

FINANCING SUSTAINABLE HEALTHCARE IN EUROPE: NEW APPROACHES FOR NEW OUTCOMES

**Conclusions from a collaborative investigation
into contentious areas of healthcare**

February 2007



“Financing Sustainable Healthcare in Europe” presents the results of a year-long study into the sustainability of healthcare financing in Europe which was first proposed in Luxembourg in late 2004. It is endorsed by Luxembourg's Ministry of Health and by Sitra, the Finnish Innovation Fund, and is partnered by Pfizer, Inc.

The views expressed in this work are those of the authors and do not necessarily represent the views and policies of the organisations to which they belong. The independence of the authors, and of all other parties who contributed to this work, is absolute. Pfizer's intention in partnering this initiative was to stimulate novel thinking and to contribute to finding solutions for sustainable healthcare financing in Europe.

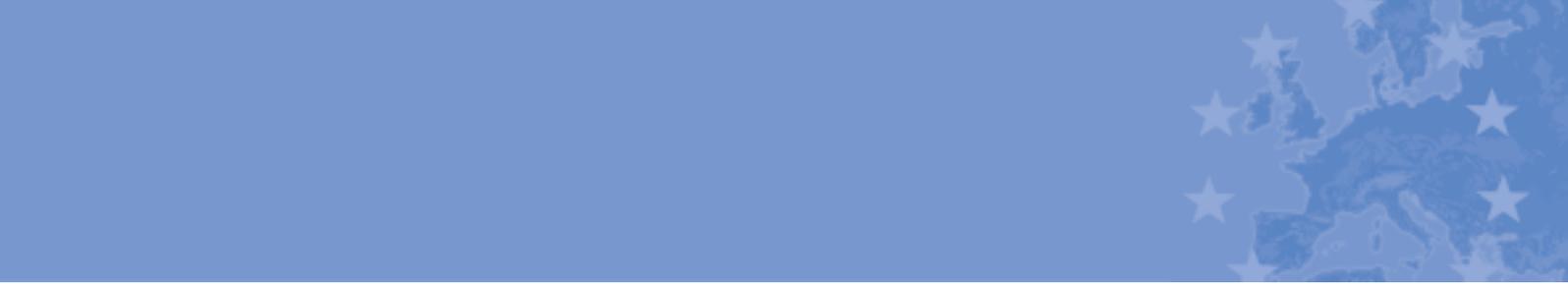


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- **Ensuring value for money in health care: the role of HTA in the European Union**

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Financing Sustainable Healthcare in Europe

Dr. Otto Graf Lambsdorff

It is no secret that health and welfare systems around the world are facing enormous challenges in meeting the increasingly conflicting objectives of providing wide accessibility and efficiency while delivering high quality and choice in healthcare. The historically generous social welfare systems of most North and Middle European countries have played vital roles in alleviating poverty and raising the standard of living and life expectancy. Yet even these national icons of social consciousness are struggling to meet the needs of a changing society – and health systems are finding new ways to provide healthcare, safeguard access and increase choice, while staying true to their principles of quality, equity and solidarity.

Importantly, there is a growing understanding that healthcare systems cannot be isolated from the rest of society and economy: in order to be more effective they must interact within other areas including but certainly not restricted to, education, employment, pensions, social welfare, science and competitiveness. This almost certainly means that for public financing of healthcare to be sustainable, policy makers and citizens alike must see the broader landscape in which public health is situated and understand its contribution to our society in a much wider social, political and economic context. As the healthcare arena becomes more and more complex, the population ages and the cost of technology increases, the efficient provision of healthcare within a globalized economy is more important than ever before.

While public financing – by taxes or wages-related social contributions – is still the primary source of healthcare funding in Europe it is by no means the only one. Out-of-pocket spending varies widely but has increased in most OECD countries since 1990, indicating there are financial barriers to access to healthcare that need to be monitored. Some Member States of the European Union have introduced innovative forms of financing through partnerships between the public and the private sector to develop healthcare infrastructure. Others have even worked with the private sector to provide public/private health insurance programs. Increasingly, it is clear that Europeans are finding new and innovative means to safeguard citizens' right to access, high quality and affordable healthcare. However, only by delivering true innovation in development and implementation of public policy can we ensure that those who are positioned to do so, are equipped to make the right decisions for our society, our health and our future.

It is widely accepted that in order for Europe to rise to the challenges and opportunities posed by globalization we must become more competitive. In the face of an ageing population, any future improvement in competitiveness will be also dependent on our ability to maintain a healthy and productive older working population. This crucial variable is ultimately reliant on our ability to provide high quality and effective healthcare, promoting prevention for an ageing society and reducing the economic burden of illness. A first step therefore must directly relate to ensuring health service provision is continuously efficient, readily accessible and meaningfully accountable. Attainment of this position undoubtedly entails strengthening the transparency, flexibility and competitiveness of our healthcare systems and frameworks.

The report 'Financing Sustainable Healthcare in Europe' materialized as a result of the broad and inclusive collaboration of parties with an interest in ensuring the future provision and delivery of high quality healthcare for the people of Europe. Initially agreed during a highly successful conference of the same name, hosted by the Minister of Health of the Grand Duchy of Luxembourg in October 2005, the report synthesizes much of the knowledge and experience base of policy makers, academics, professionals, and experts in their respective fields, all of whom share a common passion for improving healthcare. Its key contribution is the generation of policy options for the delivery of continuous healthcare improvement through increased efficiency, enhanced choice and innovative models of healthcare financing.

'Sustainable Financing of Healthcare in Europe' has four specific areas of focus, each guided by leading organizations in their field of expertise. The University of Toulouse and the European Investment Bank provided clear insight by leading a work stream to consider 'Protecting equity while improving efficiency: Some possibilities for expanding the role of competition and choice in health care delivery'. Similarly INSEAD and the European Health Management Association addressed the issue of 'Patient empowerment and efficient health outcomes', the London School of Economics led a work stream on 'Ensuring value for money in health care: The role of HTA in the European Union', and the World Bank guided the project on 'Issues affecting the sustainability of health financing in several countries of south east Europe'. Rather than depending on the development of entirely new research, 'Sustainable Financing of Healthcare in Europe' aims instead to provide new analysis and thinking on the basis of existing work. In this way the collaboration of rapporteurs builds on a quantity of data and opinion to guide healthcare decision makers through an undoubtedly complex area of public policy terrain. Throughout the process, all rapporteurs have worked in close cooperation under the auspices of an oversight steering committee (the Cox Group) chaired by Pat Cox, former President of the European Parliament, with the committed support of the project sponsors, the Ministry of Health of Luxembourg, Pfizer Inc. and the Finnish National Fund for Research and Development - SITRA.

Together with the Conference on 'New Approaches for Better Outcomes in Europe' of February 2007 in Helsinki, hosted by SITRA, this significant work moves from paradigm shift to concrete and actionable next steps designed to enhance efficiency and quality of our healthcare services. It is unsurprising that the healthcare systems we built in previous generations must rapidly evolve to serve the needs of today's society and prepare for the demands of the future. To accomplish this we must set ourselves high and ambitious standards for reform and improvement based on a drive for clear, measurable and attainable results. Activities and practices that can prove value through results while adhering to the principle of equity and choice must be a priority as we move toward reform. The report 'Sustainable Financing of Healthcare in Europe' and its supporting platforms serve as a best practice beacon enabling us to develop innovative models and policies into reality.

Bonn, November 2006

Setting the Scene

Pat Cox

This report in four parts is designed as a contribution to one of the great debates of the age, namely how to sustain healthcare financing in Europe without compromising quality outcomes. Conventional political wisdom suggests that higher incomes, technical progress and ageing populations combine to propel our societies towards an explosive and ultimately unaffordable growth in health related expenditure. Angst, however deeply rooted, is a poor substitute for analysis. National health policies with their diverse institutional and policy preferences and legacy effects reflect Europe's wider cultural diversity. Yet within this complex mosaic it is possible to identify unifying themes. The motto of the European Union is 'Unity in Diversity'. It serves as a useful leitmotif for our reflections. Our analysis cautions against despair and our Helsinki conference founded on this logic is an invitation to the health policy community, including those with national budgetary responsibilities, to reflect together on how to shift a gear from analysis to action.

Technological developments more than ageing explain European healthcare expenditure growth and new research suggests that proximity to death is a more important determinant of health care costs than ageing as such. This implies that the impact of ageing on health care expenditure may not be as great in future as many have feared. Moreover, spending is sensitive to whether the care of the aged takes place in institutional or non institutional settings which itself is amenable to policy influence. One must also reflect on the fact that as a public good health expenditure represents an investment as well as being a cost and additionally that prevention is less costly than cure. Technology investment is a case in point. Its use which has added to costs must be appreciated against the benefits conferred by improved health outcomes.

This is borne out in all Western European countries by the decline experienced in treatable mortality where individual longevity and quality of life have improved through timely and effective health intervention or prevention policies. Health as wealth is a keystone of the theory of human capital that links positive health outcomes to strong economic growth and labour productivity, with considerable evidence to support this claim. Indeed, conversely, a World Health Organisation study suggests that poor health is part of the explanation of low growth in low income countries. In addition, subject to balancing the costs and benefits to society and its responsible use, healthcare is itself a legitimate form of consumption. Consequently, in analysing any given level of national health expenditure the focus must be at least as much on spending wisely as on spending more.

We concentrate on the challenge of how to improve efficiency without sacrificing equity and do so through examining patient financial responsibility, public purchasing, managed care and competition among insurers.

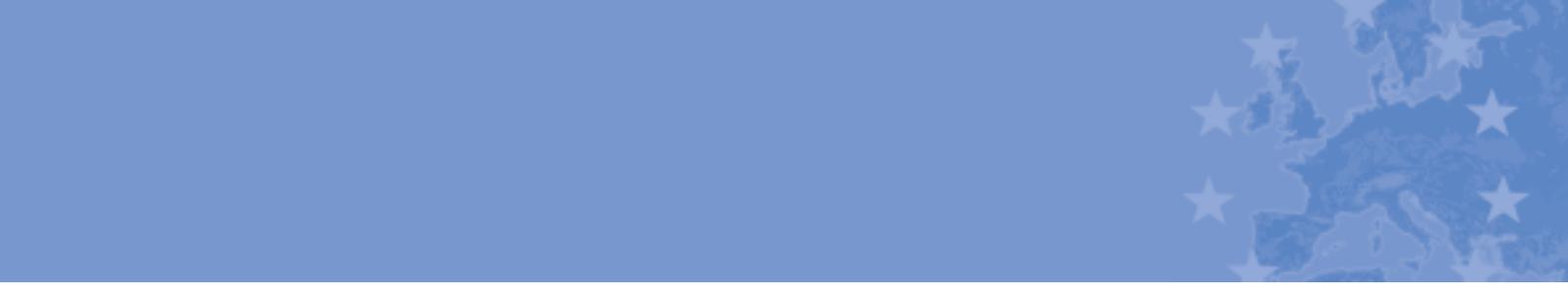
For the uninitiated generalist among health policy specialists it is as shocking as it is surprising to learn how little hard European evidence there is on the policy consequences and trade offs involved in suggesting such propositions. We have a dearth of accurate, mutually available and comprehensible information. Where there are studies they are often US based. While not automatically dismissing their relevance one wonders about their fit as regards European circumstances and preferences.

Market price-based mechanisms are likely to be the most efficient route to introduce the necessary information to the system. Through their application they can act as appropriate signals and incentives for all the key players involved on the demand or supply side of the equation. This is so whether our systems of healthcare delivery are public, private or mixed. While appreciating Europe's institutional diversity we call for properly designed trials whose evaluation would help guide policy makers' choices towards spending more wisely.

Evidence based decision making is the foundation on which Health Technology Assessment (HTA) rests. It is a methodology designed in principle to establish a correspondence between actual healthcare needs and innovation. As we have seen, technological progress more than ageing accounts for increases in European health expenditure and thus places HTA at the heart of attempts to establish a rational spending model. The diffusion of new technology, whether pharmaceutical or other, impacts not only on cost but also on healthcare outcomes and innovation policy. It can have a differential impact depending on whether costs are measured in the long or short term, especially in the field of preventative treatments. Consequently the assessment task is complex and it is clear from our deliberations that HTA is itself a work in progress. We have cast a constructive, balanced but not uncritical eye at European experience in this field. There are models of better practice and others. Where the assessment agency's role is reduced to being a de facto reimbursement agency its independence is of dubious value. HTA is focused predominantly on pharmaceuticals more than new technology in general. We recommend that it also should be used to identify ineffective and obsolete technologies and interventions thus helping better to support real innovation.

We observe a general lack of transparency in the HTA topic selection process and have issues about the extent and nature of stakeholder involvement. Initiatives such as EUnetHTA should be supported to enhance the transferability and accountability of the HTA process whose transparency, timeliness and relevance is central to its potential influence and success.

Speaking of stakeholders brings us to the role of the citizen/consumer/patient in the healthcare process. This role changes with circumstance. The wellness paradigm requires individual engagement through lifestyle choices. The illness paradigm differentiates the patient's role by types of intervention, whether urgent, elective or chronic. In general it is our view that patients are more marginalised in and by the healthcare system than should be the case and that both system and patient lose as a result. We believe that steps should be identified in the treatment process where patient power could contribute to more efficient outcomes and that barriers to inclusion should be removed. Perhaps one of the most obvious and pressing possibilities is in the area of electronic medical records. There is nothing more disconcerting for a patient in a clinical environment than to start over on each consecutive visit or in each encounter with a new element in the healthcare chain as if from the beginning, as if one had arrived without trace and would leave likewise. This inconvenience to the patient is compounded by the much wider systems costs and inefficiencies that it imposes. It suggests the need for real demand-led innovation in this aspect of health policy management.



As the European Union Institutions prepare yet again to reconsider the matter we are of the opinion that patients should have access to valid information about available choices and by this means be empowered to play a greater role in their own interest and to the general benefit of the healthcare system. Special care should be taken to include lower socio-economic groups and minorities in such initiatives.

We were anxious in this exercise which began under the auspices of the Health Ministry in Luxembourg during its Presidency of the European Union to include an appraisal of the nature of the challenges facing a number of then accession or current candidate or aspiring member states of the EU. The passage of time sees two of that number now as member states, Bulgaria and Romania. The others reviewed include Croatia, the Former Yugoslav Republic of Macedonia and Turkey. All of them have taken the first steps towards improving the financial sustainability of their health care systems.

A key difference is not only their levels of economic development relative to Western European economies but also their less developed institutional and regulatory framework so essential to achieving success and durable reform. In some of these states existing resources are inadequate and are likely to remain so. As with the states of Central and Eastern Europe they have an overcapacity in the hospital sector, an excessive reliance on inpatient care and an underdeveloped outpatient capacity. On top of this they face many of the basic cost challenges enumerated earlier related to technological changes. In close co-operation with governments private sector stakeholders can help devise effective solutions to some of these seemingly insurmountable problems.

By way of conclusion, it has been a pleasure and a privilege for me over the past year to have worked with such a talented steering committee and I wish to record my thanks to them for their courtesy and co-operation and in particular to thank Pfizer Inc. for initiating this project and for their constructive engagement. While impressed by the scholarship that I have met I have been shocked by how little we know collectively in Europe about the effects of health policy choices on health policy outcomes. There are so many questions and so few relevant answers. As an evaluation method Health Technology Assessment offers much but on its own is not a panacea. Certainly it can be improved by transparently sharing and developing models of best practice. It is striking to observe the ubiquity of information and communications technology in everyday life but its relative paucity in so many of our healthcare systems for example as regards electronic patient records. There are few more complex and sensitive areas of public policy making than healthcare. Politicians fear and the public suspects that in many countries today healthcare spending is like putting money into a black box, what goes in, what goes on and what comes out all part of a mysterious trinity. I have learned from this exercise that there can be another way.

January 17, 2007





PROTECTING EQUITY WHILE IMPROVING
EFFICIENCY: SOME POSSIBILITIES FOR
EXPANDING THE ROLE OF COMPETITION
AND CHOICE IN HEALTH CARE DELIVERY

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February 2007

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EXECUTIVE SUMMARY

This report reviews trends in health care expenditure in Western Europe. It highlights a range of market mechanisms intended to improve efficiency, while not sacrificing equity or quality, in the use of health system resources in four areas: patient financial responsibility, public purchasing, managed care and competition among insurers.

We advocate some policy propositions, to be evaluated in properly-designed trials:

- Controlled increase in patient cost-sharing;
- Increased competitive bidding for hospital contracts;
- Greater vertical coordination and integration of health services contracts; and
- *Ex ante* insurance competition for groups of patients.

These propositions are based, firstly, on our conviction that the lack of accurate, mutually-available and understood information is an absolutely critical problem for the good functioning of the health economy – for all parties. And, secondly, that market, price-based, mechanisms are likely to be the most efficient route to systematise such information and convert it into appropriate incentives for players and decision-makers – patients/“consumers”, payers, and service providers.

The report finds that levels of health care expenditure, as well as the magnitude and rate of changes in spending, vary considerably across countries. Although health care expenditure has risen substantially in most countries in Europe, the pace of expenditure growth has been slower since 2000, and there is evidence to suggest that increases in spending have, on the whole, been matched by gains in health outcomes. The study of avoidable mortality (mortality amenable to health care) provides a useful means of assessing the contribution of health care to health gain and measuring the relative performance of health systems in different countries. In addition, other forms of analysis indicate the importance of health care in promoting economic growth, with positive benefits for individuals and society.

In the past, health care expenditure has been driven mainly by developments in technology, and this is likely to be the case in the future. Although population ageing has been an issue of major concern to policy makers across Europe, new research suggesting that proximity to death is a more important determinant of health care costs than age implies that the impact of ageing on health care expenditure may not be as great in future as many have feared. It is not yet clear how developments in disability trends and the availability of informal care will affect future demand for long-term care.

These factors do not deny the importance of non-health care-related policies on health, or the need to ensure that health care is delivered efficiently. Rather, they point to the importance of ensuring that access to health care is both universal and equitable and that efforts to contain health care costs do not jeopardise efforts to enhance equity. Measures to increase both efficiency and equity in the financing and delivery of health care will be central to ensuring sustainability in the long term.

Providing incentives to patients to use health care responsibly may contribute to efficiency, although there is evidence to suggest that patient cost sharing (user charges) is a blunt policy tool as it lowers the use of appropriate as well as inappropriate health services and there is uncertainty about its impact on health status. There is little evidence to suggest that user charges lead to sustained cost control because health care costs are mainly driven by supply factors. Nevertheless, all European health systems impose user charges for some health services. Consequently, policy makers should attempt to improve patient cost sharing policies through careful design, taking into account the effect on equity and the potentially high transaction and political costs involved. While there is not yet good evidence, we believe that the Swiss and Dutch experiences of the use of deductibles to moderate demand may warrant further debate and research.



Methods of paying providers play a key role in determining efficiency and quality in health systems. Recognising that retrospective forms of reimbursement fail to control costs, many European countries are moving towards prospective payment. Prospective payment systems present purchasers with considerable challenges due to information problems that make it difficult for purchasers to assess provider cost and quality. Competitive tools can be used to overcome information asymmetry - for example, competitive bidding for hospital contracts or case-based payment linked to diagnosis (DRGs). While there is not much evidence for competitive bidding, we believe that both tools provide powerful incentives for providers to control costs, although concerns about quality and access to health care remain unresolved. European health systems increasingly use DRGs to pay for health care, for a range of reasons, usually in combination with other financial and non-financial mechanisms. Their experience requires careful monitoring and evaluation to ensure that cost savings can be achieved without lowering quality and access. Pilot experiments using competitive bidding for hospital contracts could be of great value.

The US experience of managed care provides useful insights into ways of improving efficiency and quality in health care. Policy in Europe should increase the emphasis on coordination and integration of service contracts, through structures such as vertical integration, gatekeeping, and payer influence over provider behaviour (selective contracting, utilisation review and clinical guidance). Again, however, mechanisms need to be in place to ensure quality and access, and restricting patient choice may be difficult in some contexts.

European attempts to introduce patient choice-driven competition among insurers have aimed to create incentives to strengthen purchasing and enhance equity (by encouraging convergence in contribution rates, as in Germany). However, their impact on efficiency has been limited due to the difficulty of designing risk adjustment mechanisms that are effective in removing incentives to select risks, the absence of tools permitting purchasers to exert control over providers and the high costs to patients of changing from one insurer to another. An alternative to 'ex post' competition based on patient choice is 'ex ante' competition requiring insurers to bid for groups of patients. Although this form of competition among insurers has not yet been tried, so there is no evidence to suggest what kind of impact it might have on policy goals in practice, it may offer advantages in terms of lower transaction costs and reduced incentives to select risks. Again, regional pilot experiments using this form of competition would be very helpful to assess its feasibility.

Any consideration of options for reform should bear in mind institutional contexts. Institutional arrangements vary considerably, even among western European health systems, and are likely to have substantial influence on policy goals and outcomes due to political differences as well as differences in payer, purchaser, provider and patient motives and behaviour. Market mechanisms may be effective in lowering health care costs, but there is some evidence to suggest that cost savings may not be sustained in the long-term. In addition, the strong incentives they create present opportunities for 'gaming', so policy makers require tools and resources for careful regulation, management, monitoring and evaluation. The development and use of regulatory and management tools may incur heavy transaction costs, but these costs may be worthwhile if they bring visible benefits to the society.

INTRODUCTION

1

Since the 1970s, spending on health care (calculated as a percentage of gross domestic product; GDP) has doubled in many European countries, a trend seen in high-income countries in other parts of the world (see Table 1). Consistent rises in health care expenditure have led to fears about sustainability, particularly if rising incomes, ageing populations and technological progress force countries to allocate increasingly greater levels of resources to health care. However, it is not clear whether health care spending in high-income countries is in fact unsustainable at present, or will become so in future.

This report begins with a discussion of trends in health care expenditure in high-income countries and then focuses on mechanisms intended to improve efficiency in the use of health system resources in four areas: patient financial responsibility, public purchasing, managed care and competition among insurers.

Table 1: Health care expenditure as a percentage of GDP in western European countries and the United States, 1970-2004

	1970	1980	1990	2000	2004
Austria	5.2	7.5	7.0	9.4	9.6
Belgium	3.9	6.3	7.2	8.6	**10.1
Denmark	-	8.9	8.3	8.3	*8.9
Finland	5.6	6.3	7.8	6.7	7.5
France	5.3	7.0	8.4	9.2	*10.5
Germany	6.2	8.7	8.5	10.3	10.6
Greece	6.1	6.6	7.4	9.9	*10.0
Iceland	4.7	6.2	7.9	9.2	*10.2
Ireland	5.1	8.3	6.1	6.3	7.1
Italy	-	-	7.7	8.1	8.7
Luxembourg	3.1	5.2	5.4	5.8	*8.0
Netherlands	-	7.2	7.7	7.9	*9.2
Norway	4.4	7.0	7.7	8.5	*9.7
Portugal	2.6	5.6	6.2	9.4	*10.1
Spain	3.5	5.3	6.5	7.2	*8.1
Sweden	6.8	9.0	8.3	8.4	*9.1
Switzerland	5.5	7.4	8.3	10.4	*11.6
United Kingdom	4.5	5.6	6.0	7.3	***8.1
United States	7.0	8.8	11.9	13.3	15.3

Source: OECD Health Data 2006

* estimate

** data for 2003

*** differences in methodology

1.1 Health care expenditure

The figures in Tables 1-3 show that levels of health care expenditure, as well as the magnitude and rate of changes in spending, vary considerably across countries. For example, in 2004 the United States (US) had by far the highest level of spending on health care as a proportion of GDP (15.3%), while health care spending in western European countries ranged from 7.1% of GDP in Ireland to 11.6% of GDP in Switzerland. Between 1970 and 2004, health care expenditure as a proportion of GDP more than doubled in several countries and almost tripled in Portugal but did not change in Denmark and grew by only a third in countries such as Finland, the Netherlands and Sweden (see Table 2). Most countries experienced the fastest growth during the 1970s, followed by the 1990s, with slower rates of growth in other decades, particularly during the 1980s, although this may be attributed to high rates of economic growth pushing up GDP. Looking at health care expenditure changes in terms of real prices (rather than as a proportion of GDP) confirms that expenditure growth was highest during the 1970s and 1990s, but has actually been slowest in the years since 2000 for most countries (see Table 3).

Many analysts have expressed concern about the sustainability of current spending levels due to increased demand resulting from, among other things, the ageing of European populations. In some cases this concern has been fuelled by early projections, often carried out in the United States, indicating that health care costs for those aged 65 and over would increase dramatically by the middle of the 21st century, both in absolute terms and as a proportion of GDP, mainly because of the ageing of the so-called 'baby-boomer' cohort born following the Second World War (Schneider and Guralnik 1990; Mendelson and Schwartz 1993; Denton and Spencer 1995). However, analysis of the determinants of health care expenditure growth in high-income countries show that the relationship between ageing and expenditure growth varies across countries (O'Connell 1996) and is small when compared to other determinants such as developments in medical technology, changes in the unit price of care relative to other goods and services, increases in underlying demand and utilisation of care, provider efficiency, the ratio of institutional to non-institutional care and population growth (Defever 1991; Newhouse 1992; Gerdtham 1993; Angus, Auer et al. 1995; Häkkinen and Luoma 1995; Harrison, Dixon et al. 1997; L'Horty, Quinet et al. 1997; Barros 1998; Di Matteo and Di Matteo 1998; Pettinger 1998; Okunad and Murthy 2002; Wanless 2002).

Similarly, while the number of older people is a key determinant of long-term care expenditure, other determinants may be even more influential; for example, the extent to which older people are able to take care of themselves (usually referred to as dependency and measured in terms of activities of daily living), the availability of unpaid (informal) carers and their propensity to provide care, the characteristics of a specific long-term care system, patterns of care and the unit costs of care (Evandrou and Winter 1988; Davies, Ferlie et al. 1990; Wittenberg, Pickard et al. 1998; Lagergren and Batljan 2000; Norton 2000; Comas-Herrera and Wittenberg 2003).

More recent research suggests that higher levels of health spending by older people might be caused by proximity to death rather than age (Zweifel, Felder et al. 1999; Seshamani and Gray 2004; Seshamani and Gray 2004; Zweifel, Felder et al. 2004). If this is the case, as populations age spending may be delayed to much later in life, leading to over-estimation of future costs. International projections that have accounted for proximity to death find that it does indeed lead to lower estimates of future spending on health care, although there is substantial variation across countries and no conclusive evidence to show that this is the case for long-term care (Economic Policy Committee and European Commission DG ECFIN 2006). As in the past, it seems likely that technological development leading to changes in medical practice will continue to be the dominant driver of health care costs, while future long-term care costs will depend on trends in disability and the availability of informal care that substitutes for institutional care (Dormont, Grignon et al. 2006; Economic Policy Committee and European Commission DG ECFIN 2006).

1 PROTECTING EQUITY WHILE IMPROVING EFFICIENCY: SOME POSSIBILITIES FOR EXPANDING THE ROLE OF COMPETITION AND CHOICE IN HEALTH CARE DELIVERY

Table 2: Changes in health care expenditure as a percentage of GDP in Western Europe and the United States, 1970-2004

	% growth 1970-1980	% growth 1980-1990	% growth 1990-2000	% growth 2000-2004	% growth earliest to latest available year
Austria	44.2	-6.7	34.3	2.1	84.6
Belgium	61.5	14.3	19.4	17.4	159.0
Denmark	-	-6.7	0.0	7.2	0.0
Finland	12.5	23.8	-14.1	11.9	33.9
France	32.1	20.0	9.5	14.1	98.1
Germany	40.3	-2.3	21.2	2.9	71.0
Greece	8.2	12.1	33.8	1.0	63.9
Iceland	31.9	27.4	16.5	10.9	117.0
Ireland	62.7	-26.5	3.3	12.7	39.2
Italy	-	-	5.2	7.4	13.0
Luxembourg	67.7	3.8	7.4	37.9	158.1
Netherlands	-	6.9	2.6	16.5	27.8
Norway	59.1	10.0	10.4	14.1	120.5
Portugal	115.4	10.7	51.6	7.4	288.5
Spain	51.4	22.6	10.8	12.5	131.4
Sweden	32.4	-7.8	1.2	8.3	33.8
Switzerland	34.5	12.2	25.3	11.5	110.9
United Kingdom	24.4	7.1	21.7	11.0	80.0
United States	25.7	35.2	11.8	15.0	118.6

Source: OECD Health Data 2006

Rate of growth:

highest	second highest	third highest	lowest
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In spite of the uncertainty surrounding future levels of demand for health care, several countries have recently taken steps to expand health insurance coverage. Examples include the introduction of greater coverage of prescription drugs for older Americans in 2006 (Kaiser Family Foundation 2006); the introduction of social health insurance based on citizenship rather than occupational status in France in 2000, accompanied by free complementary health insurance covering user charges for people with low incomes and the abolition of user charges for those who register with a gatekeeping general practitioner (Sandier, Polton et al. 2004; Dourgnon 2005); and an increase in the threshold for access to free primary care and prescription drugs in Ireland in 2006 (McDaid and Wiley 2006 forthcoming). Other countries have experienced deliberate efforts to increase health care spending. Since 1997, the UK government has followed a policy of driving up health care expenditure, which is regarded as having been unacceptably low in the 1990s (Oliver 2005). These examples must be seen in the context of widespread efforts to contain health care costs across western Europe, particularly during the 1990s but continuing to the present day in many countries (Oliver and Mossialos 2005). However, they suggest that rising expenditure is not viewed in an exclusively negative light. There are several possible explanations for this.

Table 3: Changes in health care expenditure (in national currency units at 2000 GDP price level) in Western Europe and the United States, 1970-2004

	% growth 1970-1980	% growth 1980-1990	% growth 1990-2000	% growth 2000-2004	% growth earliest to latest available year
Austria	105.9	16.7	73.8	8.0	350.9
Belgium	123.3	41.1	45.8	22.5	462.7
Canada	53.5	65.8	32.4	22.6	313.2
Denmark	-	9.0	28.0	12.0	56.2
Finland	63.2	65.9	2.7	23.7	244.1
France	83.8	53.2	34.5	22.4	363.5
Germany	85.1	23.1	65.1	5.4	296.4
Greece	71.1	20.2	69.1	20.0	317.2
Iceland	146.6	63.3	48.3	25.0	646.5
Ireland	160.0	4.3	106.1	39.6	680.0
Italy	-	-	22.5	11.1	36.1
Luxembourg	116.0	66.9	78.5	54.9	897.0
Netherlands	-	32.8	37.4	19.9	118.8
Norway	151.2	41.3	58.2	24.2	597.5
Portugal	234.1	53.2	99.0	9.6	1016.0
Spain	116.1	64.5	45.5	26.7	555.5
Sweden	59.5	14.9	21.8	18.1	163.5
Switzerland	53.2	38.4	39.9	14.7	240.1
United Kingdom	52.0	38.4	53.8	23.5	299.9
United States	72.2	86.6	53.8	26.9	526.9

Source: OECD Health Data 2006

Rate of growth:	highest	second highest	third highest	lowest
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First, there is increasing recognition of the contribution made by health care to addressing 'avoidable mortality' (sometimes referred to as mortality amenable to health care), a concept developed by German researchers in the 1970s as a measure of the quality of health care (Rutstein, Berenberg et al. 1976). Avoidable mortality is usually defined as deaths from specific causes that should not occur in the presence of timely and effective health care. Recent work distinguishes between causes that are responsive to medical intervention through secondary prevention and treatment ('treatable' conditions such as cervical cancer and hypertension) and causes that are often outside the direct control of the health system ('preventable' conditions such as lung cancer and cirrhosis, which can be prevented by policies to reduce smoking and drinking) (Holland 1988).

This type of analysis shows that levels of treatable mortality were lower in countries like France, Sweden, Italy, Spain and the Netherlands in the early 1990s and early 2000s than they were in Germany, Ireland, the United Kingdom and Portugal, and that all western European countries experienced declines in treatable mortality over time (Newey, Nolte et al. 2004; Nolte and McKee 2004). The rate of decline differed, however, with Portugal, Austria and Finland showing the sharpest declines, while improvements were smallest in the Netherlands. The study of avoidable mortality demonstrates the important role health care plays in improving health outcomes - suggesting that increases in health care expenditure in the 1990s were not without benefit - and provides a means of comparing health systems in terms of their relative impact on health.

Other forms of research that attempt to assess the extent to which health care spending contributes to improvements in health also find that increases in expenditure are generally matched by better health outcomes (Cutler, Rosen et al. 2006). This does not deny the importance of non-health care-related policies on health, or the need to ensure that health care is delivered efficiently. Rather, it points to the importance of ensuring that access to health care is both universal and equitable and that efforts to contain health care costs do not jeopardise efforts to enhance equity.

Second, there is the notion of 'human capital', which acknowledges that investments in health and health care are a key contributor to economic output and growth. A report prepared by the World Health Organization's Commission on Macroeconomics and Health in 2001 concluded that poor health was partly responsible for the low level of economic growth in low-income countries and that investment in a range of basic health interventions could reverse this (Commission on Macroeconomics and Health 2001). A more recent study focusing on the 25 member states of the European Union demonstrates the impact of health on economic growth in high-income countries: healthier people have higher earnings and better health increases both the number of hours worked and the probability that a person will be employed, with knock-on effects on the productivity of family members (Suhrcke, McKee et al. 2005). The study also concludes that reductions in cardiovascular mortality are a robust predictor of subsequent economic growth. Health care may contribute to economic growth in other ways. For example, the biomedical and life sciences are an important component of scientific activity and investment in health and health care-related research and development is likely to affect economic growth in some countries.

Finally, health care should be regarded as a legitimate form of consumption, so long as it is used responsibly, with clear recognition of the need to balance the costs and benefits to individuals and to society. If European health systems are to be sustainable, then health care resources must be spent efficiently and fairly. Cost-effective diffusion of new technologies and improved management will play a central role in ensuring sustainability, as well as giving patients and providers appropriate incentives to use and produce health care wisely.

All European health systems have introduced reforms to improve efficiency in the delivery of health care. In France, for example, there have been 24 reforms in 30 years, from the Barre reform of 1976 to the second Douste-Blazy reform of 2004. Whether these reforms can be considered to have been successful or not depends on a range of factors in addition to efficient delivery, such as their impact on access, equity and health. In addition, the extent to which a successful reform in one country can be implemented in another country depends largely on political and institutional constraints. Institutional features vary significantly, even among European health systems, although it is possible to make a broad distinction between National Health Service (NHS) countries, in which government agencies are predominantly responsible for delivering care, and social health insurance (SHI) countries, which rely on a greater mix of private and public providers and operate through insurers that are independent of government.

Table 4: Health systems in Western Europe

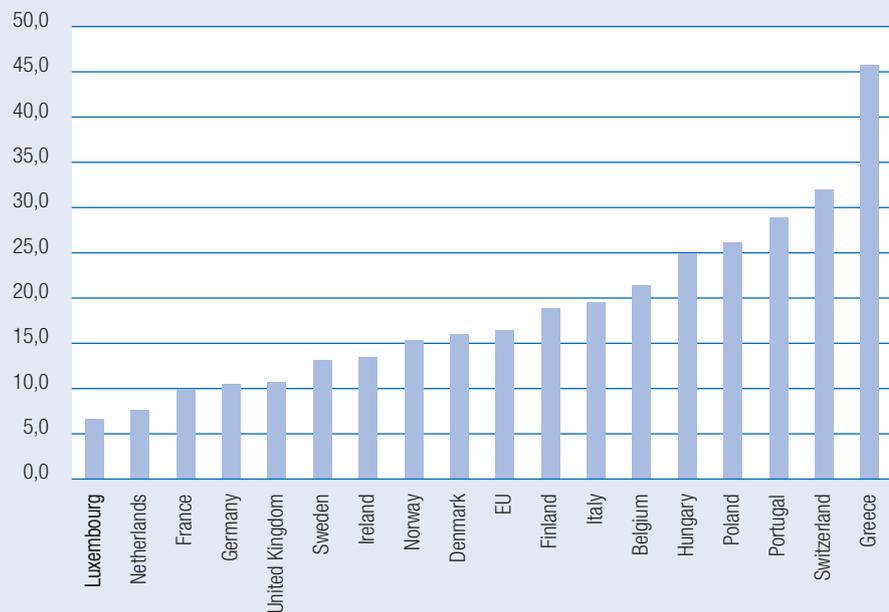
NHS countries	SHI countries
• Denmark	• Austria
• Finland	• Belgium
• Ireland	• France
• Italy	• Germany
• Portugal	• Luxembourg
• Sweden	• Netherlands
• Spain	• Switzerland
• UK	

1.2 Report outline

The rest of this report focuses on market mechanisms intended to improve efficiency in the use of health system resources in four areas: patient financial responsibility, public purchasing, managed care and competition among insurers. The section on patient financial responsibility reviews the economic rationale for patient cost sharing in health care and evidence of its impact in European countries. The section on public purchasing reviews the incentives underlying payments to providers. It discusses two different ways of promoting competition among hospitals to improve efficiency and quality. The section on managed care discusses the US experience of managed care in the light of European attempts to reorganise health care to offer patients a more integrated service. A final section reviews the introduction of patient choice-based competition among insurers and suggests an alternative method of encouraging insurer competition. This section may at present be more relevant to health systems based on the social health insurance model, although each section is intended to address concerns common to all European health systems.

Health systems in both NHS and SHI countries in Western Europe provide universal or near universal health coverage. However, all require cost sharing in the form of user charges (fixed co-payments, co-insurance rates or deductibles). The nature and extent of user charges and their contribution to health care finance vary considerably from one country to another (see Table 5 and Figure 2). Patient cost sharing in health care is often justified on the grounds of 'moral hazard'. In this section we review the economic rationale for user charges, present evidence about the impact of user charges on equity and efficiency and highlight recent reforms to user charges policy in Western Europe. The section concludes with a proposal intended to reconcile the need for financial protection with the need to control demand.

Figure 1: Out of pocket payments as a percentage of total health care expenditure in selected European countries, 2004



Source: WHO Health for All Database 2004

Note: These data should be interpreted with caution as out of pocket payments include both statutory user charges and direct payments to private providers.

2.1 Moral hazard and price sensitivity

Economic theory suggests that individuals shielded from the full cost of health care through insurance will use health services beyond the point at which the marginal benefits of use outweigh the marginal costs (Pauly 1968). This behaviour, known as moral hazard, may be apparent in public or private health insurance systems, and lowers societal welfare because scarce resources might be better spent on other goods and services. However, if some form of cost sharing is introduced to mitigate the effect of moral hazard, economists and others usually assume first, that rational consumers will forego the health services of least benefit to them ('unnecessary' use); and second, that reductions in use attributable to cost sharing will contain health care expenditure.

1 PROTECTING EQUITY WHILE IMPROVING EFFICIENCY: SOME POSSIBILITIES FOR EXPANDING THE ROLE OF COMPETITION AND CHOICE IN HEALTH CARE DELIVERY

Table 5: Patient cost sharing for different types of health care in EU-15 countries, 2006

	GP/specialist	Inpatient	Pharmaceuticals	Dental	Other
Austria	✓	✓	✓	✓	✓
Belgium	✓	✓	✓	✓	✓
Denmark	None	None	✓	✓	✓
Finland	✓	✓	✓	✓	✓
France	✓	✓	✓	✓	✓
Germany	✓	✓	✓	✓	✓
Greece	None	None	✓	✓	✓
Ireland	✓	✓	✓	✓	✓
Italy	None	None	✓	✓	✓
Luxembourg	✓	✓	✓	✓	✓
Netherlands	None	None	✓	✓	✓
Portugal	✓	None	✓	✓	✓
Spain	None	None	✓	✓	✓
Sweden	✓	✓	✓	✓	✓
UK	None	None	✓	✓	✓

Source: adapted from (Thomson, Mossialos et al. 2003)

The problem of moral hazard creates a dilemma for policy makers who may be concerned to balance the need for health insurance, which provides valuable financial protection from the costs of ill health, and the need to control patients' use of health care through user charges. From an economic perspective, health insurance covering catastrophic risks that do not occur very often but involve large financial outlays is efficient, whereas health insurance covering high-frequency but low-cost care, which may be more predictable, is generally considered to be less efficient (assuming no major market failures) (Barr 2004). However, most health systems provide both 'insurance' covering catastrophic risks and 'pre-payment' covering smaller risks and predictable expenses (for example, for those who are already ill), as both elements play a central role in ensuring financial protection, particularly for poorer people and people in ill health.

Most research in this area confirms economic theory, providing strong evidence that patient cost sharing leads to significant reductions in the use of health care in North America and that those with insurance coverage are more likely to use health services, while the generosity of insurance coverage influences the volume of consumption (Manning, Newhouse et al. 1987; Rice and Morrison 1994; Rubin and Mendelson 1995; Lexchin and Grootendorst 2004). Research also shows variation in the distribution of reduced use across the population, suggesting that people with low incomes are more responsive to price than others; in other words, cost sharing is a much greater deterrent to seeking care among people with low incomes.

European studies of the impact of cost sharing show mixed results in terms of reductions in the use of health care, which does not seem, on the whole, to have a significant impact on the use of primary care, outpatient specialist services or acute care (Chiappori, Durand et al. 1998; Starmans 1998; Ahlmaa-Tuompo 1999; Halldorsson, Kunst et al. 2002; Cockx and Brasseur 2003). This may be due to the relatively low levels of user charges applied in most countries. Studies assessing the impact of additional voluntary health insurance coverage on utilization also show mixed results, with some finding that voluntary coverage does not have much impact on use (Genier, Rupprecht et al. 1997; Genier 1998; Sanz de Galdeano, Pinto Machado et al. 2006) and others finding that it does (van de Ven and van der Gaag 1982; Caussat and Glaude 1993; Van Gessel-Dabekousen 1993; Christiansen, Lauridsen et al. 2002; Dourgnon and Sermet 2002; Raynaud 2002). However, studies do show that people with low incomes are most sensitive to price (van Doorslaer 1984; Klavus 1997; Elofsson, Unden et al. 1998; Jourdain 2000; Burström 2002) and that demand for prescription drugs falls when cost sharing is introduced (Thomson and Mossialos 2004).

If cost sharing only reduces the use of unnecessary health care, then it will enhance efficiency without affecting health outcomes. However, evidence shows that cost sharing is non-discriminatory in its effect. North American studies have found that increased cost sharing had the same impact on the use of effective and ineffective or medically inappropriate health care, including the consumption of prescription drugs (Lohr, Brook et al. 1986; Foxman, Valdez et al. 1987; Rice and Morrison 1994; Rubin and Mendelson 1995; Lexchin and Grootendorst 2004).

Few studies have attempted to measure how cost sharing affects health status or been able to measure the long-term health effects of reductions in use due to cost sharing, although the RAND study in the United States found three areas in which those with free care experienced better outcomes: diastolic blood pressure, corrected vision and the risk of dying for those for whom the risk had been higher (Brook, Ware et al. 1983; Lurie, Ward et al. 1986; Lurie, Kamberg et al. 1989). The study also found that cost sharing affected people with low incomes and those in poor health disproportionately. A Canadian study found that increases in prescription charges led to significant reduction in the use of discretionary and essential drugs and that the fall in the use of essential drugs led to a 117% increase in hospitalizations and doctor visits and a 77% increase in emergency department visits (Tamblyn, Laprise et al. 2001). The study also found that relatively modest increases in prescription charges targeted at welfare recipients resulted in larger reductions in the use of drugs than that observed for older people, and similar increases in the rate of adverse events. A review found that cost sharing adversely affected the health of unemployed and homeless people (Rubin and Mendelson 1995).

European studies have not attempted to measure the impact of cost sharing on health status, although a number of observational studies provide some evidence suggesting that cost sharing deters the use of preventive and emergency health care, particularly among individuals in higher risk groups (O'Grady, Manning et al. 1985; Laidlaw, Bloom et al. 1994; Christensen 1995; Christensen 1995; Nexoe, Kragstrup et al. 1997).

Mixed results from European research suggest that it may be important to take into account the non-monetary costs associated with the use of health services when determining price sensitivity. The time and costs of transport and waiting seem to represent an important part of the total cost for patients, especially when monetary costs are almost fully covered by insurance.

Overall, there is no evidence to suggest that cost sharing leads to sustained cost control over time. First, few studies have been of sufficient duration to allow assessment of long-term expenditure control. Some find lower expenditure in the short term (generally the first one or two years) with little effect beyond this period. Second, reductions in expenditure on the services subject to user charges may cause expenditure to rise in other parts of the health system, particularly if patients substitute more expensive forms of free care for non-free care (for example, use of accident and emergency departments rather than primary care providers or prescription drugs), leading at best to minimal net savings and at worst to higher overall spending on health care.

2.2 What should be done?

European health systems have introduced several changes to their cost sharing policies. Some reforms have increased cost sharing and some have tried to lower the burden of user charges. For example, in 2004 the German government introduced a flat rate of €10 per quarter for visits to a doctor (Riesberg 2005). Conversely, the threshold for exemption from user charges for primary care and prescription drugs has been raised in Ireland and the French government has lowered user charges for those who agree to register with a gatekeeping doctor, and provided free voluntary health insurance covering user charges for people with low incomes (since 2000), in recognition of the detrimental effect of both user charges and voluntary health insurance on equity of access to health care (Dourgnon 2005). Evaluation of the German reform suggests that the new cost sharing regime has had little impact on utilisation (Augurzky, Bauer et al. 2006), perhaps because the rate of co-payment is relatively low in comparison to user charges for prescription drugs (€5-10 per pack) (Riesberg 2005). In the past, increases in cost sharing in France have also had limited impact due to the availability of voluntary health insurance covering user charges, which is why the latest reform introduces a flat rate of €1 per doctor visit (up to an annual limit of €50) that cannot be covered by voluntary health insurance (MISSOC 2003).

In spite of the lack of evidence in support of cost sharing to control health care expenditure, user charges are well-established in most European health systems. Well-designed cost sharing policies should balance the need for financial protection with the need to control demand through financial incentives. Co-payments (for example, a fixed fee per prescription or visit to a doctor) are a poor instrument in this respect because the price to the patient does not vary based on the actual value of the care being provided. Co-payments that vary according to type of care or co-insurance rates create stronger incentives, but having a separate rule of reimbursement for each type of care might not be cost-effective or transparent.

A simpler solution may be to introduce an appropriate level of deductible below which there is a high co-insurance rate (for example, 100% in Switzerland). A lower co-insurance rate could be applied between the deductible, with an out of pocket ceiling above which all expenses would be fully reimbursed by the health system. In order to address concerns about equity, the level of co-insurance, deductible and out of pocket ceiling could be linked to income. The advantage of this system is that it requires patients to pay for small and regular health care expenses while at the same time protecting them against catastrophic expenditure. Insurers would benefit from lower administrative costs as minor expenses would not involve billing (Van Kleef, van de Ven et al. 2006).

The Swiss and Dutch governments allow people to choose health insurance plans with different levels of deductibles. In Switzerland insurers must offer five levels, ranging from 230SF to 1,500SF per year. A co-insurance rate of 10% applies to health care expenditure above the deductible up to an annual ceiling. Swiss research shows that changing the level of deductible from 230SF to 1,500SF lowers total expenditure per patient by 2,860SF (see Table 2) (Gardiol, Geoffard et al. 2006). However, after controlling for the fact that low risk individuals are more likely to choose a high deductible (the selection effect), the reduction in expenditure per patient falls to 697SF. In the Dutch system individuals can choose plans with different levels of deductibles (including no deductibles).

A system of deductibles raises several issues for policy makers. First, there is the question of whether, in a system subject to risk equalisation among insurers, premium subsidies should be community-rated (the same for all members of a particular plan) or risk-rated (based on the risk profile of each member). Van Kleef et al (Van Kleef, van de Ven et al. 2006) argue that if the premium rebate is community-rated, it may be lower than the deductible. As a result, people would be unlikely to choose a high deductible, exacerbating the moral hazard problem. To avoid this, the government can allow insurers to adjust their premium rebates so that unhealthy members would have premium rebates higher than the deductible, thereby inducing them to choose high deductibles. Alternatively, it could subsidise the difference between the premium rebate and the deductible, encouraging individuals to choose a high deductible. Gains obtained by a reduction in moral hazard could then offset the amount spent on subsidies.

A second issue concerns feasibility. Voluntary take up of deductibles might be low. For example, early reports from the Netherlands suggest that in the first year following the reform introducing deductibles (2006), 92% of people purchased plans without a deductible (Bartholomé and Maarse 2006). Compelling people to pay a deductible might be unpopular and there might be difficulty in setting not only the levels of deductible available, but also the ceiling on out of pocket expenditure.

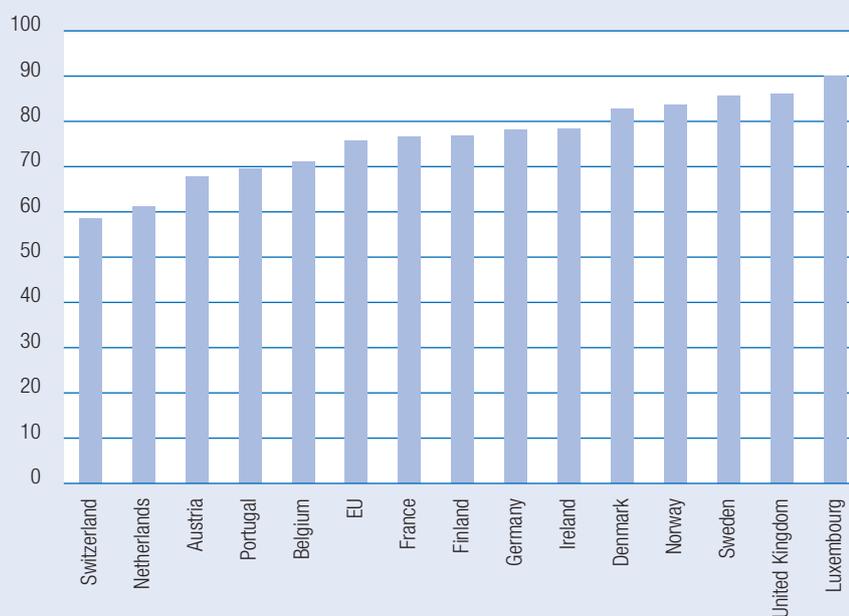
Third, efforts to preserve equity through targeting (for example, by using income-related (means-tested) user charges and ceilings) involve a trade-off with administrative efficiency and fail to address the problem of financial barriers to access for those who are just above any income threshold. Fine-tuning exemption systems by having several income bands incurs additional administrative expenditure. Also, once individuals have reached the level up to which they are required to pay charges, there is no further incentive to moderate health care use. Well-designed cost sharing policies should attempt to preserve equity on a systematic and transparent rather than ad hoc basis, and consider the potentially substantial transaction costs involved.

We acknowledge that at present these issues remain unresolved, partly due to the absence of relevant evidence drawn from empirical research in Europe, which in turn reflects a lack of useful and reliable data. Nevertheless, the Swiss and Dutch attempts to control demand warrant both debate and further research to establish their effect on efficiency and equity.

In European health systems, publicly-raised revenue is a major source of health care expenditure, ranging in 2004 from 58.1% of total health expenditure in Switzerland to 90.2% in Luxembourg (see Figure 2). Public expenditure covers the financing of publicly-owned hospitals or clinics as well as payments by government agencies to (for-profit or not-for-profit) private providers.

This section begins by discussing payments from purchasers to providers from a theoretical perspective. The former includes public agencies in NHS and SHI countries as well as private (for-profit or not-for-profit) insurers, while the latter comprises physicians and hospitals. It then considers the introduction of tools such as competitive bidding and yardstick competition to enhance provider efficiency and quality.

Figure 2: Public health expenditure as a proportion of total health expenditure in European countries, 2004



Source: WHO Health For All database

3.1 Provider payment

Payments to providers should meet several objectives. First, they should induce providers to keep costs down. Second, the care provided should be appropriate. Third, patients should have equal access to health care. Here, equal access implies that no patient is refused appropriate treatment and that the quality of care provided should be the same for all patients. Research into different methods of paying providers in order to meet these objectives has focused on the effects of provider payment on cost control, quality and access.

Provider payments can be made on a spectrum ranging from full retrospective reimbursement to some form of purely prospective payment. Retrospective payments reimburse part or all of the cost of treatment. As a result, they do not give providers incentives to control costs. Prospective payments attempt to anticipate the cost of providing care rather than the actual cost itself, with the intention of creating powerful incentives for providers to control costs. In recent years many European health systems have moved from retrospective to prospective systems of paying both individual and institutional providers, mainly in the interests of containing health care expenditure. Some have introduced case- or activity-based payment mechanisms, which estimate average payments based on case or diagnosis-related groups (DRGs; see below).

Purely prospective payment is desirable only when several conditions are met. Prospective payment of total costs requires knowledge of a provider's cost function and case mix and quality must be verifiable. As this is rarely the case in health care, there is some role for purchaser-provider cost sharing to avoid problems such as 'cream skimming' or 'quality skimping'. For example, provider case mix is not usually fully observable because the cost of treatment may vary considerably from one patient to another; even where purchasers can identify costs, providers may be able to refuse treatment to patients who are likely to incur costs higher than the prospective payment or provide services of varying quality to different patients in order to deter high risk (and therefore unprofitable) patients. In such cases, a degree of cost sharing combined with payment of below average cost might enhance efficiency and equity. Given that purchasers can not fully identify costs, cheaper providers will benefit from a purely prospective payment, allowing them to receive payments that are greater than their costs ('rent'). The introduction of some retrospective reimbursement will enable the purchaser to extract this form of rent from providers, and the desired degree of retrospective payment will be determined by the trade-off between higher incentives to control costs and lower levels of provider rent (Laffont and Tirole 1983). Finally, cost sharing may be desirable when the provider faces unexpectedly high costs.

A socially optimal level of care should balance the cost of providing a service with the benefit of the quality of the treatment. Purchasers who know the cost incurred by a provider for a given level of quality can choose a prospective payment that induces the desired level of quality (Ma 1994). As noted above, however, reliable information about both costs and quality is often absent in the health sector (and other sectors). A key concern related to prospective payment systems is that providers will react to incentives to control costs by lowering the quality of care.

Another issue is whether the purchaser's lack of information leads to over-provision or under-provision of quality. Providers who can achieve high quality at low cost may overstate their costs in order to boost their margins (rent extraction). Thus, the higher the level of quality desired by the purchaser, the higher the level of rent extracted by low cost providers, leading to a trade-off between quality and rents. Consequently, the level of quality induced by the optimal payment mechanism will be lower than the efficient one (Mougeot and Naegelen 2003). However, this problem can be mitigated.

The problem of prospective payment is complicated by the fact that patients may have their own views on quality. Where the prospective payment involves a fixed fee per patient, providers have an incentive to influence demand by investing in forms of quality attractive to patients. This generally leads to under-provision or over-provision of quality, depending on patient demands on quality (Tirole 1988). Financial incentives can also affect the appropriateness of care, perhaps by inducing providers to treat all patients referred even when the benefits of treatment are low (Chalkley and Malcolmson 1998). One way of addressing this problem is to use a payment mechanism that accounts for the number of patients referred as well as the number of patients treated. In practice, purchasers would pay a fixed price per patient treated and a fixed price per patient referred (for example, for each patient added to a waiting list). This would provide an incentive to improve quality to attract patients, even if patients are not treated beyond the first consultation.

3.2 Competition to enhance provider efficiency and quality

Many European countries are looking for ways of introducing competition among providers in order to enhance efficiency, moving away from systems based on regulation of monopoly providers. From a theoretical perspective, monopolies can be justified on the grounds of economies of scale and scope, or if the regulatory framework is efficient. In such instances, regulation may be preferable to a policy that encourages new entrants. However, there is little evidence of major economies of scale and scope in the hospital sector (Vita 1990) and regulation is unlikely to be efficient due to the asymmetry of information between purchaser and providers.

Provider competition can be used to generate more information about costs and to enhance the efficiency of payment systems. Bearing in the mind the potentially negative effect of competition on quality, we focus on two tools that attempt to combine cost efficiency with improved quality.

Competitive bidding

The problems of lack of information, and information asymmetries between the various players, in healthcare are both endemic and well-known, leading as well to principal-agent problems. One potential way of tackling the information problems associated with purchasing and provider payment which needs to be explored in carefully-controlled experiments is to establish a system of auctions involving competitive bidding for contracts. Bidding systems have been introduced in some parts of the United States to determine fixed payments to hospitals for patients under the Medicaid programme (a state-operated programme providing coverage for people with low incomes). Paringer and MacCall (Paringer and McCall 1991) showed that whereas traditional Medicaid programmes experienced a rise in costs of 60.7% between 1983 and 1989, Medicaid programmes using the bidding system experienced a much lower rise of 34.2%.

Bidding systems can take several forms. For example, some purchasers use detailed requests in which they specify a list of minimum standards, allowing providers to bid based on price alone. Other purchasers permit providers to propose different combinations of price and non-monetary features such as quality, and then choose the alternative that best suits their interests. Purchasers can also request a single offer per provider, without revealing how offers will be ranked ('single bid auction with secret scoring rule'). Alternatively, in 'scoring auctions' purchasers announce in advance how different offers will be ranked (the scoring rule), and choose the provider with the highest score. This last form of auction is likely to be more efficient than other types. The preferred mechanism identified in a recent analysis (Mougeot and Naegelen 2003) was a 'first score auction' in which the purchaser commits itself to a score based on a quality measure and a price per patient admitted. The winning hospital then receives a unit price per patient corresponding to its bid.

Although there is little research into the use and effectiveness of competitive bidding for hospital contracts, and auctions have had unexpected results in other sectors (see for example Lee and Malmendier, 2006 on the bidder's curse problem), it may present policy makers with a means of dealing with asymmetrical information and facilitate cost-effective purchasing of quality health services, and therefore warrants further investigation. However, it is unclear whether the gains from competition will offset losses in terms of higher transaction costs (John and Ward 2005).

Yardstick competition

Here we review the impact of yardstick competition in the form of case-based payment for hospital care (commonly referred to as DRGs). Since their introduction for Medicare patients in the United States in 1983, DRGs have emerged as an almost universal method of paying hospitals in high-income countries and have also been adopted in some middle-income countries.

The Medicare prospective payment system (PPS) was the first to use yardstick competition (that is, competition based on the relative performance of different hospitals) to pay hospitals. Under a system of DRGs or case-based payments, providers receive a fixed sum per patient once a specific diagnosis or need for care has been established. The sum depends on the diagnostic group or category to which the patient has been assigned and is fixed based on average costs, usually for a group of hospitals in a region, although it may also be set centrally to reflect average national costs. DRG payments do not cover all types of treatment payments and, when applied, complemented with fee for service payment (see Robinson 1999).

A case-based payment system introduces a range of incentives, encouraging treatment of patients whose expected costs are lower than the expected reimbursement, discouraging treatment of patients whose expected costs are likely to be higher than the expected reimbursement (known as 'dumping' or cream skimming), encourage 'up-coding' if this upgrades the severity of the case and leads to higher reimbursement, encouraging more intensive treatment for the same reason, encouraging providers to minimise costs within a treatment group or shift costs to other parties and also encouraging quality skimming (Busse, Schreyogg et al. 2006). Depending on the mix of payment methods involved, these incentives may be extremely strong, so in spite of the advantages of case-based payment in terms of generating valuable information on costs and case-mix and encouraging cost control, many technical and policy questions remain unresolved, leading to concerns about impact on equity of access and quality (Busse, Schreyogg et al. 2006).

Evaluation of the impact of DRGs on cost containment suggests that case-based payment results in cost savings in the short run, although it is not clear if these savings are once-off or can be sustained over a longer period. For example, DRGs reduced the average length of stay of Medicare patients by one quarter from 1980 to 1985, without any sign of a decrease in the health status of discharged patients (Carroll and Erwin 1987; Feinglass and Holloway 1991). After the introduction of DRGs for Medicare patients, hospital expenditures grew by 10% a year between 1980 and 1990 and 8% a year between 1990 and 1998 (Rosenberg and Browne 2001) and the costs per discharge fell by 2% per year over three years (Ellis and McGuire 1993). Other reviews also conclude that DRGs decreased length of stay in the short run (Newhouse and Byrne 1988), although there is evidence of cost shifting from Medicare to the private sector (Rosenberg and Browne 2001), increased prices for non-Medicare payers (Sloan and Becker 1984), upcoding (Keeler, Kahn et al. 1990) and premature discharges from hospital (Rock 1985; Rogers, Williams et al. 2005). At the same time, several reviews have concluded that the PPS did not lower the quality of care for Medicare patients (Feinglass and Holloway 1991; Rosenberg and Browne 2001). Nevertheless, the impact of DRGs on quality continues to be debated in the United States.

European studies of the impact of DRGs in Sweden, Portugal, Norway, Italy and England support the US findings of increased productivity in the short term (Dismuke and Sena 1999; Louis, Yuen et al. 1999; Mikkola, Keskimaki et al. 2001), as well as cost shifting (Jonsson 1996), cream skimming (Bibbee and Padrinin 2006) and up-coding ('DRG creep') (Charpentier and Samuelson 1999; Louis, Yuen et al. 1999; Rogers, Williams et al. 2005; Bibbee and Padrinin 2006). In some countries, the growth in readmission rates following the introduction of case-based payment has led researchers to suggest that quality has been compromised (Louis, Yuen et al. 1999; Kjerstad 2003). An international study also found that the adoption of DRGs led to slower quality gains with regard to mortality from surgical and medical errors (Forgione et al. 2004). On the whole, however, the evidence is inconclusive and, as in the United States, this continues to be a major concern.

Researchers generally acknowledge that case-based payment requires a degree of cost sharing between purchaser and provider, at least for high cost patients, although there is no agreement on the definition of 'outliers' or the design of cost sharing mechanisms (Busse, Schreyogg et al. 2006). In addition, while some argue that patient demand will ensure that providers pay attention to quality, others note that explicit additional incentives may be necessary to achieve desired levels of quality.

Finally, it may be important to consider institutional contexts when assessing the potential impact of case-based payments on policy goals, particularly when so much of the evidence originates from the US experience of DRGs. Market structure in the United States differs markedly from market structure in NHS or SHI countries, with a greater diversity of payers and payment systems. In the US context, DRG financing for Medicare patients replaced a system of retrospective fee-for-service reimbursement. In contrast, the shift to DRGs in many European countries replaces or supplements other forms of prospective payment such as the use of global budgets, so the potential for cost savings may be smaller. The goals underlying the introduction of DRGs in Europe may differ not only from the United States but also among countries, with some aiming to lower waiting times, increase activity, stimulate provider competition and facilitate patient choice of hospital, and others aiming to control costs, improve transparency in hospital financing and harmonise payment systems for public and private providers (Ettelt, Thomson et al. 2006). Notable variation in the design and implementation of case-based payment systems in Europe, and the extent to which these systems are combined with other payment methods, are likely to be a reflection of diverse institutional norms and policy goals.

European health systems increasingly recognise the need to encourage co-ordination and integration in the delivery of health care, particularly for patients with chronic illnesses. Co-ordinated care benefits patients by providing them with an integrated service and continuity of care, even when the care takes place in different settings. It can result in efficiency gains by avoiding fragmentation and duplication and lowering transaction costs. NHS health systems with a vertically integrated structure (in which the payer also provides services) and gatekeeping at primary care level have traditionally been better able to offer co-ordinated care than SHI systems characterised by a plurality of contracted providers and direct access to specialists by patients. More recently, however, there has been greater convergence between the two types of health system: purchaser-provider splits in NHS systems have made new forms of organisational structure and purchaser-provider relations possible, while several SHI systems have introduced measures to encourage gatekeeping and co-ordination among providers. In some countries, these changes are the result of greater recognition of the contribution of primary care to health system efficiency and quality (Macinko, Starfield et al. 2003).

In the United States, the concept of managed care was originally developed to address the problems created by traditional insurance systems in which third party payers simply reimbursed patients for their health care costs and patients were free to visit any provider, leading to poor cost control and wasteful fragmentation. By encouraging insurers to contract with networks of providers or follow the model of vertical integration adopted by large non-profit organisations such as Kaiser Permanente, managed care aimed to create incentives for insurers to exert greater control over provider behaviour, to experiment with different methods of paying providers, to provide their patients with a less fragmented service and to limit their transaction costs. In return for some restriction of choice of provider and possibly gatekeeping, patients would be rewarded with lower premiums, fewer user charges and better access to services such as preventive care, which had previously been poorly covered by insurers. In other words, managed care was intended to control costs and improve quality. This section reviews the US experience of managed care and examines its relevance to European health systems.

4.1 The US experience of managed care

Managed care organisations in the United States take several forms. Initially, they tended to be health maintenance organisations (HMOs). HMOs are vertically integrated organisations that employ their own physicians on a salary basis and use monitoring and performance-related pay to enhance efficiency. Vertical integration creates strong incentives for providers to operate efficiently and lowers transaction costs. Consequently, premiums and user charges are usually lower than in other plans. More recently, other types of plan have emerged, the most common of which are preferred provider organisations (PPOs) and independent practice associations (IPAs) (see Table 6 for the key characteristics of different types of plan) (Gaynor and Haas-Wilson 1999). PPOs form a network of providers and use discounted fees to control costs. Patients can choose providers who are not members of the network, but are charged lower co-payment rates for those within the network. IPAs have contracts with a network of providers and employ stringent review procedures to monitor providers combined with capitation (see Enthoven and Tollen 2005 for more details on various types of HMOs).

Cost savings

Several studies have analysed the cost savings achieved by managed care plans in the United States (see Table 7). As low risk individuals are more likely to opt for managed care plans, leading to potential selection bias, the studies reviewed attempt to control for patient characteristics. The results suggest that HMOs achieve the highest per patient cost savings in comparison to conventional plans (11-39% cheaper per patient), while IPAs and PPOs plans generally compare well to conventional plans but have lower cost savings. A recent Swiss study had similar findings (see Table 8).

However, while the US studies have controlled for the possibility of lower costs due to risk selection by insurers, they do not account for cost shifting to patients through increased co-insurance and deductibles and more stringent clauses about, for example, pre-existing conditions. Robinson (Robinson 2004) has shown how much patient cost sharing has risen under a range of insurance plans in the United States, including managed care plans (see Table 9). Others suggest that the cost savings achieved through managed care have mainly benefited large employers and insurers and, as health care expenditure has risen sharply in recent years, that the savings may have been a once-off phenomenon rather than a long-term solution (Iglehart 1999). In other words, although there is a decrease in costs, this does not mean that there is a decrease in the rate of growth of cost.

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Table 6: Key characteristics of different types of insurance plan in the United States

Dimension	Traditional	HMO	PPO	IPA
Qualified providers	Almost all	Network	Almost all (network)	Network
Choice Of providers	Patient	Gatekeeper (in network)	Patient	Gatekeeper (in network)
Payment Of providers	Fee-for-service	Salary	Discounted fee-for-service	Capitation
Cost sharing	Moderate	Low in network, high/all out of network	Low in network, high out of network	Low in network, high out of network
Roles of insurer	Pay bills	Provide care	Pay bills; form network	Pay bills; form network; monitor utilization
Limits on utilisation	Demand side	Supply side (price, quantity)	Supply side (price)	Supply side (price, quantity)

Source: (Cutler and Zeckhauser 2000)

Table 7: Cost comparisons between managed care and conventional health plans in the United States

Authors	Method of controlling for differences in patient characteristics	Cost difference between managed care and conventional plans
PPO		
(Hosek, Marquis et al. 1990)	Socioeconomic characteristics, health status	-11% to +9%
(Wells, Hosek et al. 1992)	Mental health status, level of prior care, age sex, education	-3%
(Smith 1997)	Socioeconomic characteristics	-12%
IPA		
(McCombs, Jasper et al. 1990)	Socioeconomic characteristics, prior care	+11%
(Stapleton 1994)	Socioeconomic characteristics	-23%
(Christensen 1995)	Socioeconomic characteristics	-4%
HMO		
(Manning, Leibowitz et al. 1984)	Randomised assignment, age, sex	-28%
(McCombs, Jasper et al. 1990)	Socioeconomic characteristics, prior care	-39%
(Hill 1992)	Socioeconomic characteristics	-11%
(Christensen 1995)	Socioeconomic characteristics	-20%
(Buchanan and Cretin 1986)	Age, family size, education, prior care, subjective health status	-29%

Source: (Lehmann and Zweifel 2006)

Table 8: Cost comparisons between managed-care and conventional health plans in Switzerland

Authors	Method of controlling for differences in patient characteristics	Cost difference between managed care and conventional plans
PPO	Age, socioeconomic characteristics, entitlement to subsidy, health status	-24.1%
IPA	Age, socioeconomic characteristics, entitlement to subsidy, health status	-18.6%
HMO	Age, socioeconomic characteristics, entitlement to subsidy, health status	-30.7%

Source: (Lehmann and Zweifel 2006)

Table 9: Changes in premiums and patient cost sharing in the United States, 1998-2003

	1998	2003
Monthly employee premium	\$52	\$201
Monthly employee premium (as a % of total premium)	29%	27%
Average PPO deductible	\$106	\$275
% of HMO enrollees paying \$15 or more for a doctor visit	13%	57%

Source: (Robinson 2004)

Efficiency

Managed care organisations offer considerable scope for efficiency gains through economies of scale, particularly if they are able to share expertise in the performance of key functions such as utilisation review or clinical guideline formation or develop a brand name that has value across markets. One study found evidence of large economies of scale among US HMOs and IPAs, although these economies appeared to be exhausted once insurers had over 50,000 enrollees (Wholey, Fledman et al. 1996).

The higher cost savings attributed to HMOs over IPAs may be due to lower use and lower unit price (Miller and Luft 2002). However, some studies suggest that IPAs are likely to be more efficient than HMOs because their doctors generally come from private practice so may be more mature in their dealings with patients; they also have greater discretion over the provision of care than HMO doctors, so may be more likely to treat patients that more tightly controlled organisations might not accept; that is, they may not be so prone to the problem of risk selection (Brockett, Chang et al. 2004).

Quality of care

One of the main preoccupations associated with the cost savings achieved by managed care plans relates to quality of care. Many US studies have compared the quality of care provided by managed care plans and other plans. A review of the literature suggests that quality of care is broadly comparable (Miller and Luft 1997). Of 47 studies, 14 suggested a higher quality of care in HMOs, while 15 suggested a higher quality of care in non-HMOs; the others showed no difference. However, the literature shows strong differences between studies looking at the relationship of quality to providers and geographical areas.

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Effects of managed care penetration

In a market characterised by different types of insurance plan, the introduction of managed care plans (and particularly HMOs) may have knock-on effects on other insurers. For example, managed care plans tend to attract young and healthy individuals, especially if they offer a narrow network of providers, as older patients and those in poor health may prefer a larger selection of providers that includes doctors with whom they already have a relationship. This form of selection bias can segment the market as a whole, pushing up premiums for traditional insurers and, ultimately, leading to a 'death spiral' caused by high risks opting for more generous plans and low risks preferring cheaper plans (Cutler and Zeckhauser 1997).

Managed care plans have other implications for market structure because they compete for providers as well as patients (Bardey and Rochet 2006). On one hand, having more providers in the network attracts high-risk patients, which may lead managed care plans to limit the network to encourage the enrolment of low risks. On the other hand, high risks mean more work for providers, allowing managed care plans to negotiate lower fee-for-service rates, which lowers their costs. Market domination by highly restrictive HMOs during the 1980s led to the emergence of PPOs during the 1990s, lowering HMO market share, so risk selection by HMOs may not have been profitable in the long run. Table 10 shows how market shares changed between 1996 and 1999.

Table 10: Enrolment of those with employer-sponsored health insurance, 1996 and 1999, United States

Type of plan	1996 (%)	1999 (%)
Indemnity	27	8
HMO	31	29
PPO	28	41
Point-of-service	14	22
Total	100	100

Source: (Dudley and Luft 2001)

A mixed market may also result in cost shifting by providers, who can charge higher prices to non-managed care plans, and changes in behaviour by traditional plans, who may lower the generosity of their coverage to mirror the benefits offered by managed care plans. Traditional plans may also lower their premiums so as not to lose market share. Baker and Corts (Baker and Corts 1996) studied the relation between HMO market shares and the level of premiums charged by traditional insurers. They found an inverse relationship between premiums charged by traditional insurers and HMO penetration. An increase in the market share of HMOs from 0% to 10% reduced the premiums of traditional insurers by 13.8%. However, changing the HMOs' market share from 20% to 30% increased the level of premium charges by traditional insurers by 20.3%. The minimum level of premium was attained when the market share of HMOs was between 10% and 15%. Again, it is not clear whether lower premiums benefit patients in the longer term, as patient cost sharing may also increase.

4.2 Towards managed care in Europe

The US experience of managed care provides an interesting case study for European health systems considering ways of strengthening purchasing and improving co-ordinated care. Vertical integration in the form of HMOs was certainly successful in lowering costs for insurers and employers, although it is not evident that cost savings have been fully passed on to patients or sustained over time. However, in some cases the incentives created may have been too strong. During the 1990s the United States underwent what some analysts have called the 'managed care backlash': a period of deep dissatisfaction, on the part of patients and providers, with the perceived restrictions of HMOs, which were seen as acting primarily in the interests of the insurer (Blendon, Brodie et al. 1998). This led to the emergence of new types of less restrictive managed care plan (PPOs, IPAs, etc) and, more recently, to the rise of 'consumer-driven care'. Consumer-driven care, sometimes in the form of medical or health savings accounts, allows patients to make the choice-cost trade-off themselves, giving them more choice if they want it, but making them pay for it through increased cost sharing (Robinson 2002). It represents a process of de-insurance and a return to demand-side rather than supply-side efforts to control costs.

As with the introduction of new payment systems, institutional contexts are important, particularly in determining the type of organisational structure that is most likely to contribute to national policy goals. English primary care trusts (PCTs) resemble managed care plans in that they require gatekeeping, engage in selective contracting of hospitals, pay primary care doctors through capitation and employ a system of performance-related pay to reward quality. The newer development of practice-based commissioning also gives general practitioners incentives to control costs and to use cost savings to improve services (Department of Health 2006). Whereas patients cannot choose their PCTs, they can choose the primary care practice with which they register. However, practice-based commissioning may restrict patients' choice of hospital, which goes against the grain of the UK government's policy of expanding patient choice in general.

For SHI countries, IPA-style arrangements may be more appropriate. Allowing insurers to compete to attract doctors to their network may result in greater reductions in fees in return for greater volumes of work, which also makes risk selection less profitable. At the same time, the relative strength of purchasers and providers suggests that providers may be able to foil purchaser efforts to engage in selective contracting, as has been the case in several countries (see below).

Encouraging insurers (usually public health insurance funds known as sickness funds) to compete for patients is a relatively new feature in European health systems, although choice of sickness fund has been long-established in countries such as Belgium and Switzerland. This section focuses on the introduction and extension of choice of sickness fund in the Netherlands and Germany during the 1990s, identifying some of the limitations of insurer competition driven by patient choice. It then discusses the possibility of allowing insurers to compete for population groups, something that has not yet been tried in Europe, but offers potential advantages over traditional forms of insurer competition. Competition for population groups would, in theory, be possible in both SHI and NHS countries. In England, for example, it is conceivable that PCTs or other public and private entities could compete to provide care for particular areas.

5.1 Choice of sickness fund in SHI countries

Reforms that took effect in the Netherlands in 1993 and in Germany in 1996 made it possible for most people to choose between competing sickness funds. Prior to this people were assigned to a regional sickness fund on the basis of their place of residence in the Netherlands (den Exter, Hermans et al. 2004). In Germany, choice of sickness fund existed for some white collar workers only (other workers were assigned to sickness funds based on occupation and place of residence) and, due to differences in the risk profiles and incomes of enrollees in different types of sickness fund, contribution rates varied significantly among all sickness funds (Busse and Riesberg 2004). One should recognize that these two systems are in the very early stages of choice and competition so that it is too early to say what the impact might be.

Based on a model of regulated or managed competition (Enthoven 1988), the Dutch reform aimed to dismantle the sickness funds' (natural) regional monopolies and create incentives for them to become more active and efficient purchasers of health care (Schut and Hassink 2002; Schut, Gresz et al. 2003). In order to facilitate price competition, sickness funds are permitted to charge their own flat-rate premium above the uniform contribution rate set by the government. In contrast, the German reform primarily used choice to encourage convergence in contribution rates, although it was expected that competition would increase incentives for sickness funds to operate more efficiently (Schut, Gresz et al. 2003).

In practice, there is little evidence to suggest that price competition has been effective. Traditional indicators such as market concentration and switching rates point to relatively low levels of competition. In the Netherlands, over 70% of sickness fund members are enrolled in one of the five largest holding companies (Varkevisser and van der Geest 2001). On the whole, enrollees in German funds have been more active in switching fund than Dutch enrollees (Gresz, Groenewegen et al. 2002; Schut, Gresz et al. 2003). A survey carried out in Germany in 1999 showed that 7.3% of the population had changed funds since 1996 (Zok 1999), while more recent estimates range from 3-5% (Gresz, Groenewegen et al. 2002).

The following factors may explain low levels of competition: the lack of price incentive to encourage people to switch fund; the absence of purchasing tools to exert leverage over providers; insufficient information for enrollees; and inadequate risk equalization leading to risk selection.

The variation in contribution rates in Germany provides enrollees with a significant price incentive to change to funds offering the same benefits for a lower rate. Consequently, there is a strong correlation between price and changing fund. This relationship is much weaker in the Netherlands, where differences in the flat-rate premium of individual sickness funds are small (Gresz, Groenewegen et al. 2002; Schut, Gresz et al. 2003).

Competition has encouraged sickness funds to raise the quality of their administrative services in both countries, but it does not seem to have increased quality of care, either because funds lack the tools to purchase effectively, or because they do not make use of available tools, such as selective contracting (Gresz, Groenewegen et al. 2002). In Belgium, the benefits package and contribution rates are determined by the government and selective contracting and preferred provider arrangements are prohibited (Schokkaert and Van de Voorde 2000). In the Netherlands, selective contracting is only permitted for ambulatory care. In Germany and Switzerland, selective contracting is increasingly possible, but there is evidence to suggest that insurers do not make sufficient use of this tool, preferring instead to lower costs by competing on the basis of risk selection.

Extending choice of fund to almost the whole population initially succeeded in bringing about greater convergence in contribution rates in Germany, but more recently, the variation has begun to widen again, partly due to risk selection (Gresz, Groenewegen et al. 2002). In both Germany and the Netherlands, incentives to select risks have not been fully addressed by the risk equalisation scheme in place. German survey data reveal that those who change fund are more likely to be younger, healthier, better-educated men with no dependants (Zok 1999; Gresz, Groenewegen et al. 2002). Risk selection by funds also seems to have played some role in encouraging certain types of people to change fund, for example through activities such as internet-only marketing and enrolment, inaccessibility of offices and selective targeting of reminders of a person's right to change fund (Buchner and Wasem 2003). Other researchers suggest that risk segmentation may be caused by the fact that healthy people have lower switching costs (Knaus and Nuscheler 2005).

Two important behavioural factors may undermine the effectiveness of individual choice in the health insurance market and make competition difficult to enforce. The first is related to what behavioural economists call 'decision overload'. There is evidence that as choices grow individuals are overwhelmed by information, which reduces their capacity to make effective choices. A second factor is the so-called 'status quo bias', which leads individuals to prefer their current state. This bias was identified among Harvard employees choosing health plans in the United States (Samuelson and Zeckhauser 1988) and Zeckhauser 1988). Following the introduction of new insurance products, tenured faculty members kept their existing insurance product while younger faculty members chose the new ones. Further research suggests that the lack of competition in the US market can be explained by individuals suffering from both decision overload and status quo bias (Frank and Lamirand 2006). For example, those facing more than 50 health plan choices were less likely to switch plans than those with a more limited choice, while those who had been attached to a particular health plan for longer periods were less likely to switch, even though they were offered a lower premium (perhaps due to having an established relationship with specific providers). Clearly, too much choice and lack of comparable information about price and quality can stifle rather than stimulate competition.

Too much choice may be less of an issue in European health systems, where publicly-financed benefits packages are set by the government, although it can be problematic in markets for voluntary health insurance. Nevertheless, choice of sickness fund seems unlikely to result in substantial efficiency, equity and quality gains unless risk adjustment measures are improved so that incentives to select risks are removed, sickness funds have access to (and use) tools that allow them to exert control over providers, such as selective contracting, and people are able to change fund without incurring significant costs. In practice, however, risk equalization schemes have proven to be technically and politically problematic and expensive to operate and monitor (Puig-Junoy 1999; van de Ven and Ellis 1999).

5.2 Competition for population groups

An alternative to 'ex post' competition based on patient choice is 'ex ante' competition involving bidding and auctions, as proposed by Diamond (Diamond 1992). Diamond's proposal involves a regulator forming groups of patients and allowing private (for-profit or not-for-profit) insurers to bid for each group. One advantage of this form of competition is low administrative costs; the regulator would ensure that groups were large enough to ensure economies of scale.

A further advantage is price competition based on insurance products rather than risk selection, which can be achieved by applying two principles. First, groups should be small enough to allow most areas to be covered by different insurers, thereby enabling yardstick competition and preventing dominance by large insurance companies. Second, the regulator only allows insurers to bid on the price of a set menu of insurance products, rather than on both price and menu. This encourages insurers to focus on lowering prices rather than selecting risks, and would be supported by risk adjustment mechanisms to avoid both risk selection and regional inequalities. Community-rated premiums and subsidies for people on low incomes would preserve equity and, depending on the size of the country, regional agencies could operate local bidding procedures and other regulatory activities such as quality control and complaints. The regulator would be financed from earmarked government revenue.

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What type of auction is most suited to health insurance has not been extensively studied. A key issue is identifying an efficient procedure for allocating groups of people to insurers. The appropriate procedure will depend on health insurance market structure, insurers' cost functions and the extent of information asymmetry between the regulator and insurers (Bardey and Morand 2002). Costs will in turn depend on the aggregate risk composition of different groups (information known to both parties), insurer productivity (information known only to insurers), insurer efforts to contain costs and, importantly, economies of scale. Following Diamond's proposal, groups should be large enough to generate economies of scale, but small enough to allow fair competition. In such cases, it may be beneficial to allow insurers to bid for combinations of groups rather than individual groups.

Procurement auctions in health insurance should combine three objectives: to select the most efficient insurers; to introduce incentives for insurers to contain costs; and to benefit from economies of scale by allowing insurers to bid on combinations of pre-specified groups. The optimal auction procedure may therefore be a 'split award auction' (McGuire and Riordan 1995).

Although there is no empirical evidence to support this proposal (because it has yet to be tried in health insurance markets), it has the potential to offer some advantages over patient choice-led competition among insurers if mechanisms can be put in place to prevent risk selection and so long as quality of coverage and care can be assured and insurers have incentives to operate efficiently. The proposal might benefit from regional pilots, which would provide evidence of its impact in practice. One major disadvantage, however, is the absence of patient choice, which might be an issue in countries where people are used to choosing their insurer.

CONCLUSION

This report has reviewed trends in health care expenditure in Western Europe and focused on a range of mechanisms intended to improve efficiency in the use of health system resources in four areas: patient financial responsibility, public purchasing, managed care and competition among insurers.

It finds that levels of health care expenditure, as well as the magnitude and rate of changes in spending, vary considerably across countries. Although health care expenditure has risen substantially in most countries in Europe, the pace of expenditure growth has been slower since 2000, and there is evidence to suggest that increases in spending have, on the whole, been matched by gains in health outcomes. The study of avoidable mortality (mortality amenable to health care) provides a useful means of assessing the contribution of health care to health gain and measuring the relative performance of health systems in different countries. In addition, other forms of analysis indicate the importance of health care in promoting economic growth, with positive benefits for individuals and society.

In the past, health care expenditure has been driven mainly by developments in technology, and this is likely to be the case in the future. Although population ageing has been an issue of major concern to policy makers across Europe, new research suggesting that proximity to death is a more important determinant of health care costs than age implies that the impact of ageing on health care expenditure may not be as great in future as many have feared. It is not yet clear how developments in disability trends and the availability of informal care will affect future demand for long-term care.

These factors do not deny the importance of non-health care-related policies on health, or the need to ensure that health care is delivered efficiently. Rather, they point to the importance of ensuring that access to health care is both universal and equitable and that efforts to contain health care costs do not jeopardise efforts to enhance equity. Measures to increase both efficiency and equity in the financing and delivery of health care will be central to ensuring sustainability in the long term.

Providing incentives to patients to use health care responsibly may contribute to efficiency, although there is evidence to suggest that patient cost sharing (user charges) is a blunt policy tool as it lowers the use of appropriate as well as inappropriate health services and there is uncertainty about its impact on health status. There is little evidence to suggest that user charges lead to sustained cost control because health care costs are mainly driven by supply factors. Nevertheless, all European health systems impose user charges for some health services. Consequently, policy makers should attempt to improve patient cost sharing policies through careful design, taking into account the effect on equity and the potentially high transaction and political costs involved. The Swiss and Dutch experience of the use of deductibles to moderate demand may warrant further debate and research.

Methods of paying providers play a key role in determining efficiency and quality in health systems. Recognising that retrospective forms of reimbursement fail to control costs, many European countries are moving towards prospective payment. Prospective payment systems present purchasers with considerable challenges due to information problems that make it difficult for purchasers to assess provider cost and quality. Competitive tools can be used to overcome information asymmetry - for example, competitive bidding for hospital contracts or case-based payment linked to diagnosis (DRGs). Both tools provide powerful incentives for providers to control costs, although concerns about quality and access to health care remain unresolved. European health systems increasingly use DRGs to pay for health care, for a range of reasons, usually in combination with other financial and non-financial mechanisms. Their experience requires careful monitoring and evaluation to ensure that cost savings can be achieved without lowering quality and access.

The US experience of managed care provides useful insights into ways of improving efficiency and quality in health care. Incentives created by organisational structures such as vertical integration or gatekeeping, and payer and purchaser influence over provider behaviour (for example, through selective contracting, utilisation review and clinical guidelines) can contribute to cost savings and benefit patients through the delivery of co-ordinated and integrated services. Again, however, mechanisms need to be in place to ensure quality and access, and restricting patient choice may be difficult in some contexts.

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European attempts to introduce patient choice-driven competition among insurers have aimed to create incentives to strengthen purchasing and enhance equity (by encouraging convergence in contribution rates, as in Germany). However, their impact on efficiency has been limited due to the difficulty of designing risk adjustment mechanisms that are effective in removing incentives to select risks, the absence of tools permitting purchasers to exert control over providers and the high costs to patients of changing from one insurer to another. An alternative to 'ex post' competition based on patient choice is 'ex ante' competition requiring insurers to bid for groups of patients. Although this form of competition among insurers has not yet been tried, so there is no evidence to suggest what kind of impact it might have on policy goals in practice, it may offer advantages in terms of lower transaction costs and reduced incentives to select risks.

Any consideration of options for reform should bear in mind institutional contexts. Institutional arrangements vary considerably, even among western European health systems, and are likely to have substantial influence on policy goals and outcomes due to political differences as well as differences in payer, purchaser, provider and patient motives and behaviour. Market mechanisms may be effective in lowering health care costs, but there is some evidence to suggest that cost savings may not be sustained in the long-term. In addition, the strong incentives they create present opportunities for 'gaming', so policy makers require tools and resources for careful regulation, management, monitoring and evaluation. The development and use of regulatory and management tools may incur heavy transaction costs, but these costs may be worthwhile if they bring visible benefits to patients.

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ENSURING VALUE FOR MONEY IN HEALTH CARE: THE ROLE OF HTA IN THE EUROPEAN UNION

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EXECUTIVE SUMMARY

1. This report addresses the concept and controversy surrounding HTA in Europe. HTA plays a major part in evidence-based decision-making. Without enough good evidence, the uptake and spread of technologies is likely to be influenced by a range of social, financial, and institutional factors, and not produce the healthiest outcomes or the most efficient use of resources.
2. There must be greater correspondence between innovation and the actual needs of the health care system. Products that provide the most value for investment must be identified and supported. Manufacturers of such products must be rewarded with appropriate reimbursement and pricing schemes.
3. Many countries have bodies dedicated to HTA, with somewhat unclear and disparate roles and responsibilities. Groups involved in reimbursement and pricing decisions often differ from those engaged in independent HTA assessment and clinical guideline development. Divergent processes and roles may hinder the effectiveness and efficacy of the decision-making process, and lead to unnecessary duplication of efforts and resource use.
4. Most review bodies involve range of stakeholders, including physicians, health economists, pharmacists, and patient group representatives. Most agencies support a limited role for patients and consumers, and a greater role for industry representatives has been proposed. Greater stakeholder involvement is needed to improve the implementation of decision and policy and to manage uncertainty, while at the same time allowing access to safe technologies.
5. Some countries consider evidence and resource requirements to conduct the assessment, as well as relevance to the primary clinical and/or policy question. This is important because HTAs are only useful if they are expected to contribute to the decision-making process. If there are insufficient data, the assessment will not be helpful, and may delay access to new treatments.
6. Generally the process lacks transparency, from prioritising decision criteria to stakeholder involvement. More transparency is needed for an open, systematic, and unbiased decision-making process.
7. More attention should be paid to identifying topics for potential disinvestment so that ineffective and inefficient products and practices do not remain in the health care system.
8. Assessments should adopt a broader definition of value and product benefit by considering patient preferences, quality, equity, efficiency, and product acceptability among a wide range of stakeholders. The opinions and experiences of health professionals and individual patients are needed to understand the 'real-world' application and use of a product.
9. Assessments should take into account indirect benefits and costs. It would be helpful if review bodies could agree on the inclusion of additional years of life provided by new treatments, as well as opportunity costs related to leisure activities.
10. A better understanding of threshold values and other decision criteria and how they are applied in the overall decision process, is needed.
11. Different countries have different requirements, and it is important that the choice of parameters and methods is substantiated and well documented. The model and resulting analysis should be made as transparent as possible, with all those involved collaborating and exchanging information. As the modelling of cost-effectiveness becomes more complex, more resources should be devoted to assessing new methods of modelling and resulting impacts on uncertainty in decision-making.
12. Technical and methodological hurdles remain which need further investigation. They include the ability of summary measures to capture other benefits important to patients and the public, the generalisability of studies beyond the particular setting or country, the inability to account for the opportunity costs of new and expensive technologies, and the comparability between health state elicitation instruments.
13. The timing of assessments can significantly affect the decision-making process and patient access. Programmes have been introduced to provide more timely information on important products. These programmes should be monitored and evaluated for effectiveness and resulting impact on access to new technologies.

14. Assessments are only helpful if they are used to support decision-making. Relevant stakeholders should be involved to facilitate the acceptance and implementation of decisions. There should be a transparent and well-communicated decision-making process to give legitimacy to subsequent recommendations. The availability of relevant policy instruments and collaboration between national and international HTA bodies also facilitates effective and efficient implementation. Initiatives such as EUnetHTA should be supported.
15. In order to maintain the accuracy of assessments and ensure that the most valuable products are on the market, re-evaluation is key to the HTA process. Often the data needed to confirm the cost- and clinical-effectiveness of a technology can only be found after practical application in the market. This is particularly true of novel products and those technologies undergoing 'fast-track' assessment. Systems should be created to allow new clinical and health economic information to be introduced during the assessment process and following market entry. There must be protections so that re-evaluation doesn't lead to inefficiency, resource burden, and delayed access to treatments.
16. Some limitations and areas of recommended future inquiry deserve mention. There is a lack of understanding and evidence on the 'real world' impact of HTA, not only on decision-making, but also on health outcomes, care delivery, health care costs, and research innovation, more broadly. More focused research in these areas is needed.
17. There is limited information on the use of HTA for identifying areas of de-investment. More research is needed to identify ineffective and obsolete technologies and interventions. Further exploration is needed to find out how non-quantifiable factors such as equity concerns are accounted for in assessment and decision-making, in order to address effectively the social implications and constraints of efficient and equitable health care.
18. The scope of HTA has predominately focused on pharmaceuticals and, less frequently, on other medical technologies, such as devices. The application of the principles and methods of economic evaluation to preventive measures should be further explored. Additional research should identify if, and in what circumstances, such assessments have been conducted, and what were the opportunities and challenges.
19. The role of stakeholders in the HTA process is important, yet poorly understood. More studies on the role and influence of various stakeholders, especially patients and consumers, should be supported.
20. HTA can play a valuable role in health care decision-making, but the process must be transparent, timely, relevant, in-depth and usable. Assessments need to use robust methods and be supplemented by other important criteria. By maximising the potential of HTA, decision-makers will be better able to implement decisions that capture the benefits of new technologies, overcome uncertainties, and recognise the value of innovation, all within the constraints of overall health system resources.

In recent years most member states have experienced exponential growth in health technologies such as new medicines and diagnostic tools, tele-medicine, and surgical equipment. These innovations provide a major opportunity for governments, providers and patients to improve health care services and outcomes.

As a result of the rapid spread of these technologies, governments have faced unprecedented challenges in providing high quality and innovative care while managing health care budgets and safeguarding the basic principles of equity, access, and choice. Governments are increasingly required to manage scarce resources strategically, by investing in services that deliver the best health outcomes; this means care that is affordable, effective, safe, and patient-centred. They must also make sure that innovation is adequately supported, with sufficient access to new treatments.

Some states have developed systems that aim to identify which innovations are the best value. For example, the National Institute for Health and Clinical Excellence (NICE) in the UK was the first national attempt to provide faster access to cost-effective treatments through an evidence-based review process. Review bodies such as NICE use health technology assessment (HTA) to find out the relative costs and benefits of health technologies. The resulting evidence is used to support various forms of decision-making, such as reimbursement and pricing. This information can help to set priorities for access to limited health care resources. Beyond finding out value, the increased use of HTA in setting priorities signals a desire to make allocating health care resources more systematic and transparent.

However, neither NICE nor any of its international counterparts have operated without controversy. Concerns abound regarding the methods employed during the assessment process, the role and utility of HTA in decision-making and priority-setting, and the resulting impact on health care. How are assessments prioritised and who decides? What do authorities mean by evidence? How do HTA methods differ across agencies and what impact, if any, do they have on the assessment results? Is HTA actually used in such a way that effectively aids decision-making? What effect does HTA have on health care, in terms of patient care, innovation, and costs?

This report looks at the concept of HTA and the controversy surrounding it in Europe. In particular, it discusses the methodological and process issues related to HTA in the prioritisation and financing of modern healthcare. Through primary and secondary research, the report reviews HTA organisations and processes throughout the EU generally, and within some member states. There are extensive case studies on Sweden, the Netherlands, Finland, France, Germany, and the UK (with a particular focus on England and Wales) (see appendices).

In particular, this report addresses the overall role of HTA in applying technology and related policy. It (1) identifies the processes and challenges for identifying and prioritising assessments, (2) assesses and compares current assessment methods and procedures, and (3) highlights the barriers to effective implementation of assessments. More broadly, the report looks at the role and terms of engagement for key stakeholders, and describes the opportunities and challenges for the use of HTA guidance in general priority-setting, decision-making, and health care provision.

A systematic review was carried out, including peer-reviewed journals and grey literature. Reports and other information sources were translated into English when needed. Experts in health technology assessment were also consulted.

The review and the main themes identified in the report are intended to help improve the HTA process in Europe and its role in supporting value in health care.

2.1 Overview of innovation in health care

Health technology is an indispensable part of any nation's health care system. During the past 50 years, all member states and several other countries have increased their technological base for health care, both in terms of knowledge, and investments in equipment, devices, and pharmaceuticals. As a result, national health care systems have become more advanced, introducing a range of technological innovations such as new medicines and diagnostic tools, tele-medicine, and surgical equipment.

New technologies have brought remarkable improvements in terms of health gains, and treatment organisation and delivery. Many innovations result in therapies that have significant benefits for patients. These include improved health, better quality of life, and fewer adverse events or side effects. The adoption of innovations in clinical practice provides a major opportunity for health professionals to improve the effectiveness, safety, and quality of treatment. On a broader level, technological innovation gives governments a mechanism to improve the quality and outcomes of national health.

Although many innovations have the potential to bring a range of benefits to patients and the health care system, their spread can cause problems when there are constraints on resources. Some innovations bring the same or improved effectiveness and quality of care at significantly lower costs, while other innovations increase overall health expenditures (Cutler and McClellan 1996; Newhouse, 1992). Indeed, the relationship between health technology and costs is complex and evolving. The ageing population, along with better educated health consumers, has resulted in increased demand for new medical products and services (Deyo 2002). This is often accompanied by expectations of public financing and access. When there is lower economic growth, there will be pressure on public budgets. In the current climate, governments must try to balance innovation, medical progress, and gains in productivity.

Innovation can significantly improve clinical practice, but the rapid growth of medical technology and the increasing volume of new knowledge have made it virtually impossible for providers to keep pace with new treatments. As a result, inappropriate practices and variations in how technologies are used have encroached into health care provision across Europe, indicating that the most effective and efficient technologies are not always being used. Doctors are often reluctant to change long-standing practices, which may halt the uptake of new and effective interventions.

Many EU countries face the challenge of harnessing the benefits of innovation while managing health care budgets and following the basic principles of equity, access, and choice. With the growth in health technologies, and other changes in health care, governments must manage scarce resources by finding out which interventions are the best value and how they should be used.

Health technology assessment has had a growing role in national priority-setting and health policy processes. Some member states recently developed systems to evaluate innovations, in terms of determining their relative value for investment and mechanisms for equitable and accessible treatment provision. In the UK, for example, the National Institute for Health and Clinical Excellence (NICE) was one of the first review bodies to provide faster access to modern treatments through a systematic review process and evidence-based decision-making.

2.2 HTA: overview and key objectives

HTA originated from the spread of costly medical equipment in the 1970s and growing concerns over the ability and willingness of taxpayers and health insurers to pay for them (Jonsson & Banta 1999). There was greater public scrutiny of health care rationing decisions and a growing consumerist approach, both of which called for decision making process that were more accountable, transparent, and legitimate. A more comprehensive approach was needed to help decision-makers set priorities and obtain maximum benefit from limited resources, without compromising the ethical and social values underpinning health systems (Hutton et al. 2006). The growth and development of HTA reflected this demand for well-founded information to support decisions regarding the development, uptake, and spread of health technologies.

After the 1970s, HTA broadened to include a range of health technologies, including drugs, medical devices, medical and surgical procedures, and the organisational and support systems used in care provision (Jonsson 2002). However, most HTAs so far have been directed at pharmaceuticals, rather than at other technologies such as medical devices and surgical procedures (Hutton et al. 2006).

HTA can be defined as *'the systematic evaluation of the properties, effects, and/or other impacts of health care technology'* (International Society of Technology Assessment in Health Care 2002). It involves evaluating an intervention through the production, synthesis, and/or systematic review of a range of scientific and non-scientific evidence³. The evidence typically considered includes safety, efficacy, cost, and cost-effectiveness, as well as the social, organisational, legal, and ethical implications (Velasco-Garrido & Busse 2005; International Network of Agencies for Health Technology Assessment 2002). For example, HTA often considers the macro-economic impacts of health technologies on national health care budgets, resource allocation among different health programmes, regulation, and other policy changes on technological innovation, investment, technology transfer, and employment (Goodman 1998).

As well as identifying valuable technologies, HTA can reduce or eliminate interventions that are unsafe and ineffective, or whose cost is too high compared to the benefits. HTA can also help to identify technologies that are underused (eg, preventive screening, smoking cessation interventions) and identifying the reasons for lack of use (Asch 2000; McNeil 2001).

To review systematically the evidence on a health technology, HTA uses a multidisciplinary framework to ask four main questions (UK National Health Service R&D Health Technology Assessment Programme 2003).

- Is the technology effective?
- For whom does the technology work?
- What costs are entailed in its use?
- How does the technology compare with available treatment alternatives?

The main aim of HTA is to provide a range of stakeholders (typically those involved in funding, planning, purchasing, and investing in health care) with accessible, useable, and evidence-based information that will guide decisions about technology and the efficient allocation of resources. It has been called 'the bridge between evidence and policy making', because it provides information for health care decision-makers at macro-, meso-, and micro-levels (Battista & Hodge 1999). In particular, the increased use of pharmaceuticals and other technologies has encouraged decision-makers to rely on HTA to help determine the reimbursement status and pricing of interventions. HTA also contributes in many ways to the knowledge base for improving the quality of care, especially in supporting the development (or updating) of clinical practice guidelines and health service standards. (Zentner et al. 2005).

Without good evidence, the spread of technologies is more likely to be influenced by social, financial, professional, and institutional factors, and may not produce the best outcomes or the most efficient use of resources.

2.3 Interface between HTA and innovation

The combination of emerging health technologies and limited national budgets has resulted in tensions between delivering cost-effective health care and improving or sustaining a country's manufacturing and research base. It is therefore increasingly important to have a balance between affordable health care and innovative health technologies. To meet this end, it is necessary to consider the value of a product (in medical and economic terms), and also who benefits from innovations, the optimal usage⁴, and the appropriate placement in the spectrum of care (Drummond 2003).

HTA can help to meet these challenges by deciding which technologies are effective and which are not, and by defining the most appropriate indications for their use (Drummond 2003). HTA can be used to validate a new technology and define its role in a health care system, and also empowers governments to make decisions based on value. It supports innovation, and gives patients and physicians the information they needed to make the best treatment choices.

However, the effectiveness of HTA, particularly when it comes to encouraging innovation, relies on properly performed assessments and the appropriate implementation and use of subsequent recommendations. HTA can encourage innovation if the assessments are done properly, which means considering a wide range of costs and benefits rather than focusing solely on acquisition costs. The costs of adopting a technology must be seen in terms of the broader benefits, because budget-driven constraints on the spread of technologies do not necessarily result in most effective or cost-effective products. Governments may have to allow more funding and greater flexibility between budgets, so that spending levels are driven by value rather than arbitrary spending caps (Drummond 2003).

3 HTA typically entails 1) identifying the policy question, 2) systematic retrieval of scientific and non-scientific evidence, and analysis, and 3) appraisal of evidence, including judgments regarding the meaning of the evidence.

The evidence and its applications then inform the decision-making process.

4 Variation in uptake and diffusion can signify the sub-optimal use of technology. Excess use is signified when the costs outweigh the benefits for any additional level of technology diffusion or use. Under-use can occur when the foregone benefits outweigh the costs of additional diffusion or use. Both scenarios are sub-optimal, potentially resulting in economic costs and/or reduced health outcomes.



The usefulness of HTA in encouraging innovation and value-added health care also depends on the assessment process, including when and how the review was done, and the resulting decision-making procedures. The following issues can affect the effective use of HTA (Drummond 2006; Zentner et al. 2005; Anell 2004; Busse et al. 2002).

- Delays in the HTA process can result in deferred reimbursement decisions, restricting patient access to needed treatments.
- Evidence requirements can pose a significant hurdle for manufacturers, particularly small, innovative companies, and this may serve to discourage sponsors from pursuing breakthrough technologies.
- As HTA becomes increasingly widespread, assessments are occurring earlier in the process, which may introduce greater uncertainty.
- Current assessment methodologies may limit the comparability and transferability across countries and studies.
- Lack of transparency, accountability, and stakeholder involvement in the HTA process can decrease the acceptance and implementation of assessment results.
- Insufficient skilled HTA staff and international collaboration between review agencies can reduce the efficiency and effectiveness of assessments.
- Separate processes for, and organisations dedicated to, economic assessments, reimbursement/pricing decisions, and practice guideline development may hinder the effectiveness of the overall decision-making process, and lead to unnecessary duplication of effort and resources.

Decision makers are more likely to use HTAs if policy instruments (eg, reports, practice guidelines) are available and if they are already committed to using the assessments effectively. As the cost-effectiveness of a technology and patient demand for that technology can change over time, HTA recommendations must be reviewed constantly. This will need greater collaboration among stakeholders, particularly HTA staff, government officials, industry representatives, health providers and patients. Without adequate input and understanding of the HTA process, stakeholders may mistrust the evidence and the subsequent recommendations.

In order for HTA to be of optimal benefit, the assessment process needs to be linked with innovation and other aspects of policy-making. HTA must recognise the complexities of decision-making, where subjective and normative concerns are considered. Otherwise, HTA may be limited in its powers to impact upon the policy process and subsequent access to new and effective products. The role of HTA in encouraging innovation and value in health care could be improved by better understanding and by addressing the inherent challenges in the HTA process, as outlined below.

Health technology assessment started in the late 1970s, when the expansion of technology and health care costs began to capture the attention of decision-makers (Jonsson 2002). Its introduction to Europe came at a time in health policy that was starting to place greater emphases on measurement, accountability, value for money and evidence-based policies and practices. Other circumstances contributing to an increased need for health technology assessment were the advent of randomised control trials and subsequent availability of data, growth in medical research and information technology, and increased decentralisation of health system decision-making. (OECD 2005).

In Europe, the first organisations dedicated to evaluating health care technologies were set up in the 1980s, initially at the regional and local level in France and Spain and, later, on the regional level in Sweden in 1987 (Velasco-Garrido & Busse 2005; Garcia-Altes et al. 2004). Over the following 10 years most countries set up HTA programmes, either by providing new agencies or institutes, or by setting up academic units or governmental and non-governmental entities (see Table 1). These groups were generally (1) independent ('arms-length') review bodies that produce and disseminate assessment reports on a range of topics, and (2) entities under governmental mandate (eg, from health ministries) responsible for making decisions and setting priorities on issues such as the reimbursement and pricing of health technologies. The latter has an advisory or regulatory function.

Many EU countries are also investing in associated evaluation activities. For example, Sweden spends €5 million per year on the Swedish Council on Technology Assessment in Health Care (SBU) and the Dutch Fund for Investigative

Medicine spends €8.6 million per year on health evaluations (McDaid & Cookson 2001).

However, with additional investment comes a growing recognition that HTA must be scientifically sound, consistent across applications, transparent, and practical. (Zentner et al. 2005; Jonsson 2002). More countries are placing greater emphasis on ensuring that the results of HTA are considered in key decision-making processes.

While European agencies share many of the same objectives, their structures have developed and currently vary in the following ways:

- responsibility and membership of HTA bodies (governance, decision-making, priority-setting),
- assessment procedures and methods,
- application of HTA evidence to decision-making (criteria and timing of assessments), and
- dissemination and implementation.

Transparency and accountability are encapsulated in each element of the HTA process.

The diversity of HTA activities in the EU reflects the different health care and political systems, with different mandates, funding mechanisms, and roles in policy formulation (Velasco-Garrido & Busse 2005; Banta 2003). The use of HTA in decisions that influence the spread and uptake of technologies can be influenced by several factors, such as income levels, reimbursement mechanisms, regulatory environments and behavioural determinants (eg, demand for new technology). As HTA strives to bring together policy and evidence, it reflects the specific needs of decision-makers within a specific system, which explains the variation between countries.

Responsibility and membership of HTA groups

Most national HTA bodies have an advisory or a regulatory role in the decision-making process, depending on the intent and type of assessment required (Zentner et al. 2005). Those that act as advisors, as in the Netherlands and Denmark, make reimbursement or pricing recommendations to a national or regional government, a ministerial department, or a self-governance body (Zentner et al. 2005). Regulatory bodies are accountable to health ministries, and are responsible for listing and pricing drugs, medical devices, and other related services (Zentner et al. 2005). The HTA agencies in Finland, France, Sweden (LFN), and the UK perform this role. Other groups mainly coordinate HTA assessments and produce and disseminate reports (eg, Health Council in the Netherlands, SBU in Sweden).

The responsibilities of the assessment bodies vary by their mission and policy objectives (Anell 2004). HTA programmes are one part of the wider decision-making process, and typically reflect current national policies, such as the need to contain costs or improve access to a given intervention or service. Consequently, economic evaluations often coincide with policies on the reimbursement, pricing, and use of health technologies (Hutton et al. 2006). However, assessments often have a role providing information to providers through practice guidelines and through supporting decisions on investment and acquisitions (OECD 2005).

Table 1: Institutions and advisory bodies responsible for HTA activities*

Australia	Pharmaceuticals Benefits Advisory Committee (PBAC)/Australian Safety and Efficacy Register of New Interventional Procedures
Austria	Federation of Austrian Social Insurance Institution/Drug Evaluation Committee (<i>Hauptverband der Osterreichischen Sozialversicherungstrager/Heilmittel-Evaluierungs-Kommission</i>)
Belgium	National Institute for Sickness and Invalidity Insurance/Commission for Reimbursement for Medicines (<i>Institut national de l'assurance maladie-invalidite/Commission de remboursement des medicaments</i>)
Canada	Patented Medicine Prices Review Board (PMPRB)/Canadian Expert Drug Advisory Committee (CEDAC)/Canadian Agency for Drugs and Technologies in Health (CADTH)
Denmark	Reimbursement Committee/Danish Centre for Health Technology Assessment (CEMIV) (<i>Center for Evaluering og Medicinsk Teknologivurdering</i>)
Finland	Pharmaceuticals Pricing Board – PPB (<i>Laakkeiden hintalautakunta</i>)/FinOHTA
France	Economic Committee for the Health Products (CEPS)/Transparency Commission (<i>Comite economique des produits de sante/Commission de la Transparence</i>)
Germany	Federal Joint Committee/Institute for Quality and Efficiency in Health Care (<i>Gemeinsamen Bundesausschuss/Institut fur Wirtschaftlichkeit und Qualitatim Gesundheitswesen/Deutsche Agentur fur Health Technology Assessment (DAHTA)</i>)
Italy	Committee on Pharmaceuticals (<i>CIP Farmaci</i>), Italian Medicines Agency (AFIFA)
Netherlands	National Health Insurance Board/Committee for Pharmaceutical Aid (<i>College voor Zorgverzekeringen/Commissie Farmaceutische Hulp</i>)
New Zealand	Pharmaceutical Management Agency (PHARMAC)/Pharmacology & Therapeutic Advisory Committee
Norway	Pharmaceuticals Pricing Board (<i>Statens Legemiddelverk</i>)
Spain	Spanish Agency for Health Technology Assessment/Catalan Agency for Health Technology Assessment (<i>Agencia de Evaluacion de Tecnologias Sanitarias/Agència d'Avaluació de Tecnologia Mèdica</i>)
Sweden	Pharmaceutical Benefits Board (LFN)/Swedish Council on Technology Assessment in Health Care (SBU) (<i>Lakemedelsformansamnden/Statens Beredning för Utvärdering av Medicinsk Metodik</i>)
Switzerland	Swiss Federal Office of Public Health/Confederal Drug Commission (<i>Bundesamt fur Gesundheit/Eidgenossische Arzneimittelkommission</i>)
United Kingdom	National Institute of Health and Clinical Excellence (NICE)/National Coordinating Centre for Health Technology Assessment/Scottish Medicines Consortium (SMC)
United States	Agency for Healthcare Research & Quality (AHRQ)/Center for Medicare and Medicaid Services (CMS)

Source: Velasco-Garrido & Busse 2005; Zetner et al. 2005.

Note: *Includes the main review and advisory bodies on HTA in the EEA, Switzerland, Australia, New Zealand, and North America, as part of the broader group of organisations involved in health technology assessment.

In many countries, the health ministry oversees this appraisal process, although independent institutions (eg, NICE) are often involved in managing various aspects of the assessment (Hutton et al. 2006). In many social insurance-funded health systems the process is driven mainly by insurance organisations (Hutton et al. 2006). However, even in these countries, there is some degree of overseeing by the Ministry of Health, and often the Ministry of Social Affairs or Security is involved as well.

The way evaluations are carried out also differ. Generally the nature of the assessment will determine which organisation will conduct the evaluation. Some HTA bodies carry out the assessment through in-house committees, while others coordinate independent reviews by outside bodies, such as university research institutions or expert groups (Anell 2004). The use of independent reviews has benefits and drawbacks. Independent reviews may give greater transparency and help prevent or resolve potential disputes (Drummond 2006; Goodman 1998). They can also broaden the expertise available and bring in a wider range of perspectives. However, independent reviews may introduce methodological challenges, such as the use of particular study designs (ie, RCTs) and potential gaps between the economic model and systematic review. Decentralising responsibilities may bring about inefficiencies, divergent agendas and methodologies, and misunderstandings between assessors and decision-makers. HTA groups also have different roles once the assessment is complete. In some countries (eg, the UK), the HTA body develops guidance and/or recommends reimbursement status, while in other countries this is done by national authorities, insurance representatives, or independent bodies. Some HTA committees (eg, those in Finland and France) are also involved in negotiating price and reimbursement with manufacturers.

All HTAs have multiple technology-related policy-making needs and perspectives across a wide range of stakeholder groups. Thus HTA involves a range of people, such as physicians, pharmacists, health economists, insurance and industry representatives, and patients. Anell (2004) found that most recommendations on reimbursement are made first by scientific members (ie, physicians, epidemiologists) with expertise in evaluation of medicines. These decisions are corroborated with academic groups, representatives from patient organisations, health economists, and (in the case of NICE) health service managers (Anell 2004). The participation of these groups differs across HTA bodies, although all agencies have some level of stakeholder involvement. Some have advocated greater participation of patients and consumers (Coulter 2004). In a recent OECD study (2005), patients and consumer groups were the least involved in the process. Patient perspectives are taken into account indirectly (through safety, effectiveness, and quality of life measures), but the indicators used may not adequately reflect important broader patient values (eg, preference for one treatment over another, acceptability of various side effects). Such measures can play a major part in assessing new technologies and therefore may provide useful insights into the 'real world' value of technologies. Although few countries support a formal and integral role for patients in the HTA process, they are starting to recognise the importance of involving patient or consumer values. NICE has established a Citizens Council to gather public perspectives on key issues. The council helps to develop the social value judgments that should underpin NHS guidance.

A greater role for industry representatives has also been suggested. However, this can be controversial, because of concerns that greater collaboration between HTA groups and industry may influence the objectivity and transparency of the assessment process, particularly with regards to confidential commercial data. As a result, recommendations can be harmed by appeals and general disagreement by various stakeholders.

Stakeholder involvement is generally resource-intensive, but it can lead to improved relevancy and greater trust in the evidence. Increased engagement may facilitate better assessments, reduce the number of appeals, and result in improved implementation. (Drummond 2006). Patients and their organisations in particular should play a more integral role in prioritising and assessing of health technologies so that the process becomes based on consensus.

3.1 Assessment procedures and methods

Assessment processes within the EU differ on a variety of issues, such as topic selection, evidence/data requirements, analytical design, and the methodological approach(es) employed.

Topic selection

Most HTA agencies struggle to keep pace with new technologies and as a result priority-setting has become an important part of the process. Different countries use different mechanisms and criteria, both in terms of the emphasis they give to different approaches (proactive, reactive, or mixed) and in the way they identify needs.

5 The EuroScan Network has 12 members, predominately HTA agencies, in 10 countries, including two from outside Europe (Canada and Israel).

Some review bodies have their agenda set by national authorities (typically, the Minister of Health) or Departments of Health. However, in two countries processes have been set up to allow a wide range of stakeholders (including the public) to give suggestions for topics to be assessed. In Germany, a board of trustees (public administrators, patients, and industry representatives) determines topics using a Delphi process (OECD 2005). In the UK Health Technology Assessment Programme, advisory panels recommend priorities to the director of research and development. The Scottish Medicines Consortium (SMC), however, aims to evaluate every new drug, formulation, and indication within 12 weeks of market launch. The review bodies responsible for reimbursement decisions decide on the products to be assessed by the medicines' licensing authorities and manufacturer submissions. HTA agencies also differ in terms of the breadth of assessment topics. Some focus on health technologies (specifically drugs or devices, or both), while others attend more to particular disease areas or health conditions. Several organisations, such as the SBU in Sweden, conduct assessments on both products and health issues.

The criteria used to select topics vary across agencies, but generally includes health benefit, impact on other health-related government policies (eg, reduction in health inequality, improving access), uncertainty about effectiveness/cost-effectiveness, disease burden, potential benefits and impact of the assessment, and innovation capacity (Garcia-Altes et al. 2004; Taylor 2001; Oortwijn et al. 1999).

It is not considered cost effective to evaluate all technologies and interventions, so review bodies use various approaches to ensure that the assessment process provides decision makers with important and timely information. For example, NICE allows groups of similar technologies to be compared, while certain procedures are required in the Netherlands to guide the proper use of drugs that are not appraised. Additionally, if a drug provides several approved indications, review bodies in Sweden, the Netherlands, Norway, and the UK commonly evaluate the therapy for all conditions.

Although the range of topics covered by HTA agencies is quite broad, some areas (eg, lower-technology and preventive technologies) tend to be understudied. This is also true of research on ineffective and obsolete technologies and interventions. Moreover, HTA groups rarely undertake assessments to keep abreast of new areas of research and development, presumably because their resources are limited (OECD 2005). Assessments carried out earlier in a product's life-cycle have some impact because they can identify areas of uncertainty and highlight areas for further research (OECD 2005). Similarly, some agencies have developed 'early warning' and 'horizon scanning' systems to identify new and emerging technologies that might require urgent evaluation, consideration of clinical and cost impact, or modification of clinical guidance (Douw & Vonderling 2006; Douw 2003; Carlsson et al. 1998). The following criteria are often used to identify candidates for early warning assessments:

- needs the attention or action of politicians, hospitals, and health care administrators within certain time limits,
- deemed cost-demanding or controversial,
- expected to spread more rapidly than desired, with respect to the current scientific knowledge base, and
- expected to spread more slowly than desired, with respect to the technology's potential benefit.

This type of programme has been set up in the Netherlands, Sweden, Finland, and the UK, as well as internationally through the EuroScan Network⁵. There is limited evidence of its impact on decision-making, and also some concern that premature assessment may be biased against new technology, especially those that cost more (AdvaMed 2000). Several studies have highlighted the lack of transparency in the topic selection process (Garcia-Altes et al. 2004; Hagenfeldt et al. 2002; Henshall et al. 1997). Many HTA organisations lack explicit processes for prioritisation, such as selection methods and stakeholder involvement (Garcia-Altes et al. 2004). It is important to identify who is involved in the priority-setting process and what their objectives are. Political deliberation (or other normative considerations) that drive the assessment of certain technologies are rarely made public. Given the limited resources, it is particularly important to make clear how assessment topics are selected and a certain level of transparency is needed. (Hagenfeldt et al. 2002). A perceived lack of transparency may exacerbate tensions between manufacturers, patients, and the those in charge of health care budgets over access to technologies, product innovation, and health expenditures.

Evidence/data requirements

HTA systems vary regarding the type and quality of evidence needed for economic evaluations (Hutton et al. 2006). Manufacturers generally have to submit a comprehensive summary of data on a product's effectiveness and cost-effectiveness. Reviewing groups differ, however, on the role of industry data in this process. In Austria, Norway, and the Netherlands, they review and validate all the industry data, which must be based on a systematic review of clinical and economic evidence (Zentner et al. 2005).

Other organisations (eg, NICE, SBU) do the systematic review in-house or through an independent group. Evidence used in the assessment generally involves a broader review of various information sources and may or may not include industry data. Some countries (eg, France, Switzerland, and Finland) prefer systematic reviews but do not require them, and base their assessments mainly on a definite number of studies (eg, pivotal clinical trials) provided by industry (Zentner et al. 2005). Assessment of unpublished evidence (eg, confidential commercial data) is considered in Austria, the Netherlands, Sweden, and the UK.

Evidence from manufacturers includes systematic literature searches and analyses of clinical and economic studies, which may or may not include modelling. Most HTA institutions have guidelines on the methodological requirements for manufacturers and reviewers, but these documents vary in the level of detail and transparency (Zentner et al. 2005). The pharmaco-economic methodologies used in assessments tend to be described in greater detail than procedures for clinical review or the evaluation of other product characteristics (Zentner et al. 2005). Most guidelines cover issues such as preferred clinical and economic evidence, comparators, specification of the outcomes variable(s), sub-group analyses, costs to include in the analysis, time horizon, discounting, and use of sensitivity analyses and modelling.

Another difference in evidence requirements that has recently developed concerns the point at which manufacturers submit data on cost-effectiveness. For example, the Swedish LFN requires manufacturers to submit evidence on cost-efficacy first; if acceptable, the product under review is allowed provisional reimbursement while cost-effectiveness data is then collected and submitted.

Analytical design

Countries use different analytical frameworks to guide the assessment (Hutton et al. 2006). Most assess a range of criteria such as safety and clinical effectiveness, patient need and benefit, cost-effectiveness, and cost of therapy (typically in relation to benefit) (Zentner 2005; OECD 2005; Anell 2004). Some HTA bodies also frame the evaluation around other factors, including (table 2):

- psychological, social, and ethical considerations,
- organisational impacts,
- disease burden and severity,
- equity,
- patient perspective (ie, quality of life),
- industry research and development,
- budget impact,
- compliance with government-defined priorities, and
- lack of alternative treatment(s).

6 AT=Austria, AU=Australia, BE=Belgium, CA=Canada, CH=Switzerland, DE=Denmark, FI=Finland, FR=France, NL=Netherlands, NO=Norway, SE=Sweden, and UK=United Kingdom.

Table 2: Criteria for HTA assessment

Criteria	AT ⁶	AU	BE	CA	CH	DE	FI	FR	NL	NO	SE	UK
Therapeutic benefit	●	●	●	●	●	●	●	●	●	●	●	●
Patient benefit	●	●	●	●	●	●	●	●	●	●	●	●
Cost-effectiveness	●	●	●	●			●		●	●	●	●
Budget impact		●	●	●			●	●	●	●		●
Pharmaceutical/innovative characteristics	●		●	●				●	●			●
Availability of therapeutic alternatives	●	●							●		●	●
Equity considerations				●						●	●	●
Public health impact				●				●				
R&D		●					●					

Source: Adapted from Zentner et al. (2005) and case studies.

- 7 This section primarily refers to those decision-making bodies reviewing clinical and economic evidence for product reimbursement and pricing.
- 8 Methodologies can also differ on subgroup analyses, time horizon, instruments to measure quality of life, and approaches to calculating costs.
- 9 In the case of Switzerland, the assessment body applies a cost-analysis approach, whereby a new product is compared with the same therapeutic category and the price is compared with those in several other EU countries (Denmark, Germany, Holland, UK, France, Austria, and Italy).
- 10 QALYs provide a common unit of evaluation across multiple domains, including estimating the overall burden of disease; comparing the relative impact of specific diseases, conditions, and health care interventions; and, making economic comparisons, such as the cost-effectiveness of different health care interventions.
- 11 HRQoL measures are increasingly used along more traditional outcome measures to assess health technologies. HRQoL measures capture such dimensions as: physical function, social function, cognitive function, anxiety/distress, bodily pain, sleep/rest, energy/fatigue, and general health perception. Such measures may be disease-specific or general.

Almost all assessments consider therapeutic and patient benefit. There is also agreement that economic evaluations should be carried out from a social perspective, taking into account costs and benefits outside the health sector, and not just using a narrow budget perspective on resource use (Zentner et al. 2005; Anell & Svarvar 2000).

Assessment methods⁷

HTA uses a range of methods, with most programmes using an ‘integrative’ approach. Most agencies have similar methodological approaches and emphasise the most rigorous types of studies (eg, randomised controlled trials, cost-utility analyses), but there is no standard approach for assessments. Given their varying orientations, resource constraints and other factors, assessment programmes tend to rely on different combinations of methods, and often differ on the following issues (Zentner et al. 2005)⁸:

- type of economic assessment required,
- classification of product benefit (benefit vs. harm) – hierarchy of evidence,
- choice of comparator,
- specification of the outcome variable,
- costs included in the analysis,
- discounting,
- use of cost-effectiveness threshold,
- allowing for uncertainty, and
- missing and incomplete data.

3.2 Type of economic assessment

In general, requirements for economic assessments are similar across countries (Zentner et al. 2005). There are guidelines that product sponsors must follow in selecting the type of economic assessment they will use. In some countries, such as Switzerland, there is no requirement for assessments and therefore no guidelines⁹. Cost-effectiveness or cost-utility analyses are most often considered appropriate designs, particularly when the proposed product has significant clinical advantages to the comparator and the relative benefits need to be considered against costs. Cost-utility analysis, measuring health outcomes in terms of Quality-Adjusted Life Years (QALY)¹⁰, has increasingly been recognised as the preferred indicator of effectiveness, as it can be used to compare different therapies and set priorities (Zentner et al. 2005). Moreover, cost-utility analysis is considered to have fewer methodological problems than other approaches, such as cost-benefit analysis. Although many assessment bodies (eg, NICE) have deemed QALY the principal measure of health outcome, the number of studies actually reporting QALYs based on actual measurement of patients’ health-related quality of life (HRQoL)¹¹ is still fairly limited (Rasanen et al. 2006; Rawlins & Cutler 2004).

3.3 Evidence to classify product benefit

Zentner et al. (2005) found that all countries consider randomised controlled head-to-head trials (RCT), the most reliable and objective evidence for showing a product’s relative therapeutic benefit. This also applies to systematic reviews and meta-analysis of RCTs. Most review bodies favour RCTs in natural settings, because they reflect daily routines and country-specific care. Even where definitive primary studies exist, they do have limitations that must be taken into account. For example, elderly people and other patients with co-morbidities are often excluded from clinical trials, even though these patients are major consumers of medical products. Also, trials do not always collect a full range of economic data (eg, indirect costs, health utility measures) and the study time is often too short to detect some outcomes. To supplement available clinical data, findings from different types of studies should be combined or synthesised in order to formulate effective and comprehensive policies. To that end, other types of studies (eg, case series, registries) may be preferred to RCTs for different policy questions. Modelling is useful when making decisions under uncertainty.

When searching the literature, selecting studies, and assessing internal and external validity of clinical trials and systematic reviews/meta-analyses, all review bodies apply internationally established standards, such as guidelines from the Cochrane Collaboration, CONSORT (Consolidation of Standards for Reporting Trials), and QUOROM (Quality of Reports of Meta-analyses of Randomised Controlled Trials), or they employ their own comparable standards (Zentner et al. 2005).

3.4 Choice of comparator

Assessments are almost always comparative, with the product evaluated against some specified standard of performance or other products and treatments. The choice of an appropriate comparative treatment is crucial. Moreover, all relevant options must be included. Zentner et al. (2005) found that HTA groups usually use two different procedures when selecting a comparator. Some institutions (Finland, Sweden – for new pharmaceuticals only) require a product to be compared with up to three well-defined comparators or, in the case of the UK, all relevant comparators. The most cost-effective existing therapy is usually deemed the most appropriate, but for practical reasons, HTA bodies often accept that a product is evaluated against routine treatment or the least expensive therapy. For pharmaceuticals, routine treatment is identified by prescription or sales volume, and dosage and delivery of medication must be therapeutically equivalent. In terms of non-pharmaceutical treatment, however, few groups provide information on how usual practice is determined. Other institutions (Switzerland, Sweden) require that products be compared with all therapies in the same group, based on the WHO ATC (Anatomical-Therapeutic-Chemical) classification system¹². As such, only currently reimbursed or marketed products can be used as comparators. An equivalent dosage form should be defined for comparator medications. France combines both approaches, in which drugs in the same therapeutic group are considered, and the ones selected for comparison are the most frequently prescribed, the least expensive, and the most recently listed.

HTA groups also differ in terms of who selects the comparator for assessment (OECD 2003). In some countries (eg, the UK), it is specified by the assessment body. For others (eg, France and Sweden), the product sponsor is responsible. In such cases, HTA bodies often require manufacturers' and other relevant reviews to follow specific guidelines. Therefore manufacturers must communicate with review bodies early (the initial phases of the study design) (Zentner et al. 2005). In the Netherlands, for example, product sponsors often discuss the comparator *a priori* with the assessment body, especially when a more narrow indication than the product's label for reimbursement approval is being considered. In the UK, Portugal, and Switzerland, the selection of a comparator varies between the product sponsor and assessment group. Increasingly in the UK (England and Wales), the Department of Health specifies the comparator, particularly when recommending topics to NICE (OECD 2003). In most countries, the government has some role in determining the comparator selected. Other review bodies, particularly NICE in the UK, consider input from stakeholders when scoping the study design and comparator selection.

3.5 Selection of the outcome variable

Assessments tend to use a range of health and economic outcome measures. As with selecting an appropriate treatment comparator, specifying the outcome measure(s) can influence the conclusions of the assessment. Most countries prefer final outcome measures that reflect the long-term treatment objective (eg, changes in mortality, morbidity, and quality of life), but they differ in the selection of outcome measures and the requirement of the specification process. In the Netherlands, the outcome variable is defined by the assessment body, while in most countries product sponsors are the key decision-makers in this area¹³. The choice of outcome variable may depend on the type of analysis to be conducted, and intermediate measures are generally accepted if there is little outcome data available (OECD 2003). This type of study needs a strong and scientifically-based association between intermediate effect and final outcome (Zentner et al. 2005).

3.6 Costs included in the analysis

HTA bodies and governments differ on the type of costs that assessments should consider. The specification of costs is usually related to the purpose of the analysis and the overall objectives of the assessment (OECD 2003). The difference between varying approaches lies in the inclusion of direct and indirect costs. Some countries (eg, Sweden) allow all costs to be included, whereas others (eg, the Netherlands, UK) use only direct costs¹⁴. With indirect costs, there is disagreement over how to account for productivity loss, in terms of using a human capital or friction cost approach¹⁵ (Zentner et al. 2005). There is also disagreement over whether to include in the assessments the costs of a longer life span (as a result of treatment). The SBU does include such costs. There is also inconsistency over whether to include opportunity losses related to leisure activities and time spent on household duties when looking at changes to quality of life.

12 The ATC classification system is used for the classification of drugs. It is controlled by the WHO and was first published in 1976. Drugs are divided into different groups according to the organ or system upon which they act and/or their therapeutic and chemical characteristics.

13 Portugal and Switzerland do not directly specify an outcome variable.

14 The UK includes only those direct costs to the NHS and Personal Social Services.

15 The human capital approach employs the principal that a profit maximizing firm will employ labour up to a point when the value of the marginal product of labour is equal to the gross wage. Thus, it treats the value of per unit of lost time due to ill health to be equal to the gross wage and any additional employment costs. The friction cost approach considers that workers that are withdrawn from work due to ill health or death will, after some period of adaptation period, be replaced. Even with a very short-term absence from work, a firm can use existing space capacity in its labour pool to compensate for lost work due to ill health.

16 While it is recommended that the same rate be applied to both costs and benefits, some countries (e.g., UK, Sweden) use different rates.

17 Suppose 1 and 0 denote the intervention under study and the alternative to which it is compared, respectively. If C_1 and C_0 are the net present values of costs that result when the intervention and alternatives are used, and E_1 and E_0 their respective health outcomes, the incremental CE ratio is simply: $CE\ ratio = (C_1 - C_0) / (E_1 - E_0)$. This ratio, which is a cost per unit incremental health effects, is often used as a measure of value.

Some systems, such as that in the Netherlands, assume a social cost perspective, even though these costs go beyond budget constraints. However, wider costs are typically presented separately from system-related costs, so non-system costs may have limited impact on decisions.

Some countries have guidelines on such issues. Zentner et al. (2005) found that HTA groups or governments provided guidelines on the inclusion of costs associated with other diseases resulting from prolonged life, and placing utility measures against the preferences of a country's population. Because data is not always transferable across countries, HTA bodies often ask for resource consumption and related costs be based on national data. Most guidelines require cost calculations to be transparent. This means identifying costs accurately, presenting quantity of resources consumed separately from the respective cost, and adequately detailing any sources of data (Zentner et al. 2005; OECD 2003).

3.7 Discounting

The use and effects of many products extend for years, especially in the case of chronic conditions. When a product impacts on health for more than one year, it is considered good practice to use discounting in order to assess changes in costs and benefits over time (OECD 2003).

Most HTA groups use discounting in assessments, typically applying an annual rate of between 2.5% and 10% to costs and benefits (Zentner et al. 2005; OECD 2003)¹⁶. A discount rate of 5%, however, is recommended to reflect a social perspective. Countries differ in terms of whether the payer or product sponsor determines the discount rate. As a general rule, institutions specify that it should be included in the sensitivity analysis.

3.8 Use of cost-effectiveness threshold

In economic evaluation, the results of a cost-effectiveness analysis is summarised by the cost-effectiveness (CE) ratio¹⁷. The CE ratio compares the incremental cost of an intervention with the incremental health improvement attributable to it. The health improvements resulting from the intervention are typically measured in QALYs, and so the CE ratio is usually expressed as a cost per QALY gained. A treatment with a relatively lower CE ratio is considered most cost-effective. Essentially, CE ratios indicate which health technologies will provide health improvements most efficiently (Garber 2000).

Interpreting the results of cost-effectiveness analyses can be difficult. Consequently, a cost-effectiveness or 'willingness-to-pay' threshold is often used to find out which treatments are good value for money. An intervention's CE ratio is often compared to the threshold in order to recommended inclusion or exclusion in the benefits package. However, interventions may be adopted despite having an unfavourable CE ratio, if other factors (eg, disease burden and health equity) are a consideration.

Few countries use a formal or fixed threshold, or at least do not make such a rule explicit. In the UK, for example, there is conflicting evidence as to whether NICE employs a threshold. Recent comments by officials and particular guidance (ie, Orlistat) indicate a threshold between £20,000-£30,000/QALY (Devlin & Parkin 2004). However, NICE has officially maintained that there is no formal threshold. Rawlins and Culyer (2004) suggest that NICE bases decisions primarily on CE ratios below £20,000/QALY. However, as the CE ratio increases, the likelihood of rejection on the grounds of cost-effectiveness rises. Beyond NICE, the available evidence suggests that the threshold for adoption is between US\$20,000/QALY and US\$100,000/QALY, with thresholds of US\$50,000-\$60,000/QALY frequently proposed (Bell et al. 2006).

3.9 Allowing for uncertainty

Most review bodies conduct or require sensitivity analyses on all variables that could potentially influence the overall results, or on a subset of inputs (eg, imprecise estimates only). This is because of the uncertainty inherent in conducting health technology assessments, specifically over the value of particular estimates and their relative effect on costs and benefits. The stipulation for sensitivity analyses comes from the need to test or verify the robustness of the findings. Different countries have different requirements for sensitivity analysis (eg, univariate or multivariate) so the choice of parameters and methods must be substantiated and well documented. Most countries recommend or require this, and it is particularly important in the case of assessments for new technologies, where the necessary data for evaluations is seldom clear.

Most countries also require some form of modelling to allow for uncertainty in the variables and estimates used. Models are usually generated by manufacturers, the review body, or both. Many review bodies develop models to substantiate the estimates given by manufacturers as well as using them to compensate for missing or incomplete data. Complex models are increasingly being used to look at cost-effectiveness, but the models vary in quality and many are not transparent enough. This makes it essential to continue to assess independently the models used.

The use of sensitivity analysis and modelling (as well as sub-group analyses) may also be used to predict the effect of certain patient characteristics (eg, age, sex, and ethnicity) on cost-effectiveness and equity (Michaels 2006). Some review bodies (eg, NICE) suggest that modelling for subgroups of patients might be appropriate, but there are no recommendations as to which variables would be considered ethical. Outlining clear criteria for subgroup analyses, based on specific variables, could help to incorporate social values into decision-making in an explicit, transparent, and consistent way.

3.10 Missing and incomplete data

Many HTA agencies receiving data from product sponsors are faced with analytical challenges. For example, data may be incomplete, poorly presented, or lack transparency (OECD 2005). These problems may be caused by failure to follow specific guidelines or by incomplete data. Sponsors may be asked to report on the same information in various formats for different countries, which is expensive and inefficient.

The choice of methods can significantly influence the result of the assessment and the comparability across studies and countries. This may ultimately affect the usefulness of HTA in the decision-making process (Boulenger et al. 2005). Unfortunately, there is little information available on how agencies handle some these data issues.

Application of HTA evidence to decision-making: criteria and timing of assessments

Countries use a range of HTA evidence to support priority-setting and other decision-making (see *HTA dissemination and implementation* section for further description). In a comparative study by Zentner et al. (2005), all countries¹⁸ considered a drug's therapeutic benefit¹⁹ in comparison to available treatment alternatives. In fact, this tended to be the leading criterion to assess a product's added value in most evaluations. Health-related quality of life is considered the most appropriate criterion for a technology's added value from the patient perspective. NICE, however, is one of the few review bodies that has made explicit commitments to include this measure in its assessments and recommendations.

In terms of cost-effectiveness, many decision-makers do not operate against a fixed threshold, as an absolute decision rule. The often considered other factors, including the following:

- necessity (disease burden and severity),
- public health impact,
- availability of alternative treatments,
- equity,
- financial/budget impact,
- projected product utilisation,
- innovation of product (pharmacological characteristics, ease of use), and
- affordability.

18 The study included the following countries: Austria, Australia, Canada, Switzerland, France, Netherlands, Norway, New Zealand, Sweden, and the UK.

19 A product is considered as having a therapeutic benefit if it shows an improved benefit/risk profile compared to existing treatment alternatives. In the case of therapeutic equivalence, a drug is typically not accepted for public reimbursement or is subject to a reference pricing system. A therapy with an inferior benefit/risk profile than other viable therapies are not typically reimbursed, even in the case of lower costs.

According to Rawlins and Culyer (2004), NICE typically requires additional justification for cost-effectiveness ratios over £25,000/QALY, such as the degree of uncertainty, wider social costs and benefits, and the particular features of the condition and population using the technology. In the Netherlands, there is debate about adopting a decision framework based on both efficiency and equity criteria: different thresholds would apply according to disease burden, with higher CE ratios allowed for the most severe diseases.

The transparency of the criteria used in decision-making, however, is lacking in many countries. A recent analysis by Anell (2004) found that some review groups rarely (if ever) state the relative weight and importance of the criteria they use. This is especially true of social aspects and non-quantifiable considerations, such as equity and patient quality of life, which tend to come after efficacy and cost-effectiveness in terms of importance in the decision process (Zentner et al. 2005). A more explicit understanding of both the threshold value and the accompanying criteria and decision rules is important if the decision making process is to be transparent and coherent. It has also been suggested that the cost-effectiveness threshold should be consistent with overall budget constraints and should consider equity and fairness as well as efficiency. (Rawlins and Culyer 2004; Towse 2003).

The time taken to do assessments is subject to pressure from on the one hand ensuring comprehensive evaluations, and on the other providing timely information. Different countries have different approaches, and the time needed to complete an assessment varies. They can take between a few weeks and a few years, with the average length 3-12 months (OECD 2005). Countries such as France tend to take less time (eg, a couple of weeks), but other bodies (in the UK and Sweden) will typically take one year (Zentner et al. 2005). However, for EU member states, the European Commission Transparency Directive (89 / 105 / EEC) requires decisions on reimbursing and pricing new pharmaceuticals within 180 days after marketing authorisation (Zentner et al. 2005). Some agencies have managed to reduce the time needed to complete assessments. The SBU and FinOHTA have introduced rapid for emerging technologies. NICE recently instigated Single Technology Assessments (STAs), a new 'fast track' procedure to address concerns over the time needed for NICE's standard assessment approach. STAs place greater emphasis on evidence submitted by manufacturers and less on external review. The SMC usually applies an STA approach when it provides guidance to the NHS in Scotland.

The variation in time taken in assessment can be attributed to several factors. Some agencies do more 'overview' type assessments, which can be done rapidly. Other countries may have more resources available for primary research, which take more time (OECD 2005). The rapid pace of technology development can also add delays, as changes make results obsolete or require new tests. Another factor is the availability of skilled HTA staff, which may be due to limited resources or the pace of technologies. The UK (NICE) has tried to address this issue by offering training fellowships and by providing a steady stream of funding for appraisals, which has enabled academic units to build a critical mass of skilled people (Drummond 2006).

Early appraisals can have a number of consequences. There will generally be less information available early in a product's life cycle. They may also rely more on submissions from manufacturers. Early review may also be less able to consider sub-groups and other restrictions, unless otherwise highlighted in the company submission.

HTA dissemination and implementation

As previously mentioned, the results or evidence associated with HTA are used on a wide range of decisions to:

- plan resource capacities,
- shape the benefit catalogue,
- guide treatment provision,
- inform corporate investment decisions,
- identify R&D properties and spending levels,
- change regulatory and payment policy, and
- acquire or adopt a new technology or technologies.

Most countries need assessments in order to decide reimbursement status, although the importance of economic evidence in the decision differs from country to country (Anell 2004). France, for example, rarely considers such information when determining reimbursement. Some committees may only require assessments for patented drugs and new indications, or they apply varying requirements to different types of products, such as generic drugs (Anell 2004). Overall, health economic evidence seems to have the biggest impact on decisions about drugs with broad use (and therefore significant potential budget impact) and when cost-effectiveness varies by indication or patient sub-population.

Economic evidence is also used to restrict the use of products, especially innovative and expensive technologies where there may be uncertainty. Reimbursing such technologies can be confined to certain indications, patient populations, treatment settings, and therapeutic positioning (ie, first- or second-line therapy) (Zentner et al. 2005). In the Netherlands, for example, if expensive inpatient drugs meet certain criteria after an initial assessment (eg, projected sales higher than 0.5% of total drug sales in the hospital) then they will be given conditional reimbursement for three years. In this time additional information on the drug's 'real world' cost-effectiveness is collected. If the evidence does not show value for money then reimbursement will be withdrawn. Conditional approvals have an important role because they allow use of the technology under limited conditions in an attempt to minimise uncertainty. However, the usefulness of conditional approvals depends on further data collection and the subsequent re-evaluation of the product (OECD 2005). Technologies are generally reimbursed *without* conditions when cost-effectiveness and marginal therapeutic and patient benefits have been established (Anell & Persson 2005). But some drugs with poor cost-effectiveness are covered if the disease is severe (with a small patient population) or there is a lack of treatment alternatives (eg, orphan drugs).

HTAs play a role in the pricing of products and in negotiating special agreements with manufacturers (eg, price-volume, cash rebates) (Anell 2004). However, countries differ in terms of how closely the reimbursement and pricing process are linked. Reimbursement decisions are sometimes made before pricing, while in other cases both the reimbursement and price are considered at the same time before a final decision is determined, as happens in Sweden, the Netherlands, and Finland. The different HTA schemes and cost-containment strategies adopted by different countries may not significantly impact on individual drug prices. Rather, their effect on costs may come more indirectly, through better defining the appropriate clinical indications for the treatment (Taylor et al. 2004).

The results of assessments are also used to develop clinical or practice guidelines. Guidelines typically include recommendations on priority-setting, and provide national support to help decision-makers. However, health economic evidence is not used as well as it could be when developing guidelines, with only a few recommendations grounded in HTA. Berg et al. (2004) suggest that this could be caused by a gap between the data generated and the requirements of clinical practice; aversion among the doctors to combine economics and health; and the fact that guidelines rely more on data on effectiveness, rather than on cost-effectiveness. They argue that guidelines are of limited value for influencing the use or uptake of new health technology (Berg et al. 2004). This situation is probably made worse by the lack of coordination between the bodies that produce guidelines and those that set priorities and fund HTA studies. However, guideline development and HTA are beginning to come together.

There remains a lack of evidence on the 'real world' effectiveness of economic evaluation in terms of health care planning, clinical practice, spread of technologies, or overall health costs. Decision-makers continue to ignore the principles of economic evaluation, despite the advances in techniques and methodology (Goddard et al. 2006). In addition, the available evidence on the impact of HTA and research development is relatively weak, with an explicit link only in the Netherlands and the UK (Henshall et al. 2002).

Many factors may prevent decision-makers from using strict cost-effectiveness criteria when setting priorities and other stakeholders from using HTA products (eg, reports, practice guidelines) in health care decisions. Goddard et al. (2006) argue that the lack of impact is not so much caused by methodological shortcomings than by the wider context of public-sector decision-making. While decision-makers may value health economic information, other aspects of the public policy process result in sporadic and unsystematic application of HTA.

The place of HTA in the decision-making process can affect the extent to which evidence is used to inform policy and priority-setting. Countries often disagree on the use of HTA recommendations (Draborg & Andersen 2006; Garcia-Altes et al. 2004). Some support recommendations on the grounds that experts are the best people to provide them, while others prefer decision-makers to make recommendations in the light of political context and other country-specific circumstances (Draborg & Andersen 2006). However, decision-makers may not have the technical expertise to understand the methodological strengths and weaknesses of an assessment. Improvements are still needed, but much has been done by assessment bodies to enhance the accessibility and usability of HTA among different audiences (eg, policy-makers, health professionals, general public).

Although different decision structures provide policy-makers with a wide range of discretion, not employing HTA evidence may lead to inefficient, ineffective, and inequitable health care. As Jacobs and McGregor (1997) note, 'However excellent an HTA may be, if it fails to be used to influence the working of the health care system, it is without impact and must be considered without value'.

20 There is often the possibility that by the time a HTA is conducted, reviewed, and disseminated, its findings may be outdated by changes in a technology, in how it is employed, or in its technological alternative for a given problem.

The influence of HTA depends on several other considerations, including the information needs of decision-makers, transparency of the economic evaluation and subsequent decision-making, mechanisms for disseminating the decision, and processes for monitoring and reappraising the evidence (Hutton et al. 2006; Zentner et al. 2005). For example, the gap between the long-term perspective of assessments and the short-term perspectives of policy makers can limit the usefulness of recommendations (the ‘moving target problem’²⁰) (Neumann 2004). The uncertainty inherent in HTA may also hinder its use in decision-making, because effective assessment will identify areas of under-use as well as over-use, and can have ambiguous effects on price determination. (Crookson & Maynard 2000). Moreover, broader health system characteristics, such as decentralised management, inadequate public resources or ‘silo’ budgeting, as well as existing incentives for manufacturers and academics to deliver research that is interesting rather than practical and focused, may also prevent the best use of economic evaluation (Rutten et al. 2005; OECD 2003; Cookson & Maynard 2000).

It has been suggested that interest groups have a major influence on the process, because decision-making may benefit some groups at the expense of others, and because some groups have enough power to influence government choices (Goddard et al. 2006). The Dutch Council for Public Health and Health Care (2006) recently noted that thus far, ‘decisions regarding payment or non-payment for medical treatment are only based on a limited degree on “hard” factors, such as cost-effectiveness, and much more on less transparent considerations, as a result of pressure by lobby groups, such as consumer organisations, the media, and so on. This means that limits are indeed being set at present, but on an *ad hoc* and somewhat random basis. The result is that the available resources are not being deployed as efficiently as possible.’ The involvement of key stakeholders, such as providers and patients, is imperative for the effective implementation of HTA. A recent OECD study found that stakeholder acceptance is one of the key determinants of whether decisions are actually put into practice (OECD 2005).

The ability of HTA to maximise health for a given budget is difficult to assess in practice. In fact, few countries have formal processes to measure the impact of HTA. Obstacles to effective assessment include the many other factors influencing policy and practice decisions, and the long-term nature of some of the effects of HTA (eg, changes in expectations and behaviour patterns of users) (Hailey et al. 1990).

If recommendations are to be implemented and the technologies taken up, there must be a clear and well communicated decision-making process in place. A lack of a defined process can create doubts over the legitimacy of decisions and therefore be less likely to have the support of stakeholders. This may increase the risk of appeal procedures (Drummond 2006; Neumann 2004). It is difficult to incorporate evidence into ill-defined decision-making processes because the producers of evidence will be less likely to deliver timely and relevant advice. Part of instituting a clear decision-making process involves identifying an assessment framework that aligns incentives with evidence and health system objectives.

Improving the transparency and effective dissemination of recommendations also depends on the methods used for implementing decisions (Box 1). HTA is more likely to influence practice and health outcomes, if there are well-chosen and appropriate policy instruments, a prior commitment to make use of assessment findings, stakeholder involvement, and real-world applicability to the decisions made (OECD 2005; Henshall 2002). Clinical guidance documents on the use of health technologies are more likely to be adopted when there is strong professional and financial support, in organisations that have established systems for tracking implementation, and when the guidance reflects the appropriate clinical context (Sheldon et al. 2004).

Box 1: Examples of methods for disseminating and implementing recommendations

- Coverage/reimbursement policy
- Formulary restrictions
- Medical audit/peer review
- Clinical guidance
- Accreditation
- Standards
- Media campaigns
- Conferences/workshops
- Professional education
- Websites and newsletters

To avoid the 'moving target problem', recommendations by HTA agencies and any resulting decisions must be reviewed and re-evaluated regularly. This applies to new technologies and to those already on the market. Some countries (eg, Finland, France, and the UK) have a more structured process for re-appraisals and conduct a re-evaluation at fixed or variable intervals. Other countries (Austria and Switzerland) set up a review if new characteristics of the product emerge, or if new or better clinical and/or economic evidence becomes available (Zentner et al. 2005).

One final area of the HTA process that may improve its impact on decision-making concerns national and international collaboration. Better cooperation among assessment groups can help develop new methodology, enhance the transferability and transparency of HTA recommendations, and potentially improve the efficiency and accountability of the HTA process. The variety of HTA activities and the multiplicity of customers necessitate strong links between agencies and other groups dealing with HTA. Several countries have improved collaboration by creating assessment guidelines, holding meetings on assessment issues, devising new channels to encourage communication, and strengthening the role of international assessment organisations (eg, HTAi) (OECD 2003). In fact, most countries involved in HTA activities belong to one or more international HTA organisations. The European network for HTA (EUnetHTA), was developed recently to connect national and regional agencies, research institutions and health ministries, in order to enable effective exchange of information and support policy decisions by member states. EUnetHTA represents 59 partner organisations, including FinOHTA, IQWiG, DAHTA, NCCHTA, and the SBU.

The overall implementation of HTA could be enhanced by ensuring that it is better adapted to the specific policy question and to the needs of decision-makers. This means that methodologically-sound evidence should be available in good time, in line with decision priorities, and recognising the various dynamics of health technology markets and the public policy process. Responsibility for making sure that HTA meets the needs of stakeholder requires collaboration and effort from users and producers. Key constituencies (eg, patients, providers, industry) need to be increasingly engaged so that the decision making process is more acceptable, more relevant, and more transparent.

Health technology assessment plays a major part in evidence-based decision-making. Without enough good evidence, the uptake and spread of technologies is likely to be influenced by social, financial, and institutional factors, and not produce the healthiest outcomes or the most efficient use of resources. In order to provide the necessary information, HTA must address the challenge of delivering timely and relevant information that reflects the dynamics of technology and the health care system.

There must be greater correspondence between innovation and the needs of the health care system. Products that provide the most value for investment must be identified and supported. Manufacturers of such products must be rewarded with appropriate reimbursement and pricing schemes. Overall, the benefits of health technologies must be harnessed, while health care budgets are managed and the basic principles of equity, access, and choice are protected.

This report identifies several key issues that affect the usefulness of HTA in supporting effective and efficient decision-making and value-added health care.

- Many countries have several bodies dedicated to HTA, with somewhat unclear and disparate roles and responsibilities. The lines of division typically separate groups involved in reimbursement and pricing decisions from those engaged in independent HTA assessment and clinical guideline development. Divergent processes and roles may hinder the effectiveness and efficacy of the decision-making process, and lead to unnecessary duplication of efforts and resource use.
- Most review bodies involve a range of stakeholders, including physicians, health economists, pharmacists, and patient group representatives. However, most agencies support a limited role for patients and consumers, who are the end-users of a given technology. NICE in England and Wales has tried to enhance the role of patients and consumers in assessments and subsequent decision-making. It set up a Citizens Council and allowed stakeholders to comment on assessment priorities and recommendations. A greater role for industry representatives has been put forward and both NICE and the LFN in Sweden consult with industry throughout the assessment process. Overall, greater stakeholder involvement is needed to improve the implementation of decision and policy and to manage uncertainty, while at the same time allowing access to safe technologies.
- Countries have different processes for prioritising assessments, but most agencies select topics based on health benefit, disease burden, technology relevance, social and ethical considerations, and the costs of the technology. Some countries also consider evidence and resource requirements, as well as relevance to the primary clinical and/or policy question. This is important because HTAs are only useful if they are expected to contribute to the decision-making process. If there are insufficient data and resources, the assessment will not be helpful and may delay access to new treatments.
- There have been improvements in topic selection, but generally the process lacks transparency, from prioritising decision criteria to stakeholder involvement. A greater level of transparency is needed for an open, systematic, and unbiased decision-making process.
- In addition, most agencies focus topics of assessment on new technologies. More attention should be paid to identifying topics for potential disinvestment so that ineffective and inefficient products and practices do not remain in the health care system. This will help to support real innovation.
- Most agencies have published guidelines to steer evidence collection and the review process. While most of the guidelines cover similar requirements (eg, comparators, costs to include in the analyses), there are some important differences that can impact assessments.
 - (1) Countries have different requirements for the evidence required. Some of these differences are attributable to the particular agency's mission and mandate. For instance, those groups involved in reimbursement and pricing decisions tend to rely on manufacturer data, which may or may not include a systematic review of the evidence.
 - (2) Most countries use QALYs as their cost-utility analysis for the preferred indicator of effectiveness. However, only a few studies use QALYs, and so agencies may not have enough evidence to account adequately for quality of life benefits.

- (3) Most countries rely on (and prefer) randomised head-to-head trials (RCTs) to show a product's relative benefit. Although they are considered the most objective type of evidence, but they do have some limitations. Assessments should not only include observational studies and other important evidence, but also adopt a broader definition of value and product benefit by considering preferences, quality, equity, efficiency, and product acceptability. The opinions and experiences of health professionals and individual patients are needed to understand the 'real-world' application and use of a product. Agencies in the UK, Sweden, and the Netherlands are the only ones to consider equity issues in assessments and subsequent decision-making.
 - (4) Assessments should take into account indirect benefits and costs. Several countries include indirect costs in analyses and have a broader social perspective, but there is no agreement on whether to use a friction cost or human capital approach when accounting for productivity losses. The results of assessments may differ significantly depending on the method used. It would be helpful if review bodies could agree over whether to take into account the extra years of life provided by new treatments well as opportunity costs related to leisure activities. Evaluations should also account for other indirect benefits, such as lower treatment costs and availability of treatment alternatives in the particular therapeutic area.
 - (5) Few countries apply a fixed or formal cost-effectiveness threshold, although the evidence often suggests a range of thresholds. While the threshold can indicate an organisation's or country's willing-to-pay, other factors are often considered. But these criteria and accompanying rules are rarely made explicit. A better understanding of threshold values and other decision criteria, and how they are applied in the overall decision process, is needed.
 - (6) Most countries require sensitivity analyses and/or modelling to allow for uncertainty in the variables and estimates used in assessments. As different countries have different requirements, the choice of parameters and methods must be substantiated and documented. This is particularly true when more than one entity is involved in the development and analysis of models. The model and resulting analysis should be made as transparent as possible, with all those involved collaborating and exchanging information. As the modelling of cost-effectiveness becomes more sophisticated, it will become more difficult to establish the validity of evaluations. Consequently, more resources should be devoted to assessing new methods of modelling and resulting impacts on uncertainty in decision-making.
- Many technical and methodological hurdles remain, and they need further investigation and research. They include the ability of summary measures to capture other benefits important to patients and the public; the generalisability of studies beyond a particular setting or country; the inability to account for the opportunity costs of expensive, new technologies; and the comparability between health state elicitation instruments.
 - The timing of assessments can significantly affect the decision-making process and patient access. There has been a general trend towards setting up new mechanisms for issuing guidance on new technologies immediately after or before market entry. Several agencies have developed early warning or 'horizon scanning' systems to identify new and emerging technologies that might need urgent evaluation. NICE recently introduced STAs as a tool for 'fast-track' assessments. These programmes have been introduced to provide more timely information on important products. These programmes should be monitored and evaluated for effectiveness and the resulting impact on access to new technologies.
 - Assessments are only helpful if they are used to support decision-making. Relevant stakeholders should be involved in order to facilitate the acceptance and implementation of decisions. There must be a transparent and well-communicated decision-making process to give legitimacy to subsequent recommendations. The availability of relevant policy instruments and collaboration between national and international HTA bodies also facilitate effective and efficient implementation. Initiatives such as EUnetHTA should be supported to enhance the transferability, efficiency, and accountability of the HTA process.
 - In order to maintain the accuracy of assessments and ensure that the most valuable products are on the market, re-evaluation is a key component of the HTA process. It allows for new data to be considered as well as accounts of uncertainty during the initial valuation process. Often the data needed to confirm the cost- and clinical-effectiveness of a technology can only be found out after practical application in the market. This is particularly true of novel products and technologies undergoing 'fast-track' assessment. Systems should be created to allow for new clinical and health economic information to be introduced during the assessment process and following market entry. However, there must be protections so that re-evaluation doesn't lead to inefficiency, resource burden, and delayed access to treatments. It will be useful to monitor approaches such as the LFN in Sweden, where manufacturers are allowed to be on the market and collect effectiveness data to support their case after launch.

- Some limitations and areas of recommended future inquiry deserve mention. There is a lack of understanding (and evidence) about the 'real world' impact of HTA, not only on decision-making, but also on health outcomes, care delivery, health care costs, and research innovation. Several challenging questions remain regarding the circumstances surrounding the practical use of economic evidence in decision-making and priority-setting (*When is it specifically used? How are criteria applied in practice and how are they weighted against the broad spectrum of decision factors? For a given disease area or public health problem, has HTA appropriately and accurately identified interventions that have led to improved health outcomes? Has the use of HTA led to better managed health care budgets or a decrease in health care costs? Does HTA provide sufficient incentives to facilitate innovative research and development? Has this 'fourth hurdle' in the reimbursement process prevented manufacturers from investing in new and innovative therapies? How can HTA be more broadly applied?*). Clearly, more focused research in these areas is needed. Greater efforts should be made to set up a formal evaluation component in the HTA process. Only by securing a better understanding of the decision-making process and the practical application of HTA can the impact of economic evaluation be enhanced.

There is limited information on the use of HTA for identifying areas of de-investment. More research is needed to identify ineffective and obsolete technologies and interventions. While significant advances have been made on assessment methodologies, there is limited knowledge of (or publicly-available information on) how non-quantifiable factors are considered in the HTA process; this is especially true of equity concerns. Further exploration is needed to find out how such issues are taken into account in both assessment and subsequent decision-making, in order to address the social implications and constraints of efficient and equitable health care.

There is also a lack of research on the systematic assessment of public health interventions, especially those focused on prevention. Until now HTA has focused mainly on pharmaceuticals. The application of the principles and methods of economic evaluation to preventive measures should be further explored, in an attempt to move towards a more evidence-based approach to important population health issues (eg, obesity, smoking). Given the limited evidence on the economic evaluation of public health interventions, more research should be funded to identify what assessments have been done so far, and what they revealed.

Finally, the role of stakeholders in the HTA process is important, yet poorly understood. Existing evidence shows that stakeholder involvement can lead to greater transparency and relevancy and acceptance of decisions, but little attention has been paid to how they are involved in the assessment process and how and when their perspectives are considered. More studies should be supported on the role and influence of various stakeholders, especially patients and consumers.

In conclusion, HTA can play a valuable role in health care decision-making, but the process must include transparency, timeliness, relevance, depth, and usability. Assessments need to use robust methods and be supplemented by other important criteria in the decision-making process. By maximising the potential of HTA, decision-makers will be better able to implement decisions that capture the benefits of new technologies, overcome uncertainties, and recognise the value of innovation, all within the constraints of overall health system resources.

APPENDICES: SELECT COUNTRY CASE STUDIES

Sweden

Overview of health care and reimbursement systems

The availability of adequate health and medical care is a central tenet of the Swedish welfare state. As promulgated by the 1982 Health and Medical Services Act, equal access to health services and good health are cornerstones of the Swedish health care system²¹ (Glennard et al. 2005). Three primary principles underpin the provision of health and medical care in Sweden:

- Principle of human dignity
- Principle of need and solidarity
- Principle of cost-effectiveness

The principles are positioned such that human dignity takes precedence over the principles of need and solidarity; cost-effectiveness is subordinate to the other principles (Glennard et al. 2005). Such a priority scheme is reflected in national regulations and law.

In Sweden, health and medical care is considered a public sector responsibility²², with public ownership and political control, and is organised on three levels – national, regional, and local (municipalities). Together with a number central government bodies, the county councils²³ form the basis of the health care system. Overall goals and policies are established at the national level with the Ministry of Health and Social Affairs and the National Board of Health and Welfare, but the local authorities hold responsibility for the provision of health care, as required by the Health and Medical Services Act. Specifically, the county councils plan the development and organisation of services according to the needs of their populations and or providing publicly financed health care (Glennard et al. 2005). Accordingly, councils have a high degree of autonomy and power to make decision regarding a wide range of activities, including major investments in facilities, new technologies, user fees, and services provided by private practitioners (Carlsson 2004). The municipalities (289) are responsible for long-term care for the elderly (ie, nursing homes and housing) and social services (Glennard et al. 2005; Carlsson 2004). Moreover, local government has authority to introduce policies with regards to choice of providers, contracting, hospital mergers, new primary care models, and integrated care.

The Swedish health system is primarily funded through taxation. Both county councils and municipalities levy proportional income taxes (typically around 30%) on the population, in conjunction with state grants and user fees, to cover health care services (Glennard et al. 2005; Carlsson et al. 2000). The high tax rate allows for public financing of most health care services, including the majority of drugs costs.

Although the central government is characterised by decentralised power and responsibility for health care, it guides the overall direction of the system by ensuring that health care is efficient and in accordance with national objectives and the goals of social welfare policy. The actual responsibility of implementing and administering government policy lies with a number of central administrative bodies. One such entity, the Medical Products Agency (MPA) concerns the distribution, regulation, and financing of pharmaceuticals. In particular, the MPA is responsible for regulatory control of drugs and other related products, which includes providing information about medicines, approving clinical trials, and approving licenses (Glennard et al. 2005; Carlsson et al. 2000). In coordination, the Swedish national health insurance system is responsible for the financing of care under the auspices of the National Insurance Board, which also oversees price negotiations on pharmaceuticals (Carlsson et al. 2000).

Historically, following review of safety and efficacy by the MPA, a new therapy would undergo registration and pricing by the National Insurance Board and the product sponsor. Once a price was established, drugs were reimbursed through the health insurance system, typically without evaluation of its clinical value of relative cost-effectiveness (Carlsson 2004). However, in light of escalating drugs costs during the 1990s, the various mechanisms related to the distribution, pricing, and reimbursement of drugs underwent widespread scrutiny. Further, related discourse during that time focused on the need for more explicit priority setting, increased transparency related to access and quality, and greater opportunity for patient influence in decision-making. Consequently, in the late 1990s and early 2000s, Sweden passed several different reforms in an attempt to curb the increasing expenditures for pharmaceutical products (Glennard et al. 2005) (Figure 1). One such reform, the New Pharmaceutical Benefits Reform of 2002, was introduced to increase the cost-effective use of public-financed pharmaceuticals and to ensure drug benefits are equivalent across the country.

21 According to the Health and Medical Services Act of 1982, 'every county council shall offer good health and medical services to persons living within its boundaries', and 'promote the health of all residents'.

22 Approximately 80% of health services in Sweden are considered a public sector responsibility.

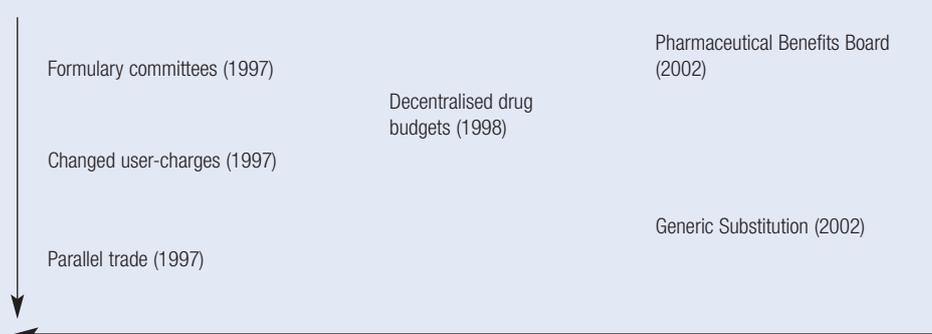
23 There are 21 county councils in Sweden, including three large regions (Stockholm, Skane region, and the west region), each with over 1.5 million residents (Carlsson 2004).

- 24 Drugs with new strengths are not required to be reviewed.
- 25 As of October 2002, any prescribed drug, which qualifies for a subsidy, is required to be exchanged for the cheapest comparable generic alternative available at the pharmacy. The Medical Products Agency, however, determines which drugs are exchangeable.
- 26 However, the SBU was formally established as a national agency in 1992, following an independent evaluation required by the central government. Subsequently, there was a significant increase in the SBU budget and demand for systematic reviews and other HTA activities.

As part of the reform, a new independent governmental agency, the Pharmaceutical Benefits Board (LFN), was established to meet this end, in addition to increasing the transparency of explicit priority-setting processes and equity of pharmaceutical benefits among the Swedish population (Pharmaceutical Benefits Board 2002). The introduction of the LFN significantly changed the principles of pricing and reimbursement of drugs in Sweden, in terms of basing decisions on cost-effectiveness data, as opposed to being automatically reimbursed within the benefit scheme (Anell & Persson 2005).

Figure 1: Principal reforms in the Swedish pharmaceutical market

Cost-effectiveness



Source: Adapted from Anell and Persson (2005).

The principal aims of the LFN are to determine if a new drug (or other medical product) should be included into the positive list for public reimbursement (ie, the National Drug Benefit Scheme), and also to set the price of the product, in negotiation with manufacturers (Zentner et al. 2005). Moreover, the LFN is responsible for reviewing already-listed drugs²⁴ to ascertain whether they meet certain criteria outlined by the 2002 Reform²⁵. A time frame of five years was delineated to review approximately 2,000 drugs (Zentner et al. 2005) (see the following section HTA process and procedures, for further details on the assessment process).

The LFN consists of one director and ten members, which are announced by the government every five years (Zentner et al. 2005). The Swedish government assigns four of the 10 members with special expertise in health economics to the board, and another four members with medical expertise are determined by the provincial parliament. Two additional members are representatives of consumers and patient groups. The actual review process is conducted by a group consisting of certain LFN members (ie, pharmacists, health economists), as well as two to four external medical experts, typically physicians and nurses.

In addition to central governmental structures, country councils have local formulary committees, which hold responsibility for making recommendations pertaining to the use of pharmaceuticals (Glennard et al. 2005).

Health technology assessment, governance, and organisation

Within the EU, Sweden has been on the forefront of HTA, as being one of the first countries to assess health technologies in the early 1970s (Carlsson 2004). The primary entity leading HTA, the Swedish Council on Technology Assessment in Health Care (SBU), was established in 1987²⁶. The primary objective of the SBU was not cost-containment, but to improve the efficiency and equity in access to and use of technologies proven safe and effective (Carlsson et al. 2000). As the focal point for HTA activities in Sweden, the remit of SBU is to provide the central government and health care providers with information on the overall value of medical technologies, especially new therapies, from medical, economic, ethical and social points of view (Glennard et al. 2005; Carlsson 2004). Specifically, the SBU reviews the benefits, risks, and costs of health technologies used in health care delivery (Glennard et al. 2005). In addition, it also assists in identifying areas in which further research is needed.

The SBU board consists of representatives from key health care organisations who set assessment priorities and organise HTA projects. For each assessment project, a multidisciplinary team, consisting of leading experts from Sweden and abroad, is recruited. Further, a number of county councils have formal links with the SBU, with a few financing local HTA units. The SBU recently established a formal agreement with the National Board of Health and Welfare and the Medical Products Agency aimed at improving cooperation within HTA activities in Sweden and improving guideline and information dissemination.

Besides the SBU, there are several other existing health assessment bodies at both regional and local levels, including the following²⁷:

- *Centre for Assessment of Medical Technologies (CAMTO) in Orebro* – established in 1999, the primary objective of CAMTO is to promote HTA at the local level. The Centre is comprised of a network of clinicians, experienced practitioners, and qualified researchers. Moreover, external experts often serve as consultants on study design issues and dissemination strategies. Overall, CAMTO conducts primary research, disseminates HTA results locally, and proposes new projects to the SBU.
- *Institute of Health Economics (IHE) in Lund* – established in the mid-1970s, IHE carries out economic evaluations and other related policy analyses. In addition, other activities carried out within the institute include independent method development, participation in scientific conferences/meetings, collaboration with external researchers on various health economics projects, coordination of commissioned courses and seminars. Most IHE projects are funded directly by stakeholders in the health care sector and resultant findings are mainly published in scientific periodicals by external publishers and other institutions.
- *Centre for Health Economics at the Stockholm School of Economics* – a well-respected international HTA body, the centre collaborates on several SBU projects.
- *Centre for Medical Technology Assessment (CMT) in Linkoping* – the objective of CMT is to carry out assessment studies of medical technology from various perspectives (eg, social, economic, ethical, medical). The majority of CMT activities are commissioned and funded by health care providers, international research foundations, and commercial clients.

HTA process and procedures

As it is too time and resource-intensive to review all existing technologies, it is necessary to prioritise the most policy-relevant technologies for assessment. To initiate this process, the SBU submits an annual report to the government outlining a review of work accomplished, plans for future work, and summaries regarding the evaluated and projected impact (Carlsson et al. 2000). In turn, the Ministry of Health notifies the SBU regarding national objectives, in accompany with the annual budget. National objectives are typically determined by the Ministry of Health, Swedish Parliament, and various health care organisations, and tend to be focused on broad health issues. Individuals, predominantly those working in the health field, also nominate topics for assessments.

Subsequent to topic nomination, the SBU sets priorities for assessment based on a two-fold process. First, SBU narrows down all possible options of assessment, which is typically achieved via an internal filtering process, comprised of scanning different fields of interest and devising a list of topics to be discussed among project coordinators and the SBU executive committee (Carlsson 2004). Second, a condensed list of options is presented to the SBU board, whereby the proposals are ranked and selected for pilot review. Pilot studies, which typically entail an extensive literature search of scientific literature, the Cochrane database, and other sources, serve to ascertain whether there is sufficient existing scientific evidence to warrant a full review. Following this phase, the SBU board makes a final decision based on the following selection criteria (Carlsson 2004; Carlsson et al. 2000):

- *Health impact* – topic should have significant impact on health outcomes, such as mortality and morbidity.
- *Breadth of health problem* – topic must relate to a common health problem, with significant economic consequences for society.
- *Societal and ethical considerations* – topic may have ethical and social implications, and be controversial or of great concern to the broader public.
- *Professional or organisational justification* – topic perceived importance should be demonstrable from an organisational or professional perspective (ie, technology may have potential to significantly alter clinical practice).
- *Methodological requirements* – types of methods required for the assessment.
- *Cost of technology* – expensive of technology, especially if the overall value is in question.
- *Technology relevance* – obsolete product that may still be extensively used.

²⁷ Although there are other HTA bodies within Sweden, this case study will predominantly focus on the SBU, as the leading HTA agency in the country.

In parallel to making a final determination, the board appoints a project chairman and an appropriate project team.

Since the 1990s, the SBU has predominantly relied on systematic reviews as its fundamental methodology used in assessments, as opposed to performing original research. Specifically, each project team, normally consisting of 10 members, conducts comprehensive assessments by systematically searching, selecting, reviewing, and evaluating available research findings. Prior to reviewing the evidence, however, projects teams establish criteria with which to review the available evidence. Typical criteria may include time to follow-up, participant dropout rates, and relevant end points (Carlsson 2004). Every study that meets the basic criteria is reviewed by at least two members of the project team and then classified into one of three quality and relevance levels – low, medium, and high. Besides the clinical aspects (eg, preventive, diagnostic, or treatment), each assessment contains an economic and, frequently, an ethical and social component. In light of reviewing the economic evidence, SBU project teams typically employ guidelines or standardised checklists to direct the review process (Carlsson 2004; Drummond et al. 1996). Such guidelines outline different evaluation criteria, including 1) study design (eg, clear relevance and associated hypotheses, analysis perspective), 2) selection of comparator(s) (rational and transparent justification for selection), 3) type of economic analysis (eg, cost-effectiveness, cost-benefit) and rationale for selected methodology, 4) breadth and quality of effectiveness data, 5) benefit measurement and valuation (appropriate outcome measures), 6) costing (methods of estimation and reporting of quantities and prices), 7) modelling (clear description and justification of any modelling, including key input parameters), 8) discounting (time horizon and discount rate provided), 9) allowance for uncertainty (sufficient consideration for uncertainty related to data inputs, extrapolation/modelling, analytical methods), and 10) presentation of study results (availability of disaggregated data, information regarding any incremental and comparative analyses, clear presentation of findings).

Once the evidence is systematically reviewed and results assembled, a draft report is passed to members of a selected committee who review the document. Subsequently, it undergoes review by the SBU board and a Scientific Advisory Committee. The board then provides final approval of a summary document and list of recommendations. All details of the assessment are presented in a comprehensive final report, termed '*Yellow Reports*'. HTA findings are monitored and updated as necessary.

The scope of assessments conducted at SBU can range from expansive, as in the case of wide-ranging health problems (eg, obesity), to more narrow, such as those evaluations addressing single interventions (eg, MRI) (Carlsson 2004). The former type of assessment (characterised by the aforementioned Yellow Reports), which was notably characteristic of evaluations in the 1990s, can take several years to complete. The duration required to complete such studies has been of concern, as the time lag may render the results irrelevant to the needs of policy-makers (Carlsson 2004). In response, the SBU instituted *SBU Alert* in 1997, a system for the early identification and assessment of new technologies. The SBU Alert aims to provide relevant, policy-oriented information on the potential impact of new technologies and to optimise their diffusion (Carlsson 2004). The Alert also functions to promote communications among both experts and non-experts on important health issues. To meet these ends, SBU Alert strives to identify relevant health technologies and assess their relative value and impact on care delivery, as well as ascertain areas for additional research. While based within the SBU, the Alert is a joint effort between SBU, the MPA, the National Board of Health and Welfare, and the Swedish Association of Local Authorities and Regions (SBU 2006).

The assessment process differs somewhat for early reviews within the Alert programme. First, new topics for assessment are identified via scientific sources, searching the EuroScan database for information from other early warning units, and requests from medical experts and policy-makers (Carlsson 2004). Potential topic proposals on new technologies are reviewed by staff and decided upon by the board, employing the following selection criteria (Carlsson 2004):

- Significant economic consequences
- Possesses ethical implications
- Considerable impact health care organisation
- Potential for medical breakthrough
- Concerns a significant patient population or affects a common health problem

Typically, an early review assessment involves one external expert and one SBU reviewer. Information is collected and synthesized on the new technology and its associated effectiveness, risks, cost-effectiveness, ethical and social concerns, and organisational impact.

To provide timely information to key stakeholders, SBU produces, in collaboration with experts, brief assessments (*Alert Reports*) that are published on the internet for review and comment, followed by any necessary revision. Moreover, a network of approximately 4,000 health care professionals receives the aforementioned information (Carlsson 2004).

SBU also develops special topic papers (*White Reports*) that explore health care problems or interventions that may need to be assessed (SBU 2006). The documents serve as the starting point for future systematic literature reviews. White Reports are reviewed by project groups and external experts only.

As of 2005, SBU has published more than 120 reports. To date, assessment reports include the following:

- Stroke (1992)
- MRI (1992)
- Prostate cancer screening (1995)
- Oestrogen treatment (1996)
- Smoking cessation methods (1998)
- Back pain (2000)
- Colorectal cancer screening (2002)
- Obesity (2002)
- Moderately elevated blood pressure (2004)

In terms of the LFN, appraisal priorities are established by sales volume in each therapeutic group. For each appraisal, the board considers the three basic principles that underpin the Swedish health care system in all related decisions. In addition, it bases decisions on both the cost-effectiveness and marginal utility of products (Anell & Persson 2005). In April and June 2004, the LFN published Working Guidelines for the evaluation of already approved drugs, as well as general pharmacoeconomic guidelines.

The LFN primarily reviews clinical and economic evaluations submitted by manufacturers as part of their application package for reimbursement for a specific product, as opposed to particular medical indications (Zentner et al. 2005; Glennard et al. 2005). (*For further detail on evidence requirements and assessment methods, see Table 3.*) However, the board can make exceptions and decide that reimbursement for a drug should be allowed for a certain indication or patient sub-group. Consequently, the LFN may allow reimbursement for a more limited indication than the drug was originally licensed for market approval by the Medical Products Agency. Prior to substantiating a final recommendation, however, manufacturers as well as the Swedish Parliament are afforded an opportunity to provide input before the LFN regarding the resultant decision(s). If the manufacturer is still dissatisfied with the final decision, it can appeal to an independent court (Anell & Persson 2005). Between 2002 and 2005, the LFN reviewed and made decisions on 107 products, with the majority approved with unconditional reimbursement (Anell & Persson 2005)²⁸.

HTA dissemination and implementation

The SBU findings are disseminated through a variety of channels, depending on the relevant target group(s), which include health care managers, patients, purchasers, quality improvement teams, country drug review committees, and other decision-makers at regional, county, and municipal levels. Such delivery mechanisms include the SBU newsletter (over 100,000 copies per issue), the SBU website, medical and academic journals, and professional conferences, seminars, and trainings. In addition, on a regional level, SBU collaborates with the National Board of Health and Welfare, MPA, LFN, and a range of professional health care and insurance organisations to effectively implement the findings of SBU assessments. Effective dissemination and implementation also requires local involvement. To meet this end, SBU has organised a network of local 'ambassadors', represented by various experts, across Sweden to initiate and promote local (and, frequently, regional) efforts to help assure that reports are used by decision makers and that the findings are applied in clinical practice (SBU 2006; Carlsson et al. 2004).

The findings from SBU assessments and manufacturer-sponsored economic evaluations (in the case of the LFN) are used to inform decisions and priority-setting activities primarily related to reimbursement, pricing, and clinical policy and practice via the promulgation of guidelines. For instance, the LFN typically makes decisions regarding the inclusion or exclusion of new drugs into the benefit package within a 12-month review process. As of the end of 2003, the LFN has made reimbursement decisions on the following therapeutic groups: migraine medications, antacids, anti-hypertensives, asthma medications, anti-depressives, cholesterol-lowering medicines, pain relief and anti-inflammatory medications, and anti-diabetics (Anell & Persson 2005).

²⁸ Of note, there may be other products that were not included on the LFN website; moreover, sponsors may withdraw submissions before a decision is made on behalf of the LFN.

Medications to treat prostate disease, incontinence, and gynaecological problems are planned for the future (Zentner et al. 2005). In general, drugs are reimbursed without conditions when cost-effectiveness and marginal benefits compared with competing alternatives have been established (Anell & Persson 2005). However, some drugs with poor cost-effectiveness are covered if the disease is severe (with a small patient population) or there is a lack of treatment alternatives (eg, orphan drugs).

In addition to other central government and assessment bodies, the National Board of Health and Welfare is involved in employing the results of assessments to develop evidence-based guidelines (Glennard et al. 2005). The board provides guidelines to the government with the overall objective of contributing to the effective use of health care decisions, within the constructs of health need and an open and transparent priority-setting process. The guidelines include recommendations or decisions on priority-setting, and provide national support to assist health care decision-makers (primarily politicians, civil servants and administrators, and providers) in determining effective models of treatment delivery. Specialist associations frequently collaborate with the board in the development of guidelines and recommendations.

The board typically publishes three versions of each guideline – one each for health care decision-makers, health care providers, and patients. As directed by the government, the board must report on the projected impact of the guidelines on the practice of medicine (National Board of Health and Welfare 2003). However, despite the participation of clinical and economic experts on the board, there is no direct link with county councils (who are responsible for regional health care systems), which may limit the ownership and implementation of guidelines. As of 2006, guidelines have been developed or are currently under way regarding cardiac care, cancer (three most common forms), stroke, venous thrombosis, chronic obstructive pulmonary disease, alcohol and drug abuse, and depression and anxiety (Glennard et al. 2005).

Due to Sweden's decentralised health care system, it is difficult to ascertain the true impact of HTA on decision-making and priority-setting. While there is a clear process for the dissemination of results, a more complex picture emerges in terms of how such information is used in both national and local decision-making. On a national level, there is evidence that certain SBU reports (eg, stomach pain, smoking cessation) have had an impact on clinical guidance and practice, and facilitated greater support for HTA (Carlsson 2004). In terms of coverage decisions, a review of the LFN by Anell & Persson (2005) suggests that health economic evaluation, particularly information on cost-effectiveness, can support decision-making related to reimbursement. Overall, however, the percentage of reimbursement decisions to date supported by substantial health economic evidence has been minimal. Rather, the majority of LFN decisions concern price changes on already-listed drugs, which normally do not require the support of economic evaluation. Moreover, health economic evidence appears to have the most significant impact on coverage decisions regarding those drugs with broad use (thus, large potential budget impact) and when cost-effectiveness varies by indication or patient sub-population. In these cases, the LFN relies more heavily on detailed health economic analyses from manufacturers. Perhaps the LFN will increasingly rely on health economic evidence to support decision-making when reviewing the remaining groups of medicines.

On a local level, assessments are most effectively used for decisions on resource allocation and treatment guidelines at both the intermediate (eg, hospitals) and clinical levels (Carlsson 2004). Moreover, coverage decisions set by the LFN influence recommendations put forth by local formulary committees. However, as county councils have responsibility for drug expenditures and most local formulary committees lack health economic expertise, many coverage decisions set at the local level are more restrictive than decisions made by the LFN (Anell & Persson 2005). To that end, national and local decision-making tends to be uncoordinated.

In addition to this, other factors influencing the impact of assessments in decision-making include the length of time required to complete systematic reviews and evaluate manufacturer data (in the case of PBB), attitudes among policy-makers regarding economic information, and the fact that HTA results can be complex and not always clear from a policy perspective (Carlsson 2004). Moreover, as is a general problem for HTA, there are limited funds and researchers in a small country like Sweden, which restricts the ability to address the large number of unevaluated technologies. However, Sweden strives to ameliorate resource issues by strengthening international collaboration on HTA activities. Specifically, the SBU participates in a number of international endeavours, including the EUR-ASSESS, HTAi, EuroScan, and the European Collaboration Network on HTA. Moreover, the LFN collaborates with the SBU on reviews undertaken for groups of drugs. In fact, Sweden is one country in particular where there is significant collaboration between the HTA and reimbursement agencies.

Table 3: Overview of HTA governance, processes, and role in decision-making in Sweden

Sweden	
HTA governance and organisation	
Institution/committees	Pharmaceutical Benefits Board (LFN) – Reimbursement and pricing decisions National Insurance Board – pricing decisions Swedish Council on Technology Assessment in Health Care (SBU) – primary national HTA body Ministry of Health/National Board of Health and Welfare – oversees the aforementioned institutions; NBHW issues health care guidelines
Entity responsible for reviewing HTA evidence for priority-setting and decision-making	LFN Various health care decision-makers utilize SBU reports.
HTA agenda-setting body(s)	Predominately, the Ministry of Health and Swedish Parliament.
Areas for HTA	New approved and already reimbursed prescription drugs.
Reimbursement requirements and limitations	Reimbursement depends on yes/no decision for inclusion on positive list. In exceptions, conditional coverage given for particular application areas or conditions.
Stakeholder involvement	LFN Board – health economists, medical experts and professionals, representatives of consumer and patient groups. SBU – health care providers, health economists, representatives from health care organisations.
International collaboration	Secretariat of the International Network of Agencies for HTA located at SBU; SBU participation in EuroScan, HTA-related trainings and conferences, EUnetHTA, HTAi, and, WHO Health Evidence Network; SBU also collaborates on multinational projects, mainly at the Nordic and European levels.
HTA topic selection and analytic design	
Governance of topic selection	Ministry of Health, Swedish Parliament, various health care organisations, health experts, and SBU Board.
Criteria for topic selection	SBU: - Health impact - Breadth of health - Societal and ethical considerations - Professional or organisational impact - Methodological requirements for assessment - Cost of technology - Technology relevance LFN: Based on manufacturer submission and/or sales volume in each product group.
Criteria for assessment	Therapeutic benefit, patient benefit, cost-effectiveness, availability of therapeutic alternatives, equity considerations.
Criteria outlined or publicly-available	Yes
Analysis perspective	Societal
Duration required to conduct assessments	3-4 years for broad health issues, shorter period for single indications or products (typically, up to 1 year).

29 Section applies primarily to the LFN.

30 N/A=not available

Table 3 (continued)

Evidence requirements and assessment methods ²⁹	
Documents required from manufacturer	Yes, LFN requires a summary of up-to-date scientific knowledge, including references, clinical and health economical studies (with modelling, if applicable). Moreover, manufacturers must present data on actual prescription volumes.
Systematic literature review and synthesis	Yes
Unpublished data/ grey literature	Yes
Preferred clinical study type/evidence	RCT
Type of economic assessment preferred or required	Cost-benefit-value analysis, cost-benefit analysis, cost-minimising analysis with constant health status.
Availability of guidelines outlining methodological requirements	Yes
Choice of comparator	For new pharmaceuticals, required to use 3 well-defined comparators. Typically, routine practice, non-medical intervention, and do-nothing. For positive list approval, compares product with all drugs in a therapeutically group – oriented on the second and fourth level of the WHO ATC classification.
Specification of outcome variable	Morbidity, mortality, life quality (QALY), and willingness to pay (WTP). Preference is given to measures under daily conditions or routine treatment.
Sub-group analyses	Yes, for sex, age, disease stage or severity, co-morbidities, risk factors, and treatment strategies (eg primary/secondary prevention).
Costs included in analysis	Direct and indirect costs; pharmaceutical costs established on basis of pharmacy costs.
Incremental analyses required	Yes
Time horizon	Period within main differences of health effects and costs appear.
Equity issues	Equity considered in decision-making, but not stated how accounted for in the analysis.
Discounting	Costs and benefit: 3%, sensitivity analysis: 0% and 5%, as well as 3% for costs with 0% for benefit.
Modelling	Yes, performed by companies and institutions.
Sensitivity analyses	Yes, for central assumptions.
Cost-effectiveness or willingness-to-pay threshold	No formal threshold, but likely ranges between £25,000-£40,000 employed.
Missing or incomplete data	Reported problems with poorly presented sponsor data.
Support for methodological development	N/A ³⁰

Table 3 (continued)

HTA dissemination and implementation	
Channels for HTA results dissemination	Yellow, White, and Alert Reports, SBU newsletter, professional conferences, seminars, and courses, academic journals, and via guidance.
Use of HTA results	Reimbursement, pricing, and health care delivery (via guidelines)
Evidence considered in decision-making	Severity of condition, evidence of effectiveness, cost-effectiveness, price, and equity.
Any reported obstacles to effective implementation	Decentralised decision-making structure, HTA results not always clear from a policy perspective, attitudes regarding economic information in decision-making/priority-setting, time required to complete systematic reviews and evaluate manufacturer data (in case of LFN).
Formal processes to measure impact	No formal process, but has participated in the EUR-ASSESS project, which studies the effect of HTA on coverage policy decisions.
Processes for re-evaluation or appeals	Yes, after a preliminary decision is made, sponsor representatives have the opportunity to present their arguments directly to the PBB. If the manufacturer is still dissatisfied with the final decision, it can appeal to an independent court.
Accountability for stakeholder input	Stakeholders are able to comment on SBU Alert reports once published on the internet, but must hold a subscription to the service.
Transparent/public decision-making process	LFN: Board's decisions are outlined in a document available on the LFN website, which includes arguments for each decision.

Source: Anell & Persson 2005; Zentner et al. 2005; Carlsson 2004; OECD 2003; ISPOR 1999.

31 In 1996, pharmaceuticals in the health benefits package were evaluated on the basis of need and effectiveness, in order to streamline and improve the quality of the overall package. The process resulted in the removal of a significant number of pharmaceuticals (as of April 1996).

32 The level of reimbursement is based on the average price of pharmaceuticals in a comparable group.

The Netherlands

Overview of health care and reimbursement systems

While every Dutch citizen in the Netherlands is entitled to health care, as set forth by the Constitution and founded on social insurance principles, the system is not centralised around political and governmental spheres. Rather, the health care system is characterised by a complex array of institutions, regulations, and responsibilities (Bos 2000). In the Netherlands, health care processes are organised and sustained within the purview of central and regional authorities, as well as private entities. Specifically, public health care, the control of infectious disease, environmental protection, and the regulation of health care professionals, forms an integral part of the central government, particularly the Ministry of Health, Welfare, and Sports (den Exter et al. 2004). In terms of health care provision, however, service delivery typically rests with independent practitioners or non-profit service organisations (Stolk & Rutten 2005; Bos 2000). Consequently, health care in the Netherlands consists of an interdependent mix of public and private initiatives under the umbrella of the central government. On a macro level, this translates to collaborative and interrelated policy processes and decision-making across public, private, and professional stakeholders.

The public-private interplay of responsibility and decisional power also extends to the financing of health care. In the Netherlands, a compulsory national health insurance scheme was implemented in 1996, with the passage of the Sickness Fund Act (den Exter et al. 2004). As part of the social security system, the sick fund historically covered about 63% of the population, while the remainder were insured through a similar social insurance scheme (for employees of provincial and municipal governmental bodies) or private plans (den Exter et al. 2004). However, as of January 2006, statutory and private health insurance integrated into one comprehensive package, the *basisverzekering*, or 'basic health care insurance policy', which now covers 100% of the population under national health insurance. National health insurance covers all acute care provided by hospitals, general practitioners and specialists, all costs of drugs and appliances, and transportation. As of 2004, there are 22 sick funds, all overseen by the Health Care Insurance Board (den Exter et al. 2004). The board represents government, employers, employees, insurance funds, health care institutions, and health professionals.

One responsibility of the Ministry of Health, Welfare, and Sport is to implement the pharmaceutical policy of the Dutch government, which is guided by the principle of safe and affordable pharmaceutical care for all. As the quality and appropriate use of pharmaceuticals is integral to public health protection, access to the market is evaluated and regulated by the Medicines Evaluation Board (under the auspices of the Medicines Evaluation Board Agency). Specifically, the board registers new pharmaceuticals based on evidence of quality, safety and efficacy (Stolk & Rutten 2005).

Historically, registration of a product by the board resulted in practically automatic reimbursement by health insurance bodies (den Exter et al. 2004). However, in attempts to control costs and assure equitable access to pharmaceutical care, the ministry has increasingly required evidence of cost-effectiveness prior to admission in the benefits package (positive list) covered by the sick funds. Conversely, the government can remove ineffective or obsolete pharmaceuticals from the package³¹. Under the Pharmaceutical Pricing Act of 1996, the government also sets the prices of pharmaceutical products.

As indicated above, not all registered drugs qualify for reimbursement. In particular, pharmaceuticals are only reimbursed by the sick fund if they are admitted onto the positive list. The positive list consists of two sections, one that includes a reference price system³² with groups of substitutive pharmaceuticals (Schedule A) and one that entails a list of drugs without alternative (Schedule B) (Figure 1) (Stolk & Rutten 2005)

Figure 2: Reimbursement decision process



To the former, pharmaceuticals are included in this part of the positive list if they are a substitute for already existing drugs. In the Netherlands, it is mandated that medicines be merged together in one group (termed a 'cluster'), if they address similar indications and a comparable method of administration, with no clinically relevant differences in their properties (Stolk & Rutten 2005). Presumably, there is at least one medicine in each group that is fully reimbursable.

If there is no available appropriate and mutually replaceable substitute for a new pharmaceutical (therefore, the reference price system does not apply), manufacturers can apply for an evaluation by way of the Ministry of Health, Welfare and Sport³³ (Zentner et al. 2005; den Exter et al. 2004). The assessment is conducted by the Committee for Pharmaceutical Aid (CFH), the body responsible for valuing pharmaceuticals and providing recommendations to the ministry regarding the positive list (see the following section *HTA process and procedures*, for further details on the assessment process). If the CFH recommends that a product be included on the positive list and is subsequently supported by the ministry, then it is included in the second section of the positive list and, thereby, reimbursed³⁴. Reimbursement conditions for the positive list are uniform to payers, both public and private (Stolk & Rutten 2005). While the majority of products are fully reimbursed, limits can be set to reimbursement. For example, reimbursement may be restricted to a particular patient population or use by a certain medical specialty.

The CFH is part of the Health Care Insurance Board and consists of 18 members, representing pharmacists, specialist physicians, economists, psychologists, epidemiologists, and representatives of the ministry (Zentner et al. 2005). Depending on the particular assessment, external medical experts are involved in supporting the assessment process.

Health technology assessment, governance, and organisation

The use and visibility of HTA in the Netherlands has grown over the last 20 years, primarily as a result of expansions in health technology, growth in health care costs, and a subsequent increase in regulation of medical products (den Exter et al. 2004). In particular, throughout the 1980s, there was increased pressure from politicians and policy-makers for systematic evaluation of new medical technology to support decision-making and improve health care status and provision. In fact, the Health Insurance Council³⁵ promulgated that all new technological innovations undergo cost-effectiveness analysis prior to determination of coverage in the benefit package (Berg et al. 2004). Moreover, there was a push to institutionalise HTA and improve coordination of assessment activities throughout the Netherlands. Subsequently, three influential advisory bodies – the Health Insurance Council, the Health Council, and the National Council for Public Health – acted together to create a National Fund for Investigative Medicine³⁶ (den Exter et al. 2004). Established in 1998 and administered by the Dutch Health Research and Development Council (formerly overseen by the Health Insurance Council), the primary aim of the Fund was to finance original research in support of scientific excellence and evidence-based policy-making (Berg et al. 2004; Bos 2000). Such inquiries included the evaluation of new and existing medical technologies, including the associated cost-effectiveness, and social, ethical, and regulatory implications, as warranted by the particular policy question or decision required (Bos 2000). In essence, the Fund served as the national HTA programme, supported primarily by the Ministries of Health, Welfare, and Sport and Education, Culture, and Science (Berg et al. 2004). However, the Fund was recently replaced by the Netherlands Organisation for Health Research and Development (ZonMw), which constitutes a merger between the Netherlands Organisation for Scientific Research (NWO) and the (previous) Netherlands Organisation for Health Research and Development (ZON) (*See below for further information*).

Subsequent to the creation of the Fund, there were several pivotal reports on streamlining the benefits package and improving the appropriate use of medical products, which further served to substantiate the role of HTA in the Dutch health care system (Berg et al. 2004; den Exter et al. 2004). More recently, the Dutch Parliament has become increasingly interested in HTA and has requested status reports on the state of such activities from the Minister of Health (Banta 2003).

Supported by the government, one of the primary institutions involved in economic evaluation is the Health Council of Netherlands. Established in 1902, the Council is an independent statutory body that advises the government (ministers and Parliament) on medicine, health care, public health, and environmental issues (Berg et al. 2004). To meet this end, the Council assembles experts (approximately 200) from various medical specialties and scientific disciplines to contribute to standing and ad-hoc committees on specific topics, at the request of government (Health Council 2006). More specifically, the committees typically evaluate the effectiveness, efficiency, safety, and availability of health interventions. Some committees may also specifically examine epidemiologic and economic aspects, as well as associated ethical, social, and legal issues.

33 Manufacturers must explain for which part of the positive list the proposed pharmaceutical seems to be qualified.

34 Since 1999, new drugs that are higher priced than existing substitutes may be reimbursed if efficacy and effectiveness requirements are satisfied. Moreover, since 2005, a pharmaceutical coeconomic study and budget impact analysis is formally required or a new drug with a premium price.

35 Name was changed to the Health Care Insurance Board.

36 Prior to the development of the Fund, the three Councils advised the Dutch government that HTA should be viewed and utilized as an important aid to decision-making. Moreover, the Health Council delineated an ideal system for HTA and how such evaluation could be employed to improve the effectiveness of policy decisions.

The committees comprise both Council members and external experts. At any given time, there are approximately 40 to 50 committees, with an average of 10 experts each (Health Council 2006). The composition of each committee reflects the need not only for appropriate scientific expertise, but also to ensure a multidisciplinary perspective.

In addition to advising the government of specific health concerns, the Council also serves an 'alerting' function, which provides unsolicited advice on various topics and related ministerial policy. The interests and activities of the Council are quite broad, ranging from issues related to health prevention and treatment (eg, cochlear implants for children, bioterrorism, and immunisation), nutrition, and environment (eg, radiation). While the Council undertook work specific to health technology assessment (primarily via an *Interim Central Committee on Medical Technology Assessment*) during the late 1990s and early 2000s, such activities were significantly reduced in 2003 due to lack of funding (Health Council 2005). However, in a report published in mid-2005, the Council recommended that projects specific to HTA be increased and supported. The Council is funded entirely by the Dutch government, with budget contributions made from various relevant Ministries.

In addition to the Council, there are several other organisations in the Netherlands involved in HTA activities, including the following (Berg et al. 2004; den Exter et al. 2004; Bos 2000):

- *Netherlands Organisation for Health Research and Development (ZonMw)* – is the national health council appointed by the Ministry of Health and the NWO. The mission of the ZonMw is to promote quality and innovation in health research and care. To that end, it is responsible for the programming, priority-setting, and the actual allocation of government funds for research projects in the field of health care and prevention. In particular, the ZonMw Health Care Efficiency Research programme actively supports cost-effectiveness studies and implementation research, with an annual budget of €12.2M. The programme covers diagnostics, therapy and care, and organisations in all medical and paramedical disciplines, focusing on services covered by health insurance.
- *Netherlands Organisation for Scientific Research (NWO)* – a statutory organisation with the primary goal of improving the quality of health-related research in the Netherlands. The NWO acts as a national general research council, playing a significant role in the development of science, technology, and culture, including the medical sector. Over the last 20 years, the NWO has supported several initiatives and projects on HTA.
- *Council for Public Health and Health Care (RVZ)* – instituted in 1995, the RVZ is an independent body that advises the government on public health and care. The council primarily issues advisory reports on governmental health care policy, covering prevention, health protection, general health care, elder care, and the disabled. Moreover, the reports cover various aspects of policy, including insurance, planning, financing, training, and patient rights.
- *National Institute for Health and Environmental Hygiene* – the institute engages in a number of activities related to technology assessment, with the outstanding task of evaluating and monitoring vaccines. Another activity is the evaluation of certain medical devices; in particular, those requiring sterility.
- *Netherlands Institute of Primary Health Care* – an independent, non-profit research body, the institute has broad expertise in health services research, including technology assessment on such topics as quality systems, home care technologies, and the evaluation of professional procedures. The Board of Governors is represented by health care providers, health insurers, patients/consumers, and academics.
- *Netherlands Organisation of Applied Scientific Research (TNO)* – the foremost institute with a focus on biomedical technology in the Netherlands. While the institute's assessment activity is fairly limited, it does engage in the evaluation of medical devices and is actively involved in coordinating HTA projects on an EU-wide scale (Bos 2000). The evaluation activities of the TNO predominantly focus on the policy aspects of technology development and diffusion, home care technology, and minimally-invasive therapies. TNO also has an established programme on preventive medicine that has issued various HTA reports.
- *National Organisation for Quality Assurance in Hospitals (CBO)* – an organisation active in both quality assurance and technology assessment. In particular, it plays a significant role in consensus and guideline development.

- *Various academic institutes* – Erasmus University in Rotterdam plays the most prominent role in HTA among the academic community in the Netherlands. Within the university, iMTA is the largest group dedicated to HTA. The primary focus on its research is on economic evaluation of health technologies, as well as on quality assessment of health care. Many projects are carried out in collaboration with health care providers, particularly hospitals, affiliated with the Fund for Investigative Medicine. The Department of Public Health and the Centre for Health Policy and Law are also involved in HTA-related activities.

Beyond Erasmus University, the Department of Health Economics at the University of Limburg is also involved in HTA activities. Moreover, virtually all medical faculties and university hospitals in the Netherlands are to some extent involved in HTA endeavours.

While the aforementioned organisations provide the driving force behind many HTA activities, there are several smaller organisations undertaking such efforts. Consequently, HTA in the Netherlands is not concentrated to or directed by one national research and policy organisation, as it is in other EU countries, such as Sweden. Rather, many different entities, with often divergent research agendas and traditions, must come together to support national policy and priority-setting activities. While coordination among those bodies historically organised around the fund has moved toward improved integration, better cooperation and harmonisation is needed.

HTA process and procedures

Although there are adequate resources for HTA, it is still insufficient to evaluate all new and existing health technologies. As a result, there has been increased focus on setting priorities in HTA, in order to capitalise on its potential to improve the efficiency and quality of health care in the Netherlands.

In the early days of the Fund, most assessments were based on proposals focusing on new, high-cost, sophisticated therapies, with minimal concern for existing technologies (Bos 2000). In relation, the submission, selection, and funding of projects often lacked direct links to areas of health care of greatest concern or those most underdeveloped. Another shortcoming was that few evaluations examined the social, ethical, and legal implications associated with health technology (den Exter et al. 2004). Consequently, there was a significant disconnect between most HTA research and health care need and policy development and decision-making. Concerns over such methods of priority generation led to efforts to make the process more explicit and rational, and to incorporate both social and scientific criteria in the determination of HTA priorities (Berg et al. 2004). As a result, throughout the 1990s, the primary organisations involved in the identification and setting of priorities for HTA (eg, Health Care Insurance Board, Health Council, and Council for Health Research) underwent formal processes to identify technologies or areas of health care in need of assessment³⁷ (Oortwijn et al. 2002). The technologies were then ranked according to a range of criteria: *degree of uncertainty concerning efficacy and effectiveness, frequency of use, costs, impact on morbidity, mortality, and quality of life, and rate of use of the technology* (Berg et al. 2004). Priority topics for evaluation included ultrasound therapy, treatment for urinary incontinence, long-term psychotherapy, and diagnostic testing.

At present, research proposals are submitted to the Health Care Insurance Board for evaluation. In order to advise the Minister of Health on funding of proposals within the Fund, the proposals are reviewed by members of the Committee for Investigative Medicine and the board. Specifically, the reviews independently evaluate, rate, and score the policy relevance of the submitted proposals based on a variety of objective criteria, including the following³⁸ (Oortwijn et al. 2002):

- Actual burden of disease, given current treatment strategies for the individual patient
- Potential benefit for the individual patient
- Number of patients
- Direct costs of the intervention per patient
- Financial consequences of applying the intervention over time (impact on total costs of health care)
- Additional aspects with an impact on health policy (eg, potential rate of diffusion).

Proposals categorised as having intermediate to high policy relevance are sent to the Council for Health Research for appraisal of scientific quality (Oortwijn et al. 2002). Following these processes, the decision is made to either accept or decline the proposal is made, or alternatively, to allow researchers to revise and resubmit to the Fund.

37 Formal process typically took the form of expert consultation and topic nomination, prioritization via a Delphi-based process, further ranking, and creating lists of nominated HTA subjects.

38 Researchers submitting proposals are explicitly requested to provide information about the policy relevance of the proposed project. Moreover, the reviewers apply a standardized weighing system to the selection criteria to rate and score each proposal.

With regards to the Health Council, priorities for assessments are based on both requests from ministries and the Parliament, as well of its own volition. Topics for further assessment and funding are generated through a variety of mechanisms, including direct inputs from the ministry or input from expert working groups that formulate funding programmes. The various priority lists, as previously described, help shape these agendas as well.

In addition to the publication of advisory-type reports requested by government, the Health Council's remit includes 'horizon scanning'. The goal of horizon scanning is to proactively draw attention to the health issues and developments that may be of relevance to government policy and associated agenda-setting (Health Council 2005). The Council's primary scanning activities focus on preventive and curative health care, nutrition and food quality, environment and health, and work and health. With regard to preventive and curative health care, the Council's secretariat participates in EuroScan to identify significant emerging health technologies. Another important aspect of horizon scanning involves the identification of ethical and legal aspects of public health-related scientific developments that may have policy implications.

The various assessment and research organisations in the Netherlands have completed numerous HTA assessments and research each year, primarily based on extensive literature review (eg, systematic literature review, meta-analysis) and consultation with experts groups (Bos 2000). In general, the Health Council and Health Care Insurance Board publish some 20 to 30 reports annually. The range of assessments is quite expansive, as illustrated by the following examples (Health Council 2005; Bos 2000):

- Use of biosynthetic human growth hormone treatment (*Health Care Insurance Board*)
- Use of lung transplantation (*Health Care Insurance Board*)
- Use of diagnostic imaging techniques for back pain (*Health Care Insurance Board*)
- Extra-corporal membrane oxygenation treatment in neonates (*Health Council*)
- Cholesterol-lowering therapy (*Health Council*)
- Silicone breast implants (*Health Council*)
- Nanotechnologies (*Health Council*)
- Use of antiviral agents and other measures in an influenza pandemic (*Health Council*).

In terms of the CFH and pharmaceutical review, as aforementioned, new drugs that cannot be substituted may be reimbursed, but only if efficiency and effectiveness requirements are satisfied. To meet this end, manufacturers provide the CFH with evidence to support the valuation process, including systematic literature reviews or meta-analyses, clinical studies, and pharmacoeconomic evaluations (with modelling, if appropriate), consensus guidelines, and prescription data (Zentner et al. 2005). In addition, manufacturers typically choose the comparator in accordance with pharmacoeconomic guidelines and may discuss the selection a priori with the relevant assessment body (For further detail on evidence requirements and assessment methods, see Table 4). Subsequently, the CFH assesses new medications compared with the relevant positive list on a range of criteria, including the following (Zentner et al. 2005):

- Therapeutic value
- Patient benefit
- Cost-effectiveness
- Financial impact, in terms of the benefits package, the pharmaceutical and health budgets, the sick fund, and Dutch society.

The therapeutic value and patient benefit is determined in comparison with standard or usual therapy. In order to evaluate the relative therapeutic benefits, the CFH employs several criteria that are regulated by law. In particular, the evaluation considers efficacy and effectiveness, and potential use of a product. To the latter, CFH categorises product use into three classifications (measured by number of prescriptions over time) (Zentner et al. 2005): satisfactory, broad, and limited. While there is a preference for either satisfactory or broad use, limited application of a drug does not necessarily result in a negative valuation, especially in cases where the comparator is more expensive. Other relevant criteria include the availability of therapeutic alternatives; disease severity; target patient population; the mode, frequency, and comfort of drug delivery; and, the impact on the quality of life (Zentner et al. 2005). While all criteria are important, efficacy, effectiveness, and side effect profile are considered with greater weight. Alongside, whether the product is a breakthrough therapy or the only available treatment are critical factors in determining additional therapeutic benefit (Zentner et al. 2005). Other criteria, such as affordability and 'leakage' (the use of a product beyond the delineated patient group), are gradually considered in reimbursement decisions (Stolk & Rutten 2005).

Beyond assessing the clinical value of a drug, the CFH requires an economic evaluation (ie, cost-effectiveness or cost-benefit analysis) for those pharmaceuticals that provide a therapeutic benefit, as claimed by the manufacturer. Moreover, as of 2005, new drugs with a price premium are formally required to undergo economic studies and budget impact analyses (Health Care Insurance Board 2005). Such studies should be carried out and submitted by the manufacturer. In 1999, the Health Insurance Board issued pharmacoeconomic guidelines to standardise such research across the Netherlands, more broadly, and among manufacturer applications for inclusion into the benefits package, in particular (Zentner et al. 2005).

Of note, two areas of pharmaceuticals are exempt from the standard valuation process as previously described. According to the decision of the Ministry of Health, Welfare and Sport, orphan drugs (treatments for conditions of low prevalence, typically <5 per 10,000) are not obliged to undergo economic evaluation (Health Care Insurance Board 2005). In addition, an expedited appraisal process exists for those drugs that treat life-threatening illnesses (ie, therapeutic breakthrough), and drugs that are the only available therapy for a given condition.

Based on the appraisal, CFH sets out its recommendations in an assessment report that is published on the internet and provided to the minister. If the CFH recommendation is supported by the ministry, then it is included in the second section (Schedule B) of the positive list.

HTA dissemination and implementation

In general, the types of activities that employ the results of assessments entail the following applications (Bos 2000):

- To address knowledge gaps on innovative technologies and to disseminate this knowledge to relevant stakeholder groups.
- To decide on the coverage or reimbursement of technologies in the benefit package (in the case of the CFH).
- To define or redefine the established indications for a technology, in order to promote its appropriate use.
- To establish guidelines for use, in attempts to reduce significant and/or unexplained practice variations.
- To underpin planning and regulation in terms of priority-setting or estimating the future need for a health technology.

While the economic assessments submitted to and reviewed by the CFH are used for reimbursement and pricing decisions, the predominant use of HTA regarding the Health Council is directed toward priority-setting and the production of guidelines. The reports produced by the Health Council are presented to the Minister of Health, who subsequently assumes responsibility for their implementation. To help facilitate the process, all reports contain recommendations or guidance for implementation of the assessment results (Bos 2000). Several reports have indeed resulted in the development of practice guidelines. For example, regarding preoperative routine screening, the effectiveness and appropriateness of auxiliary tests (eg, x-ray, ECG) was established through assessment, and the subsequent result formed the basis for new practice guidelines (Bos 2000).

Beyond providing reports directly to the minister, the Health Council employs a number of different channels to disseminate assessment results. In particular, the council publishes a bi-monthly Dutch-language journal, *Graadmeter*, each year. The journal contains information about advisory reports and other publications, and questions and responses from ministers and State Secretaries (Health Council 2005). *Graadmeter* also features brief articles on developments, both nationally and abroad, that are of direct relevance to the Council's fields of interest. The Council also distributes the publication, *Network*, three times a year to international contacts and colleagues. *Network* provides information on the Council's activities and potential opportunities for collaboration. To that end, international collaboration is a key mechanism for the Council to strengthen both the scientific rigor and implementation of its assessments. Specifically, the Council frequently recruits international experts to participate on assessment committees, and reports are often exchanged with sister organisations abroad. Moreover, it is a member of EuroScan and other European-based organisations, and often collaborates with the Institute of Medicine (IOM) and Centres for Disease Prevention and Control (CDC) in the US. Besides the aforementioned, the Council also disseminates information via their website (where many reports are publicly-available, in both Dutch and English) and conferences.

In addition to the Health Council, the Health Care Insurance Board also disseminates reports (primarily directly to the Minister of Health) that are intended to support reimbursement decisions. The majority of reports focus on diagnostic and therapeutic procedures. A number of recommendations set forth by the board have been implemented by the ministry. For instance, the effectiveness and cost-effectiveness of lung transplantation was established via economic assessment; inclusion in the benefit package was subsequently approved (Bos 2000).

Another integral use of HTA results is the development of practice guidelines. In the Netherlands, the spheres of guidelines development and HTA are only beginning to converge. The chief and established guideline development programmes, the Dutch Institute for Healthcare Improvement (CBO) and the Dutch College of General Practitioners (NHG) draw upon evidence found in the literature and, increasingly, completed technology assessments to develop practice guidelines (Berg et al. 2004). These entities typically select guideline topics based on expert consensus meetings, a method also employed to refine the development process. Only recently have the CBO and NHG started to coordinate activities between one another and steer toward employing similar methodologies (Berg et al. 2004).

Moreover, similar to the HTA process itself, guideline development rarely systematically incorporates normative considerations, such as the patient's perspective in the health care decision-making process (Berg et al. 2004). To that end, while patients have a role in clinical studies, their role in priority-setting, substantiating recommendations, and implementing results is limited in the Netherlands (as is the case in most countries). However, to some extent, patient and consumer involvement in decision-making has been strengthened by representation by such entities as the Dutch Federation of Patients and Consumers. The Federation, for example, represents patient and consumer interests on national advisory bodies, such as the Health Care Insurance Board and the National Council for Health Care (Bos 2000). That said, actual consumer participation is limited in terms of determining the direction of health policy, including HTA, which tends to be significantly influenced by scientific advisory bodies, special committees, and medical societies in the Netherlands.

While HTA has certainly generated an overall greater awareness of the importance and relevance of economic information in decision-making in the Netherlands, its impact upon the overall policy and priority-setting process is currently somewhat limited. The narrow application of HTA may, in part, be due to the topic selection process and the relative lack of coordination between the multitude of different agencies prioritising, funding, and executing HTA research, as well as the unequal application of HTA results and decisions implemented by government (Berg et al. 2004).

To the latter, HTA analyses are sometimes explicitly performed to guide national policy, and are increasingly employed to support decision-making processes. Yet, some decisions go against available HTA evidence, technologies are often introduced without any economic evaluation, and the list of excluded services is still minimal and highly diverse (Berg et al. 2004). A recent report of the Council for Public Health and Health Care (2006) emphasises the need for more systematic application of HTA criteria and evidence in decision-making. In particular, the Council argues that thus far *'decisions regarding payment or non-payment for medical treatment are only based to a limited degree on 'hard' factors, such as cost-effectiveness, and much more on less transparent considerations, as a result of pressure by lobby groups, media, etc. This means that limits [to reimbursement] are indeed being set at present, but on an ad hoc and somewhat random basis. The result is that the available resources are not being deployed as efficiently as possible'*. The council goes on to promulgate a system of decision-making that is transparent and sustainable, based on the 'justifiable' and 'coherent' application of criterion for establishing priorities regarding the public financing of health care. By 'justifiable', the council suggests that criteria should be fair and equitable from the perspective of the general public and the use thereof should guarantee equal access to health care. A 'coherent' use of criteria employs a model whereby there is a distinct assessment and appraisal phase. The assessment phase entails the quantitative evaluation of an invention, based on necessity, effectiveness, and cost-effectiveness. Subsequently, the appraisal phase involves the consideration of social aspects and other non-quantifiable factors. The council highlights that *'should the outcome of the societal examination be different from that of the assessment phase, the new verdict should be explicitly justified.'* Moreover, the council points to the use of an explicit maximum cost-effectiveness threshold (suggesting €80,000 per QALY gained), which would essentially function as a decision rule to maximise transparent decision-making.

Beyond the effective use of HTA evidence in decision-making, the impact of resulting actions (eg, guideline development) may be hampered by lack of resources, knowledge, and incentives for policy-makers and providers to utilise this information in actual decision-making and treatment provision.

Table 4: Overview of HTA governance, processes, and role in decision-making in the Netherlands

Netherlands	
HTA governance and organisation	
Institution/committees	Commission for Pharmaceutical Help (Commissie Farmaceutische Hulp (CFH) – Reimbursement and pricing negotiations Netherlands Organisation for Health Research and Development (ZonMw) *Many smaller organisations and entities are involved in HTA activities in the Netherlands (as described above).
Entity responsible for reviewing HTA evidence for priority-setting and decision-making	Health Care Insurance Board /CFH and the Ministry of Health, Welfare and Sports
HTA agenda-setting body(s)	Primarily, the Ministry of Health, Health Care Insurance Board, Council for Health Research, and Health Council. However, other organisations, such as the Dutch Health Research and Development Council and the Netherlands Organisation for Scientific Research also fund HTA activities and set priorities for research.
Areas for HTA	New approved and already reimbursed prescription drugs (CFH); variety of health care interventions (Health Council)
Reimbursement requirements and limitations	Reimbursement depends on yes/no decision for admission into reference pricing system. In exceptions, conditional coverage given for particular application areas or conditions.
Stakeholder involvement	Medical and health care professionals and experts, insurance funds, and representatives from consumer associations (Health Council, Council on Health Research, Health Care Insurance Board). Limited patient and public involvement in the HTA process.
International collaboration	EuroScan, AGREE Collaboration, EUnetHTA, IOM, CDC, International Network of Agencies for Health Technology Assessment (Health Council, Health Care Insurance Board)
HTA topic selection and analytic design	
Governance of topic selection	CHF: Based on manufacturer submissions. Other: Health Care Insurance Board/Investigative Board of Medicine; Health Council; and, Ministry of Health.
Criteria for topic selection	- Burden of disease - Potential benefit for individual patients - Number of patients - Cost of technology, in terms of cost per patient and on total costs of health care - Additional aspects related to health policy The Health Council also selects topics of 'horizon scanning', based on relevance to government policy and associated agenda-setting.
Criteria for assessment	Therapeutic benefit, patient benefit, cost-effectiveness, budget impact, pharmaceutical/innovative characteristics, and availability of therapeutic alternatives. Also, other social, ethical, and legal consideration, as appropriate.
Criteria outlined or publicly-available	Yes
Analysis perspective	Societal
Duration required to conduct assessments	A few months to a year or more.

39 Section applies primarily to the CFH.

40 N/A=not available

Table 4 (continued)

Evidence requirements and assessment methods ³⁹	
Documents required from manufacturer	Systematic literature review or meta-analyses, clinical studies, and pharmacoeconomic evaluations (with modelling, if appropriate), consensus guidelines, and prescription data.
Systematic literature review and synthesis	Yes
Unpublished data/ grey literature	Yes
Preferred clinical study type/evidence	Blind Head-To-Head RCT
Type of economic assessment preferred or required	Cost-effectiveness and cost-utility analysis
Availability of guidelines outlining methodological requirements	Yes, provided by the Health Insurance Council.
Choice of comparator	Standard therapy (routine daily practice) or common therapy. Pharmaceuticals must be compared against listed drugs.
Specification of outcome variable	Mortality, morbidity, QALY, costs
Sub-group analyses	Yes, among other patient groups, extent of disease and severity, co-morbidity. A priori definitions must be established.
Costs included in analysis	Direct costs both inside and outside the health care system. Future health care costs for unrelated disease in any additional life should be excluded. Productivity losses calculated using the friction cost method should be presented separately.
Incremental analyses required	Yes
Time horizon	Period within main differences of health effects and costs appear.
Equity issues	Social perspective is preferred.
Discounting	Costs (4%), Benefits (1.5%)
Modelling	Yes, performed by the company.
Sensitivity analyses	Yes, performed on central assumptions; employs univariate and multivariate analysis methods.
Cost-effectiveness or willingness-to-pay threshold	No formal threshold. However, the use of an explicit threshold is currently being promulgated and discussed, with potentially different thresholds applied according to severity of disease.
Missing or incomplete data	N/A ⁴⁰
Support for methodological development	N/A

Table 4 (continued)

HTA dissemination and implementation	
Channels for HTA results dissemination	CFH: Decisions/recommendations are outline in an assessment report that is published on the internet and delivered to the relevant ministries. Health Council: Graadmeter, Network, website, international conferences, and collaboration with other related agencies (both on national and international levels).
Use of HTA results	Reimbursement and pricing decisions; provide information to relevant stakeholders on the effectiveness and cost-effectiveness of health technologies; inform appropriate clinical practice via guidelines; define or redefine established indications for a technology; and, in priority-setting of government policy.
Evidence considered in decision-making	Efficacy, safety, effectiveness, cost-effectiveness, financial impact, quality of life, and social/ethical/legal considerations (where applicable).
Any reported obstacles to effective implementation	Disconnect between policy question and clinical/practice needs vs. HTA evidence; lack of coordination between myriad of agencies involved in priority-setting, funding, and execution of HTA and HTA-related activities; reluctance of health professionals and hospital administrators to use HTA information; incongruence between scientific/technical nature of HTA and the subjective/normative environment of health policy-making; and, guideline development tends to rely on efficacy/effectiveness data, not cost-effectiveness evidence.
Formal processes to measure impact	No
Processes for re-evaluation or appeals	N/A
Accountability for stakeholder input	N/A
Transparent/public decision-making process	N/A

Source: Health Council 2006; Stolk et al. 2005; Zentner et al. 2005; Berg et al. 2004; den Exter et al. 2004; OECD 2003; Bos 2000; ISPOR 1999.

41 The 1972 Primary Health Care Act obligates municipalities to provide health promotion and disease prevention, medical care, medical rehabilitation, and dental care. It also mandates the provision of student and occupational health care, screening services, family planning services, mental health care, and ambulance services.

42 In Finland, there are three tiers of reimbursement, with corresponding categories of co-payment. The first category is the basic tier, with a subgroup for 'significant and expensive' drugs, with 50% reimbursement. The second and third categories cover drugs that treat chronic conditions and those required to maintain health status or normal bodily functions. Reimbursement for these categories ranges from 75% to 100% and are publicly financed.

Finland

Overview of health care and reimbursement systems

Finland has a long tradition of supporting social programmes that promote equity and the welfare state. For example, universal access to medical care is guaranteed for all residents and provided for by public health centres and hospitals. Moreover, health policy and planning in Finland tends to be principled on a holistic approach, encompassing prevention and health promotion, community involvement, multi-sectoral collaboration, and international corporation.

In Finland, the organisation and financing of health care have long been considered a public responsibility. Each of country's five provinces is run by a provincial government that monitors the provision of health care (Lauslahti et al. 2000). However, it is the local municipalities that serve as the basic units for arranging and providing care for their citizens (Jarvelin 2002)⁴¹. As of 2005, there were 432 municipalities, with populations of 1,000 to 500,000 inhabitants. Although the main basic services provided by local authorities are prescribed by law, the scope, content, and organisation of services typically differ between municipalities.

At the national level, the Ministry of Social Affairs and Health directs and guides social and health services, with the remit to define general policy, prepare major reforms and proposals for legislation and monitor implementation, and assist the government in decision-making (Jarvelin 2002). In addition, the ministry also finances health care policy research, in collaboration with the Social Insurance Institution, the Finnish Academy, universities, and private foundations.

There are several agencies and institutions affiliated with the ministry that are responsible for various areas of health care, including the following relevant entities (Jarvelin 2002; Lauslahti et al. 2000):

- *The National Research and Development Centre for Welfare and Health (STAKES)* – the centre monitors and evaluates activities in health care services, and carries out research and development in the field.
- *The National Authority for Medico-legal Affairs* – body that regulates health professionals and the legal protection of patients.
- *The National Agency for Medicines (NAM)* – NAM maintains and promotes the safe use of medicines, medical devices, and blood products. The agency performs preliminary examination of applications for marketing authorization and monitors the manufacture, importation, and distribution of medicines.
- *The National Public Health Institute* – the institute carries out research on diseases and their prevention. It also conducts surveillance and survey activities on communicable diseases and health behaviour.

While the main levels in the organisation of health care are central government and local authorities, the private sector also plays a role in the Finnish health care system. In particular, private health care comprises mainly outpatient care, predominantly available in larger urban areas and provided via a physiotherapy unit or medical care practice (Jarvelin 2002).

The health care system in Finland is primarily tax-based, with most financing derived from the taxes levied by the municipalities (almost 50%) to cover health services (Jarvelin 2002). Local authorities also receive state subsidies to arrange health care, in addition to other social programmes and education. Other financing comes from the state, the National Health Insurance (NHI) scheme, and private sources (eg, households).

The NHI scheme is overseen by the Social Insurance Institution (under the auspices of the Parliament), which covers loss of income during illness, pharmaceuticals, private health care, occupational health care, and some other services (Jarvelin 2002). The proportion of health care financed by the NHI has increased over the last 10 years, mainly as a function to the growing use of new pharmaceuticals.

To that end, as in many other EU countries, pharmaceutical costs grew significantly during the 1990s in Finland. To address cost containment concerns, a number of actions were initiated over the last 10 years. Namely, one measure was to require the demonstration of the therapeutic value and cost-effectiveness of new drugs before eligibility for reimbursement⁴². The responsibility to evaluate new pharmaceuticals falls to the Pharmaceuticals Pricing Board (PBB).

Specifically, the PBB, which falls under the Ministry of Social Affairs and Health, handles the reimbursement and pricing of pharmaceuticals. For a drug to be licensed as a reimbursable drug, its wholesale price⁴³, as determined by the PBB, must be deemed 'reasonable' (Zentner et al. 2005). The reasonable wholesale price refers to the maximum price at which a drug may be sold to pharmacies and hospitals (Jarvelin 2002). The PBB assesses all new prescription drugs, patented drugs and generics (see *HTA procedures and processes* below for further description of the valuation process). The PBB also deals with applications to increase the wholesale prices of medicines.

The PBB is comprised of seven representatives who are appointed by the ministry. Two members represent the Ministry of Social Affairs and Health, the Ministry of Finance, and the Social Insurance Institution. At least one medical, pharmacology, economic, and legal expert must be represented.

Health technology assessment, governance, and organisation

In the early 1990s, the Academy of Finland and the National Board of Health put forth separate reports emphasising the need for assessment of medical technologies and the establishment of research entities to conduct such activities (Jarvelin 2002). Although several organisations, such as universities and hospitals, were active in HTA through the 1980s, there was a lack of corporation and collaboration. The board, in particular, proposed that a national technology unit be established at the Ministry of Social Affairs and Health, and identified the need for a team of national experts on health technology, representing different health care sectors (Lauslahti et al. 2000). Subsequently, an independent centre for health technology assessment, known as the Finnish Office of Health Technology Assessment (FinOHTA), was established in 1995 within the National Research and Development Centre for Welfare and Health (STAKES).

The FinOHTA functions as the central body for the advancement of HTA-related work in Finland. To that end, it serves as the clearing house for accumulating, evaluating, and disseminating knowledge on HTA and evidence-based assessment methods. The centre supports, coordinates, and conducts assessments, and disseminates both national and international research results within the health care system (FinOHTA 2006). FinOHTA also monitors the conduct of HTA research both within Finland and abroad, development of new research and methods in the field, and prioritisation of health technologies in need of assessment. Ultimately, through its activities, the FinOHTA strives to improve the effectiveness and efficiency of Finnish health care.

At present, the centre employs around 13 individuals, representing medicine, nursing, and economic expertise. In addition, the FinOHTA makes extensive use of an external network of experts in the field of medicine and health care. The direction and activities of the centre are overseen by an Advisory Board and Scientific Committee (FinOHTA 2006; Lauslahti et al. 2000). The Advisory Board monitors assessment activities within FinOHTA and externally and develops proposals for national and international joint assessment projects. The board consists of 26 members representing academics, hospitals, related national health care institutes, medical societies, consumer groups, and medical technology associations. The 13-member Scientific Committee, comprising leading members of Finland's medico-scientific community, examines priorities in HTA and evaluates the quality and priority of assessment projects presented to FinOHTA. The committee also participates in disseminating HTA information and results.

The FinOHTA is well placed in Stakes, whereby it is afforded access to health and social services research and resources, international contacts, and logistical support (Lauslahti et al. 2000). Moreover, Stakes houses the Cochrane Collaboration Centre and maintains official health and social services statistics, registries, and databases. FinOHTA also collaborates with other national organisations and bodies, including hospital districts, the Finnish Medical Society, the National Public Health Institute, and the National Agency for Medicines.

In addition to national entities and resources, the FinOHTA relies heavily on international collaboration. Namely, the centre has initiated joint HTA projects with the SBU and other Nordic assessment bodies (Lauslahti et al. 2000). FinOHTA also participates in the International Network of Agencies for Health Technology Assessment, International Society of Technology Assessment in Health Care, AGREE Collaboration (network to improve clinical practice guidelines), and Guidelines International Network.

43 The wholesale price is that at which the products are sold to pharmacies and hospitals.

HTA process and procedures

FinOHTA is a relatively small organisation, with limited staff and funding. Consequently, priorities must be set in terms of topics or areas of health technology for assessment. As mandated by the Ministry of Social Affairs and Health, assessment activities should concentrate on technologies that are important for the health of Finnish citizens or the national economy (Lauslahti et al. 2000). Accordingly, FinOHTA has established a formalised process for selecting assessment topics and commissioning studies, either preliminary studies or comprehensive assessments, to be performed by outside organisations and research groups. In particular, FinOHTA supports projects that examine the effectiveness and cost-effectiveness of health care technologies, as well as systematic literature reviews. The proposed assessment can be a part of a larger study or a stand-alone research project.

Initially, FinOHTA staff, in collaboration with external consultants, review all project submissions, typically every two to three weeks. Project proposals are then evaluated against the following criteria (FinOHTA 2006):

- Public health or national economy impact
- Appropriateness and quality of proposed research methods
- Feasibility of study
- Adequacy of study aims, in terms of assessing effectiveness, cost-effectiveness, and other considerations, including social, ethical, legal, and quality of life implications
- Researcher(s) conflict of interest
- Qualifications of research group or organisation
- Appropriate funding structure
- Timely duration required for study completion
- Usability of study results
- Adequate plan for results dissemination, implementation, and follow-up.

Projects meeting the aforementioned criteria are presented every two to three months to the Scientific Committee for approval. Approval is granted to those studies that address suitable topics and possess scientifically valid study designs. Projects approved by the committee are subsequently presented to Stakes' Board of Directors, when a final decision is made. The review and decision process typically takes between two and six months.

As well as commissioning health technology assessments, FinOHTA conducts a variety of evaluative research. In particular, it produces systematic reviews of available evidence. Such reviews entail collecting, analysing, and synthesising information on a range of economic evaluations, which may include national and international assessments and research examining the diffusion of technology and identification of emerging therapies (FinOHTA 2006; Lauslahti et al. 2000). For example, FinOHTA produces Rapid Reviews when information on a given health technology is needed quickly, thereby eliminating the necessity of a comprehensive assessment. The Rapid Reviews are typically based on international assessment reports, where the findings are reviewed, appraised, and applied in the Finnish context. In systematically reviewing the available evidence, FinOHTA considers a wide range of factors in assessing a given health technology, including therapeutic benefit, patient benefit, cost-benefit, cost-effectiveness, quality of life, organisational and service requirements (eg, need for technologists or staff training), budget impact, and social, legal, and ethical implications (Eskola et al. 2004).

In addition to systematic reviews, FinOHTA utilises many different assessment methodologies, depending on the particular research question at hand. Such methodological approaches include primary studies (eg, RCTs) that study the effectiveness and cost-effectiveness of various health technologies (especially when there is a lack of evidence available), surveys to clarify the use of a technology or variations in practice, and modelling (eg, costs associated with different approaches to technology utilisation) (Eskola et al. 2004).

As part of a multidisciplinary group of external experts and consultants affiliated with FinOHTA, clinicians are frequently involved in the assessment process, from reviewing project proposals, evaluating evidence, assisting in the dissemination of results and related HTA information, and proposing topics for assessment. Currently, FinOHTA is collaborating with 19 hospitals in Finland to develop rules for the uptake of new medical technologies. To date, this national project, Managed Uptake of Medical Methods (MUMM), has entailed touring participating hospitals to gather input from clinicians and administrative decision-makers on the use of new medical technologies and potential topics for assessment (FinOHTA 2006). Additional visits and collaborative workshops are planned for the future to devise recommendations and solidify a list of future assessment topics.

Patient and public involvement in HTA activities affiliated with FinOHTA is limited at present. The majority of investment in patient and public participation in assessments is at the information dissemination stage (Lauslahti et al. 2000). In particular, there has been discussion about potential collaboration with patient associations on publishing patient guides and other educational materials.

Since 1995, over 70 research projects have been completed, the majority being systematic reviews (Eskola et al. 2004). Such projects include those endeavours carried out primarily by FinOHTA staff, external organisations, and via collaboration with international assessment bodies (eg, SBU). Select examples of active and completed projects include:

- Antimicrobial treatment strategies (1998-2006)
- Glaucoma screening (2002-2004)
- Colorectal cancer screening (2000)
- Cost-effectiveness of the treatment for otitis media in children (active)
- PSA screening for prostate cancer (active)
- Orthodontics (2003-2006)
- Tele-medicine (2001, updated in 2003)

FinOHTA has also supported projects several Cochrane projects, including assessments on the effectiveness of psychoeducation and multi-professional rehabilitation in musculoskeletal diseases.

In terms of the evaluation of pharmaceuticals and the PPB, manufacturers propose a product price and accompanying justification in the application submission (Jarvelin 2002). The application is required to include detailed and comprehensive information, including the costs of the drug therapy, expected additional benefits (both therapeutic and from a societal perspective), and projected market penetration, all of which are supported on the basis of relevant clinical and health economic studies (Zentner et al. 2005). If a health economic evaluation is required⁴⁴, manufacturers are required to submit an assessment of the costs and benefits of the product in comparison to other alternative treatments, which is defined as either the most commonly used or best available treatment for a particular indication (Zentner et al. 2005). As outlined in guidelines published by the Ministry of Social Affairs and Health in 1999, manufacturers must use appropriate analysis methods (eg, cost minimisation analysis, cost-effectiveness analysis, cost-utility analysis, and cost-benefit analysis), outline all assumptions used in the evaluation, specify the target group for therapy and present any subgroup analyses, include direct and indirect costs (although reported separately), use modelling to estimate health effects if necessary, and report incremental benefits and costs (ISPOR 1999). In addition, all analyses should include a time horizon sufficiently long to permit evaluation of all the essential costs and health effects. All outcomes realized over one year or longer are required to be discounted at both 0% and 5%, and sensitivity analyses should be included on variables of uncertainty. *(For further detail on evidence requirements and assessment methods, see Table 5).*

Following submission, the PPB considers the following factors, as mandated by law, when reviewing applications for new drugs, in order to substantiate a 'reasonable' wholesale price (Zentner et al. 2005):

- Therapeutic benefit
- Patient benefit
- Health economic information (eg, cost-effectiveness)
- Comparison of wholesaler prices of competitive products in Finland
- Comparison of prices of the drug in other EU countries
- Budget impact
- Cost of manufacture, in terms of production and research and development

⁴⁴ A health economic evaluation is required if the drug under review contains a new active substance or if otherwise required by the PPB.

After the PPB approves an acceptable price, the drug is automatically qualified and included into the basic reimbursement category, covering 50% of costs. However, both the price and reimbursement category is formally confirmed by the Secretariat of the PPB and Social Insurance Institution (Zentner et al. 2005). For higher reimbursement levels (ie, 75% and 100%), applications must demonstrate the usefulness of the product and its cost-effectiveness. For 100% reimbursement, a statement on the replacement or remedial effects of the product is also required. Manufacturers must also submit information on the therapeutic value of the drug, projected dosage used in treatment, cost of treatment in comparison with existing products for the same condition, market forecast on the cost impact of granting higher reimbursement status, and an itemised statement on the costs and benefits of the treatment, especially in comparison to alternative medications and other therapies (Zentner et al. 2005). All submitted information is reviewed by the PPB and affiliated expert groups, if needed. New drugs, however, are intended to remain within the basic level of reimbursement for two years before they are considered for a special reimbursement category (Zentner et al. 2005).

The decisions of the PPB are valid for a limited duration before re-evaluation can commence. In particular, drugs with new agent properties or effects can be re-evaluated every three years; otherwise, pharmaceuticals are examined every five years (Zentner et al. 2005).

HTA dissemination and implementation

For FinOHTA, the dissemination and implementation of assessment results and other HTA-related information aims to change existing health care practices, where needed. In fact, information provision is the primary method at FinOHTA to influence the health care system (FinOHTA 2006).

The target audience for HTA information is quite broad, encompassing those that work in or affiliated with health care, as well as patients and consumers and the Ministry of Social Affairs and Health. Moreover, as a conduit for information delivery, the national media (eg, TV, radio, and newspapers) is an important audience for the work conducted at and through FinOHTA (FinOHTA 2006).

The objective of FinOHTA is to reach as wide an audience as possible. As such, it employs a variety of methods and media to disseminate information. The principal source of dissemination is through its own publications, including the bi-monthly newsletter *Impakti*, FinOHTA Reports (results from internal research projects), and Technology Updates (translation of results from research of other assessment bodies). *Impakti*, in particular, contains summaries of HTA research projects and is distributed to all hospital districts, health care providers, and to select policy decision-makers (Lauslahti et al. 2000). The majority of reviews commissioned by FinOHTA are published in both English and Finnish.

Other mediums of information dissemination include the FinOHTA website, targeted communication on international HTA results to national experts, and publications in academic and medical journals (Lauslahti et al. 2000). Furthermore, FinOHTA participates in national and international conferences, such as meetings held by the Finnish Medical Association and various specialist societies, and organises courses on evidenced-based medicine.

The findings from FinOHTA projects and manufacturer-sponsored economic evaluations (in the case of the PPB) are used to inform decision-making and priority-setting activities primarily related to reimbursement, pricing, and clinical policy and practice via the promulgation of guidelines. As indicated above, the primary use of health economic information in the context of the PPB is to decide on the pricing and reimbursement status of pharmaceutical products. In terms of FinOHTA, the primary intent of study or project results is to change clinical or health care practices, where needed. To that end, while FinOHTA plays a pivotal role in information dissemination, it is not the primary body responsible for implementation of assessment results. Although it supports such activities, it is hospital districts, health care centres, and medical and health organisations that assume a pivotal role in terms of employing HTA research in policy and planning decision-making (Lauslahti et al. 2000).

However, FinOHTA often collaborates with Duodecim, the Finnish Medical Society, to develop clinical treatment guidelines, Current Care, for common diseases and health problems (Duodecim 2006). As of February 2006, 25 guidelines were available, with another 29 in the pipeline. By 2010, there is expected to be 100 published Current Care guidelines. Topics for guidelines development are selected by the Board of Current Care from suggestions put forward predominantly by medical specialist societies. Subsequent to topic selection, a group of experts (eg, general practitioners, allied health professionals) systematically review all relevant literature, including FinOHTA assessments, based on criteria outlined by an internal Evidence-Based Medicine Working Group (Duodecim 2006). Based on the evidence, guidelines are drafted and distributed to key stakeholders for review and revision. All final guidelines are available to the public via the internet, CD-Rom, relevant medical journals, and a portal for Finnish health care professionals, called *Terveysportti*.

Another organisation, ROHTO, under the Ministry of Social Affairs and Health employs health economic information to develop and promulgate guidelines (FinOHTA 2006). Specifically, the ROHTO evaluates, summarizes, and disseminates information on evidence-based, cost-effective pharmacotherapy. The main vehicle for dissemination is published articles in the Finnish Medical Journal and via the ROHTO website. Articles typically highlight evidence-based information about drugs and current trends or challenges in prescribing patterns.

While there is significant support for guideline development in Finland, there is still opportunity to improve the process. For example, few of the most recently published Current Care guidelines included an economic component. Of those guidelines, the health economic component typically involved a cost-effectiveness evaluation. Moreover, there is no existing research evidence on the effect of the ROHTO programme on prescribing practices and on how effectively the Current Care guidelines have been adopted in practice (FinOHTA 2006).

Further areas of improvement lie within both the PPB and FinOHTA. In particular, while there has been an increased requirement for health economic evaluation by the PPB to support reimbursement and pricing decisions, authorities have allocated limited resources to health economics expertise in practice. To that end, the PPB does not have a health economist on the board, nor has it invested on expertise in health economics. Moreover, the European Court of Justice recently ruled that the pricing and reimbursement system of the PPB is too slow and lacks sufficient transparency, especially with regards to decisions regarding the special reimbursement category (Pharma Industry Finland 2004).

In 2004, FinOHTA conducted an evaluation of the centre's operations and later published a report on future strategies and recommendations to improve the HTA process (Eskola et al. 2004). Through consultation with stakeholder groups and staff, identified weaknesses included a shortage of health economic professionals to conduct needed assessments, a need for increased opportunities for formal education in technology assessment, better integration and coordination between FinOHTA and other bodies (eg Current Care and ROHTO), especially with respect to pharmaceuticals, and enhanced focus on patients and consumers in the assessment process and as a target of HTA-related information.

Table 5: Overview of HTA governance, processes, and role in decision-making in Finland

Finland	
HTA governance and organisation	
Institution/committees	Pharmaceuticals Pricing Board (PPB) – Reimbursement and pricing decisions FinOHTA– primary national HTA body Ministry of Social Affairs and Health – guides health and social services in Finland; defines related policy and legislation. Stakes – oversees FinOHTA and monitors health care and social services, and related research and development activities.
Entity responsible for reviewing HTA evidence for priority-setting and decision-making	PPB Hospital districts, health care providers, and the Ministry of Social Affairs and Health (in the case of FinOHTA)
HTA agenda-setting body(s)	Ministry of Social Affairs and Health/Stakes/FinOHTA
Areas for HTA	New pharmaceuticals (PPB); drugs, devices, procedures, and organisational and support systems in health care (FinOHTA).
Reimbursement requirements and limitations	The wholesale price, as determined by the PBB, must be deemed ‘reasonable’. Reimbursement levels range from 50%, 75%, to 100%, depending on the disease area and cost of the pharmaceutical. Restrictions can be made pertaining to indication, severity of illness, and patient population.
Stakeholder involvement	Medical and health care professionals and experts, representatives from consumer associations, hospital managers, academics (FinOHTA). Limited patient and public involvement in the HTA process.
International collaboration	SBU and other Nordic HTA bodies, HTAi, International Network of Agencies for Health Technology Assessment, EUR-ASSESS, Cochrane Collaboration, AGREE Collaboration, EUnetHTA, and Guidelines International Network.
HTA topic selection and analytic design	
Governance of topic selection	FinOHTA and Stakes
Criteria for topic selection	FinOHTA: - Public health impact - Significance for national economy PPB – dependent upon manufacturer submission
Criteria for assessment	Therapeutic benefit, patient benefit, cost-effectiveness, budget impact, and R&D (PPB). Therapeutic benefit, cost-effectiveness, budget impact, public health impact, service requirements, and social/legal/ethical considerations (FinOHTA)
Criteria outlined or publicly-available	Yes
Analysis perspective	Societal
Duration required to conduct assessments	1 year for complete HTA; a few months for Rapid Reviews (FinOHTA)

Table 5 (continued)

Evidence requirements and assessment methods ⁴⁵	
Documents required from manufacturer	All relevant clinical and health economic studies, with modelling, if necessary.
Systematic literature review and synthesis	Yes (FinOHTA); not clear for manufacturers to the PPB.
Unpublished data/ grey literature	N/A
Preferred clinical study type/evidence	Head-to-head RCT
Type of economic assessment preferred or required	Cost-minimization, cost-effectiveness, cost-utility, cost-benefit analyses
Availability of guidelines outlining methodological requirements	Yes, published by the Ministry of Social Affairs and Health
Choice of comparator	Most frequently used therapy.
Specification of outcome variable	N/A
Sub-group analyses	Yes
Costs included in analysis	Direct and indirect costs
Incremental analyses required	Yes
Time horizon	Sufficient duration to perform an appraisal of main costs and health effects.
Equity issues	Not stated.
Discounting	Both costs and benefits: 0% and 5%
Modelling	Yes, if effectiveness data not available or not applicable. Modelling performed by manufacturers. All assumptions are required to be justified.
Sensitivity analyses	Yes, for primary assumptions or other uncertainties.
Cost-effectiveness or willingness-to-pay threshold	No formal threshold.
Missing or incomplete data	N/A ⁴⁶
Support for methodological development	Yes (FinOHTA)

45 Section applies primarily to the PPB.

46 N/A=not available.

Table 5 (continued)

HTA dissemination and implementation	
Channels for HTA results dissemination	FinOHTA publications (Impakti, FinOHTA Reports, Technology Updates, brochures of FinOHTA); website; targeted communication of HTA results to network of experts; education (courses, seminars); academic journals; other medical and public health associations.
Use of HTA results	Reimbursement and pricing (PPB) Guide clinical practice and health care services (FinOHTA)
Evidence considered in decision-making	Therapeutic benefit, patient benefit, cost-effectiveness/cost-utility, budget impact, costs of product and associated R&D and manufacture (PPB).
Any reported obstacles to effective implementation	In the case of the PPB, the European Court of Justice recently ruled that the pricing and reimbursement system is too slow and not transparent enough. A recent FinOHTA study identified the following barriers: shortage of HTA staff/professionals, insufficient training in HTA, lack of patient/consumer focus to assessments, and poor coordination between HTA agencies.
Formal processes to measure impact	Project proposals approved and commissioned by FinOHTA must have a plan for evaluation and follow-up (via surveys, register research, or other methodological approach).
Processes for re-evaluation or appeals	Yes, re-evaluation every three years for pharmaceuticals for new agent properties/effects; otherwise, every five years (PPB).
Accountability for stakeholder input	Primarily clinical experts – contribute input to the selection of project proposals, evaluation of assessment results, and topics for assessment (FinOHTA).
Transparent/public decision-making process	Regarding the PPB, transparency could be improved, especially with regards to decisions on the special reimbursement category.

Source: FinOHTA 2006; Zentner et al. 2005; OECD 2003; Jarvelin 2002; Lauslahti et al. 2000; ISPOR 1999.

France

Overview of health care and reimbursement systems

The French constitution refers to health as a fundamental right; consequently, health protection and medical care is guaranteed to the entire population. The jurisdiction of the health care system is divided between the state (parliament, government, and various ministries), the statutory health insurance funds, and local communities, albeit to a lesser extent (Sandier et al. 2004).

At the state level, the direction of the health care system is substantiated by the Act on Social Security Funding, which the parliament has passed on an annual basis since 1996 (Sandier et al. 2004). The Act is based on reports of the Accounts Commission and the National Health Conference⁴⁷ and serves to set projected targets for health insurance spending, report on health policy and social security trends, and delineate any new provisions concerning benefits and regulation (Sandier et al. 2004).

In addition, a significant level of control of the health care system lies with the Ministry of Health. The Ministry of Health includes directorates of general health and policy, hospital and health care, social security, and social policy. The ministry also controls a significant portion of the regulation of health care expenditure on the basis of the overall framework established by the parliament. Key areas of responsibility include allocating budgeted expenditure between different health care sectors, approving agreements between health insurance funds and relevant unions, establishing prices of specific medical procedures and drugs, and defining priority areas of national health programmes (Sandier et al. 2004).

Over the last 10 years, the state has established a number of independent committees and agencies to fulfil specific functions and lend specialised expertise, including the following key authorities (Bellanger et al. 2005; Sandier et al. 2004; Fleurette & Banta 2000):

- *High Level Committee on Public Health* – established in 1991 and located within the Ministry of Health, the committee provides guidance and assists in decision-making regarding public health problems and issues related to the organisation of health care delivery.
- *National Committee on Medical Safety* – under the Ministry of Health, it oversees a variety of agencies responsible for the safety of health products (AFSSAPS) and food products (AFSSA), monitoring public health (Institute for Monitoring Public Health), and environmental health and safety (AFSSE).
- *National Agency for Accreditation and Evaluation of Health Care (ANAES)* – instituted in 1997, the Agency functions to create and disseminate practice guidelines, promote clinician education and professional development, accredit hospitals, and provide guidance regarding procedures eligible for reimbursement by the health insurance funds. ANAES is comprised of physicians, other health care professionals, and economists. The board of directors, along with the Ministry of Health, health insurance funds, and medical unions set the overall agenda. Under the Health Insurance Act of 2004, the High Health Authority replaced ANAES (see Box 2).
- *Economic Committee for Medical Products (CEPS)* – an inter-ministerial committee, CEPS sets prices for drugs and medical devices and monitors trends in spending on drugs in relation to annual budget targets.

Other than the Ministry of Health, the Ministry of Social Affairs and the Directorates of Social Security, Hospitals and Health Care Organisation, and Health also have some jurisdiction of the French health care system. In general, these bodies operate a powerful top-down approach to decision- and policy-making.

The second level of health care jurisdiction, the statutory health insurance (SHI) system, provides almost universal insurance coverage to the French population, as a branch of the wider social security system. The SHI is comprised of three principal schemes, determined by an individual's social and/or professional category (Bellanger et al. 2005; Sandier et al. 2004). The *general scheme (Regime General)* covers employees and pensioners from trade and industry sectors, as well as their families (approximately 84% of the population). The general scheme is financed mainly by payroll contributions made by both employers and employees. The other two schemes, the *agricultural scheme (MSA)* and the *scheme for non-agricultural self-employed people (CANAM)*, cover farmers and agricultural workers (in addition to families) and craftsmen and self-employed individuals, respectively (approximately 12% of the population). Other schemes cover certain categories of the population, also on an employment-related basis. Several of these schemes are associated with the general scheme, as is the case for civil servants, physicians working under health insurance agreements, students, and military personnel (Sandier et al. 2004).

⁴⁷ A National Health Conference takes place once a year to propose priorities and suggest policy directions to the government and parliament. It is composed mainly of health care professionals and representatives from health care organisations and from regional health councils.

48 UNCAM is also responsible for setting rates for medical procedures, drugs, and devices, and for determining levels of co-payment and coinsurance.

Box 2: High Health Authority

The High Health Authority (*Haute Autorité de Santé*) was created by the Health Insurance Act of 2004. The Authority serves as an independent scientific public authority with legal status. Its principal objective is to evaluate the medical usefulness of medical procedures, services, and products that are reimbursed by the health insurance funds. The Authority's remit falls under five main functions:

- Devise recommendations on the conditions of reimbursement of health care procedures, especially those involved in the treatment of certain diseases
- Support, via contribution of medical and public health expertise, reimbursement-related decision-making
- Distribute guidelines to health care professionals and the general public
- Develop and implement hospital accreditation procedures and requirements

The High Health Authority works closely with the French Agency for the Medical Safety of Health Products (AFSSAPS) and the National Institute for Monitoring Public Health.

In addition to the SHI, which funds about three-quarters of total health spending, a significant proportion of the French population is affiliated with voluntary, supplementary sickness funds, or purchases private insurance, which serves to complement the statutory health insurance (Bellanger et al. 2005). In fact, approximately 85% of the population is covered under complementary health insurance.

The health insurance system is under the direction of the Social Security Directorate of the Ministry of Health. However, various regional institutions collaborate with the ministry to oversee health services and the three main insurance schemes. These bodies serve both a strategic and operational role with regards to health services delivery and financing throughout the country (Bellanger et al. 2005).

The French insurance system offers expansive reimbursement within the areas of preventive, curative, rehabilitative, and palliative care. In particular, reimbursable medical products and services include hospital care, outpatient treatment, diagnostic services, the cost of pharmaceutical products and medical devices, and prescribed health care-related transport. However, the reimbursement of such goods and services depends on their registration in positive lists (Bellanger et al. 2005). In particular to health technologies, in order to be eligible for reimbursement by SHI, pharmaceuticals must be included on the *Liste de Spécialités Pharmaceutiques Remboursables aux Assurés Sociaux* (LSPRAS), medical devices and related services on the *Liste de Produits et Prestations Remboursables* (LPP), and medical procedures on the *Classification Commune des Actes Médicaux* (CCAM) (Bellanger et al. 2005). Moreover, all medical products and services must be prescribed by health care professionals (eg, physicians, midwives, dentists) and in the appropriate medical context (Bellanger et al. 2005).

Until the Health Insurance Act of August 2004, the positive lists were enforced by the relevant ministries, including the inclusion of new goods and services (Bellanger et al. 2005). Ministers used to base their decisions upon the advice of various ad-hoc commissions and agencies, especially ANAES. However, subsequent to the Act, the newly established National Union of Health Insurance Funds (*Union Nationale des Caisses d'Assurance Maladie*, UNCAM), represented by all three health insurance funds, has defined the positive lists of pharmaceuticals, procedures, and medical devices⁴⁸ (Bellanger et al. 2005). The High Health Authority, as described above, assumed the Transparency Commission (described in further detail below) and replaced the ANAES. The Authority assists UNCAM in decision-making by providing advice and recommendations regarding the positive list. Another body created from the 2004 Act, the Union of Voluntary Health Insurers (*Union Nationale des Organismes d'Assurance Maladie Complémentaire*, UNOC), also serves to assist UNCAM.

In terms of pharmaceuticals, prior to registration for reimbursement, all products must undergo a three stage process, as outlined below (Sandier et al. 2004):

- First, products must obtain market authorisation by French Agency for the Medical Safety of Health Products (AFSSAPS), which evaluates the drug under review for effectiveness, safety, and quality.
- Second, following market registration, products are reviewed for inclusion on the positive list of reimbursable drugs. The request for inclusion (accompanied by a suggested price) is provided by the manufacturer⁴⁹. Approval for inclusion and the determination of the rate of reimbursement is established by a health and social security ministerial order based on review and recommendation by the Commission de la Transparence (Transparency Commission) of the High Health Authority (see *HTA procedures and processes* below for further description of the review process).
- Third, advice from the Transparency Commission concerning the relative therapeutic value and costs of the drug is sent to the CEPS, which negotiates the price of the product with the manufacturer. The price of a product is established based on a number of factors, including therapeutic benefit (compared to other listed products in the same therapeutic class), price of other similar drugs, projected sales volume, and estimated utilisation. Following substantiation of an agreed-upon price, the drug can be included on the positive list.

The Transparency Commission consists of 31 members (including one president), represented by government, the statutory health insurance system, and medical and pharmaceutical experts (Zentner et al. 2005). As of 2005, approximately 1,340 recommendations on new pharmaceuticals had been officially published by the Commission.

With regards to medical devices, there is no one organisation that is responsible for systematic evaluations. However, manufacturers must apply for official reimbursement to be used in private institutions⁵⁰ (Orvain et al. 2004), which entails an evaluation of the product. The review process for reimbursement is conducted by the Product and Services Evaluation Commission (*Commission d'Evaluation des Produits et Prestations*, CEPP) (Bellanger et al. 2005). However, the procedures entailed in the reimbursement decision process (ie, assessment and criteria) are similar to those applied to drugs. The CEPP, chaired by AFSSAPS, consists of scientific experts as well as representatives of the health insurance funds and device manufacturers, and is overseen by the Ministries of Health and Social Security.

Health technology assessment, governance, and organisation

Growing concerns regarding the quality and efficiency of health care in the 1970s lead to increased awareness of the need for HTA to evaluate medical practice or health technology and develop priorities. Consequently, the government established the National Committee for Medical Evaluation in Health Care in 1987⁵¹ and, two years later, a non-profit, independent association, ANDEM (Fleurette & Banta 2000). The charge of ANDEM was to lead all health care and technology assessment programmes (except pharmaceuticals), with the objective of providing the Ministry of Health and the health insurance funds scientific evidence regarding the safety, effectiveness, and cost-effectiveness of health technologies. This remit involved developing internal projects in HTA, validating methods and funding of external research, and disseminating results and other relevant information (Fleurette & Banta 2000). Topics of assessment were identified by the Ministry of Health, the health insurance funds, the board of directors and scientific council within ANDEM, and other relevant professional groups. The association's staff mostly comprised physicians, who consulted with many external scientific experts and health professionals. The board of directors included representatives of the Ministries of Health, Education, Research, and Agriculture.

At ANDEM, assessments typically involved a method of combined critical appraisal of published literature with expert and professional consultation (Orvain et al. 2004). ANDEM published over 30 reports, including evaluation of bone density measurement (1991), assessment of cochlear implants (1994), silicone breast implants (1996), and implantable cardioverter defibrillators (1997). In addition to assessments, ANDEM was involved in consensus conferences, clinical practice guidelines, and evaluation activities in the public and private hospital sectors (eg, clinical audits and quality assurance programmes).

In 1996, it was decided to replace ANDEM by the National Agency for Accreditation and Evaluation of Health Care (ANAES). Until 2004, the inclusion of all medical procedures on the positive list depended on the advice of ANAES (Ballenger et al. 2005). In addition, ANAES was actively involved in consensus conferences to develop standards for practice appraisal and guidance development (Orvain et al. 2004). As previously mentioned, however, the ANAES was replaced by the High Health Authority. The majority of technology assessment of medical devices was moved from ANDEM to AFSSAPS (Ballenger et al. 2005).

49 However, as it is not necessary for a drug to be reimbursable to be prescribed in France, manufacturers can decide not to file a request for reimbursement in order to be able to keep its own freedom of pricing.

50 This is not the case for use in public hospitals.

51 The Committee mainly discussed ethical issues and methods of evaluation in health care, lacking both a budget and official agenda.

In addition to the aforementioned, there are several other organisations in France involved in HTA activities, including the following (Ballenger et al. 2005; Sandier et al. 2004; Fleurette & Banta 2000):

- *Institut National de la Santé et la Recherche Médicale (INSERM)* – the French national research institute specializes in biomedical and public health research, including evaluation projects.
- *Committee for Evaluation and Diffusion of Medical Technology (CEDIT)* – established in 1982, CEDIT was created as an advisory body for the Hospitals of Paris General Director, primarily to assist in decision-making regarding investments in new and costly medical technologies. Similar committees are or have been developed at other hospitals.
- *Collège des Economistes de la Santé (CES)* – CES, the French association of health economists, developed an analytical database on health economic evaluations and related research, *Connaissances et Décisions en Economie de la Santé* (CODECS), in collaboration with INSERM.
- *Various academic institutions* – departments of public health and medical schools are developing courses and research activity in economic evaluation.
- *Private consultancy firms* – a number of consulting companies have established practice areas related to health care evaluation and hospital management.

HTA processes and procedures⁵²

While the ANAES has now been replaced by the High Health Authority, presumably the Authority has assumed many of the processes and procedures employed by its predecessor. To that end, the ANAES prioritised topics for HTA reports following a customer consultation process. In order to define priorities and its annual HTA programme, ANAES carried out a survey of assessment needs via mail (Orvain et al. 2004). Subsequently, the responses would be evaluated according to the following factors:

- Extent of public health issue
- Variability in practice
- Disease prevalence
- Characteristics of the patient population
- Availability of supporting data
- Novelty or innovation of the technology
- Underlying policy or clinical question

After review of the responses, experts on particular topics may be interviewed and consulted, followed by a determination of the type of report required – a full report, rapid assessment, or brief update. A work-plan is prepared and presented to the Scientific Council of ANAES, who then selects topics using various voting methods. The Administrative Board subsequently approves the complete programme. Since 1999, important topics have included imaging technologies, emerging therapeutic and diagnostic techniques, and public health issues (Orvain et al. 2004).

ANAES HTA programme typically comprised two principal types of assessment, including 1) evidence-based assessments of widely used technology and of new technology prior to dissemination, and 2) rapid assessments of innovative technologies, fast-developing technologies, emerging public health issues. ANAES typically followed a standardised procedure for HTA assessment, as outlined in Box 3.

Although most of the assessments conducted by ANAES were based on systematic review of the evidence, it introduced a range of methods, such as expert panels and modelling.

With regards to assessments regarding the Transparency Commission and CEPS, the reimbursement of pharmaceuticals in France is contingent on two primary factors. In particular, products must contribute either to an improvement in the prescribed treatment, relative to other drugs in the same therapeutic class, or to a decrease in the cost of treatment (Sandier et al. 2004).

Box 3: Procedures for a standard HTA at ANAES

- Systematic literature search
- Articles are selected according to pre-established criteria
- A working group of experts is established to validate study design and provide expertise
- Health economic (or team) systematically appraises the literature and prepares a draft report, addressing technical aspects, effectiveness, and cost-effectiveness, where possible
- Draft report is reviewed by the working group; recommendations and revisions are provided
- Reviewers from various stakeholder groups and background comment on the amended report
- Report is approved following any necessary revisions and vetting by the Scientific Council
- Full report is published and posted on the ANAES website, summaries are disseminated, press conferences are convened, and articles published

Source: Orvain et al. 2004.

53 This is usually outlined in a specific document, the FIT (*Fiche d'Information Therapeutique*).

To ascertain the aforementioned factors, as of 1999, all products must undergo an Evaluation of Therapeutic Benefit (*Amélioration du Service Médical Rendu, ASMR*), conducted by the Transparency Commission (Sandier et al. 2004). Manufacturers submit clinical studies and related data to the Commission for review; a comparative health economic analysis is not required. (*For further detail on evidence requirements and assessment methods, see Table 6*). However, pharmacoeconomic evidence is taken into account to principally determine the financial impact of a drug and to inform pricing decisions (Zentner et al. 2005). A group of experts in economic evaluation, appointed by the directors of CEPS and AFSSAPS, provides advice on the quality of the evidence and methods used in the pharmacoeconomic studies (Bellanger et al. 2005; Zentner et al. 2005). Such experts are required to not possess any links with the pharmaceutical industry or the particular product sponsor. The CEPS and AFSSAPS provide guidelines to manufacturers on pharmacoeconomic study requirements (Zentner et al. 2005). Information is also assembled regarding the therapeutic situations in which the product should be most appropriately used and the projected size of the patient population.

Upon review of available evidence, the Commission evaluates a product across a variety of criterion, including (Zentner et al. 2005):

- Effectiveness of a drug and possible side effects.
- Position in the therapeutic spectrum relative to other available treatments (existence of therapeutic alternatives is classified 'yes' or 'no').
- Disease or condition severity.
- Clinical profile of the drug (curative, preventive, and symptomatic properties).
- Public health impact.

According to these criteria, the therapeutic value (termed the '*SMR*') is evaluated for each indication across 6 levels: 1) significant therapeutic benefit, 2) considerable therapeutic benefit, in terms of efficacy and side effect profile, 3) moderate therapeutic benefit, in terms of efficacy and side effect profile; already existing product, where equivalent pharmaceuticals exist, 4) minor improvement, in terms of efficacy and/or utility, 5) no improvement, but still recommended for positive list due to lower associated costs, and 6) negative opinion regarding inclusion on the reimbursement list (Zentner et al. 2005; Bellanger et al. 2005). In addition to new therapies, between 1999 and 2001, all existing pharmaceuticals on the positive list were reclassified according to the SMR criteria.

The ASMR assessment is then reviewed by UNCAM, who will determine whether inclusion on the positive list will be granted. Typically, the costs of a drug are not considered when reimbursement status is determined. However, costs of a new therapy are considered for me-too products and for generic alternatives. In such cases, a pharmaceutical may be reimbursed if the cost of therapy is lower than existing alternatives (Anell 2004). Also, in the case of new and expensive pharmaceuticals, the Commission must define any restrictive conditions (ie, prescription limitations) regarding reimbursement during their assessment⁵³.

54 Negotiations between manufacturers and CEPS are typically held privately and the reasons for its conclusions are not disclosed.

The level of the SMR, together with severity of disease, determines the reimbursement rate for each product (Sandier et al. 2004). Pharmaceuticals are granted a different rate of reimbursement at 35%, 65%, or 100% coverage (Zentner et al. 2005). The lower rate of reimbursement generally applies to drugs used for more typical, less serious conditions; the higher rate applies to products used to treat life-threatening or chronic conditions (eg, diabetes, AIDS, cancer). Approximately half of the drugs available on the market in France are included on the positive list of reimbursable drugs, and the majority fall under the 35% rate (Bellanger et al. 2005).

While UNCAM makes the final judgment regarding the inclusion or exclusion of goods and services from the positive list, the Ministers of Health and Social Security retain the right to reject the decision, especially where public health issues are concerned (Bellanger et al. 2005). As promulgated by the 2004 Act, the ministries have one month to decline the recommendations of UNCAM and must justify their decision. Previously, the ministers had several months in which to make decisions and there was no requirement for substantiation of the outcome.

The ASMR assessment and SMR categorisation by the Transparency Commission is also important in decisions made by the CEPS regarding the price of a product. The price of a reimbursable pharmaceutical is determined by negotiations between CEPS and the manufacturer⁶⁴. Price negotiations are based on the valuations of the Transparency Commission, in particular the SMR classification. In addition to the SMR, the price determination is based on the following factors (Bellanger et al. 2005; Sandier et al. 2004):

- Relevance of the respective product in the pharmaceutical market (valuated by expected sales volume)
- Research expenditure
- Advertising costs of the manufacturer

In cases where the manufacturer claims a price premium for a new, innovative product, evidence is required to justify a higher price, such that there is a clear clinical improvement over similar existing products. Moreover, pharmaceuticals that are therapeutic breakthroughs and therefore do not face any competition with other medicine, are compared internationally in order to negotiate the price between state and manufacturer (Zentner et al. 2005). However, there is no formal mechanism for setting the price of a drug in France on the basis of its price in other European countries. All prices of reimbursed drugs may not be changed without authorisation of CEPS (Bellanger et al. 2005).

Inclusion on the positive list lasts for five years, which essentially fixes the statutory reimbursement price (Zentner et al. 2005). However, the Transparency Commission can, at any time, take steps to re-assess the 'therapeutic value' (SMR) if there are changes in the therapeutic standards. Alternatively, every five years, a re-evaluation of the SMR is conducted, accounting for all current studies and the actual application of a product in clinical practice (Zentner et al. 2005). To that end, for re-inclusion of a pharmaceutical product on the positive list, prescriptions profiles are analysed in order to assess whether the drug has been correctly prescribed.

As previously mentioned, the procedures for the assessment of medical devices and criteria for reimbursement are similar to those applied to drugs (Bellanger et al. 2005; Sandier et al. 2004). The preliminary review procedures for medical devices are undertaken by the CEPP. In particular, the CEPP's remit includes a description of the product or service, an assessment of the SMR, the therapeutic and diagnostic criteria for inclusion on the positive list (if necessary), and the types of prescription and use of the medical device upon which reimbursement is conditioned (Bellanger et al. 2005). The CEPP is also responsible for any additional assessments of the SMR related to the renewal of a product on the positive list. Depending on the SMR rating, rates of reimbursement for medical devices vary from 65% to 100% (Bellanger et al. 2005). Similar to drugs, reference pricing is set by CEPS, based on the CEPP report and information provided by the manufacturers.

HTA dissemination and implementation

In terms of the positive list, all reimbursable pharmaceuticals and medical devices are published and publicly available in the official journals of the Ministers of Health and Social Security and CEPS.

According to Bellanger et al. (2005), the determination of the positive list remains a contentious issue in France, especially among those in the health and social security ministries. On one hand, French health policy promotes regulation harmonisation and health equality. However, these objectives are trying to be implemented in a context of increasing health expenditures and user fees, which may ultimately hamper the achievement of such goals. The move toward greater health equity may also be stymied by the fact that while most regulation regarding the positive list and benefits package is explicit, there exists an implicitness of coverage with particular aspects of patient care (Bellanger et al. 2005). Consequently, it may be the case that not all good and services are actually covered to the same extent in practice.

In addition, it remains to be seen whether the delegation of decision-making responsibilities regarding the benefits package to the High Health Authority and UNCAM, two self-governing bodies, is fully effective, as both the French government and physicians have historically held significant power in the health care decision-making process. To that end, the Ministers of Health and Social Security still retain rights to reject any decision rendered by UNCAM.

For ANAES, the results of assessments are used primarily to advise on research, either clinical or economic, to be conducted in the future and on resource requirements (eg, equipment or staff needs), but they have a minimal formal role in decision- and policy-making. To that end, those who commission the reports have no statutory obligation to accept or consider the recommendations set forth by ANAES. As pointed out by Orvain et al. (2004), several factors, other than economic evaluation, influence decisions, such as budget, social factors, and political priorities. Consequently, the impact of HTA assessments depends heavily on the implementation by the end decision-maker or use of the recommendations.

However, many of the ANAES report have made an impact on many different levels of decision-making and clinical practice. For example, following an ANAES recommendation against mass prostate cancer screening made two years before, the Ministry of Health requested confirmation of this advisement. Following re-evaluation of available evidence, ANAES reaffirmed the original conclusions, which was upheld by the ministry. While this example supports the use of HTA in decision-making, it remains uncertain how these reports were taken into account during the process.

Table 6: Overview of HTA governance, processes, and role in decision-making in France

France	
HTA governance and organisation	
Institution/committees	Commission de Transparence (Transparency Commission) Economic Committee for Medical Products (CEPS) Commission for Evaluation of medical devices and their related services (CEPP) *All of the aforementioned reside under the auspices of the High Health Authority.
Entity responsible for reviewing HTA evidence for priority-setting and decision-making	Transparency Commission/CEPS and CEPP/CEPS UNCAM Ministry of Health and Ministry of Social Security
HTA agenda-setting body(s)	Products for assessment are selected by manufacturers upon application for registration on the positive list.
Areas for HTA	Pharmaceuticals and medical devices
Reimbursement requirements and limitations	Therapeutic benefit and improved side effect profile relative to similar products on the positive list; decrease in the cost of treatment.
Stakeholder involvement	Medical, scientific, and pharmaceutical experts; physicians and other health professionals.
International collaboration	EUnetHTA, Guidelines International Network, International Network of Agencies for HTA, International Society for Quality in Health Care
HTA topic selection and analytic design	
Governance of topic selection	For TC/CEP and CEPP, dependent upon manufacturer submission.
Criteria for topic selection	For TC/CEP and CEPP, dependent upon manufacturer submission.
Criteria for assessment	Products are evaluated across the following criteria: <ul style="list-style-type: none"> - Effectiveness of a drug and possible side effects - Position in the therapeutic spectrum relative to other available treatments - Disease or condition severity - Clinical profile of the drug - Public health impact
Criteria outlined or publicly-available	Yes
Analysis perspective	Depends on the purpose of the assessment/study

Table 6 (continued)

Evidence requirements and assessment methods ⁵⁵	
Documents required from manufacturer	Clinical studies
Systematic literature review and synthesis	Yes
Unpublished data/ grey literature	N/A ⁵⁶
Preferred clinical study type/evidence	Double-Blind Head-To-Head-RCT
Type of economic assessment preferred or required	Any one of CMA, CEA, CUA, and CBA ⁵⁷ . The choice of method must be justified.
Availability of guidelines outlining methodological requirements	Yes, CEPS and AFSSAPS provide guidelines to manufacturers on pharmaco-economic study requirements.
Choice of comparator	Approved, listed pharmaceuticals of the same therapeutic category, in terms of the following: <ul style="list-style-type: none"> - Drugs that are most regularly used according to the amount of treatment days - Drugs with the cheapest treatment costs - Drugs most recently included into the positive list
Specification of outcome variable	Final outcomes preferred: Mortality, morbidity and quality of life.
Sub-group analyses	Yes, among other patient groups, extent and severity of illness, and co-morbidities. A priori definition must be established.
Costs included in analysis	Depends on the aim of the study/assessment. All costs that are relevant must be reported and presented in detail. Indirect costs must be reported separately.
Incremental analyses required	Yes
Time horizon	Long enough to capture long term effects and costs.
Equity issues	Not stated.
Discounting	Yes, 2.5-5% (costs and benefits). Outcomes must be presented with and without discounting.
Modelling	Yes, sufficient detail and justification required.
Sensitivity analyses	Yes, on main variables of uncertainty. Sufficient detail and reporting required.
Cost-effectiveness or willingness-to-pay threshold	No formal threshold.
Missing or incomplete data	N/A
Support for methodological development	No

55 Section applies primarily to the Transparency Commission, CEPP, and CEPS.

56 N/A=not available

57 CMA=Cost-Minimization Analysis, CEA=Cost-Effectiveness Analysis, CUA=Cost-Utility Analysis, and CBA=Cost-Benefit Analysis.

Table 6 (continued)

HTA dissemination and implementation	
Duration required to conduct assessments	A few months
Channels for HTA results dissemination	Official journals of the Ministers of Health and Social Security and CEPS.
Use of HTA results	Reimbursement and pricing decisions
Evidence considered in decision-making	Clinical, epidemiological, and economic data; financial and public health impact.
Any reported obstacles to effective implementation	N/A
Formal processes to measure impact	N/A
Processes for re-evaluation or appeals	Yes, a re-evaluation process is mandatory, every 5 years.
Accountability for stakeholder input	ANAES: Various stakeholders are able to identify priority areas for assessment and comment on draft reports. Patient participation is limited, if not non-existent.
Transparent/public decision-making process	Input required from various decision-making bodies: Transparency Commission, CEPS, CEPP, UNCAM, and Ministries of Health and Social Services. While the ministers have discretion to reject recommendations regarding the positive list, all decisions must be made within one month and explicitly justified. Pricing negotiations and conclusions are not made public.

Source: Bellanger et al. 2005; Zentner et al. 2005; Collège des Économistes de la Santé 2004; Sandier et al., 2004; OECD 2003; Fleurette & Banta 2000.

Germany

Overview of health care and reimbursement systems

A central tenet of the German political structure, especially in terms of the health care system, is shared decision-making processes between the *Länder*⁵⁸, the government, and civil society organisations (Busse et al. 2004). While the federal government, the Federal Assembly, and the Federal Council have assumed increasing responsibility of health care reform and legislation since the 1980s, the health care system is still characterised by a relatively high level of decentralisation and independent decision-making. In particular, the government typically delegates responsibilities to membership-based, independent payer and provider organisations that are involved with the financing and delivery of health care covered by the social insurance schemes, notably the Statutory Health Insurance (SHI) scheme. Such entities constitute self-regulated structures, with mandatory membership and internal control of decisions regarding membership fees and the delivery and financing of health services (Busse et al. 2004). Within these organisations reside joint committees of payers and providers, with the mandate to define benefits, rights, and prices (at the federal level) and to negotiate contracts, as well as control and sanction their members (at the regional level).

Beyond the decision-making of the aforementioned organisations, other entities contribute to decision-making and priority-setting process via consultation, shared financing of health care provision, and advocacy and the submission of proposals (Busse et al. 2004). Such entities include health provider associations, patient organisations, and private health insurance bodies.

The German constitution defines areas of exclusive federal and concurrent legislation (Busse et al. 2004). While health does not fall under an area of exclusive federal legislation, specific health issues are included in concurrent legislation, such as infectious diseases that threaten public safety, pharmaceuticals, and the economy of hospitals. All primary aspects of public health are the responsibility of the *Länder*. However, federal law, where it exists in the area of health, supersedes *Länder* law.

At the federal level, the Federal Assembly, the Federal Council, and the Ministry for Health (BMG)⁵⁹ are key actors. In terms of the latter, the ministry is responsible for eight principal areas, including European and international social and health policy; pharmaceuticals and health protection; health care, SHI, and long-term care; and, disease prevention, control, and biomedicine. The ministry collaborates with several subordinate authorities in terms of licensing and supervisory functions, and the consultation of scientific and technical matters. These entities include the following:

- *Federal Institute for Pharmaceutical and Medical Devices (BfArM)* – licenses pharmaceuticals and ensures the safety of pharmaceuticals and medical devices.
- *German Institute for Medical Documentation and Implementation (DIMDI)* – holds the responsibility for providing the public and relevant professionals with scientific and technical information in the areas of health care and medicine. Since 2000, the institute has organised, coordinated, and published health technology assessment reports. It also maintains several large health care-related databases.
- *Federal Institute for Communicable and Non-Communicable Diseases* – oversees the surveillance, detection, prevention, and control of diseases. It is responsible for disseminating reports and epidemiological bulletins to the public and professionals. Moreover, it coordinates all activities related to infectious disease control.
- *Federal Centre for Health Education (BZgA)* – develops and distributes health education materials and information, in addition to organising, coordinating, and supporting prevention campaigns and social marketing research.

Other relevant bodies that operate on the federal level include the Federal Social Insurance Authority and the Federal Authority for Financial Services, who are responsible for national social insurance and private, for-profit insurance, respectively.

58 The *Länder* is the 16 states that comprise the federal republic of Germany.

59 Add a footnote indicating that prior to 2005, the ministry was regarded as the Ministry of Health and Social Security.

60 Although public health services differ across *Länder*, they typically include health reporting, surveillance of communicable diseases, supervision of hospitals, health education and promotion, and oversight of commercial activities, including pharmaceuticals and foods.

61 Private health insurance predominantly serves to either offer full coverage to a portion of the population or provide supplementary coverage to SHI. Those individuals with full coverage are typically active or retired public employees (eg, teachers), self-employed individuals, or employed persons that opt out of SHI due to income considerations. Approximately 10% of the German population is covered by private insurance.

62 Since 2004, relates to both patented and off-patent drugs.

On the *Länder* level, there are 16 state governments, the majority of which are involved in health matters, typically in collaboration with the Ministries of Labour and Social Policy. Typically, these Ministries house several different divisions responsible for the following health-related areas (Busse et al. 2004):

- Public health services⁶⁰
- Health promotion, prevention, and AIDS treatment
- State-owned hospitals
- Hospital planning
- Supervision of health professionals and associated institutions
- Pharmaceuticals and supervisions of pharmacists.

In terms of the corporate/organisation level, the SHI scheme is overseen by affiliated physician and other health professional associations on the provider side and the sickness funds and related entities on the purchaser side. Regarding the provider side, the Federal Association of SHI Physicians is responsible for coordination between the organisational and federal levels. Moreover, within each of the *Länder*s, there is at least one provider association. The payer side is comprised of independent sickness funds organised on a regional and/or federal basis. As of January 2004, there were 292 statutory funds, accounting for approximately 72 million insured people (Busse et al. 2004). With statutory remit, the sickness funds decide upon contribution levels of members.

In terms of financing, Germany follows a pluralistic funding scheme, whereby SHI comprises the major source of health care financing (by way of sickness funds), covering greater than 85% of the population, followed by private health insurance⁶¹ and other, sector-oriented governmental schemes (eg, military). Independent of particular insurance status, contribution levels, or duration of coverage, all members and their dependents are entitled to comparable benefits, which are outlined in the Social Code Book (Busse & Riesberg 2004). The breadth of benefits offered typically includes prevention and health promotion activities, treatment of diseases (eg, ambulatory medical care, pharmaceuticals, medical devices, and home nursing care), screening, emergency care, and patient education. While the Social Code Book regulates preventive services and screening, the Federal Joint Committee has considerable discretion in defining the benefits package, especially with regards to pharmaceuticals and diagnostic and therapeutic procedures.

To that end, unlike many European countries, Germany does not have a positive list for drugs or other medical technologies, although several attempts have been made to mandate its implementation throughout the 1990s and early 2000s. Up until 2003, market registration equated to blanket SHI coverage (as well as private health insurance reimbursement), with a few exceptions, including drugs for minor conditions (eg, common cold medication); products deemed 'inefficient' and, thereby, contained on a negative list; and, those therapies limited to certain indications (Busse & Reisberg 2004). However, since the implementation of the Statutory Health Insurance (SHI) Modernisation Act in 2004, additional exclusions have been introduced, including lifestyle drugs (the Federal Joint Committee has full discretion to define the extent of this restriction) and OTC drugs for use in persons older than 12 years (Busse & Reisberg 2004). The Act also introduced new stipulations regarding off-label drug use.

While the decision-making powers of SHI bodies have been decreased in most European countries as a result of cost-containment concerns, the situation in Germany counters this trend. The aim of the federal government to exercise more control over the benefits package has translated into increased state responsibility of decisions taken by the independent entities of SHI, primarily via joint committees (Busse & Reisberg 2004). Within such entities, federal legislation promoted competition regarding the provision of services, while centralising the decision-making powers on the benefits basket.

Since the passage of the 2004 Act, various joint committees related to ambulatory care, the hospital sector, and services coordination have been combined into the Federal Joint Committee (Busse et al. 2004). Based on legislative mandate, the committee issues directives related to all sectors of care, including health technology assessment and pharmaceuticals. Specifically, such directives include setting the criteria for deciding upon benefit coverage, where a new technology is required to secure a positive evaluation in order to be covered and reimbursed by the SHI (Busse & Reisberg 2004). With specific regards to pharmaceuticals, the directives encompass a broad range of decisions on coverage, clinical guidelines, and price determination for outpatient drugs covered by the SHI. Rather than excluding drugs from the SHI coverage, the committee provides information regarding the efficacy, safety, and prices of products by indication and promulgates practice guidelines according to relative benefits and price (Busse & Reisberg 2004; Busse et al. 2004). The committee is also responsible for determining which products are to be subjected to the reference pricing scheme⁶².

All directives issued by the Federal Joint Committee are transferred to the Federal Ministry of Health for final recommendation. However, most of the decision-making processes of the Federal Joint Committee are complimented by the Institute of Quality and Efficiency (IQWiG), an independent foundation intended to support evidence-based decision-making in Germany. The responsibilities of the institute include 1) evaluating the safety and efficacy of drugs to determine inclusion in the reference pricing scheme, 2) developing reports of the quality and efficiency of the health benefits package, 3) providing recommendations on disease management programmes, 4) assessing evidence-based guidelines for epidemiological conditions, 5) disseminating reports to the public regarding the quality and efficiency of health care, and 6) evaluating and reporting on current knowledge regarding new and innovative diagnostic and therapeutic interventions for select diseases. The end duties of the IQWiG include the production of evidence-based reports on topics requested by the Federal Joint Committee and the Ministry of Health, as well as the coordination and publication of scientific work in various *areas*. (See *HTA process and procedures* below for further description of the valuation process.)

The IQWiG has an internal steering committee, which includes the director and several departmental leaders. The aim of the committee is to develop and maintain the methods of the institute. The Institute is funded through the national health insurance scheme and is overseen by the Ministry of Health.

The review and accountability of decisions made not only by the Federal Joint Committee, but other single and joint committees on the corporate/organisational level, is undertaken by the independent committees and entities themselves, the federal government (via the Ministry of Health), and the social courts (Busse & Riesberg 2004). While an emphasis on self-regulation has been supported for its foundation toward effective negotiations, public trust, and safeguards against excessive and unwarranted government involvement, it has also been criticised as lacking transparency and accountability.

Health technology assessment, governance, and organisation

Historically, both the control of health technology and the use of HTA have not been a prominent issue for Germany, despite the need for evidence-based decision-making (Perleth & Busse 2000). While German regulations, especially regarding licensing for pharmaceuticals and medical devices, meet international standards, other types of therapies and certain aspects of health technology use and diffusion did not receive sufficient attention. However, increased awareness among decision-makers (primarily the government and self-governing bodies) of the need for HTA to support decision-making on different levels of health care, in addition to enhanced networking on a European level and various health care reforms, served to strengthen and institutionalise HTA in Germany.

In particular, prior to the early 2000s, there were considerable inconsistencies in the different health care sectors with regards to coverage decisions and the management of health technology use and diffusion in Germany. For instance, the ambulatory sector was notably more regulated than the hospital sector, where explicit coverage decisions were virtually non-existent⁶³ (Busse & Reisberg 2004). Consequently, the difference(s) between sectors constituted a barrier to regulation and to rendering HTA an effective mechanism for informed decision-making and priority-setting. The SHI Reform Act of 2000 aimed at addressing this issue and strengthening HTA within the health care system by establishing a new unit within the DIMDI, the German Agency for Health Technology Assessment (DAHTA). The DAHTA develops HTA reports, along with a range of other activities, including maintaining a database-support information system on health care interventions. The information system offers access to national and international databases, and to scientific evidence in the field of HTA.

The DAHTA is supported by two leadership boards – the HTA Board of Trustees and the Scientific Advisory Board. The former comprises representatives of self-governing bodies of the German health system, consumer groups, and industry. The principal task of the board of trustees is to determine and select topics for HTA reports. In comparison, the Scientific Advisory Board is comprised of medical and health economic experts, and primarily contributes to methodological issues during the assessment process.

As previously described in greater detail, the IQWiG supports the Federal Joint Committee in deciding about the therapies and measures to be financed by the Statutory Health Insurance, among other activities related to HTA.

⁶³ This situation is primarily due to the fact that coverage of medical devices and expensive medical equipment falls under budget negotiations at the hospital level and within hospital plans at the state level.

In addition to the aforementioned, the following bodies are also involved in HTA activities (Busse et al. 2004; Busse & Reischberg 2004; Perleth & Busse 2000):

- *Office of Technology Assessment of the German Parliament (TAB)* – established in 1990, TAB, an independent scientific institution, was established to support the decision-making of the German Parliament regarding research and technology. The primary activities of TAB include designing and implementing HTA projects and monitoring major scientific and related social trends. TAB is currently moving toward expanding its range of activities by contributing to long-term technology projects, and analysing international policies and innovation developments.
- *Institute for Technology Assessment and System Analysis (ITAS)* – the ITAS is involved in a wide range of endeavours, including technology assessment, socioeconomic environmental research, and risk assessment. The ITAS is supported by the Ministries of Education and Research; Environment, Nature Conservation, and Nuclear Safety; and the EU Commission.
- *Institute for Medical Outcomes Research (IMOR)* – the institute contributes to the planning and conduct of clinical trials, meta-analyses, health economic studies, and medical decision-making.
- *Potsdam Institute of Pharmaco-epidemiology and Technology Assessment* – the institute examines the epidemiology of drug effects and utilisation and provides education on pharmaco-epidemiology and HTA.
- *German Scientific Working Group of Technology Assessment in Health Care* – the working group was established as a result of an initiative put forth by the Ministry of Health to stimulate HTA activities in Germany for improved decision-making at federal and corporate levels. The remit of the working group includes maintaining a HTA database (in collaboration with DAHTA), piloting evaluations of select medical technologies, and standardising methods for technology assessment. In addition, information about priorities for future assessments of health technologies is exchanged with the Federal Joint Committee.

HTA process and procedures

The HTA process at DAHTA is fairly standardised, guided by institutionalised standard operating procedures (SOPs), which outline a number of steps to be followed during the scope of the assessment. First, to determine and prioritise the topics of assessment, the DAHTA engages in a feasibility analysis. The aim of the feasibility analysis is to determine 1) to what extent sufficient literature is available for a topic; 2) if the policy question needs to be conceptualised more precisely; 3) whether additional research questions need to be specified; and, 4) which evaluative methods are most appropriate to the question(s). The SOPs were developed based on internal expertise and the experiences of other international HTA agencies, such as AHRQ (US), CADTH (Canada), and NCCHTA (UK).

The aforementioned objectives are determined by a systematic search of the literature, using several key databases (eg, EMBASE, MEDLINE), and comprehensive documentation of the review process. According to the list of relevant literature, a final assessment is made regarding the feasibility of the HTA report.

Prior to the feasibility analysis, topics for the production of HTA reports can be nominated by a variety of stakeholders, including the Ministry of Health. Topic nominations can be entered publicly into a database via a questionnaire available on the DAHTA website. Topic proposals can be made concerning clinical topics as well as methodical questions of HTA, evidence-based medicine, systematic reviews, or statistical methods to assess data. Nominees must clarify issues such as patient populations, purpose of technology or treatment, and patient-oriented outcome parameters to be achieved when proposing topics. Subsequent to the deadline for topic nomination, all potential topics (along with their corresponding feasibility analysis) are presented to the board of trustees, who prioritise the topics using a Delphi process and make the final selection of which reports to pursue.

The following select topics were identified as priorities in 2006:

- The determination of homocysteine in blood as a risk factor for coronary disease.
- Efficacy and efficiency of drug-eluting stents vs. coronary artery bypass graft (CABG) for the treatment of coronary heart disease.
- Evaluation of stereotactic radiosurgery (SRS) of meningiomas, compared to the fractional stereotactic radiotherapy (SRT), the 3D planned conformal radiotherapy, and microsurgical operation.
- Efficiency and effectiveness of behaviour-related measures for the prevention of smoking cigarettes.

Once the topics are selected, it is then decided what type of report is most suitable – either a full report, methods-focused report, or a brief, rapid review report. Moreover, assessments are allocated to be conducted either in-house or commissioned out to external groups. For both internal and external projects, the DAHTA employs systematic review and meta-analyses as the primary methodologies for technology assessments. In light of reviewing the available evidence, DAHTA staff typically employ pre-defined protocol or guidelines, based on methods of the Cochrane Collaboration, to direct the review process is used to review the literature, based on methods of the Cochrane Collaboration.

Once the evidence is systematically reviewed and results assembled, a draft report is passed to members of a selected in-house committee who review the document. Subsequently, it undergoes review by the Scientific Advisory Board and HTA Board of Trustees.

Since the inception of the DAHTA in 2000, it has published about 14 HTA reports. However, the number of reports published annually has been increasing, where DAHTA currently aims to complete 15 reports per year. Some of the reports published include assessments on the value of ultrasound diagnostic techniques in the prevention of fractures, the medical evaluation of using IIb/IIIa receptor blockers in the treatment of coronary syndrome patients, and a systematic overview of the methods and implementation of HTA.

Regarding the IQWiG, the institute works somewhat independently from the Federal Joint Committee and, consequently, not only receives specific commissions for economic evaluations (typically, for the evaluation of benefit of pharmaceuticals), but possesses the latitude to decide which technologies or clinical practice guidelines to assess, although no formal process is established to support that decision.

After the IQWiG receives a specific commission or decides internally to pursue an assessment, the scientific evaluation process is initiated by assembling a group of experts⁶⁴. The institute then defines the relevant patient outcomes measures to be evaluated in the assessment. The therapeutic benefit of a product must be measured against patient-relevant outcomes, typically mortality, morbidity, disease-related quality of life, and convenience of use/administration. Surrogate outcome measures are typically not considered in the evaluation, as product benefit is required to be demonstrated via high quality trials for reimbursement. To define the most appropriate outcome measures, the institute frequently consults with experts and patient organisations, supplemented by qualitative research, as required. A comprehensive evaluation plan is then developed and published.

The institute applies an evidence-based medicine approach to the evaluation. As aforementioned, the evidence required to demonstrate benefit typically falls to randomised controlled trials, with most credence given to efficacy and effectiveness data (ie, benefit), as opposed to cost-effectiveness. For the most part, there is minimal consideration given to other types of evidence. However, such evidence does not derive from manufacturer applications or submissions, but from a systematic synthesis of existing clinical data and literature. Specifically, the institute evaluates the strength of the available evidence in relation to the following factors:

- Nature and severity of disease
- Magnitude of the therapeutic effect
- Availability of treatment alternatives
- Side effect profile and risk of adverse events.

The institute consults with experts during the evaluation process, as needed, especially in terms of interrupting study results. A draft report is then developed, published, and comments are gathered from stakeholders, including patients and industry. Scientific review is also requested on the quality and interpretation of the data. Any additional analyses are completed and integrated into the report. (For further detail on evidence requirements and assessment methods, see Table 7.) The final report summarises and weighs the evidence of benefits and risks of the product; it does not contain recommendations regarding reimbursement. The report is then provided to the Federal Joint Committee.

64 However, even in the event that there is particular request for an assessment, the institute can make a decision not to undertake an evaluation, if they deem a lack of relevant data.

HTA dissemination and implementation

In terms of the DAHTA, all HTA publications are included in the in-house database; reports are publicly available either via the website or in book form. Moreover, information about HTA is disseminated in press releases, leaflets and newsletters of DIMDI, and at the annual symposia sponsored by DAHTA. To facilitate the exposure and use of the reports, the DAHTA collaborates with various HTA bodies, on both a national and international level. In particular, DAHTA corroborates with the German Network of Evidence-based Medicine, the German Cochrane Centre, the European Network for HTA, HTAi, and the International Society for Pharmacoeconomics and Outcome Research.

For reimbursement decisions, the Federal Joint Committee reviews the available evidence provided by the IQWiG to assess inclusion in the benefits catalogue and classification of the product with comparable pharmaceuticals. Beyond medical benefit, reimbursement decisions are also based on medical need and efficiency. The committee defines uniform pharmaceutical reimbursement groups for agents with similar benefit and adverse effects. If the efficacy and safety of a drug is superior to existing drugs, manufacturers are able to set the price of the product for the duration of patent protection. If they are equivalent to similar products already on the market, the new drug is classified into the reference price system. The reimbursed price for all drugs in a group is defined according to the cheapest price for a product in the group.

In contrast to earlier intentions in the early 2000s, price negotiations for truly innovative drugs were not introduced. Moreover, the evaluation of drugs is not explicitly based on cost-effectiveness and does not form the basis of inclusion to the benefits package, but as described above, into the reference pricing scheme. To that end, there has been criticism with regards to the use of 'jumbo groups' in the German reference pricing system, which essentially combines patented and non-patented drugs into a given substance class. In particular, jumbo groups are considered to diminish the acknowledgement of innovative products, erode patent protection, and distort the pricing structure of generic drugs.

The first decisions of the Federal Joint Committee, based on IQWiG evaluation, were established in mid-2004, referring to statins, sartans, triptans, and proton-pump inhibitors. Other evaluations and decisions have been made on insulin analogues and bone marrow transplants. Since its institutionalisation, there has been a number of criticisms regarding IQWiG methods. For instance, the institute's evaluation on statins and bone marrow transplant generated considerable debate on the appropriate use of clinical trial data. Moreover, when IQWiG generated an unfavourable review of Exubra, claiming no advantage over existing insulin analogues, the evaluation was highly criticised for not considering patient preferences on ease of use and other quality of life issues, despite available supporting evidence.

Broadly, IQWiG has been condemned for its methodological shortcomings, ranging from exclusion of non-trial data, lack of health economic evaluation, and not possessing a specific process for determining which technologies to assess (ie, those topics not commissioned by the ministry). However, IQWiG is newly established and will presumably undergo changes to both its mandate and processes with time and experience. In fact, there have been recent discussions surrounding the institute's remit and methodological approach. In the interim, there are some identified areas of improvement in its current evaluation procedures. First, there appears to be a disconnect between the IQWiG's principal goal of quality and efficiency in health care and its evaluative methods to assist in reaching that end. Assessments do not explicitly include or prioritise cost-effectiveness; rather, there is a narrow focus on therapeutic benefit. The divergence lies in the fact that quality and efficiency are difficult to assess (effectively) on effect only. Second, there is limited transparency in the use of stakeholders in the assessment process and the accountability of their comments and preferences in the decision-making process. Third, few assessment reports are published and disseminated by IQWiG, which hinders transparency and effective implementation of resultant decisions.

Table 7: Overview of HTA governance, processes, and role in decision-making in Germany

Germany	
HTA governance and organisation	
Institution/committees	Federal Joint Committee Institute for Quality and Efficiency (IQWiG) DAHTA German Working Group of Technology Assessment in Health Care
Entity responsible for reviewing HTA evidence for priority-setting and decision-making	Federal Joint Committee Ministry of Health
HTA agenda-setting body(s)	DAHTA, Federal Joint Committee/Institute for Quality and Efficacy
Areas for HTA	IQWiG: Pharmaceuticals DAHTA: Wide range of health technologies and health care interventions/policy issues
Reimbursement requirements and limitations	Reimbursement depends on yes/no decision for inclusion on positive list. In exceptions, conditional coverage given for particular application areas or conditions.
Stakeholder involvement	DAHTA: Stakeholders can nominate assessment topics; medical and economic experts, along with representatives from the health care system, patient organisations, and industry, participate on the leadership boards. IQWiG: Experts participate on Institute committees; experts and patient organisation contribute to defining assessment outcome measures; stakeholders are also able to comment on the draft report.
International collaboration	DAHTA: European Network for HTA, HTAi, International Network of Agencies for HTA, EUnetha, and the International Society for Pharmacoeconomics and Outcome Research. IQWiG: Guideline International Network.
HTA topic selection and analytic design	
Governance of topic selection	DAHTA: General public, stakeholder groups, HTA Board of Trustees IQWiG: Federal Joint Committee and the IQWiG
Criteria for topic selection	DAHTA: Feasibility of assessment, other criteria not stated.
Criteria for assessment	DAHTA: Typically, employs Cochrane guidance or reviewing evidence. IQWiG: Nature and severity of disease; magnitude of therapeutic benefit; availability of treatment alternatives; side effect profile; convenience of use.
Criteria outlined or publicly-available	Yes (IQWiG), but not that of the Federal Joint Committee.
Analysis perspective	Societal
Duration required to conduct assessments	DAHTA: On average, about 1 year.

65 Section applies primarily to the IQWiG.

66 N/A=not available.

Table 7 (continued)

Evidence requirements and assessment methods ⁶⁵	
Documents required from manufacturer	Not relevant.
Systematic literature review and synthesis	Yes
Unpublished data/ grey literature	N/A ⁶⁶
Preferred clinical study type/evidence	RCTs
Type of economic assessment preferred or required	Any one of CMA, CEA, CUA, CBA, depends on the purpose of the assessment/study.
Availability of guidelines outlining methodological requirements	Yes
Choice of comparator	Most effective form of treatment, most widely distributed or minimum practice.
Specification of outcome variable	Mortality, morbidity, and quality of life.
Sub-group analyses	N/A
Costs included in analysis	All direct and indirect costs.
Incremental analyses required	Yes
Time horizon	N/A
Equity issues	Not stated.
Discounting	Base case: 5% (benefits and costs); Sensitivity Analysis: 3%, 10% (benefits and costs)
Modelling	Yes, all inputs and assumptions must be reported and justified.
Sensitivity analyses	Yes, analyses conducted on main uncertain parameters. Upper and lower limits must be justified.
Cost-effectiveness or willingness-to-pay threshold	No formal threshold, but likely to employ a range between €20,000-€40,000.
Missing or incomplete data	N/A
Support for methodological development	Yes (DAHTA)

Table 7 (continued)

HTA dissemination and implementation	
Channels for HTA results dissemination	DAHTA: In-house database, available via website; press releases; leaflets and newsletters of DIMDI; and, at the annual symposia sponsored by DAHTA.
Use of HTA results	DAHTA: Primarily, provide information on health care interventions. IQWiG: Support reimbursement and pricing decisions and guideline development.
Evidence considered in decision-making	Federal Joint Committee: Medical benefit, medical need, and efficiency
Any reported obstacles to effective implementation	Use of appropriate methods, narrow definition of product value/benefit (lack of incorporation of patient preferences, etc.), and lack of transparency, especially in terms of stakeholder involvement.
Formal processes to measure impact	No
Processes for re-evaluation or appeals	IQWiG employs a review process, but not formal appeals procedure.
Accountability for stakeholder input	Stakeholders are primarily involved in topic identification and reviewing assessment reports. However, it is unclear how stakeholder input is actually used the decision-making process.
Transparent/public decision-making process	Review and accountability of decisions made by the Federal Joint Committee is undertaken by independent committees and entities, the federal government (via the Ministry of Health), and the social courts.

Source: Zentner et al. 2005; Busse et al. 2004; Busse & Riesberg 2004; OECD 2003; Perleth & Busse 2000; Hanover Consensus 1995.

67 This case study will primarily focus on England and Wales.

68 Includes the Ministries of Social Security; Environment, Transport, and the Regions; Agriculture, Food, and Fisheries; and the Department of Education and Employment.

69 This discretion partly explains the existence of variation in local service provision known as the 'post code lottery'.

70 While comprehensive bans are not allowed, exceptions are made for treatments where overwhelming evidence of clinical ineffectiveness exists. Where exclusions exist, it typically regards medicines and screening.

71 Primary Care Trusts (PCTs) are responsible for managing local primary health care services. PCTs control approximately 80% of the NHS budget. Strategic Health Authorities (SHAs) are responsible for developing plans for improving local health services, monitoring quality and performance, managing the capacity of health care services, and ensuring national priorities are integrated into local health plans. Essentially, SHAs provide a key link between the Department of Health and the NHS. As of July 2006, there are approximately 10 SHAs.

United Kingdom

Overview of health care and reimbursement systems

The United Kingdom (UK) comprises England, Scotland, Wales, and Northern Ireland⁶⁷. The UK is a constitutional monarchy, with the parliament, consisting of the House of Lords and the House of Commons, as the principal legislative body. The prime minister appoints a cabinet of senior ministers, most of whom head the main departments of state, deemed Secretaries of State. The Secretaries of State and other ministers are accountable to parliament for the work of their departments, including major policy initiatives and decisions.

In terms of health and personal social services in England, responsibility lies with the Department of Health (DH), under the auspices of the Secretary of State for Health and associated ministerial bodies⁶⁸. Separate responsibilities are held by the Secretaries of State for Scotland, Wales, and Northern Ireland. In England, the DH sets overall health policy, including policies on public health, the environment, and food matters. Moreover, the DH has responsibility for the National Health Service (NHS). In practice, health and health service provision and policy are broadly similar across the UK (Woolf & Henshall 2000), although there has been some divergence since the founding of the Scottish parliament.

The NHS was created under the National Health Services Act of 1946 to provide universal health coverage for all citizens. It is financed mainly through central government taxation, with an element of national insurance contributions. Most services are free of charge at the time of delivery, although modest co-payments apply to some medicines, dental services, and eye care.

The NHS is based on several core principles that underpin its directive. Such principles include (Department of Health 2000):

- Provision of services based on need, rather than ability to pay
- Provision of a comprehensive range of services
- Services will be developed around the individual needs of patients and different patient populations
- Services will be of high quality and with minimal errors
- Public funds for health care will be dedicated solely to NHS patients
- NHS will strive to protect the health of individuals and reduce health inequalities
- NHS will respect individual confidentiality and will provide open access to information about services, treatment, and performance

Moreover, care provision is grounded in issues of fairness and consistency, with the availability of services determined by the matter of effectiveness ('clinically appropriate') and cost-effectiveness (Department of Health 1997). To that end, the NHS is not obligated to provide specified services, but those 'necessary to meet reasonable requirements'⁶⁹. In addition, the Secretary of State is able to take economic factors, specifically NHS financial capacity, into account and blanket bans on particular services is prohibited (Mason & Smith 2005)⁷⁰. Consequently, the NHS is situated in a context where there are no specific entitlements to services, but little is explicitly excluded.

By mandate, Primary Care Trusts (PCTs) and Strategic Health Authorities (SHAs) carry out the Secretary's duties to ensure that the implantation and delivery of NHS services meets requirements and standards⁷¹. More specifically, while the SHAs carry the duty to promote comprehensive services, PCTs are responsible for prioritising service provision, with their respective financial budgets. Legislation directs these entities to regard the aforementioned principles (under the NHS Plan) when exercising their functions.

To complement its core principles and to meet 'reasonable requirements', the NHS Plan of 2000 emphasised the role of implementation and delivery, focusing on such components as the National Service Frameworks (NSFs), National Institute for Health and Clinical Excellence (NICE), waiting time guarantees, and guidance from the DH (Mason & Smith 2005). These measures also help specify the conditions under which patients may be eligible for health care services. Taken together, these mechanisms contribute to regulatory quality and control, as well as the protection of rights to health care. The adherence to these standards is regulated by the Healthcare Commission, which is responsible for monitoring compliance among NHS organisations.

The NSF, introduced in the 1997 White Paper, aim to increase quality and reduce variation in services via the introduction of standards and the identification of key interventions for a particular patient group(s). Moreover, NSFs establish strategies to facilitate implementation. Essentially, NSFs serve as positive guidance and do not explicitly delineate interventions that should not be undertaken (Mason & Smith 2005). To date, NSFs have addressed a wide range of topics, including cancer, diabetes, long term conditions, and coronary heart disease. For example, regarding coronary heart disease, the NSF set 12 standards for improved prevention, diagnosis, and treatment, and goals to secure equitable access to high quality services. Typically, one NSF is produced per year (Mason & Smith 2005).

Introduced in 1999, NICE was created to promote clinical excellence within the NHS by reducing variation in the uptake of new health technologies (Newdick 2005). Moreover, part of the remit of NICE is to support the effective use of resources, outlining that cost-effectiveness be included in the institute's decisions. NICE produces three types of guidance, including technology appraisals, clinical guidelines, and interventional procedures. Since mid-2005, NICE has assumed the responsibilities of the Health Development Agency, which gave the institute a remit for the evaluation of public health interventions.

NICE guidance essentially serves a quasi-law function, but one aspect of technology appraisals is supported by mandate. Specifically, if NICE guidance supports that a particular technology be made available by the NHS to a certain patient group(s), then associated health care organisations are obligated to implement such recommendations (Mason & Smith 2005). Moreover, they are required to do so within three months of the date the guidance was published. (See *HTA procedures and processes* below for further description regarding NICE processes and guidance development).

In addition to the NSFs and NICE, the DH often develops and disseminates guidance on a range of health care issues. Typically, the principal form of guidance involves Health Service Circulars (HSCs), which frequently supplement Local Authority Circulars (LACs). The circulars generally call for a specific, quasi-legislative action. However, some circulars take the form of directives from the Secretary and, therefore, are legally binding. Further, guidance is also generated specifically for the PCTs and other trusts, which is typically promulgated by the SHAs.

Beyond NICE, there are several 'arm's-length' entities that service the NHS under four broad areas, including regulation, standards, public welfare, and central services (Mason & Smith 2005). Key bodies include the Healthcare Commission, the Monitor, the Medicines and Health care products Regulatory Agency (MHRA), and the Pharmaceutical Price Regulation Scheme (PPRS), as described below:

- **Healthcare Commission** – an independent regulatory body for health care organisations, which includes both the NHS and private institutions. Regulatory activity of the Commission surrounds assessment of compliance with standards set by the DH to ensure quality of care and the capacity of organisations to deliver such services to patients. Health care organisations are evaluated according to adherence of standards related to safety, clinical and cost-effectiveness, governance, patient focus, accessible and responsible care, amenities and care environment, and public health.
- **Monitor** – as an independent public body, the Monitor promotes comprehensive health services, provides facilities to medical and dental schools, and ensures the financial sustainability of the NHS Foundation Trusts⁷². In managing the Foundation Trusts, the Monitor essentially stipulates the goods and services that may be provided.
- **MHRA** – the MHRA is an executive agency of the DH and is responsible for ensuring that medicines and other medical products meet appropriate standards of quality, safety, performance, effectiveness, and appropriate use. As part of its remit, the MHRA assesses the safety, quality, and efficacy of medicines; authorises medicines; operates post-market surveillance monitoring; regulates clinical trials; evaluates regulatory compliance via inspection; and, promotes the safe use of medicines.
- **PPRS** – the PPRS seeks to secure the provision of safe and effective medicines at responsible prices, promote competition within the pharmaceutical industry, and support the development and supply of medicines. It embodies a series of rules focused on regulating the profits that pharmaceutical companies receive from sales of medicines to the NHS. In so far as the PPRS influences the decisions that companies make about the prices of individual medicines, it has an impact on their cost-effectiveness in the UK.

Outside of the aforementioned organisations, several other entities play a key role in the UK health system, including consumer and voluntary groups, professional bodies (eg, British Medical Association), and the private sector. To the latter, private health insurers primarily act as a safety net for cases where demand exceeds NHS supply, with patients relying either on insurance coverage or self-payments.

⁷² NHS Foundation Trusts are a new type of NHS organisation aimed at decentralization of health care decision-making and service provision. While they are firmly situated with the NHS and abide by NHS standards, Foundational Trusts are accountable to local communities, as opposed to the central government.

Health technology assessment, governance, and organisation

As with most countries, a major contributing factor to rising health care costs is the rapid emergence of new and expensive health technologies. Some estimates have indicated that technological advances cause NHS costs to increase an average of 0.5-1% per year (Woolf & Henshall 2000). As a result of rising costs and resource-limited health care budgets, there has been growing emphasis on priority-setting and focusing resources on interventions that offer patients effective and affordable benefits. Moreover, evidence regarding effectiveness (and cost-effectiveness) has increasingly been a focus of NHS programmes.

In this context, HTA has emerged as a policy priority in the UK, not only to determine the most appropriate interventions for health care services, but also to improve quality and value for allocated resources. Consequently, there has been widespread activity in HTA in recent years. While much of HTA has stemmed from the DH, NICE, and the National Coordinating Centre for Health Technology Assessment (NCCHTA), there is on-going activity among various entities throughout the UK, which is not restricted to NHS programmes.

As previously described, NICE is an independent organisation responsible for providing national guidance on a variety of health interventions. Specifically, the roles and responsibilities of NICE encompass producing guidance on public health, health technologies, and clinical practice. NICE guidance with regards to public health focuses solely on England, while guidance on health technologies and clinical practice cover England and Wales. However, guidance regarding interventional procedures is applicable to England, Wales, and Scotland.

NICE is structured across three different centres – the Centre for Public Health Excellence, the Centre for Health Technology Evaluation, and the Centre for Clinical Practice. Created in April 2005, the Centre for Public Health Excellence develops guidance on the promotion of good health and disease prevention. The centre's guidance is targeted towards practitioners and policy-makers in the NHS, local authorities, private and voluntary sectors, and the general public. The guidance produced by the centre concerns topics central to policy on public health.

To support the production of guidance, the Centre for Public Health Excellence is organised into three Public Health Programme Development Groups, each headed by an Associate Centre Director. The development groups are responsible for supporting the development of public health guidance by scoping topics, engaging with stakeholders, organising review of the guidance, and managing public consultation (NICE 2006a). Following consultation, the development groups devise final recommendations. The directors, who are leaders in the field of public health, provide support and direction to the respective groups on generating evidence and developing guidance. In addition, they manage any work done with collaborating centres. The membership of the development groups entails researchers and practitioners, representatives of the stakeholders on the topic under evaluation, and individuals supporting the general public, as appropriate.

On a more general level, the Public Health Interventions Advisory Committee reviews the guidance developed by the development groups (NICE 2006a). The committee comprises health researchers, statisticians, epidemiologists, methodologists, practitioners, and lay stakeholder groups. The Advisory Committee is assisted by Specialist Advisors, who are clinicians nominated or approved by professional bodies. In some cases, experts on a particular subject are invited to participate in committee meetings to provide expert testimony. Moreover, NICE has a commissioned Review Body, composed of universities and an academic hospital, to provide systematic reviews of interventional procedures and collect data.

The Centre for Health Technology Evaluation develops guidance on the use of new and existing medicines, treatments, and procedures within the NHS. The work of the centre is overseen by three primary entities, including the Interventional Procedure Advisory Committee (IPAC), independent academic centres, and the Technology Appraisal Committee. The IPAC includes NHS health professionals and other individuals familiar with key issues affecting patients. The committee also collaborates with specialist advisors, nominated by relevant health professional bodies.

The Centre often commissions an independent academic centre, called Technology Assessment Report (TAR) Teams or Centres, to prepare TARs for consideration by the Technology Appraisal Committee (see below). In particular, NICE collaborates with the following centres (NICE 2004a):

- Health Economics Research Unit and Health Services Research Unit, University of Aberdeen
- Liverpool Reviews and Implementation Group, University of Liverpool
- Centre for Reviews and Dissemination and Health Economics, University of York
- Peninsula Technology Assessment Group (PenTAG), Peninsula Medical School, Universities of Exeter and Plymouth
- School of Health and Related Research (ScHARR), University of Sheffield
- Southampton Health Technology Assessment Centre (SHTAC), University of Southampton
- West Midlands HTA Collaboration, Department of Public Health and Epidemiology, University of Birmingham

In addition, the centre also holds the Technology Appraisal Committee. The Committee is an independent entity with membership drawn from the NHS, patient organisations, academia, and industry. Members are typically appointed for a three-year term, and allocated to one of two branches within the committee (NICE 2004a).

In addition to the aforementioned, the centre confers with various 'consultee organisations', ranging from national patient groups, health professional bodies, and manufacturers of the technology under review. Such entities are able to submit evidence during the evaluation process, comment on the appraisal documents, and appeal against the Appraisal Committee's final recommendations. Moreover, the centre relies on 'commentator organisations', which are represented by manufacturers of comparator products, NHS Quality Improvement Scotland, and research groups working in the relevant topic area. These bodies can comment on evidence and other documents used or produced by the appraisal process, but cannot submit evidence.

The Centre for Clinical Practice offers guidance on the appropriate treatment of specific diseases and conditions within the NHS. The guidelines interpret and provide guidance on how to implement the NSFs. To help manage guideline development and subsequent publishing thereof, the centre relies on support of National Collaborating Centres (NCCs), which represent the Royal Medical Colleges, professional bodies, and patient organisations. The seven NCCs oversee different disease areas, such as cancer, mental health, and chronic conditions. To develop a guideline, the Collaborating Centre establishes a Guideline Development Group, with member with expertise in systematic review, evidence appraisal, and clinical, cost-effectiveness, and patient issues. Registered stakeholders are invited to nominate members of the group. The Development Group also consults with stakeholders to inform guideline development.

In addition to the aforementioned, the centre also has a number of Guideline Review Panels, typically consisting of four or five members (including a chair and deputy), that serve to validate the final complete guideline. In particular, the review panels focus on how any comments received during the consultation process were considered in the final guideline.

Beyond the special committees, NICE houses a board, with various sub-committee and Partner and Citizens Councils. The Citizens Council assists NICE decision-making by offering views of the public on key issues informing the development of guidance. The council consists of approximately 30 individuals, drawn from various population groups. While participation is open to the broader public, the aim of the council is to provide involvement from stakeholders not typically represented in the assessment process. Therefore, NHS employees, patient groups, those representing lobbying organisations, and industry are not allowed to participate on the Citizens Council (NICE 2004b). The recruitment of members is carried out by independent facilitators with no direct association with NICE.

While there are different arms of NICE, collaboration between the various centres is encouraged and increasingly commonplace. For example, the outputs of one centre are occasionally used in the guidance produced by the other bodies (eg, technology appraisals often inform clinical guidance). This coordination allows for a more coherent presentation of advice to stakeholders and efficient use of resource and expertise with the institute.

Beyond NICE, the NCCHTA is another primary HTA body in the UK. The NCCHTA manages, supports, and develops the NHS HTA programme on behalf of the DH Research and Development Division. The centre is part of the Wessex Institute of Health Research and Development at the University of Southampton. The objective of the NHS HTA programme is to provide information on the costs, effectiveness, and broader impacts of health technologies, specifically for those who use, manage, and provide care in the NHS. Additionally, the HTA programme provides support to NICE via managing TAR contracts and contributing to Single Technology Appraisals (see *HTA processes and procedures*) by commissioning Evidence Review Group reports, which appraise submissions from manufacturers.

73 This section focuses on NICE HTA processes and procedures.

74 Appropriateness measured by whether
1) topic is within NICE's remit,
2) NICE has already produced or developed guidance on the topic,
3) the topic represents an emerging public health issue, and 4) the topic is an ultra-orphan disease.

The NCCHTA relies on a number of different internal and external expert bodies for its research activities. In particular, various experts contribute as members of HTA panels, the Expert Advisory Network, the Prioritisation Strategy Group, the HTA Commissioning Board, and the HTA Clinical Trials Board, as well as individual experts and referees who provide input on research proposals and final reports. The HTA panels' key function is to set research priorities. The panels represent four different areas: pharmaceuticals, diagnostic technologies and screening, therapeutic procedures, and disease prevention. The Expert Advisory Network assists in providing the HTA panels with a comprehensive range of expertise on topics and settings of care, which serves to supplement the specialties and disciplines represented in the other entities. The Prioritisation Strategy Group was established to develop an HTA research portfolio, according to the needs of the NHS and available research with the HTA programme budget. The HTA Commissioning Board is principally responsible for assessing research proposals submitted after topics have been prioritised. The board also makes funding recommendations to the director of the HTA programme, typically two or three times per year. Finally, the HTA Clinical Trials Board considers research proposals submitted to the HTA programme for clinical trials in support of assessing the effectiveness of technologies within the NHS.

In addition to formalised committees, the NCCHTA actively involves the public during the assessment process. Specifically, the public has some level of participation in the following stages (NCCHTA 2006):

- Identifying topics for research
- Reviewing and prioritising research proposals
- Reviewing draft assessment reports
- Agenda-setting for R&D priorities in the NHS and future public involvement.

As previously mentioned, in addition to NICE, NCCHTA, and associated collaborating organisations, there are a number of entities engaged in HTA activities across the UK. Such bodies include the commercial and charitable sectors, academia, Medical Research Council, the National Horizon Scanning Centre, the UK Cochrane Centre, and Joint Committee for the Review of Vaccines. In addition, NHS Trusts also produce their own local formularies and often have committees to assess the impact of new medicines on their own budget as well as on primary care.

HTA process and procedures⁷³

To initiate the guideline development process, NICE receives suggested topics from a number of sources. In general, the DH commissions NICE to develop clinical guidelines, guidance on public health, and technology appraisals, while topics for the interventional procedures programme are submitted directly to NICE, usually by clinicians. Besides the DH and clinicians, topics for potential NICE guidance derived from public health professionals, patients, and the general public; the National Horizon Scanning Centre; and, within NICE itself. The public, including patients and health professionals, can suggest a topic for guidance by completing a form (either on-line or in hard copy) and submitting it to NICE. For manufacturers, topic requests are submitted to the National Horizon Scanning Centre, which informs the DH of key new and emerging technologies that might need to be evaluated by NICE.

As a result of a public consultation process in mid-2006, NICE was given responsibility for the initial stages of the topic selection process on behalf of the Department. Once a topic is submitted, NICE initially reviews the suggestion for appropriateness⁷⁴. Subsequently, the topics are filtered according to several selection criteria set forth by the Department. The list of selection criteria was created in July 2006, following a public consultation process. Specifically, the selection criteria include (NICE 2006b):

- Burden of disease (*population affected, morbidity, mortality*)
- Resource impact (*cost impact on the NHS or the public sector*)
- Clinical and policy importance (*whether the topic falls within a government priority area*)
- Presence of inappropriate variation in practice
- Potential factors affecting the timeliness for the guidance to be produced (*degree of urgency, relevancy of guideline at the expected date of delivery*)
- Likelihood of guidance having an impact on public health and quality of life, reduction in health inequalities, or the delivery of quality programmes or interventions.

A panel composed of experts in the relevant topic area, generalists with a substantial knowledge of health service and delivery, public health professionals, and patient representatives review the topic suggestions according to the aforementioned criteria. The panel's recommendations are then reviewed by ministers at the DH, who hold responsibility for the final decision regarding which topics are referred to NICE for the development of guidance.

Depending on the type of guidance, NICE employs a slightly different assessment process. For public health issues, NICE produces two types of guidance – *public health intervention guidance* and *programme guidance*. In terms of the former, the process follows the subsequent steps (NICE 2006a):

- *Topic selection* (see above)
- *Registration of stakeholders* – stakeholders (eg, professional organisations, research and academic institutions, industry, general public) with an interest in participating in the guidance development process are requested to register with the institute.
- *Preparation of project scope* – an outline of the guidance content and development process is created and, following a consultation process, finalised. The scope aims to 1) provide a clear definition of the topic, 2) identify the relevant care settings, health delivery systems, and providers, 3) ascertain the policy context, 4) develop key questions (should relate to effectiveness, cost-effectiveness, feasibility, and acceptability, among other factors), 5) substantiate clear timelines, and 6) specify the outcome measures and any comparators. An initial literature search and development of a conceptual and analytical framework help inform and guide preparation of the scope.
- *Systematic review of evidence* – a review of the evidence and an economic appraisal is completed on the public health intervention. The review may be conducted by NICE or an external research body. A synopsis of the review is created, which is disseminated to registered stakeholders for comment.

The review is based on the best available evidence drawn from a range of disciplines and research traditions. Evidence is selected and appraised according to well-defined criteria, based on its appropriateness to answer the research question. NICE requires that the process for identifying the evidence be as transparent as possible; all search strategies and terms must be documented. Typically, each review will use one or more of the following sources of evidence:

- Evidence briefing (review of reviews)
- Systematic review of primary data
- Existing, published primary research
- New primary research, where appropriate and time and resources allow.

Stakeholders are also invited to submit potential evidence (eg, systematic reviews, RCTs, epidemiological studies, other guidelines on the topic, economic models, etc.) during consultations of the synopsis.

The review process involves a number of standardised steps, ranging from assessing the quality of the selected evidence, extracting and synthesising the evidence (eg, evidence tables, meta-analyses), to developing evidence statement (summary on each of the key questions).

The economic component of the appraisal is typically conducted if the topic is deemed a priority area, as measured by whether 1) major resource implications are present, 2) current public health practice may be challenged, 3) sufficient data exists for modelling, and 4) there is a lack of consensus among public health professionals.

A systematic review of the evidence is usually entailed, based on a standardised guidance document outlining steps for reviewing evidence, documenting the quality of studies, etc. Moreover, reviewers follow a methodology checklist in the economic evaluation. Further information on the methods used in the economic evaluation is detailed in Table 9.

Independent of the particular analytical approach taken on a given topic, all economic evaluation is underpinned by transparency in the reporting of methods and any uncertainty pertaining to both internal and external validity. Moreover, the limitations of the methods used are fully discussed.

- *Drafting of the guidance* – the Public Health Interventions Advisory Committee reviews the synopsis and drafts the guidance. Recommendations are based on the several factors, including the strength of supporting evidence, importance of outcomes, health impact, cost-effectiveness, and other considerations (eg, inequalities, implementation/feasibility).
- *Consultation on the draft guidance* – the guidance undergoes a consultation period of one month.

- *Conduct of fieldwork* – the draft guidance is tested via meetings with practitioners in the field. Meeting reports are drafted in a technical document and submitted to the Advisory Committee.
The field meetings are predicated on the notion that successful implementation of guidance depends on evidence-based recommendations informed by practical experience. To meet this end, at least four to five full day meetings are convened, and these take place across a variety of geographic regions. Independent professional facilitators are selected to facilitate each meeting. Typically, a maximum of 35 practitioners (with experience related to the topic) is invited to each meeting. The series of meetings cover the work environment in which the practitioners operate, the evidence reviewed during the assessment, and the subsequent draft guideline and recommendations. All meetings are recorded to ensure transparency and accuracy of information.
- *Production of the final guidance* – the Advisory Committee reviews the technical document and comments from the consultation period, and produces the final guidance.
- *Approval and issuance of guideline* – following peer review, NICE formally approves the final guidance and disseminates it to the NHS.

The development procedure for programme guidance is similar to the aforementioned process, except that a Programme Development Group (PDG) is created to draft and finalise the guidance (similar responsibilities as the Advisory Committee).

For interventional procedures guidance, the assessment process entails the following steps (NICE 2004g):

- *Notification of procedures to NICE* – while it is typically physicians that notify NICE of potential procedures to review, all stakeholders submit a request. NICE primarily investigates new procedures. One such stakeholder, the National Horizon Scanning Centre, notifies NICE of procedures likely to be used for the first time within the next year. NICE compiles and maintains a list of all notified procedures.
- *Registration of stakeholders* – see section on public health intervention guidance.
- *Preparation of overview* – an overview of the procedure is prepared in collaboration with at least three specialist advisors. Subsequently, the Interventional Procedures Advisory Committee considers whether to move forward with the guidance.
The overview document summaries the nature and purpose of the procedure; results of valid studies found in a rapid review of the literature; key safety and efficacy issues; and, opinions of the specialist advisors. Of note, the overview documents do not represent the result of a systematic review.
Device manufacturers and other stakeholder can submit or alert NICE to any new evidence or publications relevant to the procedure. Other non-confidential information may also be submitted at this stage.
- *Referral to the Review Body* – upon consideration of the overview document, the Advisory Committee decides whether to refer the procedure to the Review Body for further investigation, which typically involves a systematic review and/or collection and analysis of data. The committee considers public health impact, innovation of the procedure, adverse event profile, and potential uptake when making referral decisions.
- *Production of consultation document* – upon the Review Body presenting the review to the Advisory Committee, a decision is made regarding whether to proceed with the process or collect additional data on the procedure. In light of the former, a consultation document is created, outlining the safety and efficacy associated with the procedure. Evidence used in the report is provided by the Review Body. The document and all supporting materials (eg, technology appraisals, guidelines) are then posted on the NICE website for comment (open for four weeks) and key stakeholders are notified.
- *Development of final recommendations* – following the consultation period, the Advisory Committee produces final recommendations and submits to NICE for approval.
In producing the recommendations, the committee considers the efficacy and safety of the procedure. Such considerations may or may not involve comparison with other procedures or treatments.

- *Notification of recommendations* – once approved, consultees (see HTA governance and organisation section) are notified to review the guidance. Consultees can submit a resolution, within 15 days, in the event they feel the guidance is inaccurate or have complaint with the development process.
- *Issuance of guidance* – guidance is issued to the NHS. In cases where sufficient evidence exists regarding the procedure's safety and efficacy, the Advisory Committee may refer the procedure to the Advisory Committee on Topic Selection with the recommendation for a technology appraisal.

In addition to publishing the consultation document and the final guidance on the website, NICE also publishes the overview summary, minutes of Advisory Committee meetings, reports from the Review Body, and any evidence pivotal to the committee's decisions, with the exception of unpublished data deemed 'commercial or academic in confidence'. NICE publishes the aforementioned information to ensure transparency of the guidance development process.

As previously mentioned, NICE also produces technology appraisals, of which there are three different versions: *full appraisals*, *quick reference guides*, and *information for the public*. Each version targets different stakeholder groups, from the NHS and health professionals (full appraisals and quick reference guides) to patient groups and a lay audience (information for the public).

While there are some differences, the process for technology appraisals is similar to the procedures employed in developing public health guidance, as outlined below (NICE 2004a, NICE 2004c, NICE 2004f).

- *Production of provisional list of appraisal topics* – The DH produces a list of provisional appraisal topics.
- *Identification of consultees and commentators*
- *Preparation of project scope* – (see above). However, with regards to technology appraisals, NICE collaborates with the DH to develop the scope. Unless the DH specifies otherwise, appraisals do not normally consider the use of technology for indications for which regulatory approval has not been granted in the UK. For each potential appraisal topic, a consultation process with the consultees and commentators is initiated, where the scope is reviewed and available for comment. Manufacturers are asked to include in their comments any information on pending license applications and timeframe for regulatory approval. The draft scope is also posted on the institute's website. Subsequent to receiving comments, NICE convenes a scoping workshop with consultees and commentators, the DH, and the Welsh Assembly Government. Amendments are then made to the scope, where needed. The scope is then finalised and submitted to the Ministers of Health for a decision on the technology appraisal is suitable for formal referral to NICE (see above for more information on topic selection).
- *Preparation of the appraisal* – timelines and the finalising of consultees and commentators are established. Along with the final scope, this information is published on the NICE website. The Assessment Group (typically one of the TAC groups) is formally commissioned, in conference between NICE and the NHS HTA Programme (through the NCCHTA), to prepare the report upon issuance of the final scope and list of consultees and commentators. In preparation for the appraisal, manufacturers will be asked to prepare a written submission, containing available evidence on clinical- and cost-effectiveness, which will be sent to the Assessment Group and used to inform the Assessment Report. To uphold the transparency of the appraisal process, all evidence pivotal to the committee's decision is typically made publicly available. Under particular circumstances, NICE accepts unpublished or part-published evidence under agreement of confidentiality. This is particularly the case where technologies are undergoing appraisal immediately prior to regulatory approval. Such evidence includes commercial in confidence and academic in confidence data. At a minimum, a structured abstract should be made available for public disclosure. All confidential information, however, is available for review by the Assessment Group and Appraisal Committee. The same principles apply to the release of information submitted in the form of economic models. Any available models must be included with the written submission in electronic format. In particular, manufacturers are required to identify all studies relevant to the appraisal, in the form of clinical trials, follow-up studies, and registry evidence. For cohort studies and case series, a full report of baseline characteristics, rationale for case selection, and the best equivalent evidence on the best available treatment for patients is needed. Moreover, manufacturers are asked to comment on any other factors to be taken into account when interpreting the clinical- and cost-effectiveness.

75 NICE does not apply a fixed willingness-to-pay threshold, but bases decisions primarily on the cost-effectiveness estimate for incremental cost-effectiveness ratios below £20,000 per QALY (Rawlins & Culyer 2004). However, as the incremental cost-effectiveness ratio increases, the likelihood of rejection on the grounds of cost-ineffectiveness rises. Typically, NICE requires additional justification for ratios over £25,000 per QALY. Particular considerations would include the degree of uncertainty surrounding the estimate, equity and public health impacts, and the innovative nature of the technology.

- *Development of the Assessment Report* – the Assessment Group reviews the clinical and cost-effectiveness of the technology based on a systematic review of the literature and manufacturer submissions to NICE. The evidence on therapeutic effect considered in the review ranges from RCTs to observational studies, although head-to-head clinical trials are preferred. For cost-effectiveness, evidence requirements include benefit on the course of disease, impact on patients' health-related quality of life, and the value of those impacts in representation of the preferences of the general population. In addition, evidence is needed on the effect of the technology on resource use and the valuation of those effects in monetary terms. Evidence on cost-effectiveness can be obtained from original analyses and/or systematic reviews of existing published literature. Where relevant and available, evidence on acceptability, appropriateness, preference, feasibility, and equity are also considered in the assessment. Evidence is typically submitted by the Assessment Group, manufacturers, patient groups, and health professionals/providers. The Assessment Group will also consult with clinical and methodological experts, in gathering evidence for the report. The Assessment Group may also produce an economic model in support of the report. The economic model is essentially owned by the relevant Group and cannot be used for any purpose than informing the assessment.

Table 9 provides further details on the methods used for assembling and synthesising evidence on the technology being appraised in order to estimate its clinical- and cost-effectiveness.

The Assessment Report is not a comprehensive review of all the information on a given technology, but is a focused assessment of the evidence pertinent to the defined scope. The extent to which the Assessment Group uses submitted evidence depends on how closely it aligns with the criteria defined in the assessment protocol and follows recognised methodological guidance.

Upon completion of the report, it is submitted to NICE and is employed as the basis of the appraisal. NICE contacts the consultees and commentators to inform them of the availability of the report for comment. Typically, a timeframe of approximately 36 weeks is allocated to completing the report.

- *Development of the Evaluation Report* – the Assessment Report and other evidence and comments put forth by the consultees and commentators are combined into an Evaluation Report. The report does not propose recommendations on the use of the technology for the NHS. Rather, recommendations are developed that form the guidance on the use of the technology.
- *Production of the Appraisal Consultation Document (ACD)* – the report is then submitted to an independent committee, the Appraisal Committee, for consideration. The Appraisal Committee reviews the evidence and nominated clinical specialists and patient experts participate in the meeting of the committee, where they can respond to and pose questions. The committee then sets forth their recommendations in the ACD. The recommendations regard the clinical and cost-effectiveness of treatment for use within the NHS. It is also within the remit of the committee to recommend against the use of treatment where the benefits to patients are unproven or not cost-effective. The committee is not responsible for making recommendations on the pricing of the technologies to the NHS.

In appraising the evidence, the committee considers the following factors:

- The nature and quality of the evidence
- Uncertainty generated by the evidence and difference between the evidence submitted for licensing and that related to effectiveness in clinical practice
- Consideration of effectiveness and adverse events in different subgroups of patients
- The risks and benefits of the technology from the patient's perspective
- Position of the technology in the overall care pathway and in consideration of alternative treatments
- Implications for health care programmes by the adoption of the new technology
- Appropriateness of the comparator technology or technologies, as perceived by NHS stakeholders
- Estimates of cost-effectiveness (as evidenced by the incremental cost-effectiveness ratio)⁷⁵
- Robustness of the economic methods (eg, modelling, sensitivity analysis)
- Broad clinical and policy government priorities
- Extent of health need
- Effective use of available resources
- Long-term objective of encouraging innovation that will benefit NHS patients.

The ACD highlights the key evidence used in the appraisal process and highlights any areas of contention or uncertainty. Upon finalisation, the document is made available to the consultees and commentators, health professionals, and the public for comment. The comment period spans a four-week period.

In the event that new data become available during the appraisal process that materially impacts the provisional recommendations set forth in the ACD, the committee may choose to re-formulate the ACD for additional rounds of consultation. Such data would typically include new trial data, new analysis or modification of the economic model, and changes in the licensed indications of the technology.

- *Production of the Final Appraisal Determination (FAD)* – the Appraisal Committee reviews the comments on the ACD and then renders its final recommendations in the FAD. The FAD is then submitted to NICE for final approval. This process takes approximately 14 weeks to complete. Consultees are given the opportunity to appeal against the FAD or the way in which the appraisal process was conducted. The grounds for appeal include 1) NICE has failed to act in accordance with its published appraisal procedures, 2) FAD does not reflect submitted evidence, and 3) NICE has exceeded its remit. At the discretion of the Appeal Committee, appellants are given an opportunity to make an oral submission of complaint.
- *Issuance of Guidance* – if there are no appeals or one is not upheld, NICE officially issues the guidance (Technical Appraisal Guidance or TAG).

As previously discussed, to facilitate transparency of the appraisal process, NICE will make the majority of evidence pivotal to decision-making publicly available, with the exception of ‘commercial and academic in confidence’ data.

In addition to the aforementioned appraisal procedure (termed ‘multiple technology appraisals’ or MTAs), NICE developed a Single Technology Appraisal (STA) process in 2005 for the appraisal of single technologies for a sole indication. In this case, most of the relevant evidence lies with on manufacturer or sponsor, and the process is employed for new pharmaceutical products close to market launch. The decision as to whether the appraisal of a technology is appropriate the STA process is made during the topic selection stage (see above). Selection is typically based on factors, such as the complexity of current standard treatments and the likelihood of the evidence base being help principally with the sponsor. The STA process is used to ensure that NICE is able to issue guidance to the NHS on new technology quickly after their introduction into the UK market.

The STA process is similar to that of the full appraisal process, previously described. However, in terms of the former, only the evidence submission by the manufacturer is formally considered in the independent review. Moreover, formal consultation procedures only take place if the Appraisal Committee’s preliminary recommendations are substantially more restrictive than the terms of the license indication under appraisal (NICE 2006c). The timelines for the STA process are differ (NICE 2006c). Specifically, STAs require less time to produce the guidance, approximately 32 to 39 weeks, from initiation of the appraisal to publication. However, the FAD is publicly-available at 27 and 35 weeks. In cases where the appraisal is tracking regulatory approval, the first Appraisal Committee meeting is organised subsequent to a positive opinion by the EMEA. The minimum time from regulatory approval to publication of the guidance is between six and 13 weeks.

STA guidance is considered for review subsequent to being published, although the time between publication and review varies, based upon the anticipated rate of development of evidence for the technology and prior knowledge of the completion of pivotal research (NICE 2006c). In general, this period normally spans one to five years. To date, the STA process has been applied to drugs, mainly to cancer drugs.

Lastly, NICE produces *clinical guidelines*, which aim to improve the quality of health care by providing recommendations for treatment and informing standards for health care professionals and decision-making among patients. NICE develops four versions of its clinical guidelines: *full guideline*, *NICE guideline*, *quick reference guide*, and *information for the public*.

The process to develop the guidelines is similar to that of the public health intervention guidance. The procedures are delineated in brief below (NICE 2006d, NICE 2006e):

- *Topic selection* (see above)
- *Registration of stakeholders*
- *Preparation of project scope and workplan* – the National Collaborating Centre (NCC) commissioned to develop the guideline prepares the scope, in collaboration with NICE, registered stakeholders, and an independent guideline review panel. *See previous sections for further details in the scope.*
An initial literature search and development of a conceptual and analytical framework help inform and guide preparation of the scope.
The scope is subject to consultation with stakeholders over a four-week period. During this time, the scope is always published on the NICE website. Following review and response to any comments, NICE approves the scope. Following the scope, a workplan is devised to specify methods, timelines, and cost. The workplan forms an agreement between NICE and the NCC for development of the guideline.
- *Establish Guideline Development Group* – the group is comprised of health professionals, representatives of patient organisations, technical experts. Registered stakeholders can nominate people to participate in the group.
- *Systematic review of evidence* – evidence in support of the guidance typically derives from searches of electronic databases and via information submitted by stakeholder organisations. *See section on public health intervention guidance for further details on the review process.*
A health economist participates in the Guideline Development Group to provide advisement of economic issues, review the economic literature, and recommend select components of the review or guideline that would benefit from original economic analysis, such as cost-effectiveness analyses or modeling. Table 9 outlines the methods used in the guideline development process.
If the evidence is insufficient to reach consensus regarding the recommendations, then focus groups and/or a formal consensus process (eg, Delphi panels) is pursued.
- *Drafting of the guideline* – in drafting the guideline, the Guideline Development Group prioritises guideline recommendations by 1) impact on patient outcomes, 2) impact on reducing variation in practice, 3) ability to lead to more efficient use of NHS resources, and 4) expediency of patient movement through the care pathway. Moreover, recommendations typically involve areas in need of further research to inform an update to the guideline.
- *Consultation on the draft guidance* – at minimum, there is one consultation period for registered stakeholders to comment on the draft guideline. Following the consultation period(s), the guideline review panel reviews the guideline to ensure accountability of stakeholder commentary.
- *Production of the final guidance* – the guideline review panel finalises the recommendations and, subsequently, sends the draft guidance to the NCC to produce the final guideline.
- *Approval and issuance of guideline* – NICE formally approves the final guidance and disseminates it to the NHS.

In addition to the aforementioned clinical guideline process, NICE has recently instituted 'short clinical guidelines', which are designed to address clinical questions that do not meet topic selection criteria for a traditional clinical guideline or technology appraisal, but where more urgent guidance would be beneficial. The short guideline is developed in the same manner, but within a shorter timescale, typically between nine and 11 months.

Table 8 details examples of both published and planned (or in progress) NICE guidance over the last five years. To date, NICE has completed approximately 90 appraisals (Cairns 2006).

Table 8: Examples of published and planned NICE guidance

Public Health Guidance		Interventional Procedures Guidance		Technology Appraisals		Clinical Guidelines	
Published	Planned	Published	Planned	Published	Planned	Published	Planned
Physical activity	Alcohol & schools intervention	Deep brain stimulation for tremor and dystonia	Transcranial magnetic stimulation for severe depression	Bipolar disorder – new drugs	Asthma (uncontrolled) – omalizumab	Hypertension	Breast cancer
Smoking cessation	Mental health & older people	Insertion of biological slings for stress urinary incontinence	Arthroscopic knee washout	Crohn's disease – infliximab	Hearing impairment – cochlear implants	Caesarean section	Low back pain
	Substance misuse	Laparoscopic partial nephrectomy	Cryotherapy for renal cancers	Obesity – orlistat	Pulmonary arterial hypertension – drugs	Lung cancer	Incontinence
	Preventing STDs and pregnancy in those under 18	High-intensity focused ultrasound for prostate cancer		Sepsis (severe) – drotrecogin	Drug misuse – naltrexone	Self-harm	Obesity
	Workplace smoking					Urinary incontinence	Stroke

HTA dissemination and implementation

The guidelines and guidance produced by NICE are employed on a number of different levels. Specific uses of NICE guidelines include:

- Develop treatment standards for health organisations
- Inform and guide decision-making among patients and consumers
- Guide actions to meet government indicators and targets for health improvement and reduce health inequalities
- Improve communication between patient and providers
- Guide education and training of health professionals
- Reduce treatment and practice variation
- Inform decision-making regarding NHS funding and resource allocation
- Guide the development of treatment pathways for new procedures and interventions.

To facilitate the dissemination of guidance, all publications are focused on the needs of different stakeholder groups – from government and NHS decision-makers, health professionals, patients, and the general public. While all guidance is published online, NICE also send copies to chief executives of the NHS, local government organisations, health professionals working in the area covered by the guidance, NHS staff responsible for clinical governance, consultants in relevant specialties, medical, nursing and public health directors of NHS Boards and Trusts, and the Healthcare Commission, among many others. Moreover, NICE informs the broadcast and print media about newly published guidance and participates in various HTA international organisations and professional societies, such as HTAi.

With regards to implementation of technology appraisals, the Secretary of State has instituted a mandatory requirement that Health Commissioners make funds available for implementation of the guidance within three months of publication. Once issued, the NHS Quality Improvement Scotland (QIS) reviews NICE guidance for implications and validity for adoption by NHS Scotland. The NHS boards in Scotland, however, are not obligated to provide funds for the implementation of NICE guidance.

To aid the implementation process of guidance (not exclusive of technology appraisals), NICE has established an implementation programme. Each guidance is assigned an implementation team, who collaborates with those involved in the development process, and communications and field-based teams, to ensure targeted dissemination to various audiences; engage with the NHS, local government, and the wider community; evaluate uptake of NICE guidance; and raises awareness of NICE guidance.

Moreover, NICE provides a number of tools to support the implementation of guidance, all of which are available via the website. Such aids include the following (NICE 2006f):

- Forward Planner – summarises published and forthcoming NICE guidance, and explains which sectors are likely to be impacted.
- Slide sets – Highlights key messages from the guidance and makes recommendations for implementation.
- Audit criteria – Assists organisations to execute baseline assessment and monitor associated activities.
- Costing tools – Helps assess the financial impact of implementing NICE guidance.
- Implementation advice – Points to sources of support, resources, etc.
- Commissioning guides – Provides support for local commissioning and needs assessment.
- ERNIE database – The Evaluation and Review of NICE Implementation Evidence (ERNIE) Database provides details on how NICE guidance is being used.

In addition to offering implementation tools to stakeholders, NICE tracks the implementation of its guidance by the NHS trusts.

NICE conducts a re-evaluation of appraisals every four years for health technologies, every four to six years for clinical guidelines, every three years for public health guidance, and every one to five years for STAs. As described above, NICE incorporates a formal appeals process for each type of guidance. To date, there have been about 20 appeals.

Overall, NICE and its programmes for developing guidance is unique and represents a policy embodiment of evidence based medicine. As discussed by Culyer (2006), NICE promulgates a deliberate process that elicits and combines various types of evidence and from different sources in order to develop guidance. Several aspects inherent to NICE's procedures lend to an effective deliberative process, many of which are focused on ensuring the highest degree of transparency and the participation of a wide range of stakeholders. Such characteristics include:

- Open board meetings that take place bi-monthly around England and Wales
- Membership of the Technology Appraisal Committee is set broadly
- Existence and participation of a Partners and Citizens Council
- Extensive consultation and comment opportunities throughout the appraisal process
- Implementation of an appeals procedure
- Frequent and close collaboration with external review bodies, such as the NCCs, TACs, and the Royal Colleges

NICE's engagement of a broad representation of stakeholders, from multiple sectors and disciplines, serves to introduce a variety of perspectives into the appraisal and decision-making process. This is particularly helpful when reaching consensus on conflicting evidence or recommendations; making such judgments typically requires knowledge both of the scientific literature and the realities of clinical practice. Moreover, as there is a paucity of scientific evidence about patient treatment preferences and viewpoints on issues such as equity and fairness in health care, it is important to involve a variety of stakeholders in the process to elicit such perspectives. At the implementation stage, a high level of stakeholder involvement increases public and professional ownership in the guidance, which enhances the likelihood that it will actually effectively guide decision-making and clinical practice.

In terms of the methods NICE employs or promulgates, there are both advantages and drawbacks. In general, methods are transparent and standardised across appraisals. Regarding topic selection, while the transparency of the nomination and decision-making process has improved recently, to date, NICE has focused mainly on new technologies, as opposed to those currently in practice. Consequently, it is likely there are a number of cost-ineffective therapies currently employed within the NHS. STAs raise further questions regarding topic prioritisation, as the criteria for selection isn't necessarily clear or how it may differ from the typical selection process.

Additionally, NICE commonly assesses technologies (primarily drugs) in the same class. Although this approach can lead to greater efficiency and comparability across similar products, it is often associated with problems resulting from a lack of head-to-head studies and manufacturer burden to demonstrate additional benefits to justify a premium price (Drummond 2006). The latter issue is also true of STAs, which place more emphasis on analyses submitted by the manufacturer and less on external review. However, unlike assessments across product class, STAs are likely most appropriate in situations where the number of comparators is limited.

With regards to the actual appraisal process, one potential drawback of the NICE approach is an unnecessary duplication of effort. For example, as manufacturers and the academic (TAR) group often work in apparent isolation, difficulties may ensue if conflicts regarding the available evidence are resolved only late in the appraisal process. Moreover, the timeframe between the announcement of a topic and the commencement of the review process (typically, in the range of several months) may render it difficult for stakeholders to assemble the appropriate evidence, as the key questions posed by the assessment aren't necessary clear prior to the finalisation of the project scope. Furthermore, a lengthy process upfront may place time pressures on the relevant groups and stakeholders towards the end of the appraisal process. To that end, the timeframe is structured to permit incorporation of new information toward the end of the process, without necessarily allowing time for review and critical appraisal. As such, it is important for NICE to balance transparency and collective participation with efficiency.

Another issue, raised by Gafni and Birch (2004), regards NICE methods for considering resource allocation. In particular, the review of the costs and health benefits of a technology in isolation of examining the associated opportunity costs is insufficient to address issues of efficiency and equity of resource use. Without the consideration of such costs (and where to disinvest), the assessment process (and subsequent decisions) may lead to increases in NHS expenditures without evidence of health gain, greater inequalities in access to services, and problems pertaining to the sustainability of public funding for new technologies. As NICE does not consider affordability when making judgments about cost-effectiveness (ie, a particular intervention unaffordable to the NHS may be deemed cost-effective by NICE), government mechanisms should be put in place to respond to such circumstances. That said, the DH recognises that NICE has a key role advising on divestment, and is exploring means of identifying topics for such evaluation.



With regards to methodological development, however, NICE has served as a model and spurred growth in new assessment approaches (eg, probabilistic models). This is aided by steady funding for training fellowships (eg, via NHS R&D) and the recruitment of skilled health economic personnel.

Lastly, the success of guidance implementation can either hinder or facilitate the effective use of the recommendations set forth by NICE. While the implementation of guidance does not appear to be stringent, there is some evidence of influence, such as the mandated three-month requirement. However, a significant hurdle to effective implantation is securing funding to offer recommended technologies and interventions within a resource-constrained environment. In addition, restrictions in use frequently pose challenges to implementation, especially when compared to more straightforward 'yes/no' decisions.

A recent study found that implementation of NICE guidance was mixed, by technology and location (Sheldon et al. 2004). For example, the use of orlistat and taxanes grew rapidly following publication of guidance, although compliance among trusts appeared to be inconsistent across a range of guidelines. Regarding the latter, compliance is likely contingent upon the extent to which trusts are prepared for NICE guidance and have established structures and processes to manage implementation. As per Sheldon et al. (2004), implementation of NICE guidance is likely to be improved if the guidance is clear and based on an understanding of clinical practice and/or the policy process, in addition to being well supported in terms of funding and professional involvement. Moreover, the credibility of NICE guidance is dependent on the transparency of the relevant committee's decision-making process. It is crucial that such decisions are consistent across the broad range of appraisals on health technologies and interventions undertaken, and that the views of consultees to the evaluation are sufficiently taken into account. Only through the application of a coherent and explicit approach can NICE successfully achieve the central objectives of the NHS.

Table 9: Overview of HTA governance, processes, and role in decision-making in the UK

United Kingdom	
HTA governance and organisation	
Institution/committees	NICE, NHS Centre for Reviews and Dissemination, and NCCHTA. Other entities are also involved in HTA, including academia, the DH, UK Cochrane Centre, UK National Screening Committee, and the corporate sector.
Entity responsible for reviewing HTA evidence for priority-setting and decision-making	DH NICE: Advisory Committee/Programme Development Group (Public Health), Appraisal Committee (Health Technology), Advisory Committee (Interventions), and Guideline Development Group (Clinical Guidelines).
HTA agenda-setting body(s)	Primarily, DH in collaboration with NICE.
Areas for HTA	Medicines, medical devices, diagnostic techniques, surgical procedures, and health prevention/promotion activities.
Reimbursement requirements and limitations	Not relevant
Stakeholder involvement	Broad participation from a variety of stakeholders – health professionals, patient groups, general public, manufacturers, professional associations, methodological experts, etc.
International collaboration	EuroScan, HTAi, WHO Health Evidence Network (NCCHTA), EUnetHTA, INHTA, and Guidelines International Network.
HTA topic selection and analytic design	
Governance of topic selection	NICE topic selection consideration panels, Minister of Health, and DH
Criteria for topic selection	<ul style="list-style-type: none"> - Burden of disease (<i>population affected, morbidity, mortality</i>) - Resource impact (<i>cost impact on the NHS or the public sector</i>) - Clinical and policy importance (<i>whether the topic falls within a government priority area</i>) - Presence of inappropriate variation in practice - Potential factors affecting the timeliness for the guidance to be produced (<i>degree of urgency, relevancy of guideline at the expected date of delivery</i>) - Likelihood of guidance having an impact on public health and quality of life, reduction in health inequalities, or the delivery of quality programmes or interventions. <p>* Also, appropriateness and ability of NICE to commence development of a guideline.</p>
Criteria for assessment	Strength of the available evidence (nature, quality, and degree of uncertainty), importance of outcomes, health impact, cost-effectiveness, inequalities, feasibility of implementation, impact to the NHS, acceptability, broad clinical and government policy priorities, and health need.
Criteria outlined or publicly-available	Yes
Analysis perspective	For reference case: NHS and PSS (personal social services). In non-reference case: societal not include the productivity costs.
Duration required to conduct assessments	Interventional guidance: ~46 weeks Technology appraisals: ~51 weeks (MTAs); ~32 weeks (STAs) Clinical guidelines: ~72 weeks Short clinical guidelines: ~40 weeks

76 Section applies primarily to NICE.

77 N/A=not available.

Table 9 (continued)

Evidence requirements and assessment methods ⁷⁶	
Documents required from manufacturer	A complete list of all studies concerning the technology under review; an executive summary of not more than five pages; a main submission of not more than 50 pages, which should include 1) aims of treatment and current approved indications, 2) assessment of clinical effectiveness, 3) assessment of cost-effectiveness, 4) assessment of resource impact on the NHS, uptake/treatment rates, population health gain, resource implications, and financial costs, 5) data appendix, and 6) an electric copy of any model used in the cost-effectiveness analysis, if applicable.
Systematic literature review and synthesis	Yes, health effects should be identified and quantified, with all data sources clearly described. Synthesis of outcome data through meta-analysis is appropriate, provided there is sufficient relevant and valid data that use measures of outcome that are comparable.
Unpublished data/ grey literature	Yes, but not routine.
Preferred clinical study type/evidence	Preferred prospective RCT with a naturalistic design. Effectiveness is preferred over efficacy, especially long-term effectiveness.
Type of economic assessment preferred or required	Cost-effectiveness or cost-utility analysis. Health effects should be expressed in terms of quality-adjusted life years (QALYs). Cost-benefit analysis may be used in specific situations. In addition, a 'cost-consequence' approach may be adopted to take into account the complexity and multidimensional character of public health interventions and programmes. Issues such as equity and distribution can also be used to inform the analysis.
Availability of guidelines outlining methodological requirements	Yes, published by NICE.
Choice of comparator	Current best alternative care or alternative therapies routinely used in the NHS.
Specification of outcome variable	Mortality, morbidity, quality of life, willingness to pay (in some situations).
Sub-group analyses	Yes, especially high risk patients.
Costs included in analysis	Direct costs, but those that refer to the NHS and PSS. May also add travel and other public sector costs, but does not typically include productivity costs.
Incremental analyses required	Yes
Time horizon	The period over which the main differences between technologies and their likely health effects and use of health care resources are expected to be experienced.
Equity issues	Yes, an additional QALY has the same weight regardless of the other characteristics of the individual receiving the health benefit.
Discounting	Base case: 3.5% (health effects and costs); Sensitivity analysis: vary between 0%-6% (health effects and costs). For manufacturer submissions: Base case: 6% (costs), 1.5% (benefits); Sensitivity analysis: 6% (costs), vary between 0%-6% (health effects).
Modelling	Modelling is typically required. The model may be a decision analytic model using aggregated data or a statistical model using patient-level data.
Sensitivity analyses	Yes, use of probabilistic sensitivity analysis. All data sources must be justified and point estimates, ranges and distribution of values identified to test best case and worst case scenario.

Table 9 (continued)

Cost-effectiveness or willingness-to-pay threshold	No fixed threshold, but evidence suggests that NICE employs a range of £20,000/QALY-£40,000/QALY. However, NICE primarily bases decisions on incremental cost-effectiveness ratios below £20,000/QALY. While NICE may accept higher thresholds, additional justification is required (eg, innovative nature of technology, equity, public health necessity).
Missing or incomplete data	N/A ⁷⁷
Support for methodological development	Yes
HTA dissemination and implementation	
Channels for HTA results dissemination	NICE website, publications, international HTA organisations, media, and dissemination/implementation tools provided to stakeholders (via NICE website).
Use of HTA results	Develop standards; guide patient care decisions; inform strategies to meet government indicators and targets; support decision-making regarding NHS funding and resource allocation; guide education and training of health professionals.
Evidence considered in decision-making	See HTA Topic Selection and Analytic Design section.
Any reported obstacles to effective implementation	Insufficient funding, lack of health professional support, inadequate structure to support implementation among the trusts, duplication of effort during appraisal process, timelines, etc.
Formal processes to measure impact	Yes.
Processes for re-evaluation or appeals	Re-evaluation: every 4 years (NICE technology appraisals), every 4-6 years (NICE clinical guidelines), every 3 years (NICE public health guidance), every 1 to 5 years (STAs). NICE incorporates a formal appeals process.
Accountability for stakeholder input	Yes, several opportunities for stakeholder submission of evidence, review, and comment.
Transparent/public decision-making process	Yes, information regarding most appraisal and decision-making processes is publicly-available via the NICE website.

Source: Zentner et al. 2005; OECD 2003; NICE 2006 (a-e); NICE 2004 (a-g).

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PATIENT EMPOWERMENT AND EFFICIENT HEALTH OUTCOMES

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9 January 2007

EXECUTIVE SUMMARY

This report focuses on developments that can increase both patient power and efficient health outcomes.

1. *Target health conditions for patient empowerment*

Patient empowerment efforts need to be targeted to where there is a significant potential for improving efficient health outcomes through greater patient involvement. Not all conditions are equally amenable to improvement through patient empowerment. Patients faced with an acute and urgent medical crisis are less able to gather information and deliberate than those with chronic conditions.

2. *Analyse the treatment process*

Conditions should be analysed to identify the steps in the treatment process where greater patient power would have the largest impact on improving efficient health outcomes.

3. *Remove barriers to empowerment*

The key barriers to greater patient empowerment for the targeted condition and treatment process steps need to be identified and programmes designed to reduce them. This may involve:

- redefining and communicating the patients' role;
- enhancing patients' knowledge about their options, the health condition, their personal health status (eg, through electronic medical records), and their own values and preferences; and
- enhancing patients' skills to carry out the required health activities competently by improving their self-efficacy and health literacy.

4. *Create a facilitating environment for patient empowerment*

Increasing patient empowerment also requires policies that encourage patient power. These include:

- the promulgation of patients rights;
- a menu of choices that is consistent with patients' needs;
- easy access to valid information about the choices available;
- aids that will help information-processing and decision-making by patients; and
- doctors who are trained to perform different roles, who can play the role that complements each patient's preferred patient role. In addition to their role as 'God' and 'authority', they will have to learn to perform the roles of partners, to put the patient at the centre of the care process rather than the disease. This will require major changes in medical education.

5. *Ensure equity*

Because patients are different, empowerment efforts must be customised to different patient groups. In some circumstances, empowerment may provide greater benefit to those who are well-educated and better off. Policy makers must ensure that patient empowerment promotes equity in health care. The need to target efforts applies particularly to health literacy. Those with better education, better health insurance and higher incomes are in a better position to make choices than those who lack these benefits. Health literacy may need to be targeted at those in the lower socio-economic groups, or those from ethnic minorities.

6. *Motivate the empowered patient to achieve more efficient health outcomes*

Empowering patients may or may not result in improved efficient health outcomes because of lack of patient motivation. Incentives that promote healthy and/or efficient behaviours can bring about the desired behaviours. They can also have undesirable effects for certain patient groups, so must be carefully designed and tested.

The term 'empowerment' appears in many different contexts (Bartunek & Spreitzer 2006). Its meaning varies, but usually has two aspects: (1) the having and sharing of power, and (2) sources of power and ways to increase power. Empowerment can serve the goals of the empowered (eg, greater pride and self-worth), and of the empowering agents (eg, empowering employees as a way to foster productivity).

These meanings and goals are found in discussions about patient empowerment. Patient empowerment, in the first sense of having and sharing power, refers to patients' power over a range of decisions such as provider and treatment choice. Patient empowerment, in the second sense of sources of power and ways to increase patients' power, refers to patient education, legal rights, and others. The World Health Organisation, for example, defines empowerment as 'a process through which people gain greater control over decisions and actions affecting their health' (WHO 1998). Empowerment can serve to further the goals of patients but also – and possibly to a greater extent – the goals of other stakeholders (MacStravic 2000; Baggott 2005).

We use the term 'power' to refer to patients' actual exercise of control in the health care system, and 'empowerment' to refer to sources of patient power and ways to increase it. Patient empowerment provides patients with the potential to exercise power. The exercise of patient power, in turn, may improve efficient health outcomes.

After a brief overview of patient power in the health care system, we focus on the role of the patient in the treatment process. The main questions will be:

- What are the different roles for patients and physicians in the treatment process?
- Does greater patient involvement in treatment necessarily lead to more efficient health outcomes?
- What is necessary if patients are to take on more responsibility for their own treatment?
- How can the empowered patient be motivated to achieve more efficient health outcomes?

We end by summarising the main conclusions and policy recommendations.

Here, we discuss which aspects of the health care system patients can potentially influence, and through what channels.

2.1 Potential scope of patient power

Patients have the potential to influence all aspects of the health care system at all levels.

At the macro-level (eg, national policies) patients might contribute to defining health priorities, goals, standards, programmes, resources and monitoring. They might be involved in decisions about the structure of the health care system (eg, should health care services be provided by the public or private sector?), and contribute to defining the 'health benefit basket', that is, the sum of services, activities, and goods covered by publicly-funded statutory or mandatory insurance schemes (social health insurance) or by national health services (Schreyögg et al. 2005). Patients might also be involved in developing health care products and services (Boote et al. 2002) and regulatory decisions (eg, should a certain pharmaceutical product be approved for marketing, and should it be reimbursed for routine use?).

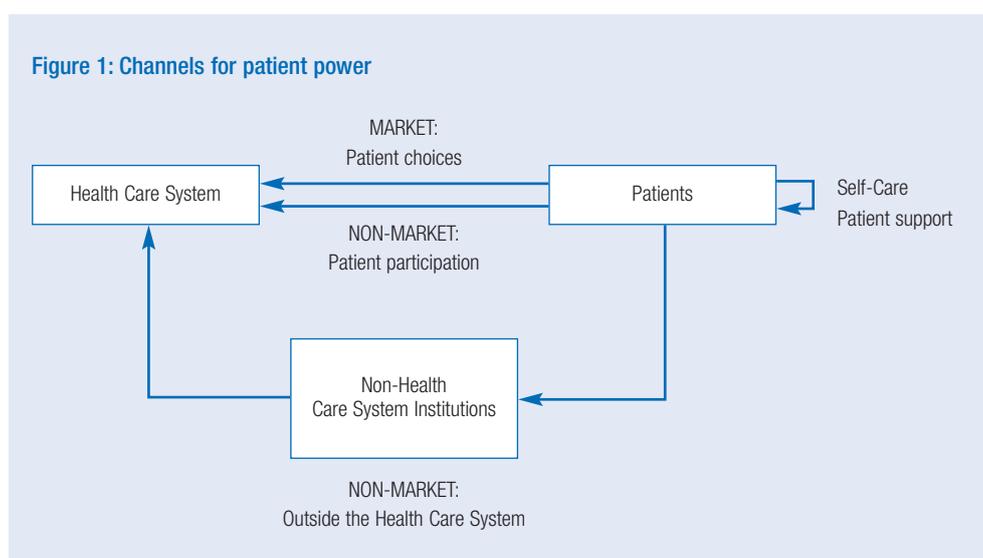
Also at the macro-level, patients might contribute to defining the scope of the health care system by transforming an illness into a legitimate disease, to be treated by health care professionals (HCPs). Examples of illnesses that have been transformed into legitimate diseases thanks to patient involvement include adult attention deficit hyperactivity disorder (ADHD), post-traumatic stress disorder (PTSD), Alzheimer's disease, and muscular dystrophy.¹

Patient power at the meso-level is relevant in countries with a decentralised or federal health care system (eg, Denmark, Sweden, Spain, Germany), where health care priorities, goals, resource allocation, and purchasing of health care products and services may take place regionally or locally.

At the micro-level, patients might be able to choose their insurance, provider, and treatment (Thomson & Dixon 2004). Other ways of influencing the health care system are providing feedback, complaining, and engaging in litigation.

2.2 Channels for patient power

Patients can influence the health care system through market ('exit') and non-market channels ('voice'; Hirschman 1970; see Figure 1).



¹ For adult ADHD see Conrad & Potter 2000 PTSD and Alzheimer's are cited in Conrad 2005 Muscular Dystrophy is analyzed by Rabeharisoa 2006.



Patients may exercise power through the market by selecting their insurer, provider, and treatment. Influence through non-market channels involves two types of activities (Coney 2004): (1) participation within the health care system, and (2) activities outside the health care system. Participation within the health care system includes feedback and participation in various health care system institutions. For example, patients can influence NICE technology appraisals by suggesting technologies for appraisals, submitting evidence as 'consultees', commenting on assessment reports, and appealing against NICE recommendations (National Institute for Clinical Excellence 2004). Patients can also influence health care systems through outside activities such as legal challenges, marches and other events, media presence, and electoral politics. Finally, patients may exercise power by managing their own care (self-care) and by supporting one another through information, mutual support, and other services, which can be substitutes for (as well as complements to) services provided by the health care system.

The availability of these different channels depends on the institutional environment in each country. But opportunities to make market choices, to take part in the health care system, and to have access to legal resources vary across countries.

We use the term treatment to refer to a range of health care activities including problem detection, diagnosis, treatment selection, treatment implementation, and monitoring/ evaluating treatment outcomes. The extent to which patients exercise control over these activities gives rise to different patient-physician treatment models (see Table 1; see also Emanuel & Emanuel 1992; Charles et al. 1999; Coulter 2002b).

Consider the following case: 'After spending a summer vacation near Cape Cod in the USA, a man develops a rash on his leg. His wife, searching the internet, finds a picture of a Lyme disease rash that looks identical. She prints it out. Other symptoms are consistent and the appropriate medication is well agreed upon. Taking her husband and the picture to their internist, they said, "Give us the prescription". With some reluctance he agreed to do so and the medicine resolved the problem.' (Neuhauser 2003).

In this case, the patient and his wife were autonomous patients, managing the condition on their own. The physician's role was limited to writing the prescription – the minimal possible role for treatment within the health care system. Had the medication been available on the internet, or as an over the counter medicine, no health care professional (HCP) intervention would have been necessary. Table 1 defines this allocation of activities as the 'autonomous patient' model. It has two variants: one involving complete self-care outside the health care system (column A), the other with a minimal HCP role (column B).

To the extent that patients are not always able to solve health problems on their own, they may share some activities with physicians. When all activities are shared by a patient and the HCP, this gives rise to the 'partnership' model (column C in Table 1).

In the 'propose-dispose' model (column D), the HCP assumes the role of the expert – generating a diagnosis and prognosis, defining goals, generating the treatment options and its characteristics, and taking into account the patient's preferences when recommending treatment. The patient's main role is to decide whether or not to accept the recommended option. In the 'paternalistic' model (column E), the HCP also makes the treatment decision.

The 'unilateral HCP' model (column F) is the opposite of the 'autonomous patient' model. The HCP manages all activities, as for example in accident and emergency situations when patients are unconscious.

3.1 Prevalence of the different treatment involvement models

The prevalence of the different treatment involvement models has been studied through patient questionnaires, and by observing and analysing consultations. The Patient Activation Measure is one such questionnaire (Hibbard et al. 2004; Hibbard et al. 2005). Examples of instruments for analysing consultations are the OPTION scale (Elwyn et al. 2003) and the Rochester Participatory Decision-Making Scale (RPAD) (Shields et al. 2005). Some observational studies focus on changes in physicians' behaviours in response to specific patient requests (eg, tests or other diagnostic studies, a new medication, or referral to a specialist) (Kravitz et al. 2003; Kravitz et al. 2005).

Questionnaire studies in Germany show a strong trend toward greater patient self-care. The proportion of respondents indicating that they immediately consulted a physician when they felt unwell or sensed the beginning of sickness went down from 56 % in 1998 to 35% in 2004 and 29% in 2005. In 2005, 56% of people tried first to self-care with OTC medication, increasingly using the pharmacist as a substitute for consulting a physician (Psychonomics 2005).

Surveys of UK and US adults aged 45 and above (Ellins & Coulter 2005; Hibbard et al. 2004) showed that 21% (UK) and 22% (US) of respondents were highly engaged in managing their health.

An observational study of 186 consultations with 31 GPs in the UK analysed with the OPTION scale showed low levels of patient involvement in decision making, corresponding to the 'paternalistic' model (Elwyn et al. 2003). In a six-country study (Australia, Canada, New Zealand, UK, US, Germany), 42% of German and 50% of UK patients reported that their regular doctor sometimes, rarely, or never told them about care and treatment choices or asked for their ideas and opinions (Schoen et al. 2005).

Table 1: Models of patient-physician treatment involvement

Activities	(A) Autonomous patient	(B) Autonomous health care system patient	(C) Partnership	(D) Propose – Dispose Model	(E) Paternalistic model	(F) Unilateral HCP model
HEALTHCARE PROVIDER (HCP) ROLE	None	Prescription writer	Partner	Expert	Authority	« God »
(1) Problem detection (signs & symptoms)	Patient	Patient	Patient + HCP	Patient + HCP	Patient + HCP	HCP
(2) Additional patient information required for diagnosis	Patient	Patient	Patient + HCP (e.g., medical record)	Patient + HCP (e.g., medical record)	Patient + HCP (e.g., medical record)	HCP
(3) Diagnosis & Prognosis	Patient	Patient	Patient + HCP	HCP	HCP	HCP
(4) Define health goals	Patient	Patient	Patient + HCP	HCP	HCP	HCP
(5) Generate treatment options	Patient	Patient	Patient + HCP	HCP	HCP	HCP
(6) Generate general information about options	Patient	Patient	Patient + HCP	HCP	HCP	HCP
(7) Generate patient information needed to assess option suitability for patient (contraindications, etc.)	Patient	Patient	Patient + HCP	Patient + HCP	HCP + Patient	HCP
(8) Evaluate options	Patient	Patient	Patient + HCP	HCP	HCP	HCP
(9) Decide on treatment option	Patient	Patient	Patient + HCP	Patient	HCP	HCP
(10) Implement treatment	Patient	Patient	Patient + HCP	Patient	Patient	HCP
(11) Monitor and evaluate	Patient	Patient	Patient + HCP	Patient + HCP	HCP	HCP



3.2 Patient preferences for different treatment involvement models

In a survey of eight European countries, 23% of respondents indicated that they should decide or make the treatment choice after consulting with their doctor, 51% preferred shared decision-making ('My doctor and I should decide together'), and 26% preferred to let their doctor decide (Coulter & Magee 2003).

A patient's preferences for involvement may vary over the course of an illness, differ across health conditions, and depend on a patient's health status, demographics, and culture. For example, in the above UK study (Ellins & Coulter 2005), the most important determinant of patient involvement was self-rated health status: only 11% of people in poor health were highly involved compared with 35% among those in excellent health. A chronic condition (and particularly depression, chronic pain, and digestive problems) reduced health care involvement. Involvement was also lower for elderly people, those from lower social classes, and those who had finished their education by the age of 16. The European survey by Coulter and Magee (2003) highlighted the role of culture: 91% of respondents from Switzerland, 87% of those from Germany and 74% of those from the UK felt the patient should have a role in treatment decisions (as primary decision-maker or sharing responsibility with the doctor), compared with 59% of Polish and 44% of Spanish respondents.

Differences in patients' preferences for involvement suggest that there can be two types of mis-matches: patients may be involved less than they desire, or they may be involved more than they would like. Under-involvement has attracted more attention than over-involvement, although there is evidence that both types of mis-matches affect patient satisfaction and 'decision regret/ambivalence' (Lantz et al. 2005). It has been suggested that some patient-physician interactions are a contest in which each party tries to establish that the health problem is the other's responsibility. Thus patient over-involvement may 'free clinicians from responsibility for suffering for which they think that they can – or for which they wish to – do little' (Salmon & Hall 2003, p. 1976).

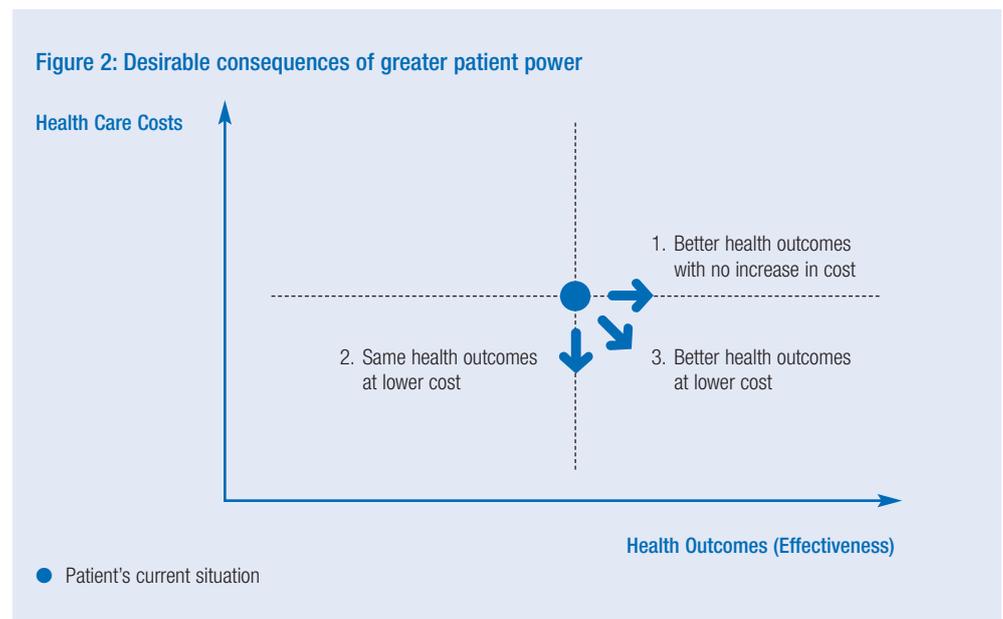
3.3 Should patients have more power over treatment?

A review of studies of clinical decision-making suggested that shared decision-making is often less than what patients desire (Coulter & Ellins 2006). For example, surveys of NHS patients in 2004 found that 30% of outpatients, 32% of primary care patients, 36% of emergency patients, 39% of coronary heart disease patients, 47% of inpatients and 59% of mental health patients would have liked more input and choice in decisions about their care (Picker Institute Europe 2005).

But should patient power increase? This question can be addressed from many different perspectives (eg, Wait & Nolte 2006). We focus here on the role of patient power as a potential tool for increasing efficient health outcomes.

Does greater patient power lead to more efficient health outcomes? More efficient health outcomes can be achieved in three ways (Figure 2):

- better health outcomes with no increase in cost;
- the same health outcomes at lower cost; or
- better health outcomes at lower cost.



Patient power does not necessarily produce these desirable results. For example, it may lead to better health outcomes at higher costs. Is this not also desirable? This depends on the incremental costs per unit of health outcome gained, which may be unacceptably high for a health care system. In any case, better health outcomes at higher costs are easier to achieve than the three desirable outcomes specified above.

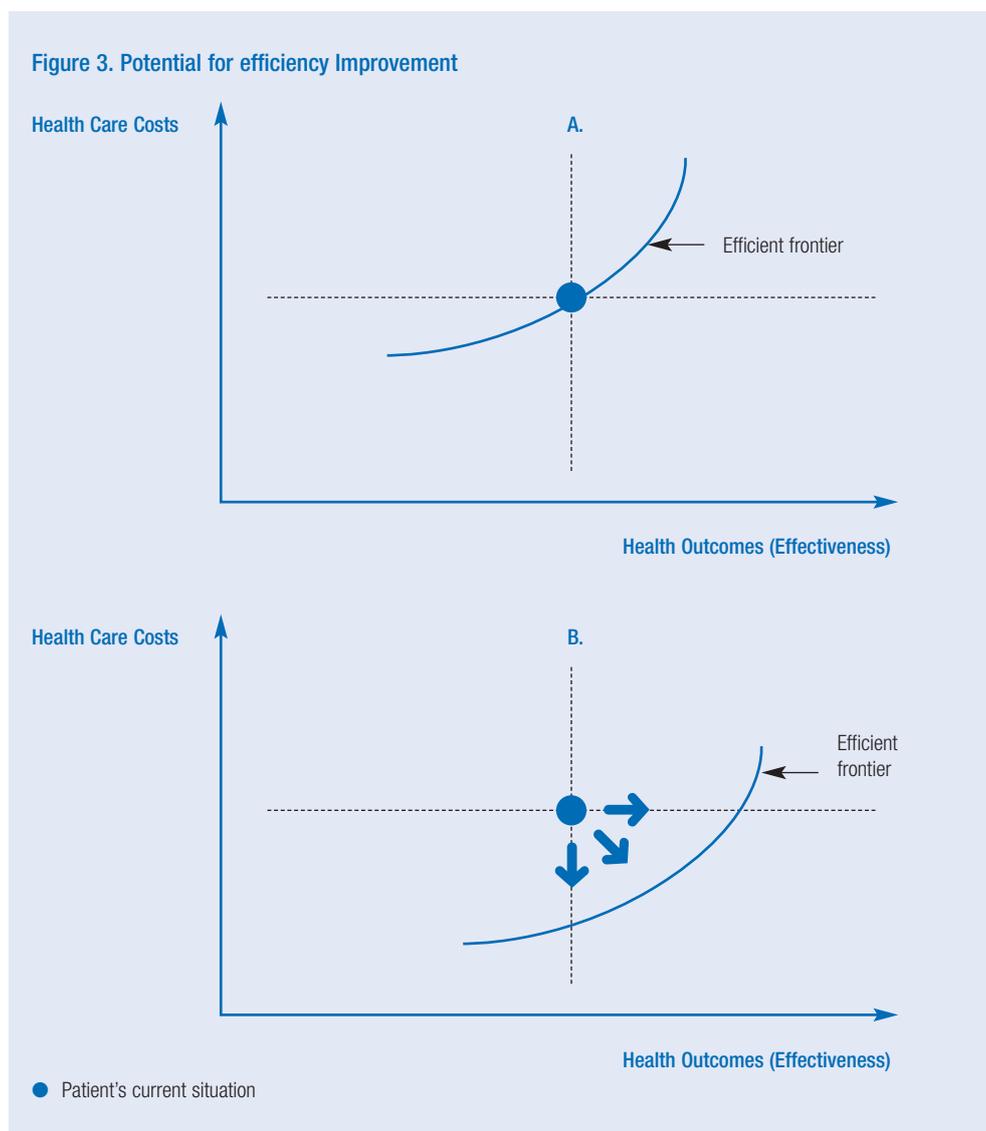
Patient power may also result in higher costs without better health outcomes, as in the study by Kravitz et al. 2005. Standardised patients (SPs) with adjustment disorder visiting primary care physicians were randomly assigned to make a brand-specific request ('... I was wondering if you thought Paxil might help'), a general drug request ('... I was wondering if you thought a medicine might help'), or no request. Antidepressants were prescribed far more often when the patients requested them, thus increasing costs. However, according to the authors, there is no professional consensus about the need for immediate treatment as opposed to watchful waiting in patients with minor depression. The exercise of patient power, therefore, resulted in greater costs while leaving health outcomes unchanged.

Patient power can even increase costs and lower health outcomes at the same time. Stevenson et al. 2000 reported the following example in their study of 62 consultations. A patient wished to stop taking his steroid inhaler for asthma. Having forgotten to take it on holiday without experiencing any ill effects, he concluded that it served no purpose and was now seeking the physician's 'permission' to stop taking the steroid inhaler. After expressing his opinion that the patient should continue with the medicine, the doctor ceded to the patient's request ('Fine'; 'It's up to you'). In the subsequent interview with the researcher the physician said that the patient would have to use the inhalers in the future as his asthma was likely to become troublesome. Asthma requires continuous treatment, even in the absence of symptoms. Lack of compliance results in poorer health outcomes, and complications increase treatment costs.

4.1 The potential for increasing efficient health outcomes

For patient power to result in more efficient health outcomes there must be room for improvement. The potential for efficiency improvement varies across conditions and patient groups.

Figure 3A shows a situation on the efficient frontier, which means that health outcomes can not be improved without increasing costs, or costs can not be reduced without lowering health outcomes. Figure 3B shows a situation where there is great room for efficiency improvement, because the current treatment is far above the efficient frontier.



There are many reasons why a condition may be inefficiently managed. Table 2 provides a summary of possible causes.

Table 2: Potential causes of inefficient condition management

Activities	Potential causes of inefficient condition management
(1) Problem detection (signs and symptoms)	Too late (eg, stroke, heart attack, cancer) Not a problem (unnecessary consultation) Could be treated equally well by lower-cost health care provider
(2) Additional patient information required for diagnosis	Missing or wrong information (test results, medical records, reasons for referral) Unnecessary tests or tests done twice
(3) Diagnosis and prognosis	Wrong diagnosis
(4) Define health goals	Doctor and patient have different perceptions of health goals
(5) Generate treatment options	More efficient options (including self-medication or watchful waiting) are ignored
(6) Generate general information about options	Missing or wrong information (including information about treatment costs)
(7) Generate patient information needed to assess option suitability for patient (contraindications, etc.)	Missing or wrong information
(8) Evaluate options	Implementation-related aspects insufficiently valued Health outcomes insufficiently valued Treatment costs insufficiently valued
(9) Decide on treatment option	Inconsistency between information, values, and decision
(10) Implement treatment	Treatment unavailable (eg, capacity constraints) Poor quality of implementation (eg, error in surgery or medication) Poor planning of care at home Poor adherence
(11) Monitor and evaluate	Poor monitoring, follow-up and feedback

Examples of inefficient practices

A recent survey of sick adults (Commonwealth Fund 2005; Schoen et al. 2005) showed the following patient-reported practices, which probably result in inferior health outcomes and/or higher than necessary costs. Hospital emergency visits were for a condition that could have been treated by one's regular doctor if he or she had been available (UK: 26%; Germany: 23%). Test results, medical records, or reasons for referral were not available at the time of the scheduled doctor's appointment (16% of respondents in the UK and 11% in Germany). Doctors ordered a medical test which was unnecessary because the test had already been done (UK: 6%; Germany: 20%). Doctors rarely or never discussed the different medications people were using, including medicines prescribed by other doctors (UK: 26%; Germany: 26%). Patients were given the wrong medication or wrong dose (UK and Germany: 10%), a medical mistake was made in treatment or care (UK: 12%; Germany 13%), and the wrong medication or medical mistake caused a very serious or somewhat serious problem (UK: 42%; Germany: 41%). Hospitals made no arrangements for follow-up visits (UK: 19%; Germany: 50%). Doctors rarely or never gave clear instructions about symptoms to watch for and when to seek further care or treatment (UK: 13%; Germany: 12%). Patients with hypertension, heart disease including heart attack, diabetes, arthritis, asthma or any other chronic lung problems, or depression did not receive a plan for managing their own care at home (ie, knowing what to do to control symptoms, prevent flare-ups, or monitor the condition) (UK: 53%; Germany: 63%).

Beyond early detection/diagnosis, which is listed as activity (1) in Table 2, primary prevention is also associated with efficient outcomes. Table 2 does not seek to reflect the complexities (eg, non-linear disease progression) and comorbidities of many patients.

4.2 Redefining roles for more efficient health outcomes

The underlying problem shown in Table 2 is that one or several of the activities needed to manage a condition are performed poorly or inefficiently. Improvement requires that they be performed better or more efficiently.

The first step is to identify the activities with the greatest inefficiency or potential for improvement. For some conditions, finding out the problem will be important; and for others the choice of treatment options may have to be changed. For many other conditions, treatment implementation (especially patient adherence) may have the greatest potential for improvement.

The second step is to look at ways of redefining the respective roles of patients and physicians for the activities singled out in the previous step: who should perform them and how?

The two extremes are on the one hand patient autonomy where the patient does everything outside the health care system, and on the other the unilateral health care professional model. Between these two extremes are models where patients and HCPs are specialised by activity or share some or all of them (see Table 1).

The question of which activities to allocate to patients and which to professionals is the kind of issue faced in other industries. Many shift activities back and forth between customers and suppliers: Ikea, for example, has revolutionised the furniture industry by shifting activities such as product assembly and transport to their consumers. Extreme function shifting takes place in backward vertical integration when customers perform all activities of their previous suppliers. Patient autonomy can be seen as an example of vertical integration, much as a do-it-yourself enthusiast manages without help from plumbers, painters, and other professionals.

Shifts in the allocation of activities are driven by efficiency goals. The reason Ikea has been successful is that there are enough consumers who can perform some activities more efficiently than manufacturers and retailers. Do-it-yourself activities have increased because of the rising cost of professional help together with their lack of availability (long waiting times), and often questionable quality.

Some of these same reasons have been advanced to explain the rise of alternative and complementary medicine (Pagán & Pauly 2005; Sointu 2006). The capacity constraints of some health systems, indicated by long waiting times, are well known. And implementing evidence-based medicine without shifting activities to patients would require a significant increase in health care system resources: implementing current practice guidelines for only 10 chronic conditions would require more time than primary physicians have available for patient care overall (Østbye et al. 2005); yet primary care physicians are expected to know and implement about 400 practice guidelines (Ma et al. 2005).

Clearly, shifting health care activities to patients, or asking patients to share some or all activities with physicians, seems a promising option for enhancing efficient health outcomes. What are the conditions that need to be present for patients to assume an active role in their health care?

The conditions necessary for patients to assume greater responsibility for health care activities can be grouped into four categories:

- role understanding
- knowledge
- skills
- a facilitating environment.

5.1 Role understanding

Self-service industries such as fast food chains and low-cost airlines work efficiently because consumers know what is expected of them. If patients are to take over more health care activities, they have to understand and accept their role.

For example, Jadad et al. 2003 proposed the following role definition for the 'good patients of the future': they will (1) bring lists of questions to the consultations and expect answers in clear terms; (2) know how involved they want to be in decisions about their health care; most will choose to share decisions with their healthcare providers; (3) have free access to their health record on paper or electronically and will use it or share it as they see fit; (4) request and receive a second opinion whenever they face a major diagnosis or decisions about treatment; and (5) use telephone, internet, and other forms of communication to complement personal visits with members of the healthcare team.

The West Virginia Medicaid programme asks persons to sign and adhere to a 'Medicaid Member Agreement', which defines 13 'member responsibilities' (Steinbrook 2006). Examples of these include adherence to prescribed health improvement programmes, reading booklets and papers provided, and adherence to medication.

5.2 Knowledge

Good role performance results from a good fit between a patient's knowledge and the knowledge required. The knowledge required to perform the patient role in the 'unilateral HCP' model are minimal, whereas the 'autonomous patient' model requires patients to have a high level of knowledge.

Patient knowledge is of several kinds: (1) knowledge about the options: insurer knowledge, provider knowledge, and treatment knowledge; (2) disease knowledge; (3) knowledge of one's personal health status; and (4) knowledge of one's values and preferences.

Knowledge about the options

Insurer knowledge: Informed choice requires patients to understand the relevant attributes of insurers and insurance plans. The patient's choices can be daunting. For example, in the USA some 'consumer-directed' plans propose as many as five deductibles and five co-insurance levels. Consumers may be able to choose from broad or narrow doctor and hospital networks and from among several prescription drug plans. There might be as many as 100 different variations within one plan (Rubenstein 2004).

Provider knowledge: In one recent study, 65% of UK and 53% of German respondents who had major surgery indicated that they had no information about their surgeon such as patient satisfaction ratings, experience with the same medical condition, success rate for surgeries, or the surgeon's training (Commonwealth Fund 2005).

While provider 'score cards' are vital for patients' informed choice of providers, they do have problems (Blumenthal 2006). They are vulnerable to 'gaming', requiring users to become more sophisticated in monitoring score card accuracy, and care that is not measured may deteriorate (Romano 2005). Providers may try to improve their scores by avoiding patients whose care may be more difficult to manage. (Dranove et al. 2003).

Treatment knowledge: This includes awareness of the existence and identity of treatments, and knowledge of their characteristics. Acquiring knowledge about health care goods is difficult. 'Few healthcare goods are *search goods* whose characteristics can be determined by consumers with certainty prior to purchase. They are mainly *experience* or *post-experience* goods whose characteristics consumers can only determine after purchase, or goods for which it is difficult for the consumer to determine quality even after they have begun consumption (Moro 2006). They are also goods, for which information asymmetry between patients and doctors has traditionally been high. Yet, as pointed out by the Standing Committee of Doctors 2002: 'The patient is the key stakeholder and accurate evidence based information must be the basis for the patient's right to decide among suggested and proven therapies including medication. All information must safeguard the patient's right to self-determination as an empowered patient.'

Disease knowledge

Patients' knowledge of diseases (identity, time course, causes, consequences) influences how they deal with them (Leventhal et al. 1997). For example, poor asthma medication adherence is often due to patients' belief that asthma is an acute or intermittent disease. Instruments for measuring patients' disease knowledge have been developed for a number of diseases.

Personal health status

Knowing one's personal health status allows one to search for information, engage in self-care, and communicate better with HCPs. Access to one's medical record adds to this knowledge.

Knowledge of values and preferences

Choosing an insurer and health plan, provider, and treatment often requires that patients make trade-offs, for example between efficacy and risk. Individuals do not always hold stable and clearly-ordered preferences that can be retrieved at the moment of the choice. Preferences often have to be constructed on the spot during the decision process (Payne et al. 1992).

5.3 Skills

Competent role performance also results from a good fit between required and actual skills.

Self-efficacy

Self-efficacy refers to the belief in one's capacity to organise and execute the action needed to produce a given result (Bandura 1997). It provides the basis for the skills needed to perform the broad range of activities that define the autonomous patient role. In the best circumstances – and for specific conditions – this will allow the patient to become an 'expert patient'. This is the goal of the Expert Patient Programme in the UK (<http://www.expertpatients.nhs.uk/>), which is based on the Chronic Disease Self-Management Programme developed by Kate Lorig at Stanford (Lorig & Holman 2003).

For example, a study of HIV-positive patients found that the following adherence behavioural skills explained patients' adherence behaviour (optimal adherence, and adherence over time): updating adherence-related facts as necessary; acquiring, self-cueing, and self-administering medications; minimising side-effects; incorporating the regimen into the social ecology of daily life; acquiring social support and instrumental support for adherence; and self-reinforcing adherence over time (Starace et al. 2006).

Health literacy

Health literacy is essential if patients are to assume more responsibility for their health. Health literacy has been defined as the 'degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions' (Nielsen-Bohlman et al. 2004). Poor health literacy has been shown to be associated with less health-relevant knowledge, poorer skills, and lower health outcomes and higher health care costs (Nielsen-Bohlman et al. 2004; Sihota & Lennard 2004). In US studies, literacy levels are lower among the elderly, those who have lower educational levels, those who are poor, minority populations, and groups with limited English proficiency such as recent immigrants (Nielsen-Bohlman et al. 2004). In the UK, low literacy skills are associated with socio-economic deprivation and long-standing illness or disability (Sihota & Lennard 2004).

Because of these inequalities, health literacy efforts may therefore need to be targeted at those in the lower socio-economic groups and with other handicaps.

5.4 A facilitating environment

Patient rights

Patients may have the knowledge and skills to exercise power appropriately, yet may not be entitled to exercise them. In March 1994, the World Health Organization issued a declaration on the promotion of patients' rights in Europe (WHO 1994), and many countries have enshrined patients' rights in their laws (<http://home.online.no/~wkeim/patients.htm#liste>). In 2002, the Active Citizen Network proposed a European Charter of Patients' Rights (ACN 2002) which stated that:

- Each individual has the right to freely choose from among different treatments procedures and providers on the basis of adequate information.
- The patient has the right to decide which diagnostic investigations and therapies to undergo, and which primary care doctor, specialist or hospital to consult. Health services have the duty to guarantee this right, providing patients with information on the various centres and doctors able to provide a certain treatment, and on the results of their activities. They must remove any obstacle that limits the exercise of this right.
- A patient who does not have trust in his or her doctor has the right to choose another.

Not all European countries would be able to meet the requirements of this charter. The Health Consumer Powerhouse organisation rated 10 countries as having a high level of patients' rights law, nine with an intermediate and six with a low level. (Health Consumer Powerhouse 2006).

Patients, in exercising their rights, should also be made aware of their responsibilities eg, in matters such as adherence. Equally, in the enthusiasm for patients' rights and empowerment, it should be remembered that doctors also have rights and responsibilities that have to be respected.

Choice

Choice in the context of health care can be defined as the practice by citizens of a relevant role in selecting treatments and services (Moro 2006). Patients can only be empowered if there are options from which they can choose. But doctors, particularly in NHS-type systems, can only offer choices that are available. It is possible, therefore, that choice will promote a two-tier system, with greater choice available to those able to pay for healthcare. Choice may therefore have an adverse impact on equity. How far can one empower people to have choices that they cannot take, either because the health system does not offer that choice, or because the patient does not have the financial resources to pay for the choice? Such ethical issues need to be considered.

Does the health care system allow patients to shape the choice menu? Are there opportunities to provide feedback? For example, England's National Patient Safety Agency encourages people to report incidents in order to drive change. And does patient feedback actually shape future offerings, for example by impacting outcomes desired by other stakeholders? The more the fate of other stakeholders is linked to patients' behaviour, the greater patients' power. For example, a physician practice that is rewarded on the basis of its patients' health outcomes (pay-for-performance) is considerably more dependent on its patients than one that receives a fixed budget per assigned patient. A hospital with declining attendance and revenues as a consequence of poor satisfaction can be expected to make efforts to improve its performance. Similarly, the power of patient advocacy groups in the political arena depends on their perceived ability to affect electoral outcomes.

Access to information

Patients' knowledge is based on many different sources of information including the patient's personal experience, friends and family, other patients, patient advocacy organisations, health care professionals, suppliers of treatment, public health organisations, and journalists. Communication channels include face-to-face conversation, print media, audiovisual media, and the internet.

Patient's knowledge may be more or less complete and more or less accurate. For example, patients (and doctors) overestimate small risks and underestimate large ones. They also tend to believe that they are at less risk of an adverse outcome than those in similar positions (Say and Thomson 2003).

If patients are given quality information on diagnosis, prognosis, treatment options, risks and side effects, then they will be less likely to accept risky procedures and more likely to have better health outcomes (Coulter 2002a). Much will depend, though, on the way in which doctors present information. Say and Thomson (2003) suggest that doctors can inform patients in a way that will encourage them to select the treatment that the doctor wants – for example by giving the relative risk, which is more persuasive than the absolute risk. But Salmon and Hall (2004) argue that patients value being given information not as a basis for decision-making but as a way of building relationships with clinicians and maintaining hope.

Information on quality of care can also be difficult for patients to understand because there are so many variables that have to be taken into account when considering the outcomes of particular hospitals or physicians. However, there are now more and more commercial websites, such as Dr Foster in the UK (www.drfooster.co.uk), which encourage people to seek and to use systematic information on the quality of care.

Information asymmetry becomes more pronounced when taking into account different socio-economic groups. Those less well-educated, less self-confident or from a different ethnic background from the doctor may not feel able to absorb or discuss the information the doctor provides. Equally, such groups may have less access to (good) internet health information.

Decision aids

Good information about the health outcomes and costs of providers and treatments is necessary but not sufficient to help patients make better choices, as shown by decision-making research (eg, Hibbard et al. 1997) and by the US experience with score cards (eg, Jha & Epstein 2006). Decision aids help patients to process information and make decisions. A person with back pain, for example, would go to the website of his choice (such as NHS Direct) and then to the section on back pain. There, he or she would answer questions about back pain, which might result in triage to (1) self-care, (2) call a nurse practitioner, or (3) rush to the emergency service. The algorithms should be updated regularly based on current research (Neuhauser 2003).

Electronic prescribing systems could be part of such a computer-assisted decision-support systems. In one study an expert panel evaluated system features that would contribute to patients' health outcomes and their ability to manage costs (Bell et al. 2004). Those that were rated highly included the provision of the patient's complete current medication list, the display of a list of medications appropriate to the diagnosis, the omission from suggested medication menus options that would be medically contraindicated for the patient, the absence of influence of promotional considerations in the display of medication options, and immediate access to the rationale for any medication choice that the system displays as being recommended or preferred for the current patient.

Patient decision aids (PtDAs) have been shown to increase knowledge of the facts about options, realistic perceptions of outcome probabilities, and agreement between patients' values and choice. Patients using PtDAs also had lower decisional conflict, participated more actively in decision-making, and were less likely to remain undecided (O'Connor & Stacey 2005).

Congruent physician role

Changing the patient's role requires physicians to understand and accept a corresponding change in their own role. Physician support can enhance the patient's exercise of power and choice, but if the physician does not endorse patient empowerment, this can seriously impede patients' exercise of power.

More generally, the variability in patients' role preferences requires congruence between the patient's and the health care practitioner's role (see Best & Harries 2006, pp. 43-46, for examples of congruent and incongruent roles). Competent role performance by the patient requires competent performance of the complementary role by the practitioner. There must, therefore, be mutual understanding and acceptance of the respective roles and practitioners, like patients, must have the skills to perform their role competently, and the time to do so.

2 Watson Wyatt Worldwide 2005.
Cited in Blumenthal 2006.

Empowered patients have the potential to behave in ways that improve efficient health outcomes. However, they may not be motivated sufficiently to exercise their power.

Why is motivation necessary? Patients who acquire and exercise power in controlling their own health invest time, effort, and money in the process. From a psychological point of view, the empowerment process through which 'people gain greater control over decisions and actions affecting their health' (WHO 1998) is a process of self-regulation (Bandura 2005; Leventhal et al. 2003), which draws on finite and precious self-regulatory resources (Vohs et al. in press; Vohs 2006), which could be invested in the pursuit of other goals.

In addition, self-regulation of health is becoming more difficult as a result of increased choice, which is a cornerstone of empowerment. An increasing number of choice options leads to overload and often to poor decisions. It also involves uncertainty over preferences, and generates negative emotions when patients have to choose among undesirable options and trade off emotion-laden attributes (Botti & Iyengar 2006).

The pursuit of more efficient health outcomes requires patients to be motivated to achieve better health outcomes and, at the same time, equal or lower costs. The motivation for better health outcomes is essential to the role of user, whereas the motivation to contain costs is associated with the roles of citizen and payer. Unless constrained by the citizen/payer role, the user role might lead to a never-ending escalation of health care costs. Unconstrained by the user role, the citizen/payer role might lead to cost reductions resulting in poor health outcomes.

6.1 Health outcome motivation

Intrinsic health outcome motivation

Patients tend to be more motivated to self-regulate for chronic conditions than for acute cases. For example, Type 2 diabetes is largely a self-managed illness where patients provide much of their own care – in effect a form of choice. Many studies of patient choice (or patient-centred care) relate to chronic conditions such as diabetes or asthma, because these conditions are largely patient-managed. In between, different illnesses provide varying degrees of choice but, in general, the more acute the illness, the less choice may either be available to or sought by the patient. Salmon & Hall 2004 suggest that being ill reduces the importance that people attach to control, and that the more acutely ill patient (other than those with chronic conditions) is less likely to want to exercise choice. Equally, in less acute cases, a distinction has to be made between diagnosis and treatment. Patients usually depend on the clinician for the diagnosis, but are more likely to seek involvement in selecting the most desired treatment options, while preferring the doctor to perform the problem-solving component of treatment decisions that requires clinical expertise (Say & Thomson 2003).

6.2 Extrinsic incentives

Incentives can be linked to health behaviours and provider choices to make desirable behaviours and choices more attractive to patients, and undesirable ones less attractive. This presumes that there is strong evidence that the targeted health behaviours and choices do result in better outcomes.

In 2005, 39% of US employers offered gifts, discounts, or low premiums to employees for completing a health-risk appraisal and 36% provided financial incentives for personal health-improvement programmes.²

The recent (May 2006) West Virginia Medicaid member agreement reduces basic benefits for all eligible persons while, at the same time, offers enhanced benefits to persons who sign and adhere to a 'Medicaid Member Agreement' (Steinbrook 2006). This agreement spells out a number of 'member responsibilities', four of which are monitored: keeping appointments, screening, medication adherence and life style programme adherence. Compliance is rewarded with 'credits' that are placed in a 'healthy rewards account' to be used for purchasing services not covered by the Medicaid plan (eg, fitness-club memberships; vouchers for healthy food for children). Lack of compliance is punished with the loss of enhanced benefits.

Issues raised by this programme (Bishop & Brodkey 2006) include the fact that non-compliance may be legitimate (eg, side effects, disagreement with the physician), may result from circumstances beyond the patient's control (eg poor literacy, no money for transportation), or difficult and uncontrollable circumstances (eg, unreliable transportation, sick children, or limited primary care hours that force emergency room visits). The programme is also seen to violate physician principles (primacy of patient welfare, patient autonomy, social justice) and, because it requires reporting by physicians, to potentially harm the doctor-patient relationship and, in case of withdrawal, the patient.

More recently, some US organisations have been designing models that try to direct patients to providers with superior performance. For example, the Leapfrog Group classifies hospitals on the basis of their performance in five different areas (acute myocardial infarction, CABG, PCI, pneumonia and deliveries/newborns). This classification becomes the basis for differential patient co-payments, co-insurance and deductibles and/or tiered network eligibility. Patients pay less for hospitals with higher quality, and more for hospitals with lower quality (The Leapfrog Group 2006).

6.3 Efficiency motivation

Some attempts have been made to appeal to patients' sense of civic responsibility so that they will be motivated to make efficient choices. For example, the French Statutory Health Insurance system ran advertisement campaigns to persuade patients to choose generic medicines for the collective good, with modest success.

The main strategy for motivating patients to make efficiency-enhancing choices has been through cost-sharing. Co-insurance, co-payment, large deductibles and other cost-sharing schemes are all designed to sensitise patients to the cost of their health care. It is assumed that raising the price of health care increases patients' motivation to reduce the use of health care products and services of low marginal value, and to seek providers and treatments offering greater value for money. Many European countries have increased cost-sharing in recent years (Saltman & Dubois 2004; Saltman & Dubois 2005).

The RAND experiment (Newhouse & The Insurance Experiment Group 1993; Newhouse 2004) showed that cost-sharing reduces use and health care costs. Demand for hospital care was least responsive, and 'well care' (preventive checkups, etc.) most price responsive, with acute and chronic outpatient care falling in between. For most people the reduced use had little or no effect on their health. For those who were poor and sick, however, reducing use was harmful. In particular, the lower control of hypertension among the poor and sick raised the annual likelihood of death by approximately 10%. This suggests that cost-sharing schemes should not be used for the poor and sick.

The RAND experiment also showed that cost-sharing leads patients to reduce the use of necessary services (including preventive care) as much as unnecessary services, a result also found in other studies (Davis 2004). This suggests that cost-sharing schemes work best when patients understand the relative value of different health care products/services and providers. Drug-reimbursement schemes which involve higher co-payments for branded products compared with their generic equivalents are an example of this strategy. Similar schemes, whereby patients would pay more for more expensive yet not better-performing doctors and hospitals, are new and less common. Such schemes would complement pay-for-performance systems for providers (Blumenthal 2006; Davis 2004).

In the absence of clear patient understanding of which products and services are necessary and unnecessary, financial incentives that reduce use tend to lead to poorer health outcomes and higher health care costs (Holst & Laaser 2003; Anonymous 2005; Hsu et al. 2006; Thorpe 2006).

These recommendations focus on developments that can increase patient power and efficient health outcomes.

7.1 Target health conditions for patient empowerment

Patient empowerment efforts need to be targeted to where there is a significant potential for improving efficient health outcomes through greater patient involvement. Not all conditions are equally amenable to improvement through patient empowerment. Patients faced with an acute and urgent medical crisis are less able to gather information and deliberate than those with chronic conditions.

7.2 Analyse the treatment process

Conditions should be analysed to identify the steps in the treatment process where greater patient power would have the largest impact on improving efficient health outcomes.

7.3 Remove barriers to empowerment

The key barriers to greater patient empowerment for the targeted condition and treatment process steps need to be identified and programmes designed to reduce them. This may involve:

- redefining and communicating the patients' role;
- enhancing patients' knowledge about their options, the health condition, their personal health status (eg, through electronic medical records), and their own values and preferences; and
- enhancing patients' skills to carry out the required health activities competently by improving their self-efficacy and health literacy.

7.4 Create a facilitating environment for patient empowerment

Increasing patient empowerment requires policies that encourage patient power. These include:

- the promulgation of patients rights;
- a menu of choices that is consistent with patients' needs;
- easy access to valid information about the choice options;
- decision aids that will help information-processing and decision-making by patients; and
- doctors who are trained to perform different roles, who can play the role that complements each patient's preferred patient role. In addition to their role as 'God' and 'authority', they will have to learn to perform the roles of partners, to put the patient at the centre of the care process rather than the disease. This will require major changes in medical education.

7.5 Ensure equity

Because patients are different, empowerment efforts must be customised to different patient groups. In some circumstances, empowerment may provide greater benefit to the well-educated and better off. Policy makers must ensure that patient empowerment promotes equity in health care. The need to target efforts applies particularly to health literacy. Those with better education, better health insurance, and higher incomes are in a better position to make choices than those who lack these benefits. Health literacy may need to be targeted at those in the lower socio-economic groups, or those from ethnic minorities.

7.6 Motivate the empowered patient to achieve more efficient health outcomes

Empowering patients may or may not result in improved efficient health outcomes because of lack of patient motivation. Incentives that promote healthy and/or efficient behaviours can bring about the desired behaviours. They can also have undesirable effects for some patient groups, so they must be carefully designed and tested.

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ISSUES AFFECTING THE SUSTAINABILITY
OF HEALTH FINANCING IN SEVERAL COUNTRIES
OF SOUTH EAST EUROPE

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EXECUTIVE SUMMARY

This report looks at the sustainability of health financing in Turkey, Romania, Croatia, Bulgaria and the Former Yugoslav Republic of Macedonia. All of them have taken the first steps towards improving the financial sustainability of their health care systems by recognising the challenge and implementing related reforms. Each reform package is of varying breadth and has a different likelihood of success. Governments will have to ensure that existing reforms have the proper institutional and regulatory framework to promote their implementation. All countries must monitor progress in such a way that enables them to recognise if further existing policies need to be changed.

Countries world-wide face challenges in funding health care systems and promoting the efficient and equitable financing and provision of care. The extent of these challenges, and the resources available to meet them, varies dramatically, depending on such factors as level of economic development and political system. In some of these five countries existing resources are insufficient and likely to remain so. In some ways, as is the case with rising pharmaceutical spending, they face similar challenges to those in wealthier economies, but have fewer overall resources and thus sometimes end up paying more of their total health expenditures on these services. Other challenges, such as overcapacity in the hospital sector, insufficient use of outpatient services and an over reliance on inpatient care, are more common in neighbouring eastern and central European countries, and must be confronted successfully in order to ensure that the relatively few available resources are allocated as efficiently as possible.

Private sector stakeholders should recognise their important role in shaping the future of their health care system, and work closely with governments to help devise creative and effective solutions to these sometimes seemingly intractable challenges.

- 1 This report draws mainly upon World Bank and WHO reports, many of which distil information gathered in the course of these organisations providing technical and policy assistance to government policymakers. However, the report is limited in some cases by the varying availability of up-to-date country-specific information, especially as it relates to the breakdown of national health care expenditures by funding source and types of service, health system characteristics and recent and ongoing health care reforms. For example, the sections on Romania and Macedonia are not as rich as they might have been had more information on recent reform efforts been available at the time of authorship.
- 2 The European Union also recognises as 'potential candidate countries': Albania, Bosnia and Herzegovina, Serbia, and Kosovo under a UN Security Resolution.
- 3 In some cases, such as Croatia, the country may have had a social insurance system before the years of Soviet occupation. Hence, in such cases, the country is transitioning back to an earlier health care coverage system, but in the context of their current economic, social and political situations.

The five countries in this study – Turkey, Romania, Croatia, Bulgaria, and the Former Yugoslav Republic of Macedonia – have clear fiscal limitations on how they manage and provide for the needs and demands of their populations. In health care, they generally face high and increasing out-of-pocket payments, informal (under-the-table) payments, inefficiencies in the pooling of funds and the provision of care, and insufficient financial incentives to reach overall health care related goals such as financial sustainability. While each country faces unique challenges, recent experiences have shown that common goals such as equity, efficiency and support for reforms will improve access to quality health care, and promote financial sustainability.

This report examines the literature on these countries' health systems and makes recommendations on health financing and provision systems, with a particular focus on financial sustainability.¹ It looks at private health insurance markets, social health insurance reform, improvements in the efficiency of funds collection, and the merits of redefining the benefit package. It highlights some examples of reforms that seek to reorient incentives and promote a more balanced and appropriate use of primary and specialist care as well as of inpatient versus outpatient services. However, a more complete description and analysis of each country's delivery system and provider payment methods is outside the scope of this paper. The paper also includes some background on a number of recent reform efforts, including efforts under way to manage cost drivers, rationalise health systems, revamp health insurance coverage schemes and improve efficiency.

These five countries have been selected because they have either recently joined the European Union (EU) or are recognised by the EU as 'candidate' or 'pre-accession' countries. Bulgaria and Romania joined on 1 January 2007 and Croatia, Turkey and the Former Yugoslav Republic of Macedonia (FYRM) are candidate countries.² As such, members of the EU and commercial stakeholders in these countries have a particular interest in their economies and social policy structures.

The report makes health care policy recommendations for each country. It also highlights the need to implement changes in a sustainable way.

1.1 Health care coverage and service provision in the study countries

Turkey, Romania, Croatia, Bulgaria and FYRM all rely heavily or exclusively on compulsory social health insurance to finance their health systems. All of the countries except Turkey are still moving over from a state-funded and state-controlled Soviet-style health system to one based on social insurance and with increasing privatisation of health care, the introduction of some market-based incentives, and limited private health insurance.³ All citizens are entitled to health care in law (if not always in practice). Turkey does not have the same history of Soviet-style health care systems, and has recently introduced universal coverage and comprehensive health reforms. The other countries are also seeking to address weaknesses in their health care systems and financing, as this report will show.

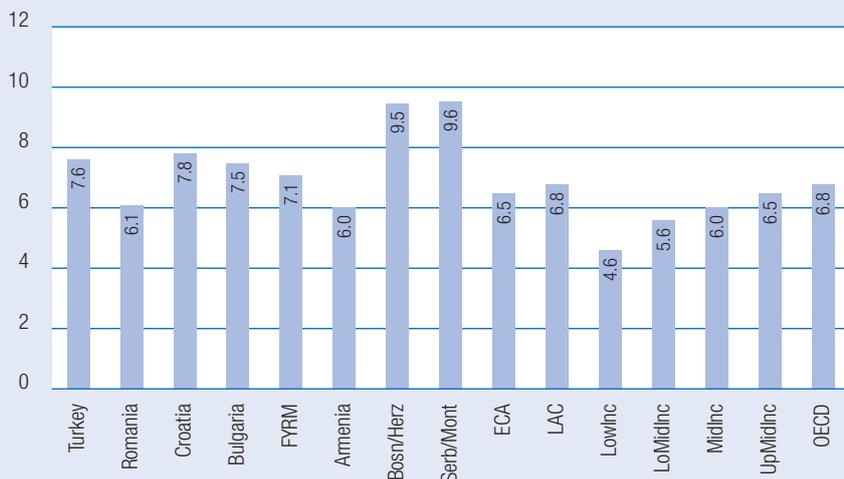
1.2 Health care expenditure trends (total and per capita)

Total health expenditures in all five study countries have increased over the past decade. However, the percentage of GDP devoted to health care and the public share of total health expenditures (THE) differ from country to country. None devotes the same level of resources (in absolute terms) to health care as do the largely high income members of the Organisation for Economic Cooperation and Development (OECD), although the health expenditures for most of the five countries studied are similar to, or above, those of countries at similar levels of economic development. Figure 1 shows recent health spending levels in these countries, expressed as a percentage of GDP, together with figures from neighbouring countries and selected regions.

Croatia and Turkey devote the highest percentage of their GDP to health care (7.8% and 7.6% respectively in 2004), closely followed by Bulgaria (7.5%) and Macedonia (7.1%). Romania's spending falls significantly behind the other countries (at 6.1%). With the exception of Romania, the countries studied contribute more than the average for upper middle income countries (6.5%) as well as above the average for countries in the Eastern European and Central Asia (ECA) and Latin American and Caribbean (LAC) regions (as classified by the World Bank). Two countries in the ECA region (Bosnia and Herzegovina, and Serbia and Montenegro) contribute well above the ECA average, spending 9.5% and 9.6% of their GDP on health. However, as Figure 2 shows, their spending is well below that of Turkey and Croatia and only slightly above the other three countries when measured on the basis of per capita spending.

4 ISSUES AFFECTING THE SUSTAINABILITY OF HEALTH FINANCING IN SEVERAL COUNTRIES OF SOUTH EAST EUROPE

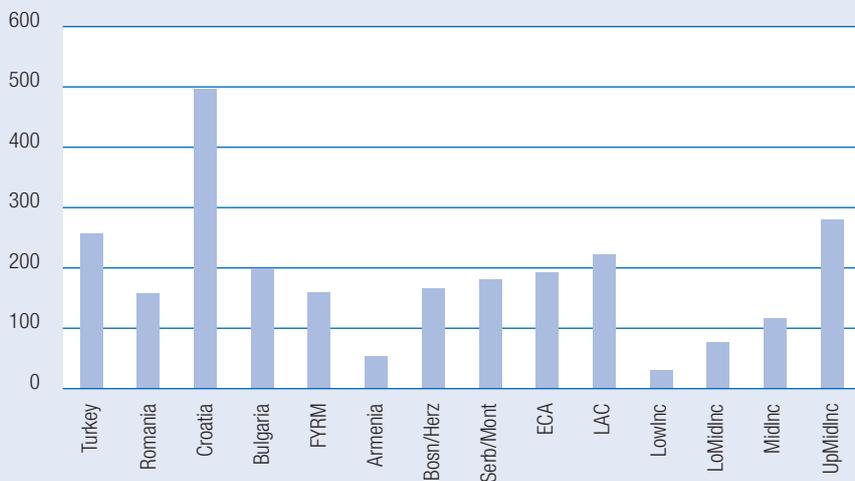
Figure 1: % GDP spent on health (all sources)



Sources: World Bank, data and statistics (2006, with 2004 figures), OECD (for OECD)

Figure 2 shows the per capita spending levels of each country, in dollars. It also includes comparisons with the Latin America and Caribbean region (with high income countries excluded) and low income countries. The per capita health spending of the study countries is lower than that of the comparator regions and country groupings, but not dramatically so. Nevertheless, it highlights the lower absolute level of resources devoted to health care in the study countries. Croatia far outspends the other countries in this study, with a per capita spending of US\$492, twice the amount spent by Turkey, with a per capita spending of US\$254. As a comparison, average per capita health expenditure of lower middle income countries is US\$77. All five countries studied spend well above the average for middle income countries.

Figure 2: Per capita spending (\$US)

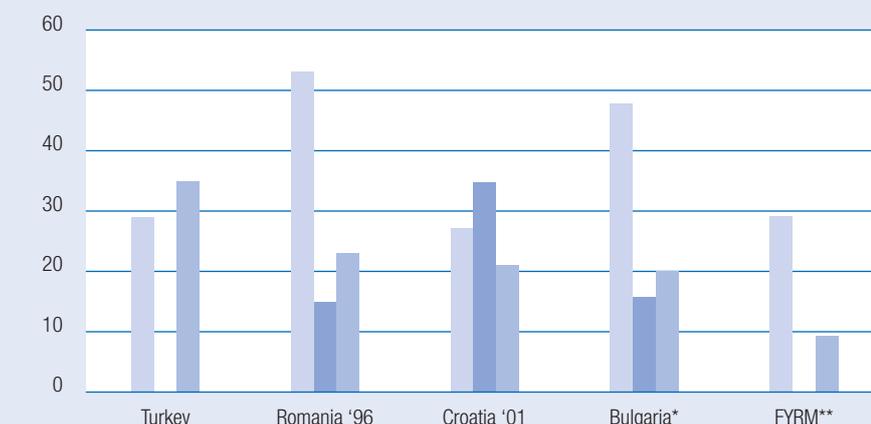


Source: World Bank, data and statistics, health (2006, with 2004 figures)

1.3 Composition of health care expenditures in the study countries

All the study countries except Croatia devote a greater proportion of their health care expenditure to inpatient care and pharmaceuticals than other European countries. This stems partly from the relatively lower level of overall health expenditures. Bulgaria, Romania and Macedonia spend the largest share on inpatient care, reflecting their use of inpatient institutions for many services that could be done on an outpatient basis, long lengths of stay and overcapacity in the hospital sector. The second largest health spending item in the study countries is pharmaceuticals, with the exception of Croatia where spending on inpatient services comes second. Nevertheless, these countries find it a challenge to provide access to drugs and the current burden of drug spending on individual households can be high. Figure 3 shows expenditures by health service category in these countries. (Data based on different years due to data availability.)

Figure 3: Health spending by category of goods or services



	Turkey	Romania '96	Croatia '01	Bulgaria*	FYRM**
Inpatient	29	53	27.3	48	29.4
Outpatient	-	15	34.7	16	N/A
Pharma	35	23	21.2	20	9.6

Source: WHO (HIT studies), World Bank. (Data should be treated with caution because, given available data on relevant countries, it is derived from different sources, for different time periods and is sometimes based on incomplete data, esp. Turkey, FYRM.)

* Bulgarian data represents breakdown of public health spending

** Macedonia data is derived from a 2000 report which included 1996 and 1997 spending.

1.4 Recent, ongoing or contemplated reforms impacting financial sustainability

All five countries have tried to tackle some of the major inefficiencies in their health care systems and some, notably Romania and Croatia, have carried out reforms very recently. One key challenge comes from overcapacity in the hospital sector and a heavy reliance on inpatient care. Most have started to close or change the use of some institutions, and to promote the use of outpatient primary care and specialty services. These actions are often difficult, given the hospital sector's role as a source of employment. Many hospitals also suffer from poor infrastructures, and limited resources have hampered their ability to make improvements.

The study countries have also looked at defining the benefit package more clearly to make clear which services the government (through social insurance or other funding source) will cover. Key benefits include making health care expenditures more predictable, and reducing state provision on less essential and luxury services. (This has run into legal and constitutional difficulties in some eastern European countries and must therefore be implemented carefully.)

Finally, as mentioned above, some of the study countries have tried to promote more appropriate breakdowns in primary care, specialist and hospital services. Some have made progress in introducing provider payment reforms that seek to reorient the incentives in the system. For example, payment methodologies for primary and specialist care have been examined and in some cases changed if they appeared to have induced heavy use of specialists and/or hospitals, as was the case with Croatia's capitation of primary care services. Referral rules for specialists have also been tightened in some cases. Efforts are also under way to manage other cost-drivers, such as pharmaceuticals, and reduce idle resources, such as overcapacity in the hospital sector. In the pharmaceutical sector, the challenges mirror those faced by wealthier European neighbours, and the study countries have included some tools to try to address these issues, but there are no 'simple answers' to some of the growing costs of technology and pharmaceuticals, and the challenge is exacerbated by the more limited resources in the study countries.

1.5 Policy recommendations

Given the scale of the reforms, it will be important to monitor progress so that early and 'mid-course' corrections can be made. It will also be important for governments to communicate and coordinate important changes in health care coverage and provision so that patients, providers and funders understand clearly their rights and roles, and can support these ambitious changes.

It will be politically difficult to alter the current mix of inpatient and outpatient services, and to clarify which services people must pay for themselves, out of their own pocket or through private health insurance. But these measures will play a key role in promoting financial sustainability and public support for the reforms. The level of payment to providers must also be addressed because this contributes to the continued practice of informal payments. Reducing the extent of under-the-table payments and delivering health services without impediments (such as queues, delays in payments or ongoing debts) will put governments, social insurers and other public funders in a better position to cover and provide important and lasting health care services.

The following five sections give an overview of the health financing and coverage systems in each of the five countries. Each will focus on key challenges to financial sustainability and will look at the reforms needed to address system weaknesses.

4 WHO, HIT (2002).

5 www.allaboutturkey.com/health

6 Chawla (2003).

7 WHO, HIT (2002).

2.1 Overview

In absolute terms, Turkey spends a low amount of its resources on health care for a country with its level of economic development, although its spending in absolute and relative terms has risen since 1998. Its total health expenditures (THE) increased from 4.8% to 7.6% of GDP from 1998 to 2003, and the latest spending figure is above the OECD average (see figure 1). From 1999 to 2003, per capita health spending also increased significantly from US\$179 to US\$257 per year.

Figure 4: Health expenditures: changes in Turkey from 1998 and 2003

	THE % GDP	% THE Public	% THE Private	Per capita Health exp. (US\$)	OOP health spending; % priv. spdg	Contribution PHI to priv.h.exp.
1998	4.8%	71.9%	28.1%	179 ('99)	99.6%	0.1%
2003	7.6%	71.6%	28.4%	257	69.9%	12.5%

Source: * WHO, World Health Statistics 2006, Core Health Indicators.

2.2 Sources and mechanisms of financing

The Turkish health care system is financed through a combination of social insurance, tax-based government expenditures, out-of-pocket spending and private insurance. Turkey has seen increased use of health care pooling mechanisms, including private health insurance and a public programme for the uninsured. However, out-of-pocket expenditures at the time of service-use still represented nearly 70% of private spending on health in 2003.

Social insurance

Recent and upcoming reforms will alter dramatically the structure of social insurance in Turkey. From January 2007, all social insurers will be merged into one coverage mechanism. The contribution level will be 12.5%, with 55% paid by employers and 45% by individuals. Those who cannot pay will be included in the scheme, and the government will bear the cost of their coverage. The benefit package will be the same for all populations covered, which differs from previous schemes, a brief description of which is found below.

Many Turkish people received their health coverage through one of several social insurance organisations. *Sosyal Sigortalar Kurumu* (SSK) has been the social security institution for private sector and blue collar public sector workers. SSK is both an insurer and a health care provider, although its members are also referred to ministry, university and private institutions. The sickness insurance premium rate has been set at 11% of earnings (the rate is 22% for miners), with 55% paid by the employer and 45% by the employee. SSK members covered under an employment service contract are compulsorily insured, whereas others who are not eligible for other social security, invalidity or pension coverage may take part voluntarily. SSK had a deficit in 1994 and 1995, but stayed within its resources for the next three years. (More recent figures are unavailable.) Collection challenges also harm its revenue stream.⁴

Artisans, merchants and other self-employed people, along with uninsured agricultural sector employees, have been obliged to join *Bag-Kur* (and are therefore compulsorily insured). Unemployed housewives, unemployed spouses of Turkish employees abroad, and foreign citizens living in Turkey may also choose to join *Bag-Kur*. Members can choose their contribution level, with certain corresponding limits on covered care.⁵ *Bag-Kur* has contracts with other public health sector providers, but has no providers of its own. Fees have been determined by institutions and paid on a reimbursement basis. *Bag-Kur* covered all outpatient and inpatient diagnoses and treatment.⁶ A 10% or 20% co-payment has been imposed on outpatient drugs, which is a large cost burden on them. *Bag-Kur* has also been plagued with more fraud and abuse than some of the other insurers, and its collection rate is only 65% of its active members. It had a deficit between 1994 and 1998.⁷

There was also a social insurance programme for pensioners, *Emekli Sandigi* (ES) and another for civil servants (GERF). Importantly, social insurance resources have not reflected their memberships because of collection problems, and *Bag-Kur's* collection rate is as low as 65%.

The creation of a single universal coverage system will extend coverage to the whole Turkish population, and also reduce the administrative complexity. Merging disparate systems and setting one contribution rate should improve collection rates and reduce unnecessary administrative expenses.

Recent public programme for low-income persons

Before the recent reforms, coverage for those on lower incomes had improved, through the income-based green card programme. In 1992, its first year of operation, it only covered 0.6% of the population, but by 2001 it covered 16.4%, thus making it a significant source of health coverage. The programme has been managed by the Ministry of Health (MOH) and funded by general taxes. It covered free inpatient and outpatient health services, and inpatient drugs. However, in recent years appropriated funds have not been constant.

Additional public sources of health financing

The state, through the Ministry of Health, has contributed to health spending and will continue to do so. Off-budget government sources, such as special funds, have also contributed to the health system.

Out-of-pocket expenditures on health

Out-of-pocket spending, the most regressive type of health financing, made up 70% of private spending on health care in 2003. It is not clear what made up the rest as private health insurance still plays a minor role (see below). In 1998, 99.6% of private spending on health care was made on an out-of-pocket basis, so there has been a substantial reduction in a relatively short time. It is not clear whether this increase in the pooling of health care resources has benefited the poor. It is also unlikely that the poor were significant purchasers of private health insurance, which is often bought by wealthier people in the absence of subsidised premiums.⁸

Private health insurance (PHI)

The reduction in out-of-pocket spending correlates with an increase of prepaid health plans. Yet private health insurance (PHI) only contributes 0.5% to overall health expenditures. The number of people with private health coverage rose from about 15,000 in 1990 to an estimated 650,000 (and more than 30 insurers) in 2002. About half of these policies were thought to be employer-based, although no firm data are available. The amount of coverage has declined since 2000, probably because of increased premiums. The average premium rose from US\$200 to US\$800 per person per year from the mid-1990s through 2001. This is probably caused by factors such as inadequate cost control, few limits on coverage, and fraud.⁹ Given the cost and link with employment, this coverage seems to have benefited those with high incomes, as often happens in countries with private health insurance markets, rather than contributing to easing the burden of out-of-pocket payments on the poor.

2.3 Health spending

Much health spending goes to pharmaceuticals and inpatient services. About half of health expenditures goes to pharmaceuticals, one-third to outpatient services (80% of which are delivered in hospitals) and one-sixth on inpatient services.¹⁰

Pharmaceutical spending

Pharmaceutical expenditures form a large part of total health expenditure in Turkey (see above), and there has been little major change since 1998.¹¹ Precise total spending on drugs is not available, nor are data on out-of-pocket payments by the uninsured.

The therapeutic class with the highest consumption level is antibiotics, followed by analgesics and anti-migraine preparations and anti-rheumatic drugs and muscle relaxants. The share of systemic anti-infectiveness drugs is high by global standards: 26.2%, compared to a global average of 9.9%. The distribution of drugs by price categories has changed, with more drugs being sold in higher price ranges, and fewer in lower price ranges.

8 Tapay and Colombo (2004).

9 WHO, HIT (2002).

10 World Bank (2006).

11 Chawla (2003).

12 Kanavos et al, citing WHO (2003).

13 France, Italy, Canada and Germany all spend more than US\$400 US\$ per capita on drugs in 2001. Huber, M. and Orosz, E., 'Health Expenditure Trends in OECD Countries, 1990-2001, Health Care Financing Review, Fall 2003.

14 Kanavos et al (2005).

15 World Bank (2006).

16 Kanavos et al (2005).

17 Kanavos et al (2005), citing Dr. Mollahaliloglu, Ankara.

18 Kanavos et al (2005).

19 WHO, HIT (2002).

20 WHO, HIT (2002).

Pharmaceutical consumption rose significantly in the late 1990s, reaching US\$110 per person.¹² This is still lower than the consumption in many western European countries, where 2001 per capita expenditures on pharmaceuticals exceeded US\$400 per capita.¹³ However, it may not be significantly lower when relative purchasing power is taken into account. Before the health reforms, the large social insurers operated large computer systems in pharmacies with information on individual patients and on patterns of use, although it is not clear how or whether this information was used for monitoring.¹⁴ Under the new reforms, this infrastructure has helped to create a national pharmaceutical tracking system which is currently operational.¹⁵

All social insurance organisations have had positive lists for prescriptions. Those covered by the three social insurers must pay a 20% co-payment on pharmaceuticals, and retired people must pay 10%. Pharmacists can make substitutions for outpatient drugs when their price is below the reference price, and may also substitute generics. Under this system, pharmacists' dispensing decisions have been heavily influenced by discount or rebate arrangements with the industry or wholesalers.

Most pharmaceutical-related expenses have been covered by social insurance or public sources (66%), with the rest paid by individuals either as co-payments or direct purchase.¹⁶ Access to pharmaceuticals does not appear to have been a problem, but there are issues of quality and prescribing, with 45% of prescriptions recently found to be inappropriate.¹⁷

The reforms plan a single positive list with access to all socially insured persons. A joint ministerial reimbursement committee has been set up under a new pharmaceutical pricing decree. The government also plans to introduce policies to influence physician prescribing behavior. Under the pricing decree, a basket of five European 'reference' countries, identified annually, will be used to help determine pharmaceutical prices. In 2005, the five countries were Italy, Spain, Greece, France and Portugal. For generics, the price is 80% of the reference price for brand drugs.¹⁸

2.4 Health care delivery

The way health care is delivered affects the sustainability of health financing. Turkey's health provision system is similar to that found in many low-income countries and could benefit from better management and more efficient resource allocation.

Primary care is provided by several Ministry of Health units, including health centres, health posts and maternal and child health and family planning centres. These are the only sources of preventive and community-based health care. They used to provide services and essential drugs free of charge, but official fees were introduced in 2002. An infrastructure for national health services, introduced in legislation in 1961, has developed in rural areas, but it is relatively weak in urban areas and expected funding reforms have not been implemented. In urban areas, outpatient departments of MOH hospitals are used extensively, and SSK members use its hospital polyclinics and dispensaries for similar purposes. Private specialist practices seem to be an important point of initial contact with the health care system. The lack of health centres in Istanbul, for example, results in people going to private polyclinics for basic services.¹⁹

In terms of inpatient care, the MOH owned about half of all hospitals, and SSK was the second largest provider with 16%, followed by the university hospitals (14%) and the Ministry of Defence (9%). There is a surplus of acute beds, with occupancy just under 60% nationally, but variation among hospitals is significant: MOH hospitals have particularly low occupancy rates. Hospitals generally lack trained managers, and are often run by chief doctors with little or no management training. This is beginning to change in private hospitals. Under the 2005 reforms, all hospitals were transferred to MOH, with no hospitals owned by the social insurance sector. This is a transitional measure until the health care providers become autonomous. This transformation is part of the government's reform agenda and aims to separate the financing of health care from the provision of services.

Turkey does not have an effective referral system. This comes from the lack of primary care doctors and the fact that hospitals treat self-referred patients in non-emergency situations. MOH hospitals do not require referrals and most consultations occur without the advice of a primary care doctor.²⁰ Turkey has relatively few trained health service workers, and they are distributed unevenly across the country. As part of an effort to address the distribution of health care providers and to promote the use of primary care, the reforms included a pilot family medicine project that will be significantly expanded in the coming years.

2.5 Efficiency, effectiveness and equity

21 Chawla (2003), Figure 12, Vol. II.

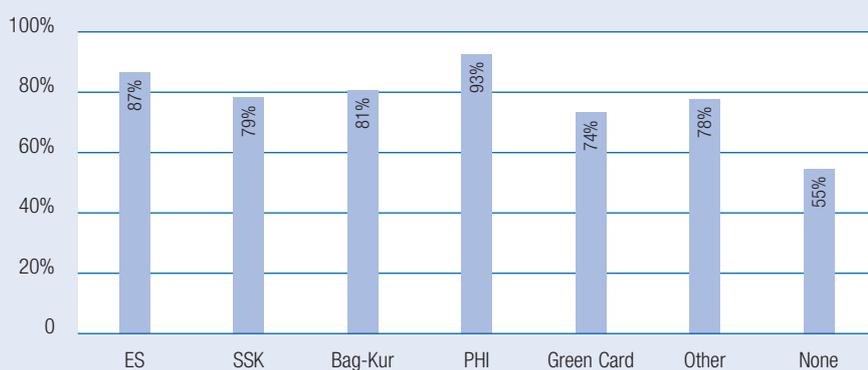
As described above, the structure of health provision – with multiple, non-coordinating public providers – has led to duplication and inefficiency. The reliance on more costly inpatient providers and on private polyclinics for basic services increases costs unnecessarily. Overcapacity in the hospital sector consumes more resources than would otherwise be necessary.

A further challenge to the financial sustainability of health care in Turkey has been the high dependency ratio (the number of non-paying per premium-paying members) for most social health insurance coverage programmes. These ratios range from 3.6:1 (*Bag-Kur*) to 4.55:1 (SSK), with an overall average ratio of 4.14:1. This meant that, on average, one person's contribution bore the cost of more than four people's health care. This placed a high burden on premium paying members and may have contributed to collection problems. While the financing may be structured progressively among insured wage-earners, it does not distribute financing fairly across age groups because dependents often have no income. The reforms have tried to solve this problem by insuring individuals rather than family groups, with certain types of individual contributions paid by the government via tax-based funding. This will result in a mixed system of health care financing that will combine tax-based funding and social insurance contributions in an attempt to spread the financial burden across more people.

There is a tiered formal provider payment structure that allows providers to charge different amounts based upon seniority. For example, heads of departments and university professors, may charge more than junior colleagues. This tiered rate schedule rewards experience and training. Nevertheless, from an equity perspective, those who can afford to pay the higher fees have a wider choice of physicians, with potential implications in terms of the quality of services received.

The type of health coverage and insurance status have historically affected people's likelihood to seek treatment. Those with private coverage tend to seek care more frequently, followed by those with social and green card coverage. Unsurprisingly, the uninsured are less likely to seek care.

Figure 6: Varied health care treatment patterns: likelihood to seek care by type of health insurance coverage



Source: Chawla (2003) Vol. II, Chapter 2, Figure 11

Particularly troubling is the fact that the most disadvantaged groups appear to have paid the most for their care, with the uninsured paying the highest amounts and those with green cards a bit less, but still more than the socially insured. The privately insured are an exception to this trend, and paid more for health services than those with green cards, but less than the uninsured.²¹

Out-of-pocket spending went down over the past two decades, partly because of the growing private health insurance market. But recent premium increases have slowed the growth in this market and may have reduced consumer interest and trust. The rate of premium increases must be controlled if this market is to continue to grow and help provide a source of additional and pooled revenue for the health system. As in other countries, higher-income persons are more likely to purchase PHI, and hence its benefits are not equally distributed across the population.

2.6 Reforms and recommendations

Key challenges to the financial sustainability of the health system

To summarise, the Turkish health system faces several financing hurdles, including:

- a significant amount of out-of-pocket financing;
- inefficient management of the provision and financing of inpatient and outpatient services, including a heavy reliance on inpatient care and overcapacity in the hospital sector;
- fluctuations in budgetary resources and allocations for health care;
- low collection rates for many of the social insurers; and
- a relatively low level of financial resources devoted to funding health care in absolute terms for a country at its level of economic development.

Past health reform efforts

- *Reforms of the 1990s*

Between 1990 and 1993, a more comprehensive and detailed reform process was carried out in an effort to increase awareness and build consensus for reform. A proposal was presented to the Second National Health Congress and the Council of Ministers in 1993. It included reforms to health care organisation (including regionalisation of MOH powers) and the establishment of a universal health insurance organisation. However, the death of the president resulted in many changes in political leadership and the main piece of the proposals that was implemented was the Green Card programme for low-earners.²² More recently, the government has been implementing comprehensive reforms that seek to address many of the issues included under the earlier proposal, plus some additional components.

- *Key goals of past reforms*

The past reforms sought to address several problems in the health care system by:

- improving health system effectiveness;
- increasing efficiency and effective use of resources;
- improving quality; and
- reducing inequalities.

- *Key components of recently enacted reforms*

The adopted reforms are in various stages of implementation and include the following components:

- Improving health system effectiveness
 - restructure MOH and make other changes in the health agencies; and
 - place all public hospitals under MOH and increase their autonomy over time.
- Increasing efficiency and effective use of resources
 - merge social insurers and integrate premium collection;
 - separate health provision and financing in order to encourage more innovative financing methods;
 - pilot family medicine in several districts and expand over time;
 - adopt pharmaceutical policies to address inappropriate demand and use;
 - define clearly the basic benefit package; and
 - provide budget support for MOH and other health financing functions.

- *Improving quality*
 - increase MOH's ability to oversee policy, regulate the private sector, health care technologies and pharmaceuticals and fulfil its public health and quality assurance roles more effectively.
- *Reducing inequalities*
 - establish a single universal health insurance (UHI) scheme to cover all citizens, with the state paying on behalf of the poor and those unable to pay.

The implementation of these reforms is just under way and it will take some time to monitor and observe their effectiveness. The important thing, however, is that the country has begun to try to address the challenges facing their health system, from the perspective of both service provision and financing.

2.7 Recommended steps for policymakers

The current reforms address a number of important areas and, if implemented successfully, could help to make significant improvements in terms of access to health coverage and services and financial sustainability. Given the scale of the reforms, it will be important to monitor implementation so that early and mid-course corrections could be made.

Areas for particular attention and quick policy intervention include:

- giving the more vulnerable populations access to services under the new universal health coverage system, and identifying quickly any administrative or financing obstacles;
- ensuring strong understanding by the public and health care providers of the scope of covered benefits under the basic benefit package; and
- considering possible pilot projects when moving towards more hospital autonomy.

23 WHO (2006).

24 World Bank, Implementation Completion Report, Romania Health Sector Reform Project, 2004, Annex 9.

25 Ionescu, Carmiola, 'Corruption targeted in Romania's health reforms,' *The Lancet*, Vol. 367, Issue 9519, 22 April 2006.

26 Bara, Ana-Claudia; van den Heuvel, W.J.A.; Maarse, J.A.M., 'Reforms of Health Care System in Romania', *Croatian Medical Journal*, 43(4):446-452 (2002). (CMJ (2002))

27 WHO, HIT (1999).

28 Id.

29 CMJ (2002)

3.1 Overview

Romania's total health expenditure (THE) was 6.1% of GDP in 2003.²³ Public health expenditure as a percentage of GDP was 4.1% that same year²⁴ and more recent figures reveal a similar allocation of public funds in 2005, when the government's health budget accounted for 4% of GDP.²⁵ As shown in figure 7 below, health expenditures as a percentage of GDP grew from 4.9% to 6.1% between 1998 and 2003. More of that spending came from public sources in 2003, although there is still a heavy dependence on private spending (37.1% in 2003). Unlike in Turkey, the out-of-pocket spending increased over this time, and the contribution of private health insurance (PHI) to private health expenditures fell dramatically. This reduced role for private health insurance may be short-lived. A package of new health care reforms in 2006 define a basic benefit package and introduce a greater role for private supplemental insurance, as described below.

Figure 7: Changes in Romanian health expenditures 1998 and 2003

	THE % GDP	% THE Public	% THE Private	Per capita Health exp. (US\$)	OOP health spending; % priv. spdg	Contribution PHI to priv.h.exp.
1998	4.9%	57.6%	42.4%	87 ('99)	82.6%	17.4%
2003	6.1%	62.9%	37.1%	159	90.0%	4.7%

Source: WHO, World Health Statistics (2006)

3.2 Sources and mechanisms of financing

Social insurance

From 1991, several laws and regulations have been enacted to improve the structure and functioning of the health care system.²⁶ Two key pieces of legislation on health insurance have been enacted: the 1997 law on social insurance (implemented from 1998), and a package of health care laws in 2006 that revised significantly the social and private health care coverage systems. The 1997 reforms are described below, together with challenges that led to the recent round of reforms in 2006 (see section 6, below).

Until 1997, Romania's centralised health system provided universal coverage, funded largely from the budget administered by the Ministry of Health (MOH) and other health provider networks. The 1997 health insurance law changed the system from a 'Semashko' state-financed model to an employer-based compulsory social health insurance system. From 1998, earmarked payroll contributions have been the main source of health funding. The 1997 law required employees to contribute 10% of their income and this was increased to 14% in 1999, with employers and employees contributing 7% each. The Ministry of Defence funded health care for the military and the Ministry of Justice funded health care for prisoners.²⁷

The 1997 law required the 42 district health insurance funds (DHIFs) to collect premiums locally and then contract for services from public and private providers. The district funds administer the money, along with a national health insurance fund (NHIF) which sets the rules and can switch to re-allocate up to 25% of the collected funds to underfinanced districts. The national fund also negotiates the framework contract with the Romanian College of Physicians.

Collecting the funds has provided a major challenge to the success of this social insurance system. Initial collections in 1998 were lower than had been anticipated (87% of conservative projections). In 1999, revenues increased by 25%, explained in part by higher collection rates.²⁸ But in 2002 there were still problems: one study attributed this to a lack of experience and skills by those collecting revenues from employers, and resistance among certain employers who have decided to evade paying social insurance by hiring 'unofficially'.²⁹

Social insurance has provided health coverage for many Romanians since 1998, but an analysis a few years after its implementation showed that several groups tended to have no health coverage. For example, those unemployed for longer than 27 months are not registered as unemployed, and end up uninsured unless they have close family members in work. Additional gaps were found among the rural population (whose unstable income made it hard to pay premiums, and thus ended up paying out of pocket); the 'unofficially employed' who are hired on the black market (at times there may be premium evasion as an employer motive); and those who live in areas where local budgets are not enough to encourage physicians or nurses to practise there.³⁰

The 1997 law gave a legal right to free treatment for any medical condition, free annual checkups, and free or highly subsidised drugs (at least 50%).³¹ However, as with other central and eastern European countries, the reform did not include a clearly defined benefit package. Patients have had problems accessing care as well as obtaining free and subsidised medicines. They complain of long queues for appointments and shortages or limited availability of medicines, including vital drugs such as insulin.³²

Additional sources of financing

Private spending has continued to make up a large proportion of total health expenditures (over 31%). Despite the 1997 social insurance law, informal under-the-table payments are still prevalent. This has a negative impact on equity and access, and remains a significant problem, according to a recent World Bank report. This survey showed that informal payments ranged from US\$5 to US\$60 for specialist treatment at a clinic or top hospital. Low-income families had to spend as much as three-quarters of their monthly wage on such payments if a family member needed hospitalisation. This study, released in 2004, also highlighted the link with low physician and provider payment levels.³³ A recent article on the Romanian situation and the World Bank study quoted the head of the Romanian Association for Doctors' Trade Unions: 'The big payments occur in hospitals for things like surgery and treatments using the latest technology. Only salary increases can solve the problem.'³⁴

As for cost sharing, co-payments (20%) were in place for drugs and certain services, yet certain groups were exempt from these, and these groups included those who could afford to pay.³⁵ This reduced the potential for co-payments to act as a mechanism for raising revenue and controlling inappropriate and excessive use of services. Also, the broad exemption categories did not address equity issues among income groups.

Wealthier households are increasingly bypassing the public system by paying out-of-pocket for private services. Surveys confirmed an increased use of private providers, paid on an out-of-pocket basis in 1998 and 1999.³⁶ An increased proportion of total health expenditure comes from government resources, which improves the potential for a fairer distribution of health care resources. But the extent of private out-of-pocket spending means that resources are not being pooled across the population, nor are they being distributed according to health care needs.

3.3 Health spending

Allocation of resources towards inpatient and outpatient services

There is a heavy bias towards inpatient services, with 53% of the health budget going to hospital care, compared to the OECD average of 40%. Romania's annual number of inpatient surgical procedures is three times the EU average.³⁷ Only 15% of the budget is devoted to outpatient care.

Pharmaceutical policy and expenditure tracking

Romania has not had a national drug information system to track public and private sector spending. It was estimated that about 23% of its 1996 health expenditure was on drugs. A much higher proportion of private health spending (31%) went to this sector than public health spending (19%).³⁸

The 1998 health insurance law limited insurance coverage of pharmaceuticals by creating two lists of reimbursed drugs: the first for generic substances treating 26 diseases (cancer, TB, diabetes, etc), and the second for generic substances subject to a reference price system and reimbursed at 70% of the reference price. The list is based on recommendations from the College of Physicians and the College of Pharmacists, but the law does not specify selection criteria.

30 Id.

31 Ionescu, C., *The Lancet*, 22 April 2006.

32 Id.

33 Ionescu, C., 'World Report: Romanians pay US\$1million extra a day for health,' *The Lancet*, 366:1515 (2005), citing World Bank study on informal payments in Romania's health sector.

34 For example, despite the years of training required to become a physician, resident doctors were reported as earning an average of US\$170 per month, increasing to US\$500 for senior professors. Monthly nurses' salaries range from US\$80 to US\$200. *The Lancet* (2005).

35 World Bank, *Romania Health Sector Strategy* (1999).

36 WHO (1999).

37 World Bank, Chapter 7.

38 WHO, HIT (1999).

39 WHO, HIT (1999).

40 WHO, HIT (1999) citing Centre for Health Policies and Services (1999).

41 WHO HIT (1999).

42 WHO, HIT (1999), citing 1998 survey results.

3.4 Health care delivery

Romania historically had a centralised health system under the authority of the MOH. Until 1999, primary care took place through a network of MOH dispensaries administered through local hospitals. In 1998, the health insurance law allowed patients to choose their family doctor, and general practitioners moved from being state employees to independent practitioners, generally contracting with the public health insurance funds but operating their practices privately.³⁹

Specialist care, which had historically been provided by polyclinics, is provided in a variety of settings, such as hospital outpatient departments, free-standing centres, or individual specialist offices. A study estimated that about 15% of physicians work in both public and private practice.⁴⁰

The number of hospital admissions (21/100) is higher than that found in most European countries, but comparable to levels in Austria, Hungary, the Baltic countries and the UK. There is a high rate of emergency admissions – about 70% of total admissions (excluding chronic care hospitals).⁴¹

With one exception, all hospitals are publicly owned and administered by the state. Hospital leaders are usually appointed by public health directorates at the district level. After the 1999 law, hospitals introduced global budgets and contracting procedures, and were also transferred to local council ownership. While these changes should improve the management of hospital resources, there are significant challenges because many hospitals are in poor physical condition and most hospital and polyclinic equipment is considered obsolete.⁴²

3.5 Efficiency, effectiveness and equity

The number of emergency admissions into inpatient care is high. This reflects the inefficient allocation of resources in favour of more costly inpatient services, the difficulty of accessing more cost-effective outpatient care, and delays in patients seeking treatment until their conditions become more serious.

Access to, and quality of, health care is uneven among geographic areas, income groups and ethnic minorities. In addition, the practice of informal payments distorts incentives in the payment system and increases inequities.

3.6 Reforms and recommendations

Given the ongoing challenges in the health care system, the Romanian parliament adopted a package of 17 health care laws in 2006.

One of the key reforms is the development of a clearer, and more restrictive, definition of the 'benefit package' (health care services covered by social insurance). Before, the package left the way open for a gap between the legal goals and ensuing public expectations on the one hand, and the actual level of services on the other.

The intention of the legislation is to stabilise funding for the social health insurance system so that all Romanian citizens have better access to health care services. This is to be achieved by narrowing the range of services covered by social insurance, and clarifying and promoting a role for private health insurance for additional services.

Reforms included the following policy changes:

Improving health system effectiveness

- separating hospital management and clinical functions;
- giving the Ministry of Health consultative approval in the appointment and dismissal of hospital leadership (but without granting oversight functions to an independent board of directors, as has been done elsewhere).

Increasing efficiency and the effective use of resources

- establishing the mechanism for paying contributions and regulating how they contribute to the National Single Health Insurance Fund;
- defining covered benefit package;
- listing medicines subject to full or partial reimbursement; and
- providing a mixed reimbursement system for family doctors – paying on both a per capita and per service basis – in order to increase outpatient activities and reduce hospital spending.⁴³

43 World Bank, Chapter 7.

44 Johnston (2002).

These reforms have the potential to improve access to services, quality of care and the financial stability. Yet they are ambitious, and public expectations may put additional pressures on their implementation in the short term. Policymakers and stakeholders will have to implement and monitor the changes carefully.

Policy recommendations

Implementing the earlier set of reforms was hampered by limited expertise with contracting and payment system design. There were other challenges, such as the legal ambiguities concerning the roles of MOH and the health insurance funds.⁴⁴ While such difficult challenges may no longer be an issue, the lessons learnt still emphasise the importance of attending to the institutional context. This means building or supporting capacity in the appropriate areas as the government moves forward with its most recent set of reforms.

A key recommendation is to monitor these wide-reaching reforms carefully to ensure their success in improving access and the stability and sustainability of health financing in Romania. Additional attention must be paid to the pharmaceutical sector, where cost increases are likely to occur and the policy and payment framework could benefit from further attention.

45 Maeda et al (2004).

46 Id.

47 Maeda et al (2004) citing Institute for Public Health, preliminary survey results (2002).

48 Maeda et al (2004).

49 The term 'complementary coverage' refers to coverage of co-payments for social insurance and is the most common type of private health insurance in Croatia, administered through HZZO. Supplemental insurance covers those services not covered by social insurance. (See Tapay and Colombo, Private Health Insurance in OECD Countries, OECD (2004)). Legislation is being considered in Croatia that would further clarify the role of different types of insurance to cover services not covered by social insurance.

4.1 Overview

Croatia's health expenditures, in absolute and relative terms, are high compared with those of the other countries studied, and represented 7.8% of GDP in 2003. The total health expenditures are consistent with spending in 1998; they had been higher in some of the intervening years (reaching 9.3% GDP in 2000), yet has declined since 2002.

Figure 8: Changes in Croatian health expenditures between 1998 and 2003

	THE % GDP	% THE Public	% THE Private	Per capita Health exp. (US\$)	OOP health spending; % priv. spdg	Contribution PHI to priv.h.exp.
1998	7.9%	85.1%	14.9%	386 ('99)	100%	0%*
2003	7.8%	83.6%	16.4%	494	100%	0%*

Source: WHO, World Health Statistics (2006)

* This figure does not appear to account for the voluntary complementary health insurance offered through the social insurance fund.

4.2 Sources and mechanisms of financing

Social insurance

Croatia has had a consolidated health financing system since 1993, organised under a single, statutory, quasi-government agency, HZZO. However, government efforts to contain health care costs in the 1990s were not successful, resulting in HZZO having significant arrears. These necessitated periodic transfers of funds from the central budget, imposing a burden on the broader fiscal situation. In 2000, the government began a series of reforms to contain costs, reduce the tax burden on labour, and raise revenues through co-payments. It also set up supply side reforms, including efforts to rationalise the structure of health care and to reform provider payment mechanisms.⁴⁵

The payroll tax for health insurance was lowered to 15% in 2000. The hope was that the lower contributions would be balanced by the increased budget allocations for special groups, together with increased cost-sharing and supplemental health insurance coverage of co-payments.

About one third of HZZO beneficiaries were actively employed between 1995 and 2002. However, the number of unemployed and retired beneficiaries has been increasing recently. These groups are among the higher users of health services but contribute the least, and this will pose challenges to HZZO's future funding.⁴⁶

Out-of-pocket spending

Household survey data suggest that direct household spending on health amounts to about 1.2% GDP and private insurer reimbursements to about 0.7% GDP. This gives a total private health spending of about 2% GDP. A study on informal payments in Zagreb suggested that about 44% of respondents who have used health services have made some type of informal payments.⁴⁷

Private health insurance

Private insurance is for services not covered by social insurance and was about 6% of total health expenditure in 2001.⁴⁸ The coverage of social insurance co-payments by complementary coverage raises concerns about moral hazard.⁴⁹ For example, countries with similar private coverage schemes, such as France, have seen this coverage contravene the potential demand-moderating effect of the co-payments.

4.3 Health spending

50 Id.

Allocation of resources for outpatient and inpatient services

Unlike other countries in this study, Croatia spends the highest proportion of its total health expenditures on outpatient services (34.7% in 2001). Inpatient services represent the second largest expenditure (27.3%).

51 Id.

52 Maeda et al (2004).

Pharmaceutical expenditures

Pharmaceutical spending is the third largest health expenditure in Croatia, and was 21.2% of the total in 2001.⁵⁰ It has also been a significant source of the rising cost of health care. In 1999, a reference price scheme was introduced, which determined prices biannually based on wholesale prices in the 'reference countries' of Slovenia, the Czech Republic and France, along with two other countries when necessary. This system has resulted in selected drug prices both below (by 36%) and above (by 64%) the prices for the same drugs in Australia. (Australia is a useful benchmark as it reimburses drugs at 50-60% of the world average.)

In order to address demand, the Croatian Institute for Health Insurance (HZZO) has imposed a ceiling of five prescriptions per beneficiary (though there can be exceptions). This has not controlled prescriptions because the average number per beneficiary rose from five to seven between 1996 and 2002. However, higher co-payment rates under the 2002 health insurance law appear to have reduced HZZO drug expenditures. Instead of reducing use, the policy appears to have shifted some of the costs to patients, although the increased out-of-pocket spending on drugs may have been mitigated by complementary PHI coverage.⁵¹

Nevertheless HZZO drug expenditures have ranged between 17.9% and 13.4% of its total health spending. This is a lower proportion than that in some other countries in this study (eg, Turkey). However, while the payment for drugs now includes private health insurance and out-of-pocket payments, and has reduced the burden on social insurance, it has not clearly addressed costs in the drug sector overall, nor utilisation.

4.4 Health care delivery

The Ministry of Health is responsible for health policy and planning, the drafting of legislation, the regulation of standards of health services and training, public health programmes, and the operation of teaching hospitals and certain specialised clinics. Local governments own and operate most public primary and secondary health care providers, including general hospitals and polyclinics. Their operating costs are funded through contracts with HZZO and they are responsible for infrastructure maintenance and capital investment. Private providers are largely found in primary and specialist care and many of them also have contracts with HZZO.

The 1993 health law established primary care physicians as gatekeepers, encouraged their privatisation, and established capitation payments. This system, however, does not create incentives to support the gate-keeping function. HZZO imposed limits on the average number of prescriptions and referrals per patient, yet these did not reflect the clinical or epidemiological profiles of the practice or service needs and exemptions were permitted if there was evidence of patient need.

The hospital payment system has created incentives for full occupancy and extended lengths of stay, because it is a point-based system based upon *per diem* reimbursement that operates like a fee-for-service reimbursement system. It is subject to a global cap with financial incentives if the hospital exceeds the ceiling. Low occupancy rates have reduced the risk that hospitals would reach the ceiling, but HZZO can lower the cap and current contracts have made it difficult for hospitals to adjust staffing levels based on efficiency gains, such as shorter lengths of stay. In addition to global budgets, the hospital system might benefit from changes in hospital management in order to realign incentives while at the same time protecting access to, and quality of, care.⁵²

4.5 Efficiency, effectiveness and equity

Provider payment mechanisms have not made the system more efficient, and in fact may have promoted inefficiency. The capitation-based payment of primary care physicians promotes referrals to specialists and to hospitals, where there are still significant inefficiencies. The government has tried to address these problems through cutting bed capacity and reforming hospital payments.

53 *Id.*

However, the point-based payment system has created incentives to keep beds occupied, with longer hospital stays and longer waiting lists for certain services. In 2002, the government introduced a case-based payment system. Hospitals could opt out of this payment mechanism, potentially undercutting its effectiveness, but so far it has succeeded in reducing lengths of hospital stays.⁵³

54 *Id.*

The health financing system does not appear to cause extensive inequities. Household spending patterns do not appear to be regressive when analysed by income quintiles. However, pensioners and disabled persons incur the highest proportion of out-of-pocket expenditure. About 7% of all pensioners spend over 10% of their household budget on health care, which is a significant burden. Despite the payment exemptions and the generally equitable distribution of health expenditures, the current system fails to protect certain sub-populations.⁵⁴

4.6 Reforms and recommendations

The government enacted new health insurance legislation in 2002 to improve the financial sustainability of the system. Key components included the following:

Improving health system effectiveness

- clarifying the role of local and central governments in providing subsidies to social cases; and
- giving HZZO the role of administering workers' compensation funds for occupational safety.

Increasing efficiency and effective use of resources

- reducing the scope of covered services;
- providing a new co-payment schedule, with higher rates for hospital and specialist services, diagnostic tests and pharmaceuticals;
- removing a provision in the health insurance law that had allowed high-income earners to buy private health insurance instead of the HZZO plan; and
- allowing the sale and purchase of supplemental coverage of co-payments, initially through HZZO but with an expectation that this market would be opened to private plans in 2004.

Reducing inequalities

- reducing some of the categories of beneficiaries exempt from co-payment.

The government imposed several administrative cost controls recently, including prescription limits, and hospital expenditure caps, both in effect since 2004. Nevertheless, deficits in the health sector have continued to grow.

These reforms represent positive steps towards improved financial stability for the Croatian health care system, but some recent policy decisions raise concerns. A large part of the covered population is still exempt from co-payments for health services and drugs, and the complementary coverage of social insurance co-payments reduces the potential for these cost-sharing tools to discourage unnecessary use.

In 2005, the Ministry of Health and Social Welfare (MOHSW) attempted to change the 1993 law in order to increase revenues and control spending. In the end it only made modest changes. The most significant was the introduction of a small, flat 'administrative fee' for health services that was to be imposed more broadly and have fewer exceptions than co-payments. More sweeping changes to the co-payment exemption and public and private insurance coverage schemes have been contemplated, as has the creation of a two-tiered drug reimbursement scheme, yet these proposals have not been made law. The recent modest changes are unlikely to raise significant revenues unless they are accompanied by broader changes such as these.

Policy recommendations

Croatia should consider more significant changes to its social insurance co-payments and also seek to define more carefully which services are covered. A clearer benefit package will make it easier for the government to monitor and stabilise its social insurance costs, and also facilitate the development of mechanisms such as private health insurance to enable people to buy services that are not covered. As with all the study countries, the government will need to devote significant effort to educating patients, health care providers and stakeholders about such changes, in order to clarify people's rights and manage expectations.

5.1 Overview

Bulgaria's total and public spending on health care has recently increased, and in 2003, total spending in health was about 7.5% of GDP, compared with 5.1% in 1998. The earlier low level can be attributed to poor economic conditions and the relatively low priority placed on health care spending.⁵⁵

Figure 9: Changes in Bulgarian health expenditures between 1998 and 2003

	THE % GDP	% THE Public	% THE Private	Per capita Health exp. (US\$)	OOP health spending; % priv. spdg	Contribution PHI to priv.h.exp.
1998	5.1%	67.9%	32.1%	97 ('99)	98.6%	0.0%
2003	7.5%	54.5%	45.5%	191	98.4%	0.9%

Source: WHO, World Health Statistics (2006)

5.2 Sources and mechanisms of financing

Social insurance

Until about 2000, Bulgaria's health care system was funded out of general revenues. Following national health insurance legislation in 1998, the country began to move towards a compulsory social insurance system. The system is funded through contributions of 6% of salaries, originally shared between employers and employees on a 5:1 ratio, and phased in until such time as the respective contributions are equal, which is expected to be in 2007.⁵⁶ The government pays the contributions of about half the population (4 million people)⁵⁷, including vulnerable groups, the unemployed and pensioners. The self-employed have to make social insurance contributions.⁵⁸ Despite this, the social insurance system has not given universal health insurance coverage. A 2001 household survey indicated that 76% of the population reported insurance with the National Health Insurance Fund (NHIF), 18% were uninsured and 6% did not know their status. All citizens have the legal right to inpatient and outpatient care, and the precise implications of being without social insurance are unclear.

Since 2003, NHIF funds have covered outpatient care, part of outpatient drugs and about 20% of the cost of inpatient services. Despite improved collection rates, which were about 94% in 2000, the contribution rates are acknowledged to be insufficient to meet expenditure.⁵⁹ The economic situation has not permitted higher contribution rates. Also, NHIF began to experience deficits in 2003 at the same time that it was expected to become the single insurer and purchaser of health care services. NHIF's lack of information on non-contributors has contributed to rising debt, with about 1.7 million people not contributing in 2004 (ranging from 3-36 months of missing contributions).⁶⁰

Public funding

Most health care is still funded by national and municipal budgets. In 2000, these sources of funding were nearly equal, with 34.5% coming from the national budget and 34.7% from municipalities.⁶¹ The relatively low contribution of social health insurance to the costs of inpatient care had to increase between 2002 and 2007.⁶² From 2001, MOH and municipalities were funding 50% of the cost of inpatient care.

Out-of-pocket spending

Private out-of-pocket payments account for an estimated 20% of total health spending.⁶³ Informal payments remain widespread. Patients pay for out-of-pocket drugs and sometimes for inpatient drugs. A household survey from 1994 revealed that 42.6% of the respondents had paid for services that were officially free. The amount of these payments ranged from 3% to 14% of the average monthly income.⁶⁴ The informal payment situation has persisted, at least through 1999. At this time a survey in Sofia found that 54% of the population had made informal payments for state-provided services.⁶⁵

55 WHO, HIT (2003).

56 Id.

57 This is based on population figures available at www.worldbank.org.

58 World Bank, 'Improving Health Care in Bulgaria: Options for Reform', (2005).

59 WHO, HIT (2003), See esp. p. 26.

60 World Bank (2005) (citing Consultant paper and other sources).

61 WHO, HIT (2003) Table 5, citing Table 4, World Health Report 2000.

62 WHO, HIT (2003).

63 WHO, HIT (2003).

64 Balabanova, D. and McKee, M., 'Health Care Reforms in Bulgaria', London School of Hygiene and Tropical Medicine, European Centre on Health of Societies in Transition.

65 WHO, HIT (2003).

66 WHO, HIT (2003).

67 WHO, HIT (2003).

68 More recent figures on public pharmaceutical spending are described in Section 3.2.

69 World Bank (2005).

70 WHO, HIT (2003).

71 World Bank (2005).

72 WHO, HIT (2003).

73 World Bank (2005).

74 WHO, HIT, (2003) citing Ministry of Health and WHO regional database.

The 1998 health insurance legislation added formal co-payments or user fees for outpatient and inpatient services in an attempt to curb unnecessary use. Co-payments, which are about 2% of the minimum monthly salary for each inpatient day, are a burden on those with lower incomes. By the end of the 1990s, the largest share of private payments went on drugs, with the second largest going on informal payments, and the lowest on formal user fees.⁶⁶

Private health insurance

There is little private health insurance in Bulgaria, with only between 1-2% of the population purchasing supplemental policies, generally through their employers. This low uptake is not surprising and there may not be much room for expanding private coverage until the economic status of the population improves.

5.3 Health spending

Allocation of resources for outpatient, inpatient and other services

In 2000, the Ministry of Health spent about 30% of its total health expenditures on inpatient care, and this was largely used to finance the costs of health care establishments. The spending of the National Health Insurance Fund (NHIF) was roughly divided as follows: 30% primary care, 20% outpatient specialty care, 10% dental and 30% pharmaceutical care.⁶⁷ NHIF data indicates that 48% of all public health spending went on inpatient care, compared to 16% to outpatient care, 20% to pharmaceuticals⁶⁸ and 16% to other services.⁶⁹

Pharmaceutical spending

The percentage of government health spending devoted to pharmaceuticals nearly doubled between 1990 and 2000, rising from 12.3% to 23.75%.⁷⁰ This was a time of declining government health spending. Nevertheless the trend continued even when health expenditures increased: by 2004, drugs made up 30% of the total public budget for health care and 28% of the budget of NHIF.⁷¹ Informal payment practices also extend to drugs, and a 1999 survey indicated that patients often paid for inpatient drugs.⁷²

The MOH and NHIF cover the cost of certain expensive drugs and NHIF reimburses for some other drugs as well. Generally, reimbursement rates are based upon a 'positive' list of covered drugs issued by MOH and validated (after changes) by NHIF. This list includes generic and brand name drugs and includes about 900 reimbursed items, 200 of which are free. The remaining drugs are subject to co-payments ranging from 25% to 75%. These price limits are the main cost containment mechanism, but it is worth noting that this mechanism alone has not been successful in containing drug costs in other European countries.⁷³

5.4 Health care delivery

Extensive reform of the structure of outpatient care began in 1999. Physicians were given the choice of working alone or in group practices. Each physician either contracted individually with NHIF or became an employee of newly created diagnostic and consultation centres that contracted with the NHIF. Most physicians chose the latter.

Bulgaria has a relatively high ratio of beds to population. But it has reduced the number of beds, which fell from 10.5 per 1000 in 1997 to 7.5 per 1000 in 2000. This ratio is still higher than those in Spain (2.8), Austria (6.3) and France (4.1).⁷⁴ The reduction in beds came partly from the closing of substandard facilities and the introduction of an accreditation process.

Inpatient beds are also used inefficiently, with low occupancy rates and high average lengths of stay compared with many European countries. Many hospitals are in poor physical shape. Regional hospitals were formed into private companies, with the government holding half of the assets. Since 2000, hospitals are now fully funded by the MOH, and since 2001, they are able to contract with NHIF for set clinical paths. National institutes and centres provide tertiary care in a range of specialties (oncology, cardiovascular medicine and others) and are financed by the MOH. The Ministry of Science and Education finances the teaching activities within the 21 designated teaching hospitals. Inpatient admissions require a physician referral, or careful assessment of need if the patient presents without a referral; otherwise the patient must pay out-of-pocket.

Since 2001, the NHIF has paid for about 20% of hospital expenses; municipalities fund the remainder of their hospital expenses through transfers from the central government and they are able to decide how to allocate their funding. The 1999 law on health care institutions introduced new contracting processes and accounting mechanisms, and better management and cost analysis tools. However, there is still no 'active purchasing'.⁷⁵ NHIF pays hospitals on the basis of diagnosis and clinical pathways (about 55% of hospital budgets), according to a fixed price for a minimum number of cases, although the number of cases can be renegotiated. The MOH (45% of hospital budgets) pays hospitals based on a number of factors, including past patient volume and average value for different hospital groups, activities performed by medical condition, a dialysis subsidy and a subsidy for disabled patients. The MOH also manages and finances national reference and specialised hospitals, which are often more expensive.

75 WHO, HIT (2003).

76 World Bank (2005).

77 Id.

General practitioners are paid on a capitation basis and can earn extra payments for certain preventive services. Specialists are generally paid on a capped fee-for-service basis, while inpatient hospital physicians are salaried.

5.5 Efficiency, effectiveness and equity

Many Bulgarians spend much of their income on health care – 20.9% of the average household income on health care according to a 2002 household survey. Drugs are the largest item of health care spending for most households. There is evidence that many households do not see a doctor because they cannot afford the cost of the examination (13% in case of a GP and 29% in case of those referred to a specialist). About 11% of households do not buy prescribed medicines (and over 25% in the case of the Roma population). Efforts to increase co-payments in order to improve revenues should include a strategy to protect the poor from the impact that cost-sharing requirements might have on their use of, and access to, health services.⁷⁶

There are also significant disparities in access for certain minority groups, especially the Roma. A total of 90% of Roma cite financial reasons as the main reason they may not seek inpatient care, compared with 50% of Bulgarians generally.⁷⁷

The state and structure of the hospital sector, and the heavy use of inpatient services, contribute to inefficiency and wasted resources.

5.6 Reforms and recommendations

As in other study countries, Bulgaria is reforming several aspects of its health care provision and financing sector. Key elements for policymaker attention are highlighted below.

Several reforms could improve the efficiency and effectiveness of the health care system in Bulgaria, and thereby improve the sustainability of health care financing. It will also be important to consider additional revenue sources.

Increasing efficiency and the effective use of resources

- *Review purchasing policy for inpatient care and pharmaceuticals*

The MOH and NHIF must review the purchasing and administration practices for their two largest budget items: inpatient care and pharmaceuticals. As recommended by the World Bank (see World Bank (2005)), it will be important to continue efforts to streamline payer and payment mechanisms, so that the NHIF will become the sole purchaser of inpatient services. Payment mechanisms should be made more efficient, perhaps via the adoption of DRGs, along with careful monitoring to prevent distortions. In primary care, GPs need better incentives to increase their caseload and more funds should be devoted to prevention. The National Framework Contract, which governs provider contracts, should be changed to ensure that hospitals are fully represented and that the NHIF can be selective in its purchasing.

Bulgaria should consider implementing ways of containing the cost of pharmaceuticals, taking into consideration the cost pressures from consumers and providers, as well as those from suppliers. Most countries in Europe use a combination of regulatory mechanisms, such as co-payments, prescription limits, and reference pricing.

- *Address overcapacity in the hospital sector*

The supply side will require more work on hospital restructuring as well as on human resources policy. Despite progress in reducing health care infrastructure, the hospital sector still has excess capacity, and hospitals are both over-used and inappropriately used (eg, used to perform social functions such as long-term care), and this is inefficient. Estimates in one region showed that hospital discharges were about 76% above estimated population needs and that the region had twice the number of beds needed for its predicted caseload. As with other European countries, Bulgaria could benefit from consolidating hospital infrastructure, trying to reduce lengths of stay, and replacing of inpatient with outpatient care whenever appropriate and possible.

- *Improve social health insurance collection and consider other possible public sources of revenue*

In order to maximise potential revenue, particularly in the light of the low required levels of contribution, it will be important to improve insurance collection rates. Potential sources of additional revenue should be identified, whether from increasing social insurance contribution rates or possible other public sources (eg, general revenues or a tobacco tax).⁷⁸

6.1 Overview

Macedonia's total health expenditure is fairly high relative to its GDP, ranging from 7.8% in 1998 to 7.1% in 2003 (similar to the portion of GDP devoted to health care in Turkey).⁷⁹ This places its health care related spending at a comparable level to EU member countries and lower than most of the countries in this study, with the exception of Romania.

79 WHO, World Health Statistics (2006).

80 World Bank, Staff Appraisal Report: Former Yugoslav Republic of Macedonia, Health Sector Transition Project (1996).

81 WHO, HIT (2000).

82 WHO, HIT (2000) citing THE figures for 1996 (citing WHO Regional Office for Europe health for all database) and state health care costs from the Health Insurance Fund, for 1997.

Figure 10: Changes in Macedonian health expenditures between 1998 and 2003

	THE % GDP	% THE Public	% THE Private	Per capita Health exp. (US\$)	OOP health spending; % priv. spdg	Contribution PHI to priv.h.exp.
1998	7.8%	87.4%	12.6%	115 ('99)	100.0%	0.0%
2003	7.1%	84.5%	15.5%	161	100.0%	0.0%

Source: WHO, World Health Statistics (2006)

6.2 Sources and mechanisms of financing

Social insurance

Legislation in 1991 created a compulsory social health insurance system, covering public and private sector employees, retirees, students, the disabled and dependents. The state subsidises care for the uninsured (such as the stateless and social care recipients) as well as child and maternal health care for the uninsured. Employees must pay 8.6% of income, pensioners 14.7% and the self-employed 8.6%. There is also a set contribution for the unemployed. There is no required employer contribution, nor any 'sin taxes' such as on tobacco or alcohol. Health care used to be administered and financed locally, but now the Ministry of Health oversees the system.

A 1993 amendment to the legislation introduced co-payments for services covered, which ranged from 10% for inpatient services to 50% for certain drugs and supplies. However, broad exemptions to the co-payments (children, elderly, pregnant women, chronic disease patients) undercut their impact on both use and revenues.⁸⁰ In 2000, the co-payment structure was revised in favour of a system of fixed co-payments subject to ceilings. Some co-insurance remains, including 20% for inpatient health care services, accommodation, and inpatient drugs. Until recently there was no positive list of drugs for secondary and tertiary care.

Private health insurance

Although the 1991 law established the legality and structure for private health insurance to cover non-covered services, no package is yet available.

Prevalence of informal payments

It is difficult to assess the level of informal payments and estimates diverge greatly. However, surgeons are limited in what services they can provide outside hospitals, which limits their potential for extra income. It is therefore believed that they commonly request informal payments.⁸¹

6.3 Health spending

Allocation of resources for outpatient, inpatient and other services

Limited data are available on the details of Macedonia's health care expenditures. One report (now outdated) indicated that inpatient costs were 29.4% of total health expenditure and pharmaceuticals 9.6%.⁸² The same report indicated that the state budget allocated 39.4% of its spending to outpatient care, 39.3% to hospital care (including inpatient drugs), and 10.3% to reimbursed drugs received from state pharmacies. (Spending on inpatient drugs was included in the 39.3% share of the public budget attributed to inpatient care.)

83 World Bank (1996).

84 *Id.*

85 WHO, HIT (2000)

Pharmaceutical spending

Since 1996, the share of national income spent on pharmaceuticals was among the highest in the world.⁸³ The prices of some common essential drugs, in both public and private pharmacies, were between five and 20 times world market prices. Problems included a lengthy registration process that included burdensome testing (even for generic equivalents), a prohibition on generic substitution by pharmacists, policies that favoured higher-priced specialty drugs, and sizeable production and import costs. The public sector did not limit its purchasing or reimbursement of drugs; the existing list includes most registered drugs and the National Health Insurance Fund (NHIF) did not limit its reimbursement level. Consumers had to make co-payments.⁸⁴

6.4 Health care delivery

Primary care in Macedonia has been provided through private sector organisations since 1991. Specialty care is provided via ambulatory polyclinics associated with medical centres; these clinics also provide primary care services. Hospital care is provided through referrals from primary care and specialty care providers, although this system could benefit from more complete implementation and enforcement (see below).

Macedonia has a low level of outpatient service use compared with most of Europe. The estimate is about three outpatient contacts per year, although the data's validity is unclear. As with some of the other countries, the hospital sector is inefficient, with long lengths of stay and low occupancy rates. While the ratio of the number of beds to population is below the EU average, the country has a young population compared with the rest of Europe (and therefore less need for hospital services).⁸⁵

Hospitals used to be paid on a point system but this has moved to a line-item billing system based on historical activity and inputs. The public sector submits inflated invoices, however, so this mechanism needs to be reviewed and refined in order to ensure appropriate incentives. Private sector providers have retained the point system.

6.5 Efficiency, effectiveness and equity

Given the limited health expenditure data and other health system related information, it is more difficult to draw conclusions regarding the financing system, but it appears to face many similar challenges to the other countries. For example, the social insurance system is structured similarly, and includes subsidies and co-payment exemptions to help assure access to coverage and care for poorer people. The fixed co-payment system may help address unintended access challenges as a result of cost-sharing that was originally based on a percentage of incurred covered expenses. Yet as seen in countries where there is more recent data, it is important to find out where access challenges may still persist. The reforms enacted in 2000 included some structural changes to contributions and benefits within the social insurance system.

The allocation of health care resources has included a heavy emphasis on inpatient care within an inefficient hospital sector. The country could benefit from an examination of pharmaceutical use and expenditure in order to look at how to reduce the burden from this sector without compromising access to important medicines. (This is a challenge in all the study countries, yet, the current proportion of national income devoted to this sector is high (unless this has been addressed in more recent years for which data was not available at the time of this report.)

6.6 Reforms and recommendations

Macedonia made some important health care reforms in 2000 (Health Insurance Law of 2000). Many provisions targeted the structure of social health insurance contributions and benefits. The changes were intended to meet the following goals.

Improving health system effectiveness

- Moving towards clear separation of primary and secondary care, with enhanced gatekeeper role.

Increasing efficiency and effective use of resources

- Changing pharmaceutical procurement methods and introducing a positive drug list for primary care (1999), with the expectation of a hospital formulary and generic substitution.

Clarifying scope of social health insurance contributions and benefits

- Changing the benefit package;
- Revising social health insurance contribution structure, with changes to premiums and penalties for non-payment; and
- Revising user fees, moving from co-insurance charges based on percentage of service charges, subject to exemptions, to a system of fixed charges with ceilings on charges for secondary care.

Improving quality

- Improving primary care and hospital infrastructure.

Reducing inequalities

- Revising scope of exemptions from co-payments.

Policy

It will be important to evaluate the implementation of the reforms, particularly regarding access to care and sustainable financing. Changes such as the benefit package, co-payments and an enhanced gatekeeper role can help to ensure access to a set of covered services. However, as with the other countries studied, it will be important to monitor public expectations and satisfaction as well as provider and stakeholder experiences in order to guide the implementation. More up-to-date information on this topic may soon be available as the World Bank completes its review of its recent loan activity in the health care sector in Macedonia.

CONCLUSION

86 Tapay, N. and Colombo, F., 'Private Health Insurance in OECD Countries,' (OECD, Paris, France: 2004).

The countries studied share several common health care financing and system challenges, including:

- insufficient or low levels of compliance with social health insurance contribution requirements
- ongoing use of informal payments, disparities in access to, and use of, health care by certain demographic, geographic or ethnic groups (although the extent of inequity varies in different countries);
- high levels of out-of-pocket financing of health care;
- low levels of pooled private resources (through private health insurance);
- overcapacity in the hospital sector; and
- heavy and less efficient reliance on inpatient care (as opposed to a more efficient balance of inpatient and outpatient care).

The overall level of health care resources in Bulgaria and Romania is unlikely to be sufficient to provide comprehensive, universal, quality care to the whole population. In other cases, ongoing deficits threaten the sustainability of the health care system and signal the need for further reform. It will be important to explore options for increasing system and financing efficiency. In some cases an increase in public revenues may need to be considered, as the high levels of out-of-pocket spending on health in these countries is already a heavy burden on much of their populations. If out-of-pocket health care costs are increased as a means of raising revenue, they should be carefully targeted to those income groups for whom they will not pose undue hardship. Similarly, PHI markets play a very small role in these countries. These markets may have the potential to grow in some of these countries, particularly among the higher-income populations, but this should be approached cautiously. Evidence from OECD countries has shown that these markets have had only limited success in reducing the public share of expenses, although they have been useful sources of revenues for certain private providers in some higher income countries. Policies are generally bought by wealthier people and have raised concerns that they may be given preferential access. Hence, governments have had to balance sometimes conflicting policy goals, and in some cases carefully regulate these markets to avoid undesirable consequences.⁸⁶

In order to address these challenges, all five countries have implemented, or have begun to implement, reforms on health care delivery and financing. Many of the reforms are ongoing or have met with mixed success. Nevertheless, the following health policy reforms represent steps that could promote the goals of financial sustainability, efficiency and equity within these countries' health systems.

Financial sustainability

- Clarify scope of covered benefit package, including scope of drug reimbursement;
- implement multi-pronged pharmaceutical policy to address drug costs and promote swift approval and reimbursement of new drugs;
- promote growth of private health insurance market and structure it to avoid possible moral hazard concerns and to avoid creating significant disparities in access to health care between those with and without coverage;
- explore additional revenue sources, such as tobacco or alcohol tax;
- improve collection systems; and
- implement clear and modest cost-sharing as a means to moderate utilisation, raise revenues and help eradicate informal payments.

Efficiency and quality

- Promote use of cost-effective primary care and general practitioner services together with a meaningful referral system for specialist and inpatient care;
- streamline or unify multiple payer systems;
- ensure true separation of financing and provision functions;
- introduce independent, trained managers into health facilities;
- introduce incentive-based provider payment mechanisms (preferably with all payers using the same mechanisms so as to align incentives);
- continue efforts to reduce overcapacity in the hospital sector and above-average lengths of hospital stays;
- explore public/private partnerships as a means of developing innovative delivery systems or procurement practices; and
- improve information systems as a means of promoting quality, updating coverage rolls, improving collection and monitoring utilisation trends.

Equity

- Limit co-payment exemptions to truly needy populations;
- improve coverage and access through universal coverage; and
- target subsidies and co-payment exemptions to needy populations.

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