

## The role of health economics in the evaluation of surgery and operative technologies



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LIMITED BUDGETS AND ESCALATING COSTS demand prioritization of deployment of medical services. Health economics addresses the allocation of resources within a specific health economy<sup>1-3</sup> and can be envisioned as the study of choices and their consequences. From this perspective, it is insufficient for an operative treatment to display efficacy; to be considered for adoption, an intervention must also display good value for the money that is being spent. In short, a decision maker should be satisfied that, by spending additional resources on these new interventions, the benefits will outweigh the potential consequences of shifting funds away from other sources.

Many national-level decision-making bodies have been established to make such judgements. In England and Wales, the National Institute for Health and Care Excellence (NICE) provides guidance to the National Health Service (NHS) on the clinical effectiveness *and* cost-effectiveness of selected new and established technologies. Various bodies addressing national health technology assessment (HTA) operating in other

countries include the Canadian Agency for Drugs and Technologies in Health in Canada, the Pharmaceutical Benefits Advisory Committee in Australia, and the Health Care Insurance Board in the Netherlands.

In the United States, decisions on the adoption of new technology are often decentralized, and individual hospitals or hospital groups frequently depend on internal value analysis committees to reconcile budgets, physician preferences, regulations, and other factors. These various national HTA groups aim to provide evidence to decision-makers regarding the medical, social, economic, and ethical implications a new intervention might have for patients and for the system as a whole.

Health systems and national processes of HTA decisions differ from region to region. For instance, some countries focus purely on clinical aspects using clinical or physician-driven outcomes, while others explicitly include economic considerations, such as cost, quality of life, and other patient-reported outcomes. Those using economic outcomes as a key factor in decision-making tend to be more explicit about the trade-offs that must be faced within systems with limited resources.

In such systems, it is vital to have methods to assess the relative health benefits associated with different interventions. For example, a new (expensive) technique for an operation might demonstrate improvements in long-term survival,

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while a new (also expensive) monitoring system might decrease the risk of perioperative complications. Health economics is about measuring and weighing the relative merits of these different types of trade-offs in order to inform decisions on health care resource allocation, including adoption of the technology.

## MEASURING COSTS

Although an operative intervention may be demonstrated to be *effective*, it is essential to estimate the health care resources that would be required to provide that intervention, since these resources could potentially be used elsewhere in the system. The costs that are considered in health care decision-making are typically limited to those that fall on the health care provider or, in some countries, an insurer.

These costs may include staff time, surgical equipment, monitoring equipment, and drug costs, among others. The specific costs to be included in an economic evaluation differ depending on the viewpoint or “perspective” of the analysis. Many different perspectives can be taken, including that of society as a whole, the health care system, the individual institution, or even a specific patient.

Depending on which perspective is being taken, costs may be categorized as direct or indirect. Direct costs typically relate to those that are paid for by the health care provider.<sup>2,3</sup> To measure these costs, the quantity of health care resources used (eg, number of clinicians and duration of the operation) are multiplied by the individual unit costs or prices of those particular resources. Evaluations sometimes use the rates derived from health care resource groups, diagnosis-related groups, or hospital billings instead, which do not provide similar levels of detail.

Indirect costs refer to any costs borne *outside* the health care system. These may include factors such as the impact on productivity due to lost work time resulting from illness or other health care needs. In some cases, the inclusion of indirect costs can have a substantial impact on the results of an evaluation, although it is important to note that any technologies displaced by the use of a new intervention may also have had an impact on productivity and other indirect costs.

It is also important to consider the implications of including long-term costs. For instance, although an operative intervention is likely to have high short-term costs, there are likely to be substantial longer-term effects. These might be cost savings, wherein a successful intervention

might avert future complications or add years of productive work and tax contributions. Alternatively, an operative intervention might lead to cost increases if a “successful” treatment increases a patient’s life expectancy and, therefore, increases overall lifetime costs. The latter scenario can, of course, penalize particularly successful interventions. The duration of time over which health care costs could be modelled depends largely on the nature of the therapeutic area and the intervention under investigation. In some cases, it is clearly necessary to consider long-term costs, while in other cases, all consequences of a treatment may be expected to occur within a few weeks after the intervention. Providers of health care tend to prefer spending money in the future compared with spending the same money today; therefore, costs are routinely “discounted” to present values. The rate at which future costs are discounted varies among countries; in the United Kingdom, NICE guidelines recommend that costs should be discounted at 3.5% per year.<sup>4</sup>

## MEASURING AND VALUING BENEFITS

To justify additional spending on a new intervention when funds are limited, it is vital to develop some measurement of the magnitude of benefit that each treatment will deliver. Common measures of benefit include survival, time to discharge, readmission rates, and event-free survival; however, keeping in mind that holders of the health care budget are often forced to allocate limited resources across a whole range of areas, decision-makers often face impossible trade-off decisions when different measures are used in each area. As a result, some countries have moved toward the use of measures that incorporate health-related quality of life (HRQoL) in addition to the “quantity” of life.

The use of the quality-adjusted life year (QALY) for measurement of health outcome has become standard practice in many countries because the measure takes into account the impact of the treatment on both the quantity and quality of life. The QALY is a measure that can be used in all disease areas, thus allowing decision-makers to readily compare the benefits of a diverse range of treatments within a system. QALYs are measured by multiplying HRQoL (or “utility”) by the duration of time that a patient spends with that utility score. Utility is measured using a scale between 0 and 1, where 0 represents a health state equivalent to death, and 1 indicates perfect health. Thus, a patient who experiences 5 years in perfect

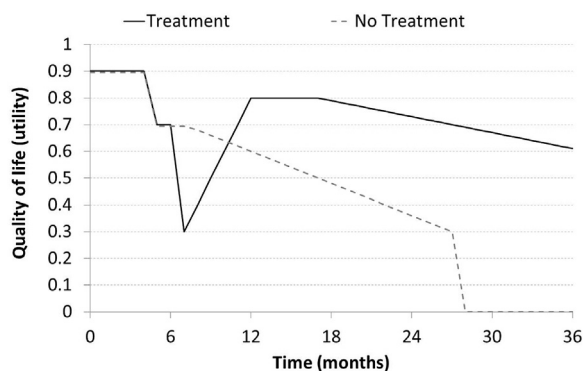


Fig 1. QALY pathway.

health will experience 5 QALYs. If an intervention produces benefits that can be demonstrated to extend life or improve QoL (or both), then these can be captured using the QALY metric.

An example of a hypothetical patient's HRQoL during his or her lifetime can be seen in Fig 1. In this example, a patient begins with a QoL score of around 0.9. After about 5 months, an event occurs that decreases the QoL to around 0.7. At this point, 2 potential options are followed. The first (solid line) shows what might happen if an operative intervention were undertaken. As can be seen, there is a short-term detriment to the patient's QoL (decreasing to 0.3) before the patient recovers to a utility of around 0.8, although some longer-term deterioration is experienced. Without intervention, the patient avoids the short-term disutility of operative intervention, but QoL deteriorates more rapidly, and the patient dies at 28 months. The QALY gains associated with the intervention can be calculated by estimating the difference in the areas under each curve.

A further benefit of the use of QALYs is that this attempt to quantitate an intervention can be additive between patients. For instance, an intervention that delivers 10 QALYs to one patient can be considered equivalent to another intervention that delivers 1 QALY to 10 different patients. In this way, the benefits of a treatment across a whole population of patients can be compared against the population benefits of another treatment in a different disease area.

A range of utility measurement tools have been developed internationally, each with a variety of different questions. It is important to note that none of these measures can provide a gold standard answer, and because QoL is highly subjective and emotive, different methods can provide systematically different answers. Some measures that

are more specific to a given condition or population can also be considered. These are often favored by clinicians because they capture nuanced changes that are specific to the intervention or disease area under consideration. Such measures, however, do not allow the comparison of different interventions for different conditions/research areas.

Limitations of the QALY approach have been noted. Many systems assume that all QALYs are valued equally, irrespective of who receives them or when they are received. This concept has been questioned, however, as QALYs may deserve a different weight according to individuals' initial state of health or the extent to which their health is improved.<sup>5</sup> Many further assumptions of the QALY approach have been criticised,<sup>2,5</sup> although it remains an equitable and transparent metric for the measurement of health benefits.

## ECONOMIC MODELS

Health economists often make use of models to help make decisions concerning health care. Models are a simplified version of reality, and they are used to attempt to predict the long-term outcomes associated with a patient treated for a particular condition. Models, rather than real, observed data, are used for a range of reasons. First, the nature of clinical trials is such that they have a specified period of follow-up, which is particularly true for trials evaluating operative interventions. While the trials may capture important information, such as short-term success rates and time to discharge, in many cases, the true benefits (and costs) of treatment may not be apparent until further into the future.

Second, models can combine evidence from several sources of information to create a whole picture. For example, the use of resources associated with a procedure could be drawn from one study, effectiveness from another, safety from a third study, and long-term outcomes from a fourth source, such as a clinical registry database.

A third benefit of such models is that, although clinical trials may provide useful outcome measures, decision-makers often want to consider alternative scenarios. These approaches might include questions such as "What would happen if the starting condition of patients were more severe?" or "What if the cost of operative intervention were different?" The development of a decision-analytic model would allow us to test such scenarios and predict the impact of such changes on the evaluation's conclusion.

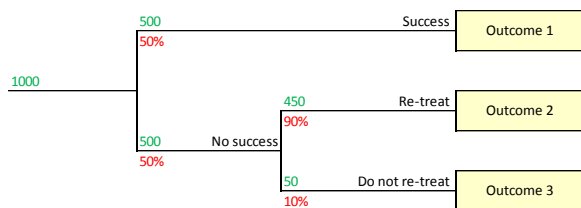


Fig 2. Example of decision tree.

Many different techniques are available for disease modeling, and the choice of technique should always be based on the nature of the disease and the intervention under consideration. Decision trees are usually best used for models that assess interventions that have *one-off* outcomes, such as “success” or “no success.” An example is shown in Fig 2.

In this model, 1,000 patients initiate treatment. Because the effectiveness of the treatment has been measured as 50%, we can calculate that 500 patients will be successfully treated. Likewise, we also estimate that 500 patients will *not* be treated successfully. We may know from other sources that 90% of those unsuccessful patients would be retreated. Therefore, we calculate that 450 (ie, 90% of 500) would receive the second course of treatment. Finally, the 10% of unsuccessfully treated patients would not receive the second course of treatment.

Suppose that we know that the procedure costs \$1,000 and that the additional cost of a patient being treated unsuccessfully is \$5,000. Therefore, for those patients who are treated successfully, the cost is only \$1,000 in total. Those patients who were not treated successfully and who receive a second treatment will cost \$7,000 (ie, \$1,000 for each of 2 interventions, plus an additional \$5,000 for the consequences associated with the unsuccessful treatment). Finally, the 10% of patients who were treated unsuccessfully and did not receive a second treatment will cost \$6,000 (ie, \$1,000 for the first procedure plus \$5,000 following unsuccessful treatment). In this way, aggregated costs for the entire population of patients can be calculated.

Although decision trees are useful in modeling outcomes that have distinct one-off outcomes, the benefits of some interventions are estimated based on the *timing* of events. For example, after a cardiovascular operation, we might know that, while all patients will ultimately die, the rate of death may be different dependent on the type of operation. In that case, a decision tree model would be

inappropriate because the probability of dying (at some time) will, of course, be 100% for all patients. Markov techniques can be used in such cases to model the rate of mortality (and other outcomes, such as readmission) over time. As with the decision tree approach, the level of detail in a Markov model will depend on the nature of the disease and should be selected to best represent the natural history of the disease.

Cost-effectiveness outcomes are typically represented by the incremental cost-effectiveness ratio (ICER). This represents both the additional costs associated with an intervention (including both the cost of the intervention and all of the “downstream” costs) and the additional benefits of the intervention (measured using a suitable outcome, such as QALYs). The ICER is calculated as follows:

$$ICER = \frac{Cost_{Treatment} - Cost_{Comparator}}{QALYs_{Treatment} - QALYs_{Comparator}}$$

The resulting ICER is usually compared against a pre-established “threshold.” Many decision-making bodies avoid explicitly quantifying such a threshold, although NICE states<sup>4</sup>

*In general, interventions with an ICER of less than £20,000 per QALY gained are considered to be cost effective. As the ICER of an intervention increases in the £20,000 to £30,000 range, an advisory body’s judgement about its acceptability as an effective use of NHS resources should make explicit reference to the relevant factors. Above a most plausible ICER of £30,000 per QALY gained, advisory bodies will need to make an increasingly stronger case for supporting the intervention as an effective use of NHS resources with respect to the factors.*

This implies that the NHS in the United Kingdom is willing to pay between £20,000 (US \$25,000) and £30,000 (US \$37,000) for every QALY gained by a new treatment. Therefore, if a new intervention produces, say, an additional 4 QALYs, the health care provider in the United Kingdom would be willing to pay up to £120,000 (US \$150,000) for it. Likewise, if a treatment offers an additional 0.01 QALYs, the NHS would be willing to pay up to £300 (US \$375) for that intervention, and so on. This value reflects the *opportunity cost* of spending money on new technologies; that is, if the same money were to be spent on something else within the health care system, would the new technology offer more or fewer benefits?

## THE WIDER USE OF HEALTH ECONOMICS

Economic models can also be useful in the early stages of the development of an intervention or procedure. Because the treatment is in its early development phase, there is often a substantial lack of available data. As such, the model would normally be relatively simple in design. Key inputs may have to be based on expert judgment rather than on robust trial data. Nevertheless, the models can be used to estimate the *likely* cost-effectiveness of the intervention based on current knowledge of its effectiveness.

Models may also be used to inform discussion on the pricing of new interventions. A model's outputs might allow a manufacturer to estimate the price point for an operative device that will achieve a specific ICER. Such analyses may, of course, contain a substantial degree of uncertainty; because of this uncertainty, the results may be presented using ranges as opposed to specific point estimates.

Another form of economic model is the budget impact analysis. Budget impact models aim to estimate the overall cost impact (across a whole population) associated with the introduction of a new intervention. They typically focus on costs rather than on outcomes (eg, QALYs) and tend to focus on short-term outcomes, usually restricted to around 5 years. A key difference between budget impact models and cost-effectiveness models is that budget impact models account for the prevalence (or incidence) of a condition as well as the individual cost per patient. Therefore, an intervention that is likely to see a large rate of uptake is likely to have a larger budget impact than an equally priced treatment that has a smaller target population.

## OTHER CONSIDERATIONS IN HEALTH ECONOMICS

A key consideration in health economic evaluation is equity. Equity in health care has been defined as meaning that "people are equally entitled to, and are considered to have the same rights to, health care, completely independently of any non-medical characteristics of the recipients (eg, most importantly income)."<sup>6</sup> Others have defined equity as involving "equal access for equal need, equality of health across individuals, and equal health expenditure per capita, amongst others."<sup>7</sup>

As discussed, the very nature of a QALY aims to address equity by ensuring that a QALY has equal worth, no matter who receives it or how (or when)

it is received.<sup>2,3</sup> However, many exceptions to this approach have been argued. For instance, it might be true that a QALY could (or should) be worth more for someone who is currently in a very poor state of health compared with someone who is in "full" health. Likewise, someone who is imminently close to death may value a QALY more highly than someone who has many years or decades remaining. Age may also be a key factor, with some arguing that QALYs may be worth more for people who are at risk of dying prematurely.<sup>8</sup> This is based on the "fair innings" argument, which postulates that every person should be entitled to a minimum quantity of health over their lifetime, which would ideally be measured using QALYs.<sup>9</sup>

There are circumstances under which conventional health economic outcomes are not routinely considered. For instance, the "Rule of Rescue" provides an example wherein conventional use of the QALY and economic evaluation for health care does not necessarily apply; it explicitly prioritizes life-saving treatments without specific consideration of the economic consequences.

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