

**2<sup>ND</sup> BASIC COURSE ON ECONOMIC BASIS OF  
HEALTH CARE INTERVENTIONS.**

**19<sup>TH</sup> TO 21<sup>ST</sup> AUGUST 1999.**

**COURSE CO-ORDINATOR: DR. K.R. JOHN, MD**

**VENUE: CHTC**

## Overall objective of the course

- 1) Define health economics and state its uses
- 2) a) state type of costs direct and indirect costs , fixed and variable costs, marginal and average costs b) Enumerate steps in costing
- 3) Distinguish cost minimisation - cost effectiveness, cost benefit and cost utility studies
- 4) How to critically review an article and derive conclusions
- 5) How to ask research questions relating to economic evaluation start collecting informations.

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## CLINICAL ECONOMICS

### MODULE 1

#### AN INTRODUCTION TO CLINICAL ECONOMICS

At the completion of this module you should understand:

- a. the foundations on which economics is based;
- b. why economics is relevant to health;
- c. the role of clinical economics.

# INTRODUCTION TO CLINICAL ECONOMICS

In the 1970s, health expenditure as a proportion of Gross Domestic Product (an indicator of the total expenditure on goods and services in a country) rose rapidly in most developed countries (Table 1). This raised interesting questions about

TABLE 1

## HEALTH EXPENDITURE AS A PERCENTAGE OF GDP (current prices)

COUNTRY	1970	YEAR	1980	1983
		1975		
New Zealand	4.5	5.2	5.7	5.7
United Kingdom	4.5	5.5	5.8	6.2
Australia	5.7	7.6	7.4	7.5
Sweden	7.2	8.0	9.5	9.6
USA	7.6	8.6	9.5	10.8
OECD average	5.6	6.7	7.2	7.6

Source: Harvey, R. "Trends in Health Service Provision and Expenditure in Australia, and their relevance to public hospitals", unpublished, Australian Institute of Health, 1987.

the appropriate level of health expenditure - for example, does New Zealand allocate too few and the US too many resources to health? In trying to answer this, related questions about value for money in the health sector were raised. Does increased expenditure lead to better levels of health, are the right choices made between expenditure on preventive vs curative services, between care for the aged vs care for infants, and between high technology vs low technology interventions, for example? These concerns are increasingly being expressed in the medical literature, and are probably even more pertinent to developing countries where the shortage of resources available to the health sector is more apparent than in developed countries.

It is not surprising that economists have played a role in this debate. The discipline of economics is based on two observations about the world, firstly that society (consisting of individuals and institutions) has virtually unlimited demands for goods and services, and secondly that the resources available to produce the goods and services society values are scarce. They are not scarce in the sense of non-renewable resources, but scarce because there will never be enough to produce everything that people would like. Choices between



competing uses of these scarce resources are, therefore, inevitable. Accordingly, the choice to use resources in a particular fashion always involves a cost in that the resources cannot be used in other ways which would have produced benefits. The value of the greatest possible benefit which could have been obtained by using the resources elsewhere is the cost of foregoing the opportunity to use them elsewhere and is known as the opportunity cost.

*The value of resources used up.*

Given these observations, economics can be defined as the "social science concerned with the problem of using or administering scarce resources ... so as to attain the greatest or maximum fulfilment of society's unlimited wants" (Jackson & McConnell 1987, p19). This general problem is usually subdivided into a number of more tractable questions, including what goods and services to produce, in what quantities and at what time, what resources will be used in their production, and how to distribute the goods and services that are produced. The guiding principle is the search for efficiency. Productive efficiency involves producing the greatest possible output from a given quantity of resources, or stated another way, producing a given output at the lowest possible cost. However, there is no point being efficient in this sense if goods which society does not value very highly are being produced. Allocative efficiency, which involves producing the goods and services which society values most highly, is important as well. This concern with efficiency highlights the fact that economics is not simply an exercise in reducing costs. Economics is as much about increasing outputs, the goods and services society values, as about reducing inputs or costs.

The observations about resource scarcity which form the basis of economics apply to the health sector as well. Peoples' desires for goods and services, including health, are virtually unlimited and individuals and governments must decide how many of their scarce resources should be allocated to health care or to other ways of gaining benefits. Health economics is simply the "discipline of economics applied to the topic of health" (Mooney 1986, p4). It is a very broad topic, encompassing all the general economic questions raised above, and efficiency is an important concern. Clinical economics examines a narrower set of questions relating to the efficiency of clinical interventions. This course is concerned mainly with clinical economics, although one of the wider concerns of health economics is introduced in Module 10.

A few general points should be made in conclusion. Firstly, two types of economic analyses exist. Positive economics is concerned with describing what happens objectively. Alternatively, normative economics involves subjective value judgements of the outcomes which are considered to be desirable. It is sometimes argued that clinical economics is an example of normative economics because the choice of what

constitutes a benefit of a medical intervention is necessarily subjective (Drummond et al 1987).

Secondly, economics is not about money. The problems of resource allocation under scarcity confront all societies, even those which have been based on barter rather than monetary exchange. Money is simply a useful tool for valuing goods and services.

Thirdly, efficient solutions can sometimes be inequitable. Economics has little to contribute to the debate about whether attempts should be made to reduce such inequities, but it does show that reductions in inequality can at times be achieved only at the expense of efficiency.

Finally, decisions about the appropriate form of treatment are not made on the grounds of efficiency consideration alone, and no economist would suggest that they should be. However, efficiency should not be ignored. Governments may legitimately decide to follow a less efficient policy for the sake of equity or social justice, but it is important that they be aware of the economic costs of doing this. Similarly, physicians cannot pretend that economics is irrelevant to their clinical decision making. Every one of their decisions to use resources involves an opportunity cost in that it prevents the resources being used somewhere else which would have produced benefits.

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DISCUSSION QUESTIONS

1. Read the article by Drummond et al and discuss the following proposition. It is ethical for a national Cancer Council to consider costs and benefits when discussing the appropriate national policy for screening for cancer of the cervix, but it is not ethical for a doctor to consider costs when treating an individual patient.
2. Discuss: opportunity costs are not involved when patients are fully covered by health insurance as they do not pay for the services they receive.
3. To what extent are economic issues relevant to clinical practice?

## Health Economics: An Introduction for Clinicians

MICHAEL DRUMMOND, Ph.D.; GREG STODDART, Ph.D.; ROBERTA LABELLE, M.A.; and ROBERT CUSHMAN, M.D.; Birmingham, United Kingdom; Hamilton and Ottawa, Ontario, Canada

Economic issues have had a growing importance in the health care field as the sector's share of the gross national product has risen. Clinicians are under increasing pressure to adopt more cost-effective treatment practices as a result of initiatives being taken by the major third-party payers, government, and business. However, recent publications suggest that there are some misconceptions about economics in health care and the extent to which it is in conflict with good clinical practice. To provide a foundation for the understanding of this field by clinicians, we have outlined several basic notions of health economics.

[MeSH terms: cost benefit analysis; cost control; decision making; delivery of health care; diagnostic-related groups; economics, hospital; economics, medical; health maintenance organizations; health planning; health policy; health resources; health services needs and demand; insurance, health reimbursement; preferred provider organizations; prospective payment system]

ECONOMIC ISSUES have had a growing importance in the health care field as the sector's share of the gross national product has risen. In the United States, in common with most developed countries, there has been concern about health care cost containment and the promotion, by the major third-party payers, of specific measures to bring about a more efficient use of resources. For example, in the hospital sector there has been a movement toward prospective payment systems, the best known being Medicare's approach based on diagnosis-related groups (DRGs). Such schemes give hospitals an added incentive to control costs, and the extension of prospective payment to physicians is now being considered (1).

In the primary care setting the largest change has been the growth of health maintenance organizations (HMOs) and preferred provider organizations (PPOs). To a great extent this change is being supported by private company executives who view it as a way of cutting the costs of health care for their workers. These company officials have also considered other measures, such as self-insurance and contracting out of specific services (2, 3). It is in clinicians' best interests to be aware of these changes and the economic forces behind them, as they are likely to have a profound impact on the market for medical services in the future (4).

The other major reason for clinicians to understand more about economics stems from their key role as gatekeepers to the use of health care resources. It has been

pointed out that physicians represent less than one half of 1% of the population yet determine, through the decisions they make about the care of their patients, how nearly 10% of the nation's gross national product will be spent (5). In discharging their responsibilities, clinicians perform a difficult dual role, of securing good care for their patients yet having a broader social responsibility for the careful use of health care resources (6). This broader role is likely to be reinforced by the changes in organization and payment and by other initiatives to influence practice behaviour such as education, feedback on resource use, peer review schemes, and direct financial incentives (6-9).

Given this pressing need for clinicians to have a good grasp of economic issues, it is disturbing to find evidence that all is not well. Although clinicians are likely to be more often exposed to economic issues and arguments through the increase in the publication of economic papers in medical journals (10), a recent article (11) pointed to the frequent misuse of the term cost-effective in medicine. The commonest errors are a confusion between cost containment and economic efficiency, and the suggestion that economic analysis is restricted to consideration of cost savings and production gains, and not concerned with general improvements in the quality of life.

Over the past few years we have been communicating economics concepts and ideas to practising clinicians within a teaching hospital setting. This paper, based on our experience, sets out ten basic notions of health economics for those clinicians wishing to have a good grasp of this field (Table 1).

### Ten Basic Notions of Health Economics

HUMAN WANTS ARE UNLIMITED BUT RESOURCES ARE FINITE

The original intention of some socialised health care systems, such as the British National Health Service, was that more investment in health care treatments and programs would remove existing "health needs." We now know that health needs will never be eliminated, as these are continually redefined. That is, there are always more legitimate ways of using resources (manpower, equipment, supplies) than there are resources available. Even if, by some miracle, a stage was reached where the community did not want more investment in health services, there would be plenty of other suggestions for using resources outside the health care system in other public or private sector investments.

Therefore, most resources used in the health care system have alternative beneficial uses inside and outside the

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health care sector, although in the short run some resources may be difficult to redeploy. In general, though, the restrictions on the resources for health care are more a reflection of the human condition than they are the creation of governments. The implication for those working within the health care system is that choices, in allocation of scarce resources to competing activities, are inescapable.

#### ECONOMICS IS AS MUCH ABOUT BENEFITS AS IT IS ABOUT COSTS

Given the limitations on resources, choices need to be made between competing beneficial activities at the planning and clinical levels. The real cost of engaging in a particular activity is the benefit lost by not using the same resources in their best (that is, most highly valued) alternative use. Thus, although one may tend to think of economists as being interested in health care expenditures, it would actually be truer to think of them as being interested in benefits; that is, in maximising the total benefits from the use of the community's scarce resources. This is what economists mean by efficiency. Therefore, when an economist poses the question, "What is the cost of X?" he or she is talking about the sacrifice made, or benefits foregone, by engaging in X. This is the distinction between the economist's notion of opportunity cost and the commoner notion of money expenditures.

Often (but not always) money prices may be considered to reflect true opportunity costs. This situation depends on the extent to which one believes that markets—the main mechanism through which resources, goods, and services are traded—are functioning perfectly. That is, a perfect market would be one where there are many buyers and sellers, where no barrier to entry to the market exists, and where consumers have perfect information.

Of course, any one decision maker cannot conceive of all possible states of the world and identify the best alternative use for a given resource. However, on a pragmatic level it is possible to use the notion of opportunity cost if one is a decision maker with a fixed budget, such as someone running an HMO. For example, the opportunity cost of more high-technology medicine may be that prevention programmes are not given funds to expand. (In individual clinical decisions, the opportunity cost of the use of resources may not be so apparent, as discussed later.)

#### THE COSTS OF HEALTH CARE PROGRAMMES AND TREATMENTS ARE NOT RESTRICTED TO THE HOSPITAL, OR EVEN TO THE HEALTH SECTOR ✓

Because secondary and tertiary care account for a high proportion of health care expenditures, much of the effort to increase efficiency has concentrated on these sectors. There have thus been many attempts to shorten hospital inpatient stays and reduce the use of laboratory services. Although such moves may be beneficial, reductions in hospital stay may mean that extra resources are required in the community care sector to aid in the rehabilitation of patients. Similarly, in the long-term care sector the

Table 1. Ten Basic Notions of Health Economics

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Human wants are unlimited but resources are finite.
Economics is as much about benefits as it is about costs.
The costs of health care programmes and treatments are not restricted to the hospital, or even to the health sector.
Choices in health care (that is, in health planning, or in treatment mode) inescapably involve value judgments.
Many of the simple rules of market operation do not apply in the case of health care.
Consideration of costs is not necessarily unethical.
Most choices in health care relate to changes in the level or extent of a given activity; the relevant evaluation concerns these marginal changes, not the total activity.
The provision of health care is but one way of improving the health of the population.
As a community we prefer to postpone costs and to bring forward benefits.
Equity in health care may be desirable, but reducing inequalities usually comes at a price.

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deinstitutionalization of patients should not be advocated on cost savings alone; the development of adequate community care programmes for the elderly or mentally ill is not without cost. Moreover, community care may or may not be more beneficial than its institutional counterpart for various categories of patient.

It should also be remembered that the health care sector is not the only resource for health care. Other public and private agencies are involved, and patients (and their families) incur costs. Family costs include the time and expense in traveling to, or waiting at, health care facilities, the provision of informal "home nursing" for sick relatives and any extra medications, equipment, or facilities required for treatment but not funded by the health service or insurance scheme. Furthermore, if patient or family time taken up in treatment is lost worktime, there is a general cost to society in that productive output may be lost.

Many clinicians are aware of these nonmonetary costs falling on patients and their families, and may moderate therapies accordingly. However, more attention could be paid to them in scheduling clinic attendances and in developing admission and discharge policies. Such costs must also be taken into account in the economic evaluation (from society's point of view) of health care programmes.

#### CHOICES IN HEALTH CARE (IN HEALTH PLANNING OR IN A TREATMENT MODE) INESCAPABLY INVOLVE VALUE JUDGMENTS

So far we have glibly talked about benefits from the use of resources in health care. But who decides what is a benefit and what is not? Obviously, the assessment of benefits (and, through the logic explained previously, costs) can only be based on subjective valuation. Therefore, choices in health care, which all require assessment of costs and benefits of alternative programmes or therapies, involve value judgments.

In discussing health care issues, it is important first to recognize this fact and also to make values explicit when possible. For example, in prescribing therapy, the clinician may be (unknowingly) making value judgments on



still acting in the wider social interest? We would not necessarily expect clinicians to take on the broader role in their day-to-day clinical work, but the answer lies in making a distinction between medical decisions made on behalf of the one patient and those made on behalf of a group of patients (such as requests for expansion of services). In our view it would be entirely consistent for the clinician to give each patient as much care as his or her condition requires, yet also to participate in a decision-making process that, in evaluating competing claims for the development of services, considers the wider social perspective.

The ideal form of such a decision-making process would be one that enabled clinicians to retain an advocacy role for their own patients, yet brought various checks and balances into play. In some health care systems this policy is attempted by encouraging clinicians to take responsibility for a defined budget within the hospital (12). In other systems it is considered more appropriate to encourage the adoption of guidelines for clinical practice that take into account cost-effectiveness considerations (6, 13). In the United States, the spread of HMOs and prospective payment systems for hospitals is likely to have a similar effect.

**MOST CHOICES IN HEALTH CARE RELATE TO CHANGES IN THE LEVEL OR EXTENT OF A GIVEN ACTIVITY; THE RELEVANT EVALUATION CONCERNS THESE MARGINAL CHANGES, NOT THE TOTAL ACTIVITY.**

In the health care field there is often a mistaken tendency to present choices on an all-or-nothing basis. For example, the question is not usually whether we do X (such as develop community programmes for the mentally handicapped), but rather how much of X do we do (that is, for which type of patient should such programmes be developed). Therefore, the relevant data for making such decisions are the marginal costs and benefits, not those of the whole activity. The marginal costs and benefits strictly relate to one more (or one less) unit of production, but are often used to refer to the incremental costs and benefits of the change in the scale of the activity.

The notion of "the margin" is very important in health care decision making and there are numerous examples reported where the marginal costs and benefits of expanding an activity differ greatly from the average costs and benefits of the activity as it stands. One study showed that the average cost (per case detected) of repeatedly screening the same patient population for cancer of the colon, up to a maximum of six times, was around \$2500 (14). Yet the marginal cost of detecting a further case by doing a sixth test, having already done five, was over \$47 000 000.

Although the sixth stool test for cancer of the colon is the most well-known example of the importance of considering marginal cost, there are many other "how much" decisions in diagnosis, treatment, and follow-up. For example, Williams (15) has calculated that performing coronary artery bypass grafting for mild angina with two-vessel diseases is more than ten times the cost (per

quality-adjusted life-year gained) of this procedure for severe angina with left main disease. Levine and associates (16) calculated that a policy of comprehensive diagnosis for cancer of unknown primary origin (searching all possible sites) would cost \$7 million more per year in Ontario than a limited diagnostic strategy (examining only sites for which effective systematic therapy were available). Stason and Weinstein (17) have shown how the cost effectiveness of strategies for the prevention, diagnosis, and treatment of hypertension depends on diastolic blood pressure before treatment.

**THE PROVISION OF HEALTH CARE IS BUT ONE WAY OF IMPROVING THE HEALTH OF THE POPULATION**

Many clinicians are familiar with the arguments of epidemiologists who have pointed out that recent technological advances in health care have had little impact on life expectancy, compared with improvements in nutrition, sanitation, and general economic wealth. Economists have done similar analyses, which attempt to estimate the relative contributions of health care and other important inputs, such as education, to the production of health. More recently, there have been studies of the relationship between health status and general economic variables, such as the level of unemployment.

Consideration of this notion does not lead to any obvious suggestions for the modification of clinical practice; rather, it places all our efforts within the health care system into perspective. Also, from the government's point of view it suggests that if improvements in health status are desired, we should look not only to changes in health policy but also industrial and educational policy. There are often conflicts here; many countries have agricultural policies that are not conducive to good health (such as subsidies to farmers producing foods with high fat content). Perhaps we have to accept that health is traded, by persons and governments, for other benefits; otherwise why do people drive fast cars, climb mountains, or smoke?

**AS A COMMUNITY WE PREFER TO POSTPONE COSTS AND TO BRING FORWARD BENEFITS**

Different investments in health care have different time profiles of costs and benefits. A large health education campaign aimed at reducing coronary risk factors may require a sizeable resource outlay now, in return for benefits in the future. Other investments, including most therapeutic programmes, involve a steady stream of costs, with a quick return in terms of improved health status for the patients treated. It is usually argued that, as individuals and as a community, we are not indifferent to the timing of costs and benefits. In fact we prefer to postpone costs and to have benefits sooner rather than later. Of course, one cannot have one's bread buttered on both sides and, as individuals, if we want to consume more now we usually have to borrow money at a positive rate of interest. The rate reflects not only inflation but the compensation we have to pay to others for postponing their consumption.

The main implication of this notion, the existence of a



behalf of the patient. However, it may be possible to set out for the patient the technical features of the alternative regimens and to let the patient make the choice. This is partly what informed consent is about.

The question of whose values should be used in making choices in health care is complex. Economists tend to believe (as a canon of faith, as a political tenet, or as an act of expediency) that each person knows his or her own interest best, although there is no such "rule" in economic theory. Obviously, in some branches of health care, such as mental illness, the proposition that the patient (consumer) knows his or her own interest best may be hard to defend. But what about health care more generally? Certainly it is possible to find examples in the literature where health care providers' values have been assessed and they differ from the values of the patients. With respect to larger planning choices, consideration of costs (as reflected by markets) incorporates an element of consumer judgment, because market prices reflect an amalgam of the valuations many consumers place on goods and services and their alternative uses. But who should value the benefits from the health services and set planning priorities? Presumably one might want to give the community a say in this, perhaps through their elected representatives. However, at the moment much priority setting is done primarily (perhaps unknowingly) by clinicians, through their advocacy for the development of particular services or through the pressures their actions place on existing resources, such as hospital laboratories. Much of this may, in turn, be a reflection of patients' demands, however.

#### MANY OF THE SIMPLE RULES OF MARKET OPERATION DO NOT APPLY IN THE CASE OF HEALTH CARE

We have already mentioned that, if markets are working well, the prices of resources (and commodities) reflect their social opportunity costs. A perfectly functioning system of markets would have additional attributes too; for any given distribution of income and wealth, it would guarantee that goods and services would be produced in the most efficient way, because in the face of competition inefficient producers would go out of business (technical efficiency), and that scarce resources would be allocated so as to satisfy the most highly valued wants (allocative efficiency). This view of the world has led many to advocate a much wider role for the market in health care delivery, with less government intervention (or interference).

There are doubts whether any markets function in the perfect way described above, owing to the existence of monopoly producers or sellers who are relatively immune to competition. However, in the case of health care there are a number of additional reasons that, taken together, suggest that the market (if left to its own devices) would not lead to an efficient use of health care resources. First, consumers may not have the knowledge to make sensible choices, which means that the providers (especially clinicians) become key players in determining the demand for care, on behalf of patients. Economists call this the agency relationship. (X)

*when there is no price there will be increasing demand*

② Second, even if consumers knew what they wanted, the health care market is different in that, because of insurance coverage or free provision of socialized health care, consumers do not pay a price that reflects the social opportunity cost of the resources used. Therefore there may be a tendency for persons to consume more care than they otherwise might. Economists would say that consumers experience "moral hazard," a phenomenon common to all insurance markets.

③ Third, the benefit from a person receiving care may not be confined to that person. The most obvious example is in the field of communicable diseases, whereby the more people that become immunized the more protection is given to others. Because of such externality relationships, the valuation of the consumer alone may understate the total value of care. Some economists extend such arguments to other forms of care, suggesting that there are philanthropic (or caring) externalities, that is, we care about other peoples' health, and hence the care they receive, in a way that we do not care about whether they have recently been able to replace their automobile. The main evidence in support of this argument is the tendency, in most countries, to socialize health care to some degree. (A)

④ Finally, there is a stronger version of the externality argument; namely that people ought to be encouraged to consume more care than they otherwise might. This is known as the "merit good argument or paternalism," and is most commonly applied to the consumption of education.

Most of these arguments can be applied, to some degree, to other commodities. However, the unique coincidence of them in the case of the commodity known as health care leads most economists to the conclusion that a market for health care would "fail"—that is, not automatically lead to an efficient allocation of resources. Furthermore, in most health care systems there are few incentives to consumers or providers for efficiency; efficiency needs to be encouraged, it cannot be assumed.

#### CONSIDERATION OF COSTS IS NOT NECESSARILY UNETHICAL

It is normally argued that the clinician's responsibility is to provide the best possible care for his patients. Does this mean that considering costs in clinical decision making is unethical? If the patient were really being treated in isolation, it would be wrong to withhold care because of resource considerations. However, a problem arises because (according to the arguments set out) once resources enter into the picture, then by definition the patient is not being treated in isolation. According to the opportunity cost principle, more resources given to one patient means that someone else will lose out. This may perhaps be a patient of a clinical colleague, or a person who could potentially benefit from care but is not yet known to the health care system. A third possibility is that increased resources used in the health care sector may mean that society goes without other things, such as education, which themselves may promote health.

Herein lies a dilemma: How does the clinician adhere to generally accepted medical and ethical principles while



positive rate of time preference, is that investments in health care need to be compared on a common basis if their time profiles of costs and benefits differ. This is accomplished by a procedure known as discounting to present values, which is essentially a compound interest calculation done in reverse. Discounting has the biggest impact when one is comparing a preventive programme with a curative one.

#### EQUITY IN HEALTH CARE MAY BE DESIRABLE, BUT REDUCING INEQUALITIES USUALLY COMES AT A PRICE

As noted, there are externality relationships in health—that is, many of us care about the health of others. Therefore, in many countries there is concern about the equity of health care provision, by exposure to risk, income class, social class, geographical location, need, and so on. Few people would openly argue against equity, but it is worth pointing out that reduction of inequalities may come at a price, in terms of other benefits foregone. One common saying in economics is that “there is no such thing as a free lunch.” In this case it is perhaps easiest to see the validity of the argument in the context of locating tertiary care facilities. Everyone would like a specialist unit on their doorstep, but such a proliferation may mean that units are underutilised or, more probably, full with “inappropriate” cases—that is, patients who could be treated perfectly well elsewhere at lower cost.

#### Discussion

This paper has contained a discussion of ten basic notions of health economics. These ten notions hardly represent the economist's “ten commandments,” but we do believe they provide a useful foundation for clinicians wishing to understand this increasingly important field. For those clinicians wishing to take matters further a number of textbooks exist (18-22), although in the main these are not ideal because they demand a higher level of economics expertise than clinicians are likely to possess, or because they are structured around economics concepts (supply and demand) rather than around notions with which clinicians are more familiar.

There is no space here to discuss teaching methods in detail, but we have found that the most promising approach is to develop problem-based materials dealing with practical issues that clinicians feel are relevant. These materials could concern the economic issues raised by the treatment of individual patients, the ways in which health policy (such as the encouragement of prepaid group practice) affects clinical practice, or the need to be able to appraise economic evidence critically in order to assess claims for the development of services (23). We hope that this article stimulates clinicians to learn more

about health economics and that teachers respond by devising more and better learning materials.

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## How to read clinical journals: VII. To understand an economic evaluation (part A)\*

DEPARTMENT OF CLINICAL EPIDEMIOLOGY AND BIOSTATISTICS,  
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Those who plan, provide, receive or pay for health services face an incessant barrage of questions such as the following: Should clinicians check the blood pressure of each adult who walks into their office? Should planners launch a scoliosis screening program in secondary schools? Should patients be encouraged to request annual check-ups? Should local health departments free the limited numbers of nursing personnel from well-baby clinics so that they can make home visits to patients with hypertension who have forgotten to present for their check-ups? Should hospital administrators purchase each and every piece of new diagnostic equipment? In other words, who should do what to whom, with what health resources and with what relation to other health-services?

The answers to these questions are most strongly influenced by our estimates of the relative merit or value of the alternative courses of action. This pair of clinical epidemiology rounds is concerned with the strategies and tactics whereby these estimates of relative value can be ascertained and interpreted; that is, with the evaluation of health ser-

vices. More specifically, the guides we present here focus on one type of evaluation, sometimes referred to as economic evaluation or efficiency evaluation. In this type of evaluation we are asking Is this health procedure, service or program worth doing compared with other things we could do with the same resources? Are we satisfied that the health care resources (required to make the procedure, service or program available to those who could benefit from it) should be spent in this rather than some other way?

It is imperative to note that although an economic evaluation provides important information to decision-makers, it addresses only one dimension of decision-making about health programs. An economic evaluation is most useful, and appropriate, when it is preceded by three other types of evaluation, each of which addresses a different question, as follows:

- *Can it work?* Does the health procedure, service or program do more good than harm to people who fully comply with the associated recommendations or treatments? This type of evaluation is concerned with efficacy.

- *Does it work?* Does the procedure, service or program do more good than harm to people to whom it is offered? This form of health care evaluation, which considers both the efficacy of a service and its acceptance by those to whom it is offered, is the evaluation of effectiveness or usefulness.

- *Is it reaching those who need it?* Is the procedure, service or program accessible to all people who could benefit from it? Evaluation of this type is concerned with availability.

Methodologic criteria for assessing efficacy, effectiveness and availability evaluations have been described in an article by Sackett, from which the above questions have been drawn. These questions were also addressed in part V of this series,<sup>2</sup> so they will not be reviewed here.

This pair of rounds is intended for those who use, rather than those who generate, evaluation data. Consequently, it stresses data interpretation rather than data acquisition. It is meant to help the careful reader acquire healthy scepticism regarding claims about the efficiency of health procedures, services and programs. In this part we describe the rationale for and clearly define the nature of economic evaluation. We then identify the basic types of economic evaluation, distinguishing the purpose and characteristics of each. In part B we will help you become a more critical assessor of evidence by identifying the elements of a sound economic evaluation, illustrated through case presentations and the current literature. We will also discuss the limitations of economic evaluation techniques.

### Why do an economic evaluation?

#### Case presentations

A. You are a staff surgeon at a busy community hospital. As the population served by your hospital grows, so does the need for surgical beds. The scheduling of elective minor surgery has become chaotic, but there is little prospect for any increase in the number of beds. You are sure that a "day surgery" program would relieve much of the pressure, but you also know that the

\*Parts I through V of this series were published in consecutive issues of the Journal, starting with the Jan. 1, 1981 issue, and part VI was published in the Feb. 15, 1984 issue.

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hospital board will not approve the establishment of the program until you give them some "hard data" on whether it really will be less expensive and, if so, by how much.

B. As a member of your hospital's medical advisory committee you are asked to approve the launching of a renal transplant program. Your colleagues claim that transplantation is "highly cost-effective" and in support of their claim have attached an article<sup>1</sup> to their request. You realize that you must wade through the article in order to make an intelligent decision.

C. As one of the few physicians on your local health council you are asked to comment on whether your town would be better served by a comprehensive blood pressure screening program (that claims to prevent untimely death) or by an influenza immunization program (that claims to prevent days of disability). Because these programs seem so dissimilar you feel that you must come up with an organized way of comparing their costs and benefits.

#### Comment

In each of these increasingly frequent situations you are being asked for an economic evaluation of alternative services. Why is economic evaluation so important? To put it simply, resources — people, time, facilities, equipment and knowledge — are scarce. Choices must and will be made concerning their deployment, and methods such as "what we did last time", "gut feelings" and even "educated guesses" are not always better than an organized consideration of the factors involved in a decision to commit resources to one use instead of another. This is true for at least three reasons:

- *Without systematic analysis it is difficult to clearly identify the relevant alternatives.* For example, in deciding to introduce a new program (e.g., rehabilitation in a special centre for patients with chronic lung disease) too often little or no effort is made to describe the existing activities (e.g., episodic care by family physicians in their offices) with which the new proposal must be compared. Furthermore, if the object is indeed to reduce morbidity

due to chronic lung disease, then prevention programs (e.g., related to cigarette smoking) may represent a more efficient avenue and should be added to the programs competing in the evaluation.

- *The viewpoint assumed in an analysis is important.* A program that looks unattractive from one viewpoint may look significantly better when other viewpoints are considered. Analytic viewpoints may include any or all of the following: the individual patient, a specific institution, a target group for specific services, the ministry of health's budget, the government's overall budget, and a focus on the community or society.

- *Without some attempt at measurement, the uncertainty surrounding orders of magnitude can be critical.* For example, when the American Cancer Society endorsed a protocol of six sequential stool tests for detecting cancer of the large bowel, most analysts would have predicted that the cost per detected case would increase markedly with each test. But would they have guessed that it would reach \$47 million for the sixth test? While this is, admittedly, an extreme example, it illustrates that without measurement and comparison of outputs with inputs we have little upon which to base any judgement about value for money. In fact, the real cost of any program is not the number of dollars appearing in the program budget but, rather, the health outcomes achievable with some other program that were forgone when the resources were committed to the first program. It is this "opportunity cost" that an economic evaluation seeks to estimate and to compare with program benefits.

#### What does economic evaluation mean?

Two features characterize an economic analysis, regardless of the activities (including health services) to which it is applied. First, it deals with *both* the inputs and outputs, sometimes called the costs and consequences, of activities. Few of us would be prepared to pay a specific price for a package whose contents were unknown until we could see what we were getting for our money.

Conversely, few of us would accept a package, even if its contents were known and desired, until we knew its price. In both cases, it is the linkage of costs and consequences that allows us to reach our decision.

Second, economic analysis concerns itself with choices. The scarcity of resources, and our consequent inability to produce all the desired outputs (even efficacious therapies), means that choices must, and will, be made in all areas of human activity. These choices are made on the basis of many criteria, sometimes explicit but often implicit. Economic analysis seeks to identify and make explicit one set of criteria that may be useful in deciding among different uses for limited resources.

These two characteristics lead us to define economic evaluation as *the comparative analysis of alternative courses of action in terms of both their costs and their consequences*. Therefore, the basic tasks of any economic evaluation will be to identify, measure, value and compare the costs and consequences of the alternatives being considered. These tasks characterize all economic evaluations, including those concerned with health services.

These two characteristics of economic analysis may be used to distinguish and label several evaluation situations commonly encountered in the literature on health care. In Table I the answers to two questions — Is there a comparison of two or more alternatives? and Are both costs (inputs) and consequences (outputs) of the alternatives examined? — define a six-cell matrix for evaluation situations. In cells 1A, 1B and 2 there is no comparison of alternatives — that is, a single service or program is being "evaluated". To put it more accurately, the service or program is being "described", since evaluation requires comparison. In cell 1A, only the consequences of the service or program are examined; thus, the evaluation is called an *outcome description*. In cell 1B, since only costs are examined, the evaluation is called a *cost description*. In cell 2, both the outcomes and the costs of a single service or program are described; thus, the evaluation is called a *cost-outcome description*. An example of



fits.\* For example, in their cost-benefit analysis of screening for spina bifida cystica, Hagard and coworkers<sup>12</sup> assumed that therapy would be given to children with spina bifida with the "no-screening" alternative.

Weisbrod and collaborators<sup>13</sup> did attempt to quantify and value a wide range of costs and benefits in their study of conventional hospital-oriented versus community-based programs for patients with mental illness. They found that although the community-based program was more expensive the costs were more than offset by the program's value in terms of the number of patients who could become, or stay, employed. (These investigators used earnings as a dollar measure of the benefits.)

A second measure of value, which is more difficult to obtain but preferred by many analysts, is "utility". Utility refers to the value of a specific level of, or improvement in, health status and can be measured by the preferences of individuals or society for a particular set of health outcomes. The notion that the utility of an outcome, effect or level of

\*Notice the different treatment of the "do-nothing" alternative. Cost-effectiveness analyses often implicitly assume at the outset that a tenable "do-nothing" alternative does not exist and that one of the program alternatives will therefore be undertaken regardless of its net benefit. While this may be quite a realistic position for health care decision-makers to adopt, cost-effectiveness analysis may lead to a decision to undertake a program that does not "pay for itself"; that is, one that entails a net resource cost instead of a benefit.

health status is different from the outcome, effect or level of health status itself can be illustrated by the following example: Suppose that twins, identical in all respects except occupation, one being a sign painter and the other a translator, both broke their right arm. While they would be equally disabled (or, conversely, equally healthy), if we asked them to rank their "having a broken arm" on a scale of 0 (dead) to 10 (perfect health) their rankings might differ considerably because of the significance, in this case based on occupation, that each twin attached to arm movement. We would also expect that their assessment of the utility of treatment — that is, the degree to which treatment of the fracture improved the quality of their life — would also differ.

Although a utility analysis is a relatively new technique in health care evaluation, it is considered extremely promising because it allows "quality-of-life" adjustments to a given set of treatment outcomes while providing a common denominator for a comparison of costs and outcomes of different programs. The common denominator is usually expressed as "healthy days" or "quality-adjusted life-years", arrived at by adjusting the length of time affected through the health outcome according to the utility value (on a scale of 0 to 1) of the resulting level of health status. Many analysts find this method of valuing the consequences of health care alternatives preferable to valuing them in dollars.

An analysis that uses utilities as a measure of the value of the effects of a program is termed a *cost-utility analysis*. The results of a cost-utility analysis are expressed in terms of the cost per "healthy day" or per "quality-adjusted life-year" gained by using one program instead of another. Examples of cost-utility analyses include the study by Stason and Weinstein<sup>14</sup> on strategies for the management of essential hypertension and that by Boyle and associates<sup>15</sup> on neonatal intensive care for infants of very low birth weight.

The different characteristics of the four types of full economic evaluation — cost-minimization, cost-effectiveness, cost-benefit and cost-utility — are summarized in Table II. Two further points warrant emphasis. First, the main purpose of classifying the types of full economic evaluation is to illustrate the different analytic characteristics of completed studies, not to prescribe a particular study. Often at the beginning of an economic evaluation the analyst may not be able to predict what form the final analysis might take, as this may depend on the results of an associated clinical evaluation. For example, it may not be known in advance that a clinical evaluation will show two treatments to have identical effects, thereby reducing a cost-effectiveness analysis to a cost-minimization analysis. Furthermore, two or more analyses are sometimes used together to tackle a particularly thorny problem. Boyle and associates<sup>15</sup> used both a cost-benefit and a cost-utility anal-

Table II—Measurement of costs and consequences in economic evaluations

Type of economic evaluation	Measurement/valuation of costs in both alternatives	Consequences	Measurement/valuation of consequences
Cost-minimization	Dollars	Identical in all relevant respects	None
Cost-effectiveness	Dollars	Single effect of interest, common to the two alternatives but achieved to different degrees	Natural units (e.g., years of life gained, days of disability saved, units of blood pressure reduction, etc.)
Cost-benefit	Dollars	Single or multiple effects, not necessarily common to the two alternatives; common effects may be achieved to different degrees	Dollars
Cost-utility	Dollars	Single or multiple effects, not necessarily common to the two alternatives; common effects may be achieved to different degrees	"Healthy days" or (more often) "quality-adjusted life-years"



Table 1—Distinguishing characteristics of health care evaluations

Table I—Distinguishing characteristics of health care evaluations									
Are both costs (inputs) and consequences (outputs) of the alternatives examined?				Yes		No		Is there a comparison of two or more alternatives?	
				Examines only consequences		1A Partial evaluation	1B Partial evaluation	Outcome description	Cost description
				Examines only costs					
				No					
				Yes					
				Examines only consequences		3A Partial evaluation	3B Partial evaluation	Efficacy or effectiveness evaluation	Cost analysis
				Examines only costs					
				No					
				Yes					
				Examines only consequences		Full economic evaluation	4	Cost—minimization analysis Cost—effectiveness analysis Cost—benefit analysis Cost—utility analysis	
				Examines only costs					
				No					
				Yes					

\*As regular users of the results of economic evaluations may have recognized, and as readers of this article will likely discover, the titles of published articles on economic evaluations are not always accurate indicators of the type of evaluation actually performed.

**a contentious issue.**

tion situations in which two or more alternatives are compared but the costs and consequences of each alternative are not examined simultaneously. In cell 3A only the consequences of the alternatives are compared; thus, this type of evaluation is called an *efficacy or effectiveness evaluation*. This, of course, is the cell in which the important literature on most randomized clinical trials would fall. In cell 3B only the costs of the alternatives are examined: in such a situation the study performed may be called a *cost analysis*. A recent example of such a study is that by Lawson and associates<sup>1</sup> on the comparative costs of three means of providing long-term oxygen therapy in the home: oxygen cylinders, liquid oxygen or an oxygen concentrator, a machine that extracts oxygen from air. The authors argued that a cost analysis was sufficient because the relative effectiveness of the three means was not

This type of study is that by Reynell and Reynell<sup>1</sup> on coronary care units. Those investigators presented the costs of one such unit and estimated the likely number of lives saved. However, there was no explicit attempt to compare the costs and consequences of the coronary care unit with an alternative.\*

The identification of various types of costs and their subsequent measurement in dollars is similar in most efficiency evaluations; however, the nature of the consequences stemming from the alternatives being examined may differ considerably. Let us consider the three case presentations we described earlier to see how the nature of the consequences affects their measurement, valuation and comparison with costs.

label "full economic evaluation". Do all efficiency evaluations use the same techniques?

None of these cells currently fulfills both of the conditions for economic evaluation. For this reason they have all been designated "partial evaluations". This does not imply that studies with these characteristics are unimportant, for they may represent important intermediate stages in our understanding of the costs and consequences of health services or programs. However, it does mean that they will not allow us to answer questions on efficiency. For this we need studies that have used the four techniques listed in cell 4 under the

be achieved to the same degree (identical number of operations) with the two programs, though presumably at different costs. The efficiency evaluation is, then, essentially a search for the least expensive alternative. An analysis such as this is often called a *cost-minimization analysis*. We might also be interested in the distribution of costs (e.g., the extent that day surgery shifts cost to the patient), but our principal efficiency comparison will be made on the basis of cost per surgical procedure.

You may wonder how the cost-minimization analysis in cell 4 of Table I differs from the cost analysis in cell 3B. In practice if the *outcomes of the alternatives are identical* (too often they are assumed to be identical in a cost-minimization analysis), there is no difference between the techniques. In principle, however, a full economic evaluation through a cost-minimization analysis requires some evidence that differences in outcome between the alternatives are nonexistent or unimportant. Therefore, such studies are often performed in association with or immediately following controlled clinical trials. Two studies of choices in minor surgery are those by Russell and colleagues,<sup>1</sup> on day surgery for patients with hernias and hemorrhoids, and by Waller and coworkers,<sup>2</sup> on 48-hour postoperative hospital stays following treatment for inguinal hernia or varicose veins. In both studies the



short-stay alternative was compared with the traditional inpatient treatment. An example of a cost-minimization study of a different health care issue is that by Fenton and collaborators<sup>9</sup> on home versus hospital treatment for patients with psychiatric problems.

Our case B focused on the prolongation of life after renal failure and compared the costs and consequences of inpatient dialysis with those of kidney transplantation. The outcome of interest, years of life gained, is common to the two programs; however, the programs may have different degrees of success, as well as different costs, in achieving this outcome. Consequently, we would not automatically lean toward the least expensive program, unless, of course, it also resulted in greater prolongation of life. In comparing these alternatives we would usually calculate the number of years of life saved and compare the cost per unit of effect (i.e., cost per year of life gained). Such an analysis, in which costs are related to a single common effect that may differ in magnitude between the alternative programs, is usually referred to as a *cost-effectiveness analysis*. The results of such a comparison may be stated either in terms of cost per unit of effect or in terms of effect per unit of cost (years of life gained per dollar spent). The latter is particularly useful when one is working within a given budget, provided the alternatives are not of a radically different scale.

Furthermore, although the alternatives in this example are similar, in that both could be considered variants of a renal program, a cost-effectiveness analysis can be performed on any alternatives that have a common effect. Thus, kidney transplantation could be compared with heart surgery (or even mandatory seatbelt legislation) if the common effect of interest was years of life saved. Similarly, an influenza immunization program could be compared with a home care program (or even a community safety education program) if a common effect of interest, perhaps days of disability avoided, could be identified.

There are many examples of cost-effectiveness analyses in the litera-

ture. Ludbrook<sup>7</sup> provided a more recent estimate of the cost-effectiveness of treatment options for patients with chronic renal failure. In addition, a number of studies have compared the cost-effectiveness of actions that do not produce health effects directly but that achieve other clinical objectives that can be clearly linked to improvements in patient outcome. For example, Hull and associates<sup>10</sup> compared diagnostic strategies for deep-vein thrombosis in terms of the cost per case detected. Similarly, Logan and colleagues,<sup>11</sup> in a study of patients with hypertension, compared care at the worksite with care at a physician's office in terms of the cost per 1-mm Hg drop in the diastolic blood pressure.

Our case C reminds us that we cannot be assured, or assume, that the consequences of alternative programs are identical. In addition, it is frequently not possible to consider the outcomes of interest as a single effect common to the two alternatives. We may be interested in effects that, although common to the two alternatives, are multiple, or we may identify single or multiple effects that are not common to the alternatives. The first case is easy to understand if we make two extensions to our case B: include home dialysis in addition to hospital dialysis and kidney transplantation, and include quality of life (perhaps measured by the occurrence of marital disruption) and the frequency of medical complications as consequences of interest in addition to years of life gained. To pursue a cost-effectiveness analysis we now have to compute cost-effectiveness ratios for three effects. In the event that one alternative was not clearly superior on all three counts, we would have to either designate (implicitly or explicitly) a primary effect on which to base the comparison or find a method whereby the multiple common effects could be combined into one common denominator.

The need for a common denominator to measure the consequences of alternatives is even more apparent in case C, where we attempt to compare the effect of a hypertension screening program (the prevention of premature death) with that of an

influenza immunization program (the prevention of days of disability). Here the outcome of interest differs between the alternatives. Consequently, a meaningful cost-effectiveness comparison is impossible.

In situations like these, when we need a common denominator to compare the outcomes, analysts frequently attempt to go beyond considering the specific effects and to attach a measure of value to the effects resulting from a particular service or program. One measure of value is dollars; the effects of a program will often be expressed in terms of their dollar benefits to facilitate a comparison with the program costs. This, of course, means that we have to translate the effects, such as days of disability avoided, years of life gained, medical complications avoided and even marital disruption avoided, into their dollar benefit. This is not always easy, but, depending on the type of effect, it is sometimes both appropriate and feasible to attempt it. An analysis that measures both the costs and the consequences of alternatives in dollars is usually called a *cost-benefit analysis*. The results of such an analysis might be stated either as a ratio of dollar costs to dollar benefits or as a simple sum (possibly negative) representing the net benefit (or loss) of one program over another.

A cost-benefit analysis, at least in theory, provides information on the "absolute" benefit of a program, in addition to information on its relative performance; that is, a cost-benefit analysis estimates the value of resources used by each program compared with the value of resources the program might save or create. This view implicitly assumes that each program is being compared with a "do-nothing" alternative that entails no costs and no benefits. However, in practice a cost-benefit analysis usually compares only costs and benefits that can easily be expressed in dollars; so very few analyses can aspire to this wider role. Also, there are very few instances in which absolutely nothing is done to tackle a given health problem; so in most cost-benefit analyses the implicit "do-nothing" alternative has some costs and bene-



# NITRONG SR

THE 8 HOUR NITROGLYCERIN

Nitroglycerin sustained-release tablets

Therapeutic classification  
Anti-anginal Agent

## Indications

Nitrong SR Tablets are indicated for the prevention of attacks of angina pectoris associated with chronic angina of effort.

## Contraindications

Nitrong SR Tablets are contraindicated in patients with severe anemia, increased intraocular pressure, increased intracranial pressure and hypotension. Nitrong SR is also contraindicated in patients with known idiosyncrasy to organic nitrates.

## Warnings

Data on the safe use of Nitrong SR during the early phase of myocardial infarction (the period during which clinical and laboratory findings are unstable) are insufficient to establish safety.

The use of Nitrong SR in patients with congestive heart failure requires careful clinical and/or hemodynamic monitoring.

Nitrate dependence may occur in patients with chronic use. To avoid possible withdrawal effects, the administration of Nitrong SR should gradually be reduced over 4-6 weeks. In industry workers continuously exposed to nitrates, chest pain, acute myocardial infarction and even sudden death have occurred during temporary withdrawal of nitrate exposure.

## Precautions

Headaches or symptoms of hypotension, such as weakness or dizziness, particularly when arising suddenly from a recumbent position, may be due to overdosage. When they occur, the dose should be reduced or use of Nitrong SR discontinued.

Nitroglycerin is a potent vasodilator and causes a slight decrease in mean blood pressure (approximately 10-15 mm Hg) in some patients when used in therapeutic dosages. Caution should be exercised in using the drug in patients who are prone to, or who might be affected by hypotension.

Nitrong SR Tablets are not intended for immediate relief of acute attacks of angina pectoris. Sublingual nitroglycerin preparations should be used for this purpose.

Tolerance to this drug and cross tolerance to other nitrates or nitrites may occur.

## Adverse Effects

Headache is the most common side effect, especially when higher dosages of Nitrong SR are used. Headache may be treated with concomitant administration of mild analgesics. If headache is unresponsive to such treatment, the dose of Nitrong SR should be reduced or the use of the product discontinued.

Less frequently, postural hypotension, an increase in heart rate, faintness, flushing, dizziness, nausea and vomiting have been reported.

## Symptoms and treatment of overdosage

Symptoms of overdosage are primarily related to vasodilation, including cutaneous flushing, headache, nausea, dizziness and hypotension. Methemoglobinemia is also possible.

No specific antidote is available. Treatment should primarily be symptomatic and supportive.

## Dosage and administration

Adult: Recommended initial dosage is 1 tablet 3 times a day before breakfast, late afternoon before meal and before retiring. Dosage may be increased progressively up to 2 tablets 3 times a day.

## Availability

Sustained-Release Tablets of 2.5 mg — Bottles of 100 and 1000.

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ysis in their evaluation of neonatal intensive care, since each explores a different dimension of value.

## Conclusions

From the user's point of view, the most important consideration is whether the complexity of the analysis matches the breadth of the question posed. Cost-benefit and cost-utility analyses, since they address outcome valuation, shed more light on whether the treatment concerned is "worth while" compared with other treatments. Cost-minimization and cost-effectiveness analyses tacitly assume that the treatment is worth while. To assess whether a particular evaluation is appropriate to the question posed, the user needs to be aware of the differences in the analyses.

The power of these analytic techniques should not be overstated. None of the approaches is intended to be a magic formula for removing judgement, responsibility or risk from decision-making activities, though each is capable of improving the quality and consistency of decision-making. They are, at root, methods of critical thinking, of approaching choices and often of placing difficult choices out in the open for discussion. While quantitatively they generate statements about program costs and consequences, qualitatively they are simply frameworks for comprehensive enumeration and display of economic factors involved in decision-making. Whether the factors covered by the economic analyses are, in fact, the dominant concerns in a specific decision and whether the limitations of an economic evaluation (which we will discuss in part B) significantly restrict its usefulness in a specific situation are judgements that, quite properly, remain the responsibility of the final decision-maker. In this sense a cost-minimization, cost-effectiveness, cost-benefit or cost-utility analysis may represent only a partial analysis of any specific choice.

Of course, identifying an economic evaluation is one thing; deciding whether it has been soundly executed, and then whether it is potentially useful for a particular decision, is quite another. Therefore, in part B

we will describe a set of readers' guides that will help you understand articles that present economic evaluations.

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## How to read clinical journals:

### VII. To understand an economic evaluation (part B)\*

DEPARTMENT OF CLINICAL EPIDEMIOLOGY AND BIostatISTICS, MCMASTER UNIVERSITY HEALTH SCIENCES CENTRE

The readers of clinical journals increasingly encounter articles on the economic evaluation of one or more clinical maneuvers or programs and are often faced with the task of assessing their results. As shown in the case presentations in part A, the question that readers of such articles are most likely to ask themselves is Are these results useful to me in my setting? The answer is determined by the answers to the following specific questions:

- Are the methods employed in the study appropriate, and are the results valid?
- If the results are valid, would they apply to my setting?

This second in the pair of articles on understanding economic evaluation relates mainly to the former question. It is designed to assist users of economic evaluations in assessing the validity of the results they encounter.

When assessing the validity of evidence, whether in terms of efficacy, effectiveness, availability or efficiency, we usually proceed by close-

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ly examining the methods used to produce the evidence. Often it is helpful to separate the various elements of a method so that each can be scrutinized, a strategy we repeatedly applied in the previous clinical epidemiology rounds. Accordingly, we shall identify the key elements of an economic evaluation and, through the use of a set of readers' guides (Table I), discuss the methodologic standards that readers can expect to find in a well executed economic analysis. Of course, it is unrealistic to expect every study to satisfy all of the guides; however, the systematic application of the guides will allow readers to identify and assess the strengths and weaknesses of individual clinical studies.

#### Elements of a sound economic evaluation

##### 1. Was a well defined question posed in answerable form?

Such a question will clearly identify the alternatives being compared and the viewpoint(s) from which the comparison is to be made. Questions such as Is a chronic home care program worth it? and Will a community hypertension screening program do any good? beg the further questions To whom? and Compared with what? Similarly, questions such as How much does it cost to run our intensive care unit? and What are the costs and outcomes of adolescent counselling by social workers? are not efficiency questions because they fail to specify the alternatives for comparison. (See part A for a review on the nature of economic evaluation.) This is not to say that

the answers to such questions will not provide important information on accounting or management. They may, but alone they do not qualify as efficiency statements.

A well specified question might be the following: From the viewpoint of (a) the budgets of both the Ministry of Health and the Ministry of Community and Social Services and (b) patients incurring out-of-pocket costs, is a chronic home care program preferable to the existing program of institutionalized extended care in designated wards of general hospitals? Note that the viewpoint for an analysis may be that of a specific provider or providing institution, a patient or groups of patients, a third-party (public or private) payer, or society (i.e., all costs and consequences to whomsoever they accrue). It may be that a program is preferable from the viewpoint of society but not from that of the providing institution. In such a case the Ministry of Health may wish to consider giving an incentive to the providing institution to ensure that the socially preferred program goes ahead. The existence of different viewpoints was highlighted by Weisbrod and colleagues<sup>1</sup> in their study of community-oriented and hospital-based treatments for patients with mental illness.

##### 2. Was a comprehensive description of the competing alternatives given?

A clear and specific statement of the primary objective of each alternative program, treatment or service is critical in selecting the type of evaluation — cost-effectiveness



Table I—Detailed readers' guides for efficiency studies

1. Was a well defined question posed in answerable form?
  - (a) Did the study examine both costs and effects of the service(s) or program(s)?
  - (b) Did the study involve a comparison of alternatives?
  - (c) Was a viewpoint for the analysis stated or was the study placed in a particular decision-making context?
2. Was a comprehensive description of the competing alternatives given (i.e., can you tell who did what to whom where and how often)?
  - (a) Were any important alternatives omitted?
  - (b) Was (should) a "do-nothing" alternative (have been) considered?
3. Was there evidence that the programs' effectiveness had been established? Was this done through a randomized, controlled clinical trial? If not, how strong was the evidence of effectiveness?
4. Were all important and relevant costs and consequences for each alternative identified?
  - (a) Was the range wide enough for the research question at hand?
  - (b) Did it cover all relevant viewpoints (e.g., those of the community or society, patients and third-party payers)?
  - (c) Were capital costs as well as operating costs included?
5. Were costs and consequences measured accurately in appropriate physical units (e.g., hours of nursing time, number of physician visits, days lost from work or years of life gained) prior to valuation?
  - (a) Were any identified items omitted from measurement? If so, does this mean that they carried no weight in the subsequent analysis?
  - (b) Were there any special circumstances (e.g., joint use of resources) that made measurement difficult? Were these circumstances handled appropriately?
6. Were costs and consequences valued credibly?
  - (a) Were the sources of all values (e.g., market values, patient or client preferences and views, policymakers' views and health care professionals' judgements) clearly identified?
  - (b) Were market values used for changes involving resources gained or used?
  - (c) When market values were absent (e.g., when volunteers were used) or did not reflect actual values (e.g., clinic space was donated at a reduced rate) were adjustments made to approximate market values?
  - (d) Was the valuation of consequences appropriate for the question posed (i.e., was the appropriate type, or types, of analysis — cost-effectiveness, cost-benefit or cost-utility — selected)?
7. Were costs and consequences adjusted for differential timing?
  - (a) Were costs and consequences that occurred in the future "discounted" to their present values?
  - (b) Was any justification given for the discount rate used?
8. Was an incremental analysis of costs and consequences of alternatives performed?
 

Were the additional (incremental) costs generated by the use of one alternative over another compared with the additional effects, benefits or utilities generated?
9. Was a sensitivity analysis performed?
  - (a) Was justification provided for the ranges of values (for key parameters) used in the sensitivity analysis?
  - (b) Were the study results sensitive to changes in the values (within the assumed range)?
10. Did the presentation and discussion of the results of the study include all issues of concern to users?
  - (a) Were the conclusions of the analysis based on some overall index or ratio of costs to consequences (e.g., cost-effectiveness ratio)? If so, was the index interpreted intelligently or in a mechanistic fashion?
  - (b) Were the results compared with those of other studies that had investigated the same questions?
  - (c) Did the study discuss the generalizability of the results to other settings and patient/client groups?
  - (d) Did the study allude to, or take account of, other important factors in the choice or decision under consideration (e.g., distribution of costs and consequences or relevant ethical issues)?
  - (e) Did the study discuss issues of implementation, such as the feasibility of adopting the "preferred" program, given existing financial or other constraints, and whether any freed resources could be used for other worthwhile programs?

cost-benefit or cost-utility — to be undertaken. A full description of the alternatives is essential for three other reasons: (a) readers must be able to judge the applicability of the programs to their own settings, (b) readers should be able to assess whether any costs or consequences may have been omitted in the analysis, and (c) readers may wish to replicate the program procedures being described. Therefore, readers should be provided with information that allows identification of both the costs (Who does what to whom where and how often?) and the consequences (With what results?).

### 3. Was there evidence that the programs' effectiveness had been established?

We are not interested in the efficient provision of ineffective services (i.e., those that have been shown to do no more good than harm by themselves or compared with no treatment). In fact, we are not interested in the provision of such services under any conditions, efficient or otherwise. If something is not worth doing it's not worth doing well. Therefore, if the economic evaluation assumes effectiveness, some indication should be given of the prior validation of effectiveness. It is also possible that the efficiency evaluation may have been conducted simultaneously with the evaluation of efficacy or effectiveness. This is the case in many randomized trials of therapies that also include a comparison of the costs of the experimental program and a control, which may be a placebo or a currently existing program. Note, however, that efficiency evaluations alone cannot establish effectiveness. There are, after all, efficient methods of worsening the quality of life as well as improving it. (If you want to know more about the methods of determining whether a therapy does more good than harm you should read part V of this series.)

### 4. Were all important and relevant costs and consequences for each alternative identified?

Even though it may not be possible or necessary to measure and value all of the costs and conse-

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quences of the alternatives being compared, the important and relevant ones should be identified. The information in the viewpoint statement and program description should allow you to judge what specific costs and consequences or outcomes it is appropriate to include in the analysis.

An overview of the types of costs and consequences that may be relevant to economic evaluation of health services and programs is provided in Fig. 1. Three categories of costs are shown. Since the costs of a health care service or program are best thought of in terms of the resources used, category I contains the costs of organizing and operating the program. The identification of these costs often amounts to listing the "ingredients" of the program — both variable costs (such as those of health care professionals' time or supplies) and fixed or overhead costs (such as capital costs, rent and the costs of light and heat). These costs are often referred to by economists as "direct costs".\*

Category II contains costs that are borne by patients and their fam-

\*Health care administrators sometimes reserve the term direct costs for variable costs only and may refer to overhead costs as indirect costs. In economic evaluations, however, economists use the term indirect costs to denote a separate and distinct type of cost, as we will explain later. Users of evaluations should be aware of this potential source of confusion.

ilies. These include any out-of-pocket expenses as well as the value of any resources they contribute to the treatment process. Patients and their families sometimes lose time from work while seeking treatment or participating in a health program. Such "production losses" are also a cost of the health care service or program and are often referred to by economists as "indirect costs". However, care must be taken when including this cost in an analysis, since its inclusion implies that the cost was incurred as a result of participation in treatment and therefore that the individual's condition alone would not have prevented productive activity.† Finally, the anxiety, and perhaps pain, associated with treatment constitutes a psychic cost frequently encountered by patients and their families.

While these two categories cover most of the costs relevant to economic evaluations of health care services, a third category also warrants mention. It may be that the operation of a health care service or program changes the use of resources in the broader economy outside the health sector. For example, an occupational health or safety pro-

†The complexity of the relation between lost work time and the value of forgone output places it beyond the scope and purpose of this article. However, for a discussion of its implications for categories II and III you can read Stoddart's article.

gram may result in more costly production processes, thereby raising the price of, say, cars. In principle such instances should be identified, though in practice they may rarely be significant. (Few economic analyses of alternative health programs take them into account.)

Fig. 1 also shows three categories of consequences of health care services and programs. Category I contains therapeutic outcomes or effects of the alternatives. These effects will usually include changes in the physical, social or emotional functioning of individuals. In principle such changes can be measured objectively and refer only to an individual's ability to function and not to the significance, preference or value attached to this ability by the individual or by others.

The therapeutic effects of a service or program give rise to two other important categories of consequences. First, the effects may result in changes in the use of resources in the future (category II). Within the health care sector, less use of resources may be required for treatment of the condition and its sequelae than would otherwise have been the case. For example, an effective hypertension screening program averts the future cost of caring for stroke victims. The saving in the use of health care resources attributable to the screening program is usually referred to by economists as the

Costs		Consequences	
I. Organizing and operating costs within the health care sector (e.g., health care professionals' time, supplies, equipment, power and capital costs)	Direct costs	I. Changes in physical, social or emotional functioning ( <i>effects</i> )	
II. Costs borne by patients and their families		II. Changes in resource use ( <i>benefits</i> )	
Out-of-pocket expenses		For organizing and operating services within the health care sector	
Patient and family inputs into treatment	Indirect costs	For the original condition	Direct benefits
Time lost from work		For unrelated conditions	
Psychic costs		Relating to activities of patients and their families	
III. Costs borne externally to the health care sector, patients and their families		Savings in expenditure or leisure time	Direct benefits
		Savings in lost work time	Indirect benefits

Fig. 1—Types of costs and consequences relevant to economic evaluation of health care services and programs (adapted, with permission, from reference 3).



direct benefit of the screening program. Notice, however, that if we adopt the viewpoint of a health care system the direct benefits are sometimes negative owing to the increased use of services for the treatment of conditions (e.g., arthritis) that may develop in patients during their newly prolonged lives. The therapeutic effects of a health care service or program may also affect the use of resources by patients and their families. Of particular interest is the possibility that patients and their families may gain working time as a result of their participation in treatment. These production gains are usually referred to by economists as "indirect benefits".

The inclusion of indirect benefits in economic evaluations is a source of some controversy among analysts. It is sometimes argued (rather narrowly it seems) that health care evaluation should confine itself to changes in the use of resources in the health care sector only, rather than in the entire economy. More serious is the assertion that changes in the output of individuals or groups are simply not the grounds upon which we usually make decisions about allocation of health care resources that will affect those individuals or groups. Therefore, it is misleading to enter the value of such changes into a cost-benefit calculation. A third criticism is that the valuation of indirect benefits (usually through increased earnings of individuals) makes a series of value judgements and assumptions that may only be appropriate in a limited number of cases. While it is not possible to discuss and evaluate these claims here, you should be aware that the inclusion of indirect benefits in a cost-benefit analysis may not be straightforward.<sup>4,5\*</sup>

The therapeutic effects of health care services and programs also give rise to another extremely important category of consequences; namely, changes in the quality of life of patients and their families (category

III). The change in quality of life produced by the therapeutic effects is distinguished from the effects themselves by the significance or value that patients and their families attach to the effects. It is, of course, possible — and, in fact, likely — that different individuals place a different importance on the same level of physical, social or emotional functioning. (This was demonstrated by the example of the impact of a broken arm on the sign painter and the translator in part A.)

With respect to both the costs and the consequences we have described it may be unrealistic to expect all relevant items to be measured and valued in an economic analysis owing to the small impact of some relative to the effort required to measure or value them accurately; however, it is helpful to users to have as many of them as possible identified. It is particularly important that the outcomes of interest be identified clearly enough for you to judge the appropriateness of the type(s) of economic evaluation chosen. That is, it should be apparent (a) whether a single outcome is of primary interest as opposed to a set of outcomes that are each of some, if not equal, interest, (b) whether the outcomes are common to the two alternatives being compared, and (c) to what degree each program is successful in achieving each outcome of interest. Similarly, it is important to know whether the consequence of primary interest is the therapeutic effect (which implies that a cost-effectiveness analysis should be done if possible), the net change in the use of resources (cost-benefit analysis) or the quality of life of the patients and their families (cost-utility analysis).

#### *5. Were costs and consequences measured accurately in appropriate physical units?*

While identification, measurement and valuation often occur si-

multaneously in economic analyses, you should view each as a separate phase of the analysis. Once the important and relevant costs and consequences have been identified, they must be measured in appropriate physical or natural units. For example, measurement of the operating costs of a particular screening program may yield a partial list of "ingredients" as follows: 500 physical examinations performed by physicians, 10 weeks of salaried nursing time, 10 weeks' use of a 100-m<sup>2</sup> clinic, 20 hours of medical librarian research time from an adjoining hospital and so forth. Similarly, costs borne by patients may be measured by the amount of medication purchased, by the number of times travel was required for treatment or by the time lost from work while the patient was being treated.

Situations in which resources are used jointly by one or more programs present a particular challenge to accurate measurement. How much use of a resource should be allocated to each program and on what basis? A common example is found in every hospital, where numerous clinical services and programs share overhead services (e.g., power, cleaning and administration) that are provided centrally. In general, there is no nonarbitrary solution to the measurement problem. You should, however, satisfy yourselves that "reasonable" criteria (e.g., number of square metres, number of employees or number of cases) have been used in the distribution of the common costs. You should definitely ascertain that such shared costs have, in fact, been allocated to participating services or programs, as this is a common omission in evaluations. Clinical service directors often argue that small changes in the size of their programs (up or down) do not affect the use of central services. Sometimes it is even argued that overhead costs are unaffected by the service itself. However, though this argument may be appealing from the viewpoint of a particular program or service director, the extension of this method to each service in the hospital would imply that all the services could be operated without light, heat, power and secretaries!

\*Those who criticize the inclusion of indirect benefits, saying You can value a livelihood but you can never value a life! appear to be confusing indirect benefits with another type of benefit. This is the intangible value we, as individuals and as a society, place on life itself (regardless of earning potential) and on the avoidance of pain and suffering. Although intangible benefits and costs of health care

services undoubtedly exist, by their very nature they are difficult to include in a cost-benefit analysis, which expresses costs and consequences in dollars. They presumably are taken into account, however, in cost-utility analyses, wherein program effects are translated into a measure of value based on preferences rather than dollars, as discussed in question 6.



With respect to the measurement of consequences, if the outcomes of interest have been clearly identified, then the selection of appropriate units of measurement for program effects should be relatively straightforward. Effects might relate to mortality and be measured in years of life gained or deaths averted, or they might relate to morbidity and be measured in reductions in the number of days of disability or improvements in health status according to some index of physical, social or emotional function. They may be even more specific, depending on the alternatives under consideration. Thus, "percentage increase in weight-bearing ability" may be an appropriate natural measurement unit for an evaluation of a physiotherapy program, and "the number of correctly diagnosed cases" may be appropriate for a comparison of venography with leg scanning in the diagnosis of deep-vein thrombosis.

Changes in the use of resources resulting from the effects will be measured in physical units similar to those used for costs. Thus, the changes in use resulting from any particular program will likely be recorded in numbers of procedures or in amounts of time, space or equipment. Changes in the use of resources by patients will continue to be measured, for example, in amounts of medication purchased or number of trips taken for treatment.

While the nature of changes in the quality of life may be described in an economic evaluation, measurement in objective, physical or natural units is difficult, although the consequence of some surgical interventions may be quantified in "number of complications". However, the adjustment of effects for quality of life is usually a matter of valuation.

#### 6. Were costs and consequences valued credibly?

The sources and methods of valuation of costs, benefits and utilities should be clearly stated in an economic evaluation. Costs are usually valued in units of local currency on the basis of prevailing "prices" of personnel, commodities, services and so forth and can often be taken directly from program budgets. All current and future program costs

are usually valued in constant dollars of a base year (usually the present) to remove the effects of inflation from the analysis.

It should be remembered that the object in valuing costs is to obtain an estimate of the worth of the resources used by the program. This may necessitate adjustments to some apparent program costs, as in the case of volunteer labour or subsidized services received by one program instead of another. In addition, valuation of the cost of a day of institutional care for a specific condition is particularly troublesome, in that the use of an average cost per day (the widely quoted "per diem"), calculated on the basis of the institution's annual caseload, almost certainly overestimates or underestimates (sometimes by a large amount) the actual cost for any specific condition. You should thus approach per-diem values with extreme caution.\*

Valuation of direct benefits proceeds in the same fashion as that of costs and is subject to the same caveats since the benefits are usually the expected future costs that are saved. Valuation of production gains or indirect benefits (i.e., changes in the value of output of individuals or groups who receive the health care program or service) usually employs the wage rates for individuals or groups to value the increased working time available. It is here that critics of cost-benefit analyses point out the inequity associated with

\*In principle, and with great effort in practice, it is possible to identify, measure and value each resource (e.g., drugs, nursing time, light or food) used in treating a specific patient or group of patients. While this yields a relatively accurate cost estimate, the detailed monitoring and data collection are usually prohibitively expensive. The other broad costing strategy is to start with the institution's total costs for a particular period and improve upon the method of simply dividing by the total number of patient days to produce an average cost per day. Quite sophisticated methods of cost allocation to individual hospital departments or wards have been developed.<sup>6</sup> An intermediate method involves acceptance of the components of the general per diem relating to "hotel" costs (since these are relatively invariant for all patients) combined with more precise calculation of the costs of medical treatment of the individual patients.<sup>7</sup> Of course, the effort devoted to estimating accurate per diems depends on their overall importance in the study; however, unthinking use of per diems or average costs should be avoided.

linking estimates of the value of health care programs to the vagaries of the market. They argue that acceptance of existing wage rates coupled with the inclusion of indirect benefits biases cost-benefit studies against programs aimed at minority groups, housewives, the elderly, children and the unemployed. Although it may be possible to adjust some of the estimates to acknowledge this problem (e.g., by imputing a value to housewives' services based on wages for similar work) the indirect benefit issue remains controversial.

In valuation of preferences or utilities we are basically attempting to ascertain how much better, all things considered, the quality of life is in one health situation or state (e.g., when dialysis is performed at home with help from a spouse or a friend) compared with another (e.g., when dialysis is performed in hospital). Several techniques are available for making the comparison: each will produce a utility value (mentioned in part A) with which one can increase or decrease the value of time spent in health situations resulting from the alternative in question relative to a baseline. Usually the results of utility analyses will be expressed in "healthy days" or "quality-adjusted life-years" resulting from the programs being evaluated.

Two broad approaches to utility analysis can be found in the literature. The first approach, outlined by Torrance,<sup>4</sup> emphasizes the development of measurement methods and empirical testing in different populations. The other approach, outlined by Weinstein,<sup>5</sup> emphasizes the estimation of utility values by a quick (and inexpensive) consensus-forming exercise and then the performance of an extensive sensitivity analysis on the chosen values to see whether the results change if the utility estimates are varied. We see a role for both approaches. The latter is useful in persuading decision-makers to think about problems in allocating resources and is, in fact, relatively quick and inexpensive. The measurement approach is useful in highlighting the fact that different individuals (doctors, policymakers, patients and the general public as taxpayers) may have dif-



ferent values, and it is clearly crucial in situations in which the result is sensitive to the utility values assigned. (An example of such a situation arose in the study by Stason and Weinstein<sup>10</sup> on the economics of hypertension therapy. The result of their study was sensitive to whether it was assumed that the side effects of antihypertensive drugs constituted a 1% or a 2% reduction in health status.)

Since the measurement of preferences in health is relatively new, there are naturally many unresolved issues in cost-utility analyses. You will probably want to know, at the least, whose preferences — patients', providers', taxpayers' or bureaucrats' — were used to construct the utility values. If patients' preferences were not used you may want further assurance that the persons whose preferences were used clearly understood the characteristics of the health state, either through personal experience or through a description of the state presented to them.

#### 7. Were costs and consequences adjusted for differential timing?

Since a comparison of programs or services must be made at one point in time (usually the present), the timing of program costs and consequences that do not occur entirely in the present must be taken into account. Different programs may have different time profiles of costs or consequences. For example, the primary benefits of an influenza immunization program are immediate, whereas those of a hypertension screening program will occur in the future. The time profile of costs and consequences may also differ within a single program; the costs of the hypertension screening program would be incurred in the present. Future dollar costs and benefits are therefore reduced or "discounted" to reflect the fact that dollars spent or saved in the future should not weigh as heavily in program decisions as dollars spent or saved today. This is primarily due to the existence of "time preference" — that is, we, as individuals and as a society, prefer to have dollars or resources now as opposed to later because we can use them in the interim. This is evi-

denced by the existence of interest rates (as well as by the popular wisdom about "a bird in the hand"). Moreover, since time preference is not exclusively a financial concept, outcomes should also be discounted in cost-effectiveness and cost-utility studies.<sup>11-14</sup>

#### 8. Was an incremental analysis of costs and consequences of alternatives performed?

For a meaningful comparison it is necessary to examine the additional costs imposed by the use of one service or program over another, compared with the additional effects, benefits or utilities it delivers. This "incremental" approach to the analysis of costs and consequences can be illustrated by one of the examples cited in part A of this article; namely, the strategies for diagnosing deep-vein thrombosis.<sup>7</sup> Table II shows the costs and outcomes (in terms of correct diagnoses\*) generated by two alternative strategies: impedance plethysmography alone and impedance plethysmography plus outpatient venography if the former gives negative results.<sup>7</sup> Impedance plethysmography is a noninvasive strategy, whereas venography, the diagnostic "gold standard" for deep-vein thrombosis, can cause pain and other side effects. Although one could compare the simple ratios of costs to out-

\*The study by Hull and associates<sup>7</sup> is an example of a cost-effectiveness analysis in which the outcomes are not therapeutic effects but, rather, intermediate diagnostic outcomes with direct implications for therapeutic effects in that the failure to diagnose deep-vein thrombosis leads directly to increased morbidity and mortality.

comes for the two alternatives one should compare the *incremental* costs with the *incremental* outcomes, since this will tell us how much we are paying for each extra correct diagnosis in adding the extra diagnostic test. In this case the relevant figure is \$4781 per correct diagnosis, not the average figure for the second program, which is \$3003 per correct diagnosis. It may be decided that \$4781 is still a price worth paying; however, it is important to be clear on the principle since, as we pointed out in part A, in screening for cancer of the colon there was a big difference between the average cost per case detected of a protocol of six sequential tests and the incremental cost of performing a sixth test, having already done five.<sup>15</sup>

Obviously similar analyses could be performed if the consequences were effects in natural units (e.g., years of life) or in utilities (e.g., quality-adjusted life-years).

#### 9. Was a sensitivity analysis performed?

Every evaluation will contain some degree of uncertainty, imprecision or methodologic controversy. What if the compliance rate for influenza vaccination was 10% higher than that considered for the analysis? What if the hospital per diem still understated the true resource cost of a treatment program by \$100? What if a discount rate of 6% instead of 2% had been used? What if indirect costs and benefits had been excluded from the analysis? You will often ask these and similar questions; therefore, careful analysts will identify critical methodologic

Table II—Economic evaluation of alternative diagnostic strategies for 516 patients with clinically suspected deep-vein thrombosis<sup>7</sup>

Program*	Cost (\$US)	Outcome (no. of correct diagnoses)	Ratio of cost to outcome (cost [\$US] per correct diagnosis)
IPG alone	321 488	142	2264
IPG and outpatient venography if results of IPG are negative	603 552	201	3003
Increment of second program over first program	282 064	59	4781

\*IPG = impedance plethysmography.



assumptions or areas of uncertainty. Furthermore, they will often attempt to rework the analysis (qualitatively at least, if not quantitatively) with different assumptions or estimates to test the sensitivity of the results and the conclusions to such changes. If large variations in the assumptions or estimates underlying an analysis do not produce significant alterations in the results, then one would tend to have more confidence in the original results. If the converse occurs, then more effort is required to reduce the uncertainty or improve the accuracy of the critical variables. In either case a sensitivity analysis is an important element of a sound economic evaluation.

10. *Did the presentation and discussion of the results of the study include all issues of concern to users?*

It will be clear from the preceding discussion that economic analysts have to make many methodologic judgements when undertaking a study. Faced with users who may be mainly interested in the "bottom line" (e.g., should they buy a computerized tomography scanner?) how should they present their results?

Decision indices, such as cost-effectiveness and cost-benefit ratios, are useful in summarizing the results of a study. However, they should be used with care, for the reader, when interpreting them, may not be completely clear on what has gone into their construction. Some analysts give a range of results. For example, in an economic evaluation of neonatal intensive care for very-low-birth-weight infants Boyle and coworkers<sup>6</sup> compared the results for infants weighing less than 1000 g and from 1000 to 1500 g in terms of costs up to the time of hospital discharge, costs and consequences to age 15 years and costs and consequences for a lifetime (Table III). They left it to the reader to decide which index (or indices) to use in judging neonatal intensive care, since the different measures incorporate different value judgements and amounts of precision. (For example, the index of net economic benefit includes production gains or

losses, and the index of cost per quality-adjusted life-year incorporates the preferences for health states of a sample of the local population.)

This leads to another general point; namely, it is important for analysts to be as explicit as possible about the various judgements they have made in carrying out the study. A good study should leave you more (rather than less) aware of the various technical and value judgements necessary to arrive at decisions on the allocation of resources in health care.

Finally, a good study should begin to help you interpret the results in the context of your own situation. This can be done if the analysts are explicit about the viewpoint for the analysis and indicate how particular costs and benefits might vary by location. For example, the costs of instituting day-care surgery may vary depending on whether a purpose-built day-care unit already exists or whether wards have to be converted. Similarly, the benefits of day-care surgery may vary depending on whether there is a shortage of beds and on whether the beds will be left empty.<sup>16</sup> Obviously it is impossible for the analysts to anticipate every possibility in every location, but one limitation of economic evaluation techniques is that they assume that freed resources will be put to other beneficial uses. Evans and Robinson<sup>17</sup> argue that in the case of

day-care surgery the full economic payoff may not have been obtained in at least one Canadian hospital.

### Limitations of economic evaluation techniques

The main purpose of this pair of articles is to make you more aware of the methodologic judgements involved in an economic evaluation in the health care field. In Table I we have consolidated the points made in the text into a checklist of questions you should ask when critically assessing the results of an economic evaluation. Some of the questions signal limitations of economic evaluation techniques. For example, economic evaluation techniques assume, rather than establish, program effectiveness. There are several other limitations of which you should be aware.

Of primary concern from a policy viewpoint is that economic evaluations do not usually incorporate into the analysis the importance of the distribution of costs and consequences. Yet in some cases the identity of the recipient group (e.g., the poor, the elderly or working mothers) may be an important factor in assessing the social desirability of a service or program. Indeed, it may be the motivation for the program. Although it is sometimes suggested that differential weights be attached to the value of outcomes to special

Table III—Measures of economic evaluation of neonatal intensive care, according to birth-weight class (5% discount rate)\*

Period	Birth-weight class: cost (\$)†	
	1000–1499 g	500–999 g
To hospital discharge‡		
Cost/additional survivor at hospital discharge	59 500	102 500
To age 15 years (projected)		
Cost/life-year gained	6 100	12 200
Cost/QALY§ gained	7 700	40 100
To death (projected)		
Cost/life-year gained	2 900	9 300
Cost/QALY gained	3 200	22 400
Net economic benefit (loss)/live birth	(2 600)	(16 100)
Net economic cost/life-year gained	900	7 300
Net economic cost/QALY gained	1 000	17 500

\*Adapted, with permission, from reference 6.

†In 1978 Canadian dollars; multiply by 0.877 to calculate equivalent cost in 1978 US dollars.

‡All costs and effects occurred in year 1.

§QALY = quality-adjusted life-year.



recipient groups, this is not usually done in an economic evaluation. Rather, an "equitable" distribution of costs and consequences across socioeconomic or other defined groups is viewed as a competing dimension, in addition to efficient deployment of resources, upon which decisions are made.

As we have already pointed out, economic evaluation techniques assume that resources that are freed up or saved by preferred programs will not, in fact, be wasted but will be used in alternative worthwhile programs. This assumption warrants careful scrutiny, for if the freed resources are consumed by ineffective or unevaluated programs, then not only is there no saving, but the overall costs of the health care system will actually increase without any assurance of additional improvements in the health status of the population.

Finally, an evaluation of any sort is costly. If we bear in mind that even a cost-benefit analysis should be subject to a cost-benefit analysis, it seems reasonable to suggest that economic evaluation techniques will prove most useful when program objectives require clarification, when the competing alternatives are significantly different in nature and when large resource commitments are being considered.

## Conclusion

In this pair of articles we have

tried to help potential users of economic evaluations to understand such studies and assess their validity and usefulness. Our intent has not been to create hypercritical users who will be satisfied only by superlative studies. As we have emphasized, it is unlikely that every study will satisfy all the methodologic criteria we have discussed. However, the readers' guides should help you to quickly identify the strengths and weaknesses of any study.

We thank our colleagues and students for their suggestions and criticisms of earlier versions of this paper.

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# Vafia

IN ANGINA AND  
HYPERTENSION

**Corcard** (Nitroglycerin)

Corcard is a powerful  
nitroglycerin preparation  
in the form of a tablet.

**Signature**

## Index Medicus

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## CLINICAL ECONOMICS

### MODULE 2

#### THE COST OF ILLNESS

After completing this module you should understand:

- a. the concept of the cost of illness,
- b. how the cost of a particular disease or condition can be calculated,
- c. how the approach can be used for policy purposes.



1

## THE COST OF ILLNESS

### Introduction

You will be familiar with the concept of the burden of illness from the epidemiology modules. It uses indicators of prevalence, incidence, mortality losses and morbidity losses to calculate the burden imposed on society by particular diseases. The reference by the Ghana Health Assessment Project Team will refresh your memory. Clinical economics builds on these foundations to provide an extra dimension to the burden of illness, known as the cost of illness. Two approaches can be used, one based on prevalence estimates, the other on estimates of incidence.

### Prevalence Based Estimates of the Cost of Illness.

Prevalence is defined as the number of cases of a particular disease or condition which exist in a given time interval, usually a year. The economic cost of these cases is:

① the value to society of all resources consumed during the period as a result of diagnosis, treatment and repercussions of the disease or condition;

PLUS ② the value of lost production as a result of morbidity during the period;

PLUS ③ the value of lost production as a result of premature mortality which occurs during the period.

Hence, the prevalence approach to the cost of illness is concerned with costs accruing in the specified period and with costs attributable to premature mortality in that period. It includes the costs incurred by both preexisting cases and new cases identified during the period. The reference by Cooper & Rice uses this method.

### Incidence Based Estimates.

Incidence is defined as the number of new cases of a disease or condition that have their onset during a specified period. In the incidence based approach to the cost of illness, only the costs incurred by new cases identified during the period are considered. As in the prevalence approach, direct health care costs and the value of lost production must be calculated. However, in this instance the expected future costs associated with the new cases detected in the specified period must be added to the costs incurred during the period. The reference by Hartunian et al uses this approach.

### Direct Costs *Resources that are used - direct medical costs*

Most cost of illness studies divide costs into direct, indirect and intangible costs. Direct costs are the costs that the health sector and the patient (or family) must bear because of the illness. Costs to the health sector include the cost of diagnosis, treatment, rehabilitation and prevention of the disease and its side effects. However, other costs incurred by the patient, such as travel, special food, and home nursing, should also be included,

though they are often omitted due to problems with quantification.

Other problems exist as well. For example, both the incidence and prevalence approaches require an estimate of the health care costs that will be incurred by new cases of the disease in the current time period. Often the only available information is the current cost of treating an average patient, which is not necessarily equal to the cost of treating a new patient.

Take the costs of hospitalization as an example. The most readily available information is derived by dividing the hospital's total costs in the most recent financial year by the number of bed days occupied in that year. This produces an estimate of the average cost per bed day in the recent past. Using this figure to estimate the cost of hospitalizing an additional patient poses at least two problems.

Firstly, the cost of additional patients in the future will be lower than the average cost of hospitalizing existing patients if the new patients take up beds that have been underutilized in the past. This is because new buildings and equipment are not required to cater for the new patients. On the other hand, the cost of hospitalizing new patients is likely to be higher than the average cost of hospitalizing patients in the past if new buildings and equipment are necessary.

Secondly, the cost of a day in hospital for all diseases is not the same. Using an average cost for all diseases will result in underestimating the cost of some diseases and overestimating the cost of others.

Another practical problem is that some patients may suffer from a number of illnesses at the same time. It is then difficult to allocate costs to each disease.

### Indirect Costs

Indirect costs are the losses in economic output due to death, morbidity, and disability. For example, a 20 year old person in Ghana (see reading 1) could be expected to live for a further 42.5 years. If, however, the person dies of malaria at 20, society has lost 42.5 years of life, and 42.5 years of work (assuming retirement at 65). The number of lost years of work multiplied by the yearly wage rate is usually taken to be the value of the output lost as a result of the person's death.

Three complications arise. Firstly, some of the people who died may have been unemployed had they lived. They would not have produced while unemployed. If the unemployment rate is 10%, it is generally assumed that only 90% of the total number of years lost through premature mortality are productive years. It is this total that is multiplied by the wage rate to obtain the cost of premature mortality.



Secondly, some of the people affected by a disease may not be paid money wages - housewives and unpaid family-farm workers for example. To use a zero wage rate for these people implies that their loss imposes no economic burden on society, and many studies therefore impute a value for this labour.

Thirdly, the extent to which morbidity and mortality result in a loss of production can be questioned when there is a large pool of unemployed or underemployed labour. People leaving the workforce can be replaced with relatively little dislocation to production. For this reason, indirect costs are often interpreted as losses of productive potential rather than losses in actual production.

The indirect costs of morbidity and disability can be estimated in a similar manner to the costs of premature mortality. Data generally are available from life tables and labour force statistics. Question 3 illustrates the procedure.

#### Intangible Costs

In general, the costs of pain, suffering and grief associated with a disease are regarded as intangible (immeasurable) costs in the cost of illness literature. This may not be important if the aim is to compare the cost of different diseases and it can be assumed that intangible costs are either proportional to the sum of direct and indirect costs, or constant across diseases. Some attempts have been made to put a money value on the costs of pain and suffering, but they are not widely used yet.

#### Time

Both the incidence and prevalence approaches involve costs which affect society in different time periods. For example, the costs of premature mortality must be estimated in both approaches. Assume that the average healthy bricklayer produces output valued at \$20,000 a year, and would retire from work at the age of 60. One bricklayer, however, dies this year at 40. Through this death, society loses 20 years of production. The cost of this lost production is \$20,000 this year, and \$20,000 for each of the following 19 years. Premature mortality, therefore, has resulted in a stream of costs over a number of years. Economists argue that it is not possible to simply add up costs which accrue in different time periods. A technique known as discounting must be used for such comparisons. This is the topic of Module 3.

#### Conclusions

In this module, two approaches to measuring the cost of illness have been identified. You will not be able to calculate the full cost of illness until you have mastered Module 3, but at this stage you should understand the concept, be able to think about which approach is preferable and the policy implications of each. These issues provide the focus of questions 1 and 2.

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### QUESTIONS

1. The following table is taken from Cooper & Rice. The calculations are based on the prevalence approach.

Total economic costs of disease in the United States in 1972				
Disease type	Total cost (millions of dollars)	Direct costs (millions of dollars)	Indirect costs (millions of dollars)	Percentage distribution of total costs
Infective and parasitic diseases	\$ 3,234	\$ 1,412	\$ 1,822	1.8
Neoplasms	15,641	3,872	11,769	8.9
Endocrine, nutritional and metabolic diseases	5,717	3,436	2,281	3.3
Diseases of the blood and blood-forming organs	875	491	384	0.5
Mental disorders	13,782	6,985	6,797	7.9
Diseases of the nervous system and sense organs	10,703	5,947	4,756	6.1
Diseases of the circulatory system	37,430	10,919	26,511	21.4
Diseases of the respiratory system	15,764	5,931	9,833	9.0
Diseases of the digestive system	16,931	11,100	5,831	9.7
Diseases of the genito-urinary system	6,344	4,471	1,873	3.6
Diseases of pregnancy, childbirth, and the puerperium	2,914	2,607	307	1.7
Diseases of the skin and subcutaneous tissue	2,040	1,525	515	1.2
Diseases of the musculo-skeletal system and connective tissue	8,913	3,636	5,277	5.1
Congenital anomalies	1,375	381	994	0.8
Accidents, poisonings, and violence	21,649	5,121	16,528	12.4
Other	11,625	7,398	4,227	6.6
Total	\$174,934	\$75,231	\$99,703	100.0

Data source: Cooper, B. S., and Rice, D. P. 1976. The economic cost of illness revisited. Social Security Bulletin, Table 7.



1. (a) Why is the cost of diseases of the circulatory system so high? (b) Why is the direct cost of neoplasms relatively low while the indirect cost is relatively high? (c) What value is this table to policy makers? Explain your answer.

2. (a) Is Table 2 in the reference by the Ghana Health Assessment Team based on the incidence or prevalence approach? (b) If you calculated a cost of illness based on Table 2, how would you expect the rankings of diseases to change? (c) What value is Table 2 to policy makers? (d) What are the strengths and weaknesses of burden of illness and cost of illness estimates?

3. You have been asked to consider the comparative burden of 4 diseases in your community based on the incidence approach. Disease A has an incidence of 7/1000 per annum and a case fatality rate of 25%. All deaths occur in the year of onset. Disease B has an incidence of 14/1000 p.a. and a case fatality rate of 5%. The incidence of Disease C is 15/1000 p.a. with a 17% case fatality rate, and Disease D's incidence is 10/1000 p.a. with 22% case fatality.

Cases of A are hospitalised in regional hospitals for an average of 6 weeks (averages are determined from the days spent in hospital by all patients including those who die). Patients who recover are then free from disability. Disease B requires an average of 3 weeks treatment at a community hospital, but 40% of survivors develop complications 5 years after the onset of the disease. These complications require 6 weeks of treatment in a regional hospital.

Disease C requires an average of 12 weeks treatment at a community hospital, with no further complications. Cases of disease D are treated in regional hospitals for an average of 5 weeks. Complications occur 10 years after onset in 25% of survivors, requiring 6 weeks treatment in a community hospital. Costs are \$20 per day at the regional hospital and \$10 per day at the community hospital.

a. The country has a population of 100,000. How many days of hospital treatment are required for each disease in the year of onset?

b. What is the total cost of hospital treatment for each disease in the year of onset?

c. How many cases will survive the first year of each disease?

d. What are the future costs of treating each disease (after the year of onset) and in what years do they occur?

The average age of onset of Disease A is 1 year, for Disease B is 25 years, Disease C is 30 years, and Disease D, 5 years.



e. Using the life expectancy table (Table A) in the reading by the Ghana Health Assessment Project, calculate the total number of years of life lost from the mortality caused by each disease.

f. What are the costs of premature mortality of each disease in terms of lost earnings, assuming that the working life span is 15 to 65 years, average yearly earnings are \$600, and the unemployment rate is 12%?

The average numbers of "disability weeks" for each disease are as follows, (including time spent obtaining hospital treatment):

Disease	Average no. of disability weeks in year of onset (year 1).	In subsequent years <u>per person with complications</u>	
		yr. 6	yr.11
A	12 -	0	0
B	6	26 <sup>W/S</sup>	0
C	24	0	0
D	10	0	52

g. What total number of years of disability are caused by each disease? (1 year = 365 days)

h. Calculate the cost of any production losses due to disability and specify the years in which they occur using the same assumptions as part f.



# A Quantitative Method of Assessing the Health Impact of Different Diseases in Less Developed Countries

## GHANA HEALTH ASSESSMENT PROJECT TEAM\*

Ghana Health Assessment Project Team. A quantitative method of assessing the health impact of different diseases in less developed countries. *International Journal of Epidemiology* 1981, 10: 73-80.

A method is described for assessing quantitatively the relative importance of different disease problems on the health of a population. The impact of a disease on a community is measured by the number of healthy days of life which are lost through illness, disability and death as a consequence of the disease. The measure is derived by combining information on the incidence rate, the case fatality rate and the extent and duration of disability produced by the disease. In Ghana, it is estimated that malaria, measles, childhood pneumonia, sickle cell disease and severe malnutrition are the 5 most important causes of loss of healthy life and between them they account for 34% of healthy life lost due to all diseases.

The methodology may be used to help determine the priorities for the allocation of resources to alternative health improvement procedures by estimating the number of healthy days of life which are likely to be saved by different procedures and by relating these savings to the costs of the procedures.

Ghana, like many less developed countries (LDCs), has put a high priority on health. In the 20 years since independence, there has been a threefold increase in the number of doctors, hospital beds, and real per capita expenditure on health, (to more than 5 cedis (about \$5) per person in 1975). In

spite of this, vital statistics have changed little: the infant mortality rate continues to average about 130 per 1000 live births; the expectation of life at birth is less than 50 years; in rural areas the maternal mortality rate is about 14 per 1000 births; and the birth rate remains at nearly 50 per 1000 population per year.

In order to analyse why there has been so little apparent change in the health status of the population of Ghana, we have developed a method whereby the health impact of different disease problems may be estimated quantitatively. The effects of various intervention programmes can be examined for the magnitude of the change which they might be expected to produce in health status. The method may be used as a tool to aid in the planning of a health care system.

Ideally, priorities should be determined such that the maximum benefit is obtained from a given expenditure. In the health sector, however, this approach has had little application anywhere, primarily because of problems related to determining health benefits. The difficulties of measuring the monetary benefits of improved health in technically advanced countries have been well reviewed in Bunker et al.<sup>1</sup> Additional difficulties arise in LDCs because of theoretical problems associated with assessing and valuing rural productivity. For these

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reasons we have developed a non-monetary measure of benefit.

The 3 most important effects that a disease may have in a community are as causes of illness, disability and death. With some exceptions, other social and economic effects of a disease are directly related to its severity as measured by these 3 factors. We have quantified each of these factors in terms of the number of days of healthy life which are lost due to a disease, and we use the total days lost in the community as a measure of the health impact of the disease.

The benefits from various health improvement procedures (HIPs) can be measured by the number of healthy days of life that can be saved by application of the procedures. By calculating the cost of each set of HIPs that may go into a particular health programme, the priority of that health programme relative to other possible programmes can be evaluated in terms of the benefit (healthy life saved) per unit cost.

In this paper we describe the method we have used to determine the relative impact of different disease problems in Ghana; this is the first step in developing priorities for health care programmes.

#### Measuring Disease Impact

We have considered all the diseases which are major causes of illness or death in Ghana (using a modified version of the International Classification of Diseases B list which categorises all disease problems into about 50 groups<sup>2</sup>). By reviewing census data, including derived estimates of age-specific death rates and life tables,<sup>3</sup> cause of death as recorded on death certificates, inpatient and outpatient statistics, and data from special surveys and studies, we have estimated for each disease: the incidence, the case fatality rate, the average ages at onset and death from the disease and the expectations of life at these ages, and the extent and duration of disability and illness among those attacked by the disease. The information has been used to obtain estimates of the days of healthy life which each disease costs the community. The data for our estimates were of variable reliability and, where possible, we derived estimates from 2 or more different sources.

Gastroenteritis may be used to illustrate the methods employed. In 1975, 9% of all certified deaths in children aged 0-4 years were attributed to gastroenteritis. (Death certificates, which include the cause of death, are issued for about 12% of all deaths in Ghana - most are for deaths which occur in hospitals and they are, therefore, a biased

sample of all deaths in some instances we have attempted to correct for this bias, but quantification of the bias is difficult). The annual mortality rate from all causes of death averages about 45 per 1000 per year among children aged 0-4 years (based on demographic analysis from the national census<sup>3</sup>) and about 20% of the population is in this age group. Thus the crude annual mortality rate from gastroenteritis may be estimated as  $0.09 \times 45 \times 0.2 = 0.81/1000$  population. We have assumed that there is negligible mortality from this cause over the age of 4 years, that there is no significant residual disability among those who recover and that each episode of severe diarrhoea (requiring rehydration therapy) completely disables a child for 2 weeks (14 days). The incidence of such severe diarrhoea in West Africa varies with the nutritional status of the population. Morley<sup>4</sup> reports that in the 0-4 year age range, 22% of normal children experienced an episode of diarrhoea each year, as compared to 62% of those with first degree malnutrition. Surveys in Ghana indicate that about 30% of Ghanaian children have first degree malnutrition. Thus we estimate that 34% ( $0.22 \times 70\% + 0.62 \times 30\%$ ) of children have an episode of severe diarrhoea each year and thus the crude annual incidence is 68 per 1000 total population ( $0.34 \times 0.2$  (20% of population in age group 0-4 years)  $\times 1000$ ). The case fatality rate is estimated to be 0.81/68 (mortality rate/incidence rate) = 1.2%. The case fatality rate, independently determined from hospital inpatient and outpatient records, was 1.1%, in quite close agreement with our estimate above. In the calculation of the days of life lost through the disease we have taken the case fatality rate to be 1.0% and the incidence rate to be 70 per 1000 per year.

We have further assumed that among children affected with severe gastroenteritis the average age of onset is 2 years and that the expectation of life at this age is 52.8 years.<sup>3</sup> The days of healthy life lost per 1000 population per year due to death is  $0.01$  (1% case fatality rate)  $\times 70$  (incidence per 1000)  $\times 52.8$  (expectation of life in years at age 2)  $\times 365.25$  (average days in a year) = 13 500 days; the days lost due to sickness per 1000 population per year is  $70$  (incidence per 1000)  $\times 0.99$  (the proportion surviving)  $\times 14$  days (average duration of illness) = 970 days. Thus a total of 14470 healthy days of life per 1000 population is lost each year due to gastroenteritis.

In the Appendix we give the algebraic details of the method used to estimate the days of healthy life lost due to each disease problem. Table 1 shows all of the disease problems considered together



TABLE 1 *Disease problems of Ghana measured in terms of the days of healthy life which each costs the community\**

Disease	Ave. age at onset (A <sub>0</sub> )†	CFR % (C)	Ave. age at death (A <sub>d</sub> )	% Dis- able- ment to death (D <sub>0,d</sub> )	% Perm. Disab. (Q)	% Dis- able- ment (D)	Days of temp. Disab. (t)	Incidence (I)	Days of life lost	% due to premature death
1. Cholera	15	7.6	15	—	0	—	14	0.05	65	99.0
2. Typhoid	20	7.3	20	—	0	—	60	4.0	4755	95.3
3. Gastroenteritis	2	1.0	2	—	0	—	14	70.0	14470	93.3
4. Tuberculosis	20	35.0	25	25	0	—	200	2.0	11005	94.6
5. Diphtheria	3	7.0	3	—	0	—	30	0.01	14	98.0
6. Pertussis	1	1.0	1	—	0	—	30	21.0	4643	86.6
7. Meningitis	10	20.0	10	—	0	—	30	1.25	4650	99.3
8. Polio	3	5.0	3	—	95	25	—	0.22	1227	17.4
9. Measles	2	3.0	2	—	0	—	21	39.0	23358	96.6
10. Malaria	1	2.3	1	—	97.7	2	—	40.0	32567	54.1
11. Venereal disease	20	0.01	30	1.25	0	—	35	1.7	80	25.3
12. Leprosy	20	25.0	30	50	75	25	—	0.5	3167	46.8
13. Chicken pox	4	0.02	4	—	0	—	14	22.0	394	21.8
14. Schistosomiasis	5	4.0	30	4	96	1	—	7.0	4368	67.4
15. Common Cold	15	0.0	—	—	0	—	0.6	1000.0	600	0.0
16. Guinea Worm	7	0.0	—	—	0	—	45	2.4	108	0.0
17. Yaws	4	0.0	—	—	1	30	90	6.0	886	0.0
18. Onchocerciasis	5	0.0	—	—	5	70	—	2.8	1926	0.0
19. Trachoma	3	0.0	—	—	5	86	45	1.6	1403	0.0
20. Hepatitis	20	3.0	20	—	0	—	60	8.87	4647	88.9
21. Trypanosomiasis	15	19.0	17	50	13.5	30	90	0.05	195	79.1
22. Tetanus (a) neonatal	0	80.0	0	—	0	—	0	0.5	6852	100.0
(b) other	15	35.0	15	—	0	—	30	.75	4473	99.7
23. Malignant neoplasms										
(a) child	6	75.0	7	75	0	—	180	0.03	436	98.3
(b) adult	50	80.0	52	75	0	—	180	0.65	3765	91.8
24. Diabetes	40	50.0	55	30	50	25	—	0.05	217	52.2
25. Malnutrition (severe)	2	60.0	2	—	0	—	180	1.5	17465	99.4
26. Sickle Cell Disease	0	80.0	5	50	20	30	—	1.25	17502	87.4
27. Hookworm Anaemia	4	0.1	5	50	5	6	—	19.0	1482	24.6
28. Rheumatic Heart Disease	25	75.0	32	50	25	30	—	0.3	3211	81.1
29. Hypertension	40	75.0	50	50	25	25	—	0.75	5071	70.5
30. Other Heart Disease	35	75.0	45	50	25	30	—	0.37	2961	72.2
31. Congenital Heart Disease	0	80.0	10	50	20	30	—	0.07	929	81.2
32. Cerebrovascular Disease	50	35.0	50	—	35	75	120	2.3	10477	56.7
33. Influenza	20	0.1	20	—	0	—	21	50.0	1825	42.5
34. Pneumonia (a) child	2	40.0	2	—	0	—	30	2.4	18557	99.8
(b) adult	30	10.0	30	—	0	—	30	7.0	9112	97.9
35. Peptic ulcer	25	2.0	35	20	98	5	—	3.88	3558	22.9
36. Other GI Disorders	25	10.0	25	—	0	—	60	2.8	4109	96.3
37. Intestinal Obstruction	30	10.0	40	20	20	10	—	4.0	4950	73.5
38. Cirrhosis	30	80.0	35	50	20	25	—	0.65	6568	86.5
39. Chronic renal disease	30	85.0	35	75	15	25	—	0.31	3387	85.0
40. Complications of Pregnancy	20	6.5	20	—	5	25	21	4.8	5864	82.6
41. Birth Diseases										
(a) Prematurity	0	10.2	0	—	0	—	0	9.6	16774	100.0
(b) Pneumonia	0	50.0	0	—	0	—	0	.46	3940	100.0
(c) Birth injury (inc. asphyxia)	0	50.0	0	—	50	20	—	1.6	16445	83.3
(d) Congenital malformations	0	15.0	0	—	85	25	—	0.96	5961	41.4
(e) Others (inc. Umbilical sepsis & Haemolytic disease)	0	50.0	0	—	0	—	0	0.54	4625	100.0
42. Skin Infections	4	0.0	—	—	0	—	6	470.0	2820	0.0
43. Psychiatric Disorders	15	5.0	35	50	95	30	—	0.66	3635	8.8
44. Other Eye Diseases	60	0.0	—	—	100	50	—	0.05	123	0.0
45. Dental Disease	10	0.0	—	—	10	15	30	2.8	852	0.0
46. Gynaecological Disorders	25	1.0	40	10	20	25	20	1.0	815	10.6
47. ENT Diseases	12	0.3	25	20	4	25	30	0.56	140	15.8
48. Accidents	15	10.0	15	—	5	25	30	7.7	14909	87.7

For some disease problems for which there are a small proportion of deaths occurring after the year of onset, average age at death is given as that at onset and the effects of deaths at later ages are subsumed in the days of life lost under permanent disability, e.g. congenital malformations. \* Per 1000 persons per year. † See Appendix for abbreviation.



with the estimates of case fatality rates, incidence rates and other relevant estimates necessary for the derivation of the number of days of life lost due to each disease (this number is shown also in the Table). For some diseases it was useful for our purposes to consider that a disease with recurrent episodes was a single life-time process. Thus, malaria was taken to be a single life-time disease with high mortality in late infancy and early childhood followed by a marked reduction in mortality by age 5 due to the development of immunity. Thereafter, everyone was assumed to have recurring disability from clinical attacks of malaria averaging 7 days of illness per year. We have assumed that everyone in Ghana gets malaria first at age 1 year and therefore, the incidence is equal to the number of 1 year olds, that is 40/1000 total population/year (4% of the population are aged 1 year). The days of life lost due to the disease are all those that will be lost during the life of the individual, but these days are attributed to the year of first onset of the disease. A document detailing the basis on which the estimates in Table 1 were made is available on request from the authors. Table 2, which is derived from Table 1, lists the 25 most important

disease problems in Ghana ranked in order of importance as measured by the days of healthy life that each costs the community each year.

#### *Priorities among Health Improvement Procedures*

Ranking disease problems as described above is insufficient to determine priorities for health services. Priorities should be determined on the basis of which procedures most reduce the burden of illness, disability and death for a given unit cost. For example, cerebrovascular accidents and cancer are important causes of disability and death, but, with present knowledge and resources, little can be done to prevent or cure them and their priority for resource allocation in LDCs should be low.

The major effects of health improvement programmes will be to reduce the incidence rate, the case fatality rate, and/or the extent of disability and sickness. A particular programme may have an effect on more than one disease (e.g., improved nutrition will not only reduce the incidence of kwashiorkor but will also reduce the measles case fatality rate), and a particular disease may be affected by more than one procedure (e.g. the

TABLE 2 Disease problems of Ghana — ranked in order of healthy days of life lost

Rank order	Disease	No. in Table 1	Days of Healthy life lost*	Percent of Total
1	Malaria	10	32 600	10.2
2	Measles	9	23 400	7.3
3	Pneumonia (child)	34 (a)	18 600	5.8
4	Sickle Cell Disease	26	17 500	5.5
5	Malnutrition (severe)	25	17 500	5.5
6	Prematurity	41 (a)	16 800	5.2
7	Birth Injury	41 (c)	16 400	5.2
8	Accidents	48	14 900	4.7
9	Gastroenteritis	3	14 500	4.5
10	Tuberculosis	4	11 000	3.5
11	Cerebrovascular Disease	32	10 400	3.3
12	Pneumonia (adult)	34 (b)	9 100	2.9
13	Tetanus (neonatal)	22 (a)	6 900	2.2
14	Cirrhosis	38	6 600	2.1
15	Congenital Malformations	41 (d)	6 000	1.9
16	Complications of Pregnancy	40	5 900	1.8
17	Hypertension	29	5 100	1.6
18	Intestinal Obstruction	37	4 900	1.6
19	Typhoid	2	4 800	1.5
20	Meningitis	7	4 600	1.5
21	Hepatitis	20	4 600	1.5
22	Pertussis	6	4 600	1.5
23	Other Birth Diseases	41 (e)	4 600	1.5
24	Tetanus (adult)	22 (b)	4 500	1.4
25	Schistosomiasis	14	4 400	1.4
Total of first 25 diseases			270 200	84.9

\*Per 1000 persons per year



incidence of neonatal tetanus can be reduced either by maternal immunisation or by well managed deliveries).

To illustrate 2 different procedures which may be directed against a particular disease, the effect of an immunisation programme against measles may be compared with the effect of outpatient care. Measles vaccine is 95% effective in the non-immune, immunocompetent child,<sup>5</sup> and under conditions in Ghana a well-managed immunisation programme may reach 70% of susceptible children.<sup>6,7</sup> Thus administration of the vaccine would be expected to reduce the incidence of measles in the country by  $0.95 \times 70\% = 66.5\%$ , but would make no change in the case-fatality rate or in the duration of illness for those who develop measles. In the absence of any medical services we have estimated that measles would 'cost' the community 27600 days of healthy life per 1000 population each year and the number of days of life which would be saved by an immunisation programme is  $27600 \times .665 = 18354$ . If the cost of the measles vaccine and its delivery are 0.5 cedis for each child immunised, the cost per thousand population per year would be 40 (the number of 1 year olds in a population of 1000)  $\times 0.5 = 20$  cedis. Thus the benefit would be about 918 healthy days of life per cedi. In fact, the cost of such immunisation is highly dependent upon the infrastructure which exists for the administration of the vaccine, and it is likely that measles immunisation would be done in conjunction with other immunisation procedures. In general, the immunisation programme should be considered as a package and the combined benefits and costs measured.

Outpatient therapy for measles is estimated to reduce case-fatality rates by 50% (chiefly in those with bacterial pneumonia and/or gastroenteritis). About 30% of families in Ghana are able to take children with measles for outpatient care; thus the days of healthy life saved by outpatient care would be 26800 (the days lost attributable to mortality, the 800 days lost due to morbidity is assumed unaffected by treatment)  $\times .30$  (the proportion of population utilising the health services)  $\times .50$  (the reduction in CFR) equals 4020 healthy days of life per thousand population per year. The cost of an outpatient visit, including drugs, is about 2 cedis.<sup>10</sup> If each child with measles makes an average of 3 visits the cost would be 6 cedis per case. The cost for outpatient care for measles would be 40 (the incidence rate/1000)  $\times .30$  (the coverage)  $\times 6$  cedis, that is 72 cedis per thousand population per year. Under these assumptions outpatient care would save 56 days of healthy life per cedi expended.

Thus compared to outpatient care an immunisation programme against measles could save 16 times as many days of healthy life per cedi.

#### DISCUSSION

The concept of healthy days of life lost is an extension of similar measures that have been based on mortality data alone. The development of these latter measures and their potential use for health planning has been reviewed by Romeder and McWhinnie<sup>11</sup> but, to our knowledge, they have not been used directly in the allocation of health resources. Sullivan<sup>12,13</sup> has proposed a similar index for measuring the effects of morbidity and mortality in technically advanced countries, but he did not relate this measure to specific diseases and thus, as presently formulated, the measure is not likely to be of direct value in determining the allocation of health resources. The concept of 'days of life lost' has been discussed for specific diseases, but a qualitative method was used to determine resource allocation.<sup>14</sup> Recently Shepard and Thompson<sup>15</sup> have proposed a measure of benefit in terms of additional quality-adjusted life-years which is conceptually similar to healthy days of life lost. They discuss four possible types of health effects resulting from health programmes — additional years of healthy survival, additional years of disease, improved health without additional survival, and additional years but with restrictions — and address both the value and the practical difficulties of adding these effects together using a common unit of measure. Other, more narrowly-defined approaches to assess benefits such as estimating the aggregate output increases of labour as a result of control of tropical diseases have been reviewed by Prescott.<sup>16</sup>

The method we have proposed has a number of advantages over qualitative approaches to health planning and resource allocation:

- (1) Quantitative assessment is made of the benefits and costs of alternative health programmes. To be able to state that for a fixed expenditure an immunisation programme against measles may save 16 times more healthy life than would outpatient care is a more persuasive argument for allocating resources to the former than the mere assertion that prevention is better than cure. Such calculations may be extended for all the procedures which might be included in a primary health care programme, and it would be possible to compare the amount of life which is likely to be saved by such a programme with that saved by equal expenditure on other resources,



such as an expansion of hospital facilities.

- (2) With the exception of the extent of disability, each of the variables required to estimate the days of healthy life lost due to a disease may be measured objectively.
- (3) Attention is focused on the key information which should be collected by health statisticians. A distressing feature of much statistical data collected routinely in LDCs is its irrelevance to health planning or care. To obtain some of the required information special studies may be needed, but it is clear what data is required to be able to apply our methodology.
- (4) A framework is set up for the evaluation of the planned programme after it has been implemented since specific targets are provided in terms of the changes in incidence, case fatality rates, and disability which were predicted.
- (5) The assumptions that are used for setting health priorities are made explicitly: if the conclusions are challenged, the individual steps for estimating the costs and benefits in the computations can be examined for their reasonableness and alternative assumptions can be readily considered.
- (6) The health planner is forced to consider the effects of each HIP on a disease by disease and community by community basis to estimate the expected amount of healthy life that will be saved and the costs that will be incurred. Examination of the amount of disability and death due to each disease may highlight those against which efforts may most usefully be directed. Similarly, analysis of the cost of programmes may indicate those for which efforts towards cost reductions should be focused.

It is important to consider the limitations and approximations in the proposed approach. Many of the data that are required to estimate the days of healthy life lost due to a particular disease (e.g. incidence rates, case fatality rates) are not available from routine sources. In deriving estimates of these rates for Ghana a variety of sources have been used; in some instances the rates used have been based upon little more than a consensus. More work is required to assess the sensitivity of the conclusions to changes in these estimates and such studies will enable us to identify which estimates are in need of further refinement. For some diseases it seems likely that our estimates are reasonable, but for others we have made, at best,

a rough approximation. In general, estimates of death and disability rates are more reliable than are estimates of the extent of disability. It is apparent from Table 1 that the most important determinant of loss of days of healthy life is premature death; disability and illness play a relatively minor role for most diseases. These latter 2 factors are difficult to quantify objectively. We have equated disability with death in the sense that a day of 'total' disability is equivalent to the loss of a day due to death. For example, we have assumed that patients with leprosy have an average disablement of 25% from onset of the disease for the rest of their lives. Such an assessment is subjective, but for all diseases combined only 30% of all healthy life lost is attributed to disability and illness. Thus changes in estimates of disability are likely to have a relatively small effect. However, for some specific diseases this is not the case. For example, if we assume that malaria completely disables an adult for 2 weeks a year (4%) rather than for one week (2% — as in Table 1) the estimated annual number of days of life lost is 47 500 days per 1000 population rather than 32 600 days per 1000 population. Which of these 2 estimates of disability rate is most reasonable might be determined through suitably designed special studies.

Our calculations use the average age at onset and death as more detailed information on age specific rates is not available in Ghana. It is unlikely, however, that the use of age and sex specific disease rates would make any substantial difference to the conclusions as the onset of most of the important diseases occurs over a small age range.

Often it is difficult to attribute sickness or death to a single disease. Malnutrition, malaria, diarrhoea and measles in childhood are very common, but frequently it is the combination of these diseases which is fatal rather than any of them individually. We were careful to avoid double counting of deaths when estimating death rates by cause, but the attribution of days of healthy life lost between causes is subject to some uncertainty. For many purposes it is useful to consider a number of diseases together — particularly when estimating the effects of different health improvement programmes. For example, a nutritional programme should prevent deaths attributable to both malnutrition and measles.

'Days of healthy life' as a measure of benefit may be useful for determining allocation of resources within the health sector, but it cannot be used to determine the appropriate allocation of resources between the health and other sectors (such as



education and agriculture). Without putting a specific monetary value on life, this is an unavoidable limitation. However, the method is a considerable advance for purposes of allocation within the health sector and can be used also to quantify the effects on health of programmes in other sectors.

The method we have proposed for measuring the importance of different diseases values individuals in direct proportion to their expectation of life at their current age. Thus the death of a child is regarded as costing the community more than the death of an adult. This is appropriate if the objective is to maximise the total amount of healthy life of the community over time and if one ignores any effect that the death or disablement of an adult has on their dependents (e.g. the death of a mother greatly increases the death rate among her dependent children — the life lost by the children should thus be attributed to the cause of the maternal death). But not all would agree that this is appropriate. We have discussed this issue at length with colleagues in Ghana, where children are valued highly (as in most societies) and have found substantial support for our assumptions. We have tried a number of alternative methods by giving different weights to years of life at different ages and of discounting future years of life. In most cases these alternatives do not produce any very marked alteration in the ranking of the relative importance of different diseases. Of course, extreme assumptions (such as totally disregarding deaths below the age of 15 years) do produce different rankings. It would be straightforward to adopt different systems of weightings if these were considered more appropriate in particular settings.

It should be noted that reduction of the death rate from any disease increases the expectation of life and consequently would increase the potential benefits of any other health improvement procedure aimed at other diseases. We have taken no account of this effect, but this, and other refinements, might be applied if the quality of data available were better.

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#### APPENDIX

*Estimation of the days of life lost due to a disease*  
Consider a particular disease problem.

Let  $A_0$  = average age at onset

$A_d$  = average age at death of those who die of the disease



$E(A_0)$  = expectation of life (in years) at age  $A_0$   
(The values used for Ghana are given in Table A)

$C$  = case fatality rate (expressed as a percent)

$D_{od}$  = percent disablement in the period

TABLE A *Abridged Life Table for Ghana, 1968 (Gaisie, 1976)*

Age Years	Expected years of life remaining*
0	46.9
1	52.4
5	53.8
10	50.6
15	46.5
20	42.5
25	38.7
30	34.9
35	31.1
40	27.4
45	23.8
50	20.2
55	16.7
60	13.5*
65	10.5
70	8.0
75	5.9
80	4.2

\*Weighted average of males and females based upon sex distribution in 1970 census population

from onset until death among those who die of the disease (i.e.  $D_{od} = 0$  = no disablement,  $D_{od} = 100$  = disablement equivalent to death)

$Q$  = percent of those affected by the disease, who do not die of the disease but who are permanently disabled

$D$  = percent disablement of those permanently disabled

$t$  = average period of temporary disablement (days) among those who are affected but neither die nor are permanently disabled, multiplied by the proportion disablement of those temporarily disabled

The average number of days of healthy life lost to the community by each patient with the disease is given by: -

Days lost due to:

$$L = (C/100) \cdot [E(A_0) - (A_d - A_0)] \cdot 365.25$$

: premature deaths

$$+ (C/100) \cdot (A_d - A_0) \cdot (D_{od}/100) \cdot 365.25$$

: disability before death

$$+ (Q/100) \cdot E(A_0) \cdot (D/100) \cdot 365.25$$

: chronic disability

$$+ [(100 - C - Q)/100] \cdot t$$

: acute illness

Let  $I$  = annual incidence of the disease (new cases/1000 population/year)

Then the number of days lost by the community which are attributable to the disease is:

$$R = LI/1000 \text{ population}$$

This is the method which was used to derive the results in the last two columns of Table 1.

(Revised version received 13 October 1980)



## 4. Cost analysis

### 4.1. SOME BASICS

The analysis of the comparative costs of alternative treatments or health care programmes is common to all forms of economic evaluation and therefore most of the methodological issues discussed in this chapter are likely to be of relevance to all analyses. Two particularly thorny issues, the treatment of overhead costs (techniques for allocating shared overhead costs to individual projects) and allowance for differential timing of costs (the techniques of discounting and annuitization of capital expenditure), will be discussed in some detail. However, the chapter begins by covering some of the basic questions that an evaluator might have when embarking on a costing study in the health field.

#### 4.1.1. Which costs should be considered?

The main categories of costs of health care programmes or treatments were identified in Fig. 3.1 of Chapter 3; these are the organizing and operating costs within the health sector, costs borne by patients and their families, and costs borne externally to the health sector, patients, and their families. The particular range of costs included in a given study is likely to be decided upon as a result of considering the following four points.

##### 1. *What is the viewpoint for the analysis?*

It is essential to specify the viewpoint since an item may be a cost from one point of view, but not a cost from another. (For example, patients' travel costs are a cost from the patients' point of view and from the point of view of society, but not a cost from the Ministry of Health's point of view. Workmen's compensation payments are a cost to the paying government, a gain to the patient (recipient), and neither a cost nor a gain to society. (These money transfers, which do not reflect resource consumption, are called transfer payments by economists. Costs are involved in their administration, but these are not measured by the amounts themselves.)

## Cost analysis

Possible points of view include: society, Ministry of Health, other provincial ministries, total provincial government, patient, employer, federal government, the agency providing the programme, etc. If the evaluation is being commissioned by a given body, this may give a clue to the relevant point(s) of view. However, when in doubt always adopt the societal point of view, which is the broadest one and is always relevant.

##### 2. *Is the comparison restricted to the two or more programmes immediately under study?*

If the comparison is restricted to the programmes or treatments immediately under study, costs common to both need not be considered as they will not affect the choice between the given programmes. (Elimination of such costs can save the evaluator a considerable amount of work.) However, if it is thought that at some later stage a broader comparison may be contemplated, including other alternatives not yet specified, it might be prudent to consider all the costs of the programmes.

##### 3. *Are some costs merely likely to confirm a result that would be obtained by consideration of a narrower range of costs?*

Sometimes the consideration of patients' costs merely confirms a result that might be obtained from, say, consideration of only operating costs within the health sector. Therefore, if consideration of patients' costs requires extra effort and the choice of programme would not be changed, it may not be worthwhile to complicate the analysis unnecessarily. However, some justification for such an exclusion of a cost category should be given.

##### 4. *What is the relative order of magnitude of costs?*

It is not worth investing a great deal of time and effort considering costs that, because they are small, are unlikely to make any difference to the study result. However, some justification should be given for the elimination of such costs, perhaps based on previous empirical work. It is still worthwhile identifying such cost categories in any event, although the estimation of them might not be pursued in any great detail.

Above all, the main point to remember when embarking on a costing study is that, to an economist, cost refers to the sacrifice (of benefits) made when a given resource is consumed in a programme or treatment. Therefore, it is important not to confine one's attention to expenditures, but to consider also other resources, the consumption of which is not adequately reflected in market prices, e.g., volunteer time, patients' leisure time, donated clinic space, etc.



#### 4.1.2. How should costs be estimated?

Once the relevant range of costs has been identified the individual items must be measured and valued. In general, the programme ingredients approach suggested in Chapter 3 should suffice and market prices will be readily available for many of the cost items. Although the theoretical proper price for a resource is its opportunity cost (i.e., the value of the forgone benefits because the resource is not available for its best alternative use), the pragmatic approach to costing is to take existing market prices unless there is some particular reason to do otherwise (e.g., the price of some resources may be subsidized by a third party such as a charitable institution).

Although the costing of most resource items is relatively unambiguous, the following five issues commonly arise in costing studies.

##### 1. How are values imputed for nonmarket items?

The major nonmarket resource inputs to health care programmes are volunteer time and patient/family leisure time. One approach to the valuation of these would be to use market wage rates (e.g., for volunteer time one might use unskilled wage rates). The market value of leisure time is harder to assess. One can argue for a value of lost leisure time of anything from zero, through average earnings, to average overtime earnings (time and a half or double time). The argument for the overtime rate is that this is the price that an employer must pay, at the margin, to buy some of the worker's leisure time. The most common practice is to value lost leisure time at zero in the base case analysis, and to investigate the impact of the other assumptions through sensitivity analysis.

A slightly different approach is to identify and measure units of, say, volunteer input and to document these alongside the other costs when reporting results. This would enable the decision-maker to note those programmes relying heavily on volunteers. It would then be up to the programme director to demonstrate that such an input could be obtained without an opportunity cost to other programmes arising from the diversion of volunteers to the new programme.

The valuation of nonmarket items is discussed further in Chapter 7 on cost-benefit analysis.

##### 2. How should capital outlays (on equipment, buildings and land) be handled?

Capital costs are the costs to purchase the major capital assets required by the programme: generally equipment, buildings and land. Capital costs differ from operating costs in a number of ways. First, they represent investments at a single point in time, often at the beginning of the

programme, rather than annual sums like operating costs. Frequently, the capital costs are not listed in the accounts or budgets of the organization because they have been funded in advance, perhaps by a one-time grant, while the budgets and accounts represent operating expenses only. Sometimes, the annual budgets and accounts contain an item called depreciation which relates to capital costs, as explained below.

Capital costs represent an investment in an asset which is used over time. Most assets, such as equipment and buildings, wear out, or depreciate, with time. On the other hand, land is a non-depreciable asset because it maintains its value. There are two components of capital cost. One is the opportunity cost of the funds tied up in the capital asset. This is clearly seen in the case of land. Although an investment in non-depreciable land will return the original capital sum when sold, there is still a 'cost'. This cost is the lost opportunity to invest the sum in some other venture yielding positive benefits. This is called the opportunity cost and is valued by applying an interest rate (equal to the discount rate used in the study) to the amount of capital invested.

The second component of a capital cost represents the depreciation over time of the asset itself. Various accounting procedures (straight line, declining balance, double declining balance, etc.) are available for use in the accounts of the organization. Often, accounting practices relate more to the company tax laws governing the depreciation of assets than to the real change in the value of the asset.

There are several methods of measuring and valuing capital costs in an economic evaluation. The best method is to annuitize the initial capital outlay over the useful life of the asset; that is, to calculate the 'equivalent annual cost'. This method and its advantages are discussed in more detail by Richardson and Gafni (1983). The method automatically incorporates both the depreciation aspect and the opportunity cost aspect of the capital cost. It is our preferred approach and is described in Section 4.2 below. An alternative but less exact method is to determine the depreciation cost each year using an accounting method and to determine the opportunity cost on the undepreciated balance for each year (See Levin 1975, Boyle, Torrance, Horwood, and Sinclair 1982). Where market rates exist for the rental of buildings or lease of equipment, these may be used to estimate capital costs. This method also incorporates both the depreciation and the opportunity components of the cost. (A series of exercises illustrating the different methods of measuring and valuing capital costs is given in Annex 4.1.)

If capital outlays relate to resources that are used by more than one programme they may require allocation in a similar fashion to 'overhead' costs. See the discussion of this point below.



3. What is the significance of the average cost/marginal cost distinction?

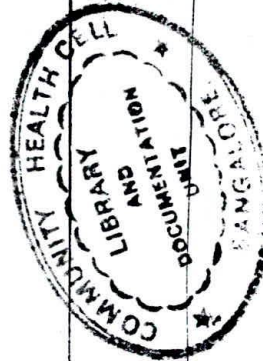
Economists tend to emphasize this point, and the example of the sixth stool guaiac in Chapter 2 illustrated the pitfalls in making decisions based on average cost. In fact, marginal cost and average cost are but two concepts relating costs to quantity (Hornigren 1982). A longer list would comprise:

- Total cost (TC) — cost of producing a particular quantity of output.
- Fixed cost (FC) — costs which do not vary with the quantity of output in the short run (about one year), e.g. rent, equipment lease payments, some wages and salaries. That is, costs which vary with time, rather than quantity.
- Variable cost (VC) — costs which vary with the level of output, e.g. supplies, food, fee for service.
- Cost function (TC) —  $f(Q)$ , total cost as a function of quantity.
- Average cost (AC) —  $TC/Q$ , the average cost per unit of output.
- Marginal cost (MC) —  $(TC \text{ of } x + 1 \text{ units}) - (TC \text{ of } x \text{ units})$ .  
—  $d(TC)/dQ$  evaluated at  $x$   
— the extra cost of producing one extra unit of output.

The major significance of the average-cost/marginal-cost distinction to the evaluator is as follows. First, when making a comparison of two or more programmes, it is worth asking independently of each, 'What would be the costs (and consequences) of having a little more or a little less?' [e.g., suppose Neuhauser and Lewicki (1975) had been comparing the six-stool protocol for detecting colonic cancer with another diagnostic test. Perhaps the question of six- versus five-tests may never have been asked!] Second, when examining the effects (on cost) of small changes in output, it is likely that these will differ from average costs. For example, the extra cost of keeping a patient in hospital for another day at the end of his treatment might be less than the average daily cost for his whole stay. (In fact, this issue usually arises in the opposite sense—the savings from a reduction of one day's stay are usually lower than the average daily cost.)

4. How should shared (or overhead) costs be handled?

The term *overhead costs* is an accounting term for those resources that serve many different departments and programmes, e.g. general hospital administration, central laundry, medical records, cleaning, porters,



power, etc. If individual programmes are to be costed, these shared costs may need to be attributed to programmes.

The main point to note at the outset is that there is no unambiguously right way to apportion such costs. The approach that is favoured by economists is to employ marginal analysis. That is, to see which (if any) of such costs would change if a given programme were added to, or subtracted from, the overall activity. Whilst this is fine up to a point, the most common situation is that the choice is not such an addition or subtraction, but one between two programmes, each of which would consume the given central services (perhaps because they are competitors for the same space in the hospital). For example, suppose the question concerned space in the hospital that could be used either for anticoagulant therapy for pulmonary embolism, or for renal dialysis. If the economic evaluation concerned a choice between these two programmes, then there would be no methodological problem, the costs associated with use of the space would be common to both and could be excluded from the analysis. However, typically the comparison might be between the anticoagulant therapy and another programme in the same field. This could be a programme of more definitive diagnosis of pulmonary embolism, which would avert some hospitalization. In such an instance it would be relevant to obtain an estimate of the value of the freed resources (e.g. hospital floor space) that could be diverted to other uses.

Essentially, the issue at stake here is that of accurately estimating all the costs attributable to a given programme or treatment when this is delivered alongside other programmes, as in the acute hospital. In Chapter 3 the reader was warned against the unthinking use of hospital (or other institutional) *per diems* or average costs. Before the methods available for apportioning institutional costs are described in more detail, the dangers of using *per diems* require more elucidation.

Many institutions calculate a *per diem* or average cost of their operations. This is essentially their total operating costs for the year divided by their total patient utilization for the year. A common example is a hospital's average cost per patient-day. It is tempting simply to multiply this figure by the number of patients and their average length of stay to determine the hospital cost of a programme. What is wrong with this procedure? First, it is only valid for truly 'average' patients—that is, patients who use an average amount of radiological services, laboratory services, operations, nursing attention, drugs, and so on. If patients in the programme being costed are not average, the result will be in error.

Second, many *per diem* calculations include arbitrary adjustments. For example, certain types of patients (outpatients, day patients, newborn patients, etc.) may be excluded from the denominator of the calculation in



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recognition that they are not typical. Then an estimate of the costs of these patients (often a very crude estimate) is subtracted from the numerator before calculating the *per diem*. The result is that the *per diem* itself is imprecise, even for the truly average patient.

Finally, typical *per diem* cost figures are incomplete, as they totally ignore capital costs. In summary, *per diem* costs are only applicable to average patients and even then are imprecise and incomplete.

A number of methods can be used to determine a more accurate cost of a programme in a hospital or other setting where shared (or overhead) costs are involved. The methods are illustrated below in terms of a hospital setting. The basic idea is to determine the quantities of service consumed by the patient (days of stay in ward A, B, or C, number of laboratory tests of each type, number of radiological procedures, number of operations, etc.), to determine a full cost (including the proper share of overhead, capital, etc.) for a unit of each type of service, and to multiply these together and sum up the results. The allocation methods described below are different ways to determine the cost per unit for each type of service. In these methods the overhead costs (e.g., housekeeping) are allocated to other departments (e.g., radiology) on the basis of some measure, called an *allocation basis*, judged to be related to usage of the overhead item (e.g., square feet of floor space in the radiology department might be used to allocate housekeeping costs to radiology).

In deciding which of the following approaches to use, the comments made in Section 4.1.1 above, should be borne in mind. That is, the more important the cost item is for the analysis, the greater the effort that should be made to estimate it accurately. There may conceivably be evaluations for which simple *per diem* costs will suffice, since the result is unlikely to change irrespective of the figure assumed for the cost of hospital care. However, we suspect that such situations are in the minority, given the relative order of magnitude of hospital costs compared to other elements of health care expenditures.

Alternatively, the intermediate approach suggested by Hull, Hirsh, Sackett, and Stoddart (1982) may suffice. Here the *per diem* cost is purged of any items relating to medical care costs, leaving just the 'hotel' component of hospital expenditure. It is then assumed that all patients are 'average' in respect of their hotel costs and that this expenditure can therefore be apportioned on the basis of patient days. Thus, the hotel cost can be calculated for the patients in the programme of interest and combined with the medical care costs attributable to those patients to give the total costs of the programme. (The medical care costs would be estimated separately, using data specifically relating to the patients in the programme.)

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If a more detailed consideration of costs is required, various methods for allocating shared (or overhead) costs are available, namely:

- (a) *Direct allocation* (ignores interaction of overhead departments). Each overhead cost (e.g., central administration, housekeeping) is allocated directly to final cost centres (e.g., programmes like day surgery; departments like wards or radiology). Programme X's allocated share of central administration is equal to central administration cost times Programme X's proportion of the allocation basis (say, paid hours). Note, Programme X's proportion is Programme X's paid hours divided by total paid hours of all final cost centres, not total paid hours for the whole organization. The latter method would underestimate the costs in all final cost centres.
- (b) *Step down allocation* (partial adjustments for interaction of overhead departments). The overhead departments are allocated in a stepwise fashion to all of the remaining overhead departments and to the final cost centres.
- (c) *Step down with iterations* (full adjustment for interaction of overhead departments). The overhead departments are allocated in a stepwise fashion to all of the other overhead departments and to the final cost centres. The procedure is repeated a number of times (about three) to eliminate residual unallocated amounts.
- (d) *Simultaneous allocation* (full adjustment for interaction of overhead departments). This method uses the same data as (b) or (c) but it solves a set of simultaneous linear equations to give the allocations. It gives the same answer as method (c) but involves less work. (The method is shown diagrammatically in Fig. 4.1.)

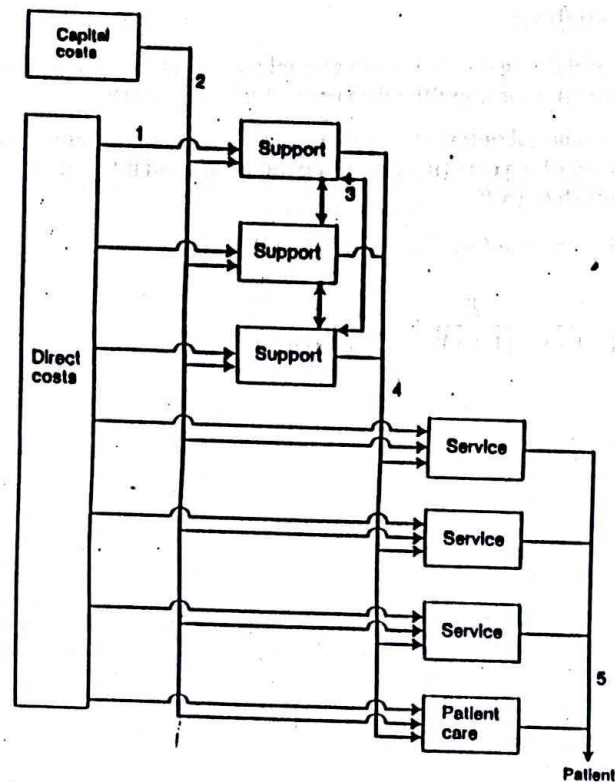
An example showing the different approaches to the allocation of overhead costs is presented in Section 4.3. Further details are available in Horngren (1982), Clements (1974), Kaplan (1973), and Boyle, *et al* (1982).

The effort that one would put into overhead cost allocation would depend on the likely importance of overhead costs (in quantitative terms) for the whole analysis. A much simpler, but cruder, approach is to

- (a) identify those hospital costs unambiguously attributable to the treatment or programme in question (e.g., physicians' fees, laboratory tests, drugs). (These are known as the directly allocatable costs.) Allocate these directly and immediately to the programme, then;
- (b) deduct, from total hospital operating expenses, the cost of depart-



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- (1) Direct costs assigned directly to cost centres. (2) Capital costs assigned to cost centres. (3) Support cost centres simultaneously allocated to each other. (4) Support cost centres allocated to other cost centres. (5) Costs assigned to each patient based on services used.

Fig. 4.1. Schematic illustration of cost allocations (from Boyle *et al.* 1982)

ments already allocated above and departments known not to service the programme being costed, then;

- (c) allocate the remainder of hospital operating expenses on the basis of number of patient days, e.g.:

Hospital cost of the programme	Directly allocatable costs	Net hospital expenditure	Hospital patient-days attributable to the programme
		$\frac{\text{Total number of hospital patient-days}}{\text{Total number of hospital patient-days}}$	
		$\times$	

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- (d) finally, undertake a sensitivity analysis.

Whilst there is nothing to suppose that this method is anything but crude, if the choice between programmes is fairly insensitive to the value derived it may suffice.

### 5. How should indirect costs be estimated?

As was mentioned in Chapter 3, this is a particularly contentious issue. The discussion of this point will be postponed until Chapter 5 since changes in productive output more often enter into the economic evaluation as a consequence of health care programmes, that is, the therapy often averts future production losses in that it enables the sick person to return to work or work until later in life. Production losses occur less often on the cost side of the equation since the patient is already off work because of his or her condition. Exceptions here would include population screening or other preventive programmes and anyone considering an evaluation of these should consult the relevant section in Chapter 5.

### 4.2. ALLOWANCE FOR DIFFERENTIAL TIMING OF COSTS (DISCOUNTING AND THE ANNUITIZATION OF CAPITAL EXPENDITURES)

As was mentioned in Chapter 3, some allowance needs to be made for the differential timing of costs and consequences. That is, even in a world with zero inflation and no bank interest, it would be an advantage to receive a benefit earlier or to incur a cost later—it gives you more options. Economists call this the notion of *time preference*.

Typically, economic evaluation texts discuss the situation where the costs of the alternative programmes A and B can be identified by the year in which they occur:

Year	Cost of Programme A (\$000s)	Cost of Programme B (\$000s)
1	5	15
2	10	10
3	15	4

In this example, B might be a preventive programme which requires more outlay in Year 1 with the promise of lower cost in Year 3. The crude addition of the two cost streams shows B to be of lower cost, but the outlays under A occur more in the later years.

A comparison of A and B (adjusted for the differential timing of resource outlays) would be made by discounting future costs to present



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values. The calculation is performed as follows. If  $P$  = present value;  $F_n$  = future cost at year  $n$ ; and  $r$  = annual interest (discount) rate (e.g., 0.05 or 5 per cent), then

$$P = \sum_{n=1}^3 F_n (1+r)^{-n}$$

$$= \frac{F_1}{(1+r)} + \frac{F_2}{(1+r)^2} + \frac{F_3}{(1+r)^3}$$

In our example this gives:

Present value of cost of A = 26.79

Present value of cost of B = 26.81

This assumes that the costs all occur at the end of each year. An alternative assumption which is commonly used is to assume that the costs all occur at the beginning of each year. Then, Year 1 costs need not be discounted, Year 2 costs should be discounted by one year, etc. Calculated in this way, the previous example is:

$$P = \sum_{n=0}^2 F_n (1+r)^{-n}$$

$$= F_0 + \frac{F_1}{(1+r)} + \frac{F_2}{(1+r)^2}$$

Present value of A = 28.13

Present value of B = 28.15

The factor  $(1+r)^{-n}$  is known as the discount factor and can be obtained for a given  $n$  and  $r$  from Table 1 in Annex 4.2. For example, the discount factor for three periods (years) at a discount rate of 5 per cent is 0.8638.

While this approach is the most convenient for a number of programme comparisons, a more common situation is that where most of the costs are easily expressed on an annual recurring basis and it is only capital costs which differ from year to year (typically these will be at the beginning of the programme, or Year 0).

Here it might be more convenient to express all the costs on an annual

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basis, obtaining an equivalent annual cost ( $E$ ) for the capital outlay by an amortization or annuitization procedure. This works as follows:

If the capital outlay is  $K$ , we need to find the annual sum  $E$  which over a period of  $n$  years (the life of the facility), at an interest rate of  $r$ , will be equivalent to  $K$ .

This is expressed by the following formula:

$$K = \frac{E}{(1+r)} + \frac{E}{(1+r)^2} + \dots + \frac{E}{(1+r)^n}$$

$$K = E \frac{1 - (1+r)^{-n}}{r}$$

$K = E$  [Annuity factor,  $n$  periods, interest  $r$ ]

As before, the annuity factor is easily obtainable from Table 2 in Annex 4.2. For example, in the cost analysis of providing long term oxygen therapy Lowson, Drummond, and Bishop (1981) found the total capital (set up) costs ( $K$ ) to be £2153.

Therefore, applying the formula given above:

$$2153 = \frac{E}{(1+r)} + \frac{E}{(1+r)^2} + \frac{E}{(1+r)^3} + \frac{E}{(1+r)^4} + \frac{E}{(1+r)^5}$$

$2153 = E$  [Annuity factor, 5 years, interest rate 7 per cent]

$2153 = E$  [4.1002] (from Table 2 in Annex 4.2)

$E = £525$  (as shown in Table III of Lowson *et al.*, (1981).

Note that Lowson *et al* (1981) assumed that the annuity was in arrears, that is, due at the end of the year. It might be argued that a more realistic assumption would be that it were payable in advance. This is equivalent to the formula:

$$2153 = \frac{E}{(1+r)} + \frac{E}{(1+r)^2} + \frac{E}{(1+r)^3} + \frac{E}{(1+r)^4}$$

The value for  $E$  can still be obtained from Table 2 by taking one less period and adding 1.000. This gives a lower value for  $E = £491$ . This is logical since the repayments are being made earlier (at the beginning of each year) rather than in arrears.



This approach can be generalized to equipment or buildings having a resale value  $S$ :

- $S$  = the resale value;  
 $n$  = the useful life of the equipment;  
 $r$  = discount (interest) rate;  
 $A(n, r)$  = the annuity factor ( $n$  years at interest rate  $r$ );  
 $K$  = purchase price/initial outlay;  
 $E$  = equivalent annual cost;

then

$$E = \frac{K - \frac{S}{(1+r)^n}}{A(n, r)}$$

The method described above is unambiguous for new equipment. For old equipment, there are two choices:

Choice 1 — Use the replacement cost of the equipment (or the original cost indexed to current dollars) and a full life.

Choice 2 — Use the current market value of the old machine and its remaining useful life.

Choice 1 is usually better as the results are more generalizable—less situational. Note that using the undepreciated balance from the accounts of the organization is never a method of choice.

It can be seen that the equivalent annual cost of buildings or equipment to a given programme depends on the values of  $n$ ,  $r$ , and  $S$ , all of which must be assumed at the time of the evaluation. Practical points that evaluators might care to note are:

### 1. Useful life and resale value ( $n$ and $S$ )

It is important to make a distinction between the physical life of a piece of equipment and its useful clinical life. The latter is highly dependent on technological change. Obviously one can undertake a sensitivity analysis using different values for  $n$ , but in general it is best to be conservative and assume short lives (say, around five years) for clinical equipment.

### 2. Choice of the discount rate ( $r$ )

There are two competing theories regarding the proper measure for the discount rate for public projects (the social discount rate):

- (a)  $r$  = the real rate of return (to society) forgone in the private sector.

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This can be estimated empirically, although not without controversy.

- (b)  $r$  = the social rate of time preference.

The social rate of time preference is a measure of society's willingness, collectively, to forgo consumption (gratification) today in order to have greater consumption (gratification) tomorrow. Frequently it is assumed that the interest rate on a risk free investment (e.g., long-term government bonds) represents the individual investor's willingness to forgo the present for the future, and that this rate is the individual's rate of time preference. Then if society's collective rate of time preference is simply the aggregate of the individual rates (a controversial assumption), the required rate is simply given by the real (adjusted for inflation) rate of return on long-term government bonds.

However, in practice it is usually admissible to select a central 'best estimate' of  $r$ , and then vary this systematically in a sensitivity analysis to determine the impact on the study conclusions. The criteria to use in selecting a central  $r$  and a range for sensitivity analysis are that these should:

- (a) be consistent with economic theory (2 per cent to 10 per cent);
- (b) include (bracket) any government recommended rates (5 per cent, 7 per cent, 10 per cent);
- (c) include (bracket) rates that have been used in other published studies to which you might wish to compare results (3 per cent to 10 per cent);
- (d) be consistent with 'current practice' (for example, 5 per cent has been used recently in papers published in the *New England Journal of Medicine*).

### 3. How to handle inflation

If it is assumed that all the items of cost in the programme will inflate at the same rate and that this will be the same rate as inflation in general, there are two equivalent choices:

- (a) Inflate all future costs by this predicted inflation rate and then use a larger discount rate that allows for the effect of general inflation (the inflation adjusted discount rate\*), or

\* Calculation of inflation adjusted discount rate: If the real discount rate is 5 per cent and general inflation is 8 per cent, then the inflation adjusted  $r = (1.05)(1.08) = 1.134$  or 13.4 per cent.



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- (b) Do not inflate any future costs (i.e., use constant dollars) and use a smaller discount rate that does not allow for inflation (the real discount rate).

Method (b) is the simpler and preferred approach.

If it is assumed that different items of cost in the programme will inflate at different rates, there are also two equivalent choices:

- (a) Inflate all future costs by their particular predicted inflation rates and then use a larger discount rate that allows for the effect of general inflation (the inflation adjusted discount rate\*), or
- (b) Do not inflate any future costs (i.e., use constant dollars) and use a smaller discount rate that does not allow for inflation (the real discount rate), but adjust the discount rate for each item to account for the differential inflation rate between this item and the 'general' rate of inflation, e.g., if general inflation is 8 per cent, this item is expected to inflate 10 per cent, and the real  $r$  is equal to 4 per cent, then  $r$  adjusted for this item is

$$r = 1.04 \times \frac{1.08}{1.10} = 1.021, \text{ i.e. } 2.1 \text{ per cent.}$$

Method (b) is again the preferred approach. In general, however, most studies perform the whole analysis in constant price terms and use a single discount rate.

### 4.3. ALLOCATION OF OVERHEAD COSTS: EXAMPLE

The following example demonstrates the various methods of handling overhead costs discussed in Section 4.1.2 (4), p. 43. Suppose we wish to determine the cost of neonatal intensive care (NIC) for a specific group of patients. For each patient we have data on the length of stay in the neonatal intensive care unit (NICU) and data on the number and type of laboratory tests performed. For simplicity, let us assume that these were the only services received by the patients—that is, the patients had no operations, no radiological or nuclear medicine investigations, no social work, etc. Furthermore, let us assume that there are only three overhead departments that serve the laboratory and the NICU: administration, housekeeping and laundry. (In principle it would be possible to consider other overhead departments, like plant operations and maintenance, bioengineering, and materials management.)

\* See footnote on p. 52.

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The first task is to determine a unit of output for those departments that directly serve patients. We will be determining a cost per unit of output, and multiplying this cost by the usage of each patient to determine the cost per patient. Thus, the unit of output must be as homogeneous as possible with respect to cost, and yet be available in the data for each patient. We have selected a *patient-day* as the unit of output of the NICU; and a *DBS unit* for the laboratory. A DBS (Dominion Bureau of Statistics) unit is a standard laboratory work unit used in Canada; each lab test is assigned a predetermined number of DBS units according to the amount of work needed to perform the test.

An allocation basis must be determined for each overhead department. For example, square feet of floor space has been selected for housekeeping. This means that housekeeping costs will be allocated to departments receiving housekeeping services in proportion to the square footage of floor space in the department. Similarly, paid hours has been selected as the allocation basis for administration costs, and pounds of laundry for the laundry costs.

The data for this simplified example are given in Table 4.1. The calculations, as performed by the different methods, are given in Tables 4.2 to 4.7.



Table 4.1. Cost allocation data

	Annual direct cost <sup>a</sup> \$	Annual units of output <sup>b</sup>	Direct cost per unit \$	Allocation basis	Annual pd-hrs	Ft <sup>2</sup>	Annual lbs laundry
<b>Overhead departments</b>							
Administration	2 000 000			pd-hrs	200 000	30 000	0
Housekeeping	1 500 000			ft <sup>2</sup>	300 000	4 000	80 000
Laundry	1 300 000			lbs	200 000	8 000	0
Other	10 200 000				300 000	158 000	120 000
<b>Subtotal</b>	<b>15 000 000</b>				<b>1 000 000</b>	<b>200 000</b>	<b>200 000</b>
<b>Final departments (Pt. service)</b>							
Laboratory	4 000 000	8 000 000	0.50/DBS unit		250 000	30 000	25 000
NICU	500 000	5 000	100/pt-day		50 000	8 000	75 000
Other	30 500 000				1 700 000	562 000	1 200 000
<b>Subtotal</b>	<b>35 000 000</b>				<b>2 000 000</b>	<b>600 000</b>	<b>1 300 000</b>
<b>Hospital total</b>	<b>50 000 000</b>				<b>3 000 000</b>	<b>800 000</b>	<b>1 500 000</b>

<sup>a</sup> Direct cost consists of salaries plus supplies. <sup>b</sup> Lab output is in DBS units and NICU output is in patient-days.

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Table 4.2. Method 1—ignore overhead

Lab cost/DBS unit = \$4 000 000/8 000 000 = \$0.50/DBS unit  
NICU cost/pt-day = \$500 000/5000 = \$100/pt-day

Table 4.3. Method 2—direct allocation of overhead  
(Note: Allocation denominator = sum of 'final' department.)

Lab cost = direct cost + lab's share of admin + lab's share of housekeeping + lab's share of laundry

$$\begin{aligned}
 &= 4\,000\,000 + \frac{250\,000}{2\,000\,000}(2\,000\,000) + \frac{30\,000}{600\,000}(1\,500\,000) + \\
 &\quad \frac{25\,000}{1\,300\,000}(1\,300\,000) \\
 &= 4\,000\,000 + 250\,000 + 75\,000 + 25\,000 = 4\,350\,000
 \end{aligned}$$

Lab cost/DBS unit = 4 350 000/8 000 000 = \$0.54/DBS unit

NICU cost = direct cost + share of admin + share of housekeeping + share of laundry

$$\begin{aligned}
 &= 500\,000 + \frac{50\,000}{2\,000\,000}(2\,000\,000) + \frac{8\,000}{600\,000}(1\,500\,000) + \\
 &\quad \frac{75\,000}{1\,300\,000}(1\,300\,000) \\
 &= 500\,000 + 50\,000 + 20\,000 + 75\,000 + \$645\,000
 \end{aligned}$$

NICU cost/pt-day = 645 000/5000 = \$129/pt-day



4. Method 3—Step down allocation of overhead

Note: Allocation denominator = sum of remaining departments in the step down sequence.)

	Admin	HK	Laundry	Other	Lab	NICU	Other	✓
Cost	2 000 000	1 500 000	1 300 000	10 200 000	4 000 000	500 000	30 500 000	50m
Admin	2 000 000 - $\frac{3}{28} = 214\,286$	$\frac{2}{28} = 142\,857$	$\frac{3}{28} = 214\,286$	$\frac{2.5}{28} = 178\,571$	$\frac{0.5}{28} = 35\,714$	$\frac{17}{28} = 1\,214\,286$		
HK		1 714 286 - $\frac{8}{766} = 17\,904$	$\frac{158}{766} = 353\,599$	$\frac{30}{766} = 67\,139$	$\frac{8}{766} = 17\,904$	$\frac{562}{766} = 1\,257\,740$		
Laundry			1 460 761 - $\frac{120}{1420} = 123\,445$	$\frac{25}{1420} = 25\,718$	$\frac{75}{1420} = 77\,153$	$\frac{1200}{1420} = 1\,234\,446$		
Cost				10 891 330	4 271 428	630 771	34 206 472	50m
					+ 8 000 000	+ 5 000		
Unit					\$0.53/DBS unit	\$126.15/pt-day		

4.5 Method 4—Step down with iterations

Note: Allocation denominator = sum of all departments except the one being allocated.)

	Admin	HK	Laundry	Other	Lab	NICU	Other	✓
Cost	2 000 000	1 500 000	1 300 000	10 200 000	4 000 000	500 000	30 500 000	50m
Admin	2 000 000 - $\frac{3}{28} = 214\,286$	$\frac{2}{28} = 142\,857$	$\frac{3}{28} = 214\,286$	$\frac{2.5}{28} = 178\,571$	$\frac{0.5}{28} = 35\,714$	$\frac{17}{28} = 1\,214\,286$		
HK	$\frac{30}{796} = 64\,609$	1 714 286 - $\frac{8}{796} = 17\,229$	$\frac{158}{796} = 340\,273$	$\frac{30}{796} = 64\,609$	$\frac{8}{796} = 17\,229$	$\frac{562}{796} = 1\,210\,338$		
Laundry	$\frac{0}{1500} = 0$	$\frac{80}{1500} = 77\,871$	1 460 086 - $\frac{120}{1500} = 116\,807$	$\frac{25}{1500} = 24\,335$	$\frac{75}{1500} = 73\,004$	$\frac{1200}{1500} = 1\,168\,069$		
Totals	64 609	77 871	0	10 871 366	4 267 515	625 947	34 092 693	50m
Admin	64 609 - $\frac{3}{28} = 6\,922$	$\frac{2}{28} = 4\,615$	$\frac{3}{28} = 6\,922$	$\frac{2.5}{28} = 5\,769$	$\frac{0.5}{28} = 1\,154$	$\frac{17}{28} = 39\,227$		
HK	$\frac{30}{796} = 3\,196$	84 793 - $\frac{8}{796} = 852$	$\frac{158}{796} = 16\,831$	$\frac{30}{796} = 3\,196$	$\frac{8}{796} = 852$	$\frac{562}{796} = 59\,866$		
Laundry	$\frac{0}{1500} = 0$	$\frac{80}{1500} = 292$	5 467 - $\frac{120}{1500} = 437$	$\frac{25}{1500} = 91$	$\frac{75}{1500} = 273$	$\frac{1200}{1500} = 4\,374$		



New totals	3 196	292	0	10 895 556	4 276 571	628 226	34 196 160	5
Iteration 3								
Allocate Admin	$\frac{3}{28}$	$\frac{342}{28}$	$\frac{2}{28}$	$\frac{3}{28}$	$\frac{2.5}{28}$	$\frac{0.5}{28}$	$\frac{17}{28}$	$\frac{1940}{28}$
Allocate HK	$\frac{30}{796}$	$\frac{634}{796}$	$\frac{8}{796}$	$\frac{158}{796}$	$\frac{30}{796}$	$\frac{8}{796}$	$\frac{562}{796}$	$\frac{448}{796}$
Allocate Laundry	$\frac{0}{1500}$	$\frac{12}{1500}$	$\frac{80}{1500}$	$\frac{120}{1500}$	$\frac{25}{1500}$	$\frac{75}{1500}$	$\frac{1200}{1500}$	$\frac{187}{1500}$
New totals	24	12	0	10 896 043	4 276 884	628 301	34 198 735	5
Final Direct Allocations	24							
				$\frac{3}{23}$	$\frac{2.5}{23}$	$\frac{0.5}{23}$	$\frac{17}{23}$	$\frac{18}{23}$
				$\frac{158}{758}$	$\frac{30}{758}$	$\frac{8}{758}$	$\frac{562}{758}$	$\frac{9}{758}$
Final totals	0	0	0	10 896 049	4 276 887	628 302	34 198 762	50
Units					+ 8 000 000	+ 5 000		
Cost/unit					\$0.53/DBS unit	\$125.66/pt-day		

Table 4.6. Method 5—simultaneous allocation (reciprocal method)  
(Note: Allocation denominator = sum of all departments).

$$\text{Admin} \quad C_1 = 2\,000\,000 + \frac{2}{30}C_1 + \frac{30}{800}C_2$$

$$\text{HK} \quad C_2 = 1\,500\,000 + \frac{3}{30}C_1 + \frac{4}{800}C_2 + \frac{80}{1500}C_3$$

$$\text{Laundry} \quad C_3 = 1\,300\,000 + \frac{2}{30}C_1 + \frac{8}{800}C_2$$

$$\text{Lab} \quad C_4 = 4\,000\,000 + \frac{2.5}{30}C_1 + \frac{30}{800}C_2 + \frac{25}{1500}C_3$$

$$\text{NICU} \quad C_5 = 500\,000 + \frac{0.5}{30}C_1 + \frac{8}{800}C_2 + \frac{75}{1500}C_3$$

$$\frac{28}{30}C_1 - \frac{30}{800}C_2 = 2\,000\,000$$

$$-\frac{3}{30}C_1 + \frac{796}{800}C_2 - \frac{80}{1500}C_3 = 1\,500\,000$$

$$-\frac{2}{30}C_1 - \frac{8}{800}C_2 + C_3 = 1\,300\,000$$

$$-\frac{2.5}{30}C_1 - \frac{30}{800}C_2 - \frac{25}{1500}C_3 + C_4 = 4\,000\,000$$

$$-\frac{0.5}{30}C_1 - \frac{8}{800}C_2 - \frac{75}{1500}C_3 + C_5 = 500\,000$$

The solution of this set of equations is:

$$C_1 = 2\,215\,531$$

$$C_2 = 1\,808\,772$$

$$C_3 = 1\,465\,790$$

$$C_4 = 4\,276\,886$$

$$C_5 = 628\,303$$

Therefore, the Cost/unit of output is:

$$\text{Lab:} \quad \$4\,276\,886/8\,000\,000 = \$0.53/\text{DBS unit}$$

$$\text{NICU:} \quad \$628\,303/5\,000 = \$125.66/\text{pt-day}$$



## Cost analysis

Table 4.7. Method 6—patient-day allocation of overhead

This is the simple method described in the footnote of page 27 of Chapter 3 and on page 46 of Chapter 4. It may be useful in some cases.

Laboratory costs would be charged without overhead: \$0.50/DBS unit.

NICU costs would be the direct costs of \$500 000 plus a share of all relevant other departments (2.0m + 1.5m + 1.3m = 4.8m) in proportion to patient-days (5 000/500 000 where the denominator is total annual hospital patient-days). Thus,

NICU cost = \$500 000 + \$4 800 000 (5 000/500 000) = \$548 000.

NICU cost/pt-day = \$548 000/5 000 = \$110/pt-day.

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## ANNEX 4.1. METHODS OF MEASURING AND VALUING CAPITAL COSTS

We are indebted to Morris Barer of the University of British Columbia for producing these examples, which should clarify the treatment of capital costs.

As a first note, we need to distinguish two classes of 'capital'—land and equipment. This is an important consideration, because in costing exercises we assume land does not depreciate, while of course capital equipment does. You can think of there being a continuum along which materials and supplies 'depreciate' or are used up instantaneously and so are costed fully in the year of use; capital equipment depreciates more slowly, and may be handled in a variety of ways; land does not depreciate at all.

As a second note, recall that 'capital equipment costs have three components—depreciation, opportunity cost, and actual operating costs. We will ignore the last of these here.

First consider *equipment*, and let us use an example of a machine costing \$200 000 that, at the end of 5 years, has re-sale value of \$20 000. Assume straight-line depreciation and a discount rate of 4 per cent. There are, then, four approaches to costing:

- (i) one can assume all costs accrue at time 0. This amounts to treating the equipment as one would less durable materials and supplies:



# Cost analysis

Time	0	1	2	3	4	5
Depreciation	200 000	0	0	0	0	(20 000)
Undepreciated balance at beginning of period	—	0	0	0	0	0
Opportunity cost	—	0	0	0	0	0
Dep'n. + opp cost	200 000	0	0	0	0	(20 000)
Present value (PV)	200 000	0	0	0	0	(16 439)
Net present value (NPV) of equipment cost = \$183 561						

Alternatively, but equivalently, one can treat the machine as instantaneously depreciating, except for the \$20 000 resale value, which then is maintained through the 5 years:

Time	0	1	2	3	4	5
Depreciation	180 000	—	—	—	—	—
Undepreciated balance at beginning of period	20 000	20 000	20 000	20 000	20 000	20 000
Opportunity cost	800	800	800	800	800	800
Dep'n. + opp cost	180 000	800	800	800	800	800
PV	180 000	769	740	711	684	658
NPV of equipment cost = \$183 562						

- (ii) One can compute depreciation and opportunity costs separately. They are related in that the opportunity cost of equipment refers to the use of the resources embodied in the equipment, in their next best use—this is 'approximated' by calculating the return on the funds implicit in the undepreciated value of the equipment at each point in time. Hence, the higher the rate of depreciation, the lower the opportunity cost, all else equal. Again, one has the choice of building the \$20 000 resale in at the end, or just depreciating less of the machine. It works out the same:

# Cost analysis

Time	1	2	3	4	5
Depreciation	36 000	36 000	36 000	36 000	36 000
Undepreciated balance at beginning of period	200 000	164 000	128 000	92 000	56 000
Opportunity cost	8 000	6 560	5 120	3 680	2 240
Dep'n. + opp cost	44 000	42 560	41 120	39 680	38 240
PV	42 308	39 349	36 556	33 919	31 430
NPV of equipment cost = \$183 562					

Time	1	2	3	4	5
Depreciation	40 000	40 000	40 000	40 000	20 000
Undepreciated balance at beginning of period	200 000	160 000	120 000	80 000	40 000
Opportunity cost	8 000	6 400	4 800	3 200	1 600
Dep'n. + opp cost	48 000	46 400	44 800	43 200	21 600
PV	46 154	42 899	39 827	36 928	17 754
NPV of equipment cost = \$183 562					

- (iii) One can compute an equivalent annual cost. This may be useful in a situation where other operating costs are the same each year, making necessary the comparison of only a single year of cost data for each alternative in the economic evaluation:

$$\text{NPV} = E \cdot \text{AF}_{3,4\%} \quad (\text{Where } \text{AF}_{3,4\%} \text{ is the annuity factor for 5 years at an interest rate of 4 per cent. See Table 2 in Annex 4.2})$$

$$183\,562 = E \cdot 4.4518 \rightarrow E = \$41\,233$$

In other words, an *equal* stream of costs amounting to \$41 233 in *each* of the five years of the program has a present value equivalent to any of the *unequal* cost streams in (i) or (ii) above. Note, therefore, that the equivalent annual cost embodies both depreciation and opportunity cost.



## Cost Analysis

- (iv) One can use equivalent or actual rental costs, if available or estimable. Note that because the renter will need to recover not only depreciation of the rental equipment but also a rate of return at least as good as that from the next best use of the resource, one can take rental cost to embody both depreciation and opportunity cost.

Second, the treatment of *land* is quite different because of the lack of depreciation. A land purchase of \$200 000 at time 0 would generate the following cost time stream:

Time	1	2	3	4	5
Depreciation	—	—	—	—	—
Undepreciated balance at beginning of period	200 000	200 000	200 000	200 000	200 000
Opportunity cost	8 000	8 000	8 000	8 000	8 000
Dep'n + opp cost	8 000	8 000	8 000	8 000	8 000
PV	7 692	7 396	7 112	6 838	6 575
NPV = \$35 613					

Converted to an equivalent annual cost.

$$NPV = E \cdot AF_{5,4\%}$$

$$\$35\ 613 = E \cdot 4.4518$$

It comes as no particular surprise that  $E = \$80001$

Annex 4.2. Discount Table 1

Present value of \$1

N	1%	2%	3%	4%	5%	6%	7%	8%	9%	10%	11%	12%	13%	14%	15%
1	0.9901	0.9804	0.9709	0.9615	0.9524	0.9434	0.9346	0.9259	0.9174	0.9091	0.9009	0.8929	0.8850	0.8772	0.8696
2	0.9803	0.9612	0.9426	0.9246	0.9070	0.8900	0.8734	0.8573	0.8417	0.8264	0.8116	0.7972	0.7831	0.7695	0.7561
3	0.9706	0.9423	0.9151	0.8890	0.8638	0.8396	0.8163	0.7938	0.7722	0.7513	0.7312	0.7118	0.6931	0.6750	0.6575
4	0.9610	0.9238	0.8885	0.8548	0.8227	0.7921	0.7629	0.7350	0.7084	0.6830	0.6587	0.6355	0.6133	0.5921	0.5718
5	0.9515	0.9057	0.8626	0.8219	0.7835	0.7473	0.7130	0.6806	0.6499	0.6209	0.5935	0.5674	0.5428	0.5194	0.4972
6	0.9420	0.8880	0.8375	0.7903	0.7462	0.7050	0.6663	0.6302	0.5963	0.5645	0.5346	0.5066	0.4803	0.4556	0.4323
7	0.9327	0.8706	0.8131	0.7599	0.7107	0.6651	0.6227	0.5835	0.5470	0.5132	0.4817	0.4523	0.4251	0.3996	0.3759
8	0.9235	0.8535	0.7894	0.7307	0.6768	0.6274	0.5820	0.5403	0.5019	0.4665	0.4339	0.4039	0.3762	0.3506	0.3269
9	0.9143	0.8368	0.7664	0.7026	0.6446	0.5919	0.5439	0.5002	0.4604	0.4241	0.3909	0.3606	0.3329	0.3075	0.2843
10	0.9053	0.8203	0.7441	0.6756	0.6139	0.5584	0.5083	0.4632	0.4224	0.3855	0.3522	0.3220	0.2946	0.2697	0.2472
11	0.8963	0.8043	0.7224	0.6496	0.5847	0.5268	0.4751	0.4289	0.3875	0.3505	0.3173	0.2875	0.2607	0.2366	0.2149
12	0.8874	0.7885	0.7014	0.6246	0.5568	0.4970	0.4440	0.3971	0.3555	0.3186	0.2858	0.2567	0.2307	0.2076	0.1869
13	0.8787	0.7730	0.6810	0.6006	0.5303	0.4688	0.4150	0.3677	0.3262	0.2897	0.2575	0.2292	0.2042	0.1821	0.1625
14	0.8700	0.7579	0.6611	0.5775	0.5051	0.4423	0.3878	0.3405	0.2992	0.2633	0.2320	0.2046	0.1807	0.1597	0.1413
15	0.8613	0.7430	0.6419	0.5553	0.4810	0.4173	0.3624	0.3152	0.2745	0.2394	0.2090	0.1827	0.1599	0.1401	0.1229
16	0.8528	0.7284	0.6232	0.5339	0.4581	0.3936	0.3387	0.2919	0.2519	0.2176	0.1883	0.1631	0.1415	0.1229	0.1069
17	0.8444	0.7142	0.6050	0.5134	0.4363	0.3714	0.3166	0.2703	0.2311	0.1978	0.1696	0.1456	0.1252	0.1078	0.0929
18	0.8360	0.7002	0.5874	0.4936	0.4155	0.3503	0.2959	0.2502	0.2120	0.1799	0.1528	0.1300	0.1108	0.0946	0.0808
19	0.8277	0.6864	0.5703	0.4746	0.3957	0.3305	0.2765	0.2317	0.1945	0.1635	0.1377	0.1161	0.0981	0.0829	0.0703
20	0.8195	0.6730	0.5537	0.4564	0.3769	0.3118	0.2584	0.2145	0.1784	0.1486	0.1240	0.1037	0.0868	0.0728	0.0611
21	0.8114	0.6598	0.5375	0.4388	0.3589	0.2942	0.2415	0.1987	0.1637	0.1351	0.1117	0.0926	0.0768	0.0638	0.0531
22	0.8034	0.6468	0.5219	0.4220	0.3418	0.2775	0.2257	0.1839	0.1502	0.1228	0.1007	0.0826	0.0680	0.0560	0.0462
23	0.7954	0.6342	0.5067	0.4057	0.3256	0.2618	0.2109	0.1703	0.1378	0.1117	0.0907	0.0738	0.0601	0.0491	0.0402
24	0.7876	0.6217	0.4919	0.3901	0.3101	0.2470	0.1971	0.1577	0.1264	0.1015	0.0817	0.0659	0.0532	0.0431	0.0349
25	0.7798	0.6093	0.4776	0.3751	0.2953	0.2330	0.1842	0.1460	0.1160	0.0923	0.0736	0.0588	0.0471	0.0378	0.0304



# Annualization Factors

	DISCOUNT RATE																			
	1%	2%	3%	4%	5%	6%	7%	8%	9%	10%	11%	12%	13%	14%	15%	16%	17%	18%	19%	20%
1	0.990	0.980	0.971	0.962	0.952	0.943	0.935	0.926	0.917	0.909	0.901	0.893	0.885	0.877	0.870	0.862	0.855	0.847	0.840	0.833
2	1.970	1.942	1.913	1.886	1.859	1.833	1.808	1.783	1.759	1.736	1.713	1.690	1.668	1.647	1.626	1.605	1.585	1.566	1.547	1.528
3	2.941	2.884	2.827	2.775	2.723	2.673	2.624	2.577	2.531	2.487	2.444	2.402	2.361	2.322	2.283	2.246	2.210	2.174	2.140	2.106
4	3.902	3.808	3.717	3.630	3.546	3.465	3.387	3.312	3.240	3.170	3.102	3.037	2.974	2.914	2.855	2.798	2.743	2.690	2.639	2.589
5	4.853	4.713	4.580	4.452	4.329	4.212	4.100	3.993	3.890	3.791	3.696	3.605	3.517	3.433	3.352	3.274	3.199	3.127	3.058	2.991
6	5.795	5.601	5.417	5.242	5.076	4.917	4.767	4.623	4.486	4.355	4.231	4.111	3.998	3.889	3.784	3.685	3.589	3.498	3.410	3.326
7	6.728	6.472	6.230	6.002	5.786	5.582	5.389	5.206	5.033	4.868	4.712	4.564	4.423	4.288	4.160	4.039	3.922	3.812	3.706	3.605
8	7.652	7.325	7.020	6.733	6.463	6.210	5.971	5.747	5.535	5.335	5.146	4.968	4.799	4.639	4.487	4.344	4.207	4.078	3.954	3.837
9	8.566	8.162	7.786	7.435	7.108	6.802	6.515	6.247	5.995	5.759	5.537	5.328	5.132	4.946	4.772	4.607	4.451	4.303	4.163	4.031
10	9.471	8.983	8.530	8.111	7.722	7.360	7.024	6.710	6.418	6.145	5.889	5.650	5.426	5.216	5.019	4.833	4.659	4.494	4.339	4.192
11	10.368	9.787	9.253	8.760	8.306	7.887	7.499	7.139	6.805	6.495	6.207	5.938	5.687	5.453	5.234	5.029	4.836	4.656	4.486	4.327
12	11.255	10.575	9.954	9.385	8.863	8.384	7.943	7.536	7.161	6.814	6.492	6.194	5.918	5.660	5.421	5.197	4.988	4.793	4.611	4.439
13	12.134	11.348	10.635	9.986	9.394	8.853	8.358	7.904	7.487	7.103	6.750	6.424	6.122	5.842	5.583	5.342	5.118	4.910	4.715	4.533
14	13.004	12.106	11.296	10.563	9.899	9.295	8.745	8.244	7.786	7.367	6.982	6.628	6.302	6.002	5.724	5.468	5.229	5.008	4.802	4.611
15	13.865	12.849	11.933	11.118	10.380	9.712	9.108	8.559	8.061	7.606	7.191	6.811	6.462	6.142	5.847	5.575	5.324	5.092	4.876	4.675
16	14.718	13.578	12.561	11.652	10.838	10.106	9.447	8.851	8.313	7.824	7.379	6.974	6.604	6.265	5.954	5.668	5.405	5.162	4.938	4.730
17	15.562	14.292	13.166	12.166	11.274	10.477	9.763	9.122	8.544	8.022	7.549	7.120	6.729	6.373	6.047	5.749	5.475	5.222	4.990	4.775
18	16.398	14.992	13.754	12.659	11.690	10.828	10.059	9.372	8.756	8.201	7.702	7.250	6.840	6.467	6.128	5.818	5.534	5.273	5.033	4.812
19	17.226	15.678	14.324	13.134	12.085	11.158	10.336	9.604	8.950	8.365	7.839	7.366	6.938	6.550	6.198	5.877	5.584	5.316	5.070	4.843
20	18.046	16.351	14.877	13.590	12.462	11.470	10.594	9.818	9.129	8.514	7.963	7.469	7.025	6.623	6.259	5.929	5.628	5.353	5.101	4.870
21	18.857	17.011	15.415	14.029	12.821	11.764	10.836	10.017	9.292	8.649	8.075	7.562	7.102	6.687	6.312	5.973	5.665	5.384	5.127	4.891
22	19.660	17.658	15.937	14.451	13.163	12.042	11.061	10.201	9.442	8.772	8.176	7.645	7.170	6.743	6.339	6.011	5.696	5.410	5.149	4.909
23	20.456	18.292	16.444	14.857	13.489	12.303	11.272	10.371	9.580	8.883	8.266	7.718	7.230	6.792	6.399	6.044	5.723	5.432	5.167	4.925
24	21.243	18.914	16.936	15.247	13.799	12.550	11.469	10.529	9.707	8.985	8.348	7.784	7.283	6.835	6.434	6.073	5.746	5.451	5.182	4.937
25	22.023	19.523	17.413	15.622	14.094	12.783	11.654	10.675	9.823	9.077	8.422	7.843	7.330	6.873	6.464	6.097	5.766	5.467	5.195	4.948
26	22.795	20.121	17.877	15.983	14.375	13.003	11.826	10.810	9.929	9.161	8.488	7.896	7.372	6.906	6.491	6.118	5.783	5.480	5.206	4.956
27	23.560	20.707	18.327	16.330	14.643	13.211	11.987	10.935	10.027	9.237	8.548	7.943	7.409	6.935	6.514	6.136	5.798	5.492	5.215	4.964
28	24.316	21.281	18.764	16.663	14.898	13.406	12.137	11.051	10.116	9.307	8.602	7.984	7.441	6.961	6.534	6.152	5.810	5.502	5.223	4.970
29	25.066	21.844	19.188	16.984	15.141	13.591	12.278	11.158	10.198	9.370	8.650	8.022	7.470	6.983	6.551	6.166	5.820	5.510	5.229	4.975
30	25.808	22.396	19.600	17.292	15.372	13.765	12.409	11.258	10.274	9.427	8.694	8.055	7.496	7.003	6.566	6.177	5.829	5.517	5.235	4.979



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## National Health Service

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### COSTING NEW SERVICES: LONG-TERM DOMICILIARY OXYGEN THERAPY

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**Summary** An economic appraisal of different methods of long-term treatment with oxygen in the home has shown that the oxygen concentrator is the cheapest and most convenient one. The only method at present generally available in the National Health Service, the use of small oxygen cylinders, is the most expensive and least convenient of those studied. There is need for a more flexible administrative system which will allow patients and the Health Service to benefit from the economies which are offered by technical advances.

#### INTRODUCTION

RESEARCH over the past 15 years<sup>1-6</sup> has indicated that oxygen given for 12-24 h a day to patients with chronic bronchitis and chronic hypoxaemia reduces pulmonary arterial pressure and red cell mass. More recently, clinical trials in the U.S.A.<sup>7</sup> and a Medical Research Council (M.R.C.) multicentre controlled trial<sup>8</sup> have confirmed that long-term domiciliary oxygen therapy reduces mortality and improves general quality of life. The M.R.C. trial employed three methods of delivery: cylinder oxygen, liquid oxygen, and oxygen from concentrators, and all seemed to be equally effective.

Although medical research inevitably leads to demands for new services, the resource consequences of new treatments are typically underexplored. In the case of oxygen therapy the resource consequences take on extra significance, since the

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three treatment methods have similar medical attributes, yet vary considerably in cost. Furthermore, detailed examination of the relative costs of the treatments reveals firstly that one of the methods (oxygen concentrators) is more capital intensive, and is therefore sensitive, in terms of cost per patient, to the size of the patient population; and secondly that only one of the treatment methods examined in the trial is currently funded on a regular basis within the National Health Service (N.H.S.).

This paper describes the use of economic appraisal<sup>9</sup> in examining the resource consequences of providing long-term oxygen therapy. The costing exercise also attempts to illustrate some of the problems facing those researchers and clinicians who wish to examine the resource consequences of introducing new services.

#### METHODS OF OXYGEN ADMINISTRATION

*Cylinder oxygen* comes in large (120 cu ft, 3400 litres) or small (48 cu ft, 1360 litres) containers. If large cylinders are used for 15 h per day, the patient consumes  $\frac{3}{4}$ –1 cylinder of oxygen daily, necessitating approximately one delivery of 6 cylinders a week. Small cylinders are supplied and delivered by the local pharmacist; 15 cylinders are used per week, necessitating approximately 2 deliveries per week. The cylinders have to be stored, for example, in a cupboard or the hall, and the oxygen is piped through tubing to, say, the lounge and bedroom.

*Liquid oxygen* provides a large volume of gaseous oxygen from a small storage space. Each patient has a reservoir weighing 32 kg when full which contains the equivalent of 13 800 litres of gaseous oxygen. This reservoir, which is refilled twice weekly from a delivery service of liquid oxygen, stands in a corner of the bedroom or living room; oxygen evaporates through coils in the top of the reservoir and is then fed via the flow meter and plastic tubing to the patient's nasal prongs. Most patients also receive a patient-carried liquid oxygen reservoir (Union Carbide 'Walker' System) weighing 4.5 kg when full of oxygen (1026 equivalent litres of gaseous oxygen). The portable container can be refilled with liquid oxygen from the larger reservoir by the patient.

The oxygen concentrator<sup>10</sup> is an electrically driven machine which separates oxygen from the other gases in the air. The concentrator output is 95% oxygen and the machine incorporates a small storage cylinder. Concentrators, once installed into, for example, a corner of a bedroom or an outhouse from which the oxygen is piped as before, are easy for the patient to use, compact, quiet, easy to maintain, and reliable.

#### COSTING METHODOLOGY

The costs considered here are those falling on the N.H.S. and patients as a result of the *incremental* resource use in providing long-term oxygen therapy. Other costs incurred in treating patients with chronic bronchitis regardless of the method of oxygen provision, such as the cost of drugs and visits by the general practitioner, are not considered since there is no evidence that they differ greatly among the three treatment methods. Furthermore, the question being posed here is "what is the most efficient way to administer long-term oxygen therapy?", not "is treatment worthwhile *per se*?" given the other priorities facing the N.H.S. This latter question would also require estimates of the benefits to patients and to the N.H.S. of improvements in morbidity and mortality resulting from treatment.

Points to note in the cost calculations include, firstly, the distinction between costs which are relatively fixed regardless of the

number of patients served (such as the provision of a workshop to maintain concentrators) and those which vary with the patient population (such as the electricity required to run the concentrators). This distinction becomes important in this study because concentrators have a higher element of fixed costs than the other two treatment methods.

Secondly, assumptions have to be made about the length of life of the capital cost items, such as buildings, workshop facilities, and equipment. The assumptions made here of 30 years, 10 years, and 5 years, respectively, are conservative but the assumption of longer lives does not change the results very much.

Thirdly, it is necessary to allow for the fact that the alternatives with a larger capital component require a larger proportion of the resource outlays earlier in the life of the project. In industry the interest a company would have to pay on the capital would be reflected in investment appraisals. Although the N.H.S. does not pay for its capital in the same way, one could still argue that as a community we are not indifferent to the timing of resource commitments; that is, we prefer to incur costs later rather than sooner. The most widely accepted way of incorporating this notion into public sector appraisals is to apply a public sector discount rate to costs and benefits occurring in future years.<sup>9</sup> Since most of the costs of oxygen therapy can be expressed on an annual basis, the discount rate is used to convert the capital outlays to an annual charge which reflects not only the actual sums involved but also the fact that they occur sooner rather than later.

Several models of oxygen concentrator are commercially available, so costs may vary. Firstly, the type of concentrator determines not only its purchase price, but also the running costs, because the more recent models are smaller and require less power. Secondly, the maintenance costs vary according to whether this service is provided by technicians operating from purpose-built workshops, or technicians attached to an existing unit.

Thus, two methods of providing oxygen by concentrators have been costed, the purchase of a new machine being assumed in both cases:

*Alternative A.*—To maintain the concentrators effectively hospitals or health authorities with very few or no specialised workshop facilities have to be provided with a workshop. This must be equipped with furniture and tools and a vehicle in which to make home visits, and it has to be staffed by two technicians to allow for illness and holidays. If more than 60 concentrators are serviced, three technicians and an extra vehicle may be required.

*Alternative B.*—Where hospital workshops are currently operating below full capacity the additional cost of providing basic servicing facilities for the concentrators through existing workshops would not be very large. It would consist of the costs of providing extra equipment, tools, furniture, and a vehicle; and only one technician need be employed for servicing 30 concentrators since cover could be provided by the existing staff. For up to 60 concentrators, two technicians are assumed to be employed, and three, plus an extra vehicle for more than 60. Finally, only a proportion of the running costs of the whole workshop need be apportioned to the concentrator servicing.

Since the number of patients served is a key factor in determining the relative costs of the treatment alternatives, the figures for total cost and cost per patient are given below for varying population sizes. Some of the assumptions made in deriving the costs are given in the accompanying discussion. A background paper giving fuller details of the cost calculations can be obtained from the authors.

#### RESULTS

The set-up costs and running costs (tables I–IV) are based on 15 h of oxygen use per day at 1980 prices. Some of the set-up costs are common to all methods, for example, the cost of the piping; whilst others differ between methods, such as the cost of the base for the liquid oxygen reservoir, the stands for the cylinders, and the electricity sockets for the concentrators. The running costs differ between methods, for example, for



TABLE I—COST PER ANNUM PER PATIENT FOR SMALL CYLINDERS

Item	Amount (£)
<i>Running costs</i>	
780 cylinders at £3.78*	2948
104 deliveries at £6.00†	624
Rental for sets and stands at £3.60 per month	43
Total running cost, including value added tax	3615
<i>Set up costs</i>	
Per annum installation cost discounted at 7%	24
<b>Total cost</b>	<b>3640</b>

\*Rental cost of cylinders includes cost of oxygen and the maintenance charge, although there can be a separate cost for out-of-hours calls.

†Charge fixed per delivery regardless of number of cylinders per delivery, but may vary according to geographical location of patient.

TABLE II—COST PER PATIENT PER ANNUM FOR LARGE CYLINDERS

Item	Amount (£)‡
<i>Running costs</i>	
365 cylinders at £3.78*	1380
60 deliveries at £9.50†	570
2 call-out charges at £8.32	16
Total running cost, including value added tax	2261
<i>Set up costs</i>	
Per annum installation cost discounted at 7%	24
<b>Total cost</b>	<b>2286</b>

\*Rental cost of cylinders includes cost of oxygen and the maintenance charge.

†As for table I.

‡There is no general N.H.S. tariff for large cylinders, and costs are calculated from typical costs incurred by hospitals.

TABLE III—COST PER ANNUM PER PATIENT FOR LIQUID OXYGEN

Item	Amount (£)
<i>Running costs</i>	
48 refills at £13.80*	662
<i>Set-up costs</i>	
Costs of main and portable reservoir	2000
Costs of installation, flow meters and fire extinguisher	153
Total set up costs	2153
Discounted per annum set-up cost	525
<b>Total cost</b>	<b>1486†</b>

\*Includes delivery charge and cost of routine maintenance.

†Individual cost items at 1978 price levels; total cost adjusted to 1980 price level.

costs for delivery of the oxygen, or for electricity for the concentrators. Costs per patient and costs in relation to number of patients are shown in figs. 1 and 2, respectively.

## DISCUSSION

The figures indicate a cost advantage for concentrators for all but small numbers of patients. However, all cost figures are to some extent the product of the assumptions made in

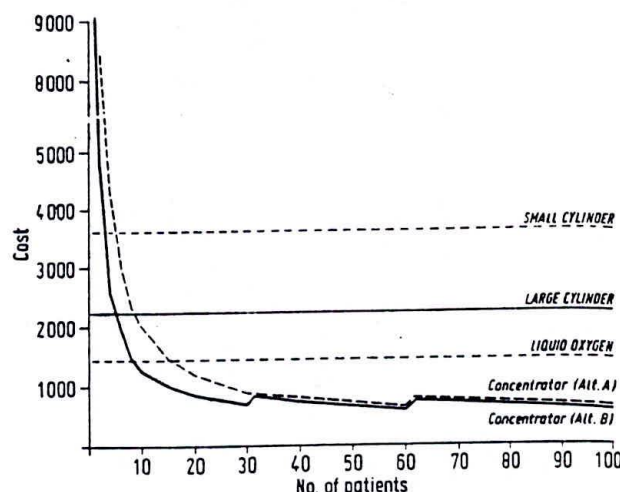


Fig. 1—Cost per patient for all methods of providing oxygen.

Cost in £.

Discount rate of 7% assumed.

Kinks in graphs for concentrators are due to sharp increases in workshop costs (see text) after 60 patients for alternative A, and after 30 and 60 patients for alternative B.

their calculation. Also they must be interpreted in the light of local circumstances: what is cost effective in one location may not necessarily be cost effective in another. We discuss here how the consideration of some economic issues may aid decision making.

The choice of discount rate is often a contentious issue in economic appraisals, but although concentrators and liquid oxygen need larger resource outlays in the form of equipment, the choice of discount rate has little effect on the results. In practice the capital outlays on equipment are much more likely to present financial problems.

The results show that size of patient population is one of the key influences on the relative cost (per patient) of the various treatment modes, largely because of the high set-up costs of concentrators. Maintenance facilities and technicians must be provided to service the concentrators irrespective of the number of patients, and the level of such provision only increases slightly with larger numbers. The least expensive treatment modes are large cylinders for less than 8 patients, concentrators (serviced by alternative B) for 8–13 patients, concentrators (and irrespective of the method for servicing) for any number above 13. As numbers of patients increase the analysis of costs with increasing numbers of patients becomes more complex—e.g. larger patient numbers may mean that

TABLE IV—COST PER ANNUM AND COST PER PATIENT FOR OXYGEN CONCENTRATOR (ALTERNATIVES A AND B)

No. of patients	Workshop set up cost*		Workshop running cost		Capital cost (concentrators, installation)*		Running costs per concentrator†		Total cost		Cost per patient	
	A	B	A	B	A	B	A	B	A	B	A	B
1	3062	1557	12593	7102	287	287	127	127	16069	9072	16069	9072
5	3062	1557	12593	7102	1433	1433	635	635	17723	10726	3545	2145
10	3062	1557	12593	7102	2865	2865	1270	1270	19822	12794	1982	1279
20	3062	1557	12593	7102	5731	5731	2540	2540	23927	16930	1196	846
50	3062	1667	12593	12042	14328	14328	6350	6350	43600	34386	727	688
100	4428	2996	17583	17032	28657	28657	12700	12700	63368	61384	634	614

\*Discounted at 7%.

†Includes electricity and maintenance.



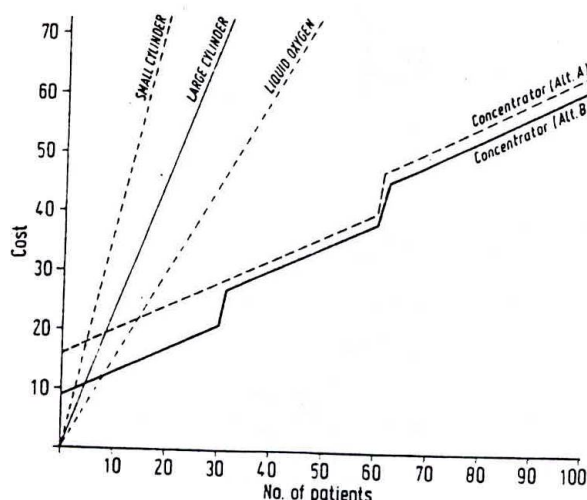


Fig. 2—Total costs of providing oxygen for all methods.

Cost in £ x 1000.

Discount rate of 7% assumed.

technicians could be given geographical zones, thereby reducing the amount of travelling between patients.

The most cost-effective method for a given health authority may depend upon the facilities already available. Whereas the costs of both cylinder and liquid oxygen include the costs of maintenance and repair by the supplier, concentrators would probably be maintained by health authority employees and therefore the costs of this must also be included in the cost of providing concentrators. In addition to the two methods of maintenance which have been costed, rental schemes (see below) or servicing by the concentrator manufacturer or the provision of a basic service by the use of existing facilities and staff should be considered. These may be most appropriate for servicing small numbers of concentrators but one must be sure that methods which appear "cheap" do not result in an opportunity cost to the authority, in that staff and facilities are diverted from other important activities. Even in such circumstances a charge should be imputed to the use of facilities even if they have "already been paid for" by the authority.

All of the methods of treatment require very little instruction to patients. We have no reason to believe that training costs differ greatly between treatment methods or that they are large for any method. If the oxygen systems are regularly checked or maintained by hospital technicians who are also in contact with the hospital doctors, patients gain confidence in their oxygen system, and know that they have a point of contact in case of difficulty.

Some companies are now offering rental or leasing schemes. The costs, including maintenance and running costs, vary somewhat, but are similar to those determined for machines purchased and maintained. Although these schemes are fairly new and untried, they seem to be worthy of consideration when small numbers of patients are to be treated, and when capital to purchase machines is not available. They also provide some assurance that up-to-date equipment will be available for use—an important consideration given the current rapidity of technological change in this field.

Economic appraisals attempt to assess the opportunity costs, in terms of changes in resource use, brought about by treatment alternatives. However, given the present

budgetary restrictions, one also needs to look at the purely financial aspects—that is, does the authority have the cash available and from which budgets would it come?

The financial aspects of the treatment choices examined here are of particular interest for two reasons. Firstly, the concentrator method, although less costly overall, requires a larger capital outlay on buildings and equipment. Paradoxically, there may not be money in the capital building or equipment budgets to enable the authority to launch such a service. Therefore, this study illustrates again the need for increased flexibility (or virement) between budgets, a point made recently by researchers appointed by the Royal Commission on the N.H.S.<sup>11</sup>

Secondly, the only existing funded service is the provision of small 'F' sized cylinders. Under the present arrangement the Family Practitioner Committee (F.P.C.) will pay for these if they are prescribed by a general practitioner and delivered by the pharmacist. Our study shows this to be the most expensive and least convenient method of providing oxygen. Although the F.P.C. budget is not cash-limited, the budget from which concentrators would be provided should an authority launch such a service, is almost certainly cash-limited.

In order that patients and the N.H.S., should benefit from the use of the most effective, convenient, and economical method, administrative change is necessary. It seems reasonable that once the need for long-term domiciliary treatment has been established for a patient by appropriate investigation in hospital, the cost of the continuing treatment should be met from the F.P.C. budget, in the same way as that for long term drug treatment for a chronic disorder. This paper is not the place for discussing the ways in which the cost of treatment could be funded from the F.P.C. budget, but none of them would be necessary in a health service which was unified so that all care, primary and secondary, were provided by one authority. Meanwhile the question remains, is it sensible for the N.H.S. to finance only the most expensive and inconvenient treatment method? There is little point in encouraging clinicians and managers to become more cost effective in their actions, if some of the budgetary incentives operate in the opposite direction.

We thank our many technical colleagues for their help. The study began when K. V. L. was a member of the M.Sc course in Health Economics at the University of York. Thanks are due to Mr A. K. Maynard the course Director, and Mr Ken Wright for helpful comments during the course of study.

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## Cost of Long-Term Complications of Deep Venous Thrombosis of the Lower Extremities: An Analysis of a Defined Patient Population in Sweden

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**Background:** Little information is available on the epidemiology and economic effect of long-term complications developing after deep venous thrombosis.

**Objective:** To determine the extent of, timing of, and treatment costs associated with long-term complications developing after deep venous thrombosis of the lower extremities.

**Design:** 15-year retrospective cohort study.

**Setting:** County hospital in Sweden.

**Patients:** 257 patients with deep venous thrombosis and 241 age- and sex-matched controls without deep venous thrombosis.

**Measurements:** Data on use of health care resources and costs of inpatient and outpatient care, pharmaceutical agents, and treatment of complications.

**Results:** After 15 years of follow-up, 35% of the patients with thrombosis and 57% of the controls were alive. Two hundred forty-two complications were reported among the patients with thrombosis, and 25 similar events were reported among the controls. The average expected present value of the health care cost of treating complications of thrombosis was estimated to be about \$4659 in the patients with thrombosis and \$375 in the controls. In controls, primary deep venous thrombosis cost about \$6000; thus, the additional long-term health care cost of post-thrombotic complications is about 75% of the cost of primary deep venous thrombosis.

**Conclusions:** The economic effect of post-thrombotic complications is considerable. The use of measures to prevent thromboembolism and its long-term complications are justified on both clinical and economic grounds.

Although information on prevention of, risk factors for, and treatment of complications of venous thromboembolism has increased substantially, epidemiologic data and data on characteristics of patients with previously verified thrombosis are largely lacking. Despite treatment, long-term complications of thrombosis are a major problem. In older patients, leg ulcers are prevalent and place great demands on the health care system (1). However, no information is available on the use of health care resources by affected patients and the costs of treating complications of thrombosis.

We therefore used an incidence approach (2) to retrospectively collect patient data. Our objectives were to document the extent and timing of long-term complications and recurrent thromboembolism and to estimate the health care costs of treating these conditions. Eight types of complications were defined (for controls, these complications are called events): superficial venous thrombosis, deep venous thrombosis, cellulitis, venous ulcer, varicose veins, stasis dermatitis, deep venous insufficiency, and pulmonary embolism.

### Methods

The medical records of 257 patients with a history of deep venous thrombosis of a lower limb (verified by phlebography) and 241 controls without a history of thromboembolic disease were reviewed for clinical outcomes and use of health care resources. By using hospital diagnosis registries, we identified consecutive patients with deep venous thrombosis whose condition was diagnosed between 1970 and 1985 at Skövde County Hospital, Sweden, or 1 of its 18 associated outpatient settings. Patients who were registered in error, had thrombosis in a part of the body other than lower limb, or had thrombosis that had not been verified by phlebography were excluded. The 257 study patients were selected for thrombosis only. Controls were selected from among all persons living in Skövde, Sweden, on 31 December 1979; this date was chosen to allow a duration of follow-up similar to that for the patients with thrombosis. Controls were matched to the patients by age (the closest date of birth) and sex.

All patients who survived the follow-up period had been followed for at least 10 but no more than 15 years. Patients who died were followed until the year of death. Controls were followed for 15 years or until the year of death. At study entry, mean ages were 64 years in the thrombosis group (60% men) and 66 years in the control group (59% men).

The following complications or events were recorded: superficial venous thrombosis (verified by

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phlebography or clinical diagnosis); deep venous thrombosis (verified by phlebography); cellulitis, venous ulcer that was not caused by arterial insufficiency or diabetes, varicose veins, and stasis dermatitis (each verified by clinical diagnosis); deep venous insufficiency (verified by Doppler ultrasonography); and pulmonary embolism (verified by scintigraphy or autopsy). Total use of medical care for each recorded complication or event was ascertained from records of primary care and hospital care from six hospital departments. About 3000 medical records were surveyed to determine total number of outpatient visits, days in the hospital, diagnostic measures, surgical procedures, and pharmaceutical agents.

Costs of the health care resources were based on reported unit prices of inpatient and outpatient care and pharmaceutical agents. In Sweden, health care purchasers use pricing data to reimburse providers for cross-boundary health services. Thus, such billing data are available from local, regional, and national health services. From an economic point of view, pricing data cannot generally be considered a true measure of actual costs. However, true cost measures that reflect full-opportunity costs are not regularly produced in the health care system. In our study, we assumed that reported unit prices are reasonable approximations of costs. All estimated costs were calculated in Swedish kronors (SEK) in fixed 1990–1991 prices and then converted to U.S. dollars (in 1991, 1 U.S. dollar = SEK 5.5). A 5% discount rate was used to adjust for the different timings of complications or events.

To estimate the average present value of expected lifetime costs of treating post-thrombotic complications per patient of cohort *i*, discounted to the

time of the primary thrombosis, we added all present and expected future costs according to the following formula:

$$\left[ \sum_{t=0}^{15} TC_{it} / (1 + r)^t \right] / N_i$$

where *TC* is the total treatment cost for cohort *i* year *t* after primary thrombosis, *r* is the discount rate, *N* is the sample population of cohort *i*, and *i* is 1 for patients with thrombosis and 2 for controls.

None of the funding parties had any role in the collection, analysis, or interpretation of study data.

## Results

The results of our analysis are presented in Tables 1 and 2. Table 1 shows the differences in the frequency of complications or events and the survival pattern for the two groups. At the end of the follow-up period, 242 post-thrombotic complications were recorded among the patients with thrombosis and 25 events were recorded among the controls (17 of these events were cases of primary deep venous thrombosis). In the patients with thrombosis, approximately two thirds of the complications occurred within 5 years after primary deep venous thrombosis had developed. The survival pattern also differed substantially between groups: Thirty-five percent of patients with thrombosis and 57% of controls were alive at the end of the period.

Because of differences in the frequency of complications or events and survival, the differences in the frequency of complications or events per patient

**Table 1. Annual Number of Complications or Events, Probability of Survival, Number of Complications or Events per Exposed Patient, and Total Costs of Treatment during 15 Years of Follow-up\***

Year of Follow-up	Thrombosis Group				Control Group			
	Complications	Probability of Survival	Complications per Exposed Patient	Total Cost	Events	Probability of Survival	Events per Exposed Patient	Total Cost
	<i>n</i>		<i>n</i>	SEK	<i>n</i>		<i>n</i>	SEK
0		1	0.0000					
1	89	0.8872	0.3903	3 050 422	5	0.9627	0.0000	
2	26	0.8171	0.5141	922 780	2	0.9295	0.0216	220 264
3	22	0.7665	0.6258	334 777	0	0.8963	0.0305	14 300
4	14	0.7121	0.7023	334 028	6	0.8548	0.0305	0
5	18	0.6848	0.8046	1 189 057	1	0.8299	0.0596	154 226
6	10	0.6342	0.8660	354 273	1	0.8299	0.0646	8 872
7	10	0.6186	0.9289	263 806	2	0.7884	0.0751	78 602
8	14	0.5754	1.0235	572 053	3	0.7801	0.0911	38 386
9	16	0.5556	1.1356	515 598	1	0.722	0.0968	8 189
10	5	0.5355	1.1719	86 114	0	0.6971	0.0968	0
11	4	0.4861	1.2039	43 053	0	0.6846	0.0968	0
12	5	0.4388	1.2483	78 433	2	0.6473	0.1097	75 706
13	4	0.3921	1.2880	57 015	0	0.6349	0.1097	0
14	5	0.3671	1.3410	49 287	0	0.5975	0.1097	0
15	0	0.3516	1.3410	0	2	0.5892	0.1237	1200
Total	242			7 850 696	25	0.5726	0.1310	7359
								607 104

\* SEK = Swedish kronors.



**Table 2. Average Costs per Complication or Event in Fixed 1990–1991 Prices by Post-Thrombotic Complications or Events\***

Complication or Event	Thrombosis Group		Control Group	
	Average Cost per Complication	Complications	Average Cost per Event	Events
	SEK	n	SEK	n
Superficial venous thrombosis	15 638	58	600	2
Recurrent deep venous thrombosis	36 877	74		
Primary deep venous thrombosis			33 455	7
Cellulitis	14 907	22	28 017	3
Venous ulcer	43 630	19	38 433	5
Varicose veins	11 420	11	6105	4
Stasis dermatitis	7300	3		
Deep venous insufficiency	6413	3		
Pulmonary embolism	33 932	32	17 771	4
Combinations of several conditions	90 262	20		
Overall average	32 441	242	24 284	25

\* SEK = Swedish kronors.

exposed to risk were even larger. At the end of the follow-up period, a surviving patient in the thrombosis group had had, on average, 10 times more complications than a surviving control. The total costs of treating complications or events were SEK 7 850 696 (\$1 427 399) for patients with thrombosis and SEK 607 104 (\$110 383) for controls.

For the entire follow-up period, the average costs per complication or event were SEK 32 441 (\$5898) for patients with thrombosis and SEK 24 284 (\$4415) for controls. Venous ulcer was the most expensive type of complication, followed by deep venous thrombosis and pulmonary embolism (Table 2). For both groups, however, the treatment cost per complication or event varied greatly, indicating similar variation in the severity of the complications or events.

Among the patients with thrombosis, more than one third of the treatment cost was attributable to recurrent deep venous thrombosis. Among the controls, primary deep venous thrombosis accounted for 38.6% of the total treatment cost. The estimated average cost of primary deep venous thrombosis was SEK 33 455 (\$6083) (Table 2).

At the end of the follow-up period, the discounted average present values of treatment cost were SEK 25 625 (\$4659) for patients with thrombosis and SEK 2060 (\$375) for controls. The difference in the discounted present values of treatment cost between the thrombosis and control groups (that is, SEK 25 625 – SEK 2060 = SEK 23 565 [\$4285]) can be interpreted as the expected cost of treating post-thrombotic complications. Thus, an estimate of the present and expected cost of treating both primary deep venous thrombosis and related post-thrombotic complications is SEK 57 020 (\$10 368) (that is, SEK 33 455 + SEK 23 565). According to this estimate, approximately 60% of the cost is attributable to primary deep venous thrombosis and 40% is attributable to post-thrombotic complications.

## Discussion

In our study of long-term complications of deep venous thrombosis of the lower extremity, we compared patients who had phlebography-verified thrombosis with age- and sex-matched controls who served as a baseline benchmark. We considered the inclusion of controls to be important because the prevalence of nonthrombotic deep venous insufficiency increases with age (3). One limitation of our study could be that we matched the groups for age and sex only; we were unable to match them for health conditions or factors that predispose patients to deep venous thrombosis or venous insufficiency. Nonetheless, even controls matched only for age and sex provide the incidence of deep venous insufficiency in an unselected population.

In our study, the post-thrombotic complications that occurred over 10 to 15 years of follow-up could be corrected for similar events among controls: In patients with thrombosis, the risk for a thrombotic complication was 10 times greater and the cost of such a complication was 12 times greater compared with controls. To our knowledge, ours is the first study to compare clinical and economic post-thrombotic complications with what could be considered the natural occurrence in an age- and sex-matched population.

In the control group, all patients were followed for 15 years or until death. In the thrombosis group, however, 30 patients (12%) were censored because they were followed for 10 to 14 years. These patients represent a loss of 3.7% of all years of follow-up. The number of complications per exposed patient decreased with time (Table 1). Through the 10 to 15 years of follow-up, the annual risk for a complication is about one third of the risk during the first 10 years. Thus, the number of complications in the thrombosis group is underestimated by about 1.2% (3.7% × one third) as a result of the censored



years of follow-up. Because of the discounting principle, however, costs that are incurred after 10 years and are discounted by 5% will result in a present value of only about 50% of the original. Because of censored patients, therefore, we may have underestimated the present value of post-thrombotic complications by less than 1%. We did not adjust for these censored patients; thus, our estimate of the costs of post-thrombotic complications is conservative.

We obtained data on complications from patient records. This suggests that the frequency of complications was lower than that seen in Lindhagen and colleagues' study (3), in which each patient was investigated at follow-up. However, because our goal was to assess clinically important long-term consequences, our approach seems reasonable.

We estimated that the average cost per complication or event was approximately SEK 33 000 (\$6000) for primary deep venous thrombosis and SEK 34 000 (\$6182) for pulmonary embolism. In an earlier study of patients from Malmö General Hospital in southern Sweden (4), these estimates (converted to 1991 prices) were approximately SEK 20 000 (\$3600) for deep venous thrombosis and SEK 24 000 (\$4400) for pulmonary embolism. Because use of hospital resources and costs are local, our cost estimates (obtained from one hospital) may not be generalizable to other settings. One of our more general results is the ratio between the expected costs of long-term treatment of post-thrombotic complications and primary deep venous thrombosis. This ratio was approximately 0.75 (that is, the expected long-term costs of treating post-thrombotic complications are about 75% of the costs of treating primary deep venous thrombosis).

In the classic study by Bauer (5), the incidence of complications increased during the first several years of follow-up and decreased after about 5 years. However, decrease in incidence may start earlier when venous function is measured objectively (6). During the first 5 years of our study period, complications developed in about two thirds of the patients with thrombosis and in 56% of the controls. Pulmonary embolism and recurrent thrombosis, however, usually occurred within the first year.

A high mortality rate in patients with thrombosis could be partially explained by concomitant cancer or cardiovascular disease (7, 8). In our study, the mortality rate after 15 years was 65% in the thrombosis group and 43% in the control group.

Medical records contained little data on use of oral anticoagulation therapy, ulcer dressings, and supportive stockings. Thus, the costs of these measures are not included. Indirect costs resulting from loss of productivity were not estimated because no appropriate data were available. However, because two thirds of the patients were younger than 70

years of age at the time of thrombosis and most of them could be considered to be employed, the inclusion of indirect costs would further increase the long-term cost. This suggests that the estimated cost difference between the groups is minimal.

The estimated incidence of deep venous thrombosis in Nordic countries is 1.5 to 2 cases per 1000 persons per year; surgery without prophylaxis is an important risk factor (9, 10). Untreated venous thromboembolism is associated with considerable risk for death and chronic venous insufficiency. Moreover, our findings show that long-term complications have a notable economic effect. Economic evaluations (4, 11, 12) have shown that prophylactic measures are cost-effective compared with no prophylaxis or surveillance and selective treatment of venous thromboembolism. We conclude that the use of measures to prevent thromboembolism and its long-term complications is justified on both clinical and economic grounds.

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## Original Articles

# Morbidity pattern, health care utilization and per capita health expenditure in a rural population of Tamil Nadu

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### ABSTRACT

**Background.** Information on the existing morbidity pattern, pattern of health care utilization and the per capita health expenditure is essential to provide need-based health care delivery to a rural population. To obtain this information we performed a study in the K.V. Kuppam Block, North Arcot Ambedkar District, Tamil Nadu.

**Methods.** We did a cross-sectional study, interviewing respondents from 300 households, from 3 panchayats using a multistage sampling technique. Information relating to 1440 persons was collected. The morbidity data was obtained initially for the week prior to the day of interview, followed by one week to one month and then for two months to one year.

**Results.** During 1990–91, 825 of the 1440 persons (57.3%) did not have any illness. Sex had no bearing on the number of illnesses. Of the 60 children less than 2 years of age, 42 (70%) had one or two illnesses. The period prevalence of infective and parasitic diseases was found to be 21.9% with an average of 3 episodes. Services rendered by private practitioners (registered, non-registered and indigenous) were utilized by 59% of the households and 79% of the households had used allopathic treatment at some time. The average per capita per annum health expenditure was Rs 89.9 (Rs 449 per household). This increased significantly with increase in the household size ( $p < 0.001$ ) and per capita income ( $p < 0.01$ ).

**Conclusion.** The health-seeking behaviour of this population can be changed if efficient services are rendered through government primary health centres and subcentres. This would allow the existing voluntary agency to withdraw without much change in the per capita health expenditure.

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### INTRODUCTION

Health surveys are a useful tool for assessing a population's health care needs reliably. Morbidity and health care utilization surveys ideally go together. It is useful to know the pattern of health problems suffered by a population, what was done about them as well as the expenditure incurred on treatment.

An important factor in providing primary health care is the

cost. Cost studies provide valuable information on health expenses, help develop cost-consciousness and are a means of budgetary control. Such information includes treatment costs, patterns of health expenditure in specific settings and the prevalence of diseases in the area.<sup>1</sup>

This study was carried out in a rural area of south India to study the morbidity pattern, the pattern of utilization of health services and the mean expenditure on health per household and per person.

### SUBJECTS AND METHODS

A cross-sectional study was carried out in July 1991 in 3 panchayats of K.V. Kuppam Block, North Arcot Ambedkar District, Tamil Nadu. The subjects were chosen using a multistage sampling technique. A stratified random sampling method was adopted at the first stage to select 3 of the 39 rural panchayats based on their distance from the main road with <3.3 km, 3.3–6.6 km and >6.6 km as cut-offs. The selected panchayats represented three major population groups with different socio-economic characteristics. A systematic sampling method was used at the second stage to choose 23% of the households (a total of 331) from each panchayat. Of these, 31 (2%) could not be studied, since the houses were found locked or were vacant during the survey period. Thus, respondents from 300 (21%) households of the 3 panchayats were interviewed. There was no instance of non-cooperation.

A pre-tested interview schedule was used by trained interviewers to collect the data. Information relating to a total of 1440 persons was obtained from these 300 households. The morbidity pattern was obtained by asking the respondent first about the one week period prior to the day of interview, followed by the one week to one month period and then the 2–12 months period. This was done to minimize the relapse bias. Subsequently, the place of treatment for each episode of each illness was obtained and the type of treatment given recorded. Health expenditure was defined as the expenditure incurred for preventive and curative health care; but money spent on home treatment (use of balm and buying medicines from shops) was excluded. The health expenditure incurred included treatment cost, travel, food and wages lost during illness; other expenses were obtained corresponding to each episode of each illness.

The other variables recorded were the age, sex, caste, income, education, illness and number of episodes. The income through different sources and through wages of different persons were carefully obtained. The respondent was the head of the household or any responsible person within that household. The morbidity was classified according to ICD codes.<sup>2</sup>

The terms 'person', 'illness' and 'episodes' were defined as

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recommended by the Expert Committee on Health Statistics of the World Health Organization (WHO).<sup>3</sup> If a person within a given period of observation (e.g. a year) suffered from illness A twice and from illness B three times and if the episodes of illness A and B occurred at different times, this person contributed one unit to statistics of persons for each illness, two units to statistics of illness, and 5 units to episodes (2 'episodes' to illness A and 3 to B). Period prevalence (persons) was defined as the number of ill persons during a defined period (a year divided by the average number of persons). Period prevalence (episodes) was the number of episodes of illness which were current at some time during a defined period divided by the average number of persons exposed to risk during the period.

Means, percentages, period prevalence (persons), period prevalence (episodes), Chi-square test, correlation in univariate analysis and step-wise regression in multivariate analysis were the statistical measures used.

## RESULTS

Of the 300 households studied, 48 belonged to forward communities, 144 to backward communities and 108 to scheduled castes. Half the households had a thatched roof, 29% a tiled roof and 21% a terraced roof. No morbidity was reported in 7.7% (23) of households. Of the 1440 persons from 300 households, 615 (42.7%) had one or more illness during the year. The sex of the person had no bearing on the number of illnesses (Table I).

Among children below 2 years of age, 70% had one or two illnesses. This group also had the highest proportion of two illnesses (21.7%) and 63% of the under-fives had been ill once or twice. As a group, school-going and adolescent children (6-19 years) had the least (31.7%) instances of illness while 45% of the 20-44 years group had had an illness. Three illnesses were reported only in the age group ≥45 years (Table II).

Sixty per cent of the sampled households had infective and parasitic diseases, 34% had diseases related to the nervous system and sense organs, 15.3% had diseases of the digestive system, 10% had injuries and poisoning, 10% disease of the skin and 10% needed preventive care.

Table III details the morbidity pattern. Period prevalence

TABLE I. Sex distribution of the population related to the number of illnesses

Number	Male (n=731)	Female (n=709)	Total (n=1440)
One	261 (35.7)	272 (38.4)	533 (37.0)
Two	33 (4.5)	44 (6.2)	77 (5.3)
Three	1 (0.1)	4 (0.6)	5 (0.3)
Total	295 (40.4)	320 (45.1)	615 (42.7)

Figures in parentheses are percentages

TABLE II. Age distribution of the population related to the number of illnesses

Age	n	Number of illnesses			Sick persons
		One	Two	Three	
0-2	60	29 (48.3)	13 (21.7)	-	42 (70.0)
3-5	67	36 (53.7)	2 (3.0)	-	38 (56.7)
6-19	372	139 (29.2)	12 (2.7)	-	151 (31.7)
20-44	533	210 (39.4)	30 (5.6)	-	240 (45.0)
≥45	308	119 (38.7)	20 (6.5)	5 (1.7)	139 (45.2)
Total	1440	533 (37.0)	77 (5.3)	5 (0.3)	615 (42.7)

Figures in parentheses are percentages

(persons) of infective and parasitic diseases (including fever, cold, cough and headache) was found to be 21.9% and that for diarrhoea and dysentery was 2.8%; the period prevalence (episodes) were 74.7% and 8.3%, respectively. Illnesses related to the nervous system and sense organs accounted for a period prevalence of 8.6% (persons) and 75.5% (episodes) followed by diseases of the digestive system.

Less than 1% of the population had chronic diseases such as asthma (0.7%), ulcer (0.6%), tuberculosis (0.3%), diabetes (0.3%), leprosy (0.2%), mental disorders (0.1%), cancer (0.06%) and acute diseases such as typhoid (0.2%), measles (0.2%) and jaundice (0.1%).

Of the total population less than 1% had problems related to pregnancy, childbirth and puerperium. However, the period prevalence among women only for menstrual problems was 1.4%, for

TABLE III. Period prevalence of illness (persons and episodes) during 1990-91

ICD codes	Type of illness	No. of persons	Period prevalence (persons) per 100 (n=1440)	No. of episodes	Period prevalence (episodes) per 100 (n=1440)
I	Infective and parasitic diseases	351 (179)	21.9	1076	74.7
II	Neoplasm-cancer*	1	0.06	-	-
III	Diabetes mellitus*	5 (4)	0.3	-	-
IV	Anaemia	2	0.1	25	1.7
V	Mental disorders*	2	0.1	-	-
VI	Nervous system and sense organs	124 (103)	8.6	1087	75.5
VII	Circulatory system	5 (5)	0.3	13	0.9
VIII	Asthma	10 (8)	0.7	110	7.6
IX	Digestive system	67 (46)	4.7	229	15.9
X	Genito-urinary system*	6	0.4	-	-
XI	Complications of pregnancy, childbirth and puerperium	42 (32)	2.9	202	14
XII	Skin and subcutaneous tissues	46 (30)	3.2	343	23.8
XIII	Musculoskeletal system and connective tissue	15 (13)	1.0	136	9.4
XVII	Injuries and poisonings	43 (32)	3.0	142	9.9
	Dosham/Sevappu/Medical checkup	5	0.3	9	0.7

Figures in parentheses are number of households \*Episodes not applicable  
Sevappu local term used to describe a child who turns blue and dies

Dosham local term used to describe children suffering from fever, diarrhoea and dysentery



antenatal checkup 1.8% and for child immunization 1.6%.

More than half the households (59%) preferred to go to private practitioners (registered, non-registered or indigenous) and only 28% used the services provided by a voluntary agency serving the block (Table IV). Only 2% had adopted home treatment and 3% had gone to a medical shop. This was either for pain-relieving medicines or just for simple cold, cough or fever. While 79% of the households had used allopathic treatment at some time, 33% had used homoeopathic medicines (Table IV).

The annual health expenditure was Rs 89.9 per person and 7.7% of households had not incurred any expenditure. Considering an average household size of 4.8 persons, the annual health expenditure worked out to Rs 469 per household. As the per capita income (PCI) increased, the per capita health expenditure (PCHE) also increased significantly ( $p < 0.001$ ; Table V). Similarly, as the family size increased the PCHE also increased. However, caste had no association with PCHE.

In the correlation analysis the PCHE correlated positively with PCI ( $p < 0.01$ ) and household size ( $p < 0.001$ ). However, the PCHE was not related to the social status of the family ( $p > 0.01$ ).

In the step-wise regression analysis the estimated coefficient indicated that when the PCI increased by Rs 1.00, the average increase in PCHE was Rs 0.03. When the household size increased by one unit, the PCHE increased by Rs 8.58 and when the PCI was Rs 1200 step-wise regression showed that on an average every individual spent Rs 36 per annum. The  $R^2$  value of PCHE with household size (0.11) was higher than the  $R^2$  value of PCHE with PCI (0.06), thereby implying that the regression fit of the PCHE and household size was comparatively better than that of PCHE and PCI.

## DISCUSSION

Considering the methodological issues in a morbidity survey, the use of tracer conditions has been found to significantly increase completeness of reporting. This consists of the use of a checklist of specific symptoms associated with a given health problem in the questionnaire and asking the respondent whether she/he had

any of these during the period in question. The WHO has produced a select list of symptoms associated with various health problems that may be used by a lay interviewer in a health survey.<sup>4</sup> Tekle-Haimanot Makonnen picked up all morbidity by using tracer conditions in a rural health survey in Ethiopia.<sup>5</sup> We did not use any systematic list of tracer conditions, but spent time by probing into various morbid conditions to increase completeness of reporting.

The duration of the recall period also influences the completeness and reliability of reporting. The longer the recall period, the less likely a person will remember an illness. The health survey conducted in 1954–55 in California, USA<sup>6</sup> established this fact. A morbidity survey in Japan confirmed that recall lapse affects the not-so-serious health conditions much more. We asked the respondents for information with regard to the incidence of illness for each of the four calendar weeks preceding the interview. The total samples were then randomized over a period of 52 weeks so as to accurately reflect the prevalence. We adopted a systematic recall of one week prior to the interview, two weeks to one month and then one month to 1 year which, to some extent, assures the completeness and reliability of reporting. This method also allows the seasonal variations in morbidity to be included and estimation of the PCHE per year.

Rao *et al.*<sup>7</sup> have stated that a longitudinal study overcomes the problem of a recall bias. However, longitudinal studies are expensive and hence can cover only a short duration. A combination of retrospective and longitudinal studies are considered ideal.

Another methodological issue relates to not including over-the-counter purchases and self-care. The proportion reporting self-care was low and these tended to be symptomatic treatment of one or two doses which would not contribute substantially to the total cost. With the information available from this study and with our own experience of this area we do not anticipate any major bias in the total costs incurred by the households.

The findings of a previous study have shown that for one visit to the RUHSA Health Centre each person on an average paid only Rs 8.80.<sup>8</sup> This fact, as also the information available from this study, suggest that it is unlikely that any significant bias in the total costs incurred has been introduced.

In Mumbai,<sup>9</sup> 75% of urban poor households suffered from infective diseases while we found that 60% of rural households had the same diseases. In rural Nigeria<sup>10</sup> in 1991 the prevalence of fever, gastroenteritis and chest infection was estimated at 50%, 37% and 10%, respectively. We found that 60% of the households studied had had infective and parasitic illnesses. A longitudinal study carried out in the same population between 1990–92 had indicated that the incidence (number of episodes/child-year) of diarrhoea and respiratory diseases among children less than 3 years of age was 1.77 and 2.56 respectively.<sup>11</sup> The low incidence may be related to the existence of a rural health project providing primary and secondary health care in this area for fifteen years.<sup>12</sup> For the same reason, 30% of the less than 2-year-olds in this study had no disease compared to only 16.3% in another study from the same state.<sup>13</sup>

The positive relationship between PCI and PCHE is highly significant with the chi-square test and correlation analysis. However, in the multivariate analysis the relationship between PCI and PCHE is not as strong.

In 1971–72 the annual health expenditure in the same district<sup>8</sup> was estimated at Rs 13.09 per person and Rs 75 per family. In 1983–84 Scheer *et al.*<sup>14</sup> reported an average health expenditure of Rs 250–300 per year per family in the same area. The present

TABLE IV. Place and type of treatment ( $n=277$ )

Place/Type of treatment	<i>n</i> (%)
<b>Place</b>	
Voluntary organization (Primary and secondary care)	85 (28)
Christian Medical College Hospital (Voluntary tertiary care)	12 (4)
Government (Primary, secondary and tertiary)	75 (25)
Private practitioners (Registered, non-registered, indigenous)	177 (59)
<b>Type</b>	
Allopathy	238 (79)
Homoeopathy	98 (33)
Medical shop	10 (3)
Native doctor	7 (2)
Petty shop	4 (1)
Home treatment	6 (2)

TABLE V. Per capita income v. per capita health expenditure

Per capita income (Rs)	Households	Mean (SD) health expenditure
<600	109	40.0 (94.1)
601–1200	96	68.0 (140.5)
1201–2400	59	140.1 (408)
>2400	36	216.9 (407.6)
Total	300	89.9 (254.4)



study showed the annual health expenditure to be Rs 89.9 per person and Rs 449 per household. The increase in the health expenditure over this period is possibly due to inflation. In 1975 *Srinivasan et al.*<sup>13</sup> estimated the annual PCHE in a rural area of Tamil Nadu to be Rs 24 whereas a study from Mumbai<sup>9</sup> among the urban poor, found the annual per household health expenditure to be Rs 300 or more.

The morbidity pattern of this rural community, the health care utilization pattern and the PCHE indicate that strengthening of the government primary health centres and subcentres in this area and changing the health-seeking behaviour of the population may allow the voluntary agency to withdraw. Also the PCHE can be kept at an affordable level if sufficient and efficient health care services are provided.

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## Growth hormone-producing pituitary tumours: Clinical profile and results of surgery

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#### ABSTRACT

**Background.** Growth hormone-producing pituitary tumours present with a wide variety of manifestations. The optimum diagnostic work up, management and follow up of such patients is complex and involves a multidisciplinary approach. There is paucity of data from India with regard to the clinical presentation and results of surgery for growth hormone-producing tumours.

**Methods.** We studied the first 50 patients presenting during 1989-94 with growth hormone-producing pituitary tumours to our centre. The work up included detailed endocrine and radiological assessment. The surgical outcome was analysed for 35 patients who were operated (trans-sphenoidal 29, transcranial 6) at our centre.

**Results.** All the patients had macroadenomas [mean (SD) diameter 3.12 (0.87) cm]. Seventy-five per cent of the patients had supra- and/or parasellar extension and 57% had visual field defects. Tumour size correlated with the preoperative basal ( $r=0.57$ ) and glucose-suppressed ( $r=0.54$ ) growth hormone levels. Thirty-three of the 35 patients operated at our centre (trans-sphenoidal 28, transcranial 5) were available for follow up (median duration 34 months). After trans-sphenoidal surgery alone, 12 of the 28 (43%) patients had normalization of growth hormone levels (post-glucose growth hormone

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Special Articles

COSTS AND CHARGES ASSOCIATED WITH THREE ALTERNATIVE TECHNIQUES OF HYSTERECTOMY

JAMES H. DORSEY, M.D., PATRICE M. HOLTZ, R.N., M.S., ROBERT I. GRIFFITHS, Sc.D., MARGARET M. McGRATH, M.S., AND EARL P. STEINBERG, M.D.

ABSTRACT

**Background** Many hysterectomies are now performed by a laparoscopically assisted vaginal technique. This procedure is controversial, partly because of concern about cost. We studied hospital charges and costs for the procedure as compared with those for total abdominal hysterectomy and total vaginal hysterectomy in clinically similar groups of patients.

**Methods** From hospital-discharge data and patients' charts, we identified hysterectomies performed in 1993 and 1994 by 96 surgeons at a community teaching hospital to treat benign conditions. The patients were grouped according to the surgical procedures performed in conjunction with the hysterectomy. Data on hospital charges and cost-to-charge ratios for 64 hospital cost centers were used to assess charges and costs for specific resources, as well as for the hospitalization overall.

**Results** Of 1049 patients studied, 26 percent underwent laparoscopically assisted vaginal hysterectomy, 54 percent underwent abdominal hysterectomy, and 20 percent underwent vaginal hysterectomy. The average hospital stays were 2.6, 3.9, and 2.9 days, respectively, and the mean total charges (facility charges plus professional fees) for the hospitalizations were \$6,116, \$5,084, and \$4,221 ( $P < 0.001$  for the comparison of the laparoscopic technique with both other techniques). The mean facility costs were \$4,914, \$3,954, and \$3,116, respectively ( $P < 0.001$  for the same comparison), with similar findings in all subgroups. The higher charges and costs for laparoscopically assisted vaginal hysterectomy were due to higher supply costs, particularly when disposable supplies were used, and to longer operating-room time.

**Conclusions** Despite shorter hospital stays, in-hospital charges and costs for laparoscopically assisted vaginal hysterectomy are higher than for either alternative procedure, because of the disposable supplies that are typically used and the longer operating-room time. (N Engl J Med 1996; 335:476-82.)

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LAPAROSCOPICALLY assisted vaginal hysterectomy has come into widespread use, primarily because morbidity is presumed to be less when the large abdominal incision and invasive intraabdominal manipulations associated with total abdominal hysterectomy are eliminated.<sup>1-3</sup> The laparoscopically assisted procedure has been controversial, however, largely because of concern that it is sometimes used instead of total vaginal hysterectomy, generally considered the simplest and least morbid method of removing the uterus, and because the costs of the laparoscopic procedure may be substantially higher than those of either alternative procedure.<sup>4-8</sup>

According to several studies,<sup>9-11</sup> the average hospital stay of patients undergoing laparoscopically assisted vaginal hysterectomy is shorter than that of patients undergoing the other procedures. However, these findings have often been confounded by differences in the surgical procedures performed in conjunction with hysterectomy, such as salpingo-oophorectomy, adhesiolysis, and repair of pelvic-support defects. Previous assessments of variation in operating-room time for hysterectomy, as well as in the costs of different procedures, have also not determined whether the variation was due to differences inherent in the three techniques or to differences in the types of patients undergoing each procedure.

To assess costs, hospital charges, and use of resources associated with alternative techniques of hysterectomy, we grouped hospitalizations for hysterectomy on the basis of the surgical procedures performed in addition to the removal of the uterus. We then compared overall and specific costs and charges associated with the various techniques.

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## METHODS

## Study Site

The Greater Baltimore Medical Center, a 372-bed community teaching hospital, has the largest gynecologic-surgery service in Maryland. Laparoscopically assisted vaginal hysterectomy has been performed since February 1, 1990. In 1993 and 1994, the period of this study, 21,610 gynecologic-surgery procedures were performed at the center.

## Sources of Data

Three sources of data were used in the study: a computerized file containing hospital-discharge abstracts, with diagnoses, procedures, and charges for all hospitalizations in Maryland, as reported to the state Health Services Cost Review Commission; a computerized data base maintained by the medical center, containing information on diagnoses and procedures, use of resources, and charges submitted for each service provided by the hospital; and patients' hospital records, which we reviewed in a structured fashion.

## Selection of Patients

Patients who underwent hysterectomy in 1993 and 1994 were identified in the data bases of the Health Services Cost Review Commission and the medical center when one of the following procedure codes established in the *International Classification of Diseases, 9th Revision, Clinical Modification* (ICD-9-CM) was assigned: 68.4 for abdominal hysterectomy, 68.5 for vaginal hysterectomy, or 68.5 plus 54.21 (indicating laparoscopy) for laparoscopically assisted vaginal hysterectomy. We reviewed all secondary procedures listed in the data base of the medical center for the 1420 patients identified, and we excluded 182 patients who had undergone one or more major secondary procedures unrelated to hysterectomy (such as partial colectomy or appendectomy). We also excluded 45 patients who had undergone either radical or subtotal hysterectomy (ICD-9-CM codes 68.6 and 68.3), since our focus was on hysterectomy performed to treat benign conditions. Of the remaining 1193 patients, hospital records were not available for 39 (3 percent). After a detailed review of the charts, we excluded an additional 105 patients because their hysterectomies had been performed to treat cancer. Thus, 1049 patients (74 percent of those who underwent hysterectomy at the center in 1993 and 1994) were included in the analysis. The 1049 procedures were performed by a total of 96 surgeons.

## Demographic and Clinical Data

Data were abstracted from the hospital charts by one of five registered nurses. The information collected included each patient's age, height, weight, medical history, indications for surgery, operative procedures (including information on whether a vaginal hysterectomy had been converted to an abdominal procedure), intraoperative findings and complications, postoperative complications, and results of pathological studies, including the uterine weight. Each indication for hysterectomy was classified in one of four categories: (1) uterine abnormalities, defined as any clinically diagnosed abnormalities that involved the uterus (such as myomas) or resulted in uterine dysfunction (such as a bleeding disorder); (2) adnexal abnormalities, defined as any clinically diagnosed abnormalities involving an ovary, a fallopian tube, or both (such as an ovarian cyst or a tubo-ovarian mass); (3) abdominal or pelvic abnormalities, defined as any other abnormalities of the abdominal or pelvic region, such as endometriosis, pain, pelvic inflammatory disease, or a mass that was not described as adnexal or a uterine fibroid; and (4) abnormalities of pelvic relaxation, defined as any abnormalities resulting from a support defect of the pelvic fascia. Thus, a patient could have had more than one indication for surgery. An intraoperative finding of extensive adhesions was recorded if the operative note described adhesions as numerous, massive, thick, or requiring extensive adhesiolysis for

the surgeon to "free up" or gain access to a pelvic structure. From the records of anesthesia and the nursing records, data were collected on the time spent in the operating room, under anesthesia, and in the recovery room.

## Economic Data

Charges made by the facility for all resources used during a hospitalization, such as operating-room time and supplies, and for the hospitalization as a whole, were obtained from the medical-center data base. Facility charges for anesthesia were based on the time under anesthesia and on per-minute charges as provided by the finance department of the medical center.

To estimate the professional fees for each hospitalization, we assigned relative-value units based on Medicare's resource-based relative-value scale to all ICD-9-CM procedure codes that had a professional component, as well as to surgical-pathology services with professional-service components but no ICD-9-CM procedure code. The estimated professional fees for anesthesia were based on the time under anesthesia. The anesthesia time, expressed in minutes, was divided by 15 and rounded to the nearest whole number to obtain relative-value units for anesthesia time for each patient. A base number of relative-value units for each procedure (8 for abdominal hysterectomy and 6 for vaginal hysterectomy and laparoscopically assisted vaginal hysterectomy) was added to the relative-value units for time to obtain the total number of relative-value units for anesthesia. The relative-value units were converted to charges with Medicare's 1993 and 1994 conversion factors for Baltimore. The estimated professional fees for each hospitalization were then totaled.

The medical center's costs, as opposed to its charges, were also estimated for each hospitalization. We computed the proportion of the total hospital charges that was attributable to each of 64 cost centers (such as the operating room, medical and surgical supplies, the pharmacy, and the pathology department). We then selected the cost centers that accounted for the 10 largest shares of the total charges (for example, the operating room accounted for 30 percent of charges). For each of these 10 cost centers, we evaluated all resources that were used in the care of the patients in our sample and ranked the resources in terms of the proportion of the cost center's total charges that was attributable to each resource (for example, within medical and surgical supplies, sutures accounted for 14 percent of charges, endoscopic staplers for 12 percent, and so on). We then identified the 10 resources with the highest total charges in each cost center or, if 90 percent of the charges in a cost center were attributable to fewer than 10 resources, the resources that accounted for 90 percent of the charges.

We estimated the direct and indirect costs of these resources with data from the finance department. For example, we calculated the direct cost for the operating rooms by dividing the total operating-room expenses by the total number of minutes patients spent in the operating room. The costs of supplies and pharmacy services were estimated by reducing the average charges for each supplied item and pharmaceutical by the amount of the hospital's markup. Costs for the use of the blood bank and histologic tests were derived from the cost-accounting system of the hospital laboratory.

For each of the top 10 cost centers, we computed a ratio of costs to charges by dividing the total costs of the top 10 resources in that cost center by the total charges for the same resources. The cost-to-charge ratio for each cost center was applied to all resources in that cost center. We then calculated a weighted average cost-to-charge ratio for the top 10 cost centers by taking the total costs for each center and dividing them by the sum of the charges for all 10 cost centers. Finally, we applied this weighted average cost-to-charge ratio to each of the 54 cost centers that were not included among the top 10 cost centers. The cost-center-specific estimates of cost were summed to obtain an estimate of the total facility costs for each hospitalization. We did not assign costs (as opposed to charges) to the professional-service components of the procedures.



## Statistical Analysis

To account for differences in operative complexity and the postoperative care of patients who underwent different surgical procedures, each patient was assigned to one of the following seven mutually exclusive subgroups on the basis of the surgical procedures performed in conjunction with the hysterectomy: (1) no related secondary procedure; (2) repair of vaginal prolapse, surgical treatment for urinary incontinence, or both, but no other procedure ("surgical repair"); (3) adhesiolysis, but no other procedure; (4) salpingectomy, oophorectomy, or both, but no other procedure; (5) surgical repair and salpingectomy, oophorectomy, or both; (6) salpingectomy, oophorectomy, or both, and adhesiolysis; and (7) other procedures.

The characteristics and outcomes of the patients treated by each technique of hysterectomy were assessed separately for each of the first six categories, and for all the patients in the study, on an intention-to-treat basis. For example, a patient whose procedure began as laparoscopically assisted vaginal hysterectomy but was converted to abdominal hysterectomy because of technical difficulty or a complication was considered to have undergone laparoscopically assisted vaginal hysterectomy. Pairwise comparisons were performed by Student's *t*-test (for continuous variables) or the chi-square test (for categorical variables).<sup>12</sup> Separate multi-

variate linear regression analyses were performed for three categories — all patients, those with no related secondary procedures, and those who underwent salpingectomy, oophorectomy, or both — in which there were enough patients for the independent association between the technique of hysterectomy and various economic outcomes (such as operating-room time and facility charges) to be assessed, with control for the patient's age, the number of coexisting medical conditions, and uterine weight.<sup>13</sup>

Finally, to assess the association between the use of disposable instruments and the cost of laparoscopically assisted vaginal hysterectomy, the patients who underwent that procedure were divided into three mutually exclusive subcategories on the basis of the type of supplies used in the operation. Disposable instruments can be used in each step of laparoscopically assisted vaginal hysterectomy. If such instruments (that is, an endoscopic stapling device, an endoscopic hemoclip, staple-reloading cartridges, disposable hand instruments, and disposable trocars) were used during every step of the procedure, we categorized the surgery as performed with disposable instruments. If the surgeon used several types of these disposable instruments, but not all (for example, if he or she used disposable trocars but relied on electrocautery or sutures for hemostasis), the procedure was classified as one that used a combination of disposable and nondisposable instruments. The third category was one in which no disposable

TABLE 1. CHARACTERISTICS OF THE PATIENTS ACCORDING TO TECHNIQUE OF HYSTERECTOMY.\*

CHARACTERISTIC	LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY (N=273)	TOTAL VAGINAL HYSTERECTOMY (N=210)	TOTAL ABDOMINAL HYSTERECTOMY (N=566)
Age (yr)	44±8†	50±13	45±9†
Body-mass index‡	26.0±5.4§	26.2±5.0	28.4±6.9†
Coexisting conditions			
No. per patient	0.4±0.8¶	0.6±0.9	0.4±0.7†
Percent of patients	46¶	58	57
Preoperative indications (% of patients)			
Uterine abnormality	78†**	56	84†
Adnexal abnormality	7†††	0.48	15†
Abdominal or pelvic abnormality	52†	17	45†
Pelvic relaxation	10†**	60	6†
Secondary procedures (% of patients)			
None	32‡‡	41	21
Surgical repair	1	38	0.4
Adhesiolysis	6	0	5
Salpingectomy, oophorectomy, or both			
As only secondary procedure	43	8	45
With repair of vaginal prolapse	3	11	3
With adhesiolysis	0.73	0.48	0
Intraoperative findings (% of patients)			
Extensive adhesions	21†	2	27†
Endometriosis	26‡‡	1	15
Uterine weight (g)	171.1±159.2‡‡	113.3±84.1	333.5±343.9

\*Plus-minus values are means ±SD.

†P<0.001 for the comparison with total vaginal hysterectomy.

‡Body-mass index was calculated by dividing the weight in kilograms by the square of the height in meters.

§P<0.001 for the comparison with abdominal hysterectomy.

¶P=0.01 for the comparison with total vaginal hysterectomy.

||P=0.002 for the comparison with abdominal hysterectomy.

\*\*P=0.05 for the comparison with abdominal hysterectomy.

††P=0.007 for the comparison with abdominal hysterectomy.

‡‡P<0.001 for each pairwise comparison.



laparoscopic instruments were used. Costs of medical and surgical supplies, operating-room time, and total charges for these subcategories were compared by Student's *t*-test. All statistical analyses were performed with SAS version 6.10.

## RESULTS

### Characteristics of the Patients

Of the 1049 patients, 273 (26 percent) underwent laparoscopically assisted vaginal hysterectomy, 566 (54 percent) underwent abdominal hysterectomy, and 210 (20 percent) underwent vaginal hysterectomy (Table 1). The group undergoing vaginal hysterectomy was slightly older, on average, than the other two groups, which were similar in age. The patients who underwent abdominal hysterectomy tended to have higher body-mass indexes and heavier uteri than the patients in either of the other groups. In 89 percent of patients with a uterine weight of at least 400 g, abdominal hysterectomy was performed.

Secondary procedures related to hysterectomy were performed in 79 percent of the patients undergoing abdominal hysterectomy, 68 percent of the patients undergoing laparoscopically assisted vaginal hysterectomy, and 59 percent of the patients undergoing vaginal hysterectomy (Table 1). The most common secondary procedure performed in conjunction with laparoscopically assisted vaginal hysterectomy and abdominal hysterectomy was salpingectomy, oophorectomy, or both, with or without adhesiolysis. The most common secondary procedure performed in conjunction with vaginal hysterectomy was repair of vaginal prolapse or surgical treatment for incontinence.

### Surgical Outcomes

Intraoperative complications occurred in 6 percent of the patients undergoing laparoscopically assisted vaginal hysterectomy, 2 percent of those un-

dergoing vaginal hysterectomy, and 4 percent of those undergoing abdominal hysterectomy ( $P=0.02$  for the comparison of the first and second groups, and  $P=0.10$  for the comparison of the first and third groups). Twelve percent of laparoscopically assisted vaginal hysterectomies were converted to open laparotomy, as compared with 2 percent of total vaginal hysterectomies ( $P<0.001$ ).

### Use of Resources and Costs of Care

The mean hospital stay of the patients who underwent laparoscopically assisted vaginal hysterectomy (2.6 days) was significantly shorter than that of those who underwent vaginal hysterectomy (2.9 days) or abdominal hysterectomy (3.9 days) ( $P<0.02$  for all comparisons). The mean stay for patients undergoing laparoscopically assisted vaginal hysterectomy was more than one day shorter than that for patients undergoing abdominal hysterectomy both when no secondary procedure was performed and when salpingectomy, oophorectomy, or both were performed, regardless of whether adhesiolysis was performed. For the patients undergoing laparoscopically assisted vaginal hysterectomy and those undergoing vaginal hysterectomy, the mean stay was similar when no secondary procedure was performed. Salpingectomy, oophorectomy, and the two together did not influence the mean stay, but adhesiolysis and repair of prolapse both increased it.

Despite the shorter mean stay with laparoscopically assisted vaginal hysterectomy, the mean total charges (including both facility charges and professional fees) were highest for the patients undergoing that procedure (Table 2). The average total charges for laparoscopically assisted vaginal hysterectomy were higher than those for abdominal hysterectomy by \$1,032 ( $P<0.001$ ) and higher than those for vaginal hysterectomy by \$1,895 ( $P<0.001$ ). The total charg-

TABLE 2. TOTAL CHARGES FOR VARIOUS SUBGROUPS OF PATIENTS, ACCORDING TO TECHNIQUE OF HYSTERECTOMY.\*

SUBGROUP	TOTAL NO. STUDIED	LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY		TOTAL VAGINAL HYSTERECTOMY		TOTAL ABDOMINAL HYSTERECTOMY	
		NO.	TOTAL CHARGES (\$)	NO.	TOTAL CHARGES (\$)	NO.	TOTAL CHARGES (\$)
All subgroups	1049	273	6116±1816†	210	4221±1174	566	5084±1768
No secondary procedure	293	87	5804±1581†	87	3522±737	119	4548±763
Surgical repair only	85	4	7856±3642‡	79	4673±920	2	5808±1939
Adhesiolysis only	43	17	6674±2389§	0	—	26	5078±1429
Salpingectomy, oophorectomy, or both							
As only secondary procedure	389	117	6030±1681	17	3976±702	255	4890±1252¶
With repair of vaginal prolapse	49	7	7694±1486	23	5077±1344	19	6004±1210**
With adhesiolysis	181	37	6236±2044	1	6448	143	5689±2724

\*Plus-minus values are means ±SD.

† $P<0.001$  for the comparison with total vaginal hysterectomy.

‡ $P=0.003$  for the comparison with total vaginal hysterectomy.

\*\* $P=0.03$  for the comparison with total vaginal hysterectomy.

† $P<0.001$  for each pairwise comparison.

§ $P=0.009$  for the comparison with abdominal hysterectomy.

|| $P=0.007$  for the comparison with abdominal hysterectomy.



es for laparoscopically assisted vaginal hysterectomy were \$1,140 higher than those for abdominal hysterectomy when oophorectomy, salpingectomy, or both were performed and \$1,256 higher when no related secondary procedure was performed.

The differences in facility costs associated with hospitalizations for the three types of hysterectomy paralleled the differences in charges (Table 3). The mean overall facility costs for laparoscopically assisted vaginal hysterectomy were \$1,167 higher than those for abdominal hysterectomy when no related procedure was performed and \$1,060 higher when salpingectomy, oophorectomy, or both were performed.

In part, the higher costs and charges for laparoscopically assisted vaginal hysterectomy were due to longer operating-room times. When there was no related procedure, laparoscopically assisted vaginal hysterectomy required 35 minutes more operating-room time than abdominal hysterectomy (158 vs. 123 minutes) and 70 minutes more than vaginal hysterectomy (158 vs. 88 minutes) ( $P < 0.001$  for both comparisons). When salpingectomy, oophorectomy, or both were performed, but not adhesiolysis, the mean operating-room time needed for laparoscopically assisted vaginal hysterectomy was 46 minutes more than for abdominal hysterectomy and 72 minutes more than for vaginal hysterectomy. A similar amount of recovery-room time was needed for all three techniques both when there was no secondary procedure and when salpingectomy, oophorectomy, or both were performed.

The average charge for medical and surgical supplies was \$1,190 higher for laparoscopically assisted vaginal hysterectomy (\$1,485) than for abdominal hysterectomy (\$295), and \$1,251 higher than for vaginal hysterectomy (\$234) ( $P < 0.001$  for both

comparisons). These differences were similar regardless of which secondary procedures were performed, or whether any were performed.

We compared the total charges, facility charges, and costs for medical and surgical supplies that were associated with laparoscopically assisted vaginal hysterectomy according to whether the procedure was performed with disposable supplies, nondisposable supplies, or a combination of the two (Table 4). Mean costs for supplies were higher by \$1,496 when procedures were performed with disposable supplies than when they were performed with nondisposable supplies. Despite the potential savings of time associated with the use of an endoscopic stapler, the average operating-room time with disposable supplies was greater, not less, than for operations performed with nondisposable supplies. Among the patients who underwent laparoscopically assisted vaginal hysterectomy with no related secondary procedure, the mean operating-room time was 165 minutes when disposable supplies were used (67 patients), 143 minutes when nondisposable supplies were used (7 patients), and 122 minutes when a combination of the two was used (13 patients). Thus, overall facility charges and total charges (with professional fees added) were substantially higher for laparoscopically assisted vaginal hysterectomy only when disposable supplies were used.

Multivariate regression analyses were performed to compare the three techniques of hysterectomy with respect to costs and the use of resources, with adjustment for age, the number of coexisting medical conditions, uterine weight, and the secondary procedures performed. These adjustments had little effect on the results. Regression analyses also demonstrated that patients at least 60 years old had mean total charges that were \$938 higher than those of patients

TABLE 3. FACILITY COSTS FOR VARIOUS SUBGROUPS OF PATIENTS, ACCORDING TO TECHNIQUE OF HYSTERECTOMY.\*

SUBGROUP	TOTAL NO. STUDIED	LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY		TOTAL VAGINAL HYSTERECTOMY		TOTAL ABDOMINAL HYSTERECTOMY	
		NO.	FACILITY COSTS (\$)	NO.	FACILITY COSTS (\$)	NO.	FACILITY COSTS (\$)
All subgroups	1049	273	4914±1710†	210	3116±969	566	3954±1601
No secondary procedure	293	87	4642±1496†	87	2626±659	119	3475±676
Surgical repair only	85	4	6397±3515‡	79	3400±771	2	4110±1485
Adhesiolysis only	43	17	5449±2207§	0	—	26	3960±1312
Salpingectomy, oophorectomy, or both							
As only secondary procedure	389	117	4851±1622‡¶	17	2978±621	255	3791±1128
With repair of vaginal prolapse	49	7	6177±1376‡**	23	3747±1242	19	4601±1082††
With adhesiolysis	181	37	5010±1890	1	5224	143	4510±2499

\*Plus-minus values are means ±SD.

† $P < 0.001$  for the comparison with total vaginal hysterectomy.

‡ $P < 0.001$  for the comparison with abdominal hysterectomy.

\*\* $P = 0.005$  for the comparison with abdominal hysterectomy.

†† $P < 0.001$  for each pairwise comparison.

§ $P = 0.008$  for the comparison with abdominal hysterectomy.

|| $P = 0.004$  for the comparison with total vaginal hysterectomy.

¶ $P = 0.024$  for the comparison with total vaginal hysterectomy.



TABLE 4. CHARGES AND COSTS FOR LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY ACCORDING TO WHETHER THE SUPPLIES USED WERE DISPOSABLE.\*

TYPE OF SUPPLIES	NO. OF PROCEDURES	TOTAL CHARGES (\$)	FACILITY CHARGES (\$)	COST OF MEDICAL AND SURGICAL SUPPLIES (\$)
Disposable	210	6419±1818†	5514±1770†	1782±1089†
Nondisposable	10	4563±7089‡	3644±6115§	286±515§
Both combined	53	5208±1401	4295±1328	581±344¶

\*Plus-minus values are means ±SD.

†P&lt;0.001 for the comparison with procedures using disposable and nondisposable supplies in combination.

‡P&lt;0.002 for the comparison with procedures using disposable supplies.

§P&lt;0.001 for the comparison with procedures using disposable supplies.

¶P=0.01 for the comparison with procedures using nondisposable supplies.

under the age of 40, and facility charges that were \$817 higher, after adjustment for the number of coexisting conditions and for uterine weight. After we controlled for uterine weight and the number of coexisting conditions, an increase of 10 years in age (for example, when a patient 65 years old was compared with a patient 55 years old) was associated with an increase of \$246 in facility costs ( $P<0.001$ ). In addition, patients with a uterine weight of at least 400 g had mean total charges and mean facility charges that were \$280 higher than those of patients with a uterine weight below 400 g, after we controlled for age and the number of coexisting conditions. Finally, after we controlled for age and uterine weight, patients with one or more coexisting conditions had mean facility costs \$239 higher than those of patients with no coexisting conditions ( $P=0.01$ ).

## DISCUSSION

Despite the reduced invasiveness and shorter hospital stay associated with laparoscopically assisted vaginal hysterectomy, we found that the operating-room time, anesthesia time, cost of supplies, facility costs and charges, and total charges (facility charges plus professional fees) for that procedure were substantially higher than those for either vaginal hysterectomy or abdominal hysterectomy. The cost of a hospitalization for laparoscopically assisted vaginal hysterectomy was higher regardless of which related surgical procedures were also performed, or whether any such procedures were performed. In addition, the procedure was substantially more expensive when disposable, as compared with nondisposable, supplies were used in every step of the laparoscopic portion of the procedure. When laparoscopically assisted vaginal hysterectomy was performed with either nondisposable supplies or a combination of disposable and nondisposable supplies, the facility charges were not substantially higher than for abdominal hysterectomy.

It is not surprising that the costs associated with laparoscopically assisted vaginal hysterectomy were higher than those of the two alternative procedures. Because laparoscopically assisted vaginal hysterectomy combines both abdominal and vaginal approaches, two sets of instruments and drapes and two different operating configurations are required, increasing both time and labor. Moreover, when uterine weight is 400 g or more, the vaginal portion of the operation often becomes more difficult, increasing the operating-room time.

Few disposable instruments are routinely used in either abdominal hysterectomy or vaginal hysterectomy. With laparoscopically assisted vaginal hysterectomy, however, disposable instruments are available for every step of the laparoscopic portion of the procedure. The most expensive of these instruments are the endoscopic stapling devices. Some surgeons believe that stapling instruments substantially reduce the operating time required for this portion of the hysterectomy. In addition, disposable instruments are always clean and sharp and are designed to facilitate specific steps in the operation. Nonetheless, there was no overall reduction in operating time when disposable instruments were used for all steps in the laparoscopic portion of the procedure.

We compared costs and use of resources in the care of patients defined as clinically similar on the basis of the secondary procedures (if any) performed in conjunction with hysterectomy. We adjusted the analysis for age, the number of coexisting conditions, and uterine weight. As a result, we believe the differences in cost were attributable to differences between the techniques of hysterectomy used, rather than differences in the type of patients treated. To make our comparisons accurate and exclude patients who underwent more substantial surgery for cancer, we reviewed more than 1000 patients' hospital charts in detail, instead of relying solely on computerized



administrative data. These reviews enabled us to obtain data on age, weight, and indications for surgery for each patient and to identify procedures that began as laparoscopically assisted vaginal hysterectomy but were converted to abdominal hysterectomy and thus were coded and billed as the latter on the discharge abstracts.

We estimated facility costs, as well as facility charges, using cost-to-charge ratios specific to each cost center. We could thus draw conclusions about the costs associated with each technique from the perspective of the hospital as well as the insurer.

The most noteworthy limitation of our analysis is that we studied only a single institution. The costs and charges for the three techniques of hysterectomy may differ at other institutions, but it is likely that our major conclusions are generalizable. We examined the experience of nearly 100 surgeons but did not control for differences among them in technical expertise.

Judgments about the preferred approach for hysterectomy should be based on several factors, including the indications for the procedure, the clinical characteristics of the patient (such as estimated uterine size and weight), and the morbidity and cost associated with the technique. When vaginal hysterectomy can be performed, our analysis confirms that it is the least costly approach and that intraoperative complications are less frequent with it than with laparoscopically assisted vaginal hysterectomy. Laparoscopically assisted vaginal hysterectomy may offer patients several advantages over abdominal hysterectomy, such as reduced postoperative discomfort, a shorter period of recuperation after discharge, and the chance to avoid a major abdominal incision, but our analysis suggests that when disposable instruments are used for all steps in the laparoscopic portion of the procedure, the in-hospital costs to both the hospital and the insurer are substantially higher for the laparoscopic procedure.

It is not likely that using disposable instruments throughout laparoscopically assisted vaginal hysterectomy confers enough advantages over abdominal hysterectomy to justify the added cost. Whether the benefits to the patient of the laparoscopically assisted technique without the use of disposable instruments are worth the extra cost is a question requiring a value judgment. A prospective study now under way will evaluate patients' quality of life, ability to return to work, and productivity after hysterectomy, to clarify the relative benefits and cost effectiveness of the two procedures.

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Dr. Dorsey has been a consultant to the United States Surgical Corporation, Norwalk, Conn., which makes disposable laparoscopic instruments, and owns stock in C.R. Bard, which has a subsidiary that makes laparoscopic instruments.

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## RECOMMENDATIONS FOR FUTURE STUDIES

The case for low-protein diets in CRF is not established in man. For further study we make the following recommendations. (1). Patients should be proven to have progressive renal failure with no obvious reversible factor before administration of a low-protein diet. (2). The rate of decline of renal function should be assessed over several months. This will allow for the placebo effect and ensure treatment of conditions such as hypertension. (3). Renal function should be monitored by isotopic clearances. (4). Assessment of nutrition should include anthropometric and biochemical measurements. (5). Patient compliance should be assessed by an experienced dietitian and also by the measurement of urea nitrogen appearance. (6). If a randomised trial is undertaken, groups of patients should be matched for age, sex, diagnosis, rate of progression, degree of renal failure, hypertension, and proteinuria. Control and experimental diet groups should be treated and followed up in the same way, and should be kept apart at clinics to prevent inadvertent "crossover" of diets. (7). In future trials we would favour the less restricted diets (standard 0.6 g/kg protein intake) since they are a more realistic option for large-scale use. (8). Follow-up should be for at least two years.

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## Child Health

## COST OF NEONATAL INTENSIVE CARE FOR VERY-LOW-BIRTHWEIGHT INFANTS

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**Summary** A detailed costing of the Mersey region neonatal intensive care unit was made in 1983 (at 1984 prices) for three levels of care; costs inpatient day were £297, £138, and £71 for intensive, special and nursery care, respectively. Regression of ungrouped patient-specific costs against birthweight showed explanatory power of birthweight to be negligible. The average cost per very-low-birthweight (<1500 g) infant was £4400 for survivors and £3446 for non-survivors. A study elsewhere showed an almost six-fold difference in medical management policy largely determines difference and is crucial to any investigation of efficiency.

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## INTRODUCTION

THE reduction in mortality associated with improvements in neonatal care is well known,<sup>1</sup> but costs may still outweigh economic benefits for infants weighing less than 1500 g at birth. Compared with larger infants, the costs for very-low-birthweight (VLBW) infants are likely to be high and benefits reduced by greater mortality and morbidity in the postnatal period. North American evidence supports this view. Walker and colleagues demonstrated the low viability and high cost of intensive care for infants of birthweight below 900 g,<sup>2,3</sup> and Boyle et al reported that neonatal intensive care had more favourable effects among infants weighing 1000–1499 g than among those weighing 500–999 g.<sup>4</sup> When expected future earnings and costs were taken into account, the smaller infants showed a net economic loss for any positive discount rate. It does not follow that it is not worth treating the smallest infants, but Boyle et al concluded that if resources are scarce, they might be better concentrated on infants in the higher birthweight ranges.

In the United Kingdom, economic evaluation of neonatal care is hampered by a shortage of costing studies. We report here a costing of the regional neonatal intensive care unit (NICU) at Liverpool Maternity Hospital and investigate the relation between birthweight and the cost of care.

## METHODS

The total cost of the NICU in 1983 was estimated in terms of 1984 pay and prices. Most costs were incurred at the NICU but services were provided by other centres including Liverpool Maternity Hospital, other hospitals, and specialised units. Costings were as specific as possible to neonatal care and to each cost centre. In addition to neonatal care, the NICU carried out research, teaching, and outpatient clinics. Estimates of the time and equipment used for these activities were subtracted from total costs to give the cost of care for all 542 infants treated. The costs were allocated between three care levels defined as:

*Intensive care*—infants given respiratory support by either mechanical ventilation or constant positive airway pressure.

*Special care*—infants given both electronic monitoring and intravenous infusions for any reason; respiratory support not required.

*Nursery care*—infants given special observation or care but fed orally; respiratory support or intravenous infusions not needed.

The study included all infants treated, some of whom received neither intensive nor special care.

The NICU provided 7193 days of inpatient care. These were allocated to care levels from case notes. The cost of care for each level was divided by inpatient days to give an average day cost. Multiplying the day costs by the number of days each of 182 VLBW infants spent at each care level gave a patient-specific cost estimate for each infant.

### Costing Methods

*Medical and nursing staff.*—Medical staff could be readily allocated to care levels. Nurses had principal responsibilities in specific rooms corresponding to the three care levels, but they moved between rooms as required. To take account of this movement, the working of the unit was observed and several case studies were made to estimate the nursing time spent at each level.

*Equipment.*—The estimate of the cost of capital equipment included items donated by charities and took account of capital consumption and maintenance. Estimates were available of the replacement cost in 1983 of the 227 items of equipment identified in use. This estimate was converted into an annual charge for capital consumption by straight-line depreciation on the assumption that the average lifetime was 10 years for mechanical and 7 years for electronic equipment. These were towards the upper end of the

range of plausible assumptions; another calculation was done for lifetimes of 5 and 3 years.

*Consumables.*—Annual consumption was estimated from quantities of 55 items used in one week in mid-1984. It was priced from delivery notes, invoices, and information provided by manufacturers. On the advice of the nursing officer, it was allocated in the proportions 2/1/1 between intensive, special, and nursery care.

*Drugs and pharmaceuticals.*—The estimate of annual consumption was based on a 6-week sample period in mid-1984. 92 items were costed and allocated to miscellaneous (allocated equally between the three levels), parenteral nutrition, and antibiotics (both allocated equally between intensive and special care).

*Diagnostic tests.*—Costing tests was more difficult than any other item. Case notes recorded the number of test requests for each infant but a request usually required more than one test. Numbers of tests were estimated by multiplying requests by an average weighting for each type. Tests were carried out in departments serving other hospitals as well as the NICU. An existing study of the costs of radiology to the NICU was updated. The average cost of an X-ray (£18.04) included taxi fares and other extra costs for out-of-hours tests. The cytogenetics department estimated the cost of a test at £40 in 1983. The average costs of haematology and biochemistry (£1.16) and bacteriology (£1.37) tests were calculated from an estimate of the NICU's share of each department's workload. Milk tests were not recorded in case notes and were priced separately. Tests were allocated between intensive, special, and nursery care in the proportions 6/4/1. This assumption, based on medical advice and observation, was not used in the analysis of costs for VLBW infants because patient-specific estimates were used.

*Overheads.*—Most overhead expenditure and a small amount of income was shared between the NICU and Liverpool Maternity Hospital. Seven items (administration, records, training and education, laundry, transport, crèche, and income) were allocated by inpatient days. Only staff catering costs (43% of the total) were apportioned to the NICU, since food for newborn infants was prepared in the unit. Four items (cleaning, engineering maintenance, building maintenance, and estate management) were allocated according to the cubic capacity of the NICU as a proportion of the Liverpool Maternity Hospital. Specific estimates were made for portering, heat-steam, water, electricity, and oxygen. No allowance was made for the depreciation of buildings. Overheads were allocated between care levels by inpatient days.

## RESULTS

VLBW infants accounted for 34% of admissions but 65% of inpatient days. Of the 182 VLBW infants, 131 (72%) were born at the Liverpool Maternity Hospital. The mothers of 35 of these had booked at the hospital, 96 transferred there during pregnancy, and 51 were postnatal transfers.

VLBW infant mortality was 25%. It ranged from 100% for birthweight <700 g to 10% in the 1400–1499 g range. The mortality rate was 22% for inborn infants and 33% for outborn. Of the 182 VLBW infants, disabilities were identified in 16 (8.8%).

Table 1 shows the cost of the whole unit for 1983 in terms of 1984 pay and prices by principal cost categories. The most expensive items were nursing staff, tests, and overheads. If average lifetimes of equipment had been taken as 5 and 3 years for mechanical and electronic items (instead of 10 and 7 years) equipment costs would have been £91 069, total costs £1 057 903, and the proportion of equipment costs in the total 8.6%.

Table 1 also shows total costs allocated to the three care levels and divided by inpatient days to give average day costs. Day costs are sensitive to the capacity level achieved in the unit. In some months during 1983 the NICU treated more than twice its notional capacity. If it had cared for fewer



TABLE I—TOTAL COST\* OF CARE FOR 542 INFANTS ALLOCATED BETWEEN CARE LEVELS

	Total (£)	%	Intensive care (£)	Special care (£)	Nursery care (£)
Medical staff	87 691	8.6	41 060	41 060	5571
Nursing staff	361 129	35.6	201 239	82 616	77 274
Equipment	47 873	4.7	24 482	13 375	10 016
Consumables	97 958	9.7	48 980	24 489	24 489
Drugs	84 689	8.3	33 797	33 797	17 095
Tests	174 179	17.2	73 446	74 447	26 286
Overheads	161 188	15.9	34 398	53 625	73 165
Total	1 014 707	..	457 402	323 409	233 896
Inpatient days	7193	..	1541	2343	3309
Cost per day	£141.07	..	£296.82	£138.03	£70.68

\*In terms of 1984 pay and prices.

infants, day costs would have been higher, since fixed costs would have been spread over fewer days.

Intensity of effort by staff was an important missing variable. Its influence might be found in staff turnover and quit rates and in other less readily quantifiable forms. A true cost would include an adjustment for achieved capacity levels.

The mean ( $\pm$ SD) cost of care for all surviving VLBW infants was £3615 $\pm$ 3014 and that for non-survivors was £3446 $\pm$ 6143. Outborn infants (survivors £4664 $\pm$ 3685, non-survivors £4656 $\pm$ 7667) were more expensive than inborn (survivors £3265 $\pm$ 2685, non-survivors £2736 $\pm$ 5064). These data had very high variance, especially in the lowest birthweight ranges. Some of the smallest infants survived for only a short time and were among the cheapest to treat. Others survived for long periods in intensive care and were the most expensive.

Table II shows the cost of producing a survivor in 100 g birthweight ranges. If the objective of neonatal care is to save lives, without reference to their expected length or quality, this figure is a rough measure of the cost-effectiveness of intensive care for different birthweight ranges.

The best statistical relation between birthweight and cost for VLBW infants was obtained from ordinary least squares regression of birthweight grouped in 100 g class intervals against the cost of producing a survivor ( $R^2=0.6$ ) but it was shown to depend on the selection of class intervals, which was entirely arbitrary. This variation in the explanatory power of birthweight was due partly to the tendency to round weights to the nearest 10 g.

When ungrouped, patient-specific cost estimates for all VLBW infants were used, the relation between birthweight and cost disappeared ( $R^2=0.04$ ). Improvements in the statistical explanation of cost were sought by including dummy variables for survivors, inborn infants, and in-utero

TABLE II—TOTAL COST OF PRODUCING A SURVIVOR\*

Birthweight (g)	n	Cost of care (£)	No of survivors	Cost of a survivor* (£)
500–599	4	27 906	0	..
600–699	5	22 878	0	..
700–799	11	67 066	5	13 413
800–899	20	69 561	11	6324
900–999	18	65 847	13	5065
1000–1099	21	107 226	16	6702
1100–1199	26	95 836	22	4356
1200–1299	28	62 831	25	2513
1300–1399	28	70 646	25	2826
1400–1499	21	60 336	19	3176

\*Total cost of care divided by number of survivors.

transfers, the number of weeks of gestation, and the square of birthweight (a test for non-linearity). Over many equations, most of the signs of the independent variables were as predicted and their coefficients were usually significant ( $p<0.05$ ) but their explanatory power was negligible ( $R^2<0.1$ ). No improvement was obtained by restricting the sample to infants who had at least 1 day in intensive care nor was there evidence of a structural break in the data at either 900 g or 1000 g.

## DISCUSSION

Clinicians and economists concerned with neonatal care have analysed outcomes in birthweight ranges. Boyle et al.<sup>4</sup> implied that birthweight ranges might guide the planning of medical resource allocation. When full data are available, this procedure can be shown to be statistically inefficient and possibly misleading. The division of the VLBW range at 1000 g suggests that an infant weighing 999 g is different from one weighing 1000 g. Of course, this would not be true even if birthweight were measured as accurately as this. The selection of birthweight ranges is arbitrary, and grouping involves the use of averages taken from cost data which have a high variance and are bimodal for the smallest infants.

Our data, grouped in 100 g ranges, showed a correlation coefficient of 0.6 between birthweight and cost, which leaves 40% of the variance unexplained. Whether this correlation would be an adequate guide to resource allocation in matters of life and death is doubtful. However, the result was shown to depend on the choice of birthweight ranges and was not confirmed by the ungrouped data. The severity of infants' symptoms was probably the principal determinant of cost but it was not captured by restricting the sample to those who received mechanical ventilation.

These findings fall short of a full evaluation to be compared with that of Boyle et al.<sup>4</sup> In particular, the costs were restricted to those incurred in the NICU. No attempt was made to quantify either the benefits or the future costs attributable to intensive care, though work is proceeding in this direction. It may be that as future costs become known, the cost-benefit calculation will swing against the smallest infants, but this is by no means certain. For all but the most severely incapacitated, neonatal costs are likely to be the most expensive episode in the medical history, and these costs do not seem to be related systematically to birthweight.

The problem of selection bias in a regional referral unit is well known. It has been claimed that regional units attract from district hospitals the infants with the best prognoses, so that improvement in outcomes in referral units may be offset by deterioration elsewhere.<sup>5</sup> It is equally likely that as intensive-care techniques become more widely disseminated, local hospitals will retain infants with good prognoses and refer the difficult cases. Referral rates from district hospitals differ widely in Mersey Region. They are not explained by distances from the NICU and seem to be related to unexplained variations in medical practice. In this study, outborn cases were more expensive than inborn and their mortality rates were higher. The selection bias seemed to work against the NICU.

The only similar UK study was of infants treated in the regional NICU of Birmingham Maternity Hospital in 1980–81.<sup>5</sup> Comparisons must be very tentative, since the studies are separated by time and regional circumstances and differ somewhat in their methods and costing procedures. The day costs for care levels (defined similarly but not identically) in 1984 pay and prices are given in table III. The



High as possible: long time is needed to show results  
may not be true

## CLINICAL ECONOMICS

### MODULE 3

#### ECONOMIC COSTS AND DISCOUNTING

At the completion of this module you should:

- a. understand the distinction between economic and financial costs;
- b. understand the reasons for discounting costs which are expected to accrue in the future;
- c. be able to calculate the present value cost of an illness for a given discount rate.



## ECONOMIC COSTS AND DISCOUNTING

### Introduction

In Module 2 it was shown that the concept of discounting was central to estimates of the cost of an illness. Discounting is the focus of this module, but first the meaning of the term "economic cost" must be clarified.

The cost to an individual, a hospital, or a government is the money used to pay for something - for example, the fee an individual pays to visit a doctor, or the money the government pays to subsidise health care for the poor. These costs are called financial costs. They measure actual money transactions.

An economic cost is the cost to society as a whole rather than the cost to one section of society. This corresponds to the concept of opportunity cost that was described in Module 1.

To refresh your memory, suppose a decision is made to build a hospital. The resources consumed (building materials, labour, linen etc.) cannot be used to build rural health clinics or sports centres, for example. The opportunity cost is the value society places on the best alternative use for resources that must be foregone. The decision to build the hospital is efficient if the value society places on the services produced by the hospital exceeds the opportunity cost.

### Transfer Payments

Economic costs often differ from financial costs. Consider an X-ray machine purchased by a local doctor at a cost of \$4950. Assume that this price included a government tax of \$450 on the wholesale price of \$4500. The private financial cost of the machine to the doctor was \$4950, but this was not the cost to society. The tax payment did not use up any resources which then could not be used elsewhere - it involved no opportunity cost to society. It simply transferred the command over resources from one person in society, the doctor, to the government which represents society as a whole. Accordingly, taxes are examples of transfer payments which are financial but not economic costs. The true cost of the machine is the value of the resources used in its construction which cannot be used elsewhere. Social security payments are also transfer payments. In this case they transfer the command over resources from society as a whole (the government) to the recipient.

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### Economic Costs and Cost of Illness Studies

Cost of illness studies seek to measure the costs which a disease or condition impose on society rather than on an individual. As such, economic costs should be estimated in preference to financial costs. Consider a direct cost such as the cost of hospitalisation. The resources used to provide hospital services cannot be used elsewhere, so it is the value of the foregone opportunity which should be included in a costing study. The charge to a patient for hospitalisation will rarely be a good indicator of the economic cost, especially where governments subsidise hospital care.

The indirect costs of an illness are similar in that they represent the value of potential production lost because people cannot work, or cannot work efficiently. They are opportunities lost because of the illness.

It is sometimes difficult to estimate economic costs accurately. This issue is considered again in a later module, but at this stage it is important for you to recognize that economic costs are not necessarily the same as financial costs.

### DISCOUNTING

#### Reasons for Discounting

Most people would prefer to receive \$1000 today than \$1000 in a year's time. This is largely because the person loses the opportunity to earn income from the money, for example by earning interest, if payment is delayed for a year. Likewise, people prefer to pay a bill of \$1000 in a year's time rather than today. Again, the reason is that the person loses the opportunity to earn income from the \$1000 over the forthcoming year by paying the bill today.

In both cases, the implication is that people value \$1000 today more highly than \$1000 a year later. The general principle is that money now is valued more highly than an equal sum that will be paid or received in the future. This preference for money now over money in the future is called the rate of time preference.

Assume that the best interest rate you can obtain is 10% per year. If I offered you the choice between \$1050 payable in a year and \$1000 now, you probably would take the money now. If you invested the money now it would be worth \$1100 in a year. However, if I offered you the choice between \$1200 payable in a year and \$1000 now, most of you would choose to wait for the year as long as you were reasonably confident of my honesty. Therefore, there must be a sum of money payable in a year, somewhere between \$1050 and \$1200, which you consider to be of equal value to having \$1000 today. (For some of you it may be greater than \$1200.)



For me it is \$1150 (\$100 to compensate for the lost interest, and \$50 to compensate for the uncertainty). I am indifferent between a payment of \$1150 in a year and \$1000 payable today as long as the interest rate is 10%. In other words, \$1150 in a year is worth \$1000 today. I have discounted the future sum of money to find its value to me today, which is called its present value. I discounted \$1150 by 15% to obtain the present value of \$1000, so 15% is called the discount rate.

As long as the discount rate is known, it is possible to find the present value of any sum of money that is expected to be paid or received at any time in the future. If you think through the logic of the earlier examples, you will discover that the further into the future a sum of money is expected, the lower will be its present value. Similarly, the higher is the discount rate, the lower will be the present value.

### Discounting and the Cost of Illness

You will remember from Module 2 that in calculating the cost of an illness it is necessary to estimate the cost it will impose on society in the future. Consider a disease which is estimated to cost \$1 million a year for 5 years. Viewed from today's perspective, the total cost of the disease to society is not \$5 million because \$1m this year is worth more than \$1m next year, which in turn is worth more than \$1m in 2 years time etc. It is necessary to convert each year's cost to its present value. The stream of present values can then be summed to obtain the present value cost of the illness. The following table shows that the present value cost of our example is \$3.79m using a 10% discount rate.

YEAR	COST (\$)	PRESENT VALUE (\$)
1	1m	909,000
2	1m	826,000
3	1m	751,000
4	1m	683,000
5	1m	621,000
<b>TOTAL</b>	<b>5m</b>	<b>3,790,000</b>

Handwritten calculations for present value factors:

- $\frac{1}{(1+0.1)^1} \times 1,000,000 = 909,090.91$
- $\frac{1}{(1+0.1)^2} \times 1,000,000 = 826,446.28$
- $\frac{1}{(1+0.1)^3} \times 1,000,000 = 751,314.80$
- $\frac{1}{(1+0.1)^4} \times 1,000,000 = 683,013.46$
- $\frac{1}{(1+0.1)^5} \times 1,000,000 = 621,021.32$

Sum of present values: 3,790,466.77

The mechanics of this process are described in Evans et al (1984) and Drummond (1980), so will not be repeated here. It will be necessary to read one of these references in order to complete question 2.

### The Discount Rate

Cost of illness estimates are calculated as present values. Present value costs are sensitive to the choice of discount rate, and the appropriate rate depends on a number of factors. There is disagreement in the literature about the correct rate, and appendix 4 in Drummond (1980) discusses some of the



problems. The arguments cannot be summarised easily, and they are not particularly important to your understanding of why discounting is necessary. At this point you should be able to calculate the present value cost of an illness if you are given the appropriate rate. Question 2 asks you to consider some of the factors influencing the choice of the rate.

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#### Major References:

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### QUESTIONS

1. Read the article by Barnum. Are you convinced that it is necessary to adjust healthy days of life gained by an intervention for time preference and for productivity? Discuss.

2. THIS QUESTION IS BASED ON QUESTION 3, MODULE 2.

a. In Q3, parts b and d you calculated the present and future costs of treating the four diseases. Now calculate the present value cost of treating each disease using a 5% discount rate. (Define the year of onset as year 1).

b. Repeat part a using a 10% discount rate. Explain any differences you observe. *The importance of disease may change if interest changes*

c. In Q3, part f, you calculated lost earnings due to premature mortality. Explain how you would calculate the present value of these lost earnings. (Do not do the calculations unless you have a lot of spare time.)

d. Using your results in Q3, part h, calculate the present value of losses from disability days for each disease, using a 5% discount rate.



e. Had you completed the calculations for part c above, you would have found that the present values of lost production due to premature mortality, with a 5% discount rate, were A = \$789,928; B = 627,285; C = 2,202,307; and D = 1,265,912. Calculate the total present value cost of each disease at a 5% discount rate.

3. A company borrows money to build a private nursing home. It has to repay the loan and interest over 10 years. Is the repayment of  
 a. the loan; *Financial cost to nursing home*  
 b. the interest,  
 an economic cost?

4. Everyone has the same rate of time preference, so it is easy to determine society's rate. Discuss.

5. a. What factors would influence the choice of discount rate in a cost of illness study?

b. A high discount rate discriminates against preventive medicine in favour of curative medicine. Discuss.



Copied for use by students enrolled  
in Clinical Economics,  
Lecturer: Dr. D.B. Evans.  
University of Newcastle, 1987.

A GUIDE TO PROJECT PLANNING AND APPRAISAL  
IN THE SOUTH PACIFIC  
(Revised Edition)

Volume I

D.B. Evans, F.V. Sevele, and A. McDonald

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### Time Value of Money

Most people if offered the choice between a certain amount of money today and the same amount in several years' time would choose to have the money today. This preference for money now as distinct from money later has several explanations, but most of these are connected with a loss of opportunity, commonly called opportunity cost. In other words money obtained now can be put to a productive purpose which will generate income. If the receipt of money is delayed then so is the opportunity to generate income. Similarly, money obtained now may also be used for 'non-productive' (in terms of income) activities such as leisure pursuits and current consumption. Although these may also be enjoyed in the future, the uncertainty of the future may mean that people prefer to enjoy them now rather than at a more uncertain later date.

Because money received in the future as distinct from the present represents a loss of opportunity, anyone lending money, and thereby foregoing opportunities, will need to be compensated when the money is repaid in the future. Thus, if a farmer lends money to his neighbour he is foregoing the opportunity to use that money to generate income by increasing, say, his fertilizer applications. On the other hand, his neighbour is gaining the use of that money to put to a productive purpose, say to irrigate his land. Obviously the lender would expect to be compensated for the income he is foregoing. This compensation generally takes the form of interest where the borrower is in fact paying the lender for the use of his money. The interest rate reflects peoples' preference for money now as distinct from money in the future; that is, it is the 'time rate of preference'. The higher the farmer values the opportunity of income foregone the higher the rate of interest that he will charge the borrower.

### Compounding

If an amount  $A_1$  is loaned to a person at an interest rate of  $r$  per annum, then after 1 year the amount to be repaid is:

$$A_1 + A_1 r = A_1 (1 + r)$$



In this as well as in the remainder of the chapter,  $r$  is expressed in decimal form, e.g. for an interest rate of 10%,  $r = 0.10$ . After two years, the amount to be repaid would be:

$$\begin{aligned} - \quad A_1 (1 + r) + A_1 (1 + r)r &= A_1 (1 + r) (1 + r) \\ &= A_1 (1 + r)^2 \end{aligned}$$

Therefore, if the loan is for  $n$  years, the amount to be repaid in year  $n$  is  $A_1 (1 + r)^n$ .

The amount  $(1 + r)^n$  is the factor by which a sum of money will increase in value when earning compound interest at a rate of  $r\%$  per annum for  $n$  years; this is referred to as the compounding factor. For example, an amount of \$100 invested for 3 years at 10% per annum will be worth after 3 years:

$$\begin{aligned} \text{Value} &= A_1 (1 + r)^n \\ &= 100 (1 + 0.10)^3 \\ &= 100 (1.1)(1.1)(1.1) \\ &= 110 (1.1)(1.1) \\ &= 121 (1.1) \\ &= 133.10 \end{aligned}$$

Through the process of compounding, the \$100 grows to \$110 at the end of year 1, \$121 at the end of year 2, and to \$133.10 at the end of year 3.

#### Discounting and Present Value

The time rate of preference can be considered from the opposite point of view. Rather than ask how much a particular amount of money would be worth at sometime in the future, the present value of an amount of money expected in the future can be calculated. A 'penalty' must be imposed on this money to compensate for the fact that it is to be received in the future rather than now.

The process of finding the present value of a future amount is called discounting and the discount rate at this stage will be assumed to be the interest rate since they are both concerned with the same time rate of preference, but applied from different ends of the time scale. This assumption is discussed further in Chapter 5. The interest rate involves looking from the present to the future, while the discount rate looks backward from the future to the present.

It has been shown that for an interest rate of  $r\%$ :

$$A_n = A_1 (1 + r)^n; \text{ therefore } A_1 = \frac{A_n}{(1 + r)^n}$$

and  $\frac{1}{(1 + r)^n}$  is the factor by which a sum to be received  $n$  years in the future must be discounted to determine its present value; it is referred to as the discount factor. Thus, if a person is promised \$133.10 in 3 years' time, and the rate of interest is 10%, the present value of this amount is:



$$A_1 = \frac{A_n}{(1 + r)^n}$$

$$= \frac{133.10}{(1 + 0.1)^3} = \$100.$$

As expected, this is consistent with the earlier compounding example.

The concept of discounting may be applied to each year of a cash flow stream just as well as to an amount applying for only one year, and the present value of a future income stream can be determined. The World Bank has produced a set of Compounding and Discounting Tables for project evaluation which gives the different discount factors for different combinations of  $n$  and  $r$ , and these or similar tables can be used for the various calculations associated with project appraisal. Volume II (Part III) contains tables giving compound, discount and annuity factors for selected combinations of  $n$  and  $r$ .

For example, for a discount rate of 15% per annum, the tables give the following discount factors for a five-year period:

<u>Discount Factor</u>	<u>Year 1</u>	<u>Year 2</u>	<u>Year 3</u>	<u>Year 4</u>	<u>Year 5</u>
	.870	.756	.658	.572	.497

Note that these discount factors can be calculated using the formula outlined earlier. Note also that costs and returns can accrue at any time during a given year which implies that a different discount rate could apply for each day of a project's life. This obviously is impractical and for convenience it generally is assumed that all transactions are made on 31 December of each year. This is the reason that the costs and benefits of the first year of the project are also discounted.

The following shows how to calculate the present value of a five-year income stream discounted at 15%.

	<u>Income to be received (1)</u>	<u>Discount factor (2)</u>	<u>Present Value (3) = (1) x (2)</u>
Year 1	\$400	.870	\$348
Year 2	500	.756	378
Year 3	400	.658	263
Year 4	600	.572	343
Year 5	500	.497	249
Total	\$2,400		\$1,581



*Handwritten notes:*  
 5000 x 0.530 = 2650  
 3602  
 23602  
 53  
 all... 1/2 yrs...  
 2... 1/2...

Year	1%	3%	5%	6%	8%	10%	12%	14%	15%	16%	18%	20%	22%	24%	25%	26%	28%	30%	35%	40%	45%	50%
1	0.990	0.971	0.952	0.943	0.926	0.909	0.893	0.877	0.870	0.862	0.847	0.833	0.820	0.806	0.800	0.794	0.781	0.769	0.741	0.714	0.690	0.667
2	0.980	0.943	0.907	0.890	0.857	0.826	0.797	0.769	0.756	0.743	0.718	0.694	0.672	0.650	0.640	0.630	0.610	0.592	0.549	0.510	0.476	0.444
3	0.971	0.915	0.864	0.840	0.794	0.751	0.712	0.675	0.658	0.641	0.609	0.579	0.551	0.524	0.512	0.500	0.477	0.455	0.406	0.364	0.328	0.296
4	0.961	0.888	0.823	0.792	0.735	0.683	0.636	0.592	0.572	0.552	0.516	0.482	0.451	0.423	0.410	0.397	0.373	0.350	0.301	0.260	0.226	0.198
5	0.951	0.863	0.784	0.747	0.681	0.621	0.567	0.519	0.497	0.476	0.437	0.402	0.370	0.341	0.328	0.315	0.291	0.269	0.223	0.186	0.156	0.132
6	0.942	0.837	0.746	0.705	0.630	0.564	0.507	0.456	0.432	0.410	0.370	0.335	0.303	0.275	0.262	0.250	0.227	0.207	0.165	0.133	0.108	0.088
7	0.933	0.813	0.711	0.665	0.583	0.513	0.452	0.400	0.376	0.354	0.314	0.279	0.249	0.222	0.210	0.198	0.176	0.159	0.122	0.095	0.074	0.059
8	0.923	0.789	0.677	0.627	0.540	0.467	0.404	0.351	0.327	0.305	0.266	0.233	0.204	0.179	0.168	0.157	0.139	0.123	0.091	0.068	0.051	0.039
9	0.914	0.766	0.645	0.592	0.500	0.424	0.361	0.308	0.284	0.263	0.225	0.194	0.167	0.144	0.134	0.125	0.108	0.094	0.067	0.048	0.035	0.026
10	0.905	0.744	0.614	0.558	0.463	0.386	0.322	0.270	0.247	0.227	0.191	0.162	0.137	0.116	0.107	0.099	0.085	0.073	0.050	0.035	0.024	0.017
11	0.896	0.722	0.585	0.527	0.429	0.350	0.287	0.237	0.215	0.195	0.162	0.135	0.112	0.094	0.086	0.079	0.066	0.056	0.037	0.025	0.017	0.012
12	0.887	0.701	0.557	0.497	0.397	0.319	0.257	0.208	0.187	0.168	0.137	0.112	0.092	0.076	0.069	0.062	0.052	0.043	0.027	0.018	0.012	0.008
13	0.879	0.681	0.530	0.469	0.368	0.290	0.229	0.182	0.163	0.145	0.116	0.093	0.075	0.061	0.055	0.050	0.040	0.033	0.020	0.013	0.008	0.005
14	0.870	0.661	0.505	0.442	0.340	0.263	0.205	0.160	0.141	0.125	0.099	0.078	0.062	0.049	0.044	0.039	0.032	0.025	0.015	0.009	0.006	0.003
15	0.861	0.642	0.481	0.417	0.315	0.239	0.183	0.140	0.123	0.108	0.084	0.065	0.051	0.040	0.035	0.031	0.025	0.020	0.011	0.006	0.004	0.002
16	0.853	0.623	0.458	0.394	0.292	0.218	0.163	0.123	0.107	0.093	0.071	0.054	0.042	0.032	0.028	0.025	0.019	0.015	0.008	0.005	0.003	0.002
17	0.844	0.605	0.436	0.371	0.270	0.198	0.146	0.108	0.093	0.080	0.060	0.045	0.034	0.026	0.023	0.020	0.015	0.012	0.006	0.003	0.002	0.001
18	0.836	0.587	0.416	0.350	0.250	0.180	0.130	0.095	0.081	0.069	0.051	0.038	0.028	0.021	0.018	0.016	0.012	0.009	0.005	0.002	0.001	0.001
19	0.828	0.570	0.396	0.331	0.232	0.164	0.116	0.083	0.070	0.060	0.043	0.031	0.023	0.017	0.014	0.012	0.009	0.007	0.003	0.002	0.001	0.000
20	0.820	0.554	0.377	0.312	0.215	0.149	0.104	0.073	0.061	0.051	0.037	0.026	0.019	0.014	0.012	0.010	0.007	0.005	0.002	0.001	0.001	0.000
21	0.811	0.538	0.359	0.294	0.199	0.135	0.093	0.064	0.053	0.044	0.031	0.022	0.015	0.011	0.009	0.008	0.006	0.004	0.002	0.001	0.000	0.000
22	0.803	0.522	0.342	0.278	0.184	0.123	0.083	0.056	0.046	0.038	0.026	0.018	0.013	0.009	0.007	0.006	0.004	0.003	0.001	0.001	0.000	0.000
23	0.795	0.507	0.326	0.262	0.170	0.112	0.074	0.049	0.040	0.033	0.022	0.015	0.010	0.007	0.006	0.005	0.003	0.002	0.001	0.000	0.000	0.000
24	0.788	0.492	0.310	0.247	0.158	0.102	0.066	0.043	0.035	0.028	0.019	0.013	0.008	0.006	0.005	0.004	0.003	0.002	0.001	0.000	0.000	0.000
25	0.780	0.478	0.295	0.233	0.146	0.092	0.059	0.038	0.030	0.024	0.016	0.010	0.007	0.005	0.004	0.003	0.002	0.001	0.001	0.000	0.000	0.000
26	0.772	0.464	0.281	0.220	0.135	0.084	0.053	0.033	0.026	0.021	0.014	0.009	0.006	0.004	0.003	0.002	0.002	0.001	0.000	0.000	0.000	0.000
27	0.764	0.450	0.268	0.207	0.125	0.076	0.047	0.029	0.023	0.018	0.011	0.007	0.005	0.003	0.002	0.002	0.001	0.001	0.000	0.000	0.000	0.000
28	0.757	0.437	0.255	0.196	0.116	0.069	0.042	0.026	0.020	0.016	0.010	0.006	0.004	0.002	0.002	0.002	0.001	0.001	0.000	0.000	0.000	0.000
29	0.749	0.424	0.243	0.185	0.107	0.063	0.037	0.022	0.017	0.014	0.008	0.005	0.003	0.002	0.002	0.001	0.001	0.000	0.000	0.000	0.000	0.000
30	0.742	0.412	0.231	0.174	0.099	0.057	0.033	0.020	0.015	0.012	0.007	0.004	0.003	0.002	0.001	0.001	0.001	0.000	0.000	0.000	0.000	0.000
35	0.706	0.355	0.181	0.130	0.068	0.036	0.019	0.010	0.008	0.006	0.003	0.002	0.001	0.001	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
40	0.672	0.307	0.142	0.097	0.046	0.022	0.011	0.005	0.004	0.003	0.001	0.001	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
45	0.639	0.264	0.111	0.073	0.031	0.014	0.006	0.003	0.002	0.001	0.001	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
50	0.608	0.228	0.087	0.054	0.021	0.009	0.003	0.001	0.001	0.001	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

TABLE 3.2 - DISCOUNT FACTORS - VALUE of  $(1+r)^{-n}$



## CLINICAL ECONOMICS

### MODULE 4

#### COST-MINIMIZATION ANALYSIS

After completing this module and the recommended readings, you should understand:

- a. the approach used in a cost-minimization analysis;
- b. the strengths and limitations of the approach.

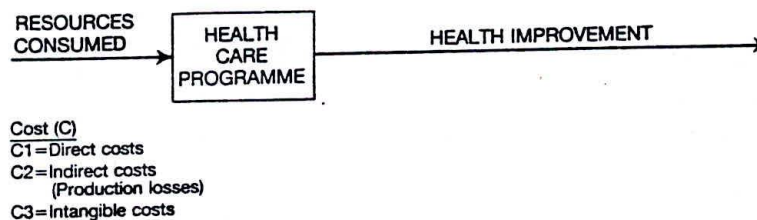


## COST-MINIMIZATION ANALYSIS

NOTE: In modules 1-3 it was necessary to introduce some basic economic concepts in addition to Cost of Illness and Cost Analysis. Now that you understand some of the principles underpinning Clinical Economics, the remaining modules will be substantially shorter. You should devote more attention to the recommended readings and the associated questions.

### INTRODUCTION

Clinical economics is concerned with the economic efficiency of health interventions, where efficiency depends on both the inputs and outcomes of a programme. The relationship between inputs and outcomes is represented in the following diagram:



(adapted from Drummond et al, p. 2)

From previous modules, you should be aware how the cost of a programme can be estimated. The benefits are more difficult to measure. Cost-analysis, the technique introduced in Module 3, is used where the benefits generated by alternative programmes can be assumed to be identical. It does not require the outcomes to be measured. The techniques which will be introduced in this and subsequent modules do require outcomes to be measured.

### COST-MINIMIZATION ANALYSIS

Cost-minimization analysis is used to compare alternative interventions for the same disease or condition where it can be proved that the alternatives have identical outcomes. The technique requires a test of equivalence of outcomes rather than the assumption that outcomes are equivalent which is central to cost analysis.



To test for equivalence it is necessary to define an outcome indicator. It is not possible to recommend a general outcome indicator because outcome often depends on the type of intervention and medical condition. Accordingly, a large number of indicators are found in the literature.

For example, Piachaud and Weddell tested whether surgery (method 1) and injection-compression sclerotherapy (method 2) were equally effective treatments for varicose veins. They randomly allocated patients to the two techniques and followed the subjects for three years.

Their outcome indicator was the proportion of patients who had required no further treatment in the 3 years. These patients were regarded as having been treated successfully because unsuccessful treatments would have required some form of follow up action. Of the patients treated with method 1, 86% required no further action compared to 78% of those treated with method 2.

However, a larger number of patients failed to attend for surgery than for sclerotherapy. The authors argued that patients who avoided treatment should be added to the group that were treated unsuccessfully. With this adjustment, 75% and 73% of patients allocated initially to methods 1 and 2 respectively, did not require further treatment. This difference was not statistically significant.

Once the outcomes of alternatives are shown to be identical, cost-minimization employs the same technique as cost analysis. It chooses the cheapest alternative. Remember that this may depend on whose viewpoint is considered. Piachaud and Weddell showed that sclerotherapy was cheaper than surgery from the viewpoint of the patient, the Health Service and the community.

#### REFERENCES

- Drummond M.F., G.L. Stoddart and G.W. Torrance, Methods for the economic evaluation of health care programmes, OUP, Oxford, 1987, chapter 4.
- Piachaud D. & J.M. Weddell, "The economics of treating varicose veins", International Journal of Epidemiology, 1972, 1(3): 287-294.
- Pineault R. et al, "Randomized clinical trial of one day surgery", Medical Care, 1985, 23:171-182. (attached)



QUESTIONSQUESTION 1 WILL BE ASSESSED AND MUST BE SUBMITTED

1. Read the article by Pineault et al.
  - a. What outcome indicator is used?
  - b. Do you think the authors have proved that the outcomes of the 2 alternatives are identical? If not, why not?
  - c. Describe how your response to this paper might vary depending on whether you took the viewpoint of (i) the patient, (ii) the surgeon, (iii) the hospital, (iv) the community of patients requiring surgery.
2.
  - a. Do you agree with Piachaud & Weddell that the outcomes of surgery and injection-compression sclerotherapy are identical? If not, why not?
  - b. Define a single outcome indicator which could have been used in both studies - Pineault et al and Piachaud and Weddell.
3. What are some of the strengths and limitations of cost-minimization analysis?



## Randomized Clinical Trial of One-day Surgery

### Patient Satisfaction, Clinical Outcomes, and Costs

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MARIE VALOIS, MSc‡ MARIE-LYNN BASTIAN, BA†  
AND JEAN-MARIE LANCE, MSc§

One hundred and eighty-two patients undergoing tubal ligation, hernia repair, or meniscectomy were randomly assigned to either one-day or inpatient surgery. The study's objective is to compare these two modes of care with regard to patient satisfaction, clinical outcomes, and costs of the episode of care. A significantly higher proportion of one-day patients than their hospitalized counterparts found their stay to be too short and would prefer hospitalization as an alternative. Clinical outcomes were comparable in both groups. One-day tubal ligation and hernia repair were found to be cost-efficient and averaged hospital savings of \$86.00 and \$115.00 more than inpatient care. Meniscectomy deviated from this trend in that treatment costs were significantly higher for one-day surgery patients. Analysis of personal and physician costs did not show any significant difference between the two modes of care. Key words: satisfaction with surgery; outcome of surgery; costs of surgery. (Med Care 1985, 23: 171-182)

One-day surgery has been advocated as an efficient means for increasing hospital productivity in the context of cost containment.<sup>1,2</sup> During the last decade, the development of 1-day surgery has been well documented.<sup>3-5</sup> In response to various measures that impose severe limita-

tions on the supply of hospital beds, there has been a tendency to admit increasingly complex cases to 1-day surgery units.<sup>6</sup>

Much of the literature concerned with 1-day surgery has dealt solely with the organization and the functioning of these units as well as with utilization variables such as number and type of surgical procedures performed, differential length of stay, and use of resources.<sup>7-9</sup> Among research-oriented studies, few have included comparison groups in their research protocol.<sup>10-13</sup> Special attention has been given to hernia repair.<sup>12-16</sup> With few exceptions, most studies have limited their investigation to one or two of the three aspects that our research embraces, i.e., patient satisfaction, clinical outcomes, and costs.<sup>16-18</sup>

The development of this new surgical mode raises an important question: How efficacious and efficient is 1-day surgery

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compared with traditional inpatient care? This question constitutes the central concern of this article. More specifically, the objective is to compare 1-day and inpatient surgery in terms of patient satisfaction, clinical outcomes, and the cost of the episode of care for three selected surgical procedures: tubal ligation, hernia repair, and meniscectomy.

### Methods

#### Study Setting

The study was carried out in a Montreal acute-care hospital with an inpatient capacity of 350 beds and a 20-bed 1-day surgery unit. This unit uses all hospital facilities including operating and recovery rooms. Nine surgeons participated in the study: two gynecologists, three orthopedists, and four general surgeons. For each operation, the different surgeons agreed to use the same techniques and protocol.

For a better understanding of this article, it is necessary to outline some of the main characteristics of the Quebec medical care system. Physician and hospital services are totally covered under a national health insurance program providing free access to these services. Hospitals are financed through a global operating budget established on an annual basis by the Department of Social Affairs, whereas physicians are directly paid on a fee-for-service basis by the Quebec Health Insurance Board. The fee schedule for surgical procedures is established through an agreement between physicians' professional associations and the government. Overbilling is prohibited.

#### Selected Procedures and Surgical Modes

The criteria for selecting tubal ligation, hernia repair, and meniscectomy were

1. The procedures had to be frequently performed in the last current year before the study began;

2. They had to be relatively complex in order to include "border line" cases as well as more simple procedures generally performed on an ambulatory basis;

3. General anesthesia had to be used in all cases;

4. The surgical procedures had to represent different major surgical specialties;

5. The performance of these procedures in an ambulatory setting had to conform to ethical requirements.

Two surgical modes were studied: "One-day surgery" refers to the process by which the patient is admitted the morning of the operation and discharged the same afternoon. "Inpatient surgery" refers to the more traditional process, whereby the patient is admitted for a hospital stay of at least one night. In both surgical modes, the operation was performed under general anesthesia.

The decision as to whether a patient was eligible for inpatient or 1-day surgery was made by the surgeons, on the basis of explicit criteria e.g., the severity of the condition, the existence of previous or chronic health problems, and the patient's age. Our research protocol also specified that no other surgical procedure be performed concurrently to avoid the combined effects of multiple procedures on outcome measures. Furthermore, all subjects had to be 18 years old or older to circumvent the requirement of obtaining parental consent.

Once the patients were found to be eligible for 1-day surgery, the surgeon informed them that the procedure could be carried out in either setting. If a patient expressed a preference for one mode of care, he was then booked according to his personal preference, but not included in the study. Those stating no preference were invited to participate in the experiment. They were told that the treatment choice would be left to chance. Those who accepted were asked to sign an informed consent. In all cases, the operation was performed by their own physician.



### Patient Satisfaction

Since consumer acceptability can be a contributing factor in the development and widespread use of a new program such as 1-day surgery, patient satisfaction becomes an important element in this study. Patient satisfaction has generally been measured either directly or indirectly. Direct measures of satisfaction are obtained by asking the patient to what extent he (she) is satisfied with various elements of the medical care process. There is a great deal of literature on this subject.<sup>19,20</sup> The problem with direct measures of satisfaction is that they are not specific enough and thus fail to discriminate between different modes of care.

For these reasons, our study retained indirect measures of satisfaction with regard to patients' perception and their assessment of the process of care. Specifically, the following indicators were selected:

1. accessibility, as measured by perception of distance between home and hospital, controlling for real distance;
2. physician availability, as measured by at least one postoperative visit (excluding follow-up visits);
3. patients' opinion concerning the appropriateness of the length of stay, and overall preference for the alternative mode of care.

### Clinical Outcomes

The clinical outcomes evaluated in this study come from two sources: the patient and the medical chart. The patient's view was obtained on the following variables: the seriousness of discomfort felt in the first 24 postoperative hours and the self-reporting of postsurgical problems. The medical chart provided objective data regarding complications, general health status, symptoms, and complaints.

### Costs of the Episode of Care

The episode of care is defined in this study as the period of time from the sur-

geon's request for the patient's admission up to the 3rd postoperative month. Total costs for an episode of care have three components, each of them financed by a different party (Table 1).

**Hospital Costs.** Previous attempts to establish the potential savings associated with 1-day surgery were made by referring either to average daily costs or direct patient charges. Both costing methods are considered inaccurate since they do not take into account all the types of services received by the patient.<sup>21</sup> A more appropriate technique consists in identifying and costing all services received during an episode of care. The financial comparison between a 1-day and an inpatient episode can then be performed more accurately.

For this purpose, assessment of hospital costs per episode of care was carried out in two steps: 1) determination of all services used by the patient during the episode of care. The utilization data obtained from medical records included items such as number of inpatient days, number and type of diagnostic tests (laboratory, radiology, electrocardiogram), number and type of medication, number of units of physiotherapy, operating room and recovery room time, ward nursing care time, and home nursing care visits; 2) calculation of a unit cost for each service. Since the 1-day surgery program was an established unit, already in operation within the hospital confines, no capital expenditures are considered in the cost accounting process.

TABLE 1. Financing the Costs of the Episode of Care

Components	Financed by
Hospital costs	Department of Social Affairs through the hospital's operating budget
Physician costs	Quebec Health Insurance Board on a fee-for-service basis
Personal costs	Patient



TABLE 2. Patient Distribution by Surgical Procedure and Mode of Care (n = 182)

Surgical Procedure	Mode of Care		
	One-day	Inpatient	Total
Tubal ligation	31	30	61
Hernia repair	32	31	63
Meniscectomy	30	28	58
Total	93	89	182

Rather, it is based on the hospital's 1979-1980 annual operating expenses. Because it is a global budget that does not provide actual costs for individual surgical procedures or episodes, a step-down costing technique was applied.<sup>22</sup> This is done by allocating support costs (e.g., plant overhead, housekeeping, laundry and linen, dietary, central supplies, medical records, and admission costs) to patient treatment costs, which finally produces a unit cost for each service. After these two steps had been taken, a disease costing analysis was performed in order to compute total costs for each episode of care.<sup>23,24</sup>

**Physician Costs.** Since under the Quebec National Health Insurance scheme, uniform fees are paid to physicians and overbilling is prohibited, it is possible to determine the cost of physician services throughout the episode of care by multiplying the tariff contained in the fee schedules by the number of services rendered.

**Personal Costs.** There are few personal expenses in the national health insurance system. But the financial burden imposed on the patient and his/her family during the episode of care may be different for the two modes of care. Information pertaining to this type of cost was gathered through the questionnaires, in order to substantiate this presumption. Included are transporta-

tion, domestic help, baby sitting, medication, supplies, special equipment, room charges, # and private physiotherapy costs. Cost estimations for unpaid help and salary loss were also calculated. The main purpose here was to determine if personal costs increase when surgery is performed in the 1-day mode, since the hospital does provide medication, support, and hostelry services during immediate postoperative recovery for inpatients.

#### Data Sources

Financial data were obtained from the Finance Department's record files. The other data source is three questionnaires. The first was a home interview conducted on the 7th postoperative day. Subsequent telephone interviews were done 1 and 3 months after the operation for follow-up purposes. The first questionnaire gathered information on patient satisfaction, immediate clinical outcomes, and costs of the episode of care. The second and third were aimed at collecting further information on these parameters. In addition, the medical record of each patient was reviewed to identify the use of specific services and evaluate clinical outcomes.

#### Study Population

During the study period from October 1979 to March 1981, a total of 672 patients were operated for the three selected procedures: 249 for tubal ligation, 296 for hernia repair, and 127 for meniscectomy. Of this total, 295 patients (44%) were effectively considered eligible for 1-day surgery by their surgeons. Of this number, 182 (62%) were randomly assigned to either mode of care. Of the remaining subjects, 54 (18%) chose their mode of care, 13 (4%) served as pretests, three subjects refused to

<sup>24</sup> See reference 24; this report can be provided by authors on request.

# Hospital can charge for a semiprivate or private room requested by the patient without medical prescription.



participate (1%), and 43 (15%) were lost to the study because of communication problems with the surgeons. The overall participation rate can thus be established at 84%. This article, however, is concerned only with the 182 patients that have been randomly allocated to the two alternative forms of surgical care. Distribution of the study population by mode of care and for selected procedures is shown in Table 2.

Since the sample size is small, the groups were compared for several factors, e.g., age, income, education, and previous hospitalizations. No significant difference was found between the two groups.

### Results

**Accessibility.** This variable was expressed by the patient's perception of the distance between his home and the hospital. As shown in Table 3, the total study population of the 1-day surgery group found the distance between the hospital and their home significantly longer than their hospitalized counterparts, although an objective measure of actual dis-

TABLE 3. Patient Perception of the Distance from Home to Hospital by Surgical Procedure and Mode of Care (n = 182)

Surgical Procedure	Mode of Care		$\chi^2$
	One-day (%)	Inpatient (%)	
Total for all procedures	100.0	100.0	
Too far	15.0	6.0	4.33 <sup>a</sup>
Not too far	85.0	94.0	
Tubal ligation	100.0	100.0	
Too far	19.4	6.7	2.15
Not too far	80.6	93.3	
Hernia repair	100.0	100.0	
Too far	6.3	3.2	0.32
Not too far	93.7	96.8	
Meniscectomy	100.0	100.0	
Too far	20.0	7.1	2.01
Not too far	80.0	92.9	

<sup>a</sup>P ≤ 0.05.

TABLE 4. Patient Postoperative Contacts with Surgeon by Surgical Procedure and Mode of Care (n = 182)

Surgical Procedure	Mode of Care		$\chi^2$
	One-day (%)	Inpatient (%)	
Total for all procedures	100.0	100.0	
At least one visit	33.3	79.8	39.8 <sup>a</sup>
None	66.7	20.2	
Tubal ligation	100.0	100.0	
At least one visit	19.4	60.0	10.5 <sup>a</sup>
None	80.6	40.0	
Hernia repair	100.0	100.0	
At least one visit	50.0	80.6	6.5 <sup>a</sup>
None	50.0	19.4	
Meniscectomy	100.0	100.0	
At least one visit	30.0	100.0	30.7 <sup>a</sup>
None	70.0	—	

<sup>a</sup>P ≤ 0.01.

tance between the hospital and their home failed to show any significant difference between the two groups.

**Physician Availability.** This variable refers to the situation where at least one visit has been made by the surgeon before the patient leaves the hospital. As shown in Table 4, only 33.3% of the 1-day surgery patients had a visit from their surgeon compared with 79.8% of inpatients. This significant difference, seen for all three surgical procedures, could be anticipated since the reduced length of stay associated with 1-day surgery makes it increasingly difficult for surgeons to visit their patients.

**Appropriateness of Length of Stay.** The patient was asked whether he/she found the length of stay too short or appropriate. As revealed by the data in Table 5, 53.9% of the 1-day surgery group think their hospital stay was too short as opposed to 21.3% for the inpatient group. Again, this significant difference holds for all three surgical procedures.



TABLE 5. Patient Perception of the Appropriateness of Length of Stay by Surgical Procedure and Mode of Care (n = 182)

Surgical Procedure	Mode of Care		$\chi^2$
	One-day (%)	Inpatient (%)	
Total for all procedures	100.0	100.0	
Too short	55.9	21.3	22.8 <sup>a</sup>
Appropriate	44.1	78.7	
Tubal ligation	100.0	100.0	
Too short	51.6	20.0	6.6 <sup>a</sup>
Appropriate	48.4	80.0	
Hernia repair	100.0	100.0	
Too short	59.4	25.8	7.3 <sup>a</sup>
Appropriate	40.6	74.2	
Meniscectomy	100.0	100.0	
Too short	56.7	17.9	9.3 <sup>a</sup>
Appropriate	43.3	82.1	

<sup>a</sup>P ≤ 0.01.

*Preference for Alternative Mode of Care.* Patients were asked if, given their actual experience, they would choose the same setting again or the alternative mode of care. The data in Table 6 are unequivocal. For all three categories, a significantly greater proportion of 1-day surgery patients expressed their preference for hospitalization than did inpatients for 1-day surgery.

In summary, hospitalized patients seem to express a greater degree of satisfaction than short-stay patients. Differences between the two groups are both important and statistically significant. Furthermore, dissatisfaction with 1-day surgery is much greater among meniscectomy patients. This seems to indicate that, for meniscectomy, 1-day surgery is a less acceptable form of treatment than for the two other conditions.)

#### Clinical Outcomes

The study found that clinical outcomes as a whole, differed very little between 1-day surgery and inpatient care.

*Postoperative Complication Rate.* Postoperative complications, i.e., complications occurring before the patient's discharge from either surgical facility, were established at 5.3% for 1-day surgery and 7.8% for inpatients. These differences are not statistically significant. The slightly higher rate for inpatients could well be explained by the longer observation period that averages 2.7 days for inpatients compared with 8.7 hours for 1-day surgery patients. The nature of the reported complications were relatively minor, none of them constituted an emergency or life-threatening situation.

*Severity of Postoperative Discomfort.* Patients' assessments of the severity of postoperative discomfort were obtained during the home interview on the 7th postoperative day. Data show no significant difference between groups, and this for all surgical procedures (Table 7). Approximately 88% of 1-day patients and 91% of

TABLE 6. Patient Preference for Alternative Mode of Care by Surgical Procedure and Mode of Care (n = 182)

Surgical Procedure	Mode of Care <sup>a</sup>		$\chi^2$
	One-day (%)	Inpatient (%)	
Total for all procedures	100.0	100.0	
Same mode	50.5	86.5	26.3 <sup>c</sup>
Alternative mode	48.4	13.5	
Undecided <sup>a</sup>	1.1	—	
Tubal ligation	100.0	100.0	
Same mode	56.7	93.8	10.8 <sup>c</sup>
Alternative mode	46.3	6.7	
Undecided <sup>a</sup>	1.0	—	
Hernia repair	100.0	100.0	
Same mode	53.1	77.5	4.09 <sup>a</sup>
Alternative mode	46.9	22.5	
Meniscectomy	100.0	100.0	
Same mode	43.3	89.3	23.54 <sup>c</sup>
Alternative mode	56.7	10.7	

<sup>a</sup>Not included in analysis.

<sup>b</sup>P ≤ 0.05.

<sup>c</sup>P ≤ 0.01.



inpatients rated their discomfort in the first 24 hours following surgery as being either "not very serious" or causing "no discomfort."

*Postoperative Symptoms Rate.* Patients' assessment regarding the absence or presence of symptoms during the 3 months following their initial surgery is shown in Table 8. Data analysis reveals that there is no significant difference in the postoperative symptoms rate between 1-day surgery and inpatients. It should also be noted that meniscectomy patients show a much higher rate than hernia repair or tubal ligation, since 53.3% of 1-day and 60.8% of inpatient meniscectomies still indicate the presence of symptoms at the 3rd postoperative month. Patients were also asked the

TABLE 7. Patient Perception of the Seriousness of Postoperative Discomfort by Surgical Procedure and Mode of Care (n = 182)

Surgical Procedure	Mode of Care		$\chi^2$
	One-day (%)	Inpatient (%)	
Total for all procedures	100.0	100.0	
Very serious or serious	11.9	8.9	
Not very serious or not serious	82.8	86.5	0.5
No discomfort	5.4	4.5	
Tubal ligation	100.0	100.0	
Very serious or serious	9.7	3.3	1.0
Not very serious or not serious	90.3	96.6	
No discomfort			
Hernia repair	100.0	100.0	
Very serious or serious	9.4	9.7	
Not very serious or not serious	87.6	83.9	0.4
No discomfort	3.1	6.5	
Meniscectomy	100.0	100.0	
Very serious or serious	16.7	14.3	
Not very serious or not serious	70.0	78.6	0.7
No discomfort	13.3	7.1	

TABLE 8. Patient Reporting of the Presence of Symptoms Three Months after Surgery by Procedure and Mode of Care (n = 180)

Surgical Procedure	Mode of Care		$\chi^2$
	One-day (%)	Inpatient (%)	
Total for all procedures	100.0	100.0	
No symptoms	72.0	72.0	0.07
Symptoms	26.0	28.0	
Missing data <sup>a</sup>	2.0		
Tubal ligation	100.0	100.0	
No symptoms	90.3	90.0	0.00
Symptoms	9.7	10.0	
Hernia repair	100.0	100.0	
No symptoms	78.1	87.1	0.00
Symptoms	15.7	12.9	
Missing data <sup>a</sup>	6.2		
Meniscectomy	100.0	100.0	
No symptoms	46.7	39.2	0.32
Symptoms	53.3	60.8	

<sup>a</sup> Not included in analysis.

general question, "How do you feel," 1 month and 3 months after their operation. Here again, the data (Tables 9, 10) indicate that the recovery period is much longer for meniscectomy, but no difference could be found between hospitalized and short-stay patients.

In sum, the different parameters used to evaluate clinical outcomes reveal a great similarity between the two surgical groups. In this regard, 1-day surgery can be considered as efficacious as inpatient care. The case of meniscectomy, however, deserves special attention. It is clear that the recovery period is much longer for meniscectomy than for other surgical procedures. Since our observation period covered the first 3 postoperative months, this study cannot assess long-term recovery for these patients.

#### Costs

*Hospital Costs.* Average hospital costs for each surgical procedure are presented



TABLE 9. Self Rating of Health Status by Patient One Month After Operation by Surgical Procedure and Mode of Care (n = 180)

Surgical Procedure	Mode of Care		$\chi^2$
	One-day (%)	Inpatient (%)	
Total for all procedures	100.0	100.0	
Good	74.0	76.0	1.3
Fair	16.0	14.0	
Bad	9.0	10.0	
Missing	1.0	0.0	
Tubal ligation	100.0	100.0	
Good	81.0	86.0	1.2
Fair	6.0	7.0	
Bad	10.0	7.0	
Missing	3.0	0.0	
Hernia repair	100.0	100.0	
Good	81.0	84.0	1.4
Fair	19.0	13.0	
Bad	0.0	3.0	
Meniscectomy	100.0	100.0	
Good	60.0	58.0	
Fair	23.0	21.0	
Bad	17.0	21.0	

in Table 11. One-day surgery costs range from a low of \$278.62 for tubal ligation to a high of \$816.66 for meniscectomy. Hernia repair occupies a middle ground at \$367.58.† Inpatient procedures follow the same progressive increase in costs, reflecting the relative importance of resources used in the treatment of each condition. Analysis shows that inpatient hospital costs are significantly higher for tubal ligation and hernia repair and are mainly imputable to nursing care costs. The itemized cost breakdown also indicates that 1-day tubal ligation incurs significantly higher outpatient visits costs. Because a high proportion of 1-day surgery patients do not see the physician before their discharge, it is possible that they prefer consulting the surgeon rather than their family physicians for subsequent follow-up visits. The higher cost of diagnostic services is related to an

† All money figures presented are in Canadian dollars.

increased use of test procedures for tubal ligation inpatients.

Meniscectomy presents a totally different pattern, since average hospital costs are significantly higher in the 1-day mode. Although 1-day meniscectomy continues to show lower overall nursing care costs, albeit the added expenses of home nursing care, a condition set by the surgeons in this study, any potential saving is offset by the substantial increased use of physiotherapy services. This rise in costs for treatment services would tend to support the clinical evidence that has found more severe post-operative symptoms associated with this mode of care.

**Physician Costs.** In a national fee-for-service system in which overbilling is prohibited, the costs of medical services should not vary considerably. As expected, no significant difference was found in total medical costs between 1-day and inpatient surgery (Table 12).

TABLE 10. Self Rating of Health Status by Patient Three Months After Operation by Surgical Procedure and Mode of Care (n = 182)

Surgical Procedure	Mode of Care		$\chi^2$
	One-day (%)	Inpatient (%)	
Total for all procedures	100.0	100.0	
Good	72.0	72.0	4.2
Fair	24.0	21.0	
Bad	2.0	7.0	
Missing	2.0	0.0	
Tubal ligation	10.0	100.0	
Good	90.0	90.0	1.2
Fair	10.0	7.0	
Bad	0.0	3.0	
Hernia repair	100.0	100.0	
Good	78.0	84.0	2.0
Fair	16.0	16.0	
Bad	0.0	0.0	
Missing	6.0	0.0	
Meniscectomy	100.0	100.0	
Good	47.0	39.0	1.7
Fair	47.0	43.0	
Bad	6.0	18.0	



TABLE 11. Average Hospital Costs by Surgical Procedure and Mode of Care

Surgical Procedure	Mode of Care		Value ( $\tau$ )
	One-day (\$)	Inpatient (\$)	
Tubal Ligation			
Outpatient visits	48.35	38.46	2.44 <sup>b</sup>
Diagnostic services	46.43	54.74	- 3.65 <sup>c</sup>
Operating room	113.05	116.25	- 0.66
Nursing care <sup>a</sup>	62.75	147.58	-12.59 <sup>c</sup>
Medication	8.04	7.84	0.27
Total	278.62	364.87	- 8.55 <sup>c</sup>
Hernia Repair			
Outpatient visits	47.54	41.47	1.14
Diagnostic services	33.83	34.27	- 0.14
Operating room	215.79	212.12	0.28
Nursing care <sup>a</sup>	62.07	185.97	-13.70 <sup>c</sup>
Medication	8.34	8.85	- 1.24
Total	367.58	482.68	- 5.65 <sup>c</sup>
Meniscectomy			
Outpatient visits	85.00	87.71	- 0.40
Diagnostic services	70.18	74.96	- 1.52
Operating room	200.35	210.68	1.02
Nursing care <sup>a</sup>	64.20	200.10	-13.48 <sup>c</sup>
Home nursing care	94.38	—	—
Physiotherapy	274.33	41.49	3.94 <sup>c</sup>
Medication	8.22	9.18	- 1.42
Total	816.66	644.12	2.76

<sup>a</sup> Nursing care costs include hostelry costs.<sup>b</sup>  $P \leq 0.05$ .<sup>c</sup>  $P \leq 0.01$ .

TABLE 12. Average Physician Costs by Surgical Procedure and Mode of Care

Surgical Procedure	Mode of Care		Value ( $\tau$ )
	One-day (\$)	Inpatient (\$)	
Tubal Ligation			
Visits	23.84	20.28	0.90
Surgery	164.42	163.78	1.74
Diagnostic services	35.60	37.79	-1.93
Total	223.86	221.85	0.47
Hernia Repair			
Visits	24.42	20.78	0.60
Surgery	204.31	199.45	1.19
Diagnostic services	15.46	17.98	-1.46
Total	244.19	238.21	0.75
Meniscectomy			
Visits	48.93	50.41	-0.19
Surgery	191.48	191.38	0.10
Diagnostic services	49.46	49.87	-0.29
Physiotherapy	—	27.36	-1.41
Total	289.87	319.02	1.32



TABLE 13. Average Personal Costs by Surgical Procedure and Mode of Care

Surgical Procedure	Mode of Care		Value ( $\tau$ )
	One-day (\$)	Inpatient (\$)	
Tubal Ligation			
Transportation and domestic help	18.11	19.40	-0.26
Medication	3.49	1.87	1.93
Room	—	19.27	
Total out-of-pocket	21.60	40.54	-3.10*
Unpaid help	75.35	113.76	-1.28
Salary loss	63.73	73.10	-0.15
Total	160.68	227.40	-1.08
Hernia Repair			
Transportation and domestic help	17.09	31.79	-1.11
Medication	5.65	3.15	1.85
Room and other	0.75	32.06	
Total out-of-pocket	23.50	67.00	-2.92*
Unpaid help	45.51	41.09	0.24
Salary loss	210.33	368.53	-1.30
Total	279.33	476.62	-1.60
Meniscectomy			
Transportation and domestic help	121.18	74.22	1.59
Medication	22.28	21.38	0.18
Room and other	7.30	49.45	
Total out-of-pocket	150.76	145.05	0.18
Unpaid help	69.23	48.49	1.13
Salary loss	146.95	266.54	-1.02
Total	366.94	460.08	-0.68

\* $P \leq 0.01$ .

*Personal Costs.* Data presented in Table 13 show that there is no statistically significant difference for total personal costs between the two surgical modes. However, out-of-pocket expenses, i.e., actual dollars paid by the patients, were significantly higher in the case of inpatient tubal ligation and hernia repair. This is mainly due to supplementary semiprivate and private room charges. Although inpatient meniscectomy also registers room supplement charges, its significance is offset by higher transportation costs for 1-day surgery patients who required an ambulance for their home return. The high variability of estimated personal costs for unpaid help and salary loss accounts for the statistically nonsignificant results found in total personal costs.

### Discussion and Conclusion

In putting together the findings on patient satisfaction, clinical outcomes, and costs, the following pattern emerges. Tubal ligation and hernia repair seem to be surgical procedures for which 1-day surgery is an appropriate form of care. More than 50% of 1-day surgery patients would accept to repeat their experience of 1-day surgery in both conditions. In addition, this form of care is cost efficient, since it represents an average saving of \$86.00 and \$115.00 per patient for tubal ligation and hernia repair, respectively. Meniscectomy, on the other hand, represents the extreme case in which 1-day surgery is associated with a lower patient acceptance rate of 43% and is actually cost inefficient, since it increases total



hospital costs by an average of \$173.00, in comparison with hospitalization. Clinical outcomes are similar in both modes of care.

The findings tend to support the general consensus that 1-day surgery can be an acceptable, efficacious, and cost-efficient organizational arrangement for performing certain types of surgery.<sup>25</sup> They also reveal the limits of this form of care, which must be implemented with concern for the potential disadvantages associated with different types of surgical procedures that may be performed on a short-stay basis.<sup>26</sup>

At another level, one must ask the difficult "cui boni" question, who benefits from 1-day surgery, the patient, the doctor, the hospital, or society? This study clearly indicates that, for the patient, there is a limit beyond which 1-day surgery becomes a less acceptable form of treatment. As far as cost is concerned, although one-day surgery can reduce out-of-pocket expenses by avoiding supplementary room charges, it may also increase personal costs by imposing ambulance expenses, as seen with meniscectomy patients.

In a fee-for-service mode of remuneration for doctors, it is evident that shortening the length of stay of surgical patients may increase the volume of surgical procedures over a period of time, thus yielding financial benefits to doctors, in a context where the supply of acute care beds is limited.\*\*

The hospital may take advantage of 1-day surgery to maximize the use of operating room facilities when occupancy rates are high. After reaching this point, the relative advantages depend on the prevailing financing mechanism. A shorter length of stay means increased average daily costs. For example, in the Canadian system, there is no real incentive for hospitals to increase this type of productivity by

shortening length of stay, since they are financed through a global operating budget established annually by the government.

At the societal level, the question of the utility of these measures must also be raised. A program that has been proven to be cost efficient at the organizational level can be cost inefficient at the societal level. For example, in a situation where rates for surgical operations have been reported as unusually high, possibly reflecting unnecessary surgery, one can question the rationale for extending eligibility of 1-day surgery to cases normally requiring inpatient care.<sup>27</sup> Thus for society, 1-day surgery must be assessed in the light of the alternative use of the beds that are freed by 1-day surgery as well as in terms of the quality of care as reflected by the appropriateness of these procedures.<sup>28</sup>

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\*\* In Quebec, the number of acute care beds per 1000 dropped from 5.32 in 1974 to 4.30 in 1978.



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## CLINICAL ECONOMICS

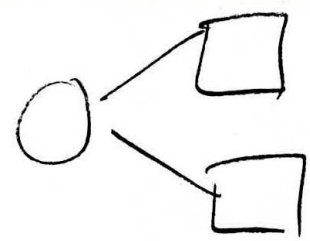
### MODULE 5

#### COST-EFFECTIVENESS ANALYSIS

After completing this module you should understand:

- a. how a cost-effectiveness analysis is undertaken;
- b. the strengths and weaknesses of the approach;
- c. what is meant by incremental cost-effectiveness analysis.





## COST-EFFECTIVENESS ANALYSIS

### INTRODUCTION.

Cost and cost-minimisation analysis are used to choose between alternative ways of using resources when the alternatives have identical benefits. The techniques give preference to the lowest cost alternative. In many cases, however, both the benefits and costs of alternatives differ. It is then not rational either to choose the least cost alternative without regard to benefits, or the most effective alternative without regard to costs. Costs must be compared to benefits in some way.

### COST EFFECTIVENESS (CE) ANALYSIS.

CE analysis measures the benefits of a health intervention in terms of physical units. This can be in terms of either the intermediate or the final health output.

For example, Altman et al compared three anti-smoking interventions and used an intermediate outcome indicator, the number of smokers who quit, to measure the success or effectiveness of the programmes. In contrast, Cummings et al measured the success of their anti-smoking intervention in terms of a final outcome indicator, the number of years of life saved.

Intermediate output <sup>given as a Proxy.</sup> indicators of effectiveness must be chosen carefully to be relevant to the particular programme. Accordingly, a wide variety of indicators are found in the literature including the number of correct diagnoses, the number of successful immunisations, and the number of new acceptors in a family planning programme. However, only two final output indicators are used frequently:-

- (i) the number of lives, and
- (ii) the number of years of life (often called "life-years")

saved by an intervention.

Clearly, economists must rely on the epidemiological data for information about effectiveness. In fact, Drummond et al argue that CE studies are more commonly criticised for the quality of the medical evidence on which effectiveness indicators are based than on the subsequent economics. You should be aware of the techniques and problems of estimating effectiveness from the epidemiology modules. In any case, some of the references in this module illustrate the difficulties involved.



Extra yrs of life early death deferred death

1000 drops } cost (C1)  
product 1 cancer drug } cost (C2)  
50 QHD  
AS stroke

THE COST-EFFECTIVENESS RATIO.

The CE ratio is obtained by dividing the total cost of a programme by the indicator of effectiveness. It represents the cost per unit of effectiveness - for example, cost per life saved, cost per life-year gained, or cost per success for intermediate outcome indicators. In general, the lower this ratio the more efficient is the programme.

CE analysis can be used to compare alternative designs of the same project, such as different methods of treating dehydration in children caused by diarrhoea. It can also be used to compare unrelated programmes if they have the same objective. Projects aimed at saving lives can be compared, but it does not make sense, for example, to compare the cost per life saved of a medical programme with the cost per birth prevented, the latter being the CE index commonly used in family planning projects.

Note that CE analysis is used as a means of choosing between competing programmes. It is meaningless to compute a CE index for a single project in isolation.

NET COSTS. = cost of intervention - Savings of medical intervention. Indirect benefits not included

Dispute on which benefits are included  
Imps 1  
Common view  
cost is low  
not all  
E + Immune response

The numerator in a CE ratio is usually the net direct cost of the intervention. For example, a hypertension treatment programme incurs direct costs (doctor visits, drugs, investigations etc), yet also saves direct costs by preventing future strokes. The net cost is the direct cost of the intervention minus the saving in direct costs resulting from fewer strokes (with appropriate discounting). There is dispute in the literature, however, about whether the economic consequences of extending life should be included in the calculation of net costs. For example, the hypertension control programme may allow some people to work longer (an indirect benefit), but on the other hand some of the people whose lives are extended may develop cancer and incur additional direct costs. A fairly persuasive reason for ignoring these effects is that they are already implicitly incorporated into the numerator, the indicator of benefit, assuming that society values extensions of life regardless of the net productivity of the life that is extended.

INCREMENTAL ANALYSIS.

Hull et al compared three ways of diagnosing symptomatic deep vein thrombosis (DVT) and measured effectiveness in terms of the number of sufferers correctly diagnosed by a technique. For a given group of sufferers, they found that impedance plethysmography (IPG) cost a total of \$395,359 (Canadian) and correctly identified 142 cases of DVT. The CE ratio was \$2784 per correct diagnosis. IPG with Fibrinogen leg scanning cost



To different  
Programs to  
be presented  
analysis



## REFERENCES

### Major References:

Drummond et al, (see Module 4), chapter 5.

Creese A.L. "Cost effectiveness of potential immunization interventions against diarrhoeal disease", Social Science & Medicine 1986, 23(3):231-240.

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Altman D.G., J.A. Flora, S.P. Fortmann & J.W. Farquhar, "The cost-effectiveness of three smoking cessation programs", American Jnl of Public Health, 1987, 17:162-165.

Cummings S.R. et al, "The cost-effectiveness of counseling smokers to quit", JAMA 1989, 261(1):75-79.

Hull R, J. Hirsh, D.L. Sackett & G. Stoddart, "Cost effectiveness of clinical diagnosis, venography and noninvasive testing in patients with symptomatic deep-vein thrombosis", NEJM, 1981, 304:1561-1567.

## QUESTIONS

### ANSWERS TO ALL QUESTIONS SHOULD BE PREPARED BEFORE THE CLASS

1. Read the article by Creese.
  - a. Are final or intermediate outcome indicators used? What are the advantages and disadvantages of each type (in general)? *See module 4*
  - b. How do you think the results would have differed if effectiveness had been measured in terms of the number of years of life rather than the number of lives saved? *Don't have much more different*
  - c. Discuss whether it is preferable to use years of life saved or the number of lives saved as an indicator of effectiveness?
  - d. Discuss the way that costs were measured, including whose viewpoint was taken, whether any important costs were omitted, and whether marginal or average costs were used?
  - e. What policy conclusions can be drawn from this article?
2. What are the advantages of CE analysis over cost and cost-minimization analysis? What are some of the weaknesses of CE analysis?
3. Would you expect the net costs of any programmes to be negative? If so, what type of programmes?

*net cost (Cost Int - Saving from it)*



- d. What difference does it make to your CE ratios if you find that only 100 patients comply with 120 drug courses?
- e. You can now compare the CE ratio of the scheme with the education to the CE ratio without education under the two assumptions about compliance. If the CE ratio with education is the higher, does this imply that the education programme is worth undertaking? If not, how should the cost effectiveness of the education programme be assessed?

Marginal cost effectiveness: Extra benefit received

Extra cost = 100 £

Margin Extra benefit = 40

2.50

Extra income = 56

$$\text{Cost ratio} = \frac{100}{56} = 1.3$$

Option 2 -

$$\text{Ex. 20} = 5 \text{ £/week}$$

$$32 \text{ extra weeks} = 3 \text{ £/week}$$

What is the best intermediate outcome & how does it relate to final outcome



death prevented = death postponed.

5

4.a. Calculate the CE ratio for the following programmes. Rank them in order of cost effectiveness.

(Taken from Shepard & Cash, Manual for assessing the cost-effectiveness of oral rehydration therapy in the treatment of diarrhoeal disease, 1983)

Programme	Annual cost per 100,000 pop.	Annual deaths averted/100000.
pilot projects in primary health care	\$400,000	303
oral rehydration	\$18,000	75
immunization	\$5,000	35
measles vaccination	\$30,000	63
DDT spraying for malaria	\$200,000	800
home distributed oral rehydration	\$7,000	69

b. Do these data imply that pilot projects in primary health care should not be undertaken?

4. You are responsible for a dispensary which provides drugs worth \$400 per month. You are worried that many of the patients who receive these drugs do not maintain the prescribed regimen of drug taking. (You accept that correctly taking the drugs in the doses prescribed is good for your patients.) You feel that much of your drug budget is wasted by patients who are not compliant.

In the last month, the dispensary served 200 patients and dispensed 250 different drug courses. You have followed up these patients and found that 80 were compliant, and that 88 regimens were followed correctly. You wish to provide an education programme that will enhance patient compliance and you wish to discover if the additional cost of education is worthwhile. You expect that the cost of the education programme will be \$100 per month and that it would serve all of the patients attending the dispensary.

- What is the cost of drugs per patient under the existing drug dispensing scheme (no education)? What is the cost per drug course?
- What is the cost per patient under the scheme with education?
- With education, you expect that 120 patients will comply with 144 drug courses. Calculate a CE ratio for the scheme without education, and for the scheme with education.

Handwritten calculations:

$$\frac{400}{250} = 1.6$$

$$\frac{500}{200} = 2.5$$

$$\frac{500}{120} = 4.17$$

$$\frac{500}{144} = 3.47$$

$$\frac{500}{100} = 5$$



# Cost-Effectiveness of a Worksite Hypertension Treatment Program

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WENDY P. CAMPBELL, M.A., AND R. BRIAN HAYNES, M.D., Ph.D., F.R.C.P.(C)

**SUMMARY** The cost-effectiveness of treating hypertension at the patient's place of work was compared in a randomized controlled trial with care delivered in the community. The average total cost per patient for worksite care in this 12-month study was not significantly different from that for regular care ( $\$242.86 \pm 6.94$  vs  $\$211.34 \pm 18.66$ , mean  $\pm$  SEM). The worksite health system cost was significantly more expensive ( $\$197.36 \pm 4.99$  vs  $\$129.33 \pm 13.34$ ,  $p < 0.001$ ) but the patient cost was significantly less ( $\$45.40 \pm 3.23$  vs  $\$82.00 \pm 6.20$ ,  $p < 0.01$ ). The mean reduction in diastolic blood pressure (BP) at the year-end assessment was significantly greater in the worksite group ( $12.1 \pm 0.6$  vs  $6.5 \pm 0.6$  mm Hg,  $p < 0.001$ ). The incremental cost-effectiveness ratio of  $\$5.63$  per mm Hg for worksite care was less than the base cost-effectiveness ratio of  $\$32.51$  per mm Hg for regular care, indicating that the worksite program was substantially more cost-effective. Our findings support health policies that favor allocating resources to work-based hypertension treatment programs for the target group identified in this study. (Hypertension 3: 211-218, 1981)

**KEY WORDS** • cost-benefit analysis • allied health personnel • ambulatory care • industrial medicine • delivery of health care • hypertension • occupational health services • patient acceptance of health care

At the present time, physicians in private practice are largely responsible for the delivery of health care in North America. Most surveys in the past have shown that these practitioners have been successful in getting no more than 30% of the total hypertensive population under good blood pressure (BP) control.<sup>1-3</sup> The main reasons documented for this poor rate of success are low detection rates, high treatment dropout, and low compliance with medication.<sup>4</sup> An additional problem found in the studies is the lack of therapeutic vigor in the application of antihypertensive therapy by many physicians.<sup>4</sup>

As a solution to these problems, alternative medical care approaches to control hypertension have been developed.<sup>5-12</sup> Although in most instances these approaches have been judged to be effective, safe, and acceptable, detailed economic analyses of these programs have not been published. The importance of such analyses is paramount now that the benefit of treating mild hypertension has been convincingly demonstrated,<sup>11-13</sup> making it desirable to treat even larger numbers of people with available health resources. The randomized controlled trial reported here was undertaken to assess the cost-effectiveness of a work-based hypertension program in which all care for hypertension was provided onsite.

## Methods

Participants in the trial were selected from 21,906 volunteers, aged 18 to 69 years, in 41 business locations in Metropolitan Toronto who were screened for hypertension in 1976-77. Those with an average fifth phase diastolic BP greater than 90 mm Hg on the sec-

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ond and third readings were scheduled for a second screen 1 week later. At that time a nurse administered a brief eligibility questionnaire and took three more BP readings. Eligibility criteria were as follows: 1) mean diastolic BP at or above 95 mm Hg, or a mean diastolic BP between 91-94 mm Hg and mean systolic BP greater than 140 mm Hg; 2) intention to remain in employment for the year following entry into the study; 3) not on any treatment for hypertension for at least 3 months before screening; 4) not on other daily medications, oral contraceptives, or estrogen replacement therapy; 5) not pregnant nor planning to become so during the year of the study; and 6) no objections from the family physician. Those eligible and willing to participate were scheduled for a third screen and received two attitudinal questionnaires to be answered and returned at the third session. At Session 3, additional BP readings were taken as well as baseline laboratory tests (hemoglobin, white blood cell count, urinalysis, serum electrolytes, serum creatinine, serum cholesterol, serum uric acid, blood glucose, and an electrocardiogram). Individuals who were still eligible by BP criteria and who had no evidence of remediable secondary forms of hypertension were given an explanation of the study and invited to sign a consent form, indicating their willingness to participate.

Participants were stratified for sex, median age, and median diastolic BP, and then randomly allocated within strata to treatment at the worksite ("worksite care", WS) or in the community from physicians in private practice ("regular care", RC). All WS patients were evaluated at entry by a physician to exclude complicating or concurrent problems, to establish a goal BP, and to initiate antihypertensive therapy. Long-term follow-up was provided at the worksite on company time by two nurses who were taught to manage hypertension according to a standard protocol<sup>13</sup> and who reported to physicians of the Hypertension Service of the Mount Sinai Hospital in Toronto. An appointment with their own doctor was made for all individuals in RC groups. All screening data including the results of the baseline laboratory tests were enclosed in the referral letter to the family doctor. At 6 and 12 months after entry, all participants were assessed at work by a specially trained BP technician who was unaware of group allocation. A questionnaire was administered to determine medication status, and three BP readings were taken.

#### Medical Care Costs

These were itemized for each patient under health system and patient costs. Health system costs were those attributed to case-finding and treatment. Patient costs were those related to lost time from work or leisure and travel. Costs incurred before randomization (screening costs) were distributed equally across both groups. Treatment costs reflected actual difference in the costs generated by the two types of health care delivery. Costs are expressed in 1977 Canadian dollars.

#### Screening Costs

Costs for all who underwent any part of screening were included in the analysis. The costs involved in screening included personnel, equipment and supplies, travel, participants' time, and administrative costs. Personnel costs for screening comprised the salaries and fringe benefits of the five BP technicians and two nurses. For the latter, time was recorded prospectively on a weekly log, including travel, service, and office time, and was converted into monetary terms using their salaries and fringe benefits. The cost of the laboratory evaluation, which included the interpretation fee of the electrocardiogram by a cardiologist, was determined using the Ontario Medical Association fee schedule and was considered a personnel cost. Equipment used in the study included seven sphygmomanometers and stethoscopes and one electrocardiograph. Equipment costs were calculated using an annual depreciation rate of 16.75% on the purchase price (The Canadian Hospital Association's average annual depreciation rate for clinical equipment was used, as described in the *Canadian Hospital Accounting Manual*, 1963.) Cost of the participants' time was prorated according to hourly wages at the year-end assessment, and included waiting, service, and questionnaire completion time at screening visits. Actual wage values were obtained on 85.3% of the participants, and an average annual income was substituted for missing data (source of data was Statistics Canada). The administrative cost was estimated as 30% of the health system cost of the screening program and included arranging the screening operation, scheduling participants and technicians, printing, telephone, physical facilities, postage, and other such expenses.

#### Treatment Costs

Health system costs of treatment included the provision of care and laboratory examinations, hospitalization, and drugs. The source of payment for physician visits and laboratory examinations was the Ontario Government universal health insurance plan. Each participant had a contract number and, within a contract, services were sorted by date for all medical services received during the study year. For each claim, the service file identified the physician who provided the service, the specialty of the physician, the diagnosis specified by the physician, and/or the type of service provided and the amount paid. Diagnostic and therapeutic procedures, diagnostic radiology and laboratory tests were designated by specific codes. Only services properly identified as related to hypertension were included in cost calculations. The cost of the nurses' service was calculated from weekly logs by converting the total time spent in patient care activities (direct care, travel, and paper work related to patient care) into a dollar value according to their hourly wage. The cost of physician's time to supervise the nurses was added to the cost of the nurses' service and was calculated by converting total time spent into



a dollar value using the average net income and annual working hours of physicians in Ontario (source of data was the Ontario Medical Association). The total number of days of hospitalization per participant was obtained from the service file, and only those days used for diagnostic evaluation and management of hypertension, as determined by direct questioning at the year-end assessment, were included in the cost calculation. The average per diem cost of hospitalization in Ontario in 1977 was used to determine hospital cost rather than more elaborate methods because of the small numbers involved. Drug costs were determined from many of the insurance companies who sponsored drug insurance programs in industries involved in the study. Complete drug cost data were available for 36.6% of those in the WS group and 44.1% in the RC group on medication. Missing data were due to varying insurance company accounting practices at the different worksites rather than lack of patient cooperation. For those with no drug data (15.1% of those on medication), the average cost for those with complete data in each group was used. For the remainder with incomplete data, an individual average monthly drug cost was computed from available data, and this value was used for missing monthly data to calculate the total cost.

Patient cost for physician and laboratory services was calculated in the following fashion. Log forms, recording the distance travelled, and time spent in travel, waiting, and service for a single visit to the doctor's office or laboratory, were obtained from 95 RC and 82 WS patients. Time was converted into dollar value using the midpoint of the wage category to which the individual belonged, and travel costs were calculated by converting distance into dollars at the rate of 17 cents per mile. The total patient cost for single visits to the laboratory or doctor's office was then multiplied by the number of visits for these services by the individual during the study year, as determined from the health insurance plan contract file.

For individuals who did not complete single visit logs, patient cost was calculated as the product of their actual wage and visit frequencies times the average value for travel and time from the logs. In the WS group, the waiting and service time for each participant to visit the nurse was obtained from encounter forms completed at each visit. The patient cost of hospitalization was taken as the monetary value of time lost from work.

Only complete data were used to compare results for individual cost items between groups. In the calculation of health system, patient and total costs, averaged values for individual cost items were substituted for missing results. In addition, a sensitivity analysis was performed using extreme rather than average values, as described below.

#### Effect of Program

The effect of each treatment program was calculated as the average reduction in diastolic BP. Entry BP was calculated by averaging all diastolic BP

measurements at the first and second BP screens and the endpoint BP by averaging all diastolic BP measurements at the year-end assessment.

#### Cost-Effectiveness Analysis

The cost-effectiveness (C/E) of each program was the ratio of the average cost per patient to average reduction in diastolic BP over 1 year. The incremental C/E ratio was obtained by dividing the net increase in medical care cost of the WS program by the net increase in effectiveness. No discounting of future costs and effects was employed because of the short duration of the study.

#### Sensitivity Analysis

Assessment of the effects of variation in key estimated parameters was carried out by substituting for missing data the maximum cost in the WS group and minimum cost in the RC group. In the WS group, the highest individual drug cost from the group with complete data were used in all patients on medications for whom no data were available. To calculate the total cost for individuals with incomplete drug cost data, the highest monthly cost was substituted for missing monthly data. In the RC group, the least drug cost was substituted for missing data in an analogous manner. The maximum patient cost to visit the physician's office and laboratory in the WS group was calculated by using the longest time (travel, waiting, and service) and the farthest distance when no time-distance data were available and the highest salary category when no wage category was designated. The minimum value for each was used in the RC group whenever data were missing. For patient cost of nursing visits, the highest participant's salary was used whenever salary data were missing. Patients completely lost to follow-up were not included in the sensitivity analysis because they were small in number and evenly distributed between two groups (8% in each group).

#### Statistics

Means are presented with a standard error of the mean as the index of dispersion. Statistical analysis was carried out using the unpaired two-tail Student's *t* test, with *p* value < 0.05 indicating a statistically significant difference. The chi-square statistic was used to assess differences in proportions.

#### Results

The volunteers who were screened for hypertension represented approximately 50% of the employees offered this service. As shown in figure 1, 457 employees, or 2.1% of the initial population screened, were eligible and willing to participate in the study. Selected characteristics of the two study groups are outlined in table 1, and no significant differences were noted. Data on cost and effect were obtained on 214 (92.2%) employees in the WS group and 207 (92.0%)



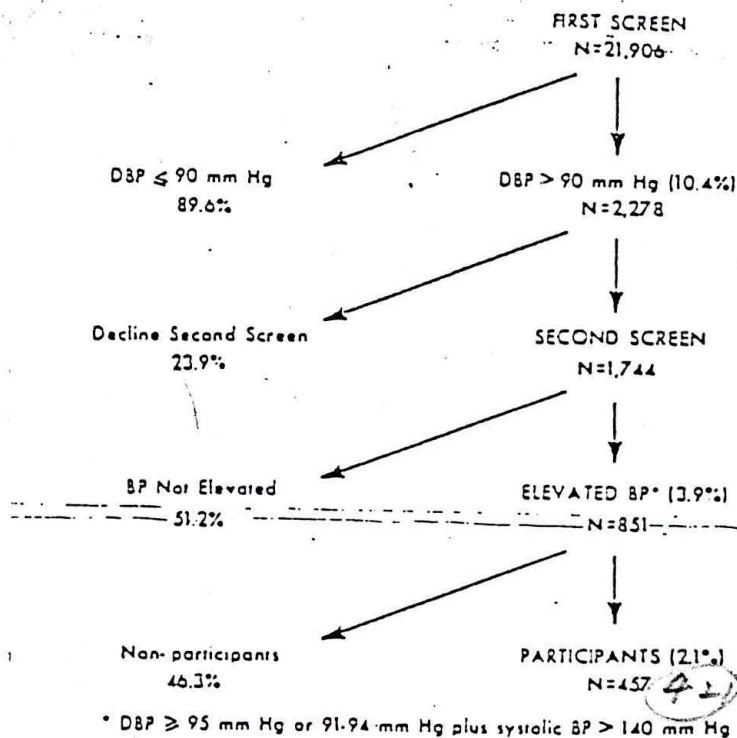


FIGURE 1. Flow diagram showing results of two-stage blood pressure screening in industry and government, 1977. The percentages in brackets represent the percent of initial population screened.

in the RC group. The other 36 patients had either no cost or effect data and were excluded from further analysis.

#### Screening Costs

The cost of individual screening items is outlined in table 2. The total screening cost was \$102,009; the cost per study participant, \$223; and the cost per employee with elevated BP after two BP screenings, \$120. Personnel and participants' costs were the two largest expenses, accounting for 86.1% of the total expense.

TABLE 1. Comparability of Worksite Care (WS) and Regular Care (RC) Participants at Entry by Selected Characteristics

Patient data	WS	RC
No.	232	225
Age (mean yr)	46.8	46.3
Systolic BP (mean mm Hg)	152.9	153.9
Diastolic BP (mean mm Hg)	100.3	100.4
Male (%)	80.6	76.9
White (%)	88.0	88.0
Known hypertension (%)	37.9	38.7
BP measured in past year (%)	52.6	54.2

BP indicates blood pressure.

#### Treatment Costs

##### Health System Cost

Table 3 summarizes the health system cost of care of the two programs. As expected, the mean government insurance expense was higher in the RC group, being  $\$76.03 \pm 3.19$  compared to  $\$58.17 \pm 2.92$  in the WS group ( $p < 0.001$ ). The WS expense included both the cost of laboratory tests ordered by the WS care team as well as the cost of any care for hypertension received from community physicians during the study period. Although 37.5% of WS patients including study dropouts made physician visits, the frequency of their visits was substantially lower (2.9 per annum compared to 5.7 in the RC group;  $p < 0.001$ ). The mean cost of the nursing service alone was  $\$67.38 \pm 1.29$ . The frequency of visits to the nurse was 8.6 per annum, being significantly higher than the number of physician visits in the RC group ( $p < 0.001$ ).

There were four admissions to hospital for hypertensive evaluation and management in the RC group, and the mean health system cost was  $\$1,080.71 \pm 280.62$ . No WS patients were admitted to hospital for diagnostic assessment and treatment.

Significantly more WS than RC participants were on drug therapy at some point during the study (205 vs 145,  $p < 0.001$ ). Moreover, 55.8% of those on drugs in the WS group, compared with 14.9% in the RC group, were on more than one type of antihypertensive medication ( $p < 0.001$ ). Of those with complete data, the mean drug cost in the WS group was significantly higher ( $\$87.34 \pm 7.16$  compared to  $\$51.01 \pm 5.24$  in the RC group,  $p < 0.001$ ), reflecting the more frequent initiation of efficacious therapy and the more vigorous application of this treatment.

The total health system cost of hypertensive care provided by the WS care team was  $\$197.36 \pm 4.99$  compared to  $\$129.33 \pm 13.34$  by community physicians, a difference that was significant ( $p < 0.001$ ).

##### Patient Cost

As shown in table 3, the average patient cost for physician visits in the RC group was  $\$65.57 \pm 4.84$ , which was significantly higher than the comparable cost of  $\$38.71 \pm 10.54$  in the WS group ( $p < 0.03$ ). The difference was due to more frequent physician visits by RC participants. The average patient cost to visit the laboratory was not significantly different in the two groups, with the WS group cost being  $\$37.40 \pm 18.24$ , and the RC group,  $\$26.67 \pm 4.88$ . The monetary value of the loss of time from work to visit the nurse was  $\$24.09 \pm 0.92$  per employee and, for the four RC participants to be evaluated in hospital,  $\$372.25 \pm 91.65$  per patient. The total patient cost was  $\$45.50 \pm 3.23$  in the WS group and  $\$82.00 \pm 6.20$  in the RC group ( $p < 0.01$ ).

##### Total Cost

Using treatment costs only, we found that the average total cost of the WS program was  $\$242.86 \pm 6.94$  per participant, which was not significantly



## WORKSITE TREATMENT PROGRAM/Logan et al.

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TABLE 2. Cost of the Screening Program

Item variable	Cost (\$)
Personnel	41,139
Equipment/supplies	898
Travel	490
Participants' time	46,724
Administration	12,758
Total screening cost	102,009

different from the cost of  $\$211.34 \pm 18.66$  for RC. When screening costs were added to the treatment costs, the difference in cost of medical care between the groups was still not significant.

## Effect

The mean reduction in diastolic BP, the measure of effectiveness, was  $12.1 \pm 0.6$  mm Hg in the WS group and  $6.5 \pm 0.6$  mm Hg in the RC group ( $p < 0.001$ ).

## Cost-Effectiveness Analysis

The C/E ratios of the WS and RC programs using treatment costs only were  $\$20.07$  and  $\$32.51$  per mm

Hg respectively (table 4 and fig. 2). When screening costs were also included, the C/E ratios were higher (WS,  $\$38.50$  per mm Hg; RC,  $\$66.82$  per mm Hg). The WS program, although more costly by  $\$31.52$  per patient per year, was able to achieve an additional mean reduction in diastolic BP of 5.6 mm Hg. Thus, the incremental cost of lowering BP in the WS program, that is, the cost over and above RC, was a  $\$5.63$  per mm Hg reduction. Because this is substantially less than the cost of lowering BP in the RC group (at  $\$32.51$  per mm Hg reduction), the WS program was highly cost-effective by comparison. If conventional treatment of hypertension (RC) is considered worthwhile, it is clearly more cost-effective to replace RC with WS treatment for the target group identified in this study.

## Assessment of Incomplete Data

Data for the travel and time part of visits to the physician's office were complete for significantly more patients in the RC group than in the WS group (50.3% vs 33.3% respectively,  $p < 0.025$ ). No significant differences in completeness existed for drug cost or the patient cost to visit the laboratory. All other data were available for more than 85% of patients in both groups.

TABLE 3. Cost of Medical Care Per Patient for WS and RC, Total and Patients With Complete Data

Cost variable (\$)	Worksite	Regular care	Significance (p)
Total patients:	<del>6-5</del> 12-1	6-5	5-6
Health system cost			
Total	197.36 $\pm$ 4.99 (214; 100%)*	129.33 $\pm$ 13.34 (297; 100%)*	0.001
Patient cost			
Total	45.50 $\pm$ 3.23 (214; 100%)*	82.00 $\pm$ 5.20 (207; 100%)*	0.01
Patients with complete data	4-5 21-6	211-32	3-4 11-5
Health system cost:			
Government insurance	58.17 $\pm$ 2.92 (214; 100%)*	76.03 $\pm$ 3.19 (207; 100%)*	0.001
Drugs	87.34 $\pm$ 7.16 (75; 37%)*	51.01 $\pm$ 5.24 (64; 44%)*	0.001
Nurse	67.38 $\pm$ 1.29 (211; 99%)*		
Hospital		1030.71 $\pm$ 250.52 (4; 100%)*	
Patient cost:			
Visiting doctor	38.71 $\pm$ 10.54 (26; 33%)*	65.57 $\pm$ 4.84 (95; 50%)*	0.03
Visiting laboratory	37.40 $\pm$ 18.24 (22; 25%)*	25.67 $\pm$ 4.48 (29; 22%)*	0.53
Visiting nurse	24.09 $\pm$ 0.92 (184; 86%)*		
Hospital		372.25 $\pm$ 91.65 (4; 100%)*	

WS indicates work site care; and RC, regular care.

\*Figures in parentheses are the number of participants for whom data are available used in calculating the mean  $\pm$  SEM and the percentage for whom the item is applicable. For example, for government insurance, complete information was available on all 214 WS patients, whereas for drugs, complete information on expenditures was available on 75 WS patients who represented 37% of those for whom drugs were prescribed.



TABLE 4. Cost-Effectiveness Analysis of Worksite (WS) and Regular Care (RC) Programs

Cost-effectiveness	WS	RC	WS-RC
Cost (\$)			
Treatment costs	242.86	211.34	31.52
Treatment & screening costs	465.86	434.34	31.52
Effect (mm Hg)			
Reduction in diastolic BP	12.1	6.5	5.6
Cost-effectiveness ratio (\$/mm Hg)			
With treatment costs only	20.07	32.51	5.63
With treatment & screening costs	38.50	66.82	5.63

Patients with incomplete data did not differ from patients with complete data in terms of entry BP, year-end BP, change in BP over the study year, or medication compliance.

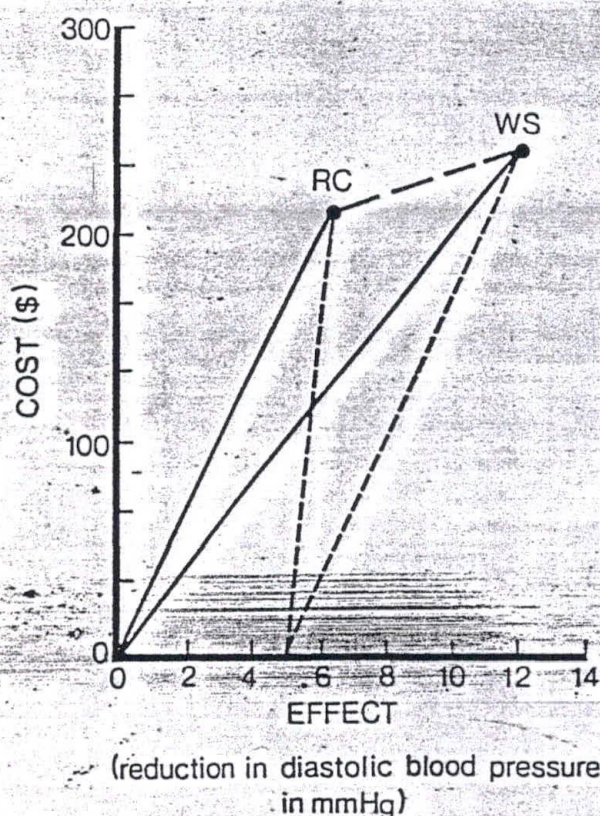


FIGURE 2. Cost-effectiveness graph. The points represent the treatment cost and effect of each program. If it is assumed that each group's average blood pressure (BP) would be unchanged in the absence of identification, the slopes of the solid lines represent the cost-effectiveness (C/E) of each program. The intervention for which the slope is steepest is the most costly for the effect. Under the assumption that diastolic BP would fall by 5 mm Hg in 1 year without any expenditure, the slopes of the small-dashed lines represent the C/E ratio of each program. The incremental C/E ratio is given by the slope of the large-dashed line connecting the RC and WS points. (WS, indicates worksite; RC, regular care).

### Sensitivity Analysis

The health system, patient and total costs were recalculated using maximum cost for missing individual items for the WS group and minimum cost for the RC group (table 5). The incremental C/E ratio was still less than the C/E ratio for RC.

### Discussion

We have shown that treatment of employed hypertensives at their place of work is both more effective and more cost-effective than usual care in the community.

The C/E ratios for the WS and RC groups were calculated in each case under the assumption that the effect was entirely caused by the treatment program. This supposes that if the two patient groups had not been identified and treated, the group's average BP would be unchanged after 1 year. In the absence of a third "no treatment" control group, this assumption cannot be tested. In the report of the Medical Research Council Working Party on mild-to-moderate hypertension, however, control subjects taking inert tablets or only under observation had approximately a 5 mm Hg fall in their diastolic BP 1 year after entry, which was attributed to familiarity with the measurement procedure and regression toward the mean of the BP in the general population.<sup>14</sup> To test the effect of such a change, we recalculated the C/E ratios after subtracting 5 mm Hg from the effect, and found that patients receiving RC had little BP reduction (table 6 and fig. 2). The WS group, on the other hand, continued to experience a substantial effect beyond the estimated natural reduction in BP.

The health system cost of the WS program was significantly higher than RC. This was related primarily to the use of more medication by the WS care team to control hypertension and the cost of parallel care from community physicians. The latter expense appeared to reflect some initial ambivalence of WS patients to participate in a work-based program without some collaboration from their physician. However, the infrequency of physician visits and the low dropout rate in the WS group suggested good patient acceptance of the medical care provided at the work place.



TABLE 5. Sensitivity Analysis of Worksite (WS) and Regular Care (RC) Programs

Cost	WS	RC	WS-RC *
Health system cost (\$)	\$249.44	\$130.51	\$118.83
Patient cost (\$)	74.81	55.22	19.59
Total cost (\$)	324.24	185.73	138.40
C/E treatment costs only (\$/mm Hg)	26.80	28.59	24.71
C/E treatment & screening costs (\$/mm Hg)	45.23	62.90	24.71

C/E indicates cost-effectiveness.

The major cost saving of the WS program was the reduction in patient cost, while the health system cost of this program was more expensive. Up to this point we have assumed that patient and health system costs are of equal value. It may be argued, however, that the former should be valued at some fraction of the latter. The effect of using different fractions of patient cost in both groups on C/E ratios is illustrated in figure 3. Even if patient cost is completely ignored (fraction of patient cost = 0) and as a consequence the health system cost becomes the total cost, the WS program is still more cost-effective since the C/E ratio for RC, while falling to \$19.90 per mm Hg, continues to be higher than the incremental C/E ratio of \$12.15 per mm Hg.

While all hypertensive care in the WS program was given on company time, in the RC group visits to the doctor may have been made either on company or leisure time. Because time away from work is not closely monitored in the white collar companies that participated in this study, it was not possible to quantitate this cost. In our cost calculations, equal value was assigned to the time lost from work in the WS group and from work or leisure in the RC group. Since loss of leisure time may not represent a cost to society (no effect on worker productivity), it may be argued that patient cost in the RC group should be valued at some fraction of the patient cost in the WS group. Using different fractions of patient cost for the RC program only, we found that the incremental C/E ratio for the WS program was less than the C/E ratio for RC until the fraction of patient cost was 0.01. We know, however, from the year-end questionnaire that 51.7% of RC patients (roughly equivalent to a fraction of patient cost = 0.52) stated that they took time off work to visit their physician. Moreover, since this time often appeared to be in excess of the actual time required to obtain medical care, the assignment of

equal value to patient cost in both groups is not an unreasonable assumption.

Use of the work setting to manage hypertension has many advantages. First it facilitates access to care for a population for whom usual care in the community

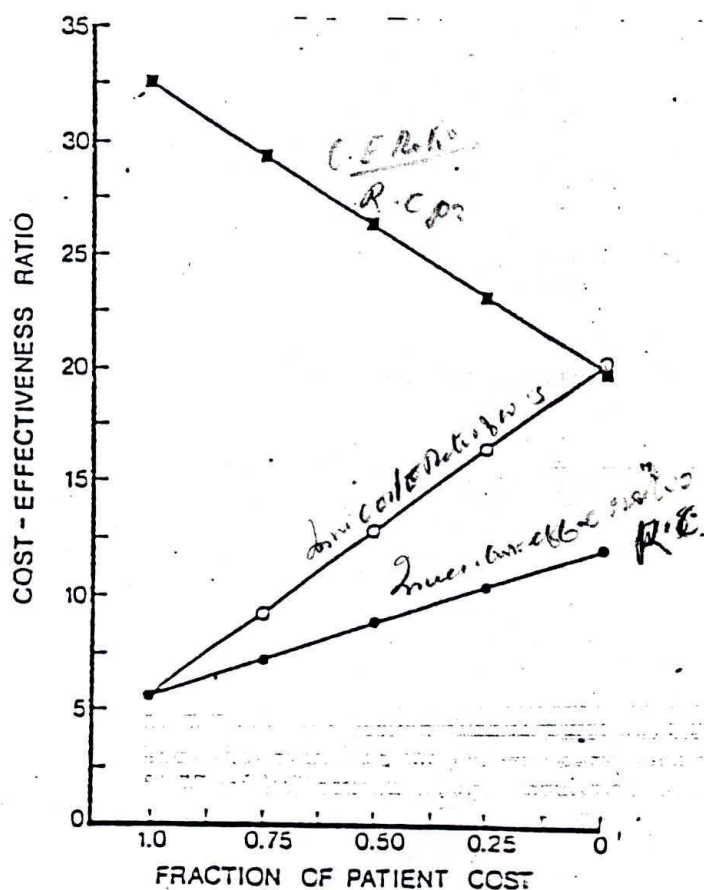


FIGURE 3. Use of fraction of patient cost (FPC) in computing cost-effectiveness (C/E) ratios. The effect on incremental C/E ratio for the worksite care (WS) program is shown under differing assumptions of FPC. While health system and patient costs may be of equal value (FPC = 1), patient cost may also be valued at some fraction of the health system cost. For all FPC values, the incremental C/E ratio (closed circles) is less than the C/E ratio for RC program (closed squares). While equal value was assigned for patient cost in the two groups (FPC = 1), based on different assumptions the patient cost in the RC group may be some fraction of that in the WS group. The incremental C/E ratio for the WS program (open circles) is less than the C/E ratio for RC (closed squares) until the FPC is 0.01.

TABLE 6. Cost-effectiveness Analysis of Worksite (WS) and Regular Care (RC) Programs Assuming 5 mm Hg Reduction in Diastolic Blood Pressure with no Treatment

Cost-effectiveness	WS	RC	WS-RC
Treatment cost (\$)	242.86	211.34	31.52
Effect (mm Hg)*	7.1	1.5	5.6
Cost-effectiveness (\$/mm Hg)	34.21	140.89	5.63

\*Subtraction of 5 mm Hg from the observed change in diastolic blood pressure in the WS and RC programs.



may be inconvenient. Over a third of the participants at entry were previously aware of having hypertension, and almost one-half had not had a BP measurement for more than 1 year. Second, the population reached at the worksite is primarily middle-aged men in whom the risk of adverse consequences of hypertension is large and the benefit of therapy is more likely to be high.<sup>13</sup> Third, as we have shown here, it is a cost-effective alternative to primary-care practice for the treatment of hypertension. Finally, health care facilities are already available in most places of work with 200 or more employees (in Ontario this is mandatory), which eliminates the need for high capital expense to develop worksite hypertension care programs.

The economic impact of cardiovascular and cerebrovascular disease is enormous, ranking fourth as a cause of sick leave absenteeism among male employees in a heavy industry plant in Ontario.<sup>14</sup> In the same study, the mean work days absent per sick leave episode was much higher for this disease group than for all other diagnostic categories, and vascular deaths accounted for almost half of the total mortality among male employees during the assessment period. Since hypertension is a major independent risk factor for cardiovascular and cerebrovascular disease in the adult<sup>17-20</sup> and antihypertensive drug treatment will reduce morbidity and mortality from hypertension,<sup>11, 12, 21-23</sup> effective industrial hypertension control programs have great potential for improving productivity and/or reducing costs associated with absenteeism or premature death for those employees with asymptomatic, uncontrolled hypertension.

From a policy perspective, decision makers may take into account any or all of the following objectives: 1) to spend the limited resources available for hypertension screening and treatment in a way that will maximize the average BP reduction; 2) to identify and reduce the BP of hypertensive patients by a specified amount as economically as possible; and 3) to maximize the BP reduction per patient. In each instance, the worksite program is more advantageous. Thus, for the target group identified in this study our findings support health policies that favor allocating resources to work-based hypertension treatment programs.

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# Randomised Controlled Study of Chloramphenicol vs Ofloxacin in the Treatment of Enteric Fever : A Pharmacoeconomic Analysis

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## INTRODUCTION

Globally, each year, 13.5 million persons are affected by typhoid fever. It remains a serious health issue in the developing world and is a major reason for hospitalisation. The traditional treatment with chloramphenicol is long, usually given for 2-3 weeks, is associated with relapses and exposes the patient to needless toxicity. Besides these, the causative organisms, *Salmonella typhi* and *Salmonella paratyphi*, exhibit varying degrees of resistance 20%-74% in different areas.<sup>1-3</sup>

Therefore, an effective alternative choice would be beneficial. Ciprofloxacin, a fluoroquinolone, is given orally, 500 mg twice daily for 14 days<sup>4</sup> or 750 mg twice daily for 7 days.<sup>5</sup> It is a safe, bactericidal drug and has an efficacy of 90% to 100% in the treatment of typhoid fever.<sup>4</sup> In an open non-randomised trial we have shown that pefloxacin is safe, curing effectively 25 of 25 culture positive cases of *S. typhi* at doses of 400 mg administered twice daily for periods of 5-7 days.<sup>6</sup> Ofloxacin, another quinolone could be an ideal choice for the treatment of typhoid fever as it concentrates well in tissues, especially in the biliary tree, and also within macrophages and needs to be given orally only once a day as it has excellent bioavailability.<sup>7,8</sup>

Moreover, the need to deliver health care efficiently in the developing world has made economic evaluation of care a major consideration. The costs of health care are largely supported by the national health plan and/or by the individual payer. Thus, cost-containment and effective therapy with newer but more expensive drugs need to be addressed. We therefore conducted a prospective, randomised, controlled trial to study the safety and efficacy of ofloxacin in comparison with chloramphenicol, in the treatment of

acute uncomplicated typhoid fever occurring among adults and hospitalised at a large, referral, teaching centre. A pharmacoeconomic analysis, from the purchaser's perspective, of the choice of the higher priced drug ofloxacin, against the less expensive drug chloramphenicol was done, and we developed a clinical decision analysis model for physicians to determine the choice of initial therapy using either drug.

## MATERIAL AND METHODS

### Study patients

Adults patients (> 16 years) with fever of over 5 days, clinically resembling enteric fever, (seen between March 1991 and December 1992) were enrolled in the study after obtaining informed consent. They were admitted in the hospital and randomised to receive either chloramphenicol (CHLORO) 500 mg six hourly for 10 days (Group-I), or ofloxacin (OFX) 400 mg once daily for 10 days (Group-II). Blood culture, blood smear examination for malarial parasites and microfilaria, and urinalysis for pus cells were done on all patients. Only those with *S. typhi* or *S. paratyphi* A isolated in blood culture were continued in the study. Pregnant or lactating women, those known to have allergy to nalidixic acid, subjects with serum bilirubin > 3 mg%, SGOT or SGPT > 120 U/L, creatinine > 2mg%, concomitant infection requiring other antibiotics, gastrointestinal bleeding, intestinal perforation or encephalopathy and those requiring parenteral therapy were excluded from the study. The study protocol was approved by the research review board of the institution.

The sample size was calculated based on bacterial clearance rates after 48 hours. In the first assumption, clearance with ofloxacin was 80% and chloramphenicol 60%; and in the second assumption, clearance with ofloxacin was 95% and with chloramphenicol remaining at 60%. Therefore, it was estimated that for fulfilling the first assumption, 91 cases in each arm was needed and for the second assumption, 27 in each arm, would be required to prove a significant difference with a type I error (alpha) of 5% and the power of the test being 80%.

The randomization was done by computer generated random number. The blinding was not done as the outcome chosen was clearance of organism noted by microbiologist at the end of 48 hours. The time of defervescence was noted by the nursing staff not involved in the study.

### Microbiological techniques

Five ml of blood was inoculated into each of biphasic infusion

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medium, MacConkey biphasic medium and brain-heart infusion broth, which were incubated at 35°C. Any organism grown was subcultured on MacConkey and blood agar plates and identified using standard techniques. Antibiotic susceptibility was tested by the disc diffusion method of Kirby and Bauer using the newer interpretation chart. The minimum inhibitory concentration (MIC) was determined by agar dilution method using Mueller-Hinton agar with 18-24 hours incubation in air and with an inoculum of 10<sup>5</sup> organisms/ml. Serum levels of ofloxacin were determined by a bioassay using *Pseudomonas aeruginosa* ATCC 27853 as the test organism.<sup>9</sup>

The stool sample was directly inoculated onto plates of xylose-lysine-desoxycholate agar, desoxycholate-citrate agar and MacConkey agar. In addition, about 1-2 ml of liquid fecal suspension or about 1 gm of solid fecal matter was inoculated into a tube containing selenite F enrichment broth. The latter was subcultured on MacConkey agar and *Salmonella*-*Shigella* agar.

#### Patient Monitoring and Follow-up

Ofloxacin, (Tarivid 200 mg : Hoechst) (OFX) 400 mg, was given orally once a day or chloramphenicol (Chloromycetin : Parke Davis each cap. 500 mg every 6 hours) for 10 days. Oral temperature was measured every 6 hours. Defervescence of fever was defined as achieving temperature not > 99.5° over a 24 hours period. The hematocrit, leucocyte count, platelet count and measurement of serum creatinine, bilirubin, SGOT, SGPT, albumin, globulin and alkaline phosphatase were done on admission and prior to discharge. Blood cultures were drawn on day 1,2 and 3. Stool culture was done on day 7, and at least once during the follow up period. The patients were followed up through hospital visits, letters and house visits. Where stool samples were collected from patients in their homes, phosphate buffered glycerol saline was used to preserve viability of salmonellae.

After giving at least four doses of ofloxacin or chloramphenicol, serum levels of the drugs were determined. Blood for drug assay was drawn 30 minutes after an oral dose (for peak level) and 30 minutes before the next oral dose (for trough level).

#### Statistical Analysis

Qualitative parameters were tested by Fisher's exact test and quantitative parameters by Mann-Whitney test.

#### Economic analysis:<sup>9-12</sup>

The following direct medical costs were considered.

Drug cost referred to approximate retail costs of chloramphenicol, (Chloromycetin: Parke Davis) Rs. 2.50 per 500 mgm capsule. Ofloxacin (Tarivid : Hoechst) Rs. 46 per 400 mg tablet.

Cost of antipyretics : Paracetamol Rs. 2 per day.

Standard hospital bed charge at Rs. 50 per day.

Cost of blood culture and sensitivity testing Rs. 200/-

Perspective of analysis was that of the individual being the payer. The indirect cost of morbidity and mortality was not assessed.

Sensitivity analysis, both one way and two way of the assumptions to varying susceptibility of the organism to the drug and cost of hospital stay was done.

#### RESULTS

Sixty-four patients were randomised; 32 received chloramphenicol (Chloro) (Group-I) and 32 received ofloxacin (OFX) (Group-II) Table 1 shows the baseline characteristics of the patients at randomization.

Table 1 : Baseline characteristics of the patients at randomisation

	OFX Group n=32	CHLORO Group n=32
Duration of illness prior to hospitalisation (Mean ± SD)	12.27 (± 8.1)	12.00 (± 8.1)
Male	22 (68.8%)	20 (62.5%)
Age (Mean ± SD)	31.91 (± 2.2)	27.47 (± 11.3)
Body mass index (Mean ± SD)	18.81 (± 3.3)	18.91 (± 2.2)
Weight, kg (Mean ± SD)	51.03 (± 9.8)	48.53 (± 8.4)
Height, cm (Mean ± SD)	164.17 (± 8.1)	159.73 (± 8.2)

Fifty-five were culture positive; *Salmonella typhi* in 47, and *Salmonella paratyphi* A, in 8. There were 28 patients in Group-I and 27 in group-II. In Group-I, 18 patients had in vitro resistance to chloramphenicol detected after randomisation, and as blood culture remained positive, 16 were switched to receive ofloxacin, 1 continued to receive chloramphenicol and 1 dropped out. Four (2 in each group) did not complete the period of observation in hospital and were excluded from the analysis, which had 10 patients in Group-I and 41 in Group-II (Table 2).

Table 2 : Summary of patients enrolled, culture-positive and culture-negative cases, changes to alternative study medication and dropouts/withdrawals

	Chloramphenicol (CHLORO) Group-I	Ofloxacin (OFX) Group-II	Total
Patients enrolled at randomisation	32	32	64
Culture-negative cases (withdrawn)	5	4	9
Total culture-positive cases	27	28	55
In-vitro resistance to study drugs	18	0	(1 patient clinically improved and was thus continued in the same group despite in vitro resistance)
Switched from CHLORO group to receive study drug	0	16	
*Subtotal	11	44	
Withdrawals:			
- discharged against medical advice	1	2	
- non-study antibiotic therapy during trial	0	1	
*Total	10	41	51

Despite 1:1 randomisation, the imbalance in the patient numbers was due to in vitro resistance seen in 18 of 27 patients assigned to CHLORO, 16 of whom were switched to OFX. For costing purposes the 27 and 28 patients originally allocated to the CHLORO and OFX study arms, respectively, were considered.

Eleven patients had received ampicillin, chloramphenicol or co-trimoxazole prior to hospitalisation but they were included in the study, as organism could still be isolated from blood.

The time required for defervescence of fever, was shorter among patients who received ofloxacin (81.95 ± 36.39 hrs) com-



pared to those who received chloramphenicol ( $125.33 \pm 56.00$  hrs)  $p = 0.05$ . Thirty one patients (76.61%) who received ofloxacin had defervescence of fever by day 5, as compared to 2 (20%) patients who received chloramphenicol, ( $p < 0.05$ ) (Table 3).

Table 3 : Response to therapy

Clinical parameter	CHLORO n=10	OFX n=41	P value
Defervescence by day 5, n (%)	2 (20%)	31 (75.6%)	$p = 0.001$
Mean time to defervescence, $\pm$ SD in hours	125.33 ( $\pm 56$ )	81.95 ( $\pm 36.69$ )	$p = 0.005$
Mean no. of signs and symp. by day 4	1.80 ( $\pm 1.1$ )	0.59 ( $\pm 1.3$ )	$p = 0.02$

#### Micro-organisms

All 55 isolates (100%) were susceptible to ofloxacin whereas 17 (31%) were susceptible to chloramphenicol, 21 (38%) to cotrimoxazole and 25 (45%) to ampicillin (Table 4). In the Chloro arm of study 18/27 (66%) was resistant to chloramphenicol. In the ofloxacin arm there was no resistance. The difference was significant  $p = < 0.0002$ .

Table 4 : Microbiology-antibiogram of blood isolates  
Number susceptible (at baseline)

Study group	Organism isolated	Ofloxacin	Chloramphenicol	Cotrimoxazole	Ampicillin
OFX (n=28)	<i>S. typhi</i> (24)	24	4	7	8
	<i>S. paratyphi</i> (4)	4	4	4	4
CHLORO (n=27)	<i>S. typhi</i> (23)	23	5	6	9
	<i>S. paratyphi</i> (4)	4	4	4	4
Total	55	55 (100%)	17 (31%)	21 (38%)	25 (45%)

Minimum inhibitory concentration (MIC) of ofloxacin and chloramphenicol were estimated for 36 strains of *S. typhi* and 6 strains of *S. paratyphi* (Table 5). Peak and trough serum levels were estimated for both drugs (Table 6).

Table 5 : MIC of ofloxacin and chloramphenicol

		OFX $\mu\text{g}/\text{ml}$	CHLORO $\mu\text{g}/\text{ml}$
<i>S. typhi</i>	(Range)	0.015-0.62	1.87-240
	(Mean)	$0.016 \pm 0.01$	$157.7 \pm 97.7$
<i>S. paratyphi</i>	(Range)	0.07-0.62	1.87-240
	(Mean)	$0.24 \pm 0.18$	$42.9 \pm 96.9$

Table 6 : Serum drug levels

		Drug level $\mu\text{g}/\text{ml}$	
		Peak	Trough
Ofloxacin	Range	0.124-31.74	0.124-1.98
	Mean	$5.05 \pm 7.37$	$0.99 \pm 0.62$
Chloramphenicol	Range	15-240	0.248-15
	Mean	$64 \pm 52.6$	$5.6 \pm 6.9$

#### Side effects

Two patients who received ofloxacin complained of nausea and vomiting. There were no untoward effects reported in the Chloro group. In the OFX group one patient developed perforation of the bowel for which she was operated.

#### Follow-up

All 64 patients were followed up for safety parameters. Forty four of the evaluable patients were followed up for 14-32 weeks (mean  $14 \pm 12.6$ ) after discharge from the hospital, and stool samples collected after cessation of therapy were negative for enteric pathogens.

#### Economic analysis

The details of the costing based on typical case treated by each arm of the study is given in Table 7. The average cost per case cured in the chloramphenicol arm is Rs. 1163/- while the average cost in ofloxacin arm is Rs. 964/-. The incremental cost for treating one case by chloramphenicol and subsequently switching over to ofloxacin is Rs. 199/- per case cured with the assumption of bed cost being Rs. 50/- and 67% showing resistance to chloramphenicol with the extra hospitalization of 15 days each.

The robustness of these assumptions were further tested using one-way sensitivity analysis by changing drug resistance to chloramphenicol (Ref. Fig. 1). At 40% drug resistance the cost exceeds Rs. 964/- which is the mean cost fixed for treatment with ofloxacin. Thus if there is more than 40% resistance to chloramphenicol, use of ofloxacin is justified. In Fig. 2 a two way sensitivity analysis is done by changing the drug cost and degree of resistance to chloramphenicol. If the bed cost is Rs. 200/- even a resistance level of 20% to chloramphenicol will justify the choice of ofloxacin.

The only untoward effect observed with ofloxacin was nausea which occurred in 2 patients. Perforation of bowel was more likely to be a complication of the disease as it occurred on day 1 and with discontinuation of the drug ofloxacin. It needed to be included for documentation of untoward effect and as this was not attributable directly to a side effect of the drug, it was not costed in the ofloxacin arm.

## DISCUSSION

Ofloxacin given for 10 days in doses of 400 mg once daily was successful in treating all the 41 patients with typhoid and paratyphoid fever. Ofloxacin also produced more rapid defervescence of fever compared to chloramphenicol. There were no relapses and none became chronic carriers during the follow-up period. Ofloxacin also cured the acute infection in the 8 patients with paratyphoid fever.

The MIC 90 of the isolates *S. typhi* and *S. paratyphi* obtained ranged from  $0.016 \pm 0.01$  mcg/ml (range 0.015 - 0.62 mcg/ml). The mean serum levels of ofloxacin,  $5.05 \pm 7.37$  mcg/ml (peak) and  $0.99 \pm 0.62$  mcg/ml (trough), seen among patients were several folds greater than the MIC of *S. typhi* or *S. paratyphi* A (Table 6).

Serum levels of the drug achieved in our patients, even at the trough levels, were at least 15 times more



Table 7: Costing of the clinical trial (in Indian rupees)

	CHLORO (n=27)				OFX (n=28)			
	Days	No.	Rs.	Total Rs.	Days	No.	Rs.	Total Rs.
Number sensitive			9				28	
Cost of antibiotic:								
Duration treated		10				10		46
Cost for one day				10				46 =
Total cost	(A)	10 x	9 x	10 =	900	10 x	28 x	12,880
Number resistant			18				0	
Extra cost of CHLORO	(B)	2 x	18 x	10 =	360			00
Extra cost of OFX to treat resistant cases	(C)	10 x	18 x	46 =	8,280			00
Cost of antipyretics:								
Duration in days		5				2		2
Cost per day				2				2 =
Total cost	(D)	5 x	27 x	2 =	270	2 x	28 x	112
Cost for culture and sensitivity tests for resistant cases:								
Cost per culture and sensitivity				200				
Cost per 18 cultures	(E)		18 x	200 =	3,600			
Cost of hospitalization:								
Hospital charge per day				50				50
Hospital charge for drug-sensitive cases	(F)	10 x	9 x	50 =	4,500	10 x	28 x	50 =
Hospital charge for CHLORO resistant cases	(G)	15 x	18 x	50 =	13,500			
Total (A+B+C+D+E+F+G)					31,410		(A+D+F) =	26,992
Cost per case cured					1,163			964
Extra cost per case on CHLORO					199			

than the MIC of the organism.

We have also confirmed that there is resistance to ampicillin, chloramphenicol and co-trimoxazole with various rates, but all isolates were susceptible to fluoroquinolones.<sup>5,6</sup>

Ofloxacin allows once daily dosing unlike twice daily with ciprofloxacin and its oral dose of 200 mg was equivalent to the oral dose of 500 mg.

All patients needed hospitalisation for 10 days as the study was primarily designed to evaluate efficacy and safety. All of the three quinolones we have studied ciprofloxacin,<sup>5</sup> pefloxacin,<sup>6</sup> and ofloxacin in this study cleared organism from the blood within 24 hours. It is likely that the duration of hospitalisation could be less in the OFX arm as defervescence was achieved sooner. A five day short course of ofloxacin was effective for treatment of multidrug resistant typhoid with such high serum levels of drug being obtained.<sup>15-18</sup>

Indirect costs which include cost of travel, food and

accommodation expenses of attendants when a family member (patient) is hospitalised would account for more than 50% of total expenses but is also excluded as they were common to both. It is also assumed that morbidity and mortality due to multi-drug resistant or drug susceptible strain would be the same, if left untreated. Since typhoid is a self-limiting fever, those likely to respond to chloramphenicol therapy despite demonstrating *in vitro* resistance needs further study. Costs of inefficacy due to non-compliance in taking chloramphenicol, which needs a dosing frequency, of four times daily vs ofloxacin once daily, and the long term costs of changes upon the intestinal microflora and the ecological problem related to the inappropriate use of the drug ofloxacin where chloramphenicol would have sufficed was not addressed.

Typhoid fever occurs in populations subject to high unemployment and the effect on productivity of this intervention cannot be calculated as it is assumed that an individual who is absent from work can easily be replaced. Changes in man-days gained or lost due to



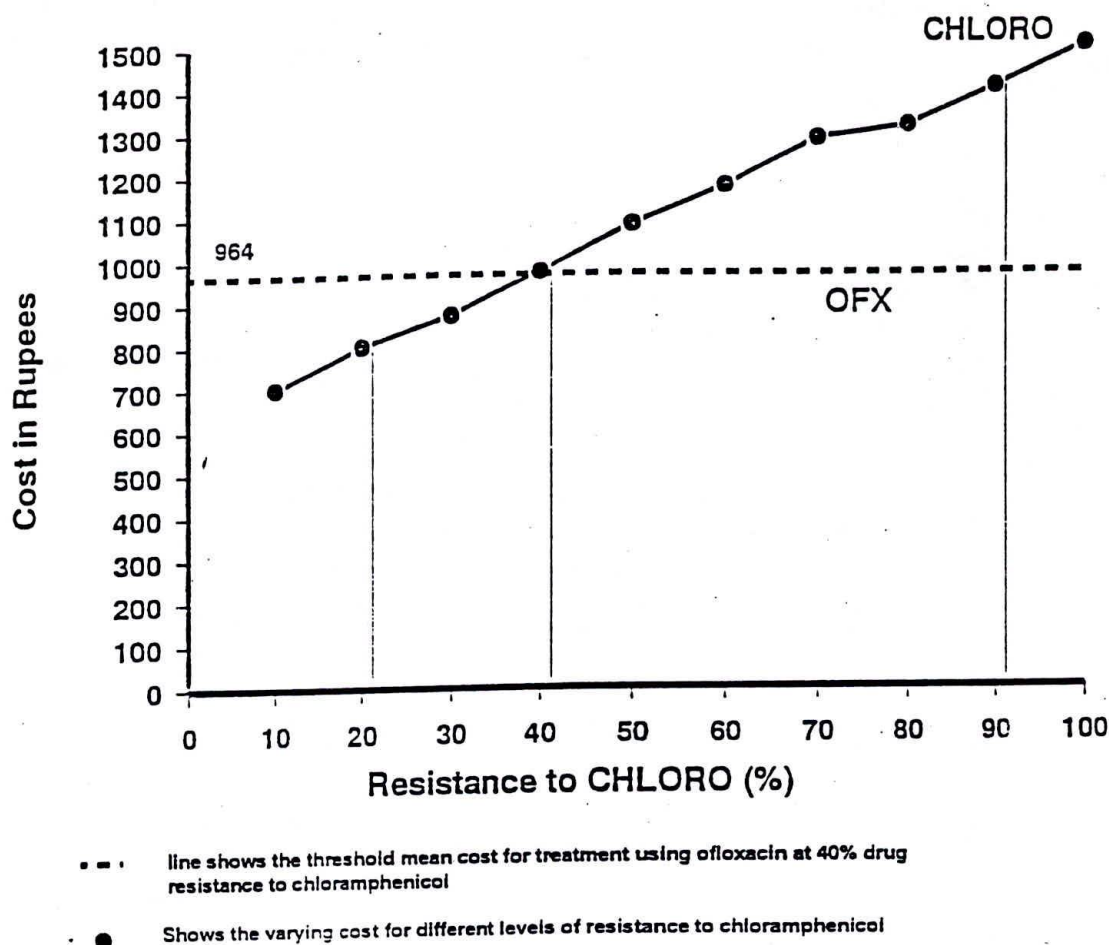


Fig. 1: One-way sensitivity analysis showing the costs of ofloxacin and chloramphenicol at different levels of bacterial resistance to chloramphenicol and at a hospital bed cost of Rs. 50 per day.

early or late return to work of patients in either group need to be considered. We could equate the average daily wage of a labourer in India at Rs. 30/- a day.

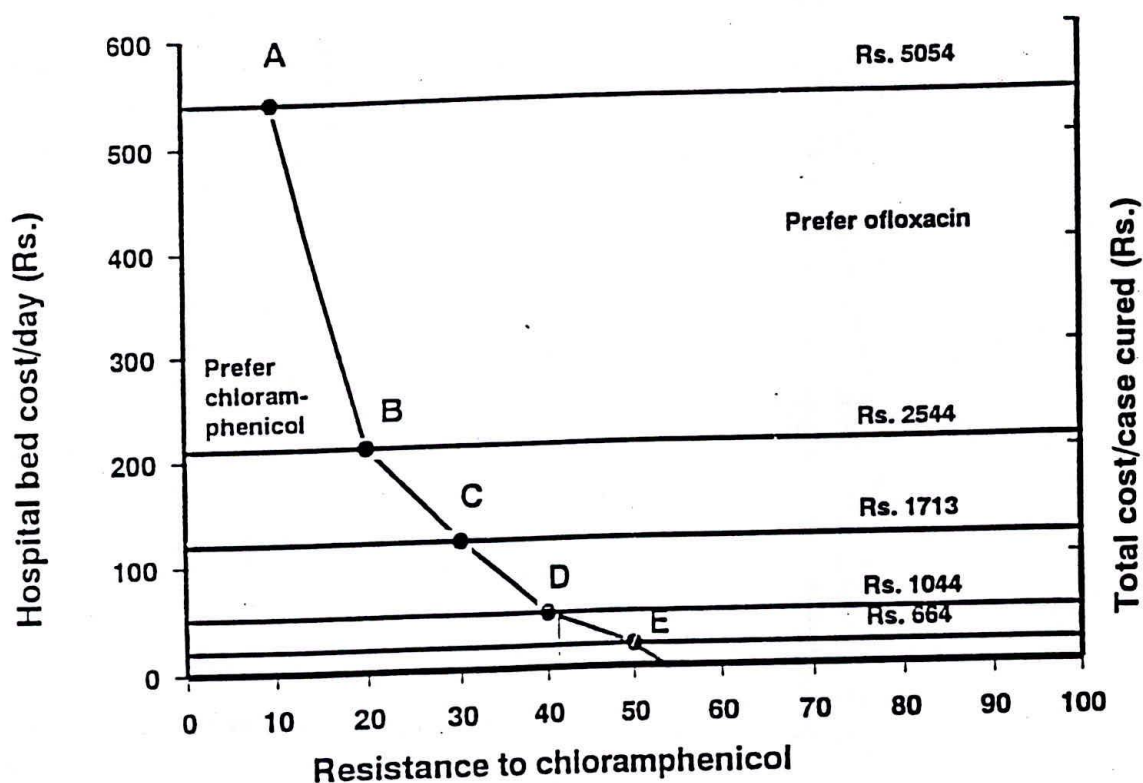
Our conclusions in the pharmacoeconomic analysis relating to such broad variable factors as the, susceptibility of the organism and drug costs related to treatment.

This study indicates that initial drug costs alone should not be the basis of choice of drugs. The cost effectiveness assessed with this reduction of 43.34 hr (i.e. 2 days) in defervescence time among those treated with OFX, translated into lower overall costs despite the drug ofloxacin, being 4.5 times more priced than chloramphenicol (Table 3).

In view of the recently emerging multi-drug resistant strains of *S. typhi* in India.<sup>1-3</sup> It is important to make every attempt to establish the diagnosis by blood culture and determine the antibiotic susceptibility pattern of all isolates. The choice of the drug to be used,

should be guided by these results or based upon epidemiological studies of drug resistance. This cost would need to be added to the chloramphenicol group as susceptibility studies need not be done among those receiving ofloxacin as quinolone resistant strains have not been reported from India. An extra total cost of Rs. 199/- for the Chloro group with the prevailing resistance of 69% to chloramphenicol makes justification for replacing chloramphenicol with ofloxacin at a hospital bed cost of Rs. 50/- a day. At any hospital cost less than Rs. 20/- a day, at 50% prevailing drug resistance to chloramphenicol (point E Fig. 2), the use of ofloxacin becomes as cost effective as chloramphenicol. The only untoward effect observed with ofloxacin was nausea which occurred in 2 patients. Perforation of bowel was more likely to be a complication of the disease as it occurred on day 1 and with discontinuation of the drug ofloxacin. It needed to be included for documentation of untoward effect and as this was not attributable directly to a side effect





● Points A B C D and E show the threshold points of total cost according to changing cost of hospitalization and resistance to chloramphenicol

Fig. 2 : Two-way sensitivity analysis showing the effect on variation in cost per case cured by changing the levels of chloramphenicol resistance and hospital costs.

of the drug, it was not costed in the ofloxacin arm. If the costs of toxicity of chloramphenicol, fatal pancytopenia (1 in 50,000), poor compliance, potential for relapse (4%), carrier state following treatment (3%) and complications are calculated, there would be further savings using ofloxacin, as a quinolone is the drug of choice for all of these clinical situations. From the view point of both society and the patient as payer, if the other direct and indirect costs are also to be added, it would make chloramphenicol a less attractive option than this newer quinolone ofloxacin to the practising physician in developing countries. Where multi-drug resistance similar to ours may be a problem, we would recommend quinolones as the drug of first choice. Ofloxacin given once a day would ensure better compliance and would ensure total eradication of the organism and particularly the multi-drug resistant strains.

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## ANNOUNCEMENT

**National Asthma Update 99**, organised by **Department of Medicine, SP Medical College, Bikaner** will be held on **2nd and 3rd January 1999** and followed by **Patient's Education Programme** on **4th January 1999**.

Co-sponsors - **Medical Council of India and Bikaner Asthma Care Society.**

For details contact : **Dr. M Sabir**, Organising Secretary, Assoc Prof and Head, Resp Div.,  
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## **Cost-effective footwear for leprosy control programmes: a study in rural Ethiopia**

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**Summary** A randomized, controlled trial of commercially available canvas shoes was carried out in a rural area of Ethiopia. Subjects with deformed and anaesthetic feet, most with ulceration, were given either canvas shoes or plastazote/moulded shoes and followed up for one year. Seventy-five percent of subjects with ulcers who used canvas shoes had no ulcer at the end of the study, while no significant change was noted in the plastazote group. The durability and acceptability of the shoes were also examined. Clients in remote areas who have no access to an orthopaedic workshop, but who have anaesthetic feet, with or without deformity, should have access to canvas shoes with an MCR insole. Two pairs are needed per year at a cost of US\$6-7 per pair.

### **Introduction**

Plantar ulceration is a major complication of leprosy, which can lead to chronic infection, bone destruction, deformity and eventually amputation, often with prolonged periods of hospitalization.<sup>1</sup>

The cause is repeated trauma to a foot rendered anaesthetic by leprosy neuritis,<sup>2</sup> while deformity may exacerbate the problem by causing an abnormal distribution of pressure during normal activities.<sup>3</sup>

It is well known that immobilization alone, which breaks the cycle of repeated trauma, leads to healing of most simple ulcers;<sup>4,5</sup> this process may be augmented by simple wound care.<sup>1</sup> Many programmes, however, find that it is difficult in the long-term to assist people affected by leprosy in keeping themselves ulcer-free.<sup>6</sup> This may be due to lack of knowledge in the care of feet, but is more likely to be due to their socioeconomic status which precludes rest for prolonged or even short periods.

The provision of special footwear can help to overcome this problem by spreading the pressure more evenly over a wider area of the foot, reducing the trauma to specific pressure points. The person can then effect a compromise between normal activity and complete rest, by reduced activity, the use of protective footwear and wound care.<sup>7</sup> While the provision of footwear should be an integral part of any leprosy control programme,<sup>8</sup> it may be very difficult for financial and logistic reasons to make this service available in practice, on a continuing basis.<sup>9,10</sup>



Many leprosy control programmes have developed, or have access to, orthopaedic workshops which produce a range of special shoes, including plastazote shoes and boots, open MCR sandals and more sophisticated custom-made boots. However, there are major problems with special footwear, including:<sup>6,9</sup>

Cosmetic: clients are easily identified as leprosy patients; this means that many do not wear the special shoes much, if at all.

Custom: e.g. shoes may never be worn inside the house (mentioned from Asia).

Occupation: e.g. working in paddy fields (also mentioned from Asia).

Maintenance and repair: most shoes only last 6 months if worn regularly and repairs are difficult to organize efficiently.

Provision in adequate numbers: this is impossible for most programmes, and often only hospitalized patients are served. In other words, the shoes are not used as a preventive measure, until severe damage has already occurred.

Recent studies in China<sup>11,12</sup> using canvas shoes with an MCR insole showed an impressive record of ulcer healing and ulcer prevention. At ALERT, we have used the Chinese canvas shoes but found them to be of very poor durability.

More recently, the Ethiopian Canvas Shoe Factory has been able to produce a shoe deep enough to take an additional MCR insole (shore 15°, thickness 8 mm) and we have started to provide these in our control programme. The major advantages are the high acceptability to clients and the possibility of providing adequate numbers of shoes at short notice.

This study addresses certain important questions regarding the provision of footwear on a routine basis to people affected by leprosy:

- 1 Given the difficulty in supplying moulded sandals in the required numbers, would the provision of canvas shoes to people with deformed feet give acceptable results?
- 2 Can the provision of canvas shoes lead to the healing of existing ulceration, and the prevention of further ulceration, in people with anaesthetic feet (and even deformed feet)?
- 3 How acceptable and durable are the canvas shoes under field conditions?
- 4 How cost-effective are canvas shoes as compared to other methods of managing plantar ulceration in the long-term?

## **Methods**

### **STUDY DESIGN**

A prospective, randomized controlled trial was carried out near Sheshemane, Ethiopia from November 1994 to November 1995.

### **SUBJECTS**

Seventy people affected by leprosy with deformed and anaesthetic feet, who were regularly attending a foot-care clinic, were randomly allocated to receive either canvas shoes or plastazote/moulded sandals; all had been using moulded sandals in the recent past and most had ulcers; verbal consent to take part in the study was obtained.



Randomization was by day of attendance at the clinic. Subjects were examined at the start and subsequently at 2, 4, 6 and 12 months by one of us (GS), together with one of two local supervisors. The majority were farmers living in and around the village of Kuyera.

Health education had been given in the past to these people, but no additional educational measures were taken during this study.

There were two exclusions from the plastazote group (one was admitted to hospital and the other refused to attend for follow-up). Results are reported for 68 subjects.

#### OUTCOME MEASURES

Ulcer size was measured at each visit and the area of ulceration was calculated according to the following formula:  $0.785 \times \text{length} \times \text{width}$ .<sup>13,14</sup> At all follow-up visits, the shoes were examined for wear and tear and the subjects were asked a series of questions concerning the acceptability of the footwear and how helpful they found the shoes in assisting with their foot care.

#### COSTS

The cost of providing both types of footwear was also examined in order to provide a cost-effectiveness analysis (CEA). The canvas shoes were sold at the wholesale price to us, namely US\$6.7 per pair. The true cost of manufacturing the moulded sandals could not be ascertained, but is likely to be more than US\$20 per pair, the materials alone costing US\$12.7 per pair. Distribution costs were not examined.

### Results

#### SAMPLE CHARACTERISTICS ON ENTRY

Table 1 shows the sample characteristics at the start of the study.

#### AREA OF ULCERATION

Figures 1 and 2 show the area of ulceration found at the start and at subsequent follow-up visits, for the plastazote sandal and canvas shoe groups, respectively.

Three of 28 subjects in the plastazote group never had an ulcer during the period of study, so 25 are included in Figure 2. Five subjects who were initially ulcer free, developed ulcers, at least one because the new plastazote shoes did not fit well. Twelve of 40 subjects in the canvas shoe group never had an ulcer during the period of study, so 28 are included in Figure 1. None who were initially ulcer free developed ulcers.

The geometric mean size of ulcers over time for the two groups is shown in Figure 3, with confidence intervals for each value. There is a highly significant difference between the two groups at the end of the study. All ulcers in the canvas shoe group decreased in size (the majority of them healing completely), except in two instances. In one case, the only one in which a large ulcer showed no improvement over the year, a biopsy showed epidermal hyperplasia (requiring surgical excision); in the other case, a new ulcer appeared at the one-year follow-up, said to be due to inexpert trimming of dead skin by the person himself.



Table 1. The characteristics of the two groups at the start of the study. Inversion was said to be present when part of the medial aspect of the sole was not in contact with the ground on standing or walking.

	Control group plastazote shoes	Experimental group canvas shoes
Total analysed	28	40
Age <45	16	21
>45	14	19
M:F	8:20	20:20
<i>Foot pathology:</i>		
Complete loss of protective sensation	28	40
Adsorbed toes (1 or more)	28	40
Ulceration	20	28
superficial ulcers (<5 mm deep)	7	14
deep ulcers (range: 5-15 mm deep)	13	14
Inversion of both feet	4	2
Inversion of one foot	8	9
Footdrop without inversion	5	6
Adsorbed forefoot: bilateral	10	4
unilateral	7	7

Deformed feet also did better with canvas shoes. Of the 11 subjects with inverted feet in this group, 9 had ulcers at the start (5 deep, 4 superficial) but only 4 had ulcers at one year. Of the 12 subjects with inverted feet in the plastazote group, 9 had ulcers at the start (6 deep, 3 superficial), but 11 had ulcers at the end of the study.

#### DURABILITY

In general, both types of shoes have a useful life of not more than 6 months if used on a daily basis. The plastazote insoles wore out in the majority of cases by 6 months while the soles and leather uppers remained in good condition. The canvas uppers were usually badly torn by 6 months, but the soles and MCR insoles of the canvas shoes remained in good condition.

We have attempted, in conjunction with the Canvas Shoe Factory, to strengthen the canvas uppers and the initial results are encouraging.

#### ACCEPTABILITY

Clients were asked how they themselves, their families and their neighbours liked the shoes and also how suitable the shoes were for their work. These questions were asked at each follow-up visit.

All the clients using canvas shoes found them excellent and more than 80% reported an excellent acceptance by family and neighbours, as well as suitability for work. One client, with a severely inverted foot in which the ulcer improved but did not heal, requested a pair of plastazote sandals for use at home and a pair of canvas shoes for work and activity away from home.

Approximately 60% of clients using plastazote sandals found them excellent, but full



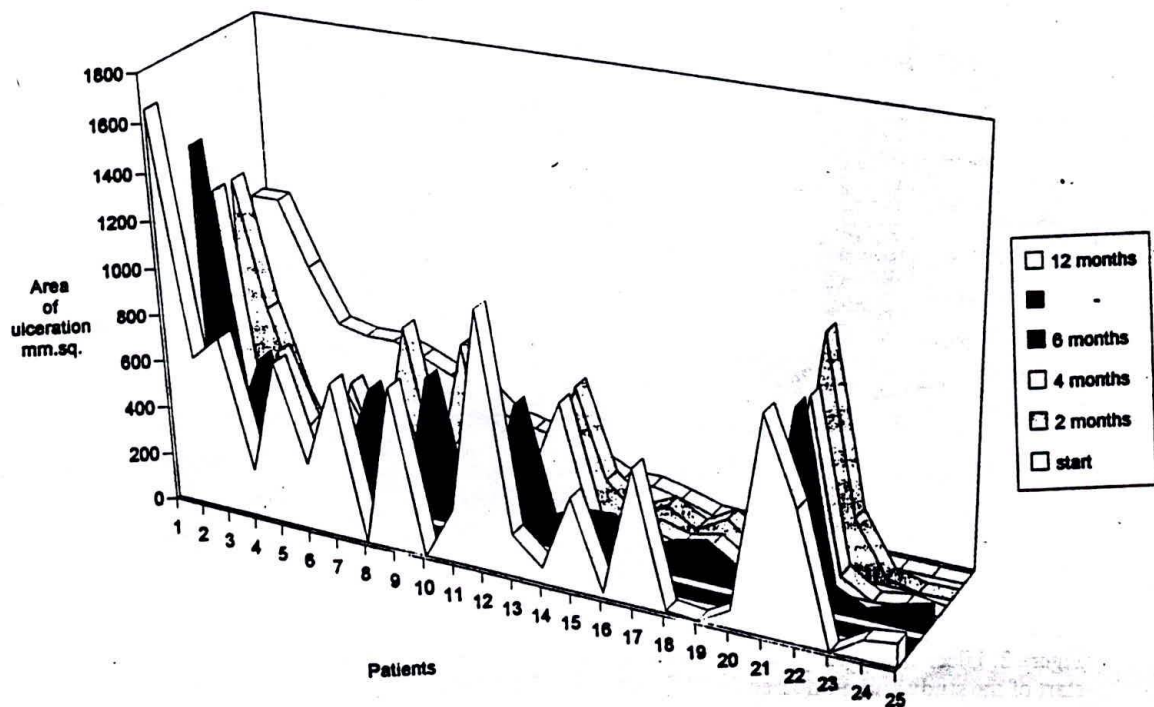


Figure 1. Ulcer size over time for the plastazote sandal group. The patients are placed in order of ulcer size at the start of the study and numbered 1–25. The area of ulceration for each patient at the start, is shown at the back of the diagram; moving towards the front, the area of ulceration at 2, 4, 6 and 12 months is seen for the same patients.

acceptance by family and neighbours was reported by no more than 20% at any time. Suitability for work was between 30% and 60%.

#### COST-EFFECTIVENESS ANALYSIS

##### *Canvas shoes*

We have shown that 21 (75%) of 28 subjects with deformed feet and chronic ulceration showed healing of the ulcers during a one-year period of regular use of canvas shoes.

The cost of these shoes is approximately US\$ 6.7 per pair and two pairs are required per person per year. For comparison MDT for MB patients costs about US\$ 15 per year.

*Cost per ulcer healed:* 16 ulcers were healed in the first 6 months and 6 more in the second 6 months. The first 16 ulcers were healed at an average cost of  $28 \times 6.7 / 16 = 11.7$  US\$. The subsequent 6 were healed at a cost of  $12 \times 13.4 / 6 = 26.8$  US\$. The average cost per ulcer healed was  $28 \times 13.4 / 22 = 17.1$  US\$, over a one-year period.

*Cost of ulcer prevention:* 12 clients without ulcers but with anaesthetic and deformed feet, did not develop ulcers during the year; and 15 out of 16 clients with healed ulcers at 6 months remained ulcer-free for the second six months.

Ulcer prevention was therefore attempted for 40 subject/half-years at a cost of  $40 \times 6.7 = 268$  US\$. Ulcers were prevented in 39 of these half-year periods. The cost per ulcer prevented was therefore  $268 / 39 = 6.9$  US\$.



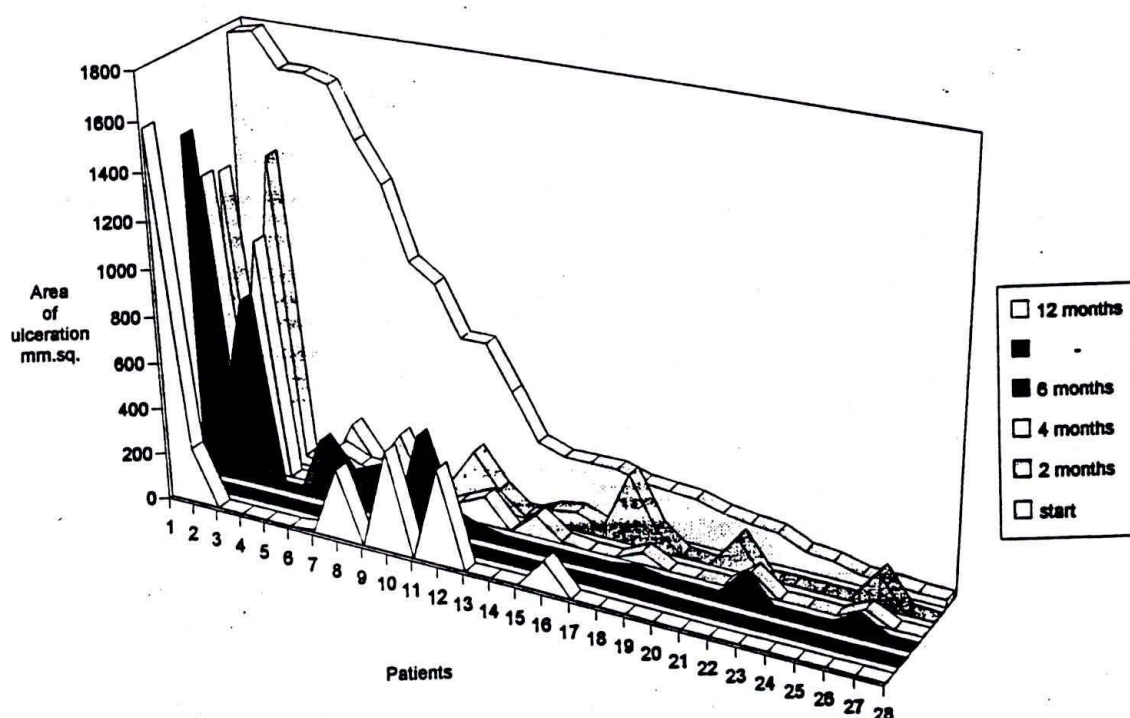


Figure 2. Ulcer size over time for the canvas shoe group. The patients are placed in order of ulcer size at the start of the study and numbered 1-28. The area of ulceration for each patient at the start, is shown at the back of the diagram; moving towards the front, the area of ulceration at 2, 4, 6 and 12 months is seen for the same patients.

### *Plastazote sandals*

Plastazote sandals showed no overall benefit in healing and preventing ulceration. Eight of the group started without ulcers and 7 were ulcer-free at one year. Only 3 clients remained ulcer-free throughout.

### LABORATORY TESTING OF CANVAS SHOES

Neuropathic plantar ulceration develops over areas of high pressure associated with deformity or joint limitation. Laboratory methods have been developed to show how effective different shoes are in reducing peak walking pressures.<sup>15</sup> A sample of the Ethiopian Canvas Shoes (ECS) used in this study has been tested at the University of Liverpool, UK, and compared with a range of products available in different leprosy control programmes around the world. Pressure was measured at 10 points on the plantar surface of the foot during normal walking. Forty-one different shoes, sandals and insole materials were examined (including the ECS).

Table 2 compares the results for the ECS with the means and ranges for other samples and the results from walking barefoot. No shoes were consistently at the low end of the range across all measurements, but the ECS was one of about 6 pairs to have consistently below average pressures.



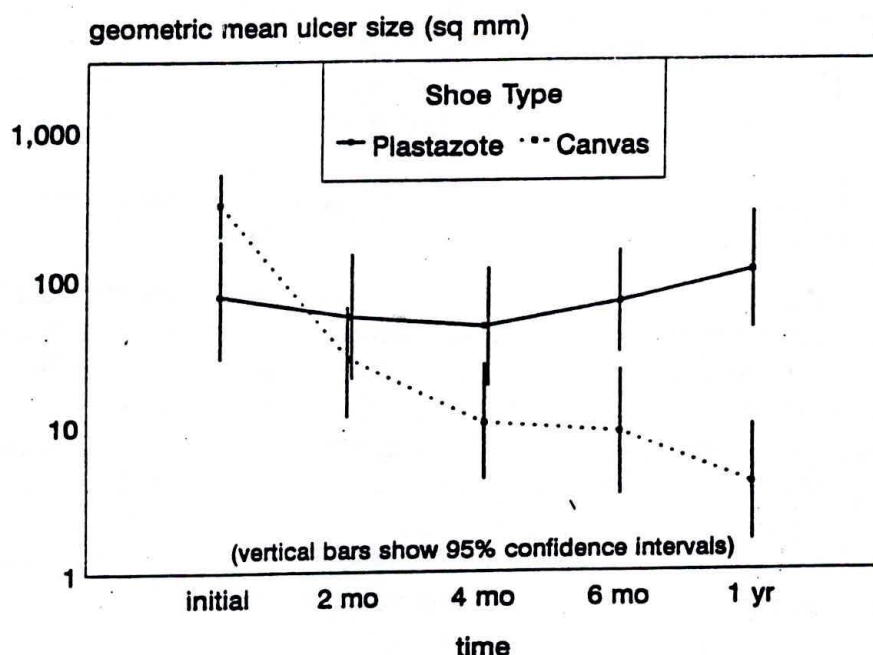


Figure 3. Geometric mean size of ulcers ( $\text{mm}^2$ ) over time for 25 Ethiopian subjects with plastazote sandals and 28 subjects with canvas shoes.

## Discussion

Previous studies have shown that it is possible to achieve high rates of ulcer-healing through various techniques, such as: good wound care and immobilization in a centre of excellence—94% healed;<sup>4</sup> podiatric orthoses—57% healed;<sup>14</sup> and the use of canvas shoes in China—84% healed.<sup>11</sup> The challenge for control programmes is to achieve and maintain ulcer-healing on a wide scale at the lowest possible cost and by a method straightforward enough to be applied through the general health services.

This study was carried out under field conditions in a rural part of Ethiopia, 250 km from Addis Ababa, where a large number of people affected by leprosy have settled. It

Table 2. The maximal force and peak pressures recorded at various points on the sole of a normal foot during walking, in the Ethiopian Canvas Shoe (ECS), in 40 other shoes or sole materials from other leprosy projects and barefoot.

	Mean and range for all 41 samples				
	ECS	mean	low	high	Barefoot
Maximal force (Newtons)					
mean of readings for metatarsal heads	50	75	44	100	93
mean of readings for all 10 sites	76	88	68	105	103
reading for the heel	394	394	290	461	472
Peak pressure (N/cm sq)					
mean of readings for metatarsal heads	16.1	16.4	9.2	22.1	25
mean of readings for all 10 sites	12.8	13.3	9.5	17.3	20.7
reading for the heel	19.2	19.7	13	27.5	31.5



was prompted by the awareness that:

- People affected by leprosy have been taught how to carry out self-care, but a large number (which can only be guessed at) are unable to prevent chronic or recurrent ulceration of their anaesthetic feet, without appropriate protective footwear.
- The large numbers of former patients with anaesthetic feet (whether deformed or not) cannot be supplied with special footwear made in orthopaedic workshops. It is logistically impossible at present.
- Various commercial footwear manufacturers can make shoes which are protective for anaesthetic feet and are socially acceptable.

The study has shown that commercially produced canvas shoes are beneficial for clients who have deformed as well as anaesthetic feet. They are a cost-effective method of achieving ulcer-healing and or preventing new ulcers. Probably the most important aspect of the canvas shoes is their ready acceptance by both clients and community, while the specially made plastazote sandals immediately stigmatize the person as a leprosy case. It appears also that the canvas shoes are preferred for farm work and for walking on dusty and stoney grounds.

The study was unable to investigate why subjects with plastazote shoes showed no improvement overall. However, it is our impression that because of poor acceptability by the families and neighbours of clients, these shoes may not be worn on many occasions. However appropriate as a technical solution, plastazote sandals and even open MCR sandals, appear to be socially (and often functionally) unacceptable in Ethiopia.<sup>10</sup> Conditions in different countries must be examined closely; for example, canvas shoes may not overcome problems such as working in paddy fields and not wearing shoes in the house, which are issues in India.<sup>6</sup>

At ALERT, we are trying to move away from the traditional monthly care clinic, where patients come for soaking, trimming and oiling, but then may do very little else for the rest of the month. We have recently started a pilot study of community-based self-care, in which a group of clients living near each other meet weekly to assist each other in self-care and to discuss problems. A supervisor and foot-care specialist have been visiting monthly in the initial phase and early results are very promising.

We would therefore advocate a foot-care programme in which self-care is promoted and commercially available footwear is provided twice a year. In the long-run, most clients would only see a health worker or supervisor twice a year. People who still have an apparently simple ulcer after 1 year of using canvas shoes would require further investigation to discover the reason and may need referral for surgery. There may be epidermal hyperplasia, as in one of our subjects, or even a malignancy; surgical correction of deformities and reduction of pressure points may be indicated. This would also be the most appropriate stage for the provision of special footwear, after discussion between surgeon, orthotist and technician. It may be that two types of footwear, for use on different occasions, will be the best solution for some people with deformed feet.

While the annual cost of providing footwear is noted to be very similar to the cost of MDT for MB patients, the provision is not limited to the two years of MDT. Thus there are many more clients requiring footwear than are registered for MDT and they will require it for many years. It may be that some manufacturers can produce such shoes for a lower cost, and part of the cost can be recovered from clients, but this will still be an expensive programme, requiring further long-term commitment from donors.



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# The Cost-effectiveness of Three Smoking Cessation Programs

DAVID G. ALTMAN, PhD, JUNE A. FLORA, PhD, STEPHEN P. FORTMANN, MD,  
AND JOHN W. FARQUHAR, MD

**Abstract:** This study analyzed the cost-effectiveness and distribution of costs by program stage of three smoking cessation programs: 1) a smoking cessation class; 2) an incentive-based quit smoking contest; and 3) a self-help quit smoking kit. The self-help program had the lowest total cost, lowest per cent quit rate, lowest time requirement for participants, and was the most cost-effective. The most effective program, the smoking cessation class, required the most time from participants, had the highest total cost, and was

the least cost-effective. The smoking contest was in-between the other two programs in total costs, per cent quit rate, and cost-effectiveness; it required the same time commitment from participants as the self-help program. These findings are interpreted within the context of community-based intervention in which the argument is made that cost-effectiveness is only one of several factors that should determine the selection of smoking cessation programs. (*Am J Public Health* 1987; 77:162-165.)

## Introduction

Cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA) are used by some public health professionals as one aspect of evaluation.<sup>1-3</sup> Accordingly, one of the goals of the Stanford Five City Project (FCP) is to conduct cost-analysis of its health interventions. The FCP is a comprehensive, long-term, quasi-experimental community health education study designed to reduce heart disease risk, morbidity, and mortality in two intervention cities (total population of 117,000).<sup>4</sup> The findings reported here examine the cost-effectiveness<sup>2,5</sup> of three smoking cessation programs and are the results from experiences gained during the first five years of the FCP. The study does not attempt to quantify the monetary costs or benefits to society of a person who quits smoking.

Cost analysis has not been used equally to analyze different types of health interventions. For example, there are fewer studies examining the cost-effectiveness of prevention programs than of treatment-oriented programs.<sup>2</sup> In particular, the cost-effectiveness of smoking prevention/cessation programs has rarely been studied. In one of the few CEA studies of smoking cessation programs, a secondary analysis of 43 published studies, program costs were estimated on the basis of "... the dollars expended on contacts with smokers, based on the duration and number of contacts multiplied by the national average hourly salary or fees of workers of the kind used in the contact."<sup>6</sup> This method of cost estimation probably underestimates the costs of these programs because only rough estimates of a single cost category (i.e., personnel) were made whereas the total costs include many other categories (e.g., overhead, benefits, volunteers, supplies, travel, data analysis).

This study examines in detail the cost-effectiveness of three smoking cessation programs while addressing some of the limitations of previous cost analyses. Specifically, a comprehensive analysis of program costs is included, the distribution of costs in program stages is analyzed, and cost-effectiveness is examined over the lifespan of a program and under different quit rate assumptions.

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## Methods

The three interventions selected for this study were community-based smoking cessation programs developed for use in the two education communities of the Stanford Five City Project.

### Smoking Cessation Programs

**Smoking Cessation Class**—This program was designed by Stanford Five City Project staff and implemented by a county health department. The classes included eight one-hour sessions, the first five offered in consecutive weeks and the last three offered every other week; attendance ranged from 8-25 participants. Quitting techniques included behavioral problem solving, self-monitoring, tapering, deep muscle relaxation, goal setting, and group social support. Before leading a class, instructors received two to three hours of training and attended a class led by another instructor.

**Incentive-based Smoking Cessation Contest**—This program was a six-week community smoking cessation contest. Smokers enrolled in the contest provided verification of their smoking status and then attempted to quit by a predetermined day. Following a six-week period, a random drawing was held for the grand prize (a trip for two to Hawaii) and 21 other donated prizes. All winners had to verify their non-smoking status by submitting to a carbon monoxide assessment. One month following the drawings, a questionnaire was sent to all entrants assessing smoking status and habits. A large majority of the participants quit on their own even though self-help materials and smoking classes were available to them.\* The contest was promoted through television, radio, newspapers, posters, schools, and word of mouth. Phone surveys indicated that 60 per cent of the community population was aware of the contest.

**Self-help Quit Smoking Kit**—The third program was a four-step self-help quit kit<sup>7,8</sup> containing four "tip sheets" and an introductory page. Each tip sheet had two sides, one providing general information and the other providing tips on quitting and specific action steps to take. Tips include use of substitutes for smoking, social support, public commitment, planning, record keeping, and goal setting. A heart-shaped magnet is included in the kit for use in posting each of the tip sheets on a refrigerator or other prominent place. The kit can be distributed through a variety of channels, including libraries, health agencies, and physician offices.

\*King AC, Flora JA, Clark M, et al: Smokers' challenge: evaluation of a community smoking cessation contest. Paper presented at the annual meeting of the Society of Behavioral Medicine, New Orleans, 1985.



### 3. Estimation

The seven major categories of costs are: 1) staff and staff benefits (Stanford, community, and volunteer staff, and consultants); 2) overhead; 3) rent; 4) supplies and materials (printing, advertisements, telephone, postage, prizes, supplies); 5) travel; 6) data analysis (keypunching, computer time); and 7) time required of smokers for participation in each program. In addition, program costs were divided into three project stages: 1) development (costs for program development and planning, leader training, formative research); 2) promotion/implementation (promotion of program, entry form distribution and collection, program implementation including the costs for prizes, and community organization); and 3) evaluation (pre- and post-test surveys, data entry and analysis, and feedback to participants). Developmental costs were limited to those directly related to the smoking cessation programs under study rather than to related resources required to develop the program (e.g., costs of theory development and intervention research by other investigators). To account for the fact that many health professionals use interventions developed by other people rather than developing their own, we also conducted analyses under the assumption that there were no developmental costs. In these analyses, only promotion, implementation, and evaluation costs were included.

Assumptions of the Cost Estimation—Each program was analyzed on the basis of one-year and five-year lifespans. The projection of a five-year lifespan is based on experiences from the FCP in which the smoking class has been conducted for five consecutive years, the smoking contest for three consecutive years, and the self-help quit kit has been used for five years in a variety of settings. All of these programs are still being implemented and it is conceivable that their lifespan would be greater than five years although such factors as program obsolescence, program saturation due to a finite number of interested smokers, and general degradation of intervention quality certainly limit the lifespan of community programs such as these. Quit rates were projected to remain the same over the life of the program and it was assumed that each program would attract equal numbers of people each year of implementation. These assumptions are also based on experiences from the FCP which indicate that quit rates remain the same or improve slightly each year a program is implemented and recruitment of participants decreases slightly until program saturation in the community is reached, at which point recruitment drops significantly.

The classes required about nine hours of participant time while the contest and self-help quit kit each required about 25 minutes. The value placed on each hour of participant time was assumed to be \$10.

After the first year of each program, we assumed that the developmental costs in each subsequent year is 15 per cent of first year costs. This estimated figure was based on previous experiences repeating these and other community programs, and it accounts for the minor changes that are made in the design of a program when it is implemented in different settings, with different people, and at different times. We assume, however, that the basic intervention remains unchanged throughout its lifespan. Evaluation costs in subsequent years are also assumed to be 15 per cent of first year costs since the programs were evaluated extensively in the first year.

The smoking class and self-help programs were implemented in 1981 while the smoking contest first occurred in

1983. By using present value analysis techniques,<sup>2,4</sup> cost outlays were compared in 1981 dollars. A discount rate of 5 per cent was applied to cost outlays in each year of a program. The sum of these discounted values represents 1981 dollars needed to implement each program over its expected five-year lifespan.

### Program Effects

The primary outcome variable was post-program smoking status (smoker or non-smoker) defined as complete abstinence from smoking at the time of assessment. Participants in the class quit, at the latest, by the fifth week of an 11-week class. Smoking status was assessed on average six weeks after the final date for cessation. Participants in the contest quit, at the latest, by the fourth week of a six-week contest. Smoking status was assessed four to six weeks after the final date for cessation. Participants in the self-help kit program quit, at the latest, by the third week of a four-week program. Smoking status was assessed on average five weeks after the final date for cessation. Thus, assessment of smoking status for all three programs occurred at a minimum from 4-6 weeks and at a maximum 8-11 weeks after cessation. In addition, it was assumed that participants who dropped out of a program (stopped attending classes, failed to return post-test questionnaire) between pre- and post-test measurement were still smoking at post-test. Because only the contest used biochemical validation of self-reported smoking status, comparisons of the three programs are based on self-report measures. It was assumed that smoking relapse rates would not differ between programs.

Quit Rates—The quit rate and number of participants on which the quit rate was based for each program is as follows: self-help (N = 101, quit rate = 21 per cent); contest (N = 498, quit rate = 22 per cent); class (N = 541, quit rate = 35 per cent). The quit rate for the self-help intervention is based on a sample of 101 people who contacted the Stanford community office for materials after they were described in a weekly newspaper column. Approximately 46 per cent of the households in the study area subscribed to the newspaper. During the period of program implementation, however, the self-help materials were actively distributed and widely used in many other settings. Thus, it is misleading to consider the costs for developing the self-help program materials to be limited to the particular community program that attracted 101 participants. Therefore, the cost-effectiveness ratios for the self-help program are based on a more realistic sample size of 500 in order to reflect the actual community-wide distribution of materials. It is reasonable to assume that in moderate-to-large sized communities, a self-help program would be of interest to even greater numbers of people.

### Data Analysis

The cost per quitter was estimated by dividing the total cost of each program at one year and five years by the number of people who would be expected to quit. To examine the robustness of this CEA, a sensitivity analysis was conducted. The quit rate was changed to account for recidivism after the two-month quit date as well as for differences in quit rates obtained, either lower or higher, when the program is implemented in different settings. Nine quit rates were examined: 5, 10, 15, 21, 22, 25, 30, 35, and 40 per cent.

### Results

#### Demographic Data

As Table 1 indicates, participants in the self-help program (mean age = 45) and class (mean age = 45) were older than those in the contest (mean age = 38). There was a greater



TABLE 1—Demographic Distribution of Participants in Smoking Cessation Programs

Program	Mean Age	Mean Education	% Males	% Females	Mean Cigarettes Smoked, Pretest
Class (N = 541)	44.8 (13.4)	13.5 (2.9)	33.7	66.3	26.8 (12.3)
Self-Help (N = 101)	47.0 (13.9)	not available	32.7	67.3	27.0 (15.2)
Contest (N = 498)	38.2 (12.6)	13.6 (2.8)	44.6	55.4	24.9 (12.6)

percentage of males in the contest (45 per cent) than in either the class (34 per cent) or the self-help kit program (33 per cent). Contest participants also smoked slightly fewer cigarettes per day at pre-test (mean=25) than did participants in the other two programs (both means=27). In addition, data on smoking rates in the FCP education communities indicate that 31.6 per cent of the population aged 25–74 smoked in 1981–82 while 26.6 per cent smoked in 1983–84. Likewise, the mean number of cigarettes smoked per day among smokers was 20.3 in 1981–82 and 19.1 in 1983–84.\* These differences in the population and in the smoking rates at the time of the interventions should be noted in interpreting the findings from this study.

#### Total Costs by Program Stage

The total first year costs for each program are: self-help (\$15,144), contest (\$25,832), and class (\$75,632). If developmental costs are excluded and only the costs for implementing, promoting, and evaluating the programs are considered, first year total costs drop as follows: self-help (\$4,698), contest (\$17,671), and class (\$50,383). Development costs made up a higher proportion of total costs in the self-help program (69 per cent) than in either the class (33 per cent) or the contest (31 per cent), reflecting the substantial time needed to develop self-help materials but the limited time necessary to implement a self-help program, the reverse of the smoking class and contest.

#### Cost-effectiveness Analysis

The cost-effectiveness ratios (cost per quitter) for the three programs are presented in Table 2. The relative ranking of cost-effectiveness ratios across the three programs under the different conditions is consistent: the most cost-effective program is the self-help program, the least cost-effective program is the class. Depending on the assumptions made about program lifespan and costs included the following upper and lower range of costs per quitter by program were found: class (\$399 to \$235), contest (\$236 to \$129), and self-help (\$144 to \$22).

#### Sensitivity Analysis

Sensitivity analyses were conducted to examine the impact of different quit rates on the cost-effectiveness of each program in year one (see Figure 1). In all programs, the cost per quitter decreases as the per cent quit rate increases. Comparison of the ratios across the three programs is informative. The class, even at a 5 per cent higher quit rate than actually found (i.e., 40 per cent), is approximately as cost-effective as the smoking contest at a 7 per cent lower quit rate than actually found (i.e., 15 per cent) and is less cost-effective than the self-help program at a 16 per cent lower quit rate than actually found (i.e., 5 per cent). The point at which the contest and self-help programs become equally

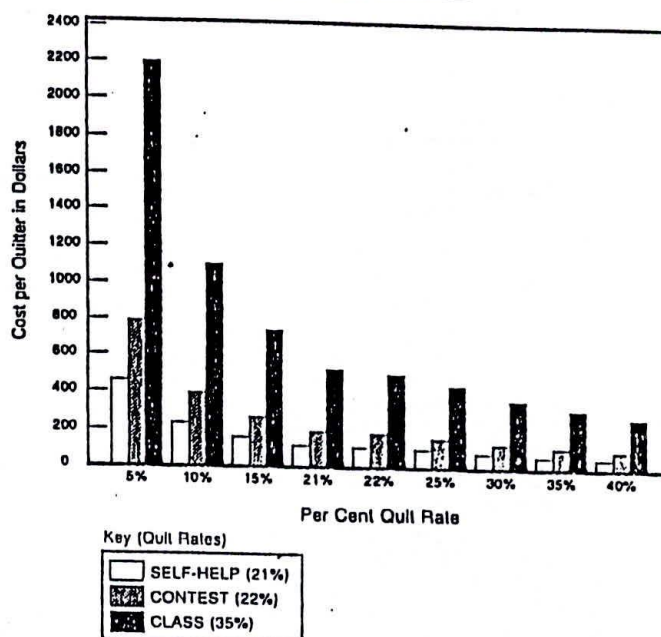


FIGURE 1—First Year Cost per Quitter under Different Quit Rate Assumptions (excluding developmental costs)

cost-effective occurs when the contest achieves a 35–40 per cent quit rate and the self-help program drops to approximately a 10 per cent quit rate.

#### Discussion

The total costs as well as the costs per quitter reported in the current study are generally higher than those reported by Green and Johnson.<sup>6</sup> This is due, in part, to their incomplete estimation of program costs, which is understandable given that their study was an archival analysis of published smoking cessation studies.

Our findings are apparently robust within a number of varied assumptions. Moreover, if the number of participants recruited to smoking cessation programs, particularly self-help programs, is greater than the numbers assumed in the present analysis, the cost per quitter drops due to economies of scale.

Because it is unusual for health professionals or organizations to have resources available to develop all of their own programs, ratios with and without developmental costs were reported. In many, if not most, instances, previously developed programs or program components are adopted. Health professionals should carefully consider this issue since developmental costs can be substantial. Possible reasons for developing new programs include unavailability of interventions for a specific population, unacceptable effectiveness of

\*Internal report, Stanford Five City Project, 1986.

Cost/interior to quit



TABLE 2—Cost-effectiveness Ratios in Three Smoking Cessation Programs

Smoking Cessation Programs	Total Costs		Total Costs Excluding Developmental Costs	
	One Year	Five Years	One Year	Five Years
<b>Class</b>				
Total cost	\$75,832	\$261,589	\$50,383	\$222,911
Number of participants	541	2,705	541	2,705
N of quitters (at 35% quit rate)	189	947	189	947
Cost-effectiveness ratio <sup>a</sup>	\$399	\$276	\$266	\$235
<b>Contest</b>				
Total cost	\$25,832	\$82,925	\$17,671	\$70,423
Number of participants	498	2,490	498	2,490
N of quitters (at 22% quit rate)	110	548	110	548
Cost-effectiveness ratio <sup>a</sup>	\$236	\$151	\$161	\$129
<b>Self-Help</b>				
Total cost	\$15,144	\$26,190	\$4,698	\$11,498
Number of participants	500	2,500	500	2,500
N of quitters (at 21% quit rate)	105	525	105	525
Cost-effectiveness Ratio <sup>a</sup>	\$144	\$50	\$45	\$22

<sup>a</sup>In 1981 dollars,  $r = 5\%$ .

previously developed interventions, or an interest in evaluating a new technology of intervention.

The findings from this study must be interpreted within a broad community context.<sup>3,9</sup> In a given community, there are multiple demographic groups with different preferences for health services, and diverse smoking histories. Different smoking cessation programs may attract different types of people and preferences for cessation programs may shift over time. In this study, for example, the data indicate that the contest attracted a slightly younger population and a higher percentage of males than did either the self-help program or the class. Future research should collect more extensive data on the differential attraction of cessation programs for population subgroups. Moreover, the target population for community smoking cessation programs may vary over time due to changes in community social norms and health services utilization. For these reasons, the absolute cost-effectiveness should not be the only evaluative criterion employed. It may be important for a community to offer a range of integrated smoking cessation programs in order to meet the needs of diverse groups of citizens. In short, if the goal is to reduce smoking in the community-at-large, it makes little sense to limit the smoking programs offered to only the most effective or cost-effective if in fact they only attract a small fraction of the population in need. Moreover, if the cost of smoking cessation programs are below their value, the cost-effectiveness of a specific program may not be as important because a higher cost-effectiveness ratio implies only that the cost for achieving a given effect is higher in one program than in another. Thus, a higher cost-effectiveness ratio does not necessarily imply that a program is undesirable.

Similarly, there may be a need at the community level for sequencing or combining intervention strategies. Because of the unique nature of some cessation programs (e.g., a smoking contest), the community may not fully accept it until

other more visible and better understood programs (e.g., a smoking cessation class) are offered. Combining cessation strategies across programs (incorporating self-help materials into a smoking contest) may further increase the effectiveness. Findings from the current study may help professionals determine the most effective approaches to reducing cigarette smoking in free-living community populations.

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## Cost-effectiveness of ambulatory surgery in Cali, Colombia

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To compare the cost and effectiveness of a system of simplified ambulatory surgery against traditional inpatient surgery, we studied a surgical procedure commonly performed in both settings – non-recurrent elective inguinal herniorrhaphy. We compared the 17 operations performed in an 'intermediate health unit' (IHU) or outpatient hospital in Cali, against the 15 performed in a traditional secondary hospital from mid-January through mid-April, 1989. Pre-surgical characteristics of the patients were similar. After the operation, the IHU patients had few complications, were more satisfied, and resumed their usual activities sooner than the hospital patients (34 versus 52 days, respectively). The average cost per procedure was US\$39.12 in the IHU as compared to US\$148.76 in the hospital – a four-fold difference. Intermediate health units seem to offer important advantages for uncomplicated surgery in both cost and outcome.

### Introduction

Among 29 developing countries for which consistent data were available, an average of 57% of public recurrent health expenditures was spent on hospital care. Colombia, according to a 1984 study, used 67% of these funds on hospital care.<sup>1</sup> All curative services typically consume 80% of health resources in developing countries.<sup>2,3</sup> Faced with shrinking public sector budgets and mandated to expand preventive and promotive health services, policy makers are always searching for ways to deliver curative services more efficiently.

To enhance efficiency, the types and sophistication of curative services have to be carefully matched to patient need. In Cali, Colombia's third largest city with 1.5 million inhabitants, previous studies of surgical services have shown that reorganizations offered substantial opportunities for greater efficiency.<sup>4-6</sup> Cali's operating rooms, one of the most expensive hospital resources, had a mean utilization of only 42% in 1974; other expensive resources were also used inappropriately. In the university hospital, the tertiary hospital for the city and surrounding region, 69% of the surgical operations were in

the two least complex levels, whereas only 2% were in the most complex category.<sup>5</sup>

In response to these data, university and government officials in Cali developed a new type of health facility in 1983, an intermediate health unit (IHU) or 'health centre-hospital', and instituted an innovative surgical technology called 'simplified ambulatory surgery', which is practised primarily in IHUs.<sup>7-11</sup> Primary care facilities (health posts and centres) refer most surgical, and obstetric and selected medical cases to IHUs, which in turn refer cases they cannot treat to secondary and tertiary hospitals.

Simplified ambulatory surgery was designed to diminish the costs of low to intermediate-risk surgical procedures without decreasing the quality of care. This surgery provides pre-operative patient education, early ambulation and discharge (generally on the day of surgery), and family home care. The operating rooms are furnished only with equipment needed for a carefully-defined set of uncomplicated surgical procedures. Few medical personnel are assigned to each operation. Furthermore, operating



rooms are equipped with two operating tables, which could permit two surgical procedures to be performed simultaneously in the same operating room, under the supervision of a single anaesthetist. A 1975 study predicted that the system would lower costs by 75%, compared to traditional care in the university hospital with a 3-day hospitalization. It would also be more efficient than standard ambulatory surgery, in which the surgery uses the same facilities and personnel as traditional inpatient surgery. A leading public health journal praised the system's potential to use existing resources more efficiently.<sup>14</sup> This study is a controlled evaluation of the costs and effectiveness of simplified ambulatory surgery as it is routinely practiced in Cali, a decade after its implementation.

## Methods

### Study setting

When this study began in 1989, Cali's public health system had three secondary hospitals and four IHUs. The study sites were Hospital San Juan de Dios (SJD), a 127-bed secondary-level hospital, and Centro Hospital Joaquin Paz Borrero (JPB), an IHU with 20 beds. Both facilities were representative examples of their type of institution.<sup>15</sup> In 1988, the IHU performed approximately 1100 operations of all types, while the hospital performed 3500. Both facilities covered their operating costs through a combination of patient fees and government subsidy.

### Selection of procedure and patients

Inguinal herniorrhaphy was selected because of the frequency with which it is performed at both facilities, its moderate degree of technical complexity, and the existence of standardized indices of surgical risk at both facilities.<sup>16,17</sup> Eight per cent of each facility's operations were herniorrhaphies. This study included all patients aged 16 years or older with a low surgical risk,<sup>16,17</sup> who received an elective inguinal herniorrhaphy (which was not for a recurrent or incarcerated hernia) in the three months from January to mid-April, 1989. Thirty-two patients met these criteria: 17 at the hospital and 15 at the IHU. In theory, all uncomplicated cases should be treated at the IHU, and only complicated cases referred to the secondary hospital. In practice, uncomplicated cases were also treated at the

hospital, due to previously established patterns of referral or utilization.

We compared the two groups of patients on demographic and medical characteristics (sex, age, per capita income, education, underlying pathologies, previous hospitalization, household size, and preoperative pain expectation). The auxiliary nurse who admitted the patients interviewed all available patients on the day of admission (the day before surgery at the hospital, and the day of surgery at the IHU) about these characteristics.

### Measures of effectiveness

Using indicators similar to those in previous evaluations of surgery,<sup>18-23</sup> we compared effectiveness of the two settings based on complication rates, patient satisfaction, and duration of postoperative disability. Trained Colombian health professionals assessed complication rates until the eighth post-operative day through systematic abstraction of patients' medical records. We assessed several components of patient satisfaction through a second and third survey. The second survey was generally conducted at the facility in which the surgery had taken place, one week after surgery, when the patient returned for his surgical follow-up visit. If the patient did not report for his follow-up visit, however, we tried to interview the patient at home. At this stage, we also asked patients about their out-of-pocket costs.

The third interview took place at the patient's home in August, 1989, four to seven months after the surgery. The second and third interviews were conducted by Colombian medical students who were not employed by either study facility. We assessed the period of convalescence at the second and third survey - the patient's expectation at one week after surgery, and the actual experience four to seven months later.

### Average cost per herniorrhaphy

To fully capture health system costs related to the site of care, we measured each patient's health care costs, from the patient's admission to the facility for surgery until the eighth post-operative day. We excluded costs of diagnostic tests and examinations, which were done prior to admission in both settings. We assessed direct service costs in each department of each facility



that provided care and the associated overhead costs (such as administration, cleaning, and building maintenance). We determined direct service costs in the operating and recovery rooms for both facilities, and also in the surgical ward for the hospital.

Direct service costs consisted of medical supplies (sutures), general supplies (disinfectant, gauze), which could not be readily assigned to an individual procedure, personnel, and the finance for medical equipment. Costs of medical supplies were obtained by multiplying the utilization of each item for the surgeries in the study (obtained from abstraction forms completed by nurses and technicians in each facility, and direct observation) multiplied by their unit costs. Costs of general supplies, personnel, and depreciation were allocated to a single hernia repair, based on the ratio of the average time for a single herniorrhaphy (estimated as the mean for study patients in each facility), compared to the total time that the operating room was in use for all procedures during the year (derived from each facility's operating room log-books). Financial records of each institution provided financial data. All monetary amounts were valued in July 1988 prices converted to US dollars at the then exchange rate of 307 Colombian pesos (COP) per dollar.

## Results

### Patient characteristics and clinical outcomes

Although patients at the hospital tended to be older, there were no statistically significant differences between the means of the two groups on any of the preoperative patient characteristics examined (that is, the chance probability was at least 10%) (Table 1).

The study provided no evidence of inferior quality at the IHU. The inpatient group actually had higher rates of both surgical and anaesthetic complications. Among the 17 hospital patients, three had surgical complications (two wound infections and one haematoma) and four had anaesthesia complications (two failed anaesthesia, one intraoperative hypotension, one perforation of duramater). No complications were reported among the fifteen IHU patients.

Table 1. Characteristics of study patients by facility

Variables*	Hospital (N = 13)*	IHU (N = 15)
Gender		
Male	69%	66%
Female	31%	34%
Age (years)	57.4 ± 6.1	45.0 ± 4.8
Years of education	4.4 ± 0.7	4.6 ± 0.7
Household size	5.1 ± 0.7	4.7 ± 0.7
Total monthly household expenditures:		
Colombian pesos	72 843 ± 14 785	77 056 ± 12 634
US dollars	237 ± 48	251 ± 41

\*Statistical significance of differences between the two groups revealed  $P > 0.10$  for all variables shown. Means = standard error of the mean.

\*Data unavailable for four hospital patients who were not interviewed.

### Patient satisfaction

Patients treated at the IHU tended to be more satisfied than those at the hospital at both assessments (Table 2). At the eighth post-operative day, patients at the IHU expected to spend less time away from work than those treated in the hospital. The follow-up survey confirmed that IHU patients had, indeed, returned to work sooner. Because of the small sample size, none of the differences are statistically significant, although they consistently favour the IHU. No complications requiring rehospitalization were reported among the 26 patients followed post-operatively from both groups. Conservatively, these results indicate that the IHU outcomes were at least as good as those in the hospital.

### Personnel involved

While the total number of personnel present during the hernia operations at the two types of facilities was comparable (5.5 in hospital and 6.1 in IHU), the mix differed. The hospital had almost twice as many physicians including residents for surgery and anaesthesia, as the IHU (3.5 versus 2.0), but only half as many nurses and technicians (2.1 versus 4.1). Thus the IHU relied more heavily on less costly personnel. The IHU had almost twice as many nurses and technicians as the hospital.



Table 2. Postoperative results

Variable	Hospital (N = 17)	IHU (N = 15)	Difference (Hosp-IHU)
<i>At eighth postoperative day</i>			
Perceived stay was too long	15%	0%	-15%
Satisfied with appearance of scar	46%	80%	-34%
Would have preferred alternative type of facility	-	-	-
Postoperative perception of severity of pain*,**	3.1 ± 0.8	2.8 ± 0.7	0.3 ± 1.1
Expected number of days from operation to resume usual activity**	52 ± 14	35 ± 9	17 ± 17
<i>At 4-7 months*</i>			
Days after surgery to return to regular activity**	56 ± 7	49 ± 6	7 ± 7
Days after return until all limitations ended**	53 ± 19	23 ± 11	30 ± 17
Total days with any limitation**	108 ± 23	72 ± 14	36 ± 17
Patient satisfied with length of hospitalization**	64% ± 15%	77% ± 12%	-13% ± 13%

\*On a scale from 1-5 of increasing severity

\*\*Mean ± Standard Error of Mean

\* 5 hospital and 1 IHU study patients had moved from Cali region or were otherwise not available for interview

\*\* Borderline statistical significance ( $P = 0.12$  with Yates continuity correction)

•Difference not statistically significant.

### Average cost per herniorrhaphy

The average cost of an inguinal herniorrhaphy was US\$39.12 (12010 COP) at the IHU and US\$148.76 (45 668 COP) at the hospital - almost a four-fold difference. When the cost of hospitalization was excluded, the cost of the procedure is three times greater at the hospital than at the IHU. The largest differences occur in three categories: overhead costs, personnel costs, and surgical ward costs (Table 3). The average length of the operations (from incision to closure) performed at the hospital was 37 minutes compared to 26 minutes at the IHU. Because computations of costs in both facilities involved allocating shares of total operating room and surgical ward costs to sample patients, standard statistical tests on cost differences would not be meaningful.

### Patients' costs

The facility's charge to the patient for the operation and follow-up care was US\$38.96 (12 000 COP) in the hospital and US\$16.23 (5000 COP) in the IHU. In addition, patients had to pay for some of the drugs and supplies, raising their total medical charges to US\$44.07 and US\$18.77, respectively. Thus, patient charges represented 30 and 48% of costs, respectively. Patients' transportation expenses were also

Table 3. Medical care cost per inguinal herniorrhaphy by type of facility

Cost category	Hospital		IHU	
	US\$	%	US\$	%
<i>Operating and recovery rooms</i>				
Direct service costs:				
Personnel	57.4	39.1	19.31	49.4
General supplies	1.4	1.2	0.59	1.5
Medical supplies	3.7	2.5	2.21	5.7
Equipment depreciation	1.2	0.8	4.07	10.4
Overhead costs	55.1	37.1	12.93	33.1
Subtotal	118.8	80.7	39.12	100.0
Surgical ward	33.7	22.5	0.00	0.0
Total	148.7	100.0	39.12	100.0

greater in the hospital (US\$5.16) than the IHU (US\$1.38), so out-of-pocket costs were 2.5 times higher in the hospital (US\$44.07) than for the IHU (US\$20.15). For the average patient in each setting, these out-of-pocket costs represented 21% of monthly household expenditures for hospital patients, but only 1% for IHU patients.



A worker earning the minimum wage of US\$3 per day would have to work 16 days to pay for the heavily subsidized hospital operation, compared to only 7 days for the less subsidized IHU procedure.

## Discussion

This study has found that an elective inguinal herniorrhaphy costs 74% less at an IHU than at a secondary level hospital. The IHU's lower cost is due to both its shorter time for the surgery (probably due to its standardized protocols), and its lower cost-per-minute. The average direct service cost-per-minute of operating room time

US\$1.99 (610 COP) at the IHU compared to US\$3.14 (965 COP) at the hospital. Both the savings in operating room costs and the overall proportional savings from simplified ambulatory surgery are consistent with the previously mentioned predictions from 1975.<sup>8</sup> Shorter hospitalization and devaluation have also lowered the cost of inpatient surgery compared to 1975.

The generalizability of the clinical outcomes is somewhat limited by the modest sample size in each facility, the absence of randomization, and the inclusion of only one facility of each type. These design characteristics could not, however, change the direction of our findings. Although eligibility criteria for the study produced generally comparable samples of patients in the two settings, hospital patients tended to be older (though not significantly so) and might have had more undocumented risk factors for complications. Even if adjustment for such characteristics could have explained all, or most, of the complications in the hospitalized patients, it would only equalize the risk-adjusted complication rates between the two settings. As no complications were observed in the IHU, its estimated complication rate would always remain the lowest possible value, zero.

Sensitivity analyses showed that neither sample variation nor the absence of randomization could explain the lower cost of the IHU. To examine the impact of sample variation, we obtained independent estimates of the duration of a hernia repair from separate samples of 19 consecutive herniorrhaphies taken from operating room log-books during three to four randomly

chosen weeks at each institution. The mean time was 43 minutes for hospital surgeries versus 34 minutes taken for IHU operations. As complicated hernias were not excluded from these samples, the times were longer than those of study patients. Recalculating costs using these times, the hernia repair still cost 70% less in the IHU than in the hospital.

To estimate the largest possible bias that the absence of randomization would have introduced, we assumed that in a randomized study, hospital patients would have spent as little time as IHU patients in the operating room (26 minutes) and in postoperative ward care (0 days). Even under these implausible assumptions, an operation in the IHU would remain 52% less costly than in the hospital. The IHU retains its cost advantage largely because its cost-per-minute for the operating room (both direct service and overhead) is considerably lower.

Previous studies have reached conflicting conclusions regarding the relative costs of ambulatory and traditional surgery. A randomized clinical trial found ambulatory surgery to be cost-effective for certain types of surgery.<sup>24</sup> Most studies found that when surgery is performed at a hospital and the patient is hospitalized, the costs exceed similar procedures performed on an outpatient basis, because in the latter case, the cost of hospitalization is saved.<sup>22-31</sup> Studies which compare the cost of performing ambulatory surgery at a hospital with the cost at a free-standing clinic, however, have not always found savings.<sup>32-33</sup>

With increased utilization, surgery in both an IHU and a secondary hospital could become more efficient. Because virtually all operating and recovery room expenses except those for supplies are fixed, a higher volume of services will lower the average cost per procedure. In 1988, the occupancy rates of Cali's surgical services were 56% in IHUs and 60% in secondary hospitals.<sup>34</sup> If both occupancy rates were raised to 90%, the average cost of an elective herniorrhaphy would drop to US\$25.40 in the IHU and US\$111.67 in the secondary hospital.

While an IHU might have been expected to exhibit lower quality than a more sophisticated hospital, the complication rates demonstrate the



opposite, probably a result of the systematic protocols for simplified ambulatory surgery. The results from the IHU are consistent with the complication rate in a larger series in a comparable IHU in Cali (the only other such data we are aware of). Carlos Carmona IHU had a 2.3% complication rate in 1431 consecutive ambulatory surgeries through 1988 (Wooley, unpublished data). Assuming this same rate applied to hernia repair in JPB, 0.3 complications would have been expected among the 15 herniorrhaphies studied: in fact, zero were observed. The IHU's advantage in patient satisfaction adds to findings in other populations showing one-day surgery to be comparable to traditional surgery in quality, and acceptable to consumers.<sup>13-19</sup>

From a social viewpoint, ambulatory surgery at the IHU entailed considerable advantages over inpatient hospital surgery. An average IHU patient saved US\$3.68 in transport costs, gained 7 days of his time (through earlier resumption of his usual activities), and reduced the time and expenditure his family and friends spent visiting the hospital and assisting in the patient's care. These are slightly offset by the one extra day a family member was estimated to spend caring for an ambulatory surgery patient at home (approximated by the length of stay of the hospitalized patients). On balance, the patient and his family gain at least 6 days from ambulatory surgery. Most importantly, the easier access to, and lower charges at IHU's, may encourage patients to have hernias and other health problems diagnosed and treated more promptly.

Simplified ambulatory surgery and other IHU functions can be adapted to various organizational and physical settings. Although surgeons in Joaquin Paz Borrero receive salaries from the local government, in another IHU, the surgeon is paid fee-for-service directly by patients. While the newer IHUs were specially built, older ones were upgraded from health centres.

### Conclusion

Reflecting its commitment to IHUs, Cali officials opened a fifth IHU after this study began, and plan to open a sixth one this year. Building on Cali's experience, Mexico has started to establish similar units. A WHO consultation which reviewed this experience<sup>35</sup> recommended

that cities carry out a situation analysis to help establish reference health centres (its term for IHUs) in appropriate locations.

In conclusion, uncomplicated hernia operations in intermediate health units cost only a quarter of what they would in a traditional hospital. Outcomes, complication rates, patient satisfaction, and return to work were comparable, if not superior, in IHUs. Cali's IHUs provide services organized around similar principles for other surgical services and obstetrics with, presumably comparable results.

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## CLINICAL ECONOMICS

### MODULE 7

#### COST-BENEFIT ANALYSIS

After completing this module, you should understand:

- a. the difference between cost-benefit analysis and the techniques introduced in earlier modules;
- b. what shadow prices are and why they are necessary;
- c. the difference between financial, economic and social analyses.



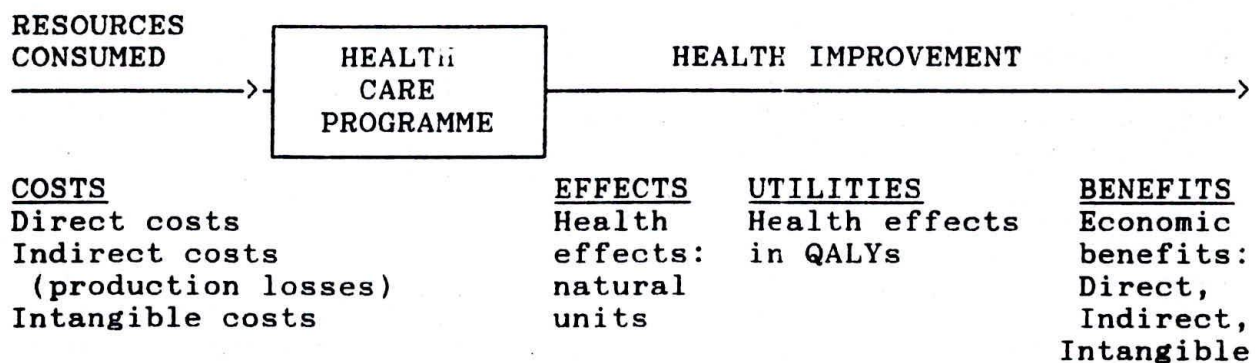
## COST-BENEFIT ANALYSIS

### INTRODUCTION

The analytical techniques introduced in Modules 4 to 6 were designed to compare alternative ways of using resources where the aim is to ensure that the resources produce the greatest possible benefits. The techniques cannot be used to determine if a single project is worthwhile. This is because costs and benefits are measured in different units: costs in terms of money, and benefits in terms of physical health outcomes, sometimes adjusted for changes in the quality of life. This makes it difficult to decide if the benefits of a programme justify the costs.

In common with these techniques, cost-benefit analysis (CBA) can be used to compare alternative interventions but it also provides a means for deciding if a single programme is worthwhile. It does this by requiring that benefits and costs both be measured in terms of money.

The relationship between CBA and the other techniques is represented in Figure 1. Cost-minimisation, cost-effectiveness, cost-utility and cost-benefit analyses all relate benefits to costs, and costs are measured in the same way in all cases. However, the techniques differ in their methods of measuring benefits. Cost-minimisation and cost-effectiveness analysis are based on physical effects, cost-utility analysis on utilities, and cost-benefit analysis on economic benefits.



(Source: Drummond et al, p2)



## MEASURING BENEFITS

The economic benefit of an intervention is the reduction in the cost of illness that results from the intervention. The costs of illness were divided into direct, indirect and intangible costs in Module 2, so the benefits of an intervention are typically categorised in the same way. The method of estimating the indirect costs of illness described in Module 2, and hence the indirect benefits of an intervention, is known as the human capital approach.

## DECISION RULES

Costs and benefits expected to accrue in the future must be discounted (see Module 3). The present value of the costs divided by the present value of the benefits is called the cost-benefit (CB) ratio. If it is less than 1, the project is viable or worthwhile.

NPV =

An alternative indicator of viability is the net present worth or net present value (NPV) of the intervention. The NPV is defined as the present value of the benefits minus the present value of the costs. The intervention is viable if the NPV exceeds 0, which implies that discounted benefits exceed discounted costs. If the NPV is positive, then necessarily the CB ratio will be less than 1, so either indicator can be used when assessing an individual intervention. However, if you wish to rank alternative projects using CBA there are technical reasons why you should use the NPV.

$\frac{\sum \text{Disc B}}{\sum \text{Disc C}}$

$\frac{\sum \text{Disc B}}{\sum \text{Disc C}}$

> 1

## WHOSE VIEWPOINT?

As with the techniques discussed in earlier modules, it is crucial to specify whose viewpoint is being considered in CBA. The literature commonly takes the viewpoint of a health care provider, for example a hospital or a government, whose costs are the money costs of providing the care. In this case there is no need to consider either the costs borne by the patient, or whether the prices paid reflect opportunity costs. Benefits are simply the increase in revenue resulting from the intervention.

$\frac{B}{C}$  Ratio

$\frac{C}{B}$  Ratio

This approach is not appropriate if society's viewpoint is being considered in which case all costs and benefits affecting society must be taken into account. Moreover, the prices used to value costs and benefits will often differ from those used when considering the viewpoint of the provider.

## SHADOW PRICES

You will recall from Module 3 that the cost to society of using a resource is its opportunity cost. Economists believe that the best indicator of benefit is society's willingness to pay for a product or service. In many cases, market prices do not reflect

example of  
-ve NPV =

all health  
programs

But not for  
very high.



either economic costs (opportunity costs) or economic benefits (willingness to pay).

This is partly because market prices can be affected by taxes and other transfer payments (see Module 3), but there are other reasons as well. For example, in the human capital approach the indirect benefits of saving a life are the increases in production which result. It is often assumed that this increased production is equal to the wages the person would earn over the remainder of their working life. There are many reasons why market wages do not reflect contributions to production and the case of unpaid housewives is a good illustration.

Accordingly, in order to conduct the analysis from society's viewpoint, economists must impute values for cost and benefits which reflect economic rather than financial values. This applies to all the techniques which were introduced in earlier modules as well as to CBA. These imputed values are called shadow prices.

Two major methodologies for calculating shadow prices have been developed. Both are complicated to apply and require a fairly thorough knowledge of economic theory. You should seek the help of an economist if you wish to use shadow prices.

To date they have not been used extensively in the analysis of health interventions. This may be because the literature has been dominated by North American examples, and many economists believe that the deviation between economic and financial prices is not large in the USA. If this is true, the effort of calculating shadow prices may not be justified.

Regardless of whether it is true in North America, it is not true in much of the rest of the world. In any case, the effort of ascertaining shadow prices is not great in many countries. They can often be obtained from publications by international organizations such as the World Bank, and the Planning Office/Departments of many developing countries regularly calculate them for their own purposes.

### SOCIAL ANALYSIS

Project appraisal using market prices is called financial analysis. When shadow prices are used, it is called economic analysis. A third form, social analysis, has become popular recently.

Economic analysis is a form of efficiency analysis. It seeks to maximise the gain to society from a particular investment. How this gain is distributed within society is not relevant. Social analysis is an extension of economic analysis where distribution issues are relevant and are examined explicitly.



Intra- and inter-temporal distribution can be incorporated. The former gives a higher weight to benefits which accrue to a particular group of people (usually the poor) in the current time period. The latter gives higher weights to benefits which will not be consumed immediately, but will be saved. Savings can then provide benefits in a subsequent time period. The rationale is that society does not save enough to provide for future generations, so preference should be given to projects which will result in relatively high savings in relation to consumption.

Sometimes this is extended to give preference to government savings over private savings on the grounds that the government would use them to benefit society whereas individuals may not do so. As yet, social analysis has not been applied to health projects and it is not intended that you should attempt to use it. It was introduced so that you will be familiar with a concept which appears in the literature.

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#### Major References:

Drummond et al (see Module 4), chapter 7.

Gill M. et al, "An economic appraisal of screening for Down's Syndrome in pregnancy using maternal age and serum alpha fetoprotein concentration", Social Science and Medicine 1987, 24(9):725-731.

#### Other Reference:

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### QUESTIONS

1. Read the article by Gill et al.
  - a. Whose viewpoint was taken in the analysis and is the ~~conclusion~~ <sup>conclusion</sup> likely to differ if another viewpoint is taken?
  - b. Comment on the way that costs were calculated, including whether any important costs were omitted and whether marginal or (average) costs were used? *A survey was taken - of the results are correct or the same holds, something is wrong.*
  - c. Have all the important benefits been included and measured correctly?
2. Mindful that economic costs are opportunity costs, how would you measure the costs to society of using:
  - a. unskilled labour;



## Contemporary Themes

# Preventing the birth of infants with Down's syndrome: a cost-benefit analysis

SPENCER HAGARD, FELICITY A CARTER

*British Medical Journal*, 1976, 1, 753-756

### Summary

The costs and economic benefits of providing routine prenatal diagnosis of Down's syndrome with termination of affected pregnancies in older pregnant women in the west of Scotland were examined. The potential economic benefits would be greater than the costs for women aged 40 and over, probably about equal to costs for those aged 35 and over, but less than costs if the service were extended to women under 35.

### Introduction

Down's syndrome accounts for between a quarter and a third of all moderate and severe mental handicap (intelligence quotient (IQ) <55) in children of school age.<sup>1,2</sup> Its birth prevalence is currently being slightly reduced by providing prenatal diagnosis and selective abortion to older pregnant women on request. To make a major impact on the problem, however, would require mass prenatal diagnostic programmes directed, in the first instance, towards all older pregnant women—that is, those at higher risk. We consider here the relation between the likely costs and economic benefits of establishing such a programme in the west of Scotland. In evaluating the economic benefits resulting

from terminating pregnancies affected with Down's syndrome we considered two situations, one in which women do not become pregnant again after termination (no replacement), and the other in which termination is followed by a further pregnancy (replacement). The outcome of replacement pregnancies is assumed to be normal. Since a programme testing for Down's syndrome could also diagnose fetal myelocoele, the costs and economic benefits of this are also taken into account.

### Method

For the population living in the area covered by the six west of Scotland health boards and served by the Genetic Advisory Centre in Glasgow, we estimated for 1975-94 for Down's syndrome: (a) the number of births by five-year maternal age groups; (b) the survival rates and degree of handicap of survivors; (c) the costs to society of caring for survivors; (d) the characteristics, including number of affected births prevented, of a prenatal diagnostic programme; and (e) the costs of running such a programme.

The savings in resources made by preventing affected births, in both replacement and no replacement circumstances, were calculated. The costs and economic benefits of testing all specimens for fetal myelocoele were also considered.

All costs were standardised to a value for July 1974, using the Retail Price Index,<sup>3</sup> and future costs were discounted at 10%, the rate currently used by the UK Treasury, to obtain the net present values. The variations of costs with benefits under different conditions were examined.

### Results

#### EPIDEMIOLOGY AND NATURAL HISTORY

Differences in methods of ascertainment probably account for much of the reported variation in the rates of prevalence of Down's syndrome: the more exhaustive the case finding the higher the rate recorded. The highest rates yet recorded in a European population<sup>4</sup> (table 1) were applied to west of Scotland 20-year birth projections, derived from

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TABLE 1: Live birth prevalence of Down's syndrome by five-year maternal age groups after Lindsjö<sup>1</sup>

Maternal age (years):	<19	20-24	-29	-34	-39	-44	≥45
Birth prevalence, 1 in:	1685	1352	1133	687	267	67	16

population and age-specific fertility predictions.<sup>5, 6</sup> This gave estimates of the number of births of infants with Down's syndrome in each five-year age group of women in each of the years 1975-94. We calculated that total births to women over 40 would vary a little about a mean of 550 a year while to women aged 35-39 the number would vary between 1780 and 2340 a year. Over the 20 years an average of 5.4% of all births but 29% of births of infants with Down's syndrome would be to women aged 35 and over; 1.1% of all births but 16% of births of infants with Down's syndrome would be to women aged 40 and over.

**Survival**—An increasing proportion of infants with Down's syndrome survive.<sup>7</sup> Estimates of likely survival to various ages were calculated from the results of two comprehensive surveys<sup>8,9</sup> and are shown in tables II and III.

**Mental handicap**—Using data collected in north-east Scotland<sup>10</sup> we estimated that 20% of children with Down's syndrome would have an IQ in the range 50-69, 75% in the range 20-49, and the rest below 20.

TABLE II—Estimated proportion of cohort of 100 people with Down's syndrome  
surviving at various ages

Age (years):	1	2	3	4	5	10	15	20	25	30	35	40	45	50	60	70
No of survivors:	76	73	71	69	69	65	60	55	49	44	39	33	27	22	11	0

## USE OF RESOURCES BY THOSE WITH DOWN'S SYNDROME

The economic benefit of preventing the birth of handicapped people is the cost to the community of their care. In the case of an abortion followed by a successful normal pregnancy (replacement) this is the difference between the cost of caring for a handicapped person and that of caring for an average person. When there is no further pregnancy (no replacement) the cost is the total cost of caring for a handicapped person. In estimating these costs the use of resources by a nominal cohort of 100 people live-born with Down's syndrome was assessed. An estimate of the costs that would be incurred in the replacement situation is illustrated for representative years in table III. The derivation of these costs is indicated below; more detailed consideration is available elsewhere.<sup>11</sup>

**Permanent care**—We estimated the percentages of survivors in permanent care using projected Down's syndrome survival rates and the results of a recent west of Scotland survey.<sup>12</sup> We considered that

out a quarter of patients would be in permanent care by the age of 15, half by the age of 25, about three-quarters by the age of 35, and all by the age of 45. The additional cost of permanent care over residence at home is higher for children than for adults: the childhood costs include those of education. For a birth cohort of 100 the costs of permanent care were calculated to lie in the range £3000-£16 000 a year (replacement and no replacement).

**Education**—In general children with Down's syndrome with IQs over 50 (20%) attend special schools, while the remainder attend

junior occupational or day care centres.<sup>13 14</sup> For those continuing to live at home special education was estimated to cost £100-£400 per child per year than normal schooling—£10 000-£25 000 per year for a birth cohort of 100 (replacement and no replacement

**Lost maternal income**—As their children get older an increasing proportion of women go out to work, but many of those with handicapped children stay at home to look after them. We assumed labour force participation among mothers of children with Down's syndrome would be half that of average mothers with children of the same age. Hence, using published wage and employment data,<sup>11</sup> we estimated that for a birth cohort of 100 six mothers would forgo potential earnings of over £6000 a year when their children were young, and 11 to 15 mothers would forgo around £14 000 a year later on (replacement and no replacement).

**Additional costs**—Since no useful data are available on the additional services required to cope with the greater physical morbidity of those with Down's syndrome, we omitted the possible costs of such services from our calculations. The inability of most people with Down's syndrome to work, however, imposes a considerable economic burden on society. We assumed that only those with IQs over 50 could work and then only with half the productivity of an average person. Using average lifetime earnings and consumption data,<sup>15 16</sup> we calculated that in the replacement situation for a birth cohort of 100 this would imply costs rising from about £45 000 a year at age 16 to a maximum of about £110 000 a year at age 25.

*Total costs*—Estimates of total annual costs in each age group were obtained by adding the estimates under each heading for each year. In the replacement situation and for a birth cohort of 100 they were calculated to increase from under £5000 a year in infancy to over £120 000 a year in middle life. A discount rate of 10% was applied to each year's total, and the discounted individual year totals added together to give the net present value of caring for a birth cohort of 100 people live-born with Down's syndrome. In the replacement situation this was £415 000—that is, £4150 per person, and for no replacement £10 620 per person. The lifetime consumption data available for calculation were not entirely appropriate to no replacement circumstances, however, and they probably exaggerated the present value of costs.

**Myelocoele**—The figure of £3940, estimated as the economic benefit from preventing the birth of an infant with myelocoele,<sup>17</sup> was used to calculate the economic benefits of preventing such births in the context of a Down's syndrome programme.

## PRENATAL DIAGNOSTIC PROGRAMME

We calculated the costs of a programme to examine 550 women aged 40 and over each year; these women were estimated to be at risk of having 9.1 live-born infants with Down's syndrome. We assume that 90% (495) of the women would attend antenatal clinic at the appropriate time for diagnosis (14th-18th week of gestation), that this would not entail extra antenatal clinic visits, that the characteristics of attenders and non-attenders would be the same, and that, at genetic counselling, all attenders would accept amniocentesis (done on condition that affected pregnancies diagnosed would be terminated). All would receive ultrasonographic examination and amniocentesis. About 1% (5) of amniotic fluid chromosome analyses would require repetition (calculation based on data supplied by Glasgow and West of Scotland Genetic Advisory Service), which would entail repeat attendance, ultrasonography, and amniocentesis. A diagnostic success

TABLE III—Costs of caring for cohort of 100 people live-born with Down's syndrome in the replacement situation

[illegible]



rate of 99%, would be expected.<sup>13</sup> Thus 8.1 cases (99% of 90%) of 9.1) would be identified. In addition, 1.4 cases of anencephaly and 1.2 cases of myelocoele (1 infant born alive) would be identified in this population.<sup>17</sup>

**Costs**—Costs to the Health Service and participants were calculated and are shown in table IV. Costs relating to time lost from work were derived from government data<sup>15</sup> and those to medical genetics provision from local data (supplied by the Glasgow and West of Scotland Genetics Advisory Centre). **Publicity**, directed primarily at general practitioners, obstetricians, and the pregnant women, was estimated to cost the service £2500 a year with an additional £2500 in the first year. Attendance for *genetic counselling* would impose costs on women and husbands through lost working time and travelling (£2871 a year) and on the service (£2094 a year). We assumed that *ultrasonographs* in routine use would be available, but a small staff cost would be incurred (£372 a year). Attendance for *amniocentesis* would impose costs on women (£2500 a year) and on the service (£1448 a year). *Laboratory costs* would all be borne by the service.

TABLE IV—Cost of prenatal diagnostic programme for Down's syndrome for women aged 40 and over in west of Scotland

	Initial Cost to Health Service (£)	Capital costs			Annual recurring costs	
		Recurring after:			To Health Service (£)	To patients and or husbands (£)
		5 years (£)	10 years (£)	20 years (£)		
Publicity	2500				2500	
Genetic Counselling (495 consultations)						
Staff costs:						
5 Senior registrar sessions/week					2094	
Patient costs:						2871
at £1.60 (women)						
at £4.20 (men)						
Ultrasonography (500 examinations)						
Staff costs:						
2 Midwifery sister sessions/week					372	
Amniocentesis (500 examinations)						
Staff costs:						
4 Registrar sessions/week					1448	
Patient costs:						2500
at £5.00						
Laboratory costs					9929	
Staff				35 700		
Accommodation		20	25 054	102		81
Equipment						3704
Running costs						
Totals	2500	20	25 054	35 302	20 128	5371
Total cost of diagnostic programme		Capital: 63 376; recurrent: 25 499				

They were estimated to be (a) £35 700 for site and construction with at least 20 years' life, (b) £9929 a year for medical, scientific, technical, and records staff, (c) £25 176 for equipment, which would need replacing from time to time, and £81 a year for its servicing, and (d) £3704 a year for disposable materials, utilities, rates, and administration. The total cost of the first year of the 20-year programme was given by adding the initial capital costs (£63 376 to the service) to the annual recurrent costs (£20 128 to the service and £5371 to the participants). The cost of each of the subsequent 19 years was the annual recurrent cost, plus the cost of equipment replacement if indicated—that is, plus £20 in the sixth year, £25 074 in the 11th, and £20 in the 16th. Accommodation and certain equipment costs (total £35 802) would not recur within a 20-year programme. A discount rate of 10% was applied to each year's total, and the discounted individual year totals added together to give the net present value of total costs of establishing and maintaining a 20-year diagnostic programme—£311 855.

#### TOTAL BENEFITS AND COSTS

The programme described, costing £311 855, would prevent the births of 8.1 children with Down's syndrome each year and 1.0 with myelocoele, and thus in the replacement situation produce an annual economic benefit of  $(8.1 \times £4150) + (1.0 \times £3940) = £37 555$ . A discount rate was applied to this sum for each of the 20 years of the programme and the discounted individual year totals added together

to give a net present value for the total economic benefits of the programme, amounting to £351 699. The corresponding value of economic benefits from preventing Down's syndrome alone in the no replacement situation would be £805 587. In each case therefore the value of economic benefits would exceed that of costs.

**Programme for women aged 35 and over**—Corresponding calculations were made, and the findings were: costs, £1 193 312; economic benefits, £752 579 (replacement situation) and £1 496 358 (no replacement situation).

#### Discussion

Economic benefits were divided by costs to give benefit:cost ratios. For women aged 40 and over these were: 1.13 (replacement) and 2.58 (no replacement). If, after genetic counselling, only half accepted amniocentesis and possible termination the benefit:cost ratios would be reduced by 25% (to 0.84 in the replacement situation, for example). But the no replacement situation would probably apply to almost all women of this age, so the overall benefit:cost ratio would considerably exceed unity, even were participation reduced so considerably and even after allowing for the probable exaggeration of the no replacement ratio caused by the inappropriate nature of the available lifetime consumption data. This suggests that there would be net economic benefits from providing a prenatal diagnostic programme for this age group. This view is reinforced by new evidence from several centres, including Glasgow, that the birth prevalence of Down's syndrome among women over 40 may be up to twice that reported by Lindsjö.<sup>18</sup>

For the complete over-35 age group the benefit:cost ratios were: 0.63 (replacement) and 1.25 (no replacement). If after genetic counselling only half accepted amniocentesis and possible termination the benefit:cost ratios would again be reduced by about 25% (to 0.48 in the replacement situation, for example). But were this 50% participation confined to those under 40, perhaps as a result of their acting on self-recognition of their low risk of fetal abnormality, the benefit:cost ratios would be slightly higher than 0.63 and 1.25. The availability and inclusion of such resource use data as those relating to morbidity from physical illness or to social services would probably also raise the benefit:cost ratios; incorporation of better lifetime consumption data in the no replacement situation, however, would probably have the opposite effect. Furthermore, although no replacement could be expected to apply to most of the age group, the bias in its favour would presumably be less pronounced than among the over 40s. With all these factors taken into account, the costs of a prenatal diagnostic programme for the complete over-35 age group would probably be about equal to the net economic benefits, so that, on economic grounds, this programme too could probably be justified. Its development might follow initial provision to the over 40s, from which the collection of appropriate epidemiological and resource use data would provide for more accurate economic calculation for the younger age group.

It has been suggested that it would be economically justifiable to extend prenatal diagnosis of Down's syndrome to women under 35.<sup>19</sup> The data and calculations presented here make this seem unlikely. Such a decision would therefore have to rest on other considerations of the priorities for health expenditure. In any case the view that amniocentesis should be offered to women whose risk of diagnosable severe fetal abnormality is remote<sup>19</sup> needs critical re-examination.

Our conclusions rest on the assumption that those responsible for health planning embrace the cost-benefit analysis approach—perceiving their responsibilities beyond the narrow framework of health services accountability, and accepting a long-term economic perspective. The findings also re-emphasise that society's response to the problem of Down's syndrome cannot rest solely on consideration of economic costs and benefits. If Down's syndrome is socially unacceptable provision of a programme to reduce its birth prevalence by scarcely a third would be an inadequate response. Conversely, failure to implement a programme for all maternal age groups would imply that their



were other, perhaps more appropriate, responses to the problem of Down's syndrome. Since this would call into question any programme directed at identification and termination of affected pregnancies, it would be logical to resolve this dilemma before any programme was started.

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# Problems of Childhood

## Wheezing children

J K SARSFIELD

*British Medical Journal*, 1976, 1, 756-759

The wheezing child is a common clinical problem. Asthma is by far the commonest cause of wheezing, but other conditions must be considered, especially in the young child. These include respiratory tract infection, especially viral bronchiolitis, inhalation of a foreign body, cystic fibrosis, primary tuberculosis, and congenital anomalies. Clinical and radiological examination will usually identify these conditions.

The role of infection in wheezing in the young child is not clear. Acute bronchitis with airways obstruction may produce a wheeze with associated respiratory distress, fever, leucocytosis, and general malaise. If these attacks recur terms such as "wheezy bronchitis," "asthmatic bronchitis," and "pseudo-asthma" are applied. Antibiotics are often prescribed but with doubtful benefit. Viral infection may be responsible for some attacks, but several studies have shown that viruses can be isolated from only about a third of patients and their role in the pathogenesis is uncertain. Williams and McNicol<sup>1</sup> made a valuable contribution to our understanding of this group of young wheezing children who have apparent preceding infection. After a prospective long-term epidemiological study they concluded that they could not separate recurrent "wheezy bronchitis" from asthma. Their evidence suggests that both conditions exhibit a common basic asthmatic disorder, but the

spectrum of severity varies greatly from a few mild early attacks that abate to established severe asthma persisting into adult life.

## Asthma

In the absence of any widely accepted definition of asthma it seems reasonable to consider it, simply, as a constitutional disorder characterised by hyper-reactivity of the airways. Various factors may provoke this reactive state and lead to paroxysmal attacks of airways obstruction producing respiratory distress and wheezing. The basic constitutional disorder is probably biochemical and almost certainly has a genetic basis, but the precise mode of inheritance is unknown. This familial tendency, however, may help the doctor towards an earlier diagnosis and hence more appropriate management.

An understanding of the known basic mechanisms concerned in the cause of asthma is essential to proper assessment and management.

## Allergy

Most asthmatic children have demonstrable allergies. The incidence of hay fever, eczema, and urticaria is much higher in these children and their families than in non-asthmatics. The fact that an acute attack of asthma may be a manifestation of immunological hypersensitivity reaction to an external provoking antigen (allergen) has been recognised for many years. Recent advances have established that antibodies belonging to a newly recognised immunoglobulin class, IgE, are concerned. These antibodies are firmly attached to mast cells in the bronchial mucosa, and on exposure to an offending allergen the antibody-antigen reaction causes the release of vasoactive amines from

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## Basic Analytical Toxicology

This book provides a practical guide to the laboratory analysis of over 100 substances frequently involved in episodes of acute poisoning. Noting that many hospitals, especially in developing countries, lack the support of analytical toxicology services, the book aims to help laboratory staff perform a range of simple tests known to produce rapid and reliable results for the management of poisoning emergencies. All tests described can be performed without the need for sophisticated equipment, expensive reagents, or a continuous supply of electricity.

The manual opens with general information about the organization and functions of an analytical toxicology laboratory, the principles of safe laboratory practice, and the essentials of emergency medicine and intensive care that will influence the laboratory's work. A brief introduction to the apparatus, reference compounds and reagents needed in the laboratory is followed by an explanation of basic clinical issues. Details range from a table listing the clinical features associated with some common poisons to a description of essential symptomatic and supportive measures that can be taken before the diagnosis is confirmed.

Chapter three explains the most useful biochemical and haematological tests for the diagnosis of acute poisoning and for assessment of prognosis. The final introductory chapter goes through the do's and don'ts of laboratory practice pertaining to safety, the performance of colour tests, the pretreatment of samples, and procedures for the use of thin-layer chromatography and ultraviolet and visible spectrophotometry.

The remaining two chapters, which constitute the core of the manual, describe the many simple analytical tests that can be used to detect and identify poisons, whether in biological fluids or in powders, tablets, or other items found near the patient. The first chapter, on qualitative tests for poisons, sets out a three-part series of tests designed for use as a routine, rapid screen, especially appropriate in the many cases where the identity of the poison is unknown.

The second and most extensive chapter provides step-by-step instructions for the performance of qualitative tests and some quantitative methods for 113 specific poisons or groups of poisons. Substances covered range from pesticides and other industrial chemicals, through compounds contained in household products, to pharmaceuticals, plant toxins, and drugs commonly abused. To assist communication between the toxicologist and the clinician, each monograph also contains information on clinical signs of intoxication and recommended treatment. All techniques and procedures have been tested by laboratory technicians in developing countries to assure reliable performance using relatively simple apparatus.

### Basic Analytical Toxicology

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## Global eradication of poliomyelitis: benefit-cost analysis

K.J. Bart,<sup>1</sup> J. Foulds,<sup>2</sup> & P. Patriarca<sup>3</sup>

*A benefit-cost analysis of the Poliomyelitis Eradication Initiative was undertaken to facilitate national and international decision-making with regard to financial support. The base case examined the net costs and benefits during the period 1986–2040; the model assumed differential costs for oral poliovirus vaccine (OPV) and vaccine delivery in industrialized and developing countries, and ignored all benefits aside from reductions in direct costs for treatment and rehabilitation. The model showed that the "break-even" point at which benefits exceeded costs was the year 2007, with a saving of US\$ 13 600 million by the year 2040. Sensitivity analyses revealed only small differences in the break-even point and in the dollars saved, when compared with the base case, even with large variations in the target age group for vaccination, the proportion of case-patients seeking medical attention, and the cost of vaccine delivery. The technical feasibility of global eradication is supported by the availability of an easily administered, inexpensive vaccine (OPV), the epidemiological characteristics of poliomyelitis, and the successful experience in the Americas with elimination of wild poliovirus infection. This model demonstrates that the Poliomyelitis Eradication Initiative is economically justified.*

### Introduction

Developing countries are confronted with destabilizing health problems and with a serious shortage of resources. The prospects for per capita income growth in many countries have deteriorated, and the adoption of structural adjustment policies calls for a rigorous review of public investment programmes. The allocation of resources in the health sector in the past has not been efficient and equitable, owing to an emphasis on expensive urban and hospital-based curative care, and was not directed at the main causes of ill health in the majority of the population, especially in the less developed countries.

Only in the past decade has immunization, one of the least expensive and most cost-effective of all health interventions, which has been confirmed by cost analyses, been accorded a high priority (1). The prospect of removing the burden of a disease and its treatment for ever, and at the same time eliminating the continuing costs of vaccinations, is an attractive policy alternative. Prior to the development and

introduction of poliomyelitis vaccine, up to 32 out of every 100 000 children born in the world had permanent lameness as a result of infection with poliovirus (2–4).

The early successes in the Americas, through the expanded programmes on immunization (EPI), led the Forty-first World Health Assembly in May 1988 to adopt a resolution (WHA41.28) to eradicate poliomyelitis from the world by the year 2000 (5). This goal was confirmed in 1990 at the World Summit for Children (6). Poliomyelitis eradication is an example of the EPI focus on the impact of immunization on a target disease. In addition, the progress towards such eradication is seen as providing a measure of the progress towards achieving the WHO goal of Health for All by the year 2000, i.e., reaching and maintaining >90% coverage with current EPI antigens for all children (7, 8). Under WHO's global leadership of EPI, an estimated 80% of the world's children were fully immunized in 1993 against poliomyelitis; even so, the disease still causes paralysis in over 100 000 individuals each year and kills perhaps more than 10 000 (9).

The decision to undertake eradication has economic implications for the poorest countries and donors who are concerned about the potential to divert resources from other activities with a potentially greater impact or to interfere with the development of primary health care (10–13). A benefit-cost analysis of global poliomyelitis eradication was therefore recommended so that decisions about national and international financial support for this effort could be made.

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## Methods

### The model

The global poliomyelitis eradication programme has been modelled as a unit effort from the beginning of the first eradication efforts, with projections beyond eradication; benefits have been calculated up to the year 2040. The number of children to be immunized with oral poliomyelitis vaccine (OPV) annually, the disease incidence and morbidity, and the vaccine's efficacy permit an estimation of the number of cases prevented by vaccination and the cost of achieving these reductions. Reductions in the morbidity and mortality, and the consequent drop in demand for treatment and rehabilitation constitute the principal benefits of OPV vaccination in the base case (see below). In addition, in order to approach a more complete estimate of net present value, additional direct benefits of eradication, i.e., the savings in vaccine and its delivery, have been added to the treatment and rehabilitation costs and compared with the cost of the programme to determine whether the programme is economically justifiable (14-18).

The analysis has attempted to maximize the costs and minimize the benefits in order to construct the least favourable balance in the benefit-cost relationship of poliomyelitis eradication. Because it is difficult and often controversial to place dollar values on many of the elements on the benefit side of the benefit-cost equation, only the savings in treatment and rehabilitation following the reduced incidence of disease have been used as the benefits in this analysis. If eradication can be seen to have a favourable benefit-cost ratio while ignoring all other tangible reductions in the costs to the community and the family, the long-term handicaps, the value of life and income calculations as well as intangible and external benefits, it would be expected to be even more cost-beneficial when these other benefits are taken into account, no matter how or at what level they are valued. In addition, this approach enables comparison with the analysis that was carried out for the Americas (19).

For each of the years of the model programme, estimates were made of the number of paralytic poliomyelitis cases that would be prevented, the costs

of treatment and rehabilitation of that number of poliomyelitis cases, the cost of the eradication effort (the vaccine, the cold chain, administration of the programme, the deployment of delivery teams, social mobilization and the immunization strategy chosen), and the net benefit (i.e., the reduced treatment and rehabilitation costs). The analysis compares the annual total costs with the total benefits throughout the entire period from pre-eradication till after eradication (20, 21).

The analysis presented is a model designed to simulate as closely as possible the global eradication programme now being undertaken. While the model simulates what is taking place, some inputs, costs and programme projections can only be estimated and may differ from country to country within regions as well as between regions. For example, what proportion of a childhood population will be reached during a national vaccination day, "mop-up", or outbreak response; and will there be just 5 years of national vaccine days or more than that, 2 years of mop-up, and the undertaking of significant outbreak response activities? Estimates of costs and benefits and projections were selected from country experiences.

Sensitivity analyses were performed where differing programme strategies, e.g., age of the target population for national vaccination days, discount rate and the cost of vaccine, or where costs vary widely in published data between country experiences, such as the cost to immunize a child or the amount of vaccine wastage. Only one assumption is varied at a time in the base case to test the effect of each parameter in question. Since the estimates of costs are only available from some countries, data reviews and surveys for the less developed countries<sup>1-3</sup> and for industrialized countries<sup>4</sup> were used in addition to individual published

reports and personal communications to establish cost parameters.

Two additional models were constructed, the first using 1988, the year of the World Health Assembly resolution on eradication of poliomyelitis, as the base year and measuring the marginal additional costs and benefit-cost of moving from control of the disease to eradication. In the second, benefits included savings in the cost of vaccine and delivery as well as treatment and rehabilitation in order to reflect more closely the true benefits of poliomyelitis eradication.

### The base case and sensitivity analyses

(1) The base case includes the identification, valuation and summation of the cost and benefits in each year of the project's life. Costs (C) and benefits (B) were summed over the years, projected and discounted to calculate the Net Present Value using the formula given below. The present value of this stream of net benefits is the sum of these individual terms over the years of the model programme. In the model, net benefits remain positive, but because of discounting the benefits are smaller in future years.

$$\text{Net Present Value} = \sum_{t=0}^n \frac{B_t - C_t}{(1+r)^t}$$

(2) Eradication of poliomyelitis is taken as that point where the transmission of the causative organism has ceased in an irreversible manner, vaccine is no longer in use and, as a result, cases and infection have disappeared from all countries of the world.<sup>5</sup>

(3) The estimates of global population, the global birth cohort and the population living in industrialized and developing countries in each region are derived from the 1992 mid-year United Nations population estimates (22). No attempt has been made to incorporate the growth rate into the cohort to be vaccinated.

(4) The population to be vaccinated during the routine vaccination programme is estimated as the 1992

### Benefit-cost analysis of poliomyelitis eradication

global birth cohort of surviving infants (133831500, of which 115272400 are in the developing world and 18559100 are in the industrialized world and Eastern Europe) who receive four doses of OPV during routine immunization (at birth, 6, 10 and 14 weeks) during the first year of life.<sup>6</sup> It is projected that 90% of the target population is reached. In addition, children aged 13-59 months (1-5 years) who have been identified with incomplete vaccination during routine facility-based vaccination sessions during their first year of life are assumed to be vaccinated at these routine contacts. It is estimated that 1/5 of unvaccinated children aged 13 to 59 months are identified and vaccinated each year.

(5) Immunization coverage estimates are those estimated and reported by the EPI as of October 1993. Coverage estimates are for three doses of oral poliomyelitis vaccine (OPV 3), since no systematic coverage estimate for the birth dose is available. Costs are projected for four doses to all children, i.e., as if all infants had received a birth dose, to maximize the costs of the model.

(6) National vaccination days are projected twice a year for 5 years in addition to the routine vaccination programme for all children aged  $\leq 59$  months. These are projected as two doses one month apart. It is projected that 90% of the target population is reached during each national vaccination day. Sensitivity analyses are done for target populations aged  $\leq 36$  months and  $\leq 48$  months (Table 1).

(7) In addition, after 5 years of national vaccination days are completed, in response to the continued occurrence of cases, 10% of children aged  $\leq 59$  months are projected to be vaccinated in annual "mop-up" campaigns. It is projected that 90% of the target population is reached during each mop-up campaign. These are projected as two doses one month apart for two years. Sensitivity analyses are done for target populations aged  $\leq 36$  months and  $\leq 48$  months, with 1% and 0.1% of all children targeted to be vaccinated.

(8) Outbreak response is projected surrounding cases in which 1% of all children aged  $\leq 59$  months are immunized with two doses one month apart. It is projected that 90% of the target population is reached during outbreak response. Sensitivity analyses are done with 0.1% of children aged  $\leq 59$  months vaccinated.

(9) Vaccination costs are expressed in 1993 US dollars, and are based on the planned regional programmes of eradication (Table 2). All costs are modelled beginning in 1986. The programme for the Americas is assumed to have begun in 1986 with national vaccination days and outbreak control car-

<sup>1</sup> Garlow DC. Mass vaccination to combat polio: a cost-benefit analysis for Brazil. Instituto de Pesquisas e Estudos Econômicos, Universidade Federal de Rio Grande do Sul, 1993 (In English, unpublished).

<sup>2</sup> Mop-up efforts are intensive house-to-house vaccination campaigns designed to reach and immunize children who are at special risk of infection.

<sup>3</sup> World Health Organization. Expanded Programme on Immunization: EPI costing guidelines. Unpublished document WHO/EPI/79/5, 1979.

<sup>4</sup> Brenzel L. The cost of EPI: lessons learned from cost and cost-effectiveness studies of immunization programs. REACH Project Paper, 1990 (unpublished document).

<sup>5</sup> Patrícia P. Cost of delivering OPV in the developing world - Egypt, Vietnam. Personal communication, 1993.

<sup>6</sup> John TJ. Cost of full immunization with IPV and OPV vaccine and treatment and rehabilitation for poliomyelitis, North Arcot District in India (personal communication, 1991).

<sup>7</sup> Grabowski M. Cost of IPV and OPV vaccine and delivery of vaccine in the industrialized countries of the European Region (personal communication, 1992).

<sup>8</sup> EPI. Poliomyelitis surveys by regions. EPI Information System. Section 3, Table 3.4, July 1988 (unpublished).

<sup>9</sup> World Health Organization. Global poliomyelitis eradication by the year 2000: plan of action. Revised 1992. Unpublished document WHO/EPI/Polio/92.2, 1992.

<sup>10</sup> World Health Organization. Progress towards the global eradication of poliomyelitis: status report. March 1994. Unpublished document WHO/GPI/Polio/94.1, 1994.



Table 1: "Base case" costs and benefits and sensitivity analysis for poliomyelitis eradication programme model

<b>I. Costs</b>	
<b>1. Routine vaccination</b>	
a. Population <12 months old	133 830 000 plus 20% of 1-5-year age group (107 064 000)
— Industrialized countries	18 580 000
— Developing countries	115 207 000
b. Industrialized countries	
Vaccine cost — OPV	US\$ 4.16/dose (base case)
Delivery cost — OPV	US\$ 5.09/dose (base case)
c. Developing countries	
Vaccine cost — OPV	US\$ 0.08/dose (base case)
(Sensitivity analysis: US\$ 0.12/dose)	
Delivery cost — OPV	US\$ 1.51/dose (base case)
(Sensitivity analysis: US\$ 3.00/dose)	
d. Wastage	
OPV	33%
(Sensitivity analysis: 50%)	
<b>2. Accelerated vaccination activities (national vaccination days (NVD), mop-up, outbreak control)</b>	
a. Population <59 months age	669 150 000
— Industrialized countries	92 800 000
— Developing countries	576 350 000
(Sensitivity analysis: for mop-up 1% and 0.1%; for outbreak control 0.1% of the target population.)	
b. Industrialized countries	
Vaccine cost — OPV	US\$ 4.16/dose
Delivery cost — OPV	US\$ 1.48/dose
c. Developing countries	
Vaccine cost — OPV	US\$ 0.08/dose
Delivery cost — OPV	US\$ 0.10/dose
(Sensitivity analysis: US\$ 0.79/dose)	
<b>3. Target population for accelerated activities &lt;59 months old (base case) (Sensitivity analysis &lt;48 and &lt;36 months old)</b>	
<b>4. Discount rate 6% (Sensitivity analysis at 0%, 3%, 10%)</b>	
<b>II. Benefits</b>	
<b>Case of paralytic poliomyelitis — pre-EPI 5/100 000 (Sensitivity analysis: 2/100 000 and 19/100 000)</b>	
<b>Proportion of paralytic cases receiving treatment and rehabilitation</b>	
Industrialized countries	100%
Developing countries	33%
(Sensitivity analysis: 0%)	
<b>Cost of treatment and rehabilitation</b>	
Industrialized countries	US\$ 25 000/case
Developing countries	US\$ 250/case

ried out for 5 years until 1990, with mop-up efforts that continued for two additional years. Routine immunization is planned to continue till the year 2005 when eradication is projected to be declared globally.

For the Western Pacific Region (WPR) the programme is assumed to have begun in 1991 with "subnational vaccination days" (20% of the children less than 5 years of age) having been carried out for two years prior to the first national vaccination days in 1993. It is projected that 90% of the target population was reached during each subnational vaccination day. Children were vaccinated with two doses one month apart.

In the European Region (EUR) only one-third of the population are in countries expecting to conduct national vaccination days, i.e., the former Soviet Union, the former Yugoslavia, Turkey, Romania, Bulgaria and Albania. This effort is projected to have begun in 1992, and 90% of the target population was reached with two doses one month apart.

In the Eastern Mediterranean Region (EMR) two years of subregional vaccination days began in 1992 to be followed by national vaccination days for five years. Subregional vaccination days are defined as targeting 10% of the children aged <59 months for vaccination with two doses one month apart. It is projected that 90% of the target population was reached.

National vaccination days began in the South-East Asia Region in 1994 although individual countries e.g. India, started subnational vaccination days in 1992. The African (AFR) Region began national vaccination days in 1995. It is projected that there will be 90% coverage with two doses one month apart.

(10) Globally, each country will be monitored for three years by a Global Eradication Certification Committee after the last case of poliomyelitis has been reported, and after vaccinations have been stopped and poliomyelitis is declared as eradicated in the year 2005. Routine immunization is projected to continue in all regions until they are polio-free.

(11) Although an incidence as high as 32 per 100 000 has been reported, the global incidence of paralytic poliomyelitis at the outset of the eradication effort is estimated conservatively at 669 158 or 5 per 100 000 surviving newborns.

(12) It is assumed for the purposes of this calculation that, in industrialized countries, 95% of those vaccinated with OPV were immunized, i.e. developed detectable levels of neutralizing antibodies (23). In developing countries it is assumed that 80% of those vaccinated with OPV were immunized. From the limited data available, seroconversion rates with OPV during national vaccination days may be 10% higher than during routine immunization programmes, but this is not taken into account in these calculations.

Table 2: Global poliomyelitis eradication model programme: projected activities, by WHO Region, 1986 to 2005

Year	WHO Regions									
	Africa	Americas	Eastern Mediterranean	Europe	South-East Asia	Western Pacific				
1986	Routine*	NVD* + Outbreak* + R	Routine	Routine	Routine	Routine				
1987	Routine	NVD + Outbreak + R	Routine	Routine	Routine	Routine				
1988	Routine	NVD + Outbreak + R	Routine	Routine	Routine	Routine				
1989	Routine	NVD + Outbreak + R	Routine	Routine	Routine	Routine				
1990	Routine	NVD + Outbreak + R	Routine	Routine	Routine	Routine				
1991	Routine	NVD + Outbreak + R	Routine	Routine	Routine	Routine				
1992	Routine	Mop-up + Routine	Subregional*	Routine	Routine	Subnational* + Routine				
1993	Routine	Routine	Subregional	NVD/3 + Outbreak + R	Routine	Subnational + Routine				
1994	Routine	Routine	NVD + Outbreak + R	NVD/3 + Outbreak + R	Routine	NVD + Outbreak + R				
1995	Routine	Routine	NVD + Outbreak + R	NVD/3 + Outbreak + R	Routine	NVD + Outbreak + R				
1996	Routine	Routine	NVD + Outbreak + R	NVD/3 + Outbreak + R	Routine	NVD + Outbreak + R				
1997	Routine	Routine	NVD + Outbreak + R	NVD/3 + Outbreak + R	Routine	NVD + Outbreak + R				
1998	Routine	Routine	NVD + Outbreak + R	NVD/3 + Outbreak + R	Routine	NVD + Outbreak + R				
1999	Routine	Routine	NVD + Outbreak + R	NVD/3 + Outbreak + R	Routine	NVD + Outbreak + R				
2000	Routine	Routine	NVD + Outbreak + R	NVD/3 + Outbreak + R	Routine	NVD + Outbreak + R				
2001	Routine	Routine	NVD + Outbreak + R	NVD/3 + Outbreak + R	Routine	NVD + Outbreak + R				
2002	Routine	Routine	NVD + Outbreak + R	NVD/3 + Outbreak + R	Routine	NVD + Outbreak + R				
2003	Routine	Routine	NVD + Outbreak + R	NVD/3 + Outbreak + R	Routine	NVD + Outbreak + R				
2004	Routine	Routine	NVD + Outbreak + R	NVD/3 + Outbreak + R	Routine	NVD + Outbreak + R				
2005	Routine	Routine	NVD + Outbreak + R	NVD/3 + Outbreak + R	Routine	NVD + Outbreak + R				

\* Routine (R) vaccination: 4 doses of OPV administered to 90% of all children <12 months old: at birth and at 6, 10 and 14 weeks of age.

\* National vaccination days (NVD): 2 doses of OPV one month apart administered to 90% of all children <59 months old.

\* Outbreak response: 2 doses of OPV one month apart delivered to 1% of all children <59 months old.

\* Mop-up: 2 doses of OPV one month apart delivered to 10% of all children aged <59 months in persistently high-risk areas.

\* Subnational and subregional vaccination days: 2 doses of OPV one month apart administered to 90% of all children aged <59 months within a portion of a country or region.

\* Subnational days target 20% of all children aged <59 months; subregional days target 10% of all children aged <59 months.

\* NVD/3: the one-third portion of the children aged <59 months in the European Region targeted for mass campaigns; 2 doses of OPV one month apart administered to 90% of the targeted children aged <59 months.



(13) Analysis of secular trends in countries where substantial coverage has resulted in a significant reduction in disease demonstrates that with routine immunization programmes cases fall at an estimated 40% per year. With mass campaigns the reduction is estimated at 70% per year. The projected decline in cases with the continued application of vaccine is projected linearly for ease of presentation. At the end of the programme 669 158 patient-cases are projected to have been prevented worldwide annually.

(14) Programme costs, treatment and rehabilitation costs, and vaccine costs are stratified by developing and industrialized countries and are presented in 1993 US dollars.

(15) The cost of acute care and subsequent rehabilitation is conservatively assumed to be US\$ 25 000 per case in industrialized countries and US\$ 250 per case in developing countries. The base case assumes that only one-third of all cases in developing countries receive acute care and rehabilitation; 100% of cases are assumed to receive treatment and rehabilitation in industrialized countries. A sensitivity analysis is done assuming that only 10% of cases in developing countries receive acute care and rehabilitation; and that 0% of cases in developing countries and 75% in industrialized countries receive treatment and rehabilitation.

(16) The expenses of poliomyelitis vaccination, which are derived from studies sponsored by the expanded programme on immunization (EPI), are the result of summing capital costs (buildings, vehicles, refrigeration and the cold chain), operational costs (including staff salaries, supervision), and the cost of transport (including fuel and spare parts). Only the costs to the delivery system are used in this model. In addition to the costs of purchasing and delivering vaccine, additional resources are needed to effect eradication such as training, increased surveillance activities; improvements in the cold chain; improved laboratory support; data collection and processing, etc. Since the largest portion of the costs are due to vaccine and delivery, these additional costs are not included to streamline the model.

(17) For simplicity of the model it is assumed that all countries use only OPV, the WHO-recommended vaccine of choice. The cost of OPV for the programme in developing countries at 1993 UNICEF prices is US\$0.08/dose at port of entry. Sensitivity analysis is done with OPV vaccine costs using US\$0.12/dose (a 50% increase as an estimate of future inflation). In industrialized countries the average cost of OPV is US\$4.16/dose.

(18) The cost of vaccinating a child in the developing world with OPV is estimated at US\$1.51/dose. A sensitivity analysis is done at US\$3.00. This is based on the EPI estimates that in the developing world the delivery system costs are estimated to be US\$15.00 to fully immunize a child. Assuming OPV is given at 4 of the 5 visits required to fully immunize a child, the cost of fully vaccinating a child with OPV is estimated to be four-fifths of US\$15.00/child. In order to fully test the benefit-cost relationship, the cost of vaccinating a child with all vaccines during each of these four visits is attributed to poliomyelitis, i.e., US\$3.00/visit. For industrialized countries, estimates for the delivery of vaccine are estimated at US\$5.09/dose.

(19) Based on EPI estimates, the cost of delivery during national vaccination days, mop-up and outbreak response activities in a developing country is US\$0.10 per dose. A sensitivity analysis is done at US\$0.79/dose. In industrialized countries the cost of a contact is US\$1.48/dose. A sensitivity analysis is done at US\$2.47/dose.

(20) The estimate of the benefits of poliomyelitis eradication takes no account of the reduced pain and suffering or deaths due to poliomyelitis, the greater productivity of individuals who would otherwise be paralysed and become unproductive, the improved quality of life, or the reduction of other vaccine-preventable disease that could be expected to result from a successful programme against poliomyelitis.

(21) As an additional model, eradication of the 267 663 cases (2 per 100 000, down from 5 per 100 000) estimated to be occurring in 1988, the year of the World Health Assembly resolution on global eradication of poliomyelitis, is taken to represent the marginal additional costs to move from a routine vaccination programme directed at control of the disease to one directed towards eradication.

(22) To explore further the full net present value of eradication, a second additional model is projected, adding the costs of vaccine and delivery to those of treatment and rehabilitation as items of benefit.

(23) Costs and benefits are discounted at 6% annually. A sensitivity analysis is done at 0, 3 and 10%.

(24) Vaccine wastage is estimated at 33%. A sensitivity analysis is done at 50%.

(25) While vaccine-associated poliomyelitis can, in individual cases in industrialized countries, rarely be associated with substantial treatment and litigation

costs, and since the rate of vaccine-associated poliomyelitis is so low, vaccine-associated poliomyelitis has not been included in these calculations.

(26) The costs of treatment, rehabilitation and vaccination will end at eradication, and the net benefits accrued are estimated beyond the year 2007 for a total of 55 years.

## Results

### The base case

Using the assumptions and parameters described, the net costs and benefits of the global eradication of poliomyelitis were calculated for a period of 55 years from 1986 to 2040. As shown in Table 3, the costs exceed the net benefits in 2007, at a base case discount rate of 6%. By the year 2040, the saving will amount to US\$ 13 640 million.

### Benefit-cost analysis of poliomyelitis eradication

Fig. 1. Global poliomyelitis eradication model: base case.

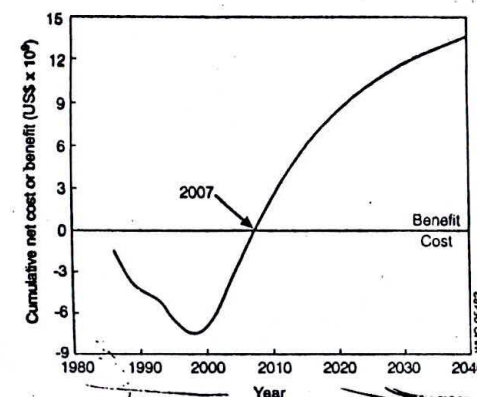


Table 3. Net costs or benefits of global poliomyelitis eradication: base case and sensitivity analyses, for the year 2040

	Costs or benefits in 2040 (US\$ millions)	Year when benefits exceed costs
I. Base case	13 640	2007
II. Sensitivity analyses		
a. Target age of accelerated activities (base case <59 months):		
<36 months	16 310	2005
<48 months	14 970	2008
b. Proportion of target age reached by mop-up (base case 10%):		
1.0%	14 240	2007
0.1%	14 260	2007
c. Cost of routine vaccine (OPV) and delivery (base case is US\$ 0.08):		
Developed countries US\$ 3.00	13 690	2007
Developing country US\$ 0.12	3 790	2024
d. Cost of accelerated activities/contact:		
Developing country US\$ 0.79 (Base case US\$ 0.10)	11 270	2010
Industrialized country US\$ 2.47 (Base case US\$ 1.48)	13 480	2008
e. Access to treatment and rehabilitation (base case 33% for developing and 100% industrialized):		
10%/100%	13 480	2007
0/100%	12 870	2008
0/75%	3 070	2023
f. Vaccine wastage (base case is 33%):		
50%	10 210	2011
g. Discount rate (base case is 6%):		
0%	86 130	2004
3%	34 500	2005
10%	1 850	2017
III. Additional models		
a. Treatment and rehabilitation plus vaccine and delivery	27 360	2005
b. Acceleration from control to eradication (base case 5/100 000)	11 440	2010
2/100 000 to zero (treatment and rehabilitation plus vaccine and delivery)	3 380	2026



The net cumulative cost or benefits of the base case are shown in Fig. 1 in millions of US dollars. Each data point represents the net cumulative costs or benefits for the model programme to that date. The slope of the line falls as a result of net costs increasing as each of the Regions begins its accelerated vaccination efforts. In the year 2000 the benefits of the programme are seen as the number of averted cases increase, and the curve begins to turn upwards. For the base case, the year 2007 is the break-even point, the year in which the savings exceed the programme costs. From this point on, the benefits of the programme exceed the costs in every year, and the net benefits continue to increase. This increase continues after the planned end of the eradication effort since the benefits of eradication continue beyond the programme, i.e., through cases prevented and since treatment and rehabilitation are no longer needed.

As seen by the plateau of the curve, although the benefits of eradication continue in perpetuity (no cases with the attendant costs are occurring, and there is no longer any requirement to vaccinate), the dollar benefits decrease substantially as a result of discounting.

#### Sensitivity analysis

When alternative assumptions were tested, the eradication of poliomyelitis was still shown to be cost-beneficial. Different assumptions about the discount rate, the proportion of cases receiving treatment and rehabilitation, vaccine wastage, the age and proportion of the target population vaccinated during accelerated activities, and the cost of delivering immunization services may modify the results of the base case, but do not significantly alter them.

**Target age of accelerated activities.** Alternative target ages of accelerated immunization activities were evaluated. The base case assumes the target age is <59 months. The shortage of resources to purchase vaccine has the potential to force a lowering of the target age group for accelerated activities as was the case in China in 1992. For all target age groups eradication is cost-beneficial. Each year of lowering of age group in the target population to be vaccinated decreases the year of breaking even by one year: for the base case (<59 months) the break even year is 2007; for <48 months it is 2006, and for <36 months it is 2005.

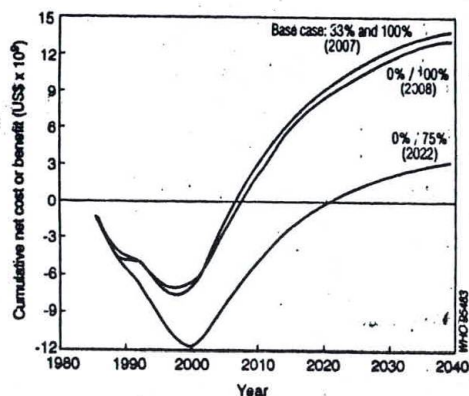
**Cost of vaccine and delivery.** The effect of an increase in OPV price from US\$0.08 to US\$0.12 has no significant impact on the year of breaking even or the overall slope of the curve (Table 2). Increasing the costs of delivering OPV by nearly eightfold in

developing countries (US\$0.79) had the effect of only delaying the year of breaking even by two years (Table 2).

**Access to treatment and rehabilitation.** The impact of varying the assumptions about access to treatment and the availability of rehabilitation in both developing and industrialized countries are assessed. Fig. 2 compares the base case (33%) with the overall impact of a reduction in treatment and rehabilitation rates to zero percent in developing world children. Little impact is seen on the shape, slope or break-even year. At zero percent of the developing world's children reaching treatment and receiving rehabilitation, it is still cost-beneficial to eradicate poliomyelitis. The minimal treatment and rehabilitation rate at which eradication leads to savings is 0% access in developing countries and only 60% of children in industrialized countries receiving treatment and rehabilitation.

**Vaccine wastage.** The effect of vaccine wastage on net costs and net benefits is tested by increasing the vaccine wastage rate from the base case 33% to 50%.

Fig. 2. Global poliomyelitis eradication: varying treatment rate assumptions in developing and industrialized countries. Base case: in developing countries, 33% of acute poliomyelitis patients received care and rehabilitation; in developed countries, 100%. Sensitivity analyses: 0%/100% — no acute poliomyelitis patients receive care in developing countries, while 100% do so in industrialized countries; 0%/75% — no acute poliomyelitis patients receive care or rehabilitation in developing countries, while 75% do so in industrialized countries. The year in parentheses is the break-even year.



While this increase delays the time when net costs are exceeded by net benefits from the year 2007 to 2011, eradication remains cost-beneficial.

**Proportion of the target population reached during accelerated activities.** Reducing the population covered by mop-up and outbreak response from 1% to 0.1% had no significant effect on whether eradication or the year of breaking even is cost-beneficial, as compared to the base case (Table 2).

**Discount rate.** The effect of alternative discount rates is shown in Table 2. At a 3% discount rate, the break-even point is two years earlier as compared to the base case at 6% in the year 2007. Discount rates of 0% and 10% demonstrate a family of curves, all of which are cost-beneficial with break-even points between 2004 and 2017. The rate of 3% is more commonly used for social sector programmes such as poliomyelitis eradication. At 3% the net savings will be US\$ 34 500 million by the year 2040.

#### Additional models

**Addition of the cost of vaccine and delivery to the cost of treatment and rehabilitation as benefits.** The annual global cost of routine vaccination with OPV under the base-case assumptions, which includes the cost of vaccine, delivery and wastage, is US\$1774 million. If the costs of routine vaccination (vaccine and delivery costs) are added to the cost of treatment and rehabilitation as benefits accrued from eradication, the year of breaking even is 2005, two years earlier than for the base case (Table 2), and precedes the year of the declaration of eradication, which makes the eradication even more cost-beneficial.

**Marginal additional costs of accelerating from control to eradication.** After the World Health Assembly resolution (WHA41.28) had established the goal of global eradication of poliomyelitis, there was concern about the diversion of resources from primary health care development and other priority disease control activities towards eradication activities. Routine administration of OPV had reduced cases from an estimated 5/100 000 to 2/100 000 in 1988, the year of this resolution. This level would be expected to be maintained if there was no acceleration of activities towards eradication. Reducing cases from 2/100 000 to zero represents the marginal additional cost of moving from control to eradication. The base case is compared with the acceleration of the programme beginning in 1988. Similar to the base case model, the benefits accrued were modelled in terms of treatment and rehabilitation alone, and

treatment and rehabilitation plus vaccine and delivery costs. When the combined costs are tested, beginning with the level of 2 cases per 100 000, an accelerated programme is cost-beneficial, and moves the break-even point to the year 2026. Poliomyelitis eradication, whether modelled from pre-eradication to eradication or as an acceleration from routine immunizations after the substantial initial impact, is cost-beneficial and saves US\$ 3380 million. (Table 2).

#### Discussion

In spite of systematic underestimation of the benefits of a poliomyelitis eradication programme, there is evidence of positive and high returns from such an investment; the base case demonstrates that the net benefits exceed the net costs of the programme only two years after eradication is declared. By the year 2040, the savings will be US\$ 13 600 million. Poliomyelitis eradication, through sensitivity analysis and under the most stringently unfavourable test conditions, is economically beneficial, and the break-even point is always close to the date of eradication. This is true under various assumptions — increase in cost of vaccine and delivery, high vaccine wastage, limited access to treatment and rehabilitation, limited target age groups for accelerated activities, and high discount rates. The world would therefore not have to wait many years for eradication to pay off.

The eradication of poliomyelitis is a justifiable investment even without making any allowance for savings (benefits) other than those due to real reductions in expenditures to treat and rehabilitate some of the victims of the disease. Morbidity in the form of a post-poliomyelitis handicap affects a child's activity throughout life. This loss is associated with both real and intangible costs (missed work, unemployment, family loss of work time and income, reduction in anxiety, pain and the social stigma of handicaps). The cost of treating even a small fraction of those who need treatment and rehabilitation is large enough to pay for the total prevention of poliomyelitis. The addition of vaccine and delivery costs, which will cease after eradication, makes the tangible saving even larger — an additional annual savings of US\$ 1700 million.

Experience with poliomyelitis epidemiology and with elimination of poliomyelitis in the Americas has demonstrated that eradication is technically feasible. Like smallpox, humans are the only reservoir of the virus, and there are no long-term carriers. An effective and inexpensive vaccine is readily available. While the ease of poliovirus transmission and the high infection-to-case ratio would suggest that the virus potentially is difficult to contain, little evi-



## CLINICAL ECONOMICS

### MODULE 6

#### COST-UTILITY ANALYSIS

After completing this module, you should understand:

- a. how utility values can be incorporated into cost-effectiveness analysis;
- b. how the resulting cost-utility analysis differs from cost-effectiveness analysis;
- c. the strengths and weaknesses of cost-utility analysis.

Also cultural costs how to do -



## COST-UTILITY ANALYSIS

### INTRODUCTION

You will recall from Module 5 that cost-effectiveness analysis (CEA) can be used to compare either alternative interventions for the same disease or condition, or alternative programmes which aim at extending or saving lives. In the latter case, the most common indicators of effectiveness are the number of lives saved and the number of life-years gained.

Many health interventions do not aim purely to save lives but seek to improve the quality of life as well. Other interventions, such as chemotherapy for some types of cancer, may extend life but reduce the quality of life. It is not appropriate to measure benefits by extensions in the quantity of life in these situations. Some way of combining quantity (reduced mortality) and quality (reduced morbidity) must be found. Cost-utility analysis (CUA) seeks to do this.

### COST-UTILITY ANALYSIS

CUA is based on CEA, and the first step is to estimate the number of life-years gained by an intervention. The extra years of life are then adjusted to account for changes in the quality of life. The CUA indicator of benefit is called a quality adjusted life-year (QALY) or a well-year.

The quality adjustment is based on a set of weights called utilities, a term economists use to describe the benefits people consider they get from consuming a good or utilizing a service. Each possible health state has an associated utility or rating which reflects the desirability of that state compared to other possible states. Usually a scale of 0-1 is used where 0 represents death and 1 is good health. (More complicated scales which allow some health states to be less desirable than death also exist.)

Thus, CUA requires that the possible states of health be described and the corresponding utilities determined. For example, the US Congress' Office of Technology Assessment described four outcomes which may result from an influenza epidemic. They were death, sick in bed, sick but mobile, and healthy. They ascribed the utilities of 0, 0.4, 0.6, and 1.0 to these states respectively, which implied that a day sick in bed gave 40% of the satisfaction of a day's health, for example.

Let us apply these data to a hypothetical project which will vaccinate a single healthy male against flu. Epidemiological data reveal that unvaccinated healthy men who contract flu are



confined to bed for 1 week (1/52 of a year), and are mobile but sick for a further week. They then return to full health. If we assume that the vaccine is 100% effective, the man will not contract flu but will be in good health all the time. His quality of life improves. However, no extra life-years have been gained, so the benefits of the intervention would not have been captured in a CEA. The patient gains  $[(1/52)(1.00) - (1/52)(0.4)] + [(1/52)(1.00) - (1/52)(0.6)] = 1/52$  QALYs.

#### DESCRIBING HEALTH STATES

$$\frac{1}{52}(.4) + \frac{1}{52}(.6)$$

A group of academics from McMaster University have developed a system which can be used to classify health states for a wide variety of diseases and conditions. They define health as a function of four attributes - physical activity, level of self-care, social-emotional wellbeing, and the nature of the health problem. Each attribute has a number of levels, and a person's state of health at a particular time can be identified with one of the 960 possible health states defined by the system. Drummond et al describe the system in more detail. (Anderson and Moser base their analysis on an even more complicated system.)

To use the McMaster approach it is necessary to obtain utilities for each of the 960 states of health. This generally involves assigning utilities to each level of the four attributes, then mathematically modelling the way the attributes combine to form a single utility for the state of health. The advantage of these systems is that they are applicable to a large number of diseases and conditions, and are sensitive to small changes in the quality of life.

A less complicated approach is to define a limited number of states of health which are specific to a particular condition. Each state is then described in a way which includes information about how a patient functions in terms of each of the four attributes described above. This method is simpler to use than the larger system, but is less sensitive to small changes in the quality of life. Moreover, it is less easy to compare the efficiency of interventions aimed at different diseases if disease specific QALYs have been estimated. This problem is discussed in more detail in the reference by Donaldson et al.

#### ESTIMATING UTILITIES

Three methods of deriving utilities can be used. The first relies on the judgement of either the analyst or a group of experts. The second uses weights from the literature, while the third estimates utilities directly from a sample of subjects.

In the third case, the analyst must identify the appropriate subjects. In theory the sample should be representative of society because CUA is generally undertaken from society's



viewpoint. However, members of the public can be unaware of the full ramifications of different states of health, so researchers often resort to taking samples from health professionals or patients. Drummond et al argue that generally this does not matter as the different groups tend to rate states of health in a similar manner although there is some evidence to the contrary (Lomes & McKenzie).

Once the sample has been selected, the analyst asks a series of questions designed to reveal the preferences the subjects have for different states of health. Three systems of doing this have been developed - the rating scale, standard gamble and time trade-off. Again some studies have shown that they result in similar ratings for the same states of health while others have shown large differences.

A full description of the way utilities can be estimated is beyond the scope of this module which is designed to help you understand the rationale behind CUA. Should you wish to estimate utilities, you will need to read the literature more extensively, and Drummond et al is a good place to begin. It is also recommended that you seek the advice of an economist.

### COSTS

Costs are measured in the same way in both CEA and CUA. The CUA indicator is the cost per QALY (or cost per well year). Like CEA, CUA must be used to compare alternative interventions. By itself, a CU ratio rarely provides useful information.

### UTILITIES AND CLINICAL DECISIONS

An assumption behind CUA is that people are willing to sacrifice years of life to gain extra quality of life. If this is true, utilities can also be used as an aid to clinical decision making and clinicians could elicit utilities from patients before deciding on the appropriate treatment. This would be particularly useful for treatments which extend life but result in serious side effects which reduce the quality of life. The article by McNeil et al provides some justification for this suggestion. Formal methods of incorporating utilities into clinical decision making are considered later Module 9.

### PROBLEMS

CUA is controversial whether it is used to guide clinical decisions for individual patients or as a basis for resource allocation. One practical problem is that utilities elicited for a given state of health can vary with the way the question is framed. A more theoretical difficulty is the implicit assumption that people's willingness to sacrifice years of life for a given improvement in health status is constant. This would not be true if people valued good health more highly at different times of their lives (perhaps while raising children),



if they they had a rate of time preference for years of life in a given state of health, or if they were less willing to sacrifice quantity of life if they believed they had only a short time to live. McNeil et al, for example, found that patients were willing to trade years for improved quality only if they expected to live more than five years. Another problem concerns the way QALYs are aggregated in evaluating an intervention. A QALY gained by a 70 year old person is given the same weight as a QALY gained by a 20 year old, but it is not clear that society wishes to make decisions about resource allocations on this basis.

The problems with CUA are widely recognised and are discussed in Loomes & McKenzie (a difficult but worthwhile reference). Two conflicting conclusions have been drawn. The first is that CUA is flawed and should not be used. The second is that it is at least as good as other methods of resource allocation which do not take quality into account and should be given an extended trial.

#### REFERENCES

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Anderson J.P. & R.J. Moser, "Parasite screening and treatment among Indochinese refugees", JAMA 1985, 253:2229-2235.

Drummond et al, (see Module 4), chapter 6.

##### Other References:

Donaldson C. et al, "Should QALYs be programme-specific?", Jnl of Health Economics 1988, 7(3):239-259. See also the comment by Weinstein "A QALY is a QALY is a QALY - or is it?" in the same issue, pp. 289-290.

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McNeil B.J., R. Weichselbaum & S.G. Pauker, "Speech and survival: tradeoffs between quality and quantity of life in laryngeal cancer", NEJM, 1981, 305:982-987.

Torrance G.W. "Measurement of health state utilities for economic appraisal", Jnl Health Economics 1986, 5:1-30.



### QUESTIONS

1. Read the article by Anderson and Moser.
  - a. Estimate a CE ratio in the way that you learned in Module 5 using the data contained in the article. (Define your own indicator of effectiveness).
  - b. What are the relative merits of using CUA and CEA in this case?
  - c. Discuss the use of discounting in the article.

HINT: Consider Table 4 and the following questions:

- i. In calculating column D, what assumption is made about when a life is saved?
  - ii. Is the same assumption implicit in calculating column F?
  - iii. In calculating column I, what assumption is made about when the savings (H) occur?
  - d. Can you detect any problems with the way that utilities were measured?
2. What are the advantages and disadvantages of using subjects from the following groups to determine utilities?
    - a. patients,
    - b. doctors,
    - c. members of the general public.

3. Consider the following table which adjusts the results of a number of studies by different authors to costs per QALY in 1983 US dollars. The table is adapted from Torrance G.W. & A. Zipursky, "Cost effectiveness of antepartum prevention in Rh immunization", Clinics in Perinatology 1984, 11(2):267-281.

*Try to assign a value to hospital < Rh sup*

PROGRAM	COST/QALY
PKU screening	negative
antepartum anti-D	1220
coronary bypass surgery:	
- left main disease	4200
- single vessel disease (moderately severe angina)	36300
treatment of severe hypertension (diastolic above 104 mm Hg) in males aged 40	19100
continuous ambulatory peritoneal dialysis	47100
hospital haemodialysis	54000

- a. How do you think such tables could be used to evaluate the efficiency of a particular programme?
- b. Can you see any problems with using such tables?