Rational Decision Making in Resource Allocation

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Chapter 3

Rational Decision Making in Resource Allocation

Patients, providers and payers have a common interest in ensuring that health care systems do not waste resources. Evidence-based medicine (EBM) and health technology assessment (HTA) can help by focusing on two simple questions: does it work, and is it worth it? This chapter explores potential efficiency gains that might be achieved by introducing more rational decision making into clinical care and looks at how clinical guidelines and health technology assessment can be used to inform these decisions. It then reviews how these functions are realised in institutions throughout the OECD.
1. Introduction

Most patients assume that doctors and other health care providers are giving them care of the highest quality possible, using the latest knowledge and most efficient technology. Health care funders would like to think they are getting the best possible value for their money. Both groups are often wrong. A number of studies over the past few decades have examined the evidence concerning the medical and cost effectiveness of treatments and techniques across a wide spectrum of health care activities. Whatever the level of analysis, and whatever the specific concern examined, the findings are similar: you do not always get what you pay for.

For one, higher spending on health at country level does not always correlate with better health outcomes for the population. Likewise, there are widespread variations in health spending by regions and even cities that appear to have no discernable impact on health outcomes.

Patients, providers and payers have a common interest in ensuring that health care systems do not waste resources. Evidence-based medicine (EBM) and health technology assessment (HTA) can help by focusing on two simple questions: does it work, and is it worth it? The first question is so simple it seems absurd, but analyses have shown that a large percentage of medical interventions – up to a third in some cases – has questionable benefits.\(^1\) Technology assessment (in the wide sense of drugs as well as machines and other technical supports) asks not only whether a molecule or medical act works, but whether it represents a significant improvement over previous methods, and if it is the most efficient use of limited resources.

This chapter examines the potential to achieve efficiency gains by introducing more rational decision making into clinical care. It reviews the methods for doing so: clinical guidelines and health technology assessment. It then looks at how these functions are realised in institutions throughout the OECD. There are many different ways to organise these functions and countries could benefit from learning from each other’s experience.

2. The potential for enhanced efficiency

Evidence from a number of studies suggests that health systems have some room to achieve efficiency gains.

**Macroeconomic studies suggest potential efficiency gains in many countries**

In a recent study (Joumard et al., 2008), the OECD estimated the impact of health care spending on population health status, controlling for other determinants of health (income, education, life-style factors and pollution). Taking life expectancy as the best available proxy for population health status, panel regressions suggest that health care spending does not provide the same value for money across OECD countries. If all countries were to become as efficient as the best performers, people would live two additional years on average across
OECD countries, for the same level of spending. Similar conclusions arise when using data envelopment analysis to derive relative efficiency scores (Joumard et al., 2010).

These estimates should not be taken at face value, however: identifying health gains that can be unambiguously attributed to the health system is challenging and many health care services are not designed to increase length of life but instead to improve the quality of life of patients. However, the 2008 study suggests that health spending growth contributed by 46% to the observed increase in life expectancy of women and 39% for men in OECD countries between 1991 and 2003, which means that “health spending matters for longevity gains”.

**International variations in medical practice cannot entirely be explained by epidemiology and uptake of innovation**

Variations in medical practice have been observed both across countries and within countries since the early 1970s (Mullan and Wennberg, 2004). Data regularly collected by the OECD provide multiple examples of such variations across countries. For instance, the rate of revascularisation procedures per 100 000 population ranges from 5 in Mexico to 692 in Germany (see Figure 3.1, Panel A). The consumption of anticholesterolls varied from 49 defined daily doses per 1 000 people in Germany to 206 in Australia (see Figure 3.1, Panel B). The number of MRI exams ranges from 12.7 per 1 000 population in Korea to 98.1 in Greece (see Figure 3.1, Panel C).

**Figure 3.1. International variations in medical practice**

Panel A. Coronary revascularisation procedures per 100 000 population, 2008

<table>
<thead>
<tr>
<th></th>
<th>Percutaneous coronary interventions (PTCA and stenting)</th>
<th>Coronary bypass</th>
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1. The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law.

**Note:** Some of the variations across countries are due to different classification systems and recording practices.

**Source:** OECD (2010).
Figure 3.1. **International variations in medical practice (cont.)**

Panel B. Anticholesterols consumption, defined daily doses per 1 000 people per day, 2000 and 2007

![Graph showing international variations in medical practice for anticholesterols consumption between 2000 and 2007.](image)

Source: OECD (2009).

Figure 3.1. **International variations in medical practice (cont.)**

Panel C. Number of MRI exams per 1 000 population, 2008 (or latest year available)

![Graph showing international variations in medical practice for MRI exams per 1 000 population.](image)

1. Data include only exams for out-patients and private in-patients (excluding exams in public hospitals).

StatLink: [http://dx.doi.org/10.1787/888932319478](http://dx.doi.org/10.1787/888932319478)
These variations cannot entirely be explained by differences in the epidemiologic context, though it certainly plays a role. Differences in the adoption of new technologies, itself influenced by ability and willingness to pay, payment methods for providers, manufacturers’ strategies, professional skills and preferences, are deemed to explain most of these variations. For example, whether or not the treatment or procedure is covered by health insurance is an important factor.

**Local variations in medical practice suggest a potential for increasing the effectiveness and efficiency of health care provision**

Studies on medical practice variations (MPV) also suggest that savings could be achieved for the same level of health outcomes with a more efficient care process. Local variations in medical practice have been observed in several OECD countries (Denmark, the Netherlands, Norway, and Sweden) and even documented in great detail in the United States (Mullan and Wennberg, 2004; Mulley, 2009). The Dartmouth Institute has been providing information for many years about local practice variations and their explanatory factors. Working on Medicare data, researchers of this Institute have shown that some geographical areas tend to offer more care to chronically ill patients – care that yields no added benefits and sometimes even adverse outcomes (see Figure 3.2; Dartmouth Institute, 2008; Mulley, 2009).

Such variations are found elsewhere too: studying utilisation rates of stents and implantable cardioverter defibrillators (ICDs) in Spain in Italy, Capallero et al. (2009) observed variations both across and within countries. In 2006, the rate of percutaneous coronary interventions (PCIs) was 2,112 per million population in Italy and 1,276 per million in Spain. The proportion of PCIs performed with at least one stent was slightly higher in Spain than in Italy (96.1% against 92.5%) just like the number of stents implanted per procedure (1.59 against 1.45). The proportion of drug-eluting stents was similar (55% in Italy and 59% in Spain), but showed high variations across regions (from 23% to 78% in Italy and from 40% to 78% in Spain). ICD implantation rates differed both between and within countries. In 2006, Italy reported 189 implants per million population and Spain 60, with regional variations ranging from 39 to 285 in Italy and from 24 to 116 in Spain.

Most of those studies on MPV have tried to identify explanatory factors. In the United States, local variations can be partly explained by differences in coverage, organisation of care or payment methods. Researchers of the Dartmouth Institute conclude that a share of observed practice variations is “supply sensitive” – i.e. explained by differences in supply. For instance, regions served by organised systems of care (group practice or integrated hospital systems) typically provide less intensive care. In countries with uniform coverage policy, institutional features and providers’ payment schemes, other factors have been identified, such as the influence of peers or industry, personal characteristics of physicians (such as age, gender, initial medical education, training and aversion to uncertainty) or of their patients (see de Jong et al., 2010; Mousques et al., 2010 for reviews).

In conclusion, if part of MPVs can be explained by socio-economic characteristics and the health needs of different populations, another part remains unexplained and potentially indicates inefficient use of resources.
Clinical practice often deviates from effective care as defined by evidence-based medicine research

The American Institute of Medicine estimates that half of all health care is currently provided in the United States without any evidence of its effectiveness (Institute of Medicine, 2009). In addition, where evidence exists, health care services are not always provided in accordance with best practice recommendations.

A study conducted by the Rand Corporation in 1998-2000 in the United States showed that patients received only 54.9% of recommended care for a set of 439 quality indicators defined for 30 acute and chronic conditions. Quality care indicators were based on recommendations pertaining to screening, diagnosis, treatment and follow-up for each condition. While more than 75% of recommended care was provided for senile cataract or breast cancer, this percentage did not exceed 50% for ten conditions. Only 22.8% of recommended care was provided for hip fracture and 10.5 for alcohol dependency. In many but not all cases, non-adherence with recommended care corresponded to an underuse of health care services (McGlynn et al., 2003).

Other studies have produced more anecdotal evidence of non-adherence to recommended care in medical practice. For instance, in France, the High Authority in Health (HAS) issued a recommendation about pharmaceutical treatments for hypercholesterolemia: initial drug treatments should only be prescribed above a certain level of LDL-
cholesterol and after the failure of a diet. In 2002, more than half of patients who received a first prescription of anticholesterol drugs had not undertaken any diet. For one-third of patients with new treatments, the level of LDL-cholesterol had not been tested, and for another third, drugs were prescribed in spite of a LDL-cholesterol level lower than the recommended threshold. Similarly, antibiotics were too often prescribed for viral and non-bacterial conditions in the 2000s. For some anxiolytics, prescribed dosages exceeded the maximum recommended dose in one-third to one-fourth of cases, and treatment duration exceeded the recommendation in 30 to 50% of cases. As many as 500 000 patients received a single prescription of long-term asthma treatment, which is inappropriate and does not conform to recommendations (see Polton et al., 2007 for a summary).

**Patients’ preferences are not always taken into account**

The participation of well-informed patients in clinical decision making is another promising way to improve efficiency. Sometimes, when evidence is produced about the relative benefits and harms of alternative treatments for a given condition, no solution is found to be superior to its alternative(s) in all respects. In such cases, clinicians and patients have to trade-off different types of benefits and harms, with a variable level of uncertainty for each of them. Ideally, the selection of the treatment should reflect patient preferences, which is not always the case.

The treatment of prostatic hyperplasia is an example. A study showed that when patients are informed through “decision aids” about the benefits and harms of surgical treatment, the rate of surgery falls by 40% from baseline levels. The experience showed that patients more bothered by their symptoms were more likely to choose surgery than those who were more worried about the prospect of sexual dysfunction (Mulley, 2009). The preference for less invasive treatment options has also been identified for some conditions, such as back pain and osteoarthritis of the knee or the hip (Dartmouth Institute, 2008). This suggests that the consideration of well-informed patients’ preferences may not only increase patients’ well-being and satisfaction but has also the potential to save money in some circumstances.

### 3. EBM and HTA offer opportunities to rationalise health care provision

Evidence-based medicine (EBM) and health technology assessment (HTA) have very different origins and do not serve identical purposes, though they can both influence health care provision.

**Evidence-based medicine**

EBM has been a gradual revolution in medical thinking. This movement began after the Second World War with the application of experimental design – randomised controlled trials (RCTs) – into medical practice. The first RCT, performed for tuberculosis by Bradford Hill and Archie Cochrane, created a new paradigm of experimental clinical epidemiology. This technique became widely used for the introduction of new drugs as part of the drug regulatory process from the 1960s. However, its diffusion into the rest of medical practice has been slower.

In the 1990s, evidence-based medicine developed into a more formal movement based on new techniques for synthesizing RCTs into meta-analysis including comprehensive bibliographic searches of all available literature. These techniques were first brought to bear on obstetrics, by Sir Ian Chalmers and a team that systematically reviewed all
available literature on childbirth including positions, bed rest, use of steroids, etc. What they found was striking: many techniques long in use had no firm basis in evidence. Some things were unequivocally wrong and others had relatively firm evidence that they worked. This meant that some practices should be encouraged, some discouraged, and some studied further. This realisation spawned a whole international movement known as the Cochrane collaboration, institutions that systematically review medical literatures. There are now several groups studying most domains of health care.

To practically implement evidence-based medicine required a new generation of clinical protocols or guidelines. There have always been protocols in medicine. This is what constitutes a medical textbook: a summary of knowledge in the field. In any clinical domain, there are textbooks that lay out clinical treatments for different diseases like myocardial infarction or stroke. Societies of specialists often put out guidelines for their members on how to treat different diseases. The main change was that new guidelines were developed using comprehensive reviews of medical literature, meta-analysis, and other methods of critical appraisal.

Comparative effectiveness research (CER), recently promoted in the United States by the 2009 American Recovery and Reinvestment Act, aims to generate and synthesise evidence on comparative benefits and harms of alternative treatments. This is not a new activity, since many payers and institutes, including in the United States, have been doing such research for years. However, the additional USD 1.1 billion invested by the government to scale up CER increases the initial government budget by 73% (Docteur and Berenson, 2010). Just as EBM, CER’s primary goal is to inform decision making at the patient level. Both have the potential to foster patient involvement in treatment choice, provided that results are made available to patients. It may also be used by third-party payers to inform decisions about coverage.

4. Health technology assessment

Health technology assessment goes one step further than EBM or CER. It does not only try to answer the question: “does it work?” or “what works best?” but also the question: “is it worth it?”

Health technology assessment has a different lineage through economics. It began with cost-benefit analysis which was introduced as part of the managerial revolution in government. It was widely used in many government departments such as the treasury and defence and diffused into health care in the late 1970s, as a response to the pressure of technological progress and the spread of high cost equipments. Cost-benefit analysis was closely linked to the introduction of new technologies. The first assessments, in the health field, were produced for CT scanners.

In 1993, Australia was the first country to use cost-effectiveness analysis for decision making on drug coverage. It was followed by several OECD countries. The largest and most visible example was the UK National Institute of Health and Clinical Excellence (NICE).

Any HTA process includes a systematic review of the available clinical evidence about the benefits and harms of the technology considered (i.e. EBM, and CER when available). But HTA usually considers a broader set of benefits – not limited to patients’ outcomes – and often includes an economic assessment. Institutions in charge of HTA have some latitude to define HTA method and process to reflect the preferences of their targeted audience (an insurer, the government, the general public, etc.), though guidelines exist in
Box 3.1. **Evidence-based medicine, comparative effectiveness research and health technology assessment: working definition**

Evidence-based medicine (EBM) was defined by Sacket and colleagues in 1996 as “the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients”. As noted by Drummond et al. (2008), this definition was “expanded by usage to policy and group-focused evidence-based decision processes to produce evidence-based guidelines, make insurance coverage decisions, and develop drug formularies”.

A definition of comparative effectiveness research (CER) is proposed by the American Institute of Medicine: CER is the generation and synthesis of evidence that compares harms and benefits of alternative methods to prevent, diagnose, treat and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.

Many definitions have been proposed for health technology assessment (HTA). According to the International Network of Agencies for Health Technology Assessment (INAHTA), HTA is defined as “a multidisciplinary field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology”. However, in practice, HTA processes do not always consider the wide range of social, ethical and economic implications of the use and diffusion of new technologies and instead focus on health and organisational impacts. The main objective of HTA is to inform decisions of coverage, but it can also inform clinical guidelines.

**Use of EBM and HTA**

![Diagram of the relationship between EBM, HTA, and decision making]

Source: Adapted from Drummond et al. (2008), Institute of Medicine (2009), www.inahta.org/HTA/, consulted on 8 March 2010.

this domain too. The main objective of HTA is to inform decision making, but it can also inform practice guidelines (see Box 3.2).
In OECD countries, there is a trend towards the institutionalisation of EBM and HTA, as well as a trend towards an increased use of both for the production of clinical guidelines and coverage decisions. However, countries show a high diversity in development stages. The sections below describe briefly the current use of EBM and HTA in OECD countries, as well as perspectives for the future.

5. The current use of technology assessment in OECD countries

Attempts have been made to draw a comprehensive picture of HTA settings and use at the European level (Sorenson et al., 2007; Velasco-Garrido et al., 2008), as well as in other countries (special issue of the International Journal of Technology Assessment in Health Care, 2009). A survey undertaken by the OECD in 2008-09 collected a minimum set of information on the effective use of health technology assessment in decision making (see Table 3.1). According to this survey, all but four countries (the Czech Republic, Greece, Luxembourg and Turkey), reported the existence of structures or capacities for health technology assessment. However, HTA capacities vary widely across countries.

Most countries reported that HTA is used to determine the coverage of medical procedures, medicines and high-cost equipments. In some countries, such as Portugal, HTA is only used to determine coverage of pharmaceuticals. Many countries indicated that HTA results are also taken into account to establish reimbursement prices, especially for drugs. Finally, in a majority of countries, HTA is also used to produce clinical guidelines. All countries using HTA but France reported that cost effectiveness and affordability are considered in health technology assessment.

Institutions: status, mandate and range of activities

The first national HTA agency was created in Sweden in 1987 (see Box 3.2), followed by many countries. Today, most OECD countries have national agencies responsible for health technology assessment, with different institutional settings (independent or attached to the ministry of health or national insurance), scope (in terms of technologies to be assessed) and mandates (inform decision making, issue practice guidelines, horizon scanning, accreditation of health care institutions). However, HTA activities are not limited to national agencies. HTA efforts have preceded the creation of such agencies and, in several countries, ministries in charge of health have been funding activities for decades (e.g. Mexico). In several European countries, and in Canada, regional or hospital HTA agencies co-exist with national agencies (Velasco-Guarrido et al., 2008). In the United States, public payers (Medicare, the Veterans Health Administration) and private insurers undertake HTA activities to inform formulary decisions. Korea and the Slovak Republic have recently created HTA agencies (Kim, 2009).

Only a few OECD countries have not established national HTA agencies, among which are the United States and Japan. In Japan, the Ministry of Health and Welfare funds HTA activities, and the production of EBM practice guidelines are commissioned to academic centres. Yet there is no formal link with decision making on reimbursement and pricing (Hisashige, 2009).

Use of HTA to inform coverage decisions

In a few cases, agencies responsible for HTA are also responsible for the “appraisal” of technology, as is the case for NICE in England and Wales or for the Swedish LFN (in charge of assessing new drugs for coverage decisions). Most often however, their role is confined
Box 3.2. Health technology assessment in Sweden

The Swedish National Agency for Health Technology Assessment (SBU) was created in 1987, as an independent organisation. Its mandate is defined by the government: “SBU is mandated to make scientific assessments of new and established technologies from a medical, economic, societal, and ethical perspective. The agency shall present and disseminate these assessments so that providers of health care and others may be able to use the findings of the assessments. The agency shall assess how the findings have been used and what results have been achieved” (Jonsson, 2009).

The SBU actively disseminates the results of its assessments. Full reports, as well as syntheses for different audiences, including the general public and the international community (English versions). The latest results are available on its website and in pharmacies. SBU organises press releases and press seminars, as well as local and national conferences and education programmes. Experts who participated in the assessment process used to be, on a voluntary basis, appointed as “ambassadors” and travelled in the country to inform colleagues and other stakeholders. This process recently changed and now, “receivers” are appointed in each county to promote the dissemination of results. Finally, assessment results are published in the Journal of the Swedish Medical Association and in other national and international journals.

The SBU regularly evaluates the use of assessment reports in medical practice and publishes the results of evaluations in its annual activity report. Studies have shown a positive impact of SBU reports. For instance, in accordance with SBU recommendations, the use of pre-operative routine tests has been reduced for young and healthy patients, as well as the prescription of sick-leave for back pain, and investments in equipment for bone density measurement. The prescription of diuretics and beta-blockers, shown to be as effective as newer and costlier drugs in the treatment of mild hypertension, increased after the publication of the SBU report. In the treatment of depression and alcohol and drug abuse, the prescription of more effective drugs increased, in accordance with SBU recommendations.

The Pharmaceutical Benefits Board (LFN) was created in 2002, as an independent agency in charge to determine whether a drugs will be reimbursed under the national pharmaceutical benefit scheme. For each new drug applying for reimbursement, the LFN assesses the extent to which it satisfies three criteria: cost effectiveness (from a societal perspective); human value (i.e. absence of discrimination); and the “need and solidarity principle” (which can justify to prioritise treatments targeting people with the greatest needs). The LFN has also undertaken the systematic review of several classes of drugs since 2003, which led to delisting in some occasions.

For example, the evidence assessed by the Swedish CBU on drug use among the elderly people is synthesised in a 28 pages document (including an English version) [www.sbu.se/upload/Publikationer/Content1/1/Drug_Consumption_among_Elderly_summary.pdf](http://www.sbu.se/upload/Publikationer/Content1/1/Drug_Consumption_among_Elderly_summary.pdf).

Source: Jonsson (2009); Moïse and Docteur (2007).

to scientific assessment while third-party payers, government or joint associations of bodies make decisions.

In the pharmaceutical sector, where the use of HTA is the most developed, HTA agencies or independent scientific institutes normally conduct the assessment while coverage decisions remain in the hand of governments or third-party payers. In France, the High Authority in Health (HAS) provides recommendations about the coverage of pharmaceuticals
### Table 3.1. Use of HTA in OECD countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Structure and capacity for health technology assessment</th>
<th>Cost-effectiveness and affordability taken into account in HTA</th>
<th>New medicine Coverage</th>
<th>Reimbursement or price</th>
<th>Guidelines</th>
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Note: HTA: Health technology assessment; n.a. not available; “–”: not applicable.
1. In Mexico, the use of HTA is yet limited.

Source: Paris et al. (2010), updated with information available in July 2010.
but the government and health insurance funds make ultimate decisions. In Germany, the Institute for Quality and Efficiency in Health Care (IQWiG) makes recommendations to the Federal Joint Committee of Health Insurance Funds, Hospitals and Physicians (G-BA), which issues final guidance. In Canada, the intergovernmental Common Drug Review, part of the Canadian Agency for Drugs and Technology in Health, issues recommendations about the coverage of new drugs but provincial and federal governments remain responsible for their inclusion in the formularies of their programmes (Paris and Docteur, 2006; OECD, 2008).

Recommendations for coverage decisions do not always result in “yes or no” options. They may suggest restricted coverage (to some indications or population sub-groups) or “coverage with evidence development”. This last option, conditioning coverage to the generation of further research on effectiveness, has been used increasingly, especially when there is a high level of uncertainty about the effects of the assessed treatment.

HTA has also widely been used in OECD countries to design public health programmes for the early detection of cancer. It allowed for example to define that systematic breast cancer screening by mammograms only “worth it” after the age of 50. Under this age, direct and indirect costs exceed the benefits of such programmes.

**Use of HTA to establish practice guidelines**

Many HTA agencies only inform coverage decisions and do not provide clinical guidance for professionals. A few agencies, however, integrate the two functions. The extent to which clinical guidelines condition reimbursement or are binding for physicians varies across systems.

NICE guidance, for instance, defines what should be covered by the NHS and in which circumstances. NICE’s clinical guidance typically restricts coverage to a target population or to second line treatment, but guidance also defines patients’ rights to access treatments when appropriate. In principle, clinical guidelines are thus binding for NHS practitioners. However, there is no national programme to monitor or control professional behaviour, since the system relies on confidence in professional judgement and economic incentives received by Primary Care Trusts. Recently, NICE has been involved in the definition of quality targets used in the Quality and Outcomes Framework (QOF), which provides incentives to physicians to improve the quality of care through pay-for-performance payments.

On the contrary, the Swedish SBU and the French HAS produce guidelines that are not binding for health professionals. Efforts are made to promote professional adherence, including academic detailing by health insurance funds (in France), but there is no formal obligation to comply with guidelines. The pay-for-performance scheme recently introduced in France includes quality targets drawn from HAS guidelines, thus providing economic incentives to comply with these guidelines for the one-third of physicians who participate in this programme in 2010.

**The role and methods of economic evaluation**

Many countries use economic evaluation in HTA, especially for recommendations pertaining to the coverage of new drugs and technologies. Each country or agency determines the methods to be used. Most countries compute incremental cost-effectiveness ratios (ICERs), which indicate additional costs incurred by the new treatment for an additional unit of benefit or outcome. Outcomes are generally measured in quality-
adjusted life years (QALYs). The German Institute IQWiG, which was asked to develop its methodology in 2007, decided to use efficiency frontiers to determine the most efficient therapy among the set of all alternatives for which costs and benefits are known. This method is original and may be adopted by France but it does not allow the comparison of costs and benefits across therapeutic areas (IQWiG, 2009).

Health economists have been debating for years about methodological aspects of economic evaluation in health (costs and outcomes to be considered, modelling and assessing uncertainty, discount rates to be used for future costs and benefits, etc.), that are not addressed here. Instead, the focus is on two subjects which are particularly relevant for policy makers: should there be a single and explicit ICER threshold beyond which technologies would not be funded? What should be the role of budget impact assessment?

**Threshold or not?**

In 2008, the Belgian institute KCE issued an extensive set of reflections on the rationale and current practice of ICER thresholds (Cleemput et al., 2008). In theory, the ICER threshold should be the value of the ICER which maximises health gains under a budget constraint: if payers were able to establish a league table ranking all health systems interventions according to their (decreasing) ICER and compute budget impact for each intervention, the ICER threshold would be the ICER of the last intervention to be funded before the exhaustion of the available budget. However, with the exception of the experience in the Oregon Medicaid programme, no payer or government has ever considered the construction of such a league table for several reasons, including the lack of information on costs and benefits for all interventions and the fact that all interventions cannot be considered independent. In addition, policy makers often have goals other than the maximisation of health gains. For instance, they may favour distributional aspects (e.g. favour interventions which will offer less “QALYs per unit cost” but for a high number of people over a more cost-effective intervention useful for a small number of people). A further argument against such thresholds is that it could provide incentives for manufacturers to set prices at the highest possible level to meet the threshold criteria. All these constraints suggest the adoption of a flexible threshold rather than a fixed one. This is indeed the strategy usually adopted by policy makers (for NICE, the Swedish LFN and the Canadian Common Drug Review).

**Budget impact analysis**

Economic evaluation may or may not include budget impact analysis (BIA), i.e. a measurement of the prospective impact of the adoption of the assessed technology on health care costs (or public budget). The role of BIA in decision making is often ambiguous and not clearly defined (Niezen et al., 2009). HTA-based recommendations may incidentally lead to cost savings, in which case BIA is always welcome. However, most often, BIA provides estimates of the additional amount of money needed for the implementation of an HTA recommendation (e.g. adoption of a new technology). Then, decision makers have to consider whether the implementation of this recommendation is affordable.

BIA is not always performed and published in a transparent manner, but it is hard to imagine that decision makers do not use it, at least for planning and budgeting purpose. Does BIA have a role to play in HTA and decision making? Niezen et al. (2009) spell out rationales for the consideration of BIA in decision making. First, any decision entailing additional spending has opportunity costs: this amount of money will have to be diverted
from other health care interventions, or from other public sector investments. BIA allows the consideration of those opportunity costs. Second, if trade-offs have to be made within the health systems, the loss aversion or endowment effect – i.e. the fact that people typically value more what they do not want to lose (e.g. a reimbursed drugs that could be delisted to supply a new one) than what they could gain (e.g. the new drugs), make policy makers adverse to the delisting of current benefits. These preferences increase the opportunity costs of new decisions, especially those with high budget impact. Third, when benefits of health care interventions are assessed with a high degree of uncertainty, policy makers may be more reluctant to engage large amounts of money. Fourth, BIA can serve policies aiming to preserve “equal opportunity”. The fact that budget impact is small is often mentioned to justify the reimbursement of orphan drugs which are not cost effective (by common standards). In conclusion, budget impact cannot be ignored by decision makers: more explicit consideration of BIA would make decisions more transparent, though it may not be possible to establish definitive rules for joint consideration of cost effectiveness and affordability.

**Dissemination of HTA results**

The publication of an HTA report is important both for transparency and for implementation (as far as guidelines are concerned). HTA complete reports typically include hundreds of pages of complex information compiled in a more or less friendly manner. Consequently, HTA agencies must make efforts to disseminate information to various stakeholders.

The minimum that HTA agencies should do is to provide a summary of the assessment and recommendations, that professionals can easily consult and use in their current practice. Most HTA agencies do so. However, more active strategies of dissemination, as adopted by the SBU in Sweden (see Box 3.2), are desirable.

Communication with patients and the general public is all the more important in a context of overwhelming information, whose quality is not always easy to assess for lay people. Some HTA agencies publish useful information for patients and their relatives. In the United States, the Agency for Healthcare Research and Quality (AHRQ) publishes guides for patients in both English and Spanish on its website, as well as audio versions. Sixteen guides are currently available, for instance on treating prostate cancer, antidepressant medicines, treating high-cholesterol and osteoporosis treatments. They typically include a description of the disease or symptoms, benefits and risks associated with alternative treatments and prices for monthly supply of the main medications.

NICE publishes booklets on its website named “Understanding NICE guidance” and written for NHS users. For instance, the booklet on depression in adults describes the usual symptoms of depression, alternative treatments that can be supplied by the NHS for the different degree in severity of depression, and proposes sets of questions that patients should ask to their doctors to better understand their disease and treatment. Costs of alternative therapies are not mentioned since all treatments are provided free of charge by the NHS.

**Monitoring of implementation**

Evidence-based practice guidelines are not always binding for health professionals, except when they determine funding by a national health system or an insurer. Third-
Third-party payers should first monitor the compliance of medical prescriptions with conditional reimbursement clauses, where they exist. In a few cases, prior authorisation is required for the treatment to be reimbursed, but most often, physicians are responsible for the appropriateness of prescription. In many countries, third-party payers do not have access to patients’ diagnoses and cannot assess whether the prescribed treatment is adequate. However, the analysis of reimbursement claims can sometimes shed some light about compliance with conditional reimbursement clauses. For instance, it can reveal that the initial target population has been widened to ineligible populations.

Similarly, compliance of health professional practices with HTA-based practice guidelines should be assessed, if only to measure the effectiveness of HTA. However, very few countries have institutionalised systematic review of impact of HTA reports, Sweden being one of them (see Box 3.2). In England, NICE produces and commissions reports on the uptake of implementation of guidelines. More than 30 reports have been published to date mainly using administrative data on prescription claims.

6. The impact of health technology assessment

Velasco-Garrido et al. (2008) carried out a systematic literature review on the impact of health technology assessment, using a framework with six types of impact: awareness (knowledge of HTA reports by stakeholders), acceptance by stakeholders, impact on the policy process, impact on policy decisions, impact on clinical practice and outcomes (health gains and economic impact). The following paragraphs will concentrate on three important aspects: impact on decision making, impact on practice and impact on costs.

Impact of HTA on decision making

When HTA is conducted to inform coverage decisions, recommendations are generally not binding for the government(s), health insurance funds or other bodies who ultimately make decisions. For instance, in Canada, formulary decisions of provincial drug plans generally follow recommendations from the Common Drug Review, with varying delays, but tend to add restrictions to initial listing recommendations (McMahon et al., 2006). In France, HAS positive recommendations for drug coverage are generally followed, while recommendations for delisting are not always implemented or are only implemented with a considerable delay.

Do HTA-based guidelines contribute to changes in medical practice?

In their literature review, Velasco-Garrido et al. (2008) identified 17 studies on the impact of HTA on clinical practice, concentrated on two countries: the United Kingdom (NICE recommendations) and Sweden. Results of these studies are mixed.

Sheldon et al. (2004) analysed the impact of 12 sets of NICE guidance produced between 1999 and 2001 and found mixed results. In several cases, NICE did not have a significant impact on current practice trends (e.g. wisdom tooth extraction, hearing aids, implantable cardioverter defibrillators, prescription of zanamivir in influenza). In other cases, the recommendation was followed by a significant change in practice (e.g. higher prescription of Orlistat for obesity, and of taxanes for breast cancer) and/or a reduction of practice variations (Orlistat and drugs for Alzheimer’s disease). However, in the Orlistat
case, a closer audit showed that the drug was prescribed in accordance with the guidance only in 12% of cases (age, BMI and weight loss). The authors concluded that professional acceptance to published guidance largely influences their compliance.

In Sweden, impact studies conclude that SBU’s recommendations impacted medical practice in conformity with recommendations in most cases (see Box 3.2).

**HTA does not always reduce costs**

The primary objective of HTA activities is to enhance the effectiveness, quality and efficiency of health care. HTA activities can save costs when coverage of a new technology is denied or restricted, or when guidelines recommend cheaper treatment alternatives. On its website, NICE published a list of NICE guidance expected to reduce costs.9

However, the use of HTA does not obviously always lead to savings. In fact, empirical estimates show that NICE’s recommendations for the adoption of new technologies have cost the NHS an additional GBP 1.65 billion per year (Chalkidou et al., 2009).

**7. The future of health technology assessment**

There is no consensus among OECD countries on the use of health technology assessment, and more specifically, economic evaluation. Several arguments, regularly developed against its use are discussed below, along with key principles developed by an international expert group for the improved conduct of HTA for resource allocation decisions (see Box 3.3; and Drummond et al., 2008).

**Discussing three arguments against the use of HTA and economic evaluation**

The first argument against the use of HTA and CEA (cost-effectiveness analysis) is that they do not encourage innovation in health care and may indeed compromise private investments in R&D. In fact, the extent to which HTA will affect technological innovation, negatively or positively, depends on methods used, especially for the valuation of outcomes.

By using HTA and economic assessment in coverage decisions, government and third-party payers send signals to manufacturers about the type of innovation they value and their willingness to pay. The selection of outcomes of interest is a first type of signal. For instance, while some HTA agencies will consider surrogate markers as reasonable measures of outcomes,10 others will be more reluctant to do so. By making this choice explicit, policy makers provide useful information to innovators about the type of evidence they must produce for the adoption of their products. Similarly, when HTA agencies assess the degree of innovativeness of a new product to inform price decisions, as is the case in France,11 the industry receives a transparent and explicit assessment of the value attributed to incremental (or radical) therapeutic improvements of their products. This may help the industry to direct investments towards the most valued therapeutic areas and the most valued incremental changes of existing therapies.

The impact of the use of the cost-effectiveness criteria on private R&D investments is not straightforward. Vernon et al. (2005) show how firms can use cost-effectiveness thresholds in their R&D investment decision-making process to determine a range of expected returns on investments, according to different levels of effectiveness, price and volume. The existence of (implicit or explicit) ICER thresholds may potentially reduce the firm’s uncertainty about policy makers’ decisions and willingness to pay but, on the other
hand, it may discourage R&D investments with low returns on investments at the given threshold.\textsuperscript{12, 13}

It is worth noting that HTA and economic assessment do not always result in negative recommendations and indeed have in the past promoted the use of new technologies and increased their uptake in systems otherwise under tight budget constraints (for instance in the United Kingdom).

The second argument is that the length of HTA and CEA processes delay patients’ access to innovation. Typically, the production of an HTA report can take several years (e.g. two to three years in Sweden for reports on the treatment of a condition which compares several alternatives). However, in many countries, products and treatments can be marketed and sometimes reimbursed before being assessed through an HTA process. Access is thus not delayed in principle. This is the case in the United Kingdom, where a new drug, for instance, can be supplied to NHS patients until NICE decides it should not be.\textsuperscript{14} In addition, countries have the possibility to create accelerated procedures for promising technologies. For instance, in Sweden, the SBU developed a specific programme (Alert) to quickly review new and innovative treatments (Jonsson, 2009). Finally, third-party payers may design special access programmes to provide immediate access to promising treatments for patients with life-threatening diseases, pending the results of the assessment and appraisal process. Several Canadian federal and provincial drug coverage plans have introduced such programmes (Paris and Docteur, 2006).

The third argument is that HTA raises ethical concerns and is not accepted by the population, especially when HTA recommendations are negative. Such decisions are often perceived as rationing by the general public or patients and receive high attention from the media (especially in the United Kingdom). However, budget constraints, strict or soft, entail trade-offs. HTA just provides an opportunity to make trade-offs more explicit, rational, consistent and equitable. This argument certainly needs to be popularised among professionals, patients and the general public. The involvement of stakeholders in the HTA process, its transparency, the publication of criteria considered to make final decisions should contribute to a wider acceptability of the process and the final decisions (Gruskin and Daniels, 2008).

**Principles for good conduct and good use of HTA**

Among the principles proposed for HTA good practices (Box 3.3), many have already been adopted by several OECD countries and are consensual while others have been subject to national adaptations. Some of these recommendations seem particularly relevant given the current status of HTA practices in OECD countries.

The idea that HTA should include all technologies is probably one of the most important one, with several implications. In many countries, HTA activities focus on new drugs and costly medical devices, which are assessed against existing ones. Resource limitations partly explain such a focus. However, HTA should ideally be extended to all technologies (all products, diagnostics and procedures, disease management) and to the review of existing treatments for a more rational decision-making process. Even if countries do not need to generate HTA reports for the thousands of medical procedures and products that are currently used, there is scope for improvement in this matter in a number of countries. The experience from most countries is that major savings can be achieved in existing clinical practice, not new technologies. The real savings or efficiency
Box 3.3. **Key principles for the improved conduct of HTA for resource allocation decisions**

- The goal and scope of the HTA should be explicit and relevant to its use: they should be agreed by a wide range of stakeholders; the link between HTA and decision making should be explicit.

- **HTA should be an unbiased and transparent exercise:** HTA should be conducted by bodies independent from decision-making bodies, third-party payers or professional associations; HTA process and criteria for decision making should be transparent. HTAs should be freely and publicly accessible to stakeholders.

- **HTA should include all relevant technologies, i.e. drugs, devices, diagnostic procedures and treatment strategies,** to prevent distortions in resource allocation. The current focus on drugs and new technologies is not ideal.

- **A clear system for setting priorities for HTA should exist,** to ensure cost-effective HTA activities. For instance, NICE selects technologies to be assessed on six criteria: burden of disease, resource impact, clinical and policy importance, presence of inappropriate variations in practice, potential factors influencing the timeliness of guidance, and likelihood of the guidance having an impact.

- **HTA should incorporate appropriate methods for assessing costs and benefits:** methods should be adapted to purpose and context, be transparent and consistent across assessments, and be periodically reviewed. HTAs should be conducted by trained experts.

- **HTAs should consider a wide range of evidence and outcomes:** randomised clinical trials data may need to be completed by observational studies, surrogate endpoints must be considered and extrapolated to outcomes of interest; benefits, risks and costs must be defined broadly. Outcomes should include changes in quality of life for patients, as well as benefits for patients’ relative, employers and the society. Variations in costs and benefits across population subgroups should be assessed.

- **A full societal perspective should be considered when undertaking HTA** to ensure efficient resource allocation at the level of the society.

- **HTA should explicitly characterise uncertainty surrounding estimates and include sensitivity analyses and confidence intervals for results.**

- **HTA should consider and address issues of generalisability and transferability across patients, populations and settings of care.**

- Those conducting **HTAs should actively engage all key stakeholder groups,** in the definition of objectives of HTA reports, of treatment alternatives and patient populations to be considered and modeling. They should be given opportunities to comment HTA drafts and appeal decisions.

- Those undertaking **HTA should actively seek all available data,** including confidential data, though this may contradict the transparency principle.

- **The implementation of HTA findings should be monitored.**

- **HTA should be timely:** ideally, HTA should follow marketing authorisation and be subject to review periodically, or when new information is available.

- **HTA findings need to be communicated to different decision makers, i.e. decision makers, managers of health care institutions, health professionals, patients and the general public.**

- The link between **HTA findings and decision-making processes needs to be transparent and clearly defined.** Criteria for decision makers can legitimately differ across payers or jurisdictions, ideally they should be transparent.

Source: Based on Drummond et al. (2008).
gains come from rationalising the current medical practice. This means not only discontinuing out-dated techniques that are marginally effective, but also making sure that effective procedures and technologies are properly disseminated and used by all.

The involvement of stakeholders (producers, professionals and patients) in the HTA process is certainly desirable. However, the involvement of these stakeholders should be clearly defined (consultation or participation?). It is interesting to note that stakeholders’ involvement does not necessarily mean stakeholders’ “endorsement” of HTA conclusions. In the case of NICE, manufacturers have appealed against 30% of decisions, half of which have been upheld, in spite of their involvement in the process (Drummond et al., 2008).

Two recommendations, however, do not make consensus. First, while Drummond et al. (2008) recommend adopting a full societal perspective in health technology assessment, many countries only consider costs for “health care” payers. In theory, the societal perspective should be used in order to maximise social welfare. In practice, however, the policy mandate of people in charge of health policy is to maximise gains obtained from health budgets or health spending. Therefore, economic evaluation often considers costs for the public payer or for all health care payers (Johannesson et al., 2009).

Second, some countries consider that confidential data cannot be taken into account in health technology assessment, because it would break the rule of transparency.

8. Conclusions

Rationalising health care provision is a promising way to achieve efficiency gains. The production and dissemination of clinical guidelines, based on evidence-based medicine (EBM), can contribute to such a rationalisation process. Health technology assessment (HTA) can complement the use of evidence-based clinical guidelines by informing coverage decisions to make sure that new technologies are worth it.

Conducting HTA requires information. The development of information systems, providing data on volumes and costs of procedures performed and treatments prescribed is a prerequisite to the development of HTA. Some countries also need to develop a skilled workforce necessary to perform assessments.

Countries should seek more actively to monitor the implementation of HTA recommendations, especially for guidelines. Currently, only a few HTA agencies or institutions undertake or commission studies to monitor the impact of recommendations.

Countries that are interested can build on an already rich international collaboration in the field of HTA. European and international networks exist and allow participants to share experiences and skills, to produce guidelines for HTA good practice, and to co-ordinate early detection of technologies needing assessment.15 Consumers and payers would probably benefit from more standardised HTA methods. Though results of economic evaluation will inevitably differ across countries – due to differences in the organisation of care, in relative prices of various inputs, and in professional practices and epidemiological contexts – uniform standards in data requirements would be desirable.

Institutions matter. It appears promising to combine the functions of looking at new drugs and technologies with the development of evidence-based guidance. It is important to bring together medical thinking about clinical effectiveness with economic thinking about cost effectiveness and the use of economic evaluation techniques. This is leading to clinical-economic appraisal that lies at the heart of rational decision making for health care.
Notes

1. From a synthesis of several studies conducted in the United States, researchers concluded that one-third or more of all procedures performed in the United States in the 1990s were of questionable benefit (RAND, 1998).

2. However, due to a long tradition of self-regulation of the medical profession, these activities still rely on medical associations and colleges in several countries. For instance, in Switzerland, the promotion of good practices for pharmaceutical prescriptions mainly rely on quality circles gathering physicians and pharmacists (Paris and Docteur, 2007), with no intervention from the government and only logistic support (for data collection) from insurers.

3. The OTA, created in 1972, was dissolved by the US Congress a few years later.

4. The German Institute for Medical Information and Documentation (DIMDI) manages HTA programmes, commissions HTA reports to qualified experts and maintains a database with all HTA reports, including IQWiG’s reports (see www.dimdi.de/static/en/index.html).

5. According to this definition, ICER thresholds should not exist in social security systems with no strict budget constraints or when the societal perspective is adopted.


10. Surrogate markers are sort of “intermediary measures of outcomes”. For instance, the available evidence can show that a drug effectively lowers the cholesterol level (which is known to lower mortality risks) without demonstrating yet that it effectively reduces mortality.

11. The French HAS rates on a five-level scale a “degree of innovativeness” for each new drug, by comparison with existing competitors. Though no formal economic assessment is conducted, this assessment, together with the prices of existing competitors, will inform price decisions. The most innovative products will be granted higher “price premium”.

12. Hollis (2005) suggests that policy makers should publish ICER thresholds for orphan drugs (which will be typically higher than usual thresholds) to encourage firms to invest in this type of products.

13. In addition, some authors argue that ICER thresholds could encourage firms to set higher prices than they would have done without regulation, but without exceeding the threshold.

14. However, in such cases, providers may prefer to wait for NICE’s decision (and NHS additional funding) to uptake the innovation.

15. See for example: EUenetHTA (European Network for Health Technology Assessment: www.eunethta.net/); INAHTA (International Network of Public Agencies for HTA: www.inahta.org/Publications/) – INAHTA was established in 1993 and has now grown to 46 member agencies from 24 countries; Euroscan Network (www.euroscan.org.uk); and Inno HTA (HTA methodology for innovative healthcare technologies: www.inno-hta.eu/).

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