Guidelines for
cost and cost-effectiveness analysis
of tuberculosis control

DOCUMENT

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INTRODUCTION,
IMPORTANT ECONOMIC
CONCEPTS, PROTOCOLS,
AND USEFUL REFERENCES

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SPECIAL NOTE TO USERS OF THE GUIDELINES

Though considerable effort has been made to ensure that the guidelines are user-friendly and accurate, it is possible that those using them will identify mistakes or a need for additional explanation, have queries, or be able to make suggestions for improvement. Any comments or questions are welcome, and should be sent to Dr Katherine Floyd, email address: floydk@who.ch

CHAPTER 1. INTRODUCTION

At a meeting among National Tuberculosis Programme managers and WHO staff at the World Health Organization in Geneva in June 1998, it was suggested that it would be useful to develop generic guidelines related to key aspects of tuberculosis (TB) services. Generic guidelines for assessing the cost and cost-effectiveness of tuberculosis services were felt to be one of the most useful areas for initial guideline development.

This appears to reflect a number of factors. First, policy-makers and planners are increasingly needing to know the cost and cost-effectiveness of their services to justify continued allocation of resources to their programmes. Second, donor agencies and mission services may reduce their funding of tuberculosis services in the near future, so that governments will require good data concerning the additional cost implications of assuming responsibility for funding services previously financed from other sources. Third, the introduction of sector-wide investment programmes rather than dedicated funding to tuberculosis services means that cost data are becoming more relevant to inform planning and resource allocation at national level. Where services are being decentralized to the district level, it is also becoming important to identify the costs of tuberculosis services at local level to enable appropriate budgets to be developed for this area of service provision. Fourth, when new interventions such as preventive therapy are being considered, planners and managers need to know both their cost implications and their likely cost-effectiveness, in order to judge whether they are affordable and worth investing in. Finally, with health sector resources decreasing or static in many areas in combination with growing tuberculosis caseloads, there is pressure to identify approaches to service delivery that are more affordable (lower cost) than existing approaches to care, but that are still cost-effective. For example, community-based directly observed therapy has been compared with more conventional approaches to case management, such as a two-month hospital stay at treatment outset, in a multi-agency project co-ordinated by WHO in several East, Southern and Central African countries.

The problem with economic analyses of tuberculosis services is that they are not straightforward. Tuberculosis diagnosis and treatment is typically provided in many health facilities within a country, including tertiary hospitals, district hospitals, and clinics. It involves the use of laboratory and X-ray departments, programme management, training and, sometimes, overall supervision of patients and follow-up of absconders in the community. In addition to there being a number of distinct elements in tuberculosis diagnosis and treatment, financial reports for hospitals and clinics often show only expenditure for the facility as a whole, with no breakdowns by service area provided. Even laboratory and X-ray expenditure is rarely recorded as a separate item. This means that the costs of tuberculosis services cannot simply be identified from expenditure records. Furthermore, annual expenditure data are not suitable for assessing the costs associated with items such as buildings and vehicles. Expenditure on these items is only incurred periodically, so records for particular years give an inaccurate picture of the real costs of these items.

Despite these difficulties, it is possible to conduct useful assessments of the cost and cost-effectiveness of tuberculosis services. The documents included in these guidelines have been designed to show how this can be done. The focus is on how to assess the costs and cost-effectiveness of the diagnosis and treatment components of *existing* programmes, but guidance concerning how to assess the costs that would be associated with alternative approaches to diagnosis and treatment is also provided.

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1.1 What the guidelines include

The guidelines are divided into three main parts and documents.

1.1.1 Document 1

The first document (this document) covers nine main areas:
- **introduction and general background** to the guidelines (Chapter 1);
- **definition and explanation of key terms and concepts** that are important in conducting cost and cost-effectiveness analyses (Chapter 2);
- explanation of **12 key issues to consider when designing a cost and cost-effectiveness analysis** (Chapter 3);
- protocols that explain, step by step, **how to cost individual components of tuberculosis diagnosis and treatment services from the perspective of providers of health services** (i.e. health services/provider perspective) (Chapter 4). The protocols cover the costing of the following components of diagnosis and treatment: a day in hospital, a hospital outpatient visit, a clinic visit or a visit to a similar non-hospital facility such as a dispensary or health post, a visit to a community health worker, a sputum smear, a sputum culture, a drug regimen, an X-ray, training, district supervision, regional/provincial supervision, and national-level supervision. They also cover an explanation of how to cost other components of diagnosis and treatment not included in this list;
- **assessment of patient, family and community volunteer costs** (Chapter 5). The chapter begins by discussing important methodological issues. It then identifies and recommends a generic and pragmatic approach that is consistent with two widely used textbooks on economic evaluation, and provides suggestions regarding how to collect and analyze data;
- a protocol that explains, step by step, how to use the cost data analysed for each component of diagnosis and treatment to make **calculations of the total cost per patient treated with the existing programme and with different programme designs** (Chapter 6);
- protocols that explain, step by step, **how to conduct cost-effectiveness analyses of tuberculosis diagnosis and treatment services**. They show, for (a) new sputum smear-positive pulmonary tuberculosis patients and (b) new sputum smear-negative and extra-pulmonary tuberculosis patients, how to calculate three different measures of cost-effectiveness – the cost per cure, the cost per death averted, and the cost per DALY gained. A general introduction to the protocols also discusses key issues in the cost-effectiveness analysis of tuberculosis diagnosis and treatment services (Chapter 7);
- protocols that explain, step by step, how to estimate the **total costs associated with provision of tuberculosis diagnosis and treatment services in a given district, region/ province, or country** (Chapter 8); and
- **useful references,** which provides details of the papers and standard textbooks that have been drawn on in developing these guidelines, as well as some other relevant publications and reports (Chapter 9).

1.1.2 Document 2

Document 2 consists of six main elements:
- an exercise to help guideline users define and design the cost and cost-effectiveness analysis that they would like to undertake;
- data entry sheets for data collection and analysis related to health service (provider) costs.

There is one set of data entry sheets for each of the protocols included in Chapter 4 of Document 1, i.e. one set for each component of diagnosis and treatment;

· data entry sheets for data collection and recording of patient/family/community costs. There is one set of data entry sheets for each of the protocols included in Chapter 5 of Document 1;

· data entry sheets for combined recording and analysis of both health system and patient/family/community costs, i.e. for the protocols included in Chapter 6 of Document 1;

· data entry sheets for cost-effectiveness analysis, i.e. for the protocols included in Chapter 7 of Document 1;

· data entry sheets for estimating the total costs associated with tuberculosis diagnosis and treatment services at district, regional/provincial and national level, i.e. for the protocols included in Chapter 8 of Document 1.

1.1.3 Document 3

Document 3 provides 2 worked examples of a cost and cost-effectiveness analysis, using real data from pilot projects that have evaluated the cost and cost-effectiveness of community-based tuberculosis care in comparison with conventional approaches to care delivery that do not involve community members. One analysis is based on data from Machakos, Kenya; the other is based on data from Guguletu, in Cape Town, South Africa.

1.2 Important points for users of the guidelines

At the outset, it is worth emphasizing 6 general points. These concern how to use the guidelines; the general design of the protocols in Chapters 4 through 8; who should use the protocols; what the protocols do not cover; the length of the protocols; and the need for flexibility in using the protocols.

1.2.1 How to use the guidelines

The guidelines should be used by reading and working through Chapters 2 to 8 in that order. This is important because each chapter builds on the previous one. If chapters are omitted or not followed in this way, they will not make sense. However, Chapter 2 may not be required if an economist is available to use the protocols.

1.2.2 General design of protocols – a recipe analogy

Each of the protocols in Chapters 4 through 8 of Document 1 is designed to be like a **recipe** in a cookery book. In other words, each protocol begins with a list of what is required (the "ingredients") to complete the protocol. After this, detailed instructions are provided. These show, step by step, how to undertake the analysis required to calculate the cost or cost-effectiveness measure that is the title of the protocol.

1.2.3 Who should use the protocols?

The protocols in Chapters 4 through 8 of Document 1 have been written so that non-economists should be able to use them. However, they involve a lot of numerical calculations and, in places, the use of equations. It is therefore recommended that people who are comfortable with numerical calculations are assigned to complete the protocols.

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1.2.4 What the protocols do not cover

The protocols in Chapters 4 through 8 of Document 1 do not explicitly cover the costing of **private sector** tuberculosis services, for two reasons. First, it would make the protocols longer and more complicated. Second, it is assumed that, initially, there may be most interest in assessing the costs and cost-effectiveness of (a) government services and (b) mission services - the latter because governments may increasingly need to take responsibility for the funding of mission services. The protocols therefore concentrate on the costs associated with (a) government services and (b) mission/other NGO services. However, the protocols should help to indicate how to conduct cost and cost-effectiveness analyses in the private sector, even if they are not explicitly designed for this purpose.

There are five other specific exclusions from the protocols included in these guidelines. The first is that they do not show how to assess the likely costs and cost-effectiveness of **preventive therapy** for tuberculosis. In most countries this would represent an entirely new form of service provision: the protocols in these guidelines are focused on services that are already in place. Second, assessment of the costs associated with **active case finding** is not covered, since the aim has been to cover aspects of tuberculosis services common to most countries. Third, analysis of the costs and cost-effectiveness of **BCG vaccination** is not included. This reflects the fact that the protocols focus on curative care rather than prevention. Fourth, the protocols do not specifically address the costs and cost-effectiveness of diagnosing and treating **multidrug-resistant tuberculosis (MDR-TB) cases** (MDR-TB is defined as resistance to both isoniazid and rifampicin). In particular, the cost-effectiveness calculations are for new tuberculosis cases who do not have MDR-TB; and some of the costs that are important in management of MDR-TB cases are not covered in the protocols e.g. drug susceptibility testing; and management of side-effects. The exclusion of MDR-TB at present reflects the fact that the vast majority of tuberculosis cases do not have MDR-TB. Finally, there is no protocol that shows how to assess the **long-term cost-savings that might be generated by extra investments in tuberculosis services**, if these extra investments resulted in improved cure rates. It is difficult to write a protocol for this type of analysis – it is relatively complicated, requires modelling, and is best done by an experienced analyst.

Despite these exclusions, those interested in conducting cost or cost-effectiveness analyses on these topics should find Chapters 2 and 3 in this document useful, and the general costing principles and ways of calculating costs and cost-effectiveness used in the protocols should be of some help. It is also anticipated that a protocol specifically focused on the cost and cost-effectiveness of managing MDR-TB will be added in the near future, based on evaluations of "DOTS-plus" pilot projects that are planned over the next 2-3 years. This recognizes that, in some parts of the world (e.g. the Russian Federation and the Baltic States), MDR-TB has become a major problem. It is possible that protocols related to the other items can also be added to the guidelines at a later date.

1.2.5 Length of protocols

The chapter of protocols for costing individual components of tuberculosis diagnosis and treatment (Chapter 4) is long (approximately 50 pages of instructions and, in Document 2, 50 pages of data entry sheets for data collection and analysis). This is because the instructions for undertaking cost analysis are relatively detailed. The aim of this detail has been to make the costing analysis as simple as possible for those using the protocols. It is also worth noting that in many instances, some sections of the chapter will not be required e.g. the sections on costing hospital stay will not be required when admission is not a standard component of case management.

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1.2.6 Need for some flexibility in using the protocols

It is difficult if not impossible to write protocols that will exactly match the way tuberculosis diagnosis and treatment services are designed in all countries, or that will exactly match the way data are collected, or that will exactly match the needs of particular projects or studies. It is therefore necessary to highlight the fact that, where appropriate, the protocols in Chapters 4 through 8 of Document 1 need to be used flexibly and adapted where appropriate. For example, if a new programme design has been introduced but has not yet been in place for a year, the recommendation to use data from the most recent full year cannot be implemented. Protocol users will then need to adapt by collecting data for a shorter time period and by adjusting some of the tables and calculations to allow for this. Nonetheless, it is important to stress that standardization of methods is important for cost and cost-effectiveness analyses, to allow meaningful comparisons among different settings. Such standardization is now being emphasized within WHO, and its importance is reflected in the publication of recent textbooks and guidelines which have attempted to establish standard methodologies (e.g. Gold et al, 1996; Drummond et al, 1997; British Medical Journal and Journal of the American Medical Association guidelines, both published in 1996). Therefore, the general approach taken in the protocols should be followed as closely as possible[1].

In general, a simple approach to costing is suggested, but in one instance (costs of visits to health clinics/other non-hospital facilities) a more complex analysis would be expected to increase precision (although not substantially). Those who feel confident about undertaking a more complex analysis should feel free to do so.

Overall, it is hoped that the guidelines provide enough explanation and general principles for users to be able to make any adaptations and additions required to meet the needs of particular countries/projects/studies.

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[1] This is because all the protocols are consistent with these existing guidelines and textbooks on cost and cost-effectiveness analysis. While this introduction is not the place to discuss methodological issues in detail (these are discussed in later chapters where appropriate), 5 methodological issues are worth highlighting briefly. First, wherever possible, costing should consist of three main steps: the quantification of all resources used (e.g. staff; size of buildings used; type of drugs used) in non-monetary units, followed by the valuation of each type of resource used in terms of its unit cost (e.g. the cost of 1 nurse, the cost of 1 drug regimen, the cost of one metre of floor space), followed by calculation of total costs of each input to care or diagnosis by multiplying unit costs by the quantity of units used. This is known as an "ingredients" approach to costing. It is sometimes not feasible for non-staff recurrent expenditures, where available data only quantify the resources consumed in monetary terms. Second, a standard discount rate should be used. Third, the assumptions about the useful life of capital items should be made clear. Fourth, the year for which cost data were collected should be specified. Fifth, methods used to allocate "joint" costs should be made explicit (note that the terms used above with which guideline users may not be familiar (e.g. discount rate, capital costs, joint costs) are defined in Chapter 2.

CHAPTER 2. KEY ECONOMIC CONCEPTS IN COST AND COST-EFFECTIVENESS ANALYSIS

Introduction

There are a number of key economic terms and concepts that are important in cost and cost-effectiveness analysis, and which are commonly referred to by economists. This chapter briefly explains them, since in order to understand and complete the exercises and protocols in Chapters 3 through 7, users of these guidelines will need to understand what they mean.

To set cost and cost-effectiveness analysis within the broader framework of economic evaluation as a whole, the first four sections define the 5 major types of economic evaluation that exist: cost analysis; cost-minimization analysis, cost-effectiveness analysis, cost-utility analysis, and cost-benefit analysis.

Subsequent sections define the following terms: QALYs (quality-adjusted life years) and DALYs (disability-adjusted life years); the short and long-run; fixed and variable costs; economies and diseconomies of scale; average, marginal and incremental costs; opportunity cost; financial and economic costs; allocation of shared/joint costs; capital and recurrent costs; discounting; annualization of capital costs; the perspective of an evaluation; sensitivity analysis; and incremental cost-effectiveness analysis.

2.1 Cost analysis

A cost analysis focuses on assessing the costs of providing a service, programme or intervention. It is useful for assessing the affordability of a programme (for example by comparing costs with the budget available for tuberculosis services or for the health sector as a whole), and for guiding budgetary planning. Analysis of costs is also useful for assessing what the costs of expanding or contracting a particular service, programme or intervention might be. However, as the name implies, a cost analysis does not consider the effectiveness of a programme/intervention/service, and therefore cannot say anything about the extent to which incurring costs is worthwhile.

2.2 Cost-minimization analysis

Cost-minimization analysis is used when an evaluation is comparing 2 or more strategies which have the *same effectiveness* but which are assumed to have *different costs*. The question that the analysis is designed to answer is: which strategy has the lowest costs? For example, within tuberculosis control it is possible that 2 different drug regimens are associated with identical cure rates but that they have different costs. In this instance, a cost-minimization analysis would identify which one has the lowest cost.

2.3 Cost-effectiveness analysis

A cost-effectiveness analysis is appropriate when the aim of an evaluation is to compare alternative strategies that are associated with *both different costs and different effectiveness*. The aim is to identify the strategy with the lowest cost per unit of output, or alternatively the strategy that delivers the highest output for a given fixed budget.

In cost-effectiveness analyses in the health sector, the effectiveness indicator is the same for each strategy being compared, and consists of a health outcome measure. This output measure can be

specific to a particular type of health care intervention/programme, or it can be generic (i.e. a measure that can be used for all types of health care intervention/programme).

Within tuberculosis control, an example of a programme specific measure is the cure rate. Another (relatively) programme specific measure could be the deaths averted by tuberculosis treatment (this is "relatively" specific because it would allow comparison with some other types of health care intervention that, like tuberculosis treatment, primarily have an impact on mortality rather than morbidity). The two most widely used generic health outcome measures are the DALY and the QALY (see 2.6 for definitions).

2.4 Cost-utility analysis

Like cost-effectiveness analysis, cost-utility analysis is relevant when the aim is to compare alternative health services/interventions that are associated with different costs and different outcomes. It can therefore be seen as a form of cost-effectiveness analysis: in fact, many analysts refer to it as cost-effectiveness analysis. The main distinguishing feature of cost-utility analysis is that, as its name implies, it involves measurement of the "utilities" associated with different interventions.

"Utility" is not an easy term to define, and its definition is confused by the fact that the word is used in different ways by different people. In common usage, utility means "usefulness". In micro-economics, it refers to the consumer satisfaction associated with consumption of goods and services. Meanwhile, "expected utility theory", also referred to as von Neumann-Morgenstern utility theory (after the mathematician and economist who developed it), is a theory of rational decision-making under uncertainty. The theory consists of fundamental axioms that are used to define how a rational individual should behave when faced with uncertain outcomes. Some authors[2] define cost-utility analysis strictly as analyses that are based on von Neumann-Morgenstern theory: the key point here is that utility measurement is based on decisions made when outcomes are uncertain (as they often are in the health sector). The existence of uncertainty in the analysis is important, because it captures the extent to which individuals are risk averse, risk-seeking or risk-neutral. "Values" or "preference scores" associated with different health states are, in contrast, defined as being based on decisions made under conditions of certainty; and their use involves cost-effectiveness analysis, not cost-utility analysis.

This chapter is not the place to explain the methods used to quantify either utilities or values/preferences, since they are not required to use any of the protocols. Interested readers should consult one of the 2 major textbooks given in the "Useful References" list (Chapter 9) if they want to develop a more in-depth understanding of them. However, it is relevant to the explanation of QALYs and DALYs given in 2.6 to briefly summarize the methods used for measuring utilities/preferences/values, and to define the circumstances under which their measurement is relevant.

The method that is used to assess "utilities" is known as the standard gamble. As the word "gamble" suggests, this involves asking respondents to make choices under conditions of uncertainty; the choices made reveal the utility assigned to different outcomes. Methods that are used to measure values or preferences (i.e. to value outcomes when the outcome is presented as a certain event) can be divided into two: those that simply require respondents to define preferences using a scale (e.g. rating scale, category scale, visual analogue scale); and those that require respondents to "reveal" their preferences or values through making choices about alternative options (2 examples of the techniques that operationalize this choice are the "time trade-off" approach and the "person trade-off" approach).

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[2] e.g. see Drummond et al., 1997, p. 146.

Measuring utilities is important – and hence cost-utility analysis is important – in the following circumstances:

· when there is a need to compare very different types of health interventions/programmes, since "utilities" are a generic outcome measure;

· when health-related quality of life, and not just averted mortality, is an important outcome of an intervention;

· when an intervention affects both mortality and morbidity and there is a need to have an outcome measure that captures both; and

· when the aim is to compare an intervention with others that have already been evaluated using "utilities" as an outcome measure.

However, outcome measures that are used when the first three set of circumstances apply are not always "utilities" (in the sense of their strict definition given above). Outcome measures that combine mortality and morbidity, that allow health-related quality of life to be measured, and that do allow very different types of health intervention to be compared, but which do not involve measurement of "utilities", do exist {the DALY and, in many instances, the QALY (see section 2.6) are good examples of this}.

2.5 Cost-benefit analysis

Cost-benefit analysis involves assessing both the costs and outcomes associated with a health intervention/programme/service in monetary terms. This is unlike the 3 previous forms of evaluation, which assign a monetary value to costs only. It requires that a money value be assigned to improvements in health status.

2.6 QALYs and DALYs

QALYS and DALYs are generic health outcome measures that capture the impact of a health intervention/programme on both mortality *and* morbidity. As generic measures combining both mortality and morbidity, they allow the cost-effectiveness of health interventions targeting very different kinds of health problem (e.g. heart surgery vs. cancer treatment vs. immunization vs. vector control) to be compared. This is extremely important, because it enables analysis of how to use resources most efficiently *at the level of the health sector as a whole* (this type of analysis, using the DALY as the measure of outcome, is currently being emphasized within WHO).

2.6.1 The QALY

The QALY is an acronym for "quality-adjusted life year". It is the classic example of an outcome measure that allows life years gained in full health as the result of an intervention, and life years gained in less than perfect health as the result of an intervention, to be combined in one summary measure. When QALYs gained are analysed with the costs of gaining them, a cost per QALY measure can be calculated.

The QALYs associated with an intervention can be measured in several ways. These include use of the "standard gamble", time-trade-off approaches, person trade-off approaches, and the use of rating scales. The QALY may therefore be a "utility" in some cases only (strictly defined – see 2.4 above – though even when the standard gamble is used, a QALY is only a von Neumann-Morgenstern utility under certain restrictive assumptions[3]). Typically, the QALY is a value/

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[3] It is not appropriate to go into details here as the arguments are not directly relevant to use of these protocols. Interested readers should consult Drummond et al., p.183.

preference measure. In the measurement of QALYs, death is valued as 0 and perfect health as 1 (though values of less than 0 are possible for states regarded as worse than death).

2.6.2 The DALY

More recently, the disability-adjusted life year (DALY) has been developed. Like the QALY, this is an outcome measure that combines life years gained in full health, and years of life gained in less than perfect health (defined as disability, hence the term disability-adjusted life-year), in one single outcome measure. The DALY has been used by the World Bank and WHO for two major purposes:

·   to estimate the global burden of disease - the DALY is the measure of outcome used in "The Global Burden of Disease" (eds. Murray CJM and Lopez AD), first published in 1990; and

·   as a generic outcome measure that, in combination with cost data, allows the cost-effectiveness of very different kinds of health interventions to be compared.

The DALY was the outcome measure used in the World Bank's 1993 World Development Report "Investing in Health", which had a major focus on comparing the cost-effectiveness of different types of health intervention. Since 1993, it has been increasingly used in economic evaluations for developing countries (in developed countries, the QALY is a more commonly used measure of effectiveness). Within the field of economic evaluation of tuberculosis treatment, it is the background study to the World Bank's World Development Report that produced the figure that the cost per DALY of tuberculosis treatment for sputum smear-positive tuberculosis patients was US$ 1-3.

Unlike the QALY, the DALY assigns a value of 0 to perfect health and a value of 1 to death. All measurement of the values/preferences associated with years of life lived with disability were undertaken using the person-trade-off approach: as such, the DALY never meets the strict criteria defined above for an outcome measure to be a "utility" (as explained above, this is also true of the QALY in most circumstances). Strictly speaking, therefore, DALYs are relevant to cost-minimization and cost-effectiveness analyses.

It is important to highlight one specific feature of the DALY that is not used in calculating QALYs. This is that the DALYs gained either in full health or in less than perfect health are weighted differently according to the age at which they are gained. In particular, years of life gained in the most economically productive years of life are given more weight (or valued higher). A further feature of the DALY is that it is typically calculated by assuming a discount rate of 3% for DALYs gained in future (see 2.15 below for a definition of discounting). There is also a specific formula for calculating DALYs, which is given in Appendix 2, Chapter 7.

2.7 The short and long-run

The **short-run** is the time period in which at least one input required for the production of a good or service is fixed. In the case of tuberculosis control, basic infrastructure such as hospital tuberculosis wards might be fixed in the short-run. If the budget period is one year, many more inputs might also be fixed for one year e.g. dedicated national tuberculosis programme staff such as district tuberculosis officers and the national programme manager; national tuberculosis programme vehicles.

The **long-run** is the period in which all inputs can be varied.

2.8 Fixed and variable costs

Fixed costs are those costs that are incurred even when the output of a good or service is zero and that cannot be varied in short-run situations (this might be a year in the case of tuberculosis services). For example, fixed costs in tuberculosis services may include basic infrastructure such as buildings, and programme managers.

Variable costs are those costs that vary with output levels (in the case of tuberculosis services output is the numbers of patients diagnosed and treated). For example, in tuberculosis services the costs associated with items such as drugs and hospital food will vary according to the number of patients being treated.

2.9 Economies and diseconomies of scale

Economies of scale occur when average costs per unit of output (e.g. per patient) fall as output increases. Diseconomies of scale occur when an increase in output levels (e.g. the total number of patients treated) is associated with a rise in the average cost per unit of output. Economies of scale are commonly observed when output levels rise from zero or relatively low levels, for a number of reasons. These include the fact that both fixed and variable production capacity (e.g. staff, buildings) may be more fully utilized as output increases compared to under-utilization at low/zero output levels; that as output rises possibilities for bulk purchase of inputs occur (e.g. bulk buying of tuberculosis drugs); and that at high output levels it may become feasible to use particularly efficient technology/production systems. Typically quoted examples of diseconomies of scale are managerial inefficiency and rising costs of some inputs (e.g. the cost of staff with a specialism in tuberculosis might rise if at high tuberculosis caseload levels these staff become scarce/difficult to recruit and higher wages/overtime need to be paid as a consequence). Another useful example of diseconomies of scale within tuberculosis control is active case-finding. Average costs may fall for the first 70% of cases detected, but then start to rise as it becomes increasingly difficult and costly (e.g. with the need to conduct active-case finding in more remote areas among harder-to-reach population groups) to detect additional cases. The same principle applies to vaccination campaigns, such as those for BCG.

Empirical evidence indicates that for many types of goods and services, economies of scale are common; and that once economies of scale are exhausted, average costs are stable in the long-run over a wide range of output. However, in the short-run empirical evidence also suggests that diseconomies of scale often occur. This is because in the short-run at least one factor is fixed and therefore not all inputs can be varied. When increasing amounts of a variable factor are applied to a fixed quantity of another factor, the output per unit of the variable factor tends to decrease i.e. for a given increase in cost, progressively smaller increases in output are achieved (this is known as the law of diminishing returns).

2.10 Average, marginal and incremental costs

There are three major types of cost referred to in economic evaluation: average costs (or unit costs), marginal costs and incremental costs. The theoretical relationship between these three types of cost is illustrated in the three figures on p.11-12. A more detailed explanation of each type of cost is given below.

Figure 1: Theoretical Relationship between Average and Marginal Costs in the Short-run

Cost

SRMC   SRAC

SRMC =
Short run marginal cost

SRAC =
Short run average cost

O   X   Output

O to X: economies of scale
Above X: diseconomies of scale

Figure 2: Theoretical Relationship between Average and Marginal Costs in the Long-run

LRAC

Cost

LRMC

LRMC =
Long run marginal cost

LRAC =
Long run average cost

LRAC = LRMC

O   Y   Output

O to Y: economies of scale
Above Y: average/marginal costs stable over large
                    range of outputs
Point Y: Known as "minimum efficient scale"
                    ie minimum output level where all economies of scale are realised

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Figure 3: A Framework for Thinking About the Costs of TB Services

Total Cost (y-axis)

C = Total variable costs (eg drugs, laboratory supplies, staff on TB wards, hospital food)

B = Total fixed costs of TB services (eg dedicated TB programme staff)

A = Fixed costs associated with provision of general health services (eg general clinic / hospital buildings; hospital and district level general management and administrative staff)

a

O   xy   Y

Output (Q)
(Number of patients)

Total costs for any given output level Q = (A + B + C)

Total Incremental Costs for any given output level Q = (B + C)

Marginal Cost = change in total costs when output levels increase by 1 e.g. if increase in output between x and y represents one extra patient, marginal cost = a

Average Cost per patient for any given output level Q = (A + B + C) ÷ Q

Average *Incremental* Cost per patient for any given output level Q = (B + C) ÷ Q

A = Fixed costs associated with provision of general health services = costs which do not change however many patients use health services

Note: slope of total cost curve for variable costs falls between O and Y as significant economies of scale are realized.

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Marginal cost

The marginal cost is the cost of the last unit of a good or service that was produced. This means that it is calculated as the change in total costs that occurs when one extra unit is produced. Within tuberculosis services, an example of marginal cost is the change in total costs when the caseload increases by one (this would be the marginal cost per patient diagnosed and treated).

Why average and marginal costs are different

Average and marginal costs differ over output levels where economies or diseconomies of scale exist (i.e. increasing output could result in lower costs for drugs being negotiated; see 2.9 and Figure 2).

When economies of scale exist, the marginal cost of one more unit of output will be less than the average cost of that extra unit of output over a range of output levels. At high output levels, average costs will tend to be similar to marginal costs, since the fixed costs will be spread over a high number of units of output and all economies of scale (see 2.9 and Figure 2) will have been realized.

In the short-run, differences between average and marginal costs also occur because variable costs can be relatively "lumpy" over a range of output. For example, an increase in patient numbers may at some point require the addition of an extra nurse to a hospital tuberculosis ward, or the addition of an extra laboratory technician to carry out sputum smears. The additional patient who necessitates such an increase in costs may well have a marginal cost that is higher than average costs (they have necessitated an increase in costs equivalent to the annual salary of a nurse and a laboratory technician, as well as an increase in other variable costs such as food and drugs). However, subsequent increases in patient numbers will not cause an increase in these "lumpy" variable costs, and so until another "lumpy" investment is required, marginal costs will be lower than average costs (since average costs include all costs and do not just measure the change in total costs when output increases by one). In the long-run, inputs should be adjusted so that inputs are matched with outputs, so that the issue of "lumpy" investments is not relevant.

Incremental costs

Incremental costs are the costs associated with an addition to an existing service. For example, if it was decided to implement a directly observed therapy strategy, the incremental costs would be the costs associated with this addition to tuberculosis services. They might, for example, include training and additional health clinic visits. Outside tuberculosis services, a good example of incremental costs is the additional costs associated with adding an extra vaccination to an existing EPI programme.

The total costs of tuberculosis services could also be defined as incremental costs, because tuberculosis services can be seen as an addition to general health services. Their incremental costs could be seen as all those costs that are necessary to provide tuberculosis diagnosis and treatment, over and above the general costs associated with basic health services infrastructure and staff that are shared among all health services.

One of the major studies of the costs and cost-effectiveness of tuberculosis treatment (done as background to the World Bank's World Development Report 1993 "Investing in Health") used the terms average, average incremental, and marginal costs in their analysis. The relevance of this observation is discussed in Chapter 3, which is concerned with what costs a cost and cost-effectiveness analysis should focus on. The distinction that was made between these costs, and how they are calculated, is illustrated in Figure 3.

2.11 Opportunity cost

Opportunity cost is a measure of the benefits that would have been gained from using resources in their next best alternative use. It is therefore a measure of the sacrifice made by using resources in a programme. It is often measured as the monetary cost of the good or service provided, but can also be expressed in terms of the goods or services that, with the same resources, could have been produced instead. For example, the opportunity cost of increased investment in tuberculosis services might be the number of people who could have been treated for malaria with the equivalent expenditure.

2.12 Financial and economic costs

Any input which must be paid for with money (such as nursing staff, drugs, equipment, vehicles or fuel) represents a financial cost. All such costs are also economic costs. Inputs made to the production of a good or service at no financial cost, but which nevertheless represent a cost in the sense that those inputs could have been applied to another productive use, also represent economic costs. Therefore economic costs do not always involve monetary expenditure, whereas financial costs do.

Within tuberculosis services, inputs provided by donor agencies to Ministries of Health do not constitute a financial cost from the perspective of the Ministry, but they do constitute an economic cost. Another useful example is voluntary input to supervision of DOT, which does not constitute a financial cost but which may have an economic cost.

Financial costs may be useful when tuberculosis programmes want to develop a clear picture of money flows and who is paying for services. Economic costs are, however, the ones that are relevant when assessing the efficiency of a service (for example when calculating its cost-effectiveness). In practice it should be feasible to assess both types of cost, since for many inputs they may be the same.

2.13 Allocation of shared/joint costs

Shared or joint costs are costs that are shared by more than one service. For example, a laboratory technician shares their time over many different types of test, a doctor employed on a tuberculosis ward may also spend time working in other parts of the hospital or in the community, and in hospitals in particular there are many costs that are shared by wards and outpatient departments (e.g. catering services, laundry services, administration).

When costing a service or programme, a proportion of the total cost of any items that it shares with other services or programmes needs to be allocated to it. A number of different allocation criteria can be used. For example, a share of laboratory staff costs may be allocated to tuberculosis services according to the fraction of total tests for which sputum smears account; and a proportion of hospital inpatient overhead costs may be allocated to tuberculosis services according to the fraction of total inpatient days for which tuberculosis patients account. Typical allocation criteria include patient days, staff time, and occupied floor space.

2.14 Capital and recurrent costs

Capital costs are costs that are incurred only every few years rather than every year. Examples include vehicles, equipment and buildings. Recurrent costs are costs that are incurred every year. Examples include supplies, staff, maintenance and fuel.

2.15 Discounting

Discounting is a process that accounts for the fact that, in general, costs in the future are preferred to costs now, and benefits are preferred now to benefits some time in the future. Discounting therefore accounts for differential timing in the costs and benefits associated with the production of a particular good or service, to enable fair comparison of alternative programmes/services that incur costs and deliver benefits in different timeframes. A discount rate is also relevant for calculating the annualized value of capital costs (see 2.16).

2.16 Annualization of capital costs

Costing needs to account for both capital and recurrent costs. Annualizing capital costs (i.e. calculating the annual value of a capital item) is the easiest way to combine these two types of cost in a meaningful way. Calculation of annualized capital costs is based on three pieces of information: (a) the existing cost, now (also known as the "current replacement cost"), to purchase the item, (b) the item's expected useful life, and (c) a discount rate. Standard discount rates used in economic evaluations are 0%, 3% and 6%, but the discount rate used is also sometimes calculated as the difference between a country's interest rate and the annual rate of inflation. Tables of "annualization factors" that make the annualization of costs straightforward once the discount rate is chosen, the purchase price new[4] (i.e. current replacement cost) is known, and the expected years of useful life are estimated, are provided as Appendix 1. The use of these tables is also explained in the Appendix.

2.17 The perspective of an evaluation

An evaluation can be undertaken from a number of perspectives. The usual choices are a societal perspective, a health services (provider) perspective, or a patient perspective. However, it could also be from the perspective of a particular provider if there is more than one relevant provider (e.g. government services, mission services). If a health services (provider) perspective is chosen, this means that the cost analysis focuses only on the costs incurred by those providing a service – in tuberculosis control this would generally mean the government health system, missions, NGOs and donor agencies. If the analysis takes the perspective of a particular provider, it might focus on government health services. If a patient perspective is chosen, the focus is on costs borne by patients, such as expenditure on travel to a health facility, fees paid for services, and lost income due to time away from work. If a societal perspective is chosen, then the costs incurred by all those involved in providing or using services (this may include community and family members, as well as patients and health services) are considered. Economists typically emphasize the importance of a societal perspective, since this is the most comprehensive.

2.18 Sensitivity analysis

A sensitivity analysis involves assessment of whether changes in some of the key costs or estimates of effectiveness would affect the conclusions to be drawn from the baseline analysis. This provides an indication of how much confidence those using the analysis for decision-making purposes can have in the results. The sensitivity analysis should focus on those costs or effects about which there is some uncertainty.

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[4] This is the purchase price now, in the year in which the study is being undertaken, and NOT the purchase price when the item was originally bought.

2.19 Incremental cost-effectiveness analysis

In a cost-effectiveness analysis, a programme or service may be both more costly and more effective than the alternative programmes/services evaluated. An incremental cost-effectiveness analysis assesses the additional cost and additional effectiveness of the most effective programme compared to the other less effective alternatives (and should be carefully distinguished from incremental costs). The result is expressed as the additional cost per unit of additional effectiveness e.g. the additional cost per additional case cured in the case of tuberculosis treatment.

Appendix 1: Annualization of capital costs

Annualizing capital costs is important for enabling capital and recurrent costs to be meaningfully combined in a costing analysis. Tables of annualization factors, which show the factor to be used for any given combination of expected years of useful life and discount rate, are available to facilitate the annualization of capital costs. The basic approach is:

(i) estimate the expected years of useful life of the capital item to be costed e.g. building, vehicle

(ii) identify the purchase price new of the capital item i.e. the cost to build/buy the capital item new, now (current replacement price)

(iii) read off the relevant annualization factor for the expected years of useful life and discount rate chosen from annualization factor tables

(iv) divide the purchase price new (i.e. current replacement cost) by the annualization factor identified from annualization factor tables. This gives the annualized cost.

The table below is extracted from p94-5 in the textbook "Methods for the Economic Evaluation of Health Care Programmes", Drummond et al. 1997, Oxford University Press.

Note that with a discount rate of 0%, the purchase price new (current replacement cost) of any given item can simply be divided by the number of years of expected useful life of the item to give the annualized cost.

Table 1: annualization factors for different combinations of years of expected useful life and discount rates

Years	Discount rate									
	1%	2%	3%	4%	5%	6%	7%	8%	9%	10%
1	0.99	0.98	0.97	0.96	0.95	0.94	0.93	0.93	0.92	0.91
2	1.97	1.94	1.91	1.89	1.86	1.83	1.81	1.78	1.76	1.73
3	2.94	2.88	2.83	2.78	2.72	2.67	2.62	2.58	2.53	2.49
4	3.90	3.80	3.72	3.63	3.55	3.47	3.39	3.31	3.24	3.17
5	4.85	4.71	4.58	4.45	4.33	4.21	4.10	3.99	3.89	3.79
6	5.80	5.60	5.42	5.24	5.08	4.92	4.77	4.62	4.46	4.36
7	6.72	6.47	6.23	6.00	5.79	5.58	5.39	5.21	5.03	4.87
8	7.65	7.33	7.02	6.73	6.46	6.21	5.97	5.75	5.53	5.33
9	8.57	8.16	7.79	7.44	7.11	6.80	6.52	6.25	6.00	5.76
10	9.47	8.98	8.53	8.11	7.72	7.36	7.02	6.71	6.42	6.14
15	13.87	12.85	11.94	11.12	10.38	9.71	9.11	8.56	8.56	7.61
20	18.05	16.35	14.88	13.59	12.46	11.47	10.59	9.82	9.82	8.51
25	22.02	19.52	17.41	15.62	14.09	12.78	11.65	10.67	10.67	9.08
30	25.81	22.40	19.60	17.29	15.37	13.76	12.41	11.26	11.26	9.43
35	29.41	25.00	21.49	18.66	16.37	14.50	12.95	11.65	11.65	9.64
40	32.83	27.36	23.11	19.79	17.16	15.05	13.33	11.92	1.92	9.78
45	36.09	29.49	24.52	20.72	17.77	15.46	13.61	12.11	12.11	9.86
50	39.20	31.42	25.73	21.48	18.26	15.76	13.80	12.23	12.23	9.91

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CHAPTER 3: KEY ISSUES TO CONSIDER WHEN DESIGNING A COST AND COST-EFFECTIVENESS ANALYSIS

Introduction

This chapter draws on a major textbook on methods for the economic evaluation of health care programmes[5] . It highlights twelve key issues (listed as 3.1 to 3.12) to consider when conducting a cost or cost-effectiveness analysis, and provides useful background to the protocols in Chapters 4 and 5. The exercise at the end should also help reinforce guidelines users' understanding of Chapters 2 and 3, as well as providing the basis for the detailed cost and cost-effectiveness analysis to be undertaken using the protocols.

3.1 The question the analysis is attempting to answer

Any economic evaluation should be based on a clearly-defined and answerable question. For example, recent questions that have been the subject of economic evaluations in the area of tuberculosis control include:

1. What is the cost to the government of providing tuberculosis services through the DOTS strategy in China?

2. Is a community-based approach to tuberculosis treatment more affordable and cost-effective than traditional approaches relying on health facilities only in rural Uganda?

3. Is a community-based approach to tuberculosis treatment more affordable and cost-effective than other widely used approaches to treatment in South Africa?

4. What cost-savings could the government make if it reduced the length of hospitalisation for smear-positive tuberculosis patients from 2 months to 1 month in Blantyre, Malawi?

5. Are the pilot projects implementing the WHO DOTS strategy in the Russian Federation more cost-effective than the traditional approach to tuberculosis treatment in Russia?

6. How does the cost and cost-effectiveness of the WHO DOTS strategy recently implemented in Syria and Egypt compare with the cost and cost-effectiveness of the previous approach to tuberculosis control?

7. Is tuberculosis treatment a relatively cost-effective health intervention compared to interventions such as childhood immunization, treatment for malaria, and control of schistosomiasis?

These types of questions address different issues. For example, cost analyses are useful for showing what funding is required to sustain a new strategy or project. This could, for example, inform budgetary allocations at national, regional or district levels. Cost-effectiveness analyses are useful for identifying which approaches to tuberculosis control are most efficient, and which therefore make best available use of the resources available for tuberculosis control. Cost-effectiveness analyses comparing tuberculosis control with other types of health service are useful for indicating how resources can be most efficiently used across the health sector as a whole. This approach is currently being emphasized within WHO's "Global Programme on Evidence for Health Policy".

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[5] This book is "Methods for the Economic Evaluation of Health Care Programmes", by Drummond M. et al, Oxford University Press 1997. The first author of this book has also been one of the key people responsible for the development of guidelines for the conduct of economic evaluations for the British Medical Journal (published in 1996).

3.2 The perspective of the evaluation

Generally, it is recommended that a societal perspective (see Chapter 2 for definition) is adopted, since this gives the most complete picture of costs. However, the appropriate perspective will depend on the question the evaluation is aiming to answer. In Questions 1 and 4 in section 3.1 above, for example, it is a government or provider perspective that is relevant to the questions being asked.

In the case of tuberculosis services, it is worth noting that consideration of patient costs in addition to provider/health system costs may be of particular importance, since the patient costs associated with different treatment strategies may have an important effect on compliance with treatment. When tuberculosis programmes use community members in some aspects of treatment e.g. directly observed therapy, it may also be important to assess what costs they incur, especially if an expansion of the use of community members is being considered. To develop a comprehensive picture of costs, family costs could also be assessed, especially in countries where family members typically attend patients while they are in hospital. Chapter 4 shows how to assess costs incurred by health services/providers, and Chapter 5 provides guidance concerning assessment of the costs incurred by patients, volunteers involved in tuberculosis services, and family members.

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3.3 What kind of economic evaluation is relevant?

As defined in Chapter 2, the main types of economic evaluation are:
· cost analysis;
· cost-minimization analysis;
· cost-effectiveness analysis;
· cost-utility analysis; and
· cost-benefit analysis.

It is assumed that users of these guidelines are interested in either (a) a cost analysis (b) a cost-minimization analysis or (c) a cost-effectiveness analysis.

3.4 Identification and description of the alternatives to be compared

It is worth stressing that to be meaningful, an economic evaluation should involve the assessment of at least two alternative strategies. Cost or cost-effectiveness results for a particular way of delivering health services such as tuberculosis diagnosis and treatment are of little value in the absence of a relevant comparison.

The alternatives should be clearly identified at the start of the evaluation. For example, in some African countries this might involve the assessment of the costs and cost-effectiveness of community-based DOT in comparison with the costs and cost-effectiveness of conventional treatment involving two months of hospitalisation. One alternative strategy could also be the alternative of "doing nothing" i.e. a comparison of the costs and cost-effectiveness of tuberculosis services compared with what would happen if there was no programme.

The aim might also be to compare the cost-effectiveness of tuberculosis treatment with the cost-effectiveness of other, very different types of health care intervention e.g. provision of insecticide-impregnated bednets for prevention of malaria, immunization, HIV prevention programmes. This reflects the fact that such analyses can help to identify the most efficient way of using resources across the health sector as a whole.

Such analyses require a generic measure of health outcome, such as the DALY or QALY (see Chapter 2 for an explanation of these measures).

The alternative strategies being compared should also be clearly and comprehensively described. This is particularly helpful at an initial stage in the costing process, since it is a good way of identifying all the important elements of tuberculosis services that need to be costed (see also 3.6).

3.5 What evidence will be used to establish each alternative s effectiveness and what measure of effectiveness will be used?

A cost-effectiveness analysis requires good evidence on effectiveness. This should be available for existing tuberculosis programmes. However, if new programme designs (e.g. community-based DOT) are being considered it may be necessary to use effectiveness data from elsewhere, where the strategy of interest has been implemented. The measure of effectiveness to be used also needs to be chosen. For smear-positive pulmonary tuberculosis cases, this could be the cure rate; for other types of tuberculosis patients, it could be the completion of treatment rate. If comparisons are to be made with other types of health intervention/programme, it is essential to use a measure of health outcome (e.g. the QALY or DALY) that allows comparisons across very different types of health intervention (Chapter 6 explains how to calculate three measures of cost-effectiveness: cost per patient cured, cost per death averted, and cost per DALY gained).

3.6 Identification of all the important costs

All the costs – both financial and economic (see Chapter 2 for definitions) – should be identified. Costs such as staff, vehicles, drugs etc. are often the first types of costs to be identified by staff being introduced to costing. However, when costing tuberculosis services it is probably easiest to focus on identification of the costs associated with individual components of diagnosis and treatment. These components include hospital stay, outpatient visits to clinics/health centres, outpatient visits to community health workers (CHWs), outpatient visits to non-health workers, outpatient visits to a hospital outpatient department, the drug regimen, sputum smear examinations, sputum culture examinations, X-rays, supervision of patients/health staff/ supervisors of DOT to encourage compliance with treatment, programme management/audit, and training. Identifying the costs of these items is useful because it facilitates assessment of the likely costs of alternative programme designs, in which the number of these inputs (e.g. outpatient visits, days in hospital) is different or in which some inputs (e.g. hospital stay) do not apply at all. It also makes it easier to use the results of costing studies conducted in a few representative facilities to estimate costs at regional/provincial or national level.

It is, however, useful to identify all the important inputs that will need to be costed in order to calculate the cost of each component (e.g. staff, equipment, supplies, and buildings might be four key inputs in the case of sputum smears; staff and buildings might be important inputs for clinic visits).

3.7 How to measure costs in appropriate physical units

For each cost that needs to be calculated, it is important to quantify the resource inputs required in appropriate physical units. For example, for each cost item identified in 3.6, all the relevant resource inputs should be listed and quantified e.g. numbers of nursing and clinical staff, type of equipment, supplies, number and type of vehicles and how often they are used, fuel, overheads such as fuel/electricity/support staff, buildings. For relevant cost items, it is also helpful to identify

how many times the cost is incurred for the average patient e.g. the number of days spent in hospital, the number of smears done, the number of clinic visits made, etc. Focusing attention on this issue is designed to ensure the clear identification of (a) how many times a particular cost is incurred and (b) the nature of the inputs required for each cost component.

3.8 How costs are to be valued

It is important to consider both what sources of cost data are to be used, and whether the analysis is to focus on marginal, incremental or average costs (see Chapter 2 for definitions). The way in which joint/shared costs (see Chapter 2 for definition) are to be allocated, and non-financial inputs such as volunteer time valued, also needs to be decided, and a discount rate (see Chapter 2 for definition) should be chosen.

One of the key issues is whether to focus on average, incremental or marginal costs. The difference between these costs is explained in Chapter 2. There is no "right" cost to focus on, since different economic evaluations will have different objectives. The protocols in Chapter 4 show how to assess all three types of cost. However, a number of points are worth noting here:

- tuberculosis programmes should be aiming to maximize the overall efficiency with which services are provided. In the long-run, which is the period that tuberculosis programmes should be planning for, tuberculosis services will be most efficient when long-run average costs, for a given level and quality of output (caseload), are minimized (see illustrative diagrams in Chapter 2). This suggests that a cost analysis should focus on average costs;

- in the long-run at high output (caseload) levels, average and marginal costs should be similar (see Figure 2 in Chapter 2);

- average and marginal costs should only diverge sharply when services are being heavily under- or over-utilized. However, under- or over-utilization is not efficient and therefore programme managers should aim to minimize under- or over-utilization. Nevertheless, in the short-run when over or under-capacity cannot be dealt with, marginal cost figures may be useful for tuberculosis programme managers to know, since in this situation the average cost will not be a good measure of the extra costs being incurred to manage additional patients (see Figure 1 in Chapter 2 for the divergence between average and marginal costs that can occur in the short-run);

- the World Bank's World Development Report, "Investing in Health", had a major emphasis on assessment of the cost-effectiveness of health interventions. The analyses focused on long-run average costs;

- average costs give the most complete picture of the costs involved in providing a service/ intervention/programme, since all possible inputs (including the very general ones that are not specific to any particular programme but which are required to support all health services) are included in the costing analysis;

- incremental costs (the costs of "adding on" a new service/intervention to a pre-existing service/ intervention) are most relevant when (a) a new intervention or programme is being added to existing services and (b) the new intervention/programme does not involve any other changes to health service delivery. For example, an incremental cost analysis might be relevant for an economic analysis of the cost and cost-effectiveness of adding a preventive therapy intervention to existing services, if this new intervention will not change the way other services are delivered. However, if the introduction of a new programme/intervention *will* change the way tuberculosis services are delivered (e.g. the introduction of community-based DOT may involve not only the addition of extra inputs to a tuberculosis programme, but also a substantial reduction in hospital costs), simply focusing on the "new" additional costs due to this programme/ intervention will provide an inaccurate picture of its overall economic implications;

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- the choice between focusing on incremental or average costs needs to reflect the question that an economic evaluation is attempting to answer. If the question relates to the cost and cost-effectiveness of adding an intervention to an existing service, a focus on incremental costs is appropriate. On the other hand, if the question concerns the overall cost-effectiveness of providing existing services – which is important for reviewing what is currently done well as well as for considering what should be added – average costs are important;

- average costs – simply because they are an average figure and therefore the best overall estimate of costs – may be more useful than marginal costs in situations where the total number of patients is continually increasing and not just changing marginally;

- use of marginal cost figures, especially short-run marginal cost figures, has the potential to be misleading. In the short-run, costs may end up as only, for example, supplies for sputum smears and X-rays, drugs and hospital food - the costs that do always increase with every new tuberculosis patient. These costs would provide a very inaccurate picture of the total costs of tuberculosis diagnosis and treatment because they would not include either the fixed costs associated with provision of tuberculosis diagnosis and treatment, or the variable costs that do not vary over output levels of one (such as tuberculosis ward staff), both of which may be relatively high. Long-run marginal cost figures could also be misleading if they were taken by programme managers to the Planning Unit/Minister of Health/Ministry of Finance as the basis for budget allocations to tuberculosis control. This is because they would not include the costs associated with provision of tuberculosis diagnosis and treatment services when output is zero – for example, to have the capacity to provide tuberculosis services, programme managers, some basic infrastructure such as tuberculosis clinics, and district officers may be required even when there are no patients. These may represent important costs. Estimates of total costs based on marginal costs could therefore represent a serious under-estimate of the resources really required for adequate tuberculosis control;

- average costs are required for estimating the total costs associated with tuberculosis services in a country. Total costs may be a very useful piece of information for programme managers; and

- recent thinking on cost-effectiveness analysis within WHO's "Global Programme on Evidence for Health Policy" suggests a greater focus on average costs rather than incremental costs, and on average cost-effectiveness rather than incremental cost-effectiveness (Murray, Evans et al, GPE Discussion Paper No. 4, July 1999[6]).

These points suggest that average, incremental and marginal costs may all be of relevance, depending on circumstances and depending on the studies with which comparisons need to be made. The recent BMJ guidelines on economic evaluation offer a useful summary comment, and appear to suggest that average costs may be more relevant in the case of tuberculosis programmes. They say: "(the) choice (between average and marginal costing) can be related to context and time-frame. In the short-run few costs may be variable if a change in treatment is introduced, whereas over longer periods all resources, including buildings, can be switched to other uses. Thus if the study relates to a decision of a hospital manager the short-run marginal costs of the various options in his or her hospital may be the most relevant in the current budget period. If the decision relates to a matter of national policy, however, average costs may be more appropriate as these reflect the true variable costs when many services are provided in a large number of facilities across the country". Tuberculosis control strategies are a matter of national policy and tuberculosis treatment is provided in many facilities, so in the long run this suggests a focus on average costs.

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[6] See Murray CJL, Evans DB, Acharya A and Baltussen RMPM "Development of WHO Guidelines on Generalised Cost-Effectiveness Analysis". GPE Discussion Paper No. 4, July 1999. World Health Organization.

This protocols in these guidelines are designed to enable all types of cost to be calculated. It is also worth highlighting the fact that in many ways it makes sense to start by assessing average costs, since once the data for average costs are collected the analyst should have all the information required for assessment of incremental and marginal costs too. However, *overall it appears that either average, or average incremental costs, are the most useful for those managing tuberculosis programmes*. Average incremental costs may be justified on the grounds that general basic health infrastructure costs will be the same (a) whether or not tuberculosis services are provided (b) whatever the level of the tuberculosis caseload and (c) whatever the diagnostic and treatment strategy in place. Average incremental costs are therefore a good measure of the costs specifically associated with provision of tuberculosis services. On the other hand, average costs are the best overall representation of costs. In practice, average and average incremental costs may be little different. Finally, whichever measure is focused on should be made clear in presenting results e.g. to programme managers or policy makers; and the reason for the choice of measure clearly explained and justified.

3.9 Sensitivity and incremental cost-effectiveness analyses

Guidelines and standard textbooks recommend that cost and cost-effectiveness analyses should include both sensitivity and incremental cost-effectiveness analyses. These terms were explained in Chapter 2.

3.10 Site(s) where the cost/cost-effectiveness analysis is to be undertaken

The way in which financial and other relevant data required for costing are recorded in many countries means that it is unlikely to be realistic to assess the costs associated with provision of tuberculosis services in all districts/regions of a country - this would be too time-consuming. Therefore a key decision when undertaking a cost analysis of tuberculosis services is *where* to assess costs.

If the interest is in the cost and cost-effectiveness of services in a particular district, it does not matter whether or not the district is typical of the region/province/country as a whole. The protocols in Chapters 4 through 8 can simply be applied in that district. However, if one of the major objectives of the cost and cost-effectiveness analysis is to estimate costs at regional/ provincial or national level, it is very important that **a representative district** (or set of districts) is chosen, so that the costs identified can be generalised to services in other areas.

If costs and effectiveness are expected to be fairly similar across districts, a random sample of districts may be used. If there is likely to be wide variation in costs or effectiveness, however, it is recommended that districts are grouped so that, within each group, costs and effectiveness are expected to be broadly similar. One or more districts should then be selected (ideally at random) from each group, and cost and effectiveness data collected for these. National level estimates can then be obtained by taking a weighted average of costs and effectiveness in each of the sampled districts (weighted according to the proportion of total tuberculosis cases occurring in each group).

It is worth stressing that a statistician should always be consulted to help with decisions concerning sample size and how the random sample should be generated.

3.11 The year of prices in which costs are valued

The monetary values estimated for each type of cost will always apply to a particular time period, usually a particular year. It is important to ensure that when making comparisons of the costs of alternative strategies, the cost of each strategy is not distorted by the year in which costs were valued. In other words, any costs need to be standardised in terms of prices in a given year, so that comparisons among strategies are not distorted by changes in prices but reflect *real* differences in the value of resources used.

Usually, it is standard practice to value costs in the most recent year for which data were used in the study. Therefore, if a study is comparing 2 strategies, one implemented in 1997 and one implemented in 1998, costs would be valued in terms of prices in 1998 (e.g. 1998 US$).

In practice, when a study involves studying costs in different years, costs from years prior to the latest year need to be either (a) valued in the first place in terms of prices in the most recent year for which data are being collected or (b) valued in the year for which data are being collected, and then inflated to the most recent year for which data are being analysed.

For many types of cost, option (a) is possible. The quantities of resources used can be identified for any year being studied, and then costs in monetary terms can be calculated by multiplying these quantities by prices in the most recent year for which data are being analysed. This should be relatively straightforward for staff, buildings, equipment, vehicles and motorbikes (for example, the quantity of each staff employed in 1997 can be multiplied by the price of such staff in 1998).

The main type of costs for which option (b) is likely to be necessary is non-personnel recurrent expenditure. This is usually difficult to quantify in anything except monetary terms, unless information systems are very sophisticated and/or a large amount of time is available for quantification of resource use in non-monetary terms (e.g. number of units of electricity used, quantity of different type of food item consumed, quantity of water used etc.). Therefore, the easiest way to handle these costs is to inflate the value of expenditure from the year in which expenditure was incurred to the most recent year for which costs are being assessed, using the consumer price index.

A useful source of consumer price index data for all countries is the annually produced "IMF International Financial Statistics Yearbook". In addition, a very helpful paper for converting cost data from any given year to prices in another year was published in 2000[7]. This provides a table of factors by which costs need to be multiplied to convert US$ costs in any given year into US$ in year 2000 prices.

3.12 The currency in which costs will be quoted

Costs are always valued in a particular unit of currency e.g. US$, UK£, South African Rand, Malawi Kwacha. When undertaking an economic evaluation, it needs to be decided what currency costs will be valued in. For most analyses, it is probably most useful to value costs in both (a) the currency of the country in which the study is being undertaken, and (b) in US$, as this is most useful for international comparisons.

Exercise 1 in Document 2 should now be completed *before using the protocols in Chapters 4 through 8*. **This is important because the exercise will help protocol users to consider/ think through the key issues highlighted in 3.1 to 3.12. Completion of the exercise should therefore help facilitate effective use of the protocols. Note that some guidance concerning the answers is provided in Appendix 1, and that in some cases, the protocols assume particular answers. These answers are indicated where appropriate.**

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[7] Kumaranayake L. The real and the nominal? Making inflationary adjustments to cost and other economic data. *Health Policy and Planning* 2000; 15: 230-4.

Appendix 1: Guidance notes for Exercise 1

1. At which sites will the cost analysis be undertaken?

It is important to choose sites that are likely to be broadly representative e.g. an urban district with a tertiary hospital; a rural district. If sites are representative, cost results can be used to estimate the costs of tuberculosis services at, for example, national and regional level. The costs most likely to vary are transportation costs (which may be higher in rural areas) and hospitalisation costs (which are likely to be higher in more specialized facilities e.g. tertiary hospitals in urban areas). It may also be worth studying a district where services appear to work well, since this may give a good indication of the costs of providing an effective service.

If there is more than one major provider of tuberculosis services in the districts chosen, *and* they provide hospital care, it is suggested that the cost of a day in hospital is assessed (using Protocol 1 in Chapter 4) in both (a) a representative government hospital and (b) a representative mission/ other NGO hospital (it will be too time-consuming to assess costs in all hospitals if there are more than two). Assessing costs for both types of provider is worthwhile because hospital costs are (a) likely to be a major component of tuberculosis service costs in countries where inpatient stay at treatment outset is an important part of case management and (b) may vary among providers. Therefore if hospital cost data from one provider only are used in estimations of total tuberculosis service costs at national or district level, these estimates will be inaccurate. Hospital cost data from all the major providers will enable more accurate assessments of total costs to be made.

A good example to illustrate this point is the existence of both mission and government facilities in some countries, with missions providing perhaps 50% of all services. In such a situation, an accurate assessment of the costs of tuberculosis services will require costing studies in both mission and government facilities.

2. What question(s) is the cost and cost-effectiveness analysis addressing?

The guidelines assume that the questions to be answered are:

- what is the cost and cost-effectiveness of existing tuberculosis diagnosis and treatment services?
- what would be the likely cost and cost-effectiveness of alternative diagnosis and treatment management strategies?

3. What will be the perspective of the evaluation?

The protocols in Chapters 4 and 5 show how to assess costs from a societal perspective. This results in all relevant costs being identified. However, if protocol users wish to focus on a health services (provider) perspective, this simply means that Chapter 5, on patient/family/community costs, need not be used.

4. What kind of evaluation is going to be undertaken?

This protocol assumes that a cost or cost-effectiveness analysis is relevant.

5. Describe the existing approach to diagnosis and case management, and describe the alternatives (if any) with which this is to be compared

The various strategies being compared should be clearly and comprehensively described. This should include, at least, the existing diagnostic and treatment strategy. Strategies should be described in terms of the key components listed above in 3.6 (hospital stay; outpatient visits to clinics/health centres, outpatient visits to CHWs; sputum smear examinations; sputum culture examinations; X-rays, etc.), since these are the components which the protocols in Chapter 4 are designed to cost (see also the data entry sheets that accompany Chapter 4 for the components which the protocols are designed to cost). If other components are also included, these should be stated too.

6. What evidence will be used to establish each alternative's effectiveness and what measure(s) of effectiveness will be used?

The source of effectiveness data should be identified. Examples may include the tuberculosis register or annual programme reports. The effectiveness measure(s) to be used are likely to include one or all of: the cure rate; the completion of treatment rate; deaths averted; and DALYs gained.

7. What are the costs to be identified?

List the costs to be calculated e.g. the cost of a day in hospital, the cost of a sputum smear etc. These costs should be based on the answer to question 5.

8. Are there any costs that will not be assessed? If not, why not? Will this cause a problem?

List any costs that will not be considered in the analysis, and justify why they are not being included.

9. How will costs be measured in appropriate physical units?

For each cost item listed as the answer to question 7, explain the inputs required (e.g. nursing and clinical staff, equipment, supplies, vehicles, fuel, overheads such as fuel/electricity/ support staff, buildings). Also note what data sources will be used to quantify these inputs (e.g. interviews with staff, staff allocation rotas/books, vehicle logbooks). For relevant cost items, also identify how many times the cost is incurred for the average/typical patient e.g. the number of days spent in hospital, the number of smears done, the number of clinic visits made etc. (this should be based on the description of the strategies being evaluated i.e. the answer to question 5)

Answers to this question are therefore designed to identify (a) how many times a particular cost is incurred and (b) the total inputs required for each cost component.

10. What type of costs are to be assessed?

The protocols in Chapters 4 and 5 assume that average, incremental and marginal costs will all be assessed. This is because they are all potentially useful, and if the data required for the calculation of average costs are collected, protocol users should have all the information required to assess incremental and marginal costs too.

11. How will shared/joint costs be allocated?

Guidance is provided in Chapter 4.

12. What discount rate is to be used?

The guidelines use a discount rate of 3% for the baseline analysis. This was the rate used in the World Bank's cost per DALY assessments, so that using this discount rate permits fair comparisons with widely quoted figures. Sensitivity analyses using discount rates of 0% and 6% are commonly recommended, and 6% has been used in some important recent economic evaluations (e.g. the recent cost-effectiveness analysis of improved STD treatment for reducing HIV infections in Mwanza, Tanzania[8]).

13. Where can building cost data be found?

A good source is the Ministry of Works, or alternatively quantity surveying firms.

14. Where can data on the annual number of inpatient days in a hospital, and the annual number of visits to other facilities, be found?

Typical sources include hospital administrators, midnight bed state statistics books (for inpatient days) often kept by the Chief Matron, or annual reports kept by, for example, district health officers.

15. In what year of prices will costs be valued?

The year should be the most recent for which data are being collected.

16. How will costs in years prior to the most recent year for which costs are being assessed be converted into costs in the most recent year for which costs are being assessed?

The easiest approach is as follows:
- Quantify staff, building, equipment, vehicle/motorbike costs in non-monetary terms and then multiply quantities by unit prices in the most recent year for which costs are being assessed;
- For non-personnel recurrent expenditure, inflate costs from the year in which expenditure was incurred to the most recent year for which costs are being assessed using the consumer price index.

17. In what currency will costs be valued?

US$ are the best for facilitating international comparisons and are also useful when a local currency is changing rapidly in value. Quoting costs in the local currency is also helpful.

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[8] Gilson L, Mkanje R, Grosskurth H et al "Cost-effectiveness of improved treatment services for sexually transmitted diseases in preventing HIV-1 infection in Mwanza Region, Tanzania". *Lancet*, 1997, Vol. 350:1805-9.

CHAPTER 4. PROTOCOLS FOR ASSESSING THE COSTS ASSOCIATED WITH INDIVIDUAL COMPONENTS OF TUBERCULOSIS DIAGNOSIS AND TREATMENT SERVICES (HEALTH SYSTEM/PROVIDER PERSPECTIVE)

4.1 Introduction

The main components of any tuberculosis diagnosis and case management strategy are broadly similar. A strategy will typically consist of most, or all, of the following elements:

- hospital stay;
- outpatient visits to a hospital outpatient department;
- outpatient visits to clinics/health centres or similar non-hospital facilities;
- outpatient visits to community health workers (CHWs);
- outpatient visits to non-health workers;
- drug regimen;
- sputum smear examinations;
- sputum culture examinations;
- X-rays;
- supervision of patients/health staff/supervisors of DOT to encourage compliance with treatment;
- training; and
- programme management.

What will vary is whether all or just some of these items form part of case management, the details of each element (e.g. drug regimens differ), and the relative importance of each item e.g. the length of hospital stay will vary, as will the number of outpatient visits required for collection of drugs or direct observation of treatment.

The most important challenge for those wanting to cost tuberculosis diagnosis and treatment services is to calculate the costs of the relevant individual components of diagnosis and treatment. This is because these costs form the essential building blocks for assessing the costs of managing a single patient to treatment completion (a very useful piece of information for planners in budget development), for cost-effectiveness analysis, and for estimation of total tuberculosis service costs at district, regional/provincial and national level. **The protocols in Chapter 4 and the guidelines in Chapter 5 show how to calculate these costs, and are therefore the most important chapters in these guidelines.** They identify, for each component, what data to collect, and how to analyse them. The data entry sheets (see Document 2) that accompany Chapters 4 and 5 should be filled in using the instructions provided. This chapter (4) covers health services (provider) costs; Chapter 5 deals with calculation of the costs incurred by patients, family members and community volunteers. The protocol for health services (provider) costs starts with the calculation of average costs, and then shows how to use these to assess average, incremental and marginal costs (see Chapters 2 and 3 for definition and discussion of these terms). For patient/family/community volunteer costs, average, average incremental and marginal costs should be equivalent.

There are several general points that it is important to note before using the protocols in Chapter 4. These are:

- the level at which the protocols and data entry sheets should be used;
- which protocols are the most difficult and need to be given particular attention;
- noting who funds each type of cost;
- whether or not to collect data for all providers of health services in a district;
- how to deal with costs for inputs not covered in the protocols;
- sources of data;
- handling staff costs accurately; and
- data analysis.

Each of these is explained below.

4.1.1 Level at which the protocols and data entry sheets should be used

It is worth stressing that except for national/regional programme management and drugs, ***the data entry sheets are designed for use at district level.*** In other words, completion of the protocol will enable the costs of tuberculosis services to be assessed in a particular district. If more than one district is chosen for study (this depends on the answer to question 1 of Exercise 1 in Chapter 3), all the appendices should be completed ***for each district***.

The data entry sheets are also designed to be used as follows:

- the sheets for the cost of a day in hospital and a hospital outpatient visit should be used at the level of ***an individual facility*** e.g. a government hospital, a mission hospital. ***If the cost of a day in hospital is to be assessed for more than one facility in the district, the set of data entry sheets that accompany the protocol (in Document 2) should be completed for each hospital studied***;
- the sheets for the cost of a visit to a clinic/other non-hospital facility, programme management, district supervision, and supervision and follow-up of patients in the community should be used ***at district level***; and
- the sheets for the cost of a sputum smear and an X-ray should be used at the level of ***an individual department*** i.e. a single laboratory, or a single X-ray department, rather than at the level of all laboratory and X-ray services in the district.

4.1.2 Which protocols are the most difficult and need to be given particular attention?

The first two protocols, concerned with calculating the cost of a day in hospital and the cost of a hospital outpatient visit, are probably the most difficult. It is therefore worth paying particular attention to them.

4.1.3 Noting who funds each type of cost

The protocol is designed to enable all economic costs to be identified, rather than simply the financial costs (see Chapter 2 for definition of these terms). However, it is recognised that in some countries a mixture of agencies fund tuberculosis services, and it may be important to identify the breakdown of these funding sources (e.g. donor agencies, missions, NGOs, regional or local administrations as well as central government). Therefore, for each cost item the protocols involve identifying who finances that cost, by including the question "Who pays?". *Once the data entry sheets are completed, it should then be possible to assess both (a) the total costs of each care component and (b) the breakdown of funding sources.*

Note that costs that are sometimes not covered by the government include:

· staff funded by NGOs/missions/donor agencies;

· drugs when these are provided free of charge by donor agencies; and

· vehicles and equipment when these are donated.

These should therefore be paid particular attention when cost data are being collected and analysed, if one of the aims of the cost analysis is to identify the sources of funds for each type of cost (note that ALL costs need to be identified for the purposes of a cost-effectiveness analysis).

4.1.4 Should data be collected for all providers of health services in a district?

Within a district, there may be more than one important provider of tuberculosis services e.g. government and mission facilities. To avoid making data collection and analysis extremely time-consuming and complicated, and because mission/NGO *hospitals* are likely to be the major non-government provider of tuberculosis services, it is suggested that:

· cost data collection and analysis is undertaken for all care components for government services;

· a day in hospital is the only care component for which costs are assessed for mission/NGO facilities. The costs of any other care components provided by missions/NGOs can be assumed to be similar to those for government services.

This approach will enable the costs associated with government provision to be accurately assessed and the costs associated with other important providers to be estimated (see also comments on question 1 in Exercise 1 Chapter 3).

4.1.5 How to deal with costs for inputs not covered in the protocols

It is likely that tuberculosis diagnosis and treatment services in some countries will include inputs not covered in this protocol. The protocol should include the most important cost items, but where there are gaps it is hoped that protocol users will be able to address these by using principles similar to those already applied in other sections (see also final section in this chapter).

4.1.6 Sources of data

Identifying appropriate sources of data is obviously critical for any cost analysis. Therefore, typical sources of relevant data are summarized in Table 4.1. Where these do not appear to be available, it is suggested that the senior medical, nursing, managerial and administrative staff in the district or facility being analysed are consulted and asked to identify appropriate data sources. Another option would be to consult local economists who have done costing work in the past, perhaps on other types of health services besides tuberculosis.

Table 4.1: Typical sources of data relevant to costing analyses

Type of data	Typical source
Staff costs (i) Basic salaries	(i) District/hospital payrolls; list of salary scales from personnel officers (locally or at Ministry of Health)
(ii) Pension/insurance contributions paid by employer	(ii) Senior district/hospital administrator/financial staff e.g. accountants; expenditure records; also the Ministry of Health (especially if the contribution is a standard percentage of the basic salaries paid)
(iii) Housing allowances	(iii) Expenditure records/local administrator/ interviews with staff
(iv) Value of accommodation provided	(iv) Local rental values for similar accommodation, if available; if not, consult local architects/quantity surveyors for an estimate
(v) Special incentives paid	(v) Local administrators/interviews with staff
(vi) Uniforms	(vi) Hospital/district expenditure data
Number and type of staff allocated to TB ward, and proportion of time spent on this ward	Nursing allocation books kept at ward level and by senior matron; interviews with senior medical or nursing staff
Drug costs	Staff at the headquarters of the national tuberculosis control programme, pharmacy price lists, Central Medical Stores, donor agencies if these supply the drugs, or international agencies such as WHO
Purchase price new (current replacement cost) of X-ray and laboratory equipment	Medical equipment companies
Size of buildings	Architectural plan which may be kept by senior managerial or administrative staff; Ministry of Works or Ministry of Health which may know the size of standard types of buildings; direct measurement
Building costs	Ministry of Public Works (can typically quote the cost per square metre for buildings and/or the cost to replace a standard type of facility e.g. district hospital, clinic); also local quantity surveying firms or architects
Purchase price new, now, of vehicles (current replacement cost)	Local car dealers
Rates per kilometre or mile paid for vehicle usage	Ministry of Health or Ministry of Transport
Laboratory and X-ray supplies and reagents	Local, regional or national laboratory managers; district or hospital expenditure records which may have specific lines for recording these items; medical supply companies
General hospital recurrent expenditure data (excluding those staff costs listed above)	Expenditure records often maintained by local hospital administrator; may also be available in national level reports prepared by the Ministry of Health
General clinic/other non-hospital facility recurrent expenditure (excluding those staff costs listed above)	As above for general hospital recurrent expenditure
Miles or kilometres travelled for supervision or management	Vehicle logbooks
Annual number of visits to clinics/ other non-hospital facilities	District Medical Officer; District Health Office
Annual number of inpatient days associated with the hospital as a whole and for different hospital wards	Midnight bed state statistics kept by Chief/senior Matron; statistics kept by Admissions office; annual reports kept by District Health Office/senior management/administrative staff
Exchange rate data	Ministry of Finance; Ministry of Economic Planning or similar

4.1.7 Handling staff costs accurately

Staff are likely to be one of the most important costs associated with provision of tuberculosis diagnosis and treatment services. Therefore, special care should be taken when analysing these costs.

As noted in Table 4.1, staff costs may consist of several elements:
- basic salaries;
- pension/insurance contributions paid by employer;
- housing allowances;
- value of accommodation provided;
- special incentives paid; and
- provision of uniforms.

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Therefore, while the use of salary data is a key element of staff costs, and while this may dominate staff costs in many settings, it is not sufficient to rely on salary data alone when calculating staff costs. In each of the protocols that involve staff costs, "annual staff costs" rather than "annual salary costs" are therefore referred to. The importance of identifying all costs, and not just salary costs, is also emphasized in each protocol where the costing of staff is being addressed.

Protocol users need to ensure that when the annual cost of any type of staff is calculated, all relevant items are included. In using these protocols, it is suggested that when calculating staff costs, the first 5 items only are considered. This is because expenditure on uniforms may not appear as a distinct item in expenditure records; and even if it does, it is not always clear which type of staff or how many staff the expenditure is for. If these protocols are followed strictly, the cost of uniforms will instead be covered in the calculations for non-personnel recurrent expenditure.

Finally, it is worth emphasizing that in the case of basic salary costs, the costs that apply *before* individual tax/insurance/pension etc. contributions are subtracted should be used. Either the average salary for each relevant grade, or the mid-point of standard salary scales, can be used.

4.1.8 Data analysis

There are 3 key points to highlight for the analysis included within the protocols:
- data from the most recent full year should be used;
- whenever proportions need to be identified, they should be written as a number between 0 and 1; and
- in addition to analysing and reporting costs, ***reporting utilization is important***. This is because costs will, in part, be dependent on the extent to which services are under-used, over-used or optimally used. ***This is especially the case for inpatient hospital care, where the average cost per day can be heavily influenced by bed occupancy rates***. The protocols therefore include a section where utilization should be considered and commented on.

Protocol 1: The cost of a day in hospital, excluding drugs, laboratory tests and X-rays

Wherever TB diagnosis and case management relies on at least some hospitalisation, it is likely to be a major component of the total cost of TB services. It is therefore important to assess hospital costs as accurately as possible. Unfortunately, assessment of hospital costs is not particularly straightforward. This protocol has tried to make the analysis as simple as possible, with the needs of those with little or no experience of costing in mind.

It is suggested that although TB patients may spend time on both TB and medical wards, attention should be concentrated on the TB wards. Costs for days spent on medical wards can be extrapolated from this if necessary. However, *if there is no dedicated TB ward, the data entry sheets that accompany the protocol can still be used: "medical ward" should simply be substituted for "TB ward", and "medical patient" should be substituted for "TB patient" (see Worked Example number 2, for Kikoko mission hospital in Machakos District, Kenya, for an example of this).* This will enable the cost of a day on a general medical ward to be assessed, and it may be assumed that the cost per day on a medical ward for a TB patient is, on average, the same as for any other medical patient.

The main costs to be assessed are:
- the total cost of nursing and medical staff (e.g. doctors; clinical officers) employed on the TB ward;
- the total cost of support staff employed on the TB ward;
- the total cost of TB ward buildings;
- a share of total staff overhead costs i.e. the costs associated with staff not involved in direct patient care;
- a share of total recurrent non-personnel hospital overhead costs e.g. water, electricity, food; and
- a share of general hospital building and equipment costs.

Note that the costs associated with drugs and the laboratory and X-ray departments need to be excluded, since they are to be calculated as separate cost components (see Protocols 5 to 8 below). Vehicle costs are also excluded, since the major vehicle costs associated with TB diagnosis and treatment services should be covered in Protocols 9 and 10. Kitchen and laundry service costs are calculated separately from other types of recurrent overhead costs. These costs are associated with inpatient care only, and therefore the cost analysis for these items does not involve allocation of costs between outpatient and inpatient services (whereas the cost analysis for other overhead items does require such allocation).

Data required for completion of protocol

1. List of medical staff employed on TB ward (or general medical ward, if appropriate[9])
2. List of nursing staff employed on TB ward (or general medical ward, if appropriate)
3. List of support staff employed on TB ward (or general medical ward, if appropriate)
4. Proportion of their total working time each person employed on the TB ward (or general medical ward, if appropriate) spends working on the TB ward (or general medical ward, if appropriate)
5. Average annual cost (salary plus other benefits) of each type of staff who works on the TB ward (or general medical ward, if appropriate)
6. Source of finance for TB ward medical, nursing and support staff costs
7. Current replacement cost of the TB ward building (or general medical ward, if appropriate) *and/or* the current replacement cost per square metre for the TB ward building (or general medical ward, if appropriate) and the floor area (in square metres) of the TB ward building (or general medical ward, if appropriate)
8. Source of funding for TB ward building costs
9. List of the number and type of staff employed at the hospital who are not involved in direct patient care
10. Annual cost of each type of staff not involved in direct patient care
11. Source of funding for staff who are not involved in direct patient care
12. Total annual cost of staff who are involved in *direct patient care* on the <u>hospital wards</u>
13. Total annual cost of staff who are involved in *direct patient care* in the <u>hospital outpatient department</u>
14. Current replacement cost of the laundry and kitchen department buildings *and/or* the current replacement cost per square metre for the kitchen and laundry department buildings and the floor area (in square metres) of the kitchen and laundry departments
15. Source of funding for the kitchen and laundry building costs
16. Total annual non-personnel recurrent expenditure for the kitchen and laundry departments
17. Total annual non-personnel recurrent expenditure for hospital inpatient care, <u>excluding</u> laboratory tests, drugs and X-rays, expenditures associated with the kitchen and laundry departments, and any items clearly irrelevant to TB patients; *if this is not available*, the total annual non-personnel recurrent expenditure for the hospital as a whole (again excluding laboratory tests, drugs and X-rays, expenditures associated with the kitchen and laundry departments, and any items clearly irrelevant to TB patients) or, *if this is also not available*, for the district as a whole (excluding laboratory tests, drugs and X-rays, expenditures associated with the kitchen and laundry departments, and any items clearly irrelevant to TB patients)
18. Source of funding for non-personnel recurrent expenditure
19. List of the buildings in the hospital that are used for general support services (e.g. administration, transport, stores)
20. Current replacement cost of buildings that are used for general support services *and/or* the current replacement cost per square metre for buildings used for general support services and the floor area (in square metres) of these buildings
21. Source of funding for the buildings used for general support services
22. Total annual number of hospital inpatient days
23. Total annual number of hospital inpatient days accounted for by TB patients (or general medical patients, if appropriate)

The data entry sheets for a day in hospital should be completed by following the instructions listed below in sub-sections (a) through (h).

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[9] This is appropriate if TB patients are cared for in a general medical ward rather than in a specialized TB ward.

(a) Nursing staff costs

In the table provided:

1. In columns 1 and 2, list the type (e.g. job category, job title, grade) of nursing staff that are typically employed on the TB ward (interviews with senior nursing staff or nursing allocation books are useful sources of this information) and the number of each type of staff that are typically allocated to work on the TB ward (remember to include those who do night duty).

2. List, for each type of staff (e.g. professional nurse, enrolled nurse, nursing auxiliary etc.), their annual cost (column 3). *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

3. For each type of nursing staff, state the proportion of their time that is spent on the TB ward (this may require interviews with relevant staff) (column 4).

4. For each type of nursing staff, calculate the total annual cost of work on the TB ward i.e. complete column 5 by multiplying the number of each type of nurse by the proportion of each type of nursing staff's time which is spent on the TB ward by their annual cost.

5. Note who pays for nursing staff by completing column 6 of the table.

6. Add up the totals calculated in column 5 of the table. ***This figure gives the total annual costs associated with nursing staff employed on the TB ward.***

(b) Medical staff costs

In the table provided:

1. List the medical staff (e.g. clinical officers, doctors) who work on the TB ward (column 1), and the number of each type who work on the ward (column 2).

2. List the annual total cost of each type of medical staff (column 3). *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

3. For each type of medical staff, state the proportion of their time that is spent on the TB ward (this may require interviews with relevant staff) (column 4).

4. For each type of medical staff, calculate the total cost of work on the TB ward i.e. complete column 5 by multiplying the number of each type of medical staff by the proportion of each type of medical staff's time which is spent on the TB ward by their annual cost.

5. Note who pays for medical staff by completing column 6 of the table.

6. Add up the totals calculated in column 5 of the table. ***This gives the total costs associated with medical staff employed on the TB ward.***

(c) Support staff costs

In the table provided:

1. In columns 1 and 2, list the type (e.g. job category, job title, grade) of support staff that are typically employed on the TB ward (interviews with senior nursing staff on the TB ward are often a useful source of this information) and the number of each type of staff that are typically allocated to work on the TB ward.

2. List, for each type of staff (e.g. cleaner, clerk), their annual cost (column 3). *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance*

contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).

3. For each type of support staff, state the proportion of their time that is spent on the TB ward (this may require interviews with relevant staff) (column 4).

4. For each type of support staff, calculate the total cost of work on the TB ward i.e. complete column 5 by multiplying the number of each type of support staff by the proportion of each type of support staff's time that is spent on the TB ward by their annual cost.

5. Note who pays for support staff by completing column 6 of the table.

6. Add up the totals calculated in column 5 of the table. ***This figure gives the total annual costs associated with support staff employed on the TB ward.***

(d) Building costs

1. Identify what it would cost to build the existing TB ward now (i.e. current replacement cost), and enter this total in column 1. The Ministry of Works or similar may have this information. If not, calculate, the floor area of the TB ward and find out (from the Ministry of Works or similar) what the cost per square metre for construction of a new building is. Then multiply the number of square metres by the cost per square metre. Enter this total in the first column of the table provided.

2. Calculate the annualized cost of the TB ward building. Do this by assuming that the building would be expected to last 50 years and by using a discount rate of 3%. This means that the annualized cost can be calculated as: (cost to build the building now i.e. its current replacement cost ÷ 25.73). Note that 25.73 is the relevant annualization factor (see also Appendix 1 in Chapter 2) for an expected useful life of 50 years and a discount rate of 3%. Enter the figure in the second column of the table provided. ***This figure is the total annual cost of the TB ward building.***

3. Complete the third column of the table by noting who is responsible for the funding of building costs.

(e) Staff overhead costs, *excluding* kitchen and laundry staff (i.e. those hospital-based staff not involved in direct patient care, excluding kitchen and laundry staff)

In the table provided:

〈 List all the types of staff employed at the hospital who are not involved in direct patient care. Exclude laboratory, X-ray department, laundry and kitchen staff. Also exclude any support staff who have already been identified in part (c). Staff can be identified from the personnel department, the administrator, or from the payroll.

〈 Calculate the total annual costs of each type of staff and enter the total for each in column 2. *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

〈 Note the number of each type of staff who are employed in column 3.

〈 Calculate the total annual cost associated with each category of staff by completing column 4.

〈 Note who pays for each category of staff by completing column 5.

Then:

1. Note the total annual costs of staff not involved in direct patient care, excluding those involved in kitchen/laundry services and any support staff listed in (c).

2. Note the total annual costs of *staff involved in overall administrative duties/general management* e.g. medical super-intendent, chief matron, administration clerks, personnel officers, accountants, telephone operators (this is important for calculation of incremental costs in the protocol).

3. Calculate the total annual cost of general overhead staff *excluding* those involved in administration/ general management (i.e. total recorded in step 1 minus the total recorded in step 2).

4. Estimate what share of the annual staff costs calculated in steps 2 and 3 should be allocated to (a) inpatient services (b) outpatient services. This can be done by calculating the total costs of staff employed in direct patient care for both outpatient and inpatient services, and then allocating a proportion of total staff overhead costs to inpatient services in accordance with the proportion of total direct care staff costs for which inpatient care accounts[10]. Therefore, fill in 4 (i) and (ii).

5. Calculate the proportion of total hospital-based staff overhead costs to be allocated to inpatient care (note that this is [(4i)÷{(4i)+(4ii)}]).

6. Calculate the value of total hospital-based staff overhead costs to be allocated to inpatient services. Do this separately for (i) staff involved in administration/general management and (ii) all staff *except* those involved in administrative/general management duties. Note that the value to be allocated is, for (i), the proportion calculated in 5 multiplied by the total costs of hospital-based staff involved in administration/general management (calculated in 2) and, for (ii), the proportion calculated in 5 multiplied by the total annual costs of all staff not involved in direct patient care *excluding* those involved in administration/general management (calculated in 3). The total costs associated with (i) and (ii) should have been recorded in steps 2 and 3 respectively.

7. Record the total annual number of hospital inpatient days that are accounted for by TB patients. These data should be available from sources such as midnight bed state statistics books, often kept by the Chief Matron; the hospital administrator; or annual reports kept by staff such as district health officers.

8. Record the total annual number of hospital inpatient days. These data should be available from sources such as midnight bed state statistics books, often kept by the Chief Matron; the hospital administrator; or annual reports kept by staff such as district health officers[11].

9. Calculate the proportion of total hospital inpatient days that are accounted for by TB patients. Note that this is {total annual inpatient days accounted for by TB patients ÷ total annual hospital inpatient days} i.e. total recorded in 7 divided by total recorded in 8.

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[10] It is worth noting that another allocation method sometimes used is to assume that 3 outpatient visits are equivalent to one inpatient day. In this method, the number of outpatient visits would be divided by three to convert outpatient visits into inpatient day equivalents. A proportion of total overhead costs should then be allocated to inpatient services according to the proportion of total equivalent inpatient days for which they account. This method is not suggested here, because research has shown that the number of patient days to which outpatient visits are equivalent can vary enormously (see Mills et al, 1993).

[11] A useful way to check the accuracy of the figure for total hospital inpatient days, if this is provided by hospital staff rather than being calculated directly from raw data, is to multiply the number of beds in the hospital by 365. This will give an estimate of the annual patient days for the hospital. It is worth doing this because experience with costing studies in some countries has shown that inaccurate data have sometimes been supplied, probably because it was not understood what was required. If bed occupancy in the hospital is known to be over 100%, the total annual number of patient days should be higher than the estimate calculated; if it is less than 100% the total annual number of patient days should be less than the estimate calculated. Patient days for TB patients can be estimated by multiplying the estimated average length of stay of TB patients by the number of patients admitted in the year being studied.

10. Calculate the cost of administrative/general management staff to be allocated to TB patients. Note that this is the total costs of administrative/general management staff allocated to inpatient care {in step 6 part (i)} multiplied by the proportion of patient days for which TB patients account (calculated in step 9) ***This figure gives the total administrative/general management staff overhead costs associated with TB patients.***

11. Calculate the cost of general overhead staff *excluding those involved in administration/ general management* to be allocated to TB patients. Note that this is the total costs of general overhead staff allocated to inpatient care {in step 6 part (ii)} multiplied by the proportion of patient days for which TB patients account (calculated in step 9) ***This figure gives the total staff overhead costs (excluding staff involved in administration/general management) associated with TB patients.***

(f) Kitchen and laundry service costs

1. **In the table provided,** enter:
   - the type (e.g. job category, job title, grade) of staff who work in kitchen and laundry services (column 1);
   - the annual cost of each type of staff who work in kitchen/laundry services (column 2). *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32)*;
   - the number of each type of staff who work in kitchen/laundry services (column 3);
   - multiply the total number of each type of staff by the annual cost of that grade of staff and enter this total in column 4:
   - who pays for kitchen/laundry staff by completing column 5.

2. Add together the totals in column 4. This gives the total annual costs of staff who work in kitchen/laundry services.

3. Find out what it would cost to build the kitchen and laundry buildings now (i.e. current replacement cost) and enter the total. The Ministry of Works or similar may have this information. If not, calculate, the floor area of kitchen and laundry buildings and find out (from the Ministry of Works or similar) what the cost per square metre for construction of a new building is. Then multiply the number of square metres by the cost per square metre.

4. Calculate the annualized cost of the kitchen and laundry buildings. Do this by assuming that the building would be expected to last 50 years and by using a discount rate of 3%. This means that the annualized cost can be calculated as: (purchase price new i.e. current replacement cost ÷ 25.73). Note that 25.73 is the relevant annualization factor (see also Appendix 1 in Chapter 2) for an expected useful life of 50 years and a discount rate of 3%. Note down this annualized cost.

5. Find out the total non-staff annual recurrent expenditure for laundry and kitchen services and record this total (this information should be available from hospital/district recurrent expenditure records).

6. Complete the table provided to record the total annual staff costs, the total annual non-staff recurrent expenditure costs, and the annualized building costs. Then add the totals together to give the total annual costs associated with kitchen and laundry services for the hospital as a whole.

7. Record the proportion of inpatient days for which TB patients account (this proportion should already have been recorded in step 9 in section (e) above).

8. Allocate a share of the total annual costs of kitchen and laundry services (recorded in step 6) to TB patients by multiplying the total costs recorded in step 6 by the proportion recorded in step 7. ***This figure gives the total annual kitchen and laundry costs associated with TB patients.***

(g) General hospital recurrent overhead costs, excluding staff, items associated with drugs, the laboratory and the X-ray departments, the kitchen and laundry departments, and any other items clearly irrelevant to TB patients

1.   Identify (i) the total annual recurrent non-personnel *hospital* expenditure for all items, except those associated with drugs, the laboratory and the X-ray department, kitchen and laundry services, and any other items clearly irrelevant to TB patients OR, (ii) if available, identify the total annual recurrent non-personnel *hospital* expenditure *for inpatient services specifically* (some expenditure records may record outpatient and inpatient general recurrent expenditure separately), again excluding items associated with drugs, laboratory tests and X-rays, kitchen and laundry services, and any other items clearly irrelevant to TB patients OR (iii) the total annual recurrent non-personnel *district* expenditure for all items, again excluding items associated with drugs, laboratory tests and X-rays, kitchen and laundry services, and any other items clearly irrelevant to TB patients. This information should be available from hospital expenditure records/reports. *If information is available for inpatient services specifically, steps 2 and 3 can be ignored.*

2.   If expenditure is not recorded for inpatient services specifically, estimate what proportion of the total costs recorded in 1 should be allocated to (a) inpatient services and (b) outpatient services, using the allocation criteria explained in (e) step 4 above. Note that if expenditure is recorded for the district as a whole, the same principles apply but the difference is that in this case the staff allocations in all inpatient and outpatient facilities in the district will need to be identified.

3.   Calculate the total overhead recurrent costs associated with inpatient services by multiplying the total recorded in 1(i) or 1(iii) by the proportion calculated in 2.

4.   Record the proportion of inpatient days for which TB patients account (this proportion should already have been recorded in step 9 in section (e) above).

5.   Allocate a share of the total inpatient general recurrent costs calculated in EITHER step 1 part (ii) OR step 3 to TB patients. This should be done by multiplying the total costs recorded in EITHER 1 (ii) OR 3 by the proportion of total inpatient days for which TB patients account (the proportion recorded in step 4). ***This figure gives the total non-staff recurrent overhead costs associated with TB patients.***

6.   Complete the table to summarize the total non-personnel recurrent expenditure associated with TB patients. In the second column, note who pays for these expenditures.

(h) General building and equipment costs

1.   Identify the buildings in the hospital used for general support services e.g. buildings for administration/general management, transport offices, stores.

2.   Identify what it would cost to construct the buildings identified in 1 new (i.e. current replacement cost).

3.   Divide the cost calculated in step 2 by the annualization factor of 25.73 to give the annualized cost of buildings.

4.   Estimate the annualized cost of general equipment used by all services by multiplying the figure calculated by buildings by 0.1 (i.e. this estimates that equipment costs are 10% of building costs, a proportion that has been suggested in some costing manuals).

5.   Add together the annual costs of buildings and equipment (i.e. sum the totals recorded in steps 3 and 4).

6.   Estimate what proportion of the total costs calculated in 5 should be allocated to inpatient services. This proportion should already have been recorded in step 5 of sub-section (e).

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7. Calculate the building and equipment costs associated with inpatient services by multiplying the total recorded in 5 by the proportion recorded in 6.

8. Record the proportion of total inpatient days for which TB patients account (this should already have been done in step 9. in sub-section (e) above).

9. Allocate a share of the inpatient general building and equipment costs to TB patients. This should be done according to the proportion of total inpatient days for which TB patients account i.e. (total calculated in step 7 x proportion recorded in step 8) ***This figure gives the total general buildings and equipment costs associated with TB patients.***

10. Complete the summary table for the costs of general buildings and equipment, including the column for "who pays" for these items.

Complete the table at the end of sections (a) to (h). This should result in the average cost of a day in hospital for a TB patient, excluding drugs, laboratory tests and X-rays, being calculated.

Average incremental cost per day: To calculate the average incremental cost of a day in hospital for a TB patient, assume that administrative/general management staff and general buildings and equipment represent costs that would exist whether or not TB services were provided. Therefore the average incremental cost of a day in hospital is:

{(average cost - (cost per day associated with administrative/general management staff + cost per day associated with general building and equipment costs)}

The only exception to this is if the hospital is a dedicated TB hospital/sanatorium, in which case the average incremental cost per day will be equivalent to the average cost per day.

Marginal cost per day: To calculate the short-run marginal cost of a day in hospital for a TB patient, identify the costs that are likely to increase with the addition of one more patient. This can be done by deciding whether extra staff would be required, whether extra building space would be required, and whether an increase in general non-personnel expenditure would be required. It is likely that, in the short-run, some non-personnel items would increase in cost while others would be unaffected: the value of those that are likely to increase should be identified from expenditure records. The cost per day of all those items whose costs are likely to increase can then be calculated by adding the total annual value of these costs together (ensuring still that costs are allocated appropriately) and dividing by the total annual number of patient days on the TB ward.

In the long-run, marginal costs are likely to be close to average costs if the number of TB patients being treated is high.

Utilization

Finally, comment on the extent to which hospital inpatient services are under-utilized, over-utilized or optimally utilized. Do this as follows:

1. Note the average bed occupancy rate for the hospital as a whole.

2. Note the average bed occupancy rate on the TB ward, or the main ward on which TB patients are cared for (this may be a general medical ward).

3. Comment on whether the hospital appears to be very over-utilized, over-utilized to some extent, relatively optimally utilized, under-utilized to some extent, or very under-utilized. Possible benchmarks that could be used (but these are **not** definitive and protocol users should use their own judgement) are:
   - very over-utilized = average bed occupancy rate of over 100% and sometimes well in excess of 100%
   - over-utilized to some extent = average bed occupancy rate of over 80% and sometimes close to or more than 100%
   - relatively optimally utilized = average bed occupancy rate of around 80%
   - under-utilized to some extent = average bed occupancy rate of less than 80% and sometimes much less than 80%
   - very under-utilized = average bed occupancy rate of considerably less than 80%

4. Justify the choice made in 3.

Important note: If there is noticeable under- or over-utilization, the impact of different bed occupancy rates on costs should be considered in a sensitivity analysis (such sensitivity analysis is covered in Chapter 6).

Also, note that the rate of 80% is based on the following quote from Luce et al., p196 in Gold et al, 1996 (see Chapter 9 for full reference):

> "The literature suggests that 80% utilization of capacity in hospitals and other health facilities is a norm."

Financing

1. Complete the table at the end of the data entry sheets for Protocol 1, using the data entered in the "Who pays?" columns of the tables completed in sections (a) to (h). This will show the breakdown of financing for inpatient services for TB patients.

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Protocol 2: The cost of a hospital outpatient visit, excluding drugs, laboratory tests and X-rays

Data required for completion of protocol

1. List of medical staff employed in the hospital outpatient department

2. List of nursing staff employed in the hospital outpatient department

3. List of support staff employed in the hospital outpatient department

4. Proportion of their total working time each person employed in the hospital outpatient department spends working in the hospital outpatient department

5. Average annual cost (salary plus other benefits) of each type of staff who works in the hospital outpatient department

6. Source of finance for hospital outpatient department medical, nursing and support staff costs

7. Current replacement cost of the hospital outpatient department building *and/or* the current replacement cost per square metre for the hospital outpatient department and the floor area (in square metres) of the hospital outpatient department

8. Source of funding for hospital outpatient department building costs

9. List of the number and type of staff employed at the hospital who are not involved in direct patient care, excluding staff who work in the kitchen, laundry, X-ray, and laboratory departments

10. Annual cost of each type of staff not involved in direct patient care

11. Source of funding for staff who are not involved in direct patient care

12. Total annual cost of staff who are involved in *direct patient care* on the <u>hospital wards</u>

13. Total annual cost of staff who are involved in *direct patient care* in the <u>hospital outpatient department</u>

14. Total annual non-personnel recurrent expenditure for hospital outpatient care, <u>excluding</u> laboratory tests, drugs and X-rays, and any items clearly irrelevant to TB patients; *if this is not available*, the total annual non-personnel recurrent expenditure for the hospital as a whole (excluding laboratory tests, drugs and X-rays, expenditures associated with the kitchen and laundry departments, and any items clearly irrelevant to TB patients) or, *if this is also not available*, for the district as a whole (excluding laboratory tests, drugs and X-rays, expenditures associated with kitchen and laundry departments, and any items clearly irrelevant to TB patients)

15. Source of funding for non-personnel recurrent expenditure

16. List of the buildings in the hospital that are used for general support services (e.g. administration, transport, stores)

17. Current replacement cost of buildings that are used for general support services *and/or* the current replacement cost per square metre for buildings used for general support services and the floor area (in square metres) of these buildings

18. Source of funding for the buildings used for general support services

19. Total annual number of hospital outpatient visits

The data entry sheets for Protocol 2 (in Document 2) should be completed by following the instructions given below.

(a) Nursing staff costs

In the table provided:

1. List the number and type of nursing staff that are typically employed in the outpatient department (columns 1 and 2).

2. List, for each type of staff (e.g. professional nurse, enrolled nurse, nursing auxiliary etc), their annual cost (column 3). *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

3. For each type of nursing staff, state the proportion of their time that is spent working in the outpatient department (this may require interviews with relevant staff) (column 4).

4. For each type of nursing staff, calculate the total annual cost of work in the outpatient department i.e. complete column 5 by multiplying the number of each type of nurse by the proportion of each type of nursing staff's time which is spent working in the outpatient department by their annual cost.

5. Note who pays for nursing staff by completing column 5 of the table.

6. Add up the totals calculated in column 5 of the table. ***This figure gives the total annual costs associated with nursing staff who work in the outpatient department.***

(b) Medical staff costs

In the table provided:

1. List the number and type of medical staff that typically work in the outpatient department (columns 1 and 2).

2. List the annual total cost of each type of medical staff (column 3). *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

3. For each type of medical staff, estimate the proportion of their total costs that should be allocated to the outpatient department (e.g. if a clinical officer spends 25% of their time on the TB ward, allocate 25% of their annual costs to the TB ward i.e. a proportion of 0.25).

4. Calculate the total annual cost of work in the outpatient department for each type of medical staff i.e. complete column 5 of the table.

5. Note who pays for medical staff by completing column 6 of the table.

6. Add up the totals calculated in 5. ***This gives the total costs associated with medical staff employed in the outpatient department.***

(c) Support staff costs

In the table provided:

1. List the number and type of support staff that typically work in the outpatient department (e.g. clerk, cleaner) (columns 1 and 2).

2. List the annual total cost of each type of support staff (column 3). *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

3. For each type of support staff, estimate the proportion of their total costs that should be allocated to the outpatient department and enter this in column 4 (e.g. if a clerk spends 25%

of their time on the TB ward, allocate 25% of their annual costs to the TB ward i.e. a proportion of 0.25).

4. Calculate the total annual cost of work in the outpatient department for each type of support staff i.e. complete column 5 of the table.

5. Note who pays for support staff by completing column 6 of the table.

6. Add up the totals calculated in column 5. ***This gives the total costs associated with medical staff employed in the outpatient department.***

(d) Building costs

1. Identify what it would cost to build the existing hospital outpatient department now. The Ministry of Works or similar may have this information. If not, calculate, the floor area of the hospital outpatient department and find out (from the Ministry of Works or similar) what the cost per square metre for construction of a new building is. Then multiply the number of square metres by the cost per square metre. Enter the relevant total in the first column of the table provided.

2. Calculate the annualized cost of the hospital outpatient department. Do this by assuming that the building would be expected to last 50 years and by using a discount rate of 3%. This means that the annualized cost can be calculated as: (cost to build the building now i.e. its current replacement cost ÷ 25.73). Note that 25.73 is the relevant annualization factor (see also Appendix 1 in Chapter 2) for an expected useful life of 50 years and a discount rate of 3%. Enter the figure in the second column of the table provided. ***This figure is the total annual cost of the hospital outpatient department.***

3. Complete the third column of the table by noting who is responsible for the funding of building costs.

(e) Staff overhead costs i.e. those staff not involved in direct patient care, *excluding* those involved in kitchen/laundry services

Note that if inpatient care is a component of case management, many of the following steps will have already been undertaken. If so, the relevant entries in the data entry sheets can be copied from the data entry sheets completed for Protocol 1.

In the table provided:

- List all staff employed at the hospital who are not involved in direct patient care. Exclude laboratory, X-ray department, laundry and kitchen staff. Also exclude any support staff who have already been identified in part (c). Staff can be identified from the personnel department, the administrator, or from the payroll.

- Calculate the total annual costs of each type of staff and enter the total for each in column 2. *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

- Note the number of each type of staff who are employed in column 3.

- Calculate the total annual cost associated with each category of staff by completing column 4.

- Note who pays for each category of staff by completing column 5.

Then:

1. Note the total annual costs of staff not involved in direct patient care, excluding those involved in kitchen/laundry services and any support staff listed in section (c).

2. Note the total annual costs of *staff involved in overall administrative duties/general management* e.g. medical super-intendent, chief matron, administration clerks, personnel

officers, accountants, telephone operators (this is important for calculation of incremental costs at the end of the protocol).

3. Calculate the total annual cost of all hospital staff not involved in direct patient care *excluding* those involved in administration/general management *and* those who work in the laboratory and X-ray departments (i.e. total recorded in step 1 minus the total recorded in step 2).

4. Estimate what share of the annual staff costs calculated in steps 2 and 3 should be allocated to (a) inpatient services (b) outpatient services. This can be done by calculating the total costs of staff employed in <u>direct</u> patient care for both outpatient and inpatient services, and then allocating a proportion of total staff overhead costs to outpatient services in accordance with the proportion of total direct care staff costs for which outpatient services account[12]. Therefore, fill in 4 (i) and (ii).

5. Calculate the proportion of total hospital-based staff overhead costs to be allocated to outpatient care (note that this is [(4ii)÷{(4i)+ (4ii)}].

6. Calculate the value of total hospital-based staff overhead costs to be allocated to outpatient services. Do this separately for (i) staff involved in administration/general management and (ii) all staff *except* those involved in administrative/general management duties. Note that the value to be allocated is, for (i), the proportion calculated in 5 multiplied by the total costs of hospital-based staff involved in administration/general management and, for (ii), the proportion calculated in 5 multiplied by the total annual costs of all staff not involved in direct patient care *excluding* those involved in administration/general management. The <u>total</u> costs associated with (i) and (ii) should have been recorded in steps 2 and 3.

   These figures give the total administrative/general management staff overhead costs associated with the hospital outpatient department.

(f) General hospital recurrent overhead costs, excluding staff and items associated with drugs, the laboratory and the X-ray departments, kitchen and laundry services, and excluding any items clearly irrelevant to TB patients

Note that if inpatient care is a component of case management, some of the following steps will have already been undertaken. If so, the relevant entries in Protocol 1 can be copied from the data entry sheets completed for Protocol 1.

1. Identify (i) the total annual recurrent non-personnel *hospital* expenditure for all items except those associated with drugs, the laboratory and the X-ray department, kitchen and laundry services, and also excluding any items clearly irrelevant to TB patients OR, (ii) if available, identify the total annual recurrent non-personnel *hospital* expenditure *for outpatient services specifically* (some expenditure records may record outpatient and inpatient general recurrent expenditure separately), except those associated with drugs, the laboratory and the X-ray department, kitchen and laundry services, and also excluding any items clearly irrelevant to TB patients OR (iii) the total annual recurrent non-personnel *district* expenditure for all items except those associated with drugs, the laboratory and the X-ray department, kitchen and laundry services, and also excluding any items clearly irrelevant to TB patients. This information should be available from hospital expenditure records/reports. *If information is available for outpatient services specifically, steps 2 and 3 can be ignored.*

2. If expenditure is not recorded for outpatient services specifically, estimate what proportion of the total costs recorded in 1 should be allocated to (a) inpatient services and (b) outpatient

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[12] It is worth noting that another allocation method sometimes used is to assume that 3 outpatient visits are equivalent to one inpatient day. In this method, the number of outpatient visits would be divided by three to convert outpatient visits into inpatient day equivalents. A proportion of total overhead costs should then be allocated to inpatient services according to the proportion of total equivalent inpatient days for which they account. This method is not suggested here, because research has shown that the number of patient days to which outpatient visits are equivalent can vary enormously (see Mills et al, 1993).

services, using the allocation criteria explained in (e) steps 4-5 above. Note that if expenditure is recorded for the district as a whole, the same principles apply but the difference is that in this case the total staff allocations in all outpatient facilities will need to be identified.

3. Calculate the total overhead recurrent costs associated with outpatient services by multiplying the total recorded in 1(i) or 1(iii) by the proportion calculated in 2.

This figure gives the total non-staff recurrent overhead costs associated with outpatient services.

(g) General building and equipment costs

Note that if inpatient care is a component of case management, many of the following steps will have already been undertaken. If so, the relevant entries can be copied from the data entry sheets completed for Protocol 1.

1. Identify the buildings in the hospital that are used for general support services e.g. buildings for administration, catering, laundry facilities, transport offices etc.
2. Identify what it would cost to construct the buildings identified in 1 new.
3. Divide the cost calculated in step 2 by the annualization factor of 25.73 to give the annualized cost of buildings.
4. Estimate the annualized cost of general equipment used by all services by multiplying the figure calculated by buildings by 0.1 (i.e. this estimates that equipment costs are 10% of building costs, a proportion that has been suggested in some costing manuals).
5. Add together the annual costs of buildings and equipment.
6. Estimate what proportion of the total costs calculated in 5 should be allocated to outpatient services. This proportion should already have been recorded in step 5 of (e).
7. Calculate the building and equipment costs associated with outpatient services by multiplying the total recorded in 5 by the proportion recorded in 6. ***This figure gives the total general buildings and equipment costs associated with outpatient services.***
8. Complete the summary table for the costs of general buildings and equipment, including the column for "who pays" for these items.

Complete the table at the end of sections (a) through (g). This should result in the average cost of a hospital outpatient visit, excluding drugs, laboratory tests and X-rays, being calculated. Note that it may be assumed that the average cost of an outpatient visit for a TB patient is the same as this average cost i.e. the average cost of a hospital outpatient visit by a TB patient is the same as the average cost for any other patient.

Average incremental cost per visit: To calculate the average incremental cost of a hospital outpatient visit, assume that administrative staff and general buildings and equipment represent costs that would exist whether or not TB services were provided. Therefore the average incremental cost of a hospital outpatient visit is:

{(average cost - (cost per visit associated with administrative staff + cost per visit associated with general building and equipment costs)}.

For the average incremental cost per visit *by a TB patient*: assess whether the total costs associated with staff or buildings would be lower if there were no TB patients to provide care for. If total costs would be reduced, estimate by how much (e.g. by how much could staff numbers be reduced? by how much could clinic space be reduced?). The amount by which costs could be reduced if there were no TB patients to care for represents the total incremental costs of TB patients. The average incremental cost per patient would then be these total annual incremental

costs divided by the number of TB patient visits made per year. If TB patients account for only a tiny fraction of the hospital outpatient workload, it is possible that the average incremental cost per TB patient could be assessed to be zero.

Marginal cost per visit: To calculate the short-run marginal cost of a hospital outpatient visit for a TB patient, identify the costs that are likely to increase if the number of outpatient visits by TB patients increased by one. This can be done by deciding whether extra staff would be required, whether extra building space would be required, and whether an increase in general non-personnel expenditure would be required. The total annual cost of all those items whose costs are likely to increase should then be calculated (ensuring still that costs are allocated appropriately), and then divided by the total annual number of hospital outpatient visits. It is possible that the marginal cost of a visit by a TB patient could be assessed to be zero.

The long-run marginal cost is likely to be equivalent to the average incremental cost for a visit by a TB patient.

Utilization

1. Comment on the extent to which hospital outpatient services are under-utilized, over-utilized or optimally utilized. The easiest way to measure this would be to assess the average number of visits per full-time staff member who is involved in direct patient care (e.g. nurses, doctors, clinical officers, medical attendants). However, no standard benchmarks are suggested here because it is not clear what these should be. It is suggested that protocol users make the assessment themselves. For example, this could be done in consultation with local staff and managers. It could also be done with reference to any national or regional norms that may have been defined as "appropriate utilization" – though care should be taken in using these and judgements made as to what extent they really are appropriate (e.g. How were they defined? Who defined them? When were they defined?).

2. Justify the choice made in 1.

Financing

1. Complete the table at the end of the data entry sheets, using the data entered in the "Who pays?" columns of the tables completed in sections (a) to (h). This will show the breakdown of financing for outpatient services.

Protocol 3: The cost of an outpatient visit to a clinic or health centre (or similar non-hospital facility), excluding drugs, laboratory tests and X-rays

Data required for completion of protocol

Approach 1

1. Total annual cost of staff employed in clinics and other non-hospital facilities in the district.
2. Total annual recurrent expenditure for all items except those associated with staff, laboratory supplies, drugs, and X-rays in clinics and other non-hospital facilities in the district.
3. Current replacement cost of clinic/other non-hospital facility buildings in the district.
4. Source of funding for building, staff and non-personnel recurrent expenditure costs.
5. Total annual number of visits to clinics/other non-hospital facilities in the district.

Approach 2

1. List of the number and type of medical, nursing and other staff employed in clinics and other non-hospital facilities in the district.
2. Proportion of their total working time each person employed in clinics/other non-hospital facilities spends working in clinics/other non-hospital facilities.
3. Average annual cost (salary plus other benefits) of each type of staff who works in clinics/ other non-hospital facilities.
4. Source of finance for staff employed in clinics/other non-hospital facilities in the district.
5. Current replacement cost of the clinic/other non-hospital facility buildings in the district *and/ or* the current replacement cost per square metre for the clinic/other non-hospital facility buildings in the district and the floor area (in square metres) of these buildings.
6. Source of funding for clinic/non-hospital facility building costs.
7. Total annual recurrent expenditure for all items except those associated with staff, laboratory supplies, drugs, and X-rays in clinics and other non-hospital facilities in the district.
8. Source of funding for recurrent expenditure except that associated with staff, laboratory supplies, drugs, and X-rays in clinics and other non-hospital facilities in the district.
9. Total annual number of visits to clinics/other non-hospital facilities in the district.

The data entry sheets for Protocol 3 (in Document 2) should be completed by following the instructions given below

It is worth noting here at the outset that health clinics/health centres may not be uniform in nature. Some may have inpatient facilities, some may have an area set aside for TB patients while others do not, and some have special clinic times for TB patients while others do not. Some countries may also have more than one type of non-hospital facility e.g. dispensaries, rural health units. This protocol suggests two very simplified approaches for costing an outpatient visit to a non-hospital facility that should nevertheless be sufficiently accurate. Two approaches are outlined because the nature of the data available may mean that the first approach is not possible. If it is felt more appropriate, protocol users should also feel free to use this protocol and the accompanying data entry sheets for each type of facility available (e.g. health clinic, health post, dispensary), rather than analysing them all together.

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Approach 1

1. Within the area being studied (e.g. the district), identify the total annual cost of staff employed in clinics/other non-hospital facilities. *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

2. Identify the total annual recurrent expenditure for all items except those associated with staff, laboratory supplies, drugs and X-rays (note that the latter 3 are excluded because their costs are specifically addressed in subsequent protocols).

3. Identify what it would cost to build, new, the clinics/other non-hospital facilities that exist in the area (i.e. their current replacement cost).

4. Annualize the total building costs calculated in 3 by dividing their total cost by the relevant annualization factor. Assume that buildings would be expected to last 50 years and apply a discount rate of 3%. This means that the annualized cost can be calculated as: (cost to build new ÷ 25.73). Note that 25.73 is the relevant annualization factor (see also Appendix 1 in Chapter 2) for an expected useful life of 50 years and a discount rate of 3%.

5. Estimate the annualized cost of equipment by multiplying the annualized building costs by 0.1.

6. Add the totals calculated in 1, 2, 4 and 5 together.

7. Find out the total annual number of visits that were made to clinics/other non-hospital facilities.

8. Divide the total calculated in 6 by the total number of visits identified in 7. This gives the average cost of a visit to a health clinic/other non-hospital facility.

9. Complete the summary table for the costs of clinic/other non-hospital outpatient services, including the column for "who pays" for these items.

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Approach 2

In the tables provided:

1. Identify the type and number of nursing staff that work in health clinics/other non-hospital facilities (columns 1 and 3 in the first table).

2. Identify the total annual cost for each type of staff (column 2). *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

3. Multiply the number of each type of nursing staff by the annual cost of each type of nurse to complete column 4. Then add the total costs for each type of nurse together and enter this in (a).

4. Identify the source of funds for nursing staff by completing the "Who pays?" column of the table.

5. Identify the number and type of medical/other staff who work in health clinics/other non-hospital facilities (columns 1 and 3 in the second table).

6. Identify the annual cost of each type of medical/other staff that works in health clinics/other non-hospital facilities (column 2). *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

7. Identify the proportion of time that each type of staff spends working in health clinics/other non-hospital facilities and use this information to complete column 4.

8. Multiply the number of each type of medical/other staff by their annual cost, and then by the estimated proportion of time that each type of staff spends working in clinics/other similar non-hospital facilities i.e. complete column 5.

9. Add up the total costs for each type of medical staff/other staff i.e. the totals entered in column 5, and enter this amount in (b).

10. Identify the source of finance for medical/other staff in column 6 of the table.

11. In (c), identify the total annual recurrent expenditure for all items except those associated with staff, laboratory supplies, drugs and X-rays (note that the latter 3 are excluded because their costs are specifically addressed in subsequent protocols).

12. In (d), identify what it would cost to build, new, the clinics/other non-hospital facilities that exist in the area (i.e. current replacement cost).

13. In (e), annualize the total building costs by dividing their total cost by the relevant annualization factor. Assume that buildings would be expected to last 50 years and apply a discount rate of 3%. This means that the annualized cost can be calculated as: (cost to build new ÷ 25.73). Note that 25.73 is the relevant annualization factor (see also Appendix 1 in Chapter 2) for an expected useful life of 50 years and a discount rate of 3%.

14. In (f), estimate the annualized cost of general equipment used in clinics by multiplying the annualized cost of buildings (calculated in step 13) by 0.1.

15. In (g), add the totals calculated in steps 3, 9, 11, 13 and 14 together i.e. (a) + (b) + (c) + (e) + (f).

16. Complete the table to summarize the costs associated with visits to clinics/other non-hospital facilities

17. In (h), identify the total annual number of visits to health clinics/other non-hospital facilities.

18. Divide the total calculated in 15 by the total number of visits identified in 16, i.e. (g) ÷ (h). This gives the average cost of a visit to a health centre/other non-hospital facility.

It may be assumed that the average cost of a visit for a TB patient is the same as the average cost for all other patients.

Average incremental cost per visit: To calculate the average incremental cost of a clinic/other non-hospital facility visit, assume that the buildings and equipment constitute general basic health services infrastructure. Therefore the average incremental cost of a clinic/other non-hospital facility visit is: {(average cost per visit - (cost per visit associated with general buildings + cost per visit associated with general equipment)}

Average incremental cost per visit *for a TB patient*: assess whether the total costs associated with staff or buildings would be lower if there were no TB patients to provide care for. If total costs would be reduced, estimate by how much (e.g. by how much could staff numbers be reduced? by how much could clinic space be reduced?). The amount by which costs could be reduced if there were no TB patients to provide care for represents the total incremental costs of TB patients. The average incremental cost per TB patient would then be these total annual incremental costs divided by the number of TB patient visits made per year. If TB patients account for only a tiny fraction of the clinic/other non-hospital facility workload, it is possible that the average incremental cost per visit for a TB patient could be assessed to be zero.

Marginal cost: to calculate the short-run marginal cost of a health clinic/other non-hospital facility visit, assess whether the addition of one extra TB patient would necessitate an increase in the staff employed at these facilities, or in the building space available. If not, the marginal cost is zero. If extra staff or building space would be required, the marginal cost will be the cost of this extra staff or building space. The marginal cost will be zero if clinics are considered to have spare capacity. In the long-run, marginal cost is likely to be equivalent to the average incremental cost per visit for a TB patient.

Utilization

1. Comment on the extent to which clinic/other non-hospital outpatient services are under-utilized, over-utilized or optimally utilized. The easiest way to measure this would be to assess the average number of visits per full-time staff member who is involved in direct patient care (e.g. nurses, doctors, clinical officers, medical attendants). However, no standard benchmarks are suggested here because it is not clear what these should be. It is suggested that protocol users make the assessment themselves. For example, this could be done in consultation with local staff and managers. It could also be done with reference to any national or regional norms that may have been defined as "appropriate utilization" – though care should be taken in using these and judgements made as to what extent they really are appropriate (e.g. how were they defined? Who defined them? When were they defined?).
2. Justify the choice made in 1.

Financing

1. Complete the table at the end of the data entry sheets. This will show the breakdown of financing for clinic/other non-hospital outpatient services.

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Protocol 4: The cost of a visit to a community health worker (CHW)

Data required for completion of protocol

Approach 1

1. Payment per visit made to a CHW

Approach 2

1. Average annual cost of a CHW
2. Proportion of their time that a CHW spends on individual consultations/visits
3. Number of individual consultations/visits a CHW is expected to make per year

The data entry sheets for Protocol 4 (in Document 2) should be completed by following the instructions given below

One of 2 approaches can be used. Approach 1 applies if there is a standard payment per visit to a community health worker. Approach 2 applies if there is no such standard payment.

Approach 1

1. Identify the payment per visit made to a CHW.

Approach 2

1. Identify the average annual cost of a CHW. *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*
2. Estimate the proportion of their time that a CHW is expected to spend on individual consultations/visits.
3. Allocate a proportion of the CHW total annual costs to individual visits/consultations, in accordance with the proportion of their time that they are expected to spend on these visits (e.g. if half of their time is expected to be spent on individual visits/consultations, allocate 0.5 of their total annual cost to these visits).
4. Identify the number of visits a CHW is expected to make per year.
5. Divide the total cost allocated to consultations/visits by the number of visits CHWs. are expected to make each year. This gives the average cost of a CHW visit.

It may be assumed that the average cost of a visit to a CHW is the same for a TB patient as for any other patient.

Average incremental cost of a visit to/by a CHW by/to a TB patient: since there are no basic health service infrastructure costs associated with CHWs, it may be assumed that the average incremental cost of a visit to a CHW is equivalent to the average cost of a visit to a CHW.

Marginal cost of a visit to/by a CHW by/to a TB patient: in the short-run, this may be estimated by assessing whether any extra costs would be incurred if one more visit was made to/by a CHW. It is possible the marginal cost could be assessed as zero. In the long-run, marginal cost is likely to be equivalent to the average incremental cost of a visit to/by a CHW by/to a TB patient.

Utilization

1. Comment on the extent to which CHWs are under-utilized, over-utilized or optimally utilized. No standard benchmarks are suggested here because it is not clear what these should be. It is suggested that protocol users make the assessment themselves. For example, this could be done in consultation with local staff and managers. It could also be done with reference to any national or regional norms that may have been defined as "appropriate utilization" – though care should be taken in using these and judgements made as to what extent they really are appropriate (e.g. how were they defined? Who defined them? When were they defined?)

2. Justify the choice made in 1.

Financing

1. Complete the table at the end of the data entry sheets. This will show the breakdown of financing for CHWs.

Protocol 5: The cost of a drug regimen

Data required for completion of protocol

1. Quotes of the average cost per regimen for the major types of TB patient
2. If a more sophisticated analysis is considered worthwhile, a breakdown of the weight distribution of patients for the major weight categories used for defining drug dosages to be prescribed

The data entry sheets for Protocol 5 (in Document 2) should be completed by following the instructions given below

The cost of the standard drug regimens used should be easy to identify. Possible sources include staff at the headquarters of the national TB control programme, pharmacy price lists, Central Medical Stores, donor agencies if these supply the drugs, or international agencies such as WHO.

A simple or a more sophisticated approach can be used to calculate the average cost of drugs per patient. Since drug dosages vary by weight category, one approach would be to cost the regimen for each weight category and then to calculate an average figure based on the weight distribution of patients (i.e. the proportions falling in the relevant weight categories). A simpler approach would be to use the cost of the drug regimen for the most common weight category. There are unlikely to be large differences between costs for different weight categories, so the choice of approach depends on the level of accuracy the analyst wishes to achieve. Whichever approach is adopted, the conclusions to be drawn from the overall results of the cost and cost-effectiveness analysis should not be affected. Some blanks are left in the data entry sheets for the protocol user to fill in as appropriate, since the drug regimens that are used vary by country.

In the case of a drug regimen, average cost = incremental cost = marginal cost.

Financing

1. Complete the table at the end of the data entry sheets. This will show the breakdown of financing for drugs. Financing should be assessed at national level, since it is usually at this level that drugs are procured.

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Protocol 6: The cost of a sputum smear

Data required for completion of protocol

Approach 1

1. Quoted cost or price per sputum smear from specialist laboratory
2. Source of quote of cost or price of sputum smear
3. Source of finance for sputum smears

Approach 2

For an individual laboratory department in the district being studied:

1. List of the number and type of the staff who work in the department
2. Average annual cost of each type of staff who work in the department
3. Source of finance for laboratory staff costs
4. Total annual number of sputum smears carried out in the department
5. Total annual number of tests (ALL tests) carried out in the department
6. List of the type of equipment that is used for the analysis of sputum smears
7. Current replacement cost of each type of equipment used to analyse sputum smears
8. Estimates of the expected years of useful life of each piece of equipment, when new
9. List of the number of pieces of equipment that exist, for each type of equipment used to analyse sputum smears
10. Estimate of the proportion of time each piece of equipment used for analysis of sputum smears is used for analysis of sputum smears (as opposed to other tests) *and/or* for each type of equipment, the annual number of all tests done that use that piece of equipment and the proportion of these that were sputum smears
11. Source of funding for each type of equipment that is used for sputum smears
12. Estimate of the cost of supplies per smear
13. Source of funding for laboratory supplies
14. Current replacement cost of the laboratory department building
15. Source of funding for building costs

    Optional (for simple approach to estimating transport costs associated with collection/delivery of sputum samples).

16. Estimate of the number of vehicles and drivers required if their sole purpose was collection and delivery of sputum smears
17. Total annual cost of a driver
18. Estimate of the annual distance to be travelled
19. Current replacement cost of the vehicle(s) used for transport of sputum specimens
20. Rate paid per km for use of a vehicle (if this covers depreciation costs, 19 is not required)
21. Estimate of the expected years of useful life of the type of vehicle used for transport of sputum specimens, when new
22. Source of funding for transport of sputum smears

    Optional (for more complicated approach to estimating transport costs associated with collection/delivery of sputum samples).

23. List of all the purposes for which transport is used when sputum smears are delivered/collected

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24. Estimate of the number of days per year that a vehicle is used for collection/delivery of sputum smears

25. Estimate of the miles/km travelled, on average, per day when a vehicle is used for collection/delivery of sputum smears

26. Current replacement cost of the vehicle(s) used for transport of sputum specimens

27. Estimate of the expected years of useful life of the vehicle used for transport of sputum specimens, when new

28. Rate paid per km for use of a vehicle (if this covers depreciation costs, 26 is not required)

29. Total annual cost of a driver

30. Estimated number of days that a driver would be expected to work per year

31. Estimate of the number of days per year that the vehicle would be expected to be used for ALL purposes

32. Source of funding for transport of sputum smears

The data entry sheets for Protocol 6 (in Document 2) should be completed by following the instructions given below.

Two approaches can be used to assess the cost of a sputum smear. Note that the detailed costing in Approach 2 is more likely to reflect actual costs, as a quoted cost may be more a reflection of prices charged rather than the actual value of resources used (see also Chapter 2 for the distinction between financial and economic costs). However, Approach 1 is easier, and since sputum smears are likely to be a fairly minor cost, it may be acceptable even if the quoted "cost" is more of a price than a cost.

Approach 1

1. Some countries may use specialized laboratory facilities that quote a price per smear. If so, enter the cost quoted in the data entry sheets for Protocol 6.

2. Identify the source of the cost figure.

3. Note who pays for sputum smears.

Approach 2

Alternatively, the cost of a sputum smear can be estimated by following the steps explained below. ***It is recommended that the analysis be undertaken at the level of an individual laboratory.***

(a) Staff costs

1. **In the table provided (Table 1):**
   (i) Identify the number and type of laboratory staff in the laboratory department;
   (ii) Identify the average annual cost of each type of laboratory staff. *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32)*;
   (iii) Multiply the number of staff of each type by their average annual cost;
   (iv) Note who pays for each type of staff in column 5.

2. Sum the totals calculated in column 4 of Table 1 to give total laboratory staff costs.

Then:

3. Find out the total annual number of sputum smears analysed in the laboratory department.

4. Find out the total annual number of tests (ALL tests) done in the laboratory department.

5. Estimate the proportion of laboratory staff time that is spent on sputum smears by calculating what proportion of total laboratory tests is accounted for by sputum smears i.e. divide the total in 3 by the total identified in 4. {Note that if staff workload figures for each type of test are available, it would be more accurate to calculate the proportion of total workload that is accounted for by sputum smears}.

6. Allocate staff costs to sputum smears in accordance with the proportion of total staff workload/ total number of tests for which they account (e.g. if sputum smears account for 0.1 of all laboratory tests, allocate 0.1 of total staff costs to sputum smears) i.e. {proportion of all laboratory tests accounted for by sputum smears x total annual cost of laboratory staff} i.e. total calculated in step 2 x proportion calculated in step 5. **This figure gives the total staff costs associated with laboratory smears.**

(b) Equipment costs

Complete the two tables as follows:

In Table 2a:

1. Identify the equipment that is used for analysis of sputum smears (some is already listed but any other equipment that is used should be added in the blank rows).

2. Find out the purchase price new for each type of equipment (i.e. its current replacement cost) and estimate its expected years of useful life when new, and enter this information in columns 2 and 3. Note that if the expected years of useful life when new is not known or difficult for laboratory staff or others to estimate, assume an expected useful life of ten years.

3. Calculate the annualized cost of each piece of equipment and enter this in column 4. {Note that most equipment will be estimated to last 5, 10 or 15 years. Assuming a discount rate of 3%, use an annualization factor of 4.58 for 5 years, 8.53 for 10 years, and 11.94 for 15 years. i.e. calculate the annualized cost by dividing the purchase price new (i.e. current replacement cost) by 4.58, 8.53 or 11.94, as appropriate}.

In Table 2b:

4. Enter the annualized cost data from Table 2a into column 2.

5. Enter the number of pieces of each type of equipment that exist in column 3.

6. Identify whether the equipment is used only for sputum smears or whether it is used for other tests too. If it is used for other tests, estimate what proportion of time it is used for sputum smears (e.g. by asking laboratory staff to provide an estimate; alternatively identify the annual number of all tests done using that equipment and identify the proportion of these that were sputum smears. This should provide a reasonable estimate of the proportion of time that the equipment is used for sputum smears). Enter this figure in column 4 (e.g. 25% = 0.25, 45% = 0.45 etc). If the equipment is used only for sputum smears, enter 1 in column 4.

7. Calculate the total annualized cost of each piece of equipment used for sputum smears i.e. (a) x (b) x (c) in the table. Enter this total in column 5 of Table 2b.

8. Note the source of funding for each type of equipment by completing column 6 of Table 2b.

9. Add up the totals listed in Column 5 of Table 2b. **This figure gives the total cost of equipment used for sputum smears.**

(c) Supplies costs

1. Laboratory services' managers or local laboratory staff should be able to provide an estimate of the cost of supplies per smear (it is probably around US$ 0.1 to US$ 0.2). Note down this figure.

2. Identify the annual number of smears done in the laboratory.

3. Calculate the total annual cost of supplies by multiplying the cost per smear (entered in step 1) by the annual number of smears done (entered in step 2).

4. Identify the source of funding for laboratory supplies.

(d) Building costs

1. Identify the cost of building a new laboratory.

2. Calculate the annualized cost of the laboratory using a discount rate of 3% and an expected useful life of 50 years i.e. divide the cost of building a new laboratory by the annualization factor 25.73.

3. Note the proportion of total laboratory tests accounted for by sputum smears {this proportion should already have been estimated in step 5 of (a)}.

4. Estimate the total building costs associated with sputum smears by multiplying the total recorded in step 2 by the proportion identified in step 3. **This gives the total building costs associated with sputum smears.**

5. Note the source of funding for building costs.

(e) Transport costs

In some areas, collection and delivery of sputum smears may be important. However, transport for sputum specimens is frequently shared. It may therefore be difficult to assess what transport costs should be allocated to sputum specimens in such cases. Three approaches are possible: the first two are simple, the third is more complicated. Choice of which to use should be based on (a) how confident the protocol user feels in undertaking the more complex analysis and (b) the protocol user's judgement concerning whether collection and delivery of sputum specimens does or does not always occur only when transport is being used for what may be judged a more fundamental purpose.

Two Simple Alternatives

(a) The simplest approach is to assess the costs associated with transport of sputum specimens as zero. This is reasonable if sputum specimens are only collected when vehicles are being used, anyway, for other purposes that would be undertaken whether or not sputum specimens needed to be collected or delivered. It is then possible to argue that the opportunity cost (see Chapter 2 for a definition of this term) of sputum specimen collection and delivery is zero, since no benefits are being given up in order to collect or deliver sputum specimens.

(b) A second but still simple approach to assessing transport costs associated with collection and delivery of sputum specimens is as follows:

1. Estimate the number of vehicles and drivers that would be required if their sole purpose was collection and delivery of sputum smears.

2. Calculate the total annual costs of the drivers assumed to be required. *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

3. Calculate the annualized cost of the vehicles required i.e. divide the purchase price new of the vehicles (i.e. current replacement cost) required by the expected years of useful life of the vehicle when bought new.

4. Estimate the annual distance travelled for collection and delivery of sputum specimens.

5. Multiply the annual distance to be travelled by the relevant kilometre/mileage rate. Note that if the rate is designed to cover depreciation costs, step 3 can be ignored.

6. Add together the total annual cost of the staff, the annualized cost of the vehicle (if appropriate i.e. depending on the mile/km rate used) and the annual cost of fuel/maintenance etc. calculated using the mile/km rate. This total provides an estimate of the total transport costs associated with collection/delivery of sputum specimens.

7. Identify the source of funding for transport of sputum smears.

A more complicated approach

1. Identify all the purposes for which transport is used when sputum smears are delivered/collected.

2. Identify how many of these purposes there are.

3. Estimate the number of days per year that a vehicle is used for collection/delivery of sputum smears.

4. Estimate the miles/kilometres travelled, on average, per day when a vehicle is used for sputum smear collection/delivery. For example, vehicle logbooks may be a useful source of such information.

5. Identify the rate paid per mile/km for vehicle usage.

6. Multiply the distance calculated in 4 by the rate per kilometre/mile identified in 5. Rates should cover either (a) all costs, including depreciation or (b) fuel and maintenance only. If (a) is available, steps 7 to 11 can be ignored. If only (b) is available, steps 7 to 11 should be undertaken.

7. Identify the purchase price new (i.e. current replacement cost) of the type of vehicle that is typically used for sputum delivery/collection.

8. Estimate the expected years of life of the vehicle.

9. Use the expected years of useful life of the vehicle when new and its purchase price new, now (i.e. current replacement cost) in combination with the relevant annualization factor (see discount tables in Appendix 1 of Chapter 2) to calculate the annualized cost of the vehicle.

10. Estimate the number of days per year the vehicle would be expected to be used for all purposes.

11. Calculate the vehicle cost per day by dividing by the total calculated in 9 by the total days estimated in 10.

12. Identify the annual cost of a driver. *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

13. Estimate the number of days that a driver would be expected to work per year.

14. Calculate the cost per day of a driver by dividing the total calculated in 12 by the number of days estimated in 13.

15. Add together the cost per day of a driver, the vehicle, fuel and maintenance.

16. Multiply the cost per day calculated in 15 by the number of days a vehicle is used for collection/delivery of sputum smears, and then divide this figure by the number of purposes of which the vehicle is used. **This figure gives an estimate of the total transport costs associated with sputum smears**.

17. Identify the source of funding for transport of sputum smears.

Finally, complete the summary table. This should result in the average cost of a sputum smear being calculated.

Average incremental cost: the average incremental cost = average cost - (building cost per smear). {note that the building cost per smear is subtracted because the laboratory building could be viewed as basic health services infrastructure}.

Marginal cost: to calculate the short-run marginal cost of a sputum smear, identify the costs that would increase when one extra sputum smear has to be done and by how much they would increase. This gives the short-run marginal cost of a sputum smear. In the long-run, marginal cost is likely to be equivalent to average incremental cost.

Utilization

1. Comment on the extent to which laboratory services are under-utilized, over-utilized or optimally utilized. One benchmark for doing this is that it has been estimated by the International Union for TB and Lung Disease that a laboratory technician working on sputum smears full-time should be able to do around 20 sputum smears per day. It should be possible to assess, with laboratory staff, how many sputum smears they analyse per day, and how much time they spend on this. This would give an average time per sputum smear. This could then be compared with the 20 sputum smears a day benchmark, which suggests an average time per smear of approximately 24 minutes.
2. Justify the choice made in 1.

Financing

1. Complete the table at the end of the data entry sheets, using the funding source data recorded above. This will show the breakdown of financing for sputum smears.

Protocol 7: The cost of a sputum culture

Data required for completion of protocol

Approach 1

1. Quoted cost or price per sputum culture from specialist laboratory
2. Source of quote of cost or price of sputum culture
3. Source of finance for sputum cultures

Approach 2

1. Estimate of the cost of a sputum *smear* (from completion of Protocol 6)
2. Source of funding for sputum cultures

The data entry sheets for Protocol 7 (in Document 2) should be completed by following the instructions given below.

Costing laboratory services is relatively complicated while their importance in the total costs of treating a TB patient is relatively small. Sputum cultures are normally only done for a small fraction of patients. It is therefore suggested that, rather than repeat the lengthy steps outlined in Protocol 6 for sputum smears, one of the following two alternatives is used to estimate the cost of a sputum culture.

Approach 1

1. Use a quoted figure, if available, for the cost of a sputum culture.
2. Note the source of the quoted figure.
3. Note the source of funding for sputum cultures.

Approach 2

1. Assume that a sputum culture is approximately 1.6 times the cost of a sputum smear. This is based on costs calculated by government laboratory services in South Africa, which used costing methods based on international standards for workload measurement. Therefore enter the cost of a sputum culture using the equation provided in the data entry sheet.
2. Note the source of funding for sputum cultures.

Financing

1. Complete the table concerning the funding of sputum cultures, using the funding source data recorded above. This will show the breakdown of financing for sputum cultures.

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Protocol 8: The cost of an X-ray

Data required for completion of protocol

Approach 1

1. Quoted cost or price per X-ray
2. Source of quote of cost or price of X-ray
3. Source of finance for X-rays

Approach 2

For an individual X-ray department in the district being studied:
1. List of the number and type of the staff who work in the department
2. Average annual cost of each type of staff who works in the department
3. Source of finance for X-ray staff costs
4. List of the type of equipment that is used in the X-ray department
5. Current replacement cost of each type of equipment
6. Estimates of the expected years of useful life of each piece of equipment, when new
7. Source of funding for each type of equipment used in the X-ray department
8. Estimate of the annual cost of supplies required for the X-ray department
9. Source of funding for X-ray supplies
10. Current replacement cost of the X-ray department building
11. Source of funding for building costs

The data entry sheets for Protocol 8 (in Document 2) should be completed by following the instructions given below.

As for sputum smears, there are 2 ways in which the cost of an X-ray may be estimated. Note that the detailed costing in Approach 2 is more likely to reflect actual costs, as a quoted cost may be more a reflection of prices charged rather than the actual value of resources used (see also Chapter 2 for the distinction between financial and economic costs). However, Approach 1 is easier, and since X-rays are likely to be a fairly minor cost, it may be acceptable even if the quoted "cost" is more of a price than a cost.

Approach 1

1. If there is an available source of average cost per X-ray figures, this could be used. If available, enter this cost.
2. Enter the source of the average cost of an X-ray.
3. Identify the source of funding for X-rays.

If there are no sources of quotes for X-ray costs, use Approach 2 below.

Approach 2

(a) Staff costs

In the table provided:

1. Identify the type and number of staff who work in the X-ray department (columns 1 and 2).
2. Identify the annual cost of each type of staff (column 3). *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*
3. Multiply the number of each type of staff by the relevant annual cost to give the total staff costs associated with each staff type (i.e. for each row, multiply the figure in column 2 by the figure in column 3), and enter the totals for each grade in column 4.
4. Add together the total staff costs for each type of staff to give total staff costs overall i.e. add together the totals entered in column 4.
5. Note who funds X-ray staff by completing the "Who pays?" column (column 5).

(b) Equipment costs

In the table provided:

1. Identify the equipment required for X-rays (column 1).
2. Identify the purchase price new (i.e. current replacement cost) of the equipment required for X-rays (column 2).
3. Identify the expected years of useful life of each piece of equipment, when new (column 3).
4. Calculate the annualized cost of each piece of equipment by using the relevant annualization factor (given a discount rate of 3% and the numbers of expected years of useful life when new - assume 10 years if unsure). Enter this annualized cost in column 4.
5. Sum the annualized costs of each item of equipment to give the total annualized cost of equipment used for X-rays i.e. add together the totals entered in column 4.
6. Identify who pays for X-ray equipment in the "Who pays?" column (column 5).

(c) Supplies costs

1. Identify the annual cost of supplies required for the annual workload of X-rays.
2. Identify the source of funds for X-ray supplies.

(d) Buildings costs

1. Identify the cost to build the X-ray department new.
2. Calculate the annualized cost of the building by assuming a discount rate of 3% and a life expectancy of 50 years i.e. divide the cost to construct the building new (estimated in 1) by 25.73.
3. Identify who funds the X-ray department building.

Finally, identify the annual number of X-rays done and then complete the table for the average cost of an X-ray at the end of sections (a) to (d).

Average incremental cost: the average incremental cost = average cost - (building cost per smear). {Note that the building cost per smear is subtracted because the X-ray building could be viewed as basic health services infrastructure}.

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Marginal cost: identify which costs would increase when one extra X-ray is done and by how much. This is the marginal cost per X-ray. In the short-run, this might simply be the cost of X-ray supplies. In the long-run, it is likely to be equivalent to the average incremental cost.

Utilization

1. Comment on the extent to which X-ray services are under-utilized, over-utilized or optimally utilized. The easiest way to measure this would be to assess the average number of X-rays done per full-time staff member. However, no standard benchmarks are suggested here because it is not clear what these should be. It is suggested that protocol users make the assessment themselves. For example, this could be done in consultation with X-ray staff and managers. It could also be done with reference to any national or regional norms that may have been defined as "appropriate utilization" – though care should be taken in using these and judgements made as to what extent they really are appropriate (e.g. how were they defined? Who defined them? When were they defined?).

2. Justify the choice made in 1.

Financing

1. Complete the table at the end of the data entry sheets, using the funding source data recorded above. This will show the breakdown of financing for X-rays.

Protocol 9: The cost of outpatient supervision of patients/ health staff/supervisors of DOT to encourage compliance with treatment

Data required for completion of protocol

1. List of the inputs required for overall supervision of patients/health staff/supervisors of DOT to encourage compliance with treatment

2. List of the staff involved in supervision

3. Annual cost of each type of staff involved in overall supervision

4. Proportion of their total working time each person involved in supervision spends on supervision activities

5. Source of funds for staff costs

6. Estimate of the number of miles/km travelled per year for supervision activities by district vehicles

7. Rate per mile/km for use of vehicles

8. Estimate of the number of miles/km travelled per year for supervision activities by district motorbikes

9. Rate per mile/km for use of motorbikes

10. Source of funds for costs associated with use of vehicles and motorbikes

    If the rate per mile/km covers fuel costs only and does not cover the capital cost of the vehicle/motorbike, the items listed as 11 to 15 are also required:

11. List of the vehicles/motorbikes that are used for overall supervision

12. Current replacement cost of each type of vehicle/motorbike that is used for overall supervision

13. Estimate of the expected years of life of vehicles/motorbikes, when new

14. Number of days per year each vehicle/motorbike is used for TB-related supervision activities

15. Number of days per year each vehicle/motorbike is used for ALL activities

16. Data on any expenditures associated with overall supervision other than those associated with vehicles, motorbikes, staff and buildings

17. Source of funds for any expenditures associated with overall supervision other than those associated with vehicles, motorbikes, staff and buildings

Note: this component is not programme management: it is overall supervision of patients or their DOT supervisors when treatment is being taken on an outpatient basis, with the aim of supervision being to encourage compliance with treatment/check compliance/follow-up absconders. It may also include arrangements for and organization of directly observed therapy. Typical staff involved in such work include fieldworkers and adherence officers.

The data entry sheets for Protocol 9 (in Document 2) should be completed by following the instructions given below.

1. Identify the inputs required for outpatient supervision: the staff (e.g. fieldworkers, drivers), vehicles/motorbikes, fuel, etc.

(a) Staff costs

In Table 1:

1. List the members of staff involved in supervision in column 1.

2. For each member of staff, record their annual cost in column 2. *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

3. Enter the proportion of their time that each person spends on supervision in column 3 i.e. if 100% of a person's time is spent on supervision, enter 1; if 30% of a person's time is spent on supervision, enter 0.3, etc.

4. Complete column 4 of the table to give the total annual costs associated with staff involved in supervision i.e. for each row of the table, multiply the data entered in column 2 by the data entered in column 3.

5. Note who funds the staff involved in supervision by completing column 5.

6. Add together the totals entered in column 4. This gives the total annual cost of staff involved in supervision.

(b) Fuel/ALL costs associated with vehicles/motorbikes* (delete as appropriate depending on what data are available on mileage rates/rates paid per km)

1. Identify how many miles/kilometres are travelled per year for supervision by district vehicles (e.g. from vehicle logbooks). *If data are hard to access, take a random sample of supervisory trips (30 trips should be sufficient) and note the miles/kilometres travelled in each case. Then use this information to calculate the average distance travelled per trip. This average distance per trip should then be multiplied by the number of trips made per year, to give the total miles/km travelled in a year.*

2. Identify the rate per kilometre/mile paid for vehicle usage.

3. Multiply the rate per km/mile by the number of kilometres travelled per year to give the total annual costs of fuel/ALL costs associated with vehicle usage (depending on what the rate covers).

4. Identify the total annual number of miles/kilometres travelled by motorbikes for overall supervision of patients/health staff/DOT supervisors.

5. Identify the rate per kilometre/mile paid for motorbike usage.

6. Multiply the rate per km/mile by the number of kilometres travelled per year to give the total annual costs of fuel/ALL costs (depending on what the rate is designed to cover) associated with motorbike usage.

7. Enter the total annual cost of fuel/ALL costs associated with vehicle <u>and</u> motorbike usage (depending on the mileage/km rate used) by adding together the totals calculated in steps 3 and 6.

8. Identify the source of funds for the fuel/all costs associated with use of vehicles/ motorbikes for overall supervision of patients/health staff/DOT supervisors.

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(c) Vehicle/motorbike, etc. costs

Note that this section is ONLY relevant if the km/mileage rate used in (b) covers only fuel costs.

In Table 2:

1. List the vehicles/motorbikes/other transport that are used in column 1.
2. For each item recorded in column 1, identify its purchase price new (i.e. current replacement cost) in column 2.
3. For each item entered in column 1, record its expected years of useful life when new in column 3.
4. Use the purchase price new (i.e. current replacement cost) and the expected years of useful life in combination with a discount rate of 3% to calculate the annualized cost of each item. Enter this information in column 4 i.e. for each item, look up the relevant annualization factor for a discount rate of 3% and the expected years of useful life estimated. The annualized cost is then calculated by dividing the purchase price new (i.e. current replacement cost) by this annualization factor (note that the annualization factor is 2.83 for life expectancy of 3 years, 4.58 for 5 years, 6.23 for 7 years and 8.5 for ten years. One of these life expectancies is quite likely to be one of those identified in column 3, and should therefore help in completion of column 4).

In Table 3:

1. In column 1 re-enter the data from column 1 of Table 2.
2. In column 2 re-enter the data from column 4 of Table 2.
3. In column 3 identify how many days of the year each item is used for supervision.
4. In column 4 identify the total number of days each item is used for <u>all</u> purposes each year.
5. For each item, calculate the annualized cost that should be allocated to supervision of TB patients/their supervisors by completing column 5 of the table {i.e. for each row, multiply the figure in column 2 by the figure in column 3, and then divide this total by the figure in column 4}.
6. Identify the source of funds for vehicle/motorbike costs in column 6.
7. Add together the costs calculated in the column 5 of the table. This gives the total annualized cost of vehicles/motorbikes etc.

(d) Maintenance costs

Note that this section is ONLY relevant if the km/mileage rate used in (b) covers only fuel costs.

1. Multiply the total fuel cost calculated in step 7 of section (b) by 0.15. This results in maintenance costs being estimated as 15% of fuel costs. This is a proportion suggested in some costing manuals. However, if an alternative figure is considered more appropriate, use that instead.
2. Identify the source of funds for maintenance costs.

(e) Other costs

1. Vehicles, fuel and staff are likely to be the major inputs to this component of TB services. However, if other costs are involved, attempt to estimate their annual costs too.
2. Identify the source of funds for these "other costs".

Finally, complete Table 4. The total costs calculated give the total costs associated with supervision of TB patients/their supervisors. These total costs should then be divided by the number of patients being supervised in the area. This gives the average cost per patient supervised.

Average incremental cost: to calculate average incremental costs, identify the costs that would not exist if there were no TB patients. The total of the costs that would not exist if there were no TB patients divided by the number of TB patients being supervised is the average incremental cost per patient supervised. It is quite likely that none of the costs for supervision would exist if there were no TB patients, in which case the average incremental cost will be equivalent to the average cost.

Marginal cost: For short-run marginal costs, identify the costs that would increase with the addition of one extra patient, and by how much they would increase. This is the short-run marginal cost per patient. In the long-run, marginal cost is likely to be similar to average incremental cost, or may be lower if, for example, the average distance travelled per patient falls as the number of patients increases.

Utilization

1. Comment on the extent to which provision of supervision is under-utilized, over-utilized or optimally utilized. The easiest way to measure this would be to assess the average number of patients supervised per supervisory trip made and whether this appears to be a reasonable number for the cost incurred. However, no standard benchmarks are suggested here because it is not clear what these should be. It is suggested that protocol users make the assessment themselves. For example, this could be done in consultation with those responsible for supervision.

2. Justify the choice made in 1.

Financing

1. Complete the table at the end of the data entry sheets, using the funding source data recorded above. This will show the breakdown of financing for outpatient supervision of patients/health staff/supervisors of DOT to encourage compliance with treatment.

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Protocol 10: The cost of TB programme management at district level

Data required for completion of protocol

1. List of the staff involved in management of TB services at district level

2. Annual cost of each type of staff involved in management of TB services at district level

3. Proportion of their total working time each person involved in district TB programme management spends on district TB programme management activities

4. Source of funds for staff costs

5. Current replacement cost of buildings used for district TB programme management activities *and/or* the current replacement cost per square metre for the buildings used for district TB programme management activities and the floor area of these buildings

6. Total annual expenditure on fuel/maintenance for district TB programme management activities, if 6 is not available, items 7 to 10 are also required:

7. Estimate of the number of miles/km travelled per year for district TB programme management activities by district vehicles

8. Rate per mile/km for use of vehicles

9. Estimate of the number of miles/km travelled per year for district TB programme management activities by district motorbikes

10. Rate per mile/km for use of motorbikes

11. Source of funds for costs associated with use of vehicles and motorbikes

If the rate per mile/km covers fuel costs only and does not cover the capital cost of the vehicle/motorbike, OR fuel/maintenance costs are estimated using district expenditure records, the items listed as 12 to 16 are also required:

12. List of the vehicles/motorbikes that are used for district TB programme management activities

13. Current replacement cost of each type of vehicle/motorbike that is used for district TB programme management activities

14. Estimate of the expected years of life of vehicles/motorbikes, when new

15. Number of days per year each vehicle/motorbike is used for district TB programme management activities

16. Number of days per year each vehicle/motorbike is used for ALL activities in the district. Data on any expenditures associated with district TB programme management other those associated with vehicles, motorbikes, staff and buildings

The data entry sheets for Protocol 10 should be completed by following the instructions given below (note: take care not to double-count items included in the data entry sheets for Protocol 9)

(a) Staff costs

In the table provided:

1. Identify who is involved in the management of TB services at district level (column 1).

2. Identify the annual costs of the staff who manage TB services at district level (column 2). *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

3. Identify what fraction of their time these staff spend on managing TB services (column 3). Enter this as a number between 0 and 1 e.g. 20% is equal to 0.2; 60% is equal to 0.6; 100% is equal to 1, etc.

4. Allocate a share of staff costs to district TB programme management, according to the share of their time each staff member spends on district TB programme management. This can be done by multiplying column 2 by column 3 for each row.

5. Identify who funds the costs of staff involved in district level TB programme management by completing column 5 of the table.

6. Add together all the staff costs allocated to district TB programme management to give the total staff costs associated with district TB programme management i.e. sum the totals in column 4.

(b) Building costs

1. Find what it would cost to build the buildings used for district TB programme management now. The Ministry of Works or similar may have this information. If not, calculate the floor area of the buildings that are used and find out (from the Ministry of Works or similar) what the cost per square metre for construction of new buildings is. Then multiply the number of square metres by the cost per square metre. Enter this total in the first column of the table provided.

2. Calculate the annualized cost of the buildings used for district TB programme management. Do this by assuming that buildings would be expected to last 50 years and by using a discount rate of 3%. This means that the annualized cost can be calculated as: (cost to build buildings now i.e. its current replacement cost ÷ 25.73). Note that 25.73 is the relevant annualization factor (see also Appendix 1 in Chapter 2) for an expected useful life of 50 years and a discount rate of 3%. Enter the figure in the second column of the table provided. ***This figure is the total annual cost of the buildings used for district TB programme management.***

3. Complete the third column of the table by noting who is responsible for the funding of building costs.

(c) Fuel costs/ALL costs associated with vehicle usage (see instructions below for which applies)

The easiest way to identify annual fuel costs is if there are district programme expenditure reports that list these costs. If these are available, the total amount can be automatically entered in point 7, ignoring steps 1 to 6. If these data are not available, fuel costs (and quite possibly other costs associated with vehicle usage) can be established as follows:

1. Identify the total annual number of miles/kilometres travelled by vehicles for district TB programme management.

2. Identify the rate per kilometre/mile paid for vehicle usage.

3. Multiply the rate per km/mile by the number of kilometres/miles travelled per year to give the total annual costs of fuel/ALL costs associated with vehicle usage (depending on what the rate covers).

4. Identify the total annual number of miles/kilometres travelled by motorbikes for district TB programme management.

5. Identify the rate per kilometre/mile paid for motorbike usage.

6. Multiply the rate per km/mile by the number of kilometres/miles travelled per year to give the total annual costs of fuel/ALL costs (depending on what the rate is designed to cover) associated with motorbike usage.

7. If steps 1 to 6 have been followed, enter the total annual cost of fuel/ALL costs associated with vehicle usage (depending on the mileage/km rate used) by adding together the totals calculated in steps 3 and 6. Otherwise, if fuel expenditure is known without requiring steps 1 to 6 (e.g. from district expenditure records), enter this amount.

8. Identify the source of funds for the fuel/ALL costs associated with use of vehicles/motorbikes for district TB programme management.

{Note that if the rate per km/mile used for vehicles and motorbikes is designed to cover maintenance costs and the costs associated with vehicle/motorbike depreciation, as well as fuel costs, sections (d) and (e) can be ignored}

(d) Vehicle/motorbike/other transport costs

Note that this section is ONLY relevant if the km/mileage rate used in (c) covers only fuel costs OR if fuel costs were estimated using district expenditure records and the capital costs associated with vehicles/motorbikes/other transport still remain to be estimated.

In Table 1a:

1. List the vehicles/motorbikes/other transport that are used in column 1.
2. For each item recorded in column 1, identify its purchase price new (i.e. current replacement cost) in column 2.
3. For each item entered in column 1, record its expected years of useful life when new in column 3.
4. Use the purchase price new (i.e. current replacement cost) and the expected years of useful life in combination with a discount rate of 3% to calculate the annualized cost of each item. Enter this information in column 4 i.e. for each item, look up the relevant annualization factor for a discount rate of 3% and the expected years of useful life estimated. The annualized cost is then calculated by dividing the purchase price new (i.e. current replacement cost) by this annualization factor (Note that the annualization factor is 2.83 for life expectancy of 3 years, 4.58 for 5 years, 6.23 for 7 years and 8.5 for ten years. These life expectancies are quite likely to be those identified in column 3 and should therefore help in completion of column 4).

In Table 1b:

1. In column 1 re-enter the data from column 1 of Table 1a.
2. In column 2 re-enter the data from column 4 of Table 1a.
3. In column 3 identify how many days of the year each item is used for district TB programme management.
4. In column 4 identify the total number of days each item is used for all purposes each year.
5. For each item, calculate the annualized cost that should be allocated to district TB programme management by completing column 5 of the table {i.e. for each row, multiply the figure in column 2 by the figure in column 3, and then divide this total by the figure in column 4}.
6. Identify the source of funds for vehicle/motorbike costs in column 6.
7. Add together the costs calculated in the column 5 of the table. This gives the total annualized cost of vehicles/motorbikes, etc.

(e) Maintenance costs

Note that this section is ONLY relevant if the km/mileage rate used in (c) covers only fuel costs OR if fuel costs were estimated using district expenditure records and the maintenance costs associated with vehicles/motorbikes still remain to be estimated.

1. Record the annual cost of vehicle/motorbike maintenance. This may be recorded in district programme expenditure reports, but alternatively may be estimated by multiplying total fuel costs (entered in (c) step 7, if this section (e) has been considered relevant) by 0.15.
2. Identify the source of funds for maintenance costs.

(f) Other costs

1. Estimate (e.g. from programme expenditure records) the annual cost of any other cost items not covered in the above five categories {i.e. (a) through (e)}.
2. Identify the source of funds for these "other costs".

Finally, in the table provided:
1. Enter the total costs of each input to district TB programme management (column 2).
2. Add together the total annual costs calculated for staff, buildings, vehicles/motorbikes, fuel, maintenance and other general recurrent costs and enter this in the TOTAL row. This gives the total annual costs associated with district TB programme management.
3. Record the annual number of TB patients treated in the district.
4. Divide the annual total cost calculated in step 2 by the annual number of patients for whom programme management is undertaken (i.e. the number of TB patients treated in the district in a year). This gives the average cost per patient of programme management at district level.

Average incremental cost: to identify incremental costs, identify which costs would not exist if there were no TB patients. This gives the total incremental costs associated with TB patients. The average incremental cost per patient is then these annual total costs divided by the annual number of TB patients in the district. It is likely that the average incremental cost per patient is the same as the average cost.

Marginal cost: to identify marginal cost, identify which costs would increase if the number of patients increased by one, and by how much. This gives the marginal cost per patient. Programme management costs are likely to be relatively fixed, so long-run and short-run marginal costs may be assessed to be zero.

Utilization

1. Comment on the extent to which district management appears under-utilized, over-utilized or optimally utilized. The easiest way to measure this would be to assess how the average number of patients in the district compares with the resources (staff, vehicles etc.) that are devoted to district management activities. However, no standard benchmarks are suggested here because it is not clear what these should be. It is suggested that protocol users make the assessment themselves. For example, this could be done in consultation with those responsible for district management.
2. Justify the choice made in 1.

Financing

1. Complete the table at the end of the data entry sheets, using the funding source data recorded above. This will show the breakdown of financing for district TB programme management.

Protocol 11: The cost of TB programme management at regional/provincial level

Data required for completion of protocol

1. List of the staff involved in management of TB services at regional/provincial level

2. Annual cost of each type of staff involved in management of TB services at regional/provincial level

3. Proportion of their total working time each person involved in regional/provincial TB programme management spends on TB programme management activities

4. Source of funds for staff costs

5. Current replacement cost of buildings used for regional/provincial TB programme management activities *and/or* the current replacement cost per square metre for the buildings used for regional/provincial TB programme management and the floor area of these buildings

6. Total annual expenditure on fuel/maintenance for regional/provincial TB programme management activities,

    if 6 is not available, items 7 to 10 are also required:

7. Estimate of the number of miles/km travelled per year for regional/provincial TB programme management activities by regional/provincial vehicles

8. Rate per mile/km for use of vehicles

9. Estimate of the number of miles/km travelled per year for regional/provincial TB programme management activities by regional/provincial motorbikes

10. Rate per mile/km for use of motorbikes

11. Source of funds for costs associated with use of vehicles and motorbikes

If the rate per mile/km covers fuel costs only and does not cover the capital cost of the vehicle/motorbike, OR fuel/maintenance costs are estimated using regional/provincial expenditure records, the items listed as 12 to 16 are also required:

12. List of the vehicles/motorbikes that are used for regional/provincial TB programme management activities

13. Current replacement cost of each type of vehicle/motorbike that is used for regional/provincial TB programme management activities

14. Estimate of the expected years of life of vehicles/motorbikes, when new

15. Number of days per year each vehicle/motorbike is used for regional/provincial TB programme management activities

16. Number of days per year each vehicle/motorbike is used for ALL activities in the region/province

17. Data on any expenditures associated with regional/provincial TB programme management other those associated with vehicles, motorbikes, staff and buildings

The data entry sheets for Protocol 11 should be completed by following the instructions given below.

(a) Staff costs

In the table provided:

1. Identify who is involved in the management of TB services at regional/provincial level (column 1).

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2. Identify the annual costs of the staff who manage TB services at regional/provincial level (column 2). *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*

3. Identify what fraction of their time these staff spend on managing TB services (column 3). Enter this as a number between 0 and 1 e.g. 20% is equal to 0.2; 60% is equal to 0.6; 100% is equal to 1, etc.

4. Allocate a share of staff costs to TB service management, according to the share of their time each staff member spends on TB service management. This can be done by multiplying column 2 by column 3 for each row.

5. Identify who funds the costs of staff involved in regional/provincial level management by completing column 5 of the table.

6. Add together all the staff costs allocated to TB services to give the total staff costs associated with regional/provincial programme management i.e. sum the totals in column 4.

(b) Building costs

1. Find what it would cost to build the buildings used for regional/provincial TB programme management now. The Ministry of Works or similar may have this information. If not, calculate the floor area of the buildings that are used and find out (from the Ministry of Works or similar) what the cost per square metre for construction of new buildings is. Then multiply the number of square metres by the cost per square metre. Enter this total in the first column of the table provided.

2. Calculate the annualized cost of the buildings used for regional/provincial programme management. Do this by assuming that buildings would be expected to last 50 years and by using a discount rate of 3%. This means that the annualized cost can be calculated as: (cost to build the buildings now i.e. its current replacement cost ÷ 25.73). Note that 25.73 is the relevant annualization factor also Appendix 1 in Chapter 2) for an expected useful life of 50 years and a discount rate of 3%. Enter the figure in the second column of the table provided. ***This figure is the total annual cost of the buildings used for regional/provincial TB programme management.***

3. Complete the third column of the table by noting who is responsible for the funding of building costs.

(c) Fuel costs/ALL costs associated with vehicle/motorbike usage (see instructions below for which applies)

The easiest way to identify annual fuel costs is if there are regional/provincial programme expenditure reports that list these costs. If these are available, the total amount can be automatically entered in point 7, ignoring steps 1 to 6. If these data are not available, fuel costs (and quite possibly other costs associated with vehicle/motorbike usage) can be established as follows:

1. Identify the total annual number of miles/kilometres travelled by vehicles for regional/provincial TB programme management.

2. Identify the rate per kilometre/mile paid for vehicle usage.

3. Multiply the rate per km/mile by the number of kilometres/miles travelled per year to give the total annual costs of fuel/ALL costs associated with vehicle usage (depending on what the rate covers).

4. Identify the total annual number of miles/kilometres travelled by motorbikes for regional/provincial TB programme management.

5. Identify the rate per kilometre/mile paid for motorbike usage.

6. Multiply the rate per km/mile by the number of kilometres/miles travelled per year to give the total annual costs of fuel/ALL costs (depending on what the rate is designed to cover) associated with motorbike usage.

7. If steps 1 to 6 have been followed, enter the total annual cost of fuel/ALL costs associated with vehicle usage (depending on the mileage/km rate used) by adding together the totals calculated in steps 3 and 6. Otherwise, if fuel expenditure is known without requiring steps 1 to 6 (e.g. from district expenditure records), enter this amount.

8. Identify the source of funds for the fuel/ALL costs associated with use of vehicles/ motorbikes for regional/provincial TB programme management.

{Note that if the rate per km/mile used for vehicles and motorbikes is designed to cover maintenance costs and the costs associated with vehicle/motorbike depreciation, as well as fuel costs, sections (d) and (e) can be ignored}

(d) Vehicle/motorbike/other transport costs

Note that this section is ONLY relevant if the km/mileage rate used in (c) covers only fuel costs OR if fuel costs were estimated using regional/provincial expenditure records and the capital costs associated with vehicles/motorbikes/other transport still remain to be estimated.

In Table 1a:

1. List the vehicles/motorbikes/other transport that are used in column 1.

2. For each item recorded in column 1, identify its purchase price new (i.e. current replacement cost) in column 2.

3. For each item entered in column 1, record its expected years of useful life when new in column 3.

4. Use the purchase price new (i.e. current replacement cost) and the expected years of useful life in combination with a discount rate of 3% to calculate the annualized cost of each item. Enter this information in column 4, i.e. for each item, look up the relevant annualization factor for a discount rate of 3% and the expected years of useful life estimated. The annualized cost is then calculated by dividing the purchase price new (i.e. current replacement cost) by this annualization factor (Note that the annualization factor is 2.83 for life expectancy of 3 years, 4.58 for 5 years, 6.23 for 7 years and 8.5 for ten years. These life expectancies are quite likely to be those identified in column 3 and should therefore help in completion of column 4).

In Table 1b:

1. In column 1 re-enter the data from column 1 of Table 1b.

2. In column 2 re-enter the data from column 4 of Table 1b.

3. In column 3 identify how many days of the year each item is used for regional/provincial TB programme management.

4. In column 4 identify the total number of days each item is used for all purposes each year.

5. For each item, calculate the annualized cost that should be allocated to regional/ provincial programme management by completing column 5 of the table {i.e. for each row, multiply the figure in column 2 by the figure in column 3, and then divide this total by the figure in column 4}.

6. Identify the source of funds for vehicle/motorbike costs in column 6.

7. Add together the costs calculated in column 5 of the table. This gives the total annualized cost of vehicles/motorbikes etc.

(e) Maintenance costs

Note that this section is ONLY relevant if the km/mileage rate used in (c) covers fuel costs only OR if fuel costs were estimated using regional/provincial expenditure records and the maintenance costs associated with vehicles/motorbikes still remain to be estimated.

1. Record the annual cost of vehicle/motorbike maintenance. This may be recorded in regional/ provincial programme expenditure reports, but alternatively may be estimated by multiplying total fuel costs (entered in (c) step 7, if this section has been considered relevant) by 0.15.
2. Identify the source of funds for maintenance costs.

(f) Other costs

1. Estimate (e.g. from programme expenditure records) the annual cost of any other cost items not covered in the above five categories {i.e. (a) through (e)}.
2. Identify the source of funds for these "other costs".

Finally, in the table provided:
1. Enter the total costs of each input to regional/provincial TB programme management (column 2).
2. Add together the total annual costs calculated for staff, buildings, vehicles/motorbikes, fuel, maintenance and other general recurrent costs and enter this in the TOTAL row. This gives the total annual costs associated with regional/provincial TB programme management.
3. Record the annual number of TB patients treated in the region/province.
4. Divide the annual total cost calculated in step 2 by the annual number of patients for whom programme management is undertaken (i.e. the number of TB patients treated in the region/ province in a year). This gives the average cost per patient of programme management at regional/provincial level.

Average incremental cost: to identify incremental costs, identify which costs would not exist if there were no TB patients. This gives the total incremental costs associated with TB patients. The average incremental cost per patient is then these total annual costs divided by the annual number of TB patients in the region/province. It is likely that the average incremental cost per patient is the same as the average cost.

Marginal cost: to identify marginal cost, identify which costs would increase if the number of patients increased by one, and by how much. This gives the marginal cost per patient. Programme management costs are likely to be relatively fixed, so long-run and short-run marginal costs may be assessed to be zero.

Utilization

1. Comment on the extent to which regional/programme management appears under-utilized, over-utilized or optimally utilized. The easiest way to measure this would be to assess how the average number of patients in the district compares with the resources (staff, vehicles etc.) that are devoted to regional/provincial management activities. However, no standard benchmarks are suggested here because it is not clear what these should be. It is suggested that protocol users make the assessment themselves. For example, this could be done in consultation with those responsible for regional/provincial management.
2. Justify the choice made in 1.

Financing

1. Complete the table at the end of the data entry sheets, using the funding source data recorded above. This will show the breakdown of financing for regional/provincial TB programme management.

Protocol 12

The cost of TB programme management at national level

Data required for completion of protocol

1. List of the staff involved in management of TB services at national level
2. Annual cost of each type of staff involved in management of TB services at national level
3. Proportion of their total working time each person involved in national TB programme management spends on national TB programme management activities
4. Source of funds for staff costs
5. Current replacement cost of buildings used for national TB management activities *and/or* the current replacement cost per square metre for the buildings used for national management of TB activities and the floor area of these buildings
6. Total annual expenditure on fuel/maintenance for national TB programme management activities,

    if 6 is not available, items 7 to 10 are also required:
7. Estimate of the number of miles/km travelled per year for national TB programme management activities by national vehicles
8. Rate per mile/km for use of vehicles
9. Estimate of the number of miles/km travelled per year for national TB programme management activities using motorbikes
10. Rate per mile/km for use of motorbikes
11. Source of funds for costs associated with use of vehicles and motorbikes

If the rate per mile/km covers fuel costs only and does not cover the capital cost of the vehicle/motorbike, OR fuel/maintenance costs are estimated using national programme expenditure records, the items listed as 12 to 16 are also required:

12. List of the vehicles/motorbikes that are used for national TB programme management activities
13. Current replacement cost of each type of vehicle/motorbike that is used for national TB programme management activities
14. Estimate of the expected years of life of vehicles/motorbikes, when new
15. Number of days per year each vehicle/motorbike is used for national TB programme management activities
16. Number of days per year each vehicle/motorbike is used for ALL activities in the country. Data on any expenditures associated with national TB programme management other those associated with vehicles, motorbikes, staff and buildings

The data entry sheets for Protocol 12 (in Document 2) should be completed by following the instructions given below.

(a) Staff costs

In the table provided:

1. Identify who is involved in the management of TB services at national level (column 1).
2. Identify the annual costs of the staff who manage TB services at national level (column 2).

Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).

3. Identify what fraction of their time these staff spend on managing TB services (column 3). Enter this as a number between 0 and 1 e.g. 20% is equal to 0.2; 60% is equal to 0.6; 100% is equal to 1, etc.

4. Allocate a share of staff costs to TB service management, according to the share of their time each staff member spends on TB service management. This can be done by multiplying column 2 by column 3 for each row.

5. Identify who funds the costs of staff involved in national level management by completing column 5 of the table.

6. Add together all the staff costs allocated to TB services to give the total staff costs associated with national programme management i.e. sum the totals in column 4.

(b) Building costs

1. Find what it would cost to build the buildings used for national TB programme management now. The Ministry of Works or similar may have this information. If not, calculate the floor area of the buildings that are used and find out (from the Ministry of Works or similar) what the cost per square metre for construction of new buildings is. Then multiply the number of square metres by the cost per square metre. Enter this total in the first column of the table provided.

2. Calculate the annualized cost of the buildings used for national programme management. Do this by assuming that buildings would be expected to last 50 years and by using a discount rate of 3%. This means that the annualized cost can be calculated as: (cost to build buildings now i.e. its current replacement cost ÷ 25.73). Note that 25.73 is the relevant annualization factor (see also Appendix 1 in Chapter 2) for an expected useful life of 50 years and a discount rate of 3%. Enter the figure in the second column of the table provided. ***This figure is the total annual cost of the buildings used for national TB programme management.***

3. Complete the third column of the table by noting who is responsible for the funding of building costs.

(c) Fuel costs/ALL costs associated with vehicle usage (see instructions below for which applies)

The easiest way to identify annual fuel costs is if there are national programme expenditure reports that list these costs. If these are available, the total amount can be automatically entered in point 7, ignoring steps 1 to 6. If these data are not available, fuel costs (and quite possibly other costs associated with vehicle usage) can be established as follows:

1. Identify the total annual number of miles/kilometres travelled by vehicles for national TB programme management.

2. Identify the rate per kilometre/mile paid for vehicle usage.

3. Multiply the rate per km/mile by the number of kilometres/miles travelled per year to give the total annual costs of fuel/ALL costs associated with vehicle usage (depending on what the rate covers).

4. Identify the total annual number of miles/kilometres travelled by motorbikes for national TB programme management.

5. Identify the rate per kilometre/mile paid for motorbike usage.

6. Multiply the rate per km/mile by the number of kilometres/miles travelled per year to give the total annual costs of fuel/ALL costs (depending on what the rate is designed to cover) associated with motorbike usage.

7. If steps 1 to 6 have been followed, enter the total annual cost of fuel/ALL costs associated with vehicle usage (depending on the mileage/km rate used) by adding together the totals calculated in steps 3 and 6. Otherwise, if fuel expenditure is known without requiring steps 1 to 6 (e.g. from district expenditure records), enter this amount.

8. Identify the source of funds for the fuel/all costs associated with use of vehicles/motorbikes for national TB programme management.

{Note that if the rate per km/mile used for vehicles and motorbikes is designed to cover maintenance costs and the costs associated with vehicle/motorbike depreciation, sections (d) and (e) can be ignored}.

(d) Vehicle/motorbike/other transport costs

Note that this section is ONLY relevant if the km/mileage rate used in (c) covers only fuel costs, OR if fuel costs were estimated using national expenditure records and the capital costs associated with vehicles/motorbikes/other transport still remain to be estimated.

In Table 1a:

1. List the vehicles/motorbikes/other transport that are used in column 1.

2. For each item recorded in column 1, identify its purchase price new (i.e. current replacement cost) in column 2.

3. For each item entered in column 1, record its expected years of useful life when new in column 3.

4. Use the purchase price new (i.e. current replacement cost) and the expected years of useful life in combination with a discount rate of 3% to calculate the annualized cost of each item. Enter this information in column 4 i.e. for each item, look up the relevant annualization factor for a discount rate of 3% and the expected years of useful life estimated. The annualized cost is then calculated by dividing the purchase price new (i.e. current replacement cost) by this annualization factor (note that the annualization factor is 2.83 for life expectancy of 3 years, 4.58 for 5 years, 6.23 for 7 years and 8.5 for ten years. These life expectancies are quite likely to be those identified in column 3 and should therefore help in completion of column 4).

In Table 1b:

1. In column 1 re-enter the data from column 1 of Table 1b.

2. In column 2 re-enter the data from column 4 of Table 1b.

3. In column 3 identify how many days of the year each item is used for national TB programme management. In column 4 identify the total number of days each item is used for all purposes each year.

4. For each item, calculate the annualized cost that should be allocated to national programme management by completing column 5 of the table {i.e. for each row, multiply the figure in column 2 by the figure in column 3, and then divide this total by the figure in column 4}.

5. Identify the source of funds for vehicle/motorbike costs in column 6.

6. Add together the costs calculated in column 5 of the table. This gives the total annualized cost of vehicles/motorbikes, etc.

(e) Maintenance costs

Note that this section is ONLY relevant if the km/mileage rate used in (c) covers only fuel cost OR if fuel costs were estimated using national expenditure records and the maintenance costs associated with vehicles/motorbikes still remain to be estimated.

1. Record the annual cost of vehicle/motorbike maintenance. This may be recorded in national programme expenditure reports, but alternatively may be estimated by multiplying total fuel costs (entered in (c) step 7, if this section (e) has been considered relevant) by 0.15.
2. Identify the source of funds for maintenance costs.

(f) Other costs

1. Estimate (e.g. from programme expenditure records) the annual cost of any other cost items not covered in the above five categories {i.e. (a) through (e)}.
2. Identify the source of funds for these "other costs".

Finally, in the table provided:

1. Enter the total costs of each input to national TB programme management (column 2).
2. Add together the total annual costs calculated for staff, buildings, vehicles/motorbikes, fuel, maintenance and other general recurrent costs and enter this in the TOTAL row. This gives the total annual costs associated with national TB programme management.
3. Record the annual number of TB patients treated in the country.
4. Divide the annual total cost calculated in step 2 by the annual number of patients for whom programme management is undertaken (i.e. the number of TB patients treated in the country in a year). This gives the average cost per patient of programme management at national level.

Average incremental cost: to identify incremental costs, identify which costs would not exist if there were no TB patients. This gives the total incremental costs associated with TB patients. The average incremental cost per patient is then these annual total costs divided by the annual number of TB patients in the country. It is likely that the average incremental cost per patient is the same as the average cost.

Marginal cost: to identify marginal cost, identify which costs would increase if the number of patients increased by one, and by how much. This gives the marginal cost per patient. National programme management costs are likely to be relatively fixed, so long-run and short-run marginal costs may be assessed to be zero.

Utilization

1. Comment on the extent to which national programme management appears under-utilized, over-utilized or optimally utilized. The easiest way to measure this would be to assess how the average number of patients in the country compares with the resources (staff, vehicles etc.) that are devoted to national programme management activities. However, no standard benchmarks are suggested here because it is not clear what these should be. It is suggested that protocol users make the assessment themselves. For example, this could be done in consultation with those responsible for national programme management.
2. Justify the choice made in 1.

Financing

1.   Complete the table at the end of the data entry sheets, using the funding source data recorded above. This will show the breakdown of financing for national TB programme management.

Protocol 13: The cost of training

Data required for completion of protocol

1. Description of what training is typically provided each year, by whom and for whom
2. List of staff involved in providing training
3. Annual cost of each type of staff involved in provision of training
4. Number of days per year that each person involved in providing training spends on providing training
5. Number of days per year, in total, that each person involved in provision of training is expected to work
6. Source of funds for staff involved in providing training
7. List of number and type of staff who typically receive training each year
8. Annual cost of each type of staff that typically receives training
9. Number of days of training per year that each person receives
10. Number of days per year, in total, that each person who receives training is expected to work
11. Source of funds for staff who receive training
12. Subsistence rate/other payments per day paid to staff when they receive training
13. Source of funds for subsistence/other payments made to staff when they receive training
14. Estimate of other costs associated with provision of training e.g. training materials, supplies

The data entry sheets for Protocol 13 (in Document 2) should be completed by following the instructions given below.

1. Note the training that is typically provided to staff involved in delivery of TB services in a year.

(a) Cost of staff <u>providing</u> training

In Table 1:

1. Identify the staff who are involved in providing training (column 1).
2. In column 2, record the annual cost of each member of staff who provides training. *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/ insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*
3. In column 3, record the number of days per year that each member of staff spends providing training.
4. In column 4, record the number of days each member of staff would be expected to work each year.
5. Complete column 5 by dividing the annual cost of each member of staff by the number of days they work per year, to give their cost per day.
6. Complete column 6 by multiplying the number of days each member of staff spends providing training (column 3) by their cost per day (column 5).
7. Identify who pays by completing column 7.
8. Write down the total cost associated with staff providing training (i.e. the sum of the figures in column 6).

(b) Cost of staff who <u>receive</u> training

In Table 2:

1. In column 1, identify the type of staff who typically receive training each year.
2. In column 2 record, for each type of staff, the number who typically receive training each year.
3. In column 3, identify the number of days per year that each type of staff spends receiving training.
4. In column 4 record, for each type of staff identified in column 1, their annual cost. *Remember to take care that all relevant staff costs are included i.e. basic salaries; pension/ insurance contributions paid by employer; housing allowances; value of accommodation provided; and any special incentives paid (see also p32).*
5. In column 5 record the number of days each type of staff is expected to work per year.

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In Table 3:

6. For each type of staff, copy column 1 from Table 2.
7. In column 2, calculate the total number of days spent training each type of staff by multiplying (column 2 x column 3) from Table 2 for each type of staff.
8. Enter the cost per day of each type of staff in column 3 by dividing their total annual cost by the number of days per year they are expected to work (both entered in Table 2).
9. In column 4 enter the subsistence rate/other payments made per day, while staff are receiving training.
10. In column 5 enter the costs associated with training each type of staff by multiplying, for each row, column 2 by (total in column 3 + total in column 4).
11. Sum the totals in column 5 to give the total annual costs associated with staff being trained.
12. Identify the source of funds for training of staff by completing column 6.

(c) Other costs

1. Identify/estimate the other costs associated with provision of training e.g. training materials, supplies, etc.

Finally:

Complete Table 4 to give the total annual costs associated with training. Then record the total number of patients in the area for which training costs were estimated (i.e. the district). Then divide the total costs calculated in Table 4 by the total number of patients in the district for which training costs have been estimated. This gives the average cost of training per patient.

Average incremental cost: identify what training would not occur if there were no TB patients. Estimate the cost of this training and then divide this by the number of TB patients being managed. This gives the average incremental cost of training per patient.

Marginal cost: identify what training costs would increase with the addition of one more patient, and by how much. This gives the marginal cost of training per patient.

Utilization

1. Comment on the extent to training appears under-utilized, over-utilized or optimally utilized. The easiest way to measure this would be to assess how the average number of staff attending training sessions compares with the average number of staff providing training. However, no standard benchmarks are suggested here because it is not clear what these should be. It is suggested that protocol users make the assessment themselves. For example, this could be done in consultation with those responsible for training.

2. Justify the choice made in 1.

Financing

1. Complete the table at the end of the data entry sheets, using the funding source data recorded above. This will show the breakdown of financing for training.

How to cost other components not included in Protocols 1 to 13

As stated at the beginning of this chapter, there may be other important elements in TB diagnosis and case management that have not been covered in Protocols 1 through 13. This is because the protocol has aimed to focus on those care components that are common to most countries and are generally the most important in cost terms. Aspects of TB services that are less common and which may differ in important ways across countries - for example active case finding - have not been included.

If there are other care components which need to be costed, protocol users should be able to draw on the methods already applied in Protocols 1 to 13. In general, the approach should be:

- describe the service component to be costed;
- identify the inputs required to provide that service component e.g. staff, equipment, supplies, buildings, vehicles, etc.;
- quantify the inputs required e.g. how much equipment, how many and what type of staff, how many and what kind of supplies, etc.;
- calculate or estimate the total annual costs associated with all items – annualization of capital costs should now be a procedure with which protocol users are familiar, so this should present no major difficulties; and if some costs are shared (e.g. staff) with other uses, the methods used for allocation of shared/joint costs in other sections of this chapter should provide guidance;
- add together the total annual costs for each input and divide this by the total number of patients in the area for which costs have been assessed. This gives the average cost for the care component. Incremental and marginal costs may then be assessed.

CHAPTER 5. ASSESSMENT OF PATIENT, FAMILY AND COMMUNITY COSTS ASSOCIATED WITH USE OF TB SERVICES

Introduction

Cost and cost-effectiveness analyses of TB services have in the past tended to concentrate on health services (provider) costs. Relatively little attention has been given to assessing the costs that are incurred by patients, or the costs associated with provision of TB treatment that are incurred by family or other community members. If an evaluation is to adopt a societal perspective (see Chapter 2 for definition) – the perspective typically preferred by economists – it is important to consider these costs.

Assessment of the costs incurred by patients, their families and other members of the community in provision of TB treatment does, however, raise some important methodological issues. For certain types of cost, this is reflected in the fact that there is not universal agreement among economists about whether they are worth measuring at all; and if they are measured, how they should be valued.

This chapter therefore starts by devoting a section to a discussion of the methodological issues raised by measurement of patient/community/family costs. This is designed to help protocol users make their own judgements about the value or otherwise of assessing these costs.

The "discussion" part of the chapter is structured as follows:
· How can the major patient, family and other community member costs associated with TB diagnosis and treatment be categorised (5.1.1)? This section includes the justification for inclusion of some non-financial costs, with reference to the concept of "opportunity cost";
· Approaches available for the measurement of the major costs incurred by patients, families and other community members (5.1.2);
· Criticisms that can be made of the approaches available for measurement of the time costs incurred by patients, families and other community members. This section concentrates on the problems of quantifying (as distinct from valuing) time costs (5.1.3). The focus on time costs, of the costs defined in 5.1.1, reflects the fact that it is measurement and valuation of these costs that is most controversial;
· Approaches available for the monetary valuation of the time costs incurred by patients, families and other community members, and how these relate to economic theory (5.1.4); and
· Criticisms that can be made of the approaches available for valuation of time costs (5.1.5).

While recognizing that there are important methodological issues to consider in relation to the measurement and valuation of time costs, and that economists disagree on how to handle these, this chapter also recognises two other issues as well:
· these guidelines are intended as a practical and generic tool; and
· a generic tool should be consistent with existing major textbooks and guidelines.

Therefore, the second section of these guidelines (5.2) explains the recommendations/suggestions concerning how to handle these costs that are made in 2 recent major textbooks. It is these recommendations that are followed in the rest of the chapter (sections 5.3 and 5.4).

5.1 Discussion of important methodological issues in the economic analysis of patient, family and community costs associated with TB diagnosis and treatment

5.1.1 How can the major patient, family and other community member costs associated with TB diagnosis and treatment be categorised?

From the perspective of patients, their family and community members in general, the use of TB diagnosis and treatment services may be associated with 3 major types of cost. These are:

1. expenditure on travel;
2. fees paid for items such as hospital services, medications or outpatient visits; and
3. time costs.

Other items may also be important (e.g. expenditures on special types of food, beyond what would normally be purchased, may be made).

Expenditure on travel

Travel expenditure is relatively self-explanatory. It includes, for instance, expenditure on items such as bus or train fares, or use of taxis. Expenditure on travel may be incurred for several reasons. Examples include travel expenditure incurred when a patient visits health facilities for diagnosis, for collection of drugs, for observation of therapy, or for monitoring; when volunteers involved in treatment visit health facilities e.g. to collect drugs on behalf of the patient; and when family members visit health facilities, either to see a patient while they are in hospital or in order to accompany the patient on outpatient visits.

Fees paid

Fees are also a relatively obvious category of costs. For example, patients may pay a fee per day for hospital admission, especially in mission hospitals. They may have to incur some expenditure for purchase of medications, and in some areas a fee may be charged per outpatient visit. Patients may also have to pay for items such as X-rays and sputum smears[13] .

Time costs

Time costs are a less obvious concept[14] . However, patients spend time getting to health facilities for collection of drugs or direct observation of treatment. They may spend time visiting volunteers if these are involved in observation of treatment. They may spend time waiting at health facilities. They may spend several days on hospital wards at treatment outset, and possibly many days when they are relatively well (in the case of strategies that rely on lengthy hospitalisation of patients at the beginning of treatment). Family members may also spend time getting to a hospital or a health facility, and they may spend time in hospital caring for the patient. In addition, volunteers involved in treatment may spend time collecting drugs, observing treatment, or attending training or community mobilization activities.

Such time represents a "cost" in the sense of "opportunity cost" (see Chapter 2 for definition). This is because spending time visiting or staying in health facilities could have been spent in an alternative way. For example, patients could have worked during this time – work that could

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[13] Note that when patients pay fees for items such as X-rays and laboratory tests, it is important not to count these costs twice in a costing analysis i.e. they should not be included as both health system and patient costs.

[14] Though the saying "time is money" is a good illustration of the concept that the use of time and money may be related.

have been for financial gain, or that could have involved unpaid productive work such as domestic household activities or subsistence agriculture. Patients could also have used this time for "leisure" purposes – activities that do not involve "productive" work. The importance of such costs and the relevance of including them in a cost or cost-effectiveness study is illustrated in the following comment (where CEA = cost-effectiveness analysis):

> *"The time a patient spends seeking care or participating in or undergoing an intervention constitutes a real change in the use of a resource by the patient and society. It is, in effect, a part of the intervention itself…Failure to include these costs would bias the CEA against interventions that relied on inputs or outputs that were purchased in favour of ones that relied on patients' time. While these costs have frequently been omitted from studies in the past, time is clearly a resource in limited supply, and its consumption should be reflected in CEA".*

(Luce et al., p180 in Gold et al., 1996)

5.1.2 Approaches available for the measurement of the major costs incurred by patients, families and other community members

Travel costs and fees

The relevance of measuring expenditure on travel costs and payment of fees is comparatively uncontroversial. Both items represent clear financial and economic costs; these costs are also clearly, and directly, associated with use of health services. In addition, these costs can be (reasonably) easily assessed through the use of simple patient/family/community surveys, using structured questionnaires (some examples are given as Appendices)[15].

Time costs

The measurement of the time costs associated with community involvement in provision of services (e.g. work done by community volunteers) is also not controversial. Indeed, it is essential when comparing costs across different programmes and settings – since some programmes might have relatively low costs because of high community involvement, and others might have relatively high costs because of low community involvement.

The measurement of time costs is much less straightforward, and correspondingly more controversial, when patients are the subject of analysis. This is not because the time spent in hospital, or the time spent to visit health facilities, or the time spent waiting in health facilities cannot be quantified. Indeed, such quantification is relatively straightforward – again, through the use of patient surveys. What *is* difficult to define is what patients would have done with this time if they had not spent it staying in or visiting health facilities, or visiting volunteer supervisors for DOT. In other words, it is the ***opportunity cost*** that can be difficult to define.

What approaches are available for the definition of the opportunity cost of time spent on activities such as visiting or staying in health facilities, or visiting volunteer supervisors of DOT? Logically, one could ask patients what they would have been doing if they had not been spending time travelling to or staying in health facilities, or if they had not been spending time visiting volunteer supervisors for DOT. Responses could be recorded according to categories such as "would have been doing paid work", "would have been at home, doing household tasks", "would have

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[15] Though in some cases it may still be difficult to be sure that the main reason for travel was to access health care. In addition, if a visit to a clinic, for example, is combined with a visit to go shopping, then arguably only some of the travel costs should be attributed to the clinic visit. See also 5.1.3 for potential criticisms of the approaches available for measurement of time costs.

been working on my kraal", "would have been watching TV", "would have been spending time with my children", and "nothing" (responses would obviously have to be made culturally specific). Such responses would define, albeit not in monetary terms, the "opportunity cost".

5.1.3 Criticisms that can be made of the approaches available for measurement of the time costs incurred by patients, families and other community members

Despite the apparent logic of the above approach to definition of opportunity costs, several criticisms can be made of it. These include:

· the opportunity cost – what patients would have been doing if they had not been spending time on TB diagnosis and treatment – may consist of a mixture of activities e.g. both some paid work and some household work. It may be hard for patients to quantify the amount of time they would have spent on each activity very precisely;

· the opportunity cost may vary over time. Some visits to health clinics, for example, might come at the cost of time spent doing nothing; others might come at the cost of time spent with children; others might come at the cost of paid employment. The criticism is not that there is variation over time, but rather that designing standardized data collection tools that capture this variation adequately may be very difficult. At the least, they are likely to require the employment of a skilled interviewer. At the other extreme, getting accurate data may require detailed observation at household level. This is very time-consuming and for that reason alone may be impractical; there is also the possibility that patients may not be willing to participate;

· the approach can ignore the dynamics of economic activity within households and the adjustment/compensatory mechanisms that may exist at this level. For example, a patient may state that they would have been doing domestic, household work if they had not been visiting a health clinic to collect drugs. However, in practice another household member may have taken over these activities, but given up leisure time as a consequence. The true opportunity cost would then be foregone leisure time, and it would not have been foregone by the patient. However, the patient questionnaire response would indicate (wrongly) that the cost was incurred by the patient, and that it was foregone domestic work; and

· patients may have spent time getting to a clinic or other type of health facility, but they may have combined this with other useful activities (e.g. shopping, visiting relatives or friends). In such a case, how much of the time spent should be seen as attributable to visiting a health facility for treatment? This example shows that it can be very difficult to tease out exactly what time costs were involved in items such as outpatient visits to health facilities (though this is not the case with time spent in hospital).

Given these criticisms, the ideal approach would be to use an "epidemiological approach" in which cases (TB patients) and controls (people with similar characteristics to the "case" but who do not have TB) are followed for a period of time (e.g. the time for which the "case" has TB), and their use of time is compared. The disadvantage is that this kind of study is time-consuming (for both study subjects and researchers), intrusive, and expensive.

5.1.4 Approaches available for the monetary valuation of time costs incurred by patients, families and other community members, and how these relate to economic theory

Even assuming that it has been possible to define the opportunity cost of time spent accessing TB diagnosis and treatment, a second difficult methodological issue is apparent: how should the

opportunity cost be valued in monetary terms? This question can be discussed by considering 3 broad categories of opportunity cost:

- productive work for which financial payment would have been received was foregone;
- productive work for which financial payment would <u>not</u> have been received was foregone;
- "leisure time" (very broadly defined as "non-productive work") was foregone.

The main approaches available (see Table 5.1) are:

- valuing foregone productive work for which payment would have been made according to the average wage rate among the population receiving the intervention – in this case, TB patients;
- valuing foregone productive work for which payment would not have been made according to either (a) the average wage rate in the area being studied (b) the average wage rate for paid productive work among the population receiving the intervention (c) the minimum wage rate for unskilled labour (d) the market value of work that was foregone or (e) the cost to employ someone to undertake the activities that were foregone; and
- valuing foregone leisure time as anything between zero and the wage rate that would be paid to the population receiving the intervention (in this case TB patients) for overtime work.

The extent to which each alternative relates to economic theory varies (column 3, Table 5.1).

5.1.5 Criticisms that can be made of the approaches available for valuation of time costs

As Table 5.1 suggests, several criticisms can be made of some of the available approaches for placing a monetary value on time costs. In particular:

- use of the minimum wage rate for unskilled labour may not be a very good approximation of the true economic value of productive work for which no financial payment is made – for example the rate may be set artificially high or artificially low. Also, much productive work for which no financial payment is made is skilled, not unskilled;
- except in the unlikely (or impossible) instance in which everyone earns the same wage, reliance on any average wage/income figure will over-estimate costs for some (those who have relatively high economic status) and under-estimate costs for others (those with relatively low economic status including, typically, an important proportion of TB patients – TB often being associated with poverty);
- defining the market value of productive work for which no financial payment is made can be extremely difficult. This is especially the case where there is no local market for activities such as household work, since this makes it very hard to put a value on such work. This presents severe problems when the intervention being studied is used by many people whose participation in the cash economy is very limited – for example, areas where subsistence agriculture is the dominant economic activity (though it could be argued that a possible proxy for annual income and the annual value of production would be the minimum amount of cash needed for survival if no domestic production of food is possible. It might be possible to estimate this using household expenditure survey data for urban areas);
- the wage rate for overtime labour has little relevance to the true cost of "leisure" time in the case of people who are unemployed or under-employed (and many TB patients may fall into one of these 2 categories); and
- though it has been suggested in one textbook that a baseline analysis initially value leisure time as zero, leisure time may often be valued at greater than zero, especially by those who are in full-time employment.

Table 5.1: Possible approaches to the valuation of opportunity costs, and how these relate to economic theory

Type of opportunity cost	How opportunity cost could be valued	How suggested approaches to valuation relate to economic theory
Foregone productive work for which financial payment would have been received	1. the monetary value of the financial payment that was foregone e.g. the reported wage or salary per day/hour could be used to estimate a cost per unit of time (e.g. per hour or day). This could then be analysed in combination with the quantity of time foregone to estimate time costs	This should reflect opportunity cost, assuming financial payment reflects economic costs (as is usually assumed in most analyses of health service costs)
Foregone productive work for which financial payment would not have been received	Possible alternatives: 1. the market value of the productive work that was foregone 2. the average wage rate for paid productive work among the population receiving the intervention 3. the cost to employ someone else to undertake the activities that were foregone 4. the minimum wage rate for unskilled labour 5. the average income or wage rate per hour/day in the area being studied	1. may be consistent with economic theory if the market value can be defined, but may overestimate given that "home production" indicates that this is less costly than "buying" what is produced in the marketplace 2. may be consistent but could overestimate (e.g. for those who are unable to find paid employment) or underestimate (e.g. for those who are choosing to do unpaid productive work in preference to paid productive work) 3. as above for 1 4. not consistent as the minimum wage rate may not accurately reflect the true economic value of unskilled labour; also, not all productive work for which financial payment is not made is "unskilled" 5. not consistent as this may under- or over-estimate the value of the work done – and as an average, it will clearly under- or over-estimate for many activities
Foregone leisure time	Possible alternatives: 1. the wage rate that would be paid to the population group targeted by the intervention for overtime labour 2. the average wage rate for paid productive work among the population group targeted by the intervention 3. the minimum wage rate for unskilled labour 4. the average income/wage rate in the area being studied 5. value time as zero	1. may be justified in theoretical terms for those already in full-time employment because, as commented, "this is the price that the employer must pay, at the margin, to buy … leisure time"[16]. Does not apply to those who are under-employed or unemployed 2. may be justified as close to what is given up to benefit from leisure time 3. not consistent (see above comments for productive unpaid work) 4. not consistent (see above comments for productive unpaid work) 5. has been suggested is common practice for a baseline analysis[17], but in many instances it seems likely that leisure time will be valued as more than zero (though its value may be closer to zero for those who are unemployed or under-employed compared to those who are in full-time employment or those already doing overtime work)

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[16] See Drummond et al, 1997 "Methods for the Economic Evaluation of Health Care Programmes", Oxford University Press, p55.

[17] See Drummond et al, 1997 "Methods for the Economic Evaluation of Health Care Programmes", Oxford University Press, p55.

Some broader criticisms can also be made.

The first relates to equity concerns. The higher the income of a patient, the higher the value of their time. Valuing time according to an individual's income leads, logically, to the cost of the time of poor people being less than the cost of the time of wealthier people. This has 2 major implications (one of which is, interestingly, the opposite of the concern that applies with the use of incomes to value benefits in cost-benefit analyses):

- when comparing across different types of interventions, interventions that tend to be used by wealthier people will appear more costly than those that primarily benefit poor people. Other things being equal, this approach will therefore make interventions that target the poor appear more cost-effective (unlike in cost-benefit analysis, where the valuation of time lost to morbidity and/or mortality tends to affect the benefits more than the costs, and where the use of patients' incomes in an analysis will tend to favour wealthier people); and

- when comparing different approaches to the delivery of any one given intervention, it is possible that the lowest cost strategy overall will benefit wealthier patients (if this strategy reduces the time they spend accessing health facilities substantially) but penalise poorer patients (by slightly increasing their costs, but not by enough to outweigh the reduction in costs that is realized by wealthier patients). This may raise equity concerns, and gender concerns too (for example if women tend to be poorer than men).

For these 2 reasons, many people may be uncomfortable with valuing time according to an individual's reported financial losses or according to the estimated value of their income. To the extent that there may be less variation in income among patients when only one disease is being considered, this will be less of a problem when assessing different strategies for a particular health care intervention (e.g. TB treatment).

A second issue is that in some instances, the inclusion of all patient costs, including travel expenditure costs and fees as well as time costs, may be considered a form of double-counting. This is because, in theory, some approaches to the valuing of intervention effectiveness (e.g. use of QALYs) may have already taken these costs into consideration[18] .

For the measures of effectiveness used in this protocol, however, this argument about time costs already being included in the valuation of the health outcomes associated with treatment does not apply. The outcome measures of cure and deaths averted do not incorporate such a valuation – it is quite possible that a TB programme will achieve equal cure rates and an equal number of deaths averted under 2 very different treatment strategies, one of which imposes much higher costs (e.g. travel expenditure or the quantity of time spent accessing treatment) than the other. In the case of the DALY, the disability weight used to value a patient's health state while they have TB (i.e. the health state associated with TB morbidity) varies according to a patient's age and whether or not they are HIV+[19]. However, it does not vary according to the type of treatment strategy used (e.g. relatively hospital-based; based almost entirely on outpatient treatment in health facilities; largely community-based with much input from non-health workers), though the patient costs associated with alternative strategies are likely to be different. Therefore, to date, the different patient costs that are likely to be associated with different treatment strategies are not reflected in the DALY measures that have been estimated for tuberculosis. An additional relevant point here is that the values given to time lived with TB morbidity in the DALY measures that have been estimated were based on expert opinion. In the case of TB at least, this may not have captured the costs incurred by patients to access TB treatment.

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[18] Though Luce et al comment that "adjustment for time in treatment is not common or accepted practice in the measurement of health-related quality of life" (see Gold et al, 1996, p180).

[19] See Murray C and Lopez A (eds) "The Global Burden of Disease" WHO 1996.

A final issue is that patients may be reluctant to provide data concerning their income/earnings, and as a consequence the data collected may not be of high quality.

5.2 Generic, practical approach to time costs consistent with the recommendations of two recent and widely used textbooks

The methodological issues highlighted above make it difficult if not impossible to handle the quantification and valuation of time costs in a way that can be agreed upon by everyone. Pragmatically, the approach in these guidelines therefore follows the suggested approaches defined in 2 recent and widely used textbooks (Gold et al, 1996; Drummond et al, 1997).

The Gold et al. book, "Cost-effectiveness in health and medicine", recommends the following:

- for those who work for pay, use the average wage rate of the population targeted by the intervention under study (for the purposes of the protocols in this chapter, this means the average income[20] among those with tuberculosis) to value time spent accessing TB treatment. Note that this method is to be used for all time, irrespective of whether the time would have been used for productive paid work, productive unpaid work, or leisure time. This is justified as follows[21]: "Although the practice of using wage rates to estimate the value of time has some drawbacks, we recommend it as a tractable means for obtaining estimates for the Reference Case Analysis[22]";

- when individuals do not do any paid work, use the hourly wage rate for individuals with similar characteristics – such as age, gender, education, labour experience – who do work for pay; and

- if time costs are a significant component of the analysis, conduct a sensitivity analysis using the average wage among the population as a whole in the area being studied, describe the effect of this on the results and encourage users of the analysis to consider this effect in their interpretation of the study.

The Drummond et al. book "Methods for the Economic Evaluation of Health Care Programmes" suggests the following for time costs associated with foregone <u>productive</u> (whether unpaid or paid) work (see p107 of this book):

- report the quantities (e.g. days of work, or normal activity lost or gained) separately from the prices used to value the quantities;

- though not directly stated, it is implied that the initial valuation of productive time lost should be estimated using a patient's reported earnings. This is implied for two reasons. First, because it is suggested that those undertaking an economic evaluation consider whether earnings adequately reflect the value of lost production. Second, it is indicated that the equity concerns that might be raised by this approach (see next point) should be considered; and

- pay attention to equity implications, and consider a sensitivity analysis to explore the impact of more equitable estimates e.g. a general wage rate rather than age, gender or disease-specific rates.

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[20] Note that "average income" is used here deliberately instead of "wage rate", because many people – especially in developing countries – are self-employed. For them, it is more appropriate to talk of an average income rather than an average wage rate.

[21] See Luce et al, Chapter 6 in Gold et al, 1996, p200.

[22] The "Reference Case Analysis" means the main analysis that is presented, before the application of sensitivity analysis.

In relation to <u>leisure</u> time, Drummond et al make the following comment (rather than suggestion): "the most common practice is to value lost leisure time as zero in the base case analysis, and to investigate the impact of other assumptions through sensitivity analysis".

It is important to note that these recommendations/suggestions are not entirely compatible (Table 5.2), though there are some strong areas of agreement. Therefore, the protocols in this chapter do the following:

- follow the points of agreement i.e. for those patients who are employed in financially rewarded productive work, the average income of the population group that receives the intervention is used to value time; a sensitivity analysis using the average wage of the population as a whole in the area being studied is recommended; and it is suggested that the estimated quantities are reported separately from their estimated money values;

- for patients who are unemployed, or who do not earn a cash income, two analyses are suggested – one valuing their time as zero (conservative approach to costs) and one valuing their time according to the average income of those patients who do earn cash income (relatively generous estimate of their time costs); and

- suggest carrying out one analysis that excludes consideration of time costs altogether[23], and commenting on the difference that this makes to the conclusions to be drawn from the analysis.

Finally, it is suggested here that if the inclusion and exclusion of time costs leads to conflicting interpretation of results (e.g. inclusion favours strategy A but exclusion favours strategy B), the analysis should be supplemented with other types of research. For example, qualitative research exploring in some detail how patients perceive the alternative treatment approaches available could be done.

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[23] Note that this is equivalent to valuing everyone's time as zero.

Table 5.2: How the recommendations of each textbook compare

Recommendations/ suggestions made in both textbooks	Where recommendations/ suggestions made are not compatible	Recommendations/suggestions made by one but not the other that nevertheless do not conflict with the other
1. Value the opportunity cost of time for those who are in paid work as the average wage among the population group receiving the intervention. 2. Pay attention to equity implications e.g. through undertaking a sensitivity analysis that uses the average wage among the population as a whole in the area studied.	1. For those who are employed or self-employed, the Gold et al recommendations imply the use of the average wage among those targeted by the intervention to estimate the cost of time spent on receiving a health care intervention. This means that the average wage is used to estimate all types of opportunity cost (whether this is foregone paid productive work, foregone unpaid productive work, or leisure time) associated with time spent receiving a health care intervention. The Drummond et al suggestions for the use of this wage apply to the opportunity cost of foregone productive time only (whether this is spent on paid or unpaid work), and not leisure time. 2. When individuals have no paid work, the Gold et al book recommends that the hourly wage rate for individuals with similar characteristics – such as age, gender, education, labour experience – who do work for pay – be used. 3. The Drummond et al book indicates that a common approach is to value leisure time as zero in a baseline analysis. This is not recommended by Gold et al (as noted in point 1., they suggest use of the average wage rate among the population group being targeted by the intervention to value leisure time).	1. The Drummond et al book suggestion that quantities (e.g. days of work, or normal activity lost or gained) should be reported separately from the prices used to value the quantities is not specifically made by Gold et al. However, the suggestion is completely consistent with the approach to costing emphasized throughout the Gold et al book - which is that quantification and valuation of all resources used should be done separately. 2. The Drummond et al book suggests considering whether earnings adequately reflect the value of lost production at the margin.

5.3 Collection and analysis of patient cost data

Sections 5.1 and 5.2 have discussed some of the issues that arise in assessing the costs incurred by patients in completing TB treatment, and what the recommendations of two major recent textbooks are. This section builds on 5.1 and 5.2 by suggesting how relevant data may be collected, and how they could be analysed. Unlike the other chapter for health services (provider) costs, however, it does not provide a ready-made data collection and analysis tool. This is because the exact nature of the costs may vary quite widely, so it is not possible to develop data collection tools that will be suitable in all settings. Guideline users should be able to use the broad guidance provided in this chapter to undertake data collection and analysis that is appropriate in their context. To assist with this, some examples of questionnaires for the assessment of patient and community costs associated with TB treatment are provided in Appendix 1.

5.3.1 Role and design of questionnaires

A questionnaire is probably the most suitable data collection tool for assessment of patient costs. The following steps should aid in the design of a suitable questionnaire and subsequently in the relevant analysis of the data collected using it.

1. Based on the management strategy(ies) being assessed, identify what costs patients are likely to incur to access TB treatment. These are likely to include some or all of the following:
    *   time and travel costs associated with visits to health facilities (e.g. the hospital outpatient department, clinics) for collection of drugs and/or observation of treatment;
    *   time and travel costs associated with visits to a volunteer supervisor;
    *   time costs associated with days spent in hospital; and
    *   payment of fees.

Note that it is important to ask about the *quantities* of time involved (minutes, hours, days), because this is useful information to report even though there is controversy about its valuation.

2. Based on the costs defined in 1, develop a simple questionnaire that can be administered to a sample of patients. Examples of the questions that are likely to be relevant are:
    *   How much does it cost you to travel to the hospital (both there and back)?
    *   How long does it take you to travel to and from the hospital (both there and back)?
    *   How much does it cost you to travel to your nearest health clinic/centre (both there and back)? and
    *   How long does it take you to travel to and from your nearest health clinic/centre (both there and back)?

If a DOT programme is in place that uses community volunteers, it is also relevant to ask:
*   How much does it cost you to travel to your supervisor (both there and back)?
*   How long does it take you to travel to your supervisor (both there and back)?

To assist with estimation of time costs, patients may also be asked about the following:
*   their estimated financial income per hour or per day. This information can be used as one source for estimating time costs[24];

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[24] It is worth noting that one reviewer of this document commented that the answers to a question like this would be meaningless for farmers, unless there is daily production and sale (as opposed to seasonal production and sale). They noted that agricultural economists have found that people cannot, or will not, answer questions about yearly income, and that it is better to use consumption as a proxy measure of income.

- what they would have been doing if they had not been spending time in hospital or spending time travelling to health care facilities/community volunteer supervisors. This may be useful in assessing the value of lost time e.g. would they have been doing household work, would they have been spending time with their family, etc. (though see above for the problems with this);
- their main occupation. This is another source of data that may be useful for valuing the cost of time, especially if the reliability of incomes reported by patients is uncertain.

Note that it is worth asking how much it costs a patient to access their nearest health facility (in terms of both travel and time costs) *even if* **they only visit a community volunteer for supervision of treatment. This is because it is then possible to assess how much the use of community volunteers can reduce the time (and costs, depending on how time is valued) involved in accessing TB treatment compared to strategies that rely on health facilities only.**

5.3.2 Pilot testing and administration of questionnaires

Once draft questionnaires have been developed, they should be pilot-tested to assess whether they are understood by patients, whether they result in useful data being collected, and whether there are any additional questions that should be asked. If necessary, questionnaires should be modified based on this pilot work.

Following questionnaire development, questionnaires should be administered to a random sample of patients. It is advisable to seek some advice from a statistician concerning sampling strategy (i.e. how to select patients) and sample size (i.e. how many patients should be interviewed), so that useful estimates of the time and travel costs of interest will be generated.

5.3.3 Protocol 1: Analysis of patient cost questionnaire data

To analyse questionnaire data, the following steps are useful.

1. Based on the data collected through administration of the questionnaire, calculate the relevant average travel costs associated with each cost item identified in step 1, 5.3.1. For example, these may include:
- the average travel cost of a visit to hospital;
- the average travel cost of a visit to the nearest health facility e.g. a health clinic (or similar non-hospital facility); and
- the average travel cost of a visit to a community volunteer supervisor.

2. For each item that includes a time cost, calculate the average time involved in non-monetary terms i.e. in terms of hours and/or minutes. For example, it may be relevant to calculate the following:
- the average time involved in making a visit to hospital;
- the average time involved in making a visit to a health clinic (or similar non-hospital facility); and
- the average time involved in making a visit to a community volunteer supervisor.

3. Calculate the estimated average cost of one hour and one day of a patient's time that is spent travelling to or staying in a health facility. Alternative estimates should be made as follows:
- for those who are in paid work (either employed or self-employed), calculate the *average income per month of interviewed patients,* and then convert this into an hourly/daily rate using reasonable assumptions about the number of hours/days a person would work in a month;

- for those who are in paid work, estimate time costs as their average income. For those who are not in paid work, estimate their time costs as zero. Then calculate a weighted average according to the proportion of patients who are in paid work and the proportion of patients who are not in paid work;

- collect data concerning the *average daily or monthly wage paid in the area being studied,* and convert this into an hourly/daily rate, using reasonable assumptions about the number of hours a person would work in a month;

- value time as zero for everyone i.e. in effect this is the same as excluding time costs from the analysis.

4. Enter the alternative estimates of time costs made in 3 on the first page of the data entry sheets for assessment of patient costs.

5. Complete Tables 1-4 in the data entry sheets to summarize patient costs according to various assumptions about time costs (note that the data entry sheets are for analysis of all patient survey data, they are not designed to be used to record the analysis for each individual patient). Those items likely to be relevant in all settings have been entered in the table; blanks have also been left for protocol users to complete for other items, if appropriate.

Important note in analysis of patient cost data: It is important to mention here that a common mistake in analysis of patient cost data is to calculate an average among only those observations where the cost is greater than zero. This is incorrect, as it results in patients reporting costs of zero not being considered in the analysis. It will result in costs being overstated. A very simple example will illustrate this point. Suppose that among 10 patients surveyed, the travel expenditure that is reported to be associated with a visit to a health clinic is as follows: US$ 0, US$ 2, US$ 0, US$ 5, US$ 4, US$ 3, US$ 0, US$ 8, US$ 5 and US$ 0.

The average is calculated as: $(0 + 2 + 0 + 5 + 4 + 3 + 0 + 8 + 5 + 0) \div 10$ i.e. US$ 2.7

It is NOT $(2 + 5 + 4 + 3 + 8 + 5) \div 6$. This may seem obvious, but is a common mistake and for that reason is highlighted here. An average, by definition, needs to be an average among all those in the sample i.e. total costs divided by total number of observations on which total costs are based.

Incremental/Marginal costs: in the case of patient costs, incremental and marginal costs are (on average!) equal to average costs.

5.4 Collection and analysis of family and volunteer cost data

The main family/community costs associated with TB diagnosis and treatment are likely to include:
- time spent by volunteers involved in directly observed therapy programmes e.g. time spent observing treatment or collecting drugs;
- time spent by family members providing care to TB patients, either at home or while they are in hospital;
- time spent by family members accompanying TB patients on visits to hospital/other health facilities;
- involvement in training activities; and
- involvement in community mobilization activities.

5.4.1 Role of Questionnaires

As for patient costs, a questionnaire is probably the easiest way to collect data on these costs. However, a balance needs to be struck between the level of accuracy achieved in assessing these costs and the time required for data collection. For example, it may be very time-consuming to collect data for all family members who spend time caring for patients. In the case of family members, a compromise could be to collect data for the main carer only.

The following two sub-sections suggest possible approaches to data collection and analysis.

5.4.2 Collection and analysis of family cost data

It is suggested that data collection focuses on the main family member providing care. Note, however, that it may not be very easy to collect family cost data unless (a) the main carer can be interviewed while the patient is in hospital or when accompanying a patient on a visit to a health facility during treatment or (b) it is feasible to visit a sample of family members at home. Family costs are likely to be most important if hospitalisation at the beginning of treatment is an important part of case management and it is common practice for family members to stay with the patient in hospital. If hospitalisation is not an important component of TB services, family costs may be relatively low. *The protocol user should bear these considerations in mind and make an informed judgement on the importance of collecting these cost data.*

If it is considered feasible and worthwhile to collect family cost data, the following steps should be useful. The focus is on costs associated with hospital stay, since it is these that are likely to be the most important.

1. Identify the major costs which the main family member providing care incurs.

2. Design a simple questionnaire that covers questions on the time and travel costs incurred by the main family member providing care, and any other costs identified in step 1. Questions may include:
- what does it cost you to visit the hospital (both there and back)?
- how many times did you visit the hospital?
- how many days did you spend attending the patient in hospital?
- what would you have been doing if you had not been at the hospital? (e.g. paid employment; work at home); and
- what is your usual average income per month (if in paid employment or self-employment).

3. Administer the questionnaire to the main carer, for the same sample of patients selected for assessment of patient costs. If patients are hospitalised for a lengthy period at treatment outset, interviews at discharge are the best way to collect the data. This is because many of the carer costs are likely to be associated with hospitalisation, and interviews at discharge mean that these can be captured (interviews at the outset of treatment will be unreliable as carers will not be able to accurately identify costs at this point).

4. Use the data collected to calculate:
- the average travel cost for a visit to hospital;
- the average time cost per day associated with providing care (conversion of time costs into monetary costs can be done in one of the ways discussed in 5.3 for patient costs);
- the average cost of any other cost items identified in step 1.

Using the data collected and analysed, complete the tables in the data entry sheets (there is one table for each of the different approaches to valuation of time costs). Some items likely to apply in many countries have been written in already: blanks also exist to be filled in as appropriate.

5.4.3 Collection and analysis of the costs incurred by volunteers involved in TB care (non-family members)

1. Identify the costs that may be incurred by volunteers involved in TB diagnosis and treatment e.g. time spent supervising therapy; time spent at DOT training sessions; time spent collecting drugs.

2. Develop a questionnaire that will facilitate collection of data on the costs identified in 1.

3. Administer the questionnaire to a sample of volunteers involved in TB care (it may be worthwhile to validate responses e.g. by asking other people who can be expected to be well-informed about the amount of time involved. This may be important because people may have an incentive to exaggerate how much time is involved, for example to illustrate that they are working hard or that some form of monetary compensation may be justified).

4. Use the data generated to estimate the average cost for each cost item relevant to volunteers providing TB care (conversion of time costs into monetary costs can be done in one of the ways discussed in 5.3 for patient costs).

5. **Complete the tables in the data entry sheets**. There is one table for each of the approaches to valuation of time costs.

An alternative would be to conduct group interviews/focus group discussions with volunteers involved in TB treatment. These could be used to estimate the average cost per patient that volunteers incur when they are involved in TB treatment. This is a relatively quick way of assessing costs.

Appendix 1

Example questionnaires

1. Example questionnaire for assessment of patient costs in Hlabisa District, South Africa, including results generated by analysis of questionnaire data

Patient cost questionnaire

Name of patient: **Male/Female:**   **Age:**

1. Where do you live?

2. When you came to hospital, did you travel by bus, by taxi, or did you walk?

3. How much did you pay for your journey to hospital (*one-way*)?

4. Approximately how long did it take you to get to the hospital? (*Include time spent walking to place from where bus/taxi was taken, if a bus/taxi was used, as well as the time actually spent on the bus/taxi.*)

5. What is the name of the health clinic nearest to where you live?

6. To get to this health clinic, would you take the bus, a taxi, or would you walk?

7. If you use a bus/taxi, how much would it cost you to get to the health clinic? (*Include cost of going there and return journey.*)

8. How long would it take you to get to the health clinic, both there and back? (*Include time spent walking to place from where bus/taxi was taken, if a bus/taxi was used, as well as the time actually spent on the bus/taxi.*)

9. Is there a Community Health Worker close to where you live?

10. How long would it take you to get to the Community Health Worker (both there and back)?

To be asked when supervisor is decided upon:

11. Who is to be your named supervisor?

12. How long does it take you to visit this named supervisor *(both there and back)*?

Note: from a separate questionnaire, the average wage per month was found to be R520. It was assumed that people work 25 days a month, and 8 hours a day, and time was valued at R0.04 per minute (i.e. R20.8 a day, R2.6 per hour, R0.04 per minute). The results generated by the data collected from the patient questionnaire, and this valuation of time, are shown below.

Results generated through analysis of questionnaire data

The data collected using the questionnaires were analysed and, using the value of time as R0.04 per minute, and using reported travel costs, the following results were obtained for the patient sample as a whole:

Average cost of a day in hospital = R17.3 (travel cost = 0; time cost = R17.3)

Average cost of a visit to hospital = R41.6 (travel cost = R29.6; time cost = R12)

Average cost of a health clinic visit = R11.1 (travel cost = R6; time cost = R5.1)

Average cost of a visit to a CHW supervisor, where a CHW was chosen as a named supervisor = R2 (travel cost = 0; time cost = R2)

Average cost of a health clinic visit for DOT, where a health clinic was chosen for DOT

$\qquad$ = R2.9 (travel cost = R0.5; time cost = R2.4)

Average cost of a hospital visit, where the hospital was chosen as the site for DOT

$\qquad$ = R4.1 (travel cost = R2.2; time cost = R1.9)

Average cost of a DOT visit to a non-health worker named supervisor

$\qquad$ = R1.4 (travel cost = 0; time cost = R1.4)

Average cost of a DOT visit in Hlabisa, with pattern of provision 21.4% using health clinics, 20.6% using CHWs, 1.7% using the hospital and 56.3% using non-health worker supervisors = {(21.4 x R2.9) + (20.6 x R2.02) + (1.7 x R4.1) + (56.3 x R1.4)} ÷ 100 = R1.9

2. Example questionnaires for assessment of patient/attendant and community volunteer costs in Kiboga District, Uganda, for "Community Care for TB in Africa" project

PATIENT/ATTENDANT COST QUESTIONNAIRE FOR KIBOGA DISTRICT

(to be administered to all TB patients *at hospital discharge* from 1 February 1998 by sub-county health workers)

Patient TB Number:

Age:

Sex:　　Male/Female (please circle as appropriate)

1. How many days did you stay in hospital?

2. What do you do for a living?

3. Are you the main source of income in your family?　　　　Yes/No

4. How many dependants do you have?

5. Did you lose any income as a result of being in hospital? (for example, due to time spent away from work, loss of job, time spent away from home etc.)

Yes/No

If yes: About how much?

6. How much time does it take to get to the hospital from your home (one-way)?

7. How much does it cost you to get to the hospital (one-way)?

8. Did you have to buy anything for staying in hospital?   Yes/No

If Yes: about how much did these things cost?

9. Can you tell me who looked after you while you were in hospital?

10. How long did the person(s) who looked after you stay at the hospital (in days)?

11. What would the person(s) who looked after you have been doing if they had not been at the hospital?

12. How many trips did the person(s) who looked after you make between the hospital and their home?

13. Did these person(s) bring you anything e.g. food, drinks, soap etc. while you were in hospital?

(Interviewer to note what was brought)

14. About how much do you think these things that were brought for you while you were in hospital cost?

15. How long does it take you to get to your nearest health facility (one-way)?

16. How much does it cost you to get to your nearest health facility (one-way)?

17. How long does it take when you go for your daily medication (one-way)?

18. How much does it cost you when you go for your daily medication (one-way)?

Appendix 2

Useful References

Textbooks

1. Drummond M, O'Brien B, Stoddart GL and Torrance GW. Methods for the Economic Evaluation of Health Care Programmes, Oxford University Press, 1997

   (see especially Chapter 5 "Cost-effectiveness analysis")

2. Gold MR, Siegel JE, Russell LB and Weinstein MC (eds). Cost-effectiveness in health and medicine, Oxford University Press, 1996

   (see especially Chapter 6 "Estimating costs in cost-effectiveness analysis" by Luce BR, Manning WG, Siegel JE and Lipscomb J)

Examples of papers in peer-reviewed journals that have assessed, or discuss, patient or volunteer costs

1. Posnett J and Jan S. Indirect cost in Economic Evaluation: the opportunity cost of unpaid inputs. *Health Economics*, 1996, Vol. 5:13-23

2. Mills A. The economic evaluation of malaria control technologies: the case of Nepal. *Social Science and Medicine*, 1992, Vol. 34 No. 9 p965-972

3. Picard J, Aikins M, Alonso PL et al. A malaria control trial using insecticide-treated nets and targeted chemoprophylaxis in a rural area of The Gambia, West Africa. *Trans R Soc Trop Med Hyg,* 1993, Vol. 87 supplement 2:53-57

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CHAPTER 6. PROTOCOLS FOR ASSESSING THE COST OF MANAGING A TB PATIENT FROM DIAGNOSIS TO TREATMENT COMPLETION

Introduction

This chapter shows how the results from using the protocols and general guidance in Chapters 4 and 5 can be used to:

- present useful data concerning the costs associated with existing TB diagnosis and treatment services; and

- assess the cost of managing a patient from diagnosis to treatment completion for existing and alternative case management strategies, and for different types of patient.

Protocol 1: Summary of the costs of individual components of diagnosis and treatment

Data required for completion of protocol

1. Completed data entry sheets for Protocols 1 through 13 in Chapter 4
2. Completed data entry sheets for patient and (if they were considered relevant) family/volunteer costs based on use of the guidelines in Chapter 5

Special note related to completion of Protocols 1 and 2 in this chapter

It is very important to avoid double-counting when presenting health system (provider), patient, and volunteer/family costs together. For example, it is possible that patients incur expenditures through payment of fees for hospitalisation (as may occur in mission facilities, for example), and that they are required to pay for X-ray and sputum smear examinations. If so, this expenditure will have been recorded using the guidelines in Chapter 5. At the same time, the full costs of providing hospital care, X-rays and sputum smear examinations should also have been analysed using the protocols for analysis of provider costs in Chapter 4.

When presenting the cost per patient treated overall, it is important that costs are not recorded twice, otherwise the total cost per patient treated will be over-estimated.

It is therefore suggested that the costs of any item that is partly funded by health services and partly financed by patient contributions is recorded under the heading of health system/provider costs. This is because the cost represents resources used within the health system (unlike expenditure by patients on transportation or special foods, for example, which represents use of resources outside the health sector). A special note can be made in the data entry sheets to note what contribution to the financing of these costs is made by patients, if such a contribution exists.

Bearing in mind the special note above, the data entry sheets for Chapter 6 Protocol 1 (see Document 2) should be completed in conjunction with the following instructions

1. Complete Table 1 using the results from the data entry sheets completed using Protocols 1 through 13 in Chapter 4 and the data entry sheets completed using the guidelines in Chapter 5.

Note that:

- some gaps have been left. These are for protocol users to enter any costs that have been estimated, but that were not specifically identified in the protocols in Chapters 4 and 5. Gaps can be left for any items for which costs were not identified or for which costs were irrelevant;

- if costs have been estimated for more than one district, the analysis in this section can EITHER be done separately for each OR an average cost for each component (for average, incremental and marginal costs) across all districts can first be calculated and then these data used in this section;

- it is probably most relevant to enter long-run marginal cost figures rather than short-run cost figures; and

- to account for different approaches to the valuation of time costs (see Chapter 5), start by using the costs that are based on one of the first 2 alternatives for estimation of time costs[25] (since these are most consistent with the recommendations of standard textbooks). The other alternative values, using the other 2 approaches to valuation of time costs, should be used in a sensitivity analysis.

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[25] i.e. these are (i) valuing time as the average wage rate among those patients receiving TB treatment who are in paid work, either employed or self-employed and (ii) valuing time as the average wage rate among patients receiving TB treatment, where those not involved in paid work have their time valued as zero.

Protocol 2: Calculating the cost of managing a TB patient from diagnosis to treatment completion, for any defined case management strategy and type of TB patient

Data required for completion of protocol

1. Precise definition of each of the strategies for diagnosis and treatment of TB patients whose costs are to be evaluated in terms of the number of times each type of cost is incurred (e.g. number of days in hospital, number of hospital outpatient visits required, number of outpatient visits to clinics/other non-hospital outpatient facilities required, number of X-rays done, number of sputum smears examined, number of sputum cultures examined, etc.). This should have already been done through completion of Exercise 1 in Chapter 3.
2. Completed Protocol 1, Chapter 6

Special note prior to using Protocol 2

Table 1, completed using Protocol 1 above, provides the basic cost data required for:

*   calculating the costs of managing a patient to treatment completion with existing services;
*   estimating the costs of managing a patient to treatment completion with alternative programme designs.

In addition, it provides the data required for assessing the costs of managing a patient to treatment completion for different types of patient e.g. new smear-positive patients, new smear-negative patients, retreatment patients.

To avoid considerable repetition in Protocol 2 below and the accompanying data entry sheets, Protocol 2 provides an *illustration* of how to calculate the total costs associated with managing a patient to treatment completion. Exactly the same principles/steps can be applied to any strategy being considered and any type of patient, as appropriate.

For any alternative strategy and for any given type of patient, the basic approach is to:

1. Define any alternative approaches to service delivery that may be considered for implementation.
2. For each alternative, repeat steps 1 to 7 in Protocol 2 below to complete tables for the analysis of alternative strategies. Protocol users may wish to focus their attention on particular types of patients or particular types of cost (e.g. restrict the analysis to average costs) - otherwise an enormous number of tables will need to be completed.

Bearing in mind the special note immediately above (p108), and the special note on p106, the data entry sheets for Chapter 6 Protocol 2 (see Document 2) should be completed in conjunction with the following instructions

1. State what strategy is being considered.
2. State the type of patient that is being considered.
3. Complete Table 2. This will result in the average cost of managing a patient to treatment completion from the perspective of health services (providers), patients, family members (if data were collected) and volunteers (if relevant) being calculated, for the strategy and type of patient specified. In column 2, note that for the final five items, enter N.A. if the item is not relevant and 1 if it is. Note that column 3 should be copied from Table 1, as appropriate. If the cost of a day in hospital has been assessed in mission/NGO facilities, enter the relevant costs in brackets in the relevant rows, i.e. those marked with an asterisk (*).

For volunteers it is important to remember that they may not be involved in the treatment of all patients. This means that to complete column 2 correctly in part (d) it is necessary to multiply the number of DOT visits and visits for collection of drugs required for a patient in whose treatment they *are* involved by the *proportion* of patients in whose treatment volunteers are involved. For example, if a volunteer is expected to visit a health clinic 6 times to collect drugs for a patient, and if volunteers are involved in the supervision of 40% (as a proportion this is 0.4) of all patients, the average number of volunteer visits per patient *across all patients* is 6 x 0.4 = 2.4. The figure of 2.4 and not 6 should be entered in column 2 of part (d). Similarly, for training of volunteers, the average cost of training per patient being supervised by a volunteer (i.e. total cost of volunteer training divided by the number of patients being supervised by volunteers) should be multiplied by the proportion of patients being supervised by volunteers.

4. At the bottom of part (a) of Table 2, note (i) the total cost of managing a patient to treatment completion when government services are used and (ii) the total cost of managing a patient to treatment completion when mission/other NGO services are used, as appropriate.

5. Complete Tables 3a and 3b. Column 2 should be copied from Table 2, as appropriate; and column 3 should be copied from columns 3 and 4 in Table 1 (from Protocol 1 Chapter 6), as appropriate. Completion of the tables results in the average incremental and marginal costs of managing a patient to treatment completion from the perspective of health services (providers) being calculated (note that for patients, family members and volunteers, marginal and incremental costs should be equivalent to average costs, so separate tables for these are unnecessary).

6. At the bottom of Tables 3a and 3b, note (i) the total incremental or marginal cost of managing a patient to treatment completion when government services are used and (ii) the total incremental or marginal cost of managing a patient to treatment completion when mission/other NGO services are used, as appropriate.

7. Complete Table 4. This results in the average, average incremental and marginal costs for health services (providers), patients, family members and volunteers being calculated for the existing diagnosis and treatment management strategy; and also the overall total cost of managing a patient to treatment completion with the existing diagnosis and treatment management strategy. Note that patient/family/volunteer costs should be copied from Table 2 parts (b), (c) and (d), with average cost = incremental cost = marginal cost. For health services, costs should be copied from the totals entered in Table 2 part (a) and Tables 3a and 3b.

Sensitivity analysis

A sensitivity analysis is an important component of any economic evaluation (see also Chapter 3). As explained in Chapter 2, a sensitivity analysis should focus on those costs and effects about which there is some uncertainty. In a sensitivity analysis of the cost of managing a patient to treatment completion, protocol users should therefore assess whether there are any particular costs about which there is some uncertainty. A range in cost estimates that seems plausible for these items can then be used to re-analyse the costs of managing a patient to treatment completion. This analysis will indicate how confident protocol users can be in the conclusions to be drawn from their analyses. This is likely to be particularly important for comparisons of the costs associated with alternative diagnosis and treatment strategies e.g. for the certainty with which it can be concluded that one approach to diagnosis and treatment is lower cost than another.

Sensitivity analyses also typically assess whether changes in the discount rate used would make any difference to the results. It is therefore suggested that the analyses are re-worked using (a) a discount rate of 0% and (b) a discount rate of 6%.

Sensitivity analyses should also explore the impact of different assumptions about the value of time costs on the results (see Chapter 5).

Finally, if considerable under- or over-utilization of services is detected (see Chapter 4 and the data entry sheets for Chapter 4), the impact on costs of changing to more optimal utilization should also be considered.

CHAPTER 7. PROTOCOLS FOR ASSESSING THE COST-EFFECTIVENESS OF TB TREATMENT

Introduction

The protocols in this chapter show how to use the results from completion of the protocols in Chapter 6 to calculate 3 different measures of cost-effectiveness for (a) existing services and (b) alternative approaches to diagnosis and treatment. The 3 measures of cost-effectiveness are:

1. cost per patient cured;

2. cost per death averted;

3. cost per disability-adjusted life year (DALY) gained.

Calculation of these measures is covered in Protocols 1 to 3 in this chapter. Protocol 1 focuses on cost-effectiveness calculations for smear-positive pulmonary TB patients; Protocol 2 focuses on cost-effectiveness calculations for smear-negative and extra-pulmonary TB patients; Protocol 3 shows how to summarize cost-effectiveness results from Protocols 1 and 2; and Protocol 4 shows how to calculate various types of incremental cost-effectiveness indicators.

It is important to emphasize at the beginning of this chapter that cost-effectiveness analyses of TB services can range from very straightforward calculations to sophisticated analyses in which effectiveness is estimated using mathematical models. While the emphasis in the protocols in this chapter is on measures of cost-effectiveness that (a) can be calculated using standard programme outcome data and (b) can be calculated by those without a background in either economics or mathematical modelling, there are some important issues related to the cost-effectiveness analysis of TB services of which it is important to be aware. Therefore, this chapter starts with a discussion of these issues. In turn, they are:

· the circumstances in which measures of cost-effectiveness that are relatively straightforward to calculate are sufficient;

· when more complicated analyses are relevant;

· the information required for more complicated analyses;

· difficulties in generating the information required for more complicated analyses;

· the role of mathematical modelling;

· the lack of a "generic" answer to the question of "what benefits (e.g. total deaths averted, total DALYs gained) are achieved through successful TB treatment, when the effect of successful treatment *beyond* the individual being treated is included?";

· the use to which mathematical models of TB have been put to date; and

· why, in the end, it may not be a major limitation if mathematical modelling cannot be employed.

The discussion ends with some recommendations concerning which type of cost-effectiveness analyses protocol users should focus on, how to justify this choice to relevant audiences (e.g. policy-makers; donor agencies), and how to explain the likely effect of a more sophisticated analysis on results.

7.1 Important issues in the application of cost-effectiveness analysis to TB treatment

7.1.1 Circumstances in which measures of cost-effectiveness that are relatively straightforward to calculate are sufficient

The first cost-effectiveness measure listed above (cost per patient cured) focuses only on the costs and effects directly associated with the individual being treated. This makes it relatively straightforward to calculate. It is also sufficient for the purposes of an economic analysis *if TB control is accepted as an important health service and the main interest is in which of the alternative strategies available for delivery of TB treatment is most cost-effective*. In other words, it is sufficient so long as it is not necessary to make comparisons with other types of health intervention where outcomes are (obviously) not measured in terms of TB cure rates.

If the aim of an analysis is to compare the cost-effectiveness of TB treatment with *other* health interventions, a more generic measure of health effect, such as deaths averted, QALYs gained, or DALYs gained, is required. Following the publication of the World Bank's World Development Report "Investing in Health" in 1993, the cost per DALY has become a widely used measure of cost-effectiveness for health interventions in developing countries. Calculating the cost per DALY for TB treatment is also not too difficult *if* the focus is restricted to the costs and effects directly associated with treated TB patients (i.e. the assessment of effects is restricted to the DALYs gained by the individual being treated, and does not consider secondary benefits that may accrue to other members of the population).

The protocols in this chapter focus on how to calculate (a) the cost per patient cured, (b) the cost per death averted and (c) the cost per DALY measures that are restricted to the direct benefits (i.e. deaths averted and DALYs gained) to the individual being treated only. DALYs are included rather than QALYs because this outcome measure has already been used for TB care and because this measure has tended to be used for developing country economic evaluations where the burden of TB is greatest. It is also the measure currently being emphasized within WHO's "Global Programme on Evidence for Health Policy".

7.1.2 When more complicated analyses are relevant

In the protocols in this chapter, use of the 3 measures listed above is restricted to the direct effect of treatment on the individual being treated. However, successful TB treatment, by removing infectious cases from the population, will prevent some new infections and some new cases (unless all transmission to others is assumed to occur prior to accessing treatment). In turn, this means that treatment *now* helps to prevent morbidity and mortality, among others, *in future*. Therefore, the benefits of treating TB cases may extend far beyond the individual actually being treated, saving life years, or gaining DALYs, in other members of the population of which the treated individual is a part.

Quantifying these secondary benefits (secondary because they accrue to those not currently being treated) *is important if the aim is to assess the value of investing in TB control compared with the value of investing in other types of health service. This is because if only the direct benefits to individuals being treated are assessed, the value of TB control programmes may be seriously under-estimated.*

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7.1.3 What information is required to quantify all benefits arising from TB control?

A cost-effectiveness analysis of TB treatment that incorporates the secondary benefits of treatment requires, ideally, 5 pieces of information. These are:

1. the total costs of TB control (i.e. the costs of implementing a TB control programme), for a given population over a given time period[26];

2. the number of deaths that would occur due to tuberculosis, in the absence of control, in the same population and over the same time period. Deaths could (fairly) readily be converted into years of life/DALYs lost due to tuberculosis;

3. the deaths that would occur due to TB in the presence of a control programme, in the same population and over the same time period. Deaths could, again, be converted into years of life/DALYs lost due to tuberculosis;

4. the morbidity that would occur due to tuberculosis, in the absence of control, in the same population and over the same time period; and

5. the morbidity that would occur due to tuberculosis, in the presence of control, in the same population and over the same time period.

Cost-effectiveness, in cost per death averted or cost per DALY terms, could then be calculated by dividing total costs (defined as the costs of implementing TB control) by total effects (with effects defined as the difference between the deaths occurring/DALYs lost without control and the deaths occurring/DALYs lost with control: the difference is the deaths averted/DALYs gained through implementation of a control programme). In other words, the cost per death averted or cost per DALY gained would be (total costs ÷ total deaths averted, or total DALYs gained). Such an analysis does not focus on the cost for a particular patient or the effect of treatment on an individual patient; it is a population-based analysis that takes account of important interactions among all individuals in that population.

7.1.4 Difficulties with acquiring the information needed to estimate secondary benefits arising from TB treatment

Unfortunately, with this population perspective, quantifying the costs and deaths/DALYs associated with different TB control scenarios is not easy.

Control scenario

In a control scenario, major determinants of treatment costs will be:

1. the number of cases registering for treatment per year;

2. the approach to diagnosis and treatment that is adopted[27].

In addition, the number of cases registering for treatment per year will be affected by several factors. Examples include:

1. the case detection rate;

2. the default rate, which affects the number of relapses;

3. the proportion of the population that is infected with the tubercle bacillus;

4. the age structure of the population (since some age groups are known to be at higher risk of progressing from infection to disease than others);

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[26] To realistically capture costs and secondary effects, a relatively long time period would need to be studied.

[27] For example, a patient management strategy that relies on extensive hospitalisation is likely to be much higher cost than one that is entirely based on outpatient treatment.

5. HIV seroprevalence, since HIV infection is known to heighten the risk of an infected individual developing disease;

6. general socioeconomic factors e.g. extent of poverty, malnutrition, overcrowding.

The benefits (effects) that are due to control will also depend on a variety of factors, including:

1. the average age at which individuals develop TB (this will be one influence on the number of life years/DALYs gained through successful treatment). This figure is likely to vary geographically;

2. the average life expectancy of a TB patient if they are cured of TB (as for average age, this will affect the number of life years or DALYs gained through successful treatment). This figure is likely to vary by country, and among regions within a country;

3. HIV seroprevalence, since the higher the HIV seroprevalence among patients, the lower the number of life years gained, on average, through successful treatment. Many HIV+ TB patients may only gain 2-3 years of life through being cured of tuberculosis, whereas an HIV-negative individual is likely to gain many more (20 to 30 years may be more typical);

4. the cure rate achieved by the control programme – the higher the cure rate, the more effective control will be;

5. the case detection rate achieved, since this will have an impact on the amount of transmission that occurs;

6. the situation prevailing when control is implemented e.g. the number of prevalent cases, the annual risk of infection, the extent of drug resistance etc.

No control scenario

The deaths or DALYs lost due to TB in a "no control" scenario will depend on similar factors, other than the cure rate and case detection rate that are relevant to a control scenario only.

With so many factors (with many more besides those identified above) affecting both the costs and effects associated with TB control, and the outcomes (deaths, DALYs, etc.) associated with no control, there is no simple way of calculating any of the 5 key pieces of information[28] required for a cost-effectiveness analysis that incorporates the secondary effects of TB treatment.

7.1.5 The role of mathematical modelling

The main analytical tool available to generate the required information is mathematical modelling. However, this is a specialized discipline that, to be done well, requires a high level of technical skills. In itself, this would not be a particularly serious limitation if modelling could be used to provide a *generic* answer to the question of how many deaths are averted, or how many DALYs are gained, by curing a TB case, including the secondary deaths averted/DALYs gained from the reduction in transmission achieved by curing that case. Then, modelling would be a one-off exercise that could be done by specialist modellers; and with such a generic figure, the cost per death averted or cost per DALY gained through TB treatment could be easily calculated as: the cost per patient cured (which is relatively easy to calculate – see 7.2 below) divided by the deaths averted/DALYs gained (through both direct and secondary effects) per patient cured.

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[28] i.e. those listed at the top of p114.

7.1.6 Lack of a "generic" answer to the question of "what benefits (e.g. total DALYs gained) are achieved through successful TB treatment, when the effect of successful treatment *beyond* the individual being treated is included?"

However, it is not possible to provide a single generic figure that applies across all countries and time periods – or even across all regions, provinces or districts within a country. This is because some of the key influences on the deaths or DALYs lost under different TB control scenarios vary geographically and over time. This is true both of general underlying factors that affect what would happen in the absence of control (e.g. annual risk of infection, proportion of the population that is infected, age structure, HIV seroprevalence, socio-economic conditions such as the degree of crowding, malnutrition, and poverty) and factors that affect the impact of control when implemented (e.g. some countries report cure rates below 60%; others report cure rates in excess of 90%; and case detection rates differ). In relation to time factors, in some parts of the world there has been a general tendency for TB to decline in importance (irrespective of whether or not TB treatment is available), while in others (e.g. sub-Saharan Africa, Russian Federation) it is resurgent; and any projections of what will happen in the future, in the presence and absence of treatment, will depend on what has been in place in the past (or at least the recent past).

7.1.7 Implications of the absence of a generic figure

Without a generic figure, use of a model that can be easily tailored to particular circumstances (which could be relatively broad e.g. typical TB control in sub-Saharan Africa) is needed. At present, this is not readily available. For the time being, therefore, illustrating how to undertake a cost-effectiveness analysis that incorporates the effect of TB treatment on the population as a whole is beyond the scope of the protocols in this chapter.

7.1.8 Use to which mathematical models of TB have been put to date

Though the protocols in this chapter do not include cost-effectiveness measures that account for the impact of TB treatment on the population as a whole, it is useful to provide a brief outline of two pieces of modelling work that have been done in recent years, and their implications for the cost-effectiveness analyses covered in the protocols.

Murray et al, 1991

One of the most widely known cost-effectiveness analyses of TB treatment, for Malawi, Mozambique and Tanzania in the late 1980s, used modelling to estimate the effectiveness of treatment (Murray et al, 1991[29]). This was also one of the background studies used in the World Bank's World Development Report 1993, and is the source of the figure that short-course TB treatment costs US$ 1–3 per DALY. This figure was important, because it indicated that TB treatment was one of the most cost-effective of all available health sector interventions. A key reason for this low figure was the substantial benefits estimated to accrue through the effect of TB treatment on the future level of TB morbidity and mortality, which was modelled over a time period of approximately 18 years. It was estimated that, in the absence of treatment, of all the deaths attributable to a given group of smear-positive pulmonary TB cases, 18% are due to "direct mortality" (i.e. mortality among the "index" group) and 82% to mortality among secondary cases that arose due to transmission from index cases. Taking into consideration the fact that

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[29] See Murray CJM, DeJonghe E, Chum HJ, Nyangulu DS, Salomao A, Styblo K. Cost-effectiveness of chemotherapy for pulmonary TB in three sub-Saharan African countries. *Lancet,* 1991, Vol.338:1305-1308.

deaths also occur when treatment is available, the number of deaths averted per smear-positive pulmonary TB case treated was approximately 3 (this figure is approximate because the exact value varied in the countries analysed, depending on the cure and death rates associated with their control programmes). For the purposes of the protocols included in this chapter, these modelling results have two important implications:

1. cost-effectiveness analyses that focus on the deaths averted or DALYs gained as an effectiveness measure may seriously under-estimate the cost-effectiveness of treatment, if they do not take secondary benefits that accrue to non-index cases into consideration;

2. this problem does not apply to the cost per cure measure of cost-effectiveness, which is related only to the individual being treated.

It is also worth pointing out that, while this modelling analysis estimated that approximately 3 deaths are averted per smear-positive case treated, this figure cannot be used as a generic one within a protocol[30]. The figure, as indicated above, applies to specific countries, which had particularly successful control programmes at the time the analysis was done ("effective" cure rates[31] of close to or more than 90%). Other things being equal, when such high cure rates are not being achieved, the deaths averted per treated case will be lower. Also, the analysis focused on smear-positive patients: the benefits of treating smear-negative pulmonary or extra-pulmonary TB patients, who may form an important share of the TB caseload (approximately 56% at global level[32]), will be lower (reflecting the fact that their transmission potential to others is much less, so that secondary benefits – estimated to account for such a large proportion of the benefits of treating smear-positive pulmonary cases – will be lower). Another reason is that the modelling results quoted above apply in the absence of an HIV epidemic; in countries heavily affected by HIV, they will almost certainly be different.

Dye et al, 1998

More recently, a model has been developed to explore the possible impact of the WHO DOTS strategy on TB incidence and death rates in various geographical regions (Dye et al, 1998[33]). This is capable of generating many useful results for the purposes of cost-effectiveness analyses, but at present is not easy for a non-modeller to use.

7.1.9 Why, in the end, it may not be a major limitation if mathematical modelling cannot be employed

Despite the fact that, ideally, a cost-effectiveness analysis would incorporate the secondary benefits arising from TB treatment, there is one major reason why failing to include them is not necessarily a serious problem. This is that, even when only the direct effects on the individual being treated are considered, TB treatment may be highly cost-effective. This means that TB treatment will compare favourably with other health interventions, even if its benefits are very conservatively estimated.

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[30] For example, it may appear that the cost per DALY could be readily calculated for any setting by dividing the cost per patient treated (calculated using Chapter 6 of Document 1) by the following equation: (3 x number of DALYs gained per death averted).

[31] The "effective" cure rate accounted for the fact that some of the patients who are not included in the cured or "treatment completed" outcome categories would actually be cured. In calculating the effective cure rate, it was assumed that 65% of those who default or transfer from their district of registration during treatment.

[32] See Dye C et al. Global Burden of Tuberculosis: estimated incidence, prevalence and mortality by country. *JAMA*, 1999, Vol. 282:677-686.

[33] Dye C, Garnett GP, Sleeman K, Williams BG. Prospects for world-wide TB control under the WHO DOTS strategy. *Lancet*, 1998, Vol.352:1886-1891.

7.1.10 Recommendations

Based on this discussion, the following is suggested:

1. focus initially on the direct effects among treated cases using the 3 cost-effectiveness measures noted earlier (cost per case cured, cost per death averted, cost per DALY gained). This can be justified on the grounds that quantifying the effects of treatment that extend beyond the individual being treated requires mathematical modelling, that this requires specialist skills, and that there is no generic figure that can be used by a non-modeller to estimate all the benefits that may accrue from TB treatment. In addition, existing analyses indicate that TB treatment is cost-effective even when direct effects only are considered i.e. when the estimate of cost-effectiveness is conservative;

2. in presenting results that use a generic measure of health effect (e.g. the DALY), point out that, when the cost per DALY includes only direct effects, it under-estimates cost-effectiveness because the secondary benefits that accrue from the effect of treatment on onward transmission have not been accounted for. It could also be pointed out that one modelling exercise has suggested that, for smear-positive cases, these secondary benefits account for 82% of all of the benefits due to TB treatment;

3. compare the cost per DALY figure that only accounts for the direct impact of treatment with cost per DALY figures for other types of health intervention– they may compare very favourably. For guidance, it has been suggested that in low to middle-income countries, a cost per DALY of less than US$ 25-30 is "highly attractive", and a cost per DALY of less than US$ 150 is "attractive"[34]. These are very general benchmarks, but may be useful indicators. Results can also be compared with those estimated in the World Bank's World Development Report 1993.

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[34] See WHO. Investing in health research and development. Report of the ad hoc Committee on Health Research Relating to Future Intervention Options. WHO, 1996.

Protocol 1: Cost-effectiveness calculations for smear-positive pulmonary TB patients

Protocol 1a: Cost per patient cured

Data required for completion of protocol

1. Standard treatment outcome data for a cohort of patients, recorded according to the treatment outcome categories recommended by WHO
2. Completed data entry sheets for Protocol 2 Chapter 6 for each type of treatment strategy for which cost-effectiveness is to be evaluated for smear-positive TB patients

The data entry sheets that accompany this protocol (see Document 2) should be completed by following the instructions provided below.

At the top of the data entry sheet, state the type of case management strategy for which the cost-effectiveness analysis is to be undertaken (e.g. existing management strategy; alternative strategy of community-based DOT; hospital-based approach used until 1999). Then complete Table 1, using programme outcome data.

1. Calculate the minimum cure rate achieved in government services using the equation provided (note that this is a minimum because it is based only on those patients who are known to have been cured or to have completed treatment, even though some patients in the defaulting/ transferred out categories may also have been cured).
2. Calculate the maximum cure rate achieved in government services using the equation provided (note that this is a maximum because it assumes that the same cure rate would occur among those patients who defaulted or transferred out as the cure rate among those for whom treatment outcomes are known).
3. Calculate the minimum cure rate achieved in mission services using the equation provided.
4. Calculate the maximum cure rate achieved in mission services using the equation provided.

Complete Table 2, using (a) the cost data from the data entry sheets completed using Protocol 2 in Chapter 6 and (b) the cure rates calculated in steps 1 to 4.

5. Calculate the estimated cure rate that would apply without treatment using the equation provided (note that this assumes a self-cure rate of 20% in the absence of treatment for individuals who are not otherwise immuno-compromised, as suggested by natural history data; and a self-cure rate of 0% for those who are HIV+).
6. Calculate the minimum cost per patient cured in government services using the equation provided.
7. Calculate the maximum cost per patient cured in government services using the equation provided.
8. Calculate the minimum cost per patient cured in mission services using the equation provided.
9. Calculate the maximum cost per patient cured in mission services using the equation provided.

Protocol 1b: Cost per death averted

Data required for completion of protocol

1. Standard treatment outcome data for a cohort of patients, recorded according to the treatment outcome categories recommended by WHO

2. Completed data entry sheets for Protocol 2 Chapter 6 for each type of treatment strategy for which cost-effectiveness is to be evaluated for smear-positive TB patients

The data entry sheets that accompany this protocol (see Document 2) should be completed by following the instructions provided below.

1. Estimate the minimum death rate in government services that applies when TB treatment is available using the equation provided (note that this is a minimum because it assumes that the death rate that applies among all patients for whom treatment outcomes are known[35] also applies to those patients who default from treatment or who transferred out of the district during treatment).

2. Estimate the minimum death rate that would apply in the absence of treatment using the equation provided.

3. Estimate the maximum death rate that would apply in the absence of treatment using the equation provided.

4. Estimate the maximum death rate that applies in the presence of TB treatment in government services using the equation provided (note that this assumes that the death rate that occurs without treatment would apply to all those who default from treatment or who transfer out of the district during treatment).

5. Calculate the minimum cost per death averted in government services using the equation provided.

6. Calculate the maximum cost per death averted in government services using the equation provided.

7. Estimate the minimum death rate that would apply in the presence of TB treatment in mission facilities using the equation provided.

8. Estimate the minimum death rate that would apply in the absence of treatment in mission facilities using the equation provided.

9. Estimate the maximum death rate that would apply in the absence of treatment using the equation provided.

10. Estimate the maximum death rate that applies in mission facilities in the presence of treatment in government facilities.

11. Estimate the minimum cost per death averted in mission facilities using the equation provided.

12. Estimate the maximum cost per death averted in mission facilities using the equation provided.

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[35] This is why the death rate is divided by (100 – e – f) i.e. the total percentage of patients for whom outcomes are known.

Protocol 1c: Cost per DALY gained

Data required for completion of protocol

1. Standard treatment outcome data for a cohort of patients, recorded according to the treatment outcome categories recommended by WHO

2. Completed data entry sheets for Protocol 2 Chapter 6 for each type of treatment strategy for which cost-effectiveness is to be evaluated for smear-positive TB patients

3. Completed data entry sheets for Protocol 1b, Chapter 7 (specifically, the cost per death averted is required)

4. Average age of TB patients in the area being studied

5. Life expectancy in the area being studied, at the average age of TB patients

Some introductory notes related to estimating the cost per DALY gained

The cost per DALY gained through TB treatment can be estimated based on the cost per death averted, *provided* the number of DALYs gained per death averted can be estimated. This is not straightforward. The number of DALYs gained per death averted is the difference between the following:

- the number of DALYs gained with treatment, which depends on the number of years of life gained with treatment, the disability weighting attached to these years, and the ages at which these years are gained (a); and

- the number of DALYs associated with a death due to untreated tuberculosis, from the time a person develops TB until the time that they die from it (b). Immediate death from TB is rare and the evidence indicates that some people with untreated TB can survive for more than five years.

In other words, the number of DALYs gained per death averted is (a) – (b).

The number of DALYs gained with treatment, (a), can be estimated using the standard formula for calculating DALYs (see Appendix 2). This requires information on the age of TB patients, life expectancy at the age at which TB is developed, and the disability weighting that would be associated with these years of life. Not all of the years gained would be at full health. However, for premature mortality it is typically assumed in DALY calculations that the years gained are in full health.

Estimating the DALYs associated with untreated TB (b) is more difficult. This requires good data concerning the natural history of tuberculosis, ideally for a representative cohort where everyone is followed from the time they develop TB to the time that they die. The best data available are probably from India. In a 5-year epidemiological study of cases with *untreated smear-positive pulmonary tuberculosis*, it was found that less than 50% of cases had died after 5 years of follow-up (see Murray et al, 1990)[36] . Among those who died, the average years of life lived was approximately 2. Allowance for self-cure (around one-third of patients in the India study) is allowed for in the cost per death averted calculations (since a 64% mortality rate is estimated overall for untreated TB in these calculations). Therefore, it seems reasonable to assume that the number of years of life associated with *untreated smear-positive pulmonary* tuberculosis, among those who die from it, is approximately 2. Given the paucity of this type of natural history data for smear-negative pulmonary and extra-pulmonary TB patients, the same assumptions are applied for this group[37] .

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[36] The full reference is: Murray CJL, Styblo K, Rouillon A. TB in developing countries: burden, intervention and cost. *Bull Int Union Tuberc Lung Dis,* 1990; 65:2-20.

The number of DALYs associated with these 2 years can be estimated using the standard DALY formula. The key pieces of information required are the disability weightings (estimated for untreated TB in "The Global Burden of Disease" studies as 0.264 for adults aged 15-44 and 0.274 for adults aged 45 and over[38]) and the age of TB patients.

Simplifying assumptions and ready-calculated values

The DALY formula is not particularly easy to use. Therefore, these protocols use some simplifying assumptions and some already-calculated values are provided.

Ready-calculated values

Table 1, in Appendix 1 of this chapter, can be used to estimate the number of DALYs gained per averted death among those treated *and who are HIV-negative*. To use this table, all that is required is to know the average age of a TB patient, and the average life expectancy of a TB patient at that age. The average age of a patient can be estimated from a random sample of existing patients (a statistician should be consulted regarding appropriate sample size); the average life expectancy at that age can be estimated from life tables (a demographer may be consulted for assistance with the analysis of life tables and for advice concerning local sources of life table data[39]). With these 2 pieces of information, the estimated number of DALYs can be read off from the table. For example, if the average age of TB patients is 33, and the average life expectancy at age 33 is 30 years, the number of DALYs gained by averting a death is 23. If the average age of TB patients is 30, and the average life expectancy at age 30 is 40 years, the number of DALYs gained per death averted is 27.

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Simplifying assumptions

For HIV-negative TB patients who do not receive treatment, it is assumed that the period from developing TB through to death would be associated with 2 DALYs. This is because, for the age range 15-44 years, 2 years of life with a disability weighting of 0.264 (which for DALYs means that 1 year of life is equivalent to 0.736 DALYs) is equivalent to 2 DALYs (when the number of DALYs is rounded to the nearest whole number). In most if not all parts of the world, the average age of TB patients will fall within the range 15-44, so that this seems an acceptable assumption.

For HIV+ TB patients, the protocols assume that 3 DALYs would be gained. This estimate is considered reasonable because if a disability weighting of 0.264 is assumed (i.e. one year of life is worth 0.736 DALYs) and it is assumed that HIV+ patients who are cured of TB live for approximately another 3 years, the number of DALYs gained is 3 for the age range 15-44 (when the number of DALYs is rounded to the nearest whole number). Since the majority of HIV+ TB patients are likely to fall within this age range, and since existing follow-up data concerning the outcomes of HIV+ TB patients suggests that 3 years is a reasonable estimate of the expected years of life for HIV+ TB patients, this seems an acceptable assumption.

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[37] Since the net DALYs gained are most influenced by years of life gained among those who are treated and cured, results calculated should not be particularly sensitive to the estimated DALYs associated with untreated TB from the time of developing the disease until the time of death.

[38] Where 0 is defined as perfect health and zero as death - see also Chapter 2.

[39] While a relatively minor point, it is worth noting that, typically, standard life tables (which are most commonly used for estimating life expectancy at different ages) slightly underestimate the benefits of an intervention. This is because cohort life expectancy (i.e. the life expectancy, for each age, of those currently alive at that age) is usually higher, due to the tendency for life expectancy to have increased over time. Note that one exception may be countries seriously affected by the HIV epidemic, where the opposite may be true and standard life tables may overestimate cohort life expectancy.

Based on the above assumptions, the cost per DALY can be estimated using the instructions provided below.

The data entry sheets that accompany this protocol (see Document 2) should be completed by following the instructions provided below.

1. Estimate the number of DALYs gained per death averted for HIV- patients, using Table 1 in Appendix 1 of this chapter. Note that, as explained above, the number of DALYs estimated to be gained per death averted depends on the average age of a TB patient and the age to which they would be expected to live. Since these figures will vary by location, Appendix 1 in this chapter provides the number of DALYs gained for several possible combinations of average age and life expectancy at that age. The relevant number can be read off from this table, or alternatively calculated using the standard DALY formula provided in Appendix 2 of this chapter. The formula may be difficult for some people to use, which is why the alternative of using already-calculated values is provided.

2. Estimate the <u>net number</u> of DALYs gained per HIV- patient treated by subtracting 2 DALYs from the total DALYs estimated in step 1.

3. Estimate the number of DALYs gained per death averted for HIV+ patients as 3 and enter this figure in the data entry sheets.

4. Estimate the *<u>overall net number</u>* (i.e. across both HIV+ and HIV- patients) of DALYs gained per death averted using the equation provided.

5. Estimate the minimum cost per DALY gained through treatment in government services using the equation provided.

6. Estimate the maximum cost per DALY gained through treatment in government services using the equation provided.

7. Estimate the minimum cost per DALY gained through treatment in mission services using the equation provided.

8. Estimate the maximum cost per DALY gained through treatment in mission services using the equation provided.

Protocol 2: Cost-effectiveness calculations for smear-negative pulmonary and extra-pulmonary TB patients

Protocol 2a: Cost per patient cured

Data required for completion of protocol

1. Standard treatment outcome data for a cohort of patients, recorded according to the treatment outcome categories recommended by WHO.

2. Completed data entry sheets for Protocol 2 Chapter 6 for each type of treatment strategy for which cost-effectiveness is to be evaluated for smear-negative and extra-pulmonary TB patients.

The data entry sheets that accompany this protocol (see Document 2) should be completed by following the instructions provided below.

At the top of the data entry sheet, state the type of case management strategy for which the cost-effectiveness analysis is to be undertaken (e.g. existing management strategy; alternative strategy of community-based DOT; hospital-based approach used until 1999). Then complete Table 1, using programme outcome data.

1. Write down the estimated minimum cure rate achieved in government services i.e. this is the proportion of patients known to have completed treatment (a) in Table 1.

2. Calculate the maximum cure rate achieved in government services using the equation provided (note that the equation is based on the fact that the maximum cure rate occurs if those who default from treatment or who transfer out of the district of registration during treatment have the same outcomes as those for whom treatment outcomes are known).

3. Write down the minimum cure rate achieved in mission services i.e. this is the proportion of patients known to have completed treatment (a) in Table 1.

4. Calculate the maximum cure rate achieved in mission services using the equation provided.

Complete Table 2 using the average cost to manage a patient to treatment completion calculated using the protocols in Chapter 6, and the minimum and maximum cure rates calculated in steps 1 to 4.

5. Calculate the estimated cure rate that would apply without the availability of treatment using the equation provided.

6. Calculate the minimum cost per patient cured in government services using the equation provided.

7. Calculate the maximum cost per patient cured in government services using the equation provided.

8. Calculate the minimum cost per patient cured in mission services using the equation provided.

9. Calculate the maximum cost per patient cured in mission services using the equation provided.

Protocol 2b: Cost per death averted

Data required for completion of protocol

1. Standard treatment outcome data for a cohort of patients, recorded according to the treatment outcome categories recommended by WHO

2. Completed data entry sheets for Protocol 2 Chapter 6 for each type of treatment strategy for which cost-effectiveness is to be evaluated for smear-negative and extra-pulmonary TB patients

The data entry sheets that accompany this protocol (see Document 2) should be completed by following the instructions provided below.

Government services

1. Estimate the minimum death rate that applies when TB treatment is available using the equation provided.

2. Estimate the death rate that would apply in the absence of treatment using the equation provided.

3. Estimate the maximum death rate that applies when TB treatment is available using the equation provided.

4. Calculate the estimated minimum cost per death averted using the equation provided.

5. Calculate the maximum cost per death averted using the equation provided.

Mission services

6. Estimate the minimum death rate that applies when TB treatment is available using the equation provided.

7. Estimate the death rate that would apply in the absence of treatment using the equation provided.

8. Estimate the maximum death rate that applies when TB treatment is available using the equation provided.

9. Calculate the estimated minimum cost per death averted using the equation provided.

10. Calculate the maximum cost per death averted using the equation provided.

Protocol 2c: Cost per DALY gained

Data required for completion of protocol

1. Standard treatment outcome data for a cohort of patients, recorded according to the treatment outcome categories recommended by WHO.

2. Completed data entry sheets for Protocol 2 Chapter 6 for each type of treatment strategy for which cost-effectiveness is to be evaluated for smear-negative and extra-pulmonary TB patients.

3. Completed data entry sheets for Protocol 2b, Chapter 7 (specifically, the cost per death averted is required).

4. Average age of TB patients in the area being studied.

5. Life expectancy in the area being studied, at the average age of TB patients.

The data entry sheets that accompany this protocol (see Document 2) should be completed by following the instructions provided below.

1. Estimate the number of DALYs gained per death averted for HIV- patients, using Table 1 in Appendix 1 of this chapter. Note that, as explained above (see p120-121), the number of DALYs estimated to be gained per death averted depends on the average age of a TB patient and the age to which they would be expected to live at that age. Since these figures will vary by location, Appendix 1 in this chapter provides the number of DALYs gained for several possible combinations of average age and life expectancy. The relevant number can be read off from this table, or alternatively calculated using the standard DALY formula provided in Appendix 2. The formula may be difficult for some people to use, which is why the alternative of reading already-calculated values is provided as an alternative.

2. Estimate the net number of DALYs gained per HIV- patient treated by subtracting 2 DALYs from the total DALYs estimated in step 1.

3. Estimate the number of DALYs gained per death averted for HIV+ patients as 3 and enter this figure.

4. Estimate the *overall net number* (i.e. across both HIV+ and HIV- patients) of DALYs gained per death averted using the equation provided.

5. Estimate the minimum cost per DALY gained through treatment in government services using the equation provided.

6. Estimate the maximum cost per DALY gained through treatment in government services using the equation provided.

7. Estimate the minimum cost per DALY gained through treatment in mission services using the equation provided.

8. Estimate the maximum cost per DALY gained through treatment in mission services using the equation provided.

Protocol 3: Summary of cost-effectiveness indicators

Data required for completion of protocol

1. Data from completed versions of Protocols 1a through 1c and 2a through 2c, Chapter 7
2. Average US$:local currency exchange rate in the year for which costs have been evaluated, if costs have not previously been recorded in US$

The data entry sheets that accompany this protocol (see Document 2) should be completed by following the instructions provided below.

1. Complete Tables 1 and 2 in the data entry sheets by using the results from Protocols 1 and 2. These tables will result in a useful summary of the cost-effectiveness of TB services using different measures of cost-effectiveness. Note that the cost-effectiveness indicators should be recorded in US$. This is because cost per DALY figures are usually quoted in dollars, and US$ figures are generally more useful for making both international comparisons, and comparisons with other health interventions. This means that the costs expressed in local currency should be divided by the number of units of local currency that are equivalent in value to US$ 1. Ideally the average exchange rate for the year for which cost data have been collected should be used. This should be available from a source such as the Central Bank, the Ministry of Finance or the Ministry of Economic Planning and Development.

Special note on using the data entry sheets for multiple analyses (i.e. for several alternative approaches to treatment) of the cost-effectiveness of TB treatment

For each alternative approach to delivery whose costs were assessed using the protocols in Chapter 6, the steps in Protocols 1a through 1c, 2a through 2c and 3 should be repeated. Extra copies of the data entry sheets should be made for this purpose. These are not reproduced in Document 2 to avoid the document becoming overly lengthy.

Note that the effectiveness of each alternative will have to be estimated based on either (a) informed judgement (b) results from pilot projects in particular districts or (c) effectiveness (outcome) data from other countries where a similar management strategy has been implemented.

Protocol 4: Incremental cost-effectiveness analysis

If the results show that the most effective strategy is also the most costly, an incremental cost-effectiveness analysis is relevant. This asks the question "What is the additional cost per additional unit of effectiveness?" e.g. what is the additional cost per additional patient cured?

The incremental cost-effectiveness of the most effective strategy can be calculated as explained below. ***Data entry sheets for these calculations are not provided in Document 2, since the calculations can be readily made using one of the equations provided below.***

Protocol 4a: Incremental cost per case cured

Data required for completion of protocol

1. Completed data entry sheets for Protocol 2 in Chapter 6
2. Completed data entry sheets for Protocols 1a and 2a in Chapter 7

The incremental cost per case cured can be calculated using the following equation:

{(average cost to manage a patient to treatment completion in most effective but higher cost strategy x 100) - (average cost to manage a patient to treatment completion with less effective but lower cost strategy x 100} ÷ (cure rate achieved in most effective but higher cost strategy - cure rate achieved in less effective but lower cost strategy)}.

Protocol 4b: Incremental cost per death averted

Data required for completion of protocol

1. Completed data entry sheets for Protocol 2 in Chapter 6
2. Completed data entry sheets for Protocols 1b and 2b in Chapter 7

The incremental cost per death averted treatment can be calculated using the following equation:

{(average cost to manage a patient to treatment completion with higher cost and more effective strategy x 100) – (average cost to manage a patient to treatment completion lower cost and less effective strategy x 100)} ÷ (estimated death rate with higher cost and more effective strategy – estimated death rate with lower cost but less effective strategy).

Protocol 4c: Incremental cost per DALY gained

Data required for completion of protocol

1. Completed data entry sheets for Protocol 2 in Chapter 6
2. Completed data entry sheets for Protocols 1b and 2b in Chapter 7

The incremental cost per DALY gained can be calculated using the following equation:

(incremental cost per death averted ÷ average number of DALYs gained per death averted).

Sensitivity analysis

As with the analysis of the cost of managing a patient to treatment completion in Chapter 6, a sensitivity analysis is recommended for any cost-effectiveness analysis. In this case, there may be uncertainty concerning both costs and effects (rather than only costs, as in Chapter 6). It is therefore suggested that sensitivity analysis is conducted both (a) using the range in costs estimated in the sensitivity analysis for the cost of managing a patient to treatment completion and (b) using a range of effectiveness estimates – especially if some cost-effectiveness estimates have been made using data from other countries/regions or from pilot projects. The results from these sensitivity analyses will indicate how robust are the conclusions to be drawn from the analysis.

Appendix 1: DALYs gained per death averted

Table 1: DALYs gained per death averted for a variety of plausible average ages of TB patients and average life expectancy at that age

Average life expectancy at average age of TB patients (years)	Average age of TB patients (years)										
	25	26	27	28	29	30	31	32	33	34	35
25	24	24	23	23	23	23	22	22	22	21	21
26	25	24	24	24	23	23	23	22	22	22	21
27	25	25	24	24	24	23	23	23	22	22	22
28	25	25	25	25	24	24	23	23	23	22	22
29	26	26	25	25	25	24	24	23	23	23	22
30	26	26	26	25	25	25	24	24	23	23	23
31	27	26	26	26	25	25	25	24	24	23	23
32	27	27	26	26	26	25	25	24	24	24	23
33	27	27	27	26	26	26	25	25	24	24	24
34	28	27	27	27	26	26	25	25	25	24	24
35	28	28	27	27	27	26	26	25	25	24	24
36	28	28	28	27	27	26	26	26	25	25	24
37	29	28	28	28	27	27	26	26	25	25	24
38	29	29	28	28	27	27	26	26	26	25	25
39	29	29	28	28	28	27	27	26	26	25	25
40	29	29	29	28	28	27	27	26	26	26	25
41	30	29	29	28	28	28	27	27	26	26	25
42	30	29	29	29	28	28	27	27	26	26	25
43	30	30	29	29	28	28	27	27	27	26	26
44	30	30	29	29	29	28	28	27	27	26	26
45	30	30	30	29	29	28	28	27	27	26	26
46	31	30	30	29	29	28	28	27	27	27	26
47	31	30	30	29	29	29	28	28	27	27	26
48	31	31	30	30	29	29	28	28	27	27	26
49	31	31	30	30	29	29	28	28	27	27	26
50	31	31	30	30	29	29	28	28	27	27	26
51	31	31	30	30	30	29	29	28	28	27	27
52	31	31	31	30	30	29	29	28	28	27	27
53	32	31	31	30	30	29	29	28	28	27	27
54	32	31	31	30	30	29	29	28	28	27	27
55	32	31	31	30	30	29	29	28	28	27	27
56	32	31	31	31	30	30	29	29	28	28	27
57	32	32	31	31	30	30	29	29	28	28	27

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Appendix 2: Formula for calculating DALYs

The formula for calculating DALYs is as follows:

$$-[\{DCe^{-\beta a}\} \div \{(\beta+r)^2\}] \times [\{e^{-(\beta+r)L}(1 + (\beta+r)(L+a)\} - \{(1 + (\beta+r)a\}]$$

where:

D = disability weight (1 for premature mortality)

C = age-weighting correction constant, assumed to be 0.16243 in standard DALY calculations

ß = parameter from age-weighting function, assumed to be 0.04 in standard DALY calculations

r = discount rate, with 0.03 (i.e. 3%) used in standard DALY calculations

L = time lost to disability/premature mortality

a = age of onset

(For full explanation of derivation of formulae, see Murray CJL. Quantifying the burden of disease: the technical basis for disability-adjusted life years. *Bulletin of the World Health Organization,* 1994, *72(3):429–445*)

Appendix 3: Explanation of how cost-effectiveness calculations, that incorporate the effect of treatment on prevented onward transmission, were undertaken in the study of Malawi, Mozambique and Tanzania that was used in the World Bank s World Development Report 1993

The cost-effectiveness analysis of TB treatment in Malawi, Mozambique and Tanzania, which was one of the background studies for the World Bank's World Development Report 1993, has been widely cited and used to justify investment of public sector resources in TB programmes. One of the important aspects of this analysis is that it used mathematical modelling to estimate the effectiveness of TB treatment. This allowed the inclusion not only of the benefits of treatment for the individual being treated (the focus for analysis in the protocols in Chapter 7), but also the secondary benefits associated with prevention of onward transmission to others. As highlighted in 7.1 above, this is important for capturing the full effectiveness of TB treatment – particularly in the case of sputum smear-positive cases, who are most infectious. Indeed, the study focused on this sub-set of patients, and the key results from the analysis that are typically quoted are not directly applicable to smear-negative and extra-pulmonary TB patients, who may form a substantial share – sometimes a majority – of TB programmes' caseloads (though cost-effectiveness could conceivably be similar if the costs of treatment are sufficiently lower to compensate for more limited treatment benefits).

Given the importance of this study, this appendix explains, in brief, the assumptions and key modelling results that formed the basis of the cost-effectiveness calculations undertaken. For fuller details, the best reference is a paper published in 1994: DeJonghe E, Murray CJL et al Cost-effectiveness of chemotherapy for sputum smear-positive pulmonary TB in Malawi, Mozambique and Tanzania, International Journal of Health Planning and Management, Vol. 9 p151-181[41].

Programme costs were calculated using standard methods, with average, average incremental and marginal costs presented. Mathematical modelling was then used to estimate the benefits of treatment in terms of deaths averted. A description and explanation of the modelling itself is beyond the scope of this Appendix. However, the key results quoted from this analysis, and used in the cost-effectiveness analysis, were:

· of all deaths that would be associated with an untreated smear-positive pulmonary TB patient, 18% would be associated with the "index" case; and

· of all deaths that would be associated with an untreated smear-positive pulmonary TB patient, 82% would be associated with onward transmission of the disease from the index case to other members of the population.

Three other assumptions were then important in the analysis of effectiveness:

· 65% of treated patients in the outcome categories "transferred out" and "defaulted" would be cured[42]. This meant that what was termed the "effective cure rate" was calculated as: [% of patients cured + % of patients completing treatment + {0.65 x (% of patients defaulting + % of patients who transferred during treatment)}];

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[41] The best-known reference is probably Murray CJL, DeJonghe E, Chum HJ, et al. Cost-effectiveness of chemotherapy for pulmonary TB in three sub-Saharan African countries. *Lancet*, 1991, Vol. 338:1305-1308. However, methods (both in terms of costing and estimation of effectiveness) are discussed at greater length in the 1994 paper.

- 5% of all cases diagnosed as smear-positive pulmonary TB cases would be "false-positives" i.e. 5% of programme costs would be consumed by treatment of individuals without tuberculosis. This meant that the cost per true positive case treated was calculated as: 1.05 times[43] the cost of treating one patient diagnosed with tuberculosis;
- the death rate in the absence of treatment for new smear-positive pulmonary TB cases would be 64%.

Using these assumptions and results, the calculation of the cost per death averted by TB treatment, allowing for the benefits to the individual being treated only, can be represented in the following equation:

Cost per direct death averted =

$$\{(\text{cost per patient treated} \times 1.05) \times 100\} \div \{64 - (100 - \text{effective cure rate})\}$$

Note that multiplying by 100 allows for the fact that for every 100 patients treated, the number of deaths averted will be the difference between the mortality rate (64 per 100 patients) and the number of patients per 100 patients treated who are not cured (i.e. 100 – effective cure rate). The difference in the number of deaths without treatment and with treatment is used in the calculation because it represents the *net* direct benefits of treatment due to a TB programme.

Also using these assumptions and results, the calculation of the cost per death averted by TB treatment, *including* the benefits for both the index case *and* those to whom transmission is prevented, can be represented by the following equation:

Cost per total death averted = Cost per direct death averted ÷ 0.18

Or, alternatively, as

$$\{(\text{cost per patient treated} \times 1.05) \times 100\} \div [\{(64 - (100 - \text{effective cure rate})\} \div 0.18]$$

Note that dividing by 0.18 accounts for the fact that the deaths averted among individuals treated were estimated using modelling to represent only 18% of the total deaths that would be associated with an untreated TB patient.

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[42] Note that this protocol has used minimum and maximum estimates of the cure rate instead of this assumption. The assumption of a 65% cure rate among those for whom treatment outcomes are not known will produce a value in between these two extremes.

[43] 1.052 to be exact i.e. cost to treat one true case = 100/95 times the cost per case treated, since to treat 95 cases correctly 100 cases are treated in practice.

CHAPTER 8. PROTOCOLS FOR ESTIMATING THE TOTAL COST OF TB DIAGNOSIS AND TREATMENT SERVICES AT DISTRICT, REGIONAL AND NATIONAL LEVEL

Introduction

The protocols in this chapter show how to use the results of the analyses undertaken in previous chapters to estimate the total health services (provider) costs of TB diagnosis and treatment services at district, regional and national level. The protocols focus on health services (provider) costs because estimating the total cost of TB diagnosis and treatment services is of most relevance to health services (providers). For example, estimates of the total cost of diagnosis and treatment services may be useful for the purposes of budget planning.

The protocols should be used ONLY when the costing analysis in all the districts selected for costing has been completed. Note that in the data entry sheets, region or province can be deleted, as appropriate.

The word estimate (rather than calculate) has been used in the protocols, for two main reasons:

- the costs of TB services in districts where costs have *not* been assessed are unlikely to be exactly the same as those in the districts for which costs *have* been assessed. Therefore, the costs that apply in the districts where a costing analysis has been undertaken can only be seen as estimates of the costs that apply elsewhere;
- if costs at district level have not been estimated in all hospitals within that district, total costs at district level will also only be an estimate.

Protocol 1: Estimates of the total cost of TB services at district level

Data required for completion of protocol

1. Completed data entry sheets for Protocol 2 in Chapter 6
2. Annual number of TB patients diagnosed and treated in each district for which costs were assessed

The data entry sheets that accompany this protocol (see Document 2) should be completed by following the instructions provided below

1. Complete Tables 1a and 1b. This results in the total costs associated with TB services in each of the districts for which costs have been assessed being calculated for (a) government and (b) mission/other NGO services.

   Note that similar tables can be constructed for any district in which there is an interest in assessing the total costs of TB services. For each district for which total costs are to be assessed, use either (a) the average cost per patient <u>across all districts</u> in which costs have been assessed or (b) the average cost per patient in the district <u>considered to be most similar</u> to the district for which total costs are being estimated.

2. Complete Table 2. Column 2 should be completed by adding together the total costs calculated for government and mission/other NGO services in step 1 and entered in Tables 1a and 1b.

Protocol 2: Estimates of the total cost of TB services at regional/provincial level

Data required for completion of protocol

1. Completed data entry sheets for Protocol 2 in Chapter 6
2. Annual number of TB patients diagnosed and treated in each region/province for which costs were assessed

The data entry sheets that accompany this protocol (see Document 2) should be completed by following the instructions provided below

1. For government services, record EITHER (a) the average cost of managing a patient to treatment completion <u>across all districts</u> in the region/province for which costs have been assessed OR (b) the average cost to manage a patient to treatment completion in the district(s) <u>considered to be most representative</u> of the region/province for which total costs are being estimated.

2. For mission/other NGO services, record EITHER (a) the average cost of managing a patient to treatment completion <u>across all districts</u> in the region/province for which costs have been assessed OR (b) the average cost to manage a patient to treatment completion in the district(s) <u>considered to be most representative</u> of the region/province for which total costs are being estimated.

3. Note the annual number of TB patients diagnosed in the region/province in government facilities.

4. Note the annual number of TB patients diagnosed in the region/province in mission/other NGO facilities.

5. Estimate the total costs associated with TB services provided through government facilities by multiplying the average cost estimated in 1 by the total number of patients recorded in 3.

6. Estimate the total costs associated with TB services provided through mission/other NGO facilities by multiplying the average cost per patient estimated in 2 by the total number of patients recorded in 4.

7. Add together the estimated total cost of services provided in government and mission/other NGO facilities. This gives the estimated total overall cost of TB diagnosis and treatment services provided in the region/province.

Note that steps 1 through 7 can be repeated for any region/province in which there is an interest in estimating the total costs associated with TB services.

Protocol 3: Estimates of the total cost of TB services at national level

Data required for completion of protocol

1. Completed data entry sheets for Protocol 2 in Chapter 6
2. Annual number of TB patients diagnosed and treated in the country as a whole

The data entry sheets that accompany this protocol (see Document 2) should be completed by following the instructions provided below.

1. Calculate the average cost to manage a patient to treatment completion in government services across all districts where cost data have been collected. It is important to ensure that the average is calculated by giving appropriate weight to each type of district chosen for sampling (see also 3.10 in Chapter 3). For example, if districts were stratified into rural and urban areas, and 70% of patients are diagnosed and treated in rural areas and 30% are diagnosed and treated in urban areas, the weighted average cost per patient will be (average cost per patient in rural districts x 0.7) + (average cost per patient in urban districts x 0.3).
2. Calculate the average cost to manage a patient to treatment completion in mission/other NGO services across all districts where cost data have been collected.
3. Note the annual number of TB patients diagnosed at national level in government facilities.
4. Note the annual number of TB patients diagnosed at national level in mission/other NGO facilities.
5. Estimate the total costs associated with TB services provided through government facilities by multiplying the average cost estimated in 1 by the total number of patients recorded in 3.
6. Estimate the total costs associated with TB services provided through mission/other NGO facilities by multiplying the average cost estimated in 2 by the total number of patients recorded in 4.
7. Add together the estimated total cost of services provided in government and mission/other NGO facilities. This gives the estimated total overall cost of TB services provided in the country as a whole.

Note that it may be useful to estimate a range in total costs, using (a) the lowest estimated average cost to manage a patient to treatment completion and (b) the highest estimated average cost to manage a patient to treatment completion.

CHAPTER 9. USEFUL REFERENCES

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