

# CHAPTER 1

## Principles and methods

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# THE SOCIAL VALUE OF INNOVATION

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How to go about finding the true social value of innovation? This is an urgent question given that health authorities worldwide struggle with determining which new health technologies are worthwhile adopting and how much to pay for them.

**H**ow to value innovation in health care is an increasingly important issue. It is clear that limited resources and ever increasing technological development in health care means only a selection of new innovations will be allowed into our healthcare systems. We simply cannot pay for every intervention which has a positive effect on our health status.

Traditionally, welfare economists have dealt with the issue of valuation by suggesting that the utility which a person derives from new goods or a service should be decisive in assessing their value. When at least one or more people gain from the introduction of a new programme and nobody loses, the value of that programme is then simply the sum of all positive changes in utility. Unfortunately, most programmes will have both benefits and costs, which would require that the utility of one person can be weighted against the disutility of another. If this were possible, as is assumed in cost-benefit analysis, but rejected by traditional economists, the value of the programme is then the difference of all positive and negative utilities, preferably expressed in monetary terms.

It can be asked, however, whether individual valuations of interventions which improve health status should be decisive in establishing the value of innovation. Most empirical studies on measuring the value of a quality-adjusted life year (QALY), or one year in perfect health, take the perspective of the individual, but have not been used greatly in determining the societal willingness-to-pay for innovation. These individual valuations may also vary with individual circumstances such as income, or phase of life: for instance, when a person approaches the end of their life, his valuation of interventions which prolong life is infinite because the marginal utility of money approaches zero for that person (no utility after death). It is clear that a large or infinite value is not very helpful in setting priorities among innovative programmes. It is, therefore, becoming more and more accepted that the preferences of individuals are, at most, a building block for determining value from a societal perspective.

Other studies have tried to use aggregate data to study the effect of new healthcare programmes, in general, and new pharmaceuticals, in particular, on the health of the population (both quality

of life and longevity) or on healthcare savings [1-4]. If the improvement in health can be expressed in monetary terms, which it is in these studies, this may provide an estimate of the societal value of the innovation studied. Furthermore, if healthcare savings, as a consequence of the use of innovative drugs, can be demonstrated these may even add to the benefits of health improvement.

The central question addressed here is how should we go about finding a true societal value? This is an urgent question given that health authorities worldwide struggle with determining which new technologies are worthwhile adopting and how much to pay for them. So how do policymakers deal with this problem? What is the view of health economists and healthcare providers? What value may be attached to the econometric approaches mentioned previously?

### DEFINING HEALTH BASKETS IN EUROPE

One way to study this issue is to see how different countries value new technologies when deciding upon their incorporation in the basic package of health services which all citizens are entitled to (the so-called 'health basket'). A European study on health baskets in 11 Member States [5] revealed that there is large variation in the criteria for establishing the value of new technologies, and thus defining the basic package, as well as in the process of deciding upon the package. Regarding the latter the government itself plays a dominant role in tax based systems while in social insurance systems other bodies such as the *Gemeinsamer Bundesausschuss* in Germany or the Health Care Insurance Board in The Netherlands take the lead. In some countries, such as Italy and Spain, there is a trend towards a lower level of decision-making.

In Northern Europe cost-effectiveness is more prominent in decision-making than in Southern Europe and this criterion is used especially in decisions on the reimbursement of pharmaceuticals. But other criteria are also used, such as need, necessity, and whether or not a technology can be seen as being a health status rather than welfare enhancing. So different criteria, which in some cases are related, enter the valuation. In The Netherlands, for instance, cost-effectiveness is related to the burden of illness for the patient: when the burden is high the cost-effectiveness

threshold below which technologies are accepted seems to increase making access to the package easier. Similarly, if the burden is low, authorities are more reluctant to accept technologies of higher cost-effectiveness.

There is a large variety of procedures across the various EU Member States and from the different weights given to the various criteria for assessing new technologies it is obvious we are still some distance from a clear and uniform view in European health policy.

### **THEORETICAL CONSIDERATIONS FROM THE HEALTH ECONOMIC PERSPECTIVE**

Health economists tend to focus on cost-effectiveness as a criterion to determine the value of new innovations in health care. The most commonly used is the cost-utility analysis, in which the benefits of health care are valued in terms of QALYs. This requires a judgement on what the 'monetary' value is of a QALY, in order to be able to conclude from a cost-utility analysis whether the innovation under study is worthwhile. It would be useful for a consensus on what should be incorporated in the QALY.

### **WHAT SHOULD BE INCLUDED IN THE BENEFITS?**

There may be several extensions to the concept of the QALY, which is traditionally confined to the health effects on the person being treated for a certain disease. Patients need not be seen in isolation from their social environment, so family and friends may derive a positive utility from the health improvement of a person; caregivers may also gain positive effects from the effective treatment of the person for whom they provide care and support. Another extension is the effect of health improvement on social functioning, including labour. This is often incorporated in the analysis as productivity savings. When the value of innovation is considered, broadening of the QALY-concept seems appropriate.

### **HOW TO DETERMINE THE VALUE OF A QALY?**

The other issue is then determining the value of a QALY. The best approach to this is the use of the concept 'willingness-to-pay' (WTP). Estimates of the WTP for a QALY can be produced by a contingent valuation approach, in which respondents state values for certain benefits in health gains (sometimes by providing them with different values for a given benefit from which they are asked to choose). More recently discrete choice experiments are also being used. In this approach attributes of the commodity to be assessed are first defined and levels are assigned to these attributes. Then different choice sets are presented to respondents in a context which is familiar to them, and if the price of the commodity is one of the attributes, WTP can be estimated through this technique. The WTP approach

through contingent valuation has been used a great deal, but not specifically for the purpose of estimating the WTP for a QALY. Very different results have been found, ranging from GBP 0.02 (Euros 0.023) to GBP 30,300 (Euros 34,899) for a QALY [6].

As already suggested, assessment of WTP from the individual's perspective may be inadequate for measuring societal WTP. Other dimensions may be incorporated when taking a societal perspective. One is the significance of the 'rule of rescue', suggesting that interventions are inclined to be valued more in those disease areas where no other options are available. This may explain the acceptance of high prices for orphan drugs for Pompe's disease or Gaucher's disease. Also the 'severity of illness', or more general 'equity considerations', may be factored in the societal assessment as suggested previously. And finally process may matter too. The way in which health care is provided and the information which becomes available during the process may have a utility of its own, additional to the health gains involved. One way to find out more, about this societal valuation, may be to ask policy makers using discrete choice experiments as well. This is being tried at the moment in various projects around Europe and can be used to identify the weights that policy makers attach to the different efficiency and equity criteria.

The last resort to be considered is whether revealed preference in other areas of the economy, such as building construction or traffic safety, provide a clue to the valuation problem. Unfortunately, this is not the case as the values derived for a QALY [7] range from US\$ 25,000 (Euros 18,349; based on valuing production capacity using a human capital approach) to US\$ 425,000 (Euros 311,926; based on additional salary benefits for risky jobs) to over one million dollars for a life year saved (Euros 733,945; safety measures in buildings).

### **THE PERSPECTIVE OF HEALTH POLICY MAKERS AND HEALTHCARE PROVIDERS**

Healthcare providers, such as physicians, are generally looking for the best solution for the patient they are treating at that moment, irrespective of the cost. In the one to one situation in the doctor's office a strategy is selected which offers the best patient outcome. Cost is secondary, and it is a major effort for healthcare authorities to guide decisions in a cost-effective direction. The innovative industry is continuously producing data to convince prescribers that the newest drugs offer the best solution for doctors and patients, as it is claimed to be more effective and/or safer (less side effects). Countervailing power is rather limited.



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**Table 1: Drug sales in selected countries 1998–2007 (US\$/capita)**

Country	1998	2007	% increase
Czech Republic	100	321	221
Denmark	284	641	126
Finland	200	459	130
France	280	559	100
Germany	247	413	67
Greece	187	953	410
Italy	257	434	69
Netherlands	183	376	105
Norway	287	629	119
Portugal	138	280	103
Slovak Republic	68	217	219
Sweden	234	532	127
Switzerland	420	612	46
United Kingdom	199	472	137

Source: OECD health data 2009

From a health policy perspective there is a dilemma between value-for-money and valued innovation, or static and dynamic efficiency. From the latter perspective governments want to promote innovation which contributes to better effectiveness in the future, but are at the same time under pressure to get value-for-money from public expenditure. It is now well known that in the UK the pharmaceutical industry was subsidised via a drug pricing scheme which was highly advantageous for the innovative UK pharmaceutical industry. With the advent of the National

Institute for Health and Clinical Excellence, which operates on the principles of evidence-based medicine and pharmaco-economics, this drug pricing scheme was no longer sustainable. In the way reimbursement systems operate in most EU countries, actually allowing freedom to set profit-maximising price levels in many countries, there was less pressure to reduce product price after market entry. Only in recent years have price-curbing schemes come into force, as the growth of drug budgets became unsustainable. On the other hand, lower prices of current medicines, together with value based reimbursement maintaining stringent cost-effectiveness thresholds may produce strong disincentives for innovation.

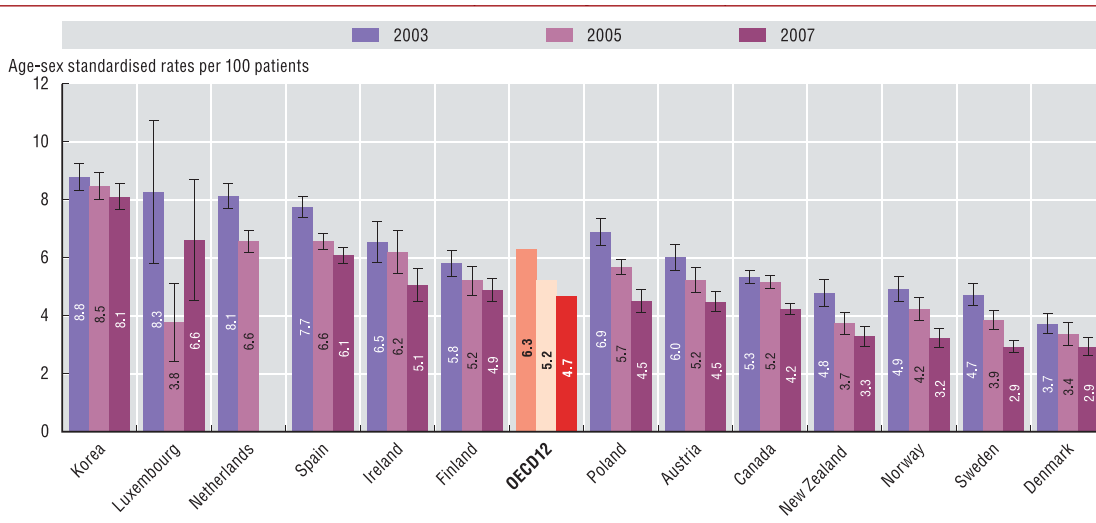
In his book *The Rise and Fall of Modern Medicine*, Dr James Le Fanu, a family practitioner in London, complains about the almost autonomous explosion of healthcare costs, whilst the benefits are far from clear [8]. He states: “In the US, health expenditure over the last decade has soared by over 60% from US\$ 800 billion in 1990 to a staggering US\$ 1,300 billion in 1997. During this time there have been neither the substantial improvements nor wider access for the uninsured that would begin to justify such an increase”. Similar data can be produced for Europe.

The increase in the drug bill as paid by European citizens, of 67% (Germany) to 410% (Greece) over a 10-year period (1998–2007; see Table 1), and a clear, large scale health benefit is hardly discernable from population statistics. For these reasons both health authorities and patients are questioning whether this tremendous

rise in drug expenditure is justified in the absence of a clear concomitant improvement in longevity or health.

From a provider perspective, innovation is valued highly due to the real or perceived advantage of new technology, including medicines for the patients they treat. However, from the payer’s side there is considerable reservation, making reimbursement increasingly dependent on proof of cost-effectiveness.

**Figure 1: In-hospital mortality rates following heart attack are decreasing in all OECD countries**



Source: OECD Health Care Quality Indicators Data 2009. Rates are age-sex standardised to 2005 OECD population (45+). 95% confidence intervals are represented by I—I.

## ECONOMETRIC STUDIES ON AGGREGATE DATA

Several economists have tried to assess the value of new innovations by estimating their impact on aggregate benefits (increased longevity) and/or on aggregate healthcare expenditure. One of the first, and most prominent, was David Cutler [1] who considered various disease areas and tried to analyse whether technological innovation was worth the increased cost of care. One example is the changing technology in treating heart attacks, such as the emergence of thrombolysis and angioplasty. Technological change accounted for half or more of cost growth in 1984–1998. With regard to benefits, survival after a heart attack increased from just under five years in 1984 to six in 1998, valuing the benefits to society of an additional year at US\$ 75,000 (Euros 55,046) or US\$ 70,000 (Euros 51,376), with discounting. As treatment cost is about US\$ 10,000 (Euros 7,339) higher, the net benefits are US\$ 60,000 (Euros 44,037) per heart attack, indicating that the new technology is well worth the cost.

Another well-known study by Lichtenberg [2], tried to measure the effect of new drugs on total medical expenditure. A reduction in the age of drugs utilised reduced non-drug expenditure 8.3 times as much as it increases drug expenditure, once again suggesting the technological change in medicines is also well worth the cost.

Both these studies have been influential in policy making. Although there has been criticism of the methodological limitations of the econometric analyses of aggregate data and the difficult task of appropriately specifying the key relationships to be studied. In 2007, Lichtenberg tried to address this in a more specific study [3], attempting to exclude non-drug effects from the equation. However, it was still found that a reduction in the age of drugs utilised reduces non-drug expenditure (in particular later in hospital expenditure) 7.2 times as much as it increases drug expenditure.

The OECD continuously monitors the development of the health and well-being of citizens versus expenditure in health care. The 2009 report ([www.oecd.org](http://www.oecd.org)) illustrates some remarkable changes in healthcare outcome. For example, in-hospital case fatality within 30 days after a stroke reduced on average by 15% (range 5–35%) over a five year period (2002–2007). In 2007 less than 5% of people hospitalised after a heart attack died within 30 days of being admitted to hospital. Five years earlier, this was still more than 6%, and it can be argued that this is largely due to the introduction of new technologies. In the area of cancer, however, slower progress is being made.

Notwithstanding these encouraging examples, new technologies only marginally affect longevity at large, whilst producing considerable costs.

Santerre has been testing ‘the new drug offset effect’, as it is called, for a number of non-US countries belonging to the OECD [4]. Based on a sample of seven countries (Belgium, Canada, Finland, Germany, Japan, Sweden, UK) it was calculated that a new drug typically reduces the growth of total healthcare spending by 0.063 percentage points in the short-run and by 0.084 percentage points in the long-run, which amounts to millions of dollars. This study has also been criticised. The aggregate approach assumes that drug effects are homogenous across all disease/therapeutic groups, which is rather unlikely. As a result, it is difficult to tell whether a particular new drug is paying for itself and, therefore, it must be concluded that a detailed cost-utility evaluation is still warranted for each costly innovation.

## CONCLUSION

Governments are struggling to assess the value of innovation in order to make informed decisions about the benefit packages for their citizens. But also producers, notably pharmaceutical companies, are keen to demonstrate the value of their products in an environment where they have to compete against drugs which are already on the market and have often lost their patent protection. They argue that innovation should not only be seen from a static perspective but that gradual improvements may add to the dynamic efficiency of the system. But most pricing and reimbursement systems tend to make the assessment from the perspective of the current value to society rather than wanting to reward gradual technological progress.

In that respect, the quest for a comprehensive and well-informed method for determining the value of innovation is still ongoing and was never more urgent. With the ever increasing drug bill and spiraling prices for innovative drugs, society needs to know what healthcare value they are buying, as in the current economic climate budgets for health care are, by necessity, shrinking.

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