28/h).

†Includes the costs outlined above plus susceptibility testing for second-line agents ($87.75) on two cultures and an additional 1.5 h of nursing time and 2 h of physician time.

‡In this model, all relapses are assumed to be treated with DOT.

§These costs are less than the corresponding entries in Table 1 because 80% of the patients are assumed to have received their first 2 weeks of therapy while hospitalized.

‖Includes monthly serum bilirubin and AST for all patients; monthly CBC counts, and monthly audiometry while receiving a parenteral aminoglycoside for patients being treated for multidrug-resistant tuberculosis.

¶Assumes that 20% of DOT doses are delivered.

Table 1—*Estimated Costs of Initial Treatment for Drug-Susceptible Tuberculosis Using DOT or SAT*

Expenditure (Cost/Unit)	DOT		SAT	
	No. of Units	Cost, $	No. of Units	Cost, $
Antituberculous drugs		193*		584†
Nursing cost ($25.28/h)	0.25 h/dose×62	392	0.33 h/visit×8	67
Sputum culture ($58.50)	4	234	7	410
Chest radiograph ($40)	2	80	2	80
Serum bilirubin and AST ($16)	5	80	5	80
Delivery of DOT dose ($18.30)‡	0.20×62 doses	227	Not applicable	
Total treatment cost		1,206		1,221
Patient's time costs (1.25 hours per clinic visit, $11.75/hour	62 doses, 77.5 h	911	8 visits, 10 h	118
Total cost (including patient time costs)		2,117		1,339

*Sixty-two-dose, largely intermittent regimen of isoniazid, rifampin, pyrazinamide, and streptomycin for 2 months, followed by twice-weekly isoniazid and rifampin for 4 months.[13]

†Daily isoniazid, rifampin, pyrazinamide, and ethambutol for 2 months, followed by daily isoniazid and rifampin for 4 months.[15]

‡Twenty percent of all DOT doses given through the Denver Metro Tuberculosis Clinic are delivered to patients.

system, costs included the cost of initial therapy plus all subsequent costs for treatment failures. In analyzing costs from the health-care system perspective, results both excluding and including patient time costs were obtained.

The results of the cost-effectiveness analysis for a cohort of 100 patients with active tuberculosis are presented in Table 4. Considering first the results from the perspective of a tuberculosis control program, DOT is less expensive, $1,405 vs $2,314 per patient treated, and results in cost savings of $90,900 for a cohort of 100 patients. DOT is therefore a dominant strategy in that it leads to both lower treatment costs and better health outcomes than SAT.

We then analyzed costs from the perspective of the health-care system, but initially excluded patient time costs. The inclusion of hospitalization costs for treatment failures greatly increases the cost advantage of DOT over SAT, $2,785 vs $10,529 per patient treated, for a net savings of $774,400 for a cohort of 100 patients. When patients' time costs are included, the cost of initial therapy with DOT becomes considerably greater than with SAT, $2,117 vs $1,339 per patient treated, reflecting the greater time costs required of patients on DOT regimens (Table 1). However, when the patient time costs of treatment failures are included, DOT has an even greater cost advantage over SAT, $3,999 vs $12,167 per patient treated, resulting in a savings of $816,800 for a cohort of 100 patients. This is attributable to the "downstream" time savings for patients that arise from the lower number of treatment failures with DOT.

Sensitivity Analysis

We examined the sensitivity of these results to changes in the values of a number of parameters in the model using threshold analysis. Since DOT is a dominant strategy in comparison with SAT, threshold analysis is an appropriate technique as it indicates the changes in the values of various model parameters that would be necessary to offset the cost advantage of DOT. The threshold analyses conducted in our study are all one-way analyses, *ie*, each parameter value is varied separately while maintaining all other parameters at their model values.

The threshold analysis demonstrates that substantial changes in cost estimates would be necessary to reverse the cost advantage of DOT (Table 5). For example, a fivefold increase in nursing time (0.25 vs 1.25 h) would be necessary to make SAT less expensive than DOT from the tuberculosis control program (or a 35-fold increase, 0.25 vs 8.75 h, from the health-care system perspective). Since the net cost advantage of DOT arises largely from the lower costs of hospitalization of drug-susceptible or multidrug-resistant treatment failures, a reduction in these costs would reduce this net cost advantage. However, the threshold analysis demonstrates that DOT retains a cost advantage even if the costs of hospitalization for either drug-susceptible or multidrug-resistant treatment failure are eliminated.

The cost advantage of DOT is also stable through a wide range of event rates. For example, the failure rate of DOT would have to increase fivefold over the

Table 4—*Cost-effectiveness of DOT vs SAT for a Cohort of 100 Patients With Initial Drug-Susceptible Tuberculosis**

	Cost of Initial Therapy, $ (1)	Cost of Therapy for Treatment Failures, $ (2)	Total Cost, $ (3)=(1)+(2)	No. of Patients Cured After Initial Therapy† (4)	Net Cost per Additional Patient Cured With DOT, $‡ (5)=(3)/(4)	Conclusion of the Cost-effectiveness Analysis§
Tuberculosis control program perspective (outpatient costs only)						
DOT	120,600	19,900	140,500	94.5		
SAT	122,100	109,300	231,400	79.0		
DOT−SAT	−1,500	−89,400	−90,900	15.5	−5,865	DOT dominates
Health-care system perspective (excluding patient time costs)						
DOT	120,600	157,900	278,500	94.5		
SAT	122,100	930,800	1,052,900	79.0		
DOT−SAT	−1,500	−772,900	−774,400	15.5	−49,961	DOT dominates
Health-care system perspective (including patient time costs)						
DOT	211,700	188,200	399,900	94.5		
SAT	133,900	1,082,800	1,216,700	79.0		
DOT−SAT	77,800	−894,600	−816,800	15.5	−52,697	DOT dominates

*This analysis uses discounted costs at 5%/yr.
†Assuming the event rates in reference 16.
‡A negative net cost means that the use of DOT results in a savings per additional patient cured.
§DOT dominates if both the cost per patient is lower and the number of patients cured after initial therapy is greater.

mile), for a total estimated cost of $18.30 for each dose delivered. The percentage of doses delivered to patients was included as a variable in the cost analysis.

We used the "institutional rate" at a commercial laboratory in Denver to estimate laboratory costs. We assumed that all patients would have monthly serum aspartate aminotransferase (AST) and bilirubin tests ($15.92) while receiving therapy and that those receiving second-line agents for multidrug-resistant tuberculosis would have a CBC count and serum electrolytes ($12.08) as well. Follow-up sputum cultures ($58.50) were assumed to be done more frequently for those receiving SAT or those being treated for a relapse (every 2 weeks until negative×3, then at 6 months, average of seven cultures) than for those receiving initial DOT (monthly×3, then at 6 months, total of four cultures). The Blue Cross/Blue Shield reimbursement rate ($40) was used to estimate the cost of follow-up chest radiographs (2 and 6 months).

Because DOT requires patients to attend a clinic much more frequently for supervised administration of therapy, there are differences in the amounts of time required of patients receiving DOT and SAT. Including travel time to and from the clinic, one clinic visit for either DOT and SAT was assumed to require 1.25 h of a patient's time. The cost of a patient's time was estimated at $11.75/h, based on mean earnings per day worked of $94 and assuming an 8-h work day.[28]

In summary, the direct treatment costs of initial therapy are estimated to be $1,206 for DOT and $1,221 for SAT, while a patient's time costs are estimated to be $911 for DOT and $118 for SAT. This gives overall costs for initial therapy of $2,117 for DOT and $1,339 for SAT (Table 1).

Estimated Costs for Treatment Failures

We estimated the cost of hospitalization for a drug-susceptible treatment failure by determining the cost for patients hospitalized between 1988 and 1993 at Denver General Hospital for the purpose of respiratory isolation and initiation of tuberculosis therapy. The charges for all services (laboratory, radiology, pharmacy, room charge, and physician fees) for these hospitalizations were obtained from computerized billing records. The figures were updated to 1994 dollars[31] and adjusted for the charge/cost ratio at Denver General Hospital (0.66, unpublished data; Chief Financial Officer; Denver General Hospital). With these adjustments, the average cost per day of hospitalization for tuberculosis at Denver General Hospital was $693. We assumed that 80% of patients with drug-susceptible failure of initial therapy would be hospitalized for an average of 14 days and included the cost of treating drug-susceptible treatment failures as a variable in the cost analysis.

We used the estimate from Mahmoudi and Iseman[21] of $180,000 for the average charge for hospitalization for multidrug-resistant tuberculosis and assumed that all such patients would require hospitalization. We updated this estimate to 1994 dollars and adjusted for the payment/charge ratio for such patients (0.50) at the National Jewish Center for Respiratory Medicine and Immunology (J. Cook, MD; personal communication; April, 1995). With these adjustments, the estimated cost for hospitalization for treatment of multidrug-resistant tuberculosis is $115,740.

Patients with multidrug-resistant tuberculosis were assumed to require 24 months of chemotherapy, 21 months of which would be administered after a 3-month hospitalization. Drug regimens for multidrug-resistant tuberculosis are not standardized, but for the cost analysis, we assumed a regimen of ofloxacin, cycloserine, ethionamide, and capreomycin[32] for 6 months followed by 18 months of therapy with the oral drugs (drug cost, $7,834). Outpatient therapy for multidrug-resistant tuberculosis was assumed to be given as DOT, 5 d/wk, and SAT on weekends. Monitoring during therapy included audiograms while receiving capreomycin ($86.75, cost at Denver General Hospital) and frequent sputum cultures (average of 13) with drug-susceptibility determinations for second-line agents ($87.75, charge at National Jewish Center for Immunology and Respiratory Medicine) on initial cultures.

Considering a patient's time costs, it was assumed that a patient with a drug-susceptible failure would be unable to work for 3.5 weeks after diagnosis, because of the illness itself and the need to isolate those with pulmonary disease. For multidrug-resistant treatment failures, we estimated that a patient would be unable to work for 6 months after the diagnosis, because of prolonged hospitalization and the need for intensive therapy, including parenteral medications, during the first 3 months after hospitalization.

For multidrug-resistant disease, treatment extends beyond 12 months from initial diagnosis of active tuberculosis. Treatment costs and patient time costs incurred in the second and third years were discounted to reflect the lower present value of costs to be incurred in the future.[29] All hospitalization costs are expected to arise during the first year of therapy. The effects of discounting future costs of treatment of multidrug-resistant failures using discount rates of 5% and 8% are shown in Table 3. Since most of the costs of treating these patients are incurred in the first year of therapy, discounting and the choice of discount rate have little effect on the overall treatment and patient time costs.

RESULTS

Cost-effectiveness Analysis

In comparing the costs and effectiveness of DOT and SAT, we analyzed costs from the perspectives of a tuberculosis control program and health-care system. From the perspective of a tuberculosis control program, costs include the cost of initial therapy plus the cost of diagnosis and outpatient treatment for those who fail to respond to treatment or suffer a relapse. From the perspective of the health-care

Table 3—*Undiscounted and Discounted Costs of Diagnosis and Treatment of Multidrug-Resistant Treatment Failures*

	Undiscounted	r=5%	r=8%
Year 1			
Treatment costs			
Diagnosis and hospitalization	$116,427	$116,427	$116,427
Outpatient DOT	$ 1,989	$ 1,989	$ 1,989
Patient time costs	$ 12,891	$ 12,891	$ 12,891
Total—year 1	$131,307	$131,307	$131,307
Year 2			
Treatment costs, outpatient DOT	$ 7,958	$ 7,579	$ 7,369
Patient time costs	$ 2,686	$ 2,558	$ 2,487
Total—year 2	$ 10,644	$ 10,137	$ 9,856
Year 3			
Treatment costs, outpatient DOT	$ 3,979	$ 3,609	$ 3,411
Patient time costs	$ 1,343	$ 1,218	$ 1,151
Total—year 3	$ 5,322	$ 4,827	$ 4,562
Total	$147,273	$146,271	$145,725

Table 5—*Threshold Analysis for the Comparison of Costs of Tuberculosis Treatment Using DOT vs SAT From the Perspectives of a Tuberculosis Control Program and the Health-Care System**

Variable	Model Value	Threshold Value	
		Tuberculosis Control Program	Health-Care System
Cost of medications used for initial treatment using DOT, $	193	1,102	7,937
Cost of medications used for initial treatment using SAT, $	584	Not found[†]	Not found
Nursing time to administer one DOT dose, h	0.25	1.25	8.75
Cost of hospitalization for a drug-susceptible treatment failure, $	7,662	Not applicable	Not found
Cost of hospitalization for a multidrug-resistant treatment failure, $	15,740	Not applicable	Not found
Failure rate of initial therapy using DOT	0.055	0.306	0.325
Proportion of DOT treatment failures acquiring multidrug resistance	0.16	Not found	Not found
Failure rate of initial therapy using SAT	0.210	0.035	0.035
Proportion of SAT treatment failures acquiring multidrug resistance	0.29	Not found	Not found
Hourly cost of a patient's time, $	11.75	Not applicable	Not found

*The tuberculosis control program perspective includes the cost of outpatient treatment, including outpatient therapy for treatment failures. The health-care system perspective includes inpatient and outpatient costs of treatment. Costs for this threshold analysis are discounted at 5%/yr; patient time costs are excluded except for the analysis of the hourly cost of a patient's time.

[†]Not found—the cost advantage of DOT remained through all relevant values of the variable.

model value, or the failure rate of SAT would have to fall to one sixth of the value in the model to reverse the cost advantage of DOT.

Discussion

Using cost estimates and event rates from two urban tuberculosis control programs,[16] this decision analysis predicts that the use of near-universal DOT would substantially decrease the overall cost of treating tuberculosis. Although the cost of initial therapy with DOT is greater than that with SAT when patient time costs are included, DOT is less expensive because of its greater effectiveness in preventing failure and acquired drug resistance.[16] Previous cost comparisons of DOT and SAT have focused on the costs of initial therapy,[33,34] but our analysis suggests that the cost of initial therapy is only a small part of the overall cost of treating tuberculosis. Although our model does not include the costs of initial diagnosis (which may include hospitalization), it is sobering that approximately 90% ($9,308/$10,529) of the estimated direct cost of treating tuberculosis with an SAT program may be due to treatment failures.

It is important to recognize that an additional investment in tuberculosis control programs may be required to achieve this reduction in overall costs. This is particularly true if the tuberculosis control program has been inadequately funded in the past. The increase in funding required to institute widespread DOT in New York City[17] was the result of a long history of inadequate public funding for tuberculosis in that city.[8] Reports from areas with adequate public health infrastructure for tuberculosis control indicate that the conversion from SAT to near-universal DOT was not associated with increases in overall costs.[16] Depending on personnel costs and the amount of outreach necessary to ensure ingestion of doses, the cost of initial treatment with DOT may be substantially higher than initial therapy with SAT. Finally, the fiscal benefit of a switch to DOT may not become evident for several years, as the incidence of failure and relapse decrease. However, this analysis strongly suggests that an investment in a DOT program is a cost-effective use of limited public health funds.

The validity of a cost-effectiveness analysis model is determined by the accuracy of the assumptions regarding event rates and costs. In this analysis, we used the comparison of event rates with DOT and SAT from the Tarrant County study.[16] Although this study is a retrospective review of the application of SAT and DOT during two different time periods, to our knowledge, it is the only such comparison that has been published. Results from our clinic, which has practiced near-universal DOT with similar regimens for 15 years, corroborate the event rates from Tarrant County during the DOT era.[13] Reported rates of completion of tuberculosis treatment suggest that the results of SAT from the Tarrant County study are representative of other tuberculosis control programs; only 77% of US tuberculosis cases reported to the CDC in 1994 were documented to have been in patients who completed therapy within 12 months of its initiation.[35] The sensitivity analysis demonstrates that the event rates can vary substan-

tially from those seen in Tarrant County without changing the conclusion that DOT is a less expensive method of administering tuberculosis therapy.

There may be considerable local differences in the use of hospitalization for the treatment of patients who fail to respond to the initial course of therapy. However, a recent report suggests that hospitalizations are common in the treatment of tuberculosis.[36] An analysis of hospital discharges in 16 states found that the number of hospitalizations for tuberculosis was approximately equal to the number of incident cases of tuberculosis and that the average length of hospitalization was nearly 20 days. In that many patients with tuberculosis are treated entirely as outpatients, this study suggests that a substantial percentage of tuberculosis patients are hospitalized multiple times and that extended hospitalizations are common. Other brief reports suggest that hospitalizations for multidrug-resistant tuberculosis are frequently long[37] and expensive.[22] We also used two techniques to analyze the effects of differential use of hospitalization on the overall cost analysis. First, we analyzed outpatient costs separately from the costs of therapy, including hospitalization (the tuberculosis control program perspective vs the health-care system perspective). Second, we included the costs of treating drug-susceptible and multidrug-resistant treatment failures, which are driven by costs of hospitalization, as variables in the sensitivity analysis. These analyses demonstrate that our assumptions about the use of hospitalization were not decisive factors in concluding that the use of DOT is less expensive than the use of SAT. While the exact cost-benefit from the use of DOT will vary substantially based on local conditions and practices, our analysis suggests that DOT will be cost-effective under the conditions likely to be found in most US urban tuberculosis control programs.

The cost estimate for treatment of multidrug-resistant tuberculosis in this analysis was based on the published data from a tertiary referral center.[21] Although the cost for initial therapy for multidrug-resistant tuberculosis might be lower in other settings, it should be noted that we included only the costs associated with a single relapse, though multiple courses of therapy and hospitalizations are common in patients with drug-resistant strains.[21] This analysis assumes that secondary drug resistance would be promptly recognized and appropriately managed, yet such patients are often treated for years prior to referral for definitive care.[21] Finally, the sensitivity analysis demonstrates that DOT is less expensive than SAT regardless of the cost of treatment for multidrug-resistant tuberculosis.

To strengthen the conclusion that DOT is cost-effective, we used a number of estimates that may bias the analysis against DOT. We assumed that the costs of initial diagnosis and hospitalization for tuberculosis would be the same in a DOT and SAT program. It is quite possible, though, that the knowledge that a patient will be followed up very closely in a DOT program may shorten, if not obviate, hospitalization for some patients at the time of the initial diagnosis of tuberculosis.[38] Our estimate for the cost per day of hospitalization for drug-susceptible tuberculosis ($693) appears to be conservative; in a recent study, the average cost per day for inpatient tuberculosis treatment ranged from $740 to $1,210.[39] We used a rate for acquired multidrug resistance with DOT that came from an intention-to-treat analysis, yet in that study, no patient who received DOT from the initiation of antituberculosis therapy developed drug resistance.[16]

Due to the complexity it would entail, we did not include in this cost analysis other outcomes of treatment that are likely to make DOT more cost-effective than SAT. We did not include an analysis of the costs of a fatal relapse of tuberculosis, yet the mortality of recurrent tuberculosis may be appreciable, particularly in an HIV-infected patient.[40] Finally, we did not include any costs that result from transmission during the period of infectiousness related to treatment failure. One of the major benefits of effective treatment of active tuberculosis is the prevention of further transmission. The decrease in primary drug resistance in Tarrant County[16] and the recent report of decreasing case rates in New York City[17] after the widespread application of DOT support the assertion that DOT decreases secondary cases.

The resurgence of tuberculosis in the United States is due to a number of factors and the effectiveness of DOT offers an important measure to reverse this trend. This analysis shows that, far from discouraging the use of DOT, economic considerations are an additional powerful argument for the widespread implementation of DOT. Furthermore, the effectiveness and cost-effectiveness of DOT should be studied in developing countries, where the burden of tuberculosis is greatest.[2]

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Expenditure and loss of income incurred by tuberculosis patients before reaching effective treatment in Bangladesh

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SUMMARY

This small study undertook to assess the economic consequences of developing tuberculosis (TB) among patients presenting to the TB clinic run by the Danish Bangladesh Leprosy Mission in NW Bangladesh. The loss of income resulting from the illness, and the actual expenditure incurred by medicines and doctor's fees before registration for treatment, were estimated and totalled for 21 patients serially registered at the clinic. The results showed a mean financial loss to the patient of US$ 245—an exorbitant sum for a village Bangladeshi. Perhaps economic deprivation suffered by TB patients could be used as a measure of success of the programme.
KEY WORDS: tuberculosis; Bangladesh; treatment; expenditure

THE DANISH-BANGLADESH LEPROSY MISSION (DBLM), a large leprosy control programme in NW Bangladesh, introduced a pilot tuberculosis (TB) control programme into part of its project area in 1994. There are many similarities between the case finding and case holding activities of both TB and leprosy, but one aspect that came to our attention which is totally different is the financial cost incurred by patients before they ever reach our clinics. We decided to conduct a small study to investigate the economic consequences of TB.

PROJECT BACKGROUND

DBLM is a large leprosy control project operating in four northern districts of Bangladesh, an area estimated to have the highest prevalence of leprosy in the country (5/1000).[1] In two of these districts, Thakurgaon and Panchagar, the control programme has now been operating since 1978, and multidrug treatment was introduced in 1984. The area covers 3214 km^2 and has a population of 1 723 000. It is supported by a small hospital of 16 beds in the district town of Thakurgaon.

TB is a major public health problem in Bangladesh. The prevalence rate is reckoned to be 2–3/1000 across the country (Dr Liisa Parkkali, personal communication), and our impression is that the level of TB in northern Bangladesh is of that order. Thus in Thakurgaon and Panchagar districts there is a prevalence of roughly 4 500 cases.

The TB programme was started in June 1994 following a short training course for the staff involved. Since then there has been a weekly diagnostic and treatment clinic at Thakurgaon Centre and monthly diagnostic clinics operating at another four peripheral clinics. After completing their initial intensive phase of treatment patients can collect their medicines monthly from their nearest Leprosy (now Leprosy/TB) Clinic. A Government TB Clinic has existed for many years in Thakurgaon town, but treatment has not been free and outreach very limited. The DBLM TB control programme is the first serious attempt at TB control in these two districts offering free treatment.

Diagnosis is by sputum examination, and treatment follows the Bangladesh National TB Control Programme's guidelines. All TB medicines are obtained quarterly from the government. All new sputum positive patients receive an 8-month treatment regimen consisting of a 2-month intensive phase of daily rifampicin, pyrazinamide, ethambutol and isoniazid, followed by a 6-month continuation phase of isoniazid and thiacetazone.

Table 1 shows how TB case finding has grown since the programme started.

METHOD

Twenty-one TB patients registered serially in March 1996 were interviewed after completing 1 month of treatment to assess the cost of their illness before attending our clinic. The interviewer visited patients in their own homes in order to visually confirm the information given. The patients were treated in their own homes, and were not hospitalised.

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[A version in French of this article is available from the IUATLD Secretariat in Paris.]

Table 1 New TB case finding, Thakurgaon and Panchagar districts 1994–1996

Year	1994	1995	1996
New TB cases	204	635	798

RESULTS

The results of the interview are summarised in Table 2.

Money needed for treatment was raised in eight cases by selling land or livestock and in three cases by taking out a loan. It is emphasised that these costs were incurred before the patients began receiving short-course chemotherapy at the DBLM clinic.

The DBLM clinic provides all services and medicines free of charge (drugs are given free by the Government of Bangladesh to the DBLM), and the only expenditure on the part of the patient is transport costs to and from the local clinic. Six of the 21 patients lived near enough to the clinic to walk. Of the remaining 15, five felt that the transportation costs necessary (US$ 0.25–1.25) were a relatively large amount of money for their family.

The average annual income for a Bangladeshi family is US$ 780.[2] The average total loss of income and expenditure (US$ 245) thus represents nearly 4 months of family income. Two patients actually suffered a loss of US$ 1000.

DISCUSSION

Saunderson, evaluating the economic costs of alternative programme designs for TB control in rural Uganda, included the costs to the patients and their families; 32 patients were interviewed in detail, and of these 21/22 subsistence farmers had lost production because of their disease, 8/10 employees had stopped or closed their businesses, two wives had been divorced since their illness and five of the children had been withdrawn from school because of their parents' inability to pay school fees.[3]

This small study undertaken in Bangladesh confirms Saunderson's general findings in another, very different Asian context. The total expenditure and loss of income caused by a family member developing TB in northern Bangladesh is of a very high level, higher than either we or our national staff expected to find. It is an interesting contrast to the social stigmatisation faced by the project's leprosy patients. A local Bangladeshi synonym for TB is 'Rajer rog'—King's disease—since it is a disease that only kings can afford to suffer.

At present the success of a TB control programme is assessed by looking at case finding rates compared to estimated incidence and prevalence rates, sputum conversion rates, relapse rates and other statistical indicators. Little attention is paid to the economic impact of the disease on the individual or his family and community. As TB programmes and access to free treatment become more widespread, it seems logical that sufferers will seek treatment earlier and from free treatment sources, thus diminishing the economic impact of the disease. It is worthy of note that the DBLM TB programme is the first organised TB programme operating in the districts of Thakurgaon and Panchagar which offers completely free treatment. Perhaps the level of economic deprivation suffered by TB patients could be used as a measure of success of the programme.

Table 2 Results of patient survey

A General data

Sex	Male = 15, Female = 6 (Total 21)
Mean age	38 years (range 16–60)
Mean duration of illness	16 months (range 2–60 months)
Patients unable to work	12/21
Mean loss of work time	14 months (range 5 days–60 months)

B Loss of income/extra expenditure before reaching DBLM clinic

	Mean/US$	Range/US$
Loss of income (estimated)	115	(0–500)
Doctor's fees	9	(0–25)
Medicine costs	112	(0–475)
Laboratory costs	8.5	(0–25)
Mean loss of income/expenditure	245	(0–1000)

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RÉSUMÉ

Cette petite étude a cherché à apprécier, dans le nord-ouest du Bangladesh, les conséquences économiques du développement d'une tuberculose parmi les patients consultant à la Clinique de Tuberculose assurée par la Mission Danoise contre la Lèpre au Bangladesh. La perte de revenus résultant de la maladie et les dépenses effectives pour les médicaments et les honoraires médicaux avant l'enregistrement pour traitement furent estimées et addi-

This article examines the costs incurred by patients before accessing treatment in Govt. run facilities. It says that cost incurred by pts. during TB treatment was small compared to what they spent before they entered the Govt. set up.

It also elaborates on how this money was raised by people & also some of the social consequences like divorce & absence from school.

It further puts forth argument that this cost is an indirect measure of the spread & success of a TB control programme.

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Costs and cost-effectiveness of different DOT strategies for the treatment of tuberculosis in Pakistan

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An economic study was conducted alongside a clinical trial at three sites in Pakistan to establish the costs and effectiveness of different strategies for implementing directly observed treatment (DOT) for tuberculosis. Patients were randomly allocated to one of three arms: DOTS with direct observation by health workers (at health centres or by community health workers); DOTS with direct observation by family members; and DOTS without direct observation. The clinical trial found no statistically significant difference in cure rate for the different arms.

The economic study collected data on the full range of health service costs and patient costs of the different treatment arms. Data were also disaggregated by gender, rural and urban patients, by treatment site and by economic categories, to investigate the costs of the different strategies, their cost-effectiveness and the impact that they might have on patient compliance with treatment.

The study found that direct observation by health centre-based health workers was the least cost-effective of the strategies tested (US$310 per case cured). This is an interesting result, as this is the model recommended by the World Health Organization and International Union against Tuberculosis and Lung Disease. Attending health centres daily during the first 2 months generated high patient costs (direct and in terms of time lost), yet cure rates for this group fell below those of the non-observed group (58%, compared with 62%). One factor suggested by this study is that the high costs of attending may be deterring patients, and in particular, economically active patients who have most to lose from the time taken by direct observation.

Without stronger evidence of benefits, it is hard to justify the costs to health services and patients that this type of direct observation imposes. The self-administered group came out as most cost-effective ($164 per case cured). The community health worker sub-group achieved the highest cure rates (67%), with a cost per case only slightly higher than the self-administered group ($172 per case cured). This approach should be investigated further, along with other approaches to improving patient compliance.

Key words: DOT, tuberculosis, direct observation, patient compliance, costing study, cost-effectiveness analysis, Pakistan

Introduction

Tuberculosis (TB) remains the most common cause of adult deaths in developing countries. Numbers of cases are continuing to grow, due to population growth, HIV and, in some circumstances, inadequate treatment. There is therefore considerable interest in improving the performance of health services in treating TB, and in particular in increasing patient compliance. Non-compliance rates are often high, and can lead to relapse and the development of drug-resistant strains, which are harder and more expensive to treat.

The current model of treatment recommended by the World Health Organization (WHO) and the International Union against Tuberculosis and Lung Disease (IUATLD) is the DOTS (directly observed treatment, short-course) strategy. The DOTS model includes strengthening diagnosis, treatment, outcome monitoring, drug supplies and direct observation of treatment. There has been little evidence to date, however, of the additional benefit provided by the direct observation of treatment (DOT) component. A study in South Africa (Zwarenstein et al. 2000) found some benefit from DOT using lay health workers, but the result was not statistically significant. A Thai study (Kamolratanakul et al. 1999) found DOT to be effective, but they had adapted the model, using DOT by family members, supported by a once-weekly home visit from health workers.

A recent review of DOT and treatment adherence (Volminck et al. 2000) emphasizes the importance of a wide array of interventions to promote adherence – such as reminder letters, financial incentives and increased supervision by staff. They observe that factors such as the quality of interaction between patients and supervisors may be more relevant than

the DOT itself, and recommend that WHO make explicit both the mixture of inputs which are required to improve adherence and the additional resources which successful implementation of DOT usually requires.

The details of the clinical trial in Pakistan are published elsewhere (see Walley et al. 2001). However, the overall conclusion – which is surprising – is that the directly observed element made little difference to cure rates. Cure rates rose from 26 to 60% in the trial group as a whole, with no statistically significant difference between the different arms and with similar results from the three sites. This raises some important questions for the implementation of the DOT strategy in this and other countries.

This paper takes a social perspective, focusing on the costs to the health service and to patients of the different treatment strategies. These can be used to shed light on a number of important questions:

What are the costs to patients of the different treatment strategies? What proportion can be attributed to the directly observed element? To what extent may these costs account for (poor) compliance levels?

(2) What are the total (patient and health service) costs of the different treatment strategies?

(3) What is the overall cost-effectiveness of the different strategies, looking at total costs and cure rates?

Methods

Strategies compared

In order to assess the effectiveness of different DOT strategies, a randomized controlled trial was carried out in three trial sites (Rawalpindi, Gujranwala and Sahiwal) in the Punjab, Pakistan, with three arms. All three received a strengthened service (i.e. the other components of DOTS), but one group had their treatment supervised by health workers, a second by family members and a third were unsupervised. Within the arm supervised by health workers, patients were divided into two sub-groups: those living within 2 km of the nearest health centre were supervised by health workers based in those centres, while more distant patients visited their local community health worker (CHW), commonly a Lady Health Worker (LHW). The health worker DOT followed the WHO guidelines, adapted to the Pakistan context. In contrast, family member DOT is not recommended by WHO, but was included as a possible alternative when access to health workers is poor. The self-administered group is the current practice in Pakistan and was included as a control.

The treatment takes 8 months. The 'intensive phase', during which observation of treatment is recommended, covers the first 2 months. Three visits to a diagnostic centre are required during the first 2 months, for initial diagnosis, sputum smears and follow-up. During the remaining 6 months, a further two visits should be made for sputum examination and clinical assessment. During this second phase, all treatment groups visit their local health facility every 2 weeks to collect their drugs.

The main difference between the arms is the number of daily visits required for direct observation of treatment during the first 2 months. Patients allocated to the health facility group made an additional 40 visits during this period to their local health facility to be watched taking their drugs, while the CHW group visited their village health worker an additional 53 times, and family member patients had 53 meetings with the family member chosen to supervise their drug taking.

Costing

Patients

From the total of 497 patients in the trial (all adult), 337 (68%) were found and interviewed after the completion of the trial. Of these, 194 were from rural areas and 143 from urban. Forty-six belonged to the health facility group, 73 to the CHW group, 107 to the family member group and 111 were unsupervised. The proportion found and interviewed from each of the three trial sites ranged from 66–69%. Forty-eight per cent were male and 52% female.

Patient costs were collected using a standardized questionnaire. Data collected included travel and transportation costs, service charges, miscellaneous out-of-pocket expenses and the opportunity costs of travelling to health facilities and receiving treatment. Service charges (though at a subsidized rate) were levied at two of the three diagnostic centres run by NGOs; treatment was free at the government-run TB Centre. Fees are added in to the totals for patient costs, in order to illustrate the real costs to patients. They are omitted from the final cost-effectiveness ratios in order to avoid double-counting with health service costs (the fees are contributing to the service costs of the NGOs). Data on the cost of family escorts were also collected (these are particularly relevant for women).

In order to value the time lost during travel and treatment, focus group discussions were held among patients arriving at the TB Centre, Rawalpindi, and for different occupational groups. Average losses (in Pakistan Rupees) were calculated for each of the six main occupation groups: unskilled daily labourers; skilled daily labourers; farmers; household women; self-employed traders; and the unemployed. An average opportunity cost of Rs.11 per hour was used to value time lost for travel, waiting, treatment, observation of drug taking, etc. This was a conservative estimate, based on the assumption that a full day's labour would not be lost. If attending treatment meant losing the opportunity to work for the full day (e.g. for day labourers), the opportunity costs would be much higher (estimated average daily cost of Rs.100).

Escorts often accompany the TB patients on their visit to the diagnostic and treatment centres. This is more commonly the case with female patients. Based on the interviews with patients, gender-specific data were collected on the frequency of use of escorts. This was then used to calculate the direct and opportunity costs that they incur. It was assumed that the time and transport costs they face are the same as for patients.

Health service costs

Data on health service costs were collected from the three trial sites (Rawalpindi, Gujranwala and Sahiwal). These included:

- the costs of clinical assessment at the diagnostic centres (including laboratory investigations and diagnostic procedures, health education, record keeping, etc.);
- contacts at the treatment centre for drug collection (for urban patients);
- cost of outpatient visits to basic health units and rural health centres (for rural patients to collect drugs);
- the TB drug regimen;
- supervision of patients by their designated supervisors;
- costs of strengthening the programme (a one-off start-up cost of setting up the TB DOTS programme).

For the diagnostic centres, expenditure data for 1997–8 were used to estimate costs. To derive unit costs, cost centres were set up for the various components of the programme (such as clinical assessment, radiological investigations, laboratory investigations, health education, record keeping and TB drugs). Administrative or overhead costs were allocated to them on the basis of the payroll costs of the service centres. Two other allocation methods were tested: one using the proportion of the budget allocated to the cost centre; the other using number of persons employed in that department. The first method was found to be weighted in favour of departments with high expenditure (e.g. with large drugs budgets); the second was found to favour departments with a large number of support staff (such as clinical assessment). The payroll method was found to be the most proportionate.

Annual building rent (based on the size of facility and market rental values) was added to reflect the capital costs of the programme. Similarly, a depreciation charge of 10% of the value of fixed assets was added to reflect the economic costs of equipment (using an estimated useful lifetime of 10 years for most equipment, such as X-ray machines). Drugs and supplies budgets were linked to number of patient visits to produce average costs per TB patient.

At the district level, budget data for 1997–8 were used as the basis for calculating average costs per outpatient visit to peripheral units – the basic health units (BHU) and rural health centres (RHC). Budgets are usually consumed, so this was thought to be a good proxy for expenditure. Costs of administration and supervision at the district level were included, as well as funds allocated directly to the peripheral centres. Based on interviews with officials, it was understood that on average RHCs consumed three times the budget of a BHU. This ratio was therefore used to allocate supervision and administrative costs. Drugs costs were taken from the annual budget for medicines. These costs were then linked to numbers of patients visiting the health centres (taken from the health management information system) to produce unit costs.

Drugs costs were estimated at Rs.2000 per patient in the provincial plan (PC-1). This was cross-checked against a retail market survey, which came out with the figure of Rs.1915 for a complete course of adult patients. As this was close, the figure of Rs.2000 was used.

To calculate the costs of community health workers, two sources were used: (1) the PC-1, issued by the government, which details the costs of LHWs; and (2) interviews with government officials to establish overall costs of employing LHWs, and what proportion might be attributed to this programme. A monthly cost for work on the programme was calculated, including salary, supervision costs, driver costs and petrol for travel. Interviews were carried out to assess the time taken by CHWs and LHWs for patient visits and the average number of patient visits per day (1997–8). From this, a daily rate for LHW services was calculated, as well as a cost per patient visit.

The costs of strengthening the programme were taken from provincial plans for implementation of community-based DOTS TB care in three of the four provinces (Northwest Frontier, Punjab and Sindh; figures not available for Balochistan). They include programme management, supervision and monitoring costs; health education; training; and investments in laboratory materials and salaries. Although these are start-up costs for the programme (i.e. non-recurrent in theory), it was decided to include them as they will be necessary in most cases and should contribute to the higher cure rate achieved. Overall costs were divided by the number of patients treated, to gain an average cost per patient across the different sites.

Although from a decision-maker's point of view, marginal cost information is preferable, this information was not available in this study, and so average cost figures are used throughout. As programme size, organization and/or utilization changes, these unit cost figures will of course be altered.

The smaller items are reported in Pakistan Rupees (Rs), while the main results are reported in US dollars ($). They are converted from Pakistan Rupees at the exchange rate prevailing at the time of the trial, which was roughly Rs.50: US$1 (1997–8), and rounded up or down to the nearest dollar.

Using the cure rates data from the clinical trial (which used the WHO/IUATLD definition of cure – sputum negative at 7 or 8 months, and on at least one previous occasion), we have calculated a cost per patient cured for the different arms.

Results

Patient and family costs

Patient costs varied by site and rural/urban status. Generally, costs increased with distance, as you would expect, so that visits to diagnostic centres were more costly than treatment centres, etc. Average figures for distance, time and direct costs incurred per visit are presented in Table 1. Note that the service charges are based on two sites only, as there were no charges made at the government centre at Rawalpindi.

Table 1. Average distances, times and costs per visit for TB trial patients

	Mean	Median
Distances – average distance from home to the:		
Diagnostic centre	15 km	12 km
Treatment centre	6 km	4 km
CHW/LHW	2 km	1 km
Family supervisor	0 km	0 km
Time – average time spent in travel to and from:		
Diagnostic centre	136 minutes	120 minutes
Treatment centre	76 minutes	60 minutes
CHW/LHW	19 minutes	20 minutes
Family supervisor	0 minutes	0 minutes
Costs – travel, to and from:		
Diagnostic centre	18 Rs.	16 Rs.
Treatment centre	8 Rs.	6 Rs.
CHW/LHW	2 Rs.	1 Rs.
Family supervisor	0 Rs.	0 Rs.
Costs – misc. out of pocket expenses:		
Diagnostic centre	33 Rs.	10 Rs.
Treatment centre	13 Rs.	0 Rs.
[illegible]W/LHW/Family supervisor	0 Rs.	0 Rs.
Co - service charges at diagnostic centre (apply in two sites only; averaged over three):		
Clinical assessment	29 Rs.	20 Rs.
Lab. Investigation: ESR	12 Rs.	0 Rs.
Lab. Investigation: Sputum microscopy	35 Rs.	0 Rs.
Lab. Investigation: X-ray/MMR	90 Rs.	0 Rs.
Pharmacy	21 Rs.	0 Rs.

An urban patient incurred direct costs of Rs.32 per visit to the diagnostic centre (either for diagnosis/treatment, or drug collection). Added to this was Rs.38 in opportunity costs for diagnosis/treatment (based on the valuation of Rs.11 per hour), and Rs.18 in opportunity costs of drug collection. A rural patient incurred direct costs of Rs.63 per visit to the diagnostic centre and Rs.13 per visit to the treatment centre. Their average opportunity costs were Rs.59 for visits to the diagnostic centre and Rs.17 for visits to the treatment centre.

A[illegible]atients make five visits to the diagnostic centres, and 17 to [illegible]eatment centres to collect drugs. The health centre group had an additional 40 visits to their treatment centre for DOT; while CHW and family supervision patients had 53 additional visits for DOT. The average costs of visiting the CHW for an urban patient was Rs.5 (i.e. Rs.265 total), while rural patients incurred Rs.2 per visit (Rs.106 total). These reflected opportunity costs only: no direct costs were incurred. For family member patients, no additional costs (direct or opportunity) were thought to have been incurred. Table 2 shows total patient costs, by treatment arm. The differences in total patient costs are attributable to the DOT element.

A patient follow-up survey (with a 67% response rate) carried out as part of this trial sheds some light on compliance issues (see Table 3).

Table 2. Total patient costs, by treatment arms

	Unsupervised/family member DOT (US$)	Health facility DOT (US$)	Community health worker DOT (US$)
Patient direct costs of visits to diagnostic centre	5 (3 urban; 6 rural)	5	5
Patient direct costs of fortnightly drug collection from local health facility	8 (11 urban; 4 rural)	8	8
Direct costs of additional DOT visits	n.a.	18 (26 urban; 10 rural)	2
Opportunity costs of visits to diagnostic centre	5 (4 urban; 6 rural)	5	5
Opportunity costs of fortnightly drug collection	6	6	6
Opportunity costs of additional DOT visits	n.a.	14	5
Total patient costs	23	55	31

Table 3. Constraints to treatment – patients' responses

Barriers to treatment	Intensive phase (%)	Continuation phase (%)
Health-related problems	36	19
Time for round trip	31	21
Cost of travel/visit	29	17
Excessive waiting time at treatment centre	16	7
Unavailability of person to accompany	14	6
Social events – birth, death, marriages, etc.	11	9
Job/occupational reasons	9	10
Unfriendly attitude of staff	4	1
Lack of support by 'significant people'	1	0
Other	2	1

Table 4 shows the total escort costs, by treatment arm, gender and place of residence. These costs are not included in the total cost and cost-effectiveness results as their influence on compliance is not established and they may be less applicable in other contexts.

Health service costs

An average visit to the diagnostic centre cost the health service Rs.24 for clinical assessment. Adding in the costs of other inputs, such as pharmacy costs, record-keeping, etc. the costs of treating one patient were estimated at Rs.1364 in the intensive phase (for three visits) and Rs.1149 in the continuing phase (for two visits). This comes to a total of Rs.2513 per patient.

The cost of a visit to the treatment centre for drug collection came to Rs.93 per patient (including the cost of drugs). The total for rural patients was therefore Rs.1581 for 17 visits. The urban patients collected their drugs from the diagnostic centre, at a cost of Rs.40 per visit, or Rs.680 in total for 17 visits.

The additional costs to the health service of DOT depend on the treatment arm. Rural patients in the health centre sub-group made 40 additional visits for DOT to the treatment centre, at a cost of Rs.93 per visit (Rs.3720 in total). Urban patients visited the diagnostic centre 40 additional times, at a cost of Rs.24 per visit (Rs.960 in total). CHW-supervised patients had an extra 53 visits from CHW/LHW, at a cost of Rs.6 per visit (Rs.106 in total).

Programme strengthening costs averaged Rs.425 per person for all treatment arms.

Table 5 presents the total health service costs, by treatment arms. As with the total patient costs, the differences between the final figures are entirely due to the DOT element of the package.

Table 4. Costs of escorts (by treatment arm and by gender)

	Urban, male (US$)	Urban, female (US$)	Rural, male (US$)	Rural, female (US$)
Unsupervised treatment	10	18	8	16
Health facility	26	46	12	33
Community health worker	9	19	7	19
Family member	10	18	8	16

Table 5. Average health service costs for DOT per patient (by treatment arm)

	Unsupervised/family member DOT (US$)	Health facility DOT (US$)	Community health worker DOT (US$)
Programme strengthening cost	8.5	8.5	8.5
Costs of clinical contacts at diagnostic centre for diagnosis and follow up	50	50	50
Costs of clinical contacts at local health facility for fortnightly drug collection	23 (14 urban; 32 rural)	23	23
Health service costs of additional DOT visits	n.a.	47 (19 urban; 74 rural)	6
Total health service costs	81.5	128.5	87.5

In Table 6, patient and health service costs are added to give the overall cost of each treatment arm. Total costs are presented for rural and urban areas, within each treatment arm. The cost of the health facility and CHW DOT arms are presented in relation to the benchmark of self-administered or family DOT approaches, in order to illustrate the magnitude of increase in total costs for these arms.

The results (in Table 7) suggest that self-administered treatment has been the most cost-effective approach in this case ($164 per case cured), though CHW supervision is only slightly more costly ($172 per case cured) and achieves a higher cure rate. Least cost-effective is health centre DOT ($310 per case cured).

A sensitivity analysis was done on the final cost per case cured, to see how it was affected by changes in the cure rates. The upper and lower limits of confidence intervals for differences between the different DOT arms and the control group cure rates were taken from the original clinical trial. The results are shown in Table 8.

Discussion

In terms of cost-effectiveness, from this analysis health centre DOT comes out as least cost-effective, which is an interesting result as this has been the recommended model of practice within the current WHO DOTS package. According to these results, self-administered treatment is the most cost-effective. However, the preferred option might be treatment supervised by CHWs, which is slightly more costly but has a higher cure rate. The incremental cost of shifting from self-administered to CHW supervision is $239 per extra case cured.

The sensitivity analysis supports these conclusions. At every level of likely cure rates, the health centre option comes out as the least cost-effective, and the self-administered group as most cost-effective. The only exception is when the CHW group cure rates are at the top of their range; this option then becomes the most cost-effective approach.

Cure rates for the CHW group have to be treated with some caution though, as this group was not fully randomized in the clinical trial (patients were randomized to the health worker arm as a whole, but within that were divided into health centre and CHW sub-groups according to how far they lived from the health centres). It is therefore possible that there is some bias in the allocation of patients between these two sub-groups.

For the health worker group as a whole, there is no statistically significant improvement in cure rates compared with the other two arms. As the cure rates are broadly the same

Table 6. Total cost to health service and patients of different treatment arms

	Unsupervised/family member DOT	Health facility DOT	Community health worker DOT
Total cost	$102 ($93 urban; $110 rural)	$180 ($153 urban; $208 rural)	$115 ($107 urban; $124 rural)
Total cost as % of benchmark (unsupervised arm)	100%	176% (164% urban; 189% rural)	114% (115% urban; 113% rural)

Table 7. Cost-effectiveness of the different treatment strategies

	Health centre DOT	Community health worker DOT	Family member DOT	Unsupervised
Cure rate	58%	67%	55%	62%
Cost per patient treated	$180	$115	$102	$102
Cost per case cured	$310	$172	$185	$164

Table 8. Sensitivity analysis of cure rates and their effect on cost per case cured

Treatment arms (or sub-groups)	Lowest estimate of cure rate (95% CI)	Highest estimate of cure rate (95% CI)
Family member group	38% cure rate $276 per case cured	59% cure rate $178 per case cured
Health centre group	50% cure rate $360 per case cured	70% cure rate $257 per case cured
Community health worker group	59% cure rate $195 per case cured	79% cure rate $146 per case cured

across the different treatment arms, it is possible to speculate that some of the positive motivational effects of DOT were cancelled out by the increased costs which patients faced, leaving the results roughly the same as if no DOT had taken place.

What the cost data highlights is the degree of additional financial burden that direct observation imposes, especially in the case of the health centre patients. This approach increases the health services costs by 126% for urban patients and 182% for rural. At the same time, patient costs rise by even more: 267% for urban patients and 207% for rural patients. During the intensive phase of treatment, DOT at health facilities accounts for 62% of patient costs in urban areas and 52% in rural areas. For the CHW group, DOT accounts for roughly 25% of rural and urban patient costs.

The high costs to the patient of direct observation by health workers (especially in the health centres) are likely to have an influence on compliance levels. Within the trial, 18% of patients randomized to the health worker DOT (either health centre or CHW) were unable to persevere and were given self-administered treatment (Walley et al. 2001). For family member DOT, the figure is 2%, reflecting perhaps the lower patient costs incurred by this arm.

One issue is whether the patients who responded (68%) are representative of the total sample in the trial. The breakdown by trial site, by gender and by location suggests that they should be fairly representative. The proportion responding by trial site has a narrow range of 66–69%. Fifty-two per cent of respondents were female and 48% male (compared with 49% female and 51% male in the full trial sample). In terms of location, 58% were rural and 42% urban (not very different from the trial sample of 56% rural and 44% urban).

Consistent with other results, the escorts' costs show the health facility approach to be most costly. For all treatment arms, women are likely to incur about twice the cost of men in terms of escorts' time and expenses. Another interesting feature is that the costs of access, for escorts, to urban health facilities appears to be higher than for rural patients, which is contrary to what we might have expected.

The reason why CHW patients' escorts incur lower costs in some categories than family member escorts is that family member patients have to visit their local health facility fortnightly to collect drugs, whereas this function is performed by the CHW on behalf of their patients.

This study provides a very comprehensive view of the costs to the health service and to patients of the different DOT strategies. The decision to include patient costs can be justified by the nature of the programme itself, which imposes considerable inconvenience on patients (daily visits to receive drugs), and on their family members where escorts are required. The decision to list escort costs separately is debatable; arguably if the study takes a societal perspective these should have been included. Had we done so, it would have reinforced existing conclusions, as the highest costs are incurred by the health centre group. Similarly, a less conservative valuation of the opportunity costs of patient time would have increased the strength of the current conclusions.

Another debatable item is the inclusion of programme strengthening costs. It might be argued that these are a one-off investment that would not form part of the on-going costs of running the programme. However, we have included them for three reasons: first, because they are a necessary part of implementing DOTS in most regions; secondly, because they may contribute to higher effectiveness and utilization rates, and may therefore lower unit costs in the medium to long term; and thirdly, because they contributed to the cure rates achieved here, and so it would be false to report cost-effectiveness results without including them.

How typical are the costs included here – how likely are they to be valid for other settings? One issue is whether patients are charged for drugs and treatment. In some situations these are free; at other times (especially in the private for-profit sector) patients have to pay. This picture is reflected in this study, with two centres charging (at a subsidized rate) and the third providing treatment free of charge.

The costs reported here do of course reflect utilization levels. How typical are they of other regions? In Pakistan, generally, utilization is high for diagnostic centres, but lower for peripheral treatment centres. As many of the programme costs are stable over large ranges of output, an increase in utilization would result in lower costs per case treated or cured.

One of the main questions of interest is how to increase utilization and compliance rates for TB programmes worldwide. This study suggests that there may be a link with the costs to patients, although this conclusion needs to be examined further in in-depth interviews with patients and relatives. One of the striking differences in the trial was between drop-out rates for men and women: 15% of women dropped out in the intensive phase, compared with 25% for men (a statistically significant difference). One possible explanation for this is that men face higher opportunity costs of treatment and direct observation because they are more likely to be economically active (the focus group discussion suggested that housewives were likely to be able to rearrange and share activities to fit in with treatment). This may have contributed to a dramatic difference in overall cure rates: 71% for women, compared with 50% for men. (In Walley et al. 2001, sex was the only factor tested which was found to have a statistically significant impact on treatment outcome. The relationship with income was not investigated.) Another factor may be that the social consequences of the disease (e.g. on marriageability) are more significant for women than for men (Khan et al. 2000).

Analysis of default rates by treatment arm provides a more complex picture. Default rates are highest for the self-administered arm (33%) and lowest for the health worker arm (27%). However, within the health worker arm, CHW

patients had a lower rate (25%) compared with health centre patients (30%). There may be a number of factors at play here, including positive motivation of health workers and the disincentive effects of distance and time.

In the survey of constraints to treatment, from a patient perspective, time, costs and poor health come out as the top three factors. In addition, there are probably social costs to being identified as having TB. Two-thirds (63%) stated that they keep their disease secret from most of their relatives, while a similar proportion (64%) felt that their relationship with 'significant people' was affected by the disease. Inasmuch as direct observation makes their condition more public, it is likely to generate additional non-monetary social costs, such as stigma effects. When asked why they agreed to direct observation in this trial, the largest response was 'to get short, free and quality treatment' (68%). It seems likely that from a patient's perspective, it is the non-DOT components of DOTS that are attractive.

Conclusion

This study highlights the costs – both direct (fees, transport costs, etc.) and indirect (the cost of time lost from work as a result of treatment) – for patients as well as for health services of the DOT. If this model results in improved outcomes, then the costs may be justified. However, the clinical trial found no significant improvement in cure rates attributable to the element of direct observation within the DOTS model. In this context, there is little justification for imposing a high burden of inconvenience and economic costs on patients – costs that may constitute a major barrier to utilization and compliance with treatment.

Some of the correlations found between drop-out rates and different patient groups (by sex, economic occupation and treatment arm) merit further investigation in a social study to establish more clearly the factors that influence health-seeking behaviour.

On the basis of the analysis here, a provisional recommendation might be made to broaden the range of strategies employed to enhance patient compliance, beyond the element of direct observation (e.g. blister packs of drugs and patient education). Using CHWs for DOT also looks promising. This conclusion is consistent with the results of other related studies carried out to date (for example, Floyd et al. 1997 and Wilkinson and Davies 1997), and also with trends in WHO. WHO/StopTB is now using the DOTS label to refer to the broad TB strategy, and putting less emphasis on the direct observation component.

Cure rates for health centre observation were lower than self-administered patients, and this category generated the highest costs, both to patients and the health service ($310 per case cured). The standard type of observation recommended by the WHO DOTS model therefore came out as having the highest cost per case cured, while the CHW arm achieved the best cure rates and at a cost only slightly above the self-administered group ($172 per case cured, compared with $164). While the cost figures will vary from place to place, the underlying conclusion is likely to remain the same: that DOT (especially at health facilities) imposes considerable patient and health service costs, which can only be justified by proven benefits.

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ORIGINAL ARTICLES

TUBERCULOSIS

Over the past two years, the World Bank has been undertaking, with a number of collaborators Sector Priorities Review". The core of this Review is a series of studies on the public health s of major clusters of diseases in the developing world and on the costs and effectiveness o available technologies for their prevention and case management. This analysis of tuberculosis as one of these studies has proven to be one of the most surprising; because of the tremendous tuberculosis and the existence of interventions of proven efficacy that are some of the most co in the international public health armamentarium.

The present document (some clinical parts have been shortened for our readers who spe tuberculosis – the figures and content are final) comprises Chapter 11 of Evolving Health Sector in Developing Countries edited by Dean T. Jamison and W. Henry Mosley (see below in Intro

Tuberculosis in developing countries : burden, intervention and cost

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Introduction

Drafts of other components of the Review are now available from the Population, Health and Nutrition Division, Room S-6141, the The World Bank, Washington DC 20433. The conclusions of these studies, including the one on tuberculosis, do not necessarily reflect the policies of the World Bank.

Tuberculosis is an ancient disease that has long been a major public health challenge in the world, and remains a major health problem in developing countries. In the last century, tuberculosis was responsible for nearly one in ten deaths in Europe (Preston *et al.*, 1972). There is reliable evidence that irrespective of its magnitude, the tuberculosis problem in developed countries has been decreasing at least for the last 40 years, after the introduction of antituberculosis chemotherapy. In many developed countries, a steady decrease in mortality from tuberculosis in the pre-chemotherapy era was observed from the turn of this century if not before (Frost, 1937 ; Styblo, 1980). The elimination of tuberculosis in most developed countries will not be substantially influenced by AIDS because of the low prevalence of tuberculous infection in subjects aged 20 to 50 years in whom HIV infection is most frequent (Styblo, 1986, 1989).

On the other hand, in developing countries tuberculosis continues to be a major problem and there appears to have been virtually no tendency for tuberculosis to eliminate itself, in the absence of intensive control measures. U developed countries, HIV infection will result in a co able increase of tuberculosis cases in those developing tries where both tuberculous and HIV infections are lent. Tuberculosis remains, therefore, one of the top ties for action in developing countries, since tools e diagnose and cure infectious cases of tuberculosis and decrease transmission of tuberculous infection.

The purpose of this article is to review the present of tuberculosis in the world, with emphasis on the situat developing countries, and to examine various policy op concerning the prevention and treatment of tubercu with attention to their cost-effectiveness.

Tuberculosis incidence and mortality

Tuberculosis incidence

To put tuberculosis in the proper perspective we nee know the number and the age-distribution of new case tuberculosis which develop in a community each yea well as the number and the age-distribution of patients die from tuberculosis each year. Health information syst in developing countries are too incomplete to provide m ingful information on the incidence or mortality of tube losis (Styblo and Rouillon, 1981). We are forced to estim the burden of tuberculosis indirectly using several epide ological parameters. These include the average annual ris

tuberculous infection and the incidence of smear-positive pulmonary tuberculosis, the proportion of all cases of tuberculosis that are smear-positive and case-fatality rates for smear-positive tuberculosis and other tuberculosis.

Annual average risk of tuberculous infection

Tuberculosis epidemiologists have used the ability to detect the presence of infection using skin tests to measure the prevalence of infection in communities. A technique has been developed for converting this information on prevalence of tuberculous infection into a series of annual risks of tuberculous infection (Styblo *et al.*, 1969a ; Sutherland, 1976). If several tuberculin surveys of the same population have been made at different times (using similar techniques and testing a representative sample of non-BCG-vaccinated subjects of the same age) the level of and percentage decrease in the risk of infection can be estimated. The annual risk of infection tells us the probability that any individual will be infected or reinfected with *M. tuberculosis* in one year. This measure has become the standard indicator of the tuberculosis burden in a community (Leowski, 1988).

Since the 1950's a variety of tuberculin sensitivity surveys in developing countries provide us with an approximate picture of the annual risk of infection in different regions of the developing world. Table 1 presents our best estimates based on a recent review of survey data on the annual risk of infection (Cauthen *et al.*, 1988). The annual risk of tuberculous infection is probably highest in sub-Saharan Africa, followed closely by South and East Asia. For comparison the annual risk of infection in the Netherlands in 1985 was 0.012 % (Styblo, 1989).

Incidence of smear-positive tuberculosis

The natural history of tuberculosis illustrates that the main source of infection are patients suffering from smear-positive pulmonary tuberculosis. For the rest of this paper, therefore, tuberculosis will be divided into two categories : i) sputum smear-positive tuberculosis, which will be referred by the shorthand smear-positive tuberculosis, and ii) other tuberculosis, which includes those cases of pulmonary tuberculosis that are sputum smear-negative and extra-pulmonary tuberculosis. As children rarely suffer from sputum smear-positive tuberculosis, most cases of tuberculosis in children will be included in the category other tuberculosis. (If children are smear-positive, they are, as adult patients, highly infectious sources of infection. If they are smear-negative/culture-positive or smear-negative/culture-negative they are much less infectious.) The above two categories are sometimes labelled infectious tuberculosis and non-infectious tuberculosis, respectively (*e.g.* Ministry of Health and Family Welfare, India 1986). The distinction between sputum smear-positive tuberculosis and other tuberculosis is particularly important when considering the policy options for tuberculosis control and prevention (Rouillon *et al.*, 1976).

Lack of data on smear-positive tuberculosis cases in developing countries makes it difficult to convey the enormity of the tuberculosis problem to the public health community. It is not possible to readily obtain reliable information on incidence of smear-positive tuberculosis in developing countries because case-detection rates can be only a fraction of the respective true incidence rates.

The relationship between the annual risk of infection and the incidence of smear-positive tuberculosis can provide one of the only means of estimating the incidence of smear-positive tuberculosis (Styblo, 1985, 1988). Styblo examined the relationship between the annual risk of infection and the incidence of smear-positive pulmonary tuberculosis using a variety of data sources from the developing and developed world. We have recomputed this relationship using only the results of a series of WHO sponsored surveys in developing countries and data from the Netherlands before chemotherapy was widely available. We must note that for some of these surveys data are available on the prevalence of smear-positive tuberculosis, not the incidence. In such cases, the incidence rates were derived using the historical observation that the prevalence of smear-positive tuberculosis was usually twice the incidence in the communities without widespread institution of chemotherapy (Holm, 1970). In these developing countries, the relationship beween the annual risk of infection and incidence of pulmonary smear-positive tuberculosis was linear. A least squared regression line (Figure I) gives an estimate of 49 cases of smear-positive tuberculosis per 100,000 for every 1 % annual risk of infection. The 95 % confidence interval for the coefficient is 39 to 59.

Table 1. Estimated risks of tuberculous infection and their trends in developing countries, 1985-90

Area	Estimated risk of tuberculous infection (%)	Estimated annual decrease in risk of infection (%)
Sub-Saharan Africa	*1.50 - 2.50*	*1 - 2*
North Africa and Western Asia	*0.50 - 1.50*	*5 - 6*
Asia	*1.00 - 2.00*	*1 - 3*
South America	*0.50 - 1.50*	*2 - 5*
Central America and Caribbean	*0.50 - 1.50*	*1 - 3*

Source : Based on data presented in Cauthen *et al.* (1988).

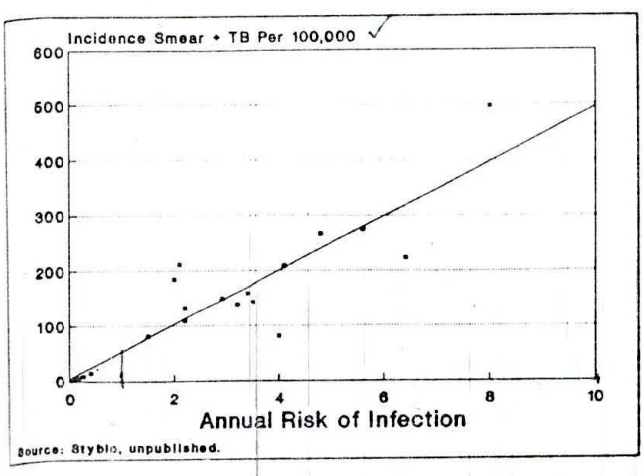

Figure I. The relationship between the annual risk of infection and the incidence of smear-positive tuberculosis.

Table 2. Estimated incidence of smear-positive tuberculosis in developing countries, 1990

Area	Estimated number of cases			Incidence
	Low	Midpoint	High	rate
Sub-Saharan Africa	296,000	521,000	745,000	103
North Africa and Western Asia	53,000	146,000	239,000	54
Asia	1,142,000	2,298,000	3,455,000	79
South America	57,000	160,000	263,000	54
Central America and Caribbean	30,000	83,000	136,000	54
Total	1,578,000	3,208,000	4,838,000	77

Note : Based on the annual risk of infection for each region presented in Table 1, the 1990 population and an incidence of 39 to 59 cases per 100,000 for each one percent annual risk of infection.

Using the estimates of the risk of infection for different regions in Table 1 and the confidence interval for the relationship between incidence of pulmonary smear-positive tuberculosis and the risk of infection, the low and high estimates of the incidence of smear-positive tuberculosis for different regions in Table 2 have been calculated. The midpoint of the confidence interval of the estimates of smear-positive incidence is 3,208,000 cases or an incidence of 77 per 100,000 in the developing world. These must be viewed as only crude estimates, which nevertheless illustrate the continuing magnitude of the tuberculosis problem.

Age distribution of smear-positive tuberculosis

The age-distribution of incidence is important in determining the public health impact of smear-positive tuberculosis and the most appropriate means of preventing or controlling tuberculosis. From the historical record of developed countries and epidemiological models, the age and sex distribution of incidence appears to change as the annual risk of infection declines. As the majority of developing countries have an annual risk of tuberculous infection between 1.0 % and 2.0 %, we propose to use the age-distribution of the incidence of smear-positive tuberculosis from a developing country with an annual risk of infection in this range (Tanzania). There is no reason to believe that the epidemiology and thus the age distribution of incidence for a given annual risk of infection will vary substantially between communities. Because the tuberculosis control programme in Tanzania is well organized and captures the majority of tuberculosis cases, the age-distribution from Tanzania will be used as representative of the developing world where the risk of tuberculous infection is between 1 and 2 %. Figure II shows the age-distribution of smear-positive tuberculosis in Tanzania for 1985-87 (Chum *et al.*, 1987 ; Chum, 1989). The pattern is similar to other developing countries such as Mozambique, Malawi and Benin that have good reporting systems (IUATLD 1988). It is important to note that BCG coverage in Tanzania was roughly 50 % in 1983-87 (Bleiker *et al.*, 1987) – based on scar examination in the National Tuberculin Survey in Tanzania carried out from 1983 to 198 on 80,000 schoolchildren from 20 regions selected at rando which is below the officially reported average for the deve oping world (UNICEF, 1988). Thus, any effect such BC coverage may have on preventing tuberculosis in children partially represented in the age-distribution ; as world BC coverage is probably higher than in Tanzania, the estima for the incidence of smear-positive tuberculosis in childr based on this age-distribution may be slightly high. Clearl smear-positive cases are relatively rare in children ; smea positive tuberculosis is concentrated in adults – more th 80 % of cases occur between the ages of 15 and 54, accordi to the data from Tanzania.

Incidence of other forms of tuberculosis

Estimates of the incidence of smear-negative pulmona and extra-pulmonary tuberculosis are also needed. The forms of tuberculosis are particularly difficult to quantify the major diagnostic tool used in developing countrie sputum microscopy, does not detect these cases. Because t diagnosis of extra-pulmonary tuberculosis is often based clinical criteria, no survey data are available to estimate t relationship between the risk of infection and other tuberc losis. In the past, estimates of smear-positive tuberculo have simply been doubled to provide a figure for oth tuberculosis (Styblo and Rouillon, 1981 ; Leowski, 198 The distribution of total cases between the categories sputu smear-positive and other tuberculosis cannot be accurate established. Whereas smear-positive tuberculosis and tub culosis positive by culture only can be objectively dete mined, the number of culture-negative cases detected d pends on various factors, such as active case-finding by M Miniature Radiography (MMR) extensively used in Euro in the 1950's, 1960's and 1970's, criteria for activity asymptomatic cases detected by active case-finding, ag groups, etc. However, we will assume that within each ag group using the same diagnostic approach the percentage cases that are sputum smear-positive and other should be t same relatively independent of the overall annual risk

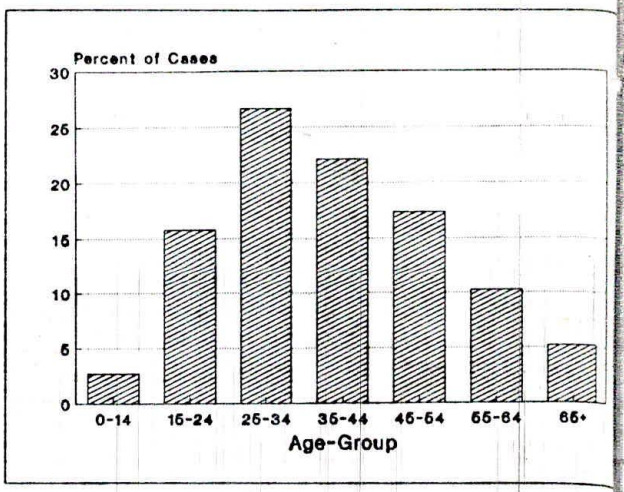

Figure II. The age distribution of smear-positive tubercul detected in Tanzania, 1985-1987.

infection. Using data for the United States and Norway, Figure III illustrates the proportion of all tuberculosis cases that are smear-positive by age (Galtung, 1955 ; CDC, 1989). Because the data set for the US is larger and no MMR was used on a large scale, we will use the ratio of cases of other tuberculosis to smear-positive tuberculosis within each age-group in the United States. Using the age-distribution of the incidence of smear-positive tuberculosis in Tanzania and the age-specific ratios of other to smear-positive in the United States, we have derived a rough estimate of the age-distribution of other tuberculosis shown in Figure IV. While the assumptions underlying these estimates of other tuberculosis may be challenged on many grounds, we feel it is preferable to make some objective attempt to estimate the age-distribution of smear-negative and extra-pulmonary tuberculosis in developing countries because it is an important input to policy decisions.

Our estimations imply that there are 1.22 cases of smear-negative and extra-pulmonary tuberculosis for every case of smear-positive tuberculosis in developing countries with an annual risk of infection between 1 and 2 % and an overall age-distribution similar to Tanzania. Table 3 provides low and high estimates of the number of new cases of smear-negative and extra-pulmonary tuberculosis for each region in the developing world. For all types of tuberculosis combined, Table 4 indicates that the incidence of tuberculosis exceeds 220 per 100,000 in sub-Saharan Africa.

Tuberculosis mortality

Case-fatality rates, untreated

In order to calculate tuberculosis mortality from the estimates of incidence derived above, we need to estimate the case-fatality rate. Without appropriate chemotherapy, tuberculosis is highly fatal. The results of several studies in developed countries before chemotherapy became available demonstrated mortality rates consistently in the 50 % to 60 % range (Drolet, 1938 ; Lindhart, 1939 ; Galtung Hansen, 1955). These observations were confirmed in the five-year study of the natural history of tuberculosis in Bangalore,

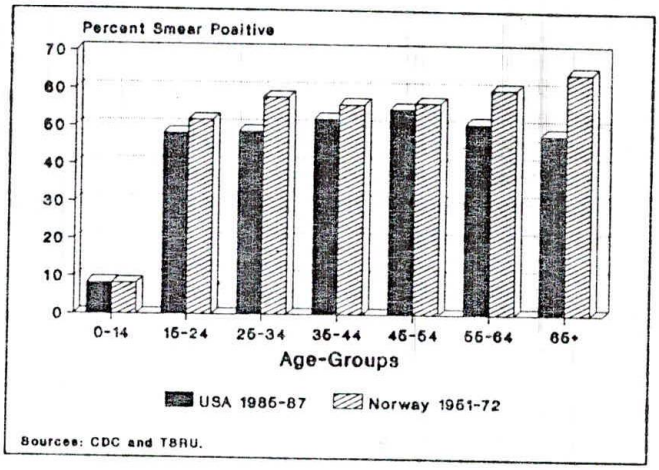

Figure III. The percent of all cases of tuberculosis that are smear-positive, USA 1985-1987 and Norway, 1951-1972.

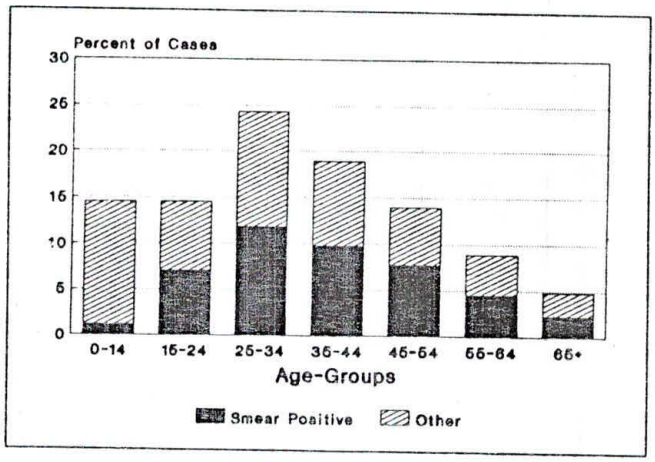

Figure IV. The estimated incidence of smear-positive and other tuberculosis by age for the developing world in 1990.

India : 49 % of bacteriologically confirmed cases (smear- and culture-positive cases or smear-negative and culture-positive) died within five years (National Tuberculosis Institute,

Table 3. Estimated incidence of other tuberculosis in developing countries, 1990

Area	Estimated number of cases			Incidence
	Low	Midpoint	High	per 100,000
Sub-Saharan Africa	361,000	635,000	909,000	126
North Africa and Western Asia	64,000	178,000	291,000	66
Asia	1,393,000	2,804,000	4,215,000	96
South America	71,000	196,000	321,000	66
Central America and Caribbean	37,000	101,000	166,000	66
Total	1,926,000	3,914,000	5,902,000	94

Note : The incidence of other tuberculosis has been based on USA data showing the relationship between smear-positive tuberculosis and other tuberculosis by age combined with the age-distribution of smear-positive tuberculosis in Tanzania.

Table 4. Estimated incidence of all forms of tuberculosis in developing countries, 1990

Area	Estimated number of cases			Incidence
	Low	Midpoint	High	per 100,000
Sub-Saharan Africa	656,000	1,156,000	1,655,000	229
North Africa and Western Asia	117,000	323,000	530,000	120
Asia	2,535,000	5,102,000	7,670,000	174
South America	129,000	356,000	584,000	120
Central America and Caribbean	66,000	185,000	302,000	120
Total	3,503,000	7,122,000	10,741,000	171

Bangalore, 1974). As expected, the case-fatality rate for smear-positive tuberculosis is even higher; Rutledge and Crouch (1919) and Lindhart (1939) reported 66 % mortality in these cases (no information is available from the Bangalore study). For the rest of this paper, we will assume that the case fatality rate for smear-positive tuberculosis is 60 % to 70 %, for other tuberculosis as a whole it is 40 % to 50 % and for all forms combined it is 50 % to 60 %.

Tuberculosis death rates in developing countries

The tuberculosis death rates in developing countries cannot be as high as implied by the incidence rates and a case-fatality rate of 50-60 % because a significant proportion of cases are detected and treated, which lowers the tuberculosis death rate. Accordingly, we adjusted our estimates for this effect by using estimates of the number of cases that receive treatment to derive the likely range of tuberculosis death rates in developing countries. For all those cases that are detected and receive treatment, we assume the case-fatality rate is reduced to 20 % after 5 years. For example, in the East African and British Medical Research Council surveys in Tanzania and Kenya the case-fatality rates for patients receiving standard chemotherapy were 12 % and 16 % respectively after 12 months (EAMRC 1977, 1979). In many countries, however, the case-fatality rate may be over 20 % for those receiving chemotherapy, after five years of follow-up, making the following estimates of mortality conservative.

Estimates of the percentage of new cases that are detected and treated are based on the number of cases of tuberculosis detected that are reported by countries to the World Health Organization (Table 5) (WHO, 1988). Because reporting is extremely variable, these estimates are based on the highest number of cases reported by each country for any year in the last decade. This is justified by the assumption that year to year variation in the number of cases reported, which can be greater than an order of magnitude, is due more to incomplete reporting of health service activities than to change in the epidemiology of tuberculosis. In addition, the highest number of cases reported in the last ten years has been adjusted upwards by 20 % to try and account for those cases that are detected in the private sector that do not report to the government ; in Asia where data for some large countries may include a large number of retreatment cases we have adjusted the figures by 20 %.

Separate estimates for the percent of smear-positive and other cases are needed. As the primary means of detecting tuberculosis in developing countries is sputum microscopy the detection rate of smear-positive tuberculosis is higher than for smear-negative or extra-pulmonary tuberculosis. Based on data from the National Tuberculosis and Leprosy Programme in Tanzania, we will assume that 60 % of detected cases are smear-positive and 40 % are other tuberculosis. The detection rate of the various forms of tuberculosis and the likely range of case fatality rates discussed above can be combined to estimate the tuberculosis death rate from smear-positive tuberculosis and other tuberculosis. Because the detection rate for smear-positive tuberculosis is higher despite a higher case fatality rate, the overall death rate from smear-positive tuberculosis is similar to the death rate from other tuberculosis.

Table 5. Estimated tuberculosis cases detected and case fatality rates in developing countries, 1990

Area	Estimated cases detected	Percent all cases detected	Estimated case fatality rates (%) Low	High
Sub-Saharan Africa	325,000	*28*	*41*	*48*
North Africa and Western Asia	223,000	*69*	*28*	*31*
Asia	3,087,000	*61*	*30*	*34*
South America	222,000	*62*	*32*	*36*
Central America and Caribbean	50,000	*27*	*41*	*49*
Total	3,907,000	*55*	*32*	*37*

Note : The calculations of effective case-fatality rates are based on the assumption that 15 % of those patients receiving standard chemotherapy die. As discussed in detail in the section on chemotherapy this is a conservative assumption.

Table 6. Estimated deaths from all forms of tuberculosis developing countries, 1990

Area	Estimated number of cases Low	Midpoint	High	Dea... per 100,...
Sub-Saharan Africa	266,000	528,000	790,000	1...
North Africa and Western Asia	33,000	99,000	166,000	...
Asia	771,000	1,709,000	2,646,000	...
South America	41,000	125,000	211,000	...
Central America and Caribbean	28,000	88,000	148,000	...
Total	1,139,000	2,549,000	3,961,000	...

Table 6 shows estimated deaths each year from all forms of tuberculosis for regions based on the calculations of tuberculosis death rates discussed above. The wide confidence intervals reflect the cumulative uncertainty in paremeters of the estimation procedure. Using the midpoints of the confidence intervals, the total number of deaths from tuberculosis in the developing world comes to 2,549,... **Tuberculosis, therefore, accounts for approximately ... of all deaths in the developing world in 1990 (United Nations, 1989).**

Age-distribution of tuberculosis deaths

To estimate the age-distribution of tuberculosis deaths we must take into consideration the age-distribution of cases and the relationship between case-fatality rate and age. Clearly, the relationship is complex ; for example, death rates may also vary by age because certain age-groups may be more likely to seek treatment and be cured. Without hesitation, we will apply the age-specific case-fatality rates from London 1933-1934 to the age-distribution of tuberculosis incidence derived above (Styblo, 1984). Tuberculosis case-fatality rates tend to increase steadily ...

Table 7. Distribution of tuberculosis deaths by age

Age-group	Czechoslovakia 1940	1931	Norway 1941	1951	1931	Netherlands 1941	1951
0-14	*11.7*	*11.8*	*10.3*	*8.0*	*24.0*	*19.4*	*13.6*
15-24	*22.0*	*30.6*	*25.4*	*10.8*	*22.4*	*20.3*	*12.8*
25-34	*18.7*	*25.9*	*25.4*	*24.4*	*20.8*	*20.7*	*16.9*
35-44	*14.0*	*14.5*	*16.1*	*19.5*	*11.7*	*13.1*	*12.8*
45-54	*12.5*	*7.7*	*9.6*	*13.2*	*7.7*	*9.6*	*11.6*
55-64	*11.4*	*5.0*	*6.6*	*10.7*	*6.3*	*8.2*	*13.4*
65+	*9.7*	*4.5*	*6.5*	*13.4*	*7.1*	*8.7*	*18.9*
Risk of infection	*5.5* (1938)				*3.7*	*1.8*	*0.5*

Age-distribution of deaths have been adjusted using the population age-structure of the developing world in 1990.

ages. Figure V provides the crude estimates of the age-pattern of tuberculosis deaths in a country with an annual risk of infection of 1 % to 2 % where the probability of detection is equal for smear-positive tuberculosis across all age-groups and equal for other tuberculosis across all age-groups.

This estimated pattern can be compared to the age-distribution of tuberculosis deaths in Western countries when the annual risk of infection was similar to that now seen in the developing world. Table 7 illustrates the age-distribution of tuberculosis deaths adjusted to the age-structure of the developing world in Czechoslovakia, Norway and the Netherlands (TSRU, 1966). The percentage of deaths in children under 15 ranged from approximately 10 % to 20 %. In the Netherlands, the tuberculosis death rates in children were considerably higher than in Czechoslovakia even at lower risks of infection. Clearly, there are other variables that are major determinants of the reported age-distribution of tuberculosis death rates. One explanation may be the high rates of *M. bovis* infection in the Netherlands at the time. According to our estimates for Tanzania, less than 8 % of tuberculosis deaths occur in children under age 15, which is less than in the three

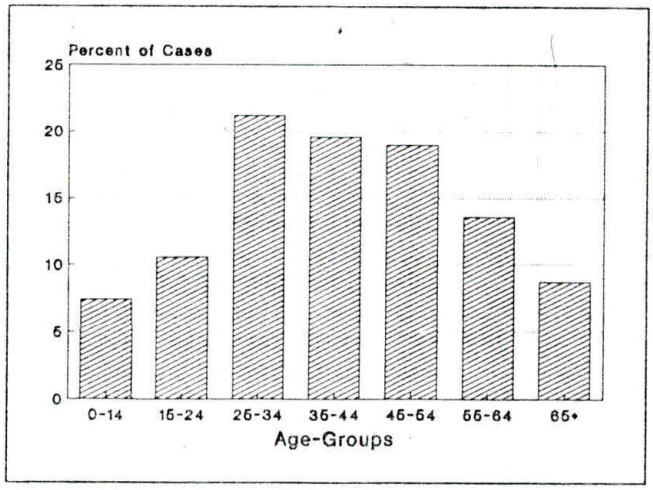

Figure V. Estimated age-distribution of tuberculosis deaths in the developing world in 1990.

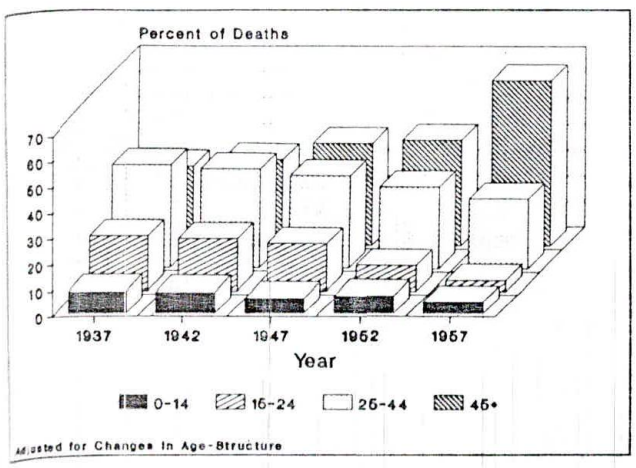

Figure VI. The shifting age-structure of tuberculosis deaths as the annual risk of infection declines, USA 1937-1957.

developed countries in Table 7. This may be due to the higher BCG coverage in Tanzania now than in these countries at the time. Variation in the age pattern of tuberculosis deaths highlights the tentative nature of the estimates presented here. The basic conclusion, however, that tuberculosis is concentrated in the adult age-groups, appears to be robust.

As the discussion above implies, the age pattern of tuberculosis deaths shifts towards higher ages as the annual risk of infection declines. Using data from the US which has been adjusted to the 1990 age-structure of the developing world, Figure VI demonstrates how the mean age of death increases as the risk of infection declines. The number of deaths in children declines faster than the annual risk of infection ; this relationship will become important in considering the cost-effectiveness of BCG.

Trends in incidence and mortality

Using the midpoints of the ranges of the annual risk of infection in Table 1, population projections, and the rates of decline in the annual risk of infection also reported in Table

1, cases and rates of tuberculosis in 2015 have been estimated (Table 8). These estimates are based on the assumption that the rates of decline in the annual risk of infection observed between 1970 and 1985 will continue into the future. In other words, the projections are based on the assumption that the socio-economic changes and tuberculosis control activities that caused the decline in the risk of infection in the last two decades will continue at the same rate. Such projections suffer from all the same limitations that any projection of current trends does.

According to these assumptions, tuberculosis will remain a major problem in all developing world regions referred to in Table 8. In Africa, population growth will probably exceed the projected decline in the annual risk of infection, so that the absolute number of cases will increase. **These projections for Africa have not taken into consideration the interactions between HIV infection and tuberculosis.** As discussed below, the annual risk of infection in Central and East Africa may stop declining or even increase in the next decades. The figures in Table 8, therefore, may be significant underestimates for Africa. The relationship between HIV infection and tuberculosis will be explored more fully below.

Social and economic costs

There are few if any studies of the actual costs or consequences of tuberculosis on the family, community or economy in developing countries. The special burden of ill-health and death caused by tuberculosis, however, follows from the age-distribution of its incidence. While morbidity and mortality in any age-groups has significant social and economic costs, deaths in prime aged adults who are the parents, community leaders and producers in most societies have a particularly onerous burden. The incidence of tuberculosis is concentrated in adults 15-64. For example, while the overall incidence of tuberculosis in Africa is estimated to be 230, in adults it is approximately 360 per 100,000.

One of the greatest costs to society and the economy from tuberculosis is mortality. It has been estimated that there are just under 10.6 million deaths in adults 15-59 in the developing world (Murray and Feachem, 1990). Of these, our figures suggest approximately 18.5 % are due to tuberculosis. Not all these deaths are preventable. **Of avoidable adult deaths, 26 % are probably due to tuberculosis.**

The consequences of adult death from tuberculosis on children and other dependents can also be great. Studies have shown that when a mother dies her children suffer higher rates of mortality (Greenwood *et al.*, 1987). One can speculate that similar relationships may exist for paternal death. Several studies from developed countries have shown that tuberculosis is concentrated in lower socio-economic groups, those households least able to cope with the burden of tuberculosis. Pryer (1989) found that children in households where one parent suffers from a serious debilitating disease such as tuberculosis, are two and half times more likely to be severely malnourished. **As tuberculosis deaths are concentrated in the segment of the population that is economically most productive, the economic cost of tuberculosis, in terms of lost production, must be greater than a disease that affects exclusively children or the elderly.**

Prevention

There are three major strategies for preventing tuberculosis : BCG vaccination, chemoprophylaxis and decreasing sources of infection through case-finding-treatment. Each will be discussed in turn.

BCG

The bacillus of Calmette and Guérin (BCG) was developed in 1921. Since that time, it has become one of the most widely used yet controversial vaccines. While BCG coverage has been up to now on average quite high compared to other immunizations, the effectiveness of BCG in preventing tuberculosis in adults remains controversial. Clinical trials in the United Kingdom and in the USA found that BCG was up to 80 % effective (Aronson *et al.*, 1958 ; Medical Research Council of Great Britain, 1972). Major vaccine trials in South India, however, found no effectiveness of BCG (Tuberculosis Prevention Trial, 1979). A variety of prospective trials in the developed world and more recent case-control studies in developing countries have reported effectiveness ranging from 0 to 80 % (Smith, 1987 ; Clemens *et al.*, 1983).

Many explanations and theories have been advanced to explain this variance including differences in strains of BCG, infections with other mycobacteria and differences in sus-

Table 8. Cases and deaths from all forms of tuberculosis, 2015

Area	Estimated number of cases			Deaths
	Smear +	Other	Total	
Sub-Saharan Africa	766,000	934,000	1,701,000	777,000
North Africa and Western Asia	98,000	120,000	218,000	66,000
Asia	1,871,000	2,283,000	4,154,000	1,391,000
South America	98,000	120,000	218,000	77,000
Central America and Caribbean	80,000	97,000	177,000	84,000
Total	2,913,000	3,554,000	6,468,000	2,395,000

Note : These projections are based on the following assumptions : 1) the current rate of decline in the annual risk of infection will continue over the next 25 years ; 2) the percent of cases detected will remain the same in each region ; and 3) the cure rate and implicitly the percent of cases treated with standard chemotherapy will remain the same for those cases that are detected and treated.

ceptibility due to factors such as nutritional status (Fine, 1989). While there is no consensus on the effectiveness of BCG, we will assume that BCG is between 40 % and 70 % effective in preventing tuberculosis in children 0-14 when given at birth. Some would argue that BCG given at birth may protect beyond 15 years ; there is, however, no evidence of this especially in developing countries.

BCG is given as early as possible in life, preferably at birth, in the vast majority of developing countries. In addition, one could give serious consideration to "indiscriminate (re)vaccination" (*i.e.* without prior tuberculin testing) at older ages, irrespective of vaccination at birth. Depending on the feasibility of coverage, BCG (re)vaccination could be given to children entering school, leaving school, pregnant women attending for prenatal care of other routine contacts of the population with health workers. For example, tetanus toxoid is now considered by many to be an integral component of prenatal care ; BCG could be delivered at the same time for only a small increase in the total cost. The actual effect of BCG (re)vaccination at older ages has not been thoroughly studied but there seems little reason that it would be harmful and it may have some beneficial impact.

We must realize, however, that vaccination of newborns with BCG is a problem in those developing countries where there is a high prevalence of HIV infection among mothers. The WHO Expanded Programme on Immunization, which is responsible for the programme of vaccination against six selected childhood diseases in the world, has been continuing BCG-vaccination of newborns and small children including when the mother is known to be or suspected of being HIV-infected. As of the time of writing, evidence remains inconclusive regarding the rate of adverse reactions after BCG immunization among symptomatic HIV-infected individuals. BCG should be withheld from individuals with symptomatic HIV infection (WHO, 1987). The current recommendations on HIV and BCG-vaccination will be reviewed in the fall of 1990.

The impact of mass BCG-vaccination on the epidemiological situation of tuberculosis was overestimated until the mid-1970's (Styblo and Meijer, 1976). As mentioned earlier, tuberculosis is largely transmitted by sputum smear-positive cases of pulmonary tuberculosis. From the age-distribution of smear-positive cases, it is clear that even complete BCG coverage can have little effect on the annual risk of infection. Total coverage with BCG, however, will have a major impact on tuberculosis mortality in children, if BCG is 40 % to 70 % effective as we have assumed. Based on the assumptions discussed above, complete coverage could reduce total tuberculosis mortality by approximately 6 %. BCG will most likely have very limited effect on the remaining 90 plus percent of tuberculosis mortality. Evidently, the expansion of BCG coverage alone cannot or should not be the sole means employed to control tuberculosis in any community.

Cost-effectiveness of BCG

For two principal reasons, generalizable estimates of the cost-effectiveness of BCG cannot be made. First, there may be substantial differences in the computed average and marginal costs of BCG programmes depending on the programme considered. Second, the cost-effectiveness of BCG is inversely proportional to the annual risk of infection.

When more than one vaccine is given at the same time, average costs for delivering each particular immunization are often calculated by dividing the cost per client contact by the number of vaccinations received. Thus the difference between marginal costs and average costs for a BCG programme will depend on whether BCG is delivered in an independent campaign or contact with mother and child or along with other immunizations such as the first DPT. The Expanded Programme on Immunization was, unfortunately, unable to indicate how BCG is delivered in each country. We conclude that the marginal cost-effectiveness of expanding BCG will necessarily depend on the location and timing of vaccination in a particular country.

As the annual risk of infection declines, *ceterus paribus*, the cost of vaccinating all newborns does not change. The benefits of BCG vaccination in terms of cases or deaths averted, however, will decline inversely to the risk of infection. For example, as the risk of infection declines from 2 % to 1 %, the cost per death averted will more than double. The increase in the cost per death averted is greater than the decline in the risk of infection because the age-distribution of deaths also shifts away from children as the risk of infection declines – see Figure VI. The expected relationship between the risk of infection and the cost per death averted by BCG is illustrated in Figure VII.

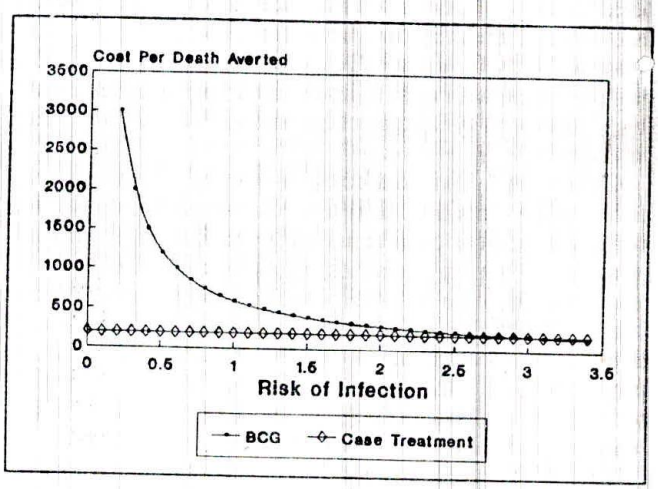

Figure VII. A hypothetical comparison of the cost-effectiveness of BCG immunization and case-treatment.

Only one study has attempted to cost a BCG programme and estimate its effect in a developing country. Barnum *et al.* (1980) estimated the cost of operating a BCG programme alone and also the marginal cost of adding a BCG programme to an existing DPT programme. His estimates of deaths averted were based on local incidence and case-fatality rates of tuberculosis and an assumed effectiveness for BCG of 50 %. We have recalculated using his original data the cost per discounted death averted in 1986 dollars. Deaths prevented by BCG vaccination now occur over the next 14 years, these are discounted to present value for comparison with interventions that avert deaths in the current time period. The cost per death discounted at 3 % was $ 644 for the BCG programme alone and $ 144 for the marginal BCG

programme – both prices are in 1986 US dollars. At the time in Indonesia survey data suggest the risk of infection was approximately 3 % ; regional surveys report annual risks of infection between 2 % and 4 % (Cauthen *et al.*, 1987). It must be stressed that these estimates of cost-effectiveness do not take into consideration the potential benefits of BCG in reducing leprosy (Fine *et al.*, 1986).

Chemoprophylaxis

Clinical tuberculosis can be secondarily prevented by treating patients with tuberculous infection. Chemoprophylaxis is applied either to freshly infected so-called tuberculin-converters or to those who have been infected with virulent tubercle bacilli in the more distant past. The latter either do or do not have abnormalities in the lungs on X-ray.

Tuberculin converters undoubtedly represent a very rewarding group in terms of chemoprophylaxis results and thus chemoprophylaxis policy has been adopted as a routine procedure in a number of low prevalence countries. However, mass chemoproplylaxis of converters is impossible, since their identification depends on repeated tuberculin tests of the population. On the other hand, a selective search for converters in high risk groups, such as close family contacts of smear-positive sources, is a feasible alternative. As discussed below 6-8 % of recent infections evolve into clinical tuberculosis. In developing countries, where large percentages of the population have been infected, the IUATLD recommends chemoprophylaxis (in HIV low prevalence countries) only for all non-BCG-vaccinated children aged 5 years or under, with no symptoms suspicious of tuberculosis. In children with symptoms chemotherapy should, of course, be given.

Chemoprophy axis in tuberculin-positive subjects but who have not developed clinical tuberculosis would reduce the number of sources of infection, if given for 6 to 12 months. In most developing countries, this group is very large and resources would be far better directed to case-detection and treatment. However, chemoprophylaxis might play a very important role both in developed and developing countries in subjects with the dual HIV and tuberculous infections without clinical and bacteriological signs of tuberculosis. Research in this field is urgently needed.

Studies in developed countries have found cost-effectiveness rates per case averted on a 24 week regimen to be greater than $ 17,000 (Snider *et al.*, 1986).

Without accurate data to review the cost-effectiveness of chemoprophylaxis in developing countries, we can only make some comparisons to the costs per case treated. Since only 6-8 % of recent converters evolve into clinical tuberculosis, 12.5-16.7 recent tuberculin positive patients must be given chemoprophylaxis to prevent one case of tuberculosis assuming prophylaxis is 100 % effective. In tuberculin positive subjects as opposed to new converters, the ratio would be one or two orders of magnitude higher. The drug costs for chemoprophylaxis are lower than for treatment, but the costs of administration, screening, transport, delivery and monitoring would be similar. Thus, chemoprophylaxis is unlikely to be more cost-effective in developing countries than case-finding/treatment of patients presenting with symptoms suspicious of tuberculosis as discussed below. One exception may be in children under 5 exposed to an adult with active smear-positive pulmonary tuberculosis.

Decreasing sources of infection

It has already been suggested that the best way to reduce transmission of tuberculous infection and thus the number of tuberculosis cases is to cure patients with smear-positive tuberculosis. This was stated by Crofton (1962) already in the mid 1950's. A variety of epidemiological studies can be used to quantify this transmission effect. The number of new infections caused each year by a case of smear-positive tuberculosis can be estimated from survey data on the number of new infections and the prevalence of smear-positive tuberculosis. It has been estimated using data from developing and developed countries, that an undiagnosed and untreated smear-positive source of tuberculous infection would infect on average between 10 and 14 persons per year (Styblo, 1984 ; Sutherland and Fayers, 1975). Breakdown of primary infection with tubercle bacilli to clinical tuberculosis is the next link in the chain of transmission. Reference is made to three reports of newly infected subjects to determine the percentage that developed clinical tuberculosis : the MRC study (Sutherland, 1968) found 8.1 % of converters developed clinical tuberculosis within 15 years ; in Saskatchewan of recently infected individuals, 6.4 % developed clinical tuberculosis within a few years after primary infection (Barnet *et al.*, 1971) ; and a TSRU study of European data found 6.0 % of converters developed bacillary tuberculosis in five years (Sutherland, 1976). For the purposes of modelling transmission, we will assume that from 6 % to 8 % of new infections will eventually develop some form of clinical tuberculosis.

The studies cited above refer to the risk of developing clinical tuberculosis soon after primary infection. What about the risk of developing clinical tuberculosis in cases previously infected with tubercle bacilli, without or with a fresh reinfection ? As it is not possible to detect reinfection with tubercle bacilli by tuberculin testing, it cannot be discovered directly whether or not exogenous reinfection is important in the development of tuberculosis in an adult. It is evident that in countries with low annual risks of infection, tuberculosis in elderly and old persons is predominantly due to endogenous exacerbation among those remotely infected with tubercle bacilli. In developing countries, exogenous reinfection seems to play an important role in developing active tuberculosis in the adult population, since 0.5 % to 2.5 % or more of previously infected individuals are annually reinfected with tubercle bacilli as was the case in developed countries some 2 to 4 decades ago (Canetti, 1972 ; Jancik and Styblo, 1976). Strong evidence for the latter is the rapid decline in tuberculosis incidence in Eskimos over the space of 20 years, not only in children and young adults but also in elderly and old people, when aggressive case detection and adequate chemotherapy was introduced (Grzybowski *et al.*, 1976).

We will assume, therefore, that each undiagnosed and untreated smear-positive case will cause 10 to 14 infections per year of infectivity. These 10 to 14 infections will subsequently cause over the next few years 0.6 to 1.2 cases of tuberculosis. These cases will be approximately equally distributed between smear-positive and other tuberculosis. The mean period from infection to onset can be estimated more precisely from data reported by Sutherland (1968) as 1.4 years. These parameters highlight the importance of case treatment in preventing further cases and will be used in estimating the cost-effectiveness of treating smear-positive tuberculosis in the pages that follow.

Curative care

The subject of curative care can naturally be divided into tuberculosis detection and chemotherapy. Each of these will be addressed in turn, highlighting the policy options.

Case detection

There are two major issues in detecting cases of clinically significant tuberculosis : active versus passive detection strategies and the choice of diagnostic technology. Active detection means attempts to screen the population at large, or target populations such as military recruits, for evidence of tuberculosis. Passive case detection means screening and diagnosing only those patients who present to a health service provider because of symptoms suspicious of tuberculosis. In the 1950s and 1960's, the choice between active and passive detection in developed and developing countries was a controversial topic (Styblo *et al.*, 1967 ; Meijer *et al.*, 1971 ; WHO Expert Committee on Tuberculosis, 1974 ; Styblo and Meijer, 1980 ; Toman, 1979). In the last two decades, a consensus for passive case detection of tuberculosis in all countries has developed, and both the WHO and IUATLD advocate this policy.

There are three assumptions that underlie the wide acceptance of passive case detection as the primary strategy in tuberculosis control. First, 90 % of patients with smear-positive pulmonary tuberculosis have objective symptoms, such as cough (with or without sputum), fever, loss of weight or hemoptysis. These symptoms develop quite soon after the onset of the disease prompting the patient to seek medical advice. Second, the great majority of sputum smear-positive tuberculosis cases develop in a shorter period of time than the shortest feasible interval between two mass radiography survey rounds. That is why smear-positive tuberculosis cases were detected outside (usually earlier than) the periodic case-finding campaigns by the regular health services that the patient can consult whenever he feels ill. Third, appropriate diagnostic and curative care ought to be physically, socially and economically available. Most infections, before chemotherapy is instituted, would therefore occur within the family. Whereas in developed countries, it is estimated that 2-3 persons would be infected by a smear-positive case before its detection, this number may be 4-5 in developing countries, because of higher number of close contacts. No contacts will be infected after the start and completion of adequate chemotherapy.

The validity of these assumptions depends on local conditions, cultural perception of disease, access to care and the efficacy of health services.

Regardless of the technology used, active case detection is more expensive per case detected because the yield of tuberculosis per patient screened is lower. For example, if the incidence of smear-positive tuberculosis is 100/100,000 then more than 1,000 people's sputum would have to be screened to detect one case of smear-positive tuberculosis provided that the general population is screened. If specific high risk groups can be identified, the yield would clearly be higher. For comparison, screening patients who present with cough in Tanzania using sputum microscopy yields one patient in 10 cases with smear-positive tuberculosis. The second argument against active case detection is that cases actively identified may be less likely to comply with long drug regimens. Clearly, they did not yet consider their health to be impaired enough to seek treatment to start with. Moreover, a proportion of smear-negative cases with few or no clinical symptoms cure spontaneously and in a number of cases the disease is in regression (National Tuberculosis Institute in Bangalore 1974 ; Meijer *et al.*, 1971, Styblo *et al.*, 1967). In developing countries, active case-finding was studied by the Kenyan and British Research Councils in the late 1970's and early 1980's. There are seven reports on these studies and the conclusion in the last study is that a patient suffering from symptoms suggestive of pulmonary tuberculosis nearly always attends, usually several times, a health unit seeking medical advice (EAMRC, 1987). However, health workers at the peripheral level do not think in many instances of tuberculosis and do not send the sputum or do not refer the patient to the nearest microscopy centre for sputum examination for tubercle bacilli. In many developing countries, public transport is very rudimentary; even if available, it is not always affordable to poor people. Moreover, the Kenyan studies have shown that active case-finding, except in health units, is not feasible.

The second issue in case-detection is the choice of technology. At present, the major options are sputum microscopy, sputum culture and radiology. To illustrate the yield and likely cost of case-detection using microscopy (Ziehl-Neelsen), we shall examine data from the National Tuberculosis and Leprosy Programme in Tanzania. In that country, one in ten tuberculosis suspects screened by smear examination is identified as a smear-positive case. Normally, three smears are conducted on each patient. The costs of supplies and reagents alone for these thirty smears is $ 4.05. A microscopist can examine about 20 sputa per day and is paid US$ 45 per month. The effective cost per case detected in Tanzania is US$ 7.30. This is a high estimate since each case has three sputa examined to increase sensitivity ; the increased sensitivity achieved with the third smear is in fact small and could be sacrificed to reduce the cost.

Sputum culture is used to diagnose pulmonary tuberculosis in those patients that produced too few bacilli to be detected on a smear, to confirm sputum microscopy, and to characterize the type of mycobacterium. (Finally, culture is a prerequisite to sensitivity test examination.) As culture takes several weeks to yield results, it is not useful as a primary diagnostic tool in developing countries.

The third diagnostic tool is radiography. While it can be an effective tool particularly for diagnosing smear-negative pulmonary tuberculosis, the capital cost of an X-ray machine limits its use to those facilities with a high case load. In Tanzania, we can estimate that the cost per case detected for both smear-positive and smear-negative pulmonary tuberculosis combined to be around US$ 10. This calculation, however, attributes only one sixth of the depreciated capital cost of an X-ray machine to diagnosing tuberculosis, because we assume an X-ray machine in a district hospital would be used for many other purposes. An X-ray facility exclusively for diagnosing tuberculosis would be much more expensive. The calculation also assumes a case-load of at least 1,000 patients per year. The optimal use of radiography in passive case-detection clearly depends on the health system infrastructure, population distribution, and possibilities for referral. Usually, in 25-30 % of all pulmonary cases detected in a developing country, the diagnosis of smear-negative tuber-

culosis is based on X-ray of the chest with a pathology suspicious of active tuberculosis and on clinical examination.

New diagnostic technologies based on the enzyme linked immunoabsorbant assay or DNA probes for mycobacterial DNA or RNA are currently being investigated (Daniel, 1989 ; Bloom, 1989). If these approaches yield new tools that can be cheaply applied in developing countries, passive case detection may be improved especially for smear-negative and extra-pulmonary tuberculosis which are not diagnosed using sputum microscopy. Active case detection in some high risk groups would perhaps become feasible.

A limited number of interventions are available to improve the effectiveness of passive case detection. The most effective factor for improvement in case-finding is a high cure rate of diagnosed cases and a friendly relationship between the treating health staff and the patient. Public education can increase general awareness of the symptoms of tuberculosis and encourage suspects to seek medical advice resulting in diagnosis of tuberculosis and its treatment. Improved diagnostic skills of primary health care providers, transport of sputum or a patient to a microscopy center, and X-ray facilities, if available, can also improve the detection of both smear-positive tuberculosis and other tuberculosis. Finally, if diagnosis and adequate treatment are free, as recommended by WHC and IUATLD, more patients will seek care earlier.

Table 9. Examples of tuberculosis chemotherapy regimens used in developing countries

Regimen	Duration
New smear-positive cases	
Long-course (12 months)	
2SH/10TH	12
2SH/10EH	12
2SH/10S_2H_2	12
Short-course	
2SHRZ/6TH	8
2SHRZ/4HR or 2EHRZ/4HR	6
2HRZ/4HR	6
2HRZ/4H_3R_3	6
New smear-negative cases	
2STH/10TH	12
2SHRZ/6TH	8
Retreatment cases	
2SHRZE/1HRZE/5$H_3R_3E_3$	8
2SHRZE/1HRZE/5TH	8

S : streptomycin ; H : isoniazid ; R : rifampicin ; Z : pyrazinamide ; E : ethambutol ; T : thiacetazone. Subscripts refer to intermittent therapy where drugs are given a limited number of times each week.

Treatment

The six drugs recommended by WHO and the IUATLD and most commonly used in developing countries for tuberculosis are isoniazid, streptomycin, thiacetazone, ethambutol, rifampicin and pyrazinamide. These drugs are used in a host of combinations for different durations. See Table 9. However, despite the availability of powerful and potentially effective antituberculosis drugs, tuberculosis treatment programmes in most developing countries have not been very successful. Overall cure rates for most national programmes in poor developing countries are below 50 %. Evidently, the "standard" 12-month chemotherapy (isoniazid, streptomycin and thiacetazone) recommended by the WHO Expert Committee on Tuberculosis (1974) for use in developing countries is presently, and probably will be in the future, beyond the organizational resources of many of them.

While there are many interesting issues in tuberculosis treatment, this discussion will stress the choice between standard 12-month chemotherapy regimens that use fewer and cheaper drugs (isoniazid, streptomycin and thiacetazone), and short-course chemotherapy that lasts from 6 to 8 months and uses multiple and more expensive drugs (rifampicin and pyrazinamide). To compare these two approaches to chemotherapy, we must examine the relative effectiveness of each and the relative costs of each. Because of the great diversity in effectiveness and costs between countries, the emphasis will be on the key determinants of the effectiveness and costs of the two regimens. It should be stressed that the regimen with a higher cure rate leads to a more rapid reduction in the risk of tuberculosis infection and the incidence of active tuberculosis.

Effectiveness of chemotherapy

The effectiveness of standard and short-course chemotherapy depends on three major factors : (i) the cure rate ; (ii) acquired drug resistance ; and (iii) the impact on the trend of the risk of tuberculous infection. Without question, the most important of these factors today in nearly all contexts is the cure rate which decisively influences the remaining two factors.

The first determinant of the cure rate is the biological effectiveness of standard 12-month and short-course chemotherapy given under ideal conditions of 100 % compliance. With short-course chemotherapy after 2 months of treatment 85-95 % of smear-positive pulmonary cases will have converted to sputum negative status. Under standard 12-month therapy after 2 months 50 % will remain smear-positive. The "permanent" cure rate is a more important aspect of the treatment regimens. The schematic (Figure VIII) shows the

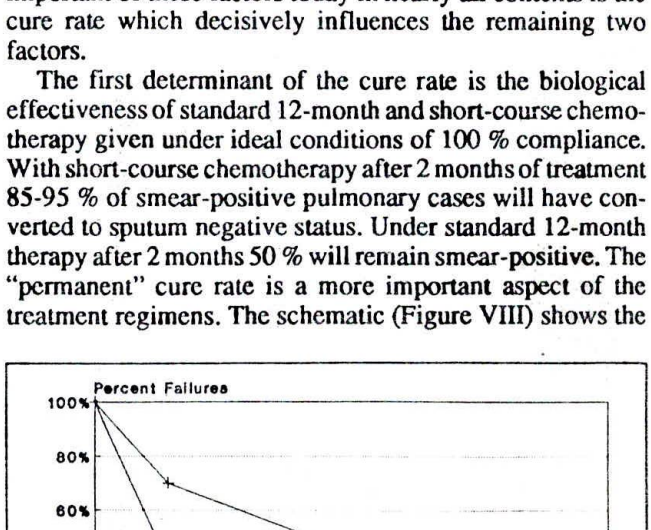

Figure VIII. The percent of patients failing therapy after 2 years of follow-up as a function of the number of months of chemotherapy completed hypothetical values.

ercent of patients who will remain or become smear-ositive, say, 2 years after the start of the (first) treatment with no retreatment during the first 2 years) provided that hemotherapy is discontinued at each point in time. We shall fer to them as "failures". (If a patient remained or became near-positive and died during the first 2 years, he/she will lso be referred to as a "failure") (the upper part of Figure III above the interrupted lines). Under short-course chemo-erapy (*e.g.* 2SHRZ/6TH), about 40 % may be "failures" at months if they discontinue chemotherapy at that time com-ared with approximately 8-10 % if they complete 6 months f short-course chemotherapy. Under standard 12-month iemotherapy (*e.g.* 2STH/10TH), the "failure" rate in pa-ents who discontinue after 2 months may reach 65-70 %, id in those who complete 6 months it might be approxi-ately 50 %. The "failure" rate only begins to drop signifi-ntly on standard 12-month chemotherapy after 6 months. If eatment is stopped at 12 months, under ideal conditions of 0 % compliance approximately 10-15 % including deaths ill become failures at two years.

nce standard 12-month and short-course chemotherapy n give high cure rates and do not lead to secondary resis-nce in controlled clinical trials compliance is the most portant determinant of the cure rate in national tuberculo-s programmes. There is a vast and detailed literature on mpliance in general and on tuberculosis in particular aynes *et al.*, 1979 ; Fox, 1983, 1985 ; Chaulet, 1987 ; WHO berculosis Chemotherapy Centre, 1963 ; Reichmann, 1987). any of the factors that one might expect would influence tients compliance with antituberculosis drugs regimens, ch as the severity of side effects, have not been empirically served. There is a clear consensus, however, that the ration of treatment adversely affects compliance (Haynes, 79). Moodie (1967) in unusual circumstances in Hong ng found that most non-compliers dropped out in the first ee weeks ; but all other studies have observed a steady p out over time (EAMRC 1977, 1979). Improved net mpliance due to a shorter regimen is a major advantage of rt-course chemotherapy over standard chemotherapy. ven the relapse rate as a function of months of treatment cussed above, in a situation where patients continue to out over time, short-course chemotherapy will have a her total cure rate.

The second major determinant of tuberculosis chemother-y compliance is the degree of supervision of treatment. A ctrum exists from giving supplies of drugs for multiple nths to patients all the way to hospitalization for the entire ation of treatment. Between these extremes, a wide vari-of supervision strategies are possible, including daily its to health centres, health visitors contacting patients in home, periodic urine tests to monitor compliance and pitalizations for the first 2 months of treatment. While reased supervision increases compliance in most settings ynes, 1979) ; increased supervision also means increased t. The balance of this trade-off will depend on the specific titutional and cultural characteristics of each community. example, in Madras, in areas where most of the popula-n has ready access to health centres, entirely ambulatory has been successful (Tuberculosis Chemotherapy Centre, dras 1959, Dawson *et al.*, 1966). On the other hand, in parts of rural sub-Saharan Africa, the only way to rantee daily supervision of chemotherapy may be to hospitalize patients for the first 2 months of chemotherapy ; this has been the experience in 7 African countries (Tanzania, Kenya, Mozambique, Malawi, Benin, Senegal and Mali) (Styblo and Chum, 1987).

The rationale for hospitalizing patients to ensure close supervision of the initial intensive phase is much greater in short-course chemotherapy than in standard 12-month chemotherapy because 2 months of short-course chemotherapy will convert smear-positive sputum into smear-negative in about 90 % of patients and in the remaining 10 % in a further 2-4 weeks. Even if they stop taking drugs one or 2 months after they leave hospital many will not relapse. In Tanzania, approximately 50 % of smear-positive patients enrolled on standard 12-month chemotherapy remain smear and culture-positive at 2 months. For standard 12-month chemotherapy, it is crucial to continue to take regularly daily isoniazid and thiacetazone combined tablets for at least another 2-3 months to achieve 90 % sputum conversion.

In all probability, the patient's perception of the effectiveness of treatment and the balance between discounted future costs and benefits of treatment are also important determinants of compliance. In Tanzania and other IUATLD-assisted National Tuberculosis Programmes, it has been observed that both the perceived effectiveness of treatment and individual and group education of patients during the initial intensive phase of short-course chemotherapy positively affected compliance during the continuation phase.

Other possible determinants of compliance include the number of medications taken at each time, the number of doses per week and the costs to the patients of therapy. Combination tablets of isoniazid and thiacetazone and isoniazid and rifampicin have been in use in National Tuberculosis Programmes of many developing countries for several years. On the other hand, intermittent standard chemotherapy (streptomycin and isoniazid) has never been used on a large scale in developing countries. In India, it has been shown that intermittancy leads to increased irregularity (Pamra and Mathur, 1973). Also Blackwell (1979) could not validate the expected relationship between reduced number of doses and improved compliance. The advantages and disadvantages of intermittent standard chemotherapy will not be addressed further here. The common sense notion that increasing costs both in terms of time and money will decrease compliance has been confirmed in most studies (Haynes, 1979). To maximize compliance, tuberculosis chemotherapy should be free and the spatial and temporal ease of access to treatment should be improved. When alternative treatments are available in the private and public sector, patients may initially prefer to pay for therapy perceived as better, but when funds run out they may switch to the public sector (Uplekar, personal communication). This mixing of different drug regimens will tend to increase the failure rate and the probability of secondary resistance.

The second factor determining the effectiveness is the development of resistance. Under ideal conditions, such as in many clinical trials in patients with sensitive bacilli, the cure rates for both standard and short-course chemotherapy are over 95 %. In patients infected with tubercle bacilli that are isoniazid resistant, the cure rate with total compliance is greatly reduced (Shimao, 1987). Isoniazid resistance is already a major problem in many developing countries (Kleeberg *et al.*, 1980). A systematic application of short-course che-

motherapy referred to above (2SHRZ/6TH) in new smear-positive cases makes it virtually impossible to select for a bacillus resistant to all four drugs, provided that the 2-month initial intensive phase is closely supervised. Decreased development of resistance means that short-course chemotherapy is a substantially more effective long-term strategy for tuberculosis control than standard 12-month chemotherapy. It has to be stressed that acquired (and in contacts of the index cases, primary) resistance to both isoniazid and rifampicin results in incurability of the majority of such cases in developing countries with serious consequences for elimination of tuberculosis.

Costs of chemotherapy

The costs of any tuberculosis control programme comprise many components including drugs, staff costs, transport, training and the cost of hospitalization. While drugs form a considerable portion of the budget, probably from 20 % to 40 %, they are not the only cost. Cost differences between short-course and standard 12-month chemotherapy, however, center on drug costs and hospitalization costs. Table 10 shows prices for the five major drugs from three sources : the UNICEF (UNIPAC), and bulk purchase rates given to the IUATLD by major drug companies. Using different suppliers will substantially alter the relative costs of standard and short-course chemotherapy. Resolution of this question may pave the way for cheaper tuberculosis drug regimens -both standard and short-course. In general, the short-course regimen used in IUATLD National Tuberculosis Programme is approximately $ 25 more per patient than standard depending on the supplier.

Table 10. Costs of antituberculosis drugs

Drug	Unit	Unit cost IUATLD	Unit cost UNIPAC
Isoniazid			
Isoniazid	100 mg x 1000	$2.95	$2.70
Isoniazid	300 mg x 1000		$3.80
Isoniazid/ thiacetazone	300 mg/150 mg x 1000	$10.50	$9.11
Isoniazid/ thiacetazone	100 mg/50 mg x 1000	$4.80	$4.93
Streptomycin			
Streptomycin	1 gm vial	$0.07	
	1 gm vial	$0.09	
	1 gm x 50		$3.55
Pyrazinamide			
Pyrazinamide (CIF)	500 mg x 1000	$31.58	
Pyrazinamide	500 mg x 100		$8.34
Ethambutol			
Ethambutol	400 mg x 1000	$17.00	
Ethambutol	400 mg x 500		$17.13
Rifampicin			
Rifampicin	150 mg x 1000		$40.90
Rifampicin	300 mg x 1000		$58.00
Rifampicin/ isoniazid	150 mg/100 mg x 1000	$79.50	
Rifampicin/ isoniazid	300 mg/150 mg x 1000	$159.00	

The second potential source of cost differentials between short-course and standard 12-month chemotherapy is the level and intensity of supervision. Both standard 12-month and short-course chemotherapy should be given whenever possible on an entirely ambulatory basis. However, in rural areas, where 80-85 % of the African population live and where patients do not have easy access to a health centre, daily regimens may only be delivered in district hospitals. Not only will this improve compliance, but expensive and valuable drugs can be better accounted for in these conditions. For these reasons, short-course chemotherapy may justify higher hospitalization rates and more expense in some countries.

This discussion has thus far been implicitly restricted to the treatment of smear-positive tuberculosis. Once other forms of tuberculosis have been identified, treatment costs for other tuberculosis should be similar to standard 12-month chemotherapy except for serious forms of smear-negative tuberculosis, such as miliary tuberculosis, tuberculous meningitis, Pott's disease, etc., who should be enrolled on short-course chemotherapy (in cases with tuberculous meningitis, rimactazid should also be given in the continuation phase). For treatment of cases that failed to sputum or culture convert in the first round of treatment, the drug costs are particularly high because these patients harbour tubercle bacilli frequently resistant, in developing countries, to isoniazid and/or streptomycin. Many of them have to be treated with short-course chemotherapy for retreatment cases which should ideally contain 3 drugs to which the bacilli are sensitive. A retreatment regimen includes, as a rule, rifampicin and pyrazinamide. In the IUATLD-assisted National Tuberculosis Programmes the following regimen is used : 2SHRZE/ 1HRZE/5$H_3R_3E_3$ in patients resistant to isoniazid or 2SHRZE/ 1HRZE/5TH in patients sensitive to isoniazid. In programmes that are committed to treating all patients that present for care, retreatment must also be considered in examining short-course and standard 12-month chemotherapy. As failure rates are higher for standard 12-month chemotherapy, more resources would have to be devoted to retreatment of these patients.

Cost-effectiveness

The cost-effectiveness of tuberculosis treatment will vary depending on the type of tuberculosis case that is treated. In general, the cost per death averted directly and indirectly will be lowest for smear-positive tuberculosis, higher for other tuberculosis and highest for retreatment cases. While this statement may run counter to intuitive notions of the clinical costs of treating each type of tuberculosis, the rationale is based on the effect of interrupting transmission as explained more fully below. Treating smear-positive tuberculosis may be as much as twice as cost-effective as treating other tuberculosis because of the benefits of reduced transmission in the former. Whether a country with limited resources would choose to target treatment in adult patients to exclusively smear-positive tuberculosis is a difficult ethical, medical and economic choice. The calculations presented here pertain largely to treatment of smear-positive tuberculosis because little information is available on the results of treating other tuberculosis ; this emphasis should not be interpreted as a recommendation to treat only smear-positive tuberculosis

Few studies have examined the cost-effectiveness of tuberculosis treatment in developing countries (Barnum, 1986 ; Joesoef *et al.*, 1989 ; Feldstein *et al.*, 1973). Two of these investigations reported that per case cured short-course chemotherapy was more cost-effective. They did not, however, report figures on the cost per death averted. To fill the gap in information on the cost-effectiveness of short-course and standard 12-month chemotherapy, we have analyzed the tuberculosis control activities over the last seven years of the National Tuberculosis and Leprosy Programme (NTLP) of Tanzania.

Our assumption and calculations are summarized in Tables 11 and 12. The NTLP has been assisted by the IUATLD since 1979. Excellent data are available on the results of both standard 12-month and short-course chemotherapy (Styblo and Chum, 1987, Chum *et al.*, 1988). Comparing the results of standard and short-course chemotherapy with the natural history of tuberculosis as documented in South India (National Tuberculosis Institute, 1974), we can estimate (Table 13) the net improvement in cure rates and death rates. For

Table 11. Assumptions used in estimating the effectiveness of standard 12-month and short-course chemotherapy in the National Tuberculosis and Leprosy Programme of Tanzania

Fate of 100 cases smear-positive tuberculosis with no treatment based on 5 year epidemiological study in South India (1974)

Year	Number of cases			Cured per year	Died per year
	Cured	Excreting bacilli	Dead		
0	0.0	100.0	0.0	0.0	0.0
1	18.5	61.3	20.1	18.5	20.1
1.5	27.8	42.0	30.2		
2	27.8	38.6	33.6	9.3	13.6
3	27.8	31.7	40.5	0.0	6.9
4	30.3	24.9	44.9	2.5	4.4
5	32.5	18.0	49.2	2.2	4.4

Fate of 100 cases smear-positive tuberculosis receiving standard 12-month chemotherapy based on treatment results in Tanzania*

Year	Number of cases			Cured per year	Died per year
	Cured	Excreting bacilli	Dead		
0	0.0	100.0	0.0	0.0	0.0
1	61.1	23.2	15.8	61.1	15.8
1.5	61.1	23.2	15.8		
2	61.1	21.3	17.7	0.0	1.9
3	61.1	17.5	21.4	0.0	3.8
4	62.4	13.7	23.8	1.4	2.4
5	63.7	9.9	26.2	1.2	2.4

Fate of 100 cases smear-positive tuberculosis receiving short-course chemotherapy based on treatment results in Tanzania*

Year	Number of cases			Cured per year	Died per year
	Cured	Excreting bacilli	Dead		
0	0.0	100.0	0.0	0.0	0.0
1	79.6	11.6	8.8	79.6	8.8
1.5	81.3	7.9	10.7	1.8	1.9
2	81.3	7.3	11.4	0.0	0.6
3	81.3	6.0	12.7	0.0	1.3
4	81.8	4.7	13.5	0.5	0.8
5	82.2	3.4	14.3	0.4	0.8

* Styblo and Chum (1987) ; Chum *et al.* (1989).

Table 12. Budgeted costs for tuberculosis chemotherapy, Tanzania, 1986

Cost category	STD	Short	Retreatment
Diagnosis			
Slides/reagents	$2.10	$2.10	
Sputum container	$1.95	$1.95	
Bacteriological			
Monitoring	$0.81	$0.81	
Culture	$1.50	$1.50	$1.50
Sensitivity			$3.90
Drugs	$17.00	$40.00	$65.00
Administration	$2.85	$2.85	$2.85
Labor costs and hospitalization	$67.65	$90.20	$169.12
Transport	$20.35	$20.35	$20.35
Training	$2.37	$2.37	$2.37
Supervision	$2.90	$2.90	$2.90
Capital 20 % depreciation	$3.22	$3.22	$3.22
Total cost per case	$122.70	$168.25	$271.21

Notes : 1) Labour costs and hospitalization include the salaries and wages of all staff working on tuberculosis control and the cost of hospitalizing all tuberculosis patients. As more disaggregated information was not available, the costs in this category have been distributed according to the hospitalization rate for each type of treatment (60 % standard, 80 % short-course, 100 % retreatment). This underestimates the cost per case treated for standard chemotherapy and overestimates the cost per case treated for short-course and retreatment because all staff costs are included in this category.

2) Drug costs are based on 1986 prices and 1986 exchange rates. Since that date the price has declined but the value of the US dollar has also declined.

3) Transport costs include 25 % of the entire purchase cost of all vehicles and operating expenses. The assumption that vehicles will last only 4 years on average may be overly conservative.

Table 13. Cost-effectiveness of standard 12-month and short-course chemotherapy for smear positive pulmonary tuberculosis in Tanzania, 1986

	Standard chemotherapy	Short-course chemotherapy
Cost per case treated	$123	$168
Cost per case cured at 18 months	$368	$314
Cost per death averted	$569	$514
Cost per death averted including one round of transmission	$275	$243

Note : Based on a 3 % discount rate.

standard 12-month chemotherapy and short-course, the cost per patient treated in 1986 US dollar was $ 122 and $ 168 respectively. In a programme where all patients that continue to excrete bacilli receive retreatment, this would raise the cost per case treated under standard 12-month chemotherapy to $ 186 and $ 190 for short-course chemotherapy.

Per case cured at the end of 18 months in excess of spontaneous cure, it was $ 368 for standard 12-month chemotherapy and $ 314 for short-course. Short-course chemotherapy is more cost-effective per patient cured. The difference would be greater except that in Tanzania approximately 80 % of short-course patients are hospitalized for the first 2 months and only 60 % of standard chemotherapy are hospitalized.

For standard 12-month chemotherapy, the cost per death averted was $ 569 and $ 514 for short-course, based on a three percent discount rate. These estimates are serious overestimates for two reasons. First, the benefits of treating patients relative to no treatment have only been examined for five years after treatment. In the South Indian epidemiological study tuberculosis patients were only followed for five years (National Tuberculosis Institute, Bangalore, 1974). Thus the improvement in the death rate due to standard 12-month or short-course chemotherapy has been underestimated by only examining the effect for five years. Second, treatment also reduced the number of new infections of tuberculosis. Using the lowest estimates of the number of cases that each case of smear-positive tuberculosis causes in one year derived in the section above, we can calculate the number of deaths averted by reduced transmission in one cycle. The resulting estimates show standard 12-month chemotherapy to cost $ 274 per death averted and for short-course chemotherapy only $ 242 per death averted.

These estimates of the cost per death averted through tuberculosis chemotherapy are specific to Tanzania but probably represent the higher end of the range for most other developing countries for four reasons. First, the hospitalization rate in Tanzania for short-course chemotherapy is especially high. Any country with a more developed peripheral health system could deliver short-course chemotherapy with a lower hospitalization rate. This observation must be tempered by the fact that the cost per bed-day in many developing countries is considerably higher than the $ 1.50 reported by the Tanzania Government. In a country where the cost per bed-day is $ 5, the cost of hospitalizating patients for 2 months would be increased by $ 210. Second, the benefits of chemotherapy over no treatment have only been considered for the first five years following treatment. Consideration of years 6, 7 and 8 if such data were available would reduce the cost per death averted. Third, the assumption on transmission were the lowest reasonable assumptions, not the midpoint of the expected range of cases transmitted per excretor. Fourth, the rate of capital depreciation was assumed to be extremely high 20-25 % per year. In other developing countries, the true cost per death averted may be considerably lower than $ 265 ; although in some countries where staff costs and hospitalization is more expensive, they may be higher.

Taken together the **studies on the cost-effectiveness of both standard 12-month and short-course chemotherapy show that tuberculosis chemotherapy is an excellent investment relative to virtually any health intervention.** Most interventions including immunizations and oral rehydration therapy yield estimates per death averted in the same range (Haaga, 1982). Second, the analysis clearly indicates that short-course chemotherapy is preferable to standard 12-month chemotherapy. The most significant advantages of short-course chemotherapy over standard 12-month chemotherapy are summarized in Table 14. Not only is it more cost-effective per death averted, as calculated above, but it provides other advantages not included in the estimates. The cure rate taking into consideration the natural history of tuberculosis for standard 12-month chemotherapy under excellent conditions is 63.7 % while under short-course it is 82.2 %. The percentage of cases requiring expensive retreatment is nearly three times greater with standard 12-month chemotherapy as compared to short-course chemotherapy. Finally the death rate with standard 12-month chemotherapy is nearly twice as high as with short-course chemotherapy. Short-course chemotherapy, because of a higher cure rate, will also accelerate the decline in the risk of infection by reducing transmission. Short-course chemotherapy will also limit the development of resistance to isoniazid and rifampicin in the long term. In summary, short-course chemotherapy for tuberculosis is an excellent cost-effective health intervention.

Table 14. Comparison of standard 12-month chemotherapy and short-course chemotherapy for smear-positive cases of tuberculosis based on data from the NTLP of Tanzania

	Standard chemotherapy	Short-course chemotherapy
Cost per death averted including one round of transmission	$275	$243
Percent of patients cured	*63.7*	*82.2*
Percent of cases requiring retreatment	*23.2*	*7.9*
Death rate after 5 years assuming no retreatment (%)	*26.2*	*14.3*

All these computations of cost-effectiveness have been based on the assumption that all patients treated for smear-positive tuberculosis do indeed have smear-positive tuberculosis. As the cost per case treated is high, false positives are a particularly onerous burden on the health system. In Tanzania, where a reference laboratory is available to monitor diagnoses made in the periphery, the false positive rate is low. The most important parameter from a cost point of view is the predictive value positive or the percent of cases diagnosed with tuberculosis who actually have the disease. In Tanzania, this is greater than 97 %. The cost per death averted must be divided by the predictive value positive to get the true cost-effectiveness in a particular situation. In countries with poorly trained microscopists or frequent atypical mycobacteria infections, the predictive value positive could be much lower than 95 %. The potential of wasting scarce resources on patients without tuberculosis puts a high premium on training health workers and microscopists to diagnose tuberculosis correctly.

BCG and case treatment

One would like to compare the two major interventions for

tuberculosis control : BCG and case treatment. They are, however, not truly comparable because even complete BCG coverage at birth will only affect 10 % of mortality. Case treatment is absolutely necessary to reduce the other 90 % of mortality. How does the cost-effectiveness of expanding BCG coverage compare to expanding case treatment activities ? The cost per death averted can be compared directly using the studies mentioned in the text above. Some may object that a death between the ages of 0 and 14 represents a greater loss of years of life than a death at age 35. However, if we choose to examine discounted years of life lost it will not significantly alter the comparison. A death at age 7, the midpoint for deaths averted by BCG, represents at a 3 % discount rate 29.7 years of life lost ; while a death at age 34 the average age of a tuberculosis death represents 23.4 years at a similar discount rate. Therefore, we can examine the cost-effectiveness of the two interventions using the cost per death averted bearing in mind that discounted years of life lost would change the relationship by less than 20 percent.

The cost per death averted through tuberculosis chemotherapy should change little as the risk of infection in a community declines. *Ceterus paribus*, the only change would be the slight increase in the cost of detection as more cases or cough would have to be screened per case of tuberculosis detected. This does not hold true for any immunization including BCG. The costs of vaccinating all infants will not change as the risk of infection declines, but the benefits in terms of deaths averted will decline proportionately to the risk of infection. In other words, the cost per death averted through BCG must be inversely proportional to the risk of infection. Figure VII shows two hypothetical curves for the cost per death averted as a function of the risk of infection. The curves are fitted to the single data point on BCG for Indonesia and the single point on case treatment for Tanzania. While the data are clearly weak, the principle is clear. At low annual risks of infection case treatment is substantially more cost-effective than expanding BCG coverage. At higher risks of infection, the costs of both interventions are of the same order of magnitude. This curve should not be interpreted to mean that countries with low risks of infection should curtail BCG vaccination activities. The discussion so far provides no insight into the savings from cutting back an existing activity versus the potential reduction in benefits. This discussion does not imply that the policy choice in tuberculosis control is between BCG and case-treatment. Some combination of the two is likely to be desirable in many countries. It does, however, indicate that BCG becomes relatively less attractive as the risk of infection declines.

Research priorities

This discussion of tuberculosis leads naturally to some general recommendations for tuberculosis research. These can be divided into six areas :

– **Epidemiology.** The wide confidence intervals in the estimates of incidence, prevalence and mortality highlight the need for epidemiological research. Many countries require basic information on incidence and mortality rates and their distribution by age and socio-economic status, in order to establish the importance of tuberculosis as a health sector priority. For those countries without vital registration, new survey techniques based on the verbal autopsy may provide the tools with which tuberculosis mortality can be quantified.

– **Prevention.** Because of the uncertain and variable effectiveness of BCG, a new effective vaccine would be a major tool, especially if it would also prevent tuberculosis in already infected individuals. Fine (1989), however, has pointed out that it will be difficult to test appropriately the effectiveness of any new vaccines for moral and technical reasons. Research is also needed to explore the most appropriate role for chemoprophylaxis in developing countries, especially in subjects infected with tubercle bacilli and HIV.

– **Diagnosis.** Development of new tools for the rapid and early diagnosis of tuberculosis would substantially improve case detection. Research into serological or sputum diagnosis that can be deployed at reasonable cost in peripheral health facilities in developing countries should be a priority.

– **Chemotherapy.** Development of new shorter acting, cheap drugs would help address two major issues in tuberculosis control : compliance and cost. While opportunities exist for developing new drugs (Sensi, 1989), relatively little research is underway. Another possibility that seems worth exploring is the use of depot preparations which would solve many of the compliance problems.

– **Programme design.** There is an urgent need for operational and health economics research on strategies for tuberculosis control.

Some key issues have been highlighted in this piece : what is the trade-off between the cost of supervision and the improvement in compliance, taking existing infrastructure into consideration ? What is the cost-effectiveness of alternative diagnosis strategies ? These and many other issues need to be addressed in an organised fashion.

– **HIV and tuberculosis interactions.** The interaction between HIV and tuberculosis has not been fully addressed in this piece. It is evident that immune suppressed patients with HIV and tuberculous infections have a high probability of developing clinical tuberculosis. In Central East Africa, tuberculosis programmes are already reporting a considerable increase in the number of cases of tuberculosis. The impact of any HIV-tuberculosis interaction in developing countries with a high prevalence of tuberculous infection on the annual risk of infection for the rest of the population is not yet known. Epidemiological study of these relationship has just begun and should be considered a priority for research.

Major operational conclusions

This review of tuberculosis can be summarized in five major points :

– The magnitude of the tuberculosis problem is simply staggering. Our estimates suggest that more than 2.5 million people die from tuberculosis each year. This is probably more than any other single pathogen ; the only disease that come close in terms of total deaths is measles, estimated to kill 2.5 million per year (Walsh, 1988). The burden of tuberculosis extents beyond mortality ; the annual incidence of new cases of all forms of tuberculosis is over 7.1 million cases in the developing world. Tuberculosis is unique amongst the major killers of the developing world in that it afflicts nearly all age-groups. Many children die from tuberculous meningitis and miliary tuberculosis. But the greatest burden of tuberculosis incidence and mortality is concentrated in adults 15 to 59. These are the parents, workers and leaders of society. This heavy toll of the care givers for the rest of

society makes tuberculosis a truly unique problem.

– In at least the last decade, tuberculosis has been ignored by much of the international health community. Shimao (1989) has outlined the decline of the human and institutional capacity to address the tuberculosis problem over the last decades which is but one symptom of a general lack of priority attached to tuberculosis action and research. Another example is the Institute of Medicine (1986) study of vaccine development priorities for the developing world. They classified diseases into three levels of priority for research on vaccines. While leprosy received significant attention tuberculosis was not even mentioned in the lowest priority group. Clearly, focussing international attention on tuberculosis is necessary first step if more resources are to be directed to combating tuberculosis.

– Existing diagnostic technology and chemotherapeutic agents can be used effectively in developing countries to cure tuberculosis. The IUATLD-assisted National Tuberculosis Programmes (e.g. Tanzania, Malawi) have shown that short-course chemotherapy can be applied on a national scale with excellent results. Cure rates approaching 90 % even taking into consideration compliance can be achieved in even the most difficult circumstances.

– Tuberculosis chemotherapy and BCG vaccination (in countries with high risks of infection) are some of the most cost-effective health interventions available in the health armamentarium. Our analysis of the National Tuberculosis and Leprosy Programme in Tanzania has shown that treating smear-positive tuberculosis costs less than $ 250 per death averted. The cost per discounted year of life saved is therefore substantially less than $ 10. There are few interventions that are as cost-effective as tuberculosis case-treatment. Given our estimates that slightly more than half of all new cases of tuberculosis receive some form of treatment that in most cases is not highly effective, we estimate that the total increased cost of treating all new cases of tuberculosis through a well managed chemotherapy programme to be less than 700 million US dollars per year.

– Evidence has accumulated that the HIV/tuberculosis interaction may significntly exacerbate the epidemiological situation of tuberculosis. The potential rise, due to this interaction, in the risk of infection in Africa and other regions depending on the spread of HIV makes all our operational conclusions about tuberculosis all the more pressing.

The combination of an enormous burden, years of neglect, the existence of effective interventions, the demonstrated interaction between tuberculous and HIV infections and one of the most cost-effective interventions available must make tuberculosis one of the highest priorities of action and research in international health.

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DIS-5.

SERIOUS IMPLICATIONS OF THE WORLD BANK'S REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME FOR INDIA

(A POSITION PAPER FOR DISCUSSIONS AMONG CONCERNED SCHOLARS OF THE COUNTRY. THE AUTHOR WELCOMES COMMENTS AND CRITICISM)

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CHAPTER 1

AN OVERVIEW

The proposal of the World Bank for what they call "Revised National Tuberculosis Control Programme" (RNTCP) for India is going to have very damaging consequences for development of the health services of the country, as it suffers from serious infirmities. The Voluntary Health Association of India and the Nucleus for Health Policies and Programmes have got together to produce this document, which contains a scientific analysis of the RNTPC to draw attention to its infirmities and to formulate an alternative proposal for strengthening the National Tuberculosis Programme (NTP) of India. While the RNTCP will be analysed in detail at a later stage, it will be worthwhile here to note that the infirmities belong to three categories. The most important among them is that the RNTCP has been developed without paying adequate attention to the process of formulation of the NTP and the factors which have come in the way of its implementation over the more than three decades since it was adopted by the Government of India. Secondly, in considering the conceptualisation of the RNTCP as an outcome of an interdisciplinary study, adopting a systems approach, there are very serious flaws in project formulation in terms of system optimisation, epidemiological and sociological analyses, managerial and technological perspectives, coverage, epidemiological impact, repayment of the World Bank loan, replicability of the RNTCP, and other such considerations. Thirdly, the World Bank promoted RNTCP is a part of the sequence of what are termed as "International Initiatives" thrust on the country from outside at the instance of international agencies, backed up by strong support from many powerful western countries, which make substantial contributions to the budgets of the former. Ironically, as will be demonstrated later on, it is these international initiatives which have been proved to be the major hurdles in the way of implementation of the NTP all these years. The RNTCP thus appears as a not well thought out operation performed by persons from the very same group who, in the first place, have been responsible for the damage done to the NTP.

Even from this very broad mention of the RNTCP it is possible to discern an underlying deep streak of dogmatism among the exponents of the RNTCP, which has impelled them to 'forget' the enormous and very substantial public health research in tuberculosis conducted within the country and put enormous

pressure on the national authorities to submit to 'models' developed by them outside the country. Apart from very serious conceptual flaws, these western models are technocentric, imposed on the people from above and make the country dependent on assistance from outside. 'Forgetting' ideas developed indigenously has thus become almost a prerequisite for taking international initiative in health fields; the fields gets closed to scientific discussions and only those 'natives' who do not do question them, or are incapable of doing so, are allowed entry into the privileged group by the international syndicate. Soon after the poor countries of the world had dared to make a declaration of self-reliance in health in the Alma-Ata Declaration of 1978 (WHO 1978), the affluent countries 'invented' what they called "Selective Primary Health Care" (Walshe and Warren 1979), which was almost immediately followed by the unleashing of a series of international initiatives in health. This provides a frightening example of the extent to which the more affluent countries of the world are prepared to go in imposing their will on the countries that are economically and politically dependent on them. Significantly, there has been little protest from the concerned community of public health scholars even in the affluent countries to such brazen forms of manipulation of science to impose programmes on 'defenceless' countries, from outside. The World Bank backed RNTCP is a particularly unfortunate example of imposition of such international initiatives.

The drive towards globalisation of the economy and polity has made the poor countries even more vulnerable to manipulation by the rich countries. In the so-called global village, the poor countries are condemned to serve as bonded hirelings of the rich kulaks and cowboys. A 'dialectical' outcome of this form of international relations is for the oppressed peoples to make conscious efforts to prevent the dominant powers to 'forget' their historical heritage. To adapt a quotation from Milan Kundera, it becomes a struggle between memory and forgetfulness. Just as ahistoricity becomes an important weapon in the hands of those who would fight to continue to monopolise the control over the bulk of the resources of the world, breaking into their consciousness to 'remind' them about the history they try to forget becomes a weapon in the hands of the oppressed to fight oppression.

At a time when a concerted effort is being made by World Bank officials to promote RNTCP in this country, this document may be considered as a modest effort to 'remind' them as well as the concerned authorities in the country about the very significant work that has been done in India to deal with tuberculosis as a

public health problem. No apologies will be offered here for consciously taking the side of the people by bringing out well researched data which had formed the basis of the NTP some three and a half decades ago. A very deliberate effort is made here to describe the work rather extensively. The 'battle lines' are clear: on one side are the indigenous research efforts made to formulate a nationally applicable, socially acceptable and epidemiologically effective tuberculosis programme, and on the other side is a 'foreign inspired', prepackaged programme that is sought to be thrust on the country by powerful countries and international organisations.

CHAPTER 7

CONCLUSIONS AND AN ALTERNATIVE FRAMEWORK FOR ACTION

The above account shows how a well researched and reasonably simple and straight forward programme can get hopelessly confounded due to interplay of a variety of social, political and economic forces. NTP essentially involved offering diagnosis and treatment to the very substantial portion of tuberculosis patients who were actively seeking treatment in various health institutions, both in rural and urban areas. These institutions were offered a referral support system which extended right up to the super-specialists in post-graduate teaching hospitals. State Tuberculosis Centres and NTI and other tuberculosis research and teaching institutes were meant to provide support to the programme in the form of training, monitoring, evaluation and operational research.

But as pointed out by Halfdan Mahler, 'even the simplest technology, if it is not properly deployed and utilised by the infrastructure, just will not move, will not control tuberculosis, will not meet people's felt-needs.' This is what has befallen on NTP. The infrastructure has been grievously damaged because of sharp decline in the quality of public health practice and research, filling up of key public health posts by the persons who do not have technical competence, by imposition of target oriented specialised programmes on an already weak infrastructure and a correspondingly sharp fall in the quality of administrators and research personnel in the field of tuberculosis.

From the basic premises presented above, some important suggestions are being made below:

1. While tuberculosis workers cannot take on themselves the onerous task of rejuvenating the moribund health and family planning services systems, the crisis has become so profound that there are good chances that the political leaders will have to wake up to it. A detailed programme for rejuvenation of the health services is given in the author's B.C.Dasgupta Oration of the Indian Public Health Association in 1988 (Banerji 1988b; 1984b). Some important components are:

a. Building up a critical mass of public health workers in the fields of education, training, research and practice.

b. Restructuring the cadre structure to place competent public health specialists in key public health positions.

c. Concurrent removal of the square pegs in the round holes of the system.

d. Making "conditional" integration of the special target oriented family planning and other programmes "unconditional". This will lead to according much higher priority to NTP as the problem is responsible for a substantial part of the total suffering caused by health problems as a whole.

2. Tuberculosis workers can help in the process of rejuvenation of the health and family planning service systems by insisting that this process is critical for providing good tuberculosis services to be suffering masses of the country.

3. On its own, even considering the constraints of the general health services as given, there is still considerable scope for improving the NTP system through use of operational research and systems analysis. The Surajkund Conclave recommendations can serve as a starting point.

4. The very improvement in the NTP system might stimulate improvement in the wider health and family planning services systems, by providing an example.

5. NTI can be rejuvenated by bringing together a competent interdisciplinary team of workers, so that it can play a role in strengthening the NTP. It can even extend its activities to serve as one of the many institutions which would be necessary to strengthen the general health services.

6. Concurrently, competent tuberculosis workers are placed as heads of tuberculosis wings of the central and state health services.

7. Other tuberculosis institutions, such as TRC, should be tuned to serve the NTP, i.e., the problems they deal with must emerge from the field situation, and not the other way round, as is often the case at present.

8. The idea of Task Force (Editorial 1990), or a similar set up (Fox 1990), which is vested with power and resources to act as a watchdog for the implementation of NTP, very well blends with the other suggestions for improving NTP given here.

9. Again, there is considerable scope for optimising the urban components of the NTP.

10. Tuberculosis Association of India and its branches can be revamped to perform a complementary role in strengthening of NTP - e.g., conducting independent evaluation, offering technical assistance, providing logistical support, providing training, and so forth.

In sum, the suggestion is that we take steps to unleash the social forces which ensure that simple and efficacious technology developed in India is made accessible to the hundreds of thousands of sputum positive cases, who are actively seeking relief for suffering but who are still being thrown out of the health institutions with a bottle of useless cough mixture. Sociologically, it is contended that the very meeting of the felt need generates more needs, and, if that does not happen, active educational steps are taken to generate more needs to reach a level when it starts having an epidemiological impact. This epidemiological impact will occur in consonance with the impact that might occur as a result of changes in the natural history of tuberculosis in India.

Tuberculosis Control in India

Social Assessment of Target Audiences in 13 Slums

by FEMCONSULT

Proposed TB Control Project

Public Policy Division

Voluntary Health Association of India
40, Institutional Area, South of IIT
New Delhi - 110 016

Slum Sites

Bangalore
- *Frazertown (very poor)*
- *Koramangala(better off)*

Pune
- *Abedgar Nagar (poor)*
- *Vaidu Wadi (better off)*

Hyderabad
- *Indirammanager (poor)*
- *Allapoor (less poor)*
- *Mahatma Ghandi Nagar (better off)*

Lucknow
- Banija Mohal (very poor)
- Vija Khera (very poor)
- Ambedgar Nagar (better off)

Jaipur
- Valmiki Basti (poor)
- Fauji Basti (poor)
- Hathroi Basti (better off)

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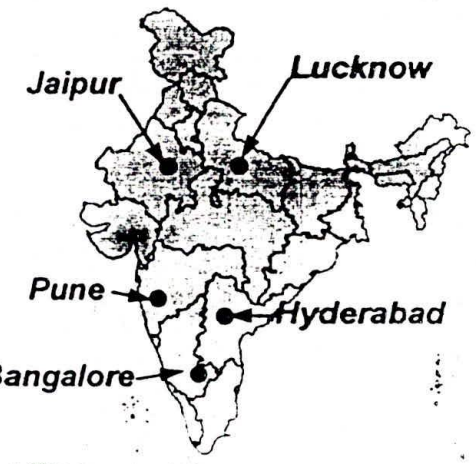
Slum Sites



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Slum Study Methodology

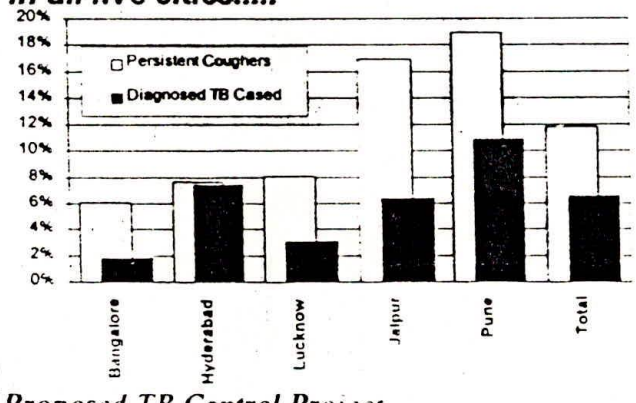
- **Individual In depth Interviews**
  - Community households
  - Health providers - public
  - Health providers - Private (all categories of doctors)
  - Pharmacy Owners & staff nurses
- **Group Interviews**
  - community embers
- **Exit Interviews**
  - Patients
- **Observation**
  - Government health care facilities and community

Interviewers were locals - some were members of NGOs

TB/Persistent Cough

Prevalence among households

Based on a total of 1,042 households interviewed in all five cities.....



Findings (Community Members)

TB is.....

- ✓ **Curable** *(according to most)*
- ✓ **Something best kept hidden**
- ✓ **Contagious** *(through air, food, clothes)*
- ✓ **Dangerous**
- ✓ **Disease of the poor**
- ✓ **Never heard of TB** *(1/3 of sample)*

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Findings (Community Members)

TB Symptoms.....

- ✓ **Cough**
- ✓ **Fever**
- ✓ **Blood in sputum**

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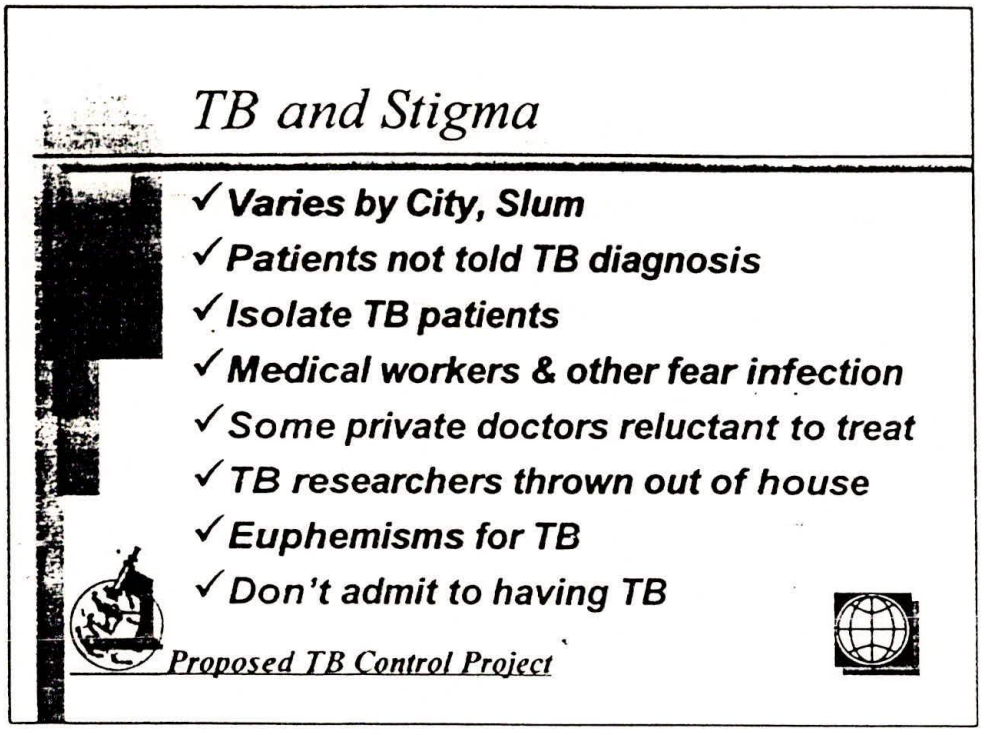


•Amount varies by slum and city

•Doctors often do not tell patients with TB their diagnosis

•Widespread community perception that TB patients, their food and clothing must be isolated

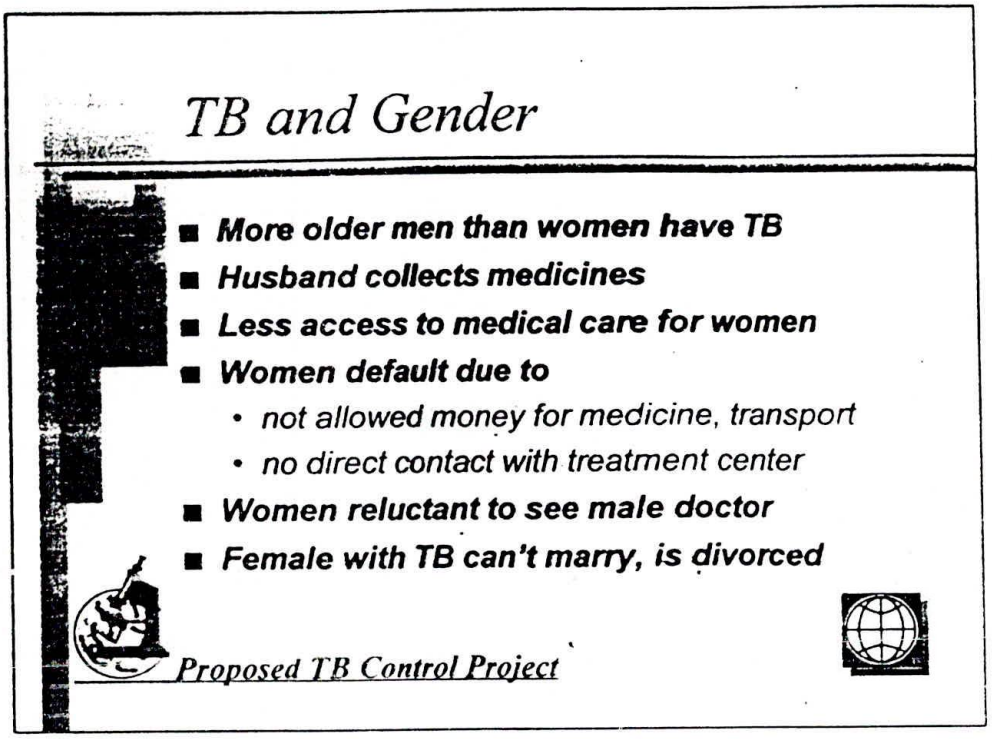
•Afraid of being infected - medical practitioners, TB treatment facility staff, patients in large hospitals

•Some private doctors do not want to treat TB patients

•In a few slums, researchers thrown out of community member's houses when topic raised

•Euphemisms for TB used

•TB patients do not admit to having TB



•More common in older men than women

•Husband usually collects medicines for wife

•Women have less access to medical care for may use cheaper care

•Sometimes women defaulted because

⇨Husbands did not allow them to spend money on medicine or transportation once wife was well enough to work

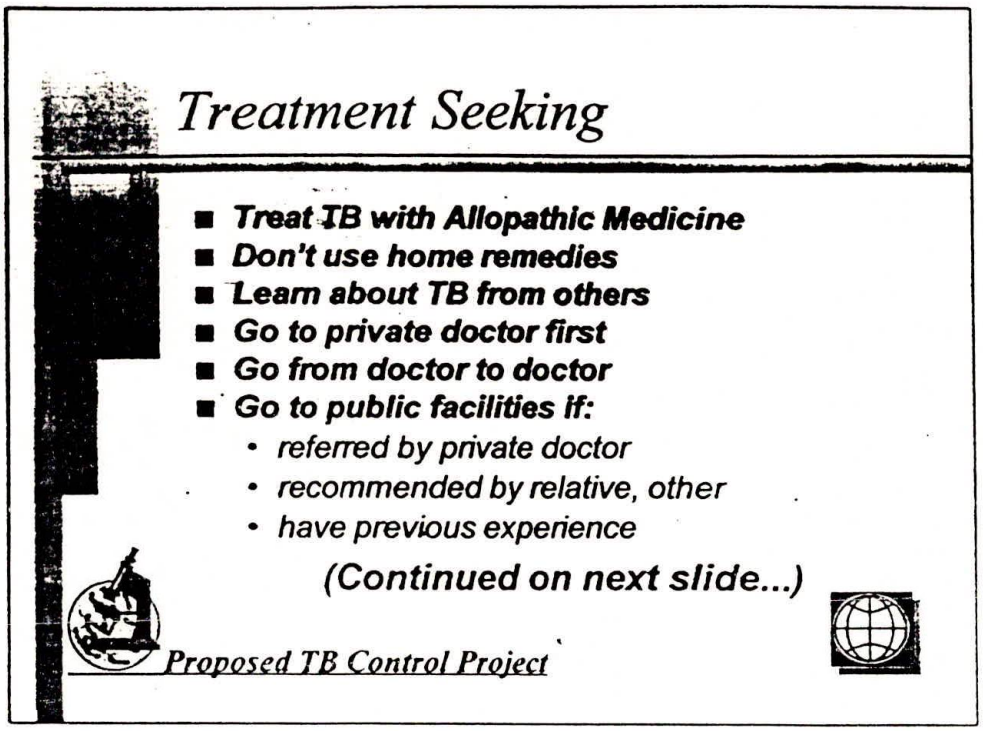
⇨Husband acted as intermediary so wife did not have direct contact with treatment center

•Women reluctant to visit male doctors

⇨prefer female doctors

⇨prefer places other women go

•difficult for female TB patient to marry or stay married



•TB Believed best treated by allopathic medicines

•Very few report use of home remedies for TB

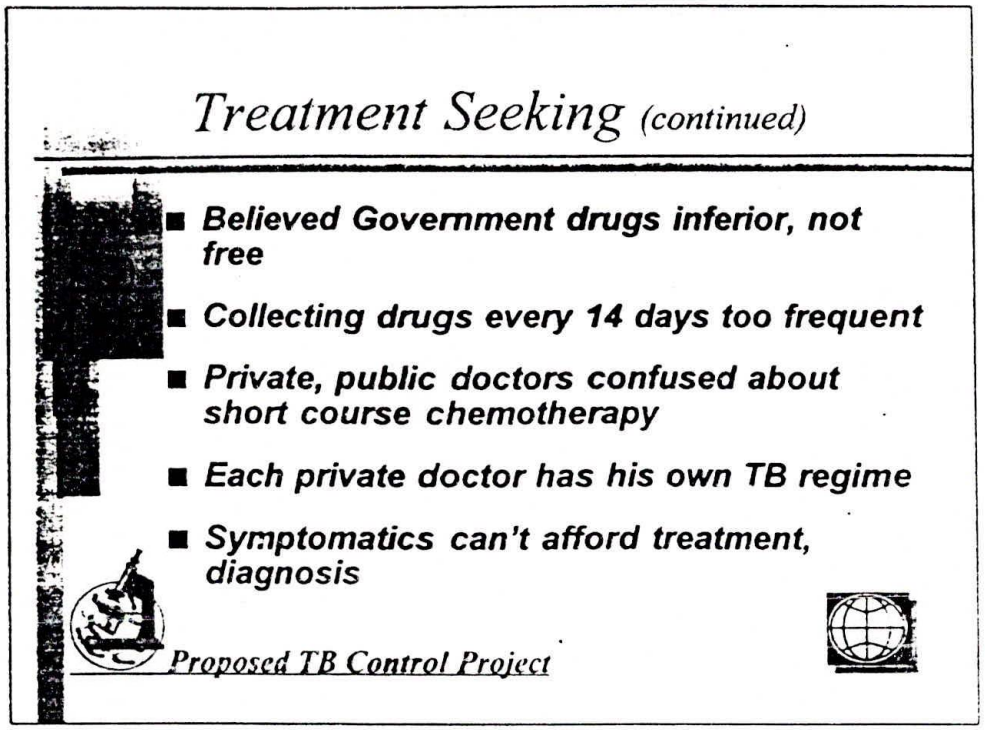
•People learn about TB through interpersonal communications

•Those who seek treatment go first to private doctors because:

- ⇨conveniently located
- ⇨cheap (Rs 10-2 sometimes includes drugs
- ⇨privacy accorded shameful disease
- ⇨treated better than at Government facilities
- ⇨Government medicine believed to be inferior

•Patients go from doctor to doctor seeking correct treatment and diagnosis

- ⇨People attend public facilities
- ⇨referred by private doctor
- ⇨recommended by relative or friend
- ⇨previous experience



•People believe medicines are not free and inferior in public sector

•Doctors in both public and private sectors showed confusion about SCC during interviews

•Even fortnightly visits to collect drugs problematic because:

⇨No extra money for transportation - few or no public health facilities in slums

⇨Government facilities often out of medicines

⇨Day laborers cannot afford lost wages (including husband coming for wives)

•Each private doctors has his/her own drug regime for treating TB

Incomplete Treatment

- ***Main reasons financial***
  - *funds needed to live*
  - *transportation expensive*
  - *private doctors expensive*
  - *TB drugs expensive*
- ***Stop when better***
- ***Doesn't know why has TB***
- ***Don't understand treatment duration***
- ***Doctor says TB cured***
- ***Can't afford second treatment cycle***
- ***No outreach workers follow up***

Proposed TB Control Project

FEMCONSULT Recommendations

- *Issues to address through I.E.C*

  → *shortening path between **INITIAL** symptoms and **APPROPRIATE** diagnosis*

- *addressing defaulters problems*
- *Address stigma (e.g. by emphasizing that **TB is curable**)*
- *Charge small fee for medicines (**refunded upon completion** of treatment)*

Proposed TB Control Project

D15-5.

SERIOUS IMPLICATIONS OF THE WORLD BANK'S REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME FOR INDIA

(A POSITION PAPER FOR DISCUSSIONS AMONG CONCERNED SCHOLARS OF THE COUNTRY. THE AUTHOR WELCOMES COMMENTS AND CRITICISM)

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Commisioned by
Voluntary Health Association of India
40, Institutional Area, South of IIT
New Delhi - 110 016

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CHAPTER 1

AN OVERVIEW

The proposal of the World Bank for what they call "Revised National Tuberculosis Control Programme" (RNTCP) for India is going to have very damaging consequences for development of the health services of the country, as it suffers from serious infirmities. The Voluntary Health Association of India and the Nucleus for Health Policies and Programmes have got together to produce this document, which contains a scientific analysis of the RNTPC to draw attention to its infirmities and to formulate an alternative proposal for strengthening the National Tuberculosis Programme (NTP) of India. While the RNTCP will be analysed in detail at a later stage, it will be worthwhile here to note that the infirmities belong to three categories. The most important among them is that the RNTCP has been developed without paying adequate attention to the process of formulation of the NTP and the factors which have come in the way of its implementation over the more than three decades since it was adopted by the Government of India. Secondly, in considering the conceptualisation of the RNTCP as an outcome of an interdisciplinary study, adopting a systems approach, there are very serious flaws in project formulation in terms of system optimisation, epidemiological and sociological analyses, managerial and technological perspectives, coverage, epidemiological impact, repayment of the World Bank loan, replicability of the RNTCP, and other such considerations. Thirdly, the World Bank promoted RNTCP is a part of the sequence of what are termed as "International Initiatives" thrust on the country from outside at the instance of international agencies, backed up by strong support from many powerful western countries, which make substantial contributions to the budgets of the former. Ironically, as will be demonstrated later on, it is these international initiatives which have been proved to be the major hurdles in the way of implementation of the NTP all these years. The RNTCP thus appears as a not well thought out operation performed by persons from the very same group who, in the first place, have been responsible for the damage done to the NTP.

Even from this very broad mention of the RNTCP it is possible to discern an underlying deep streak of dogmatism among the exponents of the RNTCP, which has impelled them to 'forget' the enormous and very substantial public health research in tuberculosis conducted within the country and put enormous

pressure on the national authorities to submit to 'models' developed by them outside the country. Apart from very serious conceptual flaws, these western models are technocentric, imposed on the people from above and make the country dependent on assistance from outside. 'Forgetting' ideas developed indigenously has thus become almost a prerequisite for taking international initiative in health fields; the fields gets closed to scientific discussions and only those 'natives' who do not do question them, or are incapable of doing so, are allowed entry into the privileged group by the international syndicate. Soon after the poor countries of the world had dared to make a declaration of self-reliance in health in the Alma-Ata Declaration of 1978 (WHO 1978), the affluent countries 'invented' what they called "Selective Primary Health Care" (Walshe and Warren 1979), which was almost immediately followed by the unleashing of a series of international initiatives in health. This provides a frightening example of the extent to which the more affluent countries of the world are prepared to go in imposing their will on the countries that are economically and politically dependent on them. Significantly, there has been little protest from the concerned community of public health scholars even in the affluent countries to such brazen forms of manipulation of science to impose programmes on 'defenceless' countries, from outside. The World Bank backed RNTCP is a particularly unfortunate example of imposition of such international initiatives.

The drive towards globalisation of the economy and polity has made the poor countries even more vulnerable to manipulation by the rich countries. In the so-called global village, the poor countries are condemned to serve as bonded hirelings of the rich kulaks and cowboys. A 'dialectical' outcome of this form of international relations is for the oppressed peoples to make conscious efforts to prevent the dominant powers to 'forget' their historical heritage. To adapt a quotation from Milan Kundera, it becomes a struggle between memory and forgetfulness. Just as ahistoricity becomes an important weapon in the hands of those who would fight to continue to monopolise the control over the bulk of the resources of the world, breaking into their consciousness to 'remind' them about the history they try to forget becomes a weapon in the hands of the oppressed to fight oppression.

At a time when a concerted effort is being made by World Bank officials to promote RNTCP in this country, this document may be considered as a modest effort to 'remind' them as well as the concerned authorities in the country about the very significant work that has been done in India to deal with tuberculosis as a

public health problem. No apologies will be offered here for consciously taking the side of the people by bringing out well researched data which had formed the basis of the NTP some three and a half decades ago. A very deliberate effort is made here to describe the work rather extensively. The 'battle lines' are clear: on one side are the indigenous research efforts made to formulate a nationally applicable, socially acceptable and epidemiologically effective tuberculosis programme, and on the other side is a 'foreign inspired', prepackaged programme that is sought to be thrust on the country by powerful countries and international organisations.

CHAPTER 7

CONCLUSIONS AND AN ALTERNATIVE FRAMEWORK FOR ACTION

The above account shows how a well researched and reasonably simple and straight forward programme can get hopelessly confounded due to interplay of a variety of social, political and economic forces. NTP essentially involved offering diagnosis and treatment to the very substantial portion of tuberculosis patients who were actively seeking treatment in various health institutions, both in rural and urban areas. These institutions were offered a referral support system which extended right up to the super-specialists in post-graduate teaching hospitals. State Tuberculosis Centres and NTI and other tuberculosis research and teaching institutes were meant to provide support to the programme in the form of training, monitoring, evaluation and operational research.

But as pointed out by Halfdan Mahler, 'even the simplest technology, if it is not properly deployed and utilised by the infrastructure, just will not move, will not control tuberculosis, will not meet people's felt-needs.' This is what has befallen on NTP. The infrastructure has been grievously damaged because of sharp decline in the quality of public health practice and research, filling up of key public health posts by the persons who do not have technical competence, by imposition of target oriented specialised programmes on an already weak infrastructure and a correspondingly sharp fall in the quality of administrators and research personnel in the field of tuberculosis.

From the basic premises presented above, some important suggestions are being made below:

1. While tuberculosis workers cannot take on themselves the onerous task of rejuvenating the moribund health and family planning services systems, the crisis has become so profound that there are good chances that the political leaders will have to wake up to it. A detailed programme for rejuvenation of the health services is given in the author's B.C.Dasgupta Oration of the Indian Public Health Association in 1988 (Banerji 1988b; 1984b). Some important components are:

a. Building up a critical mass of public health workers in the fields of education, training, research and practice.

b. Restructuring the cadre structure to place competent public health specialists in key public health positions.

c. Concurrent removal of the square pegs in the round holes of the system.

d. Making "conditional" integration of the special target oriented family planning and other programmes "unconditional". This will lead to according much higher priority to NTP as the problem is responsible for a substantial part of the total suffering caused by health problems as a whole.

2. Tuberculosis workers can help in the process of rejuvenation of the health and family planning service systems by insisting that this process is critical for providing good tuberculosis services to be suffering masses of the country.

3. On its own, even considering the constraints of the general health services as given, there is still considerable scope for improving the NTP system through use of operational research and systems analysis. The Surajkund Conclave recommendations can serve as a starting point.

4. The very improvement in the NTP system might stimulate improvement in the wider health and family planning services systems, by providing an example.

5. NTI can be rejuvenated by bringing together a competent interdisciplinary team of workers, so that it can play a role in strengthening the NTP. It can even extend its activities to serve as one of the many institutions which would be necessary to strengthen the general health services.

6. Concurrently, competent tuberculosis workers are placed as heads of tuberculosis wings of the central and state health services.

7. Other tuberculosis institutions, such as TRC, should be tuned to serve the NTP, i.e., the problems they deal with must emerge from the field situation, and not the other way round, as is often the case at present.

8. The idea of Task Force (Editorial 1990), or a similar set up (Fox 1990), which is vested with power and resources to act as a watchdog for the implementation of NTP, very well blends with the other suggestions for improving NTP given here.

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10. Tuberculosis Association of India and its branches can be revamped to perform a complementary role in strengthening of NTP - e.g., conducting independent evaluation, offering technical assistance, providing logistical support, providing training, and so forth.

In sum, the suggestion is that we take steps to unleash the social forces which ensure that simple and efficacious technology developed in India is made accessible to the hundreds of thousands of sputum positive cases, who are actively seeking relief for suffering but who are still being thrown out of the health institutions with a bottle of useless cough mixture. Sociologically, it is contended that the very meeting of the felt need generates more needs, and, if that does not happen, active educational steps are taken to generate more needs to reach a level when it starts having an epidemiological impact. This epidemiological impact will occur in consonance with the impact that might occur as a result of changes in the natural history of tuberculosis in India.

D15-5.

PUBLIC HEALTH

Cost effectiveness of chemotherapy for pulmonary tuberculosis in three sub-Saharan African countries

CHRISTOPHER J. L. MURRAY ERIC DEJONGHE H. J. CHUM
D. S. NYANGULU A. SALOMAO KAREL STYBLO

The value of programmes to control pulmonary uberculosis in developing countries remains the subject of debate. We have examined the cost-effectiveness of chemotherapy programmes for the control of pulmonary sputum-smear-positive tuberculosis in Malawi, Mozambique, and Tanzania.

Effective cure rates of 86–90% were achieved with short-course chemotherapy and of 60–66% with standard chemotherapy. The average incremental costs per year of life saved were US $1·7–2·1 for short-course chemotherapy with hospital admission, $2·4–3·4 for standard chemotherapy with hospital admission, $0·9–1·1 for ambulatory short-course chemotherapy, and $0·9–1·3 for ambulatory standard chemotherapy.

Chemotherapy for smear-positive tuberculosis is thus cheaper than other cost-effective health interventions such as immunisation against measles and oral rehydration therapy. Because the greatest benefit of chemotherapy is reduced transmission of the bacillus, treating HIV-seropositive, tuberculosis smear-positive patients would be only slightly less cost-effective than treating HIV-seronegative, tuberculosis-smear-positive patients.

Lancet 1991; **338**: 1305–08.

Introduction

Tuberculosis is a major public health problem for many countries in the developing world. There are about 7·1 million new cases of all forms of tuberculosis every year in the developing world,[1] of which 3·2 million are smear-positive pulmonary tuberculosis. Tuberculosis causes 2·6 million deaths per year, making it the world's largest single infectious cause of death. The importance of tuberculosis as an impediment to development is due not only to its huge incidence and mortality but also to the age-distribution of cases and deaths: although people of all ages are affected, the heaviest toll (more than 75%) is on adults aged 15–59 years, the parents, workers, and leaders of society.[2]

Much research effort has been devoted to finding the most appropriate method of delivering chemotherapy for tuberculosis.[4–10] Until the 1960s, almost all patients with tuberculosis were confined to tuberculosis sanatoria for long periods (8 months or more). Studies in Madras, India, in the late 1950s showed that completely ambulatory treatment had as high a rate of cure as inpatient treatment and did not contribute to significant transmission within the family or close contacts of tuberculosis patients.[4–7] However, the high rates of compliance achieved in urban Madras with completely ambulatory treatment and drug regimens lasting in excess of 1 year have not been achieved in most developing countries.[2]

Several studies have looked at the cost-effectiveness of tuberculosis chemotherapy.[2,6,11,12] One study[2] provided estimates of the cost-effectiveness of chemotherapy for tuberculosis compared with other health interventions. It showed that in Tanzania chemotherapy for smear-positive pulmonary tuberculosis was one of the cheapest health-sector interventions available. Short-course chemotherapy was also found to be more cost-effective than 12 months' standard chemotherapy.

Here we present a preliminary report of an in-depth study of the costs and impacts of chemotherapy for sputum-smear-positive tuberculosis in the national tuberculosis control programmes of Tanzania, Malawi and Mozambique.

Methods

This study used data collected by the national tuberculosis programmes that are part of the Mutual Assisted Programme of the International Union Against Tuberculosis and Lung Disease (IUATLD). The programmes in Malawi, Mozambique, and Tanzania were selected because of the completeness of data from these programmes. In all of these countries, short-course chemotherapy has been introduced during the past decade and is replacing standard chemotherapy, providing an opportunity to compare the effectiveness of the two regimens at a national level. In these programmes, the short-course regimen is 2 months of

ADDRESSES: Center for Population Studies, Harvard University, 9 Bow Street, Cambridge, Massachusetts 02138, USA (C. J. L. Murray, MD); Ministry of Health, Brussels, Belgium (E. DeJonghe, MD); Ministry of Health, Dar es Salaam, Tanzania (H. J. Chum, MD); Ministry of Health, Lilongwe, Malawi (D. S. Nyangulu, MD); Ministerio da Saude, Maputo, Mozambique (A. Salomao, MD); and Tuberculosis Surveillance Research Unit, The Hague, Netherlands (K. Styblo, MD). Correspondence to Dr Christopher J. L. Murray.

TABLE I—COSTS (US$) PER CASE TREATED

	Malawi	Mozambique	Tanzania
Short-course chemotherapy with hospital admission			
Average	160	217	174
Average incremental	99	155	127
Marginal	69	140	101
Standard chemotherapy with hospital admission			
Average	91	73	72
Average incremental	71	54	63
Marginal	42	40	37
Ambulatory short-course chemotherapy			
Average	139	196	152
Average incremental	75	132	103
Marginal	46	117	77
Ambulatory standard chemotherapy			
Average	66	55	50
Average incremental	45	36	41
Marginal	19	18	15
Retreatment chemotherapy with hospital admission			
Average	209	323	252
Average incremental	141	232	182
Marginal	97	206	146

For Malawi the estimates of cost of ambulatory therapy are hypothetical based on measured costs but no ambulatory therapy is actually provided

The period of hospital admission is 60 days during the intensive phase of short-course chemotherapy and 90 days during retreatment chemotherapy

TABLE II—RESULTS OF CHEMOTHERAPY PROGRAMMES (GIVEN AS % OF PATIENTS) IN MALAWI, MOZAMBIQUE, AND TANZANIA

	Malawi	Mozambique		Tanzania	
Treatment results	Short-course 1984–88	Standard 1985–88	Short-course 1984–88	Standard 1980–82	Short-course 1982–88
Cured	87·2	43·7	70·8	38·3	76·9
Treatment completed	0·0	10·4	7·3	15·0	0·0
Failed	1·3	4·3	1·5	11·0	2·4
Died	6·5	4·7	1·5	6·7	6·5
Absconded	2·2	24·2	11·3	15·7	9·9
Transferred out	2·7	12·5	7·8	13·3	4·2
Excreting	3·1	29·2	8·3	33·2	7·4
Effective cure rate	90·4	66·2	90·3	60·2	86·1

Data are for all registered cases for the years shown, with the exception that some data are not yet available for 1988

The years refer to the year of case registration not the year of completion of treatment

Cured = those patients sputum-negative after 8 months of short-course chemotherapy or 12 months of standard chemotherapy; treatment completed = patients who complete treatment but do not have confirmation with a sputum smear at the end of treatment; failed = patients with a positive smear after 8 months of short-course chemotherapy or 12 months of standard chemotherapy; absconders = patients who do not complete treatment and are lost to follow-up; and transferred out = patients who move to another district and are assumed to be lost to follow-up (categories chosen by the IUATLD)

Effective cure rate = cured plus treatment completed, plus 35% of absconded and transferred out for standard chemotherapy and 65% of absconded and transferred out for short-course chemotherapy

streptomycin, isoniazid, rifampicin, and pyrazinamide followed by 6 months of isoniazid and ethambutol, and the standard regimen is 2 months of streptomycin, isoniazid, and thiacetazone followed by 10 months of isoniazid and thiacetazone. The treatment study has been supplemented by an in-depth study of programme costs during the period 1988–89. Data on cost were collected for all aspects of the tuberculosis programme including a unit-cost study of two hospitals with tuberculosis patients in each country.

Costs of the tuberculosis programme can be divided into three components: fixed costs associated with use of facilities outside the tuberculosis programme such as hospitals, clinics, and routine laboratory services; fixed costs associated with the tuberculosis programme itself such as the salaries of coordinators, purchase of vehicles, and purchase of equipment in the tuberculosis reference laboratory; and variable costs, which are a function of the number of patients diagnosed and treated, including drugs, reagents for sputum examination and culture, food for patients in hospital, and paper for keeping patients' records. The average unit cost is the total fixed and variable costs divided by the number of patients treated. The average incremental unit cost is defined as the variable costs plus the fixed costs attributable to the tuberculosis programme itself divided by the number of patients treated. Finally, the variable costs divided by the number of patients treated is reported as the marginal cost per patient treated.

Only costs incurred by the government or non-government organisations affiliated to the programmes have been counted. Diagnosis and treatment are free to the patient but most patients incur personal costs for transport and lost income, particularly when treatment protocols require 2 months of hospital stay during the intensive phase. These patient costs have not been included in the calculations.

The benefits of chemotherapy for smear-positive tuberculosis can logically be divided into two types: direct benefits to the patient treated, and indirect benefits to others through reduced transmission of tuberculosis. The epidemiology of tuberculosis is well known.[13-15] Tuberculosis is an unusual disease because, in the absence of human immunodeficiency virus (HIV) infection, the annual risk of infection is stable or declining at 1–2% per year in most developing countries.[1,3,14] Population growth in most parts of the developing world is equal to or greater than this rate of decline in annual risk of infection; thus, each clinical case of pulmonary smear-positive tuberculosis must cause one or slightly less than one case of pulmonary smear-positive tuberculosis.

The stable transmission pattern of tuberculosis has been incorporated into a conservative model of the transmission impact of an untreated case of smear-positive tuberculosis. The extensive epidemiological evidence for each variable in the transmission model comes largely from empirical studies, and will be published in a final report of this study. Transmission benefits have been counted for four cycles of transmission, which take over 18·5 years on average. Benefits in terms of deaths averted and years of life saved have been discounted[14,16] at 3%. During the four cycles of transmission, each untreated smear-positive tuberculosis case will lead to 5·2 deaths, or 3·8 discounted deaths. Of all the deaths attributable to a group of smear-positive cases of tuberculosis, 18% are due to direct mortality and 82% to mortality secondary to transmission of the disease to others.

The benefits of chemotherapy were calculated by construction of a life table for treated patients that was compared with a life table for untreated smear-positive subjects. The differences in the cure rates, death rates, and transmission rates between the untreated and treated populations are the benefits of the programme. Thus, we do not count the expected 25–33% spontaneous cure rate in smear-positive patients[17,18] as a benefit of treatment.

The interaction between HIV infection and tuberculosis infection, where the probability that clinical disease will develop in an individual infected with *M tuberculosis* increases from a normal of 5–10% to 35–50%, may change the stable nature of the risk of infection in some sub-Saharan African countries.[19-21] It is possible that if a large enough percentage of the population becomes HIV infected then the annual risk of infection may cease to decline and could even increase. The stable transmission dynamics of tuberculosis would then work against the community and produce a constantly increasing risk of infection. In such a case, the transmission model used here would underestimate the benefits of treating infectious pulmonary tuberculosis.

Results

Costs per case treated

The average, average incremental, and marginal costs per case diagnosed and treated with standard and short-course chemotherapy with and without hospital admission for 2 months during the intensive phase of therapy are given in table I. Not surprisingly, ambulatory chemotherapy is substantially cheaper than chemotherapy with hospital

TABLE III—AVERAGE INCREMENTAL UNIT COSTS (US$)

	Malawi	Mozambique	Tanzania
Short-course chemotherapy with hospital admission			
Per cure	165	232	202
Per direct death averted	200	267	236
Per total death averted	38	57	47
Per year of life saved	1·7	2·6	2·1
Standard chemotherapy with hospital admission			
Per cure	215	301	270
Per direct death averted	187	272	227
Per total death averted	54	76	68
Per year of life saved	2·4	3·4	3·1
Ambulatory short-course chemotherapy			
Per cure	107	81	101
Per direct death averted	130	94	117
Per total death averted	25	20	23
Per year of life saved	1·1	0·9	1·1
Ambulatory standard chemotherapy			
Per cure	111	82	107
Per direct death averted	96	74	90
Per total death averted	28	21	27
Per year of life saved	1·3	0·9	1·2

For Malawi, the estimates of standard chemotherapy with hospital admission, ambulatory standard chemotherapy, and ambulatory short-course chemotherapy are not based on actual programme results; instead, costs are based on estimates of the likely cost of ambulatory chemotherapy and the results of treatment are the average results achieved in Tanzania and Mozambique.

The results for ambulatory treatment are based on the overall results of the programmes for each country not on specific results for ambulatory chemotherapy, and as such they are only applicable to those urban areas where high compliance can be maintained with daily supervised chemotherapy in the intensive phase.

admission in the intensive phase. The differences in prices between the programmes in the three countries are largely attributable to two factors: first, there is nearly a fourfold difference between Malawi and Mozambique in the price per day of feeding an inpatient; and second, civil service salaries in Tanzania are considerably lower than salaries in Malawi and Mozambique.

Treatment results

Table II gives results of treatment in the three countries calculated from the latest data available at the time of writing. For Tanzania, results of standard chemotherapy are presented for 1980–82 when no short-course chemotherapy was in use. Data are available for all patients on short-course chemotherapy since 1982. In Mozambique, many patients still receive standard chemotherapy, so standard and short-course chemotherapy can be compared over similar periods. No standard chemotherapy data are available for Malawi because short-course chemotherapy was rapidly adopted after 1984.

Because some patients who "abscond" or "transfer out" will have received enough treatment to be cured, cost-effectiveness ratios have been calculated assuming that of those patients who abscond or transfer out 35% on standard chemotherapy and 65% on short-course chemotherapy are cured. In Mozambique and Tanzania short-course chemotherapy has increased the effective cure rate by about 25%. Well-organised standard chemotherapy programmes may be able to achieve effective cure rates of 60–65%, whereas the short-course chemotherapy programmes in Malawi, Mozambique, and Tanzania have cured 85–90% of patients. More importantly in terms of reducing transmission of the disease, the short-course programmes have reduced the number of sputum-positive patients at the end of treatment to around 8% compared with 30% with standard chemotherapy. The achievements of these programmes are particularly impressive when compared with average cure rates below 40–50% in many developing countries.[2]

In urban areas such as Dar es Salaam and Maputo, equally high cure rates have been achieved with ambulatory short-course chemotherapy supervised daily during the 2 month intensive phase (patients receive chemotherapy six times a week). The replacement of standard chemotherapy by short-course chemotherapy increased the effective-cure rate in Dar es Salaam by 25%. These results do not imply that ambulatory short-course chemotherapy programmes can achieve excellent results in all environments. Rather, in some urban environments with easy access to health facilities it is possible to achieve high cure rates with ambulatory therapy.

Cost-effectiveness

The estimates of costs for different treatment regimens and the direct and indirect benefits from various programmes have been combined to estimate cost per case cured, cost per direct death averted, cost per death averted including deaths averted due to decreased transmission over the next 18·5 years, and cost per year of life saved (table III). Results are adjusted for an estimated rate of false-positive diagnosis of 5%. In Tanzania, 5·3% of positive sputum examinations between 1982 and 1988 were classified as false positive. A more detailed study between July and December, 1989, used culture to confirm the results of positive sputum examinations, and found that 2·6% of smear-positive results were true false positives. Average incremental unit costs per case cured and per death averted are similar to figures reported previously for Tanzania,[2] but because transmission benefits are counted for 18·5 years, the costs per total death averted and year of life saved are substantially lower.

Discussion

In terms of costs per death averted and per year of life saved, chemotherapy for smear-positive tuberculosis is the cheapest health intervention available in developing countries.[22] The other highly cost-effective interventions, including immunisation for measles and neonatal tetanus, oral rehydration therapy for diarrhoea, and blood bank screening for HIV, all cost US $5–10 per year of life saved, whereas chemotherapy for smear-positive tuberculosis costs $1–4 per year of life saved.

Short-course chemotherapy is cheaper than standard 12-month chemotherapy per death averted and per year of life saved for both hospital and ambulatory care except in terms of the marginal cost of ambulatory chemotherapy. Short-course chemotherapy is also preferable to standard chemotherapy because the cure rate of the former is higher, thus more people can be helped for the same expenditure per death averted. There are further benefits to short-course chemotherapy: compared with the standard chemotherapy regimen, selection of resistant organisms is much reduced by the combination of four potent drugs in the intensive phase of short-course chemotherapy; furthermore, because the effective failure rate of standard chemotherapy is much higher than that of the short-course regimen many patients will require expensive retreatment, and the high cost of retreatment regimens may raise the implementation cost of standard chemotherapy by as much as $45 per case, effectively doubling the marginal cost per case treated.

Also the benefits are ~~can~~ divided into.

① Direct benefits → deaths averted due to treatment in the patient

② Indirect benefits → deaths averted due to stoppage of transmission by the person.

An empirical model is drawn to derive this; of all the deaths averted 18% are due to direct mortality & 82% due to indirect mortality..

Also the patients who default, ~~do~~ 35% are assumed to be cured in Standard & 65% in Short-course chemotherapy.

The author Thus shows a bias in underestimating the costs & overestimating the benefits

The author concludes by saying Short course ambulatory treatment is more cost effective than Immunization of ORS & neonatal tetanus.

The author then discusses related cure rate in hospitals, TB in HIV +ve & -ve pts etc. in light of cost - effectiveness.

Where feasible, ambulatory chemotherapy is much cheaper than hospital chemotherapy. However, the key question remains: when is the extra cost of hospital-based chemotherapy justified in order to increase the cure rate? In the programmes we describe, ambulatory chemotherapy can only be used in certain urban areas if cure rates are to be maintained. Unfortunately, there are no data on the marginal increase in the cure rate due to hospital admission in a rural area. Using the marginal increase in cost of admitting to hospital a patient in Malawi, Mozambique, and Tanzania, we calculate that if hospital admission increases the cure rate by 5% it will costs $777–2008 per case cured; if it increases the cure rate by 10% it will cost $389–1004; and if it increases the cure rate by 15% the marginal cost per case cured is not much different than the average incremental cost of curing a case with any form of chemotherapy—ie, $259–669. If a government can decide the price it is willing to pay to cure a tuberculosis patient or avert one death then we can determine the increase in the cure rate that hospital admission must provide to be relatively cost-effective.

It may be relatively cost-effective to treat patients who have X-ray evidence suggestive of pulmonary tuberculosis but are sputum-smear-negative for mycobacteria. Treating smear-negative patients who go on to become smear-positive cuts out the pre-diagnosis transmission that cannot be affected with chemotherapy for smear-positive patients. This pre-diagnosis transmission bonus accounts for nearly one fifth of total transmission. If 15% of smear-negative patients become smear-positive, we estimate that the cost per death averted of treating smear-negative patients is US $185, and this sum is reduced to $155 if 20% of patients become smear-positive. Although this is 3·5–8 times more expensive than treating smear-positive patients, compared with many other health interventions it is inexpensive per death averted or year of life saved.

There is a concern that treating smear-positive pulmonary tuberculosis patients who are also HIV-seropositive is not cost-effective. The cost-effectiveness of chemotherapy for HIV-seropositive patients with smear-positive tuberculosis depends on the survival of patients after treatment and the indirect benefits of treatment. It is unlikely that the direct benefits in terms of years of life saved will be substantial given the natural history of HIV infection in developing countries. In terms of direct benefits only, treating HIV-seropositive patients must be at least 10 times more expensive than treating seronegative patients. However, HIV-seropositive, smear-positive patients will also transmit the disease. Whether they live long enough, or have the same pattern of human contacts, to allow transmission of as much disease as an untreated HIV-seronegative, smear-positive patients remains unknown. If HIV-seropositive, smear-positive patients do transmit as much tuberculosis as HIV-seronegative patients then short-course chemotherapy should be cost-effective. As discussed above, over 18·5 years more than 80% of the benefits of chemotherapy are due to reduced transmission. Even if there are no direct benefits, treating HIV-seropositive patients would be only 25% more expensive per year of life saved than treating seronegative patients.

There are other cost and organisational reasons for treating HIV-seropositive patients. Screening all patients so as to exclude seropositive patients from treatment would be expensive. More importantly, patient confidence in the tuberculosis treatment programme would in all likelihood be severely eroded if some patients were excluded from treatment on the basis of a test result. The impact on the detection and cure rates for HIV-seronegative, smear-positive patients could be substantial. Although this discussion is speculative, the conclusion is clear: as long as HIV-seropositive, smear-positive patients transmit tuberculosis at nearly the same rate as HIV-seronegative, smear-positive patients, short-course chemotherapy is not much more expensive for HIV-sero-positive patients than for seronegative patients.

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This article examines the cost-effectiveness of treating Smear +ve cases of TB by four different approaches (i) Standard hospital chemotherapy
(ii) Standard ambulatory —11—
(iii) Short course Chemotherapy (hospital)
(iv) Short course ambulatory —11—
in three different countries.

The article begins with an introduction of the TB burden of disease in the world.

In methodology the author divides the costs into
① Fixed costs ass ē the use of facilities outside the TB Prog. i.e. hospitals, clinics & Routine labs
② Fixed costs ass ē TB Programme itself like equipment, TB officers salary, vehicle used for TB etc.
③ Variable costs which depends on no of patients treated like drugs, slides etc.

Then average cost are derived from the above like.

Average unit cost = $\frac{1+2+3}{\text{no of pts treated.}}$

Average incremented unit cost = $\frac{2+3}{\text{no of pts treated.}}$

marginal cost per pt. = $\frac{3}{\text{no of pts. treated.}}$

The author takes only health system costs but 'PATIENTS COSTS' is totally ignored.

Weakness — Problems co-

DIS-1. (RN)

Draft for Final Report.

PUBLIC HEALTH.

Dr. T Jacob John

COMMUNICABLE DISEASES

A. Situation analysis.

1.The degree of success of prevention and control of communicable diseases in a community or a country is a measure of the effectiveness and efficiency of the public health system in that setting. It is widely known that India's successes in the prevention and control of communicable diseases in general, and outbreaks of such diseases in particular, have been very limited. Therefore, it is clear that our public health system is currently inadequate to face the challenges of communicable diseases and it needs qualitative and quantitative strengthening.

2. The term communicable disease is used in this document synonymous with the term infectious disease (ID). In as mush as the causes of IDs are infection by extraneous agents, it should be relatively easy to interrupt the chains of their transmission, or to eliminate the media of their multiplication in humans or in our environment including water, food, animals or insects. Another practical intervention, in the case of certain specific IDs, is the use of vaccines in a tactical manner. Our continued heavy burdens of morbidity and mortality due to IDs is not because of a lack of public health expertise or intervention tools and modalities, but due to our apparent inability to apply them suitably in the field. The fundamental causes of this gap between knowledge and technology on the one side, and their effective and efficient use on the other, must be diagnosed and remedied, if we are to succeed in our system of public health.

3. It is pertinent to examine and learn from our past successes in this field. In mid-1970's India was able to eradicate smallpox. In late 1990's we eliminated Guinea worm infection (Dracunculiasis). By 2001 we hope to eliminate wild poliovirus infection as the essential step towards certification of elimination of polio. In each of these cases, 3 lessons stand out. One, the goal was set from outside, either from the WHO or from other international agencies. Two, the expertise for the interventions needed for success was also mainly from outside experts. Three, high quality surveillance for each specific illness had to be established for guiding the interventions and for assessing their successes. The Task Force recommends that Karnataka State sets its own goals for the prevention and control of communicable diseases, uses the considerable expertise already available in the State to the fullest extent, and

To SKK/RRP
KTFH papers on CDC for reading/comments/additions
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establishes a comprehensive disease surveillance system to guide interventions and to measure their progress and success. Section 'g' will address disease surveillance.

4. It is equally important for us to learn from our failures also. Tuberculosis control has been a major public health project for several decades. However, success has eluded us. In 1998, in Karnataka, a target of 782,172 was set as the number of sputum smears to be examined for diagnosing an estimated number of 70,284 new cases of open pulmonary tuberculosis (TB). The achievement was only 236,175 (30%) smears examined, but surprisingly 55,557 cases were detected. This amounted to 79% of the expected number of cases. It is very likely that three times as many more cases might have been diagnosed if the target for smear examination had been met.

5. The National Malaria Eradication Programme of the 1950's had met with phenomenal success. Unfortunately, the design had been flawed and malaria made a come back in late 1960's. By then the vector mosquitoes had developed resistance to insecticides. Whereas malaria had been confined to rural communities previously, the resurgent malaria is both urban and rural. Earlier, malaria parasites had been fully sensitive to antimalarial drugs, but now falciparum parasites are increasingly becoming resistant to chloroquine and other newer drugs as well. Resistance has appeared even among vivax parasites. As malariologists realized that malaria could not be eradicated, the programme was renamed as National Malaria Control Programme. In the 1990's even control was felt to be unattainable and the name has been changed to National Anti-malaria Programme. In 1997, in Karnataka, 7,304,866 fever cases were investigated with blood smear microscopy in various rural health care institutions and 161,775 cases of malaria were detected. In addition, in 8 urban populations 103,671 cases of fever were investigated and 12,548 more cases were detected. The number of falciparum cases was 40,295. In 1998 there were 107,910 rural and 7521 urban cases diagnosed with positive smear examination. Malaria is not under control, in spite of five decades of prioritized action against it.

6. Other mosquito-borne IDs in Karnataka include Japanese encephalitis (JE), dengue fever (DF) and dengue haemorrhagic fever and shock syndrome (DHF/DSS), West Nile (WN) virus encephalitis, and lymphatic filariasis. During 1999, JE outbreaks were confirmed with virological investigations in the districts of Bellary, Raichur and Kolar. JE has been known to occur periodically in the districts of Bangalore Urban and Rural, Chitradurga, Mandya and Koppal. In 1997 there was a large outbreak of DF, DHF and DSS in the districts of Bangalore

Urban and Rural, and Kolar. The virological investigations were conducted in the Field Station Laboratory of the National Institute of Virology, Pune, Maharashtra, under the Indian Council of Medical Research. The State public health system does not have a diagnostic facility for outbreak investigations. There is neither programme nor plan for the control of these diseases. The geographic spread, or magnitude, of WN virus infection, or encephalitis, remains unexplored. Kyasanur Forest disease is unique to Karnataka, and prevalent in Shimoga, Uttara Kannada, Dakshina Kannada and Chikmagalur. Infection is transmitted by the bite of ticks. Fortunately, a killed virus vaccine is made in Karnataka itself.

7. Karnataka has endemic cholera, with annual seasonal outbreaks around the monsoons. The government has established 'cholera combat teams' in the worst affected districts of Bijapur, Gulbarga, Chitradurga, Bellary amd Mysore. In 1998, 503 instances of death due to cholera or acute gastroenteritis were documented in the government health care network. Typhoid fever is rampant very widely. Viral hepatitis (due to faeco-orally transmitted viruses A and E) is also common in the State. Karnataka has a high prevalence of cerebral cysticercosis, including in vegetarians, and it is suspected that infection is transmitted faeco-orally. Thus, the environmental sanitation, personal hygiene, safety of water and food and the level of public perception of these issues leave much to be desired.

8. Sexually transmitted IDs and other reproductive tract IDs had received little attention from public health system, until HIV/AIDS emerged as a serious problem in India in general and in Karnataka in particular. It has been estimated by the National AIDS Control Organisation, that in Karnataka, over 1% of all adults (above 18 years) are already infected with HIV. As HIV disease is characterized by secondary IDs, diseases like Pneumocystis pneumonia, Cytomegalovirus retinitis, cerebral toxoplasmosis, cryptosporidial diarrhoea, cryptococcal meningitis and many others are increasingly frequently being diagnosed in teaching hospitals and in institutions with appropriate diagnostic facilities.

9. There are a number of other problems of IDs, but they do not get the attention of the public health system. Karnataka has all the ubiquitous IDs, such as the common bacterial (Pneumococcal, Staphylococcal, Streptococcal, Haemophilus) and viral (Respiratory Syncytial, Herpes, hepatitis B, C). The frequency of bacterial meningitis, leptospirosis, brucellosis, rickettsial fever, melioidosis, and human anthrax remain under-estimated. Acute rheumatic fever and chronic rheumatic heart disease continue to cause disability and premature death.

10. The extent, pattern and nature of hospital-acquired IDs remain largely unexplored. They must be investigated and preventive measures instituted in every hospital. Similarly, antimicrobial resistance is becoming common among several bacterial pathogens and public health action is needed to monitor and check this serious problem in hospitals and in the community.

11.Statistics on Rabies in Karnataka are unreliable. Everyone knows that the disease is uniformly fatal. Yet, in 1990, in the State1345 cases with only 40 deaths were reported. In 1993, only 34 deaths were reported among 1424 cases of rabies. In 1990, in the Bangalore Epidemic Diseases Hospital alone, 65 patients had died of rabies. Post-animal-bite rabies immunization is given in at least 4 major Government Hospitals in Bangalore. In the Jayanagar General Hospital, the annual number of persons so treated is about 3000. The major workload of the Vaccine Institute at Belgaum is to produce sheep brain Semple antirabies vaccine (ARV). During April-December of 1998, the Institute produced 1617 litres of ARV. The annual expenditure of the Institute is over 6.2 million (62 lakhs) Rupees. Rabies is eminently preventable, provided there is administrative coordination between several agencies. The financial loss due to the lack of rabies control, in terms of human and animal lives and in terms of expenses for the vaccine, are truly enormous.

12. Anthrax is another disease, which cuts across human and animal health. There is anecdotal information of it being a not-so-uncommon problem. This disease, as well as rabies, Brucellosis and Leptospirosis highlight the need and opportunity for cooperation and collaboration between the Governmental wings entrusted with human health, animal health and agriculture.

Remedial Measures

1.There are some root causes for this unsatisfactory state of affairs in Karnataka, and indeed in our country at large. With rising population and population density even in rural communities, and increasing urbanization and urban migration, and with industrialization and also intensive agriculture, there has been deterioration of the environment, but without **commensurate increase in public health expenditure for sanitation and hygiene**. **There is an urgent need to develop a broad based assessment mechanism to quantify the public health needs of the State and to prepare a need-based budget for public health**. (Note. This point needs a bit more professional touch)

deforestation .

2.The second half of the 20th century saw some spectacular successes in the combat against IDs, including diagnostics, antimicrobials, insecticides and vaccines. Consequently, public health was undervalued and health care was given greater importance. It was thought that IDs could be treated and prevention was unimportant. **Having realized this error, now we must give prominence to public health in teaching and in implementation. Public health expertise must be rebuilt.**

3.Even though health care and public health are two major components for enabling and ensuring the health of the people, these two are combined administratively into one Department of Health, separating it from the department of Family Welfare. The Department of Health gives prime importance to health care, but public health is not given its due importance. The Department of Family Welfare fulfills some public health functions but is not equipped to provide it in full measure. **The task Force recommends that the State Government explore the possibility of restructuring the Ministry to include two departments, one on Health Care and the other on Public Health.**

4.Public health has broader dimensions than what could be built into the Ministry of Health alone. For example, education is a critical element in maintaining the health of the people. A recent survey by the ICMR showed that immunization coverage of children correlated well with the educational level of the mother.

	Immunization status (coverage %)		
Literacy of the mother	**Fully**	**Partially**	**None**
Illiterate	46.4	33.4	20.2
Primary education	64.9	29.6	5.5
Middle school	70.4	25.9	3.7
Higher secondary	78.8	19.6	1.6
Graduate	84.3	15.2	0.5

It is obvious from the above data that education is in itself a major component of true public health, although traditionally not so perceived. **The Task Force recommends that the State Government take prompt action to ensure that the female (and male) literacy rate is increased to as high a level possible in as short a period as possible**. This one intervention

will have multiple benefits, not only in reduction in morbidity and mortality, but also in improving the socio-economic standards of the people, which will further enhance the health status of the people.

5. The supply of safe water and maintaining a pollution-free environment are not the functions of the Ministry of Health, even if it included a Department of Public Health. **It is for the Government to ensure that these functions are fulfilled through the concerned departments or wings of the Government**. On the other hand, **the Public Health Department has the moral and technical responsibility to prescribe norms of safety of water, food and the environment, and also to monitor the maintenance of these norms. The public health role of the Ministry of Health, as far as vector control is concerned, is again to prescribe norms of allowed vector densities, both of larvae in environmental waters and of adults in human habitats, and to monitor the actual densities in all communities, regularly, and to alert the local administration, if any limits are exceeded. The actual control measures are to be undertaken by the local administration**. The Public Health system shall provide the necessary technical expertise and guidance for control measures.

6. This clear definition of the functions of the various wings of the Government, in the practice of public health, is essential if Karnataka is to succeed in areas where the nation as a whole had failed for such a long time. **Another area in which the monitoring function of the Public Health system is essential is in the use of insecticides by the local administration and by the Agriculture Department.** At the present time, insecticide spray or even fogging is undertaken without adequate rationale and without safety checks and controls. Indeed Karnataka has the opportunity to provide a model for the rest of the country, in establishing a viable and vibrant public health system.

7. A close look at the real life situation makes it clear that almost all of the ingredients of public health mentioned above have been created through the vision of our administrative and political leadership of the yesteryears. What is wrong with the system, is that these functions are seen by the functionaries as independent activities, essentially as following the orders or the established procedures, without coordination or evaluation. With this assessment, it is clear to the Task Force that resources, human, material and financial, are being utilized but without achieving the desired results. Efficiency, defined as the desired outcome for the efforts (and expense) put in, is what is missing. **The Task Force recommends that a complete**

inventory is taken, of the various inputs of the Government, through health programmes both vertical and otherwise, funded by the Government itself or by extramural agencies (be it the Union Government or foreign and international agencies) and they be channeled through a unified system of commands and operation, dividing them into Health Care and Public Health. In all likelihood, the enhanced funding recommended in the first paragraph may indeed be minimal and what the State Government itself could afford.

8.As far as public health is concerned, in the context of IDs, the two foundation sciences are epidemiology and microbiology. **The State must develop a time-bound plan to establish these two disciplines within the Department of Health**. Modern epidemiology is a powerful tool to investigate the transmission pathways of IDs, in order to design and implement interventions to interrupt transmission. Modern microbiology is essential to make accurate aetiologic diagnosis, for assisting epidemiology and interventions. **The State must plan to establish a training facility for epidemiology.** Persons already in service, and new recruits interested in a career in epidemiology, should have access to such training facility. More advanced training may be obtained where such facility exists now, but it may be feasible for such advanced training facility also to be created in the State. **By 2005, there should be one trained epidemiologist in each district and a cadre of senior epidemiologists at the State level.**

9. **Similarly, by 2005, there should be a diagnostic microbiology laboratory at the district level, and the State Public Health Institute should be strengthened to function as the State level supervisory and reference laboratory to support the district laboratories**. The district laboratory should function as diagnostic laboratory for health care at the district hospital, and also as the public health laboratory for the district. The Microbiology laboratory must be headed by a specialist, ideally an MD in Microbiology. The district diagnostic laboratory will require additional expertise, such as those in clinical biochemistry and clinical and tissue pathology, each headed by trained and competent personnel, holding MD degree or equivalent.

10. It is clear from the above, that public health may be broadly divided into those activities (which are essentially outside the executing responsibility of the Health Ministry) which will keep the environment safe from the potential of transmission of pathogens, and those directly under the purview of the Health Department. The latter activities are essentially those designed to be specific for various pathogens, and are closely linked to the epidemiology

of IDs. They include such vertical programmes like TB control, anti-malaria, leprosy control, filariasis control etc. **It is strongly recommended that these vertical programmes be integrated under a common management at the State level leadership and similarly integrated at the District level and even below**.

11. It is pertinent to highlight the need for integration, for efficiency and effectiveness, in the control of vector-borne IDs. **The public health approach for the control of malaria, filariasis, dengue, Japanese encephalitis and West Nile virus infection, should be integrated at the common grounds of the control of vector breeding, prevention of human-mosquito contact, reduction of animal-mosquito contact, and maintenance of below threshold levels of adult mosquitoes in habitats**. When any of these diseases breakout as outbreak, then there should be a rapid epidemiological and entomological assessment of the vector densities by location, and the identities of vectors and their susceptibilities to various insecticides and only after these are fulfilled should there be the fogging or spraying of insecticides.

12. In our conversations with a number of involved persons, we have come to the conclusion that different levels of personnel, teachers of Medicine, those in the NGO sector, TB control personnel and other sections of the health care team do not have a uniform picture of the procedures and processes needed for TB control. There is no uniformity in diagnostic methodology or criteria. It is very clear to us, that the current processes of TB control need a clearer vision and better management, both technical and administrative. **The Task Force recommends that the relevant issues be thrashed out in a workshop, in order to stipulate the commonly agreed procedures of diagnosis, reporting, treatment and teaching. Attention should be paid to extra-pulmonary TB, childhood TB, and appropriate epidemiological investigations of every diagnosed case of TB, in adult or child. The tuberculin test must be assessed as a tool in this process, and if found useful, its methodology must be clearly defined.**

13. The State has not invested adequately in, or reaped the benefits thereof, of the strategic use of vaccines and immunization. Childhood immunization will be dealt with, in detail, under the section on Child Health. **It is recommended that the State establishes a Committee for advising the Government on immunization policies and practices.** In the opinion of the Task Force, it would appear humane and cost-effective to abandon the use of sheep brain rabies vaccine in favour of safe and purified modern rabies vaccines as well as to

introduce universal immunization against hepatitis B virus infection in order to reduce the virus carrier pool and to prevent cirrhosis and cancer of the liver in adults.

14. The school setting offers an opportunity for introducing several elements of public health. In the context of IDs, it is an opportunity for pilot testing the feasibility and usefulness of periodic one-dose de-worming in vulnerable groups of children. It is also an opportunity to catch up on adolescent immunistions such as those against tetanus and typhoid fever. **The Task Force recommends that the school health programme be made efficient, goal-oriented and systematic**. Needless to add that the opportunity must be seized for health education, to be included in school curriculum, and to provide sanitary toilet facilities and safe drinking water.

15. Modern hospital setting is a breeding ground of nosocomial pathogens. **The Task Force recommends that a mechanism be evolved for monitoring hospital acquired infections and to stipulate remedial measures.**

16. Antimicrobial resistance is a major problem, be it in typhoid fever, TB, malaria or nosocomial infections. **It is recommended that a mechanism, similar to the one on nososcomial infections, be established to constantly collect, collate and review available data on antimicrobial resistance and to issue guidelines for the proper and rational use of antimicrobials.**

DIS-5

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Archbishop Desmond Tutu,
30th World Conference on Lung Health Madrid, Spain, September 1999

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Please send or fax this declaration to : The Karnataka Tuberculosis Association
 # 3, Union Street, Infantry Road Cross, Bangalore 560001 KARNATAKA, INDIA

This campaign is organised by the International Union Against Tuberculoisis and Lung Disease
For more information, visit the website: ***www.iuatld.org***

DR. JACOB JOHN
SWAMI JAPANANDA
D15.5.

TUBERCULOSIS.

The TB control Programmes Success failures and progress.

Tuberculosis control has been a major public health project for several decades. Soon after independence, India launched the national BCG inoculation programme, in the hope that BCG would protect from infection as well as from latent infection progressing to bacillary pulmonary TB, which is the source of infection to fresh naive individuals, most often children and Youth. Soon thereafter, a study was established under the ICMR, to investigate the protective effect of BCG. This study, conducted in chingleput, Tamil Nadu, showed that the assumption that BCG would offer protection from infection or from disease progression was incorrect. BCG has no role in the public health intervention against TB.

- Inadequate budgets.
- Lack of coverage in some parts of the country
- Storage of essential drugs.
- Varying standards of care in various centers.
- Poor administration or Lack of direct observation of the treatment.
- Unmotivated and unevenly trained staff.
- Poor quality sputum microscopy.
- Focus on case detection without accompanying emphasis on treatment outcomes.
- Lack of political commitment / Lack of Accountability & monitoring.

Consequently, the Government of India designed a revised TB Control strategy, in 1993. This Strategy was pilot tested in a population of 2.35 million and was extended to cover 13.85 million, in 13 states. In these areas the diagnostic practice improved and cure rates more than doubled. Based on this experience, the Revised National TB Control Programme (RNTCP) was formally launched in India on March 26, 1997, with the plan to increase the area under coverage in a phased manner. This was supported by a soft loan (USD 142.4 million) from the World Bank, with a target to cover 102 districts with 271.2 million. The goal of RNTCP is to detect at least 70% of sputum positive pulmonary TB cased and to cure at least 85% of them. Treatment is by the directly observed therapy, short course (DOTS)

The situation in Karnataka

In Karnataka, RNTCP was established in 2 districts in 1997 and extended to seven in 1999. (This is to be verified) In the rest of the Districts the NTP is under operation. In 1998, in Karnataka, a target of 782.172 was set as the number of sputum smears to be examined for diagnosing an estimated number of 70.284 new cases of open pulmonary TB. The achievement was only 236.175 (30%) smears examined, but surprisingly 55,557 cases were detected. This amounted to 79% of the expected number of cases. It is very likely that three times as many cases

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might have been detected if the target for sputum smear examination had been met.

The south East Asia Office of the WHO has published a monograph on TB in India, in 2000 (Research for Action. Understanding and Controlling Tuberculosis in India, World Health organisation, Regional Office for South East Asia Region, New Delhi, 2000). The situation in India in general and in Karnataka in particular is not very satisfactory. The health-seeking behavior of 'chest symptomatic' is very interesting and illustrative. The vast majority of patients with chronic cough seek care quite promptly, as shown in the table below
Table.

The proportion of chest symptomatic seeking care in public or private facilities.

	Mysore		Raichur	
	Rural %	**Urban %**	**Rural %**	**Urban %**
Private provider	48	76	93	74
Government facility	51	22	5	25
Other	1	2	2	1
Total taking action	83	85	90	85
Not Yet taking action	17	15	10	15

Unqualified rural practitioners are first points of contact for most rural patients. Many patients, rural pr urban, spend a great deal of time and money "shopping for health" before they begin treatment. Very often, do not receive either accurate diagnosis or effective treatment, despite spending considerable resources.

The burden of TB and problems of its control in India.

The WHO has estimated that the annual gross economic loss for India, on account of TB is about 13,000 crores of rupees. In addition, TB patients spend, from their own resources, 645 crores of rupees, annually. Some 300,000 children lose both parents due to TB, and become orphans, annually. The Situation is rapidly deteriorating, on account of the increasing prevalence of HIV infection and AIDS. To cite one representative study from a public hospital in Mumbai, the frequency of HIV infection in-patients with TB rose from 2% in 1988 to 16% in 1998. TB has been found to be most common major secondary disease in symptomatic HIV disease (otherwise, AIDS). The widespread use of anti TB drugs in an inefficient manner, the continued transmission of infection from partially treated patients and the combination of HIV and TB are all factors that might contribute to the emergence of drug resistance in TB, making the future control of TB even more problematic.

India has an estimated 1,799,000 cases of TB, an incidence of 187 new cases per 100,000 population per and 805,000 new total annual case burden. Yet, in 1997, only 7,708 cases were under DOTS. We get an idea of the magnitude of our failure when we compare this last figure with 147,905 under DOTS in China, 19,492 in Indonesia, 25,871 in Bangladesh and 15,753 in Ethiyopia.1500 TB patients died every day due to lack of treatment, lack of political commitment

The fault lies with the medical establishment, the lack of health education and the overall leadership of TB control neither disciplined nor efficient. The following paragraphs are quotations from the WHO SEARO publication, 2000.

"All too often, health providers fail to diagnose the disease correctly, they're by delaying the start of treatment and perpetuating in the community. Many providers do not confirm their diagnosis of pulmonary TB by sputum examination realising instead on just radiograph and thus often incorrectly diagnosing patients to have TB. In one study in Bombay only 39% of doctors used sputum examination to confirm the diagnosis in TB studies in Karnataka, Delhi and Tamil Nadu relieved that, even after the multiple visits less than one third of patients had undergone even a single sputum examination, despite spending 1-6 months of their income. In rural areas lack of effective diagnosis and treatment was even more pronounced"

"Even when TB is diagnose by private practitioners, prescribing practices vary widely. A study of 100 private doctors in Bombay found that there were 80 different regiments most of, which were either appropriate, expensive, or both in a similar survey in Pune 113 doctors prescribed 90 deferent regiments (Uplekar and Shepard. Tubercle 1991; 72: 284) private doctors seldom felt that it was their duty to educate the patient about TB and never made attempts contact or trace patient who had interrupt treatment (Khari. Indian J Tube 1999 ; 46:157) Virtually no individual patients records are maintained by private practitioners."

" In one recent study, researchers interviewed several hundred patients and their families and found that most patients felt uncomfortable talking about TB, several patients denied that they were suffering from the disease are taking treatment for it, and some even refused to mention TB by the name. Patient frequently attempted to hide their disease from their family and community by registering under false names at TB clinics are by denying their identity when confirmed to their interviewers."

"Estimates in India indicate that of every 100 infected TB cases in the community, about 30 are identified in public sector, of which at most 10 are cured. Similarly about 30 are identified in the private sector, of which at most 10 are cured. Hence not more than 20%of patients who developed TB in Karnataka in each year are cured many of the remaining patients remain chronically ill are die slowly from the disease, infecting others with strains (of TB Bacilli) which may have developed drug resistance."

What needs to be done in Karnataka to control TB ?
(To be written)

1. Shift the responsibility to cure from the patient to the health system.
2. Tuberculosis diagnosis based mainly on three sputum examinations by microscope.
3. Assurance to the patient regarding regular supply of good quality Anti TB drugs.
4. Trained volunteer administers TB medicines to TB patient under direct observation.
5. A systematic monitoring and accountabilities.
6. The above strategy has to be followed in a phased manner to achieve good success rate in Karnataka.

D15-5.

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

1.0 INTRODUCTION

Tuberculosis is known to man from ancient times and continues to be a major public health problem. The disease affects primarily people in their most productive years of life and is commonly associated with poverty, overcrowding and malnutrition. Lack of education, environmental pollution and poor sanitation compound the problem. The condition of relative deprivation among economically weaker sections of the society and the high tuberculosis case rates in them seem to form a vicious cycle, one aggravating the other.

2.0 PROBLEM

2.1 World

The magnitude of the Tuberculosis problem is simply staggering. The annual occurrence of new cases of all forms of Tuberculosis is about 8 million, the greatest burden of incidence and mortality is concentrated in adults age 15-59 yrs. Estimates suggest that 3 million people die from Tuberculosis each year, which is probably more than from any other disease. Considering all this the WHO, for the first time, declared Tuberculosis as a Global Emergency in 1993.

2.2 India

It is estimated that there are about 12-14 million TB patients in the country of which about 3 million cases are highly infectious and sputum positive. Every year nearly 2-2.5 million new TB cases occur in the country and it is estimated that about 5 lakhs die due to the disease. The problem is equally prevalent in rural and urban areas.

Annually about 1.5 million cases have been reported under the programme. It is estimated that an equal number are treated by NGOs & Private Practitioners.

The experts opine that the epidemiological situation will deteriorate with the spread of HIV as it has happened in other countries. Around 60% of the AIDS cases reported in India have evidence of active Tuberculosis. TB - HIV coinfection increases the risk of turning latent TB infection (by 7-10 times) into TB cases with high fatality.

3.0 PROGRAMME

The National T.B. Control Programme has been in operation since 1962 and aims at reducing morbidity, mortality and transmission of the disease.

3.1 Objectives

i) To detect as large a number of TB patients as possible and treat them effectively;

Public Policy Division

Voluntary Health Association of India
40, Institutional Area, South of IIT
New Delhi - 110 016

ii) To establish District TB Centres in every district of the country;

iii) To extend Short Courses Chemotherapy in all districts;

iv) To strengthen the existing State TB Training and Demonstration Centers;

v) To augment health education activities under the programme.

3.2 **Strategy**

The District TB Centre functions as a nodal centre and is responsible for implementation of district T.B. programme in the entire district. Its key personnel are trained at NTI, Bangalore in X-Ray and laboratory diagnosis, treatment organization and community control of Tuberculosis.

Diagnosis of patients is through sputum testing and chest x-ray. The sputum positive cases are given short course chemotherapy for a duration of 6-9 months and sputum negative cases are treated with conventional anti-TB drugs for 12-18 months.

4.0 **CURRENT STATUS**

4.1 At present, district T.B. programme is being implemented in 391 districts and short course chemotherapy has been made available in 253 districts. Most of DTCs have been fully equipped with X-ray units, and laboratory equipments. At all such centres a team of medical and para-medical personnel duly trained at NTI, Banglore is available.

4.2 In addition there are about another 330 TB Clinics which provide TB Control services for big towns and cities.

4.3 A total of about 47,600 beds are available for hospitalisation of emergency and operative cases.

4.4 There are 17 State TB Demonstration and Training Centres providing training and guidance for supervision, coordination and technical assessment of the programme in the respective States.

5.0 **ACHIEVEMENTS**

5.1 With the inclusion of Tuberculosis Programme in the 20 point Programme, a thurst has been given for the expansion of the essential activities under the programme. **Short Course Chemotherapy (SCC)** drug regimens containing highly potent drugs have been introduced in the programme since 1983 and so far 253 districts are providing it. It is proposed to introduce these regimens in all the districts of the country in a phased manner.

5.2 As the programme is integrated with general health services, attempts are also being made for distributing anti-TB drugs through sub-centres so that the treatment facilities are available closer to the patient.

5.3 The Mortality Rate has decreased from 80 / 100,000 population in 1970 to 53 / 100,000 population in 1993. Further the severer forms of childhood tuberculosis is on the decline and extensive exudative lesions are less frequently seen.

6.0 BUDGET

The programme is run on 50:50 sharing basis between the Centre and States for drugs and logistics while the Union Territories and the NGOs are provided 100% assistance for the same. The budgetary allocation to the NTCP in preceeding 3 years is as follows:

(Figure in lakhs)

Year	Budgetary Provision
1992-93	2900.00
1993-94	3750.00
1994-95	4600.00
1995-96	5000.00

7.0 ISSUES

7.1 Over the years the programme has been continuosly monitored and reviewed. It is observed that the cure of patients, which is the prime aim of management, has not received enough priority under the NTP. The Budgetary Allocation under the programme has been inadequate to meet the cost of all the cases detected.

7.2 The case-finding and the treatment completion rates are both less than 40%. Though the incidence and prevalence rates have remained the same over the last 3 decades but the total number of cases have increased due to increasing population.

7.3 Impending threat of HIV-TB co-infection and the emergence of drug resistant tuberculosis which may further worsen the TB situation.

8.0 REVIEW

To address the above issues a nation-wide review was conducted in 1992 by Government of India with assistance from WHO & SIDA. Their salient findings were:-

i) less than 30% treatment completion.
ii) inadequate budgetary outlay and shortage of drugs.
iii) undue emphasis on x-ray diagnosis.
iv) poor quality of sputum microscopy.
v) emphasis on case detection rather than cure.
vi) poor organisational set up and support for TB.
vii) multiplicity of treatment regimens.

Based on the findings and recommendations of the review a Revised Strategy for Tuberculosis Control has been evolved.

9.0 REVISED STRATEGY OF NTP

9.1 The **objectives** of the Revised Strategy of NTP are:

i) emphasis on the cure of infectious and seriously ill patients of tuberculosis, through administration of supervised Short Course Chemotherapy, to achieve a cure rate of atleast 85%.

ii) augmentation of the case finding activities to detect 70% of estimated cases.

9.2 **Current Strategy**

i) Increase budgetary outlay.

ii) use of sputum testing as the primary method of diagnosis among self reporting patients.

iii) standardise treatment regimens.

iv) augmentation of the peripheral level supervision through the creation of a sub-district supervisory unit.

v) ensuring a regular, uninterrupted supply of drugs upto the most peripheral level.

vi) augmentation of organizational support at central and state levels for meaningful coordination.

vii) emphasise training, IEC, Operational Research and NGO involvement in the programme.

10.0 **PROGRESS OF REVISED STRATEGY IN INDIA**

10.1 **Pilot Phase - I**

With SIDA assistance the Revised Strategy was tested as Pilot Phase in 1993 in 5 project areas as follows:-

State/City	Project Area	Population
Delhi	Gulabi Bagh	1.00 Million
Bombay	H / West ward	0.35 Million
Calcutta	Tangra Topsia	0.30 Million
Bangalore	Shanti Nagar	0.25 Million
Gujarat	Mehsana Distt. (Patan & Chanasma Taluk)	0.45 Million
TOTAL		2.35 Million

These areas showed over 90% sputum conversion at 2 - 3 months and over 80% Cure Rate in initial cohorts.

1.3 Pilot Phase - II

Encouraged by the results of the Pilot Phase - I the Govt. of India decided to extend the Revised Strategy to 15 project sites covering a total population of 14 million as follows:-

State	* District	Population to be covered
Gujarat	Mehsana	1.50 million
West Bengal	Murshidabad	0.20 million
	Hoogly	0.80 million
Himachal Pradesh	Hamirpur	0.40 million
Bihar	Vaishali	0.30 million
Kerala	Pathanamthitta	1.10 million
TOTAL		4.30 million

* District	Taluks covered
Mehsana	Patan, Chanasma, Harij, Sami, Sidhopur, Mehsana
Murshidabad	Sagardigi block
Hoogly	Chandannagar sub-division
Hamirpur	Entire district
Vaishali	Lalgunj, Sadar block
Pathanamthitta	Entire district

Cities	Area	Population to be covered
Delhi	Gulabi Bagh	1.00 million
	L.R.S. TB Institute	0.70 million
Bombay	Munshi Chest Clinic area	1.50 million
Calcutta	Tangra	1.00 million
Bangalore (Urban)	Shanti Nagar Range	0.25 million
Hyderabad	Ward 6,7,8, (Hyd.) & Ward 12 (Sec.)	1.00 million
Madras	Ward 32 to 49 of Zone - III	0.40 million
Pune	Entire City	1.60 million
Lucknow	Lal Bagh Area	0.50 million
Bhopal	Itawara Area	0.20 million
Jaipur	Entire City	1.40 million
TOTAL		9.55 million
Total Population covered in States and Cities		**13.85 million**

World Bank assistance of US $ 1.996 million has been made available as Project Preparation Facility advance.

10.2 **Phase - III**

It is envisaged to extend the Revised NTCP in phases throughout the country with World Bank support involving initially a population of 187 million in 5 States and 10 Metropolitan cities as given below:-

Cities

Calcutta	-	4.50	million
Bombay	-	10.00	million
Madras	-	4.00	million
Bangalore	-	3.00	million
Hyderabad	-	4.00	million
Delhi	-	9.00	million
Pune	-	1.60	million
Jaipur	-	1.40	million
Bhopal	-	1.30	million
Lucknow	-	1.70	million
TOTAL		40.50	million

States

Initially 60 districts will be covered in 5 States. The state wise distribution of the districts and their population is as under:

Sl.No.	Name of the State	Total No. of Districts	Total no. of Districts and their population to be covered during 1st phase.	
1.	West Bengal	17	11	51.56 million
2.	Himachal Pradesh	12	10	5.07 million
3.	Bihar	50	12	28.95 million
4.	Kerala	14	10	22.20 million
5.	Gujarat	19	17	38.85 million
Total		112	60	146.63 million

The total population being covered is 187.13 million.

Besides World Bank funded projects ODA has agreed to bear the cost of implementation of Revised Strategy initially in three districts (of Delhi and Andhra Pradesh) and subsequently to extend it to the entire State of Andhra Pradesh. DANIDA is also willing to assist in implementing the strategy in Orissa and the project is being prepared for this.

11.0 EXPECTED OUTCOMES

With the successfull implementation of the Revised Strategy it is expected to achieve the following in the project areas:

(i) a cure rate of atleast 85%.

(ii) case-detection of atleast 70% of the expected.

(iii) rate of reduction in the annual risk of infection from the current 2 - 2.5% to 8 - 10%.

(iv) reduction in mortality to about 20/100,000 population.

(v) reduction in relapse rate to less than 5% from current rate of 15%.

(vi) reduction in drug resistant/failure cases to less than 5% from current figure of 20%.

12.0 FUTURE PLANS

With the implementation of Revised Strategy with the World Bank and ODA assistance it is expected to cover about 20-25% of the population. However, there is a need to extend this strategy at a faster pace to cover the entire country. This is essential to contain the transmission of the disease to an extent which will have significant epidemiological impact, prevent emergence of drug resistance and minimise the onslaught of TB-HIV co-infection.

Tuberculosis in its early stages is easily curable at a relatively low cost. If the disease is allowed to progress it reaches a stage where it becomes potentially incurable and very expensive to treat. As per WHO, this is usually the outcome in places where National Tuberculosis Programmes are not given priority. Hence it is imperative to strengthen the implementation of the TB Programme throughout the country.

In this regard the Govt. of India is preparing a Concept Paper for extension of the Revised Strategy in a phased manner throughout the country with the goal of elimination of tuberculosis.

DIS-5

SERIOUS IMPLICATIONS OF THE WORLD BANK'S REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME FOR INDIA

(A POSITION PAPER FOR DISCUSSIONS AMONG CONCERNED SCHOLARS OF THE COUNTRY. THE AUTHOR WELCOMES COMMENTS AND CRITICISM)

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CHAPTER 1

AN OVERVIEW

The proposal of the World Bank for what they call "Revised National Tuberculosis Control Programme" (RNTCP) for India is going to have very damaging consequences for development of the health services of the country, as it suffers from serious infirmities. The Voluntary Health Association of India and the Nucleus for Health Policies and Programmes have got together to produce this document, which contains a scientific analysis of the RNTPC to draw attention to its infirmities and to formulate an alternative proposal for strengthening the National Tuberculosis Programme (NTP) of India. While the RNTCP will be analysed in detail at a later stage, it will be worthwhile here to note that the infirmities belong to three categories. The most important among them is that the RNTCP has been developed without paying adequate attention to the process of formulation of the NTP and the factors which have come in the way of its implementation over the more than three decades since it was adopted by the Government of India. Secondly, in considering the conceptualisation of the RNTCP as an outcome of an interdisciplinary study, adopting a systems approach, there are very serious flaws in project formulation in terms of system optimisation, epidemiological and sociological analyses, managerial and technological perspectives, coverage, epidemiological impact, repayment of the World Bank loan, replicability of the RNTCP, and other such considerations. Thirdly, the World Bank promoted RNTCP is a part of the sequence of what are termed as "International Initiatives" thrust on the country from outside at the instance of international agencies, backed up by strong support from many powerful western countries, which make substantial contributions to the budgets of the former. Ironically, as will be demonstrated later on, it is these international initiatives which have been proved to be the major hurdles in the way of implementation of the NTP all these years. The RNTCP thus appears as a not well thought out operation performed by persons from the very same group who, in the first place, have been responsible for the damage done to the NTP.

Even from this very broad mention of the RNTCP it is possible to discern an underlying deep streak of dogmatism among the exponents of the RNTCP, which has impelled them to 'forget' the enormous and very substantial public health research in tuberculosis conducted within the country and put enormous

pressure on the national authorities to submit to 'models' developed by them outside the country. Apart from very serious conceptual flaws, these western models are technocentric, imposed on the people from above and make the country dependent on assistance from outside. 'Forgetting' ideas developed indigenously has thus become almost a prerequisite for taking international initiative in health fields; the fields gets closed to scientific discussions and only those 'natives' who do not do question them, or are incapable of doing so, are allowed entry into the privileged group by the international syndicate. Soon after the poor countries of the world had dared to make a declaration of self-reliance in health in the Alma-Ata Declaration of 1978 (WHO 1978), the affluent countries 'invented' what they called "Selective Primary Health Care" (Walshe and Warren 1979), which was almost immediately followed by the unleashing of a series of international initiatives in health. This provides a frightening example of the extent to which the more affluent countries of the world are prepared to go in imposing their will on the countries that are economically and politically dependent on them. Significantly, there has been little protest from the concerned community of public health scholars even in the affluent countries to such brazen forms of manipulation of science to impose programmes on 'defenceless' countries, from outside. The World Bank backed RNTCP is a particularly unfortunate example of imposition of such international initiatives.

The drive towards globalisation of the economy and polity has made the poor countries even more vulnerable to manipulation by the rich countries. In the so-called global village, the poor countries are condemned to serve as bonded hirelings of the rich kulaks and cowboys. A 'dialectical' outcome of this form of international relations is for the oppressed peoples to make conscious efforts to prevent the dominant powers to 'forget' their historical heritage. To adapt a quotation from Milan Kundera, it becomes a struggle between memory and forgetfulness. Just as ahistoricity becomes an important weapon in the hands of those who would fight to continue to monopolise the control over the bulk of the resources of the world, breaking into their consciousness to 'remind' them about the history they try to forget becomes a weapon in the hands of the oppressed to fight oppression.

At a time when a concerted effort is being made by World Bank officials to promote RNTCP in this country, this document may be considered as a modest effort to 'remind' them as well as the concerned authorities in the country about the very significant work that has been done in India to deal with tuberculosis as a

public health problem. No apologies will be offered here for consciously taking the side of the people by bringing out well researched data which had formed the basis of the NTP some three and a half decades ago. A very deliberate effort is made here to describe the work rather extensively. The 'battle lines' are clear: on one side are the indigenous research efforts made to formulate a nationally applicable, socially acceptable and epidemiologically effective tuberculosis programme, and on the other side is a 'foreign inspired', prepackaged programme that is sought to be thrust on the country by powerful countries and international organisations.

CHAPTER 7

CONCLUSIONS AND AN ALTERNATIVE FRAMEWORK FOR ACTION

The above account shows how a well researched and reasonably simple and straight forward programme can get hopelessly confounded due to interplay of a variety of social, political and economic forces. NTP essentially involved offering diagnosis and treatment to the very substantial portion of tuberculosis patients who were actively seeking treatment in various health institutions, both in rural and urban areas. These institutions were offered a referral support system which extended right up to the super-specialists in post-graduate teaching hospitals. State Tuberculosis Centres and NTI and other tuberculosis research and teaching institutes were meant to provide support to the programme in the form of training, monitoring, evaluation and operational research.

But as pointed out by Halfdan Mahler, 'even the simplest technology, if it is not properly deployed and utilised by the infrastructure, just will not move, will not control tuberculosis, will not meet people's felt-needs.' This is what has befallen on NTP. The infrastructure has been grievously damaged because of sharp decline in the quality of public health practice and research, filling up of key public health posts by the persons who do not have technical competence, by imposition of target oriented specialised programmes on an already weak infrastructure and a correspondingly sharp fall in the quality of administrators and research personnel in the field of tuberculosis.

From the basic premises presented above, some important suggestions are being made below:

1. While tuberculosis workers cannot take on themselves the onerous task of rejuvenating the moribund health and family planning services systems, the crisis has become so profound that there are good chances that the political leaders will have to wake up to it. A detailed programme for rejuvenation of the health services is given in the author's B.C.Dasgupta Oration of the Indian Public Health Association in 1988 (Banerji 1988b; 1984b). Some important components are:

a. Building up a critical mass of public health workers in the fields of education, training, research and practice.

b. Restructuring the cadre structure to place competent public health specialists in key public health positions.

c. Concurrent removal of the square pegs in the round holes of the system.

d. Making "conditional" integration of the special target oriented family planning and other programmes "unconditional". This will lead to according much higher priority to NTP as the problem is responsible for a substantial part of the total suffering caused by health problems as a whole.

2. Tuberculosis workers can help in the process of rejuvenation of the health and family planning service systems by insisting that this process is critical for providing good tuberculosis services to be suffering masses of the country.

3. On its own, even considering the constraints of the general health services as given, there is still considerable scope for improving the NTP system through use of operational research and systems analysis. The Surajkund Conclave recommendations can serve as a starting point.

4. The very improvement in the NTP system might stimulate improvement in the wider health and family planning services systems, by providing an example.

5. NTI can be rejuvenated by bringing together a competent interdisciplinary team of workers, so that it can play a role in strengthening the NTP. It can even extend its activities to serve as one of the many institutions which would be necessary to strengthen the general health services.

6. Concurrently, competent tuberculosis workers are placed as heads of tuberculosis wings of the central and state health services.

7. Other tuberculosis institutions, such as TRC, should be tuned to serve the NTP, i.e., the problems they deal with must emerge from the field situation, and not the other way round, as is often the case at present.

8. The idea of Task Force (Editorial 1990), or a similar set up (Fox 1990), which is vested with power and resources to act as a watchdog for the implementation of NTP, very well blends with the other suggestions for improving NTP given here.

9. Again, there is considerable scope for optimising the urban components of the NTP.

10. Tuberculosis Association of India and its branches can be revamped to perform a complementary role in strengthening of NTP - e.g., conducting independent evaluation, offering technical assistance, providing logistical support, providing training, and so forth.

In sum, the suggestion is that we take steps to unleash the social forces which ensure that simple and efficacious technology developed in India is made accessible to the hundreds of thousands of sputum positive cases, who are actively seeking relief for suffering but who are still being thrown out of the health institutions with a bottle of useless cough mixture. Sociologically, it is contended that the very meeting of the felt need generates more needs, and, if that does not happen, active educational steps are taken to generate more needs to reach a level when it starts having an epidemiological impact. This epidemiological impact will occur in consonance with the impact that might occur as a result of changes in the natural history of tuberculosis in India.

DIS-5.A

Effectiveness of BCG vaccination against tuberculous meningitis: a case–control study in São Paulo, Brazil

V. Wünsch Filho,[1] E.A. de Castilho,[2] L.C. Rodrigues,[3] & S.R.A. Huttly[4]

A case–control study was carried out in the Metropolitan Region of São Paulo, Brazil, to determine the protection against tuberculous meningitis conferred by BCG vaccination to children aged less than 5 years. The BCG vaccination coverage in the study area was about 88%. A total of 72 tuberculous meningitis patients were studied as well as 505 neighbourhood and 81 hospital controls. Analysis of the data using a conditional logistic regression for matched case–control studies indicated that the efficacy of BCG was similar for both groups of controls, that for neighbourhood controls (84.5%) being slightly greater than that for hospital controls (80.2%). No significant interactions were found between vaccination status and sex, age, or socioeconomic status.

Introduction

At the beginning of the last decade of the 20th century, tuberculosis still presents a public health challenge, particularly in developing countries. In Brazil the death rate from tuberculosis has dropped systematically since the introduction of specific chemotherapy. However, the current death rate of 5.9 per 100 000 per year from tuberculosis indicates that, apart from intestinal infections and pneumonia, it is still the infectious disease that causes most deaths in the country (*14*). According to official figures, the incidence of tuberculosis has shown a tendency to rise in Brazil (*11*). The annual risk of infection is, however, not precisely known because the policy of mass and indiscriminate vaccination with BCG has not facilitated such estimates.

To reduce the global problem of tuberculosis, international health bodies have designated the identification and treatment of cases and vaccination with BCG as the principal components of control programs (*25*). Intradermal injection of BCG is considered to be the best method of immunizing against the disease. Nevertheless, the effectiveness of BCG has been placed under doubt since several controlled trials reported contradictory results, with efficacies that ranged from zero to 76% (*2–5, 7–9, 12, 17, 18, 24*). More recently, the case–control approach has been advocated for the evaluation of the effectiveness of BCG vaccination (*21, 22*); however, such studies have also reported a wide range of efficacies (*13, 19, 23*).

Notwithstanding doubts about the effectiveness of BCG on the chain of transmission of tuberculosis, and therefore on the incidence of and death rate from the disease, the vaccine may still be useful if it gives protection against severe infantile forms of tuberculosis, although such forms are not contagious (*1, 15, 16*). The results of a study in the United Kingdom in 1950 already indicated that BCG vaccine offered such protection (*4*); however, the results of a survey conducted in Chingleput, India, were unclear on this matter (*1, 12*).

In Brazil, tuberculous meningitis is a notifiable disease. For all cases of the disease a surveillance form is completed, covering data from clinical and laboratory examinations and an epidemiological history (*6*). Despite the difficulties in diagnosing this type of tuberculosis and the lack of confidence in the data collection in countries with socioeconomic characteristics such as Brazil, the seriousness of the disease probably results in all cases being notified.

The hypothesis that BCG offers greater protection against tuberculous meningitis than against pulmonary tuberculosis (*4*) is consistent with evidence from two Brazilian states with different schedules for BCG vaccination. For example, in Rio Grande do Sul, where children aged 7 years or older are vaccinated with BCG, the incidence of pulmonary tuberculosis in 1982 was about 12.5 times greater than that of tuberculous meningitis. In contrast, in São Paulo, where children receive BCG vaccine during the first year of life, the incidence of pulmonary

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tuberculosis to that of tuberculous meningitis was 52:1; regional differences may, however, confound this apparent relationship.

BCG vaccine coverage varies markedly in different regions of Brazil. Vaccine coverage in São Paulo city is reported to be very high, exceeding 100% according to official estimates; a survey conducted in 1982–3, however, estimated that the coverage was 88% for children less than 18 months of age.[a]

In view of these facts and of the necessity to better define the role of BCG in tuberculosis control programmes, we carried out a case–control study in the Metropolitan Region of São Paulo to evaluate the effectiveness of BCG against tuberculous meningitis. Our findings are reported here.

Materials and methods

Study area

The study was conducted in the Metropolitan Region of São Paulo (MRSP), which comprises 37 municipalities within an area of 8053 km². The population of MRSP recorded in the 1980 census was 12.5 million, which corresponded to 50.3% of that of the State of São Paulo and 10.6% of the entire Brazilian population. A wide range of living standards prevail in the study region, with some areas having only very basic environmental and social amenities. MRSP is very urbanized with only a few rural areas in the outskirts of the city (*20*).[b]

Tuberculous meningitis

Between 1979 and 1983, about 150 cases of tuberculous meningitis per annum were notified in the State of São Paulo, and of these a third were among children under 5 years of age (incidence, approxtely 1.7 per 100 000 per annum). The majority of cases of the disease notified in the State of São Paulo are admitted to two hospitals: Emilio Ribas or Mandaqui.

BCG vaccination

Routine BCG vaccination (Moreau–Rio de Janeiro strain)[c] is compulsory in Brazil as part of a programme established by the Ministry of Health. It is recommended that the vaccine be given to children, without a previous tuberculin test, between birth and the end of their first year of life. Although BCG is widely used the protection afforded by it has never been assessed in Brazil.

Selection of cases

All notified cases of tuberculous meningitis which were admitted to the Emilio Ribas or Mandaqui Hospital from 1 January 1981 to 31 December 1983 that involved patients who were born after 1978 (coverage with intradermal BCG became high in Brazil only from 1979) were ascertained. Because of the difficulties in diagnosing tuberculous meningitis unequivocally, criteria were defined based on clinical and epidemiological findings, as well as on the re of bacilloscopy, culture of cerebrospinal fluid (CSF), and necropsy. All cases selected were residents of MRSP.

Data on cases were collected in two questionnaires: one based on the hospital records and the other on household interviews to clarify and complement the hospital record data, particularly in relation to the BCG vaccination status of the children. The vaccination status of children was determined from their vaccination cards and, if possible, by the presence of vaccination scars. Cases were classified as BCG-positive only if their date of vaccination preceded that of diagnosis of tuberculous meningitis. In situations where a case died, the child concerned was still included in the study and a household visit was made. The mother was then questioned about the dead child's BCG vaccination status and was asked to produce the vaccination card. If the mother had lost the child's card, health centre archives were searched. The mother's word was accepted only if she affirmed that her child never been vaccinated, and such children were c... sified as unvaccinated. Cases were excluded from the analysis if they could not be located or information could not be obtained about their vaccination status.

Selection of controls

Neighbourhood controls. Cases and controls were matched by home area and socioeconomic stratum. In order to obtain a minimum of four suitable controls per case, eight potential controls were

[a] [*Investigation of vaccination coverage in the municipality of São Paulo*]. Centre for Health Information. Government of the State of São Paulo. Unpublished document, 1982 (in Portuguese).

[b] [*Health care in the Metropolitan Region of São Paulo*]. Paper presented at the WHO/PAHO Regional Meeting of the Technical Consultation on Primary Health Care and Development Services in Urban Areas and Large Cities, Washington, DC, 20 November 1981. PAHO unpublished document (in Portuguese).

[c] Fundação Ataulpho de Paiva, Rio de Janeiro, Brazil.

sought from children in the neighbourhood of each case. The mother of the index child was asked to nominate two children of neighbours, each of whose mothers nominated two more. This process was continued until eight controls were identified. The only requisite was that the children nominated should have been born after 1978. Information on controls was collected during home visits, using a very similar questionnaire to that used for cases. To determine the BCG vaccination status of the neighbourhood controls, the same procedure was used as for cases, and only those children whose vaccination status was known with certainty were accepted. Children who had a past or present history of tuberculosis were rejected as controls.

Hospital controls. In order to detect any biases that might have been introduced by the neighbourhood controls, a second series of controls was selected from patients in Emilio Ribas Hospital. In order to ensure that there was one suitable hospital control for each case, attempts were made to identify three potential controls per case.

Hospital controls who were suspected to have had tuberculosis were excluded. Also, children with diseases which could have been prevented by vaccination, e.g., measles or diphtheria, were also excluded, because it was considered likely that those not vaccinated against these diseases would have had less chance of having received BCG vaccine. The hospital controls were selected from patients admitted with meningitis caused by *Streptococcus pneumoniae* or *Haemophilus influenzae* and who also satisfied the matching requirements of sex, home area, date of birth, and date of admission to hospital ± 6 months with respect to that of the index case.

Two questionnaires were used for hospital controls, one to obtain hospital records data and the other, which was similar to that for the neighbourhood controls, for the home visit. The BCG vaccination status of the hospital controls was determined in the same way as that of the cases and neighbourhood controls.

Sample size and estimation of vaccine efficacy

With the number of cases that were expected to be found during the study period and the level of BCG coverage, it was concluded that vaccine efficacy above 50% could be detected at the 5% level of significance at a power of 80%.

Vaccine efficacy was estimated from the relationship $1-RR$ (*21*), where RR is the relative risk of tuberculous meningitis among the vaccinated compared to the unvaccinated children, estimated from the odds ratio. The odds ratio was calculated by conditional logistic regression analysis for matched case–control studies, using the EGRET software package (*10*).

Results

Characteristics of the study population

During the study period, a total of 474 cases of tuberculous meningitis were notified in São Paulo State, 196 (41.4%) of which involved 0–4-year-olds. In the two hospitals where the investigation was carried out, 271 diagnosed cases of tuberculous meningitis were admitted, 115 (42.4%) of which were children aged less than 5 years. Any case that transferred between the two hospitals or which was readmitted was counted only once, using the initial admission to the first hospital in the respective year. A total of 94 eligible cases remained, 19 of which were omitted from the study (11 were born outside the study area, while eight could not be located). Of these 75 cases that were located and visited, there was uncertainty about the true vaccination status of two children, who were therefore also eliminated from the study. Also a control could not be obtained for one case, which was therefore removed. Altogether, 72 cases fulfilled the study criteria (25 cases from 1981, 24 from 1982, and 23 from 1983).

For these 72 cases, which formed the basis of the study, the history of contact with tuberculosis patients was traced for 46 of them (63.9%). Chest X-rays were available for only 50 of the 72 cases, and 46 (92%) were positive for tuberculosis. The results of CSF cultures were available for all cases, and *Mycobacterium tuberculosis* was isolated from 10 children (13.9%). The results of CSF smears for acid-fast bacilli were available for all cases and were positive for four children (5.5%). The overall case fatality rate was 50%, but was higher among those aged less than 1 year (60.5%). Of children who survived, many suffered neurological sequelae from which they recuperated with difficulty. Only 11 of the children investigated recovered without exhibiting apparent neurological abnormalities (Table 1).

A total of 520 neighbourhood controls and 83 hospital controls were visited. Of the neighbourhood controls, 15 were omitted (12 were born outside the defined study area, one was being treated for pulmonary tuberculosis during the period in which he was visited, and for two others doubts remained as to their true vaccination status). Neighbourhood controls could not be located for four cases. Of the 83 hospital controls, two were omitted (one was born outside MRSP and there were doubts about the vaccination status of the other), leaving 81. Hospital controls could not be obtained for 12 cases.

Table 1: **Clinical outcome of the 72 cases of tuberculous meningitis that formed the basis of the study, São Paulo, Brazil**

Outcome	No. of cases
Died in hospital	36 (50.0)[a]
Died after discharge from hospital[b]	2 (2.8)
Neurological sequelae	23 (31.9)
No apparent neurological sequelae	11 (15.3)
Total	72 (100.0)

[a] Figures in parentheses are percentages.
[b] Death was verified at a home visit.

Table 2 shows the distribution of cases and controls by age, sex and socioeconomic status (defined in terms of family income, area of residence, degree of domestic crowding, and mother's education level), and vaccination status. For ease of presentation, unmatched data are shown; however, matching was preserved to estimate vaccine efficacy. Two-thirds of subjects came from the municipality of São Paulo, most from the peripheral poorer areas, while the remainder were from the other 36 municipalities of MRSP. Hospital controls were matched by sex and by age (within 6 months) but differed from cases with respect to their socioeconomic status, more frequently coming from higher status groups. Neighbourhood controls, as expected, had the same socioeconomic status as cases, but were older and had a higher proportion of females.

Table 2: **Characteristics of the study cases and controls, São Paulo, Brazil**

Characteristic	No. of cases	No. of neighbourhood controls	No. of hospital controls
Age			
<6 months	14 (19.4)[a]	35 (6.9)	20 (24.7)
6–11 months	30 (41.7)	36 (7.1)	34 (42.0)
12–23 months	21 (29.2)	104 (20.6)	18 (22.2)
⩾24 months	7 (9.7)	330 (65.3)	9 (11.1)
Sex			
Male	49 (68.1)	250 (49.5)	51 (63.0)
Female	23 (31.9)	255 (50.5)	30 (37.0)
Socioeconomic status[b]			
1	58 (80.6)	431 (85.3)	55 (67.9)
2	13 (18.1)	74 (14.7)	26 (32.1)
Unknown	1 (1.4)		
Vaccination status			
Vaccinated	42 (58.3)	463 (91.7)	72 (88.9)
Unvaccinated	30 (41.7)	42 (8.3)	9 (11.1)
Total	72	505	81

[a] Figures in parentheses are percentages.
[b] Children were classified as socioeconomic status 1 if they satisfied at least three of the following conditions: per capita household income less than one minimum wage (about US$ 58.26 in May 1986); greater than four persons per bedroom; resident in the peripheral area of São Paulo municipality or other municipalities of the Metropolitan Region of São Paulo; and mother illiterate or only partly literate.

Efficacy of BCG vaccination

Vaccine efficacy was calculated separately for each group of controls using a conditional logistic regression analysis, and the results are shown in Table 3. The efficacies obtained were similar and high, the efficacy for neighbourhood controls (84.5%) being slightly greater than that for hospital controls (80.2%). No significant interactions were found between vaccination status and sex, age, or socioeconomic status.

Discussion

To the best of our knowledge, this is the first large study to quantify the effect of BCG vaccination against tuberculous meningitis. Previously, Miceli et al. in a case–control study in Argentina reported that BCG vaccination had an efficacy of 100% against this form of tuberculosis, although the sample size was small (*13*). Our results indicate that in the study community in São Paulo, BCG vaccination was highly effective against tuberculous meningitis in children below 5 years of age. This finding is very encouraging for the prevention of a disease that has a high fatality rate and serious neurological sequelae among many of those who survive. Tuberculous meningitis predominantly affects children from

Table 3: **Efficacy of BCG vaccination against tuberculous meningitis for matched pairs of cases and controls, São Paulo, Brazil**

	Vaccine efficacy (%)
Cases and neighbourhood controls[a]	84.5 (66.7–92.8%)[b]
Cases and hospital controls[c]	80.2 (40.6–93.4%)

[a] Adjusted for age, sex, and socioeconomic status.
[b] Figures in parentheses are the 95% confidence intervals.
[c] Adjusted for socioeconomic status.

poorer socioeconomic and environmental backgrounds, who may also be less likely to have been vaccinated with BCG. Since the majority of cases occur among children aged 3–11 months, we recommend that BCG vaccine be administered within the first 3 months of life and that efforts are made to achieve a high coverage across all socioeconomic strata.

Use of the case–control approach has been recommended for studies of the effectiveness of BCG vaccination (*15*, *21*, *22*). Compared with controlled trials, the case–control approach is both quicker to carry out and cheaper. In accord with the reports of other workers (*13*, *19*, *23*), our findings indicate that the case–control method is useful for evaluating the effectiveness of BCG vaccination. It is particularly encouraging that similar results were obtained with the two groups of controls. Hospital controls, although easy to locate, differed from cases with respect to socioeconomic status. The neighbourhood controls, although they had the same socioeconomic status as the cases, differed from the latter in their age and sex distributions; they were, however, a more plentiful source of controls. The analysis with each group of controls therefore still required some control of confounding variables, which led to similar estimates of BCG efficacy. The vaccine efficacy was slightly higher for neighbourhood controls, but this may have arisen because of further confounding. No evidence was found for interactions between vaccination status and age, sex, or socioeconomic status, but the sample size was rather small to study these effects.

In most countries where tuberculosis is endemic, its incidence has remained fairly constant. For such countries, BCG vaccination is an attractive policy to protect children against tuberculosis, although it does not significantly decrease transmission of the disease. Our results are encouraging for the prevention of tuberculous meningitis and should hopefully stimulate further case–control studies of BCG vaccination and childhood tuberculosis in other countries.

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Résumé

Efficacité de la vaccination par le BCG contre la méningite tuberculeuse: étude cas-témoins à São Paulo, Brésil

A l'approche de la fin du XXe siècle, la tuberculose pose encore un problème de santé publique, notamment dans les pays en développement. Pour y remédier, les organismes sanitaires internationaux ont décidé d'axer les programmes de lutte sur l'identification et le traitement des cas de maladie et sur la vaccination par le BCG.

Bien que le vaccin BCG soit largement utilisé dans le monde à titre de mesure préventive contre la tuberculose, sa valeur a été remise en question. L'article présente une discussion du rôle du BCG en tant que mesure de lutte contre la tuberculose et étudie la protection qu'il confère contre la méningite tuberculeuse.

Les politiques de vaccination par le BCG dans les Etats brésiliens de Rio Grande do Sul et de São Paulo, qui ont différents calendriers vaccinaux, ont été évaluées; on a pour cela examiné l'incidence de la méningite tuberculeuse dans chacun de ces Etats. Dans l'Etat de Rio Grande do Sul, où les enfants sont vaccinés à l'âge de sept ans, l'incidence de la méningite tuberculeuse est environ quatre fois plus élevée qu'à São Paulo où les enfants sont vaccinés avant l'âge d'un an. La couverture vaccinale du BCG varie sensiblement d'une région à l'autre du Brésil. Par exemple, en ville de São Paulo, elle est très élevée, dépassant même 100% selon les chiffres officiels; toutefois, une enquête réalisée en 1982–1983 conduit à estimer à 88% la couverture vaccinale chez les enfants de moins de 18 mois. L'article rapporte les résultats d'une étude cas-témoins menée dans la zone urbaine de São Paulo (Brésil) afin de déterminer la protection que confère le BCG contre la méningite tuberculeuse chez les enfants de moins de cinq ans.

L'étude a porté sur 72 cas de méningite tuberculeuse, 505 témoins de voisinage et 81 témoins hospitaliers. On a calculé l'efficacité du vaccin selon la formule 1-*RR*, dans laquelle *RR* est le risque relatif de méningite tuberculeuse chez les sujets vaccinés par rapport aux sujets non vaccinés, exprimé par le odds ratio. Avec une analyse de régression logistique conditionnelle, nous avons calculé que l'efficacité du vaccin était analogue dans les deux groupes de témoins, légèrement plus grande toutefois chez les témoins de voisinage (84,5%) que chez les témoins hospitaliers (80,2%). On n'a observé aucune relation

significative entre l'état vaccinal et le sexe, l'âge ou le niveau socio-économique.

Bien que des réserves aient été exprimées quant à l'efficacité du BCG sur la chaîne de transmission de la tuberculose et par conséquent sur l'incidence et la mortalité générale dues à cette maladie, nos observations montrent qu'il peut être utile s'il protège contre les formes infantiles graves de tuberculose. Comme la plupart des cas de méningite tuberculeuse chez l'enfant surviennent chez les nourrissons de 3 à 11 mois, nous recommandons d'administrer le BCG au cours des trois premiers mois de la vie.

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DIS-SA

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ರಾಷ್ಟ್ರೀಯ ಗ್ರಾಮೀಣ ಆರೋಗ್ಯ ಅಭಿಯಾನ
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- ಕ್ಷಯರೋಗವು **'ಮೈಕೋ ಬ್ಯಾಕ್ಟೀರಿಯಂ ಟ್ಯುಬರ್‌ಕ್ಯುಲೋಸಿಸ್'** ಎಂಬ ಸೂಕ್ಷ್ಮರೋಗಣುವಿನಿಂದ ಬರುತ್ತದೆ.
- ಕ್ಷಯರೋಗಯು ಕೆಮ್ಮಿದಾಗ ಅಥವಾ ಸೀನಿದಾಗ ಹೊರಬರುವ ತುಂತುರುಗಳಿಂದ ಈ ರೋಗಾಣುಗಳು ಗಾಳಿಯ ಮೂಲಕ ಆರೋಗ್ಯವಂತ ವ್ಯಕ್ತಿಯ ಶ್ವಾಸಕೋಶ ಸೇರಿ ಅವನಿಗೆ ಸೋಂಕು ಉಂಟಾಗುತ್ತದೆ.
- ಕ್ಷಯರೋಗದ ಲಕ್ಷಣಗಳು
  - ★ **ಎರಡು ವಾರ ಅಥವಾ ಅದಕ್ಕಿಂತ ಮೇಲ್ಪಟ್ಟು ಸತತವಾದ ಕೆಮ್ಮು ಇದ್ದಲ್ಲಿ 'ಎದೆರೋಗದ ಲಕ್ಷಣವುಳ್ಳ ವ್ಯಕ್ತಿ' ಎಂದು ಪರಿಗಣಿಸಿ ಕಫ ಪರೀಕ್ಷೆಗೆ ನಿರ್ದೇಶಿಸುವುದು.**
- **ಇತರ ಲಕ್ಷಣಗಳು**

  ಜ್ವರ ಅದರಲ್ಲೂ ಸಂಜೆ ವೇಳೆ ಹೆಚ್ಚಾಗುವುದು.

  ಎದೆಯಲ್ಲಿ ನೋವು, ತೂಕ ಕಡಿಮೆಯಾಗುವುದು. ಹಸಿವಾಗದಿರುವುದು.

  ಕಫದಲ್ಲಿ ರಕ್ತ ಬೀಳುವುದು
- ಕ್ಷಯರೋಗವು ದೇಹದ ಯಾವುದೇ ಭಾಗಕ್ಕಾದರೂ ಬರಬಹುದು. ಇದನ್ನು ಶ್ವಾಸಕೋಶದ ಕ್ಷಯ ಮತ್ತು ಶ್ವಾಸಕೋಶೇತರ ಕ್ಷಯ ಎಂದು ಎರಡು ವಿಧವಾಗಿ ವಿಂಗಡಿಸಲಾಗಿದೆ.
- ಶ್ವಾಸಕೋಶದ ಕ್ಷಯ ಒಬ್ಬರಿಂದ ಒಬ್ಬರಿಗೆ (ಸಾಂಕ್ರಾಮಿಕ) ಹರಡುವಂತಹದು.
- ಚಿಕಿತ್ಸೆ ಪಡೆಯದ ಕಫದಲ್ಲಿ ಕ್ರಿಮಿಗಳುಳ್ಳ ಕ್ಷಯರೋಗಿಯು ವರ್ಷದಲ್ಲಿ 10 ರಿಂದ 15 ಜನಕ್ಕೆ ಕ್ಷಯರೋಗದ ಸೋಂಕು ಹರಡುತ್ತಾನೆ.
- ಹೆಚ್‌ಐವಿ/ಏಡ್ಸ್ ಸೋಂಕಿರುವ ವ್ಯಕ್ತಿಗಳಲ್ಲಿ ರೋಗನಿರೋಧಕ ಶಕ್ತಿ ಕುಂಠಿತವಾಗುವುದರಿಂದ ಆ ವ್ಯಕ್ತಿಗಳು ಕ್ಷಯರೋಗದ ಸೋಂಕಿಗೆ ಬೇಗನೆ ಒಳಗಾಗುತ್ತಾರೆ.
- ಕ್ಷಯರೋಗವನ್ನು ಎರಡು ಬಾರಿ ಕಫ ಪರೀಕ್ಷೆ ಮಾಡುವುದರ ಮುಖಾಂತರ ಕಂಡುಹಿಡಿಲಾಗುತ್ತದೆ.
- ಕಫದ ಪರೀಕ್ಷೆಯಲ್ಲಿ ಕ್ರಿಮಿಗಳು ಕಂಡು ಬರದಿದ್ದವರಿಗೆ ಕ್ಷ-ಕಿರಣ ಪರೀಕ್ಷೆ ಮುಖಾಂತರ ಕ್ಷಯರೋಗವನ್ನು ಕಂಡುಹಿಡಿಯಬಹುದು.
- **DOTS ಚಿಕಿತ್ಸೆ ಎಂದರೆ (Direct Observation Treatment Short Course) 'ನೇರ ನಿಗಾವಣಾ ಅಲ್ಪಾವಧಿ ಚಿಕಿತ್ಸೆ' ಅಂದರೆ ಔಷಧಿಯನ್ನು ಆರೋಗ್ಯ ಕಾರ್ಯಕರ್ತರ ಎದುರಿನಲ್ಲಿಯೇ ಸೇವಿಸುವ ವಿಧಾನ.**
- ಕ್ಷಯರೋಗದ ಚಿಕಿತ್ಸೆ 6 ರಿಂದ 8 ತಿಂಗಳವರೆಗೆ ಇರುತ್ತದೆ.
- ಕ್ಷಯರೋಗದ ಚಿಕಿತ್ಸೆ ರಾಜ್ಯದ ಎಲ್ಲಾ ಸರ್ಕಾರಿ ಆರೋಗ್ಯ ಕೇಂದ್ರಗಳಲ್ಲಿ ಉಚಿತವಾಗಿ ದೊರೆಯುತ್ತದೆ.
- ನಿಯಮಿತವಾಗಿ ಹಾಗೂ ನಿಗದಿತ ಅವಧಿಯವರೆಗೆ ಚಿಕಿತ್ಸೆ ಪಡೆದರೆ ಕ್ಷಯರೋಗವನ್ನು ಪೂರ್ಣವಾಗಿ ಗುಣಪಡಿಸಬಹುದು.

- **ಕ್ಷಯರೋಗ ತಡೆಗಟ್ಟಲು ಅನುಸರಿಸಬೇಕಾದ ಕ್ರಮಗಳು :**
  - ★ ಕ್ಷಯರೋಗಿಗಳು ಕೆಮ್ಮುವಾಗ ಹಾಗೂ ಸೀನುವಾಗ ಬಾಯಿ ಮತ್ತು ಮೂಗಿನ ಹತ್ತಿರ ಕರವಸ್ತ್ರವನ್ನು ಇಟ್ಟುಕೊಳ್ಳಬೇಕು.
  - ★ ರೋಗಿಯು ಕಫವನ್ನು ಮನಸ್ಸಿಗೆ ಬಂದ ಕಡೆ ಉಗಿಯಬಾರದು.
  - ★ ಕಫವನ್ನು ಡಬ್ಬಿಯಲ್ಲಿ ಶೇಖರಿಸಿ ಗಟ್ಟಿಯಾಗಿ ಮುಚ್ಚಿ ಸುಟ್ಟುಹಾಕಬೇಕು ಅಥವಾ ಗುಂಡಿ ತೋಡಿ ಮುಚ್ಚಬೇಕು.
  - ★ ನವಜಾತ ಶಿಶುಗಳಿಗೆ ಬಿಸಿಜಿ ಲಸಿಕೆ ಹಾಕಿಸಬೇಕು.
  - ★ ನಿಮ್ಮ ಮನೆಯಲ್ಲಿ ಹಾಗೂ ಸುತ್ತಮುತ್ತಲಿನವರಲ್ಲಿ ಕ್ಷಯರೋಗದ ಲಕ್ಷಣಗಳುಳ್ಳವರನ್ನು ಹತ್ತಿರದ ಸೂಕ್ಷ್ಮದರ್ಶಕ ಕೇಂದ್ರಕ್ಕೆ ಪರೀಕ್ಷೆಗಾಗಿ ಕಳುಹಿಸುವುದು.

ಕ್ಷಯರೋಗದ ಪರೀಕ್ಷೆ ಮತ್ತು ಚಿಕಿತ್ಸೆ ಎಲ್ಲಾ ಆರೋಗ್ಯ ಕೇಂದ್ರಗಳಲ್ಲಿ ಉಚಿತವಾಗಿ ದೊರೆಯುತ್ತದೆ.

ಜಿಲ್ಲಾ ಕ್ಷಯರೋಗ ನಿಯಂತ್ರಣ ಕೇಂದ್ರ, ಬೆಂಗಳೂರು ನಗರ ಜಿಲ್ಲೆ.

ಡಿ.ಎಂ.ಸಿ. ಕಫ ಪರೀಕ್ಷಾ ಕೇಂದ್ರಗಳು ಬೆಂಗಳೂರು ನಗರ ಜಿಲ್ಲೆ

ANEKAL	ABBIGERE	K.R. PURA	KONANAKUNTE	YALAHANKA
ATTIBELE	TAVAREKERE	VARTHUR	BEGUR	HESARAGHATTA
CHANDAPURA	HEGANAHALLI	VYDEHI MEDICAL COLLEGE	KENGERI UPAN	K.G. HALLI
JIGANI	LAGGERE	K.N.PURA	KAGGALIPURA	BETTAHALSUR
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ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಸಂಪರ್ಕಿಸಿ

ಆನೇಕಲ್ ಘಟಕ		ಅಬ್ಬಿಗೆರೆ ಘಟಕ		ಕೆ.ಆರ್. ಪುರಂ ಘಟಕ		ಕೋಣನಕುಂಟೆ ಘಟಕ		ಯಲಹಂಕ ಘಟಕ	
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PRASHANTH KUMAR	9986783135	SHWETHA G.V.	9538949178	MOHMED NAWAZ	9900965542	RAVI M.	9902228174	SHIVAKUMAR..M	9731750736
		SHIVARACHAYYA	9916252535	SUGUNA B.A.	7259817305	KUSUMA	9731121630		
		VINAYAK KOLLURA	9663100303	VINOD G	9743301463				

PMDT

Mr. SHAURAJ : 9480682165 — ಪಿ.ಎಂ.ಡಿ.ಟಿ. ಮಾಹಿತಿಗಾಗಿ ಸಂಪರ್ಕಿಸಿ

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Today we present to you from a WHO approved plant

CAVITER™
rifampicin 120 mg; isoniazid 80 mg; pyrazinamide 250 mg

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rifampicin 450 mg; isoniazid 300 mg

CAVIZIDE* 500/750
pyrazinamide

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CAVITER FORTE
contains 1 TAB. RIFA-1

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Patient friendly anti-TB medication

Patient weight	Intensive phase: CAVITER™ (rifampicin; isoniazid; pyrazinamide) for first 2 months	Continuation phase: Cavidin™-INH (rifampicin; isoniazid) for next 4 months*
Upto 49 kg	4 tablets	1 tablet
50 kg and above	5 tablets	1 tablet

* For patient over 50 kg additional rifampicin may be required

Intensive phase: Cavidin™-INH (rifampicin; isoniazid) + CAVIZIDE® 500/750 (pyrazinamide) for first 2 months	Continuation phase: Cavidin™-INH (rifampicin; isoniazid) for next 4 months*
1 + 2	1

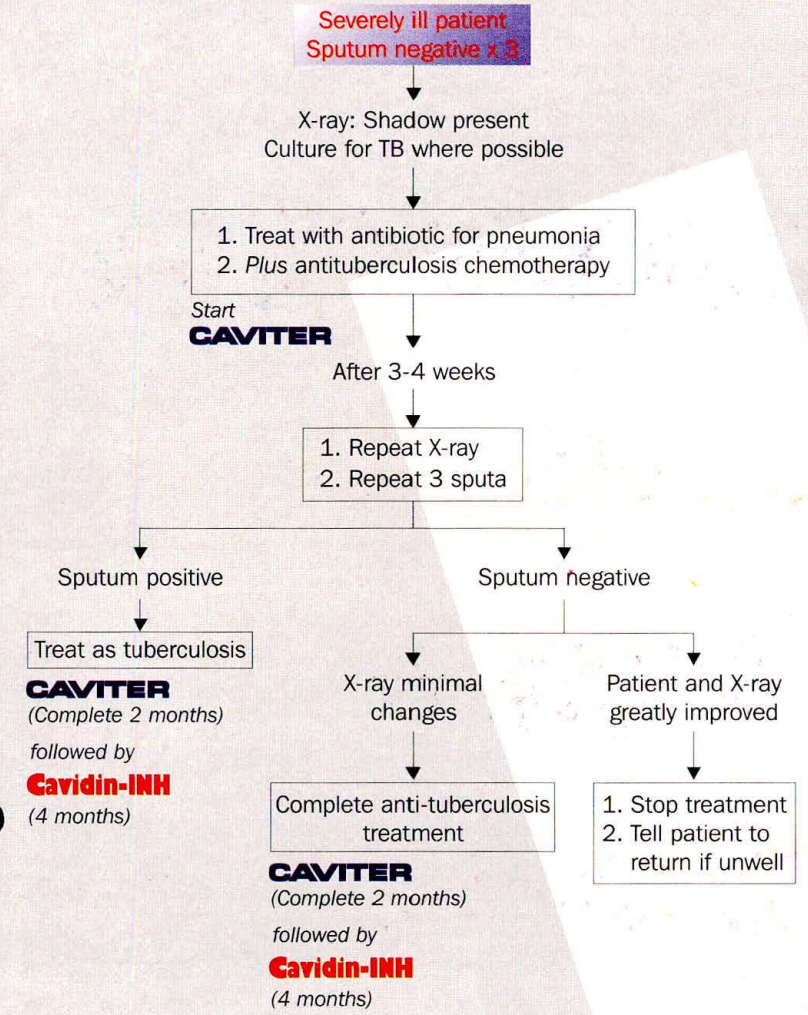
* For patient over 50 kg additional rifampicin may be required

CAVICARE

A step towards a TB-free nation

Guidelines for managing suspected pulmonary tuberculosis

Series 1



Severely ill patient with 3 sputa negative for TB. X-ray shows abnormal shadows.

Adapted from Crofton J. et al. Clinical Tuberculosis 1994; pg. 142

1989

Acocella commented that especially in India, individual patients are at a high risk of using preparations with a poor bioavailability of rifampicin*

*(Acocella had isolated combination products, which were seriously substandard)**

1993

IUATLD and WHO issued a joint statement: "Antituberculosis medications should be given in combination tablets or capsules".**

Caveat

"Must be of demonstrated bioavailability".**

1995

Right through the years we have provided your patients with 100%

* *Acocella G. Human bioavailability studies. Bull IUATLD 1989; 64: 38-40*

** *WHO Drug Information, Vol 8, No. 1, 1998; Pg. 27,28*

DIS-5A

For the use only of a registered medical practitioner or a hospital or a laboratory.

1986

A year when Tata Pharma
set the standard for
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TUBERCULOSIS TREATMENT

- EXPERIENCES OF THE URBAN POOR

A study on patients' perspectives regarding TB treatment under Revised National Tuberculosis Control Programme (RNTCP) - Implemented by the **Bangalore City Corporation**

AN ACTION RESEARCH CONDUCTED AS PART OF LARGER INITIATIVE TO IMPROVE HEALTH OF THE URBAN POOR IN BANGALORE, INDIA

S.J.CHANDER
COMMUNITY HEALTH CELL,
BANGALORE, INDIA, SOUTH ASIA

Aim

To understand patient's perspective regarding TB treatment provided by the Bangalore City Corporation under the Revised National Tuberculosis Control Programme (RNTCP) using DOTS (Directly Observed Treatment, Short course) approach.

Objectives

- Assess the socio economic status of the patients.
- Gain an understanding of patients' perception on TB.
- Understand the treatment seeking behaviour of the patients.
- Understand the impact of the disease and the treatment on patients' lives; and the adjustment they need to make towards this.

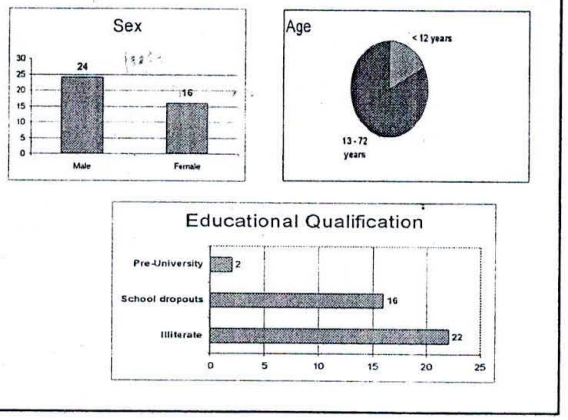
Methodology

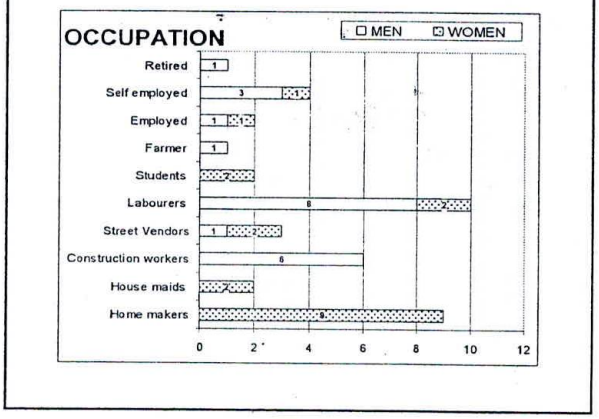
§ **Qualitative information using in-depth interview guide.**

§ **Sampling method: Systematic random sampling.**

40 patients selected out of 805 patients under treatment from 7 TB units.

Socio-economic background of the patients





Perception and awareness

Locally called: TB *Kaayele* or TV *Kaiyele*, *Kshayaroga*, TB *katti Kshayarogamu.*

- It was found that FEAR kept patients from being informed about the diagnosis
- Five (12.5%) of patients did not know that they were under treatment for TB

Perceptions about TB

ix patients said they did not know anything about TB.

People suffering from TB would have wounds inside the heart and there will be germs in his sputum.

People who suffer from TB have intermittent fever and lose weight.

A person suffering from TB would have cough, fever and loss of appetite.

When a man coughs, he might have TB.

People's peceptions about reasons for being affected by TB

It affects people irrespective of age, sex and economic status

- **The poor**

The rich

Men are affected more

People living in villages

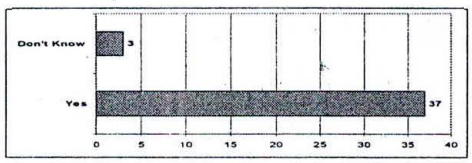
People's peceptions about reasons for being affected by TB

Not eating on time

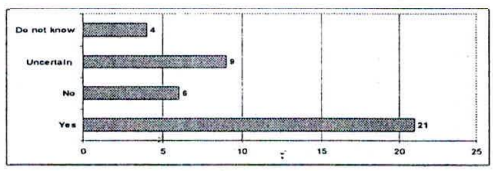
Alcohol and smoking

Occupation

People's peceptions about whether TB can be cured



People's peceptions about whether TB is communicable



Key issues

1.Communication to the patient by health services providers is inadequate.

2. Information given to patients is often limited to taking precautionary measures for preventing transmission.

3. Hence, misconceptions and ignorance about TB still continues.

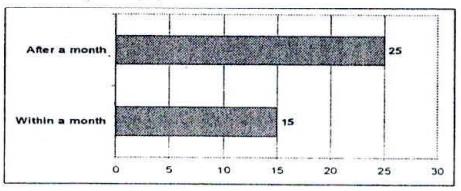
4. Motivating alcoholics who were also TB patients to take treatment and continue medication was found to be difficult. All the four alcoholics in the study were found to be irregular in taking medications or had discontinued treatment.

Health Seeking Behaviour

Except three patients, all the other patients first approached private health care service providers, but found no relief and were unable to pay the cost of treatment. Two of them however continued in private healthcare institution.

The remaining patients then approached government TB centers seeking relief.

Time taken to seek treatment at DOTS centres after the appearance of symptoms



Those who sought help from folk healers

15% (6) of the 40 patients interviewed said that they also went t folk healers, but they found no relief.

Symptoms faced

Patients under treatment for extra pulmonary TB

- Nine of the thirteen people noticed a lump, which was painful and growing bigger. For some it was not painful, though it was growing.

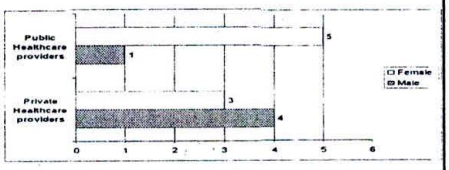
Others had the following symptoms: stomach ache, diarrhoea, fever, loss of weight, weakness, tiredness and inability to lift heavy things.

atients under treatment for pulmonary TB

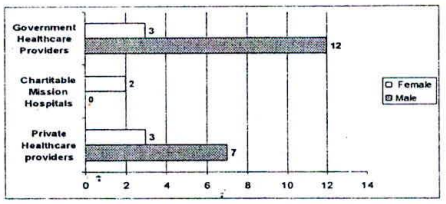
Nineteen men and eight women under treatment for pulmonary T experienced the following symptoms: fever, cough, tiredness, back pa cough and chest pain, loss of weight, fever and headache, loss

Places where TB was diagnosed

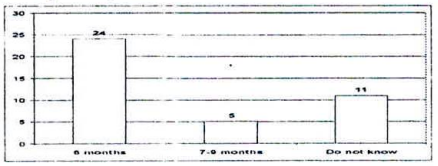
Extra pulmonary TB



Pulmonary TB



People's perception about duration of TB treatment



Patients' Perception of consequences of non-adherence to treatment

RESPONSE	Extra Pulmonary TB Patients	Pulmonary TB patients	TOTAL
Relapse	1	4	5
Person would spread the disease and die	8	14	22
Health would deteriorate	-	2	2
Do not know	4	7	11
TOTAL	13	27	40

Key issues: Communication about the disease to the patients by the health providers was not clear and adequate.

TB - patients' and family response

- Ten patients were of the view that a person suffering from TB should not get married.
- Family's attitude and support were generally supportive.
- Most of them said they could not afford special care.
- Four men and four women were given special diet by their families during treatment.
- Five men experienced social isolation. In one case, a man was abandoned by his wife when she came to know that he tested

Fear of stigma

- Most patients were afraid of being stigmatized by their neighbours.
- 14 patients (two women and twelve men) said that their neighbours were aware about their disease status.
- Two of the men were discriminated by their neighbours and were asked to stay away.
- One was served food separately when he was invited to their house.

Community attitude and support

- Most of the patients received a word of encouragement or advice.
- One man and one woman said their neighbours were supportive. While the man was lent money; the woman was given food and money by her neighbours.

Economic implications

- All the patients* interviewed said that, they had spent money for treatment ranging from a minimum of twenty rupees (less than 1 US $) to a maximum of forty thousand rupees (more than 900 US $) in private healthcare institutions, in spite of free treatment being available at Government health centres.
- (The average daily wage of the patients was less than US $ 2 per day).
- More than 40% (17) of the 40 patients borrowed money ranging from US $ 10 – 1000 for treatment.
- Six (three men and three women) of them said they had to mortgage their personal belonging to pay for treatment.

Work and treatment

- About 50% (19) of the 40 patients said their work had been affected by the disease and treatment. 15 of them were men.
- 1 person was rejected by his employer.
- 4 patients (2 men and 2 women) were unable to work, but could not take rest as they had to earn for a living.

Accessibility

Most of the DOTS centres were located close to the communities' residences.
Two women said they had difficulty in reaching the health centre. However, none of the patients discontinued treatment due to distance.

Quality of service

Most of the patients were happy with the DOTS centre staff attitude.

Positive experience: One patient said *"When they see me entering the centre to collect the tablets, they would welcome me and ask me to sit down, they speak to me well with joy, and they gave me respect".*

Quality of service - Negative experiences

- Being addressed as a "TB case" rather than by their names.
- Being ill-treated by the staff and being shouted at, for not covering their mouth while coughing.
- Fear to go back and face DOTS staff after discontinuing medication.
- Money demanded for services in government referral health centres.

Side effects

Seven patients – four under treatment for extra pulmonary and three under treatment for pulmonary TB, said they did not experience any side effects.

Thirty three patients – nine patients under treatment for extra pulmonary and twenty-four under treatment for pulmonary TB said they had side effects.

Types of side effects

The following side effects were reported:

- Reduced energy levels
  - § Sour taste
  - § Loss of appetite
  - § Nausea
  - § Bitterness in the mouth
  - § Giddiness
  - § Feeling hot
  - § Burning sensation in the stomach
  - § Increased hunger
- Itchy feeling all over the body

Key issues

Doctor's support was available in managing side-effects in most cases but not adequate.

- Seven of them said they discontinued the treatment and started again.

The reasons for discontinuing were:

- § Other ailments like fever and cough
- § Going out of town
- § Cough subsided
- § Fed up of long treatment
- § Difficulty to swallow nine tablets

Patients' suggestions to improve services

- Open the DOTS centre on time.
- Be courteous to patients.
- Keep the health centres clean.

"The room where they send people for sputum collection stinks" – A DOTS centre user

Follow-up of the study

Series of monthly training and reflection sessions were held for staff of non-governmental organisations working with the urban poor by Community Health Cell and Bangalore City Corporation.

Awareness sessions were conducted for urban poor women's self help groups (SHGs) and community members.

Mass awareness programmes for the larger public were conducted during World TB Day with National Tuberculosis Institute, Karnataka State TB Association and Bangalore City Corporation.

Recommendations

Need for wider public awareness

for removing myth and misconceptions.

to seek treatment early at DOTS centres

to minimise people from seeking treatment at unhelpful places

Social support for socio-economically weaker patients

Training and sensitisation programmes for health service providers on health education and communication