Chapter 1

HEALTH ECONOMICS: GENERAL ISSUES

The Economics of Health and Health Care

Over the past decades, the ability to provide treatment for an increasingly wide range of diseases has increased exponentially with the introduction of new technologies. Demand for care also has increased, partly in response to this, but also for other reasons. The resulting rise in health care costs has put considerable strain on finite resources, a situation that has worsened in the face of the current global economic slowdown.

Economic issues in health care are now discussed widely—in public policy forums, the medical and scientific literature, and the lay press. This is a symptom of an important change in health care markets. Attention has shifted from the "passive" funding and administration of systems to active concern about the cost of care and the health outcomes achieved. The health economic thinking that now permeates health policy and health care systems is raising questions such as: How much should we spend on health care and how do we ensure it is spent efficiently? How and when should we assess the outcome of using health technologies in clinical practice to ensure resources are used efficiently?

Box 1.1 Definition of health economics

Health economics is the application of the theories, tools and concepts of the discipline of economics to the topics of health and health care.

Economics as a science is concerned with the allocation of scarce resources; health economics is concerned with the allocation of scarce resources to improve health. This includes both resource allocation within the economy to the health care system and within the health care system to different activities and individuals.

A range of approaches to economic evaluation has been developed to help address these important questions of efficiency. This guide provides an introduction to them. The first chapter reviews contextual background, illustrating the increased level of interest in the use of economics by policy makers, payers, and health care providers. Chapter 2 introduces the various types of economic evaluation and discusses how they approach the two components of economic evaluation: what effect a treatment has on health and what it costs. The challenges are illustrated with examples of cost-of-illness studies, which seek to quantify the aggregate costs of a disease and its treatment. Chapter 3 explores the methods of economic evaluation in greater detail, focusing particularly on the use of modelling techniques that synthesise data from a range of sources. The chapter illustrates these techniques using a number of

Box 1.2 Definition of health technology assessment

Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology throughout its life span in a systematic, transparent, unbiased and robust manner.

The aim of HTA is to inform the formulation of safe and effective health policies that are patient focused and seek to achieve value for money.

examples, primarily from evaluations of drugs. Important aspects of each methodology are explained and particular challenges identified. Chapter 4 discusses methodological guidelines for the conduct of the economic evaluations that are required or suggested in several countries. Chapter 5 concludes.

Challenges in health care: the context

Total health care spending as a proportion of gross domestic product (GDP) has steadily increased in all OECD countries, albeit starting from different levels. Spending in the European Union was between 7.5% and 12% of GDP in 2010 (9.5% to 12% in Western Europe, 7.5% to 9.5% in Central/Eastern Europe). In the US, it reached over 17% of GDP (see Table 1.1).

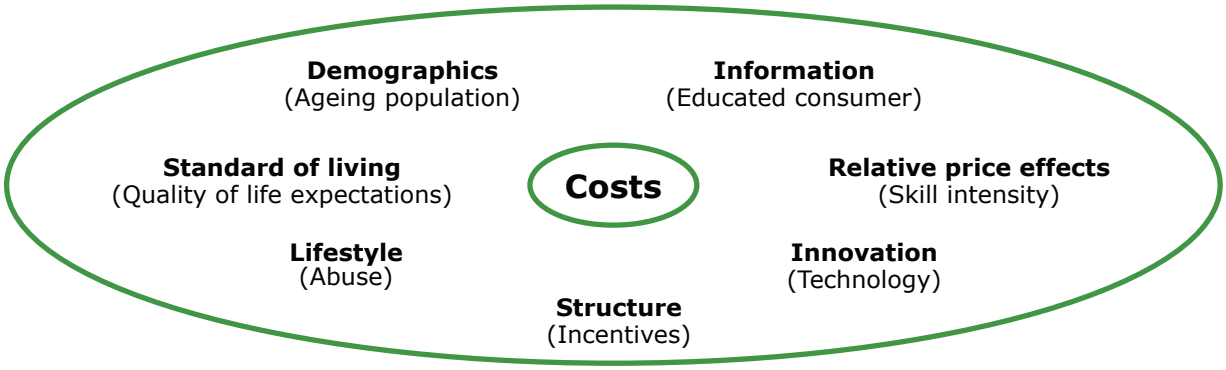
Table 1.1. Health care expenditures as percentage of GDP

Country or Region	1970	1980	1990	2000	2010
OECD average	5.8%	7.3%	8.7%	8.4%	9.3%
US	6.9%	8.7%	11.9%	13.2%	17.7%
Japan	4.6%	6.5%	6.1%	7.7%	9.6%
Western Europe	4.7%	6.7%	7.1%	8.4%	9.5%
Central/Eastern Europe	NA	NA	NA	6.1%	7.9%
Latin America	NA	NA	NA	NA	7.0%

Source: OECD (2013), WHO (2011)

Numerous interdependent factors contribute to increased health care costs, as indicated in Figure 1.1. In the industrialised world, the elderly population often is singled out for concern as it consumes a substantial and increasing share of health care resources. Health care expenditures have risen less because of demographic change, however, than because of the availability of a greater number of treatment options and continuous improvement in the quality and intensity of care. More can be done, so more is done.

Figure 1.1. Major contributors to the growth of health care costs



Concerns about the financing of health care are high on every government's agenda, particularly in countries where health care is predominantly funded with public money via taxes, social insurance or a combination of the two (see Table 1.2). Among the OECD countries, the US is an exception, with most health care being financed by private insurance, although public financing is increasing steadily. The private portion of the market in Latin American countries is substantial and growing.

Governments around the world, and particularly in Europe, have attempted to contain costs using a variety of measures aimed at both the demand for and the supply of health care. Figure 1.2 shows those that have been aimed at the prescription pharmaceutical market. These measures, however, have been less successful than hoped, partly because growth in spending is driven primarily by the availability of new and improved technology to which cost-containment measures are less easily applied.

Table 1.2. Public health expenditures as percent of total health expenditures

Country or region	1970	1980	1990	2000	2010
OECD average	73%	73%	73%	72%	72%
US	36%	41%	39%	43%	48%
Japan	70%	71%	78%	81%	81%*
Western Europe	76%	76%	77%	76%	76%
Central/Eastern Europe	NA	NA	NA	75%	72%
Latin America	NA	NA	NA	NA	52%

* Data for 2009
Source: OECD (2012), WHO (2010)

Figure 1.2. Examples of measures for containing spending on prescription drugs in Europe

Pricing	Clustering (same price for similar treatments) Price cuts, price freezes Reference pricing
Listing	De-listing (removal from eligibility for reimbursement) Positive or negative lists of products eligible for coverage
Shaping use	Greater use of generics and/or control of generic prices Increased patient co-payment Prescribing budgets and/or guidelines for doctors
Purchasing	Tendering Volume contracts
Indirect cost control	Profit limits for manufacturers Promotional budget limits for manufacturers Reductions in wholesale and retail pharmacy margins

The financial crisis that began in the late 2000s has exacerbated the situation by making further increases in public spending on health care more difficult. Discussions and decisions about prices and purchasing, as a result, are now taking place in an environment characterised more by concern about cost and value than about demand for innovation. Health care decision makers everywhere are focusing more narrowly on efficiency and within tighter budgets. New, more expensive, therapies must carry a clear additional health benefit to be deemed worthy of an additional expenditure. Decisions makers, then, will increasingly require that innovative therapies—medicines and other interventions—be assessed for relative effectiveness and cost-effectiveness, rather than only efficacy and safety (see Figure 1.3).

Figure 1.3. Assessment criteria for new therapies

Safety	Does it have side effects and are these acceptable and manageable?
Efficacy	Does it work in a controlled environment (clinical trials)?
Relative efficacy	How well does it work in a controlled environment compared to one or more alternatives (standard treatment)?
Effectiveness	Does it work in normal clinical practice?
Relative effectiveness	How well does it work in normal clinical practice compared to other alternatives (standard treatment)?
Cost effectiveness	Is it an efficient use of resources, i.e. is an additional benefit worth an additional cost?

A number of European countries long have requested cost-effectiveness assessments as an aid in deciding about the reimbursement status or price of a new technology. Demand is growing for comparative trials that can better define the incremental benefit of a new treatment. Cost-effectiveness, and even comparative analyses, however, are based on models created before the product reaches the market. Until a product has been used in routine clinical practice, considerable uncertainty remains about both clinical outcome and resource use. As a result, authorities increasingly are requesting additional evaluations using experience from actual clinical practice. In some cases, the results can lead to a renegotiation of the price and also may be used to shape clinical practice.

The Role of Health Economic Evaluation Studies in Market Access

An economic evaluation is a tool for assessing the benefits and costs of competing uses of scarce resources. It provides data in a structured format that is comparable across diseases, but does not in itself offer a decision. Since value for money is now a core concern, analyses of the consequences of the use of new and existing therapies, in terms of both benefits and costs, have become essential to decisions about resource allocation. Cost-effectiveness has become an important criterion not only for deciding which therapies ought to be funded or reimbursed, but also for identifying the patient populations that should have access.

Figure 1.4. Definition and forms of economic evaluation

Definition of economic evaluation: A comparative analysis of two or more options in terms of their costs and consequences

Types of economic evaluation	
Cost-minimisation analysis (CMA)	Comparison of costs of alternatives that have the same health outcome Allows comparison within a clinical indication
Cost-effectiveness analysis (CEA)	Comparison of costs and disease-specific health outcomes (e.g. life-years saved, patients cured, events avoided) Allows comparison within a clinical indication
Cost-utility analysis (CUA)	Comparison of costs and generic health outcomes (e.g. quality-adjusted life years) Allows comparison across clinical indications
Cost-benefit analysis (CBA)	Comparison of costs and health outcomes valued in monetary terms (e.g. willingness to pay) Allows comparison to other sectors of the economy

Many countries have official or quasi-official specialised groups that assess the value of both current and new health care technologies. These may be independent reimbursement agencies or specialised HTA agencies. Economic evaluations are an integral part of their assessments.

An economic evaluation provides a comparative analysis of alternative courses of action in terms of costs and consequences (see Figure 1.4). This entails comparing alternative treatment strategies over the entire course of a disease, or defined disease episode, in order to identify the best option for specific patient groups, given expected costs. Such evaluations use aggregate measurements and provide information for groups of patients, rather than individual patients. All evaluations use similar techniques to estimate cost, although different techniques are used for measuring consequences, depending on the disease or the desired result.

When two interventions have the same outcome, the less costly one dominates and is preferred. Interest is greater in products that improve outcomes compared to existing treatments that are only equivalent in outcome. But more efficacious technologies generally come at a higher cost. Thus, an

incremental cost-effectiveness ratio (ICER), i.e. the extra investment required for the additional health benefit, is computed. The more costly intervention will be adopted if the incremental cost per unit of health effect is less than the purchaser's willingness to pay for such a health gain.

Box 1.3. Definition of an ICER

$$\frac{[\text{Cost (B)} - \text{Cost (A)}]}{[\text{Effect (B)} - \text{Effect (A)}]} \quad \text{or} \quad \frac{\text{Difference in Cost}}{\text{Difference in Effect}}$$

where B is more effective and more expensive than A

(if B is more effective and less expensive than A, B dominates A and the ICER is not calculated)

Health-related costs may be incurred in a range of social spheres, making it important to include all costs for a relevant time period, even if they fall under different budgets. For instance, a new treatment may increase the pharmaceutical budget, but over time produce enough savings in other parts of the system to partly or fully offset this increase, such as lower hospitalisation costs or fewer monitoring requirements. Savings also may occur in other sectors of the economy, for example, when sickness absences, early retirement due to disease, or premature deaths are avoided. For efficient resource allocation, decisions should consider the full impact of therapies, regardless of where effects occur. Economic evaluations, then, must start from a societal perspective to capture all potential benefits.

Adopting a societal perspective to assessing the value of treatments matters and makes sense (Jönsson, 2009; Johannesson et al, 2009). Regulatory authorities take a societal perspective in licensing a drug, weighing risks against wider benefits. Economic analyses, similarly, need to include both costs and benefits to society overall. This can help decision makers avoid an overly narrow, budget-specific perspective, which may miss the important benefits accrued outside that budget and produce suboptimal decisions about resource allocation. Narrow decisions may inappropriately restrict access by not funding the treatment at all or by inappropriately limiting it to only some groups of patients. In such cases, the payer may achieve the objective of controlling the budget (static efficiency), but the greater benefit to society, particular patients, will be missed (dynamic efficiency).

Despite the rather obvious potential benefit of using health economic evaluations, decision makers across Europe vary in how and how much they are used. The remits of decision making organisations also differ: HTA agencies are generally concerned with whether or not to recommend treatments, but lack the power to decide on access and price; some reimbursement agencies can only accept or refuse to fund a treatment at the proposed price, while others have the power to negotiate price (Figure 1.5).

In recent years, HTA agencies have become increasingly involved in decisions about early market access, blurring the distinction between their activities and those of traditional reimbursement assessments. For example, the National Institute for Health and Care Excellence (NICE) within the National Health Service (NHS) in the UK assesses selected new treatments early on and its recommendations are binding. Decisions by the Scottish Medicines Consortium, an HTA body within the Scottish NHS, are fully binding. In France, the Haute Autorité de Santé (HAS) includes bodies that assess the absolute and relative benefit of a new technology and its reimbursement status, and those that perform full assessments of technologies after they have entered the market. In Germany, the Institute for Quality and Efficiency in Health Care (IQWiG) assesses the effectiveness—and, if requested, cost-effectiveness—of new treatments one year after their introduction. Clearly, then, the timing and impact of cost-effectiveness studies varies across countries and organisations.

Guidelines for performing economic evaluations have been produced in many countries. These fall into two categories.

1. Reimbursement guidelines, i.e. guidelines issued by authorities that make the submission of economic evaluations mandatory for listing a new product on the reimbursement formulary, and that define the format of such submissions

2. Methodological guidelines, i.e. guidelines proposed by researchers or groups of researchers with the aim of improving the techniques and methods used and making studies more transparent

Figure 1.5. Bodies involved in determining market access

	Regulatory agencies	Reimbursement agencies	HTA agencies
Role	Market authorisation; subsequent review of benefit-risk profile, if warranted	Coverage decision within a health care system, given resource constraints	Provide best evidence to inform coverage decisions (e.g. clinical practice guidelines)
Evidence used	At launch: safety and efficacy (potentially relative efficacy) data from randomised clinical trials Post launch: safety follow-up	At launch: relative efficacy/ effectiveness and budget impact, formal cost-effectiveness analyses in most countries Post launch: relative effectiveness and cost-effectiveness	At launch: seldom involved Post launch: relative efficacy/effectiveness, cost-effectiveness
Power	Decision	Decision (with/without price negotiation)	Recommendation

The first country to make submission of economic studies an official requirement for listing medicines on the national drug formulary for reimbursement was Australia, in 1993. Since then, the guidelines for submissions to Australia's Pharmaceutical Benefits Advisory Committee (PBAC) have been updated several times to incorporate experience gained (PBAC, 2008).

The second country to require economic studies was Canada, based on an initiative in the province of Ontario. Detailed methodological guidelines were developed in collaboration with all stakeholders: government, insurance companies, providers' associations (hospitals, pharmacists, physicians), academia and the pharmaceutical industry. Revised editions were published in 1997 and 2006, with addenda in 2009 that covered indirect treatment comparisons and evaluations in oncology. The Canadian document is widely considered authoritative in terms of methodological standards and most of the guidelines published subsequently by other agencies have relied heavily on the Canadian guidelines (CADTH, 2006 and 2009).

Initially, European countries took a somewhat different approach. While guidelines as an expression of methodological standards were elaborated and published in most countries, they were not at first tied to reimbursement decisions. Now, however, the majority of countries have made economic evaluations mandatory for reimbursement decisions and require studies to follow official guidelines produced by the reimbursement authorities. (See Figure 1.6 for a non-exhaustive list of guidelines.) Differences among the guidelines are limited, with the most important being the perspective that submissions are expected to adopt. Other differences relate to discount rate, time horizon, and level of detail in forecasting use of a new product, i.e. the anticipated budget impact. As many of the countries that have made these studies mandatory are rather small, they minimize additional effort by accepting the results of studies from other countries, with appropriate adaptation to local needs.

In the US, the Department of Health and Human Services commissioned a panel of academic experts, the "Washington Panel", to elaborate a set of guidelines for good practice. The effort produced a widely-quoted book (Gold et al, 1996) that has sparked intense scientific discussion aimed at further development of the methods. Since then, the Academy of Managed Care Pharmacy has published a more specific set of guidelines for submissions: *AMCP guidance for submission of clinical and economic*

Figure 1.6. Use of economic evaluation in various countries

Country	Use of economic evaluation	Formal Guidelines Year of 1st publication	Research Guidelines Year of 1st publication
Australia	Required for all new drugs	1993	NA
Austria	Required for all outpatient drugs, with focus on comparison budget impact and price	NA	2006
Belgium	Required for all outpatient drugs, with focus on added benefit assessment	NA	2002
Canada	Required at national and provincial level	1995	NA
Denmark	Voluntary submission	NA	1997
Finland	Required for all outpatient drugs	1999	NA
France	Reimbursement only based on added benefit; re-assessment by HTA agency	2011	2004
Germany	Upon request, one year after launch	2010	1995
Hungary	Required for all drugs	2002	NA
Italy	Authority to request at national and regional level	NA	2001
Netherlands	Required for all new drugs outside existing clusters	1999	NA
New Zealand	Required for all new drugs	1993	NA
Norway	Required for all prescription drugs	2002	NA
Poland	Required for innovative drugs	2007	NA
Portugal	Required for all new outpatient and inpatient drugs	1999	NA
Spain	Not required at national level; can be used at regional level	2010	1995
Sweden	Required for all new drugs	2003	NA
UK (England & Wales)	Submissions requested on defined drugs and devices, either for review of class or for single technology appraisal	1999	NA
UK (Scotland)	Required for all new drugs and devices	2000	NA
USA	Inconsistently used for listing	NA	1996; 2001

evaluation data to support formulary listing in US health plans and pharmacy benefits management organisations (Sullivan et al, 2001).

In addition to the documents and guidelines produced by individual countries, a group of academic researchers published a report on researcher independence in 1995 that attempts to deal with problems of bias in economic evaluation (Task Force, 1995). The report suggests that evaluations ought only to be performed by independent researchers with no direct financial link to the sponsor or, if a study is sponsored, researchers should have complete freedom to publish any and all results. This is based in part on concerns about inappropriate modification, at a later stage, of elements such as effectiveness measures and analytical methods. Unlike protocols for clinical trials, those for the economic evaluation of new drugs are not always defined in detail at the outset. However, the solution to potential ethical problems such as this surely must lie in adherence to good practices by all participants in this evolving field, rather than in contractual arrangements.

Similarly, allegations that only studies with positive results are published indicate a fundamental misunderstanding of the purpose of economic evaluation. First and foremost, economic evaluation studies are a tool to support decisions about resource allocation. The primary purpose of such studies, then, is not to achieve publication, but to inform decision making. By nature, they are not hypothesis testing in the way that clinical trials are, but instead seek scenarios where the product under evaluation can be expected to be cost effective. The scenarios may involve specific patient populations (subgroups), specific administrative conditions, specific positioning (first-line or second-line therapy, last resort), and so on—all variables that are informed by the clinical trial results and hence often cannot be specified in a general set of guidelines beforehand. The goal of payers is to make treatments available in an efficient way, i.e. to those patients most in need and in those settings where they are cost effective. "Negative" results (i.e. high ICERs) are thus of no interest except for rejecting that particular scenario. The only way to ensure both credibility of the claims of value for money and usefulness of the studies to decision makers is to use sound methodology and relevant data, and to report results in a complete and transparent manner.

Among those countries where economic analysis must be considered prior to deciding on reimbursement for new products, economic submissions also are required when approval is sought for a new indication for an existing treatment. But as is apparent from Figure 1.5, considerable differences exist in the extent to which economic analysis is used. Sweden and Finland informally used economic evaluations in decision making even prior to the systematic assessment of all new technologies. In The Netherlands, an economic criterion is applied to reimbursement decisions only for drugs that cannot be included in an existing therapeutic cluster under the reference pricing scheme. In Norway, all new products for general prescription (schedule 2) require an economic submission, while in Portugal both outpatient and hospital drugs are subject to economic evaluation. Belgium and Austria both require economic evaluations, but Belgium appears to have a strong focus on added benefit while Austria appears to focus on price comparisons and budget impact. In Scotland, funding decisions based on cost-effectiveness, among other parameters, are binding.

Among the large countries in Western Europe, only the UK has truly formalised its requirements. NICE was set up in 1999 by the Department of Health to assess new and existing health technologies and recommend whether and how these technologies should be used within the NHS in England and Wales. Since the beginning of 2002, in an effort to limit regional differences in access, it has been obligatory for the NHS to fund prescriptions based on NICE's recommendations.

The organisation and functioning of NICE are different from similar agencies in other countries, in part due to the long tradition of academic research in health economics in the UK, coupled with a drive for greater transparency and public discussion.

> *NICE's role is to improve outcomes for people using the NHS and other public health and social care services by:*
>
> - *Producing evidence-based guidance and advice for health, public health and social care practitioners;*
> - *Developing quality standards and performance metrics for those providing and commissioning health, public health and social care services;*
> - *Providing a range of information services for commissioners, practitioners and managers across the spectrum of health and social care* (NICE, 2013b).

A sizeable component of NICE's work has been made up of technology appraisals, which may examine complete indications, single technologies, or entire classes of drugs.

- Is the technology likely to result in a significant health benefit, taken across the NHS as a whole, if given to all patients for whom it is indicated?
- Is the technology likely to result in a significant impact on other health-related Government policies (for example, reduction in health inequalities)?

- Is the technology likely to have a significant impact on NHS resources (financial or other) if given to all patients for whom it is indicated?
- Is there significant inappropriate variation in the use of the technology across the country?
- Is the Institute likely to be able to add value by issuing national guidance? For example, in the absence of such guidance is there likely to be significant controversy over the interpretation or significance of the available evidence on clinical and cost effectiveness? (NICE, 2013c)

When developing technology appraisals guidance, NICE commissions an independent academic centre to review the existing published evidence on each technology and, in some cases, the evidence contained in the manufacturer's submission. It also may ask the academic group to perform an independent economic evaluation. A specific guidance for manufacturers has been developed to ensure that all submissions have the same format (the "reference case").

The Importance of Economic Evaluation for the Development of New Technologies

Economic evaluations have become a key element, and in many countries, a mandatory requirement, in supporting reimbursement submissions. In most pharmaceutical companies, these studies are an integral part of research portfolio management intended to developed products for the market that the market wants. A similar development is underway in the medical devices industry. However, once reimbursement status has been achieved, little attention has been given to ensuring that products still offer value for money when used in actual clinical practice. This is changing gradually and an increasing number of countries now review reimbursement decisions at regular intervals (e.g. Canada, France) or periodically (e.g. Sweden, England/Wales).

Reassessment may be a particular challenge in some cases—for instance, in chronic diseases where the treatment goal is to delay progression to severe disease states with high costs and low quality of life (e.g. multiple sclerosis, rheumatoid arthritis), or in disease areas where most treatments aim to prevent mortality (e.g. heart disease, cancer). For such diseases, it may take a number of years before it is possible to observe the effect of a new treatment in the "real world".

Economic evaluations at launch are by definition based mostly on relative efficacy observed on the controlled environment of the clinical trial. Assessing relative effectiveness and hence cost-effectiveness in the "uncontrolled" clinical practice environment presents quite different challenges. However, conditional reimbursement approvals are becoming common, tying initial reimbursement to subsequent proof of cost effectiveness in clinical practice. Contractual agreements where the financial risk is shared between manufacturers and the health care system also require economic evaluation based on clinical use. Perhaps the greatest challenge presented is availability of relevant cost and outcome data from clinical practice. Observational follow-up, cohort studies and patient registries can supply such data, provided they are set up do so.

The demand for comparative data already exerts a substantial impact on the clinical development of new treatments, a situation that is likely to intensify. Marketing authorisation traditionally has been based only on efficacy and safety evidence for the particular product. The current demand for improved, rather than similar, outcomes, however, requires comparative studies that consider relative efficacy. The choice of comparator can have crucial implications: in addition to the difficulty of choosing a comparator that is deemed an appropriate alternative treatment option in the largest number of markets, the choice made also may drive the positioning and/or the price of the new product.

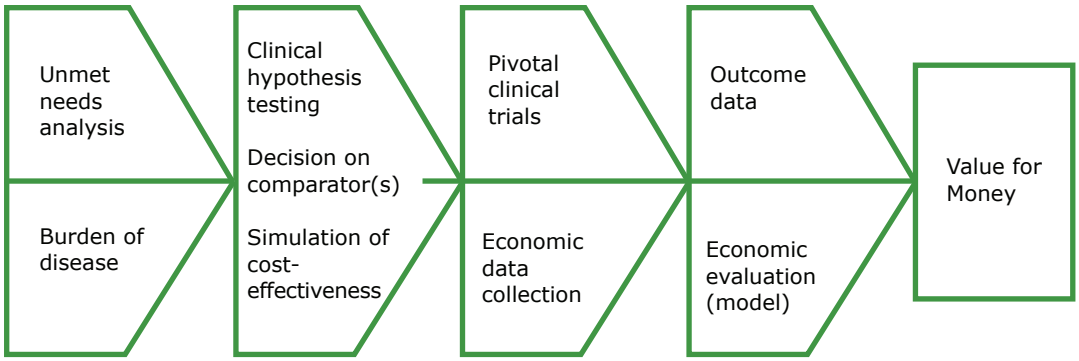
While requirements for comparisons are being better defined, reimbursement authorities and HTA agencies usually accept indirect comparisons between treatments. To give a simple example, if treatment A has been compared to treatment B, and treatment C has also been compared to treatment B, it is possible to statistically estimate the comparison of A and C. This clearly is less certain than direct comparison, particularly if the studies of B versus C were performed some years prior to those of A versus B (or vice versa). Despite this limitation, agencies tend to take the pragmatic view that it is better to have at least some supporting evidence available for decision making.

Integrating comparative research into the development process and combining clinical and economic objectives presents a number of challenges.

- How can efficacy be translated into effectiveness?
- What is an appropriate outcome measure? How can a patient's health outcome be transformed into a quantifiable measure, e.g. quality of life (utility)?
- What is an appropriate time frame for such economic analysis, compared to clinical proof of efficacy?
- What is the appropriate product or other intervention for comparison? And how can comparisons against placebo be incorporated?
- Where and how can resource-use data be collected?

Some of these points are addressed in methodological guidelines. More often, however, the chosen approach is guided by feasibility based on time frame, resource constraints, data availability, and the indication and positioning of the new treatment. Clinical trials generally are regarded as inadequate vehicles for collecting data on resource because consumption in a trial is mandated and heavily influenced by the protocol. An illustration of the overall combination of clinical and economic development is provided in figures 1.7 and 1.8. Figure 1.7 shows how the accumulation of information produces evidence of value for money; Figure 1.8 provides details about the sequence and phase timing of economic evaluation.

Figure 1.7. Documenting value for money



The evaluation process spans the entire development time for new products. It will be more successful if performed with due regard to the anticipated information needs of providers and payers, and if fully integrated into the clinical development process. In the earlier stages of development, activities mostly involve basic research about the disease, its economic consequences and the costs of treatments. In later stages, economic data are collected while Phase III clinical trials are taking place. Because economic evaluations typically consider a wider frame and longer time horizon than clinical trials, data from different sources may need to be combined: data on the disease and its development (epidemiological data), data on patient management and resource consumption (economic data), and outcomes data (clinical trials, registries). Most economic evaluations thus are modelling studies by default and such studies are now accepted as the rule, rather than the exception, by reimbursement authorities and HTA agencies.

Conducting extensive economic evaluation at all stages of development can be expensive and the knowledge gained limited, both because of the nature of clinical trials and because data about the most effective use of a product accumulates only over time in actual use. Studies conducted after launch certainly are not without cost; incentives for such expenditure are only now developing. A balance must be struck between the costs and the benefits of preparing economic evaluations throughout a product's life cycle. Generating economic information that will not be used or that could be misleading is pointless.

Figure 1.8. Economic evaluation during and after development