UNIVERSITY OF CAPE TOWN

SCHOOL OF ECONOMICS

A COST-EFFECTIVENESS ANALYSIS OF THE TUBERCULOSIS CONTROL PROCEDURES APPLIED IN THE CAPE DIVISIONAL COUNCIL AREA

By

DIANE McINTYRE

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ABSTRACT

This study evaluates the costs and effectiveness of preventive and curative procedures currently available for Tuberculosis (TB) control purposes. The procedures examined are as follows :

i) BCG vaccinations;
ii) Secondary chemoprophylaxis;
iii) Health education;
iv) Mass screening campaigns;
v) Investigation of contacts of infectious TB cases and symptomatic persons, i.e. suspects; and
vi) Treatment regimens for notified TB patients.

The analysis is largely based on data from the records of 300 randomly selected TB patients, treated at clinics in the Cape Divisional Council area in 1983.

The major finding of this study is that resources available for TB control should be reallocated in the direction of secondary chemoprophylaxis, BCG vaccination administration in the Black and Coloured populations, investigation of contacts and suspects, and ambulatory treatment of notified TB patients. Conversely, vaccinating the White population, mass screening campaigns and hospitalisation of TB patients should be given relatively less emphasis in the overall TB control programme. In addition, the proportion of patients confirmed as TB cases by means of bacteriological examinations should be increased to reduce misdiagnosis.

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The usual proviso naturally holds; any errors or omissions are entirely my own.

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INTRODUCTION

There were two major motivating factors for undertaking this particular study:

i) Dr Coogan, the Medical Officer of Health for the Cape Town City Council, is reported as having said that TB is

> "... the biggest health problem we have and the only one that is not responding to control measures ... numbers are going up by about a third every year."
>
> (The Argus, January 16, 1984 : 1)

Resources available for combatting TB are limited and there are a range of possible preventive and curative procedures for TB. In addition, there is a relative dearth of data on TB procedures in S.A., although an increasing number of studies have been initiated over the past few years.

These factors suggested that a cost-effectiveness analysis, based on statistics gathered in a random sample of TB patients, might provide a useful framework for policy-makers' reassessment of the procedures currently employed in TB prevention and treatment.

Although broad guidelines concerning TB procedures are presented in the Department of Health and Welfare's (now the Department of National Health and Population Development) National TB control programme, there is some degree of flexibility in the implementation of this programme at the loal authority

level. As a result, the outcomes and effectiveness of TB programmes differ between local authorities.

It was originally planned that the cost-effectiveness ratios of procedures implemented by the Cape Town City Council (CCC) would be compared with the ratios for the Cape Divisional Council (CDC). Regrettably, access to CCC data was restricted. It was felt nevertheless that evaluation of the CDC procedures only would still be feasible and useful, both for the CDC and for other local authorities who would be enabled to assess their procedures in relation to the CDC cost-effectiveness ratios. It is important to note in this regard that the CDC was one of the first local authorities to experiment with new TB procedures such as shorter treatment regimens.

ii) Cost-benefit analysis (CBA) and cost-effectiveness analysis (CEA) have been extensively used overseas as frameworks for health project evaluation. As yet, no studies of this nature have been published in S.A. Thus a secondary objective of this study is to demonstrate the usefulness of CEA as a technique for health project evaluation.

This dissertation is divided into five chapters which can be summarised as follows:

CHAPTER I : The theoretical frameworks of CBA and CEA are presented and compared. The selection of CEA as the most appropriate method for evaluation of TB procedures is motivated. Past applications of these techniques to health project evaluation are then assessed.

Appendix A contains a more extensive theoretical exposition of CBA.

CHAPTER II : The incidence of TB and the preventive and curative procedures available for its control are discussed in some detail. This is necessary for two reasons: a) to highlight the extent of the TB problem, and b) to provide sufficient information about TB to ensure that the content of later chapters will be intelligble to readers who have no medical expertise.

CHAPTER III : The results of a random sample of 300 CDC TB patient records are presented. The sample was performed to estimate the value of certain factors that influence the costs and effectiveness of TB procedures and for which insufficient data was available. Figures reflecting some of the sample findings are contained in Appendix B.

CHAPTER IV : The cost-effectiveness ratios of preventive and curative procedures for TB in the CDC are calculated. Appendices C - F describe cost data and its manipulation in greater detail.

CHAPTER V : These cost-efectiveness ratios are evaluated and compared to determine what combination of preventive and curative procedures should be implemented. In particular, the practical implications of the call for greater hospitalisation of TB patients by certain local authorities, other than the CDC, are evaluated. There is some discussion of what policy decisions the ratios point towards, but the emphasis is on providing a groundwork for the health authorities' own assessment of each procedure's economic feasibility, augmented by their medical understanding of TB procedures.

CHAPTER I

THE THEORY OF COST-BENEFIT ANALYSIS (CBA) AND COST-EFFECTIVENESS ANALYSIS (CEA) AND THEIR APPLICATION TO THE EVALUATION OF HEALTH PROJECTS

Introductory Note:

A very brief and general discussion of the CBA and CEA frameworks will be presented in the initial sections of this chapter with a more extensive theoretical exposition of CBA in Appendix A. The emphasis in this chapter is on examining the CBA and CEA techniques in the context of health project evaluation.

1. Cost-Benefit analysis and Cost-effectiveness analysis theory:

1.1 The Framework of CBA:

CBA is primarily a tool to assist decision makers in the assessment of proposed projects. It facilitates decision making by enumerating, and wherever possible, evaluating in monetary units, all costs and benefits associated with the projects under review and thereby explicitly brings all practically relevant factors into consideration.

The broad definitions of costs and benefits that will be used in this study are: A benefit is any utility or welfare gain resulting from the project under consideration. A cost is any loss of utility or welfare resulting from the project.

The present values of the costs and benefits are combined in

equation form to determine firstly whether each project is economically feasible, and secondly to rank alternative projects if a limited budget exists. The most common form of the CBA decision rule is:

$$\sum_{t=1}^{T} \frac{Bt}{(1+r)^t} - \sum_{t=1}^{T} \frac{Ct}{(1+r)^t} > 0$$

where B_t = Benefits in time period t,

C_t = Costs in time period t,

r = discount rate,

and T = time period over which benefits and costs are calculated.

Projects are ranked according to the magnitude by which the sum of the present value of benefits exceeds the sum of the present value of costs. If there is a budget constraint, those with the largest differences are given priority.

The result of any CBA calculation must be balanced by the judgement of decision makers. As Frost (1971:20) has pointed out, CBA

> "...should not be regarded as a machine for decisions but rather as an aid to judgement."

1.2 The Framework of CEA:

The major factor which distinguishes CEA from CBA is that benefits are not expressed in monetary units, but in terms of a predetermined,

common unit of outcome.[1] Thus, CEA is generally used to evaluate different ways of achieving the same objective, while CBA tends to be used to assist in the selection of one or more projects from a range of possible projects which may have different objectives, but for which limited resources are available. CEA is also the preferred framework for evaluating social programs, where often, no generally accepted methods of assigning monetary values to benefits are available.

In CBA, the analyst makes various value judgements in ascribing values, which may be subject to interpersonal and intertemporal fluctuations, to certain benefits. With a CEA, these value judgements are made by policy-makers. The role of the analyst in a CEA is not to conclusively determine whether a project is economically feasible, but to provide results in terms of cost per unit of outcome and to indicate what policy conclusions various value assignments point towards. The ultimate decision as to whether the cost per unit is justified or worthwhile then rests with the policy-makers and planners. (Thompson & Fortess 1980:554-555).

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1 It is important to define the terms 'output' and 'outcome', to clarify their usage in this study. Output is the expected result of a project while outcome is the desired effect of the output. To illustrate these definitions with reference to health projects, output could for example be the provision of a particular health service while outcome could be the improvement in health status of the recipients of this health service. Cost per unit of output reflects the efficiency of a project while cost per unit of outcome reflects the effectiveness of a project. (Bootman et al 1982:237 and Sintonen 1981:14).

CEA is however able to rank alternative projects. This can be presented in two ways: i) according to the lowest cost per unit of outcome, or ii) according to the greatest outcome per unit of cost.

2. CBA and CEA in health project evaluation:

2.1 A brief overview of past applications of CEA and CBA to the evaluation of health projects:

The following table, reproduced from the study conducted by Warner and Hutton (1980), shows the trends in CBA health projects literature:

Table I.1

Trends in Health Care CBA/CEA, 1966-1973 and 1974-1978

	1966-1973	1974-1978
1. Average annual number of CBA/CEA publications	17.0	73.2
2. Publications in medical journals as % of total journal publications	40.2	62.7
3. CEAs as % of CEAs & CBAs	42.1	53.2
4. % of articles on:		
Prevention	44.7	22.0
Diagnosis	18.8	30.9
Treatment	36.5	47.2
5. % of articles with orientation of:		
Individual	8.3	15.8
Organisation	21.3	10.8
Society	70.4	73.4

(Warner & Hutton 1980:1076)

Although this study only covers the period 1966 - 1978, it does highlight three important trends which have continued to the present:

a) There has been a substantial increase in the number of health projects evaluated within the framework of CBA or CEA, over the past decade. This is a reflection of the concern of those involved with the provision and planning of health services with the rising costs of health care. While attempting to minimise costs, health professionals are also continually striving to improve the quality and effectiveness of health care. Another factor promoting the growth of this literature is the statutory/ legislative requirements in the U.S.A., which compel health agencies to use either the CBA framework or a similar multiple consideration balancing technique for project evaluation. (Baram 1980).

As the number of studies has increased, so the range of aspects of health care evaluated within the framework of CBA or CEA has broadened.[2]

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2. A few examples of these publications are mentioned here to illustrate the range of medical procedures evaluated: Surgery techniques - Barnes 1977 and Barnes 1982; Curative regimens - Culyer & Maynard 1981; Weisbrod 1981 and Ludbrook 1981; Preventive regimens - Cutting 1980, Epstein et al 1981, Hagard & Carter 1976, Lave & Lave 1978, Mooney 1982, Patrick & Woolley 1981 and Ponninghaus 1980; Technological advances in health care - Paterson 1983; Medical policy research techniques - Roid 1982; Rehabilitation care - Swint & Nelson 1977; Clinics as providers of health care - Kriedel 1980; and of particular concern for this study, aspects of TB prevention and treatment - Feingold 1975, McNeil et al 1980 and Stilwell 1976.

b) In addition to studies which present results of CBA or CEA in health care projects, there are a number of articles which have the objective of explaining CBA and CEA techniques to medical practitioners.[3] As a result, the proportion of CEA and CBA studies of health care projects conducted by health professionals has increased, which partly explains the increasing proportion of such publications in medical journals.

Although it is encouraging to see that medical practitioners actively support the use of CBA and CEA in health care project evaluations, the framework is often applied in an uncritical way. Underlying assumptions and value judgements are not explicitly stated and there is thus seldom any indication of how the results would be affected by changes in these factors.

One of the most frequent criticisms of these studies is that direct costs as determined by health departments or hospitals, are the only costs of the medical procedure being evaluated taken into consideration. The indirect and sometimes intangible costs to the patient and society as a whole are ignored.

Despite these qualifications regarding certain studies, health project evaluations have been facilitated by the application of CBA and CEA frameworks. With increased co-operation between economists and providers of medical services, a suitably balanced application of economic theory and practical aspects in the provision of health services can be achieved.

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3. Drummond 1981, Thompson & Fortess 1980, Tolpin 1980 and Weinstein & Stason 1977.

c) CEA is now used more frequently than CBA in the evaluation of health projects.

2.2 Critical assessment of CEA and CBA as techniques for evaluating health projects:

As the benefits of health care most often used as criteria of clinical success, such as increased life expectancy and amelioration of pain, are not easily expressed in monetary terms, CEA is usually given preference over CBA for the evaluation of health projects.

This section will attempt to assess whether this emphasis is valid by examining the respective arguments advanced for i) using CBA and calculating all health benefits in monetary units and ii) using CEA and expressing the benefits in terms of a preselected common unit of outcome.

2.2.1 CBA in health project evaluation -Valuing a life:

Much of the discussion around the monetarisation of health benefits is centred on a lively debate about the 'value' of a human life. In general, the primary objective of health care projects is the extension of life span and thus the monetary valuation of life years is an important aspect in a CBA of these projects.

There are three major theoretical approaches to life valuation: a) the Human capital approach, b) the willingness-to-pay approach and c) the 'societal valuation' approach. Each will be examined very briefly.

a) The Human capital approach bases the value of a human life on the net present value of future earnings. (Mishan 1972:101, Conley 1976:45, Landefeld & Seskin 1982:556 and Dardis 1981:50-51). In some instances, people involved in non-market activities eg. housewives, are included in the calculations by imputing a value to their services.

The primary criticism of this approach is that the value of a human life is determined by the value to society in terms of a loss in production potential rather than the value to the person or population who face the risk of being injured or dying prematurely, i.e. critics argue that the perspective of the valuation is incorrect. (Mishan 1972:101, Linerooth 1979:53 and Dardis 1981:51). It also does not account for any pain and suffering not reflected in a change in productivity but which nevertheless affects the quality of life.

Another result of the emphasis on earnings is that children and people who have retired are 'discriminated' against, in that the value of their lives are understated relative to people who are employed. In the case of children, this effect is magnified if relatively high discount rates are selected by the analyst. (Landefeld & Seskin 1982:556 and Dardis 1981:51-52).

In spite of these deficiencies, the Human capital approach is still a popular method of evaluation. This is largely due to availability of data on earnings, labour force participation and life expectancy.

b) The willingness-to-pay approach to life valuation shifts the basis of evaluation to the perspective of the individuals who face the risk of premature death. It attempts to estimate what these individuals would be 'willing-to-pay' for a reduction (or receive as compensation for an increase) in mortality risk.

The sum of these estimates indicates the value, to the population at risk, of a programme which saves 'statistical' lives, i.e. lives which are not identifiable ex-ante. The value of a life is thus the value of the programme divided by the number of lives saved by the programme.

Alternative practical applications of this approach have been attempted which fall broadly into three categories:

i) Questionnaires: An example of this method is the survey conducted by Jones-Lee (1976) with regard to safety in airline travel.

ii) Estimating the implicit value of life as revealed in the labour market, through the income compensation required by workers in high risk occupations.

iii) Estimating the implicit value of life as reflected in consumption activity. A few examples of this method are: Blomquist (1979) estimated the 'willingness-to-pay' for a reduction in mortality risk by analysing seat-belt use; Dardis (1980) by analysing the purchases of smoke detectors; and most recently, Ippolito & Ippolito (1984) by analysing the changes in cigarette consumption patterns due to improved availability of information about the health risks of smoking.

The major problem with this theoretical approach is that it cannot be assumed that everyone will be 'willing-to-pay' the estimated amount for a reduction in mortality risk. Thus, life or risk reduction valuations will vary according to the group of people surveyed and the situation studied. In addition, a person's ability to pay will affect their 'willingness-to-pay'. (Landefeld & Seskin 1982:557).

c) The 'societal valuation' approach attempts to establish either the life valuation implicit in past governmental policy/programme decisions or the explicit valuations reflected in court awards/ decisions. Life valuation estimates based on this approach have been criticised as they are not consistent and reflect the valuation of policy makers or court officials rather than the people who are affected by the decisions. (Dardis 1981:49).

Some advocates of the monetary valuation of life procedure have attempted to establish a relationship between the Human capital and 'willingness-to-pay' approaches. In general, the methods proposed to achieve this are based on the concept of 'willingness-to-pay' for the economic effects of a change in mortality risk. (Landefeld & Seskin 1982:559).

In summary, most studies are concerned with the valuation of life or life years and largely exclude consideration of other health benefits such as a reduction in injuries or morbidity, unless the effects of these factors are explicitly reflected in terms of productivity losses.

The results of any CBA based on life valuations which exclude 'quality of life'[4] considerations could be seriously distorted, because, as Dardis (1981:58) has pointed out,

> "A study of life safety in England found that certain types of injuries were viewed as worse than death (paralysis, brain damage) while severe burning and loss of limb were given a severity value equal to ten percent of the severity value given to death."

Taking all the above-mentioned deficiencies into account, and particularly the fact that a wide range of life valuation estimates have been produced, both within and between different approaches, it would be prudent to avoid the use of such techniques to determine the value of a life using data specific to S.A., given the limitations of this study.

2.2.2 CEA in health project evaluation - Health Status Indeces:

Section 1.2 indicated that if the framework of CEA is used, the time consuming and inconclusive life valuation procedure outlined above will be unnecessary. The technique that replaces this valuation process, is the selection of a unit of outcome in which to express health benefits.

A range of possible 'outcome units' exist for every project. For example, the benefits of a screening program (to detect or diagnose a disease) could be expressed in terms of the number of people

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4. 'Quality of life' refers to the health status of an individual i.e. whether a person is healthy and free of any symptoms of illness or alternatively is suffering from a disease or disability.

screened, the number of cases of the disease found, the number of lives saved, the life years extended and so on.

Thompson and Fortess (1980:554) suggest that the following guidelines should be used:

> "Choice among the alternative output measures - and, hence among alternative cost-effectiveness ratios should be based on (1) data availability and (2) the goal of describing the program as accurately as possible for decision makers."

In health care project evaluation, the outcome units most frequently used are 'number of lives saved' or 'years of life extended'. As with most of the CBA techniques, these measures do not take the quality of life into account. However, a number of studies have been directed towards the development of measures of health outcome for use in CEA, which express both mortality and morbidity factors. This is achieved through the determination and application of a 'Health Status Index'. [4a]

Most of these studies base the expression of a person's health status on that person's ability to function biologically and socially in relation to their normal daily activities.

The first step in deriving a Health Status Index (HSI) is to define an ordinal scale of function/dysfunction by isolating and describing a number of health or functional states, ranging from well-being[5]

4a. Health Status Indeces have provided the most significant contribution to CEA literature in recent years. It was thus felt that an exposition of this framework should be included for the sake of completeness, despite the fact that the conditions of this study exclude its use in the analysis.

5. The ideal state of health is defined in the Preamble to the World Health Organisation (WHO) Constitution as "a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity." (Quoted in Holland et

to death. Then, a relative weight[6] is ascribed to each state and thus a cardinal scale of function/dysfunction is obtained. (Fanshel & Bush 1970:1029-1048). (An example of a schedule consiting of different function levels and functional or social preference weights, is provided in Addendum I).

With the assistance of medical experts, the probability of being classified at a particular functional level and the duration that a person would be in that level, can be determined for a given disease.

The HSI of an individual can then be calculated as follows:

$$E(H) = \frac{\sum_j P_j T_j F_j}{\sum_j T_j} \qquad \text{where } \sum_j T_j = T_s - T_o$$

and E(H) = HSI for an individual/mean function level (for the remainder of that individual's standard life (Ts));

Pj = probability of being in level j;

Tj = duration in level j;

Ts = standard ideal life duration (specified by the analyst e.g. 90 years);

To = current age

Fj = function weight for level j. (See Footnote 6 and Addendum I)

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6. This can be done by assuming and specifying a functional relationship between each state or by obtaining consumer-rated measures of relative importance. The set of weights can either be functional weights (i.e. Wellbeing = 1 and death = 0) or dysfunctional weights (i.e. wellbeing = 0 and death = 1) (Fanshel & Bush 1970: 1036-1048 and Epstein et al 1981:176-177).

(Note: $\sum_j P_j T_j F_j$ is an expression of expected 'quality adjusted years of life'.)

(Bush et al 1972:53-54)

The HSI of a population (E(H)n) can also be determined:

$$E(H)_N = \frac{\sum_j P_j T_j F_j N_j}{\sum_j T_j N_j}$$

where Nj = number of persons in level j.

(Bush et al 1972:55)

Kaplan et al (1976:478-479) note that a HSI is an important tool for evaluating diverse health programmes, for aggregating different outcomes from many different health problems on a single scale and for comparing the health status of different populations at different times.

The present study does not fall into any of these categories as it is concerned with one specific disease, Tuberculosis (TB). It would require unrealistic effort and resources to consult TB experts to determine acceptable estimates of Pj and Tj values and which function levels a TB patient would be in at various stages of the disease. It was decided that these considerations outweighed the benefit of having a single measure for mortality and morbidity.

3. Summary:

CBA and CEA have the same theoretical basis. Although benefits are not expressed in monetary terms in a CEA, the same procedure

for evaluating costs is used in both CBA and CEA. (See Appendix A).

CEA has been selected as the framework of analysis in this study for two reasons: i) CEA is now widely accepted as the preferred evaluation technique for health projects and ii) The practical problems involved in the monetarisation of certain benefits, especially with respect to the 'value of life', could not be overcome within the limited scope of this study.

Although it is preferable to use a HSI in a cost-effectiveness analysis, the absence of Tuberculosis specific estimates for certain HSI variables prevented its use in the present study. Thus, a 'unit of outcome' will be chosen in which to express health benefits.

Table 1. Function Levels: Combinations of Steps on Mobility, Physical Activity, and Social Activity Scales, with Associated Levels of Well-being (Social Preference Weights), F_j

Numbers in parentheses are step numbers on the three scales.

Function level number (j)	Scale			Level of well-being (F_j)
	Mobility	Physical activity	Social activity	
		NO SYMPTOM/PROBLEM COMPLEX		
L 43	Drove car and used bus or train without help (5)	Walked without physical problems (4)	Did work, school, or housework, and other activities (5)	1.000
		SYMPTOM/PROBLEM COMPLEX PRESENT		
L 42	Drove car and used bus or train without help (5)	Walked without physical problems (4)	Did work, school, or housework, and other activities (5)	0.7433
L 41	Drove car and used bus or train without help (5)	Walked without physical problems (4)	Did work, school, or housework, but other activities limited (4)	0.6855
L 40	Drove car and used bus or train without help (5)	Walked without physical problems (4)	Limited in amount or kind of work, school, or housework (3)	0.6683
L 39	Drove car and used bus or train without help (5)	Walked without physical problems (4)	Performed self-care, but not work, school, or housework (2)	0.6955
L 38	Drove car and used bus or train without help (5)	Walked without physical problems (4)	Had help with self-care activities (1)	0.6370
L 37	Drove car and used bus or train without help (5)	Walked with physical limitations (3)	Did work, school, or housework, and other activities (5)	0.6769
L 36	Drove car and used bus or train without help (5)	Walked with physical limitations (3)	Did work, school, or housework, but other activities limited (4)	0.6172
L 35	Drove car and used bus or train without help (5)	Walked with physical limitations (3)	Limited in amount or kind of work, school, or housework (3)	0.6020
L 34	Drove car and used bus or train without help (5)	Walked with physical limitations (3)	Performed self-care, but not work, school, or housework (2)	0.6292
L 33	Drove car and used bus or train without help (5)	Walked with physical limitations (3)	Had help with self-care activities (1)	0.5707
L 32	Did not drive, or had help to use bus or train (4)	Walked without physical problems (4)	Did work, school, or housework, but other activities limited (4)	0.6065
L 31	Did not drive, or had help to use bus or train (4)	Walked without physical problems (4)	Limited in amount or kind of work, school, or housework (3)	0.5913
L 30	Did not drive, or had help to use bus or train (4)	Walked without physical problems (4)	Performed self-care, but not work, school, or housework (2)	0.6185
L 29	Did not drive, or had help to use bus or train (4)	Walked without physical problems (4)	Had help with self-care activities (1)	0.5600
L 28	Did not drive, or had help to use bus or train (4)	Walked with physical limitations (3)	Did work, school, or housework, but other activities limited (4)	0.5402
L 27	Did not drive, or had help to use bus or train (4)	Walked with physical limitations (3)	Limited in amount or kind of work, school, or housework (3)	0.5250
L 26	Did not drive, or had help to use bus or train (4)	Walked with physical limitations (3)	Performed self-care, but not work, school, or housework (2)	0.5523
L 25	Did not drive, or had help to use bus or train (4)	Moved own wheelchair without help (2)	Limited in amount or kind of work, school, or housework (3)	0.5376
L 24	Did not drive, or had help to use bus or train (4)	Moved own wheelchair without help (2)	Performed self-care, but not work, school, or housework (2)	0.5649
L 23	In house (3)	Walked without physical problems (4)	Performed self-care, but not work, school, or housework (2)	0.6488
L 22	In house (3)	Walked without physical problems (4)	Had help with self-care activities (1)	0.5902
L 21	In house (3)	Walked with physical limitations (3)	Did work, school, or housework, but other activities limited (4)	0.5701
L 20	In house (3)	Walked with physical limitations (3)	Limited in amount or kind of work, school, or housework (3)	0.5552
L 19	In house (3)	Walked with physical limitations (3)	Performed self-care, but not work, school, or housework (2)	0.5824
L 18	In house (3)	Walked with physical limitations (3)	Had help with self-care activities (1)	0.5239
L 17	In house (3)	Moved own wheelchair without help (2)	Performed self-care, but not work, school, or housework (2)	0.5950
L 16	In house (3)	Moved own wheelchair without help (2)	Had help with self-care activities (1)	0.5364
L 15	In house (3)	In bed or chair (1)	Performed self-care, but not work, school, or housework (2)	0.5715
L 14	In house (3)	In bed or chair (1)	Had help with self-care activities (1)	0.5129
L 13	In hospital (2)	Walked without physical problems (4)	Performed self-care, but not work, school, or housework (2)	0.6057
L 12	In hospital (2)	Walked without physical problems (4)	Had help with self-care activities (1)	0.5471
L 11	In hospital (2)	Walked with physical limitations (3)	Performed self-care, but not work, school, or housework (2)	0.5394
L 10	In hospital (2)	Walked with physical limitations (3)	Had help with self-care activities (1)	0.4808
L 9	In hospital (2)	Moved own wheelchair without help (2)	Performed self-care, but not work, school, or housework (2)	0.5520
L 8	In hospital (2)	Moved own wheelchair without help (2)	Had help with self-care activities (1)	0.4934
L 7	In hospital (2)	In bed or chair (1)	Performed self-care, but not work, school, or housework (2)	0.5284
L 6	In hospital (2)	In bed or chair (1)	Had help with self-care activities (1)	0.4690
L 5	In special care unit (1)	Walked without physical problems (4)	Performed self-care, but not work, school, or housework (2)	0.5732
L 4	In special care unit (1)	Walked without physical problems (4)	Had help with self-care activities (1)	0.5147
L 3	In special care unit (1)	Walked with physical limitations (3)	Performed self-care, but not work, school, or housework (2)	0.5070
L 2	In special care unit (1)	Walked with physical limitations (3)	Had help with self-care activities (1)	0.4483
L 1	In special care unit (1)	In bed or chair (1)	Had help with self-care activities (1)	0.4374
L 0	Dead (0)	Dead (0)	Dead (0)	0.0000

CHAPTER II

THE NATURE AND INCIDENCE OF TUBERCULOSIS AND MEASURES FOR ITS CONTROL

1. Basic characteristics of TB:

Tuberculosis is defined by Glatthaar (1982a:1) as:

> "... a chronic (sometimes acute or sub-acute) infectious disease, caused by specific mycobacteria and characterised by the formation of lesions in any tissue or organ of the body, but mainly in the lungs."

A few facts concerning TB can be drawn from this definition and elaborated upon.

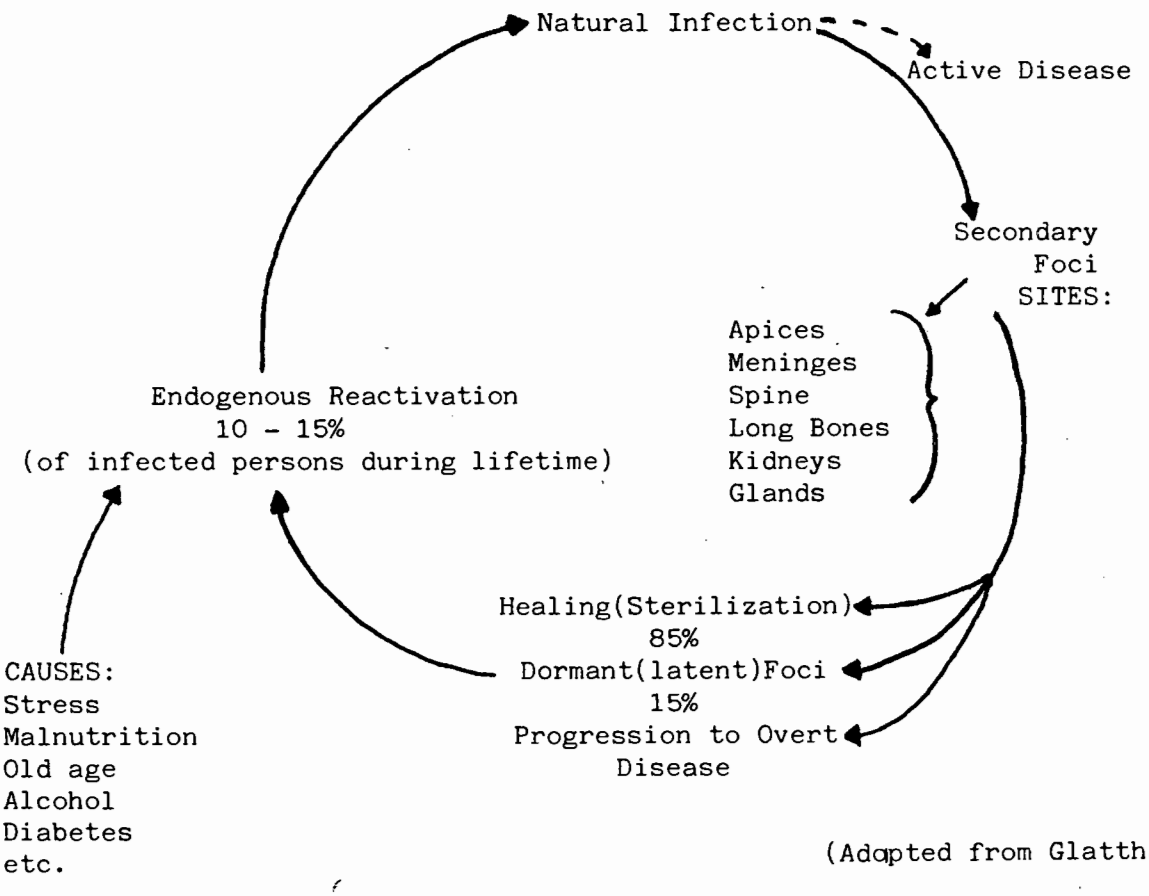
i) The tubercle bacilli (M tuberculosis) is transmitted largely through inhalation and ingestion. (Glatthaar 1982a:7). This occurs when a person with infectious TB coughs or spits/ expectorates, and another person then either inhales droplets containing the bacilli or ingests them in dust particles. This applies in the majority of cases and infection is said to have resulted from human bacilli. Very occasionally, infection may occur when bovine bacilli are ingested through drinking unpasteurised milk from infected cattle.

ii) The tubercle bacilli, once transmitted to a previously un-infected person, cause a 'primary infection' in the mid-lung region, and later a 'secondary focus of infection' develops

in one of a number of possible tissues and organs (see Figure II.1). In the majority of cases this occurs in the apices of the lungs and is thus called pulmonary tuberculosis.

FIGURE II.1

The Natural cycle of TB disease



(Adapted from Glatthaar 1982a:12

iii) As Figure II.1 indicates, most people are able to combat the infection with their cellular defence mechanisms and develop a natural resistance to further infection. In some cases this process is not completed and living bacilli may remain in the lesion which could be reactivated at a later stage if certain predisposing factors, as listed in Figure II.1, are present. If the infected person is unable to develop this resistance, the bacilli multiply and active/infectious

TB[1] results.

To summarise the process described above, the transmission of M tuberculosis from person to person results in active TB if the recipient has never before been exposed to tubercle bacilli, either through natural infection or through a BCG vaccination and developed a cellular immunity. This usually applies to children. Other cases of active TB are generally a result of endogenous reactivation of dormant bacilli in a person who has been previously infected as applies to the majority of adult TB sufferers.

It is important to emphasize the role of socio-economic factors in this process. Glatthaar (1982a:5) states that:

> "Tuberculosis is truly a disease directly influenced by unfavourable socio-economic conditions. Poor housing, overcrowding, malnutrition, lack of hygiene, emotional or physical stress, long hours of work, loss of sleep, lowered resistance, unpasteurised milk, etc., are all factors that favour the development and spread of Tuberculosis".

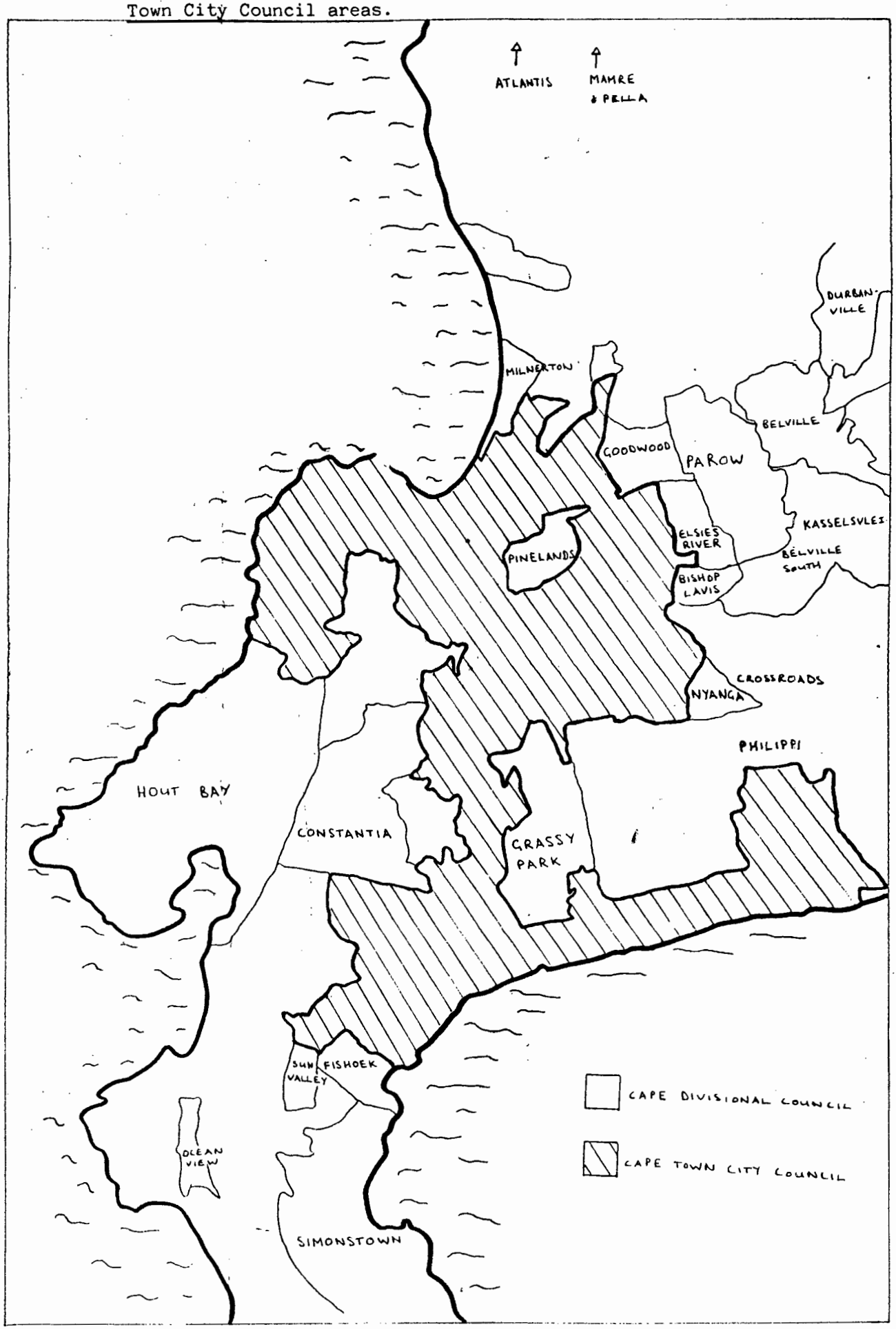
2. Indices of Tuberculosis infection:

Note: Most of the data presented in this section relates specifically to the Cape Divisional Council (CDC) area, (see Map 1). Occasionally, figures for South Africa will be referred to.

---

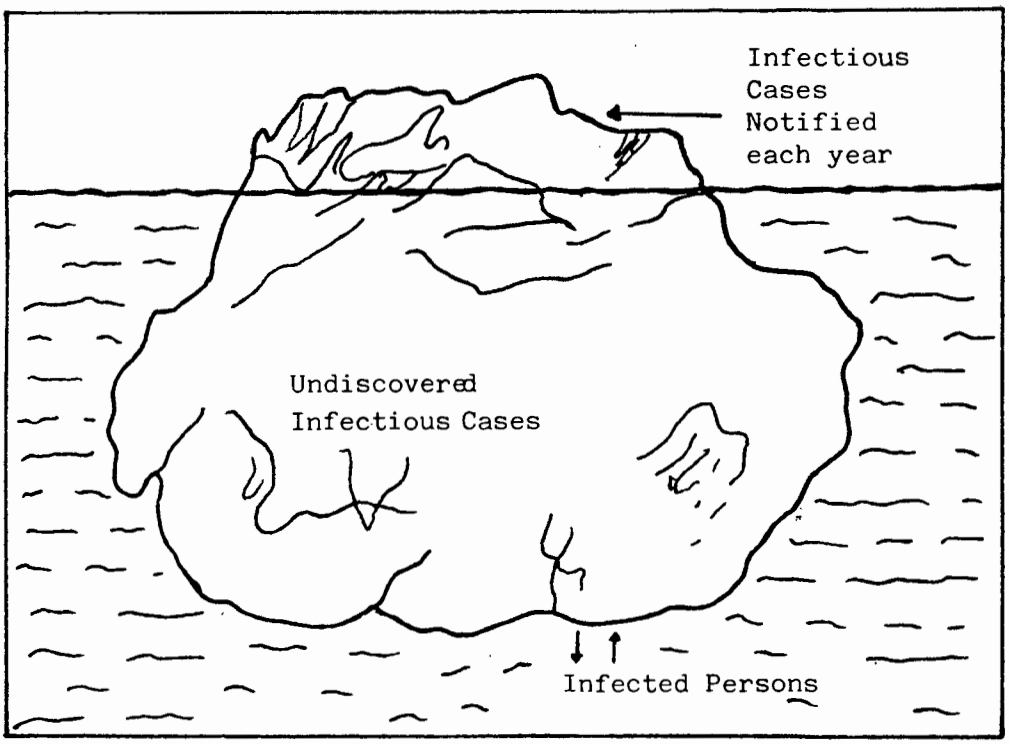
1. Toman (1979:5) clarifies this concept by stating that "...for the purposes of tuberculosis control, a "case" is an individual discharging tubercle bacilli".

MAP 1 Cape Peninsula showing Cape Divisional Council and Cape Town City Council areas.



The previous section indicated that there are two distinct groups of people which TB health workers attempt to monitor and control: i) Infectious TB cases and ii) Infected persons, i.e. those who have dormant bacilli which can be reactivated in the future. Figure II.2, which illustrates the relationship between these two groups, is based on the findings of prevalence studies conducted in South Africa.

Figure II.2: The Tip of the Iceberg



(Adapted from Glatthaar 1982a:2)

There are a number of different measures which can be used to determine and reflect the impact of TB on a given population. These measures can be broadly categorised as either incidence or prevalence rates.

2.1 Incidence rates:

The incidence of a disease is the proportion of a population that contracts the disease within a specified time interval (e.g. a year). Incidence rates are generally expressed in terms of a base, e.g. X cases of TB per 100 000 population, to formulate a rate with a value that exceeds unity. (Peterson and Thomas 1978:1-2,16).

2.1.1 Notification rate:

Data on the annual TB notifications[2] is readily available and is thus the measure used most frequently to indicate the incidence of TB. However, as depicted in Figure II.2, notification rates understate TB incidence. Notification data only accounts for the TB cases detected by the health authorities and is thus an indication of the success of case-finding efforts rather than of the total incidence of infectious TB cases.

Despite these drawbacks, notification rates will form the basis of this analysis of TB incidence in the CDC as it is the only measure for which comprehensive and consistent data is available.

Table II.1 and Figures II.3 and II.4 show the trends in annual notifications and notification rates for the CDC during the past decade.

---

2. In terms of Section 45 of the Health Act, Act 63 of 1977, all forms of TB, except cases diagnosed solely on the basis of clinical signs and symptoms and/or a positive tuberculin test must be notified to the Department of National Health and Population Development (formerly Department of Health and Welfare). (City of Cape Town 1983:161 and Glatthaar 1982a:19).

TABLE II.1 ANNUAL NOTIFICATIONS AND NOTIFICATION RATES IN CDC (1976-1984)

YEAR	RACE*	NOTIFI-CATIONS	ANNUAL % CHANGE IN NOTIFI-CATIONS	POPULATION	ANNUAL % CHANGE IN POPULATION	NOTIFI-CATIONS PER 100 000 POPULATION	ANNUAL % CHANGE IN NOTIFI-CATION RATE
1976	W	32		178 000		17.98	
	C	871		265 000		328.68	
	B	429		50 000		858.00	
	TOTAL	1 332		493 000		270.18	
1977	W	37		184 450		20.06	
	C	923	5.97	286 630	8.16	322.02	-2.03
	B	545	27.04	52 480	4.96	1 038.49	21.04
	TOTAL	1 505	12.99	523 560	6.20	287.46	6.40
1978	W	51		188 210		27.10	
	C	972	5.31	297 280	3.72	326.96	1.53
	B	447	-17.98	54 080	3.05	826.55	-20.41
	TOTAL	1 470	-2.33	539 570	3.06	272.44	-5.23
1979	W	38		193 030		19.69	
	C	1 105	13.68	307 290	3.37	359.60	9.98
	B	710	58.84	55 450	2.53	1 280.43	54.91
	TOTAL	1 853	26.05	555 770	3.00	333.41	22.38
1980	W	32		197 930		16.17	
	C	1 106	0.09	325 010	5.77	340.30	-5.37
	B	644	-9.30	56 920	2.65	1 131.41	-11.64
	TOTAL	1 782	-3.83	579 860	4.33	307.32	-7.83
1981	W	39		201 930		19.31	
	C	1 084	-1.99	337 320	3.79	321.36	-5.57
	B	826	28.26	63 660	11.84	1 297.52	14.68
	TOTAL	1 949	9.37	602 910	3.98	323.27	5.19
982	W	34		212 850		15.97	
	C	1 144	5.54	342 650	1.58	333.87	3.89
	B	1 039	25.79	68 950	8.31	1 506.89	16.14
	TOTAL	2 217	13.75	624 450	3.57	355.03	9.82
983	W	43		217 310		19.79	
	C	1 374	20.10	351 910	2.70	390.44	16.94
	B	1 083	4.23	79 750	15.66	1 357.99	-9.88
	TOTAL	2 500	12.76	648 970	3.93	385.23	8.51
984	W	28		227 620		12.30	
	C	1 520	10.63	365 960	3.99	415.35	6.38
	B	1 202	10.99	100 340	25.82	1 197.93	-11.79
	TOTAL	2 750	10.00	693 920	6.93	396.30	2.87

(DIVISIONAL COUNCIL OF THE CAPE 1984: 152)

)TE: Black population estimates are determined by the Cape Peninsula Administration Board, ıd were based on Census figures until 1982. White and Coloured population estimates are :termined by the C.D.C.

* W = White, C = Coloured, B = Black.

FIGURE II.3

ANNUAL NOTIFICATIONS IN CDC (1976 - 1984)

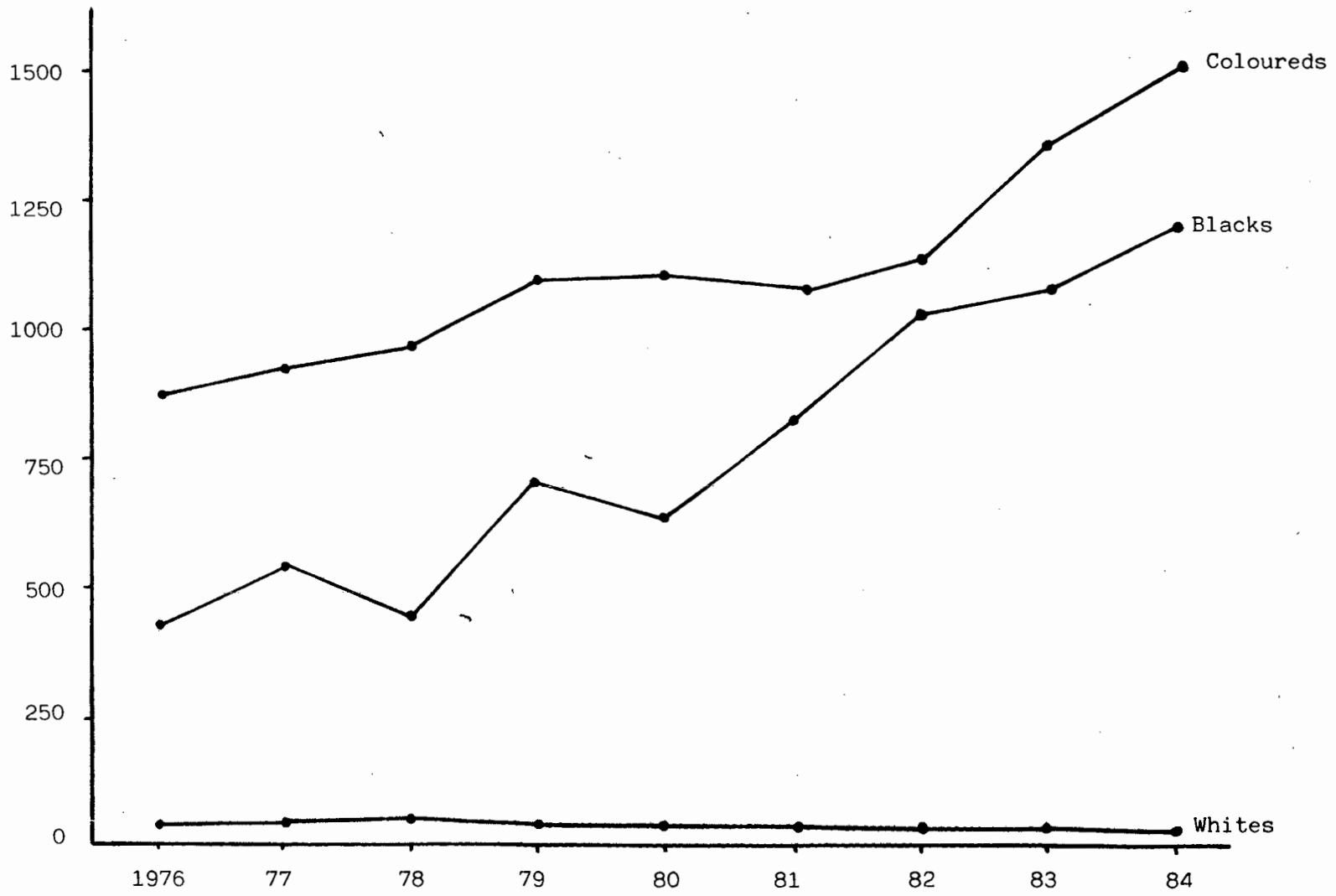
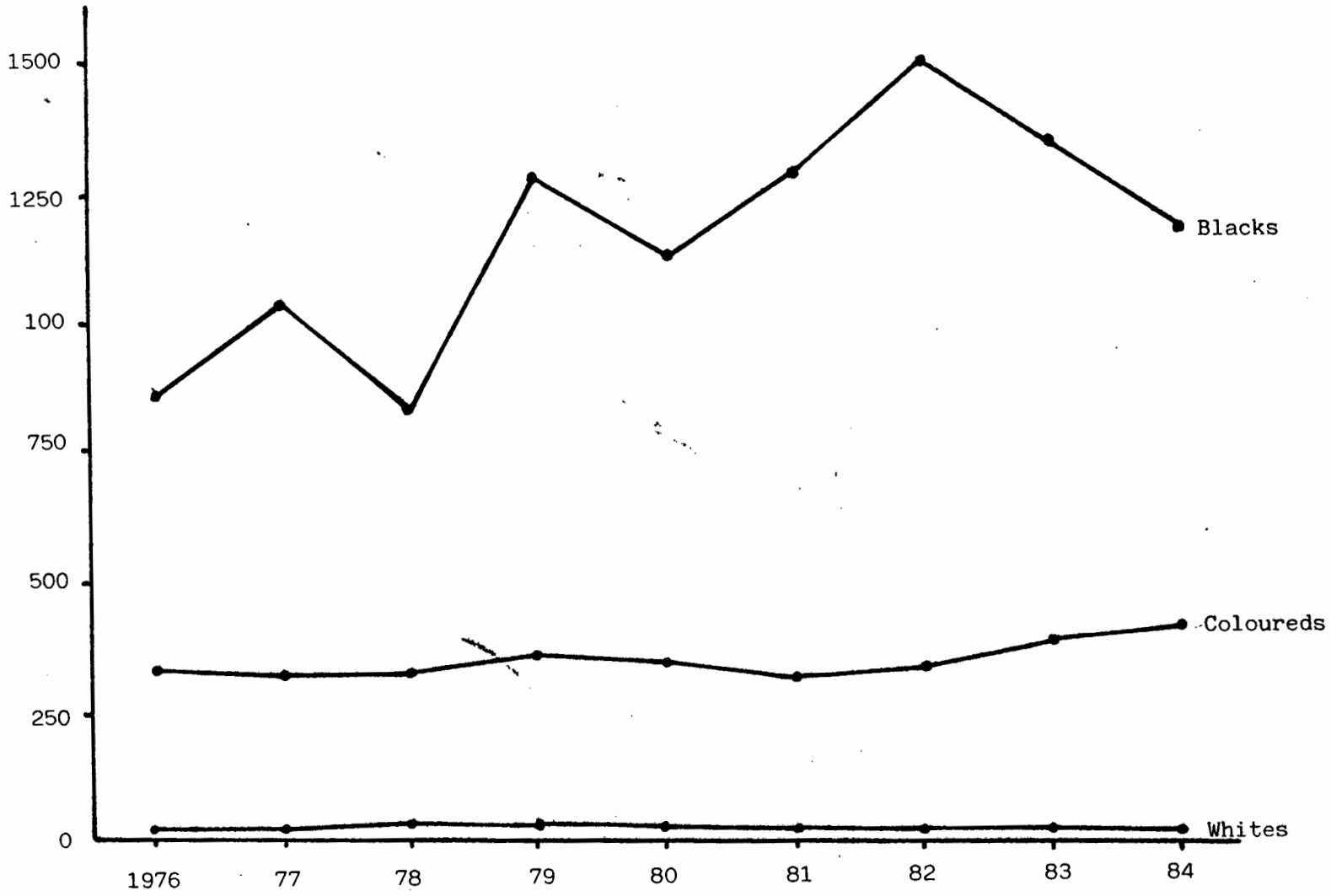


FIGURE II.4

ANNUAL NOTIFICATIONS PER 100 000 in CDC (1976 - 1984)



There have been mild fluctuations both in the total number of notifications and in the notification rates, which are of relatively insignificant magnitude in the white population.

There has been a consistent and significant increase in the number of notifications in the black and coloured populations over the past decade. This can partly be ascribed to population increases.

As notification rates are expressed in terms of a common base, which accounts for differences and changes in population levels, this measure is more functional than the number of notifications in that it permits comparison both between annual figures within each race group and between race groups.

The number of notifications of coloureds has been increasing at a faster rate than the increase in the coloured population which has resulted in a steady increase in the coloured notification rate from 322 (1975) to 415.35 per 100 000 population (1984).

The fluctuations in Black notification rates require a more detailed explanation. It is important to note that the Black population in Cape Town is very transient with a continual influx from and outflow to the Transkei and Ciskei. It is possible that some of these migrants come to Cape Town with the express purpose of obtaining treatment for TB due to the deficiencies in health facilities in these areas. (Shasha 1982).

The Medical Officer of Health for the CDC noted in his 1982 report that:

> "One quarter of the latter [Black] cases are imported i.e. they have lived for less than 6 months in our area".
>
> (Divisional Council of the Cape 1982:6)

It could be argued that the Black notification rates in the CDC are following a normal epidemiological trend and that the TB situation in the Black population is slowly improving.

However, there has been a massive influx of 'illegal' migrants from the Transkei and Ciskei during the 1980's[3] and thus the decrease in the Black notification rates is largely a result of the rapid population growth, although the rate of increase in the number of Black notifications has diminished.

Taking into account the fact that a large proportion of these new migrants settled in squatter camps (either Crossroads, KTC, Nyanga Bush, etc.) where socio-economic conditions which would facilitate the spread of TB exist, it is surprising that the notification rates have fallen so sharply since 1982. Two possible qualifications should thus be considered. Firstly, part of the increase in population figures may be attributable to improved measurement/data

---

3. In the 1984 Race Relations Survey, the Chief Director of the Western Cape Development Board, Mr J Gunther, was reported as stating that the number of 'illegal' Blacks in the Western Cape had risen to approximately 100 000. (Half of these 'illegals' resided in the Crossroads squatter camp alone) (South African Institute of Race Relations 1984:352). In 1986, the deputy City Engineer for housing, Mr Neville Riley, estimated that the influx of Blacks into the Cape Town metropolitan area had risen from 1000 monthly in 1980 to 9000 in February 1985. (The Argus 13/5/86)

collection procedures and secondly, the increased population placed additional pressures on the staff and facilities at the Nyanga and Crossroads clinics which could have resulted in a relatively lower proportion of TB cases being found.

The trends in TB notification rates for the various race groups have been summarised in the following observation from a report on the 1985 Tuberculosis Research Institute (TBRI) symposium:

> "According to one theoretical model, the morbidity rate due to TB takes the predictable form of an epidemic wave which increases, reaches a peak, and then falls, running its course in about 300 years. This wave has probably reached a late stage in whites..., and an intermediate stage in blacks. Among coloureds the epidemic wave may still be in its ascending stage."
>
> (Townshend and Aalbers 1985:8)

Another significant feature of the data presented in Table II.1 and Figure II.4, is that black notification rates are substantially higher than coloured notification rates. In 1983, 43.3% of the total notifications for the CDC arose from the black population which comprised a mere 12.3% of the total population.

Although this situation may partly be explained in terms of the coloured and black populations being at different stages of the TB epidemiological trend, another important reason for the notification gap is the difference in socio-economic conditions. The influence of socio-economic factors is illustrated in Table II.2.

A few of the CDC coloured areas, for which data was available are compared with a Black area. Although the relationship between

TABLE II.2 Relationship between TB notification rate and socio-economic indicators

	Notification Rate Per 100 000 Population	Density per Dwelling/ people per Habitable room	Personal Income (Rand per Month) Males	Females
Belhar	411.6	1.31	328.91	148.65
Bishop Lavis	343.3	1.84	178.02	109.25
Kasselsvlei (Bellville South)	416.9	1.95	250.81	182.96
Elsies River	515.4	1.81	182.98	122.57
Uitsig	743.9	1.93	197.73	184.37
Ravensmead	617.6	1.93	209.15	129.07
Grassy Park)		1.38	279.71	158.26
)	175.7			
Lotus River)		1.54	257.34	139.26
Ocean View	204.1	1.81	206.23	106.85
Nyanga	983.3	2.62	132.46	87.57

(Notification data from 1983 CDC Notification register and unpublished records of CDC, other data from Patel (1984) - based on 1980 Census figures.)

socio-economic indicators and the TB notification rate is not altogether consistent within the coloured areas, this information does provide some indication of the role of socio-economic factors, especially when comparing the coloured areas with the black area.

2.1.2 Mortality rate:

Annual mortality rates are another index of disease incidence, although they do not have as strong a correlation with the total number of infectious TB cases as some other measures, and are influenced by variations in the effectiveness of treatment regimens.

Table II.3 TB Mortality : CDC (1980 - 1984)

	Year				
Race	1980	1981	1982	1983	1984
Whites	0	2	1	2	2
Coloureds	27	46	37	41	38
Blacks	7	35	14	13	26
TOTAL	34	83	52	56	66

(Divisional Council of the Cape 1980:45, 1981:40, 1982:54, 1983:48, 1984:47)

Except for 1981, there has been a steady increase in the mortality due to TB in the five years from 1980 to 1984.

2.1.3 Annual risk of tuberculous infection:

Styblo[4] (quoted in Fourie 1983) defines the risk of tuberculous infection as:

> "... the proportion of the population which will be primarily infected, or reinfected (in those who have been previously infected) with tubercle bacilli in the course of 1 year, and is usually expressed as a percentage or as a rate."
>
> (Fourie 1983:182)

This measure thus attempts to estimate a broader group of people than that reflected in notification data.

The Tuberculosis Research Institute (TBRI) of the South African Medical Research Council (MRC) has conducted extensive tuberculin tests[5] since 1972, to establish figures for the risk of TB infection in specified years and the annual change in this risk. The results of these surveys are summarised in Figure II.5 and Table II.4.

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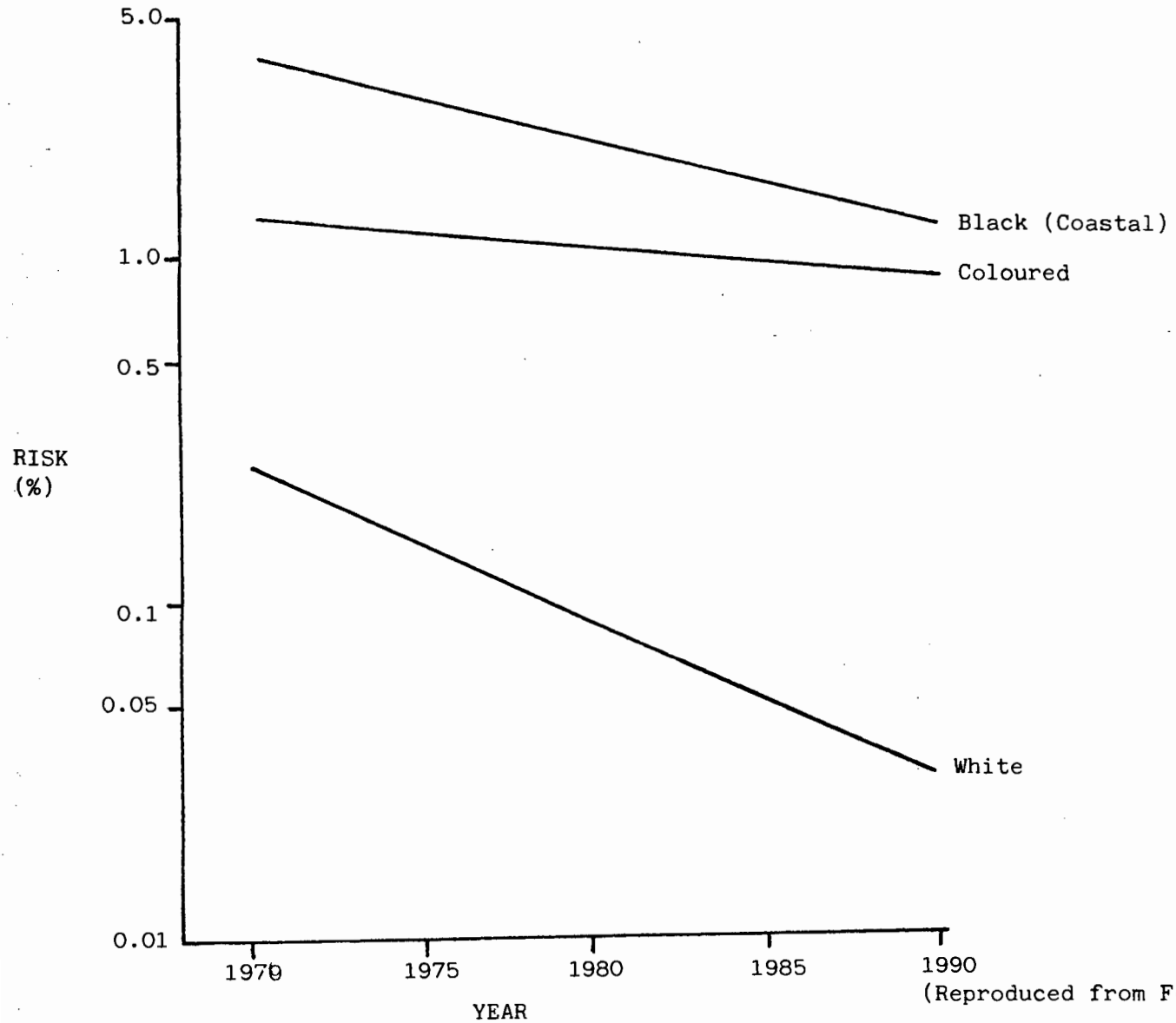
4. Styblo, K. 1980 Recent advances in epidemiological research in Tuberculosis. Advances in Tuberculosis Research, 20,1.

5. The Mantoux test was used in these surveys which entails the intradermal injection of Tuberculin PPD (Purified Protein Derivative). If a person has been previously infected with tubercle bacilli, an induration, i.e. hardened swelling, will develop at the injection site within about 72 hours. Whether the person has developed cellular immunity or not and whether they are possible infectious cases is determined according to the size of the induration. (Glatthaar 1982a:10).

Figure II.5 Estimated Risks of Tuberculosis Infection and their trends in South Africa between 1970 & 1990. TBRI Survey Data 1972 - 1985.



(Reproduced from Fourie:19

Table II.4 TB infection in Southern Africa, 1972-1985

SURVEY	MEAN YEAR*	MEAN AGE(yrs)*	NO. TESTED*	RISK OF INFECTION 1985	ANNUAL CHANGE IN RISK
Coloured	76.6	6.9	13 713		
	81.4	6.9	4 003	0.9%	-2.2%
Black (Coastal)	76.2	7.2	8 262		
	82.2	7.2	3 788	1.6%	-6.2%

(Reproduced from Fourie & Knoetze 1986)

* Periods of Data Intake : 1972-78 and 1979-85

Mean year necessary as different areas surveyed in different years e.g. CDC surveyed in 1978 & 1979, Durban in 1976 & 1977.

Mean age refers to the age of children included in survey.

The figures for the group Black (Coastal) are based largely on surveys conducted in the Eastern Cape, Durban and the Cape Divisional Council.

The following observations, based on data gathered in the TBRI surveys, were made in the 1983 MRC annual report :

> "Coloured children in Pretoria and in the Cape Divisional Council area have similar incidence rates of 13 per 1 000 (RSA 9 per 1 000), which are decreasing slowly at the rate of no more than 3% annually. However, the annual birth rate of 2% cancels out the effect of this slight downward trend and there may very well be an increase in the number of TB infections and disease cases. The annual rate of TB infection for Blacks in the Cape Divisional Council (CDC) area is 16 per 1000, which compares favourably with the RSA rate of 13 per 1 000. The annual downward trend in this group is 5-7%."
>
> (S.A. Medical Research Council 1983:22)

These findings support the general trends derived from the notification data.

2.2 Prevalence rates:

The prevalence of a disease is defined as the proportion of a population with the disease at a particular point in time, (Peterson and Thomas 1978:1) and can either be expressed as a percentage or in terms of a predetermined base (as with incidence rates). Prevalence is an indication of the total burden of a disease on the population being studied (Peterson and Thomas 1978:14), and thus TB prevalence statistics include both infectious and infected persons (see Figure II.2).

Figure II.6 shows the differences in prevalence rates for different age groups of children, estimated from the TBRI tuberculin surveys.

Figure II.6 Average Prevalence rates of TB infection in S.A. over the period 1974-1980 according to race and age.

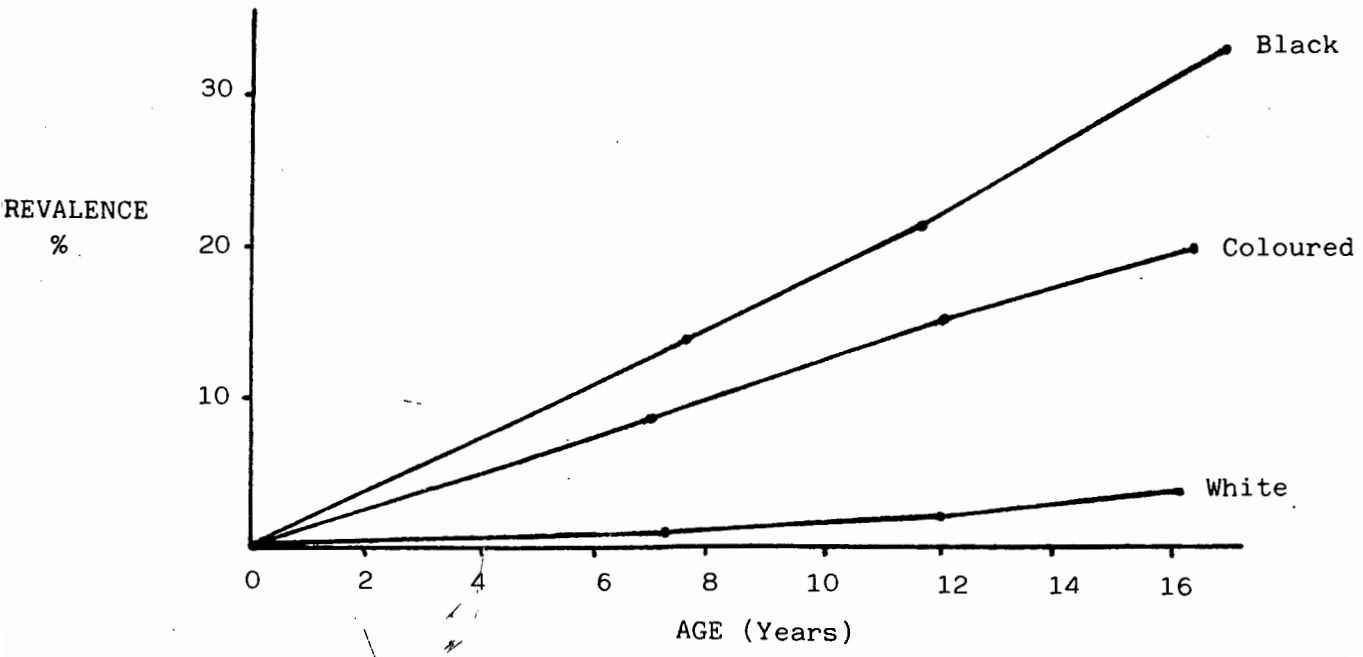


Table II.5 gives the prevalence estimates based on data for the 5-9 years age group. As vaccination of school-going children occurs on a large scale now, the size of indurations of children in the 5-9 years age group who will only have been vaccinated at birth, are less likely to be affected by BCG-induced sensitivity.[6] (Fourie 1983:184).

Table II.5 TB Infection Prevalence in S.A., 1972 - 1985

SURVEY GROUP	MEAN YEAR*	MEAN AGE(yrs)	NO. TESTED*	INFECTION PREVALENCE
Coloured	76.6	6.9	13 713	8.3%
	81.4	6.9	4 003	7.5%
Black (Coastal)	76.2	7.2	8 262	22.8%
	82.2	7.2	3 788	16.3%

*Periods of Data Intake: 1972-78 and 1979-85

(Reproduced from Fourie & Knoetze 1986:387)

It is evident from these figures that there has been a noticeable reduction in TB infection prevalence in S.A. over the past decade.

6. Sensitivity to Tuberculin PPD can either be induced by previous vaccination with BCG or by natural infection with tubercle bacilli. TB prevalence data attempts to estimate the latter category of infected persons (Fourie 1983:182-183).

2.3 Summary of TB infection indices:

The risk of tuberculous infection is decreasing in the CDC, although almost negligibly in the case of Coloureds, and thus there is a decrease in the rate at which the pool of infected persons is being supplemented (see Figure II.2). In addition, the TB infection prevalence is decreasing which indicates that the combined pool of infected and infectious persons is being supplemented at a slower rate. Until such time as these pools actually begin to decrease in size, it is to be expected that more people will be notified each year, although the increased notifications could also indicate an improvement in the TB case-finding methods.

3. Preventive measures and curative regimens for the control of TB.

Much of this discussion refers specifically to South Africa or the CDC. It is important to note, however, that this information is based on international research and experience in the field of TB prevention and treatment. The procedures implemented in South Africa are in line with generally accepted international practices. The most comprehensive summary of TB research findings is contained in Toman (1979), a World Health Organisation publication.

The only TB procedure on which international agreement has not been reached is the BCG vaccination. Studies conducted in various parts of the world found that BCG vaccinations provide effective protection against tuberculosis infection in up to 80% of the vaccinated population in some cases, while providing no protection in other cases. (See Section 1.1.2 of Chapter IV). These findings have resulted in considerable debate as to how 'useful' it is to vaccinate an entire population. In addition, certain organisations, such as the British Thoracic and Tuberculosis Association (1975), are trying to estimate at what point a BCG vaccination programme is no longer justified, in terms of cost-effectiveness criteria. (Stilwell 1976).

The Department of Health and Welfare (now the Department of National Health and Population Development) proposed a national TB control programme in 1979. Four measures were regarded as priorities i) TB health education to encourage greater community involvement, ii) treatment of notified cases must contain the drug Rifampicin and be fully supervised, iii) case-finding efforts must be increased once the previous two measures have been implemented, and iv) all children must receive BCG vaccinations. (Glatthaar 1982a:22) and Glatthaar 1982b:39).

The aim of these measures, which are currently being implemented by health authorities in S.A., is to reduce the pool of infectious cases (see also Figure II.2) and to improve protection against

TB infection by means of BCG immunisation. (Glatthaar 1982a:23)

Once these measures are in force in most areas, a second phase of the national programme will be ambarked on, which will focus on attempts to reduce the pool of infected persons (see Fig II.2) and to reduce the risk of endogenous reactivation. This can be achieved by improving socio-economic conditions and providing secondary chemoprophylaxis for persons who have a positive tuberculin test reading.[7] (Glatthaar 1982a:23)

Many of the national TB control programme measures have been an integral part of the CDC TB control programme for a number of years already.

3.1 BCG vacination:

It is compulsory in S.A. for all children to be vaccinated before 6 months of age. (Glatthaar 1982a:19). The vaccination policy of the CDC is as follows: Children are vaccinated at birth, at the age of 3 months if no BCG scar is visible, when they enter school (Pre-school or Sub A) and in Std 5 (Coloured) or Std 8 (White). (Divisional Council of the Cape 1982:191 and Thomson & Myrdal 1984a:8-9).

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7. Positive tuberculin reactors with the possibility of the existence of active tubercle bacilli can be treated with a drug such as Isoniazid (INH) to ensure complete sterilization of the secondary lesions.

3.2 Health Education:

One of the main objectives of health education is to create a greater awareness of the symptoms of TB within the broader community, in an attempt to encourage people displaying these symptoms to present themselves at a clinic for investigation at an early stage, and to thus facilitate passive case-finding. More generally, with increased knowledge of the nature of TB and its predisposing factors, much of the stigma attached to this disease can be averted and the community can play a role in improving socio-economic conditions and assisting with the supervision of treatment.

As reported in a survey undertaken by Thomson and Myrdal (1984a:10) the CDC conducts general TB education

> "...at bus stop queues, in the street, 'anywhere',...."

Particular attention is paid to educating and enlisting the support of teachers and employers who can provide supervision for the treatment of TB patients at school and work. It is felt that if employers are aware that TB sufferers are rendered uninfectious within one or two weeks of starting treatment, they will be less inclined to dismiss workers who contract the disease.

Health education is also directed specifically at TB patients. This takes place at clinics and during house visits, to motivate them to attend for supervised therapy on a regular basis.

The CDC directs some of its health education efforts at G.P.'s,

day-hospital doctors and paramedics with the objective of alerting them to the possibility of TB in persons presenting with certain symptoms, given the high incidence of this disease at present. Medical practitioners are encouraged to X-ray such patients and to refer them to CDC clinics without delay. (Thompson and Myrdal 1984a:10, and Divisional Council of the Cape 1982:188-189).

3.3 Screening and Case-finding:

3.3.1 Diagnostic Techniques

i) Chest X-rays - the CDC posesses two mobile radiographic units which produce miniature (100mm) X-rays for screening and to assess the progress of patients during treatment.

ii) Bacteriological investigation - Adult patients and suspects are asked to produce a sputum specimen which is sent to the State Health Laboratory in Cape Town for investigation. The sputum undergoes two examinations to establish whether tubercle bacilli are present, which would confirm that a person is an infectious TB case. In the first test (Direct Microscopy), a slide of a smear of the sputum is prepared and microscopically examined soon after the specimen is obtained, while in the second test (Sputum culture) a culture of the sputum is derived before examination. In addition, a Differential test may be performed on a sputum culture to confirm that the bacilli are <u>M tuberculosis</u>.

iii) Tuberculin testing - CDC uses the Heaf tuberculin test in the screening and diagnosis of children. Tuberculin PPD is

injected into the epidermis by means of a spring-loaded 'gun' and a grading system is used to classify the result, according to the size of the induration (Grade 0 for a negative result - Grade IV for a strongly positive reaction). (See also footnote 5).

Radiological investigation is used extensively by the CDC in their screening procedures and it is thus important to highlight the inadequacies of this technique. Lesions visible on a chest X-ray may not necessarily be attributable to TB, as some other lung diseases have a similar appearance. (Toman 1979:28). In addition, it cannot be indisputably determined on the basis of an X-ray alone, that active tubercle bacilli are present in a lung lesion.

Several studies have been conducted to assess the reliability of chest X-rays as a means of diagnosing TB. In these studies, a number of persons, trained in the reading of X-rays, were asked to read a set of X-rays (in some cases this procedure was repeated at a later stage). It was found that

> "The level of disagreement between readers was about 27-30% and a single reader was likely to disagree with himself in about 19-24% of cases".
>
> (Toman 1979:32).

The practical implications of these discrepancies can be illustrated by the following findings of a study, as reported in Toman (1979:35 - 36).

> "If treatment had been restricted to patients in whom 50% or more of the readers judged cavitation to be present,

> only one-third of those with positive sputum would have received treatment. On the other hand, among those who were regarded by 50% or more readers as probably tuberculous and in need of treatment, about four or five times as many bacteriologically negative persons as sputum-positive patients would have received treatment..."

Thus, there is a possibility of two types of diagnostic errors if diagnosis is based purely on an X-ray: False negative/non-diagnosis and false positive/misdiagnosis. The cost-effectiveness implications of this are discussed in Section 4.2.1 of Chapter V.

With regard to bacteriological tests, sputum culture examination yields two or three times as many cases as direct microscopy, which detects mainly those TB sufferers who discharge a high concentration of bacilli (i.e. the more infectious cases). Various studies have shown that the level of agreement in the results of sputum smear investigations performed by trained microscopists can be as high as 93%.

The greater reliability of bacteriological tests in TB case-finding, has been stressed by both the World Health Organisation (WHO) and the International Union Against Tuberculosis (IUAT). (Toman 1979:47). The generally accepted and recommended case-finding procedure is summarised in Glatthaar (1982a:15):

> "While bacteriology may suffice for the diagnosis of TB, radiological investigation must always be accompanied by bacteriological investigation to reduce misdiagnosis"

3.3.2 Case-finding regimens in the CDC

i) Suspects - The Health Department of the CDC has prescribed

that the following tests be conducted on persons who are referred to or present themselves at a CDC clinic with symptoms indicative of TB. Children under the age of 15 years are to have a Heaf test and radiological examination. Direct microscopy, sputum culture and X-rays are to be used in the diagnosis of adults, based on the assumption that persons who are 15 years of age and older, are capable of producing a sputum specimen.

It is policy in the CDC clinics to begin treatment of a patient on the basis of a positive radiological and clinical examination, without awaiting bacteriological confirmation of the diagnosis. (Thompson and Myrdal 1984a:4). The implications of this are discussed in Section 4.2.1 of Chapter V.

ii) Management of contacts - Clinic staff are advised to record the names of family members and other persons who have been in contact with recently notified TB cases (e.g. fellow employees) and to whom tubercle bacilli may have been transmitted. Contacts are then requested to present themselves at a CDC clinic for investigation, by means of home visiting or by phoning or writing to employers. The prescribed investigation procedure for contacts is the same as for suspects.

It should be noted that the primary determinant of the risk of infection in contacts, is not the intimacy of contact with an infected patient, but the bacteriological status of the patient. This risk is highest where the patient has a positive direct microscopy result (i.e. is discharging a high concentration of tubercle bacilli). (Toman 1979:66).

iii) Mass screening campaigns -

Mass X-ray screening campaigns on a regular basis (e.g. annually) are no longer conducted. Studies have shown that most TB cases develop within a relatively short period of time (a few months) and most cases would thus probably not be detected by this case-finding procedure. (Toman 1979:60-61)

The CDC provides a pre-employment radiological screening service for employers. However, through educating businessmen about the symptoms and nature of TB, the CDC has attempted over the past few years to reduce the demand for screening of workers. (See Addendum II). In 1983, approximately 6 256 X-rays were performed during pre-employment screening, whereas in 1984, there was no record of mass radiological screening of workers. In 1984, only those workers with TB symptoms who were referred to clinics by employers, were X-rayed as TB 'suspects'. (Divisional Council of the Cape 1983:153 and 1984:157).

In addition, the CDC conducted an experimental mass X-ray screening campaign in Leonsdale (a coloured residential area adjoining Elsies River) in 1983. (The results of this survey are discussed in Section 1.5.1 of Chapter IV).

Mass tuberculin testing of children at schools was discontinued in 1982. The current procedure is to identify scholars who are underweight (loss of weight is a symptom of TB) by routine weighing procedures, and to refer them to a clinic.

The MRC has compared these different case-finding procedures to

assess their relative effectiveness. The results of their survey, conducted in the large South African cities, were as follows:

> "The mean case yield achieved when screening an entire work force, regardless of symptoms, was 0.3%. Examination of family contacts of known TB cases gave a mean yield of 5% and selective screening of symptomatic cases gave a similar yield of 4%. Passive case-finding, i.e. screening self-presenting cases, gave a mean yield of 7%. These yields relate to cases which are radiologically positive for TB, but the yield of the priority cases - those which are actually infectious - will only be about a quarter of this."
>
> (S.A. Medical Research Council 1984:14)

3.4 TB treatment regimens:

Prior to the introduction of Rifampicin (a powerful bactericidal drug i.e. a drug that kills/sterilizes TB bacilli), most curative regimens for TB consisted of Isoniazid (INH), Streptomycin, Pyrazinamide (PZA) and possibly Para-aminosalicylic acid (PAS), Thioacetazone or Ethambutol (EMB), administered for a period of about 12 months (in some cases, for 24 months). Currently, short-course regimens lasting for 6 months or more, and containing Rifampicin, are the preferred means of treatment for TB. In general, short-course regimens consist of two phases; during the first or intensive phase, daily treatment comprised of four drugs is administered for at least 2 months and during the second or continuation phase, one or more drugs are taken on a daily or intermittent basis.

Short-course treatment regimens are an important development as they relieve the work-load of clinic staff (especially if treatment is fully supervised) and reduce the rate of patient default, as

it is easier to motivate a patient to attend for regular treatment for a shorter period of time. (Angel 1983:2).

Numerous controlled trials have been undertaken to assess the effectiveness of various short-course regimens. The studies have shown that short-course therapy can achieve similar, and in some cases better, results in terms of cure rates and relapse rates, than standard/conventional regimens. (Angel 1983, Aquinas 1982, Toman 1979 and Tibbit 1982.)

The CDC was the first South African local authority to introduce short-course TB treatment in 1973. This is now the recommended treatment regimen in terms of the National TB control programme.

The short-course regimen prescribed by the Medical Officer of Health for the CDC is as follows :
Daily, fully superised administration of 100 doses of Isoniazid (INH) and Pyrazinamide (PZA) and 60 doses of Rifampicin and Streptomycin to adults, and 100 doses of INH and Ethambutol and 60 doses of PZA and Rifampicin, to children.

3.5 Secondary Chemoprophylaxis:

CDC policy is to treat infected children with positive Heaf tests, and in particular, child contacts of cases who have positive bacteriological results, (Thomson and Mydral 1984a : 5&7) in an attempt to steralize tubercle bacilli and thus preventing the development of active disease. The prescribed regimen is 60 doses of INH.

4. Summary and formulation of problem to be evaluated in this study:

As explained earlier, the overall aim of the current phase of the national TB policy is to reduce the pool of infectious TB cases and to provide protection against TB infection.

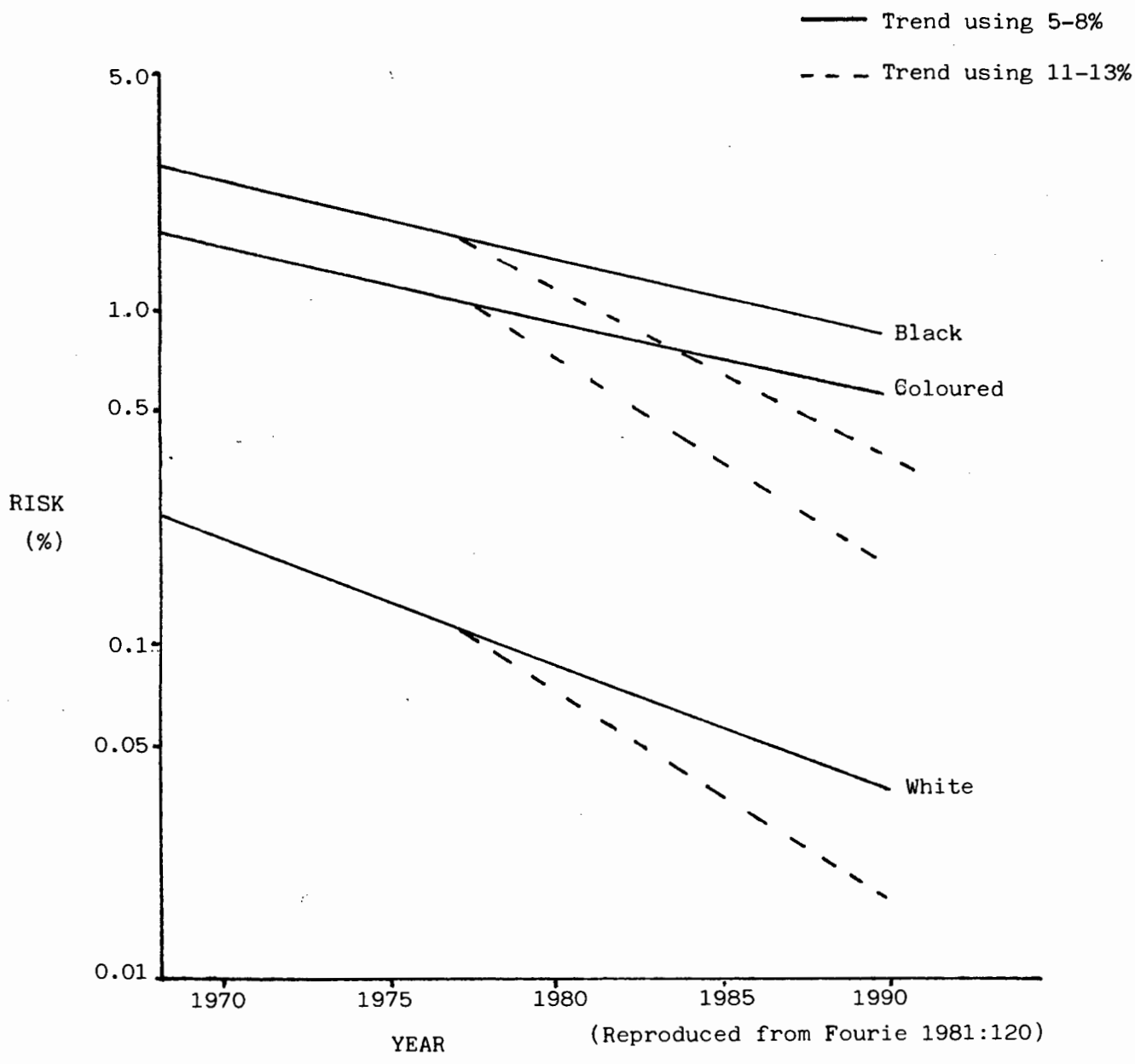
Changes in the annual rate of TB infection can be used to illustrate the practical implications of this programme. Kleeberg (1982:22) has stated that studies have established that the rate of TB infection decreased by about 5-8% per year until 1977, and thereafter by 11-13% per year. Fig II.7 indicates the projected trends based on two different estimates.

Kleeberg (1982:22) examines some possible causes of the declining annual rate of infection, based on the findings of international research:

> "Of this annual decrease in the infection risk 2-3% is probably due to the intensive BCG campaign, ... 5% of the annual decrease is usually caused by improvements in living standards, which are particularly marked in towns. The remaining 4-6% of the annual decrease must surely be due to the effect of 20-30 years of case-finding and chemotherapy".

As these various preventive and curative procedures for TB are implemented more extensively and their effectiveness is increased, the downward trend could be accelerated.

Figure II.7 Annual risks of TB infection and their trends in South Africa. (SAMRC Tuberculosis Research Institute survey data 1974 - 1980).



(Reproduced from Fourie 1981:120)

The problem to be evaluated in this study can now be presented : Given i) the limited economic resources available for the control of TB, and ii) the range of preventive procedures and curative regimens that can be employed to combat TB, the most cost-effective combination of preventive and curative procedures for the mass control of TB must be determined.

The desired outcome (improved control of TB) can be more explicitly stated in terms of the above-mentioned TB measure, as, attempting to achieve the greatest possible decrease in the annual risk of TB infection through the implementation of a coherent TB programme, determined using cost-effectiveness criteria.

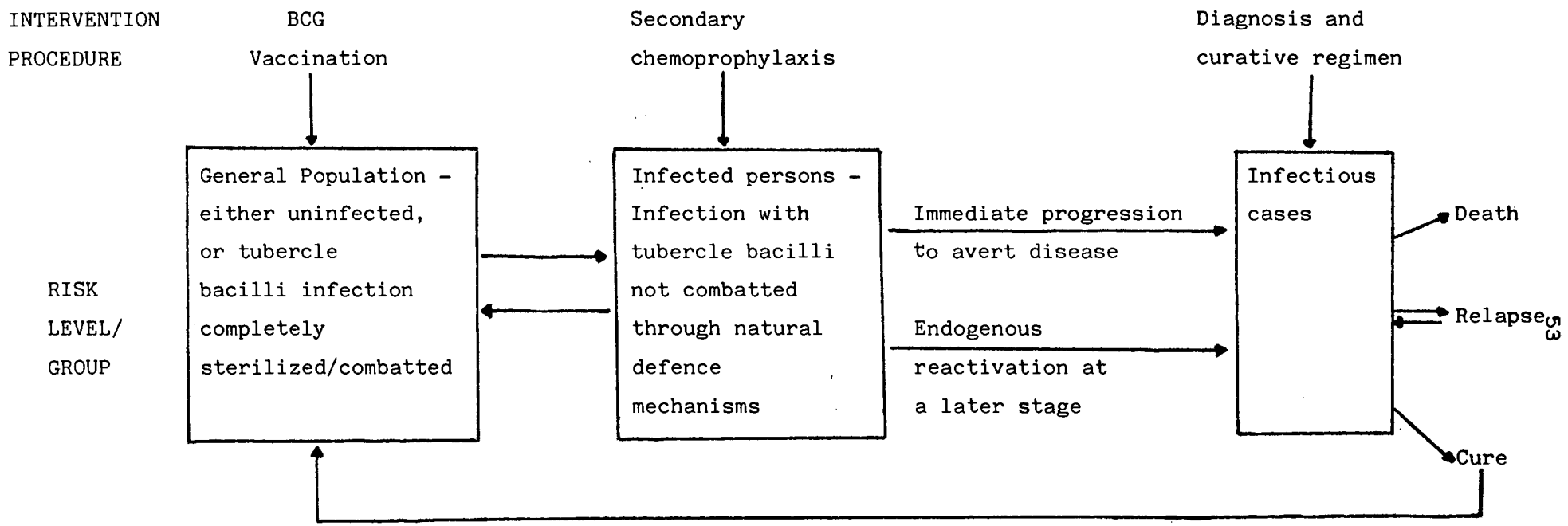
The method by which the most cost-effective combination of preventive and curative procedures is determined, must be examined in more detail.

It is necessary to differentiate between the roles of each procedure. This is achieved by demonstrating their respective applications to three defined groups of people who face different levels of risk with respect to TB : a) The general population, b) Infected persons and c) Infectious persons.

Figure II.8 presents a flow chart of the relationship between these groups and the relevant preventive or curative intervention procedures which can be implemented in each case.

The preventive and curative procedures listed in Figure II.8 can be seen as 'catch-nets', i.e. methods of preventing a person from proceeding to a higher risk level. Examples of this process are : An infected person may become infectious, i.e. progress to overt disease, if the tubercle bacilli infection is not combatted through natural, cellular defence mechanisms or sterilized through prophylactic treatment; while an infectious person may face the risk of death unless diagnosed and treated adequately.

Figure II.8 Relationship between TB procedures and TB risk groups.



There are two major considerations when determining what combination of these procedures to implement:

i) The effectiveness of each procedure, e.g. even if an entire population were given BCG vaccinations, some would proceed to the next level of risk as the protection afforded by BCG against tuberculous infection is not 100%. (Explained further : Section 1.1.2 of Chapter IV).

ii) The cost of the procedure may be so great that it would not justify the application of the procedure to the entire population of each risk level.

These two considerations will be combined in the form of a cost-effectiveness ratio for each procedure. It can then be determined how comprehensive/extensive each 'catch-net' should be i.e. what priority each procedure should be given and what combination of procedures should be implemented.

Addendum II Letter to Employers in CDC area

THE DIVISIONAL COUNCIL OF THE CAPE

COMBINED HEALTH CONTROL SCHEME

Including the Municipal areas of Bellville, Durbanville, Fish Hoek, Goodwood, Milnerton, Parow, Pinelands and Simon's Town.

44 WALE STREET
CAPE TOWN
8001

L.R. Tibbit
M.B., Ch.B., D.C.M.
MEDICAL OFFICER OF HEALTH

P.O. BOX 1073
CAPE TOWN
8000

Telephone: 24-2200 ext.
Telex: 57-21495
Ask for:
Our Reference:
Date:

TUBERCULOSIS CASE FINDING AND EMPLOYERS

Routine periodic screening of employee populations for tuberculosis by mass miniature X-Ray programmes has not been found to be cost effective and is no longer recommended by the World Health Organisation or the Tuberculosis Research Institute in South Africa. This is in line with our own experience in the Western Cape where the pickup rate of active TB in mass miniature chest X-Ray screening has been less than 2 per 1 000.

The present policy of the Divisional Council of the Cape is to take chest X-Rays :

(1) In those who report symptoms - chronic cough, weight loss or night sweats
(2) Of close contacts (i.e. those who share accommodation)
(3) As part of the pre-employment process in Coloureds and Blacks (being at higher risk than Whites of developing TB) who have not had a recent chest X-Ray.
(4) Those not X-Rayed prior to taking up their present employment.

Employers can help in the fight against tuberculosis by :-

(a) Not discharging a worker with TB. Provided he takes his treatment regularly he will not infect others.
(b) Encouraging those who have a chronic cough to report for a Chest X-Ray examination
(c) Inviting a health educator to come and talk to your staff about tuberculosis.

X-Rays are usually arranged through Mrs. Slingsby of the X-Ray Section at Vasco (021) 591-5152.

Any further information may be obtained by telephoning the Health Department in Cape Town (021) 24-2200.

Yours faithfully,

MEDICAL OFFICER OF HEALTH.

Hierdie brief sal in die ander amptelike taal aan u geaddresseer word indien skriftelik versoek binne sewe dae vanaf bovermelde datum.

CHAPTER III

SAMPLE OF CDC TUBERCULOSIS PATIENTS

Introductory Note:

Despite the fact that Tuberculosis is recognised as the most serious health problem facing authorities in the Cape Peninsula at present, very few published statistics relating to the treatment of TB patients are available. For this reason, it was decided that a sample of the records of TB patients, treated at the CDC clinics during 1983, should be examined.

The results of this sample indicated that the treatment regimen prescribed by CDC Health authorities is not strictly adhered to by the clinics. Clinic doctors are permitted a certain amount of flexibility in the application of the prescribed regimen.

The data provided by this sample is used in the cost-effectiveness analysis presented in Chapter IV, as it best describes the treatment regimen actually implemented at CDC clinics. Thus, the sample results are presented in some detail in this chapter.

1. Methodology:

1.1 Sample Population:

The only composite record of TB patients treated within the CDC jurisdiction is the Tuberculosis Notification Register, which is

compiled chronologically and divided into the respective residential areas which comprise the Combined Health Control Scheme of the CDC. A random sample of 300 patients, which constituted 12% of all notified cases of pulmonary TB in 1983 (9.3% of white TB patients, 12.95% of coloured TB patients and 10.9% of Black TB patients), was drawn from the register and their personal details (name, address, age and sex) were recorded.

The treatment records of the selected patients were then examined at the 16 major CDC clinics, during August 1985. (The patient records of satellite clinics are housed at the central clinic in each area). Before this data collection process could be completed, access to the Black townships of Nyanga and Crossroads was restricted and the clinics in these areas were temporarily closed. CDC doctors have not entered these areas since August 1985, and X-ray machines were only authorised to enter Nyanga again in July 1986. As a result it was difficult to obtain permission to complete the data collection at Nyanga Clinic until early in 1986. This has not significantly affected the data, as most follow-up work on cases notified in 1983 had been completed by the time of the initial data collection (i.e. August/September 1985).

The breakdown of the sample population by clinic is shown in Table III.1.

Table III.1 Breakdown of sample population according to clinic

Name of Clinic	No of Patients	% of Sample Popula-tion
Atlantis	14	4.7
Durbanville	5	1.7
Bothasig/Milnerton	4	1.3
Vasco (Goodwood)	4	1.3
Kasselsvlei (Bellville)	16	5.3
Ravensmead (including Uitsig)	39	13.0
Elsies River (including Leonsdale)	34	11.3
Matroosfontein (including Clarkes Estate)	22	7.3
Bishop Lavis	14	4.7
Belhar	11	3.7
Philippi	11	3.7
Lotus River/Grassy Park	9	3.0
Ocean View (including Simonstown)	4	1.3
Hout Bay	2	0.7
Nyanga	63	21.0
Crossroads	48	16.0
TOTAL SAMPLE POPULATION	300	

1.2 Replacements to the Original Sample:

40 records of patients included in the sample could not be found at the clinic located in the area in which they were resident, and were replaced by other patients' records selected at random at the respective clinics.

The CDC Notification Register does not state the source of notification and thus it is difficult to trace a patient who is treated at a clinic in an area other than that recorded in the register as his/her residential address. This often applies to patients who are treated at their workplace. In addition, patients who were notified while being treated at a hospital may not have reported for treatment at a clinic after being discharged, for a variety of reasons: i) Treatment may have been completed at the hospital and the patient failed to report to a clinic for follow-up surveillance; ii) The patient may have defaulted from treatment on discharge from the hospital; or iii) The patient's residential address may have changed in the period between notification by a hospital and reporting at a clinic for further treatment.

1.3 Information Recorded from Patient Folders :

The form used to record information from patient folders is reproduced in Addendum III.

In summary, the details recorded were : -

a) Personal details (including employment status);

b) Process by which the TB case was discovered;

c) Results of diagnostic tests (to determine, in the case of adults, how many patients were bacteriologically confirmed as suffering from active TB);

d) Length of 'bed stay' if a patient was hospitalised;

e) Treatment regimen;

f) Number and results of tests during treatment;

g) Compliance rates;

h) Default rates;

i) Relapse rates;

j) Details of follow-up surveillance.

2. Results:

Data on the demography of the sample is presented first, mainly to describe the composition of the sample population. Some of this data is used in the cost-effectiveness analysis calculations.

Thereafter, information pertaining to the treatment of patients in the sample is presented. The data is not discussed in detail as it is evaluated, in terms of its relevance to the cost-effectiveness analysis, in chapters IV and V.

2.1 Demography of sample:

Results of the total sample population and racial breakdowns will be presented in this section.

2.1.1 Racial distribution

The racial distribution of the sample is shown in Table III.2.

Table III.2 Racial distribution of sample population

Race	No. of patients	% of sample population
Whites	4	1.3
Coloureds	178	59.3
Blacks	118	39.3
TOTAL	300	

2.1.2 Age Distribution

a) Total Sample Population: Ages ranged from less than 1 year to 80 years, with a mean age of 24 years (S.D. = 18.2 years).

The breakdown of ages is shown in Table III.3.

Table III.3 Age Distribution - Total sample population.

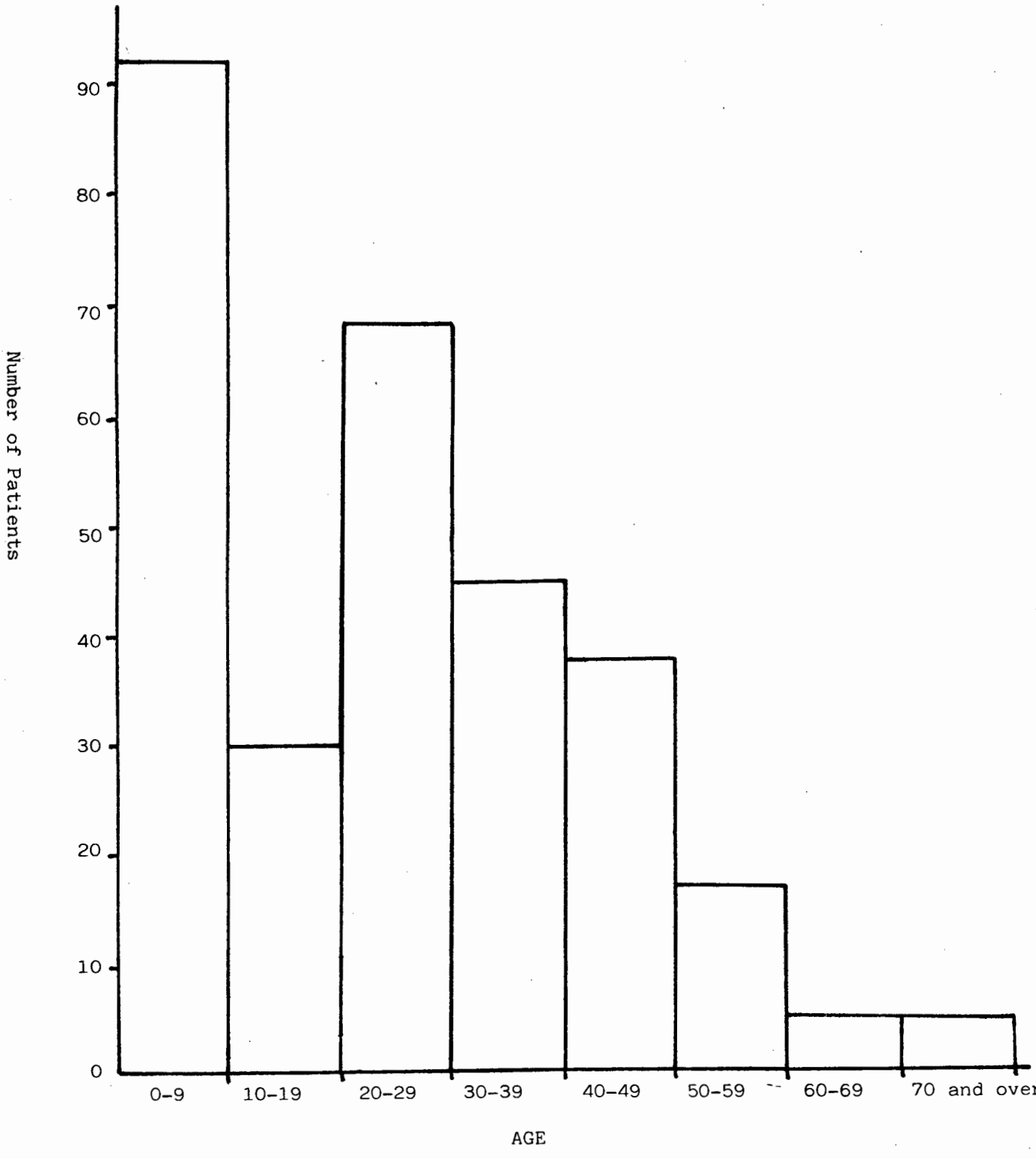
Age	No. of Patients	% of Sample Population
0 - 4 years	75	25.0
5 - 9 years	17	5.7
10 - 14 years	7	2.3
15 - 19 years	23	7.7
20 - 29 years	68	22.7
30 - 39 years	45	15.0
40 - 49 years	38	12.7
50 - 59 years	17	5.7
60 - 69 years	5	1.6
Over 70 years	5	1.6
TOTAL	300	

This data is represented graphically in Figure III.1.

The most significant aspect of this distribution in relation to the cost-effectiveness analysis, is that 50.4% of the patients in the sample are between the ages of 20 and 50 years. These are the 'prime working years' and this has economic implications in terms of possible losses in productivity/economic performance as a result of contracting TB.

FIGURE III.1

AGE DISTRIBUTION OF SAMPLE POPULATION



b) Racial breakdown: The mean age of Whites in the sample was 43.3 years (S.D. = 18.9 years), of Coloureds 23 years (S.D. = 16.5 years) and of Blacks 24.8 years (S.D. = 20.3 years).

The breakdown of ages according to race is shown in Table III.4.

Table III.4 Age distribution acording to race

	WHITES		COLOUREDS		BLACKS	
AGE	No. of Patients	%	No. of Patients	%	No. of Patients	%
0 - 4 yrs	0	0	39	21.9	36	30.5
5 - 9 yrs	0	0	11	6.2	6	5.1
10 - 14 yrs	0	0	5	2.8	2	1.7
15 - 19 yrs	0	0	18	10.1	5	4.2
20 - 29 yrs	1	25	47	26.4	20	16.9
30 - 39 yrs	1	25	25	14.0	19	16.1
40 - 49 yrs	1	25	21	11.8	16	13.6
50 - 59 yrs	0	0	9	5.1	8	6.8
60 - 69 yrs	1	25	2	1.1	2	1.7
Over 70 yrs	0	0	1	0.6	4	3.4
TOTAL	4		178		118	

2.1.3 Sex Distribution

The sex distribution as shown in Table III.5 does not significantly influence the cost-effectiveness calculations but is included for general information purposes.

Table III.5 Sex distribution of sample population according to race.

	TOTAL SAMPLE POPULATION		WHITES		COLOUREDS		BLACKS	
SEX	No. of Patients	%	No. of Patients	%	No. of Patients	%	No. of Patients	%
Male	165	55	1	25	98	55.1	66	55.9
Female	135	45	3	75	80	44.9	52	44.1
TOTAL	300		4		178		118	

2.2 Employment and disability grant statistics:

62% of the sample population (186 patients) were classified as being of employable age, assuming that this category consists of people between the ages of 18 and 65 years.

The employment status of these patients is shown in Table III.6.

Table III.6 Employment status of patients of employable age.

Employment status	No. of Patients	% of Patients of employable age
Employed	96	51.6
Unemployed	32	17.2
Not stated on patient file	58	31.2
TOTAL (patients of employable age)	186	

11.3% (21) of the patients in the sample who were of employable age received disability grants as a result of contracting TB. The mean length of time for which these grants were received was 5.9 months (S.D. = 2.6 months).

2.3 Details of Diagnostic Procedures:

2.3.1 Method of discovery of patients

Details of the means by which a patient came to be examined as a potential TB case were recorded on 79% (237) of the patient folders.

There were three main methods by which TB cases were discovered (see Table III.7).

Table III.7 Method of discovery of patients in sample.

Method of Discovery	No. of Patients	% of patients whose files record method of discovery
Self presentation	213	89.9
Contact investigation	20	8.4
Mass screening campaigns	4	1.7
TOTAL:	237	

Patients were included in the category 'self presentation' if it was noted on their folder that they had either been referred to a clinic by a hospital or private doctor to whom they had presented themselves for investigation of TB symptoms, or if they had approached the clinic directly.

Mass screening campaigns were undertaken in two residential areas in 1983: i) An experimental screening campaign of the community of Leonsdale was conducted and ii) Employees on farms in the Philippi area were screened as part of the CDC's service to employers in the Cape Peninsula. (These campaigns are discussed in greater detail in section 1.5 of Chapter IV.)

It is significant that the majority of TB cases were discovered through the investigation of suspects, i.e. self-presenting symptomatic cases, and contacts. Mass screening is a very costly and relatively ineffective TB case-finding procedure. This is

discussed further in section 1.5 of Chapter IV.

2.3.2 Results of Diagnostic Tests

Note: In this section, results for clinics in the coloured areas (which include the 4 white patients and a few Black patients) and results for Nyanga and Crossroads (the two clinics which treat only Black patients) are presented after the results for the total sample population, to highlight certain important differences.

All patients in the sample underwent at least one initial radiological examination. In the majority of cases, evidence of either cavitation in the lung/s or pleural effusion on the X-ray, was noted in the patient's folder.

As the age of a patient determines which additional tests are performed to confirm diagnosis of TB, the following results are presented according to age group.

I) ADULTS (15 years and older).

The results of the initial bacteriological tests were as follows:

Table III.8 Results of Bacteriological tests - Total sample Population.

RESULTS OF DIRECT MICROSCOPY	RESULTS OF SPUTUM CULTURE				TOTAL
	No Result	Positive	Negative	Contaminated	
No result	52	6	1	0	59
Positive	17	54	11	1	83
Negative	12	19	25	1	57
Contaminated	1	1	0	0	2
TOTAL	82	80	37	2	201

Table III.9 Results of Bacteriological tests - Coloured Clinics.

RESULTS OF DIRECT MICROSCOPY	RESULTS OF SPUTUM CULTURE				TOTAL
	No Result	Positive	Negative	Contaminated	
No result	18	3	1	0	22
Positive	12	44	8	1	65
Negative	8	16	19	0	43
Contaminated	1	1	0	0	2
TOTAL	39	64	28	1	132

Table III.10 Results of Bacteriological tests - Black clinics.

RESULTS OF DIRECT MICROSCOPY	RESULTS OF SPUTUM CULTURE				TOTAL
	No Result	Positive	Negative	Contaminated	
No Result	34	3	0	0	37
Positive	5	10	3	0	18
Negative	4	3	6	1	14
Contaminated	0	0	0	0	0
TOTAL	43	16	9	1	69

Summary of bacteriological examination results :

The information presented in Tables III.8, III.9 and III.10 is summarised in Table III.11 to highlight some important differences in the results between clinics which are not easily detectable from the above format. The results of bacteriological testing of adults in the sample (in terms of number and proportion of patients) are presented according to three general categories:

i) Patients in whom TB was bacteriologically confirmed, i.e. those patients who had a positive direct microscopy and/or a positive sputum culture result,

ii) Patients whose sputum was sent to the laboratory for bacteriological examination and the sputum was found to be contaminated, or at least one of the test results was negative and the other test result was not positive, and

iii) there was no record of either a sputum culture or a direct microscopy test being conducted.

Table III.11 Summary of Bacteriological test results.

RESULT OF BACTERIO-LOGICAL TESTS	TOTAL SAMPLE POPULATION No. of Patients	%	COLOURED CLINICS No. of Patients	%	BLACK CLINICS No. of Patients	%
i) Bacteriologically confirmed	109	54.2	85	64.4	24	34.8
ii) Sputum contaminated or negative	40	19.9	29	22.0	11	15.9
iii) No record of tests	*52	25.9	*18	13.6	34	49.3
TOTAL	201		132		69	

*Two of these patients had results for tuberculin tests despite the fact that they were over the age of 15 years.

It is significant that only 54.2% of the adult patients in the sample were bacteriologically confirmed i.e. active tubercle bacilli were observed in their sputum specimen. In the case of patients with a negative result, there was no evidence of the presence of active tubercle bacilli, despite a radiological examination indicating the possibility of TB, and it could thus be argued that these patients were treated 'unnecessarily'. It is also

important to note that a relatively large proportion of patients, particularly at the Black clinics, had no results for bacteriological tests. This was largely attributable to clinic staff shortages. Section 3.3.1 of Chapter II indicated that bacteriological tests are essential in the diagnosis of TB patients. The implications of these findings are examined in section 4.2.1 of Chapter V.

In addition to the sputum culture and direct microscopy tests, 28 (13.9%) adults had results for differential tests.

II) CHILDREN (Under 15 years).

The results of the tuberculin tests are summarised in Table III.12.

Table III.12 Summary of Tuberculin test results

	TOTAL SAMPLE POPULATION		COLOURED CLINICS		BLACK CLINICS	
RESULT OF TUBER-CULIN TESTS	No. of Patients	%	No. of Patients	%	No. of Patients	%
Grades 0, 1 & 2	36	36.4	26	45.6	10	23.8
Grades 3 & 4	35	35.4	18	31.6	17	40.5
No record of a Tuberculin test being performed	*28	28.2	*13	22.8	15	35.7
TOTAL	99		57		42	

*Three of these patients had results for bacteriological examinations although they were under 15 years of age.

These were as follows:

Positive sputum culture;	no direct microscopy result	1
Negative sputum culture;	no direct microscopy result	1
Negative sputum culture;	negative direct microscopy	1

A significant proportion of children were diagnosed as TB cases on the basis of an X-ray, i.e. either no tuberculin test was performed or the tuberculin test indicated that tubercle bacilli were not viable, i.e. active (Grades 0, 1 & 2). (Glatthaar 1982a:10). Once again, it may be argued that these patients were treated 'unnecessarily'.

2.4 Details of Treatment:

2.4.1 Hospitalisation

9.3% (28) of the patients in the sample were hospitalised. The mean length of hospitalisation of these patients was 9.6 weeks (S.D. = 6.1 weeks).

As hospitalisation is relatively more expensive than clinic treatment, it is important to note that very few CDC TB patients were hospitalised in 1983. This is examined further in section 4.3 of Chapter V.

The breakdown of hospitalisation data is presented in Table III.13.

Table III.13 Hospitalisation of TB patients according to length of stay.

Length of Hospitalisation	No. of Patients	% of Hospitalised Patients
< 6 weeks	7	25.0
6 - 9 weeks	10	35.7
10 - 13 weeks	7	25.0
> 13 weeks	4	14.3
TOTAL	28	

2.4.2 Rate of Default

The distribution of patients according to whether they have completed the prescribed treatment regimen at a CDC clinic or defaulted from treatment, the CDC definition of a defaulter being a patient who absconds from treatment for a period of two months, is shown in Table III.14.

Table III.14 Rates of default and treatment completion.

REASON FOR TERMINATION OF TREATMENT	No. of Patients	%
Treatment regimen completed	230	76.7
Defaulted	63	21.0
Other*	7	2.3

*The reasons why these 7 patients were not included in one of the other categories are:

2 Coloured patients were sent to hospital with serious health problems unrelated to TB, and the clinic had no further involvement in their TB treatment.

5 Black patients returned to the Transkei with the knowledge of clinic staff and were referred to various health facilities there.

Patients who defaulted did not complete the regimen prescribed for them. This affects both the costs and the effectiveness of TB treatment. Thus, it is important to record the details of treatment for both those patients who completed treatment and those who did not. These results will form the basis of the cost-effectiveness analysis of the curative regimen as presented in section 2 of Chapter IV. For the purposes of this analysis, the results for patients who defaulted and patients who did not complete treatment for reasons other than default are combined.

2.4.3 Number of treatment doses given

It was found that a wide range of drug regimens were administered to patients as clinic doctors were permitted a certain degree of flexibility in the application of the drug regimen specified by CDC Health authorities. Different combinations of four of the five possible drugs were used and in some cases, all five drugs were administered at some stage during treatment. The number of doses administered varied substantially and there was no clearly

dominant regimen. The only method of establishing an 'average' regimen was to calculate the mean number of doses of each of the five drugs.

In this section, data will be presented according to whether the patient was an adult or a child.

I) ADULTS (15 years and older).

The means and standard deviations of the number of doses, of each of the five drugs used by the CDC, that were actually administered to patients in the sample, are presented in Table III.15.

Table III.15 Mean number of drug doses administered to adults.

	PATIENTS WHO COMPLETED TREATMENT		PATIENTS WHO DID NOT COMPLETE TREATMENT	
DRUG	MEAN	S.D.	MEAN	S.D.
INH	110.9	28.8	51.6	46.3
Rifampicin	93.7	31.3	48.2	45.0
Streptomycin	50.4	33.6	37.5	33.3
PZA	87.3	38.0	44.9	43.0
Ethambutol	43.7	46.5	15.2	29.8

The distribution of the number of treatment doses of each

drug for the total adult sample population, is shown in Figures B.1 - B.5 in Appendix B.

II) CHILDREN (under 15 years of age).

The means and standard deviations of the number of doses, of each of the four drugs used by the CDC in the treatment of children, that were actually administered to patients in the sample, are shown in Table III.16.

Table III.16 Mean number of drug doses administered to children.

	PATIENTS WHO COMPLETED TREATMENT		PATIENTS WHO DID NOT COMPLETE TREATMENT	
DRUG	MEAN	S.D.	MEAN	S.D.
INH	88.1	27.1	38.1	25.7
Rifampicin	61.2	32.8	27.2	20.9
PZA	70.2	37.8	27.8	23.8
Ethambutol	64.2	43.1	31.3	26.9

Only two patients under the age of 15 years were treated with Streptomycin. They received 50 and 60 doses respectively. The mean number of Streptomycin doses is thus 1.5 (S.D. = 9.0).

The distribution of the number of treatment doses of each drug for the total child sample population is shown in Figures B.6 - B.9 in Appendix B.

2.4.4 Changes to the drug regimen

23 (7.7%) of the patients in the sample required changes to the drug regimen originally prescribed for them, due to an adverse reaction to one or more of the drugs. 9 experienced side-effects resulting from Streptomycin, 10 from PZA and 4 from both Streptomycin and PZA. In addition, 2 patients who were originally prescribed a regimen which included Streptomycin, were placed on a different regimen to facilitate the supervision of their treatment at their workplace, where there was no qualified person available to administer the Streptomycin injection daily.

The side-effects to these drugs were as follows:

Skin rashes	7
Gastro-intestinal / nausea	8
Dizziness	1
Joint pains	2
Hearing problems	2
Pain at injection sites	2
Skin rash and joint pains	1
	23

The suffering or discomfort resulting from these adverse reactions are an indirect cost of the drug regimen. It is thus important to note the nature of these side-effects to permit an assessment of the magnitude of this cost. This is discussed further in section 2.1.1 of Chapter IV.

2.4.5 Compliance with treatment

A compliance rate was calculated for each patient in the sample. The compliance rate is expressed in terms of the number of days on which drugs were administered, as a percentage of the number of possible treatment days. In the case of patients who did not complete treatment, the number of possible treatment days was calculated as the number of week-days between the start of treatment and the date on which they were classified as defaulters.

The mean of the compliance rates was 89.4% (S.D. = 11.3%) for patients who completed treatment and 70.4% (S.D. = 26.4%) for patients who did not complete treatment.

The distribution of the compliance rates is shown in Table III.17.

Table III.17 Distribution of Compliance Rates.

COMPLIANCE RATE	PATIENTS WHO COMPLETED TREATMENT		PATIENTS WHO DID NOT COMPLETE TREATMENT	
	No. of Patients	%	No. of Patients	%
1 - 10%	-	-	3	4.3
11 - 20%	-	-	-	-
21 - 30%	-	-	3	4.3
31 - 40%	-	-	6	8.6
41 - 50%	-	-	2	2.9
51 - 60%	6	2.6	4	5.7
61 - 70%	10	4.3	14	20.0
71 - 80%	31	13.5	7	10.0
81 - 90%	45	19.6	5	7.1
91 -100%	138	60.0	26	37.1
TOTAL	230		70	

These findings indicate that in general, patients who did not complete the prescribed regimen attended clinics for daily treatment less frequently than patients who completed the regimen. The impact of these rates on the effectiveness of treatment received by the two groups of patients is evaluated in section 2.2 of Chapter IV.

2.4.6 Tests conducted during treatment

The progress of patients is evaluated by means of the tests performed

after 60 drug doses have been administered and again after 100 doses.

i) Number of tests per patient:

ADULTS : The means and Standard deviations of the number of tests per patient during the course of treatment are given in Table III.18.

Table III.18 Mean number of Tests conducted during treatment - Adults.

	PATIENTS WHO COMPLETED TREATMENT		PATIENTS WHO DID NOT COMPLETE TREATMENT	
TESTS PERFORMED	MEAN	S.D.	MEAN	S.D.
X-ray	2.33	0.9	0.84	1.1
Sputum culture	0.77	0.9	0.22	0.7
Direct microscopy	0.55	0.8	0.11	0.4
Sensitivity	0.12	0.3	0.02	0.2

It is important to note that the prescribed procedure of performing two radiological and bacteriological tests (i.e. after 60 drug doses have been administered and again after 100 doses) on each patient who completes treatment, is not strictly applied by clinic staff. This affects both the cost and the effectiveness of treatment

- patients who are considered to be cured on the basis of an X-ray may in fact still have active tubercle bacilli which can only be determined by a bacteriological test, and may thus subsequently relapse.

CHILDREN : The mean number of x-rays per patient during treatment, was 2.0 (S.D. = 1.0) for those who completed treatment and 0.76 (S.D. = 1.0) for those who did not complete treatment.

ii) Results of tests after 60 doses:

Bacteriological and radiological tests are conducted after 60 doses of the prescribed treatment have been administered, to assess the patient's response to treatment.

It was very difficult to classify the observations from X-ray as either satisfactory or unsatisfactory, without any medical expertise. Thus, only the results of the bacteriological tests (performed on adults who completed treatment) are presented in Table III.19.

Table III.19 Results of bacteriological tests performed during treatment - Adults.

RESULTS OF DIRECT MICROSCOPY	RESULTS OF SPUTUM CULTURE				TOTAL
	No Result	Positive	Negative	Contaminated	
No result	62	0	34	0	96
Positive	1	1	2	0	4
Negative	13	1	40	1	55
Contaminated	0	1	0	0	1
TOTAL	76	3	76	1	156

In summary, 39.7% (62) of the adult patients in the sample who completed the prescribed treatment regimen did not have any record of a bacteriological test being performed after receiving 60 doses of treatment. Only 6.4% (6) of those patients who had results for bacteriological tests had either a positive sputum culture or direct microscopy results after 60 doses of treatment.

This indicates that the majority of patients who had results for bacteriological tests, had no active tubercle bacilli in their sputum after 60 drug doses had been administered, and were considered to be effectively cured.

2.5 Follow-up Tests after Treatment:

Patients are asked to return to the clinic 3 months after the completion of treatment, and again 6 months later, for radiological and bacteriological examinations. These tests are performed to ensure that no active tubercle bacilli remain.

I) ADULTS:

Of the 156 patients who completed their treatment regimen, 44 (28.2%) defaulted from follow-up surveillance. The mean number of tests per patient are given in Table III.20.

Table III.20 Mean number of follow-up tests - Adults.

TEST	MEAN	S.D
X-ray	1.5	1.3
Sputum Culture	0.4	0.8
Direct Microscopy	0.5	0.8

II) CHILDREN:

Of the 74 patients who completed their prescribed TB treatment, 19 (25.7%) defaulted from follow-up surveillance. The mean number of X-ray tests per patient was 1.2 (S.D. = 1.0).

2.6 Relapse:

10 (4.4%) of the 230 patients who completed treatment, relapsed after a mean period of 8.2 months (S.D. = 5.8 Mths.).

Of the 70 patients who did not complete the prescribed regimen of treatment, 15 (21.4%) presented themselves at a CDC clinic with active TB ('relapsed'), after a mean period of 6.3 months (S.D. = 3.3 months).

These findings are used in the determination of the effectiveness of the treatment regimen administered at CDC clinics (section 2.2 of Chapter IV).

3. Concluding remarks:

The major finding of this sample of CDC TB patients is that the treatment regimen prescribed by the CDC health authorities, as described in section 3 of Chapter II, is not strictly adhered to by CDC clinic staff.

In Chapter IV, the curative regimen cost calculations are based on the mean number of drug doses administered, the mean number of tests performed, etc., as presented in this chapter. Relapse and compliance rates, and the proportion of positive bacteriological test results after the administration of 60 drug doses, are used in effectiveness calculations. (See section 2 of Chapter IV).

The sample data findings are evaluated in more detail in Chapter IV.

DATA FROM PATIENT RECORDS

DATE : .....

CLINIC : .....

1. PERSONAL DETAILS :

NAME : .....

ADDRESS : .....

.....

AGE : ..... SEX : Male ☐ Female ☐

RACE : White ☐ Coloured ☐ Black ☐

EMPLOYED : Yes ☐ No ☐ Not Stated ☐ N/A ☐

DISABILITY GRANT : Yes ☐ No ☐ Period : .....

2. DETAILS OF DIAGNOSIS :

METHOD OF DISCOVERY		DETAILS
Contact Investigation	☐	.....
Self-presentation	☐	.....
Screening Campaign	☐	.....
Not Stated	☐	

DIAGNOSTIC TESTS		OUTCOME
X-Ray	☐	Observations : .....
Sputum Culture	☐	Positive ☐ Negative ☐ Contaminated ☐
Direct Microscopy	☐	Positive ☐ Negative ☐ Contaminated ☐
Tuberculin Test	☐	Grade : .....
Sensitivity Test	☐	Positive ☐ Negative ☐
Differential Test	☐	Positive ☐ Negative ☐

DATE OF NOTIFICATION : .....

3. DETAILS OF TREATMENT :

HOSPITALISED : Yes ☐ No ☐ Period of Hospitalisation : .....

DATE OF COMMENCEMENT OF TREATMENT : .....

DRUG	PRESCRIBED REGIMEN	TOTAL DOSES TAKEN	DOSAGE
Isoniazid	.....doses	.....doses	.....
Rifampicin	.....doses	.....doses	.....
Streptomycin	.....doses	.....doses	.....
Pyrazinamide	.....doses	.....doses	.....
Ethambutol	.....doses	.....doses	.....

ADVERSE REACTIONS : Drug ..... Nature of reaction .....

DETAILS OF ANY DEFAULT DURING TREATMENT : .....

.....

COMPLIANCE : .....

.....

TESTS DURING TREATMENT		OUTCOME				DATE
X-Ray	☐	Satisfactory	☐	Unsatisfactory	☐	.....
Sputum Culture	☐	Positive	☐	Negative	☐	.....
Direct Microscopy	☐	Positive	☐	Negative	☐	.....
Sensitivity Test	☐	Positive	☐	Negative	☐	.....

DATE OF CONCLUSION OF TREATMENT : .....

REASON FOR TERMINATING TREATMENT : Regimen Completed ☐

Defaulted/Absconded ☐

Other ☐ .....

4. POST-TREATMENT INFORMATION :

FOLLOW-UP TESTS :

X-Ray .....

Sputum Culture .....

Direct Microscopy .....

RELAPSE : Yes ☐ No ☐ Number of months after completion of treatment .....

5. DETAILS OF CONTACTS :

No. of contacts recorded : .....

No. of contacts investigated : .....

6. COMMENTS/OTHER RELEVANT DETAILS :

.....

.....

.....

.....

CHAPTER IV

CALCULATION OF COST-EFFECTIVENESS RATIOS OF PREVENTIVE AND CURATIVE PROCEDURES FOR TB IN THE CDC

Introduction:

This chapter will be devoted to calculating cost-effectiveness ratios for each of the preventive and curative procedures for TB used by the CDC. These are as follows:

BCG vaccinations, secondary chemoprophylaxis, mass screening campaigns, investigation of contacts and suspects and the 'clinic' curative regimen.[1]

The calculations for each procedure will be presented in the following manner: i) The total cost of implementing the procedure at CDC clinics in 1983 will be calculated; ii) The effectiveness of the procedure in 1983 will be calculated. The unit of outcome in which the effectiveness of preventive procedures are expressed is 'notifications' prevented while diagnostic and curative procedures are expressed in terms of 'notifications'. (The relationship between these units of outcome will be clarified in Chapter V); iii) Cost-effectiveness ratios will then be calculated i.e. the costs of each procedure will be expressed in terms of the selected unit of outcome.

---

1. As indicated in Chapter III, the curative regimen actually implemented at CDC clinics is different to the regimen originally prescribed by the CDC authorities. These regimens will be referred to as the 'clinic' and 'official' regimens respectively.

The cost and effectiveness calculations are quite extensive for certain procedures. They are a necessasry basis for understanding the evaluation and analysis of the final cost-effectiveness ratios which is presented in Chapter V. Most of the cost calculations are contained in appendices. In circumstances where such calculations are not extensive and would not impede the flow of the chapter, they are included in the main text.

As outlined in section 4 of Chapter II, each preventive and curative procedure has a distinctive role in the overall TB control programme. The individual ratios provide a basis for policy-makers to assess the effectiveness of each procedure in counteracting the movement of people to higher TB risk levels, in relation to costs.

The ratios will be evaluated and compared in Chapter V, to determine what combination of preventive and curative procedures should be implemented.

Note on Data sources:

The information and data used in the analysis presented in this chapter, was derived from three major sources: i) The results of the random sample of 300 patients treated at CDC clinics, ii) The annual reports of the CDC Medical Officer of Health (MOH), and iii) Unpublished records of the CDC and related institutions.

The sample data, as summarised in Chapter III, will be used extensively in the calculation of the cost-effectiveness ratios of curative procedures implemented by the CDC as it best describes the 'clinic' regimen as opposed to the 'official' CDC regimen.

The results of the sample also provide certain indicators of effectiveness. Reference will be made to data from other sources, such as journal articles and unpublished studies to substantiate the sample findings and to provide parameters for performing sensitivity analysis where applicable (see Appendix A).

As explained in Appendix A, the recommended theoretical procedure for assessing costs is to calculate 'shadow prices' for each input based on the value of the input's marginal product. Since the market price of an input will only equal its marginal product under conditions of perfect competition, which do not apply to the market for health services in S.A. which are largely government supplied, it is very difficult to estimate the marginal product of inputs in practice. Thus cost estimates are largely based on the market prices of inputs, with adjustments wherever necessary to ensure that they adequately reflect 'social opportunity costs,' i.e. the cost to society in terms of resources which are no longer available for use in other projects.

These estimates were derived from the departmental records of the CDC and other related institutions. All costs relating to drugs were obtained from Mr Ochse, the senior pharmacist at State Health, Bellville. Expenditure statements were examined to determine whether they reflected all relevant factors adequately, and adjustments were made where necessary in consultation with the respective departmental accountants. For example, although drugs for the treatment of TB are supplied free of charge by State Health and are thus not accounted for by the CDC, they represent a cost to society and must be taken into account. The cost of these drugs to the State was determined and a handling charge was added to account for the cost of dispensing and supplying the drugs to the clinics.

Capital outlays have been accounted for by depreciation charges on vehicles and equipment, and redemption on loans for buildings. The only factor for which inadequate provision was made, was in relation to the allocation of a portion of the expenses for office space to the Health department in the CDC head office. This does not significantly affect the final cost-effectiveness ratios.

It should be noted that the CDC and Brooklyn Chest Hospital, where TB patients are hospitalised, present their costs in terms of the 1983/84 financial year. All other information concerning their activities is presented for 1983. Other costs e.g. cost of drugs, disability grants, etc. have been assessed at the midpoint of this financial period, to ensure consistency in the cost estimates. Costs may consequently have been somewhat overstated, but this will not be significant at the unit cost level.

It must be stressed that all cost estimates supplied by TB authorities were scrutinised to determine whether they adequately reflected 'social opportunity costs'.

Information with regard to the total number of TB patients and the number of diagnostic and curative procedures for TB performed during 1983, was obtained from the MOH's annual report and unpublished records of the CDC Health department.

The major limitation of the information used in this analysis is that it applies specifically to 1983. This was necessary due to data availability and more importantly, as a suitable time period has to elapse after the completion of treatment of patients, to permit an accurate assessment of the relapse rate. Current trends and future prospects will be briefly examined in Chapter V.

1. Cost-effectiveness analysis of preventive procedures for TB in the CDC:

1.1 BCG vaccinations :

A special immunisation team visits schools falling within the jurisdiction of the CDC and administers vaccinations for TB (i.e. BCG vaccinations) as well as immunising children against Poliomiëlitis, Diphtheria and German measles. The team is also responsible for conducting tuberculin tests on certain children.

In addition to the work of the schools immunisation team, BCG vaccinations are administered at the clinics, and at hospitals shortly after the birth of a child.

In 1983, 32037 BCG vaccinations were administered by the CDC. The breakdown of this figure according to race and whether the BCG vaccination was administered to a child for the first time or was a revaccination in accordance with CDC vaccination policies (see section 3.1, Chapter II) is given in Table IV.1.

Table IV.1 BCG vaccinations: 1983

Race	1st BCG	Repeat BCG	Total BCG
White	3287	3191	6478
Coloured	4548	15437	19985
Black	4093	1481	5574
TOTAL	11928	20109	32037

(Divisional Council of the Cape 1983 : 158)

1.1.1 Costs

The tool used to administer BCG vaccinations had a unit cost of R0.56. Each tool can be used to administer approximately 100 vaccinations. One 10 dose ampule of BCG vaccine cost R0.78. The cost of clinic services, and the cost of staff and transport for the schools immunisation team has been estimated, to account for the cost of administering these vaccinations in 1983 (see Appendix C).

The total cost of administering 32037 BCG vaccinations in 1983 was as follows :

Vaccination Tool	R 179.41
BCG vaccine	R 2 498.89
Clinic services	R124 557.00
TOTAL COST	R127 235.30

An indirect cost of administering BCG vaccinations is the adverse reaction which some children may suffer shortly after being immunised. No information on adverse reactions was available from the CDC. However, the MOH of Cape Town City Council (CCC) records the incidence of adverse reactions in his annual report. It was assumed that there was no significant difference between the adverse reactions to BCG vaccinations administered within the jurisdiction of the CCC to those administered by the CDC.

In a four year period (1980-1983), 206471 BCG vaccinations were administered by the CCC. Only two children suffered from adverse

reactions during this period. One child suffered local itchiness and swelling of the eyes and the other suffered a rash. (City of Cape Town 1980 : 147 & 150, 1981 : 161 & 165, 1982 : 145 & 149, 1983 : 150 & 155).

Thus, the incidence of adverse reactions to BCG vaccinations is approximately 0.01 per 1 000 vaccinations. It was assumed that the incidence was sufficiently small to simply state that adverse reactions are a factor which should be considered without attempting to quantify this indirect cost in a form whereby it can be included in the cost-effectiveness ratio.

1.1.2 Effectiveness of BCG vaccinations

There has been a very lively and controversial debate on the effectiveness of BCG vaccinations for the past few decades. Early studies revealed that BCG vaccinations provided effective protection against tuberculosis infection in up to 80% of the vaccinated population, the protection being afforded for approximately 15 years.[2] These findings were challenged by later studies which indicated that BCG vaccinations could in certain situations provide no protection at all. Table IV.2 summarises the results of some of these studies.

---

2. The protective efficacy of BCG vaccinations is a standardised measure to indicate the proportion of TB disease reduction that is attributable to the BCG immunisation. The equation used to calculate this index is : (TB attack rate in controls - TB attack rate in vaccinees)/TB attack rate in controls x 100 (Clemens et al 1983 : 2362).

Table IV.2 Protective efficacy of BCG vaccination in eight controlled trials

Trial	Year of intake	Observation period(years)	Efficacy %
North America	1934	10	80
Chicago	1943	18	75
Georgia	1947	20	0
Puerto Rico	1950	6	31
Georgia/Alabama	1950	14	14
Great Britain	1951	15	78
South India	1955	12	31
South India	1970	7½	0

(Kent 1982:9, Table 1)

As yet, there is no generally accepted explanation for the conflicting results. Some researchers have argued that the nutritional status of the participants in the trials differed, that the BCG vaccines used had different degrees of potency, or that there were differences in the prevalence of tubercle bacilli and atypical mycobacteria in the various communities studied. (Kleeberg 1984:6). There is no apparent common basis for distinguishing between communities where vaccinating the population with BCG has proved highly effective and those communities where it is less effective.

In 1983, Clemens, et al investigated the possibility that differences in methodology was the primary cause of the conflicting results.

Their analysis of the statistical basis and methodology of eight controlled BCG vaccination trials, concluded that

> "...(1) although biased allocation of the vaccine appeared an unlikely explanation for the disparate results, adequate demonstration of unbiased detection of tuberculosis was available only for the three trials reporting 75% or greater protective efficacy; and (2) in most trials reporting low efficacy, the results had wide confidence intervals that could not exclude high efficacy but the trials reporting high efficacy all had narrow confidence intervals that excluded low efficacy. Because the trials with the best methodological quality and greatest statistical precision reported high efficacy, the evidence suggests that BCG can confer a high degree of protection against tuberculosis and that bias or inadequate statistical power may have contributed to the conflicting data."
>
> (Clemens, et al 1983:2362)

Various aspects of the BCG vaccination policy in S.A. have been studied, but no controlled trial, comparable to the overseas studies, to determine the effectiveness of BCG protection in S.A. has been conducted.

Coetzee and Fourie reported at the S.A. Medical Research Council's TBRI Symposium in 1985 that

> "The TBRI conducted a contact evaluation study to determine whether, in children exposed to confirmed adult TB cases, an association exists between the presence of BCG scars and a lowered risk of developing tuberculosis disease.
>
> A protective effect of BCG vaccination could be shown in the 0-4 year age group, where protection varied between 47% and 81%. In older children, the protective effect is uncertain because of small numbers investigated."
>
> (Townshend and Aalbers 1985:9)

As the subjects of this study were child contacts, a group at high risk of being infected with tubercle bacilli, the results do not necessarily reflect the protective effect of BCG vaccinations for

the South African population in general. It should also be noted that the absence of a BCG scar does not necessarily mean that the child has not received a BCG vaccination.

Another factor which influences the effectiveness of the BCG vaccination programme is the extent of the coverage of the population. The TB infection surveillance programme conducted by the TBRI has shown that 42% of coloured children and 40% of Black children surveyed in the CDC area had BCG scars. (SAMRC 1983:22).

The British Thoracic and Tuberculosis Association (1975) devised a method for estimating the number of TB notifications prevented by BCG vaccinations, i.e. the effectiveness of BCG vaccinations. This technique will be used to estimate the effectiveness of BCG vaccinations administered in the CDC in 1983, based on the above information (the major assumption being that any results for S.A. as a whole are similar to those for the CDC area). Although the BCG vaccinations administered in 1983 will prevent a certain number of annual notifications for several years thereafter, i.e. the effectiveness of a BCG vaccination is not limited to one year, for the purposes of this study, only the notifications prevented in 1983 will be calculated.

As this measure is based on the TB notification rate, three different cost-effectiveness ratios will be calculated according to race.

The calculation of the notification rates for the vaccinated population is as follows :

i) The British Thoracic and Tuberculosis Association (1975) study, found that 23.94% of TB notifications occurred in the vaccinated population.[3] Using this estimate, the notifications in the CDC vaccinated population can be calculated:

	Total number of notifications*	Number of notifications in the vaccinated population
Whites	43	10.3
Coloureds	1 374	328.9
Blacks	1 083	259.3

(* see Table II.1)

ii) The TBRI has shown that BCG coverage of the Coloured and Black population is approximately 40%, based on the presence of BCG scars, i.e. a lower estimate than if based on actual vaccination status. BCG coverage is significantly higher in the white population as the majority of white children are born in hospitals where they will receive their first BCG vaccination. A 90% BCG coverage is assumed for whites. The vaccinated population in the CDC in 1983 and the notification rates for the vaccinated population can be calculated as follows:

---

3. The Coetzee and Fourie study indicated that the protective efficacy of BCG vaccinations in S.A. may be lower than in Britain. Thus, a higher proportion of TB notifications may occur in the South African vaccinated population. This estimate is thus regarded as a 'lower limit' estimate.

	Vaccinated population*	Notifications per 100 000 vaccinated population
Whites	195 579	5.27
Coloureds	140 764	233.65
Blacks	31 900	812.85

(*White population data in Table II.1 x 90% and Coloured and Black population data x 40%).

As there is some dispute as to the protective efficacy of BCG vaccinations, a midpoint estimate of 65%, based on the findings of the study conducted by Coetzee and Fourie, will be used in the calculation of notifications prevented.

Whites: Given an assumed 65% protective efficacy, the 5.27 notifications per 100 000 vaccinations would refer to the 35% of the vaccinated population not afforded effective protection by the BCG vaccination. Thus, 9.79 (i.e. (5.27 ÷ 35%) x 65%) TB notifications per 100 000, i.e. 0.63 per 6 478 vaccinations, would have been prevented in the 65% of the population effectively protected by BCG vaccination.

Coloureds: Similarly, 433.92 TB notifications per 100 000 and 86.72 per 19 985 vaccinations would have been prevented if 65% of the vaccinated coloured population was effectively protected.

Blacks: 1 509.58 TB notifications per 100 000 and 84.14 per 5 574 vaccinations would have been prevented through BCG vaccinations in the Black population.

1.1.3 Cost-effectiveness ratios for BCG vaccinations

The total cost of administering BCG vaccinations is divided on a proportional basis according to the number of vaccinations administered to each race group.

i) Cost of BCG vaccinations per TB notification prevented in whites -

R 25 727.45 ÷ 1 = R 25 727.45 per TB notification prevented by BCG vaccinations.

ii) Cost of BCG vaccinations per TB notification prevented in coloureds -

R 79 370.65 ÷ 87 = R 912.31 per TB notification prevented by BCG vaccinations

iii) Cost of BCG vaccinations per TB notification prevented in blacks -

R 22 137.20 ÷ 84 = R 263.54 per TB notification prevented by BCG vaccinations.

1.2 Secondary Chemoprophylaxis :

The total number of child contacts of sputum positive cases to be prescribed a course of prophylactic treatment during 1983, was 4 015. (See appendix D). Although the usual point of division between adults and children is 15 years of age, a small number

of children who were 15 years or older were prescribed chemoprophylactic treatment and will be referred to as adults here.

Of these contacts, 1 806 (45%) completed the prescribed course of 60 doses of INH, 152 (3.8%) were transferred to a clinic or hospital outside of the CDC jurisdiction after prophylactic treatment was prescribed and 2 057 (51.2%) absconded[4] before treatment could be completed. The breakdown according to age is presented in Appendix D.

1.2.1 Costs

i) Cost of drugs -

Patients of 15 years of age or older received a dosage of 400 mg of INH. Children under the age of 15, received a variable dosage determined according to their weight at the time that treatment was started. A sample of dosages prescribed for children receiving chemoprophylactic treatment was not conducted. It was assumed that the distribution of ages, weights and thus dosages of INH for children receiving chemoprophylaxis would be similar to that for children receiving a full TB regimen. It was noted in section 1 of Chapter II that most children develop active TB as a result of natural infection through contact with an infectious TB patient.

---

4. In total, 2 120 children receiving treatment absconded, of which 63 were recovered. Tracing procedures for patients who abscond are conducted for two months after they abscond, and thus it was assumed that the majority of those who were recovered would be recorded as such within the same year (1983) in which they were originally recorded as new patients. To avoid double counting, net absconders i.e. the number of absconded patients less those who were recovered has been used in the cost calculations.

It is feasible that contacts who are merely infected have a similar age distribution to those who become infectious. (See Appendix E for the distribution of drug dosages and relevant cost calculations.)

The cost per dose of INH is R 0.0042 for adults and R 0.0017 for children 14 years of age and younger. Thus, the total cost of secondary chemoprophylaxis for those patients who completed their treatment, prescribed in 1983, is as follows :

Adults : R 0.0042 x 60 doses x 108 patients = R 27.22

Children : R 0.0017 x 60 doses x 1 698 patients = R 173.20

There is no available evidence to suggest that the behaviour of notified and prophylactic patients who default would differ. Thus, to calculate the cost of the drug regimen administered to patients who absconded/defaulted, it was assumed that the same proportion of prescribed doses of INH were taken before default by patients receiving secondary chemoprophylaxis as those receiving a full TB regimen. Based on this assumption, adults received 46.5% of their prescribed 60 doses of INH (27.9 doses), while children received 43.2% (25.9 doses of INH).[5]

The total cost of prophylactic treatment for those patients who defaulted before completing the regimen prescribed for them in 1983, is as follows :

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5. Adult and child patients who absconded, received means of 51.6 and 38.1 doses respectively, compared to those who completed the treatment regimen and received means of 110.9 and 88.1 doses respectively. (See Appendix E and Tables III.15 and III.16). The proportion of these two sets of means, provided the above

Adults : R 0.0042 x 27.9 doses x 272 patients = R 31.87

Children : R 0.0017 x 25.9 doses x 1 785 patients = R 78.59

ii) Cost of clinic services -

Secondary chemoprophylactic treatment is not fully supervised at clinics. The patient's parent/guardian is given a weekly supply of INH tablets and instructed how to administer them. If the parent/guardian does not present at the clinic to collect the tablets every week, it is recorded that the patient has absconded.

Thus, the cost of dispensing tablets to the patient's parent/guardian and the administrative costs of recording details of treatment on patient folders are the only costs included in this section. All costs of investigation of the patient as a suspect or contact before chemoprophylaxis are included in section 1.6.

The estimated cost of these clinic services in 1983 was R 93 080 (See Apendix C), i.e. approximately R24 per patient.

iii) Indirect costs -

Indirect costs of secondary chemoprophylaxis consist of the time spent by parents/guardians when collecting tablets from the clinic and the possible cost of transportation to clinics for this purpose. It was not possible within the scope of this paper to quantify these costs and it was felt that these costs would be relatively insignificant (the parent/guardian is only required to make $\pm$ 9 visits to the clinic during the period of treatment).

1.2.2 Effectiveness of secondary chemoprophylaxis

There is no specific information on the effectiveness of the CDC prophylactic regimen. However, controlled trials using INH chemoprophylaxis for differing lengths of time (usually more than 60 doses) have shown that this treatment decreases the risk of developing disease by 50-95%. (Grzybowski 1982 : 7-8). One study estimated that the effectiveness of chemoprophylaxis prescribed for household contacts was 60% (Grzybowski 1982:7). It should be noted that the only contacts admitted to this trial were ones in which it was shown that infection had occurred. In S.A., the means by which infection in children is determined is the tuberculin test, the results of which have been shown to be distorted by the effect of BCG vaccinations. Fourie (185:9) has shown that,

> "Under a prophylaxis programme using tuberculin tests as screening tools .... 85% of children selected for prophylaxis will be treated unnecessarily."

As the tuberculin test is the only means of determining infection in children at present, the costs incurred in treating uninfected patients are unavoidable. The above finding does however influence the effectiveness calculations.

The patients prescribed chemoprophylaxis by CDC, contacts of sputum positive cases, are a high risk group and thus the number treated unnecessarily, i.e. the patients who were not infected, will possibly be lower. Thus, two estimates will be used; 85% based on the findings of Fourie's study, and 50%, an arbitrary estimate to indicate how the result will be affected by a lower estimate, i.e. a variable to be used in conducting a sensitivity analysis (See Appendix A).

Of the 1 806 patients who completed chemoprophylactic treatment in 1983, 271 patients can be assumed to have been infected and in need of such treatment, using the 85% estimate. Approximately 163 (60%) patients did not subsequently develop active TB as a result of receiving 60 doses of INH, while approximately 108 (40%) would have been notified as TB patients at some stage after completing chemoprophylaxis.

Similarly, approximately 309 of the 2 057 patients who absconded/defaulted before completing chemoprophylactic treatment in 1983 can be assumed to have been infected. If one assumes that the difference in the effectiveness of treatment of those patients who completed treatment and those who did not, was similar for notified patients[6] and patients receiving chemoprophylaxis, 49.3% (152) of those patients who absconded before completing the prescribed chemoprophylactic regimen would not subsequently develop active TB while 50.7% (157) would.

The same calculations are repeated here using the 50% estimate :

903 of those patients who completed treatment were infected

542 of those patients who completed treatment did not subsequently develop TB

361 of those patients who completed treatment would subsequently be notified as TB cases.

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6. The effectiveness of treatment for notified TB patients i.e. the number of patients who did not relapse, was 95.6% for patients who completed treatment and 78.6% for patients who did not. (Based on relapse rates of 4.4% and 21.4% respectively - see section 2.2.3 of this chapter).

1 029 of those patients who absconded were infected

507 of those patients who absconded would not subsequently develop TB

522 of those patients who absconded would subsequently be notified as TB cases.

Using the 85% estimate a total of 265 patients who were prescribed secondary chemoprophylactic treatment in 1983 and who either completed treatment or absconded, would subsequently have been notified as active TB cases, while 883 would have been notified using the 50% estimate. Although the estimate that 85% of the patients prescribed prophylactic treatment were not in fact infected with tubercle bacilli initially appeared to be rather high for contacts in the CDC area, it seems feasible that this could reflect the true situation. It in effect indicates that approximately 25% of the children notified as TB cases in 1983 had previously been prescribed secondary chemoprophylaxis.[7] It is doubtful whether the proportion of total notifications emanating from this particular group of people would have been significantly larger. The 85% estimates will thus be used in the following analysis.

1.2.3 Cost-effectiveness ratio of secondary chemoprophylaxis at CDC clinics in 1983

The total costs of secondary chemoprophylaxis in 1983 are as follows :

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7. 238 children under 15 years of age who would have been notified after receiving some chemoprophylactic treatment as a percentage of 944 children notified in 1983.

Drug costs - Patients who completed treatment	R 200.42
- Patients who absconded	R 110.46
Clinic Services	R 93 080.00
	R 93 390.88

A total of 315 notifications were prevented by secondary chemoprophylaxis in 1983, based on the 85% estimate.
The breakdown is as follows :

Notifications prevented in patients who completed treatment	163
Notifications prevented in patients who absconded	152
	315

Cost of prophylactic treatment per notification prevented -
R93 390.88 ÷ 315 = R 296.48 per notification prevented.

1.3 Health education :

Health educators in the CDC are involved in community education relating to a wide range of health issues e.g. general hygiene, smoking, alcoholism, cancer, breastfeeding, cholera, tuberculosis etc. In 1983, 7.1% of the health education district work was devoted to Tuberculosis education. (Divisional Council of the Cape 1983:176).

1.3.1 Costs of health education

The total cost of health education conducted by the CDC in 1983 was R 237 782. (Unpublished CDC financial records.) This figure

includes a proportion of the CDC Health department administration costs. The cost of Tuberculosis health education was thus R 237 782 x 7.1% = R 16 882.52.

1.3.2 Effectiveness of health education

It is difficult to determine the effectiveness of health ecucation, as it does not directly 'prevent' notifications. It can inform people of the means by which tubercle bacilli are transmitted which may ultimately result in fewer people contracting the disease, e.g. by encouraging TB patients not to spit or to cough behind their hand, the spread of disease may be somewhat limited.

It is also not possible with the limited amount of information currently available, to determine the number of patients who sought medical attention at an early stage as a direct result of increased awareness of the symptoms of TB created by health education programmes.

A few studies have been conducted in S.A. to determine the effectiveness of health education. The study most relevant to this analysis is the one conducted by Thompson and Myrdal (1984c:6-7) which was based on interviews with 44 Black CDC TB patients, or the parents in the case of child patients. The overall finding was that the patients had a poor understanding of the disease from which they were suffering; e.g. 21% of the patients could not name any symptoms of TB, only 16% knew the mechanism of spread of tubercle bacilli, 21% knew that TB was a preventable disease and were able to cite changes in socio-economic factors and personal habits as preventive techniques, and no-one in the sample knew what the duration of their treatment would be.

Given that it is difficult to quantify the implications of these responses and that much of the TB health education is connected with the treatment of notified TB patients (see section 3.2 of Chapter II), it has been decided to combine the cost of TB health education with the costs of the curative regimen to ensure that it is taken into account in the analysis.

1.4 Socio-economic factors :

It is impossible within the scope of this paper to quantify the costs and effectiveness of socio-economic factors. Possibly the most important of these factors is the provision of adequate housing. An indication of the seriousness of the 'housing crisis' comes from the Cape Times (13 May, 1985) report that there was a backlog of 35 000 houses with 1 000 new applications per month in the CCC area and a backlog of 50 000 houses in the CDC area.

This is a subject which desperately requires research, as the costs and effectiveness of changes in socio-economic conditions, with regard to their impact on TB, would be significant. This has been highlighted on numerous occasions in statements by those centrally involved with TB programs, e.g. Dr Tibbit, the MOH of the CDC was quoted in the Argus on 16 January, 1984 as saying that

> "If we did nothing medically and just improved housing and nutrition, we would do just as much good."

1.5 Mass screening campaigns :

There were three mass TB screening campaigns in 1983: i) An ongoing service to employers for the screening of workers by means of X-rays;

ii) A mass screening campaign in the Leonsdale residential area, part of Elsies River, which was conducted after statistics indicated that the largest proportion of admissions to the Brooklyn Chest hospital were from the Elsies River area; and iii) A mass tuberculin test survey conducted on behalf of the TBRI as part of their investigation into annual rates of tuberculosis infection (see sections 2.1.3-2.2 in Chapter II).

1.5.1 Costs of mass screening campaigns

(See Appendix F for the calculation of costs per test.)

i) Cost of pre-employment screening -

6 256 X-rays were performed during pre-employment screening procedures in 1983.

The total cost of these radiological investigations was :

6 256 X-rays x R 2.53 = R 15 827.68

ii) Costs of the Leonsdale survey -

During the initial mass screening process, 2 325 radiological tests were performed. 156 people were X-rayed for further investigation. 1 358 children were given heaf tuberculin tests at the same time that they were X-rayed, of which 715 returned to have the heaf tests 'read' within 48-72 hours of the test being performed. (Information from unpublished report on Survey). The cost of administering the test is the same for those children who had their test 'read' and for those who didn't; the cost of clinic services is adjusted to account for those children who did not return for 'reading'

of tests i.e. children who returned to have their tests 'read' are assigned a cost estimate for two clinic visits and those who didn't return, an estimate for one clinic visit. (see Appendix C.)

The total cost of these tests was :

2 481 X-rays x R 2.53 = R 6 276.93

1 358 heaf tests x R 0.13 = R 176.54

iii) Costs of TBRI survey -

1 573 tuberculin tests were conducted by the CDC on behalf of the TBRI in 1983.

The cost of these tests was:

1 573 tuberculin tests x R 0.13 = R 204.49.

The total cost of tests performed during mass screening campaigns in 1983 was thus R 22 485.64. Clinic services costs of R 49 174 have been allocated to mass screening procedures to account for administrative work in recording details of the person being screened, the administration and 'reading' of tuberculin tests, transport costs, etc. (see Appendix C for detailed clinic cost calculations.)

1.5.2 Effectiveness of mass screening campaigns

The only CDC mass screening campaign for which effectiveness indicators are available is the Leonsdale survey. 12 cases were notified as a result of screening 2 325 people; a mean case yield of 0.52%. (Unpublished CDC report on the Leonsdale survey).

Studies conducted by the TBRI have shown that mass X-ray screening of workers produces a mean case yield of 0.3%. (S.A. Medical Research council 1984 : 14).

Assuming that the case yield is similar whether the investigative procedure was by means of X-ray and/or tuberculin, it can be estimated that between 30.5 and 52.8 cases were notified as a result of investigating 10 154 people through mass screening campaigns in 1983. A midpoint estimate of 41.65 notified cases per 10 154 investigations will be used in the calculation of a cost-effectiveness ratio.

1.5.3 Cost-effectiveness ratio of mass screening campaigns

R 71 659 ÷ 42 notifications = R 1 706.18 per case notified as a result of mass screening procedures.

1.6 Investigation of contacts and suspects :

The CDC does not distinguish in their records between investigations conducted on suspects, i.e. those people who present at a clinic with symptoms of TB, and on contacts. If a person presents at a clinic with strong clinical indications of TB and is confirmed as a TB case either radiologically and/or bacteriologically shortly thereafter, they are immediately recorded as a newly diagnosed and notified case. Other cases are recorded as suspects under investigation. The majority of those recorded as a contact/suspect under investigation are contacts of confirmed TB cases. All of the contacts recorded on a newly notified patient's folder are included in the CDC records as contacts under investigation.

The sample data indicated that a mean of 5.37 contacts per newly notified patient were recorded and of these, 51.02% were actually

investigated, i.e. a mean of 2.74 contacts per patient were investigated.

The total number of people who were registered as contacts or suspects under investigation, i.e. not diagnosed and notified immediately, in 1983, was 19 898. (See Appendix D). Of these contacts/suspects, 10 646 (53.5%) had their investigation procedures completed, 8 781 (44.1%) absconded before investigation procedures were completed[8], 463 (2.3%) were transferred to a hospital or clinic outside of the CDC jurisdiction, and 8 (0.1%) died before investigation could be completed. The breakdown according to age is presented in Appendix D.

It was noted in the CDC records that 205 child and 273 adult contacts/suspects were notified as a result of radiological investigation in 1983. It can therefore be assumed that 723 child and 1 257 adult suspects were diagnosed and notified immediately without first being recorded as suspects under investigation.[9] Based on this information, it can be estimated that 5 670 children and

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8. In total, 4 560 children and 4 462 adults absconded from investigation procedures, of which 126 children and 115 adults were recovered. As explained in footnote 4, net absconders are used here to avoid double-counting. The total of net absconders is 8 781 (4 434 children and 4 347 adults). It should also be noted that those who were classified as absconded, includes people who reported for investigation initially and then absconded, as well as those noted as a contact on a notified patient's folder who were never traced or did not present for investigation after being traced.

9. A total of 944 children and 1 556 adults were notified in 1983. Section 1.5 indicated that 42 patients were notified as a result of mass screening procedures. As children accounted for 37.76% of TB notifications in 1983 and adults for 62.24%, it can be estimated that 16 children and 26 adults were notified as a result of mass screening procedures. Total notifications - [contacts/suspects notified after investigation + persons notified as a result of mass screening procedures] = suspects

6 956 adults were fully investigated as contacts/suspects in 1983.[10]

1.6.1 Costs of investigating contacts and suspects

The CDC MOH's annual report states that 23 153 radiological examinations were performed on contacts of notified TB patients and suspected TB cases in 1983. (Divisional Council of the Cape 1983 : 153). As only 12 626 contacts/suspects were fully investigated in 1983, this indicates that some of the contacts/suspects may have been X-rayed before absconding and that more than one X-ray may have been taken in cases where a conclusive diagnosis based on the first X-ray was not possible.

A total of 7 420 tuberculin tests were performed in 1983. (Divisional Council of the Cape 1983 : 159). As the progress of notified patients is not assessed by means of tuberculin testing during treatment, all of these heaf tests will be attributable to investigation of contacts and suspects except for the 2 931 which were performed during mass screening procedures. Thus, the remaining 4 489 tuberculin tests were performed on contacts and suspects in 1983. This supports the sample data finding that only 71.7% of those child suspects/contacts who were notified had heaf tests performed on them. A small number of contacts/suspects who absconded before the investigation procedures were completed may also have had a heaf test.

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10. 10 646 people (4 947 children and 5 699 adults) who were initially registered as contacts or suspects under investigation were fully investigated. In addition, 1 980 people (723 children and 1 257 adults) were fully investigated as contacts or suspects but were notified immediately. The sum of these two categories of contacts/suspects is 12 626 (5 670 children and 6 956 adults).

The CDC does not have composite figures for the number of bacteriological tests performed in 1983. (These figures could not be obtained from the State Laboratory either.) The sample data indicated that 70.6% of contacts/suspects notified had results for Direct microscopy tests and 59.2% for sputum culture tests. The total number of bacteriological tests performed in investigation procedures can be estimated from this, given a small margin of error for those adult contacts/suspects who had these tests before absconding.

Direct microscopy: 70.6% of 6 956 contacts/suspects = 4 911

Sputum culture: 59.2% of 6 956 contacts/suspects = 4 118

Differential tests, which are able to differentiate between M tuberculosis and other non-tuberculous bacilli, are not performed routinely in diagnostic procedures. They are usually performed on patients already diagnosed as suffering from TB as a means of confirming diagnosis. 13.9% of the notified adult patients had a differential test result. It can thus be estimated that :
13.9% x 1 556 notified adult patients = 216 differential tests were performed on contacts/suspects in 1983.

The total costs of these tests were therefore, as follows :

X-rays:	23 153 x R 2.53	=	R 58 577.09
Tuberculin tests:	4 489 x R 0.13	=	R 583.57
Direct microscopy:	4 911 x R 1.68	=	R 8 250.48
Sputum Culture:	4 118 x R 4.20	=	R 17 295.60
Differential tests:	216 x R 2.10	=	R 453.60
TOTAL cost of investigative tests		=	R 85 160.34

(Unit test cost calculations can be found in Appendix F)

Clinic services costs of R 160 357 have been allocated to the investigation of contacts/suspects to account for administrative work in recording details of the contact/suspect, administering the tuberculin tests, collecting sputum samples, recording resudts of the tests, etc. (see Appendix C).

1.6.2 Effectiveness of investigating contacts and suspects

Of the 12 668 contacts/suspects who were investigated fully in 1983, approximately 2 458 were subsequently notified.[11] This gives a mean case yeild of 19.4%. This indicates that case-finding procedures in the CDC are relatively efficient when compared with the averages for large South African cities as a whole. Studies have shown that the mean case yield for family contact investigations in South African cities is 5% and for self-presenting symptomatic cases, i.e. suspects, is 7%. (S.A. Medical Research Council 1984:14).

1.6.3 Cost-effectiveness ratio of investigating contacts and suspects

R 245 517.34 ÷ 2 458 notifications = R 99.89 per notification.

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11. 2 500 patients were notified in 1983. In section 1.5, it was estimated that approximately 42 patients were notified as a result of mass screening procedures. All other patients would have been notified as a result of investigation of contacts and suspects, including those who received secondary chemoprophylaxis before developing active TB.

2. Cost-effectiveness analysis of the 'clinic' curative regimen for TB in the CDC :

2 500 people were notified and received treatment in the CDC area in 1983. The breakdown according to age is presented in Table IV.3:

Table IV.3 Number of adults and children notified in 1983 (CDC)

Age group	Number of patients
Adults (15 years and older)	1 556
Children (14 years & younger)	944
TOTAL	2 500

2.1 Costs of the 'clinic' regimen

Most of the cost calculations are contained in Appendix E and Appendix F. These calculations are based largely on the findings of the sample data. Details of mean doses of drugs administered and the mean number of tests performed per patient according to whether a patient completed treatment or not[12], have been taken from the information presented in Chapter III.

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12. The sample data indicated that some patients who did not complete their prescribed treatment regimen were not classified as defaulters (see reasons in section 2.4.2 of Chapter III). As the number of these patients was very small (6 adults and 1 child), they have been combined with defaulters for analysis purposes.

2.1.1 Cost of drugs

The sample data indicated that 77.6% of the adult and 74.8% of the child patients completed their prescribed treatment regimens. Thus it can be estimated that:

1 207 adult patients completed treatment
706 child patients completed treatment
349 adult patients defaulted
238 child patients defaulted

The total cost of the drugs administered in the CDC to notified patients during 1983 can be estimated as follows:

Patients who completed treatment:

1 207 adults x R 107.51 = R 129 764.57
706 children x R 24.13 = R 17 035.78

Patients who defaulted:

349 adults x R 55.45 = R 19 352.05
238 children x R 10.80 = R 2 570.40

(See Tables E.2, E.3, E.6 and E.7 in Appendix E for calculation of costs per patient).

The total cost of drugs administered to the 2 500 notified patients was thus R 168 722.80.

An indirect cost of the drug regimen is the adverse reaction of some of the patients to the drugs. The drug regimen is altered

immediately any adverse reactions occur and the symptoms disappear quite rapidly thereafter. None of the adverse reactions displayed in the sample population resulted in permanent physical disability. 7.7% of the patients in the sample experienced an adverse reaction either to Streptomycin and/or PZA. (See section 2.4.4 in Chapter III for a breakdown of these reactions.)

It should be noted that while a small proportion of patients receiving TB treatment at CDC clinics did experience discomfort/suffering for a limited period of time, due to adverse reactions to one or more drugs, no attempt will be made to quantify the cost of this discomfort.

2.1.2 Cost of tests during treatment

To monitor the progress of patients during treatment, radiological and bacteriological tests are supposed to be performed on adult patients, and radiological tests on child patients, after 60 doses of the regimen have been administered and again after 100 doses. In addition, drug sensitivity tests are sometimes performed if there are indications that the bacilli may have developed a resistance to one or more drugs e.g. if a patient relapses or fails to respond to treatment.

Using the cost per test as given in Appendix F and the mean number of tests per patient as presented in section 2.4.6 of Chapter III, the cost of these monitoring tests was calculated. The results for the 1 207 adults and 706 children who completed treatment and the 349 adults and 238 children who defaulted are presented in Table IV.4 and Table IV.5 respectively.

Table IV.4 Cost of monitoring tests for patients who completed treatment

Test	Adults	Children
X-rays	R 7 114.36	R 3 590.07
Sputum culture	R 3 901.80	
Direct microscopy	R 1 115.52	
Sensitivity	R 3 654.00	
TOTAL	R 15 785.68	R 3 590.07

Table IV.5 Cost of monitoring tests for defaulters

Test	Adults	Children
X-rays	R 741.29	R 457.93
Sputum culture	R 323.40	
Direct microscopy	R 63.84	
Sensitivity	R 176.40	
TOTAL	R 1 304.93	R 457.93

Thus the total cost of tests performed to assess the progress of the 2 500 notified patients during treatment, was R 21 138.61.

2.1.3 Cost of follow-up tests

The sample data indicated that 71.8% (867) of the adult patients and 74.3% (525) of the child patients who completed their prescribed regimen of treatment, had follow-up tests after treatment to ascertain whether the tubercle bacilli were in fact inactive. Using the mean number of tests per patient as presented in Table III.20, and the cost per test (Appendix F), the total cost of

follow-up/surveillance tests on patients treated in 1983 was calculated to be R 7 071.95 (see summary of calculations in Table IV.6).

Table IV.6 Cost of follow-up tests

Test	Adults	Children
X-rays	R 3 291.53	R 1 593.90
Sputum culture	R 1 457.40	
Direct microscopy	R 729.12	
TOTAL	R 5 478.05	R 1 593.90

2.1.4 Cost of treating relapses

It has been estimated that approximately 84 patients who completed treatment during 1983 relapsed, and 126 patients who defaulted were retreated. (See section 2.2.3 for further details of these calculations.) Although some of these patients relapsed in 1983 and some in 1984, it is assumed that the relapse rate was similar in 1982 and that there will thus be minimal discrepancies if the figures quoted above are used as estimates of the total number of relapses treated in 1983. (Note: Relapsed cases are not included in the figure of 2 500 notifications; this refers only to newly notified patients.)

The same regimens and procedures are applied in the treatment of newly notified patients and relapsed cases, except that a sensitivity test is performed on all adults who relapse. Given that the total cost of drugs and tests, excluding any sensitivity tests, used in the treatment of the 2 500 newly notified patients in 1983 is R 193 102.96 and the cost per patient is thus R 77.24, it can be

estimated that the cost of treating the 210 relapses will be as follows:

R 77.24 per patient	x 210 relapses	= R16 220.40
R 25.20 per sensitivity test	x 131 relapsed adults	= R 3 301.20
		R19 521.60

2.1.5 Cost of clinic services

The cost of staff and transport etc. involved in supervising and administering drugs to patients, collecting sputum samples for bacteriological tests, recording information about number of doses administered and test results on patient folders, etc. was estimated to be approximately R 923 773 for 1983. (See Appendix C).

2.1.6 Cost of hospitalisation

The sample data indicated that the mean length of stay for hospitalised patients was 9.1 weeks (63.7 days (see section 2.4.1 in Chapter III). Records at the Brooklyn Chest Hospital, where CDC TB patients are hospitalised, confirmed this finding (average length of stay for all 1983 Brooklyn patients was 9.0 weeks.)

26% (484) of the patients treated at Brooklyn Chest Hospital during 1983 were from the CDC area.

The Brooklyn Chest Hospital is funded by central government. All the costs incurred in treating and caring for TB patients at the hospital are reflected in the expenditure accounts, unlike the

clinics where the drugs, bacteriological test services, etc. are provided free of charge by the government and thus only the services financed by the Divisional Council (partly through government grants) are reflected in their expenditure accounts. The cost of drugs etc. to the Brooklyn Hospital are in effect transfer payments from one government department to another, but must nevertheless be included to accurately determine the total cost of treating TB patients.

The cost per patient per day was R 18.99 in 1983 (personal communication with Brooklyn Chest Hospital). As mentioned earlier, this included all costs ranging from food and laundry costs for patients, to occupational therapy sessions for adults, and school lessons for children. The only cost not included was the expense incurred in the upkeep of the grounds, a duty performed by the Department of Public Works. Attempts to determine this cost were unsuccessful.

The total cost of hospitalisation for CDC TB patients in 1983 was:

484 patients x 63.7 days x R 18.99 per patient per day = R 585 476.89.

In addition to these costs directly related to TB treatment, there were a number of 'indirect' costs that must be accounted for.

2.1.7. Disability grants

Information on the total number of disability grants awarded to TB patients being treated at CDC clinics in 1983 was not available and thus figures were estimated from the sample findings.

It was estimated that approximately 1 438 (31 Whites, 902 Coloureds and 505 Blacks) of the 1 556 adult TB patients were of employable age. The sample indicated that 11.3% of these patients received disability grants for a mean period of 5.9 months. Thus it can be estimated that approximately 4 white, 102 Coloured and 57 Black patients received disability grants in 1983.

The monthly disability grant in 1983 was R 152 for Whites, R 93 for Coloureds and R 57 for Blacks. (SAIRR 1983:516)

Estimates of the total amount received by CDC patients in the form of disability grants during 1983 are presented in Table IV.7.

Table IV.7 Total Estimated Disability grants received by CDC patients

Race	Disability grants
Whites	R 3 587.20
Coloureds	R 55 967.40
Blacks	R 19 169.10
TOTAL	R 78 723.70

2.1.8 Other grants

The Tuberculosis Council of the Cape Province fund provides financial assistance to families whose breadwinner has contracted TB and is unable to generate sufficient income. It is regarded as an interim grant before the results of a disability grant application are available. In 1983, R 23 225 was paid to assist 153 families in this way.

2.1.9 Loss in economic performance or productivity

With the procedures currently available to diagnose TB sufferers at the earliest possible stage and to successfully treat them, a TB patient's economic performance or productivity should not normally be significantly affected. The symptoms of TB which could be expected to affect a worker's productivity are: loss of weight, lethargy, dyspnoea (i.e. shortness of breath - in severe cases), pain in the chest and fever (usually 'low-grade'). (Glatthaar 1982a:14). These will ordinarily only affect productivity once the disease is at a relatively advanced stage.

It is important to note that it is CDC policy to attempt to ensure the least possible disruption in the TB patient's normal daily activities. Every effort is made to keep the patient working and especially to allay employers' fears about the infectiousness of workers who have TB, to prevent their dismissal. (See section 3.2 of Chapter II). One patient included in the sample was dismissed as a result of contracting TB but was reinstated after a CDC doctor had spoken to his employer. Provision is made for treatment of patients at their place of work so that the only disruption to work occurs on the 2 or 3 occasions when the patient is X-rayed or examined by the doctor to assess progress. Certain other local authorities do not provide these services and all their TB patients receive daily supervised treatment at clinics, which often results in serious work disruptions.

The age distribution of TB patients (see Tables III.3 and III.4 for sample population age distribution) indicates that a large proportion of patients are between the ages of 20-50 years, the

'prime' working years. 62% of the patients included in the sample were of employable age.

The sample data also indicated that 51.6% of these patients were specifically noted as being employed, 17.2% were noted as being unemployed, and 31.2% had no reference to employment status on their folder. Although almost a third of the patients had no reference to employment status, it should be noted that the CDC clinic staff take great care to record details of employment to provide for treatment at the workplace. The majority of those who had no reference to employment status were women and it can be assumed that many of them were 'housewives' and not receiving an independant income.

For those patients who were unemployed at the time of contracting TB, there would be no decrease in economic activity directly attributable to the TB or the treatment thereof. It would possibly be more difficult to obtain a job if one was suffering from TB, but given the relatively high unemployment rate in 1983, it is debatable whether a factor for production loss/decrease in economic activity should be ascribed to those TB patients who were unemployed. In fact, 3 of the 32 unemployed patients included in the sample found work after contracting TB and while still being treated.

Details of the patients included in the sample who were employed when they contracted TB and were either declared unfit for work for differing time periods by a CDC doctor or had a change in employment status during TB treatment, are provided below :

Declared unfit for work for : 1 week - 2 patients

2 weeks - 4 patients

1 month - 6 patients

1½ months - 1 patient

Change in employment status : 1 patient resigned

4 patients were dismissed as a result of TB.

1 patient was retrenched (unrelated to TB.)

1 patient was dismissed for alcoholism

Thus, 13 (13.5%) of the employed patients were declared unfit for work for a mean period of 3.1 weeks (S.D. = 1.5 weeks) and 4 (4.2%) of the employed patients were dismissed for reasons relating to TB. Losses due to decreases in economic activity for patients who were dismissed for other reasons or resigned, should not be included here as the analysis is concerned purely with evaluating costs which are a direct result of TB.

Loss in economic performance is also relevant to patients who are hospitalised. Of the 20 patients of employable age who were hospitalised, 13 (65%) were unemployed, 2 (10%) were employed when admitted and 5 (25%) were females for whom employment status was not recorded.

Using the proportions presented in the sample findings (see section 2.2 in Chapter III), it was estimated that approximately 742 patients (16 White, 465 Coloured and 261 Black) would have been employed at the time of contracting TB in 1983, of which approximately 100 (13.5% - 2 Whites, 63 Coloureds and 35 Blacks) would have been declared unfit for work for a mean period of 3.1 weeks. Approximately

31 patients (4.2% - 1 White, 19 Coloureds and 11 Blacks) would have been dismissed for reasons relating to their having contracted TB, assuming no racial effect on job loss probability.

Average personal incomes will be used as a proxy for the marginal productivity of labour.[12a] These income figures are drawn from the 1980 Census data for Cape Town :

Table IV.8 Average monthly personal income in Cape Town (1980)

Race	Male	Female
White	R 808.33	R 362.33
Coloured	R 229.87	R 130.78
Black	R 138.49	R 83.89

(Patel 1984: 67, 68 and 90)

Tab IV.9 Distribution of economically active population by race and sex (1980)

Race	Male	Female
White	63.0%	37.0%
Coloured	59.9%	40.1%
Black	76.3%	23.7%

(Patel 1984 : 142)

The combined average monthly personal incomes for each race group, irrespective of sex, based on the above information is presented in Table IV.10.

12a. In the case of TB patients, average personal incomes may overstate the marginal productivity of these labourers, e.g. workers declared unfit for work would probably have been incapable of producing at the marginal productivity level. The one exception may be where a TB sufferer is dismissed due to employer prejudice rather than a decrease in the worker's productivity. (see p.125 & Addendum IV).

Table IV. 10 Average monthly incomes (1980 & 1983) by race

Race	1980	1983[13]
White	R 643.31	R 948.88
Coloured	R 190.14	R 280.46
Black	R 125.55	R 185.19

Thus, the total loss in productivity, based on incomes, for TB patients declared unfit for work or dismissed in 1983 was as follows:

Declared unfit for work :	R 18 584.58
Dismissed from work[14] :	R 42 099.80
	R 60 684.38

It was estimated that approximately 35 hospitalised patients (24 Coloured and 11 Black) were employed when admitted. Assuming a mean length of stay of 9.1 weeks (see section 2.1.6 of this chapter), the total loss in productivity for these patients was R 18 363.63.

The total loss in productivity/economic performance experienced by CDC TB patients in 1983 was thus approximately R 79 048.01.

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13. The 1983 figures were calculated using the Consumer Price Index for Cape Town: Base year - 1975 (100) 1980 - 172.0 1983 - 253.7 (Hendrie 1985 : 8), assuming no loss of real income over time.

14. This was calculated only for the average of 5.0633 months for which the treatment regimen was administered.

2.1.10 Unquantified indirect costs :

There are a number of indirect costs which should be mentioned although not quantifiable for various reasons. Many of these costs were 'intangible' and their estimation would have required unrealistic effort and resources.

a) Mortality cost is the most significant indirect cost of TB. The TB mortality rate was 2.07% in 1983. (Divisional Council of the Cape 1983 : 48) Section 2.2.1 of Chapter I contains a full discussion of the reasons for not estimating the mortality cost/'value of life' in this study.

b) The cost of time spent at clinics to receive supervised treatment, for radiological and clinical examinations, etc. As stressed earlier, the CDC arranges for treatment at work and thus this cost would in general only be incurred by unemployed patients and 'housewives'.

c) Transport to clinics - this should not be significant as there are clinics in each residential area and most patients are within walking distance of a clinic. If any problems are encountered, the patient is treated at home, i.e. receives 'domiciliary' treatment, the cost of which is accounted for in clinic services expenditure.

d) The symptomatic suffering/discomfort and the possible effects of the stigma of having TB, experienced by TB patients.

e) The problems associated with a patient being removed from his/her family. This applies to hospitalised patients and those patients who come from the 'homelands' specifically to obtain treatment. In the latter case, this may have economic implications if the person was involved in the family's agricultural activities.

f) The cost of health education programmes sponsored either by SANTA or some other organisation - over the past few years, these have taken the form of information pamphlets, advertisements and articles in magazines and newspapers, and TV programmes and advertisements. These are directed both at the general population and at specific groups, e.g. employers. (See Addendum IV).

2.1.11 Total costs of CDC curative regimen

The total cost of the CDC curative regimen in 1983 was R 1 923 584.08. (The breakdown of this based on the above calculations, is tabulated on Table V.1, of Chapter V).

2.2 Effectiveness of the 'clinic' curative regimen

The three major indicators of the effectiveness of the treatment for TB patients are: i) the compliance rate, ii) the cure rate and iii) the relapse rate.

2.2.1 The compliance rate

The mean compliance rate of the patients in the sample who completed the prescribed treatment regimen was 89.4% (see Table III.17 in Chapter III). This is the mean of all patients' individual average attendance, as a percentage of the maximum possible attendances. This finding has been confirmed by a survey conducted by Dr Fisher, of all patients at the Ravensmead and Elsies River clinics. These comprised $\pm$ 37% of all CDC TB patients, in 1981. The compliance rate of patients who completed treatment was 88.3%. (Fisher 1985:14).

The mean compliance rate of patients who did not complete treatment

was 70.4%. Thus, the mean compliance rate for the total sample population was 85.3%. This indicates that even patients who did not complete their TB treatment, were receiving their treatment on a fairly regular basis before defaulting.

The CDC considers a patient's attendance of below 75% of the maximum possible attendances to be unacceptable. (Pearson 1979:420). This is based on the findings of various studies which have shown that the effectiveness of short-course treatment in curing a patient decreases as the frequency of administration of drugs decreases. (Angel 1983 and Aquinas 1982.)

2.2.2 The cure rate

Those patients who default before completing the prescribed regimen of treatment are not considered as cured as they have not received what the CDC Health authorities consider to be an 'acceptable' regimen. (Fisher 1985:10). For other patients, if their compliance rate and general progress is acceptable, the CDC signs them off as cured when they have completed their prescribed treatment regimen.

As indicated by the sample, some patients receive more doses than prescribed by the CDC Health authorities. This usually occurs when one of the clinic doctors prescribes further treatment due to inadequate progress by the patient. This is indicated either by inadequate clearing of the lungs as revealed on X-rays, or by a positive bacteriological test.

A specific measure of the progress of patients is the 'sputum conversion' rate. This refers to the rate of conversion from a

positive bacteriological result before treatment is commenced to a negative result after 60 doses of drugs have been administered.

In the sample, 53 adult patients who completed the prescribed regimen were initially sputum positive and had a bacteriological test result after 60 doses.[15] The results of the bacteriological tests conducted after 60 doses were as follows:

Sputum culture-negative, Direct microscopy-negative	21(39.6%)
Sputum culture-negative, Direct microscopy-no result	21(39.6%)
Sputum culture-no result, Direct microscopy-negative	8(15.1%)
Sputum culture-negative, Direct microscopy-positive	1(1.9%)
Sputum culture-no result, Direct microscopy-positive	1(1.9%)
Sputum culture-positive, Direct microscopy-contaminated	1(1.9%)

Thus, 94.3% of the patients who were initially bacteriologically confirmed and completed treatment, 'converted' to either a negative sputum culture and/or a negative direct microscopy result after 60 doses.

Although this information pertains to a relatively small group of patients and does not account for the possibility that the doctor may consider the clearing of the lungs to be unsatisfactory (based on a radiological examination) despite a negative bacteriological test, it does indicate that a large proportion of the most significant

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15. 109 adult patients were originally sputum positive/bacteriologically confirmed (see Table III.11). 33 of these patients did not have a sputum test result after 60 doses, 20 defaulted before completing treatment and 3 did not complete treatment for reasons other than default.

group of TB patients, i.e. those who are bacteriologically confirmed as having active tubercle bacilli and are the more infectious cases (see section 3.3.1 of Chapter II), are being rendered uninfectious and are ultimately cured.

At a more general level, the sample data indicated that 76.7% of the TB patients in the sample completed the regimen specifically prescribed for them by a CDC doctor and were signed off as cured on the basis of satisfactory test results (see Table III.14). Thus, it can be estimated that approximately 1 913 of the 2 500 notified patients were signed off as cured in 1983.

2.2.3 Relapse rate

The relapse rate of patients who completed TB treatment at a CDC clinic in 1983 was 4.4%, according to the sample data findings. Thus, of the approximately 1 913 patients signed off as cured during 1983, it is estimated that 84 relapsed after a mean period of 8.2 months (see section 2.6 of Chapter III).

The mean number of doses of INH[16] received by patients who relapsed was compared to the mean number of doses for all patients who completed treatment to ascertain whether there were any significant differences.

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16. The number of doses of INH is used as an indicator of the total drug doses administered. INH is the most consistently administered drug at CDC clinics. It is prescribed for the entire duration of treatment in the majority of cases and is only discontinued if the tubercle bacilli develop a resistance to it.

Adults:

Relapses - 113.6 doses all patients - 110.9 doses

Children:

Relapses - 63.7 doses All patients - 88.1 doses

Children who relapsed received relatively fewer doses than the mean for all patients.

The 96.5% mean compliance rate of those patients who relapsed was higher than the 89.4% mean compliance rate for all patients who completed treatment. This indicates that compliance was not a contributing factor to relapse in the case of patients who completed the regimen prescribed for them.

The sample data indicated that 21.4% (15) of the patients who did not complete the prescribed treatment regimen relapsed, or more correctly, re-presented themselves at a CDC clinic with active TB, a mean period of 6.3 months after defaulting. Generalising this to the approximately 587 patients who did not complete treatment, it is estimated that 126 would have begun a second course of TB treatment.

There are certain significant factors concerning the defaulters who 'relapsed' and were included in the sample that should be noted. The mean number of doses of INH received by 'relapsed' defaulters is compared to the mean for all defaulters:

Adults:

Relapses - 40.2 doses All defaulters - 51.6 doses

Children:

Relapses - 37.0 doses All defaulters - 38.1 doses

Adult defaulters who 'relapsed' received relatively fewer doses than the mean number of doses for all defaulters.

The compliance rate for patients who did not complete treatment and subsequently relapsed was 66.7%. This was lower than the mean compliance rate of 70.4% for all patients who did not complete treatment.

It is significant that 10 of the 13 adult defaulters (76.9%) in the sample who 'relapsed' were bacteriologically confirmed as TB sufferers, i.e they were found to have a relatively high concentration of active tubercle bacilli, whereas only 54.2% of the total adult sample population were bacteriologically confirmed. This indicates that bacteriological status is an important determining factor in the relapse of defaulters.

The number of doses received before default is also important. This can be illustrated by comparing the bacteriologically confirmed adults in the sample who defaulted and 'relapsed' with those who did not 'relapse'. A total of 24 adults who defaulted were initially confirmed as TB cases by means of either a positive sputum culture and/or direct microscopy result. The mean number of doses and the compliance rates of these patients were as follows:

10 patients 'relapsed': Mean number of doses of INH = 34.7

Compliance rate = 64.6%

14 patients did not 'relapse': Mean INH doses = 89.1

Compliance rate = 81.9%

These findings indicate that, in general, only those patients who defaulted after receiving a relatively low proportion of the total possible doses of TB drugs (approximately one third of the prescribed regimen) and in addition had an unacceptable compliance rate would subsequently relapse. Patients who did not complete the prescribed regimen, either by default or for other reasons, but nevertheless received a relatively large proportion of the prescribed drug doses and who complied well with the treatment regimen during this period, would in general not 'relapse'.

This deduction is supported by findings documented by Dr Zabow and Dr Pearson, CDC doctors, in 1982:

> "... over the last 8 years we have seen a considerable number of patients who defaulted early (between 40 and 80 daily doses) but who have been shown on examination of radiographs and sputum specimens to have remained in a stable condition for periods of up to 5 years..."
>
> (Zabow and Pearson 1982:870)

It may thus be inferred that although patients who did not complete treatment were not signed off as cured by a CDC doctor, those who did not 'relapse' were in effect cured. The total relapse and retreatment rate, based on the sample findings was 8.4%, which indicates that approximately 210 cases relapsed or were retreated in 1983.

2.2.4 Summary of measures of effectiveness

The most important measure of the effectiveness of TB treatment is the proportion of TB patients regarded as cured that did not subsequently relapse. Treatment compliance rates are not the primary determinant of effectiveness, but remain a useful auxilliary indicator.

Before calculating the effective cure rate, it should be noted that of the 2710 newly notified and relapsed patients, 56 died, i.e. there was a mortality rate of 2.07% (Divisional Council of the Cape 1983:48). Given a 8.4% relapse rate, the estimated effective cure rate was 89.54% i.e. all patients who did not relapse or die wereconsidered to be effectively cured.

2.3 Cost-effectiveness ratios for the CDC curative regimen:

Four cost-effectiveness ratios are presented here which will indicate how ratios are changed by selecting different units of outcome, and which may be useful to other analysts and decision makers who may require one of a range of possible ratios to evaluate a specific problem.

i) Cost of curative regimen per newly notified patient -

R 1 923 584.08 ÷ 2 500 new notifications

= R 769.43 per newly notified patient

ii) Cost of curative regimen per newly notified patient cured -

R 1 923 584.08 ÷ 2 238 newly notified patients cured

= R 859.51 per newly notified patient cured.

iii) Cost of curative regimen per newly notified/relapsed patient -

R 1 923 584.08 ÷ 2 710 new notifications/relapses

= R 709.81 per newly notified/relapsed patient

iv) Cost of curative regimen per newly notified/relapsed patient cured

R 1 923 584.08 ÷ 2 426 newly notified/relapsed patients cured

= R 792.90 per newly notified/relapsed patient cured

3. Summary:

Cost-effectiveness ratios were calculated for each of the preventive and curative procedures for TB used by the CDC. These ratios provide the raw-material for policy-makers to base their decisions upon regarding which TB procedures should be given priority. These individual ratios are evaluated and compared in Chapter V, to indicate what combination of preventive and curative procedures should be implemented.

It is important to note that data for certain procedures was very limited. A number of assumptions were made to facilitate the estimation of variables for which no values were available.

There is an urgent need for more research of preventive and curative TB procedures in S.A. The analysis in this chapter indicates two particular areas for further research:

i) Evaluation of the effectiveness of BCG vaccinations in S.A., and

ii) Determination of the effectiveness of secondary chemoprophylaxis.

In addition, TB authorities should be encouraged to compile more information on notified TB patients e.g. total number of defaulters, total number of relapses, treatment compliance, rates, etc.

ADDENDUM IV ADVERTISEMENT IN FINANCIAL MAIL

An ignorant employer is more dangerous than a worker with TB.

If you fire a worker with suspected TB, instead of helping to cure him you assist in spreading TB in your area. The untreated victim is dangerous to others. The worker being treated for TB is 100% safe. Your workers and their families are depending on you.

TB is a very serious problem facing South Africa. There are 62 000 reported new cases every year, 10 deaths daily and thousands and thousands of unreported cases.

If you're an employer chances are it's already affecting your company. Which puts you in an invaluable position to help curb this epidemic. Because only if all employers at every level pull their weight, can we hope to stop TB.

What can you do?

Firstly help us find the workers with TB and send them to the nearest clinic for a free TB checkup. The warning signs are a cough that has lasted more than three weeks, loss of weight, loss of appetite, pains in the chest. Whatever you do, don't fire the worker with suspected TB. This will just spread the problem without curing it.

Yet the cure for TB is so simple.

A course of tablets taken every day, for up to 6 months. From the day the worker takes his first pill he is no longer a danger to either worker or employer.

He is as capable of demanding manual labour or skilled work as he was before he contracted TB. So you needn't go to the expense of finding and training a new worker.

However, it's vital he takes his medicine daily. This is where the employer can once again help.

If your company is small check that he takes his medicine daily. If your company is large appoint someone to check on this for you.

You'll have helped keep a valuable employee. And a family will have kept a valuable breadwinner.

Please send me the "How you can beat TB Booklet".
Name.....
Address.....
.....

SOUTH AFRICAN NATIONAL TUBERCULOSIS ASSOCIATION **SANTA**

Send this coupon to SANTA, PO BOX 10501, JOHANNESBURG 2000

Help Fight TB.

FINANCIAL MAIL 30 May, 1986

CHAPTER V

ANALYSIS OF COST-EFFECTIVENESS RATIOS OF PREVENTIVE AND CURATIVE PROCEDURES FOR TB IN THE CDC

Introduction:

As information was severely limited in some areas and a number of assumptions had to be made to permit the quantification of various factors, the cost-effectiveness ratios calculated in Chapter IV should be seen as general indicators of the relative magnitude of each curative and preventive procedure, and conclusive policy decisions should not be drawn purely on the basis of these ratios. They do however, provide a basis for certain comparisons, analysis and evaluation subject to the recognition of data limitations.

As stressed in section 4 of Chapter II, the most important task facing policy-makers is the determination of the most cost-effective combination of preventive and curative TB procedures. To facilitate this decision-making process and to emphasise what policy decisions the ratios point towards, two sets of evaluations are performed in this chapter:

a) The two purely preventive procedures, BCG vaccinations and secondary chemoprophylaxis, are compared, as are the two diagnostic procedures, mass screening and contact/suspect investigation. As the treatment of notified patients comprises the major part of the CDC TB programme the 'clinic' curative regimen is evaluated in detail. The first area of consideration is whether any 1983 notified patients were incorrectly diagnosed as infectious TB

cases due to inadequate diagnostic techniques, and were thus treated 'unnecessarily'. The 'clinic' regimen is then compared with the 'official' regimen to determine whether the flexibility in application of the curative regimen prescribed by CDC authorities influences the cost-effectiveness of TB treatment significantly.

Finally, the ratios for two categories of patients, those treated at clinics only and those who are hospitalised for part of the treatment, are compared.

b) The ratios for preventive and curative procedures are then compared. The BCG vaccination and prophylactic treatment ratios are expressed in terms of notifications prevented while the diagnostic and curative ratios are expressed in terms of notifications. To make this comparison, it must be recognised that the benefit of preventing one notification is the averted cost of diagnosing and treating/curing one notified patient.

All of the cost effectiveness ratios are expressed in terms of the cost per notification prevented or the cost per notified patient diagnosed and treated. The relative priority of each procedure, i.e. how extensive each 'catch net' should be (see Section 4 of Chapter II), can be determined by comparing the cost-effectiveness ratios of preventive and curative procedures and shifting resources in the direction of those procedures with the lowest ratios.

1. Summary of cost-effectiveness ratios:

To facilitate comparison and discussion, the cost-effectiveness ratios calculated in Chapter IV are summarised here:

BCG vaccinations -

R25 727.45 per TB notification prevented in Whites

R 912.31 per TB notification prevented in Coloureds

R 263.54 per TB notification prevented in Blacks

Secondary chemoprophylaxis -

R 296.48 per TB notification prevented

Mass screening campaigns -

R 1 706.18 per notification arising from mass screening activities

Investigation of contacts and suspects -

R 99.89 per notification arising from contact and suspect investigation activities

Curative regimen for notified TB patients -

R 769.43 per newly notified patient (i.e. per notification)

R 859.51 per newly notified patient cured

R 709.81 per newly notified/relapsed patient

R 792.90 per newly notified/relapsed patient cured

As stated in Chapter I, the primary purpose of producing these ratios is to provide support for the decisions of policy makers. The ultimate responsibility for deciding whether the cost per outcome

unit is justified or worthwhile rests with the policy makers. Thus, the responsibility of the analyst is not to determine whether each procedure is economically feasible, but rather to indicate what policy conclusions the analysis points towards.

It is important to evaluate ratios of purely preventive, investigative/diagnostic procedures and curative regimen ratios separately, before comparing the ratios for preventive and curative procedures.

2. Evaluation of preventive procedures:

The cost per notification prevented by secondary chemoprophylaxis and by administering BCG vaccinations in the Black population are similar. However, the costs per notification prevented by vaccinating the White and Coloured populations are significantly higher than the cost per notification prevented by secondary chemoprophylaxis. This is partly attributable to the higher cost of clinic services involved in administering BCG vaccinations. The possibility of changes in the BCG policy to reduce the White and Coloured ratios will be considered in section 5.2.

3. Evaluation of Investigative/diagnostic procedures :

In the case of mass screening campaigns and contact/suspect investigation, the same procedures are used and the cost-effectiveness ratios are directly comparable. It has been generally accepted for many years that the case yield of mass screening campaigns is substantially lower than investigation of contacts and suspects. Their relative cost-effectiveness ratios support these findings.

As noted in Chapter II (section 3.3.2, point iii), efforts are being made to limit the pre-employment screening of workers. The Leonsdale survey was defined as a once-off campaign in its terms of reference, and given the low mean case yield of 0.52% in a geographical area with a high TB incidence, this method of screening should not be used again. (Unpublished report on the Leonsdale survey.) The TBRI survey was primarily for research purposes to establish measures of TB incidence and prevalence, but was also used to find cases of TB. Given the urgent need for more TB research, this particular mass screening procedure should be continued despite its low mean case yield.

4. Evaluation of the 'clinic' curative regimen:

The cost-effectiveness of curative procedures will be examined in some depth as they accounted for 78% of the total cost of R 2 462 561.48 for the TB preventive and curative procedures in the CDC in 1983.

Table V.1 presents a summary of the costs involved in treating notified patients.

The cost of drugs, clinic services and hospitalisation account for the largest proportions of the total cost of treating notified patients. Before evaluating these factors in more detail, a few comments on the loss in economic performance resulting from TB are necessary.

Table V.1 Breakdown of the costs of treating notified CDC patients in 1983

Cost category	Cost	%
Drugs	R 168 722.80	8.77
Tests during treatment	R 21 138.61	1.10
Follow-up tests	R 7 071.95	0.37
Treating relapses	R 19 521.60	1.01
Clinic services	R 923 773.00	48.02
Hospitalisation	R 585 476.89	30.44
Health Education	R 16 882.52	0.88
Disability grants	R 78 723.70	4.09
Other grants	R 23 225.00	1.21
Loss in economic performance	R 79 048.01	4.11
TOTAL	R 1 923 584.08	

4.1 Loss in economic performance:

Under the old treatment regimen, i.e. before Rifampicin was introduced as a first-line drug and included in the preferred treatment regimen, many patients were hospitalised for up to six months. Pearson (1980:589) indicated that the loss in economic performance for 500 of these hospitalised patients amounted to R 372 000 per annum. Thus, the current CDC policy of only hospitalising certain categories of patients and instead treating the majority of patients by means of ambulatory/clinic based treatment has resulted in significant cost savings in terms of loss in productivity.

The loss in terms of earnings foregone of R 42 099.80 due to the dismissal of workers suffering from TB, is a cost that can be averted. As indicated in Chapter IV (section 2.1.9), this cost was only calculated for the approximately 5 months of treatment. The period for which these patients would be unemployed after dismissal could not be estimated. Given the high unemployment rate, the monetary and emotional costs of dismissals could have been higher than the estimated amount.

Thompson and Myrdal (1984c:3) found that 7 of the 14 adults included in their survey who were employed at the time of contracting TB were dismissed for reasons associated with their disease, which indicates that dismissals are an important consideration for TB patients.

By intensifying the health education programmes directed at employers, which are of low cost in comparison with the loss from dismissals, the number of dismissals can be reduced. In particular, employers should be reminded that it is unlawful and an unfair labour practice to dismiss an employee who has TB, unless they are unable to perform the work required of them.[1] None of the dismissed employees in the sample had been declared unfit for work.

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1. Personal communication with Legal Resources Centre, Cape Town.

In general, the CDC should be commended on their efforts to minimise disruption of employed patients' work patterns and to explain the nature of the disease to employers, and in particular for the steps taken by some of the doctors to persuade employers to reinstate workers suffering from TB who had been dismissed.

4.2 Drug costs and clinic services:

It is noteworthy that despite the CDC treatment regimen containing Rifampicin, a relatively expensive drug, the drug costs only contributed 8.77% to the total costs of treatment. When health authorities originally considered the use of Rifampicin as a first-line drug, many decision makers felt that the substantially higher unit cost of Rifampicin in comparison with other drugs used in TB treatment, outweighed the gains in effectiveness. (Fox & Nunn 1979)

Such considerations suggest that health care policy decisions should be based on analytical frameworks such as cost-effectiveness analysis to ensure that all factors affecting costs and effectiveness are taken into consideration. For example, although drug costs per patient increased with the introduction of Rifampicin, the cost of clinic services per patient was reduced due to the shorter duration of the new treatment regimen; in addition, the cure rate increased and the relapse rate decreased.

To evaluate the drug and clinic services costs in more detail, two comparative analyses are performed.

4.2.1 Treatment of uninfectious patients:

An important consideration in analysing the cost-effectiveness of TB treatment regimens is whether any patients are being treated unnecessarily, i.e. whether there are any false positive diagnoses. Chapter II (section 3.3.1) details the findings of studies which have shown that X-rays are a relatively unreliable form of diagnosing patients with active tubercle bacilli. In the case of patients diagnosed as TB sufferers on the basis of an X-ray but who neverthless had negative bacteriological results, the lesion visible on the X-ray may contain inactive tubercle bacilli or may be due to a lung disease other than tuberculosis. In some cases, the bacteriological test may have produced a false negative result, due to factors such as inadequate sputum collection or inadequate storage of sputum specimens. (Toman 1979:10-11). Bacteriological tests are however generally regarded as being significantly more accurate and reliable than radiological tests.

To illustrate the effect of treating patients with inactive tubercle bacilli diagnosed on the basis of an X-ray, the worst possible scenario will be examined, i.e. that all patients with negative bacteriological test results are not in need of treatment.

The sample data indicated that 148 of the adult patients had recorded results for bacteriological tests. (A report that the sputum specimen was contaminated is not regarded as a 'result'.) 109 (73.6%) had at least one positive test result while 39 (26.4%) had at least one negative result while the other result was not positive. If it is assumed that the same proportions would apply to children

if they were given bacteriological tests, then it can be estimated that approximately 660 (26.4%) of the patients notified in 1983 need not have been treated.

All the costs involved in the treatment of TB patients, as reflected in Table V.1, would be reduced proportionately if no patients are treated unnecessarily except for the cost of clinic services due to the cost of overheads and staff which are difficult to alter proportionately.

If one however assumed that the clinic services costs were also reduced proportionately because fewer patients would require daily supervised treatment and other clinic services, R 507 826.20 (26.4% of the total 1983 treatment costs) would have been spent on treating patients unnecessarily in 1983. The cost-effectiveness ratio per notified patient would be unchanged.

Conversely, if it is assumed that the cost of clinic services would be unchanged, i.e. would have been incurred even if only the 1 840 notified patients who were bacteriologically confirmed were treated, R 263 950.13 (13.7% of the total 1983 treatment costs) would have been spent on treating patients unnecessarily in 1983.

It must be stressed that the objective here is not to dictate who should or should not be treated but rather to indicate that by not bacteriologically confirming diagnoses and thus treating some patients unnecessarily, a considerable misapplication of the limited funds available could occur.

Given the high incidence of TB and the apparent efficacy of health services in the CDC, it seems unlikely that such a large proportion of patients are treated unnecesarily. The responsibility rests with the CDC authorities to assess the significance of this factor.

It is important to note that the major reason advanced by clinic staff and the health authorities of the CDC when questioned about the low rate of bacteriological confirmation, particularly at the Black clinics, was clinic staff shortages. This sometimes prevented the collection of sputum specimens from adult patients and also resulted in administrative inefficiency with respect to recording the results of tests that were conducted, once they became available from the State Health Laboratory.

Unfortunately, the present study is unable to present specific data on additional staff needs, but it does appear that inefficiencies were largely a result of clinic staff shortages rather than training inadequacies. It is important for the CDC to generate more funds for this purpose. Once this initial step has been taken, it may emerge that a higher proportion of patients are in fact bacteriologically positive and thus not treated unnecessarily.

Improving the staffing of clinics would also have other repurcussions. It would result in a higher proportion of defaulters and contacts being traced. As stated in section 1.6 of Chapter IV, the sample indicated that only 51% of the contacts recorded by clinics are being investigated due to time limitations. Given the relatively high mean case yield of contact investigation, its effectiveness might be improved by the provision of extra clinic staff.

The State Health authorities, who are the providers of a large proportion of the CDC funds for TB treatment, should be persuaded that an initial outlay for improved staffing is necessary. This would result in greater effectiveness of TB preventive and curative procedures at the CDC clinics and could reduce other cost components, such as the cost of treating patients 'unnecessarily', if the rate of bacteriological confirmation is increased. This could feasibly result in a reduction of the cost-effectiveness ratios.

A major conclusion of this analysis is to reiterate the recommendation by Glatthaar (1982a:15) that all adult patients should be bacteriologically confirmed, to reduce misdiagnosis. In addition, it should be ensured that all clinic staff are given the appropriate standard of instruction in the collection and storage of sputum specimens to reduce the number of false positive and false negative results.

4.2.2 Treatment using the 'official' CDC regimen:

The major distinction between the findings of the sample data and the 'official' treatment regimen is the number of doses of drugs administered and the number and type of tests performed. In this analysis, the cost-effectiveness ratios of treating notified patients according to the 'official' regimen are calculated. It is important to note that the patients who would receive this hypothetical treatment regimen are the 2 500 patients notified in 1983, of which 300 were included in the sample described in Chapter III. One can assume that factors such as hospitalisation, clinic services, disability grants, etc. will be similar for 'official' and 'clinic' regimens. Thus, this section will be devoted to evaluating the drug regimen and prescribed testing procedures. It is also assumed,

for the purpose of this analysis, that rates of default from treatment and follow-up procedures will be the same as that reflected in the sample data, i.e. will be the same for both the 'clinic' and 'official' regimens.

COSTS:

i) Cost of drugs:

The drug costs per patient using the original CDC treatment regimen are given in Tables E.8 and E.9 in Appendix E. The total costs of drugs for patients receiving this regimen would be as follows:

Patients who completed treatment -

Adults : 1 207 patients x R 75.64 = R 91 297.48

Children : 706 patients x R 25.99 = R 18 348.94

Patients who defaulted -

Adults : 349 patients x R 51.80 = R 18 078.20

Children : 238 patients x R 16.60 = R 3 950.80

Total drug cost for the 2 500 notified patients = R 131 675.42.

ii) Cost of tests during treatment:

The tests recommended by the CDC health authorities for assessment purposes during treatment are: X-ray, sputum culture and direct microscopy for adults and X-ray for children after 60 doses and again after 100 doses. (Fisher 1985:6). As sesitivity tests are only performed in specific circumstances and at the discretion of the doctor, it can be assumed that

the same number would be performed irrespective of whether patients were treated according to the 'clinic' or 'official' regimen.

Based on this information and the cost per test as detailed in Appendix F, the costs of these tests will be as presented in Tables V.2 and V.3 (assuming a similar proportion of tests before default to the 'clinic' regimen as reflected in the sample - 36.05% of X-rays for adults and 37.8% for children).

Table V.2 Cost of monitoring tests for patients who completed treatment

Test	Adults	Children
X-rays	R 6 107.42	R 3 572.36
Sputum Culture	R 10 138.80	
Direct microscopy	R 4 055.52	
Sensitivity	R 3 654.00	
TOTAL	R 23 955.74	R 3 572.36

Table V.3 Cost of monitoring tests for defaulters

Test	Adults	Children
X-rays	R 636.62	R 455.22
Sputum culture	R 1 056.84	
Direct microscopy	R 422.74	
Sensitivity	R 176.40	
TOTAL	R 2 292.60	R 455.22

iii) Cost of follow-up tests:

Follow-up X-rays are performed on both children and adults 3 and 9 months after completion of treatment. Bacteriological tests are sometimes performed on adults in addition to the X-rays at the discretion of the doctor, and will thus be assumed to be the same as in the 'clinic' regimen.

Table V.4 Cost of follow-up tests

Test	Adults	Children
X-rays	R 4 387.02	R 2 656.50
Sputum culture	R 1 457.40	
Direct microscopy	R 729.12	
TOTAL	R 6 573.54	R 2 656.50

iv) Cost of treating relapses:

It can be estimated that approximately 100 patients would have relapsed on the 'official' regimen, given a combined relapse rate of 4% for patients who completed treatment and defaulters. (Tibbit 1982:32).

The total cost of drugs and tests, excluding any sensitivity tests, for the treatment of the 2 500 patients notified in 1983 using the 'official' regimen, would have been R 167 350.98 and the cost per patient would have been R 66.94.

Thus it can be estimated that the cost of treating relapses would have been as follows:

R 66.94 per patient x 100 relapses	R 6 694.00
R 25.20 per sensitivity test x 62 adult relapses[2]	= R 1 562.40
	R 8 256.40

v) Total costs of treatment:

If all other costs involved in the treatment of notified patients are assumed to be the same for the two regimens, the total costs of treating patients using the 'official' regimen would have been approximately R 1 886 566.90 in 1983.

EFFECTIVENESS:

An effective cure rate of 96% is the most accurate estimate of the effectiveness of the 'official' regimen available. It is based on the relapse rate of 4%, including defaulters, determined a mean period of 20 months after completion of treatment, which was calculated from various studies conducted by CDC personnel. (Tibbit 1982:32).

COST-EFFECTIVENESS RATIOS:

The same set of ratios calculated for the 'clinic' regimen are presented here to facilitate comparison of the two regimens.

---

2. This is based on the fact that 62% of the notified patients in 1983 were adults. Sensitivity tests are performed on a sputum specimen. In general, children are unable to produce sufficient sputum for a bacteriological investigation.

i) Cost of 'official' regimen per newly notified patient -

R 1 886 566.90 ÷ 2 500 new notifications

= R 754.63 per newly notified patient

ii) Cost of 'official' regimen per newly notified patient cured -

R 1 886 566.90 ÷ 2 400 newly notified patients cured

= R 786.07 per newly notified patient cured

iii) Cost of 'official' regimen per newly notified/relapsed patient -

R 1 886 566.90 ÷ 2 600 newly notified/relapsed patients

= R 725.61 per newly notified/relapsed patient

iv) Cost of 'official' regimen per newly notified/relapsed patient cured -

R 1 886 566.90 ÷ 2 496 newly notified/relapsed patients cured

= R 755.84 per newly notified/relapsed patient cured

The differences between these cost-effectiveness ratios for the 'clinic' regimen and the 'official' regimen are not significant which lends support to the CDC policy of allowing a certain degree of flexibility in the application of the official regimen, based on the doctor's assessment of a patient's progress during treatment.

4.3 Hospitalisation costs:

It is significant that 30.44% of the total costs of treating 2 500 notified patients in 1983 arise from the treatment of 484 patients in hospital for a mean period of 9.1 weeks each. To investigate this factor further, cost-effectiveness ratios are calculated for patients who are hospitalised and compared to the ratios for patients who receive purely ambulatory treatment.

The sample data showed that adult and child patients who were hospitalised received a mean of 95.5 and 88.3 doses of INH respectively at CDC clinics after being discharged from hospital. This was not considered to be significantly different from the combined means for hospitalised and ambulatory patients, which indicated that their utilisation of clinic services upon discharge from hospital was similar to that for ambulatory patients.

Thus, the total curative regimen costs, less the costs of hospitalisation and the loss in economic activity attributable to hospitalised patients, are divided between the 484 (19.4%) patients who were initially hospitalised and 2 016 (80.6%) purely ambulatory patients, on a proportional basis. Hospitalised patients are treated in the same way as ambulatory patients when receiving clinic treatment and are subject to the same possibilities of dismissal from work etc. The cost which may be different is the cost of treating relapses. However, the relapse rate of hospitalised patients could not be accurately determined, due to the relatively small number of hospitalised patients included in the sample. (1 of the 28 hospitalised patients in the sample relapsed.)

The costs are then as follows:

Hospitalised patients -

Costs of hospitalisation	R 585 476.89
Loss in economic activity while in hospital	R 18 363.63
Proportion of clinic treatment costs	R 256 030.25
TOTAL	R 859 870.77

Note: These costs do not take the indirect non-pecuniary costs arising from the separation from families, etc. into account.

Ambulatory patients -

Proportion of clinic treatment costs R 1 063 713.31

As an accurate relapse rate estimate for hospitalised patients was not calculable because of sample limitations, the only cost-effectiveness ratio calculated is the cost per newly notified patient.

Cost-effectiveness ratio for hospitalised patients -
R 859 870.77 ÷ 484 patients = R 1 776.59 per notified patient

Cost-effectiveness ratio for ambulatory patients -
R 1 063 713.31 ÷ 2 016 patients = R 527.64 per notified patient

The cost-effectiveness ratio for purely ambulatory patients is significantly lower than the ratio for hospitalised patients and the ratio for a combination of hospitalised and ambulatory patients - R 769.43 per newly notified patient as calculated from the CDC 'clinic' regimen. The hospitalisation policy should be reconsidered and every effort made to hospitalise only those patients who cannot be effectively treated by ambulatory means e.g. chronic defaulters and patients with advanced TB who are seriously ill.

The importance and practical relevance of this finding is evident when it is noted that certain local authorities, other than the CDC, are at present negotiating for the expansion of TB hospitals and hostels.

It has been internationally accepted for many years that ambulatory treatment of TB patients is preferrable to and more cost-effective than hospitalisation. One study found that

> "The results in the former [Sanitorium treatment], despite good accommodation, nursing, rich diet, and prolonged bed-rest, were not superior to those in patients treated in overcrowded homes, who had a poor diet, much less rest, and often very long working hours."
>
> (Toman 1979:128)

There are two major arguments advanced in favour of increasing TB hospital facilities i) some local authorities disagree with the findings of the above-mentioned study as they have found that their ambulatory treatment regimens are not as effective as hospitalisation, especially in terms of the default rate. Authorities should be encouraged to investigate methods of improving the default rate within the framework of ambulatory treatment. For example, health education could be improved to emphasise the importance of receiving regular treatment and of completing the prescribed regimen; defaulters could be given domiciliary treatment i.e. if a patient ceases to attend a clinic for daily treatment, they could be treated at home. The emphasis should be on making ambulatory treatment as convenient as possible for TB patients. The reasons for default must also be researched so that effective strategies for combatting it can be devised. ii) The TB notification rate is increasing and thus more patients require hospitalisation. It is once again stressed that only those patients who cannot be effectively treated by ambulatory means should be hospitalised.

5. Comparison of preventive and curative cost-effectiveness ratios:

Section 4 of Chapter II indicated that there are in general, three TB risk levels. One or more of the TB preventive and curative procedures can be applied to each risk group to counteract the movement to higher risk levels. (see Figure II.8). The purpose of this analysis is to determine what combination of preventive and curative procedures should be implemented in the CDC TB control programme.

Although diagnosis is usually regarded as a secondary preventive procedure,[3] for the purposes of this analysis diagnosis and treatment of patients will be combined. (Figure II.8 indicates that these are the two procedures applied to infectious TB cases.)

The total cost of diagnosing the 2 500 newly notified TB patients in 1983, through mass screening and investigation of contacts and suspects, was R 317 176.98 and thus the cost per notification of diagnosis is R 126.87. Although this figure is somewhat overstated due to certain mass screening procedures which are being eliminated at present, it does reflect the situation in 1983. The cost of diagnosing and curing one notified patient is R 986.38.

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3. Diagnostic procedures are preventive in the sense that by finding infectious cases at an early stage, the transmission of tubercle bacilli to others can be limited and the patient can be treated to reduce the risk of death. Primary preventive procedures such as BCG vaccination and secondary chemoprophylaxis can actually prevent infectious cases.

The cost per notification prevented by BCG vaccination or secondary chemoprophylaxis must be compared with the cost per notified patient diagnosed and cured. This comparison of preventive and curative procedures is based on the following relationship: the benefit of preventing one notification is the averted cost of diagnosing and treating one notified patient.

5.1 Comparison of secondary chemoprophylaxis and the curative regimen:

The cost of R296.48 per notification prevented for secondary chemoprophylaxis is less than the cost of diagnosing and curing one notified patient. Secondary chemoprophylaxis can therefore be considered economically feasible or cost-effective and should be an important component of the CDC TB control programme.

5.2 Comparison of BCG vaccination and the curative regimen:

The costs per notification prevented by vaccinating the Black and Coloured populations are less than the cost of diagnosing and curing one notified patient.

However, the cost of R25 727.45 per notification prevented by BCG vaccinations in the White population is significantly higher than the cost of R986.38 per notified patient diagnosed and cured. This indicates that TB policy-makers need to assess the economic feasibility of vaccinating whites.

As stated in Chapter IV (section 2.1.10) there are some indirect costs of notification such as the cost of symptomatic suffering and mortality costs, which are not quantified. These indirect

costs can be included in the evaluation by calculating the difference between the quantified costs of BCG vaccinations i.e. the cost per notification prevented, and the quantified benefit i.e. the cost per notified patient diagnosed and cured. This can be restated as follows: is it a rational resource use to spend R 24 741.03 in averting the indirect symptomatic and mortality costs which may be incurred if one additional notification occurs in the white population.

Two points should be noted here: a) Research is urgently required to determine the duration of the protective efficacy of BCG vaccinations to the South African population and whether revaccination significantly increases the protection afforded by BCG vaccinations, i.e. the policy of administering three BCG vaccinations to White children should be reviewed; b) Chapter II explained that socio-economic factors were a major determinant of TB incidence which accounted to some extent for the racial differences in notification rates, but it is possible that if significant changes were made in the vaccination policy for whites, TB incidence in this race group may increase.

The issue is thus very complicated and it is difficult to make conclusive policy decisions in the absence of comprehensive research into the protective efficacy of BCG vaccinations in S.A. One conclusion that can be drawn is that when considering the marginal TB notification prevented, given limited resources, more effort and funds should be expended on ensuring greater BCG coverage in the Black and Coloured population groups than for Whites.

6. Summary of analysis:

In general, it is more cost-effective to prevent TB notifications than to diagnose and cure a notified TB patient. Health authorities must re-assess certain aspects of the TB control programme, based on the cost-effectiveness ratios for each procedure.

These ratios are expressed in terms of the average cost per notification prevented or the average cost per notified patient diagnosed and cured. Resources should be re-allocated, giving priority to those procedures with the lowest cost-effectiveness ratios. Once this resource re-allocation takes effect, the disparities between the cost-effectiveness ratios will be reduced. It will then be important to base any further cost-effectiveness analysis on the marginal cost per notification prevented/notified patient diagnosed and cured, as the most cost-effective combination of curative and preventive procedures will be achieved when the marginal costs of all procedures are equal.

Waaler (1978:2-3)[4] explains that when determining the allocation of limited resources,

> "The relevant thing is the marginal impact, or rather the marginal epidemiological impact that one can obtain for a given amount of money. It is not a question of whether BCG can produce 10% or 90% of the problem reduction, but how much problem reduction one can obtain with $1 in the direction of BCG as compared with another direction. ... The solution is in fact achieved when the marginal impact is the same in all directions, because if this is not the case, it would pay to transfer some resources from one direction into another direction."

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4. Although Waaler argues in terms of the marginal notification prevented/notified patient diagnosed and treated per unit cost rather than the marginal cost per notification prevented/notified patient diagnosed and treated, the principle of equating the marginal ratios is the same.

Certain policy conclusions are indicated by the analysis presented in this chapter:

i) Vaccination of the Black and Coloured populations and secondary chemoprophylaxis should be prioritised in the overall TB control programme.

ii) The policy of administering vaccinations in the white population and of conducting mass screening campaigns must be reconsidered.

iii) Patients should only be hospitalised if they cannot be effectively treated by ambulatory means e.g. if the TB is in an advanced stage or if the patient is a chronic defaulter.

iv) Bacteriological confirmation of patients must be improved to reduce the number of 'false-positive' cases treated 'unnecessarily'.

7. Changes in preventive and curative TB procedures since 1983:

As the analysis presented in this study is based on 1983 data, it is necessary to determine whether there have been any significant changes in TB policy since 1983 which could influence the findings summarised above.

There have been few changes in the curative and preventive procedures prescribed by the CDC since 1983, other than an attempt to reduce the number of mass screening investigations performed. However, costs have increased as a result of two factors: i) an 18.2%

average annual increase in TB notifications between 1983 and 1985[5] and thus more patients requiring treatment, and ii) inflationary cost pressures[6].

The major changes in TB treatment and preventive activities since 1983 are related to political factors, more specifically the 'political unrest' in Cape Town since August 1985. During the initial 'unrest' in August 1985, many of the CDC clinics in both the Coloured and Black areas were closed for various time periods, as the CDC authorities felt that the safety of the staff was uncertain.

Clinic services returned to normal within a few days in the Coloured areas. However, the Nyanga and Crossroads clinics were closed for longer periods of time which resulted in quite severe disruptions in the provision of TB clinic services.[7] These two clinics were also affected by the 'squatter crisis' in May/June 1986.

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5. CDC TB notifications, according to race, in 1984 and 1985 were as follows;

	1984	1985
Whites	28	36
Coloureds	1 520	1 820
Blacks	1 202	1 555
TOTAL	2 750	3 411

6. For example, the drug costs for treating one adult patient according to the official CDC regimen were R 122.83 in 1986 compared with R 75.64 in 1983, i.e. an average annual drug price increase of 20.8%.

7. The daily TB clinic attendances at Nyanga for the period July-October 1985 were: July - 8 487, August - 2 077, September - 2 861, October - 3 251. (Unpublished CDC records).

The provision of TB services was affected in the following ways during the unrest: i) The treatment of TB patients was interrupted as no drugs were administered while the Nyanga and Crossroads clinics were closed. This could have reduced the effectiveness of the CDC treatment regimen. In addition, other TB services such as the administration of BCG vaccinations, contact tracing and prophylactic treatment were adversely affected by the closure of clinics. ii) CDC X-ray units and doctors did not enter the Black townships for a year (August 1985 - September 1986). Black patients were transported from Nyanga and Crossroads to either the Vasco (Goodwood) or Philippi clinics for radiological and clinical examinations. This would have resulted in greater transport costs and an increased work-load for staff at the Black clinics. In addition, the indirect cost to patients in terms of time spent at clinics for examination purposes was increased.

The Nyanga and Crossroads clinics lost contact with many TB patients during the 'unrest'. This was a particularly significant factor during the 'squatter crisis', when squatter refugees were sheltered in halls in many different residential areas in the Cape Peninsula. Some of the refugees suffering from TB were too far from a TB clinic and thus did not report for daily treatment, while others feared ostracism from fellow-refugees. The latter reason was highlighted by St. John's ambulance who stated that

> "... it was "obvious enough" that people sharing relief facilities and rations with tuberculosis victims would be reluctant to be with them."
>
> (Argus, July 4 1986)

This loss of contact with TB patients and the resulting treatment disruptions would also have adversely affected the effectiveness of TB treatment.

In summary, inflationary increases in TB treatment costs since 1983 were unavoidable, as were the effects of the unanticipated 'unrest' situations. However, given that the incidence of 'political unrest' is unpredictable, and based on the experiences of the 1985/86 'unrest', contingency plans should be considered now to avert certain of the increased costs and changes in effectiveness related to interruptions in treatment regimens and loss of contact with patients. For example, increased co-operation between the various relief organisations and health authorities during 'unrest' could result in speedier tracing of TB patients and recommencement of treatment.

The influence of 'unrest' on the costs and effectiveness of preventive and curative procedures for TB cannot be quantified at present, due to a lack of data. It is therefore noted as an area for further research.

CONCLUSION

The primary objective of this study was to evaluate, in cost-effectiveness terms, the various preventive and curative TB procedures currently used by the CDC.

The major findings of this analysis were as follows:

i) It is more cost-effective to prevent TB notifications by means of secondary chemoprophylaxis and BCG vaccination of the Black and Coloured populations, amongst whom the highest incidence of TB is recorded, than to diagnose and cure notified TB patients.

ii) In the case of screening procedures, it was found that contact and suspect investigation should be prioritised. Conversely, mass screening campaigns were found to be costly and to have a low mean case yield and should thus only be used as a method of investigation in exceptional circumstances.

iii) The sample data indicated that the TB treatment regimen originally prescribed by the CDC health authorities (called the 'official' regimen in this study) is not strictly adhered to by clinic staff. CDC doctors are permitted a degree of flexibility in the application of the drug regimen, based on their assessment of a patient's progress during treatment. The regimen is also affected by the availability of drugs from State Health. The comparison of the 'official' and 'clinic' regimens indicated that there was no significant difference in the cost-effectiveness of the two regimens and

thus, that strict adherance to the 'official' drug regimen should not be a primary concern of CDC Health authorities.

iv) The sample also indicated that a relatively large proportion of adult patients are not bacteriologically confirmed as TB cases. Diagnosis on the basis of radiological examinations alone could result in a significant number of 'false-positive' diagnoses. These patients would be treated 'unnecessarily', resulting in a considerable misapplication of the limited funds available for TB control. This analysis therefore suggests that all adult patients should be bacteriologically confirmed to reduce misdiagnosis.

v) It was found that ambulatory treatment of TB patients was considerably more cost-effective than hospitalisation. Thus, only those patients who cannot be effectively treated by ambulatory means should be hospitalised.

In summary, resources available for TB control should be reallocated in the direction of secondary chemoprophylaxis, BCG vaccination administration in the Black and Coloured populations, investigation of contacts and suspects and ambulatory treatment of notified TB patients. Conversely, vaccinating the White population, mass screening campaigns and hospitalisation of TB patients should be given relatively less emphasis in the overall TB control programme.

In addition, this study found that the incidence of 'political unrest' since August 1985 has adversely affected TB control measures, especially in terms of interruptions in the treatment of TB patients at Black clinics. Given that the 'unrest situation' appears likely

to continue in the foreseeable future, the realities of the political situation should be borne in mind when evaluating TB control techniques.

These findings essentially relate to short-term policy considerations, i.e. they would be affected by major changes in the socio-economic and political climate. Thus, in the longer term, two factors seem likely to influence the cost-effectiveness ratios presented in this study.

i) Current increases in factors such as unemployment indicate that the incidence of TB, particularly amongst the Black and Coloured populations, could increase.

ii) The problems faced by the CDC health authorities are likely to be enhanced by the liberalisation if influx-control measures. The 'homeland' areas provide a continual source of infectious cases which will contribute to the increasing incidence of TB in the CDC Black population.

As TB notifications increase, not only will the staff quotas at existing clinics be expanded, but the number of clinics will also be forced to rise, with the attendant overheads that this will entail. Few, if any, economies of scale can be expected in anti-tuberculosis services, given that population expansion is likely to be accompanied by the formation of new townships/suburbs in addition to increased density in existing areas. The problems of contact and defaulter tracing will increase with population density, while new clinics will have to attend geographical spread of the townships.

A study of this nature is based on certain ceteris paribus assumptions. The findings will thus be affected by factors such as changing socio-economic conditions and the introduction of new preventive and curative procedures for Tuberculosis.

Cost-effectiveness ratios should be re-evaluated when changes in these ceteris paribus assumptions occur, and the combination of preventive and curative TB procedures adapted accordingly.

APPENDIX A COST-BENEFIT ANALYSIS THEORY

The most common form of the equation used for determining whether a project is economically feasible (i.e. the CBA decision rule) is:

$$\sum_{t=1}^{T} \frac{B_t}{(1+r)^t} - \sum_{t=1}^{T} \frac{C_t}{(1+r)^t} > 0$$

where B_t = Benefits in time period t;

C_t = Costs in time period t;

r = discount rate;

and T = time horizon/period over which benefits and costs are calculated.

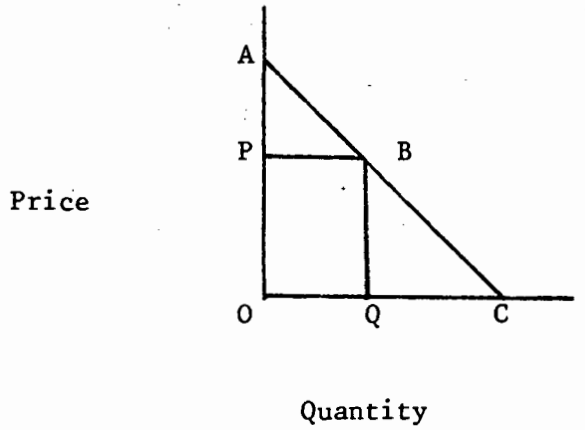
Taking into account the fact that CBA has its roots in welfare economics, and has been closely linked to the concept of pareto optimality in particular, the decision rule could be restated as follows: A project will be considered economically feasible if it is able to generate an excess of benefits over costs, so that by a costless redistribution of the gains, no one will be made worse off by the project while some will be better off. (Mishan 1975: xii and Pearce 1983: 16).

It should be noted that as CBA is merely an aid to judgement and is balanced by the judgement of decision makers, economic feasibility is not a sufficient condition for the adoption of a programme. As the 'costless redistribution' described above is in general merely hypothetical, the lobbying power of either those who would lose or those who would gain through the implementation of the

project under consideration could influence the final decision.

The starting point for the actual calculation of costs and benefits is the concept of 'willingness-to-pay'. This can be defined as the maximum sum of money a consumer would be willing to pay for a given quantity of a good which is equal to the amount he/she actually pays plus the consumer surplus. (Mishan 1975: 27).

This can be represented diagramatically as follows:



AC = Demand Curve

OPBQ = amount actually paid for quantity Q of the good at price P

PAB = consumer surplus

OABQ = OPBQ + PAB = 'willingness-to-pay'

The use of a simple Marshallian demand curve in these calculations could produce a margin of error, as it does not take the income effect into account. Most CBA advocates recommend that an adjusted demand curve (as originally introduced by Hicks), be used. This curve depicts changes in the consumer's utility in response to price variations, while the money income is varied to ensure that the consumer remains on the same indifference curve. The consumer surplus area under this

adjusted demand curve is known as the compensating variation. (Pearce 1983: 28).

Mishan (1972: 16) defines the compensating variation, emphasising the pareto basis of CBA, as

> "... the sum of money (which) if paid or received after the economic change in question, would make the individual no worse or better off than before the change."

Thus, benefits are estimated by calculating the 'willingness-to-pay' for the project, which is composed of the actual amount paid (i.e. the market price of the project output x the quantity of the output) plus the compensating variation (CV). In circumstances where this procedure is difficult to implement due to information constraints, 'shadow prices' are used to estimate the benefits. Pearce (1983: 33) describes this process as the measurement of

> "... the gain in the value of some objective if we increase expenditure on a given project by one unit."

The costs of a project can be similarly estimated if they are viewed as opportunity costs. In this case, the 'willingness-to-pay' for the forgone benefits of an alternative project would be calculated. However, the practical problems involved in such a procedure generally prohibit its use. Thus, costs are normally estimated by calculating the marginal product of each project input, although the market price of an input will only equal its marginal product under conditions of perfect competition. This has resulted in the use of 'shadow prices' to estimate the true opportunity cost of input use

in a specific project.

In addition to the estimation of direct project costs and benefits, the less obvious spillover effects and externalities must also be included in the analysis. Care must be exercised: so that only the difference in an individual's welfare which results from the particular spillover effect in question is considered.

Benefits and costs which will only materialise a year or more after the implementation of the project, must be discounted to obtain the net present value (NPV) of all costs and benefits. There is a continuing debate about which discount rate is most appropriate for use in CBA. (See for example: Layard 1980: 243-332 and Pearce 1983: 37-58). The two options most frequently considered are:

1) The marginal net product of capital/the social opportunity cost of capital (r) and

2) The social time preference rate/the rate at which society is prepared to trade present for future consumption(s).

Whichever rate is selected, it must be expressed in real terms using the same base year that was used to express the costs and benefits in real terms. If a society is operating at the constraint maximum, i.e. is on the highest possible social indifference curve given the constraints of the specific transformation function, 'r' will equal 's'. (Pearce 1983: 40-44).

There is some controversy over whether distributive effects should be taken into account in a CBA. Pearce (1983: 62) stresses that the use of distributional weights in a CBA will not ensure that income distribution is improved once a selected project is implemented, but the purpose is rather to recognise the importance of both distributional and efficiency factors. Most commentators agree that if distributive weights are used in a CBA, a range of different weights should be compared by means of sensitivity analysis, as there is no single, generally accepted method of calculating the value of these weights.

Mishan is opposed to the use of distributional weights. He argues that the correct way to take distributional factors into account is to include other criteria in the decision rule. Not only should benefits exceed costs before a project will be considered economically feasible, but the resulting distributional changes should not be regressive and no gross inequalities should be perpetrated. (Mishan 1972: 13)

With regard to risk and uncertainty in the estimation of variables, there are numerous proposals but no agreement on how this problem should be taken into account, other than recommendations that a sensitivity analysis be performed to indicate how the outcome of a project evaluation would be affected by changes in these variables.

APPENDIX B - DISTRIBUTION OF DRUG DOSES TO PATIENTS IN SAMPLE

The following figures illustrate the distribution of doses of each drug administered to patients included in the random sample. They are presented according to age i.e. adults (15 years of age and older) and children (under 15 years of age).

Figure B.1 Distribution of doses of INH to adults

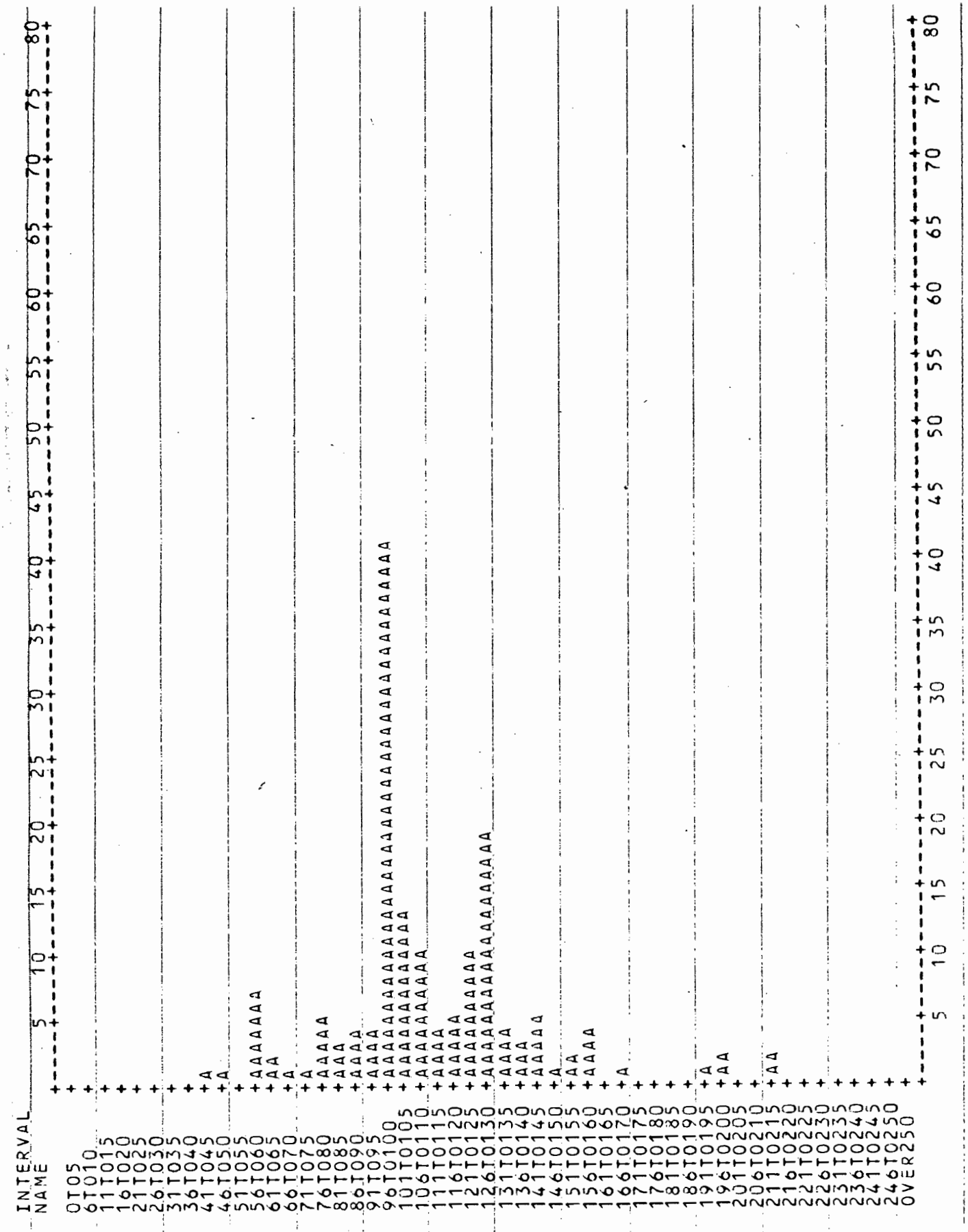
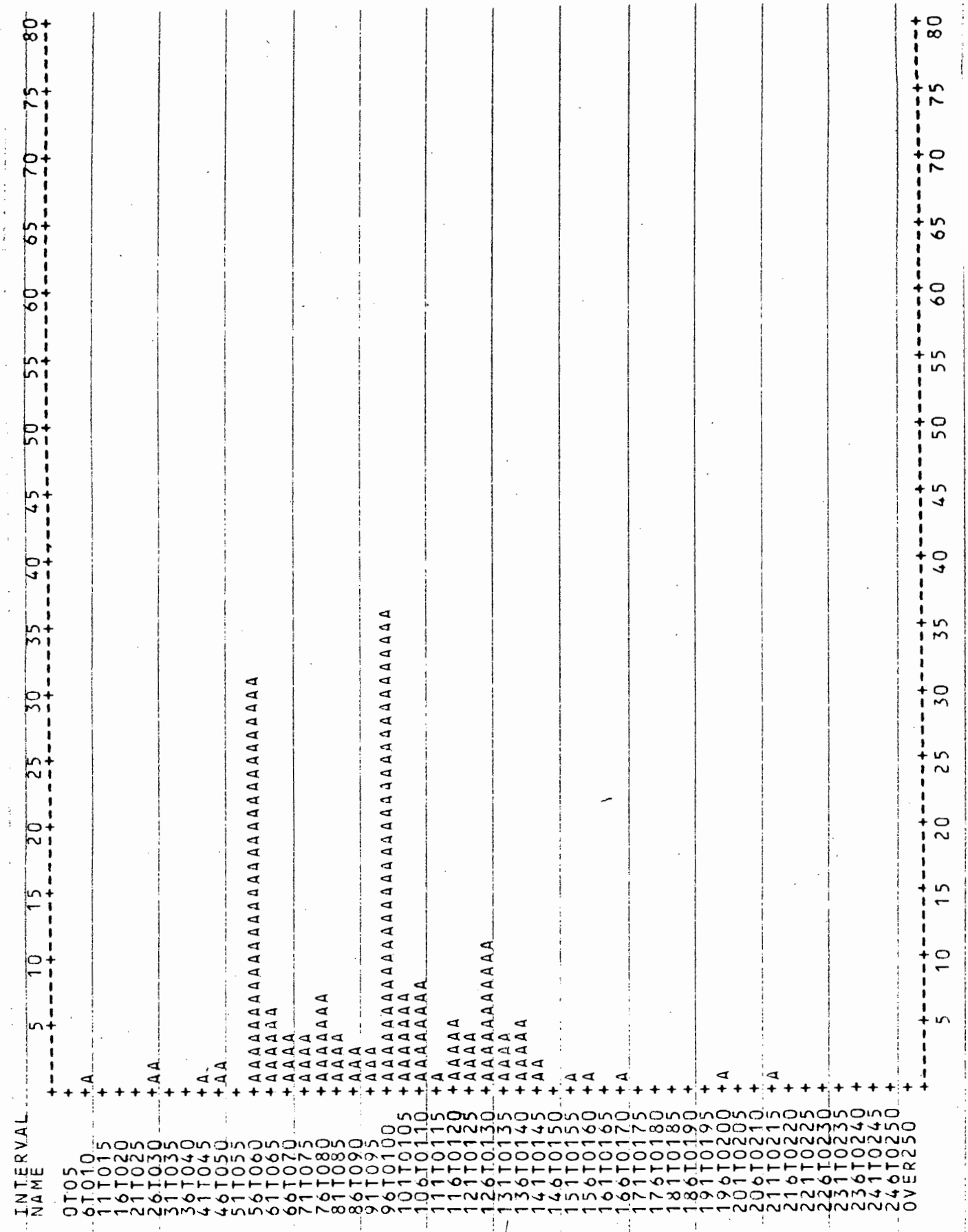


Figure B.2 Distribution of doses of Rifampicin to adults



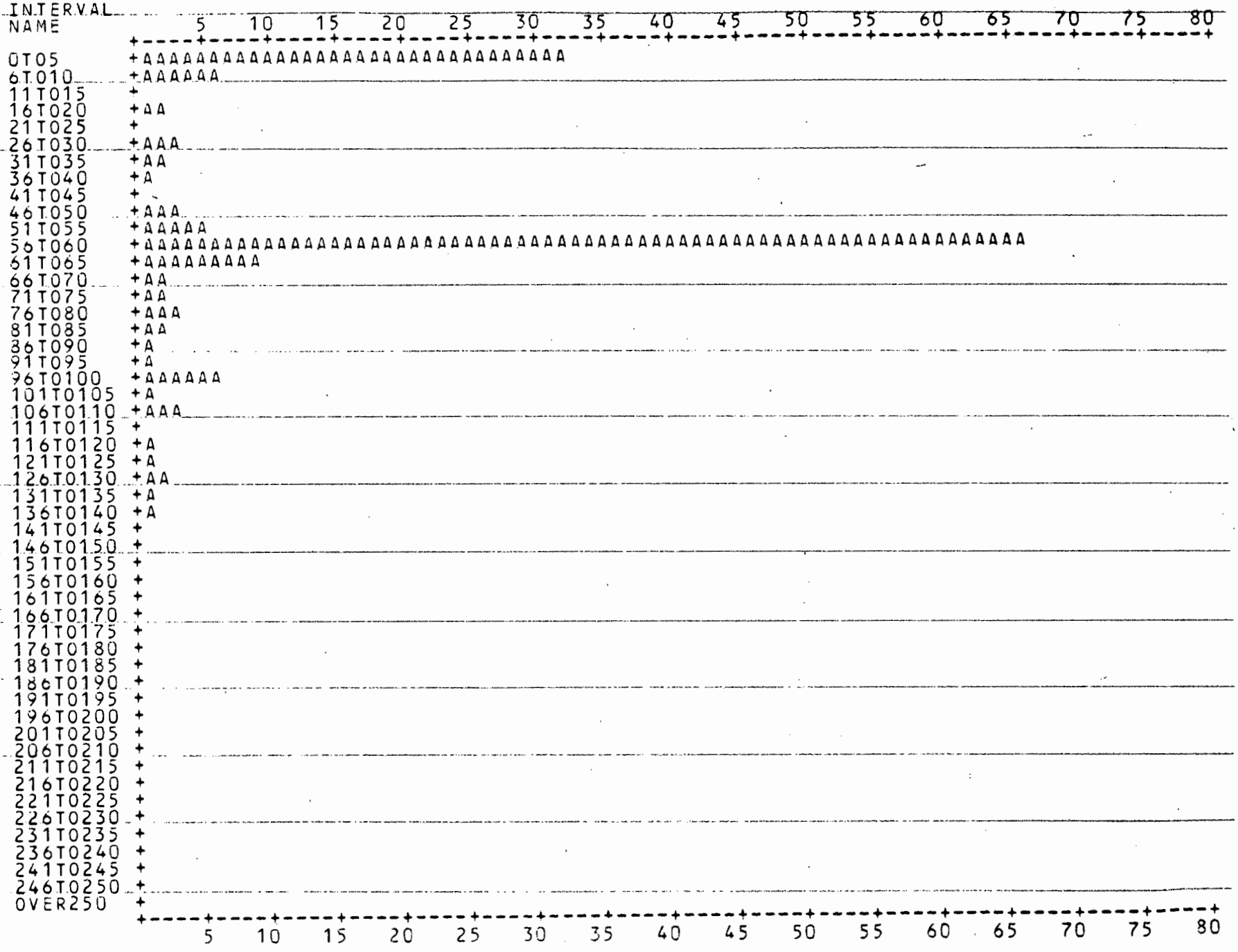


Figure B.3 Distribution of doses of Streptomycin to adults

Figure B.4 Distribution of doses of PZA to adults

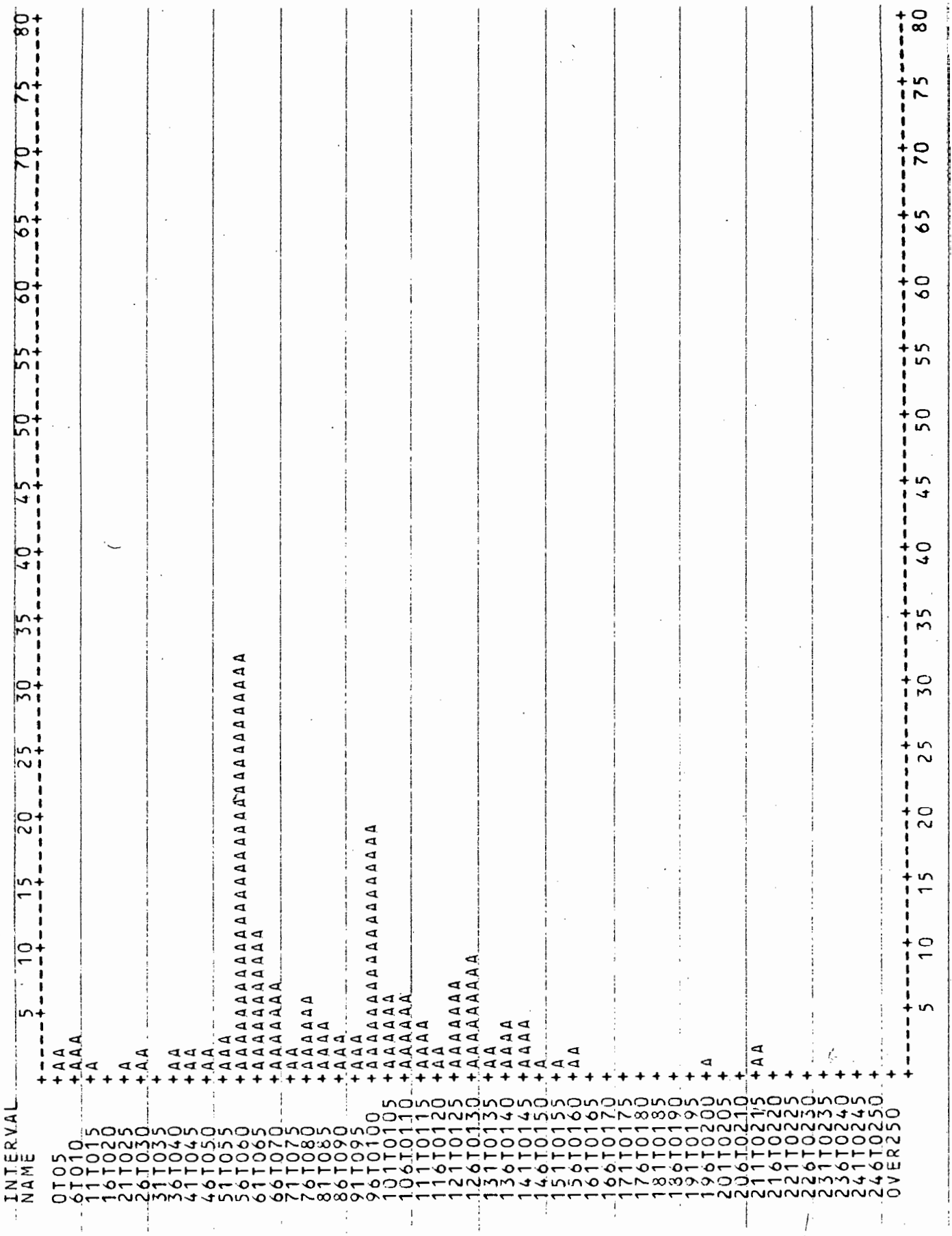
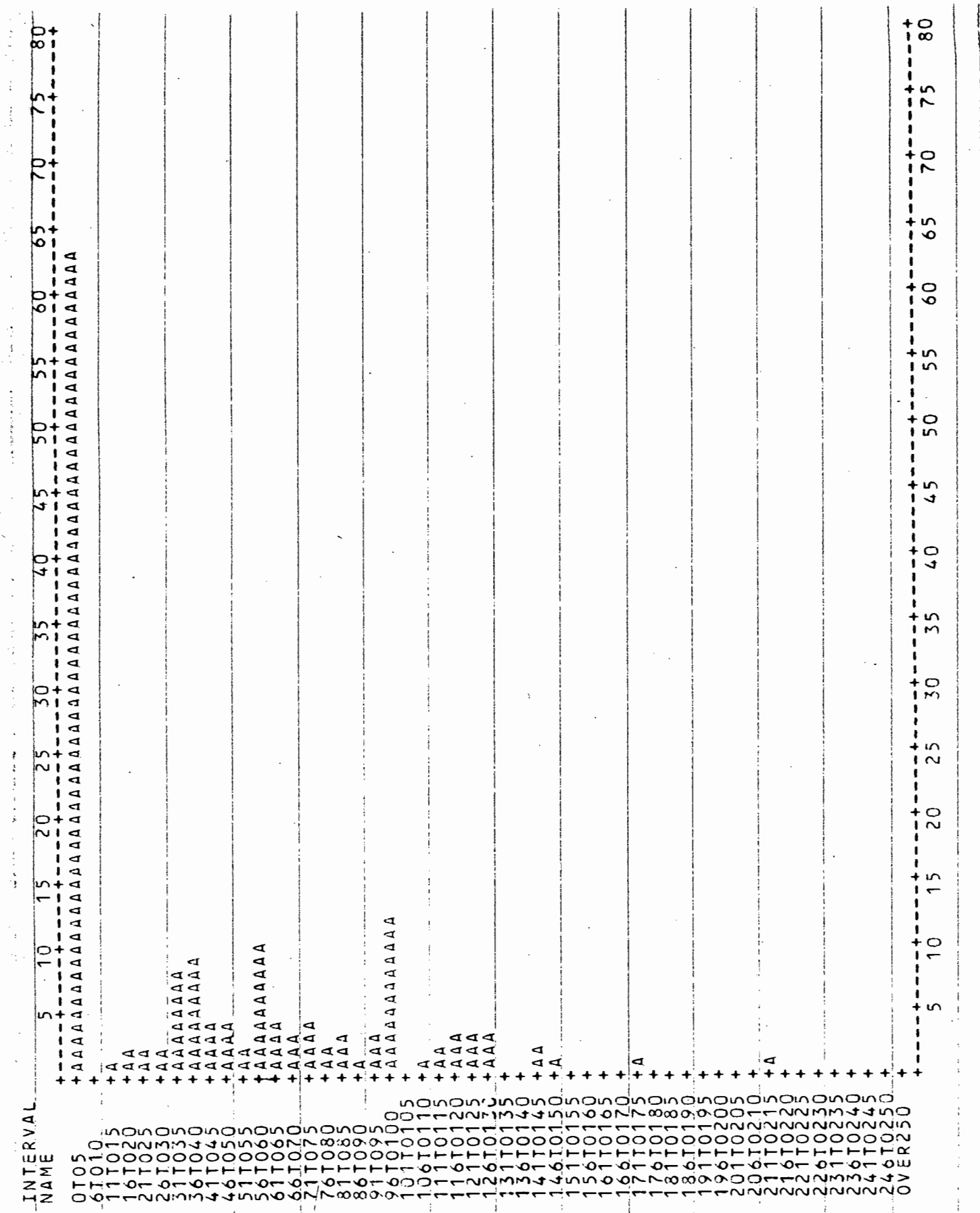


Figure B.5 Distribution of doses of Ethambutol to adults



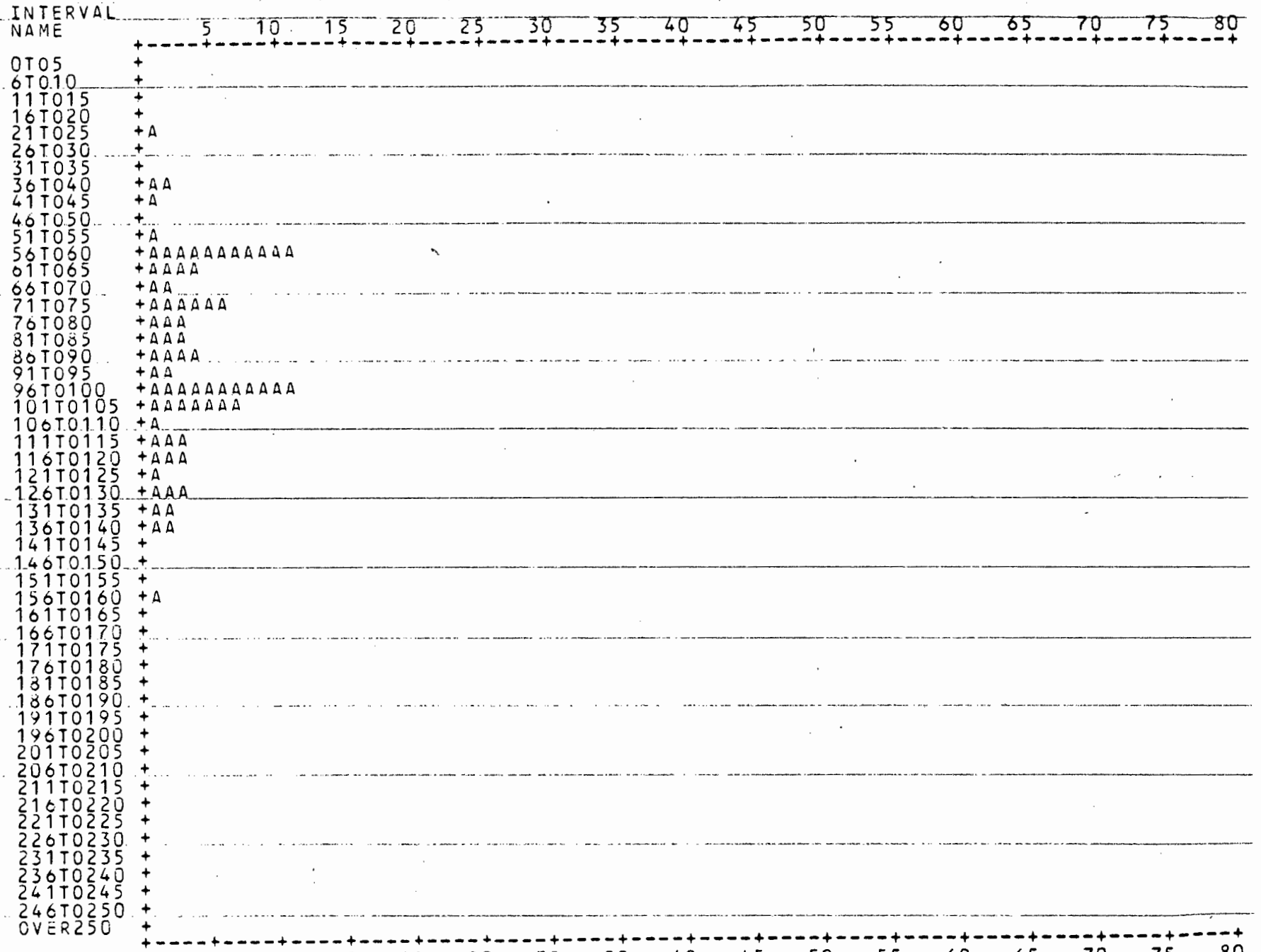


Figure B.6 Distribution of doses of INH to children

Figure B.7 Distribution of doses of Rifampicin to children

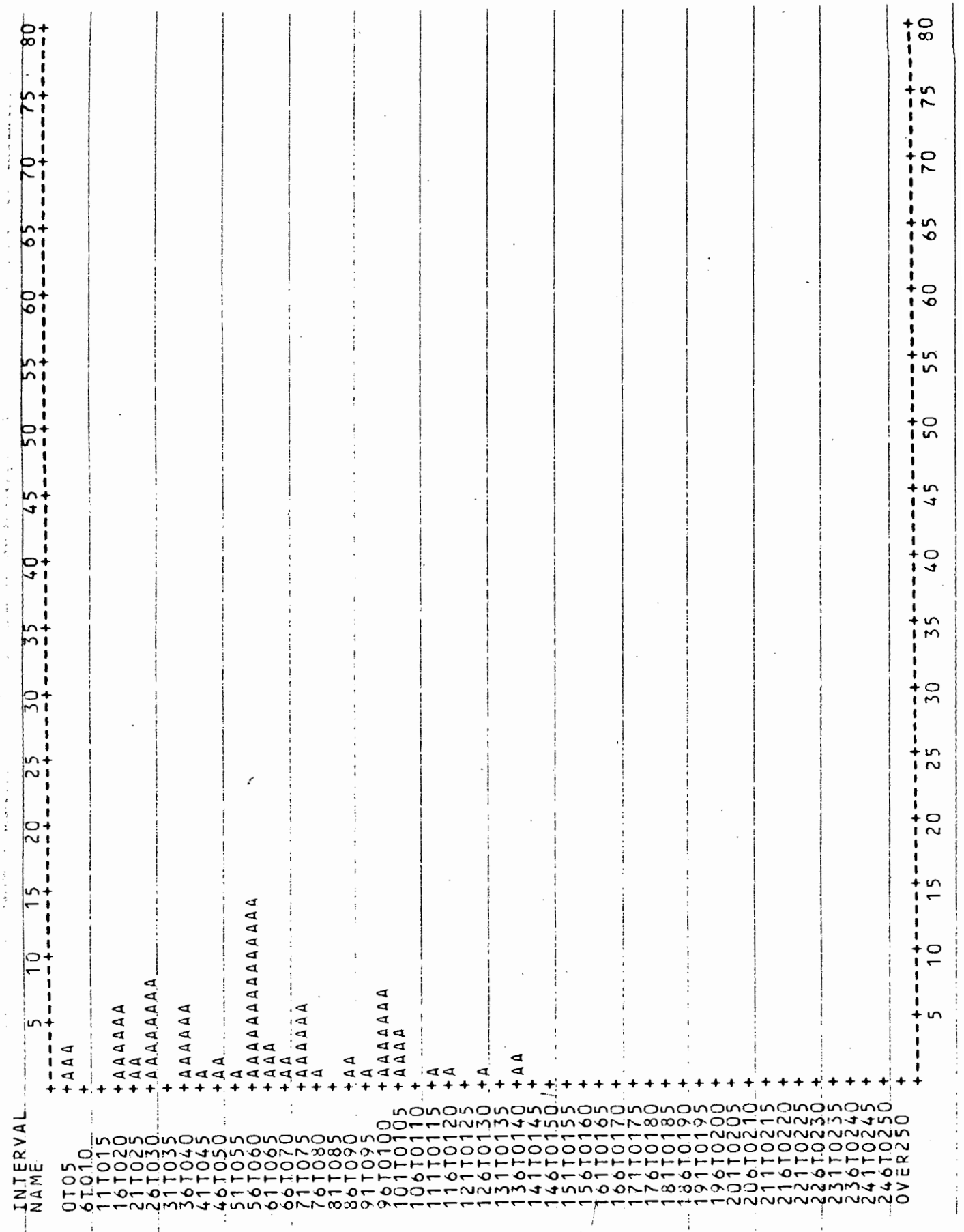


Figure B.8 Distribution of doses of PZA to children

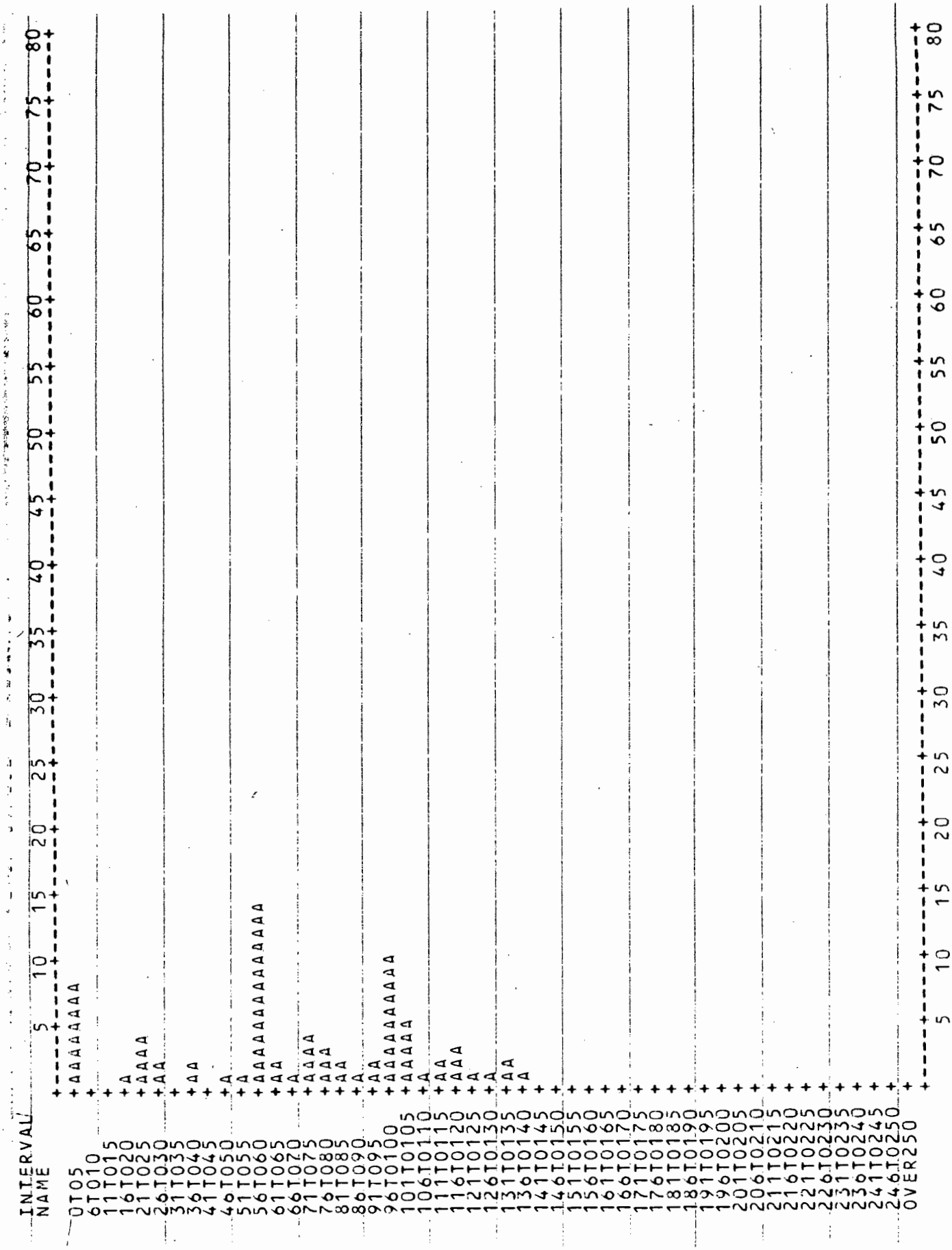
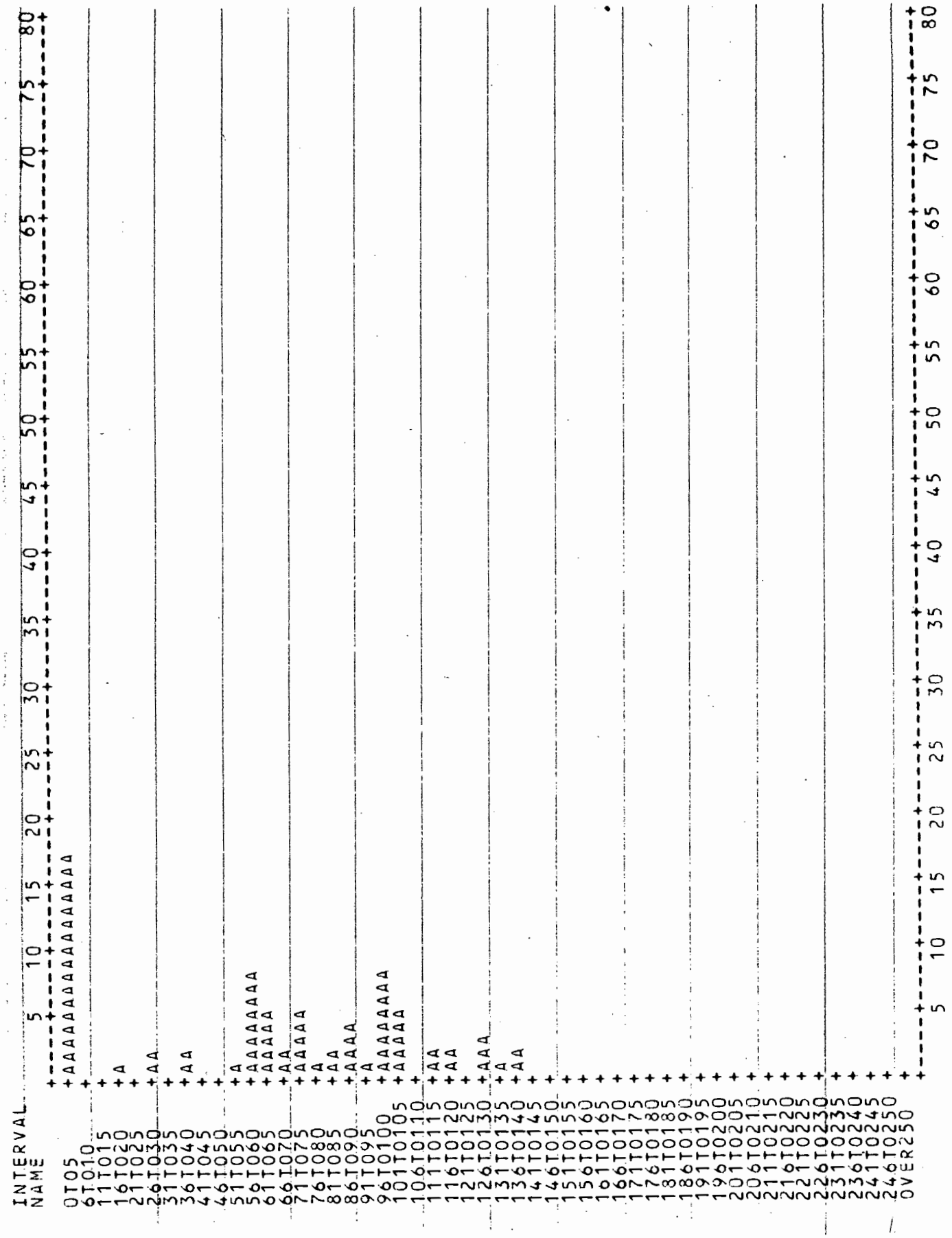


Figure B.9 Distribution of doses of Ethambutol to children



APPENDIX C - APPORTIONING THE COST OF CLINIC SERVICES TO VARIOUS PREVENTIVE AND CURATIVE PROCEDURES FOR TB

The costs of staff, facilities, transport etc. for all the CDC clinics are combined into one expenditure figure. A range of different services are provided at the clinics, e.g. services for Tuberculosis, child health, sexually transmitted diseases and family planning. A survey has been conducted in an attempt to estimate the amount of time spent by clinic staff on each service, but the final results are not yet available and the researcher (Dr Fisher of the CDC) considered the response to the questionnaire to be inadequate.

The CDC does however record the number of people who attended clinics, according to the particular service rendered. These figures are reproduced in the M.O.H.'s annual report and will be used in this study.

There are five main categories into which services provided by CDC clinic staff for the prevention and treatment of TB are divided:

i) Established sessions at which doctors are present and which are devoted to the examination and investigation of contacts and suspects, the evaluation of the progress of notified TB patients during treatment and to follow-up investigations of TB patients who have completed treatment;

ii) Daily attendance, which reflects the supervision of daily treatment of notified patients and the dispensing of weekly supplies of INH tablets to parents or guardians supervising the prophylactic treatment of children;

iii) Domiciliary treatment, which accounts for the provision of supervised daily treatment at a patient's home if they are unable to attend a clinic, or at work if alternate supervision cannot be organised;

iv) Mobile clinics, which are mainly concerned with the preliminary investigation of suspects; and

v) Home visits, which record the number of visits made by clinic staff to trace defaulters and contacts.

In addition to these clinic services which are concerned only with TB prevention and treatment, BCG vaccinations are performed during the child health sessions and are thus included in this category. Heaf tests and BCG vaccinations performed at schools by the schools immunisation team are not included under clinic attendances and thus have to be specifically taken into account.

Table C.1 gives the breakdown of the clinic attendances according to the five main categories of services:

Table C.1 Clinic attendances for TB services (1983)

Service	Number of attendances
Established sessions	60 852
Daily attendances	199 155
Domiciliary treatment	39 682
Mobile clinics	1 063
Home visits	11 635
Total	312 387

(Data from Divisional Council of the Cape 1983: 64 & 108-128, and unpublished records of CDC).

15 945 BCG vaccinations and 1 573 tuberculin tests[1] were performed by the immunisation team at schools in 1983. The other 16 092 BCG vaccinations were included in the clinic attendance figure for child health services.[2]

The total number of clinic attendances, mobile clinic services and home visits for all other non-Tuberculosis clinic services, except family planning which has a separate expenditure account, was 506 237 in 1983. When the BCG vaccinations given at child health sessions are deducted, the total is 490 145.

Table C.2 summarises the information concerning total clinic services.

Table C.2 Summary of services provided by CDC clinic staff in 1983

Service	No. of people utilising these services at clinics or schools	%
TB	347 570	41.49
Other	490 145	58.51
Total	837 715	

1. Two attendances are necessary for every tuberculin test - one when the test is originally performed and another to ' read' the test (48-72 hours later). Thus, the number of attendances for tuberculin testing at schools is 3 146.

2. The 32 037 and 3 146 clinic attendances for BCG vaccinations and tuberculin tests respectively, are added to the 312 387 other TB clinic attendances. Total TB clinic attendance is therefore 347 570.

Note: By combining all the figures for clinic attendance, one is assuming that all attendances require the same time and thus that each attendance has the same cost value. This is not necessarily true as dispensing and supervising the administration of drugs to a notified TB patient would take less time than the examination and investigation of a contact/suspect at an 'established session'. When the considerable administration involved in recording the number of doses administered, results of bacteriological tests, etc. is taken into account, these discrepancies will not necessarily be that significant. Given that clinic services have to be accounted for when evaluating each procedure and that no viable alternative method for apportioning costs exists at present, these deficiencies are merely noted and it is stressed that every precaution has been taken to ensure that all available, relevant information has been taken into account.

The total CDC clinic services expenditure for the 1983/84 financial year was R2 756 916. (The cost of the schools immunisation team is included in this figure). The only other CDC Health department expenditure item that needs to be taken into account here is administration costs. The costs of the head office of the Health department, which is responsible for the administration of clinic, family planning, health inspectorate and health education services as well as the mobile X-ray unit etc., were apportioned to the respective sub-departments on a proportional basis, according to the total expenditure of each sub-department. In general, the head office administration responsibilities are proportionately related to the size, in terms of staff, of the respective sub-departments. As the major expenditure item in each sub-department is staff costs, it was decided that sub-department expenditure totals should be used to apportion administration costs. The proportion of administration costs attributable to clinics was R499 148.

The total expenditure on CDC clinic services, including an administration fee, of R3 256 064 for the 1983/84 financial year can be divided between TB and 'other' services in the following way:

Cost of TB clinic services = R3 256 064 X 41.49% = R1 350 941
Cost of 'other' clinic services = R3 256 064 X 58.51% = R1 905 123.

The R1 350 941 must now be apportioned to account for the services provided for each preventive and curative procedure for TB. The proportion of procedures falling into each category of TB clinic services is estimated using information from the sample findings and other sources. These calculations are closely linked with information presented on each procedure in the body of the text and thus the reader should refer to the relevant section in Chapter IV if any calculation is unclear. It is suggested that this appendix be read after Chapter IV to avoid unnecessary cross-referencing.

a) Established sessions:

As radiological examinations are performed at 'established sessions', the total number of X-rays in 1983 provides a good indication of the breakdown of these sessions.

Table C.3 Number of radiological exminations performed in 1983

Category of people investigated	No. of X-rays
Notified patients	10 475
Contacts/suspects	23 153
'Other' (mass screening)	8 737
Total	42 365

(Divisional Council of the Cape 1983: 153).

These figures need to be adapted as some patients, contacts and suspects are required to make an additional clinic visit after being X-rayed. Notified patients: Each time a notified patient is X-rayed, they must also see a doctor who will assess their progress based on the X-ray, once it has been developed, i.e. two clinic attendances for every X-ray taken. Thus the number of 'established session' attendances by notified patients is 20 950.

Contacts/suspects: Those whose X-rays were normal did not have to return to see a doctor. However, the 2 500 notified patients who were originally X-rayed as contacts/suspects would have returned to see a doctor as their X-rays indicated the presence of active TB. Child contacts/suspects may be given a tuberculin test at the same time as the radiological investigation and must return to have the test 'read' within 48-72 hours. 4 489 such tests were performed in 1983. By adding these additional visits to the number of X-rays performed on contacts/suspects, it is estimated that there were 30 142 'established session' clinic attendances by contacts/suspects in 1983.

Mass screening: 6 256 X-rays were performed during pre-employment screening and 2 481 during the 'Leonsdale Survey'. When the additional clinic attendances for 'reading' of 715 tuberculin tests performed during the 'Leonsdale Survey' are added to the number of attendances for radiological examinations, it can be estimated that there were 9 452 'established session' clinic attendances for mass screening purposes.

Table C.4 presents these revised figures and the respective proportions, and the results of allocating the total established

session attendances, 60 852, to each category.

Table C.4 Breakdown of 'established session' attendances

Category of people investigated	Revised estimates of attendances	%	Final estimates of attendances
Notified patients	20 950	34.60	21 055
Contacts/suspects	30 142	49.79	30 298
'Other'	9 452	15.61	9 499
Total	60 544		60 852

b) Daily attendances:

These were estimated in the following way:

Parents/Guardians of patients receiving secondary chemoprophylaxis would have made an average of 9 visits to the clinics to collect tablets if the patient completed treatment and 3.7 visits if they absconded before completing treatment.[3] Notified patients' attendances were calculated in terms of the mean number of doses they received, as reflected in the sample findings, according to age and whether they completed treatment or not.

3. A week's supply of INH tablets are dispensed to parents/guardians at each visit. As a total of 60 doses of INH are administered to prophylactic patients who complete treatment, 9 clinic visits are necessary. Children who absconded from prophylactic treatment received a mean of 25.9 doses of INH. The estimated mean number of clinic visits to collect weekly supplies of tablets is then 3.7 for absconders.

Prophylactic patients:

1 806 finished treatment X 9 visits	16 254	
2 057 absconded X 3.7 visits	7 611	23 865

Notified patients:

1 207 adults finished treatment X 111 doses		133 977	
706 children " " X 88 doses		62 128	
349 adults defaulted X 52 doses		18 148	
238 children " X 38 doses		9 044	223 297
			247 162

As some of the notified patients received domiciliary treatment, i.e. they were treated at home, the 39 682 domiciliary treatment visits must be deducted from the above estimate to determine the daily clinic attendances. The revised figures are then

Prophylactic patients:	23 865
Notified patients:	183 615
Total daily clinic attendances:	207 480

Prophylactic patients accounted for approximately 11.5% of the daily attendances and notified patients for 88.5%. Given the recorded number of daily attendances for 1983 (199 155), it can be estimated that 22 903 were attributable to patients receiving secondary chemoprophylaxis and 176 252 to notified patients.

c) Domiciliary treatment:

All these services relate to the treatment of notified patients.

d) Mobile clinics:

All these services relate to the investigation of contacts and suspects.

e) Home visits:

These estimates are based on the total number of contacts and defaulters to be traced. Not all contacts and defaulters are followed up in tracing procedures due to time limitations. Thus, the final estimates of the number of home visits devoted to each activity are somewhat lower than the number of tracing procedures that could have been conducted if all contacts and defaulters were followed-up. The estimates are presented in Table C.5.

Table C.5 Breakdown of home visits

Tracing procedure	No. of contacts and defaulters	%	Estimated no. of home visits
Contacts	19 898	85.1	9 901
Prophylactic patient defaulters	2 120	9.1	1 059
Notified patient defaulters 4	1 364	5.8	675
Total	23 382		11 635

4. Each defaulter may be visited more than once to encourage them to return to a clinic for daily treatment. This figure thus reflects the total number of home visits that should have been conducted for for tracing notified patient defaulters. (Unpublished CDC records). Once again, not all home visits were in fact conducted due to time-

f) Miscellaneous:

In addition, 32 037 BCG vaccinations were performed and were not specifically included in the totals for TB clinic services, and there were 3 146 attendances for the administration and reading of tuberculin tests at schools.

Table C.6 summarises these estimates of the breakdown of TB clinic services according to the various preventive and curative procedures.

Table C.6 Breakdown of CDC TB clinic services for 1983

Procedure for prevention or treatment of TB	Number of services	%
BCG vaccinations	32 037	9.22
Secondary chemoprophylaxis		
- Dispensing tablets	22 903	
- Tracing defaulters	1 059	
	23 962	6.89
Mass screening campaigns		
- Pre-employment screening and Leonsdale survey	9 499	
- Schools tuberculin testing	3 146	
	12 645	3.64
Contacts and suspects		
- Tracing procedures	9 901	
- Investigation during 'established sessions'	30 298	
- Initial investigation at mobile clinics	1 063	
	41 262	11.87
Notified patients		
- Daily treatment at clinics	176 252	
- Domiciliary treatment	39 682	
- Progress assessment and follow-up procedures	21 055	
- Tracing of defaulters	675	
	237 664	68.38
Total	347 570	

These percentages are now applied to apportion the total costs for TB

clinic services, as presented in Table C.7.

Table C.7. Breakdown of TB clinic services costs

TB prevention/treatment procedure	%	Share of costs
BCG vaccinations	9.22	R124 557
Secondary chemoprophylaxis	6.89	R93 080
Mass screening campaigns	3.64	R49 174
Contact and suspect investigations	11.87	R160 357
Treatment of notified patients	68.38	R923 773
Total		R1 350 941

APPENDIX D - EXTRACTS FROM UNPUBLISHED CDC RECORDS TO DETERMINE THE NUMBER OF SECONDARY CHEMOPROPHYLAXIS PATIENTS AND CONTACTS/SUSPECTS IN 1983

Information contained in unpublished CDC records with respect to the number of contacts and suspects investigated and the number of patients who were prescribed a course of secondary chemoprophylactic treatment during 1983, is summarised here.

Note: For the purposes of this appendix, '-14' refers to people who are 14 years of age or younger and '15+' refers to those who are 15 years or older i.e. children and adults respectively.

			Totals	
Prophylactic treatment:	-14	15+	-14	15+
Number on prophylaxis at beginning of 1983:			887	148
Patients gained:				
- New patients	3 495	387		
- Transferred in from hospital/clinic	117	16		
- Recovered from being lost	57	1	3 669	404
			4 556	552
Patients lost:				
- Treatment completed/discharged	1 567	121		
- Transferred out to a hospital/clinic	119	26		
- Absconded	1 705	308	(3 391)	(455)
Number of patients on prophylaxis at end of 1983:			1 165	97

Contacts/suspects:	-14	15+	Totals -14	Totals 15+
Number under CDC control at beginning of 1983			1 656	2 510
Suspects/contacts gained:				
- New	9 494	10 087		
- Transferred in from hospital/clinic	139	178		
- Recovered from being lost	119	121	9 752	10 386
			11 408	12 896
Suspects/contacts lost:				
- Investigation completed	4 656	5 977		
- Transferred out to a hospital/clinic	233	225		
- Absconded	4 291	4 680		
- Died	4	4	(9 184)	(10 886)
Number under CDC control at end of 1983:			2 224	2 010

This data includes not only those patients investigated and treated during 1983, but also those patients who were initially included in these procedures in 1982 but were 'carried forward' to 1983, and those patients who were similarly 'carried over' from 1983 to 1984. All the other calculations in this study are concerned only with those people who were initially recorded as being investigated as possible TB cases and treated for TB, during 1983 (e.g. the calculations for treatment of TB patients are based on the 2 500 patients who were notified during 1983, irrespective of whether their treatment regimens were completed in 1983 or 1984, and excluded all patients notified in 1982 who were still receiving treatment in 1983).

To ensure data consistency throughout this study, the number of people recorded as either being investigated as TB suspects or contacts of a notified TB patient, and those beginning secondary chemoprophylactic treatment during 1983 are used as the basis of all calculations. To estimate the number of these patients who absconded/defaulted, completed treatment etc., proportions are calculated from the data supplied above and then applied to the 1983 patients. These calculations are presented

below.

Prophylactic treatment:

Total number of patients incoporated in records during 1983:

	-14	15+	Total
Patients B/F from 1982	887	148	1 035
New patients in 1983[1]	3 612	403	4 015
	4 499	551	5 050
Less: Patients C/F to 1984	(1 165)	(97)	(1 262)
Total patients	3 334	454	3 788

Number of patients and proportions, according to outcome:

	-14		15+	
Outcome	No. of Patients	%	No. of Patients	%
Course completed	1 567	47.00	121	26.65
Transferred out	119	3.57	26	5.73
Absconded	1 705	51.14	308	67.84
Recovered from being lost	(57)	(1.71)	(1)	(0.22)
Total	3 334		454	

1. This consists of new patients who either reported directly to a CDC clinic or were transferred to a CDC clinic from a hospital or clinic outside of the CDC jurisdiction. Patients recorded as 'recovered from being lost' were absconders who had been successfully traced by clinic staff. Tracing procedures for absconders are conducted for a period of two months after they abscond, and thus the majority of those who were 'recovered' would be recorded as such within the same year (1983) in which they were originally recorded as new patients. To avoid double-counting, patients who are 'recovered from being lost' are deducted from absconders instead of including them as new patients. The same procedure applies to contacts/suspects.

The outcome of patients prescribed prophylactic treatment in 1983 i.e. whether they completed treatment, absconded etc., is estimated using the proportions calculated above:

Outcome	No. of patients -14	No. of patients 15+	Total
Course completed	1 698	108	1 806
Transferred out	129	23	152
Absconded	1 847	273	2 120
Recovered from being lost	(62)	(1)	(63)
Total	3 612	403	4 015

Contacts/Suspects:

Total number of contacts/suspects incorporated in records during 1983:

	-14	15+	Total
Contacts/suspects B/F from 1982	1 656	2 510	4 166
New contacts/suspects in 1983[1]	9 633	10 265	19 898
	11 289	12 775	24 064
Less: Contacts/suspects C/F to 1984	(2 224)	(2 010)	(4 234)
Total contacts/suspects	9 065	10 765	19 830

Number of contacts/suspects and proportions, according to outcome:

Outcome	-14 No. of Patients	%	15+ No. of Patients	%
Investigation completed	4 656	51.36	5 977	55.52
Transferred out	233	2.57	225	2.09
Absconded	4 291	47.34	4 680	43.47
Recovered from being lost	(119)	(1.31)	(121)	(1.12)
Died	4	0.04	4	0.04
Total	9 065		10 765	

The outcome of investigations into contacts/suspects registered in 1983, is estimated using above proportions:

Outcome	No. of patients -14	No. of patients 15+	Total
Investigation completed	4 947	5 699	10 646
Transferred out	248	215	463
Absconded	4 560	4 462	9 022
Recovered from being lost	(126)	(115)	(241)
Died	4	4	8
Total	9 633	10 265	19 898

APPENDIX E - CALCULATION OF COST OF DRUGS USED IN THE TREATMENT OF TB PATIENTS AT CDC CLINICS IN 1983

a) Cost of drugs administered in the 'clinic' regimen:

The sample data presented in Chapter III indicates that the drug regimen received by patients treated at CDC clinics (called the 'clinic' regimen in this study) differs from the regimen actually proposed by the CDC health authorities (called the 'official' regimen in this study). Drug regimens are adapted at the discretion of the clinic doctors and based on their assessment of the patient's response or progress during treatment. The availability of drugs also influences the regimens. The mean number of doses of each drug administered to patients, as reflected in the sample results (see section 2.4.3 of Chapter III) will be used in the determination of the drug costs for the clinic based regimen.

Table E.1 lists the unit costs of the drugs used in the treatment of TB patients at CDC clinics. These costs have been examined to ensure that they reflect competitively determined market prices.

Table E.1 1983 unit costs of drugs (including handling charge)

Drug	Cost (Rand)
INH (100 mg)	0.0013
INH (200 mg)	0.0021
Rifampicin (150 mg)	0.229
Rifampicin (450 mg)	0.687
Rifampicin syrup (60 ml)	3.66
Streptomycin (5 g)	0.559
PZA (0.5 g)	0.054
Ethambutol (100 mg)	0.032
Ethambutol (400 mg)	0.102

(Data supplied by Mr Ochse, senior pharmacist at State Health)

As Streptomycin is administered by means of an injection, the cost of disposable syringes (RO.063) and needles (RO.032) also need to be accounted for.

Total drug costs for adults:

Adults are prescribed the following drug dosages:[1]

INH	400 mg
Rifampicin	450 mg
Streptomycin	1 g
PZA	2 g
Ethambutol	1 200 mg

The total drug costs per patient are calculated as follows:
Cost per dose x mean number of doses administered.

Table E.2 Drug costs per adult patient who completed treatment ('clinic' regimen)

Drug	Cost per adult patient (Rand)
INH	0.47
Rifampicin	64.36
Streptomycin	10.43
PZA	18.86
Ethambutol	13.39
Total	R107.51

1. A dose is defined as: a quantity of a drug administered at one time. Dosage refers to the proper size of a drug dose expressed usually in terms of grams or milligrams.

Table E.3 Drug costs per adult patient who did not complete treatment ('clinic' regimen)

Drug	Cost per adult patient (Rand)
INH	0.22
Rifampicin	33.11
Streptomycin	7.76
PZA	9.70
Ethambutol	4.66
Total	R55.45

Total drug costs for children:

There is no uniform drug dosage prescribed for children, and dosages are determined according to the weight of each child in terms of the following guidelines:

10 mg/kg for INH and Rifampicin,
25 mg/kg for Ethambutol, and
30 mg/kg for PZA.

The dosage of each drug received by children in the sample was tabulated, the cost per dosage was calculated and then an average cost per dose was calculated (see Table E.4 for calculations).

Table E.4 Summary of drug dosages for children and cost calculations

Drug	Dosage	Cost per dosage +	No. of patients receiving this dosage	Cost per dose for all patients receiving this dosage
INH	50 mg	0.00065	2	0.0013
	75 mg	0.00098	6	0.0059
	100 mg	0.00130	44	0.0572
	150 mg	0.00195	31	0.0605
	200 mg	0.00210	9	0.0189
	300 mg	0.00340	6	0.0204
	400 mg	0.00420	1	0.0042
Rifampicin*	50 mg	0.1413	2	0.2826
	60 mg	0.1696	1	0.1696
	75 mg	0.2120	4	0.8479
	80 mg	0.2261	1	0.2261
	100 mg	0.2826	40	11.3050
	150 mg	0.2290	34	7.7860
	200 mg	0.5653	5	2.8263
	300 mg	0.4580	5	2.2900
	450 mg	0.6869	2	1.3740
Streptomycin	500 mg	0.1509	1	0.1509
	750 mg	0.1789	1	0.1789
PZA	125 mg	0.0135	11	0.1485
	250 mg	0.0270	40	1.0800
	500 mg	0.0540	25	1.3500
	750 mg	0.0810	5	0.4050
	1 000 mg	0.1080	4	0.4320
	1 250 mg	0.1350	1	0.1350
	1 500 mg	0.1620	1	0.1620
Ethambutol	100 mg	0.0318	3	0.0954
	150 mg	0.0477	8	0.3816
	200 mg	0.0636	20	1.2720
	250 mg	0.0795	9	0.7155
	300 mg	0.0954	18	1.7172
	350 mg	0.1113	5	0.5565
	400 mg	0.1021	8	0.8168
	450 mg	0.1180	1	0.1180
	500 mg	0.1339	2	0.2678
	600 mg	0.1532	2	0.3063
	800 mg	0.2042	1	0.2042
	1 200 mg	0.3063	2	0.6126

+ These calculations are based on the unit cost of drugs (Table E.1) e.g. a patient who is prescribed 50 mg of INH is given ½ a 100 mg INH tablet. Thus the cost per 50 mg of INH is R0.0013 x ½.

* Those patients receiving 100 mg or less and those receiving 200 mg were given Rifampicin syrup (1 ml = 20 mg). Those receiving 150 mg, 300 mg, or 450 mg were given capsules. (Rifampicin is only available in 150 mg and 450 mg capsules and syrup form. The capsules are not divisable. Other drugs are in tabletform and can be divided).

The dosage specific costs per dose (i.e. last column of Table E.4) are totalled for each drug, to estimate the cost per dose for all children in the sample. Each total is divided by 99, the number of child patients in the sample, to estimate the average cost per dose per patient. Table E.5 summarises these calculations. The cost per dose per patient is then multiplied by the mean number of doses that each of the 99 patients received as reflected in the sample findings (see section 2.4.3 of Chapter III), to estimate the cost of each drug per patient (see Tables E.6 and E.7).

Table E.5 Cost per dose for child patients

Drug	Cost per dose for all child patients	Cost per dose per child patient
INH	0.1684	0.0017
Rifampicin	27.1075	0.2738
Streptomycin	0.3298	0.0033
PZA	3.7125	0.0375
Ethambutol	7.0639	0.0714

Table E.6 Drug costs per child patient who completed treatment ('clinic' regimen)

Drug	Cost per child patient (Rand)
INH	0.15
Rifampicin	16.76
Streptomycin	0.005
PZA	2.63
Ethambutol	4.58
Total	R24.13

Table E.7 Drug costs per child patient who did not complete treatment ('clinic' regimen)

Drug	Cost per child patient (Rand)
INH	0.07
Rifampicin	7.45
Streptomycin	-
PZA	1.04
Ethambutol	2.24
Total	R10.80

b) Cost of drugs administered in the 'official' regimen:

The drug regimen prescribed by the CDC health authorities is as follows:

Adults -	INH	100 doses
	PZA	100 doses
	Rifampicin	60 doses
	Streptomycin	60 doses
Children -	INH	100 doses
	Ethambutol	100 doses
	Rifampicin	60 doses
	PZA	60 doses

The sample indicated that very few patients actually receive this regimen. Drug costs calculated here for the 'official' regimen are used to compare the cost-effectiveness of the 'clinic' and 'official' regimens, to determine whether the flexibility in application of the 'official' regimen affects the cost-effectiveness

of TB treatment significantly. This analysis is performed in section 4.2.2 of Chapter V.

Costs are calculated using the procedure described above and with reference to Table E.1 and Table E.5 (mean number of doses administered is replaced by the number of doses prescribed).

Table E.8 Drug costs per patient who completed treatment ('official' regimen)

Drug	Cost per adult patient (Rand)	Cost per child patient (Rand)
INH	0.42	0.17
Rifampicin	41.21	16.43
Streptomycin	12.41	-
PZA	21.60	2.25
Ethambutol	-	7.14
Total	R75.64	R25.99

To estimate the number of doses of drugs administered to patients receiving the 'official' regimen who did not complete treatment, either by default or for other reasons, a proportion is calculated from the means reflected in the sample data, in the following manner:

Tables III.15 and III.16 indicate that a wide range of drug doses and combinations of drugs were administered. The most consistent drug administration was that of INH - this drug was prescribed in the majority of cases for the entire duration of treatment, for both children and adults, and was not subject to change due to adverse reactions or to facilitate treatment at work/school, as were Streptomycin and PZA. INH would only have been discontinued

if a patient had developed a resistance to it. Thus the proportion of mean doses of INH administered to patients who did not complete treatment, to mean doses of INH administered to those who completed treatment, gives the most accurage estimate of the proportion of drug regimen completed before default.

Using this method, 46.5% of the regimen was completed in the case of adults and 43.2% for children. Although different mean doses of each drug are reflected in the sample for defaulters, this is largely as a result of differences in the combination of drugs administered e.g. most adults received INH but the other three drugs were selected from four possible alternatives, and children were sometimes treated with only two or three drugs. As the CDC regimen specifies four drugs in each case and all drugs are administered from the commencement of treatment, it can be assumed that a mean of 46.5 doses of each drug was administered to adults before default and 43.2 doses to children.

Table E.9 Drug costs per patient who did not complete treatment ('official' regimen)

Drug	Cost per adult patient (Rand)	Cost per child patient (Rand)
INH	0.20	0.07
Rifampicin	31.94	11.83
Streptomycin	9.62	-
PZA	10.04	1.62
Ethambutol	-	3.08
Total	R51.80	R16.60

APPENDIX F - CALCULATION OF THE UNIT COSTS OF TESTS USED TO INVESTIGATE POSSIBLE TB CASES AND TO ASSESS THE PROGRESS OF TB PATIENTS AT CDC CLINICS IN 1983

a) Radiological investigations:

According to the CDC records for the 1983/84 financial year, the total cost of operating and maintaining the mobile X-ray units, including staff costs, depreciation charges and a proportion of the Health department administration costs was R95 026. The total number of radiological investigations during this period was 37 623. Thus the cost per X-ray was R2.53.

b) Bacteriological investigations:

The State Health Laboratory in Cape Town provided the following unit cost estimates, which were based on 1983 expenditure and considered to be the most accurate reflection of total costs incurred in conducting each respective bacteriological investigation:

Direct microscopy:	R1.68	
Sputum culture:	R4.20	
Differential tests:	R2.10	
Drug sensitivity tests:	R25.20	(R5.04 per drug - done routinely for five drugs)

c) Tuberculin tests:

1 ampule of Tuberculin PPD (Purified Protein Derivative) cost R3.26, including a handling charge, in 1983. Approximately 30 tests per

ampule are performed at CDC clinics (personal communication with Sister Theron, head of the CDC schools immunisation team).

It was difficult to estimate the cost of heaf guns, as they were bought over a number of years and have a relatively long lifespan. The average unit cost of the heaf guns bought by the CDC was R30.32. There are approximately 30 heaf guns in use at the various clinics. Each apparatus can be used for approximately 5 years (personal communication with technical adviser at Hospital Products (Pty) Ltd) and the lifespan is dependant on frequency of use. Assuming linear depreciation, the annual cost of heaf guns can be estimated as R181.92.

The total cost of tuberculin testing in 1983 is thus:

R806.31 for Tuberculin PPD for 7 420 tests
R181.92 for heaf guns

R988.23

The cost per tuberculin test can then be approximated as:

R988.23 ÷ 7 420 = R0.13.

BIBLIOGRAPHY

1. Angel, J.H. 1983 The Case for Short-Course Chemotherapy of Pulmonary Tuberculosis. Drugs. 26, No. 6, 1-8.

2. Aquinas, M. 1982 Short-Course therapy for Tuberculosis. Drugs. 24, No. 2, 118-132.

3. Baram, M.S. 1980 Cost-Benefit Analysis : An Inadequate Basis for Health, Safety and Environmental Regulatory Decision Making. Ecology law Quarterly. 8, No. 3, 473-531.

4. Barnes, B.A. 1977 Cost-Benefit Analysis of Surgery - Current Accomplishments and Limitations. The American Journal of Surgery. 133, No. 4, 438-446.

5. Barnes, B.A. 1982 Cost-Benefit and Cost-Effective Analysis in Surgery. Surgical Clinics of North America. 62, No. 4, 737-749.

6. Bell, J. 1986 Tuberculosis Compliance in the Western Cape. Dissertation for the Fellowship of the Faculty of Community Health (Community Medicine) S.A., College of Medicine of South Africa, Cape Town.

7. Blomquist, G. 1979 Value of Life Saving : Implications of Consumption Activity. Journal of Political Economy. 87, No. 3, 540-558.

8. Bootman, J.L., McGhan, W.F. and Schondelmeyer, S.W. 1982, Application of Cost-Benefit and Cost-Effectiveness Analysis to Clinical Practice. Drug Intelligence and Clinical Pharmacy. 16, No. 3, 235-243.

9. British Thoracic and Tuberculosis Association 1975 Present Effectiveness of BCG vaccination in England and Wales. Tubercle. 56, 129-137.

10. Broome, J. 1978 Trying to Value a Life. Journal of Public Economics. 9, No. 1, 91-100.

11. Bush, J.W., Fanshel, S. and Chen, M.M. 1972 Analysis of a Tuberculin testing Program using a Health status Index. Socio-Economic Planning Sciences. 6, 49-68.

12. Buxbaum, C.B. 1981 Cost-Benefit Analysis : The Mystique versus the Reality. Social Service Review. 55, no. 3, 453-471.

13. City of Cape Town 1980-1983 Annual Report of the Medical Officer of Health, 1980-1983. Technical Management Services Branch of the City of Cape Town Engineer's Department, Cape Town.

14. Clemens, J.D., Chuong, J.H. and Feinstein, A.R. 1983 The BCG Controversy : A Methodological and Statistical Reappraisal. Journal of the American Medical Association. 249, No. 17, 2362-2369.

15. Conley, B.C. 1976 The Value of Human Life in the Demand for Safety. The American Economic Review. 66, No. 1, 45-55.

16. Culyer, A.J. & Maynard, A.K. 1981 Cost-Effectiveness of Duodenal Ulcer Treatment. Social Science & Medicine Part C - Medical Economics. 15 C, 3-11.

17. Cutting, W.A.M. 1980 Cost-Benefit Evaluations of Vaccination Programmes. LANCET. 2, 634-635.

18. Dardis, R. 1980 The Value of a Life : New Evidence from the Marketplace. The American Economic Review. 70, No. 5, 1077-1082.

19. Dardis, R. 1981 A Critical Evaluation of Current Approaches to Life Valuation in Cost/Benefit Analysis. The Journal of Consumer Affairs. 15 No. 1, 46-63.

20. Dasgupta, A.K. & Pearce, D.W. 1972 Cost-Benefit Analysis : Theory & Practice. The Macmillan Press Ltd, London & Basingstoke.

21. De Beer, C. 1984 The South African Disease : Apartheid Health and Health Services. Southern African Research Service (SARS), Pretoria.

22. Divisional Council of the Cape 1980-1984 Annual report of the Medical Officer of Health, 1980-1984. Divisional Council of the Cape, Cape Town.

23. Drummond, M.F. 1981 Welfare Economics and Cost Benefit Analysis in Health Care. Scottish Journal of Political Economy. 28, No. 2, 125-145.

24. Epstein, K.A., Schneiderman, L.J., Bush, J.W. & Zetner, A. 1981 The Abnormal screening serum Thyroxine (T4) : Analysis of Physician Response, Outcome, Cost and Health effectiveness. Journal of Chronic Diseases. 34, No. 5, 175-190.

25. Fanshel, S. & Bush, J.W. 1970 A Health-Status Index and its Application to Health-Services Outcomes. Operations Research. 18, 1021-1066.

26. Feingold, A.O. 1975 Cost Effectiveness of Screening for Tuberculosis in a General Medical Clinic. Public Health Reports. 90, No. 6, 544-547.

27. Fisher, S.A. 1985 Experiences with extra-short course Tuberculosis chemotherapy in the Divisional Council of the Cape. Paper presented at the First TBRI symposium on current views on Tuberculosis, Pretoria, August 1985. Unpublished (used with permission).

28. Fourie, P.B. 1981 The Prevalence and Annual Rate of Tuberculosis Infection in South Africa. Phd Thesis, University of the Witwatersrand, Johannesburg.

29. Fourie, P.B. 1983 The Prevalence and Annual Rate of Tuberculosis Infection in South Africa. Tubercle. 64, 181-192.

30. Fourie, P.B. 1985 Risk of TB disease from remote, distant and recent injection. TBRI Bulletin. 6, No. 1, 8-9.

31. Fourie, P.B. & Knoetze, K. 1985 Tuberculosis prevalence and risk of infection in Southern Africa. Paper presented at the First TBRI Symposium on current views on Tuberculosis, Pretoria, August 1985. Unpublished (used with permission).

32. Fourie, P.B. & Knoetze, K. 1986 Tuberculosis prevalence and risk of infection in Southern Africa. South African Journal of Science. 82, July 1986, 387.

33. Fox, W. & Nunn, A.J. 1979 The Cost of Antituberculosis Drug Regimens. American Journal of Respiratory Disease. 120, No. 3, 503-509.

34. Frost, M.J. 1971 Values for Money : The techniques of Cost-Benefit Analysis, Gower Press Ltd, London.

35. Glatthaar, E. 1982a Tuberculosis : Basic Perspectives, MEDUNSA, Pretoria.

36. Glatthaar, E. 1982b Tuberculosis control in South Africa : 'Where have we gone wrong ?' and 'A look at the future' South African Medical Journal. Special Issue, 17 November, 36-41.

37. Grzybowski, S. 1982 The value of different diagnostic treatment and preventive programmes. South African Medical Journal. Special Issue, 17 November, 6-8.

38. Hagard, S. & Carter, F.A. 1976 Preventing the birth of infants with Down's Syndrome : a cost-benefit analysis. British Medical Journal. 1, 753-756.

39. Hendrie, D. 1985 Consumer Price Indexes 1971-1984 : SALDRU fact Sheet No. 3a. SALDRU, Cape Town.

40. Holland, W.W., Ipsen, J. & Kostrzewski, J. (Eds) 1979 Measurement of Levels of Health. World Health Organisation & International Epidemiological Association, Copenhagen.

41. Ippolito, P.M. & Ippolito, R.A. 1984 Measuring the Value of Life Saving from Consumer Reactions to New Information. Journal of Public Economics. 25, 53-81.

42. Jones-Lee, M.W. 1976 The Value of Life : An Economic Analysis. University of Chicago Press, Chicago.

43. Kaplan, R.M., Bush, S.W. & Berry, C.C. 1976 Health Status: Types of Validity and the Index of Well-being. Health Services Research. Winter, 478-507.

44. Kendall, M.G. (Ed) 1971 Cost-Benefit Analysis. The English Universities Press Ltd, London.

45. Kent, P. 1982 The relevance of short-course tuberculosis chemotherapy to the African situation. South African Medical Journal. Special Issue, 17 Novemebr, 8-12.

46. Kleeberg, H.H. 1982 The dynamics of tuberculosis in South Africa and the impact of the control programme. South African Medical Journal. Special Issue, 17 November, 22-23.

47. Kleeberg, H.H. 1984 New Arguments in the BCG controversy. TBRI Bulletin. 5, No. 1, 6-8.

48. Kriedel, T. 1980 Cost-Benefit Analysis of Epilepsy Clinics. Journal of Social Science & Medicine Part C - Medical Economics 14 C, 35-39.

49. Landefeld, J.S. & Seskin, E.P. 1982 The Economic Value of

Life : Linking Theory to Practice. American Journal of Public Health. 72, No. 6, 555-556.

50. Lave, J.R. & Lave, L.B. 1978 Cost-Benefit Concepts in Health: Examination of some Prevention Efforts. Preventive Medicine. 7, No. 3, 414-423.

51. Layard, R. (ed) 1980 Cost-Benefit Analysis. Penguin Books, Middlesex.

52. Linnerooth, J. 1979 The Value of Human Life : A Review of the Models. Economic Inquiry. 17, No. 1, 52-74.

53. Ludbrook, A. 1981 A Cost-Effectiveness analysis of the treatment of chronic renal failure. Applied Economics. 13, no. 3, 337-350.

54. McFarlan, W.M. 1984 An evaluation of the effectiveness of ambulant treatment of pulmonary tuberculosis. South African Medical Journal. 65, No. 2, 44-46.

55. McNeil, B.J., Thomson, M. & Adelstein, S.J. 1980 Cost-Effectiveness Calculations for the Diagnosis & Treatment of Tuberculous Meningitis. European Journal of Nuclear Medicine. 5, 271-276.

56. Mishan, E.J. 1972 Elements of Cost-Benefit Analysis. George Allen & Unwin Ltd, London.

57. Mishan, E.J. 1975 Cost-Benefit Analysis : An Informal Introduction, Revised New Edition. George Allen & Unwin Ltd, London.

58. Mishan, E.J. 1981 The Value of Trying to Value Life. Journal of Public Economics. 15, No. 1, 133-137.

59. Mooney, G.H., Russel, E.M. & Weir, R.D. 1980 Choices for Health Care. The Macmillan Press Ltd, London & Basingstoke.

60. Mooney, G. 1982 Breast Cancer Screening : A Study in the Cost-Effectiveness Analysis. Social Science & Medicine Part C - Medical Economics. 16, No. 13, 1277-1283.

61. Patel, E. 1984 Cape Town - A Statistical summary and analysis of socio-economic trends for local areas and the 01 economic region, (Part 2). Carnegie Conference Paper No. 302b. (Second Carnegie Inquiry into Poverty and Development in Southern Africa), SALDRU, Cape Town.

62. Paterson, M.L. 1983 Cost-Benefit Evaluation of a New Technology for Treatment of Peptic Ulcer Disease. Managerial & Decision Economics. 4, No. 1, 50-62.

63. Patrick, K.M. & Woolley, F.R. 1981 A Cost-Benefit Analysis of Immunization for Pneumococcal Pneumonia. Journal of the American Medical Association. 245, No.5, 473-477.

64. Pearce D.W. & Nash C.A. 1981 The Social Appraisal of Projects: A text in Cost-benefit Analysis. The Macmillan Press Ltd, London & Basingstoke.

65. Pearce, D.W. 1983 Cost-Benefit Analysis, Second Edition. The Macmillan Press Ltd, London & Basingstoke.

66. Pearson, J.O. 1979 Short-Course chemotherapy for Tuberculosis. The Lancet. 2, 420.

67. Pearson, J.O. 1980 False Economy in Tuberculosis Treatment. South African Medical Journal. 58, 588-589.

68. Peterson, D.R. & Thomas, D.B. 1978 Fundamentals of Epidemiology. D.C. Heath and Company, Lexington.

69. Ponninghaus, J.M. 1980 The Cost/Benefit of Measles Immunization: A study from Southern Zambia. Journal of tropical Medicine and Hygiene. 83, No. 4, 141-149.

70. Roid, G.H. 1982 Cost-Effectiveness Analysis in Mental Health Policy Research. American Psychologist. 37, No. 1, 94-95.

71. Shasha, W. 1982 Control of Tuberculosis in the homelands. In Medical Students' Conference Papers : Consumption in the land of plenty - T.B. in South Africa. UCT Medical Students' Council, Cape Town.

72. Sintonen, H. 1981 An Approach to Economic Evaluation of Actions for Health : A theoretic-methodological study in health economics with special reference to Finnish health policy. Official statistics of Finland, Special Social Studies No. 74. Ministry of Social Affairs and Health Research Department, Helsinki.

73. South African Institute of Race Relations 1983 Race Relations Survey 1983. SAIRR, Johannesburg.

74. S.A. Institute of race Relations 1984 Race Relations Survey 1984. SAIRR, Johannesburg.

75. South African Medical Research Council 1983, Annual Report of the MRC, 1983. Tuberculosis Research Institute. MRC, Parow.

76. Ibid. 1984.

77. Stilwell, J.A. 1976 Benefits and Costs of the Schools' BCG Vaccination Programme. British Medical Journal. 1, 1002-1004.

78. Swint, J.M. & Nelson, W.B. 1977 Prospective Evaluation of Alcoholism Rehabilitation Efforts: The Role of Cost-Benefit and Cost-Effectiveness Analyses. Journal of Studies on Alcohol. 38, No. 7, 1386-1404.

(1980)

79. Thompson, M.S. & Fortess, E.E. Cost-Effectiveness Analysis in Health Program Evaluation. Evaluation Review. 4, No. 4, 549-568.

80. Thomson, E. and Mydral, S. 1984a Regional Variations in Tuberculosis policy in South Africa, Carnegie Conference paper No. 173a. (Second Carnegie Inquiry into Poverty and Development in Southern Africa), SALDRU, Cape Town.

81. Thomson, E. and Mydral, S. 1984b The Implementation of tuberculosis policy in three areas in South Africa, Carnegie Conference Paper No. 173b. (Second Carnegie Inquiry into Poverty and Development in Southern Africa), SALDRU, Cape Town.

82. Thomson, E. and Mydral, S. 1984c Tuberculosis : The patients perspective, Carnegie Conference Paper No. 174. (Second Carnegie Inquiry into Poverty and Development in Southern Africa,) SALDRU , Cape Town.

83. Tibbit, L.R. 1982 The economics of short-course therapy for tuberculosis in the Cape Divisional Council area. South African Medical Journal. Special Issue, 17 November, 31-33.

84. Tolpin, H.G. 1980 Economics of Health Care - The Necessity of a Cost/Benefit approach. Journal of the American Dietetic Association. 76, No. 3, 217-222.

85. Toman, K. 1979 Tuberculosis Case-Finding and Chemotherapy: Questions and Answers. World Health Organisation, Geneva.

86. Townshend, G. and Aalbers, J. 1985 Current Views on tuberculosis: Some good news, but many problems remain. Medical Research Council (MRC) News. 16, No. 7, 1 & 8-10.

87. Waaler, H.T. 1978 The economics of Tuberculosis control. Tubercle, Suppl. 2, 1-5.

88. Warner, K.E. & Hutton, R.C. 1980 Cost-Benefit and Cost-Effectiveness Analysis in Health Care : Growth and Compostition of the literature. Medical Care. 18, No. 11, 1069-1084.

89. Weinstein, M.C. & Stason, W.B. 1977 Foundations of Cost-Effectiveness analysis for Health and Medical Practices. The New England Journal of Medicine. 296, No. 13, 716-721.

90. Weisbrod, B.A. 1981 Benefit-cost analysis of a controlled experiment : treating the mentally ill. Journal of Human Resources. 16, 523-548.

91. Zabow, M. & Pearson, J.O. 1982 Short-course chemotherapy for pulmonary tuberculosis. Points of interest. South African Medical Journal. 61, No. 23, 867-870.