

International comparison of systems to determine entitlements to medical specialist care: performance and organizational issues

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Summary

Objective

CVZ has asked us to provide a comparison of criteria and procedures that different countries use to determine entitlements to medical specialist care. This question was asked within the context of the recent introduction of the DBC (diagnosis treatment combinations) system as an alternative to existing methods of financing of hospital services.

Methods

The analysis covered priority systems in nine countries: Australia, Belgium, Canada, France, Germany, the Netherlands, Sweden, Switzerland, and the UK. To meaningfully compare existing criteria and procedures of different countries and analyze the possibilities and limitations of priority setting systems, we used an analytical framework for international comparison recently developed by Hutton and co-workers (Hutton et al., 2006). The framework was created to encompass the many aspects of fourth hurdle systems. It can deal with the legal and political characteristics at the system level and the detailed nuances of varying assessment and decision-making procedures at the decisional level. It analyses priority systems at two levels:

1. Policy implementation: the establishment of the fourth hurdle system as a policy decision of the government, the policy objectives of the system, its legal status, and its relationships with the remainder of the health system, with other public sector bodies, and with other stakeholders, such as industry and patient groups;
2. Individual technology decision: the processes by which individual technologies are dealt with by the system, for example, assessment processes, how decisions are made, and how they are implemented.

Our analysis of international policies further contained three case studies. We selected three medical services that were assessed recently: deep brain stimulation (DBS) for Parkinson patients, transurethral microwave therapy (TUMT) for patients with an enlarged prostate and position emission tomography (PET). To reconstruct the way in which the decisions about reimbursement were made, we analyzed the assessment reports and interviewed physicians, representatives of the medical industry, and policy makers by telephone. The aim of these case studies was to analyze how the formal decision procedures are put into practice, by reviewing the nature of powers of different stakeholders who are involved, strategies to settle debates or resolve problems for example when evidence is inconclusive.

Results

The study provided an in-depth view of reimbursement procedures in the nine countries. Below we summarize the details of the procedures in the different countries.

Australia

The universal health insurance system in Australia is called 'Medicare'. This system guarantees access to medical specialist care for all Australian people. The Medicare Benefits Schedule, which lists all entitlements, is updated every year. Obsolete treatments may be removed, without having to undergo any formal assessment. Yet, decisions on which services are included on these positive lists are based on the assessment and MSAC reports. The MSAC commissions HTA experts to evaluate safety, effectiveness, and cost-effectiveness of the medical procedure. It also prepares an advice on basis of provided information and additional criteria related to access and solidarity, which will be ratified by the Minister of Health. In this system, legitimacy of decisions is expected to result from explicit assessment and procedural justice.

Belgium

In Belgium, also a positive list exists that describes entitlements to medical care, i.e. the so-called 'nomenclature'. The National Institute for Sickness and Invalidity Insurance (RIZIV/INAMI) may propose changes to the nomenclature, typically on basis of advice of a committee that consists of insurers and medical professionals. As yet, there is no systematic assessment of procedures that may be added to the nomenclature, although increasingly the HTA agency Belgian Health Care Knowledge Center (KCE) is sought to fill the gap between scientific evidence and health care decision-making. Mostly however, decision-making depends on medical professionals and insurers to reach consensus about the added value of new therapies. Legitimacy of decisions is expected to result from consensus.

Canada

In Canada, health care is organized as a National Health Service, which ensures that all provinces offer medically necessary care to their inhabitants. Most provinces use medical benefits schedules to provide an overview of entitlements, but Alberta en Ontario for example define entitlements by negative lists stating which services do not belong to entitlements. The Minister formally decides on benefits. These decisions, however, depend on negotiations between the medical profession and local authorities, who discuss what services should be offered by hospitals within the available budget. Entitlements are therefore implicitly decided by means of consensus. To facilitate decision-making processes, the Canadian government stimulates assessments. For example, the Canadian Agency for Drugs and Technologies in Health performs assessments and disseminates findings to provinces. Such assessments evaluate literature on a broad spectrum of concerns like safety, health effects, and economic concerns as well as ethical and legal aspects of technologies. Typically information is only gathered and summarized, but no policy recommendations are included. It is up to the individual provinces to decide. In this process, it is implicitly assumed that decisions will be just because payers and providers will carefully weight the evidence.

France

In France, a social health insurance system exists, called the ‘Couverture Maladie Universelle’. In contrast to the other countries, the government is not involved in the decision-making process about entitlements. It is the National Union of Health Insurance Funds (UNCAM) that is responsible for execution of the health insurance system and for updating the positive lists. The medical profession is partner in the decision-making process in the sense that it has to reach agreement with UNCAM about services included on the positive lists and the tariffs that may be charged. The main concern in decisions is the proposed procedure’s effectiveness. This is assessed by the Haute Autorité de Santé (HAS), which collects its information through literature review and consultation of experts to inform UNCAM’s decisions. Also in this system, legitimacy will be implicitly derived from consensus.

Germany

A fundamental aspect of the German health care system is the sharing of decision-making powers between the federal government, the individual states, and designated self-governmental institutions. It is the medical self-governing body (Gemeinsamer Bundesausschuss (GBA), consisting of doctors and health insurers) that gives concrete definition to the legal requirements and implements them. The GBA only defines entitlements in the ambulatory sector and not in hospitals. In fact, each hospital can make independent decisions on what services will be offered to patients. In Germany, there is no strong HTA tradition. Yet, the GBA introduced assessment of new methods of medical examination and treatment in the area of ambulatory care in 2004. The assessments are performed by the ‘Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen’ and follow a standardized procedure that rests on evidence-based medicine. It is unclear to what extent assessment data influence decisions.

The Netherlands

As part of reforms that aim to open the way to a demand-driven, regulated market, the Dutch government in 2005 revised the financing system for hospital care. Hospital financing switched from a per-diem budgeting system to a prospective payment system based on diagnosis treatment combinations (DBC). The introduction of the DBC financing system was expected to increase transparency and competition within the health care system and to stimulate quality and cost containment. It has led to an explicit description of the medical specialist care products. As a result, decisions on market approval and, subsequently, decisions on reimbursement can be made more consciously now. This in turn allows for strengthening of the role for HTA. A fourth hurdle system that gives a significant role to HTA is being rolled out, with DBCs being the unit of assessment. Responsibilities for this system are shared between the Minister of Health, Welfare, and Sports (VWS), the DBC Maintenance Organization (SDO), the Health Care Insurance Board (CVZ), and the Netherlands Health Care Competition Authority (NZa). CVZ has been given the key role of benefits package manager. The NZa fixes the descriptions of the care products, fixes tariffs for DBCs not freely negotiable between health care providers and insurers, and is the competition watchdog. SDO is the private DBC maintenance organization that is responsible for the

proper functioning of the DBC system and that assists health care providers and insurers in working with the system. Applications for new or modified DBCs (either by health care providers, insurers, patient groups, the SDO itself, or others) enter the applicant-driven fourth hurdle system via the SDO. SDO asks the applicant to deliver several types of information, both medical (e.g., effectiveness, the number of patients, burden of disease), and economic (cost-effectiveness). If the SDO concludes that the care product in question is not yet described specifically enough by existing DBCs, it forwards the application to the CVZ and the NZa. CVZ undertakes an assessment, considering evidence on effectiveness, necessity, cost-effectiveness, and feasibility. This results in an interpretation of whether the DBC is insured care, and possibly in a recommendation to the Minister – who has final decision-making authority over decisions regarding the benefits package – to exclude the DBC from the benefits package. Because of its recent introduction, the assessment system is still in a developmental stage. A question that has been raised for example is how to deal with the heterogeneous composition of some DBCs in the assessment.

Sweden

In the Swedish National Health Service, responsibility for provision of care rests primarily with the county councils. Also the decision whether or not to adopt a new technology lies with the county councils. To support local decision making on the adoption of new technologies, the Swedish Government in 1987 established a health authority that is responsible for HTAs and dissemination of reports: the SBU. In evaluating technologies, the SBU staff works with external researchers and experts. The focus is often on a condition and all related treatment options (which may include more than technologies) and not just on a single technology, with the aim not just to evaluate individual services but also to optimize care paths. Strong efforts are made to ensure that SBU findings are disseminated to the target audience. Nevertheless, it is not clear to what extent provided information is actually used in decision making. Legitimacy of decisions is to be obtained from the democratic mandate of decision makers. Yet, there is increasing awareness that more openness in priority setting is required, also because the different counties have decided differently on some controversial technologies in the past.

Switzerland

In Switzerland, the organization of health care is a cantonal responsibility, but it is the federal government who is in charge of decisions on the benefits package. Health care providers, health insurers, and patient organizations can all apply for introduction of a new service into the benefits package. If the branch organizations of the insurers (Santésuisse) and that of the physicians (FMH, Foederatio Medicorum Helveticorum) consider the service uncontroversial, it will be listed and be reimbursable. Decisions about expansion of the benefits package therefore usually remain implicit and become visible as changes to the fee schedule. When either the insurers or the physicians consider coverage of the service controversial, an assessment procedure is started. The assessment procedure requires the applicant to provide an assessment report according to published standards. A federal commission on health insurance benefits (representing various stakeholders) next prepares a recommendation to the Minister on basis of the

assessment report, who then decides. The assessment reports, recommendations by the commission, and evaluation thereof by the Minister are not published. Only a short press release is published with the decision. Legitimacy of decisions is to be obtained from the democratic mandate of decision makers.

United Kingdom

The National Health Service (NHS) is the publicly funded health care system of England; it is under control of the UK. The English NHS is responsible for provision of health care, but the National Institute for Health and Clinical Excellence (NICE), which is part of the NHS, is responsible for assessing whether new or existing technologies should be available on the NHS. Guidelines for all procedural steps are published online and also all documents that lead to a decision will be published. The appraisal of a health technology is divided in three distinct phases: scoping, assessment, and appraisal. While the Minister of Health decides which technologies will be referred for NICE Technology Appraisal, NICE determines the scope. They determine what questions need to be addressed in the appraisal. The Appraisal Committee subcontracts the assessment to an independent academic body, which will perform a literature review and an economic evaluation. The Appraisal Committee considers the evidence and invites views from stakeholders, before it formulates the NICE recommendations. In these recommendations also ethical and social concerns play a role. These recommendations are also discussed with stakeholders before a final decision is made. In this respect, the UK serves as prime example of transparency. Legitimacy of decisions is well established in terms of transparency, stakeholder involvement, and consistency of decisions.

Analysis

Policy

Reviewing the HTA policy in the nine countries, we found similarities in terms of objectives of the system and its establishment. HTAs usually reflect the wish to use resources effectively and efficiently. In countries where local authorities are responsible for deciding on benefits, technology assessments are also performed to guide the use of controversial technologies and prevent inequalities. A shared characteristic in the establishment of the systems is the existence of a governmental agency or independent actor who directs the fourth hurdle systems, from topic selection to decision making. Differences are found concerning the division in responsibilities between assessment and appraisal. In the UK and Australia, one actor is responsible for both the assessment and the decision. In most other countries, decisions are shaped in a process of structured negotiations between the health care payer (government or insurers) and providers of care. Here, assessments inform decisions, but it is not clear to what extent evidence from assessments is actually used. This translates into differences in accountability: some countries rely on transparent criteria and clear procedures to weigh evidence, whereas others believe that it is inherent to a negotiation process between payers and providers that evidence is weighed carefully.

Assessment

Most countries have installed a body that is responsible for assessments, which may choose to perform the assessments internally or to commission the work to a specialized HTA institute. Assessment reports may have a broad or a narrow perspective, i.e. they may or may not cover alternatives for the technology under appraisal and they may or may not include clear recommendations to guide decision makers. Assessment criteria always include costs and effects, while sometimes also social and ethical aspects are considered. Assessments of medical specialist care are typically not technocratic, in the sense that assessment methods and procedures are not always described in detail and requirements are not stringent. The most detailed descriptions of assessment procedures exist when the link between assessments and decisions is rather direct, as is for example the case in the UK and Australia. In most countries however, assessment procedures are not clearly described and the main assessment method is literature review. This means that formal economic evaluations are only taken into account when available, which is often not the case. The lack of explicit procedures may be a pragmatic response to the observed problem that in medical specialist care evidence is typically rather limited, for example compared to pharmaceutical care. In such situations of incomplete evidence, stakeholder participation is considered relevant. Stakeholders typically participate in a project group that reviews draft reports and help to draw conclusions. Another common arrangement is that medical experts are invited to offer their views on a technology.

Decision

Final responsibility for decision making may rest with the health care payer (central or local government, or insurers) or with an independent body. In the decision-making process, equity concerns, budget impact, and priorities in health care are often taken into account besides assessment data. When little evidence is available, countries typically grant a temporary reimbursement status, conditional on future research. Typically, the decision-making process is not documented, and stakeholders are not involved, so that value judgments remain implicit. An exception is the UK, where also the decision-making criteria and procedures are made as transparent as possible, by publication of a value document, involvement of stakeholders, and publicly available documentation about the decision-making process. The perceived need for transparent decision-making procedures may reflect the fact that decisions are made by an independent institution that has to account for its decisions and actions to the government and the public, and that has to ensure that key actors in health care implement its decisions.

Outputs and implementation

In many countries, there are no specific procedures for appealing reimbursement decisions. Consumers always have general rights to make claims of the health care system. Only in the UK and France, appeal mechanisms are built into the system for making reimbursement decisions. In France, appeals can be made by the Minister of Health because of final budget responsibility, and by the major trade unions that represent the majority of the insured population. In the UK, all major stakeholders have a right to appeal. A positive reimbursement decision often involves a change to the benefits schedule. Appropriate use of

the service is a whole different matter. In some countries, the objective of central actors in the systems for priority setting is to promote appropriate care, which means that quality appraisals and guideline development are also their responsibility. These bodies are active in disseminating results of assessments and implementing decisions. In other countries, there is a distinction between procedures to delineate the benefits package and those to promote appropriate care, so that assessment agencies are not involved in implementation activities.

Case studies

In theory, the procedures imply that services should only be added to the entitlements if the evidence about its safety, clinical effectiveness and cost-effectiveness is strong. In practice, things are not so straightforward. In our first case (DBS), no conclusions could be drawn on the efficacy due to deficiencies in the studies available. Nevertheless, clinical experts perceived DBS as an established practice that should be part of the benefits package. In the second case of TUMT, the assessments were positive about the scientific evidence, at least about the safety and the effects in the first six months after the treatment. The health authorities, however, decided not to reimburse TUMT, pointing to lack of evidence on long-term clinical effects. The evidence in our third case (PET) was perceived to be limited because it remained unclear whether PET would lead to more effective medical treatments. PET however is in the benefits package in all countries. The fact that evidence is often incomplete took some countries (e.g., Australia) by surprise. Most countries deal with this problem in an ad hoc manner. Considering it unethical to postpone a decision, they are not going to wait with their decision until safety, clinical effectiveness, and cost-effectiveness have been demonstrated. Instead, they often rely on expert judgment. Their advice might even outweigh the assessment, as the DBS case has shown. At the same time, they keep investing in assessments. Because in medical specialist care evidence is often incomplete and/or inconclusive, it is especially relevant to consider how to deal with this problem in the design of decision-making procedures.

Discussion

From assessment to decision

The assessment and decision-making procedures in nine countries appeared to differ in many details. At one end of the spectrum, we find countries that rely on indirect steering for health care decisions. In these countries, governments have delegated responsibilities to insurers, the medical profession, or local authorities (e.g., France, Germany, Belgium). Similar modes of regulation exist in some countries with national health services (Canada, Sweden) where local authorities and the medical profession have to reach agreements on the benefits package. In these countries, the assessment is seen as an indirect instrument to steer the decisions of others (insurers, local authorities or hospitals). It is an aid to inform the decision makers about the evidence. The managerial process gives legitimacy to decisions. At the other end of the spectrum lie the countries that rely on direct steering. In these countries, decisions on the benefits package are made by the government or governmental agencies (e.g., Australia, UK, the Netherlands). In these

countries the decision maker is independent of the key actors in the system. The central government or the governmental agencies are responsible for the appraisal. Hence, the assessments are shaped towards the needs of the decision maker, in an integrated assessment and decision procedure. The legitimacy of a decision is derived from proper assessment and proper interpretation of the evidence within legal boundaries.

Explicit assessments and procedural justice

There seems to be a trend towards explicit assessments. For example, almost all agencies publish their assessment reports on their website. The appraisals also seem to become more explicit. One of the clearest examples is the Australian MSAC, which started to document its decision-making process by publishing the minutes of the appraisal committee. The procedures developed by UK's NICE serve as an example to most other countries. As decision maker, NICE is independent of key actors in the system. HTA consultants perform assessments, after which NICE appraises the evidence in a separate procedure. The considerations in the appraisal are made public, so that the procedure is transparent and it can be confirmed if a decision is consistent with legal principles. To ensure that evidence is looked upon from various perspectives, stakeholders participate in the process, further attributing to the legitimacy of decisions. Put briefly, legitimacy gets more and more important and the procedures derive this legitimacy from explicit assessments and procedural justice.

Timeliness versus relevance

In spite of the strengthened and formalized methods for assessment, the appraisal of collected evidence remains difficult. After all, evidence is frequently inconclusive in the field of medical specialist care. The lack of data critically impacts on the procedures. In medical specialist care, typically an HTA agency funded by the government collects information. This commonly involves a literature review of available evidence, rather than the use of specific requirements for reimbursement dossiers (like in most drug reimbursement systems). Primary data collection for the purpose of supporting reimbursement decisions is not common. Overall, the role of HTA in decisions is less formal in medical specialist care than it is in pharmaceutical care for example. In strategies for dealing with the lack of evidence, the issue of timeliness of decisions is of major relevance. Can we afford to wait for perfect information, or is it more appropriate to make a timely decision now on basis of available information? Most countries opt for the latter, making a tradeoff between timeliness and relevance of information. This explains why most countries have a policy that allows for conditional temporary funding of treatments for which insufficient evidence exists, in anticipation of future research. There is yet another reason to make a timely decision on basis of available information. To assess a service that is already introduced does not seem to be very effective. Most applications concern new services that have not been introduced to health care yet. Rarely, technologies are identified for exclusion. Consequently, if governments want to have the option to exclude certain services, the services should be assessed before they are introduced into health care or at least before they are in widespread use. At that moment however, evidence is limited. To conclude, the

question is not so much about what assessment criteria should be and how thresholds values for positive or negative decisions can be defined, but rather how the decision-making procedure can deal with incomplete evidence, considering potentially detrimental effects on innovation when all treatments whose benefits have not yet been scientifically assessed receive a negative reimbursement decision. One solution is to offer an interim positive reimbursement status and request additional evidence for procedures for which evidence is incomplete.

Involving stakeholders

In the procedures of most countries, clinical experts play a valued role in the interpretation of (incomplete) evidence. In situations where evidence is scarce, decision-makers might to a large extent rely on expert advice. Experts' responsibilities vary from a limited role in commenting on a draft assessment report to preparing the report and formulating recommendations. The role of other stakeholders differs more between countries. In countries where decisions are made in negotiation between insurers, local authorities and/or the medical profession, their involvement is inherently at a high level. In countries where decision makers act autonomously, stakeholder involvement is not always guaranteed, which may cause problems when decisions have to be implemented. If the procedure does not meet stakeholder expectations or is considered unfair, we observe a tendency to work around formal ways. This problem may occur when integrated assessment and decision procedures are established in clinical areas where medical professionals used to be autonomous, as the case of Germany illustrates for example.

Conclusions

Countries throughout the world are relentlessly improving their systems for decision-making on the reimbursement of medical specialist care. The objective of these systems is largely the same across countries, which is to guarantee high-quality health care while controlling cost. Another shared characteristic is that the assessment agencies apply similar criteria, covering both clinical and economic considerations. Next to the similarities, however, there are also significant differences between the countries' systems. To mention one, the methods for assessment have varying levels of formalization, ranging from a literature review by HTA agencies to standardized research studies by applicants. The methods for appraisal also differ in level of formalization. In most countries, the appraisal of the assessment (merely a collection of the available evidence) depends on consensus among medical professionals, local authorities, and/or insurers. The legitimacy of the decisions is expected to result from consensus and/or the democratic nature of elected decision makers. Australia and the UK are notable exceptions though. Here an explicit appraisal process follows the assessment reports. The legitimacy of decisions should result from transparency, consistency of decisions, and stakeholder involvement. A common trend between all countries is the growing focus on explicit assessments and procedural justice, which lends a broader legitimacy to the decision-making process. The procedures suggest that services should only be added to the entitlements if the evidence about its (cost-)effectiveness is strong. However, a more nuanced picture emerged from the case studies. It appeared that countries often need to base

decisions on limited evidence about the (cost-)effectiveness of a medical technology. Consequently, decision makers frequently rely on expert judgment and grant technologies a temporary positive reimbursement status. Building on subjective assessments by experts reintroduces exactly the kind of uncertainty that formalized assessment procedures aim to prevent. It is recommended therefore that, when designing their decision-making procedures, countries should at least consider how to deal with these kinds of uncertainty. To conclude, the transparency and consistency of the decision-making process benefits from improved methods for assessment. However, it is equally important to specify what procedures will be followed in the evidence appraisal. Legitimacy is often obtained from consensus among stakeholders. Since there are typically no documents that guide value judgments, it is inherent that the system becomes more ambiguous and less formalized than refined and detailed instructions for assessment suggest. So, despite formalized procedures, the expansion of the benefits package might never be as transparent as hoped.

List of abbreviations

Listed below are the most important abbreviations used in this report. Between brackets, if applicable, is the country where the institution is located or the country to which the regulation applies. Abbreviations: AU, Australia; BE, Belgium; CA, Canada; CH, Switzerland; DE, Germany; FR, France; GB, United Kingdom; NL, The Netherlands; SE, Sweden.

- AHCIP — Alberta Health Care Insurance Plan (CA)
 AHFMR — Alberta Heritage Foundation for Medical Research (CA)
 ANAES — Agence Nationale d’Accréditation et d’Evaluation en Santé (FR)
 BAG — Bundesamt für Gesundheit (CH)
 BSV — Bundesamt für Sozialversicherung (CH)
 CADTH — Canadian Agency for Drugs and Technologies in Health (CA)
 CAMTÖ — Centre for Assessment of Medical Technology in Örebro (SE)
 CCAM — classification commune des actes médicaux (FR)
 CHA — Canada Health Act (CA)
 CHAD — Canada Health Act Division (CA)
 CVZ — College voor zorgverzekeringen (NL)
 DBC — diagnosis treatment combination (NL)
 DBS — deep brain stimulation
 DoH — Department of Health
 EDI — Eidgenössische Departement des Innern (CH)
 EGK — Eidgenössische Kommission für Grundsatzfragen der Krankenversicherung (CH)
 ELK — Eidgenössische Kommission für allgemeine Leistungen (CH)
 FMH — Foederatio Medicorum Helveticorum (CH)
 G-BA — Gemeinsamer Bundesausschuss (DE)
 GDP — gross domestic product
 GVU — Wet betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen (BE)
 HAS — Haute Autorité de Santé (FR)
 HTA — health technology assessment
 IHIACC — Interprovincial Health Insurance Agreements Coordinating Committee (CA)
 INAHTA — International Network of Agencies for Health Technology Assessment
 IQWiG — Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (DE)
 KCE — Federaal Kenniscentrum voor de Gezondheidszorg (BE)
 KLV — Krankenpflege-Leistungsverordnung (CH)

- KVG — Bundesgesetz über die Krankenversicherung (CH)
- KVV — Verordnung über die Krankenversicherung (CH)
- MAS — Medical Advisory Secretariat, OHTAC (CA)
- MBCC — Medicare Benefits Consultative Committee (AU)
- MoH — Minister of Health
- MRI — magnetic resonance imaging
- MSAC — Medical Services Advisory Committee (AU)
- NICE — National Institute for Health and Clinical Excellence (GB)
- NZa — Nederlandse Zorgautoriteit (NL)
- OHIP — Ontario Hospital Insurance Plan (CA)
- OHTAC — Ontario Health Technology Advisory Committee (CA)
- OMA — Ontario Medical Association (CA)
- PBAC — Pharmaceutical Benefit Advisory Committee (AU)
- PET — positron emission tomography
- RIZIV/INAMI — Rijksinstituut voor ziekte- en invaliditeitsverzekering (BE)
- SBU — Swedish Council on Technology Assessment in Health Care (SE)
- SDO — Stichting DBC-onderhoud (NL)
- TUMT — transurethral microwave thermotherapy
- UNCAM — Union Nationale des Caisses d'Assurance Maladie (FR)
- UNPS — Union Nationale des Professionnels de Santé (FR)
- WMG — Wet Marktordening Gezondheidszorg (NL)
- WTG — Wet Tarieven Gezondheidszorg (NL)
- WZV — Wet Ziekenhuisvoorzieningen (NL)
- ZFW — Ziekenfondswet (NL)
- ZVW — Zorgverzekeringswet (NL)

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Chapter 1 Introduction

1.1 Background

Dutch law specifies a general entitlement to specialist care offered by hospitals or medical specialists (both inpatient and outpatient care). In this open system only the character of entitlements to medical specialist care is specified. The law indicates in general terms which areas of care are covered by the national health insurance, but it does not specify the entitlements in detail. In practice, this is a ‘negative list system’, which specifies which services are not covered by the insurance, whereas all remaining medical specialists services are accepted as insurable. In the absence of an explicitly defined benefits package, the expansion of the benefits package is not transparent. In the past decades, many services have implicitly been added to the entitlements. The health care provider decided on the provision of care using the so-called ‘usual care’ principle. Furthermore, entitlement only exists when the condition is met that use of a service is effective and efficient. To keep a certain level of control over the health care expenditures, the system is financed with lump sum payments to hospitals, which have to balance their own budgets.

In 2005, the Dutch government introduced a new healthcare financing system based on diagnosis treatment combinations (DBC), followed by the launch of a new insurance system in 2006. With these reforms, policymakers aim to tackle weaknesses in the financing and delivery of health services and to stimulate more efficiency in resource use and increased responsiveness to users. Prior to the reforms people had no idea of the real costs of health care (nor of the quality) and there was very little competition between insurers. Moreover, insurers had little incentive to see whether the care providers could do the job a little cheaper, because people simply accepted the care as it was offered. The reforms changed this. The new financing system led to an explicit description of the care products on the one hand, and to the abandonment of practice budgets and a switch to case-based payments on the other hand. This made the health care market more transparent, so that insurers and patients become better judges of quality of care and will be able to seek out those providers that offer greatest value for money. Since the reform of the insurance system, private insurers (who are allowed to make a profit, but who also carry financial risk) operate the market. Patients, who are required to insure themselves, have freedom of choice from insurers. The insurers have an obligation to accept all eligible applicants, and they have to offer a certain standard of health insurance policy with a statutorily defined benefits package. To survive in this market, insurers will have more incentive to negotiate the best deals with providers, so that they can win the custom of insured persons. Providers in turn compete for contracts with insurers, with whom they negotiate about the price and quality of healthcare.

Against the background of these reforms, the time is right to also reconsider the way in which the benefits package is defined. This report considers changes to decisions about medical specialist care. An underlying reason is that all possible services or health care ‘products’ have been universally described to facilitate negotiations and comparison of the services offered by different providers. This means that for

the first time a complete list of medical specialist services has become available, and new procedures that are introduced are explicitly identified. Although this list has been constructed for administrative purposes, it also means that for the first time an overview is created of health care products and related prices. This information makes it possible to refine existing procedures for benefit decisions. The reforms, however, not only offer the opportunity to get a better grip on the benefits package, but also seem to require it. The reforms changed how the Dutch health care system is operated, but additional government interventions are still required. The aim has been to combine market incentives with a framework of rules to guide competition and the capacity to intervene to tackle market failure. For example, the government remains responsible for defining the contents of the basic benefits package. To make regulated competition work, the benefits package should not be too broad (because that limits room for insurers to negotiate about products) but also not too small (because then inequalities may occur). Moreover, the reforms of the healthcare payment and insurance system imply that the government has less control over total health care expenditures, because insurers are the key actor in the new system. If the government wishes to keep some macro level control over expenditures, they should tighten their grasp on decisions regarding entitlements.

The Dutch Health Care Insurance Board ('College voor zorgverzekeringen', or CVZ) is analyzing the existing decision-making processes and exploring room for refinements. To see if it is possible to refine the decision-making system for reimbursement of medical specialist care using health technology assessments (HTAs), CVZ is keen to learn what other countries are doing and to benefit from their experiences. It is hoped that a comparison between countries would improve the understanding of the workings of the Dutch decision-making system and judge the value of importing ideas from elsewhere. In that way, this comparison aims to provide a firmer evidence base for countries designing new systems for the reimbursement of medical specialist care, enabling them to identify the key factors for a successful system in their own context. CVZ therefore asked the institute for Medical Technology Assessment (iMTA) of Erasmus MC in Rotterdam to describe and compare the decision-making procedures of nine countries, including the Netherlands, regarding reimbursement of medical specialist care. The research question posed by CVZ was:

“What procedures and criteria are used by countries that are relevant comparators to the Netherlands, to determine whether specific services of medical specialist care belong to the health insurance (or national health service) coverage entitlements?”

Because of similarities in health care systems or procedures in priority setting, the following countries are considered relevant comparators to the Netherlands: Australia, Belgium, Canada, France, Germany, Sweden, Switzerland, and the United Kingdom. In principle we describe the current situation in each country. However, health care systems are evolving and changing continuously. Where necessary, this report also includes a description of the benefits and their definition after planned reforms.

1.2 Research objectives

The research question “*What procedures and criteria are used by countries that are relevant comparators to the Netherlands, to determine whether specific services of medical specialist care belong to the health insurance (or national health service) coverage entitlements?*” refers to the various rules and regulations that guide decisions on resource allocation in different countries, but also to procedures governing the decision-making process, which specify for example which stakeholders can participate in the decision-making process. Subquestions related to this research question are:

- Who decides on benefits of medical specialist care? Is the decision procedure transparent and consistent? Are entitlements defined using ‘open’ or ‘closed’¹ descriptions?
- What assessment procedure underlies decisions? Who is responsible for assessments? What criteria are used? How are criteria operationalized? How is the assessment procedure embedded in the decision making procedure?
- Are decisions about inclusion made in a timely manner? And are also technologies identified for exclusion? What is the effect of procedures and criteria for specific technologies and conditions?
- Can stakeholders participate in the assessment or decision-making process?

Early in the project the possibilities for, and limitations of, the project were discussed, and the aims of the project were clearly set out. An obvious limitation is the time available for the project (12 months). Answering all subquestions in great detail would undoubtedly take more time, especially because much of the information may be hard to obtain by investigators who are not working in the country under review using desk research. Therefore it was considered necessary to take steps that could refine the basis of the project. Below we describe what steps were taken to answer the research question.

To analyze the merits and limitations of systems for priority setting in a meaningful way, we used an analytical framework recently developed by Hutton et al. (Hutton et al., 2006). It was developed in response to the observation that many countries apply HTA in their decision-making procedures regarding reimbursement of health care technologies, with the purpose of achieving better understanding of the potential of HTA in this context. It provides a basis for more formal assessment of the performance of systems for priority setting, against their declared objectives, and by international benchmarking. The framework is described in more detail in Section 1.3.

The framework offers a useful basis for comparison of reimbursement systems in different countries. It must nevertheless be realized that it may be difficult to obtain information on all of the important issues raised by the framework from policy documents. Furthermore, the framework may not be filled out completely without exercising judgment on some issues. Finally, it can be anticipated that practice and theory of decision-making may not automatically coincide. To maximize accuracy and

¹ A ‘closed’ character means that the entitlements are further specified, either to specific services, or even to the level of specific products. An ‘open’ character means that only the character of medical attention is described, but not the exact services or the amount of care.

comprehensiveness of the information offered in this report, our strategy was to supplement information from literature and official documents with information obtained from people who are involved in the system for reimbursement decisions in each country. For this purpose, we sent the country reports to international experts, one for each country, to review if information was correct and no issues were missing. In addition, a short query with country-specific questions was mailed to these experts.

To understand the workings of the different systems, we also interviewed stakeholders to collect their experiences with the systems. To systematically collect user experiences with the systems, we performed three case studies (see further Section 1.4). The selected therapies were transurethral microwave thermotherapy (TUMT), positron emission tomography (PET), and deep brain stimulation (DBS). These cases represented therapies for which a positive reimbursement was not evident for different reasons. Funding for these technologies is vigorously debated because of limited clinical evidence, fear of widespread (mis)use, and high costs. We interviewed stakeholders to determine whether or not these technologies were covered in eight countries (all countries studied in this report with the exception of the Netherlands), and how this reimbursement status was reached. These interviews were held by telephone.

Finally, to promote international collaboration in reimbursement decisions, to learn from international experience and to facilitate information sharing, education and knowledge transfer, CVZ decided to visit the countries included in this international comparison. This offered an excellent opportunity to collect additional information that would be shared with the authors so that it could be integrated in the country reports.

1.3 Analytical framework for comparison of HTA systems

The aim of the Hutton framework is to better understand the characteristics of existing ‘fourth hurdle systems’ and how they endeavor to use HTA. Improved knowledge of

- their establishment and purpose,
- what decisions they make,
- what processes they use, and
- which interest groups are involved,

may help to improve the operation of existing systems and provide guidance for future policy development (Hutton et al., 2006). The term ‘fourth hurdle’ refers to the requirement to justify reimbursement of medical technologies on the basis of explicit assessments. It has been labeled ‘fourth hurdle’ because it is perceived by manufacturers of technologies to be an additional barrier to market access, after demonstration of product quality, efficacy, and safety to obtain a product license. The term originates from the pharmaceutical health care sector, where the procedures for decisions about market access and funding are typically more evolved than in other sectors. Requirements for the licensing of other health technologies, such as devices and surgical procedures, differ from those for drugs, so the

term ‘fourth hurdle’ may not be strictly accurate in this context. However, it has become an internationally recognized descriptive term, understood by all stakeholders in the HTA field.

As said above, the Hutton framework was developed to understand ‘fourth hurdle systems’, i.e. systems in which funding decisions are based on product evaluations. The framework assesses legal and political characteristics of the decision-making system, as well as takes into account the detailed nuances of varying assessment procedures and the use thereof by decision makers. For this purpose, the framework describes systems for reimbursement decisions on the political system level and on the level of an individual technology decision. At the individual technology decision level, it makes a distinction between three stages: assessment, decision-making, and outcomes and implementation. Information on each of these four characteristics is requested on four different elements: (i) constitution and governance, (ii) methods and processes, (iii) use of evidence, and (iv) accountability and transparency. Accordingly, the collected information can be summarized in a four-by-four matrix for each country. Hereby, the specifications of Table 1-1 are used. To facilitate data collection to fill out this matrix, a questionnaire was developed as a data collection tool (see Appendix A).

Table 1-1 The Hutton framework for describing and classifying decision-making systems using technology assessment to determine the reimbursement of health technologies

Policy level	Elements of the system			
	Establishment	Objectives	Implementation	Accountability
Technology decision level	Constitution & governance	Methods & processes	Use of evidence	Accountability & transparency
1. Assessment	Consultation	Methodology	Evidence for assessment	Presentation & communication of assessment results
2. Decision	Who decides	Decision making process	Evidence basis and other influences	Contents & documentation of the decision
3. Outputs & implementation	Appeal & dissent	Implementation & communication	Monitoring and reappraisal	Evidence of impact of the decision

International experts considered the framework to be sufficiently broad to encompass all the issues of interest regarding the systems. Also comprehensiveness and relevance of the framework was confirmed. There are however challenges in obtaining all data necessary to complete the framework. These data can be collected from published literature on HTA processes and from documentation of institutes involved in HTA and decision-making. A potential problem is that there may be information gaps or ambiguities and discrepancies in official information sources. In fact, Hutton et al. estimated that usually about 45% to 60% of requested information is available. For example, the assessment and decision-making processes are typically better documented than the outcomes and strategies to implement decisions. While we take every care to compile accurate and comprehensive information, it is thus unlikely that the matrix can be filled out completely for each system, even in spite of the complementary research strategies. At the philosophical level, the question could be raised if this is a shortcoming of our approach, or if it should be interpreted as a research finding related to the transparency of decision-making procedures.

1.4 The case studies

As mentioned previously, the framework is of great interest in comparing reimbursement systems in different countries, but it must be realized that it may be difficult to obtain all necessary information from policy documents. In addition, it can be anticipated that practice and theory of decision-making do not perfectly coincide. We therefore conducted three case studies, selecting three medical services that were assessed recently. The three cases are: deep brain stimulation (DBS) for Parkinson patients, transurethral microwave therapy (TUMT) for patients with an enlarged prostate, and position emission tomography (PET). To reconstruct the way the decisions about reimbursement were made, we analyzed the assessment reports and interviewed physicians, representatives of the medical industry, and policy makers. (See Chapter 12 for a description of the design and the methods.)

The aim of the case studies is to understand the working of the decision procedures. As said, the listening procedures are developed to specify the entitlements to medical specialist care explicitly. HTA is introduced as it makes explicit whether the evidence is strong and supports public funding of the service. Scientific evidence, however, cannot support the decisions completely. The role of HTA in the decision procedures has been debated intensively. The advocates and opponents of HTA agree that the role of evidence should be restricted. In fact, HTAs are often combined with other sources of information like expert advice. Although HTA has become an integral part of the listening procedures, the procedures are much more heterogeneous, some might say much more messy, than the descriptions of the procedures might suggest.

We will focus on four central themes that cut across a great deal of cases and are of strategic importance for understanding the working of the procedures. First, we want to understand how evidence-based policy is made to work in these procedures given the fact that evidence is inevitably incomplete and inconclusive. Second, we want to understand the dilemma between the need for extensive research and the need to make decisions before an application is widely in use. Third, we are interested to know how health authorities and scientists separate their tasks and/or work together and make the step from the assessment report to recommendations about reimbursement. Last, we want to grasp the challenges of meeting the expectations of the different stakeholders whose position in the procedure has been changed significantly.

1.5 Structure of this report

Chapters 2 to 10 describe the general characteristics of the policy systems in different countries, and the details of the assessment and decision making procedures at the level of an individual technology. These country reports are presented in alphabetical order. Chapter 11 analyzes the differences between the countries, using the Hutton framework described above. Chapter 12 presents the case studies and analyzes what we can learn from them. Finally, Chapter 13 discusses the findings and draws overall conclusions.

Chapter 2 Australia

2.1 Organizational structure of Australian health care

2.1.1 *Characteristics of the health care system*

Australia has a federal system of government, with a Commonwealth (federal) Government and parliaments in each of the six States and two Territories within the Commonwealth. The Commonwealth has powers specified in the constitution as Commonwealth powers; states have powers in all areas not specified as such. With regard to health care, the two levels of government have overlapping responsibilities (Commonwealth of Australia, 2000). As a result, health policy-making in Australia is characterized by ongoing negotiations between the Commonwealth and the States (Dixon & Mossiales, 2002). The Commonwealth has a leadership role in policy making and in national issues like public health, research and national information management. The States and territories are primarily responsible for delivery and management of public health services. They have to ensure that services adequate to meet public patient entitlements are available to all people eligible for care under social health insurance, i.e. Medicare. The States and Territories directly fund a broad range of health services, including community and public health services, and public acute and hospital services. The Commonwealth funds most medical services out of hospital and most health research.

The Australian health care system has a large and strong private sector. A mix of public and private providers delivers health services, and private and social health insurers jointly carry the costs. Following from the State or Territories responsibility to ensure adequate medical care facilities, public hospitals are directly funded by the government. Public hospitals include hospitals established by the state. However, designated non-governmental charitable hospitals, and some hospitals that were established by private parties have also been brought under arrangements with the State government. Private parties, for example for-profit organizations or private health insurance funds, own private hospitals. Complex types of hospital care are mainly provided by large public hospitals in the cities, whilst private hospitals deliver less complex services, like day surgery and elective surgery. However, some private hospitals also offer complex care. The hospital sector was designed in the mid-twentieth century, when hospitals and hospital care could be considered as separate and distinct from the other parts of the system. With increasing transmuralization of care, health policy has to address the links and interdependencies of the component parts (Hall, 2004).

Patients can elect to be treated as private or public (Medicare) patients, depending on the hospital or provider they choose to go to. Medicare provides access to free treatment as a public patient in a State/Territory-owned hospital, or in other hospitals that have been brought under State arrangements. In addition, treatment as a private patient in public or private hospitals is possible, with some assistance from governments. Medicare thus ensures that all Australians have access to free or low-cost medical, optometrical and hospital care. People remain free, however, to use private health services. For example, if

patients want to be treated by doctors of their own choice, or want to escape waiting lists, they can also be treated in the private sector. In that case health care providers will directly charge patients. If the patients hold private insurance, this usually covers the full costs. If the patients are eligible for Medicare, Medicare will pay some benefits to subsidize the cost (fully or in part).

2.1.2 National health care funding and Medicare

In 2003–04, Australia's health expenditure totalled \$78.6 billion, representing 9.7% of the gross domestic product (GDP) (Australian Institute of Health and Welfare (AIHW), 2005). Australia's public hospital system is jointly funded by the Australian Government (i.e. the Commonwealth Government) and State and Territory governments and is administered by State and Territory health departments. The Australian Government (about 45%) and the state and territory governments (about 22%) provide the bulk of funding for health expenditure. The Commonwealth Government finances Medicare by means of subsidies for prescribed medicines, substantial grants to state and territory governments to contribute to the costs of providing free access to public hospitals, specific purpose grants to State and Territory Governments, and general-purpose grants. State and Territory governments supplement Medicare funding, by funding of public hospitals. Other parties (non governmental agencies, private insurers, and individuals) provide about 31% of expenditures. People's contribution to the health care system is based on their income and is made through taxes and the Medicare levy.

Medicare is a national health insurance system for all citizens. Medicare is a government insurance fund paid for out of taxation. It entitles patients to out-of-hospital and in-hospital services. Until 2005, the Health Insurance Commission (HIC) managed the system. On 1 October 2005, the HIC transitioned to become a prescribed agency under the Financial Management and Accountability Act 1997 and a statutory agency under the Public Service Act 1999, within the Department of Human Services. On that date, HIC was also renamed Medicare Australia. With the transition from HIC to Medicare Australia, this organization became responsible for execution of Medicare, but also for continuing the Pharmaceutical Benefits Scheme (PBS), Australian Childhood Immunisation Register (ACIR), Australian Organ Donor Register (AODR) and Family Assistance Office (FAO). Today, Medicare comprises three main components, each designed to provide access to different types of health services (Hall, 2004):

- medical services, largely funded under medical benefits scheme (MBS);
- pharmaceuticals, largely funded under the pharmaceutical benefits scheme (PBS);
- and hospitals, public hospitals which operate under capped budgets and an increasingly significant private hospital sector supported by a mix of private insurance, out-of-pocket payments, and government subsidies.

The MBS and PBS are publicly financed entitlement programs, driven by fee-for-service funding, so that the Australian government must provide the funds for whatever of volume of services (or drugs) are provided. In contrast to public hospitals, private hospitals are also driven by fee-for-service. The aim of the Australian health care funding system is to give universal access to health care while allowing choice

for individuals through a substantial private sector involvement in delivery and financing of health care, which is considered important given the geographic background of the country (80% of people live in the cities, 20% in the remainder of the land mass, which has roughly the same size as Western Europe).

A fee schedule lists prices for Medicare entitlements, but doctors can in general charge whatever they wish. A system of bulk-billing exists, which implies that doctors can send their accounts directly to Medicare. Bulk-billed fees originally were set at 85 percent of the approved fee, reflecting the savings in administration, faster transfer of funds, and reduction of bad debts. It was therefore assumed that charging patients this way did not seriously disadvantage doctors who billed in bulk. However, bulk-billing rates have fallen in areas with fewer providers. When a bulk-billing arrangement is used, the doctor may not charge additional costs to the patient, so, there are no out-of-pocket costs for the patient. Bulk-billing was introduced to allow doctors to provide services to a patient without asking questions about their financial status. Bulk-billing meant that individual accounts for each patient did not have to be processed. It is preferred by patients and gives bulk-billing doctors a competitive advantage over those who do not. Patients are charged when other than the bulk-billed tariffs are applied. In this case patients get the Medicare benefits schedule fee reimbursed, and pay any balance out of pocket.

People who are eligible for Medicare can choose to take out private insurance as well. On admission to public hospitals, patients may then choose to be public (Medicare) patients, or private patients. All people eligible for Medicare are entitled to a choice of free accommodation, and medical, nursing and other care as public patients in hospitals², or treatment as private patients in public or private hospitals, with some assistance from governments. Private patients in private or public hospitals are charged fees by doctors and some allied health/paramedical staff, and are billed by the hospital for accommodation, nursing care, and other hospital services such as use of operating rooms. If the patient holds private insurance it will contribute to these costs. If the patient is eligible for Medicare as a permanent resident of Australia, the doctors' fees generally also attract Medicare benefits. Medicare then subsidizes part of the cost of doctors' fees, and private insurance pays an additional amount towards doctors' fees. Private insurance benefits can also contribute to payment of the costs of allied health/paramedical and other costs (for example, surgically implanted prostheses) incurred as part of the hospital stay.

Private insurance offers patients a free choice of doctors, of hospitals, more flexibility in timing of procedures, and it may meet the costs of some services that are excluded from Medicare funding (e.g. glasses and contact lenses, hearing aids or other appliances, and home nursing). The fact that people can be insured under two schemes requires some regulation with regard to differentiation of parts of the costs that are covered by either scheme (Commonwealth of Australia, 2000). Under Medicare, the cost of hospital treatment for public patients is free. Private health insurance can cover both private and public hospital charges. Public hospitals then only charge those patients who want to be treated by the doctors of

² State/Territory-owned hospitals, or designated non-government religious and charitable hospitals, or in private hospitals which have made arrangements with governments to care for public patients.

their own choice, and if private patients in private hospitals are eligible for Medicare treatment, Medicare subsidizes the treatment. The rate of Medicare benefit for medical treatment provided to private patients is 75% of the Medicare benefits schedule fee (Commonwealth of Australia, 2000).

The Commonwealth Government has introduced a number of measures, to ensure that there is a good balance between the public and the private insurance sectors. For example, for some interventions the price differences between the Medicare fee and the actual fee charged cannot be insured, as to prevent unnecessary increases of the fee. Moreover, the government is stimulating people to take out private insurance to decrease pressure on the public system. Their measures focus on affordability and attractiveness of private insurance. For example, the government regulates the private insurance sector to ensure that a system of community rating is maintained (everybody pays the same to take out insurance), they have offered a 30% rebate on private health insurance, and – to protect insurers – a system of risk sharing has been installed so that insurers who cover costs of high cost clients are not disadvantaged.

2.1.3 *Entitlements to medical specialist care*

Medicare ensures that all Australians have access to free or low-cost medical, optometrical and hospital care while being free to choose private health services and in special circumstances allied health services. The benefits people receive from Medicare are based on a fee schedule set by the Australian Government. The Medicare benefits schedule of the Commonwealth's Government lists the wide range of services that are covered by Medicare, and schedule fees that apply to each of these services. The Minister of Health decides about listing of new procedures, and gets advice from the Medical Services Advisory Committee (MSAC). Table 2-1 lists what kind of services is covered or not.

2.2 Development of Medicare and interest in HTA

2.2.1 *Managerial challenges in Australia's health care system*

Australia has been on the forefront of using HTA for several decades. For example, it was among the first countries that requested an economic assessment of pharmaceuticals to inform their decision-making procedure. Furthermore, Australia is the only country where all decisions about additions to the medical specialist benefits are guided by assessments that include economic evaluations.

Australia's early interest in HTA might be traced back to the origins of Australian health care. Australia's health system has its historical origins in the United Kingdom. A defining moment was the formation of the NHS in the UK, because Australia decided not to follow the UK in creating a NHS. Instead, Medicare came into development. Fact remains, however, that the principles of Medicare are the same as the principles that underlie the British NHS, i.e. equitable access of all citizens to government funded health care. An explanation is that between 1950 and 1960 the development of the health care system was more or less left to medical professionals, and they did not want a NHS style of social health because they did not want to be financed by capitated payments and fixed budgets. Even in the earliest stages of the development of Australia's Medicare system, practitioners were financed on a fee-for-service

basis, whereby services may be offered by private or public providers. The open-ended nature of the funding system combined with the two-tier poses major policy challenges and tight regulation.

Table 2-1

Covered
In-hospital care
Out-of-hospital services:
<ul style="list-style-type: none"> • consultation fees for doctors, including specialists • tests and examinations by doctors needed to treat illnesses, including X-rays and pathology tests • eye tests performed by optometrists • most surgical and other therapeutic procedures performed by doctors • some surgical procedures performed by approved dentists • specified items under the Cleft Lip and Palate Scheme • specified items for allied health services as part of the Enhanced Primary Care (EPC) program
Not covered
<ul style="list-style-type: none"> • private patient hospital costs (for example, theatre fees or accommodation) • dental examinations and treatment (except specified items introduced for allied health services as part of the Enhanced Primary Care (EPC) program) • ambulance services • home nursing • physiotherapy, occupational therapy, speech therapy, eye therapy, chiropractic services, podiatry or psychology • acupuncture (unless part of a doctor's consultation) • glasses and contact lenses • hearing aids and other appliances • the cost of prostheses • medicines (except for the subsidy on medicines covered by the Pharmaceutical Benefits Scheme) • medical and hospital costs incurred overseas • medical costs for which someone else is responsible (for example a compensation insurer, an employer, a government or government authority) • medical services which are not clinically necessary • surgery solely for cosmetic reasons • examinations for life insurance, superannuation or membership of a friendly society

A relevant characteristic of the Australian health care system is that the State and the Government share responsibilities for health care funding. Medicare is a national program for which the commonwealth is responsible, but on the other hand States are responsible for providing services in public hospitals. Viewed differently, we could also say that both the State and the Commonwealth are in part responsible for costs that they cannot control. This obviously put pressure on the State to make sure that the public providers work efficiently, and on the Commonwealth to make sure that in Medicare no resources are wasted. The hospital sector is where most problems occur, because of the difference in funding between public and private hospitals for public patients, and because of changing rates of patients with private insurers, which means that costs shares in public sector and health insurers may change.

HTA in Australia was a response to the inherently open-ended nature of the funding system. Whilst in the Netherlands the open-ended system applied to medicines, in Australia it also concerned the hospital sector, where the majority of health care costs are located. Against that background it is not surprising that Australia was the first to implement HTA programs. In Australia, HTA is mainly performed at the federal level, because in the end the Minister of Health decides what services are covered or not by Australia's national reimbursement schemes (i.e., the MBS and the PBS). To support decisions about funding for new and in some cases existing medical procedures through these benefits schemes, formalized HTA arrangements exist (Mitchell, 2002). It has been a legislative requirement since 1987 that all decisions for listing on the PBS be considered for comparative effectiveness. Cost-effectiveness analysis has been a requirement since 1991, and is conducted by the sponsor of the application. The Pharmaceutical Benefit Advisory Committee (PBAC) appraises the clinical and economic evidence and advises the minister of health about the funding decision. The Medical Services Advisory Committee (MSAC) was established (administratively, not legislation) in 1998 with a similar purpose and mode of operation as the PBAC but with the aim of supporting decisions for listing of medical services under Medicare benefits arrangements.

2.2.2 *The Medical Services Advisory Committee (MSAC)*

The Australian Government Minister for Health and Family Services established MSAC (originally as the Medicare Services Advisory Committee) to strengthen arrangements for assessing new technologies and procedures before they are considered for reimbursement under the MBS (Medical Services Advisory Committee, 2000a). MSAC was installed in April 1998, after the 1997-98 Budget announced a measure aimed at ensuring that new and existing medical procedures attracting Medicare benefits are supported by scientific evidence as being safe, clinically effective and cost-effective. A key element of the measure is the establishment of a new body, the MSAC, to advise the Minister for Health and Ageing on the strength of evidence on new medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness, and under what circumstances funding under the MBS should be supported.

Like the PBAC, MSAC evaluates new health technologies and procedures for which funding is sought under the MBS. The procedures for this are described in detail in Section 2.3. Summarized briefly, it does this by assessing safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise. A difference with PBAC is that evaluation of a new procedure is not a formal requirement of listing. The first stage of the assessment usually involves consideration within the Department of Health and Ageing of an application's eligibility for assessment by MSAC. If an application is considered eligible for review, MSAC utilizes independent contractors to conduct the majority of the assessment.³ This involves the development of an

³ The MSAC contracted the following organizations to provide research related services to the MSAC: Adelaide Health Technology Assessment; The Australian Safety and Efficacy Register of New Interventional; Procedures D Surgical (ASERNIP-S); The Medical Technology Assessment Group (M-TAG); The Monash Institute of Health

evaluation protocol and assessing the available evidence on the safety, clinical effectiveness and cost-effectiveness of the technology or procedure. MSAC provides input in the assessment process and ensures that the contractors' assessment is clinically relevant. After the evidence is reviewed, MSAC formulates recommendations to the Minister. MSAC recommendations generally fall into one of three categories:

- The evidence is strong and supports public funding;
- The evidence does not support public funding; or
- The evidence is inconclusive but suggests that the procedure could be safer, more effective, and more cost-effective than comparable procedures that attract public funding. In these circumstances, MSAC may recommend interim funding to enable data collection and further evaluation of the procedure.

The Department makes a submission to the Minister for Health and Ageing that combines MSAC's final assessment report and recommendations with policy advice from the Department. The Minister considers this information and makes a decision to endorse or reject the MSAC recommendations. If the minister decides that Medicare will fund a new medical service, a consultative committee draws on MSAC's findings to determine funding levels. The specific nature of the medical services determines which committee evaluates budgetary requirements. Relevant committees include the Medicare Benefits Consultative Committee (MBCC), the Consultative Committee on Diagnostic Imaging, and the Pathology Services Table Committee. The MBCC is an informal consultative forum established by agreement between the Minister for Health and Ageing and the Australian Medical Association to facilitate discussion on reviews of the General Medical Services Table (GMST) of the MBS. The major function of the consultative process is to review particular (groups of) services within the schedule, including consideration of new items and appropriate fee levels, to ensure that the schedule reflects and encourages appropriate clinical practice. Following approval by the Minister of an MSAC recommendation for public funding of a new procedure, an appropriate MBS listing for the service will be negotiated through the MBCC process.

2.3 Definition of the Medicare Benefits Schedule

In Australia services of medical specialist care are funded when the services are listed on the fee schedule (i.e., the MBS). The MBS changes from time to time to reflect, for example, the availability of new medical technologies, or changing medical practice. The need for changes to the way services currently included the schedule are subsidised are considered by the MBCC of the Department of Health and Aging.

There are regular and periodic reviews of services that are already listed on the MBS. The Department of Health and Ageing undertakes this in conjunction with the relevant medical professional groups via existing consultative arrangements. The MBCC provides a forum for discussion between the Department and the medical profession on existing items in the MBS (other than items covering

diagnostic imaging and pathology items). As a result of such reviews, for example obsolete services may be deleted, there may be a change in the patient groups eligible for a service, or the MBS fee. The consultative arrangements ensure that the medical profession plays a role in ensuring that the MBS reflects current and appropriate medical practice (Medical Services Advisory Committee, 2005a).

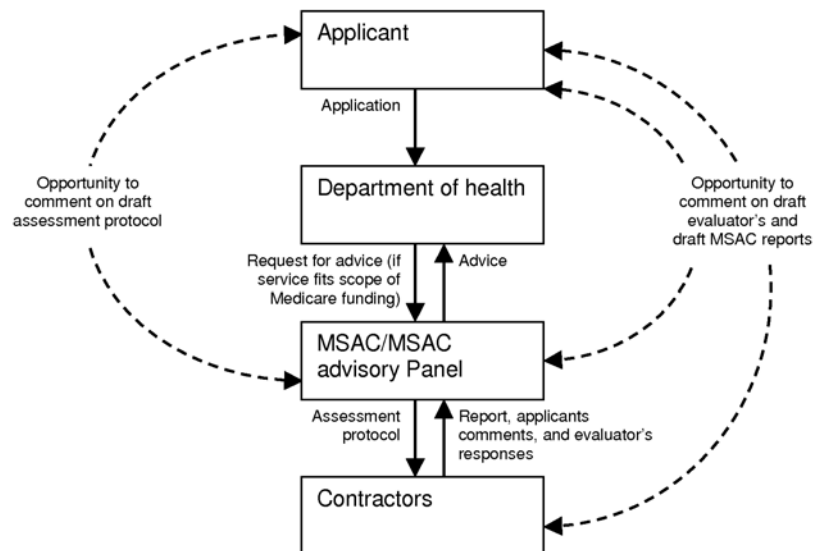
Changes to the MBS are also made through the addition of new items. This can result from the availability of new services (e.g., a new technique in an existing surgical procedure, or a new indication for an existing intervention). Proposals for new treatments to be included in the schedule are considered by MSAC. In 1998, the evidence-based medicine concept was adopted as a key feature of the health system, with the ambition that all new procedures would be independently evaluated by an expert panel before being admitted to the benefit schedule (Medical Services Advisory Committee, 2005a; O'Malley, 2006). This assessment procedure is described in detail below.

2.3.1 Policy: procedures and governance

When a new procedure is developed, an application for funding must be directed to the Department of Health and Aging. Applications may originate from different sources: industry, medical professionals, and other individuals, or reviews may be requested by the Department of Health and other health care policy institutes (Medical Services Advisory Committee, 2005b). If the application is considered eligible for Medicare funding (i.e., it fits within the scope of services that may be covered through the MBS as specified in the Health Insurance Act 1973), an assessment procedure will be undertaken. When this procedure is completed, the Minister of Health will decide about listing. Today, the assessment of evidence is an integral and formalized part of the listing procedure. The evaluation of evidence has been implicit and on an ad hoc basis until 1998. In 1998, MSAC was created by the Department of Health to formalize and strengthen the process of evidence assessment, especially in terms of the cost-effectiveness criterion (Medical Services Advisory Committee, 2005b; O'Malley, 2006). When the procedure was first launched, it was acknowledged that if many applications propose new professional services that are eligible for Medicare coverage, it may not be possible to assess them all. Then, a broad set of criteria for prioritizing assessments will be applied, reflecting among other clinical need, costs, available treatment alternatives, and potential benefit of the HTA. In practice, however, the number of applications was not as high as to warrant priority setting amongst applications.

Once an application for funding is considered in theory to be eligible for funding under the Medicare arrangements, the assessment procedure is started. Different parties are involved in the assessment procedure: the Department of Health and Aging, MSAC, contracted evaluators, and an Advisory Panel (Medical Services Advisory Committee, 2005a). The Department of Health and Aging refers the application to MSAC, whose main responsibility in the process is to contract evaluators and install an Advisory Panel. MSAC is an appraisals committee rather than an organization and has administrative support from the Department of Health and Aging. MSAC is an advisory expert panel, consisting of 22 members who are experts in varying areas of medical care, epidemiology, or health economics, and consumers, and health administration and planning. Members are appointed by the

Figure 2-1 MSAC's relations to stakeholders



Minister for Health and Aging. MSAC does not perform assessment by itself. Instead, MSAC contracts established HTA agencies. The contracted evaluators perform the assessment procedure. For each assessment MSAC installs an Advisory Panel to guide the evaluation, e.g. to ensure evaluations are conducted in accordance with agreed guidelines and time frames. The Department of Health provides project and secretariat support.

When MSAC has received the draft report from the evaluators, they prepare an advice for the Minister of Health. Their recommendations may be positive (funding is supported, sometimes with restrictions), negative (funding is denied), or their advice may be to provide interim funding (with a requirement for additional data collection, or awaiting clinical trials). Typically, the Minister endorses the MSAC advice. When the decision is that public funding will be provided, an implementation process is started, which among other things entails negotiations about the appropriate treatment fee between a consultative committee of Medicare and medical professionals. Table 2-2 presents the time frame for the decision making process. It shows that the aim is to complete the assessment procedure in about one year. However, in 27% of the cases the assessment is actually concluded within 12 months with the average duration being 18 months.

Being aware that Australia is among the first countries to use evidence-based medicine for funding of medical specialist care, the assessment procedure has been critically assessed (self-assessment). Usage of MSAC assessments, and stakeholder satisfaction with governance of the procedure, and consistency of the advices were evaluated. The evaluation of the MSAC assessment procedure showed that it is not always clear to stakeholders how MSAC comes to its recommendations or how the advice follows from the available evidence (Medical Services Advisory Committee, 2005b; Productivity

Commission, 2005). In response to these remarks, MSAC agreed to take action, e.g. define a uniform template for assessment reports, include statements in the report about disputed elements, summarize and distribute their findings and more. They also consider peer-review of the assessments. Also other concerns, for example related to stakeholder involvement, were taken into account and action points were defined for MSAC to revise its procedure (Medical Services Advisory Committee, 2005b).

Table 2-2

Stage of assessment	Responsibility	Time frame
Eligibility for Medicare funding	Department of Health and Aging	2 weeks
Assessment	Advisory Panel	35 weeks
Advice to the Minister	MSAC	8 weeks
Decision about funding	Minister of Health	4 weeks
Implementation	Consultative committee	17 weeks

2.3.2 Assessment

The assessment procedure essentially consists of a review of available evidence regarding efficacy, safety, effectiveness and cost-effectiveness of the procedure compared to its comparator. The contracted evaluators have the scientific knowledge to perform the evaluation. The Advisory Panel guides the assessment process in terms of its scope, desired outcome measures, interpretation of evidence, and so forth. Stakeholders are represented in the assessment process by membership of the Advisory Panels. The Advisory Panel always consists of MSAC member(s), clinical experts, health economists, and consumers. The MSAC executive directs which medical craft groups it wishes to have represented in the Advisory Panel, and on occasion will also identify individuals they consider would have an important contribution to make to the assessment. In addition, the draft assessment report is sent out for comment to the applicant, and to a member from MSAC who was not involved in the assessment. Their comments may give reason to amend the report, but in any event, MSAC receives the comments, any response the evaluators might have to the applicant's comments, as well as comment provided by the medical adviser to the Medicare Benefits Branch within the department.

The contracted evaluators and the advisory panel meet a first time to decide on the fundamental scope of the evaluation, decide about clinical pathways of the technology under review and its comparator, the indications and patient groups, and the health outcomes by which the technology will be assessed. Next evaluators produce a draft report that includes evidence of the safety and clinical effectiveness, and cost-effectiveness (only when the new procedure is considered effective). The Advisory Panel meets to provide advice on the interpretation of the evidence, and to indicate also where members consider the published evidence might usefully be supplemented with expert opinion, based on the experience of the members and their professions. Next, the evaluators produce a final report, that is send out for comments. An approximate time frame of the assessment procedure is presented in Table 2-3.

Table 2-3 Assessment procedure: approximate timeframes

Assessment procedure: approximate timeframes	
Advisory Panel nominations sought	Within 2 weeks
Advisory Panel established	Within 6 weeks
First meeting of Advisory Panel	Within 8 weeks
Draft evaluation protocol provided for comment	Within 10 weeks
Draft evaluation protocol finalized	Within 15 weeks
Draft assessment report for comment	Within 27 weeks
Draft assessment report for MSAC consideration	Within 35 weeks

When making their recommendations, MSAC uses the assessment of safety, effectiveness and cost-effectiveness presented in the evaluators report, but also takes into account other issues such as access and equity. They present their advice together with the evaluators' report and comments on the draft report to the Minister. The Committee's recommendation is conveyed to the Minister for Health and Ageing.

To facilitate the assessment procedure, MSAC has published a document that sets out the framework for MSAC's assessment of the evidence available on the safety, effectiveness and cost-effectiveness of new medical services, the background and context, and who may apply to MSAC (Medical Services Advisory Committee, 2005a). It also maps the stages through which an application will pass, from when it is lodged with the MSAC secretariat to decision making. This document includes Application Guidelines, which include information on the level, quality and strength of evidence it seeks so as to provide the most reliable advice it can, to the Minister. This information is intended to assist applicants who are seeking funding of a new service under Medicare to assemble and submit information in a format that can be used to assess its safety, effectiveness and cost-effectiveness. They describe the minimum amount of information that MSAC requires to assess an application. The document also contains Assessment Guidelines that are intended to be useful to both applicants and assessors. They contain more detailed information than the Application Guidelines, including guidelines on how MSAC will assess the evidence provided. Applicants have the option of submitting an application that contains only the minimum information required in the application guidelines, or a more detailed application following the procedures set out in the assessment guidelines. The latter approach may enable a faster assessment of the application by MSAC.

With regard to the ambition to assess new technologies in terms of efficacy, safety, effectiveness and cost-effectiveness, it must be noted that the adoption of evidence-based medicine for reimbursement decisions in medical specialist is impaired by limited availability of evidence. Often, for example, evaluation of cost-effectiveness is not possible, so that a cost-consequence analysis remains. MSAC deals with a very wide variety of technologies and procedures, ranging from pathology tests and diagnostic imaging, to new surgical procedures, to medical devices. The Committee will always seek the best evidence that is available, while also having regard for the opinions of expert clinicians. The nature of the evidence available will vary accordingly. The Committee found, on the basis of its experience to date, that a set of hard and fast rules on what levels of evidence would be considered acceptable in any conceivable

circumstance would not be practical or helpful. After all, if no flexibility is applied, the chance grows that funding is denied because of absence of evidence, rather than unsatisfactory performance of a treatment, so that beneficial treatments may be withheld to the patient.

2.3.3 *Decision*

In Australia, the production and use of HTA at the federal level have developed to support decisions about changes to the MBS. The assessment is not undertaken by agencies or organizations established or funded for the purpose, but is requested, administered and appraised under the aegis of different parts of the federal health administration. The assessment procedure is focused on policy makers' requirements for reimbursement decisions. The final responsibility for the decision nevertheless lies with the Minister of Health and Aging, who has to approve the recommendations of MSAC before implementation. Typically the Minister of Health and Aging ratifies these recommendations. If the financial implications are over a certain threshold, the final decision about listing of a new procedure is made by the Australian Government Cabinet (OECD Health Project, 2005). After the Minister has signed off on the Committee's advice, the final report and recommendation are conveyed to the applicant and then published and distributed to interested parties. An electronic copy is also made available on the MSAC web site (<http://www.msac.gov.au>).

2.3.4 *Outputs and implementation*

When the Minister for Health and Ageing endorses a recommendation for funding of a new medical service through the MBS, the Department of Health and Aging is responsible for implementation of the decision. This involves setting a fee level and provision of an item description for listing on the MBS. This process is not commenced when the minister has not approved the MSAC's recommendation. The fee and item descriptor are determined by the Department in consultation with a consultative body, namely the MBCC, the Pathology Services Table Committee (PSTC), or the Consultative Committee on Diagnostic Imaging (CCDI). The fee is negotiated with the medical profession. Again, the proposal of these consultative bodies will be submitted for Minister's approval. The resulting changes to the MBS are published. The MBS and changes to it are also published on the internet (<http://www9.health.gov.au/mbs/>).

MSAC plays no role in implementation of decisions, although some submissions have urged MSAC to have regard for implementation matters. There are concerns about substantial time may elapse between MSAC recommendation and the MBS listing, or the broader effects of implementation beyond the considerations of efficacy, and (cost)-effectiveness. MSAC invites unsuccessful applicants to attend a 'debriefing' meeting when the Minister's decision is conveyed (Medical Services Advisory Committee, 2005b). There is no independent review mechanism to appeal to MSAC recommendations and the ministerial decisions.

Chapter 3 Belgium

3.1 Organizational structure of health care in Belgium

The Kingdom of Belgium is a constitutional monarchy covering 30,528 km² and housing a population of 10.4 million people. The country is divided into Flemish-speaking Flanders in the north and French-speaking Wallonia in the south (European Observatory on Health Care Systems, 2000a; Algemene Directie Statistiek en Economische Informatie, 2004). In 2002, life expectancy at birth was 75.1 years (males) and 81.1 years (females). The total expenditure on health care was €23,6 billion in 2002, which comes down to 9.1 percent of the GDP (Organisation for Economic Co-operation and Development, 2004).

This chapter goes into the reimbursement of medical specialist care in Belgium. First, the next sections briefly elaborate on the main features of the Belgian political system and outline some basics of the Belgian health care (insurance) system.

3.1.1 *Main characteristics of the health care system*

Belgium is a federal state made up of overlapping geographical regions ('gewesten') and language-based cultural communities ('gemeenschappen'). The three regions are the Flemish region, the Walloon region, and the Brussels-Capital region. The three communities are the Flemish, the French, and the German community. Notice that the borders of the regions do not exactly coincide with the borders of the communities. Administratively, the country is divided into 10 provinces and 589 municipalities.

According to the Belgian Constitution (Art. 35), the federal state is only competent in matters explicitly ascribed to it by the law. The regions and communities are competent in all other matters. The federal government is responsible for defense, inner policy, foreign policy, finance, social security and health care, and justice. The communities are competent to deal with matters relating to the people composing them, such as language, culture, education, and social support. The regions are responsible for so-called territorial matters, such as town planning, housing, agriculture, and the environment.

Regarding health care, responsibilities are broadly divided as follows. The federal authorities determine the general legislative framework. This includes enacting hospital law, fixing the overall budget, and enacting health insurance laws, as well as supervising the health insurance system. Several federal departments (called 'federal public services (FPS)') have legal responsibilities in health care. The FPS Health, Food Chain Safety and Environment—hereafter referred to as FPS Health—is responsible for planning and accreditation issues (e.g., regarding hospitals, medical professionals, and certain high-technology medical services) and plays an important role in hospital budget setting for example. The FPS Social Security is responsible for the health insurance, which is part of the social security system.⁴ Since

⁴ In addition, the FPS Economy, Small and Medium-sized Enterprises, Self-employed and Energy is involved in the health care arena. For example, it fixes the maximum prices of pharmaceuticals.

the 1980s, many elements of health care policy have been a responsibility of the three communities. For example, the communities are responsible for home care and for all health education and preventive medicine, except certain national preventive measures such as compulsory vaccinations. As regards secondary care, the communities are responsible for ensuring the implementation of hospital norms and standards that have been set at federal level, for accreditation and for the authorization of construction and renovation work. Finally, the provinces and the municipalities play some role in the health care system. The provinces are responsible for environmental health, inspection of pharmacy premises, and checking the authenticity of medical professionals' diplomas. The municipalities carry out some tasks in the organization of social assistance for people on low incomes and the provision of emergency services (Cleemput & Kesteloot, 2000; European Observatory on Health Care Systems, 2000a).

A recent development has been the growing attention of the Belgian government for promoting health care efficiency. Rapidly rising health care costs (particularly in the hospital sector) in the 1980s led the government to take a series of reforms in the early 1990s that were intended to contain costs whilst maintaining the essential structure of the system. An increasingly recognized problem was that consumers had little incentive to limit their demand, while providers had every incentive to expand their services because of the dominance of fee-for-service payments (Cleemput & Kesteloot, 2000). The reforms introduced a number of exceptions to the fee-for-service financing rule, and increased the co-payments borne by the patient for a number of services. Emphasis was on making all players more financially accountable or responsible for their decisions ('responsabilisering'). Most controversially, however, they set a hard limit of 1.5% on the annual maximum growth allowed in the health care expenditures from 1995. This limit remains in place to this day, even though in later years it has been raised to 2.5% and next to 4.5% (European Observatory on Health Care Systems, 2000a).

3.1.2 Health care funding

The Belgian health care insurance in broad outlines

Belgium has a compulsory health insurance system that dates from 1945. The legal health insurance is operated by sickness funds ('mutualiteiten'), which are private not-for-profit bodies with a strong public mission. The existence of 'mutualities' is a characterizing aspect of the Belgian health care insurance that makes an important difference from the health insurance systems in neighbouring countries such as the Netherlands. The mutualities are a kind of associations of which the Belgian people are members and which offer their members health insurance. The mutualities, whose origins can be traced back to the early nineteenth century, are organized into five national alliances according to political or ideological background. Of these the Christian Mutualities and the Socialist Mutualities are the largest, together covering about three quarters of the population. In addition, there is one public sickness fund ('Hulpkas voor Ziekte- en Invaliditeitsverzekering').

The most important legal regulations in the area covered by this chapter are the Law regarding the compulsory insurance for medical care and benefits ('Wet betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen (GVU)'), the Hospital Law ('Wet op de Ziekenhuizen'), and the

Royal Decrees based on these acts.⁵ These regulations ensure that the compulsory health insurance currently covers practically the whole population, including employees, self-employed persons, unemployed persons, persons who are incapacitated for work, students, old age pensioners, and the dependants of these persons (Art. 32-33 GVU). As a condition for reimbursement from the insurance, people have to join a health insurer. As another condition for receiving the benefits, the insured in principle have to accept a waiting time of 6 months (Art. 128 GVU). However, this rule has rather become an exception in practice.

The health insurance consists of two distinct schemes: a general scheme that applies to the whole population (except self-employed people) and a scheme for the self-employed (and their dependants). Another key characteristic of the Belgian health insurance system is the distinction between major and minor risks. Major risks include, for example, hospitalization, surgical procedures, radiodiagnostic procedures, radiotherapy, pharmaceuticals during hospitalization, and delivery care. The minor risk category covers, among other things, consultations with either a family doctor or a specialist, pharmaceuticals, dental care, minor surgery, physiotherapy, and ambulatory nursing care. The general scheme covers both major and minor risks the whole population. The scheme for the self-employed only covers the major risks. The self-employed may opt for voluntary insurance against the minor risks, which most of them indeed actually do.

The mutualities (and private, for-profit companies as well) provide voluntary private insurances to cover services falling outside the coverage of the compulsory health insurance, the statutory co-payments, or, for example, hospitalization in a single room. Although its importance in terms of the share of the health care costs it bears is rather small, the role of the private insurance system is growing in Belgium. For example, about 18% of the population is covered by supplementary hospitalization insurance (European Observatory on Health Care Systems, 2000a).

Patients are free to choose their insurer, just as they are free to choose their health care provider. The mutualities compete for clients mainly through the voluntary complementary insurances, geographical convenience, and speed of settling claims.

The National Institute for Sickness and Invalidity Insurance (RIZIV/INAMI), established in 1963, performs the administrative and financial management of the health care insurance and, within this context, supervises the mutualities and the health care providers. RIZIV/INAMI, which comes under the authority of the FPS Social Security, is composed of four main services: the Medical Care Service (which is in charge of the compulsory health insurance), the Sickness Benefits Service (entrusted with the disability and the maternity insurance), the Medical Control Service, and the Administrative Control Service.

Health care providers and insurers regulate the financial and administrative relationships between them through a system of agreements and contracts ('overeenkomsten en akkoorden') (European

⁵ E.g., Royal Decree of 3rd July 1996 for the enforcement of the Law regarding the compulsory insurance for medical care and benefits ('Koninklijk Besluit van 3 juli 1996 tot uitvoering van de wet betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen').

Observatory on Health Care Systems, 2000a). These documents are drawn up by Agreements and Contracts Committees composed of an equal number of representatives of the health care providers and of the insurers (Art. 26 GVU). Each health profession and the hospital sector have their own committee in which it meets with mutualities. The essential task of these committees is to fix fee levels, which serve as the basis for health care reimbursement and for determining the level of coinsurance. Notice that in Belgium medical doctors are paid mainly according to a fee-for-service system. If no agreement is reached or if too many health care providers rejected it, the Minister of Social Affairs has the power to intervene, for example by unilaterally imposing fees.

Hospital finance

Hospitals are financed according to two co-existing systems. Summarized briefly, non-medical hospital activity (i.e., nursing care, accommodation costs, etc.) is funded via a fixed annual budget based on per diem and patient day quota rates. About 75% of the hospital budget is covered from RIZIV/INAMI sources, with the remaining 25% coming from other government funds. Medical services (surgical operations, diagnostic tests, etc.) on the other hand, are covered by RIZIV/INAMI, mainly according to a fee-for-service system. Hospitals receive a part of the fees that are paid to the doctors working in the hospital. Of note here is that, with the aim of promoting efficiency, the last decades have seen a gradual evolution from the traditional fee-for-service system to a prospective financing system (Cleemput & Kesteloot, 2000; Closon et al., 2004; Schokkaert & Voorde, 2005).

Premium

In both the general scheme and the scheme for the self-employed, health insurance premiums are related to income and independent of risk, with no fixed upper limit. Insurance premiums (the rates as a percentage of income) and the levels of public subsidy are fixed by law. In the general scheme, health insurance contributions come from both the employee (3.55% of the total income) and the employer (3.80%).⁶ The self-employed also have to pay a proportion of their income for social security, which includes health insurance.⁷ Then, there are beneficiaries who do not pay contributions, the so-called WIGW category ('Weduwen, Invaliden, Gepensioneerden en Wezen') which includes people living on minimum wage and certain other vulnerable groups (European Observatory on Health Care Systems, 2000a). The contributions of salaried workers (like their other social insurance contributions) and those of their employers are collected by the National Office for Social Security (RSZ), which then distributes the money to the government agencies responsible for the different branches of social security (such as RIZIV/INAMI). RIZIV/INAMI redistributes monies to the different sickness funds. The National Institute for the Social Security of the Self-employed (RSVZ) collects the social contributions of self-employed people, and distributes a part of these to RIZIV/INAMI.

⁶ Art. 38 of the Law concerning the general principles of the social security for employed workers ('Wet houdende de algemene beginselen van de sociale zekerheid voor werknemers').

⁷ Art. 11 of the Royal decree of 27th July 1967 concerning the institution of the social charter for the self-employed ('Koninklijk Besluit van 27 juli 1967 houdende inrichting van het sociaal statuut der zelfstandigen').

For ambulatory care, a reimbursement system is the basic rule. This means that the patient first has to pay the bill of the medical provider and gets reimbursed by the insurer afterwards. In most cases however, patients are not reimbursed 100%. People have to pay own contributions ('remgeld') (a fixed amount or a fixed proportion of the costs of a service). Own contributions vary depending on the type of treatment and the provider's capacity, but are generally around 25%.⁸ Pharmaceuticals are only reimbursed (through a third-party payer system) for a certain percentage according to 5 reimbursement categories, ranging from 20% to 100% depending on the product's therapeutic and social value. On the other hand, the costs of inpatient care are almost entirely met by the insurance funds (according to a third-party payer system). The patients' own contributions are relatively small, for example comprising a rate per hospitalization day and own contributions for certain medical services, including a per diem co-payment of €0.62 for pharmaceuticals.

The part of the costs that the insured have to pay by themselves is limited by law, in a system of maximum billing ('maximumfactuur'). Own contributions of people belonging to the WIGW category and some other socially vulnerable people are limited at a maximum of €450 per year (Art. 37octies GVU). Other people's own contributions are also limited at a maximum amount varying between €450 and €1,800 per year, depending on their income (Art. 37undecies GVU).

3.1.3 Definition of the benefits schedule

The statutory health insurance covers preventive and curative health care of some 25 categories (Art. 34 GVU), ranging from regular medical care to dental care, delivery care, pharmaceuticals, rehabilitation care, home care, and care provided by nursing homes for example. A nationally established schedule ('nomenclature') lists the medical services that are (partly) covered by the compulsory insurance.⁹ The list, which has not been changed substantially over recent years, records over 8,000 services and includes rules of interpretation. It is an extremely detailed list – far more detailed for example than benefits schedules that are based on DRGs (diagnosis-related groups). The nomenclature is coupled with other lists that contain fees for all the services,¹⁰ and as such constitutes the root of the price-setting system. The nomenclature includes a positive list of about 2,500 pharmaceuticals that are fully or partly reimbursable.¹¹

So, a broad range of health care interventions is covered. Yet, certain types of health care, such as plastic surgery, spectacles and orthodontistry, are reimbursable only under certain conditions, whereas others are excluded from reimbursement, among which are some physiotherapy and alternative medicine (e.g., acupuncture, homeopathy, and osteopathy). To give another example: the surgical extraction of teeth was excluded from reimbursement in 2005. The mutualities are legally required to reimburse any claim from their insured members for care delivered by any accredited health care provider at the agreed fee levels.

⁸ Certain vulnerable groups in society pay no or lower own contributions.

⁹ See <http://inami.fgov.be/care/nl/nomenclature/text.htm>.

¹⁰ See <http://inami.fgov.be/insurer/nl/rate/index.htm>.

Since the year 1990, the insured can appeal to a special solidarity fund ('Bijzonder Solidariteitsfonds') of RIZIV/INAMI for reimbursement of exceptional costs that are not covered by the statutory health insurance (Art. 25 GVU). This concerns, for example, very high costs or costs due to a rare disease. The costs of the fund are met from the revenues of the compulsory health insurance. The insured do not pay a separate premium.

3.2 HTA in Belgium and its use in coverage decisions

In the year 2000, Cleemput and Kesteloot in their paper on HTA in Belgium noted that in general, in all mechanisms for controlling health technologies, the very limited presence of scientific background is striking (Cleemput & Kesteloot, 2000). For example, accreditation for special high-technology, expensive services (see further below) utilizes the input of doctors, hospital representatives and insurers, but not that of scientific disciplines such as economics (cost-effectiveness) or epidemiology. The authors observed that the use of scientific evidence is larger in the area of pharmaceuticals, but it rarely includes cost-effectiveness analyses or any other form of research beyond efficacy, quality and safety evaluation. Other problems mentioned by the authors were the fact that there is no clear definition of HTA in Belgium and that Belgium did not have a national research center for HTA and health services research. Studies that are being done generally center on pharmaceuticals, diagnostic devices such as MRI, and preventive interventions – mostly new technologies rather than existing technologies. Then, such studies are frequently limited to the economic evaluation of technologies, ignoring aspects other than cost-effectiveness. Finally, Cleemput and Kesteloot noted that only limited measures have been taken to put HTA results into practice. The rare exceptions include a change in reimbursement policy and the introduction of vaccination programs following an HTA report (Cleemput & Kesteloot, 2000).

Over the last few years, this description has become outdated. Generally, extensive debate and consultation among all major stakeholders in health care have been, and to a large extent still is, a main characteristic of the system. However, there have been reforms aimed at introducing a broader scientific base to health care decision making. Although Belgium has no strong tradition regarding HTA, the interest in HTA has been growing rapidly during the last couple of years. Among the most prominent developments was the foundation of the Belgian Health Care Knowledge Centre (KCE) in the year 2003, which was done in an attempt to fill the gap between scientific evidence and health care decision making. According to law, the KCE has the task of collecting scientific knowledge (by doing clinical research, health economic analyses, or health services research for example) to support the provision of the best possible health care for everyone and the efficient and transparent allocation of the available health care resources.¹² In order to fulfill this task, the KCE produces studies and reports – among others for RIZIV/INAMI, the FPS Health, and the FPS Social Security – on a broad range of HTA-related subjects. It is managed by a Board of Directors, composed of representatives of, among others, both the FPS

¹¹ See <http://inami.fgov.be/drug/nl>.

¹² Art. 262 of the Program Law of 24th December 2002, Belgisch Staatsblad 31st December 2002, p. 58686.

Health, the FPS Social Security, RIZIV/INAMI, the health care providers, the Council of Ministers, Parliament, and the social partners. The establishment of the KCE is likely to prove an important step towards incorporating HTA in policy making, which, at least in the years before the institution of the KCE, has not been common practice. In its most recent yearly report, the KCE provided several examples of KCE reports that indeed had a significant impact and were used by decision makers such as the Minister of Health, RIZIV/INAMI, and the communities (Federaal Kenniscentrum voor de Gezondheidszorg, 2007). Next to the KCE, several other organizations not yet mentioned above have developed an interest in HTA. One of them is the High Health Council ('Hoge Gezondheidsraad'), the scientific advisory body of the FPS Health. It advises on all matters relating to the health of the Belgian population. Another is the Flemish Health Council ('Vlaamse Gezondheidsraad'), which, created in 1997, advises the Flemish government on all health matters.

It can be concluded here that, generally, HTA at present does not play a major or systematic role in defining the benefits package, which is rather defined through a complex, not highly transparent process of negotiations within RIZIV/INAMI. Systematic horizon scanning to identify new technologies, as the first stage of HTA, for example also does not exist. Consider that anyhow explicit measures on the nomenclature – apart from minor changes – are relatively small in number. Notwithstanding the increased pressure on government finances and the increased interest in less comprehensive public insurance schemes and higher reliance on complementary insurance and individual responsibility, reforms of the compulsory insurance have been limited during the last decades (which is also true for reforms in the health care system in general). Nowadays, Belgium shows a trend towards introducing a broader scientific base to health insurance policy, but the implementation of reforms is slow and gradual. This has to do with the fact that policy is made by stakeholders, such as the mutualities and medical doctors within RIZIV/INAMI, which requires consultation and thus takes time. Central direction is absent, just like radical reforms are. Another characteristic of the Belgian context that seems to delay the implementation of reforms is the strong emphasis on equity, equality of access, and freedom of choice, which has traditionally made a restriction of the benefits package hardly acceptable to the population. As a consequence, Belgium has a broad basic benefits package. Unlike in neighboring countries such as the Netherlands and Germany, the reach of the compulsory health insurance has never been substantially restricted (apart from applying the instrument of own contributions, which are relatively high in Belgium by international standards) (Veraghtert & Widdershoven, 2003; Schokkaert & Voorde, 2005).

In the following section, we will mainly concentrate on RIZIV/INAMI and KCE. When applying the Hutton framework to the situation of medical specialist care in Belgium, it appears that most attention should be devoted to these two institutions, and the relations between them.

3.3 Definition of benefits to medical specialist care

3.3.1 Policy

The nomenclature is determined by the King, except for pharmaceuticals (Art. 35 GVU). The King may make changes to the nomenclature mainly in the following ways:

- on the basis of an advice of one of RIZIV/INAMI's Technical Councils, which presents its advice to one of the Agreements and Contracts Committees – composed of an equal number of representatives of the health care providers and of the insurers – that decides on whether to submit the advice to RIZIV/INAMI's Insurance Committee;
- on the basis of an advice of the relevant Technical Council requested by the Minister or by one of the Agreements and Contracts Committees. These advices are submitted to the Insurance Committee;
- on the basis of an advice of one of the Agreements and Contracts Committees, the Minister, or the Insurance Committee (which may be changed after it has been referred for advice to the relevant Technical Council).

RIZIV/INAMI's Technical Councils ('Technische Raden') (Art. 27 GVU) fall under the Medical Care Service and are composed of representatives of health care providers, health insurance associations, and university experts. One of the tasks of the Insurance Committee (also part of RIZIV/INAMI's Medical Care Service) is to decide on the forwarding to the Minister of proposals to modify the nomenclature. The Insurance Committee may make changes to such a proposal before forwarding it to the Minister (Art. 22 GVU). Another authority of the Committee is to formulate rules of interpretation for the nomenclature. The Insurance Committee is composed of representatives from health insurers, health care providers, and, as advising members, representatives of trade union movements, employers' organizations, and associations of the self-employed (Art. 21 GVU).

At RIZIV/INAMI's Medical Care Service, there is a Scientific Council ('Wetenschappelijke Raad'). Put briefly, the Council has the task to promote the scientific advancement (in terms of efficiency, economy, and quality) of the health insurance (Art. 19 GVU). It delivers advises and recommendations on the basis of a request by the Minister of Social Affairs, the Minister of Health, the General Council or the Insurance Committee of RIZIV/INAMI, or on its own initiative. For example, it makes recommendations on the nomenclature of the benefits.

It may be concluded that RIZIV/INAMI is the key actor in the management of the statutory health insurance. RIZIV/INAMI has been given a predominant role in decisions on the benefits to medical specialist care (concerning the intake of new procedures, as well as the assessment of the current nomenclature). When saying that RIZIV/INAMI is the key actor, it must be kept in mind that RIZIV/INAMI is not really an autonomous actor, but rather the administrator of a platform where stakeholders come together.

Before finishing this section, attention must be drawn to another issue relating to the subject of benefits to medical specialist care. The use of medical services is also regulated by a system of accreditation for special high-technology, expensive services. Areas covered by this system for example include units for medical imaging (CT, MRI), centers for the treatment of end-stage renal disease, and cardiac treatment centers. The King, after being advised by the National Hospital Council ('Nationale Raad voor ziekenhuisvoorzieningen'), composes a list of expensive medical equipments and services. Services on this list may not be installed or run without prior approval of a Minister of the appropriate community (Art. 37-44ter Hospital Law). If these regulations are contravened, RIZIV/INAMI has the right to refuse reimbursement for services using that equipment (Art. 64 GVU). To inform the final decision of the Minister, one of the Technical Councils performs an HTA. The Technical Council issues an advise to the Insurance Committee on whether the new technology should be used, and what the reimbursement level should be. Remarkably, the providers and financers of health care play the major roles in this system, whereas the input of experts such as economists, statisticians, and epidemiologists is minimal. No clear attention is paid to the cost-effectiveness of technologies.

3.3.2 *Assessment*

As explained in Section 3.3.1, RIZIV/INAMI, especially the Technical Councils and the Insurance Committee, makes proposals and issues advices. From the literature it is not clear what these advices contain (as they are not published), and for example what kinds of evidence are used. It is highly unlikely however that they can be called proper HTAs. This leads to the important conclusion that HTA does not have a structural place in today's reimbursement procedure of Belgium. Yet, even though RIZIV/INAMI does not itself perform HTAs, it may since a few years request an HTA study by the KCE, which, as said above, produces HTAs using systematic methods to support health insurance policy. In this way, the KCE in fact performs tasks that used to belong to the domain of RIZIV/INAMI's Scientific Council, but which the Scientific Council never really carried out. There is a difference however, as the assessments of KCE are independent. So, there is currently a clear distinction between 'assessment' and 'appraisal', which means that KCE is not in the position to decide whether or not its advices will be used. Notice that until today the work of the KCE does not have a formal place in the procedures concerning the composition of the benefits schedule: there are no rules, for example, laying down when the advice of the KCE has to be sought.

Not only RIZIV/INAMI, but every citizen or organization may request a study by filling in a form available through the KCE website. In practice, most requests come from RIZIV/INAMI (for whose requests a part of the HTA activity is reserved in KCE's yearly programs), the FPS Health, the FPS Social Security, universities, health insurers, and health care providers. The following observations can be made on KCE's way of acting. KCE prioritizes the requests and composes yearly research programs. In the first two years of its existence, the KCE—which has a staff of some 40 people among which 30 independent experts—produced 25 study reports (not only HTA studies but also other reports). Examples of studied interventions include smoking cessation strategies, positron emission tomography (PET)

scanning, capsule endoscopy, and prostate specific antigen (PSA) testing. A study takes a period of 6 to 18 months (Federaal Kenniscentrum voor de Gezondheidszorg, 2006; Federaal Kenniscentrum voor de Gezondheidszorg, 2007). Each HTA report follows a standard methodology: all different steps of a study are fixed. The principal method to determine effectiveness, cost-effectiveness, and where relevant other aspects is a review of literature and databases. Together with policy recommendations, the study results are disseminated in a publicly available report. Furthermore, KCE started only very recently with so-called 'rapid assessments' on request of the Ministers of Health and Social Affairs or RIZIV/INAMI. These assessments are characterized by a shorter time frame than full HTAs.

Finally, an important recent development that is testimony of the growing interest in HTA should be highlighted here. KCE, in collaboration with RIZIV/INAMI, proposed a new procedure for the assessment of new and emerging technologies (medical implants and invasive devices) (Vinck et al., 2006).¹³ This procedure should make it possible for a new promising device to be quickly introduced and (provisionally) reimbursed, while at the same time a start is made with studies on the effectiveness and cost-effectiveness of the new product. As a part of the procedure, a full HTA will be jointly performed by KCE and RIZIV/INAMI. For devices for which evidence on the effectiveness and cost-effectiveness already exists, a quicker procedure to include it in the benefits schedule could be followed. So, after pharmaceuticals, the area of devices would be the next branch of medicine where HTA would get a significant place in Belgium's reimbursement procedure.

3.3.3 *Decision*

As said above, the King has final responsibility for decisions on the nomenclature regarding medical specialist care.¹⁴ These decisions are made after the advice of RIZIV/INAMI, as explained in Section 3.3.1, without the systematic use of HTA. The decision process may be characterized as 'a bilateral monopoly supervised by the central government', to quote Schokkaert and Van de Voorde: the insurance package is negotiated between representatives of the sickness funds and the health care providers, with the government having veto power. In addition, the authors observe that this complicated decision procedure leads to a rather long delay between medical innovation and inclusion in the insurance package (Schokkaert & Voorde, 2005). Information on the usual time frame for the completion of the different stages of the decision process is not available from the literature.

¹³ As another example of the growing role of HTA, we may mention the guidelines on pharmacoeconomic studies released by KCE in 2006 (Cleemput et al., 2006). In Belgium, information on the cost-effectiveness of pharmaceuticals constitutes an increasingly important element in the decision on reimbursement (since the institution of the Pharmaceuticals Reimbursement Committee ('Commissie Tegemoetkoming Geneesmiddelen') in 2002).

¹⁴ Modifications are recorded as changes to the Royal decree of 14th September 1984 to establish the nomenclature of the compulsory insurance for medical care and benefits ('Koninklijk besluit van 14 september 1984 tot vaststelling van de nomenclatuur van de geneeskundige verstrekkingen inzake verplichte verzekering voor geneeskundige verzorging en uitkeringen').

Any resulting decisions are laid down in a Royal Decree, which means that they are subject to Parliamentary control, and published in the Belgian Official Journal ('Belgisch Staatsblad'). A procedure may be included in the nomenclature only on certain conditions (for an initial time period for example). This has been laid down in the nomenclature for implants for example.¹⁵

3.3.4 *Outputs and implementation*

There are no official procedures to review decisions on the benefits to medical specialist care or to review the implementation and impact of such decisions. Yet, in another way, methods has been arranged to review the nomenclature. First, it may be noted here that each year representatives of the 'mutualities' and the health care providers negotiate the nomenclature. Second, and more importantly, at the Medical Technical Council there is a Committee for the Permanent Assessment of the Nomenclature ('Comité voor de permanente doorlichting van de nomenclatuur van de geneeskundige verstrekkingen'). It is one of this Committee's tasks to send out advices on, among other things, the modification and simplification of the nomenclature and on the introduction of new benefits (Art. 28 GVU). The Committee is composed of physicians nominated by both health care providers, health insurance associations, universities, the Minister, and RIZIV/INAMI. It makes advices when asked by the Medical Technical Council or by the Minister. As a matter of fact, it is not fully accurate therefore to speak of a permanent assessment.

Finally, it may be noted here that physicians are required to abstain from providing, at the expense of the compulsory health insurance, unnecessary or unnecessarily expensive benefits (Art. 73 GVU). The Medical Control Service is charged with the task to evaluate the unnecessary or unnecessarily expensive character of benefits, and to inform physicians in this respect (Art. 139 GVU). Health care providers who do not adhere to good medical practice may be put under monitoring and may be imposed a fine (Art. 141 GVU).

¹⁵ Art. 35, §3, category 5.

Chapter 4 Canada

This chapter describes the system for defining health care benefits for Canada in general and two Canadian provinces in particular, with regard to medical specialist care. The main characteristics of the health care system will be described, to give the context for the benefits. The main policy objectives and the legal framework of the Canadian and provincial systems related to defining the benefit package are described and related to using HTA to manage the health benefit package.

The Canada Health Act (CHA), a federal legislation, defines the ‘insured services’. These are essentially hospital and physician services. All other aspects of health care are left to the full discretion of each individual province/territory. CHA only covers arrangements for funding health care through federal government transfers to provincial governments. Federal government is responsible for implementing the funding arrangements that the CHA legislates. Health care itself is not ‘legislated’ by or under the Act. Only these intergovernmental funding policies are. The provision of the insured services in the CHA is a provincial matter. This results in differences in the health care delivery and benefits between the provinces or territories. The provinces of Alberta and Ontario will be considered here in more detail, to identify the provincial and federal processes that influence HTA, where these interrelate and where these act separately.

4.1 Organization of Canadian health care

4.1.1 *Characteristics of the health care system*

Canada is a federation of 10 provinces and 3 territories and has a population of 32.3 million (Statistics Canada). The federal government and each of the provinces and territories have their own jurisdictional parliament. Each of the jurisdictional areas has a Ministry of Health, responsible for health care for the jurisdiction. This includes (but is not exclusive) in macro terms the planning of hospital capacity, macro budgeting, public health, capital expenditure budgets for capital goods (like CT scanner and MRI), publicly funded drug plans, and physicians remuneration schedules.

The CHA defines the insured services of medically necessary care. The CHA was designed to ensure access to medically necessary care in relation to the protection, promotion and restoration of health of the Canadian population. The scope of the CHA is to provide medically necessary hospital care, both in patient and outpatient, and physician services for Canadians. Provision is exclusively a provincial responsibility. To be eligible for the federal transfer payments, the provinces must comply with the five basic principles of the CHA, namely: universality, comprehensiveness, accessibility, public administration, and portability.

- **Public administration:** All administration of provincial health insurance must be carried out by a public authority on a non-profit basis. They must be accountable to the province or territory, and their records and accounts are subject to audits. Ontario Hospital Insurance Plan (OHIP) and the

Alberta Health Care Insurance Plan (AHCIP) administer the health insurance, benefits and payments for Ontario and Alberta respectively. Each operates under their provincial health insurance act.

- **Comprehensiveness:** All medically necessary health services, including hospital inpatient and outpatient services, physicians' care and surgical dentistry, must be insured. Both provinces have defined the insured care and uninsured care (exclusions from the public insurance) in their respective health insurance acts. This is discussed in more detail in Sections 4.2.2 and 4.2.3.
- **Universality:** The insurance plan must include all residents on same terms and conditions.
- **Accessibility:** All insured persons must have reasonable access to health care facilities. In addition, all physicians, hospitals, etc, must be provided reasonable compensation for their services. The principles of universality and accessibility challenge health delivery. 21.6% of the population lives outside urban centers of 10,000 inhabitants or more, and some are very remote (Statistics Canada).
- **Portability:** A resident that moves to a different province or territory for study or work is covered for insured services by the insurance of the home province for 3 months (minimum waiting period to enlist in new province). Insurance coverage continues also during temporary absence from the home province. Insured services are to be paid at host province rates within Canada and home province rates outside Canada. This criteria is intended to enable receiving necessary services in relation to urgent or emergency services, not for elective insured services. The inter-provincial Agreement on Eligibility and Portability manages intra-provincial health care.

Each jurisdiction provides information about how each criterion is addressed in an annual report which is submitted to the Federal government. For example, Ontario's annual report 2004-05 details the benefit package under Comprehensiveness. Under universality, the eligibility criteria for provincial coverage are explained. Programs for service to remote areas, payment schedules for health care providers, availability of medical facilities and care are components of demonstrating the accessibility (Ontario Ministry of Health and Long Term Care).

The total health expenditure is divided between private spending and public funding (respectively 29.8% and 70.2% of total spending in 2003). Private spending is needed for medications given outside the hospital setting, and care that is not covered by the public insurance (for example, IVF and circumcision are de-listed care). There is a general perception that private insurance for publicly funded medically necessary care is prohibited by the CHA. This is not true. Six provinces, including Ontario and Alberta, prohibit such private insurance coverage as a means of trying to avoid losing the federal transfer payments. However, *Chaoulli v Quebec* (2005) is a recent case where the legislation of the province of Quebec to prohibit such private insurance was ruled invalid.¹⁶ Four provinces make no restrictions in this area.

¹⁶ *Chaoulli v. Quebec (Attorney General)*, 2005 SCC 35, (2005) 1 S.C.R. 791.

Federal transfer payments arrangements are a vehicle to motivate compliance with the CHA principles. The CHA tries to prevent initiatives such as extra billing by physicians and private suppliers of publicly funded health services by applying pressure through the transfer payment scheme. However, as the proportion of the transfer payment to the total provincial health care declines, the federal government leverage decreases. This proportion has started to increase again.

4.1.2 *National and provincial health care funding and Medicare*

Health care spending in Canada was CAD\$ 122.9 billion in 2003, or CAD\$3,883 per capita. OECD data reports US(ppp) \$3,001 health spending per capita that year, of which US(ppp) \$2,098 was publicly funded (Organisation for Economic Co-operation and Development, 2006a). Spending at national level was 10.1% of the GDP. Generally, spending in Canada compares favorably to the United States but looks less favorable in comparison to European publicly funded systems. Ontario's population was 12.5 million in 2005; Alberta's was 3.2 million (Statistics Canada). Alberta is a wealthy province: public funding is 72% compared with 67% in Ontario. A comparison of the spending levels is given in Table 4-1.

Table 4-1 Spending levels and sources for selected Canadian jurisdictions (Macro Spending 2003, CAD x 1000, (US\$ PPP))

Jurisdiction	Total spending	% GDP	Public spending	Private spending	Public share of total
Canada	122,959 (95,035)	10.1	86,267 (66,676)	36,692 (28,359)	70.2%
Ontario	49,706 (38,418)	10.1	33,370 (25,792)	16,337 (12,627)	67.1%
Alberta	12,664 (9,788)	7.4	9,120 (7,049)	3,543 (2,738)	72.0%

Source: (Canadian Institute for Health Information).

The Canadian healthcare system funding can be divided into a public and a private sector, accounting for 70% and 30% of the funding respectively (Table 4-1). The public sector includes health care spending by the government and government agencies. The expenditures are subdivided into four levels. The Provincial Government Sector includes health spending from provincial or territorial government funds, federal health transfers to the provinces or territories, and provincial government health transfers to municipal governments. The Federal Direct Sector refers to direct health care spending by the federal government in relation to health care services for special groups such as Aboriginals, the Armed Forces and veterans, as well as expenditures for health research, health promotion and health protection. The Municipal Government Sector expenditure includes health care spending by municipal governments for institutional services, public health, capital construction, and equipment. The municipalities in the provinces of Nova Scotia, Manitoba and British Columbia also fund some dental services. Social Security Funds are social insurance programs that are imposed and controlled by a government authority such as

health care spending by workers' compensation boards, and the drug insurance fund component of the Quebec Ministry of Health and Social Services drug subsidy program.

Private health insurance is common in Canada for products and services such as prescription drugs outside of hospital care, rehabilitative care, de-insured or un-insured care. Private spending grew at a rate of 3% per annum in the 1990s, from 25.9% in 1993 to 29.2% in 2001. The private share of prescribed drugs grew from 46.9% in 1992 to 53.7% in 2001 (Canadian Institute for Health Information, 2004). Supplementary health insurance is an important aspect of many collective agreements. Private free-standing clinics which offer privately funded care to avoid waiting lists are available, for example for cataract surgery in Alberta (Birch & Gafni, 2005).

4.1.3 *The medically necessary benefit package*

The basis for the publicly funded health care basket is medically necessary hospital and physicians care, as required by the CHA. Medical necessity has not been defined in the legislation, but governments at the federal and provincial levels have consistently interpreted this in terms of prevailing level of health or level of risk to health of an individual or group (Birch & Gafni, 2005). Each jurisdiction defines this package with local legislation for hospitalization benefits, physician benefits, and schedule of fees for services. Hospital care, including drugs, is an insured service. Drugs outside hospital care are not. Several provinces have drugs funding programs for seniors (age 65 and over), chronic or long term diseases, expensive drugs which are often associated with specific diagnosis (e.g., HIV). Public spending represents 46.3% of drug expenditure in 2001 (Ontario Ministry of Health and Long Term Care). Drugs must undergo a technocratic process, including HTA, for public funding. Public funding for new medical devices and services is strongly influenced by the negotiation of schedule of fees for services between the Minister of Health and the Medical Association for each jurisdiction. Input from HTA is a more recent development.

Each province must fulfill the CHA requirement for medically necessary care within their jurisdiction. In general there is a positive claim for medically necessary health care, which is defined by the medical benefits schedule of the province. Both Alberta and Ontario have an exclusion list which is included in the respective Health Insurance Acts. Fee schedule negotiations are a central aspect of defining the benefit package. These negotiations are structured within the Comprehensive Agreement for Ontario¹⁷ and within the Tri-lateral Master Agreement for Alberta. In both cases the negotiations determine, by virtue of agreement to list a service with a fee for service for the physician, whether a service or technology is included in the benefit package. By appearing on the schedule, all services with a fee are deemed medically necessary (Flood et al., 2004). Alberta also includes representation from the Regional Health Authorities in a tri-partite negotiating structure since the ratification of the Tri-Lateral Master Agreement in 2003 (Government of Alberta, 2004).

¹⁷ Comprehensive Agreements in Ontario started in 1994. After a short interruption they resumed in 1997 and were renewed in 2000 and 2004. A basic aspect is the negotiation of the fee schedules and services to be included in the

The benefit packages of the provinces are similar. The foundations in the CHA, with its universality and portability requirements, are important reasons for this. Nevertheless, differences may occur. The provinces typically provide services that are in addition to standard health coverage required by the CHA, such as physiotherapy, dental coverage, and prescription medicines. Provinces are not obligated to provide services not listed in the CHA, and provision of such services can be affected by changing government policies. The benefit packages of the provinces of Alberta and Ontario are elaborated on in the next section. The structure of the negotiation processes in these provinces is also discussed.

4.2 The Canada Health Act challenge: uniformity amongst diversity

The CHA sets the foundation for the health benefits for all Canadians. This section looks at organizations and policies in the Canadian system that are intended to monitor and enforce the CHA. At the national level, these include the CHA with its provision for Canada Health Transfer payment (CHT), the Canada Health Act Division (CHAD), and the Interprovincial Health Insurance Agreements Coordinating Committee (IHIACC). Efforts are also made to coordinate technology diffusion nationally. To illustrate procedures, this section discusses the benefit packages and procedures for their definition in Alberta and Ontario.

4.2.1 Organizations and policies that enforce the CHA

Compliance with the CHA is assessed by the federal CHAD, which is part of the Intergovernmental Affairs Directorate of the Health Policy Branch of Health Canada. CHAD monitors, assesses and investigates whether provincial health plans are in line with the CHA (Government of Canada, 2006). Non-compliance can be penalized by reductions in the CHT. Intervention by the CHAD typically concerns situations in which a service is offered privately whereas it is an insured service when performed within the hospital. In such cases 'extra billing' occurs for hospital services that are already covered. When these sorts of issues are verified as occurring and contravening the CHA, a penalty in the form of a reduction in the CHT payments will be implemented for the province. Examples have been the use of MRI and CT scans in the private sector. The leverage of the federal government in this area is declining with the gradual reduction in CHT in relation to the provincial health costs (Birch & Gafni, 2005).

A second organization involved in implementation of CHA is the IHIACC, which falls under the CHAD. It oversees the inter-provincial aspects of the CHA – who is eligible for what services and the allowable charges in a neighbouring province. IHIACC is responsible for developing the inter-provincial billing (that is reciprocal billing) of services in relation to the portability criteria of the CHA. There are implicit advantages to coverage and charges that are the same across the jurisdictions.

Finally, there is some coordination and management of the health care packages, including the technologies and pharmaceuticals to be made available. This is addressed formally through

publicly funded Medicare (Flood et al., 2004). The Comprehensive Agreement has been renegotiated for the period 2004-2008 (Ontario Medical Association & Ontario Ministry of Health and Long Term Care).

provincial/territorial/federal collaboration. The annual Conference of Ministers of Health is a formal vehicle to address policy and programming. It mainly concerns infusion of new technologies in the health care sector. To enhance consistent policies in different provinces, the Conference of Deputy Ministers in 2004 commissioned the HTA Strategy 1.0, which is being implemented by the Canadian Agency for Drugs and Technologies in Health (CADTH). Important programs in the strategy are Forum, Exchange and a range of HTA reports, which aim to facilitate sharing assessments and information amongst jurisdictional health policy makers. Through Forum and Exchange, policy makers are trying to access the HTA and policy analysis efforts of very diverse jurisdictional and other HTA organizations, to the benefit of (cost-)effective health care technologies. The structure has a large potential to capitalize and utilize efforts at the various jurisdictional levels – each jurisdiction does not have to repeat the evaluations.

4.2.2 Alberta

The provincial health insurance plan in Alberta is called the Alberta Health Care Insurance Plan (AHCIP). It provides coverage for medically necessary physician care (including all hospital care) and specific dental and oral surgical health care provided by dentists. The benefits and regulations follow from the Alberta Health Care Insurance Act.

The Alberta government provides some public funding for drugs through supplementary health plans. They offer three supplemental drugs plans, collectively referred to as the Non-Group Alberta Blue Cross plans. This includes ‘Coverage for seniors’ (65 and over), ‘Non-group coverage for Non-seniors’ (under 65 years of age), and the ‘Palliative Care Drug Coverage’. There are also plans that help low income and handicapped residents. The plan rules are dictated by policy more than by legislation. The Alberta Drug Benefits List describes the drugs covered by the Non-Group Alberta Blue Cross Supplementary health coverage plans. The supplemental drug plans do not cover drugs primarily used in hospitals or those covered by other special funding programs. Additional drug programs are run by the Regional Health Authorities, the Alberta Cancer Board and the Department for Disease Control and Prevention.¹⁸

Under the AHCIP, patients are also entitled to hospital care. The acute care benefits are defined in the Hospitalization Benefits Regulation (AR244/90). The Medical Benefits Regulation defines which medical services are insured. The Schedule of Medical Benefits specifies the fees for services of health care professionals. Requests for payment for unlisted services are assessed per case. Section 21 of the AHCIP defines what services are not considered to be insured services. Section 4(1) of the Hospitalization Benefits Regulation provides a list of uninsured hospital services (see Table 4-2). The AHCIP also partially covers some benefits that are in addition to the CHA requirements, for example chiropractic, podiatry and optometry, physicians services and benefits, primary care funding, on-call ruling and practitioners ICT.

Decisions of the Master Committee, which is made up of the Minister of Health, the chief of the Alberta Medical Association and an appointee from RHA CEOs, are by consensus and binding (Government of Alberta, 2004). The Physicians Services Committee in Alberta, part of the AMA, has a

¹⁸ See http://www.health.gov.ab.ca/ahcip/ahcip_list.html.

central role in assessing technical and evidence-based information for schedule reform. Once again, services and benefits on the schedule are publicly funded and deemed medically necessary (Archibald & Jeffs, 2004).

Table 4-2 Exclusions from Alberta publicly funded medical specialist care

Services that are not medically necessary
Cosmetic procedures, including cosmetic liposuction, breast enlargement
Surgical procedures for the alteration of appearance, unless prior approval of the Minister has been given
Acupuncture
Procedures associated with reproductive technologies such as gamete intra-fallopian transfer, IVF, ovarian stimulation and monitoring associated with assisted reproductive technology, sperm transfer
Chelation therapy which is not provided to a hospital inpatient for the purpose of treating lead poisoning
Eye surgery solely for eliminating the need for glasses or contact lenses
Oculo-visual examinations for residents aged 19-64

Source: <http://www.health.gov.ab.ca/professionals/somb.html>. Document: Medical Governing Rules List June 2006.

4.2.3 *Ontario*

In Ontario, health care insurance is publicly administered by the Ontario Hospital Insurance Plan (OHIP), which has been established under the Ontario Health Care Insurance Act. Ontario drug costs for 2004 were CAD 7.4 billion, 43% paid by Ontario Drugs Benefits, 20% out of pocket, and 35% by private insurance (Ontario Ministry of Health and Long Term Care). OHIP does not pay for prescription drugs. Supplementary insurance (either as employee benefits or individual insurance) helps pay for these. However, certain population groups are eligible for MOHLTC programs, which provide drugs at low cost. The Ontario Drug Benefits Program is for seniors (over 65 years of age), recipients of social assistance, and long-term care patients. The Trillium Drug Program is for families where drug costs are high relative to the income. The Special Drugs Program pays drug costs for treatment of certain diseases (HIV, schizophrenia).

The publicly funded medical specialist benefits are defined in the Health Insurance Act (R.R.O. 1990, Reg. 552). Article 7 covers inpatient care and includes necessary nursing services, diagnostic procedures (laboratory, radiologic and other diagnostics), medications and operating theatre, obstetrical delivery room and anesthetic facilities, plus accommodation. Article 8 is for outpatient care and includes diagnostic procedures (laboratory, radiologic and other diagnostics) as required by a treating physician plus a list of chronic long-term conditions that can be treated at home or on an outpatient basis, prescribed by a physician of the hospital. Exclusions are listed in Article 24 (Table 4-3). Under subsection 37.1(1) of Regulation 552 of the Health Insurance Act, a service provided by a physician in Ontario is an insured service if it is medically necessary, contained in the Schedule of Benefits, and rendered in such circumstances or under such conditions as outlined in the Schedule of Benefits. The Schedule of Benefits for Physicians Services under the Health Insurance Act is published by the MOHLTC (Ontario Ministry of Health and Long Term Care).

Table 4-3 Exclusions from Ontario publicly funded benefits

Treatment that is considered to be experimental within Ontario (Art 24,18)
Destruction of hair follicles
Cosmetic services, solely for purposes of altering or restoring appearance
Circumcision (unless medically necessary)
Reversal of sterilisation
IVF, with exceptions for some indications
Sex reassignment surgery, unless meeting specific criteria
Acupuncture

Source: http://www.e-laws.gov.on.ca/DBLaws/Regs/English/900552_e.htm#BK9.

The benefits package in Ontario is strongly influenced by the negotiations between the MOHLTC and the Ontario Medical Association (OMA). These negotiations are done within the Comprehensive Agreement (Ontario Medical Association & Ontario Ministry of Health and Long Term Care). The Physicians Services Committee (PSC), composed of 5 members each from the OMA and the MOHLTC, negotiates the physicians' services, driven by the fee negotiations. The PSC decides how to allocate funding, which services' fees will go up or down and which services are added or deleted. The Central Tariffs Committee (CTC), an OMA body, provides the advice for changes in the schedules to the MOHLTC once per year. This CTC is comprised entirely of physicians or physician economists who solicit information and review research to support their advice. In short, the Comprehensive Agreement says how much funds are available. The funds are allocated to services by the PSC which also considers the advice of CTC. The negotiations and minutes are closed to the public (Archibald & Jeffs, 2004; Flood et al., 2004).

The addition or de-listing of services on the schedule is a very sensitive subject. The provincial governments are seen as having a strong role in determining the agenda for this. The CADTH, its committees and the Liaison Officers, the provincial Medical Directors and provincial government funded HTA programs may also be involved. The CADTH can provide input to the Ministries through its reporting channel to the Conference of Deputy Ministers of Health. The DSAC branch of the CADTH has an advisory role to the Board of CADTH regarding new technologies and technology scanning. The Medical Directors of the provinces confer with their colleagues twice per year to discuss developments in technologies, health care and the insured package. The exact impact of this group on the medical package is unclear but may be significant. Awad et al. found that the meetings and decisions were virtually not accessible to the public, minutes are protected by privacy legislation and reporting to the MOHLTC is informal at best (Awad et al., 2004). In addition each of the provinces has HTA organizations closely linked to its MOH (OHTAC with its MAS and the HTA unit of the Alberta Heritage Foundation for Medical Research AHFMR). The processes or exact links of how these HTA bodies inform the MOH in particular and the stakeholders in general varies and will be considered more closely in Section 4.3.

4.3 Definition of entitlement to medical specialist care

HTA has been an important part of the national systems for resource allocation for drugs in Canada since 1989. Through the Canadian Drug Review and its predecessors, the reimbursement policy has been based

on technology assessment for all new drugs and the assessment and decisions procedures have been clearly defined. HTAs for medical technologies and services are far less technocratic, but there have been developments at the national and provincial levels. The system for medical technology and services is reviewed below in more detail. From the perspective of the policy procedure and governance it shows that the Ministry of Health is closely involved both in the top of the organizations and in financing HTA. The assessment methods used vary and include for example cost-effectiveness, costs analysis, and literature synthesis. The HTA organizations also use different sorts of recommendations, reflecting differences in their mandates.

4.3.1 Policy procedures and governance

Key actor in the system for health care policy decisions is the Canadian Agency for Drugs and Technologies in Health (CADTH). The CADTH provides Canada's federal, provincial and territorial health care decision makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies. For this purpose, CADTH is home of the Common Drug Review (CDR), the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS), and is the national coordinating body for HTA. CADTH publishes different types of reports: HTA Reports, Health Technology Information Service, Issues in Emerging Health Technologies and Health Technology Overviews. The members of Conference of Deputy Ministers of Health, to whom they report and from which the CADTH receives its annual budget, appoint its board. The budget for 2006 is CAD 21.3 million.

CADTH's vision is 'to facilitate the appropriate and effective utilization of drugs and health technologies within the health care systems across Canada'. It should provide timely, relevant evidence-based information to inform decision makers and decision-making (Canadian Agency for Drugs and Technologies in Health, 2006a). It is responsible for development of expertise in HTA and for the coordination and dissemination of HTA information. CADTH manages the HTA for new drug products via the Canadian Drugs Review. The health technologies and services review was added to the mandate of the CADTH in 2000 with the creation of the Devices and Services Assessment Committee (DSAC).

The CADTH is assisted by several advisory committees who report to the board of directors. Examples are DSAC and the Scientific Advisory Committee (SAP). The DSAC advises the CADTH Board on issues and trends related to medical devices, health systems, and health services in Canada. It also recommends priorities for device and health systems assessments. The Committee members (maximum of 13) are appointed by the Board of Directors and represent the participating provincial and territorial ministries of health and Health Canada. Funding is also from CADTH. The SAP areas of expertise include clinical methodology, economics, statistics, population health, pharmacoepidemiology and others. The panel provides credible, independent, and expert scientific advice to the Board of Directors. It reviews all project proposals and helps define their scope, and reviews all reports and makes recommendations for final approval. Terms of reference for the different advisory committees are published on the CADTH website.

Topic suggestions are received from Canadian policy makers, medical directors, managers, health care providers, industry, health care professional associations, and the public or through the Horizon Scanning Program. Proposed topics are filtered and prioritized with assistance from the CADTH Advisory Committee on Pharmaceuticals and the Devices and Systems Advisory Committee. Refinement of the topic prioritization process is planned for 2006/7. The reason is that CADTH reports are increasingly relevant to the different jurisdictions and have increasing policy impact. CADTH will expand its services accordingly towards policy options and recommendations, which also requires that the topic identification process becomes more transparent. For this purpose, the CADTH is working on a Topic Identification, Prioritization and Refinement Process document, based on a framework with six key criteria: disease burden, alternatives, clinical impact, economic impact, budget impact, and available evidence. Each criterion has been defined and scores are assigned for the level of fulfilling the criterion. The topics are filtered into 4 categories for HTA action namely: consider for a full HTA, refer to the Horizon Scanning Program (Canadian Emerging Technologies Assessment Program), refer to the Health Technology Inquiry Service (HTIS), or eliminate (that is, topics defined as not being within the scope of HTA). A preliminary HTA is done for the full HTA topics, using the criteria disease burden, clinical impact, budget impact, economic implications and (existing) evidence. Additional information may be provided by the Advisory Committee or jurisdiction CADTH Liaison Officers. The resulting one page report is used for final prioritizing by the Advisory Committee and the Director of HTA Development. Decisions must be by consensus. Projects are assigned to either internal CADTH, external resources or a Request for proposals (RFP). RFPs are posted on the CADTH website. See Table 4-4 for an indication of current activities.

Table 4-4 List of upcoming and completed HTA projects of CADTH, and RFPs

Completed list examples	Type of report (if completed)
Intra-articular Hyaluronic Acid (Viscosupplementation) for Knee Osteoarthritis	Issues in emerging Health Technology
Hot Techniques for Tonsillectomy	Issues in emerging Health Technology
Open MRI Scanners	Issues in emerging Health Technology
Upcoming HTA Projects	
Minimally Invasive Hip Arthroplasty – assessment of implications of adoption	
Antenatal Screening – assessment of antenatal screening tests	
Tele-health to extend physician services	
Para-physician service for anaesthetic care – assessment of services staffed with non-physician personnel trained to deliver anaesthetic care	
RFPs coming within 3 months	
Technologies for aiding reduction of medication errors in hospitals	
Hyperbaric oxygen therapy for the treatment of diabetic leg ulcers: an economic analysis	
Implantable cardiac defibrillators for primary prevention of sudden cardiac death	

Once an HTA topic has been selected, and specific research questions have been defined, a multidisciplinary team of researchers is assembled to collect, synthesize, and analyze available evidence on the technology. The team may comprise internal staff, externally contracted individuals, or a mixture of both, depending on the required expertise.

The provinces Alberta and Ontario also fund HTA. The HTA Unit in Alberta was started within the provincial health department in 1993. The scope was provincial, in the areas of policy development and decision making within their healthcare system (Roehrig & Kargus, 2003) with an emphasis on clinical effectiveness. The HTA unit was moved to the Alberta Heritage Foundation for Medical Research (AHFMR) in 1995. The AHFMR was established by the Government of Alberta in 1980, under the Alberta Heritage Foundation for Medical Research Act (RSA 1980 cA-26) and funded with an endowment of \$500 million. An additional \$500 million was granted in 2005. The Universities of Calgary and Alberta, plus third parties also have interests in the AHFMR. AHFMR is a corporation. Its nine member board of trustees has a strong representation from the provincial government: including one each from the College of physicians and surgeons of the Province of Alberta, the Governors of University of Calgary and Edmonton, the board of trustees of the MSI foundation and 5 other appointed by the Lieutenant Governor in Council. The HTA Unit was moved to the Institute of Health Economics in 2006. The HTA group reports to the people of Alberta through the Minister of Innovation and Science and presents an annual report to the Legislature. Menon found that health institutions and authorities in Alberta were the audience for 39% of the reports of the HTA unit (Menon, 2000).

The most relevant HTA body in Ontario is the Ontario Health Technology Assessment Commission (OHTAC) with its Medical Advisory Secretariat (MAS). The MOLHTC appoints the 2 co-chairpersons of the OHTAC and (minimum) 12 committee members and provides budget. OHTAC provides advice to the MOHLTC and its senior management, government agencies, health care providers and practitioners using systematic evidence-based technology assessment since 2002. It examines health technologies within the context of existing clinical practise and has a special interest in cancer treatment and new technologies. It takes into account economic and human resource use, regulatory and ethical considerations The OHTAC has a broad mandate to help ensure that evidence is made available to decide which technologies (new and those which are currently deemed useful but without existing evidence) should be implemented and/or diffused further into the health care system. The MAS provides evidence-based health technology policy analysis and evidence-based advice on the coordinated uptake of new health technologies and health services in Ontario for the OHTAC. Its goal is to maximize equal access and (cost-)effective health technologies. MAS delivers its report to the OHTAC.

The Institute for Clinical Evaluative Sciences, an independent non-profit organization, is a joint venture established by the Ontario provincial government and the OMA in 1992. It was designed to provide information to support decision making by the Joint Management Committee of the MOHLTC and the OMA in the early 1990s. Today its mandate is to conduct research on broad range of issues to improve support health care policy development and health care delivery. The Center for Health

Economics and Policy Analysis (CHEPA) was set up in 1992 by the University of McMaster, the Ontario provincial government and third parties and focuses on policy research.

The CADTH has the responsibility to coordinate HTA nationally. The other HTA organizations named are oriented toward the provincial mandates and needs, and may be contracted by CADTH. Their conclusions in HTA, and where available, recommendations, may be used by other stakeholders in developing the health policies and the benefit package. This independent, provincial orientation fits with the provincial responsibility for health care and the source of funding for the HTA organizations, namely the province.

CADTH has a national role in assessing both pharmaceutical and non-pharmaceutical technologies. The non-pharmaceuticals in scope for the CADTH are very broad: all medical technologies, treatments systems and medical delivery systems, both new and other phases of the technology lifecycle. The activities of CADTH are guided by their five year strategic business plan, which was approved by the Conference of Deputy Ministers of Health (Canadian Coordinating Office for Health Technology Assessment, 2005). A key objective is to provide impartial evidence-based information to support informed decisions on drugs and health technology. The HTAs of CADTH include recommendations as well as guidance on use and implementation for both drugs and technologies.

The decision to adopt and implement a technology is a jurisdiction responsibility. The Provincial Ministers of Health and the Medical Associations decisions are guided by the Comprehensive (Ontario) and Tri-lateral Master Agreements (Alberta) for the benefit package. The practical implementation will also be guided by health budgets, the investment required, the acceptance of the change by the medical field, and other factors that influence rates of diffusion of technology.

The performance of CADTH has been reviewed regularly. One reason is that financing is population based. Provinces such as Ontario with 11.3 million residents pay 32% of the costs for the same one position representation and full access to the information as a small province such as Prince Edward Island with 140,000 residents. CADTH reports annually to the Conference of the Deputy Ministers and publishes an annual report. The recent HTA Strategy 1.0 of CADTH was evaluated after one year as agreed. This sort of research¹⁹ on the HTA reports is critical lacking in clear recommendations and the clarity needed to truly inform decisions. The CADTH is praised for its role in building awareness and coordination (minimal duplication) of HTA in Canada. In preparation for the HTA Strategy development, NICE evaluated the processes of CADTH. There is also an independent evaluation of the Liaison Officers program ongoing (Canadian Agency for Drugs and Technologies in Health, 2006c). To our knowledge, these evaluations do not measure the impact of CADTH reports on technology decisions.

4.3.2 Assessment

The CADTH Guidelines for Authors of HTA reports provides a flowchart of the HTA report process (Figure 4-1) (Canadian Agency for Drugs and Technologies in Health, 2003). Topics selected for a full

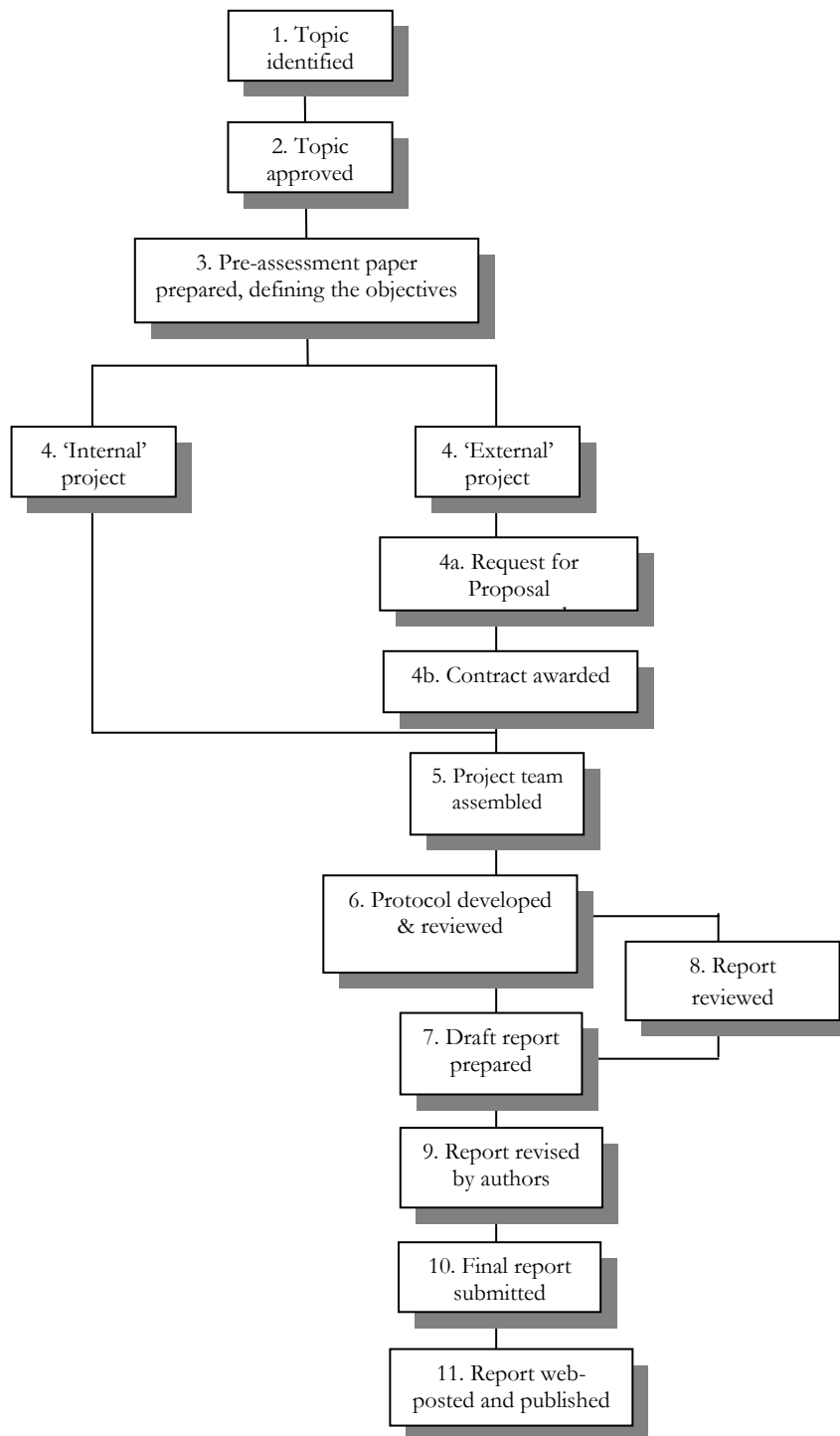
¹⁹ Other examples are (Menon, 2000) and (Lehoux et al., 2005).

HTA are assigned to a project group. A project research proposal is made and approved by the Scientific Advisory Committee (SAP). SAP is a non jurisdictional committee of CADTH, closely involved the HTA process. It provides advice in the areas of scientific structure, content and research. Consultation with stakeholders such as manufacturers, practitioners or sponsors will occur when they can provide research or data relevant for the HTA and appears to be at the initiative of the HTA project group. Most of the data for the review comes from systematic literature reviews by the project group. Stakeholders may also submit a technology for review – but their influence on the prioritization is unclear. The SAP remains involved with the projects as a quality control and source of scientific advice throughout the project. All reports are peer reviewed by at least 2 external experts and reviewed internally by CADTH before being published.

The HTA may be done in-house or contracted out, depending on availability of expertise and capacity. Requests for proposals are posted for external projects. About 20-25% of the projects are contracted out. CADTH has a large scientific staff from various areas of expertise (e.g., epidemiology, statistics, health economics) that perform the assessments. CADTH recruits staff publicly and contract consultants when needed. It is also developing a network of HTA partners through the Partners in Health Technology Assessment Program. Qualified parties are non-profit organizations, experienced in HTA with fully qualified expertise in library sciences, epidemiology or pharmcoepidemiology, biostatistics, clinical practice, economics, HTA methodologies, and health care policy (Canadian Agency for Drugs and Technologies in Health, 2006b). They can be contracted easily for external projects. Project teams will include several researchers, an information specialist, and at least one clinical expert. Team members become the authors and must meet the author requirements of CADTH including the conflict of interest declaration in which their personal affiliation to the stakeholders of the topic are expressed (part of CADTH Guidelines for Authors).

The research methodology may vary slightly depending on the type of study. However common components will include background, objectives, proposed methods (study selection criteria, data extraction and data analysis methods and forms), a detailed search strategy, and handling of uncertainty. The research protocol is approved by the SAP and is included in the report. The CADTH Guidelines for authors of HTA reports states the report requirements and provides a report template. The draft report is reviewed by experts in the area and may include clinicians, methodologists and industry. This transparency and structure, plus peer review and review by SAP all help ensure the accountability and replicability of the HTA. CADTH further recommends analyzing the available evidence using techniques that are well recognized within fourth hurdle systems such as Cochrane Collaboration's methods for systematic reviews and meta-analysis for ranking the evidence and its own economic evaluations guidelines. To our knowledge, there are no specific requirements for standards of evidence.

Figure 4-1 CCOHTA HTA report process



CADTH takes final responsibility for the reports generated within their organization. They make them easily accessible, in various formats, web based and hard copy. For example the full report, formatted in line with CADTH Guidelines, and a compact version with conclusions are published on the website. The full report with all appendixes may be ordered online. The report has an executive summary and main headings such as objectives, systematic (literature) review, economic analysis, health service impact and

conclusions. Economic information is provided in terms of costs to the health care system and cost utility in terms of cost per QALY. The conclusions for the report include the clinical efficacy/effectiveness findings, the economic findings, the appropriate uses of the technology (e.g., population sub-groups), implications for the Canadian health care system and for decision makers (e.g., how the research changes current understanding/practice and what the effects may be in terms of human resources, change in gold standard, compatibility with current technology) and limitations of the assessment or evidence.

Consultation about the content of the report is possible when the draft copy is circulated to experts in the technology area (including industry), sponsors and peer reviewers. Feedback is collected and authors must document how they deal with the substantial remarks submitted by reviewers (some are likely to be stakeholders). Uncertainty is addressed in study limitations and knowledge gaps. Decision-making bodies are not directly involved in developing the report but may have questions about it.

CADTH has seen its role as informing policy and decisions. As such it is very careful to publish recommendations that are not normative or directive. The decision is up to the jurisdiction or institution. In line with this objective, the guidelines for authors of 2001 state that only conclusions from the evidence gathered and analyzed within the report should be stated. It was not within CCOHTA's (CADTH predecessor) mandate to make recommendations. In a review of 10 years of Canadian HTA reports, Lehoux et al. (referring to Menon and Tofler) noted that only 16% of published results clearly stated the research question and 'only a few assessments offered clearly stated recommendations for decision makers' and that HTA agencies try to balance between normative recommendations and conclusive statements (Lehoux et al., 2005). This is increasingly perceived as a shortcoming of assessment reports. Therefore, CADTH has added goals and functions aimed at dissemination and use of HTA information in decision making in its HTA Strategy 1.0 in 2004. They introduced new tools such as Forum and Exchange HTA more responsive and accessible to the needs of decision makers (Health Technology Assessment Task Group, 2004).²⁰

At the provincial level, OHTAC is responsible for advice to the MOHLTC and the health care system about the introduction and diffusion of new technologies or the removal of obsolete technologies. The Medical Advisory Secretariat (MAS) has the mandate to provide evidence-based policy advice for the MOHLTC for the coordinated uptake of technologies (exclusive drugs). The MAS reports to the OHTAC about emerging and existing health technologies and health services based on systematic reviews of scientific evidence and consultation with experts in the medical community. It takes a very broad approach by considering the health benefits, safety, effectiveness and cost-effectiveness and diffusion of the technology. It also considers ethical, social, regulatory, resource, and legal aspects. The MAS may initiate field evaluations for promising health technologies for which it feels there is insufficient evidence. Based on the MAS report, OHTAC has four recommendation pathways: implementation or enhanced access; technology is recommended for field evaluation; specific safety overviews recommended or uptake of the technology is not recommended. When the OHTAC recommendation to the MOHLTC is to add a

²⁰ See http://www.health.gov.on.ca/english/providers/program/mas/mas_mn.html.

given service to the insured package, it advises the MOHLTC to make the information available to the PSC, with a request to develop fees for the service (Ontario Ministry of Health and Long Term Care). The OHTAC has brought out 46 recommendations between its inception in October 2003 and June 2006.

Timeliness has been cited as an issue for HTA services in a comparative analysis (Roehrig & Kargus, 2003; Health Technology Assessment Task Group, 2004). As HTA generally takes a year or more, quick reviews and response time are difficult. The result is that good new technologies may be delayed in implementation and conversely, the providers may not wait for evidence-based advice before implementation. CADTH has addressed timeliness with different HTA products. The Health Technology Information Service reports in 24-30 days. The Canadian Emerging Technology Assessment Program does rapid reviews and reports within 16 weeks. Full HTAs take 4 to 12 months (Sanders, 2006).

4.3.3 Decision

Once published, use of the information or the implementation is the decision of the jurisdictions. Sections 4.2.2 and 4.2.3 state that decisions whether a technology, health system, or service, is added to the benefit package are strongly influenced by negotiations under the Master Agreements. In Ontario, the MOH and the OMA negotiate under the agreement running from 2004-2008. Influential bodies in this process are the PSC and the CTC and the provincial HTA organizations. In Alberta, the MOH, the Alberta Medical Association plus the Regional Health Authority must reach a consensus within the Tri-lateral Master Agreement. The outcomes may appear as changes to the fee schedules but insight into the motivation is lacking. The ground for decisions remains usually implicit. The Tri-lateral Master Agreement describes where and by whom the decision can be made but the decision process is not made transparent.

A positive HTA report from CADTH is only one of the factors that impact the decision to adopt a new technology (Battista et al., 1994; Birch & Gafni, 2005). The MOH of the provinces have priorities for their jurisdiction which may not parallel the topics prioritized by CADTH. Provincial health care budgets or system resources may not be sufficient to enable providing a new service. For example, Ontario's framework agreement calls for spending cuts. The medical associations also have priorities of its members to consider. New services or technologies seem low on the negotiation agenda: first the existing schedule and fees changes, volume agreements. New services and technologies are planned from the remaining funds (resulting in slow development in the schedule – new items added slowly and the status quo maintained). The negotiation meetings, the resulting minutes, the decisions and the related rationale are not open to the public. Therefore opportunities for other stakeholders are not transparent.

4.3.4 Outputs and implementation

Implementation is done within the jurisdiction. The Medical Associations communicate the changes in the benefits and fee schedules within its professional groups on the AMA and OMA websites and via

bulletins. The schedules of benefits are published online.²¹ Benefit changes may involve modifying or making treatment protocols. The Alberta Medical Association has a strong role in the Clinical Practise Guidelines Program,²² which incorporates evidence-based information into guidelines. Ontario's OMA and MOHTC fulfill part of the Comprehensive Agreement by developing and updating guidelines through the Guidelines Advisory Committee.²³ The jurisdiction Liaison Officer from CADTH has a facilitating role for basing the guidelines on the HTAs. Alberta has strong regional authority structure. Since they are party to the Tri-lateral agreement process, they have a direct role in timing and method of implementation. In Ontario, a conditional recommendation may receive temporary funding for a field trial (for example PET financing with 5 clinical trial registries) (Vinck et al., 2006). The budgeting structure of the health system and pressure for cost cutting are limiting factors to implementation particularly in Ontario. The Master Agreement allows for a more open-ended financing in Alberta.

The appeal process has not been found for either province. However, there are some examples of court cases resulting from changes to the benefit package. In Ontario, the decision to restrict reimbursement of audiologists was appealed in the media and the courts (Flood et al., 2004).²⁴ The decision was strongly motivated by cost containment rather than HTA. The audiologists were not party to the decision.

The decision making process regarding benefits remains implicit, and occurs at the provincial level. In their decisions, however, provinces have to act in accordance with the CHA. If consumers feel that is not the case, they can go to court. Such situations may for example occur when provinces have decided differently on benefits. Existing policies, however, aim to avoid such disputes. For that purpose, a 'dispute avoidance and resolution process' is defined that commits governments to continue to actively participate in ad-hoc federal, provincial and territorial committees on CHA issues. As all governments are committed to respecting the principles of the CHA, the Government of Canada is confident that, together, all issues of concern can be resolved. If not, the Minister of Health for Canada has the final authority to interpret and enforce the CHA. The CHA Dispute Avoidance and Resolution process is considered to be a significant achievement for authorities at different policy makers, and there is confidence that it improves fairness, transparency, and timeliness of dispute resolving.²⁵

Reappraisal of decisions may be triggered by HTA prioritization in CADTH or by a change in the 'standard of care' whereby the existing technology becomes one of the comparators in an HTA. There has been no structured evaluation found of the impact of the HTAs produced by CADTH for Ontario or Alberta.

²¹ For Alberta, see <http://www.health.gov.ab.ca/professionals/allied.html> and for Ontario see http://www.health.gov.on.ca/english/providers/program/ohip/sob/physsserv/physsserv_mn.html.

²² See <http://www.albertadoctors.org/bcm/ama/ama-website.nsf>.

²³ See <http://www.gacguidelines.ca>.

²⁴ Archibald and Jeffs refer to the case *Shulman v. College of Audiologists and Speech Language Pathologists of Ontario* 2001 O.J. No. 5057 (Archibald & Jeffs, 2004).

²⁵ See http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2002/2002_care-soinsbk3_e.html.

Chapter 5 France

5.1 Organizational structure of French health care

5.1.1 *Characteristics of the health care system*

France has a publicly funded social health insurance system that covers the entire population of about 60 million people. The system has covered the entire French population since January 2000, when the Universal Health Coverage Act ('Couverture Maladie Universelle') came into force. This act also made sure that those below a certain income level were entitled to free coverage. Furthermore, it replaced a system of wage-related contribution with income-related contributions (tax base). The broader picture of the French health care insurance system today is that the state is responsible for the global budget allocated to health care and breaking it down to the various sectors. The state also defines the policy regarding health insurance and decides on their finance (conditions and levels of social contributions), and is in charge of planning the provision of care. The health insurers negotiate with providers to set tariffs to ensure that the health care system operates at a breakeven point (Sandier et al., 2004).

The publicly funded system can be characterized as a system that offers freedom of choice and unrestricted access for patients and freedom of practice for professionals. Services provided in in-patient or out-patient acute care are financed through a payment-per-case system. This is based on a DRG-type classification of homogeneous stays ('groupes homogènes de séjours'). This system uses the 'classification commune des actes médicaux' (CCAM) as the basic classification for medical procedures, which is a list of reimbursable goods. Care is provided by both public and private health care professionals, including private for-profit hospitals. Doctors can choose if they want to be public or private doctors, and patients can choose by whom they wish to be treated. Private doctors have different tax rules. Patients consuming private care, may be confronted with co-payments if doctors charge higher tariffs than the reimbursed ones. On the downside, the French health care system is operationally complex. This motivated reforms that are still ongoing. Especially the difficulties in the joint management of the system by insurance funds and the state, with the inherent structural difficulties, have been reconsidered, as discussed in Section 5.2.

A characteristic of the French health insurance system is that it offers universal coverage, and that there is strong state intervention in the insurance market. The public health insurance program was set up in 1945. Initially, the right to health insurance was linked to professional activity, on basis of legislation that created a compulsory insurance system for people in industry and business whose income fell below a certain level. Coverage was gradually expanded over the years to include all legal residents. The Universal Health Coverage Act of 1999 finally opened up the right to statutory health insurance on the basis of residence in France. The aim in the development of this social health insurance system was to create a single system guaranteeing uniform rights for all. There are three main health insurance schemes covering 95% of the population. These schemes are the general health insurance scheme ('régime général'), which covers employees in commerce and industry and their families (about 86% of the population), the

agricultural scheme (about 7% of the population), and the national insurance fund for self-employed non-agricultural workers (about 5% of the population). Differences between the health insurance funds have been reduced. For example, the benefits that are covered by these three schemes and the reimbursement rates are identical. Also the differences between public and private health insurance were reduced.

Another characteristic is the strong state intervention. The main problem of the French insurance system is its complexity and the lack of incentives to operate it efficiently. This can best be understood against the historical background of the French insurance system. Most health insurance funds today are private entities, which operate under the State's supervision. The health insurance funds are jointly managed by social partners (employer and employee federations). When the system covered more and more people, the legitimacy of social partner involvement in the management of health insurance funds became a topic of concern. As a result, the roles of the different actors have frequently been redefined; but in this process, compromises have been made, due to opposition of groups who benefited from insurance coverage that had more favorable terms and who succeeded in maintaining their particular systems (Sandier et al., 2004). For example, attempts to replace social partners by elected boards were unsuccessful. Potential negative effects were typically counteracted with increasing levels of state intervention. Over time, the state took responsibility for the financial and operational management of the system. This also reflects their increasing concern for cost control in the expanding health care system. The distribution of power between the state and the funds, however, did not always change in the most coherent manner. With no say in financial aspects of insurance, the management responsibilities of health insurance funds were limited and incentives to operate the system in an efficient way were lacking. As the system offered fee-for-service payment and unrestricted freedom of choice to consumers (e.g., there was no gatekeeper for specialist care), cost control policies were difficult to implement. Consumer responsibility was promoted through cost-sharing. However, near universal coverage of complementary insurance limited effects of this measure. The latest reforms attempt to make the system more coherent and more efficiently managed. We will discuss these reforms in more detail in Section 5.2.

5.1.2 Health care funding

In France, the total health care expenditures are estimated to consume about 10.5% of GDP (OECD, 2004). The state decides on the health care budget and on its distribution over health care sectors, and where public hospitals are concerned, over regions. The public health insurance system covers about 75% of these health expenditures (Bellanger et al., 2005b). Patients are responsible for paying the balance. For nearly everyone this is done through private insurance. Unlike in other countries, private insurance in France is not used to jump public sector queues or to obtain access to elite providers. Rather, it provides reimbursement for co-payments required by the public system and coverage for medical goods and services that are poorly covered by the public system, most notably dental and optical care (Buchmueller & Couffinhal, 2004).

In addition there exists a public supplementary insurance program for those whose income is below a certain threshold. This insurance covers all public co-payments at the tariffs set in the schedule

for about 6% of the population. Health insurance may not charge more than the set tariffs for this group of users, so that essentially care is free of charge for the poor. The co-payments have increased over time, as to give patients an incentive to consume less care. However, since 85% of the population has supplementary insurance, they have maximum choice and feel no encouragement to limit consumption. Problem thereby is that the largest part of the costs of moral hazard are borne by the public system.

The government responded to this development by promoting health care evaluations and setting up a process to gain more control over supply. In France, basic medical care is often privately delivered. Hospital care may be delivered in public or private hospitals. It is traditionally financed on a per case basis. All various types of goods and services reimbursed by statutory health insurance have their own particular negotiated rate. This rate serves as the basis for calculating the total amount reimbursed to the patient, even if the prices actually charged in practice are higher than the official standard rate in question (extra-billing). The extra-billing basically concerns the payment of certain health professionals, dental repair work, and spectacles and other optical appliances, and accounted for an expenditure of about 8.6 billion euros in 2003 (Haut Conseil de l'assurance maladie, unpublished data). This extra-billing represents 14.2% of specialist total fees, 5.6% of those of GPs and 47.9% of those of dentists (Bellanger et al., 2005b). For this purpose, in 2004 a DRG-like system was introduced in hospitals. The same lists of medical procedures applies to private and public hospitals. The system offers great freedom of choice to individual patients, who can choose their doctor or clinic and there is no gate keeping process for access to a medical specialist. Since 1 July 2005, the insured however are obliged to choose a main physician ('médecin traitant') who acts as a gatekeeper. Freedom of choice was left in tact, but higher charges were introduced for persons who choose to consult a specialist directly without being referred by their gatekeeper. To get a medical service reimbursed, a prescription is required which serves as confirmation of the service being medically appropriate. For some types of treatment prior authorization by the health insurer is required.

To control health care expenditures, emphasis was placed on price control through negotiations with health care professionals, and through national regulation of prices of reimbursable drugs. These measures seem to have been effective (prices in France have been relatively low), however consumption has always been relatively high. The fee-for-service system was therefore extended with regulation through restrictive budgets. If anticipated care volumes were crossed, lower refundable charges could be applied. Doctors were fiercely opposed to this system, and apparently their position in the negotiations was quite strong, because in practice, refunds by doctors have never occurred.

5.1.3 Health care benefits

In France, the general conditions of the reimbursement system are established by law. The whole range of goods and services reimbursed by the statutory scheme are specified in Article L.321-1 of the Social Security Code. In the various health care sectors, these positive lists may be itemized to a greater or lesser decree. Decision-making power is left to the sickness funds and physicians. Before the reforms, the minister had to enforce positive reimbursement decisions so that in practice most decisions were left to the Ministry of Health under advice of independent assessment agencies (Gibis et al., 2004). Decisions

about additions to the benefit package were published in a decree. In the reforms, responsibility for deciding on the benefit package has been partially moved to the health insurance funds, as discussed in Section 5.3.

5.2 Health care reforms

5.2.1 *Institutional context*

Before 2004 the French system was characterized by duality between centralized and decentralized aspects. The government's main task was to exert control over the relationship between insurers, providers, and patients. The ministries involved (Social Affairs and Health) operated a top-down approach, typically dealing with situations by setting up public institutions with competence in the required area that report to and advise the ministries (Orvain et al., 2004). Well-known agencies were for example ANAES (Agency for Accreditation and Evaluation in Health Care), the Transparency Committee, the French Drug Agency (AFSSAPS). ANAES considers effectiveness and safety of procedures and conditions under which they should be performed, AFSSAPS grants market authority, and the Transparency Committee evaluates therapeutic value of new products compared to the existing range of products. In 2004 the minister of health in France proposed reforms. As part of these reforms the government has created the High Authority on Health ("Haute Autorité de Santé") whose task is to evaluate medical services and devices and provide recommendations on reimbursement. HAS was created to bring together all expertise.

The installment of the HAS marked the moment of a strategic reorientation in French health care. In France, the health care system was confronted with steeply rising health care expenditures, which gradually became a threat to solidarity. This was reflected by the growing dissatisfaction of professionals and patients with quality and price of care. Also the methods used by the public authorities to regulate the system were increasingly criticized. To reaffirm solidarity in the system, it was believed that explicit choices had to be made in relation to changes in the organization and funding of care. HAS was installed to promote regulation by quality in the care system in four complementary ways (Haute Autorité de Santé, 2005):

1. by providing advice on quality of medical products, services and procedures and on conditions under which they are reimbursed;
2. by providing medical professionals with tools (e.g., guidelines);
3. by integrating patients' demands and strengthening their role into health care quality;
4. by participating in assessments of the quality and organization of the health care system and making recommendations for change.

In order to carry out all these responsibilities, HAS has become a central actor and has taken over the responsibilities of several specialist agencies. The founding principles of HAS were independence, transparency, and impartiality. Independence and impartiality are principles because a need was recognized for authoritative independent advice, free of any political, administrative, commercial or professional

pressure. The principle of transparency concerns the scientific evidence which should be state of the art and which should be analyzed rigorously and used without prejudgement. To guarantee this, advices are produced using an explicit and reproducible method. To ensure that HAS advices are independent, the decision-making process includes careful consideration of partner's views and in-depth discussion. To further guarantee independence, HAS was created as a financially autonomous institution that is governed by an executive board of 8 members presided by a chairman appointed by the Head of State.

5.2.2 *New responsibilities of the sickness funds*

In the reforms the role of sickness funds was also modified. The sickness funds had already been in charge of negotiating with the union of physicians and other professionals in private practice (the wages and working condition of the hospital staff being defined by the government). They will continue do to so but they will have more power in the negotiation. Basically, the reforms intend to arrange that sickness funds would be entitled to full responsibility on the economic consequences of the agreements that they negotiate.

- First until now the state had to approve the result of the negotiation and could decide not to accept for various reasons, including the impact on health care expenses. Now the denial of approval will be restricted to the legal aspect (agreement does not comply with the law) or public health general aims.
- A more dramatic change is the power given to the sickness funds to define the package of care, i.e. the list of procedures, drugs, and devices that will be reimbursed to the patient. Previously this was a responsibility of the State. The decision of the sickness funds will be enlightened by the advice of the HAS, which will replace the current National Agency for Accreditation and Evaluation in Health Care (Agence Nationale de l'Accréditation et l'Evaluation en Santé, ANAES) and the Union of Voluntary Health Insurers (Union Nationale des Organismes d'Assurance Maladie Complémentaire, UNOC). The sickness funds will also be in charge of setting the tariffs for procedures, drugs and devices (instead of the State), and define the levels of copayment/coinsurance. Until now, most user charges were coinsurance rates; now in addition there will be a small copayment for each encounter with a health professional. All these user charges will be fixed by the sickness funds and not by the State anymore. Again the State will be able to oppose these decisions for public health reasons.
- A third change is that insurers will also take responsibility for the financial stewardship of the health care system. They will set targets for health care expenditures in a financial framework that will be defined every three years. An independent committee is in charge of monitoring the evolution of health care expenditures during the year and informing the State and the sickness funds if there is a risk of not meeting the target.

The reforms grant insurance funds full autonomy to act as the central actor in the health care market. Advantage of this structure is that a central actor is defined who can act at all levels of health care that have economic consequences: insurance funds will define the level of expenditures, the benefits that are

covered and decide on tariffs and copayments. To allow insurance funds to act in this role, also a new organizational structure was established for the health insurance funds. A federation of sickness funds is created, gathering the three main schemes (the scheme for salaried workers, the agricultural scheme, and the independent workers scheme). This new body – called National union of health insurance funds (Union Nationale des Caisses d'Assurance Maladie, UNCAM) – will be the unique representative of the insured and will negotiate with the State and with the providers representatives. The purpose of UNCAM is to coordinate the three main sickness funds, links with complementary scheme (Unocam) and with health care professionals (UNPS), to obtain a better health insurance management.

The director of the sickness fund for salaried workers, the main one, is also general director of UNCAM. This person is nominated by the Government. The UNCAM board consists of all employers and employees unions. This board is now focusing on strategic orientations, and has no more day-to-day management responsibility as it used to have. The operational management is now in the hands of the general director. He will nominate the directors of local and regional fund offices. This is clearly a shift of power from the board to the general director.

5.3 Definition of entitlements to medical and surgical procedures

Reimbursement of medical specialist care depends on inclusion on a positive list (CCAM). CCAM stands for 'Classification Commune des Actes Médicaux' and is a French medical classification for clinical procedures. The CCAM has been drawn up in the period from 1996 to 2001 (replacing the different existing systems at the time) and was introduced in clinical practice in January 2002 (version 0). Since January 2003, health care professionals have to use the CCAM. Starting in 2005, the CCAM version 2, which defines about 7,200 procedures, serves as the reimbursement classification for clinicians. The CCAM is based on the rule of procedural totality, meaning that each label implicitly contains all the operations necessary for the performance of the medical procedure. It was drawn up as a resource-based relative value scale (RBRVS) by the main health insurance fund (CNAMTS) with the collaboration of health professionals, and the ANAES being involved in the selection of effective procedures.

Although developed for administrative purposes, the CCAM can be viewed as a positive list of medical services. Hence, to understand how the benefit package is defined, we need to know how the CCAM is defined. In the reforms, the procedure by which the CCAM is defined has been changed. Until the reforms in 2004, the positive lists had to be officially endorsed by the minister of health. The minister based decisions about listing of new services, goods and procedures on advice by ANAES (Bellanger et al., 2005b). ANAES considered effectiveness and/or safety and conditions under which a procedure needs to be performed. On that basis it produced an advice about inclusion of a certain procedure or medical service on the CCAM and granting it a positive reimbursement status. A change in the reforms is that the responsibility to define the package of care was delegated to health insurers who base their decisions on advice from the HAS. Below we describe how decisions about CCAM listing come to be.

5.3.1 Policy

Key actors in the definition of the CCAM are the HAS and the UNCAM. Since the 2004 reforms, the HAS has been responsible for defining the contents of the CCAM. The HAS has been setup in the same reforms to give recommendations on the scope of refundable health care. UNCAM was given decision-making power over the benefits as part of reforms that aimed to improve the health system and increase cost control. The government intended UNCAM to act as financial stewardship of the health care system. For this purpose they need to have capacity and tools to control health care costs, and specifically to stay in the limits of the national ceiling for health insurance expenditures. Since the reforms, UNCAM therefore has been responsible for both the definition of the health care package and the regulation of prices and tariffs, and the negotiation of collective agreements with the providers. This was not the case before: for several years the sickness funds were held financially responsible but claimed that all the instruments were in the State's hands.

UNCAM is informed by advice from the HAS. HAS is an independent consultative body that provides scientific expertise and advice for the purpose of improving quality of care, strengthening ties with health care professionals, and ensuring transparency of medical information. HAS will assess the medical efficacy of procedures, drugs and devices, elaborate and disseminate practice guidelines, conduct medical audits of independent professionals and hospital accreditation. The emphasis now is on the important influence that this agency will have, through its advice, on the package of care eligible for reimbursement, and on the improvement of the evaluation of effectiveness and efficiency of health care. The committee charged with these assessments is the 'Committee for the assessment of medical and surgical procedures' of the HAS. The committee produces advices about inclusion of a certain procedure or medical service on the CCAM and granting it a positive reimbursement status. HAS makes recommendations only. Decision-making is left to UNCAM, who is also responsible for implementation of the decisions. UNCAM is accountable to the minister of health, who has the right to oppose UNCAM's benefit decisions on ground of what is important for public health. A professional umbrella organization has also been established in the 2004 reforms, the so-called 'Union Nationale des Professionnels de Santé' (UNPS). The UNPS gives advice on the proposed decisions of UNCAM. The UNPS also has a say in defining the scope of the annual work programs of HAS.

HAS is entrusted with the mission to assess new technologies. The committees involved are the 'Committee for the assessment of medicinal products' and the 'Committee for the assessment of devices and health technologies'. HAS assesses all types of health care procedures, services and goods that are reimbursed by the statutory health insurance system. Advice from HAS is formally requested in the procedure for the registration of drugs for reimbursement (formerly evaluated by the transparency committee of AFSSAPS) or medical devices (formerly evaluated by the CEPP). In other health care sectors expansions of coverage are not systematically guided by the HAS advice. The HAS Board may define areas for making recommendations on its own initiative or at the request of a Minister, various bodies, e.g. UNCAM, UNPS, scientific societies, organizations representing health professionals, or users'

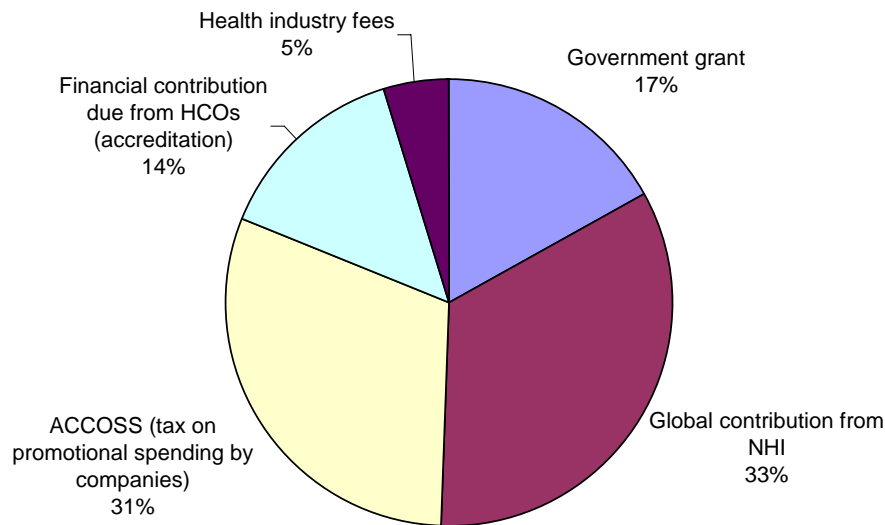
associations approved at the national level. The 2005-2006 work schedule includes assessments of 80 new diagnostic and therapeutic procedures and 7 health technologies (listed in the annual report), and the finalization of 104 assessments by ANAES (Haute Autorité de Santé, 2005).²⁶ The work program is flexible however, to be able to also take into account UNCAM's strategic orientations.

The committee's mission statement also includes periodic assessment of the expected or actual service delivered by healthcare products, procedures and services. Moreover, it is also responsible for assessment of the rationale and conditions for reimbursement of healthcare products, procedures and services. This mission statement reflects the strong ambition to strengthen control over listings and the wish to use an explicit and rational approach in defining what services of medical specialist care are covered by the national health insurance. Hence, the committee is looking into further development of its procedures and assessment methods. The purpose is to ensure that their advices are relevant and comply with legislative requirements. Moreover, the committee will produce a schedule for reviewing the 7,200 existing procedures listed in the CCAM.

To perform its duties, HAS has a permanent staff of 350 people and worked with a budget of 60 million euros in 2005, most of which came from the organizations whose work HAS had taken over, such as ANAES and the transparency committee. Reflecting the fact that it has taken over the responsibilities of several organizations, the activities of HAS are also financed from different sources (see Figure 5-1) (Haute Autorité de Santé, 2005). The HAS board members are chosen as to ensure that HAS' advices and guidelines are independent. There are 8 Board members, who are appointed by the highest authorities of the French Government and by decree of the President of the Republic. Two members are directly appointed by the president; the president of the National Assembly, the president of the Senate and the president of the Economic and Social Council nominate 2 members each which are then appointed. The Board members represent a wide variety of professions and they give up their other mandates and are under an obligation to avoid any conflicts of interest. Members are appointed for 6 years, every three year half the board is renewed. Members may be reappointed once. The validation and decision-making processes are collegiate.

²⁶ ANAES also used consultation to set priorities for HTA: suggestions made in consultation rounds were evaluated using predefined criteria (e.g. severity, motivation for HTA, availability of data), then an evaluation type was suggested and an assessment work-plan was prepared. Next the scientific council of ANAES chose topics for appraisal. Selection was validated by the board.

Figure 5-1 Sources of HAS funding



5.3.2 Assessment

Payment or reimbursement by the health insurance for any procedure or service, apart from prescription drugs, has been subject to inclusion on a list produced on scientific advice. The advisory task used to be carried out by ANAES, but has been carried over to the Committee for the Assessment of Medical and Surgical Procedures (CEAP) of HAS. HAS is an independent consultative body with scientific expertise. They are contracted to perform evaluations, typically by insurers. The HTA program includes preparation of standard reports and fast track evaluations. On principle HAS provides the methods, know-how and infrastructure for the evaluation. The medical profession is actively involved in preparing the assessment reports. Medical technology representatives are not included.

The CEAP has taken over the responsibilities of ANAES with regard to CCAM listing. Since its inception on 15 March 2005, CEAP has worked to produce procedures and assessment methods to ensure that opinions delivered are relevant and comply with legislative requirements. ANAES advised on safety and efficacy of procedures. With the establishment of HAS, the evaluation space was widened. The committee should take account of the expected or actual medical service delivered, i.e. not only of efficacy and safety but also of the treatment strategy, severity of the condition, and impacts on morbidity and mortality, the care system, and public health policies and programs (Candau & Calvache, 2005). Noteworthy is that the committee has recognized a need for health economic assessment of medical procedures. The committee has taken several steps in the direction of changing their own procedures. The first CEAP meeting for example addressed subjects like deciding the different levels of expected or actual clinical benefit; procedures for assessing the severity of a disease (this information for example may be

used for deciding on partial reimbursement levels); defining criteria for prioritizing a program for assessing medical and surgical procedures; and designing a standard response format (opinion form). The ANAES assessment procedure is continued until a new assessment procedure is defined, as well as the rules of operation and accountability of the committees it sets up.

Table 5-1 Procedure for preparing a standard HTA report at ANAES

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1. Automated and manual searches of the literature (technical, clinical, economic data) are carried out;
 2. Articles are selected according to established criteria (evidence-based approach);
 3. A working group is set up (approximately 12 experts from the public and private sectors who use, or may use, the technology). They validate the hypothesis under study and provide field expertise;
 4. A medically qualified and a health economics project leader critically appraise the literature and prepare a draft report (technical aspects, clinical effectiveness and, if possible, cost-effectiveness);
 5. The scope and content of the draft report are discussed by the working group (usually over 3 meetings); amendments are made;
 6. Reviewers from a variety of backgrounds comment on the amended draft report; justified criticisms are taken into account;
 7. The report is approved after the inclusion of changes proposed by the Scientific Council of ANAES;
 8. The full report is published and posted on the ANAES web site (<http://www.anaes.fr>); a 4-page summary is sent out; press conferences are convened; articles may be published in specialty journals.
-

The assessment procedure is common to most assessments. Reproduced from Orvain et al. (Orvain et al., 2004), Table 5-1 describes the normal procedure for preparing an HTA report on basis of literature. A project manager coordinates all the work and oversees the application of a 4-step assessment method, which involves critical appraisal of the scientific literature (1), reviewing foreign nomenclatures (2) and consultation of expert opinion through a postal survey (3) and a workgroup (4). Articles are included or rejected according to criteria about the quality of study design and level of scientific evidence. Other techniques are applied when deemed necessary, i.e. modeling techniques for purpose of comparing clinical and economic effects of technologies, or expert panels when published data are limited. When new procedures are concerned, the assessment procedure takes a broader view, also taking into account the treatment strategy, severity of the condition, and impacts on morbidity and mortality, the care system, and public health policies and programs. When all information is collected, a draft report is produced and sent out for comments. The assessment report does not include a decision. Once the Scientific Council (Evaluation Section) has examined and approved the dossier, ANAES gives its advice on the procedures.

There are four types of advice:

- ‘avis peut être défavorable’ (AD); ANAES advice is unfavorable because of possible adverse health effects – procedures with this outcome are not listed on the CCAM.
- ‘acte en phase de recherché clinique’ (RC); Temporary authorization; possible for some emerging medical and surgical procedures under evaluation. Listing status may change when clinical research data come available.
- ‘favorable sans recommandations’ (AF); A positive advice of ANAES regarding listing. No conditions.

- ‘favorable avec recommandations’ (AFR); A positive advice of ANAES regarding listing. Interventions may only be performed under specified conditions.

The report is made public on the website, a summary is sent out, press conferences may be held, and articles may be published. Reports are usually published in French. The assessment reports provide an informative overview on state-of-the-art medical technologies. A separate section describes the economic evaluation, if any. Next, conclusions are drawn and the decision is formulated. The reports are written as to influence decisions and to be used by authorities like the government and the health insurers. For this purpose the reports also advise on research to be done (clinical and economic) and on requirement of resources.

5.3.3 *Decision*

Since the reform of 13 August 2004, UNCAM has been in charge of preparing and updating the positive lists, including the CCAM that includes services of medical specialist care that are covered.²⁷ UNCAM decides on reimbursement of medical specialist care on the basis of advice from HAS. Furthermore the advice of the National Union of Complementary Health Insurance Organizations (UNOC) is considered. UNOC is involved because 95% of French people take out complementary insurance; hence decisions are coordinated for the obligatory and complementary insurance market as a whole. HAS also responds to UNCAM's plans (not yet communicated) for the listing of procedures and services, on the basis of the general principles defined annually by the Ministers for Health and for Social Security (e.g. effectiveness, severity). Furthermore, a National Union of Health Care Professionals has been created to issue opinions on UNCAM's proposed decisions. The law gives a right of opposition to the majority trade-union organizations in order to avoid the adoption of terms of collective agreements to which the profession concerned would be opposite.

The decision process itself is not documented and not transparent. There is no explicit policy on other considerations that may be introduced in the decision making process, as long as the final decision is in line with general principles of the benefit package included in the law. The responsibility for decision-making is granted to UNCAM under the assumption that optimal decisions can be made when the decision maker is also responsible for the economic consequences of decisions. UNCAM has the responsibility to negotiate the agreements and conventions governing the relations with the professionals of health, to fix the rates of refunding, set targets for volumes of use, under the limits and conditions fixed by the State. The system intends to equip the sickness insurance with new responsibilities for regulation and management of the health care system, giving UNCAM tools of regulation and control, as well as means to guide and coordinate health care practice. The fact that the ministry of finance does not approve these agreements any more is significant in this respect. The responsibility for quality and consistency of

²⁷ UNCAM (and not the state) is also responsible for setting the tariffs for medical procedures, drugs and devices (instead of the State), and for determining the levels of co-payment and coinsurance. Hereby advice from the UNPS is taken into account.

the decision-making process therefore is in hands of the people who are involved. Consequentially, the legitimacy of decisions is publicly discussed in relation to composition of the UNCAM board.

UNCAM is directed by a council of orientation resulting from the cases of the three principal modes of sickness insurance combined into UNCAM (CNAMTS, MSA, CANAM), and by a director who is also the chair of the CNAMTS council. CNAMTS covers employees in commerce and industry and their families (about 84% of the population). UNCAM was created in this way to manage the conventional relations with the professionals of health. The director is a high civil servant nominated by the government. The director leads the decision-making process and negotiations and has the power to nominate directors of local sickness funds. UNCAM fixes the orientations of the conventional policy, deliberates on the rates, on assumption of responsibility and the rules on admission to refunding. Lastly, it gives opinions on the bills and the budgets. Given the respective roles of the board and general director of the UNCAM, concerns have been expressed that the power of the State in the nomination and dismissal of the General Director is too important. Pessimists have expressed the fear that the state has only given over the responsibility on paper, but still controls decisions through the director, but now without taking the blame. Also there are concerns about the composition of the board, notably the prominent role of the employers representatives.

When UNCAM decides to add a medical service to the CCAM, this decision will be published in the 'Official Journal'. As of the next day, the service becomes reimbursable. The medical service is described in the journal so that doctors can carry out the medical services according to the specified conditions (e.g., indications, formation, environment). These conditions can be viewed as 'regulatory medical references'. Other regulations other than the lists and nomenclatures can also specify the conditions for reimbursement, as is the case with the Medical Practice Guidelines (RMO).

5.3.4 Outcomes and implementation

The ministries of health and social security retain the right to reject UNCAM's decisions and to include or exclude goods and services in or from the list, especially if public health issues are concerned. There is a time limit of one month for the rejection of decisions taken by UNCAM. This is an important change, as before the 2004 Act ministers could take several months to decide whether or not a procedure should be included on the positive list, and the procedure could not be reimbursed during this period. Moreover, they were not obliged to justify their decision (Bellanger et al., 2005a). Until the reforms the state could decide not to accept for various reasons, including the impact on health care expenses. Now the denial of approval will be restricted to the legal aspect (agreement does not comply with the law) or public health general aims.

Implementation of UNCAM's decisions involves action by regional health insurance funds joined in the union of regional health insurance funds (URCAM). URCAM was installed as part of reforms as one of the parties involved in governance of the health care system. When a decree is published stating that a certain procedure is included in the benefit package, the regional unions will conclude local contracts with health care professionals, in addition to the national agreements. URCAM's task is to

organize the hospital supply according to a fixed budget and regional health care needs. They must also implement locally health care priorities that are fixed at a national level and monitor the quality of health care delivery (Nuijten et al., 2001). In addition to regulatory prescribing rules, if any, guidelines may be developed. HAS is responsible for taking care of the diffusion of reference frames good practices and good use of the care near the professionals of health and the information of the public in these fields.

Reappraisal dates are not defined. It is HAS and UNCAM together who may decide when and why an intervention may need re-appraisal, when they decide on the HAS work program.

Chapter 6 Germany

6.1 Characteristics of the health care system in Germany²⁸

Germany is a federal republic with 82.5 million inhabitants consisting of 16 states ('Länder'), each of which has a constitution consistent with the republican, democratic and social principles embodied in the national constitution (known as the 'Grundgesetz'). The constitutionally-defined bodies with legislative functions are the Federal Assembly ('Bundestag') and the Federal Council ('Bundesrat'). Legislative authority lies principally with the 'Länder', except in areas for which this authority is explicitly given to the federal level.

6.1.1 *Organizational structure of the German health care system*

The German health care system is a so-called Bismarck system, a statutory social insurance system ('Gesetzliche Krankenversicherung' (SHI)) that currently covers about 90% of the population.²⁹ Briefly, three main groups make up the system. These are the federal government, the state governments, and the corporate bodies that comprise the sickness funds, the physicians' associations and in addition, but with fewer rights, the hospital organizations.

The Federal Ministry of Health sets the legal framework of the healthcare system and supervises six federal agencies, including agencies for licensing of pharmaceuticals, sera, and vaccines, and for supervision of medical devices. The legal framework is laid out in the Social Codebook V (SGB V). Currently, the following benefits are legally included: prevention of disease, screening for disease, diagnostic procedures, treatment of disease, and transportation. Treatment includes all necessary and state-of-the-art ambulatory medical care, dental care, drugs, non-physician care, medical devices, inpatient/hospital care, home nursing care, and rehabilitation.

Responsibilities for provision of ambulatory care are delegated to so-called corporate bodies. The most important ones are the physicians' and dentists' associations. These corporatist institutions have to provide all personal acute health care services. They have the full obligation to provide all direct and acute healthcare services since they have both the corporate monopoly and mission to secure ambulatory care. The monopoly implies that hospitals, communities, sickness funds, and others do not have the right to offer ambulatory medical care. The mission includes the obligation to obtain a total, prospectively negotiated budget from the sickness funds, which the physicians' associations distribute among their members. The SGB describes generic categories of services that must be delivered and the scope of negotiations between the sickness funds and the corporate bodies. Typically, the scope of services which

²⁸ The following information is mainly based on (Perleth & Busse, 2000) and (Busse & Riesberg, 2004). We would like to express our thankfulness to Dr. Matthias Perleth whose expertise was invaluable in drafting this chapter.

can be reimbursed is regulated through the negotiations, although sometimes legal regulations apply (Busse & Riesberg, 2004).

German health care in university and public hospitals is based on a 'dual financing' method, which means that insurance funds pay for services and personnel while states finance investment. The states are responsible for maintaining the hospital infrastructure by fulfilling hospital plans and paying for investments according to these plans. Their responsibilities also include public health (mainly supervision and monitoring of personnel, goods, and diseases); undergraduate medical, dental, and pharmaceutical education; and supervision of regional physician chambers, regional associations of sickness fund-affiliated physicians, and sickness funds operating in the state. Sickness funds are the payers/purchasers in the statutory health insurance system, and pay for delivered services.

Inpatient care is regulated differently. Due to the absence of corporate institutions in the hospital sector, individual hospitals contract with the sickness funds. The absence of corporate institutions in the hospital sector and the monopoly for ambulatory care are major reasons for the almost complete separation between the inpatient and the outpatient sectors in Germany. Hospitals may be public (meaning ownership by local governments), non-profit and for-profit. Private non-profit and for-profit providers co-exist with public providers. To all hospitals treating SHI patients, the same set of rules applies.

A problem in German health care is the fragmentation, illustrated by the separation of ambulatory care and inpatient care. Insurance is also not universal. Public (statutory) and private insurance co-exist; additionally, several insurance schemes offer health care benefits in different sectors (e.g., SHI, long-term care insurance, and the Social Retirement Insurance). Governments try to address the differences by coordinating insurance schemes and implementation of specific measures targeted to minimize differences in specialist care. Examples are highly specialized hospital outpatient clinics, ambulatory surgery at hospitals, dispensing of drugs for ambulatory care by hospital pharmacies, and integrated care models.

6.1.2 Funding

Health spending as share of the GDP in Germany was 10.9% in 2003 (Organisation for Economic Co-operation and Development, 2006b). Altogether, public sources account for about three quarters of total expenditure on health and private sources for one quarter.

Statutory health insurance is the major source of financing health care. Its contribution to overall health expenditure was 57% in 2002. The other three pillars of statutory insurance contributed an additional 10.5%: statutory retirement insurance financed 1.7% (mainly for medical rehabilitation), statutory (work-related) accident insurance 1.7%, and statutory long-term care insurance financed 7.0%. Governmental sources contributed another 7.8%. Private households financed 12.2% of total

²⁹ The following is summarized and quoted from (Perleth & Busse, 2000). Please see for details about the structure and functioning of the German healthcare system amongst others (Alber, 1992; Busse & Riesberg, 2004; Busse & Riesberg, 2005).

expenditures on health in 2002 (figures include – negligible – expenditures of nongovernmental organizations). Private insurers financed 8.4%, which includes expenditures for comprehensive health insurance. The most distinct changes over the last 10 years are the introduction of long-term care insurance and the increase in out-of-pocket payments (Busse & Riesberg, 2004).

Sickness fund membership is mandatory for employees whose gross income does not exceed a certain level. This limit was increased from €3,375 to €3,825 gross salary per month starting in January 2003 to reduce the number of high earning voluntary members leaving statutory health insurance. In 2003, about 88% of the population was covered by statutory health insurance (nearly 78% mandatory and 10% voluntarily). Contributions for SHI are dependent on income, and not risk, and include non-earning spouses and children without any surcharges. Contributions are shared equally between the insured and their employers, except for people with earnings below a threshold of €400 (only employers have to pay for contributions at a rate of 11%).³⁰ Contributions are based on income from gainful employment (up to a level of €3,488 in 2004), pensions, or unemployment benefits, and not from savings or possessions at present. The total sum of the income of all the insured up to a level of (in 2004) €3,488 (the so-called contributory income) is among the most important figures in health policy since its growth rate from year to year determines the level of cost-containment.

For out-patient care the fee-for-service model applies. The fees for ambulatory physicians' services are based on the Uniform Value Scale. The fee schedule includes specific tariffs for some interventions, but many other interventions may be charged under a broader category of this payment scheme, for example, counselling on a healthy lifestyle. Under this financing system, patients are free to choose providers. Germans do not have to see a GP before visiting a private specialist. GPs do act as gatekeepers to German hospitals, but about half of all specialists practice outside the hospitals. Payment of inpatient services has recently changed with the introduction of a DRG system that replaced per diem rates. The German type of DRGs is used in all acute hospitals for all types of services except for certain defined services and for care in departments of psychiatry and psychosomatic medicine, where per diem charges continue to apply for inpatient services as well as pre- and post-hospital care. The DRG system is still in an early stage, shown by the fact that the DRG tariffs do not always reflect actual prices yet.³¹ The sickness funds are responsible for paying for delivered services. Typically this is done through payment of providers for patients covered by statutory sickness funds. Reimbursement of patients occurs for privately insured patients.

³⁰ Since July 2005, certain services and provisions in dental care (prostheses) are born by the insured themselves.

³¹ In May 2001, the umbrella organization of the health insurance funds, the association of the private health insurances, and the German Hospital federation founded the institute of the fee-/remuneration system in hospitals (Institut für das Entgeltsystem im Krankenhaus InEK gGmbH) as a non-profit limited company. The so-called DRG institute (InEK gGmbH) supports the non-profit corporatist partners of the German joint-self regulation system and its committees with the statutory introduction and the continuous advancement of the DRG-System (<http://www.g-drg.de>).

6.1.3 *Defining the benefit package*

There is no uniform benefit catalogue defining the benefits provided by the Statutory Health Insurance (SHI) and the Statutory Long-term Care insurance. Benefits are defined by a complex structure of explicit and implicit regulations regarding each health care sector. The SHI general benefit regulation defines the overall framework for provided benefits. However this framework only gives a broad definition and seldom mentions single benefits that have to be provided. The ‘Gemeinsame Bundesausschuss’ (G-BA - Federal Joint Committee) has the function to interpret the general framework and issue general as well as special directives defining certain benefits for each health care sector. By taking into consideration the criteria of need, costs and sometimes cost-effectiveness directives can be positive as well as negative benefit decisions. Additionally there are remuneration schemes in several health care sectors being primarily designed to define provider remuneration (SHI-DRG, SHI-EBM, SHI-BEMA, SHI-BEL II). However these schemes also serve as a benefit catalogue as all listed services are covered by the SHI (Busse & Riesberg, 2004).

While the Social Code Book regulates preventive services and screening in considerable detail (for example concerning diseases to be screened for and screening intervals) it leaves the definition of benefits in other health care sectors to the G-BA (or its predecessors). The G-BA has considerable power and competence in defining the benefits package for curative diagnostic and therapeutic procedures.

The decision-making process concerning coverage in the ambulatory sector is described in more detail in the following sections. All procedures covered in the ambulatory sector are listed in the ‘Uniform Value Scale’ (‘Einheitlicher Bewertungsmaßstab’ (EBM)) together with their relative weights for reimbursement (see Section 6.2). The range of covered procedures is wide, from basic physical examinations in the office to home visits, antenatal care, terminal care, surgical procedures, laboratory tests and imaging procedures including magnetic resonance imaging.

Until 1997, exclusions were not explicitly possible but the legal mandate to evaluate already covered technologies made this possible. So far the committee has taken decisions upon only a small number of technologies with limited medical benefits, for example bone density measurement for asymptomatic patients (Busse & Riesberg, 2004).

6.2 **The health care delivery system in Germany**

6.2.1 *The joint self-governing structure*

In Germany, the health insurance system has a history of about 120 years. The state’s original aim was to prevent citizens from harm by making membership of a health insurance mandatory. Health care provision was not regulated by the state at that time. Financial responsibilities were delegated to insurers. Insurers and medical doctors operated the system together under a well-defined legal framework. The government supervised the system but the system was not state-run (Altenstetter & Busse, 2005). The state role was simply to endorse consensus reached between insurers and providers, and in these negotiations, the providers formed a powerful block. Under this system, the medical profession has always

operated with the objective to maintain their status as a free profession. Implemented policy measures only made incremental changes to the system and the power balance between state, insurers and providers.

In negotiating prices the power of providers was evident. As a result, cost containment proved difficult. The main political goal in health policy has been to keep contribution rates stable, and hence to restrict insurance funds expenditures. However, the power balance restricted possibilities for effective interventions. To illustrate this, ‘overprovision’ has been a significant problem in Germany, and services beyond the legally defined scope have been offered. The state could not intervene effectively under the existing system of self-governance.

To change the system, the focus shifted towards increasing technical efficiency. In that context, budgets caps were introduced in the 1980s. This measure was quite effective. In the end, however, it was acknowledged that technical efficiency also needed to be increased where the power balance was concerned. Only in 1993, health care reforms were implemented that shifted the balance of power and gave the Minister of Health more control. The Health Care Structure Act of 1993 shifted powers in the system, because it created a system of managed competition. An important element was that it established free choice among health insurance funds of consumers. This obviously gave health insurers more incentive to lower costs of care and increase quality, which did a lot to reduce overprovision. At the same time, also other elements of the health care system were subjected to governmental influence, such as the stability of the contribution rates, the extension of the nationwide block of all hospital budgets, and several price measures (e.g., legally set reimbursement rates), so that the government regained control over health care expenditures in some areas.³²

Key for success of the 1993 reforms was that finally at the central level and at the level of the ‘Länder’ political consensus existed that structural reforms were needed, prior to involvement of the medical profession, so that they could not act as a veto player. This gave the Minister of Health the possibility to act, in spite of opposition from providers. Successive pieces of legislation also reflect the rise of power by the governmental over the self-governing bodies, adding more components of government control.

Since the last decade, also attention increased for HTA. Since 1997, the G-BA actually was made responsible for assessment (since 2005 assisted by the Institute for Quality and Efficiency in Health Care – Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen IQWiG) of the existing benefit package to define a positive list and treatment directives. The G-BA thus faces the challenge to deal with the conflicts between the historically grown institutional setting on the one side and the ‘new’ logic and concepts of evidence-based medicine like HTA on the other side. Developments are relatively slow, because it takes time to build up an HTA network, i.e. collection of HTA data and development of methods.

³² Expenses in the hospital sector and for medication are largely uncontrolled.

6.2.2 *Separation between health care sectors*

Next to the importance of corporatist and self-governance institutions and practices another key feature of the German health care system is the health care delivery system and its clear institutional separation between (1) hospital care, which has traditionally been confined to inpatient care, (2) primary and secondary ambulatory care, and (3) the public health services. This division between health care sectors also explains why regulation and control of health technologies is relatively difficult in Germany. In fact, while licensing for pharmaceuticals and medical devices meets international standards, other types of technologies did not systematically receive the attention they deserved.

German hospitals have traditionally concentrated on inpatient care. Sectoral borders to ambulatory care were strict. While acute hospitals in the hospital plan provide outpatient emergency care, only university hospitals have formal outpatient facilities. Day surgery and ambulatory pre- and post-hospital care have become other fields of increasing activity. Since 2004, hospitals have been granted additional competencies to provide care to outpatients who require highly specialized care on a regular basis. Also, participation in integrated care models offers new opportunities to become active in ambulatory care (Busse & Riesberg, 2004).

Primary and secondary ambulatory health care is mainly provided by private for-profit providers, including physicians, dentists, pharmacists, physiotherapists, speech and language therapists, occupational therapists, podologists, and technical professions. Acute care and long-term care are commonly provided by non-profit or for-profit providers employing nurses, assistant nurses, elderly caretakers, social workers, and administrative staff (Busse & Riesberg, 2004). Patients have free choice of physicians, psychotherapists (since 1999), dentists, pharmacists, and nursing care providers. They may also choose other health professionals, however access to reimbursed care is available only upon referral by a physician. Family practitioners (about half of ambulatory physicians) are no gatekeepers in Germany, although their coordinating competencies have been strengthened in recent years. Ambulatory physicians offer almost all specialties (Busse & Riesberg, 2004).

Other public health services may be delivered either by a family physician or by a medical specialist. The German health care system has traditionally no gate-keeping system; instead patients are free to select a sickness-fund-affiliated doctor of their choice. According to the Social Code Book (Sect. 76 SGB V), sickness fund members select a family physician that cannot be changed during the quarter relevant for reimbursement of services for that patient. Since there is no mechanism to control or reinforce this 'self-selected' gate-keeping, patients frequently choose office-based specialists directly. Family physicians and specialists have different reimbursable service profiles, different reimbursement pools and, from 2005, separate representation on the board and in the assembly of regional physicians' associations (Busse & Riesberg, 2004).

6.3 The decision-making process in defining the SHI benefit package

The health care delivery system and the joint self-governing structure characterize the decision-making system of the inclusion/exclusion of new medical technologies in the German benefit package of the SHI. To understand the system one must realize that Germany has two sectors or trails of specialist doctors and care: medical specialist care is provided in outpatient practices as well as in hospitals (different from the Netherlands, for example). Patients in Germany do have the liberty to choose which ‘track’ of care they prefer; with their chip-card they can go to their general practitioner for a referral, but they can also go directly to a specialist working in a hospital or in an ambulatory practice.³³

This situation creates competition between the hospitals and the specialists having an outpatient practice not connected or related to a hospital. Odd in that respect is that the regulation for these two sectors is quite different concerning the appraisal procedures and processes for a new treatment, device etc., and for deciding if it will be covered by the SHI or not. If there are new treatments, procedures to be appraised/evaluated there are almost no hurdles to be taken in the hospital sector. That means, hospitals can introduce new services/treatments quite easily. The hospital sector is also called the ‘innovative sector’. Since 1997, definition of benefits in the ambulatory sector has been brought under control of the G-BA, which has to decide and appraise such a new service/benefit first. In the ambulatory sector, the joint self-governing bodies are responsible, which is not the case in the hospital sector. This is a crucial and fundamental difference between the two sectors.

This chapter will focus on the ambulatory sector, where the G-BA has established a system for technology assessments as part of their decision-making procedures.

6.3.1 Policy

A special feature in the regulation of medical services of the German health care system is the important role, alongside that of the legislature, played by the self-governing body of doctors and health insurance funds. The medical self-governing body, formed from the national associations of doctors and dentists, the German Hospital Federation and the health insurance funds, gives concrete definition to the legal requirements and implements them. The paramount decision-making body of the joint self-governing body is the G-BA. It has wide-ranging regulatory powers, laid down in Social Code Book No. 5, which governs statutory health insurance. One important area of responsibility of the G-BA concerns the assessment of new methods of medical examination and treatment.

Since the Statutory Health Insurance Modernization Act (‘Gesundheitssystem-Modernisierungsgesetz’) came into force in 2004, the G-BA is the most important body for the benefit negotiations between sickness funds and physicians concerning the scope of benefits. The Health Care Modernisation Act furthermore required that the G-BA was assisted by a new scientific institute governed by the G-BA: the IQWiG (‘Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen’). IQWiG’s

³³ A hospitalization is only possible as an emergency case or based on a medical referral. There are some exceptions; for example aftercare of transplantations in special outpatient clinics.

responsibility is to support the G-BA in fulfilling its legislative duties by submitting recommendations and providing scientific advice.

The main body of the G-BA consists of nine representatives of the federal associations of sickness funds (three for general regional funds, two for substitute funds, and one each for company-based, guild, farmers' and miners' funds) and nine representatives from provider groups (four from the Federal Association of SHI Physicians, one from the Federal Association of SHI Dentists, and four from the German Hospital Organization), two neutral members with one proposed by each side, and a neutral chairperson – accepted by both sides – who has the decisive vote if no agreement can be reached. In addition, nine non-voting representatives of formally accredited patient organizations have been given the right to participate in consultations and to propose issues to be assessed and decided upon. This right was established in 2004. Patients also have the right to file applications.

Based on the legislative framework of the Social Code Book, the G-BA issues directives relating to all sectors of care. Some directives are passed by the Plenary, the central decision-making body of the G-BA, e.g. the body's standing rules and the rules of procedures for assessing technologies for inclusion or exclusion from the SHI benefit catalogue. The G-BA is composed of 4 additional bodies, each of which passes directives for a distinct field of regulation. They consist of actors involved in the respective field. While federal associations of sickness funds (decision-making powers) and patient representatives (no vote) are represented in all of the four committees, the composition of providers varies, i.e. the Federal Association of SHI Physicians is represented in the Committee on Ambulatory Care, the Committee on Physician Issues, but not the Committee on Dental Care where the Federal Association of SHI Dentists is represented.³⁴ The German Hospital Organization delegates representatives to the Committee on Hospital Care and the Committee on Physician Issues. These joint committees consist of various joint sub-committees that prepare recommendations, conclusions and directives, partly supported by working groups. Their directives are legally binding for actors in statutory health insurance although subject to complaints at social courts. They are mainly concerned with the coverage of benefits and assuring that SHI services are adequate, appropriate, and efficient (Busse & Riesberg, 2004).

When the G-BA considers whether a new device or treatment should be covered by the SHI, it approaches and asks the IQWiG to work on a recommendation. The IQWiG represents the scientific arm of the G-BA; the relevant scientific information and literature is being collected and reviewed as a preparation for the G-BA. The decision upon coverage lies with the G-BA, this will not be discussed within the IQWiG. The IQWiG is a foundation that is paid for by the stakeholders of self-governance rather than the federal government, as originally planned; it receives its finance through contributions from the statutory health insurance system.³⁵ It has got currently approximately 9 million Euros as a budget at its disposal. The IQWiG is an independent scientific institute that evaluates the quality and efficiency of health care. The Institute investigates what therapeutic and diagnostic services are feasible

³⁴ This is going to be changed with the coming health care reform: there will be only one decision-making body.

³⁵ The German term is 'Systemzuschlag'.

and valuable, and communicates its findings to the health care professions, patients and the general public. The information compiled will also be relayed to the Federal Ministry of Health (and Social Security), and the G-BA.

The Institute's duties include the production of reports on specific topics requested by the G-BA or the Federal Ministry of Health, as well as the initiation, coordination and publication of scientific work in areas where care-related medical knowledge needs to be complemented. The Institute regularly screens and evaluates literature for care-related medical innovations and distributes this information in an understandable form. On the basis of international literature and its own literature searches, the Institute can provide proposals for research related to innovative health care, initiate and participate in research projects and publish its findings. This includes the evaluation of clinical practice guidelines, the submission of recommendations on disease management programmes, the evaluation of the effects of pharmaceuticals, and the publication of health information for patients and consumers. The aim of the evaluations is to contribute to the quality and efficiency of services provided by statutory health insurance, taking into account specific factors such as age, gender and living conditions. Table 6-1 summarizes the IQWiG areas of work.

Table 6-1 IQWiGs areas of work

-
- Investigation, description and evaluation of the current state of medical knowledge on diagnostic tests and therapeutic techniques for selected diseases;
 - Production of scientific reports, expert opinions and statements on the quality and efficiency of services provided by statutory health insurance;
 - Evaluation of evidence-based guidelines for the epidemiologically most important diseases;
 - Submission of recommendations on disease management programs;
 - Evaluation of the effects of pharmaceuticals;
 - Provision of easily understandable general information on the quality and efficiency of health care to the public
-

IQWiG currently has a staff of about 60 persons. As of February 2006, 53 employees have been hired, including 35 scientists, mainly physicians or life scientists. The institute's staff will be raised to a head count of approximately 60-70 over the next years (Conrad, 2006). The foundation's bodies include a Foundation Board and a five-member Board of Directors. The Institute is an establishment of the foundation and is under independent scientific management. The Institute's advisory committees are a 30-member Board of Trustees and a Scientific Advisory Board. The Scientific Advisory Board, with a minimum of six and a maximum of twelve members, is appointed by the Board of Directors. Currently, the Institute is located in Cologne. The IQWiG currently has six scientifically oriented departments, responsible for data assessment and evaluation:

- Health Economics;
- Department of Biometrics;
- Department of Pharmaceutical Assessment;

- Department for the Assessment of Non-pharmaceuticals Therapeutic Procedures, Diagnostic Procedures and Screening Measures;
- Department for Guidelines and Disease Management Programmes; and
- Department for the Generation and Methodology of Patient Information (Conrad, 2006).

The Institute's Steering Committee includes the Institute's Director and the department heads. This committee produces and modifies a manual of the methods used by IQWiG and develops and monitors the Institute's working procedures. The publication and ongoing discussion of the Institute's methods paper are explicitly desired, and should contribute both to the transparency of the Institute's work and to a continuously dynamic improvement of these methods (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, 2004; Bastian et al., 2005).

6.3.2 *Assessment*

With regard to decisions on reimbursement of medical specialist care, the IQWiG procedure is started when the topic is referred by the G-BA after the G-BA or the Federal Ministry of Health has commissioned a report. A project group is formed under management of the department concerned and a project manager appointed to take responsibility. The composition of the group is not fixed at this point, as the need for changes may arise during subsequent stages of work. If necessary, specification of the assignment takes place in agreement with the relevant committees of the G-BA or the Federal Ministry of Health. This also includes the (rough) definition of target criteria, especially patient-relevant endpoints. If required, the project group, considering external advice where appropriate, refines this definition. Finally, the project group produces the report plan, which is basically a protocol providing the basis for the subsequent literature search and scientific evaluation.

The assessment methods may vary per case. The dominant method is a literature search and scientific evaluation of the published results. Individual procedures are, amongst other things, dependent on the respective research question, the scientific evidence available, and expert opinions received. In order to use the available resources meaningfully and efficiently, the Institute will consider and, if applicable, use the preparatory work of other national and international health care institutions.

IQWiG scrutinizes the literature and results for evidence regarding effectiveness ('Nutzen'), exigency/necessity ('Notwendigkeit'), and cost-effectiveness ('Wirtschaftlichkeit'), in sequential ordering. This means, the category effectiveness is prioritized. Legally, all three categories are to be evaluated by IQWiG, but in the assignments that IQWiG gets by the G-BA, it is quite often only the effectiveness and the exigency that are explicitly mentioned. The code of procedure of the G-BA determines that the cost-effectiveness has to be evaluated separately according to the specific health sectors due to the difference in cost structures and prices. This implies that the cost-effectiveness is evaluated in the G-BA within the respective theme group. It has to be mentioned, however, that there are no formal criteria and methods used when evaluating the cost-effectiveness of new devices or treatments. In practice, it is more an

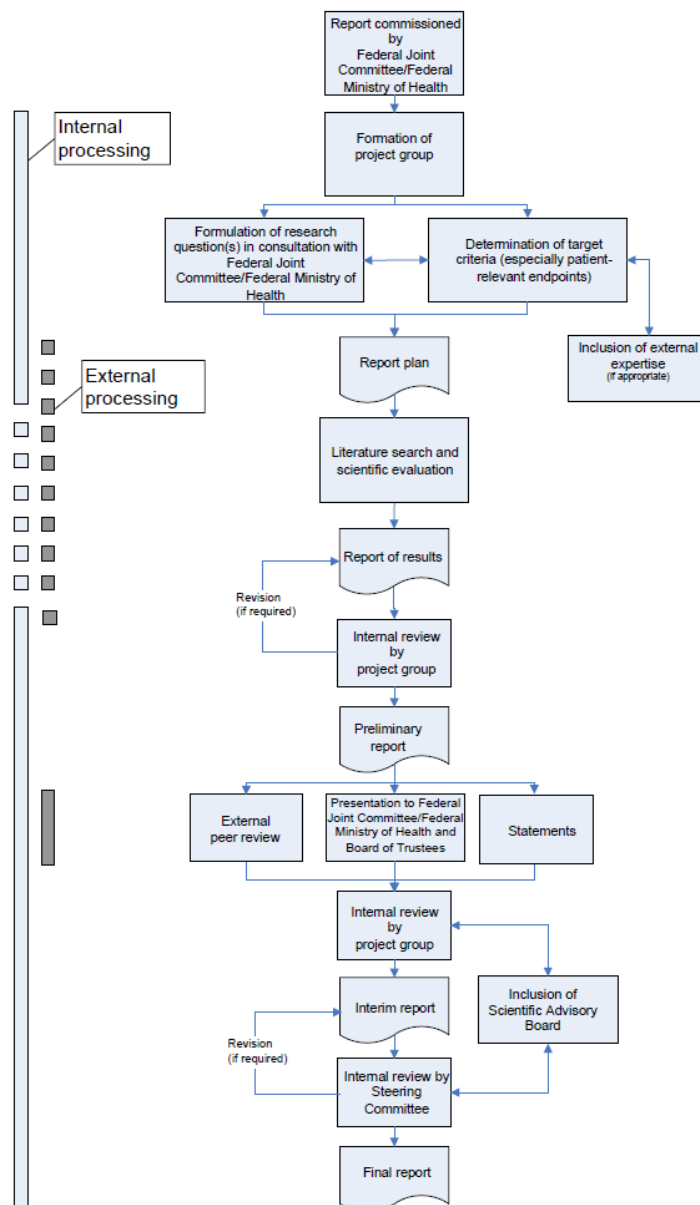
estimation of how expensive the introduction of such a device or treatment will be, that is what the probable impact on the budget will be.

One or more external experts can in part also conduct the literature search and the scientific evaluation of the information acquired. Indeed, many of the assignments that IQWiG gets are again, this time by the IQWiG, assigned to external groups of experts.³⁶ These assignments are announced via a public request for a proposal. Expert groups or single experts may apply for such an assignment. They are usually based at an academic institute or they are experts who qualify themselves for assignments announced by the IQWiG. There are two different categories of experts involved: (1) working groups that write the evidence reports (these are mainly academic institutes and/or departments based at universities) and (2) single experts who are involved as advisors and peer-reviewers in the process of elaborating an IQWiG report. Once the assignment is given to a working group, the work of the working group is closely monitored. The experts are supposed to work closely together with the IQWiG, which has got strict quality inspection and assurance procedures in place. This way of working and close monitoring proves of value: up to today there were no serious errors detected in the reports provided by the IQWiG.

The objective of the review procedure is to compile a so-called evidence report. Figure 6-1 graphically depicts the stages of the review procedure. It shows that first evidence is compiled in a protocol that is scrutinized by the project group. Next, IQWiG delivers a so-called preliminary report ('Vorbericht') to the G-BA that, however, has already been peer-reviewed. This preliminary report, which is published on the website of the IQWiG and accessible without any restrictions, is then discussed and advised in the responsible theme group of the G-BA particularly with regard to if the questions that have been addressed in the previously agreed assignment are dealt with. This is fed back to the IQWiG. The IQWiG writes then a final report including the feedback of the G-BA and other comments that have been made to the preliminary report by other stakeholders. If needed there are hearings taking place where experts and stakeholders can bring in their comments. There are a few prerequisites to such official comments: they cannot just be an expression of opinion, but should be substantial (that is, based on evidence). Comments that need to be considered are for example evidence that a study related to the discussed issue has been omitted, or results related to the issue have not been evaluated or wrongly interpreted. Such substantial comments and criticism to the preliminary report are included and listed in the appendix of the end report, and, if successful, they are of course integrated in the final report. The end report is then officially submitted to the G-BA.

³⁶ In Germany there are not that many of such working groups who are renowned and who deliver high quality work. There is, of course, the danger that issues are debated fiercely, like it happened with the recent debate about the transplantation of stem cells in Germany, that experts take the risk of ruining his/her reputation with such an assignment and his/her contribution to the issue. An expert can experience difficulties in public and it can imply that such an expert might consider not to make him-/herself available anymore for such assignments.

Figure 6-1 Process of report production (see Annual Report 2005)



The IQWiG determines on beforehand what kind of studies will be considered with reference to the quality of the evidence presented in the studies. This is, of course, always covered by the principal question and discussion ‘how far do we go’: will only those studies be considered that deliver clear and high-quality evidence and randomized-controlled studies,³⁷ or will also studies be accepted and considered that do not provide consistent and overall evidence? The IQWiG uses in this context so-called hierarchies of the design of the studies that are controversial and problematic. It concludes then up to date there is, for example, no evidence of the effectiveness, or some evidence of effectiveness under certain conditions, or only for a specific group of patients for a certain medical device and/or treatment in the literature

³⁷ Such ‘hard’ studies with strong evidence-based findings are less frequent and this implies that most of the studies would not qualify to be considered.

reviewed. This implies of course always that if there is no literature available, it can also not be proved that a certain device or treatment is useful or not. Discussions at hearings within the IQWiG often center on these ‘thresholds of acceptance’ of respective studies: which studies are to be considered and which not.

The reports of evidence are very detailed and can be compared to international standards. They consist of an introduction, a very extensive description of the methods applied, a large part with the results normally containing a lot of tables (in the text as well as in the appendices), a discussion of the results, and a comprehensive overview of the literature that have been taken into consideration and also of the literature that has not been taken into consideration including reasons for exclusion. All reports are publicly accessible on the respective websites: the preliminary reports of the IQWiG, the final recommendation of the IQWiG to the G-BA, and the final decision of the G-BA on the inclusion of a new technology into the catalogue of SHI covered benefits.

The G-BA or any other stakeholder can comment on the preliminary report of the IQWiG, which the G-BA often does, but in general it comments only on formal issues. Its comments are considered as any other comment from other stakeholders. It is special, however, that the G-BA does not have to adhere to the recommendation of the IQWiG.³⁸ The final recommendation of the IQWiG is publicly available on the website and any stakeholder can comment on the recommendation in a substantiated way.

6.3.3 Decision

The IQWiG delivers its evidence reports to the theme groups within the G-BA. These theme groups are cross-sectoral that means their members consist of representatives from the ambulatory sector and the hospital sector. On the basis of the IQWiG reports, the theme groups come up with sector specific recommendations, which are then forwarded to the respective sub-committees (‘Unterausschüsse’) of the G-BA. In the sub-committee, the recommendation for a decision of the G-BA is framed taking the effectiveness and exigency into account. There are no time limits or deadlines mentioned in the respective regulations for this.

The sub-committees are positioned directly below the decision-board within the G-BA, and they are – in contrast to the theme groups – sector specific. The sub-committees are formalized according to the various health care sectors. There is a sub-committee for hospitals, one for SHI contracted doctors, one for psychotherapy, one for DMP (Disease-Management-Programs). Hence, if an issue is only and undisputedly related to the ambulatory sector then, of course, the other sub-committees are not addressed and do not deal with this issue. For every relevant aspect there is a sub-committee and these sub-committees launch the work of the specific theme groups mentioned already previously. That means the theme groups report always to the sub-committees.

³⁸ It can happen that the interpretation of an issue can vary considerably from sub-committee to sub-committee. The sub-committee representing the hospital sector, for example, can interpret the recommendation in a different way than the sub-committee representing the ambulatory sector.

The report submitted by the IQWiG is the base for framing the recommendation for a decision. The sub-committees evaluate on a sector specific level and add the category of cost-effectiveness. The discussions and debates within the theme groups and the sub-committees are documented in the form of minutes that are very detailed and checked against by the various members of the committees. These minutes are not publicly accessible in contrast to the reports and recommendations of the IQWiG. In general, it can be said that if there is evidence for the effectiveness and exigency, there is normally little controversy about introducing also an expensive treatment or device. If a new treatment turns out to be not useful, there is also no need to investigate and discuss its exigency or cost-effectiveness.

In sect. 21 of the code of procedure of the G-BA it says³⁹ that, in general, randomized controlled studies are the gauge and benchmark for the evaluation work of the Committee; they should be taken as a point of reference. Unfortunately, in practice it cannot work always like this: patients cannot be randomized for example, or there might be ethical reasons, or because in practice, it is not working. In these cases, and only in these, the committee can deviate from randomized controlled studies as a gauge. The question and problem that arises is of course, what are justified cases where the evaluation can deviate from taking randomised controlled studies as a gauge to do their evaluation work. This question and problem is highly controversial, as there are always advocates and proponents of a specific technology who are interested in a rather low standard of evidence on the one hand. And on the other hand there are so-called 'purists', like for example the staff members of the IQWiG, for whom in principle the randomized controlled trial counts as base of evidence for the effectiveness of a specific technology. In general, the discussion taking place manoeuvres in between these two extremes: the proponents of a technology and the 'purists' or adherents to randomized controlled studies that 'prove' the effectiveness of a technology.

Publicly accessible via the Internet are the final reports by the G-BA in which all comments made are listed separately. This final report of the G-BA also presents the decision and its substantiation and the comments of the theme groups. But the minutes of the meetings themselves of the G-BA, the sub-committees and the theme groups, are not publicly available.

6.3.4 Output and implementation

Decision output

The decisions of the G-BA are published in the 'Bundesgesetzblatt'. There is further no structured or formalized procedure in place to communicate the decision to the different parties involved in the implementation of a new service. The information is rather spread in an informal process taking place via the different working groups involved on the different levels of the decision-making process of the self-governance system.

³⁹ In sect. 21 of the code of procedure the hierarchy of the evidence-based evaluation criteria are listed (Gemeinsamer Bundesausschuss, 2005).

The decision of the G-BA is legally binding and mandatory. The decisions of the G-BA are classified in judicial terms as an ‘untergesetzliche Norm’, which implies that it is below the category of law and regulation decreed by the Ministry of Health, but it has the character of a mandatory and legally binding norm and rule. These rules apply and are legally binding for the field of the SHI (not for the private insurances). Once a technology is excluded by the decision of the G-BA, the statutory sickness funds are not allowed to cover it. Private insurances are exempted of this rule and are allowed to cover such technologies. Only the legal way to appeal against G-BA decisions is through legal complaints. In general, however, such legal complaints are not successful. If there is a legal proceeding and the G-BA and the complainant is heard, then it was till now always the case that the position of the G-BA has been acknowledged and confirmed by such a legal proceeding. There were a few exceptions, but these cases were related to issues concerning competition and antitrust laws. In these cases questions are raised if the practice of the G-BA is actually compatible with existing European legislation. The G-BA can actually not be held accountable for possible incompatibilities with the European legislations. It is more the task of the government to make sure that the respective regulations and laws are compatible and not contradictory.⁴⁰

Implementation of a decision

When the G-BA decides on the inclusion of a service into the benefit package, its inclusion must be regulated. This involves definition of the actual benefit, and regulation of technical quality as well as qualification of the providers. The responsibility for definition of the benefit and quality assurance rests with separate committees who are not part of the G-BA: the committee on quality assurance and the committee on the specification of the reimbursement. The Valuation Committee works on the reimbursement details in close cooperation with the G-BA (e.g. in terms of description of the new service) and the committee working on the specifications of quality assurance. The discussions of these two aspects of the implementation are taking place in working groups that are appointed by the deciding boards. These working groups work and bargain on the details and present a proposal for the final decision. Generally, the groups work contemporarily in order to ensure a quick inclusion of the new service. Formally these entities are separate and ‘sovereign’, but practically a lot of communication and cooperation is taking place between these entities. The working groups involved in the process are ‘automatically’ (that is, by the nature of the self-governing system) aware and informed about the current issues. The moment it becomes clear that soon a certain issue will be on the agenda of the G-BA, the representatives of the joint self-governing system in the working groups can already inform their respective bodies.

Notably, implementation of a technology will not take place as long as no agreement is reached on the specification of quality assurance and the reimbursement details. This can sometimes be problematic. There is an interplay; that is the more complicated a new service, the more extensive and elaborative the quality assurance agreements and the higher the possible reimbursement for the physicians. It is of course

⁴⁰ It happened so far only once that a regulation released by the G-BA was interfering with existing European laws, but it was not related to the question of effectiveness, but to the question of free trade.

in the interest of the medical fraternity to reach an agreement for a reimbursement as high as possible for a specific service. The interest of the health insurance funds lies, however, in controlling the expenses for services. These opposing and conflicting interests of the physicians and the health insurance funds entails of course quite some bargaining. As a result, the competition is often hard in the Valuation Committee.

An agreement on quality aspects is made by a committee that is composed of representatives of the health insurance funds and of the National Association of Statutory Health Insurance Physicians. The quality assurance regulations describe which demands and standards the physicians have to meet that are offering this new service and technology. The agreement on quality assurance is normally a very detailed regulation and it can take quite some time to negotiate the details depending also very much on the degree of the controversy that the new service entails. This is for example illustrated by the acupuncture example. Acupuncture is included in the benefit package for two indications only. Physicians who want to offer this service must have a qualification for pain therapy and psychosomatic medicine. Furthermore, the quality assurance regulations discuss which needles are allowed, what kind of room facilities are appropriate, how long a acupunctural treatment should go, how many hours of training in acupunctural treatment the physicians need to exhibit, etc.

A clear description of a service in the Uniform Value Scale (EBM) is stipulated as a condition for the provision of the respective service. The Valuation Committee defines the actual benefit for the insured, in terms of the EBM and the associated reimbursement rate. The EBM is part of the contract that is concluded between physicians and insurers at the federal level (the so-called 'Bundesmantelverträge-Ärzte', or BMV-Ä), which also regulates participation in ambulatory care, the pertinent aspects of quality assurance, and entitlement to benefits. Accordingly, definition of the EBM depends on consensus between the two contract parties, the Federal Association of SHI Physicians and representatives of the federal associations of sickness funds. Also the Valuation committee is set up with people from the joint self-governing bodies. If the Valuation Committee fails to reach consensus, at least two of its members or the Federal Ministry for Health and Social Security may demand that the extended Valuation Committee be brought in to resolve a split decision (SGB V, Sect. 87 para. 4). Resolutions are to be submitted to the Ministry of Health, which in the event of unresolved objection, may define alternative executions (Busse & Riesberg, 2005).

The respective federal associations of the joint self-governing system (KBV etc.) provide channels and fora for further informal mechanisms of communication of the decision-making process. Till now there has been apparently no need to formalize such communication mechanisms; the informal mechanisms or better the joint self-governing system entails and includes the spreading and communicating aspect of the implementation of a new service.

Reappraisal

There is no systematic reappraisal mechanism in place. A decision can of course be revised or updated, but it has to be formally applied for. Any of the organizations represented in the G-BA (sickness funds, doctors, federation of hospitals, patients) can apply for such a reappraisal provided it is applied for with a

substantiated argumentation. Conflicting interests of insurers and physician sometimes drive the reappraisal process. In 2000, for example, there has been a discussion of bone densitometry for asymptomatic persons as a consequence of increased use as it was very attractive and well reimbursed as a service. It has been performed in large quantities and has been handled as a sort of ‘grey or opportunistic screening’; that is, a screening that does not need to be done in practice, but that is still performed as it is financially rewarding for the performing doctors. As a consequence, the G-BA excluded bone densitometry for asymptomatic patients (i.e., patients who do not show indications of having osteoporosis) from the SHI package. The reappraisal of including bone densitometry in the benefits catalogue has been discussed extensively and in a very controversial way. The application for reappraisal has been based on an extensive and evidence-based counselling process. Currently, the discussion about reimbursement is opened again as the situation has changed by the introduction of a new drug that allows treatment of osteoporotic patients in an early stage. This implies that the possibility of measuring the density of the bones gets a different meaning.

Interesting in this context are of course the informal mechanisms of prioritizing certain issues or not. Here there is quite some strategic and political margin. A few criteria have to be followed (see code of procedure of G-BA). There are several examples of claims for a reappraisal and re-consultation that have been made and that are waiting already for six or seven years to be dealt with. They have not been prioritized very highly and by this not dealt with, because no one of the responsible ones has a real interest to deal with them. One example is the first anamnesis in homoeopathic treatment (‘homoeopathische Erstanamnese’) which has till now only been delayed as it is not considered as important enough to be dealt with. There has been a request of reappraisal for this issue, but there is no real interest within the G-BA and till now it has been postponed by prioritizing other requests of reappraisal that are put forward.

The priorities are assigned by the G-BA itself, actually in the respective sub-committees, and the prioritizing of the applications for reappraising certain services cannot be changed from ‘outside’. The G-BA can be forced to act in a certain way from ‘outside’, but there is no other formal way of changing the priorities set by the G-BA. It can happen, like it is now the case with mammography, that pressure is coming from the political side. In the case of mammography screening it was the federal government who wanted it to be included in the benefit package of the SHI and who decreed the inclusion of mammography in the benefit package. The G-BA had no possibility of rejecting this decision as its regulating scope is overruled by federal law. The G-BA initiated pilot projects and experiments of mammogram screenings, but the federal government ignored them and did not wait for the evaluation of them.

Impact of the system for reimbursement decisions

Anything that is approved and decided by the G-BA has got – by its legal nature – a direct impact. There is unfortunately no research undertaken to evaluate what kind of impact HTA reports do have on the state of health of the patients concerned. It is a difficult undertaking in practice as so many known and unknown factors do have an influence on the health of a human being. The medical factor is always only

one factor amongst many. If we take for example the complexity of chronic pain and if we would like to investigate if an acupunctural treatment is releasing chronic neck or back pains, we would have to consider also all other factors that could have an impact on the chronic pain of a patient. This is (so far?) practically impossible.

Chapter 7 The Netherlands

7.1 Organization of health care in the Netherlands

7.1.1 *Characteristics of the health care system in the Netherlands*

The Kingdom of the Netherlands is a densely populated country in Northwest Europe with population estimated at 16.3 million in 2006.⁴¹ The Netherlands is a democracy in which the government has executive power. There are checks and balances for the power of the government, such as the two-chamber system, an independent judiciary system, administrative supervision, and the right to amendment by the second chamber. The government has a constitutional responsibility for the accessibility, efficiency, and quality of health care. The development of health policies to ensure the well-being of the Dutch is formally the responsibility of the Minister of Health, Welfare, and Sports (VWS). Regarding health care, the Dutch place a high value on universality, solidarity, and equal access.

The Dutch health care system has three characteristics important for the context of health policy decisions. First, health care is financed by a mixture of public and private sources. Over the past decade, health care for approximately 65% of the population has been publicly financed, under the Sickness Funds Act ('Ziekenfondswet', or ZFW) of 1964. Private insurance could be contracted for those not fulfilling the criteria for sickness funds. Second, the providers of health care are private enterprises. Most hospitals and other institutions are owned or run by non-profit organizations. Third, the Dutch use a neo-corporatist approach, which is visible in health care as well. There is a strong interdependency between the government, the insurance companies, and the health care providers, when reforms are considered. The social partners (employer and employee federations) often enter the discussions in relation to income-related contributions and collective funds. In addition, there are many advisory groups that strive for a place on the health agenda and at the policy table.⁴²

Next, it is important to note that the Dutch health care system has gone through various stages of development over the past decades, which can be described using Cutler's 'waves of health care reforms' (Cutler, 2002). Since the early 1980s, the healthcare system in the Netherlands was in the second wave, cost containment. Central control of the supply of health care became the focus of policy-makers' attention. Laws were enacted to manage hospital capacity, the use of expensive technologies, the number of medical specialists, and annual budgets. Perverse incentives stimulated budget maximization rather than achieving good health outcomes at an acceptable cost. During the late 1990s and early in this century, the system was seen as no longer being responsive to the growing and changing needs of the population. This has led to reforms towards a demand-driven, regulated market, with the aim of promoting efficiency and freedom of choice. These reforms are described in more detail in Section 7.2.

⁴¹ <http://www.cbs.nl>. Accessed: September 15, 2006.

From 2006 onwards, the Netherlands has had a compulsory, universal basic health insurance. The most important legal regulations in this area are the Health Insurance Act ('Zorgverzekeringswet', or ZVW), the Health Insurance Decree ('Besluit Zorgverzekering', or BZV), and the Health Insurance Regulation ('Regeling Zorgverzekering', or RZV), as explained in Section 7.1.3.

Medical specialist care, also referred to as the second compartment in the Netherlands,⁴³ is the area of interest for this report. In 2005, diagnosis treatment combinations (DBC's) have been introduced as the new prospective payment system for this part of health care, as will be described in Section 7.2. DBC's are nationally defined care products for an integral price. They include all the medical services, materials, labor and medical consultation consumed for the diagnosis and treatment of a given disease. Introduction of DBC's is expected to increase transparency and competition within the health care system and to stimulate quality and cost containment.

7.1.2 Health care funding in the Netherlands

Health care expenditure in the Netherlands was 9% of the GDP in 2004 (Organisation for Economic Co-operation and Development, 2006b), or US\$ (ppp) 49.5 billion (US\$ (ppp) 3,041 per person).

Until 2006, funding of health care was regulated under the ZFW. It came from employers' contributions, nominal premiums, and private contributions. Contributions were compulsory, income dependent and collected by the employer. In 2005, 8% of income, to a maximum income of €32,500 was collected as contributions to the Central Cash of the Sickness Funds. These funds were redistributed to the sickness insurance funds according to a risk-related redistribution scheme. Sickness funds insurance was available to all who earned less than a set wage. Private insurance was taken by those with sufficient income. This combination of different insurances resulted in insurance coverage for the entire population.

Since 2006, funding for health care in the Netherlands has been coming through the public and private contributions under the new ZVW. Public funding for health care is income-related and contributed by the employers at 6.5% of employee's gross income to a maximum of €30,623 (Art. 5.1-5.2 RZV). Employers are obliged to compensate their employees for these contributions. The private component includes nominal premiums paid by the insured, which range between €1,056 and €1,137 per year (Vektis, 2007). The government pays for all costs incurred by children. Additional care (e.g., dental care for adults) may be insured under voluntary supplementary private insurance. A subsidy scheme has been developed for those with lower incomes.⁴⁴ From January 2008 onwards, everyone will be subject to a

⁴² (Ministry of Health Welfare and Sport, 2004) gives an extensive description of the health insurance system up to 2004.

⁴³ The Dutch system divides care into 3 compartments. The first compartment is exceptional medical expenses and is compulsory for the entire population (AWBZ). It includes expensive, uninsurable and long-term health care. The second compartment is for acute medical care such as physicians, medical specialist care and hospitalization and was covered by the ZFW and other public and private plans. Since 2006, all second compartment care is grouped in the ZVW. The third compartment is for other health care that is not included in the first two compartments. It is funded by supplemental insurance and direct payments.

⁴⁴ See the Care Allowance Act ('Wet op de zorgtoeslag').

compulsory personal risk of €150 per year (excluding care by general practitioners and maternity care). According to the ZVW, all residents are required to insure themselves (and their children) (Art. 2), while health insurance companies must accept all applicants for the basic health insurance (Art. 3). This is to ensure that all residents are insured. The insured have the right to switch insurer by the end of each year (Art. 7). Insurance companies compete with the level of the nominal premium and how the care is offered. In conclusion, it may be said that this system of a national health insurance based on regulated competition in the private sector is unique in an international context (Enthoven & Ven, 2007; Ven & Schut, 2008).

7.1.3 *The benefits package*

The ZVW (Art. 10-11) broadly defines the benefits package – actually a continuation of the benefits included in the ZFW. Benefits are made more explicit in the BZV (Art. 2.1-2.15) and the RZV (Art. 2.1-2.38), which specify the sorts of care and give a list of uninsured services. The covered benefits include curative care provided by medical specialist, the general practitioner, clinical psychologists and midwifery; dental care for those under 18 years of age; dental surgery; pharmaceutical care; medical assistive devices; nursing; perinatal care; hospital stay (including drugs) and associated nursing care; paramedical care (such as physiotherapy); and transportation related to all these benefits (Art. 10 ZVW). The care must be provided by recognized professionals and, regarding medical specialist care (with the exception of emergency care), is conditional on the referral of a recognized professional, such as a primary care physician or another medical specialist (Art. 14.2 ZVW). The care should meet evidence-based medicine standards (‘stand van de wetenschap en praktijk’) or, in the absence of such standards, be considered reasonable and adequate care (‘verantwoorde en adequate zorg en diensten’) within the profession. Moreover, the insured is only entitled to care on which he or she is reasonably dependent (i.e., there has to be a medical indication) (Art. 2.1 BZV). There is a ‘negative list’, or in other words, a list of services that have been excluded from insured care. Regarding medical specialist care, the following treatments have been excluded (Table 7-1). To conclude, the Dutch system may be considered an ‘open’ system, since all care that is considered ‘evidence based’ or ‘reasonable and adequate care’ and that is not on the negative list is insured.

Table 7-1 Exclusions of medical specialists care from the basic health insurance

-
- Eyelid corrections (with the exception of congenital eyelid anomalies)
 - Abdominal liposuction
 - Breast prostheses implantation, replacement or removal (unless related to breast amputation)
 - Uvuloplasty for the relief of snoring
 - Sterilization or reversal of sterilization
 - Circumcision
-

Source: Art. 2.1 RVZ.

The introduction of the DBC financing system, which is founded on the Health Care Competition Act ('Wet Marktordening Gezondheidszorg', or WMG 2006), has led to a more explicit description of the medical specialist care products. The aim was to achieve transparency in the content and the cost of care products. Whereas new forms of care were implicitly added to the entitlements as 'usual care' prior to the DBCs, there is now an overview of care products. As a result, decisions on market approval and, subsequently, decisions on reimbursement can be made more consciously now. As we will explain below, a fourth hurdle system has been introduced and is being refined by the Health Care Insurance Board ('College voor zorgverzekeringen', or CVZ).

7.2 Health care reforms in the Netherlands

The Netherlands has begun a new wave of reforms to introduce regulated competition in the health care market. Although the more tangible changes are apparent since about 2000, the reforms have been developing in the 1990s. The reforms stem out of a conviction of the government that a regulated market will resolve the problems of the current system, most notably a lack of incentives on the part of patients and providers to optimize effectiveness and efficiency. The Cutler waves of reform can be applied to the Netherlands (Cutler, 2002): the expansion wave (1964-1980), cost containment wave (1980-2000), and structural change toward a regulated market (2000-present).

The expansion phase (1960-1980) saw the introduction of the Sickness Funds Act of 1964. This act expanded the group of citizens that were entitled to the basic entitlements of healthcare. It was a period of increasing welfare in the Netherlands. Financing of health care was open-ended and there was no restriction on building capacity. It is not surprising that the market expanded. As a result, expenditure grew quickly from 3.9% of GDP in 1960 to 7.7% in 1975 (Schieber & Poullier, 1989). Gradually, the economy came under pressure. The government implemented laws to structure the supply of health care, such as the Hospital Provision Act of 1971 ('Wet Ziekenhuisvoorzieningen', or WZV).

Consistent with Cutler's second wave, the Netherlands in the 1980s began to focus on measures to achieve cost containment. Laws to enable supply side management were passed for macro and institutional budget restrictions, tariffs and capacity planning. The Ministry set the macro national health care budget annually ('Budget Kader Zorg', or the Macro Budget for Health Care). The Health Care Tariffs Act ('Wet Tarieven Gezondheidszorg', or WTG, 1982) was passed to manage prices and budgets. The Health Care Facilities Act (1985) was designed to manage health care capacity. The Health Care Charges Board ('College voor Tarieven in de Gezondheidszorg', or CTG) operationalized the laws to achieve cost containment and central planning for the institutions. Overall, these measures were successful in stabilizing the growth of health care expenditure. Expenditures rose from 8.2% of GDP in 1980 to 8.3% in 1985-86 and 8.5% in 1987 (Schieber & Poullier, 1989).

Problems associated with the second wave of reforms appeared in the 1990s, a period of increasing waiting lists. Overspending of health care budgets, covenants between the government and health care suppliers to contain expenditures and efficiency budget cuts were commonplace. Citizens went to court to secure their right to health care. Central management of capacity and volume did not keep pace with real

demand, changes in the political arena, and technological and demographic changes. The government was faced with unmanageable expansion in health care expenditures, perverse incentives for institutions and professionals, and negative health outcomes. A lack of incentives for efficiency and innovation was an increasingly recognized problem. This made the government explore options for reforms towards a regulated market in health care. These reforms implied that the insurance laws, the pricing and contracting laws, and the laws for building health care capacity – the laws that were important for central planning and control during the cost containment wave (the ZFW, the WTG, and the WZV) – had to be changed. For example, the WTG required that negotiations for health care services and prices be done by formally recognized representatives of the parties involved. Negotiated outcomes had to be approved by the CTG and all insurers were entitled to the same conditions agreed to with one. The WTG was replaced with the WMG, which liberalized pricing for some market segments, defined the market segments that are not liberalized, and instituted the Netherlands Health Care Competition Authority ('Nederlandse Zorgautoriteit', or NZa) as the market regulator.

Also during this period, numerous reports were produced on how to change the health care system to meet the goals of providing a broad package of universal health care within a limited budget. The most influential were the Commission Dekker (1987) and the Commission on Choices in Health Care (Commission Dunning, 1991). The Dekker Commission suggested market-oriented reform within the context of a national health insurance system. The Funnel of Dunning, proposed by the Commission on Choices in Health Care, gave perspective on how to manage the benefits package. The Funnel of Dunning has four criteria to facilitate decisions on the addition, or removal, of types of care to the benefits package:

- is it necessary care;
- has it been demonstrated to be effective;
- has it been demonstrated to be efficient;
- can payment be left to the responsibility of the individual.

Unfortunately, the Funnel of Dunning proved difficult to put into practice. However, it did refocus the discussion from cost management to benefits package management. The Dunning Report has had an important influence on the criteria used by the Minister of VWS and the CVZ when making decisions on the in- or exclusion of medical technologies.

Among the most significant reforms were the introduction of the ZVW in 2006 and the introduction of DBCs in the hospital market in 2005. DBCs are the products to be negotiated in the new regulated market. They have been divided into so-called A and B segments.⁴⁵ The A segment contains national, maximized or fixed prices. Hospital care falling under this segment continues to be financed using the budget structure that is in use since 1984. In the B segment, prices are freely negotiable between

⁴⁵ See Art. 57 Sect. 4 WMG, the Decree on the expansion of the open tariffs DBC segment ('Besluit aanwijzing inzake uitbreiding DBC-segment met vrije tarieven'), and the Regulation based on Art. 7 Health Care Competition Act (regarding the preparation of 2009 hospital care) ('Regeling aanwijzing ex artikel 7 Wet marktordening gezondheidszorg (inzake voorbereiding ziekenhuiszorg 2009)').

health care providers and insurers. The first step to end mandatory contracting for medical specialist care was the introduction of the B segment and the Decree Termination of Compulsory Bilateral Contracting ('Besluit gedeeltelijke opheffing (omgekeerde) contracteerplicht medisch specialistische zorg', 2005). The B segment currently represents approximately 20% of the medical specialist care, including for example the treatments of cataract, inguinal hernia, kidney stones, diabetes, gastroesophageal reflux disease, or chronic heart failure.⁴⁶ The government intends to further expand the B segment (Tweede Kamer der Staten-Generaal, 2007; Tweede Kamer der Staten-Generaal, 2008a; Tweede Kamer der Staten-Generaal, 2008b).

The government has national health goals (standard of health of the population and macro budget), but in the regulated market it has relinquished most of the tools needed to directly manage the budgets. A key tool that remains available to the government to achieve budget goals is management of the benefits package. HTA can inform decision making for the package to give the most health outcome for the expenditure. The recent introduction of DBCs has increased the potential of HTA, allowing for its introduction in the area of medical specialist care. The next section will focus on the evaluation process for new DBCs and the role of HTA within it.

7.3 Definition of entitlement to medical specialist care

The Netherlands has a strong tradition in HTA. HTA activities began in the 1980s to help with prioritizing for cost management. Initial interest in HTA coincided with policy discussions about priority setting, definition of the benefits package for the social insurance, and stimulation of appropriate use of health care at decentralized levels (Berg et al., 2004). At first, HTA was used on an ad-hoc basis, especially targeted at expensive new technologies. The results were used to inform decisions about whether to include a new technology in the benefits package. At other times however, decisions to grant funding were not clearly related to HTA outcomes. For example, although classified as not cost-effective, lung transplants were included in the benefits package. On the other hand, a HTA study for Viagra demonstrated cost-effectiveness well within the cost-effectiveness threshold, but Viagra was not included in the package.

As indicated above, the Dunning Report (1991) increased the interest in HTA as a tool for structured assessments of effectiveness and efficiency. Ever since the 1990s, the government has been aiming for expansion of the use of HTA. CVZ stimulated the use of HTA since 1999 with its voluntary requirement for cost-effectiveness studies as a part of the reimbursement submission for pharmaceuticals. In January 2005, HTA and cost-effectiveness studies became a mandatory component of drug reimbursement applications.

The introduction of the new DBC hospital financing system increases the role of HTA in defining the benefits package. HTA is integrated into the application requirements for new and modified DBCs.

⁴⁶ See the Annex to the Decree on the expansion of the open tariffs DBC segment ('Besluit aanwijzing inzake uitbreiding DBC-segment met vrije tarieven').

Following the Hutton framework, the procedures to determine the benefits package, and the role of HTA within these procedures, are described in detail in the next sections.

7.3.1 Policy

The main parties involved in determining the benefits package are the Minister of VWS, CVZ, NZa, and the DBC Maintenance Organization ('Stichting DBC-onderhoud', SDO). In 2005, these parties set out their roles in the fourth hurdle system in the DBC Maintenance Covenant (Stichting DBC-onderhoud et al., 2005). DBC maintenance is divided into public and private responsibilities. The CVZ and the NZa are responsible for the public side: access to public funds and impact on the macro and hospital budgets. SDO is responsible for system development. It is an independent private organization, whose board is composed of people from the Dutch Hospitals Association, the Dutch Federation of University Medical Centers, the Order of Medical Specialists, the Dutch Health Insurers Association, and the Netherlands Patient and Consumer Federation (all in personal capacity). New DBCs must be accepted by the private and public DBC management organizations.

Before turning to a description of the fourth hurdle system, we will now describe these main parties in some more detail. This analysis puts particular focus on the CVZ. Managing the benefits package is one of the main responsibilities of the CVZ (Art. 64-66 ZVW). Other key areas of responsibility of the CVZ are managing the collective funds, enforcing the risk equalization scheme, and additional administrative tasks (for example regarding the uninsured and Dutch nationals living abroad).⁴⁷ CVZ is an independent government organization ('zelfstandig bestuursorgaan') with about 300 fte on roll. It has a Board of Directors of three members, who are appointed by the Minister of Health (Art. 59 ZVW). The Minister finances the CVZ.

The NZa is the independent government organization that sets the framework for budget negotiations and sets maximum charges for care products (Exter et al., 2004). NZa has its roots in the WTG and will continue its role in fixing tariffs for the A segment of the DBCs. Moreover, it fixes the descriptions of the care products (both regarding the A and the B segment). In addition, the NZa has been entrusted the tasks of competition watchdog for health care and of overseeing the application of the ZVW by the insurers (Art. 16 WMG). It employs about 235 people and has a four-person Board of Directors, appointed by the Minister (Art. 4 WMG).

The SDO was established mid-2004 as the private DBC maintenance organization. It is responsible for the proper functioning of the DBC system. Its task is to manage the medical content of the system, the addition, deletion and modification of the DBC system, and to develop the system further. It maintains the list of DBCs, which is available to the public through the internet.⁴⁸ Moreover, the SDO assists health care providers and insurers in working with the DBC system. SDO has a staff of about 25,

⁴⁷ <http://www.cvz.nl/>. See also (College voor Zorgverzekeringen, 2007).

⁴⁸ <http://www.dbconderhoud.nl/>.

and is funded through a subsidy from the Ministry of VWS. Since the year 2004, the SDO has been in a permanent process of refining and professionalizing the DBC system (DBC-Onderhoud, 2007).

The fourth hurdle system may be described as follows. Applications for new or modified DBCs enter the system via the SDO. SDO asks the applicant to deliver several types of information: the dossier includes sections for the DBC system, the medical assessment (e.g., effectiveness, indication, the expected number of patients, burden of disease), and the financial assessment (cost-effectiveness). The dossier defines the information needs of the SDO, the CVZ and the NZa in one document. The SDO assesses the application, drawing on the multidisciplinary expertise of its Medical Scientific Advisory Council ('Medisch Wetenschappelijke Advies Raad', or MWAR – formerly called the WAR). If the SDO concludes that the DBC in question requires a new DBC characterization (i.e., is not yet described specifically enough by existing DBCs), it decides that the application will be further processed and forwards the dossier to the CVZ and the NZa.

CVZ undertakes an assessment of the DBC (see further below). This results in an interpretation of whether the DBC is covered under the public insurance. If its interpretation is that it is indeed insured care, the Minister of Health does not have to take action to ensure that the care is included in the benefits package. On the other hand, if the interpretation of CVZ is that it should not be insured care, CVZ will advise the Minister to exclude the care from the benefits package. The Minister may or may not follow this advice, as he has final decision-making authority over decisions regarding exclusions from the benefits package.

The NZa assesses the cost data supplied by the SDO (via the dossier or additional info). It fixes the descriptions of the care products and fixes tariffs for DBCs within the A segment. The NZa has autonomous decision-making powers, but the Minister may give general indications and may annul an NZa decision (Art. 7-9 WMG).

CVZ has been using HTA in reimbursement of drugs at least since 1999. Today, both drug and non-drug technologies (i.e., medical specialist care) are assessed by the Insurance Benefits Management Department of the CVZ. Of note here is that a DBC dossier requires essentially the same HTA information as a drug reimbursement submission, even though in practice many differences between the systems for medical specialist care and drugs remain. There are notable differences in who is responsible for performing the assessment (regarding DBCs this is not the applicant but CVZ) and in the scope of the system. Whereas in the area of drugs all new listings undergo an assessment, when a DBC is concerned, a given technology formally comes into scope only under certain circumstances (given that it is considered 'evidence based' or 'reasonable and adequate care'). This is for example the case when CVZ issues a statement on the in- or exclusion of a technology in the benefits package, not related to DBCs. Moreover, a DBC comes within the scope of the fourth hurdle system when a submission is made for a modification of a DBC or the incorporation of a new DBC. All currently marketed technologies can come into scope if they are part of the standard care comparator for new DBCs. As an aside: the DBC system is also intended to include all medicines given within the medical specialists setting (i.e., hospital). How this should be done is not yet defined.

7.3.2 Assessment

Submissions for DBCs may be made by many different parties: health care providers, insurers, medical specialists, patient groups, the SDO itself, or others. Consultation with stakeholders is important during the development of the submission with SDO. There is a section in the application that specifically asks for input from the medical specialists and the patient groups. Furthermore, the SDO may ask for additional information from the submitting party. The SDO receives the opinion of the MWAR, the multi-disciplinary group within the SDO composed of experts such as clinical specialists, epidemiologists, and hospital managers. The MWAR may consult with other experts when reviewing the DBC submission (Tweede Kamer der Staten-Generaal, 2006). The SDO forwards the completed submission to the CVZ and the NZa for assessment.

At that moment, the HTA process for CVZ begins. In November 2006, CVZ published a report entitled 'Benefits Package Management in Practice' ('Pakketbeheer in de praktijk') (Mastenbroek et al., 2006). This report broadly describes how CVZ performs its tasks in the area of managing the benefits package. The methods described in this report are applied generally to all benefits package assessments (both care and cure). It is meant to provide a consistent and transparent process for assessment of all submissions. First, CVZ assesses whether the DBC meets evidence-based medicine standards ('stand van de wetenschap en praktijk') or, in the absence of such standards, is considered reasonable and adequate care ('verantwoorde en adequate zorg en diensten') within the profession (see Section 7.1.3), which actually comes down to a broad assessment of effectiveness (Staal & Ligtenberg, 2007). Second, if this is the case according to the interpretation of CVZ, CVZ assesses whether the DBC should be excluded from the benefits package with three other criteria: necessity (considering disease severity and medical need), cost-effectiveness, and feasibility (for example considering budget impact and possible substitution to other, more expensive types of care).

It follows that CVZ requires information, and develops an advice, in three areas: medical, cost, and cost-effectiveness (Werkgroep pakketbeoordeling DBC, 2005). CVZ follows the evidence-based medicine approach. Regarding the first area, the information required includes data on the patient group and the impact the treatment would have, epidemiologic data, a description of the proposed treatment or technology and how it works, safety and clinical effectiveness information (literature search), burden of disease, ongoing studies into safety and effectiveness, current treatment practice, future developments, and where it would fit in the DBC system. Regarding the cost of the technology, an estimate of the costs per treatment or per patient course of therapy and of the budget impact is made. A search into published cost-effectiveness studies has to be carried out. If no data on cost-effectiveness have been published before, applicants are welcomed to perform a formal cost-effectiveness study themselves, following the methodology of the CVZ (Oostenbrink et al., 2004) or another recognized HTA guideline. CVZ issued guidelines to help applicants perform a study into the cost-effectiveness of a DBC (Rodenburg-van Dieten, 2005). Finally, it may be mentioned here that a CVZ report entitled 'Working Methods for DBC Maintenance' outlines why CVZ requires the different evidence within the submission and that some

evidence may be more important for some aspects of the assessment (Rooij & Zwart, 2005). Uncertainty is accounted for within the analysis of CVZ by applying uncertainty analysis. Missing evidence is noted within the report along with the impact it has on the conclusions and recommendations of the CVZ.⁴⁹

CVZ presents their conclusions from the assessment, coupled with a recommendation on whether the proposed DBC should be excluded from the benefits package. All four criteria mentioned above (effectiveness, necessity, cost-effectiveness, and feasibility) have a role in the assessment. There is no hierarchy in these criteria, with the exception that it makes no sense to assess care that is not necessary or not effective at all (and thus should not be in the benefits package) against the criteria of cost-effectiveness and feasibility (Mastenbroek et al., 2006). Neither does CVZ have threshold levels for making a positive recommendation. It is of note that the criteria do not differ fundamentally from the criteria proposed by the Dunning Commission (see above).

An important point to observe here is that the appraisal phase (in contrast to the assessment phase) in fact starts here, at CVZ. CVZ sends a draft report to the stakeholders. After this consultation of stakeholders – their responses to the draft report may, at the discretion of CVZ, be incorporated into the final report – CVZ performs an appraisal and finalizes the report. To enhance the quality and the societal acceptance of the appraisal, in 2008 a special advisory committee ('Adviescommissie Pakket'), composed of both CVZ board members and external experts, has been instituted to give the CVZ board advices on benefits package decisions (Art. 59a ZVW). Finally, CVZ makes recommendations for the funding status of the DBC: in principle fully funded (no code), in principle not funded (code red), or funded only under certain conditions (code orange) (Halteren & Ligtenberg, 2007). It sends a letter with recommendations and a short motivation to the Directorate of Curative Care, a department within the Ministry of VWS, for a decision. Moreover, CVZ informs the applicant. The final report is public information. A summary of the assessment report and recommendation with a motivation is published on the CVZ website.

Next to these recommendations on specific types of care, CVZ publishes an annual advice ('Pakketadvies'), which includes a proposal for changes in the benefits package for the coming year and a reflection on developments regarding the composition of the benefits package management (Polman & Haan, 2007; Polman & Haan, 2008).

The DBC submission process has only been operational since 2005. Clearly, the process is in its early stages. In 2006 for example, SDO submitted only one DBC to CVZ for an assessment (regarding vagus nerve stimulation (VNS) for the treatment of depression (Projectgroep DBC's, 2006)) (College voor Zorgverzekeringen, 2007). In 2007, two DBC assessments were published, one again regarding VNS (Staal, 2007) and the other regarding cytoreduction surgery in combination with hyperthermic intraperitoneal chemotherapy (HIPEC) (Projectgroep DBC's, 2007). More dossiers must be handled before anything can be said about reproducibility, transparency, consistency, and quality of the

⁴⁹ The report on vagus nerve stimulation (VNS) also cites missing data as the reason some conclusions and recommendations cannot be made (Projectgroep DBC's, 2006). This indicates that dossiers are assessed even when not all of the evidence requirements are fulfilled or the highest quality of evidence is available.

assessments. Within CVZ, there is yet no system of prioritizing which technology or DBC should be assessed (or re-assessed). Rather, all DBCs that are submitted are assessed. CVZ does see the need to review the benefits package in a more structured way in the future (Meester, 2006). With this in mind, CVZ publishes a bi-annual agenda regarding benefits package management ('Pakketagenda') beginning in 2007 (Mastenbroek & Latta, 2007). The purpose is to spot issues that are relevant to the composition of the benefits package. It mentions types of care for which CVZ will proactively assess whether they are eligible for inclusion in or exclusion from the benefits package.

As a final remark, it is noteworthy that CVZ recognizes the potential role of conditional temporary reimbursement of innovative DBCs (Mastenbroek et al., 2006; College voor Zorgverzekeringen, 2007). At the same time, there appear to be obstacles which currently prevent innovations from getting admitted to the benefits package. This has resulted in the establishment of the so-called Innovation Office ('Innovatieloket'), which is run jointly by CVZ, NZa, and the Netherlands Organization for Health Research and Development (ZonMw). Its aim is to inform stakeholders of existing facilities through which conditional funding may be obtained for promising but yet unproven innovations (College voor Zorgverzekeringen & ZonMw, 2007).⁵⁰

7.3.3 *Decision*

The Minister of VWS makes the decision. The Ministry's Directorate of Curative Care handles the CVZ recommendations. The CVZ has been legally appointed to manage the benefits package (ZVW Section 6), so the Directorate generally, but not necessarily, approves the recommendations. The Directorate has its own (political) motivation, but bases its decisions on the recommendations from the CVZ, and does not do additional research or consultation with experts or stakeholders as a rule.

Documentation of the decision process of the Minister was not found and thus does not seem transparent to the public or to newcomers to the system. In addition to the criteria of the CVZ, the Minister considers the relevance of the DBC to the public health in the broadest sense (including for example necessity of care vis-a-vis other treatment options, or whether it is reasonable to have the individual or the collective pay, taking into account the expected impact on the health budget). There is no formal threshold in terms of cost-effectiveness (costs per quality-adjusted life year (QALY)) on which to base decisions.⁵¹ A structured reappraisal timetable for existing or new medical specialist care has not been found.

Where the decision results in changes to Article 10 or 11 of the ZVW, this change will be published in the official journal of the state ('Staatscourant'). Decisions that require changes in the regulations ('beleidsregels') will result in updates from the NZa.

⁵⁰ Facilities for funding that currently exist include the conditional funding of innovative DBCs (code orange) and the temporary subsidies by CVZ for services that are intended to be included in the benefits package (Art. 68 ZVW).

⁵¹ Recently, the Dutch Council for Public Health and Health Care suggested a threshold of €80,000 per QALY (Raad voor de Volksgezondheid en Zorg, 2006), which has been the subject of much public discussion. The Minister of

7.3.4 *Outputs and implementation*

The process of evaluating DBC applications is new. To date, there is no experience with appeals or dissent of decisions. In practice, one option is re-application at a later date, with new evidence, as was actually done in the case of vagus nerve stimulation. The courses of action open to the stakeholders will be the same as for the pharmaceutical applications. According to the ZVW (Art. 114), the insurers should see to it that there is an independent organization to which the insured can submit a dispute with their insurer. To this aim, the Healthcare Insurance Complaints and Disputes Foundation ('Stichting Klachten en Geschillen Zorgverzekeringen') was founded in 2006. This binding dispute resolution procedure is open to any insured person who questions whether a given technology belongs to the benefits package. The foundation will pass a judgment on whether a technology is insured care, but has no authority over DBCs. As part of this procedure, CVZ issues an advice on whether the care is insured care or not (College voor Zorgverzekeringen, 2007). Moreover, dissenting parties may appeal to the courts – although it will be preferred to succeed in convincing the Minister before the final decision is made –, generate publicity to move the question to the public arena, or initiate questions in Parliament to motivate reconsideration of the decisions.

Implementation follows the decision of the Minister. The implementation of a new or modified DBC within the DBC system is defined in the Covenant DBC Maintenance (Stichting DBC-onderhoud et al., 2005). In system terms, the NZa informs the SDO of the descriptions of the care products and the tariffs. The SDO incorporates the modifications in the DBC instructions and databases that are periodically delivered to the health care providers.

The Netherlands has no regional authority structure that could influence the implementation of a reimbursement decision. The provided care and the amount of such care one may obtain through the scheme are limited merely by professional norms following the 'usual care' principle. Since each hospital is independent in their decision to allocate budget and resources to a new form of medical specialist care (although of course insurers exert influence on this decision), a positive decision does not result in direct, broad availability of the DBC. There may be additional requirements to be met before funding is available, such as prior approval from the insurance company.

Implementation of the new or modified DBC may be facilitated by various bodies. The Scientific Associations of the medical specialists have a key role in developing the care profile in the DBC. The medical specialists are also involved in developing protocols to incorporate the new DBC. The CBO also develops and communicates these treatment protocols for professionals. The insurance companies can be influential by demanding the new DBC for their clients. Factors that could slow down the implementation include waiting for the periodic updates of the DBC software by SDO, which could delay administrative access to the new DBCs for a period of six months. NZa should come with a tariff. Ideally, they work synchronously with the path of CVZ. Should this not be the case, then the implementation is also delayed.

Health has announced that he will not treat this threshold as an absolute limit (Tweede Kamer der Staten-Generaal, 2008c).

The rate of diffusion of the new DBC depends on one or more of the following: the activity of the medical specialists (or another applying party), the treatment protocols that incorporate the DBC, budgets, and other factors. Diffusion may be delayed or not uniform when investment or training is needed. DBCs that would require claiming or reallocating budget in a hospital may also be implemented more slowly. The adoption and diffusion of the new DBC can be tracked through the DBC Information System (DIS) maintained by SDO, to which all hospitals must deliver their DBC registration dataset. However, there may be a lag in the registration, if the treatment has been coded under 'best alternative' before the appropriate DBC code is developed. When the medical specialists are keenly awaiting the decision, implementation in health care will occur more quickly.

The areas of reappraisal and impact analysis of the new DBC in terms of expenditure meeting expectations, number of patients treated versus the estimates has been left open. The use of the new DBC could be analyzed in the DIS, assuming the DBC is adopted and declared. The process is very new and in the developmental stage. It would be prudent to develop these now, to see whether the fourth hurdle system actually produces decisions that are efficient and effective.

Chapter 8 Sweden

8.1 Organizational structure of Swedish health care

8.1.1 *The National Health Service*

Sweden has a compulsory, predominantly tax-based health care system. The Swedish health care system is mainly region based and publicly operated by the county councils. The underlying principle is that the provision and financing of healthcare services is a public responsibility. Three political and administrative levels operate the system: central government, county councils, and local authorities (see Figure 8-1). Central government is responsible for legislation, supervision, and evaluation of the system. Responsibility for provision of care rests primarily with the county councils (20 counties and one local health authority: Gotland), which operate almost all services and levy taxes to finance them. The counties have a population that varies between 60,000 and 1.8 million people (median size is 275,000). One category of healthcare, namely the domestic care of elderly and disabled people, is the responsibility of the local authorities (municipalities).

Being the dominant player in the provision of health care, the counties make structural decisions about planning and management of health care, e.g. about the number of hospital beds, the size of the health service staff, or the number of hospitals in a region. Healthcare is provided in about 1,000 health care centers, 65 county hospitals, and 9 regional hospitals (Swedish Institute, 2003). Counties are responsible for planning and management of the services and decide on the allocation of resources to each service. They also own and run these services. The health care centers are local facilities, established for providing primary care. In the centers, a variety of medical professionals are employed, e.g. physicians, nurses, and physiotherapists, which facilitates teamwork. Hospital care is mainly provided by the county hospitals. Counties co-operate for the provision of highly specialized care. For that purpose also a regional system exists that comprises 9 regional hospitals. These regional hospitals employ a wider range of medical specialists. The system is supplemented by private providers, which – in most cases – have contracts with county councils to supply certain services that the counties pay for.

People in Sweden have freedom to choose where and by whom they wish to be treated. They can elect to visit a public or private provider. The patient may also choose which health center or hospital he or she wishes to visit. Furthermore, referral to a specialist by a GP is not required: a patient can choose to go directly to the hospital or to visit a GP first. Only when the patients opt for a provider outside the county of residence, a referral may be required. Health care provision is furthermore governed by regulations about maximal waiting times (the same day for health care centers, three months to see a specialist, one month to see a specialist when no diagnosis has been made yet). Use of the private sector is increasing. In 2000, 29% of all visits took place at private health services, counting for 9% of health care expenditure. The main obstacle to getting care is therefore the availability of care.

Sweden is proud to deliver universal access to the public health care system. Yet, it is confronted with much the same problems as the United Kingdom for example. The increase of health care expenditures has long been controlled reasonably well, but at the costs of waiting lists. Fifteen years ago, the healthcare system in Sweden was generally considered to be rigid and characterized by long waiting times and inadequate focus on the patient. Benefiting from activities of private providers, the system has improved since then, but waiting lists still exist (Carlsson, 2004).

Figure 8-1 Organization of Swedish health care

State Ministry of Health and Social Affairs National Board of Health and Welfare Swedish Council on Technology Assessment in Health Care	Federation of County Councils	20 County Councils + 1 Local Authority	9 regional hospitals	65 county/districts hospitals	1000 health centers
	Swedish Association of Local Authorities	290 Local Authorities	Housing and care for elderly and disabled		

<ul style="list-style-type: none"> • Legislation • Supervision • Evaluation 	<ul style="list-style-type: none"> • Finance • Organization • Follow-up
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8.1.2 Funding of health care

In Sweden, about 8.5% of the GDP is allocated to health care. 80% of these expenditures are financed through the counties. In fact, the health care system accounts for almost 90% of the counties expenditures. The counties finance their activities mainly by income taxes, which account for over two third of the counties' health care expenditures. Levels for hospital expenditure varied between counties by 30% in 2000, corrected for population demographics (Saltman & Berleen, 2000). Other important financial sources are grants and payments for specific services received from central government (about 19%) and patient fees (2-4%) (Swedish Institute, 2003).

Hospitals have traditionally received a high proportion of total medical resources. Also, the ratio specialists versus GPs is higher than the OECD average. Policy opinion is that there are too many specialists relative to GPs. This might explain why the average number of visits to a GP is relatively low (Swedish Institute, 2003; Rae, 2005). Having too many specialists available poses a threat to the quality of the system, because the question is if all physicians get enough practice to stay into business. Moreover, efficiency is at stake. However, financing the health care system solely through fee-for-service would pose a threat to the efficiency of the system. The search is for the right mix between capitation based and fee-for-service funding (Saltman et al., 2004). To improve efficiency also more attention is given to outpatient care.

To deal with threats to quality and efficiency of health care in Sweden, a transitional progress of change has started. This has been called the Stockholm revolution, because the Stockholm County was the

first to implement changes. Other countries were stimulated to follow this example, so that a gradual process of reforms was started, rather than a dramatic change all around the country. The Stockholm revolution implied introduction of a purchaser-provider split, a development that has also been seen in other parts of the world. In the context of the Swedish health care system, this meant that the existing public county health organization was separated into two distinct categories: service purchasers and service providers. The purchaser/provider split introduced the possibility of contracting inside the public sector, with the expectation that purchasers could extract higher quality and lower prices from service providers (particularly hospitals) (Saltman & Berleen, 2000). A limitation is that while county purchasers can negotiate contracts, they cannot require patients in their districts to receive care only from contracted providers. Hence, these contracts are nominal rather than definitive.

Requirements to providers and evaluations of quality and price are in the hands of county councils, de facto in the hands of committees that are headed by elected local politicians. In line with these developments, ties between the public policy and hospital were loosened, which boosted growth of the private sector. County councils, on the other hand, transformed authorities into purchasers. Districts within countries received budget for care, and purchasers in the districts had to enter into contracts with providers in which volumes, quality and price were specified. Similar to what is seen in other countries, several structural changes were implemented to make the reforms work. Three basic elements of the reforms are (Hjertqvist, 2002):

- Changes in finance: funding is tied closer to output. A diagnosis related group (DRG) system puts a price tag on every treatment. Instead of global budgets being used, every contracted producer is compensated according to the DRG system, but not until the services have been delivered. Competition for public contracts is open to a great number of private, as well as public, providers. The DRG system allows a better control of resources and a superior assessment of outcomes.
- A related development is that a market-oriented approach is increasingly expected from providers. This development is further stimulated by privatization. For example, publicly employed personnel receive legal and educational support to start their own companies. Moreover, although hospitals remain public properties, their management is transferred to private parties.
- Development of consumer information, which aims to support active consumer behavior.

The different counties decide on the pace of these transitions, and naturally they are not all equally active and innovative in this area. Differences may have been partially inspired by existing uneasiness with reforms. Counties in Sweden vary both in income level and health care expenditures. As these factors tend to be inversely related, budget pressure varies between countries (Diderichsen, 1999). In some countries, the immediately lack of control over total health care expenditures that is inherent to the fee-for-service system was expected (or turned out to be) a problem so that reforms were taken slowly or partly rolled back (Diderichsen, 2000). Yet overall, the effects of the system change were evident and turned out as was desired. Production increased by 19% in the first year, and waiting times were reduced by 22%. The

effects also become apparent when efficiency is compared between 'reformed' and 'unreformed' county councils. Also reformed county councils provided more services for the same expenditure, improving efficiency of the system by about 13% (Hjertqvist, 2002).

The public-private issue however, remains a hotly debated public topic, because of debates about the legitimacy of decentralizing the welfare state (Saltman & Bergman, 2005). This adds an aspect of uncertainty to the pace and the direction of reforms, which was already observed in the early 1990s (Ham & Brommels, 1994). Conservative governments take a different approach to reforms than liberal governments. This hampers policy making because in the county councils the majority changes quite often.

8.1.3 *Definition of healthcare benefits*

The central government establishes the basic principles for the health service in law. The most important law is the Health Service Act of 1982, which lays down that people shall be offered easily accessible, high quality health services. Entitlements are not defined explicitly. The benefits package is not formally described, and hence, it is not restricted. For example, when a new drug is registered, and the National Social Insurance Board and the drug company in question agreed upon the price of the new medication, this drug was as a rule reimbursed in the system. Benefits are effectively determined by availability, which means that decisions at the political and institutional level define them. County councils are formally responsible for meeting the health-care needs of their populations and for providing publicly financed health care, but they are free to make decisions concerning major investments in facilities, new technologies, organizational structures, and user fees (Carlsson, 2004). Local politicians thus are important decision makers on the allocation of resources between sectors and medical specialties. At the intermediate level (e.g., hospital or health center), decisions about particular technology and treatment guidelines are made.

There is increasing awareness that more openness in priority setting is required. One reason for this is the perceived gap between the demand for health services and available resources. Moreover, awareness among medical professionals of the need for more scientific evidence before the introduction of new health technologies into routine care has increased with the recognition that some of the newly implemented interventions proved not effective in retrospect.

This gap is partially filled by the central government, which has a role in supervising the system. The National Board of Health and Welfare ('Socialstyrelsen') is the government's central advisory and supervising agency in the health service. They are responsible for evaluating if the services provided correspond with the goal of central government. They also produce national treatment guidelines (Swedish Institute, 2003). In addition, Sweden has a long HTA tradition. Sweden was one of the first countries to assess health technologies. Initiatives started at the university, but in 1987 also a national HTA agency was established: the Swedish Council on Technology Assessment in Health Care (SBU). Their aim is to promote efficient use of resources by evaluating new and existing services from a medical, economic, and ethical point of view. Findings are disseminated to central and local governments to

provide basic data for decision making (Swedish Institute, 2003; Carlsson, 2004). Most county councils support evaluations; they may have formal links with the SBU or finance local HTA units. The SBU also cooperates with the National Board for Health and Welfare, Pharmaceutical Benefits Board, and the Medical Products Agency, transforming results into guidelines and disseminating information.

8.2 Country-specific concern

The development of the Swedish system for priority decisions can be understood against the characteristics of the health care system. In this section, we will emphasize some characteristics of the Swedish HTA and priority setting systems.

A first characteristic that is relevant to understand the role of HTA in Sweden is the decentralized decision making. The government does not make recommendations for in- or exclusion of particular services, because this responsibility is delegated to the County Councils. Instead, the central government has been active in developing a way of thinking about priority setting to assist those who are responsible. It is particularly interesting to see what tools are developed to influence local decision making, without taking over. For this purpose an HTA system has been established, but instead of embedding it in a decision making process, emphasis has always been on dissemination of the outcomes, and on activities that promote their implementation. We like to emphasize this aspect because it shows that – when adequate steering mechanisms are applied – steering from a distance is an option.

Second, the Swedish system for priority setting has always emphasized ethical values: namely that all people are of equal value and that resources need to be allocated on basis of need. As a result, assessment procedures focus less on the technology, and more on the rights of the individual (who according to the third value that underlies the priority setting system is entitled to cost-effective care). This focus on the individual as a whole enters the assessment procedure through consideration of social and ethical aspects by the assessment group, while these aspects are typically left to the decision makers in other countries. Moreover, and perhaps more importantly, it resulted in a focus of technology assessments that often goes beyond a single technology. Instead of evaluating whether or not a particular technology offers value for money, the question is more about how individual patients are treated optimally. So, it is about treatment pathways, so that evaluation reports are often very broad, but also very lengthy in terms of time. On request of users, also a fast-track procedure has been developed, so that guidance on the use of emerging technologies becomes available at an earlier stage. These reports, called Alert reports, are clearly not the dominant focus of the system yet.

8.3 Description of the fourth hurdle system

The main actor in the Swedish fourth hurdle system is the Swedish Council on Technology Assessment in Health Care (SBU).

8.3.1 Policy

By Swedish law, health service staff must work in accordance with scientific knowledge and accepted standards of practice. Research results and comprehensive clinical experience should guide the delivery of health care (<http://www.sbu.se>). To provide the actors in the health care system with necessary information to meet these requirements, Sweden has established a health authority that is responsible for technology assessments and dissemination of reports: the SBU. SBU was established in 1987 by the Swedish Government to evaluate health services on behalf of the healthcare sector. Initially, SBU was an agency under the Swedish Government Offices. In 1992, SBU was commissioned as an independent public authority for the critical evaluation of methods used to prevent, diagnose, and treat health problems. SBU is still funded by the government, which has continually increased SBU's budget since SBU was established. SBU started in 1992 with a budget of SEK 12 million (US \$1.5 million), and by 1999 the budget had increased to about SEK 37 million (US \$4.6 million) (Carlsson, 2004). In 2007, the budget is 7 million USD and SBU has 35 employees.

The mission of the SBU is to promote the efficient utilization of the resources allocated to the health services. For this purpose, SBU compiles and assesses scientific evidence about various methods used in health care. The SBU secretariat is located in Stockholm and consists of about 30 people. The small number of staff intends to make an efficient and creative team. This team does not conduct original research, but collects, reviews, and evaluates available research findings. In evaluating technologies, the SBU staff works with external researchers and experts. Around the country, about 150 researchers are employed on various SBU projects. A Board of Directors heads the SBU. The Board is appointed by government for three years at a time. They are chosen as to represent key organizations within the Swedish health care system, such as the Swedish Medical Society and the Swedish Medical Association. Other health professions (like nurses) are represented on the SBU Board as well. The SBU Scientific Advisory Committee provides specialist expertise. It outlines potential projects and makes suggestions to the Board of Directors. The Board then decides whether or not to start a project and who should participate in the work. Once a project is completed, findings are disseminated with help of SBU's so-called medical SBU ambassadors who work part-time in different regions. The ambassadors are clinicians, who visit meeting groups of doctors and administrators and discuss the results of SBU studies to influence clinical policy and practice at the regional and local levels. Currently, there are approximately 40 ambassadors.

The SBU Board and Scientific Advisory Committee set priorities for research. Generally, topics are selected that are of major importance to public health and quality of life. These issues are of great concern, involving common health problems and technologies with major economic consequences. Some projects focus on conditions for which treatment and medical outcomes vary throughout the country. Ethically controversial issues and interventions that require major changes in organization or staffing also command high priority. Priority topics are:

- Methods used for the investigation and treatment of many patients, i.e. with a significant impact on mortality and health;
- Expensive technologies, especially if they are of doubtful value;
- Emerging technologies that may profoundly alter routines;
- Obsolete methods still in extensive use.

A prerequisite for a new project is that there should be enough scientific literature to evaluate. A preliminary literature search and a search of other sources are performed (e.g., the Cochrane database and International Network of Agencies for Health Technology Assessment (INAHTA) files). The Board of Directors and the Scientific Advisory Committee then determine which of the proposed subjects should receive further assessment and what format will be used in the evaluation study (e.g. Yellow Report, Alert Report, discussed below). The SBU Board makes the final decision and appoints a chairman and members for the project group (Carlsson, 2004). This project group is a multidisciplinary team that consist of leading experts from Sweden and abroad, representing various fields of clinical practice and scientific research. Their job is to summarize medical and scientific literature from around the world.

The findings are disseminated to central and local government and health service staff to provide basic data for decision-making. SBU also documents how assessment information is applied and its influence on the health care system. SBU submits to the national government an annual report that contains a review of work accomplished, plans for the future, and statements about the impact of the work. The Ministry of Health and Social Affairs notifies SBU each year about government objectives in conjunction with the upcoming year's budget. At times, this has meant that SBU studies a topic that has been discussed in the Swedish Parliament (for example, surgery for epilepsy, the use of neuroleptics, and electronic monitoring during pregnancy).

8.3.2 *Assessment*

SBU reports aim to present the best available scientific evidence on the benefits, risks, and costs associated with different interventions. SBU identifies methods that offer the greatest benefits and the least risk, focusing on the most efficient ways to allocate healthcare resources. SBU also identifies methods currently in use that provide no benefits, have not been assessed, or are not cost-effective. Depending on the scope of the evaluation, a SBU assessment is published in one of three series of assessment reports, known as 'Yellow Reports', 'Alert Reports', and 'White Reports'. SBU has two scientific committees. One for large HTAs and one for the alert reports.

A Yellow Report covers a disease area and all possible treatments. It may cover hundreds of medical methods, while an Alert Report addresses a single, emerging intervention in health care. Yellow Reports can be viewed as problem-oriented assessments. These evaluations focus on important health problems in society (e.g., back pain), and include assessment of all relevant preventive, diagnostic, and treatment methods. This strategy covered the most important health problems in society, with the aim not

just to evaluate individual services but also to optimize care paths. Alert Reports usually review and evaluate new technologies at an early stage in their life cycle, when they have not yet been thoroughly studied or widely used. Hence, the scientific evidence may be rather limited. White Reports explore topics that may need to be assessed in the future. They give information on the 'state of the art' in certain health care areas. These documents may be the starting point for future systematic literature reviews. White Reports are reviewed by the project groups and external experts only.

The purpose of the reports is to inform decision makers (medical doctors or administrative) about particular interventions or diseases. Assessment reports contain a review of benefits, risks, and costs of methods used in healthcare delivery. For example, the reports may show which methods are most appropriate for treating particular conditions (e.g., back pain, asthma). The assessments also identify methods that are ineffective, or not cost-effective, so that they can be avoided. Social and ethical considerations are also taken into account, if any. Decisions are left to practitioners. As a result, reports do not have a political nature. This becomes also apparent from the methods of producing assessment reports: the assessment is performed by a group of experts.

At the start of each project, a working group of 10-15 people is formed. They meet informally to discuss the issue and to see if there are others with additional knowledge who should be included within the group. There are usually two or three SBU staff members in the project group; the others are physicians and other healthcare workers, health economists, and administrators. A layperson also used to be included, but this is no longer the case. SBU however does have a group of laymen who meet at SBU regularly. Early in the process, the project group participates in a 2-day seminar on critical evaluation of the scientific literature and the principles of an SBU project. Later the group has several seminars on quality criteria and findings. Initially, the members are trained in systematic literature searching and critical analysis of the literature identified. After that, the work consists of a review of literature, described in Table 8-1 below. The process is purely scientific. Leading experts undertake the review and publish the results in assessment reports. The reports describe evidence, weigh it, and draw conclusions. The quality of the overall level of evidence is presented along with conclusions that are made on basis of that evidence. The public and other stakeholders are not represented in the assessment process.

Alert Reports are developed in much the same way, but faster. The work required to develop a new Alert Report often takes 6 to 12 months. Proposals for methods to be assessed by a SBU Alert Report may come from individuals, organizations, or government agencies in Sweden or other countries. Initially, Alert prepares background information on the method. Later, the Alert Advisory Board decides on the topics to receive highest priority. The Alert Advisory Board appoints one or more experts, often in collaboration with the relevant scientific committees of professional associations. The project group also includes expert reviewers and SBU staff, as well as members of the SBU Alert Advisory Board and the SBU Board of Directors. The reports briefly describe the new method and its expected effects. Furthermore, they present an assessment of the current state of scientific evidence. Alert Reports range from five to ten pages in length and follow a standardized format. Since the reports are published on the internet, they can be updated.

Table 8-1 Steps in the process of developing a Yellow Report

-
- SBU Board of Directors and Scientific Advisory Committee discuss and prioritize topics
 - Project group appointed
 - Topics defined and project plan formulated
 - Scientific literature searched in relevant databases
 - Relevant studies identified, selected, and retrieved
 - Economic aspects analyzed, current practices studied
 - Studies read, reviewed, and graded based on quality and relevance
 - Report manuscript developed
 - SBU summary and conclusions developed
 - Review by external experts, SBU Scientific Advisory Committee, and SBU Board of Directors
 - Editing and revision of manuscript and summary
 - Typesetting, proofreading, and publishing
 - Dissemination and implementation
 - Monitoring and updating
-

In 2006, SBU had published around 80 HTA reports and the same amount of Alert Reports. The number of reviews is limited, but their scope is wide. The Yellow Reports published by SBU consider medical technologies from various viewpoints. Moreover, the focus is often on a condition and all related treatment options (which may include more than technologies) and not just on a single technology. As a result, a project typically takes 2 or 3 years to complete. This means that only three or four health problems and only a few of the hundreds of new technologies introduced in health care every year can be assessed, which makes the topic selection process important.

SBU findings are disseminated to the target audience through a variety of channels, listed below. The target groups for SBU reports vary depending on the topic, but generally include healthcare managers and staff, patients, decision makers at the administrative, county, and municipal levels, purchasers of health services, quality improvement teams, and county drug review committees.

- The results are published in one of the three aforementioned series of assessment reports, which can be downloaded from the SBU website. Most SBU reports are translated into other languages and published in international scientific journals or books.
- SBU's findings are also communicated via the SBU newsletter *Science & Practice* that appears three times a year in 225,000 copies, in the *Journal of the Swedish Medical Association*, and in other medical journals. News and media also often report on SBU findings. To promote dissemination of SBU news to target groups, Alert Reports and other news are also disseminated free of charge via an Internet subscription service. After having been translated into English, a summary of SBU's findings is sent out around the world to clinical decision-makers, policy decision-makers, medical journals, etc.
- The county councils have accepted that they have a responsibility for dissemination and implementation of results of SBU and other agencies. Most of them are very active, having established HTA receiver organizations. Furthermore, SBU's experts speak at a great number of

lectures and seminars. They also organize conferences with politicians, medical planners, and the national and international press.

To further promote dissemination and implementation of its assessments, SBU collaborates with the National Board of Health and Welfare, the Medical Products Agency, the Pharmaceutical Benefits Board, and a range of professional organizations in health care, insurance organizations, and other interested parties. Within the international arena, SBU serves as the secretariat for the INAHTA, which promotes collaboration and the exchange of information on planned, ongoing, and completed assessment projects. Among INAHTA's members are over 40 assessment organizations in 20 countries.

8.3.3 *Decisions*

The decision whether or not to adopt a new technology usually lies with the county councils. Decisions are typically made implicitly, and become visible in agreements for finance and production of health services. The evidence basis for a decision is usually not clear. Members of the county councils and the municipalities are publicly elected every 4 years, which gives legitimacy to their decisions. In a few county councils, steps are taken to develop open methods of priority setting. The Swedish Medical Society is involved in this process.

In some cases, the county councils' freedom of choice for patients is constrained by cooperative agreements with other county councils to provide specialized services on a regional basis, or even an interregional basis. Several county councils have merged into larger administrative regions with the same responsibility as traditional county councils. Sweden is divided into six healthcare regions, each of which has a population of 1-2 million and is made up of two to six counties that share one or more regional hospitals that are affiliated with a medical school and function as research and teaching hospitals. The objective of the regional system of medical services is to ensure that specific types of services are delivered at a level where they can be most efficiently provided. The hospital tiers provide a hierarchy for acquisition of sophisticated new technologies. The regional hospitals are supposed to be the first to acquire a new technology, followed by the lower tiers. At each tier, a service is provided only if the population base is sufficient. Rare procedures are, in the best-case scenario, consolidated since greater experience with such procedures by medical practitioners yields better outcomes.

Active involvement of other actors in the decision-making process is rather limited, although some actors exert certain influence through their involvement in the assessment process. In 2004, Carlsson summarized the involvement of different actors in the HTA and decision making process (Carlsson, 2004). The active involvement of medical professions in the SBU means that health care providers are actively engaged in assessments, a circumstance that also helps to disseminate results. We summarized it for the sector of medical specialist care at the macro and meso level (Table 8-2).

Table 8-2

Actor	HTA	Priority setting
Macro		
The Swedish parliament	Sometimes takes initiatives to set up particular HTAs	Decides on principles
Ministry of Health and Social Affairs	Takes initiatives to set up particular HTAs by SBU Decides on budget and mission of government agencies, i.e. SBU	Allocation of government subsidies between different sectors in society and health care sectors by annual budget processes and production of policy documents
National Board for Health and Welfare	Produces guidelines. Recent ones are based on systematic SBU reviews	From 2002, priority setting recommendations are a vital part of guidelines
Pharmaceutical Benefits Board	Review of all pharmaceuticals which had been eligible for reimbursement according to the old system	Makes decisions about reimbursement of drugs
SBU	Conducts comprehensive reviews and assessments	No explicit role
Federation of county councils	Supports regional and local HTA activities (most often related to drugs)	Involved in production and implementation of guidelines
Universities and HTA consultants	Produce HTA	No explicit role
National patient organizations	Sometimes take initiatives for HTA	Participate as members of committees. Informal also via lobby groups
Meso		
County councils	Sometimes take initiatives for HTA; setting up local HTA units; consumers of HTA; responsible for dissemination and implementation of results and for development of guidelines	Decide on financing and production of public health services (implicit priority setting), and on major investments in new technology. Some county councils work to develop open priority setting processes

8.3.4 Outcomes and implementation

Once a funding decision is made, there is no formal appeal mechanism. There are also no formal dates set for reappraisal. Most efforts in Swedish health care regarding outcomes and implementation of HTA relate to implementation activities and assessment of their impact.

The problem remains that, unlike in other countries, decision-making on investments in expensive and complicated technology is decentralized in Sweden. This makes the influence of HTA less obvious. On this regard, an important extension to the evaluative system was the establishment of the Centre for Assessment of Medical Technology in Örebro (CAMTÖ, financed by the Örebro County Council) in 1999. This center conducts primary research on trends and changes in health care practices and assesses differences in practice between different health care providers. It assists in dissemination of HTA results locally, and proposes new projects to the SBU.

SBU does not have formal power to directly change practice. Its only means to promote change has been through education and dissemination of information. One important mechanism in this regard is the project groups themselves, which involve a number of key persons in Swedish health care. Although SBU

does everything in its power to disseminate results, time available for these activities is often limited. Therefore, the central government has emphasized that other bodies must participate in this activity. This resulted in more or less formalized cooperation with professional bodies, administrators employed by the county councils, the media, and other interested parties. The county councils support HTA to a varying extent. They usually act through the Federation of County Councils to support studies locally, and they expect that results from such studies will influence local practices. Some councils have formal liaison with SBU's central office. Others support local HTA units. This shows that HTA is increasingly visible to policy makers, who find it useful in decision-making.

The state has decentralized the provision of health care, but still attempts to control the general direction of the system using various steering methods (e.g., regulations, subsidies, recommendations, and guidelines). One aspect that is related to priority setting is the development of guidelines. The National Board of Health and Welfare and the Federation of County Councils, along with medical experts, are producing national guidelines for common diseases that are based on SBU documents describing the state of the art, systematic reviews, and consensus conclusions.

Chapter 9 Switzerland

9.1 Organizational structure of health care in Switzerland

In this chapter, we will cover the reimbursement of medical specialist care in Switzerland. First, this section briefly outlines some basics of the Swiss health care sector and the health care insurance system.

Switzerland is a more than 700-year-old federal state. The Swiss Confederation is made up of 26 cantons. Moreover, it has about 2,900 municipalities that constitute the level of authority closest to the people. Switzerland has a population of 7.4 million inhabitants (Office fédéral de la statistique, 2005b). The total cost of health care amount to 50 billion Swiss Francs (SFr.), or 6,736 SFr. per inhabitant. This comes down to approximately 11.5 percent of the GDP (Office fédéral de la statistique, 2005a), which means that Switzerland occupies a high place in international rankings of health care expenditures.

9.1.1 *Main characteristics of the health care system*

Switzerland has a well-developed health care system. It is a mixed public and private system, with responsibilities divided between the Confederation and the cantons (Cranovsky et al., 2000; European Observatory on Health Care Systems, 2000b).⁵² Primary responsibility for health care lies with the cantons, which according to Article 3 of the Swiss Constitution ('Bundesverfassung der Schweizerischen Eidgenossenschaft') retain all rights not explicitly transferred to the Confederation. The cantons mainly act as financiers of public hospitals, and also pay contributions toward the costs of private hospitals admitting patients with social health insurance (Zweifel, 2000). Furthermore, the cantons are responsible for, for example, planning issues, licensing of health professionals, and for paying health insurance subsidies to the insured (see further below). The cantons may delegate responsibilities to the municipalities, which is usually done for home and nursing care services for example.

So, regarding matters of health policy, political power is rather decentralized in Switzerland. Yet, pursuant to the Constitution (Art. 117), the Confederation is responsible for the health insurance.⁵³ Consequently, most aspects of health insurance do not differ substantially from one canton to the other.

9.1.2 *Health care funding*

The Swiss health care insurance in broad outlines

During the last decades, one of the major concerns that Swiss policy makers faced has been an ongoing process of erosion of solidarity ('Entsolidarisierung'). This was one of the reasons why the health insurance system in Switzerland was fundamentally reformed in 1996. That year saw the coming into

⁵² Note that the cantons work together under an organization called 'Zentralschweizer Regierungskonferenz (ZRK)'. Regarding the health care sector, there is a 'Konferenz der kantonalen Gesundheitsdirektorinnen und -direktoren (GDK)'.

effect of the ‘Bundesgesetz über die Krankenversicherung’ (KVG), which has been in a process of permanent reform since then (Guillod, 2006). Together with the ‘Verordnung über die Krankenversicherung’ (KVV) and the ‘Krankenpflege-Leistungsverordnung’ (KLV), this law is the most important legal regulation in this area.

The underlying aims of the reforms were to ensure: strengthening of solidarity, cost containment, and equality of access to health care. A key purpose of the reforms was to introduce competition among sickness funds. One of the main innovations lay in the transformation from a voluntary to a compulsory health insurance system. Moreover, risk selection was forbidden and premiums no longer depended on individual risk. A final point worth mentioning is that the reforms brought to an end the situation whereby great differences existed between cantons with respect to entitlements. Some cantons had a generous package relative to other cantons (Polikowski & Santos-Eggimann, 2002; Maarse & Paulus, 2003; Perneger & Hudelson, 2005).

The share of social health insurance in health care finance is relatively low in Switzerland. In 2002, social insurance schemes accounted for 40.0% of the total expenditure on health in Switzerland, as against 82.9 % in the Netherlands for example. The system in Switzerland is characterized by a high proportion of private payments. In 2002 for example, out of pocket payments (comprising cost-sharing, self-medication and other expenditure paid directly by private households) amounted to 31.5% of the total expenditures on health, compared to a corresponding figure of 10.1% in the Netherlands (Organisation for Economic Co-operation and Development, 2004).

The legal social health insurance is operated by some 90 insurers (‘Krankenkassen’), which do not all operate in each of the 26 cantons. The ‘Krankenkassen’ must meet the conditions set out in Swiss legislation, such as the absence of a profit-making aim and the requirement to keep reserves. All persons domiciled in Switzerland must take out health insurance (Art. 3 KVG). The insured may choose any insurer he wants, and the insurer must accept him without reservations, irrespective of age and health state for example (Art. 4 KVG). The insured is free to switch insurer every six months. Usually there is an increase of the insurance premium that is published by the end of the year, effective for the next fiscal year. When the premium rises, the insured has the right to change insurance company without having to wait the 6 months (Art. 7 KVG). Until recently, the Swiss health care insurance fell under the responsibility of the ‘Bundesamt für Sozialversicherung’ (BSV), which focuses on the broad area of social security. From January 1, 2004 onwards however, the ‘Bundesamt für Gesundheit’ (BAG) has been responsible for the health insurance and the accident insurance.

The insured have the possibility to take out voluntary supplementary insurance (‘Zusatzversicherung’), next to the ‘Grundversicherung’, which is provided by both the ‘Krankenkassen’ and private insurers. With supplementary insurance, patients for example may have free choice of hospital beyond the canton of residence, may choose hospitalization in private wards or receive some services not

⁵³ Other responsibilities of the federal government listed in the Constitution include the eradication of communicable diseases, reproduction medicine and gene technology, and transplantation medicine.

included in the basic package. In the year 2004, about 28 percent of the insured population was covered by a supplementary insurance regarding hospital care (Bundesamt für Gesundheit, 2006). Under this insurance, the insurers may set premiums according to a patient's risk or may refuse patients. The supplementary insurance is covered by the civil laws of insurance (i.e., the 'Bundesgesetz über den Versicherungsvertrag'). The 'Bundesamt für Privatversicherung' (BPV) is responsible for supervising this insurance. It should be noted though that the compulsory basic health insurance is really very extensive, so anything covered by additional private insurance is in fact more of a luxury than a necessity.

Currently, a system of compulsory contracting exists. This means that the 'Krankenkassen' must have contacts with all authorized health care providers and reimburse all the medical services carried out by these providers (Art. 35 KVG). Contracts (normally on a fee-for-service basis) are negotiated between one or more health care providers and one or more 'Krankenkassen', or between their representing associations (Art. 46 KVG).⁵⁴ In 2004, the federal government proposed a reform that allows for the liberalization of the contracts between the ambulatory care providers and the insurers.⁵⁵ In the future, both would receive the option of choosing their own contracting partners. The state would have the task of maintaining the level of supply of health care ('Versorgungssicherheit'), fixing the minimum number of providers that each sickness fund should put under contract. The main objective of this proposal is cost containment by reinforcing competition among providers of ambulatory care and by excluding 'inefficient providers' from the compulsory insurance market. It is also expected to reduce the income level of medical practitioners. The proposal seeks to change the current situation that provides a favorable context for supply-induced demand (Crivelli, 2004).

Hospital finance

Another characteristic of the Swiss health care system to be discussed here is the provider payment system. A dual system of hospital finance exists. The 'Krankenkassen' pay at most 50 percent of the costs of an admission to a public hospital (Art. 49 KVG), while the remainder (as well as costs of hospital investments for example) is borne by the cantons (Steinmann et al., 2004). Since 1998, various cantons have been experimenting with a system based on DRGs ('diagnosebezogene Fallpauschalen'). A group called 'AP-DRG Suisse', which consisted of some 20 hospitals, health administrations from a few cantons, a few insurers, and the branch organization of physicians (FMH, Foederatio Medicorum Helveticorum), developed a classification of all hospitalizations for acute care (Guillain et al., 2003; APDRG Suisse, 2006). The necessity of DRG payment is now widely recognized by all partners of the Swiss health system. In 2009, a DRG system for hospital admissions should come into effect in the whole country.⁵⁶ This project

⁵⁴ However, the Krankenkassen have the possibility to contract selectively with preferred providers forming a managed care network. This affects the insured who opted for a special insurance modality. See further below.

⁵⁵ Bundesgesetz über die Krankenversicherung (KVG) (Vertragsfreiheit) (Entwurf). Bundesblatt 2004, 29, 27. Juli 2004.

⁵⁶ Bundesgesetz über die Krankenversicherung (KVG) (Spitalfinanzierung) (Entwurf). Bundesblatt 2004, 42, 26. Oktober 2004. The dual system will stay in force: the 'Krankenkassen' and the cantons will each pay half of the reimbursement for a DRG.

is prepared by the 'Verein SwissDRG', which will replace the temporary AP-DRG system. The aim of the DRG system, which is based on the German DRG system, is to promote efficiency and to enable comparisons between the performance of hospitals.

Premium and insurance modalities

Every insured individual pays a premium that is independent of income.⁵⁷ Insurers offer reduced rates for children and adolescents (aged 0-18) and young adults (aged 18-25). The premium varies from insurer to insurer, and from canton to canton (reflecting large differences in health care use patterns across the country). In the year 2004, the yearly premium per insured person averaged 2,430 SFr. (Bundesamt für Gesundheit, 2006). Low-income people receive subsidies from national/cantonal funds to help them pay for health insurance. This is done with the aim of keeping the net expenditures for premiums below 8% of the family income. In 2004, 31.7 percent of the insured received such subsidies (Bundesamt für Gesundheit, 2006). Finally, as should be noted here, the Swiss government is involved in the financial aspects of the health insurance system in still another way. The 'Krankenkassen' are part of a risk adjustment scheme introduced in 1993 (Art. 105 KVG). Insurers having an age and sex structure that compares favorably with that of the general cantonal population (i.e., relatively few women and/or elderly) must contribute to an equalization fund, while those showing a competitive disadvantage in this regard will receive a subsidy from it (Beck, 2000; Beck et al., 2003).

Adults have to pay a regular own contribution ('Franchise') of 300 SFr. each year, next to 10 percent of the costs exceeding the 'Franchise', but only up to a maximum amount of 700 SFr. per year (Art. 64 Sect. 2 KVG io. Art. 103 KVV). Moreover, persons who do not live in a household with one or more family members are charged a contribution of 10 SFr. per day for the costs of a hospital stay (Art. 64 Sect. 5 KVG io. Art. 104 KVV).

In return for a premium discount, the insured can opt for several insurance modalities. In a first modality ('Wählbare Franchise'), the insured pays a larger proportion of the costs, while the level of care covered does not change. Second, the insured may choose to seek treatment solely from a medical group known as an 'HMO' (Health Maintenance Organization) or to be obliged to consult, in the first instance, a 'family doctor' who will decide whether or not to refer the insured to a specialist ('Eingeschränkte Wahl der Leistungserbringer'). So, the insured is giving up his right—which he normally has—to choose his doctor and hospital freely (except in emergencies). In a third modality ('Bonusversicherung'), the insured may obtain progressive reductions in his premium for each year in which he does not claim any reimbursement from the insurer. The initial premium is 10% higher than the standard premium, and the discount may be as much as 45% of the initial premium at the end of five years. Note that especially the

⁵⁷ This model of health insurance financing receives support among the Swiss population. In 2003, a proposal to replace per-capita-premiums by a payment based on income and wealth (coupled with an increase in the value added tax) was rejected in a referendum (Perneger & Hudelson, 2005). In March 2007, there will be another referendum initiated by the people, not only on income-dependent premiums but also on the transition to a system of just one insurer for the whole population.

last two modalities are not widely chosen by the Swiss population (although their market share is rising in the last couple of years): in 2002 about 8% of the population chose one of both managed care models, only 0,1% chose the bonus model, while 41% chose the model with a higher deductible (Becker & Zweifel, 2004; Frei, 2006). This is unfortunate because the managed care model of the ‘Eingeschränkte Wahl der Leistungserbringer’ has been suggested to be associated with savings on health care costs (Schwenkglens et al., 2006).

Noteworthy, premiums rose quickly in recent years, especially after the implementation of the KVG in 1996. In 1996, the average premium per insured person amounted to 1,547 SFr., as compared to 2,430 SFr. in 2004 (i.e., a 57% rise) (Bundesamt für Gesundheit, 2006). The general feeling is that this can be largely attributed to the broadening of the basic package of covered services (Zweifel, 2000; Becker & Zweifel, 2004). Another factor contributing to the rise of the costs of the basis health insurance is the regular increase of the number of health care providers working under this insurance, especially in the ambulant health care sector.

9.1.3 Definition of the benefits schedule

The benefits schedule is defined by law. All insurers offering compulsory health insurance must provide these same benefits. They may not cover other ‘optional’ benefits under the compulsory health insurance scheme (Art. 34 KVG). The procedures that are reimbursed by the health insurance are not all set out in detail. The legal system is built on the assumption that treatment and examination by doctors is reimbursed. This also applies to treatment and examination by others upon a doctor’s order (such as radiology, physiotherapy, and nursing care at home or in a nursing home). Furthermore, admission to a general hospital ward and medical rehabilitation, for example, are reimbursed (Art. 25 KVG). In addition, certain preventive services are reimbursed (Art. 26 KVG), among which are mammography for women aged 50 years or older and two ultrasound examinations during pregnancy (Faisst et al., 2001).

A condition for reimbursement, however, is that benefits are ‘wirksam, zweckmässig und wirtschaftlich’ (Art. 32 KVG), which in this context is most properly translated as ‘effective, appropriate, and efficient’. The basic assumption is that medical care satisfies these conditions. So, there is no closed list detailing which care is reimbursed by the basic health insurance (with the exception of maternity, preventive, and dental treatment services).⁵⁸ The ‘Bundesrat’, or on its behalf the Federal Department of Home Affairs (‘Eidgenössische Departement des Innern (EDI)’)—the department responsible for public health issues—can however denominate benefits that are not reimbursed, or only under certain circumstances (Art. 33 KVG). The law stipulates that the effectiveness, appropriateness, and efficiency of the benefits have to be reassessed periodically (Art. 32 KVG).

⁵⁸ Closed lists also exist for medical devices for ambulatory use, medical laboratory tests, and drugs in ambulatory care.

9.2 HTA in Switzerland and its use in coverage decisions

Especially since the reforms brought about in 1996, Switzerland can be said to have an extensive basic package (Polikowski & Santos-Eggimann, 2002). At the same time, it is among the countries with the highest total health expenditure in the world (Organisation for Economic Co-operation and Development, 2004), which, among other things, can be attributed to the high diagnostic and therapeutic infrastructure. It is generally felt that Switzerland has too large capacities of doctors and hospital beds for example. Another factor contributing to the high healthcare costs is the large benefits package.

It is safe to say that the subject of evidence-based health policy is gaining interest. Coverage criteria have been set up, for example, for preventive technologies, psychotherapy, and methods of complementary medicine (Cranovsky et al., 2000). Notice however that, so far, the requirement that services should be effective, appropriate and cost-effective to qualify for reimbursement has only been applied to services that are to be added to the benefits package. Existing services have not been subjected to scrutiny under these criteria (European Observatory on Health Care Systems, 2000b). According to Brunner (former Head of the BAG Section ‘Kranken- und Unfallversicherung’), policy makers are—more than before—attaching importance to evidence of the effectiveness, appropriateness, and efficiency of health care interventions. Policy makers intend to systematically explore the effectiveness, appropriateness, and efficiency of all benefits included in the basic package, with a special emphasis on high cost procedures (and partly building on earlier research studies from abroad) (Kraft, 2005; Neue Zürcher Zeitung, 2005).

For the moment however, in general rather few studies in the area of health technology assessment (HTA) are available, whereas medical scientific research—especially on pharmaceuticals, diagnostics, and biotechnology—is strong in Switzerland, involving large companies such as Novartis and Roche. Cranovsky and co-workers observe that insufficient attention has been paid to the results of HTA in areas such as reimbursement issues. In addition, the authors state that activities in the field of HTA are not centralized, with no central agency responsible (Cranovsky et al., 2000). However, the foundation of the Swiss Network for Health Technology Assessment (SNHTA) in 1999 may be a relevant step to achieve a change towards a more prominent role of HTA. Several government agencies, all university institutes, several university hospitals dealing with HTA and the Swiss Medical Association are members of this association. Put briefly, SNHTA’s purposes are to promote HTA projects, to gather, exchange and disseminate information, expertise and reports, and to cooperate in (international) HTA projects and networks. A final observation on HTA in Switzerland is that HTA activities are financed by a variety of public and private sources. According to Hirschel et al., the ‘Krankenkassen’ have no tradition of furthering any research. The BAG (actually its predecessor the BSV) claims to have neither legal mandate nor any money for research into cost-saving measures. Neither do institutions such as Health Promotion Switzerland (‘Gesundheitsförderung Schweiz’) or the branch organization of the Swiss insurers (Santésuisse) regularly finance clinical and cost-effectiveness research (Hirschel & Garbino, 2002). Obviously, these constraints on financing are an obstacle toward the expansion of HTA activities.

9.3 Definition of benefits to medical specialist care

9.3.1 Policy

Whenever the coverage of a given service is contested, the interested party has to make an application to the BAG. Health care providers (individual physicians, individual hospitals, as well as medical societies), health insurers and patient organizations can all apply for the commencement of proceedings. If both Santésuisse and the branch organization of physicians (FMH, Foederatio Medicorum Helveticorum) consider the service uncontroversial, it will be listed and be reimbursable. If one of both organizations declares the respective service to be controversial, the assessment procedure is started. The applicant has to provide an assessment report following standardized methods laid down in the ‘Handbuch zur Standardisierung der medizinischen und wirtschaftlichen Bewertung medizinischer Leistungen’ (hereinafter referred to as ‘the Manual’).

In the following phase, an expert committee (‘Eidgenössische Kommission für allgemeine Leistungen’ (ELK)⁵⁹) examines the case. The ELK is comprised of 20 members, among whom are representatives of the medical profession (7), the hospitals (2), the pharmacists (1), the insurers (6), the insured (2), the cantons (1), and the BSV (1). When the ELK has finished its investigation, it voices a recommendation for or against coverage. Next, the BAG gives an advice on the public funding of the medical technology.

The final decision on coverage is taken by the Minister of Home Affairs. It is documented in Annex 1 of the KLV and published in the ‘Amtliche Sammlung des Bundesrechts’. The possibility exists that coverage is allowed temporarily or only under certain circumstances until for example scientific research has been carried out and a definitive decision can be made. Annex 1 lists all benefits examined by the ELK. There are three categories:

- 1) procedures examined by the ELK as to their effectiveness, appropriateness, and efficiency and recommended for full coverage, recommended for coverage under specific conditions or being denied coverage;
- 2) procedures still being examined, however recommended for coverage under specific conditions and within a set limit;
- 3) particularly costly or difficult procedures that will only be covered by the compulsory health insurance if they are provided by specifically qualified providers.

According to this Annex 1, many forms of complementary medicine for example (such as anthropological medicine, homeopathy, and ‘Frischzellentherapie’) are excluded from coverage. Nonetheless, other forms of complementary medicine (acupuncture) are covered, provided that they are offered by doctors skilled in that area.

The Federal Department of Home Affairs may consult the Federal Commission for Fundamental Questions of the Health Insurance (‘Eidgenössische Kommission für Grundsatzfragen der

Krankenversicherung' (EGK)). This broadly-composed advisory commission has been entrusted the task of unifying practice and quality and of considering ethical aspects related to defining the benefits package.⁶⁰

Data on the time usually needed to decide on an application is not available from the literature.

9.3.2 *Assessment*

According to the Manual, an application for reimbursement must be structured around the following parts (Bundesamt für Sozialversicherung, 1998):

- Part 1: Medical documentation (a scientific presentation of the issue);
- Part 2: Economic documentation (a cost computation for the service in question);
- Part 3: A discussion and justification of the application in view of the effectiveness, appropriateness,⁶¹ and efficiency of the method (so-called plead in favor of the new technology);
- Part 4: A formal application, including a proposal for the precise wording in the KLV.

The applicant has to provide an overview of the clinical and economic evidence on the technology as it appears from a literature search (and other possible sources of information). Besides, the applicant is asked to deliver data such as the indications for the technology, the burden of the disease and the clinical need, the estimated utilization of the technology, and its budget impact. Notice that, if evidence from published economic evaluations is incomplete and the technology is likely to represent a high cost, the BAG may require a full economic evaluation. The Manual provides a guide for conducting an economic evaluation. Finally, of note is that the assessment reports are not published.

9.3.3 *Decision*

As said above, the 'Bundesrat', or on its behalf the Federal Department of Home Affairs (EDI) takes the final decisions on coverage. After having taken cognizance of the advice of the BAG, the EDI may denominate procedures that are not reimbursed or that are reimbursed only under certain conditions. It may also determine whether and under what conditions new and controversial procedures, whose effectiveness, appropriateness, and efficiency are under investigation, are reimbursed (Art. 33 KVG io. Art. 33 KVV). Between 1991 and 2002, the EDI decided about the financing of 154 services. It approved 92 services (63 of them with restrictions) and excluded 62 services (Gress et al., 2005).

It is difficult to find out what the role of HTA studies exactly is and what importance is attached to data on costs and cost-effectiveness. The decision-making process is not particularly transparent, so that it is also difficult to comment on consistency of decision-making in Switzerland. The recommendations of the ELK and the decisions of the Minister are not published extensively—expect for

⁵⁹ Art. 33 Sect. 4 KVG io. Art. 37d KVV.

⁶⁰ Art. 33 Sect. 4 KVG io. Art. 37c KVV.

short press releases. The assessment reports that are part of the applications are not published at all (Gress et al., 2005). Greß points out that more than half of the 36 applications submitted between 1996 and 1998 contained no information about costs at all. He concludes that coverage decisions in Switzerland are taken solely on the basis of effectiveness (Gress et al., 2005). It may be concluded here that cost-effectiveness does not seem to have a serious role as a decision criterion, although the legal system prescribes that it should. Yet, it is actually becoming more relevant, as evidenced by the case of genotypic resistance testing in HIV-infected patients for example. In this case, a cost-effectiveness analysis was required (Sendi et al., 2007) before it was decided to reimburse it (i.e., to put it on the ‘Analysenliste’). Funding was provisional until the cost-effectiveness analysis was completed. Finally, the fact that the decision-making body is supported by committees with a high degree of representation of stakeholders, including patient-focused organizations, could be seen as a positive characteristic of the decision-making process in Switzerland.

9.3.4 *Outputs and implementation*

There is no internal appeal procedure that is applicable to coverage decisions of the Minister of Home Affairs. Decisions can however be challenged in court (Gress et al., 2005). In addition, the insured may of course turn to their insurers, which, according to the ‘Bundesgesetz über den Allgemeinen Teil des Sozialversicherungsrechts (ATSG)’ have an information obligation and have to respond to any questions of their clients. Subsequently, the insured may object to a written decree of the insurer (Artt. 51 en 52 ATSG), and, when this procedure has been exhausted, appeal to the ‘Kantonales Versicherungsgericht’ (Art. 56 ATSG) and next to the ‘Eidgenössischen Versicherungsgericht’ (Art. 62 ATSG). Moreover, the insured may submit all their questions and disagreements between them and the ‘Krankenkassen’ to the ‘Ombudsman der sozialen Krankenversicherung’. The ‘Ombudsman’ may make recommendations to either the insurers or the insured. In 2004 for example, 3,202 proceedings were started that pertained to the reimbursement of benefits (which comes down to 59% of all proceedings instituted) (Ombudsman der sozialen Krankenversicherung, 2005).

To our knowledge, there are no official procedures to review decisions on the inclusion of medical specialist care in the benefits schedule or to assess the implementation of such decisions in practice. Neither is there a general system for identifying when to reappraise technologies. A noteworthy point relating to the provision of medical care is that health care providers such as doctors and hospitals must restrict themselves in providing care considering the interests of the insured and the purpose of the treatment, as laid down in Article 56 of the KVG (‘Wirtschaftlichkeit der Leistungen’). Care that exceeds this limit may be excluded from reimbursement, while reimbursements that were paid wrongfully may be reclaimed. Moreover, if health care providers disregard these provisions, sanctions may be imposed, ranging from a warning to exclusion of their services from the compulsory health insurance (Art. 59

⁶¹ Appropriateness refers to the relative medical value of a procedure to the patient compared to the risks associated with it. Procedures are considered to be appropriate when the benefit is greater than the risks of the procedure itself and outweighs the risks attached to other alternative procedures or approaches (Faisst et al., 2001).

KVG). Health care providers may hand over their task to the insurers, who then have to demonstrate and control the efficiency of the benefits provided under the health insurance (Art. 76 KVV). The insurers delegated their task of controlling the efficiency of the care provided to Santésuisse, which stimulated this organization to establish a 'Kompetenzzentrum für Wirtschaftlichkeitsverfahren'. Santésuisse may reclaim reimbursements from health care providers for reasons of 'Überartzung'. In 2004 for example, Santésuisse acted against 536 doctors. It demanded back 4.1 million SFr. of fees (Wessalowski, 2005).⁶²

⁶² Total expenditures of the 'Krankenkassen' were about 16 billion SFr.

Chapter 10 United Kingdom

10.1 Organizational structure of health care in the UK

10.1.1 *Characteristics of the health care system*

In the United Kingdom (UK), a national health service (NHS) has been established on basis of the underlying principle that health care should be available for all, free at the point of use and irrespective of ability to pay (Mason, 2005). Each country (England, Wales, Scotland, and Northern Ireland) runs its own system. In all countries, health care is predominantly funded through national taxation. Within each county, Authorities and Trusts are the different types of organizations that run the NHS at a local level. This report will be about the NHS in England, which was set up in 1948 and is now the largest organization in Europe.

The NHS is funded by the taxpayer and managed by the Department of Health, which sets overall policy on health issues. The NHS policy in England is directed from the center by the Department of Health. It is the responsibility of this department to provide health services to the general public through the NHS. Local health bodies, known as primary care trusts (PCTs), are in charge of providing and commissioning services, controlling the majority of the budget. PCTs are overseen by regional organizations called strategic health authorities (SHAs). The whole of England is split into 10 SHAs. These organizations were set up in 2002 to develop plans for improving health services in their local area and to make sure their local NHS organizations were performing well. Within each SHA, the NHS is split into various types of trusts that take responsibility for running the different NHS services in a local area.

The launch of the NHS brought hospital services, family practitioner services (doctors, pharmacists, opticians, and dentists) and community-based services into one organization managed by the government. With expansion of the NHS the system became increasingly bureaucratic and difficult to manage. Therefore a purchaser-provider split was established in 1991. 'Purchasers' (health authorities and some family doctors) were given budgets to buy health care from 'providers' (hospitals and providers of community health services). One objective of the 1991 reforms was to create incentives for efficiency within the NHS. The reform also promoted purchasing as the means to a more rational, consumer-led design of services. To become a 'provider' in the internal market, health organizations became NHS trusts, independent organizations with their own managements, competing with each other. Purchasers were expected to buy the most cost-effective forms of care for their local populations and for 'contracting' with the trusts to provide necessary care.

In 1996, the Audit Commission concluded that apart from a small number of notable exceptions, most fundholding practices had brought about only modest improvements in health care and that these were probably insufficient to justify their higher cost (Audit Commission, 1996; Wilkin et al., 2001). A high level of competition was viewed as to reduce provider co-operation, fragment the healthcare system, or generate high transaction costs. Enhanced processes for performance management, and contracts

therefore have replaced competition by longer-term service agreements. Also, purchasing is increasingly being delegated from the Health Authorities down towards their constituent Primary Care Groups which encompass all General Practices and cover populations of around 100,000 (Johnson, 1999). The establishment of primary care groups and trusts in England represents a major change from the internal market that characterized the NHS in the 1990s. The Primary Care Groups will initially operate as subcommittees of health authorities, but the aim is that they become freestanding primary care trusts when they show that they can manage budgets and services. As trusts they will have full control of their budgets and be responsible for providing and managing a wide range of community based services as well as for commissioning hospital services on behalf of their patients (Wilkin et al., 2001).

In the current situation, the responsibility for provision of care has passed from central government to the PCTs. These are at the center of the NHS, consuming 80% of the total NHS budget (<http://www.nhs.uk>, accessed August 16, 2006). Because they are local organizations, they are in the best position to understand the needs of their communities. PCTs must, for example, assess the health needs of all their local population, commission services to meet these needs, and ensure that these services can be accessed by everyone who needs them. They must also make sure that organizations providing different services are working together effectively, and they must carry out annual assessments of GP practices in their area. There are more than 300 PCTs covering all parts of England. They have been in place since April 2002 and report directly to their local SHA.

SHAs are responsible for managing and setting the strategic direction of the NHS locally. Created by the government in 2002 to manage the local NHS on behalf of the Secretary of State, there were originally 28 SHAs. On 1 July 2006, this number was reduced to 10. They are the key link between the NHS and the Department of Health. SHAs monitor how well PCTs and NHS Trusts (hospitals) in their area are performing and take action to improve services when they are poor or failing. They are also responsible for developing plans to improve local health services, which includes ensuring that national policies are reflected in local health service plans. SHAs support PCTs and other NHS organizations and make sure they are performing well. As well as buying and monitoring services, they also play a crucial role in supporting NHS organizations. They help local GP practices, NHS Trusts and other parts of the NHS think more innovatively about how they deliver better, more convenient care to their local patient communities. The NHS Executive, the management body for the NHS in England further exerts control over the activities of purchasers and providers.

10.1.2 National health care funding

NHS services are largely 'free at the point of delivery', paid for by taxes. The NHS's budget for 2006-07 is £96 billion (HM Treasury, 2006). NHS activities are mainly financed by general taxation (80%). In addition, the national insurance fund, which covers social services for the population, makes a contribution to the NHS (about 12%). Contributions to the national health insurance fund are also tax-based. In addition, health care services may be paid for by private insurance or user charges (4%) (Dixon & Mossiales, 2002).

A weighted capitation formula is used to allocate resources from central government to health authorities, who in turn allocate resources to the PCTs. These PCTs directly provide primary care and community health services, and commission services from hospital trusts. Their activities are financed through a contracting system. A DRG system exists for recording activity of hospital care and payment. It includes 550 HRG tariffs for elective in-patient care (Mason, 2005). Hospital staff is salaried. GP remuneration is a mix of capitation fees, fixed allowances, and fees for specific services (Dixon & Mossiales, 2002).

10.1.3 *Defining the benefits package*

The benefits of patients to care are not explicitly defined. The National Health Services Act places a general responsibility to meet reasonable requirements (Dixon & Mossiales, 2002; Mason, 2005; Mason & Smith, 2005). On the other hand, few services are explicitly excluded. In the system therefore internal quality control mechanisms are important to ensure that people get the health care that they are entitled to. The regulatory framework therefore comprises several types of guidance, e.g. guidance from National Service Frameworks (targeting major diseases), or guidance of National Institute for Health and Clinical Excellence (NICE). This guidance contributes to specification of what can be considered a 'reasonable requirement'. Also fee schedules signal what kind of services is covered by the public health services.

10.2 The NHS regulatory framework

10.2.1 *Role of quasi-law*

In addition to legislation, NHS provision is shaped by a considerable amount of 'quasi-law'. Quasi-law is defined as 'rules which are not usually legally binding, although they may have some legal force, but which will in practice determine the way in which people act' (DBC2003).

Amongst the regulations helping to define patient entitlement to services are NSFs, NICE guidance, waiting time guarantees, fee schedules, and incentive schemes. The Healthcare Commission is the key regulator, assessing the performance of NHS organizations against national standards in its 'annual health check', a monitoring process that assesses both existing performance ('core' standards) and capacity to improve ('developmental' standards) (Adams et al., 2006).

10.2.2 *National Institute for Health and Clinical Excellence (NICE)*

The National Institute for Health and Clinical Excellence (NICE) is part of the NHS. It is the independent organization that is responsible for assessing whether new or existing technologies should be available on the NHS. The Department of Health commissions NICE to develop clinical guidelines, guidance on public health and technology appraisals. Each guidance area is the responsibility of one of the three centers of excellence:

- Center for Public Health Excellence: develops public health guidance on the promotion of good health and the prevention of ill health.

- Center for Health Technology Evaluation: develops technology appraisals (recommendations on the use of new and existing medicines and treatments within the NHS) and interventional procedures guidance (evaluates the safety and efficacy of such procedures where they are used for diagnosis or treatment).
- Center for Clinical Practice: develops clinical guidelines in interventional procedures (recommendations, based on the best available evidence, on the appropriate treatment and care of people with specific diseases and conditions).

Three types of guidance help define the availability of NHS services of curative care: technology appraisals, NICE clinical guidelines, and guidance on interventional procedures. Clinical guidelines are recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions within the NHS. They are based on the best available evidence. While clinical guidelines help health professionals in their work, they do not replace their knowledge and skills. Clinical guidelines aim to improve the quality of healthcare. Technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS, such as medicines, medical devices, diagnostic techniques, surgical procedures, and health promotion activities. NICE is asked to look at particular drugs and devices when the availability of the drug or device varies across the country. This may be because of different local prescribing or funding policies, or because there is confusion or uncertainty over its value. Recommendations in technology appraisals are based on a review of clinical and economic evidence. The aim of NICE advice is to end the uncertainty and help to standardize access to healthcare across the country. The interventional procedures program assesses whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for use in the NHS. The aim of the program is to enable clinical innovation to be responsibly conducted. Topics for the interventional procedures program are notified to NICE directly, usually by clinicians. The NHS is responsible for applying guidance to meet the need of patients.

NICE came into being in 2004. The National Institute for Clinical Excellence (established in 1999) preceded it, which was also known under the acronym of NICE. The 2004 organizational change of NICE reflects the government's wish to bring together knowledge and guidance on ways of promoting good health and treating ill-health (National Institute for Health and Clinical Excellence, 2005a). Importance of this dual objective was set out in the white paper 'Choosing health: making healthy choices easier' that discussed possibilities to tackle causes of ill-health and reduce inequalities in regard to public and individual responsibilities for health. It was noted that health improvement not just depends on the available health services, but also upon people's motivation and their willingness to act on improving their own health. It was agreed that the Government would provide information and practical support to get people motivated and improve emotional wellbeing and access to services so that healthy choices are easier to make (Department of Health, 2004). In response to this white paper, the scope of NICE responsibilities was extended to include also public health issues. In 2005, also the functions of the Health Development Agency (HDA) were transferred to NICE. The HDA was a special health authority

established in 2000 to develop the evidence base to improve health and reduce health inequalities. It advised on the setting and implementation of the public health standards for all aspects of the health improvement process.

10.3 Benefits defined by technology appraisals

Within the regulatory framework of laws and quasi-laws, there is large usage of HTA. In most cases, however, there is no statutory obligation for NHS bodies to implement standards. An exception is the status of technology appraisals. The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE's technology appraisals (National Institute for Health and Clinical Excellence, 2005b). The secretary of state for health has specified that if a technology appraisal states that a new technology should be made available, NHS bodies must ensure under the National Health Services Act 1977 that the technology is available not later than three months from the date of publication of that technology appraisal (Secretary of State for Health, 2001). Because of this formalized arrangement, this chapter describes in detail the evaluative approach that underlies technology appraisals.

10.3.1 Policy

Technology appraisals are undertaken by NICE with the purpose of considering the evidence of the health benefits and costs of a technology. The Institute's Appraisal Committee considers the evidence and judges whether or not the technology can be recommended as a cost-effective use of NHS resources. The Appraisal Committee is a standing advisory committee. It seeks the views of many stakeholders, but its advice is independent. The Appraisal Committee's judgment is published as the Appraisal Consultation Document. After comments are received from consultees and commentators, the appraisal sets out its final recommendations in the Final Appraisal Determination. The Appraisal Program Director (responsible for the whole Appraisal Program) and the Executive Lead (a member of the Appraisal Committee who is responsible for this particular appraisal) oversee the project, ensuring that the appraisal is conducted in accordance with the published guidelines for the appraisal process, signing of consultation documents in various stages of the appraisal process. They also undertake a final review of the Final Appraisal Determination, sign it off, and submit a report to the institute's Guidance Executive, who will approve it for publication. Next, NICE will issue guidance to the NHS in England and Wales.

The Department of Health and the Welsh Assembly Government are responsible for selecting topics for the NICE technology appraisal and clinical guidelines work programs, using published criteria (National Institute for Health and Clinical Excellence, 2005b). Healthcare professionals, patients and carers and the general public who suggest topics read these criteria before submitting their suggestion. The types of technologies suggested include: pharmaceuticals, medical devices, diagnostic techniques, surgical procedures, other therapeutic technologies, and health promotion activities. The Advisory Committee on Topic Selection produces a potential list of topics. The Ministers for Health decide which technologies are referred to NICE review. In general, the presumption is that guidance will take the form of a clinical guideline if no suitable guidance relating to the condition is available or in preparation. An appraisal

should be considered if the perceived need relates to a particular intervention for a particular condition, and if either (a) there is an urgent need for guidance or (b) a clinical guideline for that condition is already available or in preparation (National Institute for Health and Clinical Excellence, 2005b).

As said above, when a technology appraisal recommends the use of a particular technology, NHS organizations in England and Wales are required to provide funding for this technology within 3 months. Local NHS organizations are expected to meet the costs of those treatments out of their general annual budgets. The NHS agencies are accountable to the Department of Health. NICE tracks the progress of NHS trusts in implementing their guidance to ensure NICE guidance achieves positive and sustainable changes for patients, and to inform the development of future tools and resources. They have for example commissioned several surveys to track the uptake of NICE guidelines across the country.

To perform its various tasks, NICE has a staff of about 230 people in London and Manchester (personal communication with NICE). The staff grew exponentially over the last two years. Most of the Institute's funding comes from the Department of Health. In 2005/6 NICE received £27m. It also received £0.6m from the Welsh Assembly Government and £0.1m from other sources. Main areas of expenses are staff salaries (accounting for about 42% of expenses in 2005) and external contracts (38%) (National Institute for Health and Clinical Excellence, 2006). The overall budget is split between work programs (the Center for Clinical Practice accounts for 27% of resource use, the Center for Health Technology Appraisals for 10%) and support functions (18% of the budget is used for planning and resources, 14% for communications, and 11% for implementation).

10.3.2 Assessment

The purpose of the appraisal is to appraise health benefits (quality of life, mortality) and costs of a technology and make recommendations to the NHS in England and Wales, as described in directions of the Secretary of State for health and the Welsh Assembly Government. The appraisal of a health technology is divided in three distinct phases: scoping, assessment, and appraisal (National Institute for Health and Clinical Excellence, 2004a). Information about the scoping, assessment and appraisal procedures is published on the Internet. During the scoping process, NICE determines what questions need to be addressed in the appraisal and develops a final scoping document and a protocol for the technology assessment. Components of the scope for example include definition of the patient population and relevant subgroups, choice of the comparator technologies, and methods of the economic evaluation (e.g., outcomes measure, cost categories, perspective). The scoping process is done for a long list of technologies. The Minister of Health decides which of those technologies will be referred for NICE Technology Appraisal. The assessment procedure that follows will be done within the boundaries defined in the scoping process. The appraisal procedure includes other factors relevant to the NICE recommendation, based on guidelines received from the policy makers (see below).

When a technology is referred to NICE, the Appraisal Committee undertakes the evaluation, starting a process in which scientific evidence and patient/professional expert opinion are systematically collected for the purpose of making NICE recommendations. The evaluation of scientific evidence, i.e.

technology assessment, is subcontracted to the assessment group, which is an independent academic body. When the assessment report is received, the Appraisal Committee considers the outcomes of the assessment process, within the context of additional information supplied by consultees, commentators, clinical specialists and patient experts, who have also received a copy of the assessment report. The Appraisal Committee considers the evidence and formulates the NICE recommendations, i.e. whether or not the technology can be recommended for general use, or for use in specific groups. This judgement is referred to as Appraisal Determination. Since the Appraisal Committee is a key actor, its members are carefully selected. To ensure that evidence is evaluated independently and from a range of perspectives, members are appointed for three years, and are drawn from the NHS, patient and carer organizations, academia, and industry.

A consultation process has been designed to allow stakeholders to participate in the appraisal process as consultees or commentators. Consultees and commentators are identified relatively early in the technology appraisal, so that they can be involved in all stages of the appraisal. Consultees are: manufacturers or sponsors of a technology, national professional organizations, national patient organizations, the Department of Health and the Welsh Assembly Government, relevant NHS organizations in England and local health boards in Wales. Manufacturers of comparator technologies participate in the process as commentators. They are not asked to offer their views and, contrary to consultees, they do not have the right to appeal to a final decision. Also other organizations may be invited to participate as commentators, like the NHS Quality Improvement Group in Scotland, National Collaborating Centers, and other related research groups. When a technology first appears at a provisional list of technologies that may be referred to NICE, already organizations are identified who might wish to participate in the appraisal process as consultees and commentators. They are invited to offer their views on the draft scope of the appraisal. When the technology is referred to NICE, they will also be invited to offer their views on the assessment report, and the appraisal consultation document. In addition, consultees can nominate specialist and patient experts to present their views to the appraisal committee. They are also given the opportunity to appeal. Commentators are not asked to make a submission, and have no opportunity to appeal.

The evidence considered in the assessment and appraisal processes concerns health benefits (quality of life, mortality) and costs of a technology, as requested in the scoping documents. The assessment group performs a literature review and an economic evaluation. NICE offers methodological guidance, particularly where the economic evaluation is concerned, because of general awareness that methods of particularly economic evaluations are continuously evolving, and that there may be a shortage of the skills required to make assessments. A reference case is adopted that was considered appropriate for the Appraisal Committee's purpose. The timelines for the assessment are not fixed, because different technologies require different assessments as decided upon in the scoping phase. For each technology, however, the timelines of the whole appraisal procedure will be presented on the website of NICE within 6 weeks of referral of that technology. Table 10-1 gives an approximation of the timelines.

Table 10-1

		<u>Weeks (approx.) since process began</u>
Step 1	Organizations invited to participate in the appraisal as consultees or commentators	0
Step 2	Submissions from consultees received	14
Step 3	Submissions from manufacturers and sponsors sent to the Assessment Group	15
Step 4	Selected clinical specialists and patient experts invited to attend Appraisal Committee meeting and asked to submit a written personal perspective	16
Step 5	Assessment Report received by Institute	28
Step 6	Assessment Report sent to consultees and commentators for comment	30
Step 7	Selected clinical specialists and patient experts submit written personal perspectives	32
Step 8	Comments on Assessment Report from consultees and commentators received by Institute	34
Step 9	Evaluation Report compiled and sent to Appraisal Committee	36

Timelines may change in response to individual appraisal requirements.

The assessment group publishes its findings in an assessment report that is circulated. Comments are collected from consultees and commentators. After this the Appraisal Committee considers the evidence and comments and summarizes its findings in an Evaluation Report that will be used in the Appraisal process (described in the next section). The evaluation report contains:

- The final scope and lists of consultees and commentators;
- The assessment report;
- Comments of consultees and commentators on the assessment report;
- An overview by the Institute's technical Lead for the Appraisal;
- Submissions from consultees;
- Summaries of submissions from commentators;
- Perspective of patients and clinical experts obtained in the Appraisal Committee meeting;
- The assessment Group's written response to comments, if any, on the assessment report;
- Supplementary analysis, if any.

10.3.3 Decision

The appraisal stage of the process consists of four elements (National Institute for Health and Clinical Excellence, 2004b):

- consideration of the evidence at an Appraisal Committee meeting to develop an ACD;
- preparation of and consultation on the ACD;
- review of the ACD in the light of comments from consultation at a second Appraisal Committee meeting;
- preparation of the FAD.

The Appraisal Committee evaluates the evidence presented in the assessment report, taking the opinion of consultees and commentators into account. On basis of the assessment report and comments, the Appraisal Committee then develops an Evaluation Report that is circulated for the Appraisal Committee meeting in which the content of the Appraisal Consultation Document is discussed. At this moment, also factors beyond the health benefits and costs are taken into account, based on directions provided by the Secretary of State for health and the Welsh Assembly Government. These factors include clinical priorities, clinical need, balance of benefits and of costs, available resources, effective use thereof, and a long-term interest of the NHS in innovation. Next the Appraisal Consultation Document is prepared. What follows is a consultation of the Appraisal Consultation Document, after which in a second meeting of the appraisal committee the content of the Final Appraisal Determination is discussed. Finally, the Final Appraisal Determination will be prepared. When the Final Appraisal Determination is signed off, it is circulated to NHS trusts, who are obliged to follow included recommendations. The timelines of the appraisal procedure are summarized in Table 10-2.

Table 10-2

		Weeks (approx.) since process began
Step 10	Appraisal Committee meeting to develop an ACD, attended by patient experts and clinical specialists	37
Step 11	ACD produced and distributed. ACD posted on Institute's website 5 working days later	40
Step 12	Fixed 4-week consultation period on ACD	40-43
Step 13	Appraisal Committee meeting to consider comments on ACD from consultees and commentators and comments received through the consultation on the Institute's website. Appraisal Committee agrees the content of the FAD	45
Step 14	FAD produced and distributed. FAD posted on Institute's website 5 working days later	51

Timelines may change in response to individual appraisal requirements.

The Appraisal process requires two meetings of the Appraisal Committee. The first meeting is attended by representatives of the assessment group and representatives from the National Collaborating Center that is responsible for developing the Institute's clinical guidelines in areas related to the topic under appraisal. Patient experts and clinical specialists are asked to submit, before the meeting, a written personal view of the role of the technology, particularly providing insights not available in the published literature. They are also invited to the meeting and get the opportunity to comment on the technology and its use in the NHS. They are asked to withdraw from the committee before the contents of the Appraisal Consultation Document are discussed. Assessment Group representatives may remain present during Committee discussions in order to answer any further questions the Committee may have. However, they play no part

in decision-making. Representatives from the National Collaborating Center observe and serve as advisors to the Committee.

The Appraisal Consultation Document contains provisional recommendations that may change in response to consultation. The Appraisal Consultation Document is normally circulated three weeks after the first Appraisal Committee meeting. The document contains for example summaries of available evidence, and a description of clinical need and practice in the disease area. It is sent out to consultees and commentators, together with the Evaluation Report. Consultees and commentators have four weeks to submit their comments in writing. Purpose is to gather views on suggested recommendations and to determine whether recommendations are an appropriate interpretation of the evidence. New data will be collected only by prior agreement of the Appraisal Program Director, and only when it would significantly affect recommendations. When this happens the next meeting may be postponed. It is also possible that new data require substantial revision of interpretations and then a second Appraisal Consultation Document may be prepared, and the whole appraisal process is repeated. When views on the Appraisal Consultation Document have been collected, the second meeting of the Appraisal Committee is held to develop the Final Appraisal Determination. Representatives of the assessment group and the National Collaborating Center are invited to attend the meeting. To deal with issues raised during the consultation period, the chair may also invite experts. This meeting decides on the contents of the Final Appraisal Determination, which is normally published six weeks after the meeting when it is signed off by the Guidance Executive. It is also circulated to consultees and commentators, who in addition receive a summary of comments and a summary of the response to the comments. This information is also posted on the website.

10.3.4 *Outputs and implementation*

When the Final Appraisal Determination is finished, there is possibility for appeal. Right to appeal is limited to consultees. Appeals must be made within 3 weeks after receipt of the document. Appeals will only be considered when the grounds for appeal are appropriate, i.e. the institute has not acted in accordance with published procedures; the recommendations are 'perverse' in light of available evidence; the institute has exceeded its powers. The appeal procedure, which has been set out in detail in a document (National Institute for Health and Clinical Excellence, 2004c), should not be regarded as an opportunity to reopen the argument. Normally, when an appeal is made, an Appeal Panel will be installed. Members of the Appeal Panel include at least 5 people of the Appraisal Committee, but they will have had no previous involvement in the appraisal in question. The Appeal Panel considers the appeal in public. This panel sends its conclusions to the institute. The Guidance Executive considers the panel's decision and may decide to refer the Final Appraisal Determination back to the Appraisal Committee. If there is no appeal, an appeal is dismissed, or an appeal is upheld but the FAD does not need to be referred back to the Appraisal Committee (e.g., when only editorial changes are required), the Institute makes arrangements for the guidance to be published, together with the Appeal Panel decision, if any. Publication takes place on the fourth Wednesday of each month. If the Final Appraisal Determination is

referred back to the Appraisal Committee, the Appeal Panel's decision will also be published along with the arrangements for considerations by the Committee. This happens within 3 weeks of consideration by the Guidance Executive.

When NICE publishes its recommendations, it will also indicate when guidance or technology appraisals will be considered for reviews. The decision depends on the anticipated rate of developments in the field, and varies between 1 and 5 years. If significant evidence emerges sooner, consultees, commentators and the institute can identify it. The Guidance Executive considers the evidence and decides if the review date will be brought forward. A review will not be undertaken within 12 months of first publication of NICE recommendations.

To facilitate implementation and inform the public, NICE produces three versions of its technology appraisals (National Institute for Health and Clinical Excellence, 2005b):

- The full appraisal: presents the recommendations from the full version in a format suited to implementation by health professionals and NHS bodies;
- A quick reference guide: presents recommendations in a suitable format for health professionals;
- A lay version: information for the public is written for using suitable language for people without specialist medical knowledge.

Once NICE publishes its guidance, health professionals and organizations are expected to take the information fully into account in deciding what treatments to give to patients. NICE guidance generally acts as quasi-law: health professionals and organizations are expected to compare their clinical practice to the guidelines. Where NICE technology appraisals are concerned, the NHS has a statutory duty to provide funding and resources for the technology in question. To help ensure that NICE guidance is put into practice, NICE has established an Implementation Directorate that for example develops support tools, demonstrates cost impacts, evaluates guidance uptake, and ensures intelligent dissemination to the target audiences. NICE reports on its website the activities that are undertaken to evaluate whether or not its guidance is put into practice. A large effort was made in 2004, when NICE commissioned Abacus to measure the impact of 28 individual pieces of NICE guidance (Howard & Harrison, 2005). Another agency involved in testing implementation of NICE guidance is the Healthcare Commission. The Healthcare Commission's statutory duty is to assess the performance of healthcare organizations in the NHS. Their activities include an annual health check, programs of review, audit and assessment. Amongst other things they assess how NHS organizations perform against a set of standards for NHS services. One standard is that offered health care benefits are evidence-based. Implementing NICE guidance will help organizations meet the standards, and is obligatory for NICE technology appraisals. As a result, implementation of NICE guidance is often covered in the Healthcare Commission's assessments. A summary of NICE guidance being covered by the Healthcare Commission's assessment is published (NICE Implementation Directorate, 2006).

Chapter 11 Country comparison

In the Chapters 2 to 10 we collected the information requested by the Hutton framework to describe and analyze the systems for reimbursement decisions in nine countries. Below we analyze the similarities and differences, once again following the structure of the Hutton framework. This means that separate sections compare ‘policy’, ‘assessment’, ‘decision making’, and ‘outputs and implementation’. For each element, we compare how the systems are governed, what methods and processes are applied, how evidence is used, and in what way key actors are expected to give account of their actions and decisions.

Before this however, the following observation should be made. In comparing the countries, we have kept in mind that the Hutton framework is a descriptive framework, which has been developed to enable a detailed and comprehensive description of the decision support systems. The framework does not assign a normative value to the structure of each system. That would imply that there is a good system to which other systems might benchmark. A system that performs universally best, however, does not exist, because the health care systems in different countries are so different and regulation occurs by so many different means. Different policy settings yield different requirements to assessment and decision-making procedures. Therefore, the key question is how well a system meets the requirements of the specific context to ensure that the benefits package is defined according to broad policy objectives, and not how good its structure is per se. To do justice to the comparison of the systems for reimbursement decisions, we will discuss the main differences between the countries in conjunction with underlying characteristics of the health care system that help to understand why the systems have been established in a particular way.

11.1 Policy level

At the policy level, we have considered establishment of the system, the underlying objectives, implementation and division of responsibilities, and type of accountability embedded in the system. We found similarities in terms of objectives of the system and its establishment. HTAs usually reflect the wish to use resources effectively and efficiently. In countries where local authorities are independent in their decisions, HTAs are also performed to guide the use of controversial technologies and to prevent inequalities. Another shared characteristic regarding the establishment of the systems is the existence of a governmental agency or independent actor who directs the assessments systems, from topic selection to decision making. Differences were found concerning the division in responsibilities between assessment and appraisal. In the UK and Australia, one actor is responsible for both the assessment and the decision. In most other countries, decisions are shaped in a process of structured negotiations between the health care payer (government or insurers) and providers of care. Here, assessments inform decisions, but it is not clear to what extent evidence of assessments is actually used. This translates into differences in accountability: some countries rely on transparent criteria and clear procedures to weigh evidence, whereas

others believe that it is inherent to a negotiation process between payers and providers that evidence is weighed carefully.

The scope of the assessment systems differs across countries. In Australia, the assessment procedure is applicant-driven. Applicants have to make a request to the Department of Health for listing on the benefits schedule. A formal assessment procedure then starts to make the decision. In the Netherlands, the newly introduced DBC financing system is also applicant-driven. This implies that there is no system to scan which DBCs should be assessed. In Switzerland, to give another example, interested parties (either health care providers, health insurers, or patient organizations) may make an application to the BAG. If the branch organization of the insurers or that of the physicians considers the service controversial, the assessment procedure is started. In other countries, most notably national health services (e.g., Canada, UK, and Sweden), the benefits package can be expanded implicitly, for example because local authorities decide on benefits offered to people in a certain region. The law states what types of services have to be reimbursed. Local authorities then need to make sure that a comprehensive benefits package is offered, in accordance with national legislation. Because there exists a large gray area, assessment reports aid local decision makers. However, since the link between assessments and decisions is indirect, assessments mainly focus on controversial and/or expensive technologies, to prevent inequalities and to help local authorities in delineating the benefits package. In between are countries (e.g., the United Kingdom) where decisions on the benefits package are made for the whole country, but not by the central government. Here assessments are done to ensure that independent bodies base their decisions on sound information.

Beforehand, we expected topic selection to be an important aspect of the procedure. Governments were expected to be confronted with a rapid diffusion of (expensive) health technologies. Special committees to set assessment priorities on basis of a set of criteria have been established in some countries (e.g., Canada, Australia). To give another example: in the Netherlands the benefits package manager (CVZ) publishes a bi-annual agenda that mentions types of care for which it will proactively assess whether they are eligible for inclusion in or exclusion from the benefits package, even though the assessment procedure is applicant-driven. Although we found differences in the topic selection process between countries, the effect of these differences on the assessment agenda is not as evident as might have been expected. We observed remarkable convergence across countries with regard to technologies selected for assessment, no matter whether the countries have an applicant-driven system or a system where independent agencies decide on assessment priorities. A logical explanation is that all policy makers are concerned about the budget impact and quality aspects of new treatments in health care, regardless of the regulatory context, so that major new technologies are scrutinized timely in all systems. Similar criteria for prioritizing assessments are used across countries, namely clinical need, costs, available treatment alternatives, and potential benefit of the HTA. It is not surprising then that some technologies, like PET scans, have been evaluated in all countries. At the same time however, differences are found in the number of technologies reviewed, which can be partially explained by differences in the scope of

assessments (see Section 11.2). For example, France produced almost 200 assessments in 2005-06, while Sweden performed 50 assessments in the year 2000.

A fundamental difference between countries in procedures for topic selection is that in some countries (e.g., the UK) 'availability of evidence' is used as a criterion for assessments. The argument to use this criterion is that an assessment should be an aid to decision makers; if too little information is available, usefulness of assessment reports would be limited anyway. So studies can be omitted as well? This might seem illogical from the perspective of decision makers in countries that request assessments prior to the reimbursement decision. After all, when too little evidence is available to support funding of a service, a conclusion could be that funding must be denied because effectiveness and cost-effectiveness have not been demonstrated yet. In practice, we found that denying access to the technology because of a lack of evidence is often considered inappropriate, and other political solutions are sought, e.g. granting a temporary reimbursement status and requesting re-evaluation. This policy was observed in many countries, such as France and Switzerland. It has the advantage that policymakers can direct research, but comes at the costs of more bureaucracy.

The above already shows that there are substantial differences between countries in the division of responsibilities for assessment and appraisal. Most formal procedures for assessment exist in the UK (where NICE guidance has a legal status to prevent inequalities between regions) and Australia (where the central government decides on listing on the benefits schedule). The responsible agencies act independently from main actors in the health care system, and are responsible both for assessment and appraisal of the data. The assessment procedure is tailored to the needs of the decision maker, who has to apply some sort of judgment over collected evidence. A policy framework has been established in which transparency, consistency, and procedural elements are of utmost importance to allow the public and key stakeholders to evaluate the legitimacy of decisions. In other countries, county councils (Sweden), provincial authorities (Canada) or insurers (e.g., France, Belgium, Germany, and Switzerland) are responsible for decisions on the benefits package. Their decisions are shaped in a structured process of negotiations with providers. Agreements must be reached about the content of the benefits schedule, tariffs, and volumes of use. Because of the need to reach an agreement with the medical profession, decision makers cannot act alone. In spite of HTAs being made to inform decisions, the decision-making process is typically not transparent in these countries. It is not clear how, and to what extent, the evidence arising from HTAs is used in decisions. Of note is that many of these countries have no long tradition of HTA, although its role is growing currently – though slowly. Apparently one has the faith that the negotiation process ensures careful weighing of the evidence, since the payers are cost aware and medical doctors are inclined to offer optimal service. Moreover, the governments of these countries cannot influence the appraisal of evidence. They can only apply indirect steering techniques to influence decisions (e.g., putting down legally what requirements must be met by decision makers, or using macro-economic regulation, for example by setting a financial target of health insurance spending) (Bellanger & Tardif, 2006). Clearly, the link between assessments and decisions is not equally strong in all nine countries studied in this report, even though assessments are performed everywhere. This translates into differences

in the transparency of procedures. There is a shared trend however towards making procedures more transparent. Because inequalities have been observed, e.g. across regions in national health service systems like Canada and the UK, openness in decision making is increasingly required. The role of assessments is changing accordingly. For example, appraisal of collected evidence is increasingly explicit, and recommendations are made more often these days than in the past.

Overall, we can conclude that assessment priorities between countries are rather similar. The agenda for assessment does not differ much between countries that require assessments as part of the intake procedure and countries where expansion of the benefits package occurs implicit. However, with regard to transparency of decision-making we found substantial differences between countries. The division of responsibilities across actors represents differences in the extent of self-regulation in the health care sector. To earn the public trust, different standards of accountability are developed and maintained, meeting the local regulatory context. In several countries, decisions are made by payers (insurers/local authorities) in consultation, agreement, or negotiation with the medical profession. Although this procedural aspect helps to legitimize outcomes, we observed a tendency towards more openness in decision making because of unwanted inequalities in health care services across regions ('postcode prescribing').

11.2 Assessment

We compared the nine countries with regard to responsibility for assessment and stakeholder involvement, the methods, the evidence, and the outcomes of assessment. Our main findings are as follows. The authority responsible for decision-making usually relies on assessment reports prepared by others to make a decision. Most countries have installed a body that is responsible for assessments. An HTA can be an element of the decision-making procedure in all countries included in this comparison, but assessment strategies vary. Assessment reports may have a broad or a narrow perspective. For example, they may or may not cover alternatives for the technology under appraisal. Assessment criteria always include costs and effects, while sometimes also social and ethical aspects are considered. Assessments of medical specialist care are typically not technocratic, in the sense that assessment methods and procedures are not always described in detail and requirements are not stringent. The most detailed descriptions of assessment procedures exist when the link between assessments and decisions is rather direct. In most countries however, assessment procedures are not clearly described and the main assessment method is literature review. This means that formal economic evaluations are only taken into account when available, which is often not the case. The lack of explicit procedures may be a pragmatic response to the observed problem that in medical specialist care evidence is typically rather limited. In these circumstances, stakeholder participation is considered relevant. Stakeholders typically participate in a project group that reviews draft reports and helps to draw conclusions. Another common arrangement is that medical experts are invited to offer their views on a technology.

In the assessment of medical specialist care for the purpose of defining entitlements, it is not common that applicants are made responsible for data collection, such as for example in Switzerland, the

Netherlands, and in the UK when single technology appraisals are concerned. More often, an independent governmental agency is responsible for collecting the evidence, such as KCE in Belgium, CADTH in Canada, or the HAS in France. Generally, the institution responsible for the assessment may choose to perform the assessment internally or to commission the work to a specialized HTA institute, depending on complexity of a particular subject, capacity at the time, and the scope of assessments. The assessment agencies of most countries have made arrangements for stakeholder participation. Stakeholder involvement is frequently arranged through installation of a project group that oversees the assessment to ensure that the right procedures are followed and that no relevant data are overlooked. In the UK and Australia for example, a project group is established to guide the assessment process, i.e. regarding the scope of assessment, the interpretation of results, and the presentation in the assessment report. Such a project group might consist of representatives of the agency, the medical profession, health economists, and consumers. Another common arrangement is that stakeholders are given the opportunity to review the assessment report prior to publication (e.g., Germany, France, the Netherlands).

Assessments may be more or less complicated, also depending on the mission statement. For example, the HAS in France has the most ambitious mission statement: it should develop a procedure to review all existing benefits – which can only be realized if studies can be done quickly. Other assessment agencies, such as UK's NICE and Sweden's SBU, may conduct broad HTAs. This means that not just a single technology is explored, but also its merits relative to other treatments for the same condition. Such an assessment may involve reviewing hundreds of articles, and may take several years to complete. Less complicated HTAs can be written in a couple of weeks or months, as far less literature needs to be considered. The most common method for assessment is literature review in relevant databases. Commonly (e.g., in Germany, Canada, Australia, and the UK), the report undergoes a review procedure prior to publication. Finally, a distinction can be made between assessments that simply aim to describe available evidence and those that aim to collect additional data. In case of the latter, the timelines are obviously different from assessments based on reviews. This impacts on finance for innovation and speed of market access. Of note is that countries with long assessment procedures often offer fast track appraisals, such as is the case in the UK and in Sweden.

As said above, in all countries the evidence considered includes costs and effects. This does not necessarily imply that a formal economic evaluation is performed following explicit guidelines for economic evaluation. It may also be the case that economic consequences and budget impact are mapped and that tentative conclusions about the relation between costs and effects are drawn. Formal economic evaluations (i.e., following guidelines for how economic evaluations need to be performed in that country) are regularly performed in the UK and Australia, depending on the scope of the research question. The newly developed fourth hurdle system in the Netherlands welcomes applicants to perform a formal cost-effectiveness study for new DBCs on which no data on cost-effectiveness have been published before. By contrast, in France the assessment agency HAS has the option to build economic models to further analyze available data, when necessary. In Switzerland, the BAG may require a full economic evaluation

(following guidelines set out in a manual) if evidence from published economic evaluations is incomplete and the technology is likely to represent a high cost.

With regard to considered evidence, it is relevant to note that specific requirements for the level of evidence are not used. Instead, the quality of the available evidence is taken into account when the evidence is appraised. The reason is that available evidence on the (long-term) effects of new treatments or diagnostics is often limited, e.g. in comparison to the pharmaceutical sector. If decision makers would use strict definitions to evaluate if available evidence substantiates a positive reimbursement decision, the outcome would often be negative. The problem then becomes that absence of evidence would yield the same outcome as evidence demonstrating that a treatment is not effective or cost-effective, which is considered undesirable, for example because of potentially detrimental effects on innovation. The lack of clarity about evaluation standards could be perceived as a weakness of assessment programs. However, it is doubtful if procedures can be improved by using more stringent requirements. The question is not so much what assessment criteria should be used and how thresholds values can be defined, but rather how the decision-making procedure can deal with incomplete evidence.

The content of the assessment report varies. The most relevant difference is perhaps that assessment reports may or may not contain clear recommendations for funding of a treatment. In the UK and Australia, the body responsible for assessment is also responsible for the decision and therefore must appraise the information. In these countries, appraisal of evidence is an explicit step in the procedure. In other countries (e.g., Belgium, Canada, France, Germany, the Netherlands, and Sweden), assessment bodies deliver their report to decision makers, so that it is not evident that recommendations need to be made. In France and the Netherlands for example, assessment reports contain a proposal for the reimbursement status, whereas in Canada and Sweden reports simply describe the available evidence.

Activities to disseminate the information collected in the assessment report vary between countries. With the exception of Switzerland, assessment reports are public in all countries and can be found on the websites of the assessment institutes. The policy in Sweden, UK, and France is to additionally disseminate the information to practitioners, so that not just benefit decisions at the national level but also treatment decisions at the level of an individual patient may be informed.

What becomes clear from the country reports is that assessment procedures were not everywhere described in the same detail. For example, timelines for the assessment procedure were not always found. Documentation of the assessment procedure is most extensive in the UK and Australia, and very limited in Germany. Absence of information might be interpreted as a sign that the quality of the assessment procedure is low, but this not necessarily true. It does however indicate that the procedure is not very transparent, which is in itself not a good thing. The fact that documentation is best in the UK and Australia might reflect the long experience of these countries with HTA. On the other hand, it could also reflect the direct link between assessment and decision. Both in the UK and Australia, bodies that act independent of key actors in health care make decisions about health care. These bodies have to legitimize their work by following routines that ensure thoroughness and timeliness. In countries where the relation

between assessment and decision is less direct, the perceived need to legitimize assessment outcomes may be lesser.

Overall, the differences in assessments and assessment procedures are substantial. It seems that a tradeoff is made between the desired basis for decision-making and scope of the assessment program. In many countries the emphasis is on the scope of the program, and not on the quality of assessment: many assessments are done, but not rigorously. This may be a pragmatic response to the observed problem that in medical specialist care evidence is typically rather limited, for example compared to pharmaceutical care.

11.3 Decisions

The decision-making procedures in the nine countries were compared with respect to who is responsible for a decision, the nature of the decision-making process, the evidence base, and the content and documentation of the decision. One of our main findings is that there exists substantial variance between countries in the design of decision-making procedures. For example, final responsibility for decision making may rest with the central or local government, insurers, or an independent body. However, there are similarities as well. In the decision-making process, equity concerns, budget impact, and priorities in health care are often taken into account besides assessment data. When little evidence is available, countries typically grant a temporary reimbursement status, conditional on future research. Generally, the decision-making process is not documented, and stakeholders are not involved.

As mentioned above, responsibility for decision making on benefits for medical specialist care lies with different actors in the countries studied. In Australia, the Netherlands, and Switzerland for example, a department of the central government has final responsibility, local authorities are responsible in Sweden and Canada, insurers in France and Germany (jointly with medical professionals), and an agency with the mandate for assessment and appraisal of evidence in the UK. In Belgium, health insurers also play a key role in preparing the advice on which basis entitlements are changed by royal decree. The choice for a particular decision maker is a logical consequence of how health care is run in each country.

The level of stakeholder involvement differs across countries. Implementation of procedures requires support of the key stakeholders. The challenge is to develop a system that can count on support of these actors. An example of how the system can be frustrated is called 'item drift'. This refers to the situation where services are funded on a fee for service basis. Over time innovations redefine the services, but opportunity is not always given to decision makers to re-appraise the service or re-establish the fee. In this respect it is important to realize that the establishment of independent assessment organizations, such as NICE in the UK, HAS in France, IQWiG in Germany, or SBU in Sweden, has changed the autonomy of doctors and manufacturers. Part of the critics of such actors on assessment and decision-making systems can be traced back to reduced autonomy. Differences between countries in stakeholder participation may be relevant in that respect. Unfortunately, stakeholder involvement in the decision-making procedure is often limited. In Australia, appraisal of assessment data is done by the MSAC project group, which means that the stakeholders included in the group have a say in the process. In the UK,

stakeholder participation is arranged in the same way. In the other countries, such as the Netherlands, stakeholder participation is limited to the assessment phase as a rule.

The decision-making process is often not documented and not transparent. The final decision only needs to be in line with general principles of the benefits package included in the law. There is no need for an explicit policy on other considerations that may be introduced in the decision-making procedure. Often the decision maker has to negotiate with the medical profession about benefits, tariffs, and volumes of use. Other stakeholders are not involved. Explicit appraisal of evidence on basis of explicit value judgments with stakeholder involvement only exists in the UK. In this country, the decision-making criteria and procedures are made as transparent as possible, by publication of a value document, involvement of stakeholders, and publicly available documentation about the decision-making process. The perceived need for transparent decision-making procedures may reflect the fact that decisions are made by an independent institution that has to account for its decisions and actions to the government and the public, and that has to ensure that key actors in health care implement its decisions.

The basis for a decision often goes beyond the evidence collected in the assessment procedure. Other concerns also play a role in the decision-making process. Often, these additional concerns are mentioned in policy documents, but not clearly defined. Moreover, treatments are typically not evaluated against these other concerns. Hence, the values guiding the decision-making process typically remain implicit. For example, equity, budget impact, and priorities in the health care system are often taken into account on top of the evidence regarding (cost-)effectiveness that is collected in the assessment. Most countries have made a statement that these concerns could be taken into account, but not how they are defined and weighed against other concerns. In this way, transparency and discretionary power of policy makers are traded off. An exception is the UK where a value document has been published to facilitate the Appraisal Committee.

When a decision has been made, typically a change to the benefits schedule follows that is published in benefits schedule documents and websites. Generally, the decision is not motivated. In the UK however, elaborate information is available on how the decision was reached. In Australia, the MSAC reports motivate the decision, but less elaborately. In countries such as Sweden and Canada the decision-making process is not transparent at all.

11.4 Outputs and implementation

This report compared the outputs and implementation of the systems for decision-making with respect to possibilities for appeal, implementation and communication of the decision, systematic efforts for monitoring and re-appraisal, and evidence of impact of the decision as compared to the objectives of the decision-making system. Our main results are the following. In most countries, there are no specific procedures for appealing reimbursement decisions. Only in the UK and France, appeal mechanisms are built into the system for making reimbursement decisions. A positive reimbursement decision often involves a change to the benefits schedule. Appropriate use of the service is a whole different matter. In some countries, the objective of central actors in the systems for priority setting is to promote appropriate

care, which means that quality appraisals and guideline development are also their responsibility. These bodies are active in disseminating results of assessments and implementing decisions. In other countries, there is a distinction between procedures to delineate the benefits package and those to promote appropriate care, so that assessment agencies are not involved in implementation activities.

We found that appeal possibilities differed substantially between countries. In the UK, the right to appeal is given to all consultees (including manufacturers, patients, and medical professionals). In France, appeals can be made by the Minister of Health or by major trade unions that represent large shares of consumers. Appeals can only be made on legal grounds, which means that either the interpretation of evidence is evidently wrong, or that the procedures were not followed correctly. In Australia, where the decision-making procedure is applicant-driven, unsuccessful applicants are invited to a debriefing with MSAC. In several other countries, such as Belgium, Germany, the Netherlands, Sweden, and Switzerland, no specific appeal procedures focusing on reimbursement decisions exist. Consumers always have general rights to make legal claims of the health care system.

We also compared countries with regard to how decisions are put into practice. In many countries, responsibility of actors in the decision-making systems does not go beyond the reimbursement decision. Once a service is listed on the benefits schedule, providers can offer the service to patients and reclaim their costs, or patients can get the treatment reimbursed. Other mechanisms are then in place to evaluate quality of care in different regions or to evaluate appropriate use. Some independent assessment bodies, however, also develop instruments for decision makers to act on the assessments. The HAS in France, for example, does not only assess the efficacy of procedures, it also disseminates practice guidelines and conducts medical audits of independent professionals and hospital accreditation. In Sweden, the link between decisions and assessments is rather weak in the policy model. To ensure uptake of available evidence, SBU employees visit doctors and administrators to discuss the results of their studies and to influence clinical policy at the regional and local levels. In addition, a special institute was installed to disseminate HTA results to decision makers. In the UK, most extensive implementation efforts are made. Providers have the obligation to take NICE guidance into account, and when technology appraisals are concerned, funds must be made available to provide treatments with a positive recommendation. NICE has set up a program to help support implementation of NICE guidance. The implementation team does not get involved in developing the guideline recommendations but works alongside the guideline developers. NICE maintains a databank (ERNIE) with information regarding the implementation and uptake of NICE guidance. Finally, NICE guidance becomes part of standards against which health care organizations are evaluated by the Healthcare Commission.

A NICE technology appraisal in the UK always includes a statement about re-appraisal. In most other countries, no re-appraisal dates get fixed as part of the procedure. However, in some countries, among which are France and Switzerland, a positive reimbursement status may be granted on a provisional basis, requesting re-appraisal after for example three years. This solution seems to be the only solution in countries where treatments can only be financed on a fee for service basis. Elsewhere, re-

appraisal dates are not included in the decision. Here the general agenda setting process can allow for re-appraisal of specific services, but re-appraisal will not automatically happen.

Finally, analyses of the impact of decisions compared to the objectives of the systems for assessment and priority setting are rare. In the UK, functioning of the NHS is also evaluated with regard to the implementation of NICE guidance. The Healthcare Commission evaluates the NHS against set standards and targets for the health care system.

11.5 Summary tables

Our study into how countries define the benefits package for medical specialist care is summarized in Table 11-1 to Table 11-4. In these tables, the collected information has been grouped under four headings (policy, assessment, decision making, and outputs and implementation) and analyzed using the Hutton framework elements ‘constitution and governance’, ‘methods and processes’, ‘use of evidence’, and ‘accountability and transparency’.

Table 11-1 Comparison of systems for priority setting: policy level

Country	Establishment	Objectives	Implementation	Accountability
Australia	MSAC. It advises the MoH about public funding for medical procedures.	To ensure that evidence supports public funding of new interventions.	Central actor is MSAC.	To key stakeholders and DoH. It is assessed against stated purposes.
Belgium	KCE.	To support provision of the best possible health care and the efficient and transparent allocation of resources.	RIZIV/INAMI.	To the federal government.
Canada	CADTH, a body funded by federal, provincial and territorial governments that provides impartial, evidence-based information about health technologies.	To inform effective, evidence-based decisions about health policy and purchasing, service management, and clinical practice.	Provincial authorities negotiate agreements with the medical profession.	To the Conference of the Deputy Ministers. The HTA Strategy has been evaluated.
France	HAS, an independent public institution set up by the DoH; consultative body that provides independent advice to authorities.	Health system improvement; management of the system; cost control.	UNCAM.	Managerial (e.g., board members appointed by different authorities) and legal (obligation to consult).
Germany	IQWiG.	To assure that services included in the benefits package are adequate, appropriate, and efficient.	G-BA.	To the federal DoH.
The Netherlands	CVZ, NZa, and SDO. These are all national, independent organizations funded by and reporting to the MoH. CVZ is benefits package manager. It makes recommendations based on its assessments.	Cost management, effectiveness and efficiency. Spending should stay within the macro budget. The DBC financing system has been introduced to achieve quality and cost management goals. Managing the benefits package is an important tool to influence macro health expenditure.	CVZ makes recommendations to the MoH about the inclusion of a technology in or the exclusion from the package (with or without further conditions). The MoH decides. SDO practically incorporates modifications into the DBC system. NZa develops tariffs. Implementation depends on funding, budgets, and buy-in of medical specialists.	As public DBC maintenance organizations, CVZ and NZa are accountable to the MoH. SDO is an independent private organization, whose board is composed of people from the hospitals associations, the Order of Medical Specialists, the Dutch Health Insurers Association, and the Netherlands Patient and Consumer Federation (all in personal capacity).
Sweden	SBU. Established by the Swedish government to evaluate health services on behalf of the healthcare sector. First as a government agency, later on as an independent public authority.	To promote the efficient use of resources and to create more openness in priority setting.	Local authorities: the county councils decide on local benefits.	To the central government: SBU submits an annual report that contains a review of work accomplished, plans for the future, and statements about the impact of the work.

Country	Establishment	Objectives	Implementation	Accountability
Switzerland	BAG.	To settle disputes when the coverage of a given service is contested.	DoH.	To Santésuisse and FMH (the branch organization of physicians).
United Kingdom	NICE, the independent organization responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.	To prevent inequalities.	NHS service providers.	To the Secretary of State for Health and the Welsh Assembly Government for its resources, delivery of its work program and for guidance it produces for the NHS.

Table 11-2 Comparison of systems for priority setting at technology level: assessment

Country	Consultation and involvement of stakeholders	Methodology	Evidence base for assessment	Presentation and communication of assessment results
Australia	MSAC members, clinical experts, health economists, and consumers are represented in advisory panels, which are involved in various stages of the assessment process.	Review of available evidence. Collection of evidence contracted out to HTA consultants. Appraisal of evidence by MSAC is presented in the assessment report.	Review considers efficacy, safety, effectiveness, and cost-effectiveness. In the appraisal by MSAC also other issues such as access and equity are taken into account.	Assessment report can be found on MSAC's website, together with summaries. Reports describe the technology, current practice, research questions, collected evidence, and funding recommendations (positive, negative, or interim).
Belgium	Only indirect: stakeholders are represented in the KCE Board of Directors.	Following a standard methodology, a review of literature and databases is performed.	HTA reports contain a review of effectiveness, cost-effectiveness, and where relevant other aspects.	Together with policy recommendations, the study results are disseminated in a publicly available report.
Canada	CADTH publishes an invitation on the website to interested stakeholders to provide feedback on draft assessment reports.	A multidisciplinary team of researchers (from the CADTH staff or contracted consultants) collects, synthesizes, and analyzes available evidence. The draft report is reviewed by experts and the Scientific Advisory Panel.	Clinical effectiveness, cost-effectiveness, and broader impact of technologies. To our knowledge, there are no specific requirements for standards of evidence.	Technology reports and summaries. No recommendations for benefit decision, just reporting of evidence regarding (cost-)effectiveness, social, ethical, economic implications of use, compared with alternative treatments. Also considering indications, current treatment, regulatory issues, adverse effects, and health services impact.
France	Medical profession is actively involved, medical technology representatives are not included.	HAS evaluates evidence using literature review. The opinion of professionals is solicited by a postal survey, and in working groups.	Scientific data on efficacy and/or safety. When new procedures are concerned, also treatment strategy, severity, impacts on morbidity and mortality, the care system, and public health policies are taken into account.	The assessment report describes the intervention and clinical data. A separate section covers the economic evaluation, if any. Conclusions and advice about funding are formulated.

Country	Consultation and involvement of stakeholders	Methodology	Evidence base for assessment	Presentation and communication of assessment results
Germany	Representatives of patient organizations have the right to participate in consultations and to propose issues to be assessed and decided upon by the G-BA. Patients also have the right to file applications. Stakeholders do not participate in the assessment by IQWiG. The G-BA and other stakeholders may provide feedback on draft assessment reports.	The methodology varies per case, depending on, inter alia, the research question, the scientific evidence available, and expert opinions received. The dominant method is a literature search and scientific evaluation of the published results. IQWiG considers and may use the preparatory work of other (inter-)national health care institutions. External experts frequently participate in the assessment.	IQWiG considers effectiveness, necessity, and cost-effectiveness, in sequential ordering (i.e., effectiveness is prioritized). Legally, IQWiG has to evaluate all three categories, but in the assignments that IQWiG gets by the G-BA quite often only effectiveness and necessity are explicitly mentioned. IQWiG does not use formal methods to evaluate cost-effectiveness. In practice, it is more an estimation of the budget impact. IQWiG determines beforehand what kind of studies will be considered regarding the level of evidence (e.g., only studies that deliver high-quality evidence and randomized controlled studies or also those that do not provide consistent and overall evidence).	IQWiG communicates its final reports to the health care professions, patients, and the general public. The information compiled is also relayed to the federal MoH and the G-BA.
The Netherlands	Various stakeholders (patient groups, hospitals, medical specialists, insurance companies) may submit an application. The SDO consults experts and stakeholders. CVZ may consult with experts/stakeholders during the assessment. HTA is done by government funded, independent organizations. Applicant and SDO develop documentation.	CVZ assigns staff (or contracts a workgroup) to assess received documentation. Submission requirement is same for all DBCs. Review of submitted evidence is key process, but CVZ does search for in-depth review. Methods follow international standards (cost-effectiveness, Cochrane, structured literature review).	Systematic literature review. Evidence used to evaluate effectiveness, necessity, cost-effectiveness, and feasibility. Unclear how level of evidence or sources are valued. CVZ sends its draft report to stakeholders, whose responses may be incorporated into the final report.	The assessment report by CVZ is available to the public. Recommendations for the funding status of the DBC may be: fully funded, not funded, or funded with restrictions.
Sweden	Participate through membership of project groups, which include 2 or 3 SBU staff members, physicians and other healthcare workers, health economists, administrators, and usually one layperson.	Scientific literature searched in relevant databases.	Assessment reports contain a review of benefits, risks, and costs of methods used in healthcare delivery. Social and ethical considerations are also taken into account, if any.	Assessment reports contain a review of benefits, risks, and costs of methods used in healthcare delivery; it also identifies methods that are ineffective, or not cost-effective.

Country	Consultation and involvement of stakeholders	Methodology	Evidence base for assessment	Presentation and communication of assessment results
Switzerland	Stakeholders (other than the applicant itself) do not participate in the assessment.	Applicants have to provide an assessment report following standardized methods. It should provide an overview of the clinical and economic evidence on the technology as it appears from a literature search and other possible sources of information.	Assessment reports present clinical and economic evidence, together with data such as the indications for the technology, the burden of the disease and the clinical need, the estimated utilization of the technology, and its budget impact. In certain cases, the applicants have to perform a full economic evaluation.	The assessment reports are not published.
United Kingdom	Participate as consultees or commentators. They are involved in all stages (scoping, assessment, appraisal). Clinical experts and patients are also invited to give opinions.	NICE contracts the assessment out to HTA consultants, who perform a literature review and an economic evaluation.	Health benefits (quality of life and mortality) and costs.	The HTA consultants write an Assessment Report that is circulated.

Table 11-3 Comparison of systems for priority setting at technology level: decision

Country	Who makes the decision	Decision-making process	Evidence base and additional influences on the decision	Content and documentation of the decision
Australia	The MoH ratifies recommendations of MSAC. When MSAC assessments are not evidently wrong and correct procedures were followed.	Administrative.	Efficacy, safety, (cost-)effectiveness, access, and equity.	Following endorsement by the MoH, the final assessment reports are conveyed to applicants, distributed to interested parties, and published on the website of MSAC.
Belgium	The nomenclature is determined by the King, following advices of RIZIV/INAMI's committees or the MoH.	Not transparent. Decisions are reached by negotiations within RIZIV/INAMI, of which no minutes are made public.	Not clear, because the advices of the committees within RIZIV/INAMI are not published. Traditionally, there has been no role for HTA, but its role is growing – though slowly.	Decisions to include a new procedure in the 'nomenclature' are laid down in a Royal Decree and published in the 'Belgian Official Journal' (without much further explanatory commentary).
Canada	Decisions on the benefits package are taken within the provinces, regulated by master agreements.	Not transparent. Decisions are reached by negotiations between the MoH and the medical associations (and in some provinces regional health authorities) of each province. No insight is given into the motivation of decisions.	Both the CADTH and HTA programs funded by provincial governments may provide input. Their reports are increasingly suited to the needs of decision makers and have increasing policy impact. A problem can be however that the priorities of the provinces may not parallel the topics prioritized by CADTH. As a note: requirements of federal legislation (CHA) also affect the composition of the benefits package.	Decisions on the benefits package are laid down in the provinces' health insurance acts.
France	UNCAM, which exercises judgment over delivered information.	Not transparent. Decisions are reached by negotiation. Responsibility and quality of process is in hands of the people involved.	Decisions are based on HAS reports and stakeholder influence. Opinions on UNCAM's planned decisions are issued by HAS and the medical profession. Complementary health insurance organizations are consulted.	Decisions to include a new procedure on the benefits schedule are published in the 'Official Journal' of UNCAM. As of the next day, services become reimbursable.

Country	Who makes the decision	Decision-making process	Evidence base and additional influences on the decision	Content and documentation of the decision
Germany	G-BA, supported by IQWiG.	The Social Codebook broadly describes categories of services that must be delivered. Negotiations within G-BA between representatives of the sickness funds and health care providers determine the specific entitlements. Minutes of the discussions within the G-BA theme groups and sub-committees are not publicly accessible.	Recommendations from IQWiG reports.	The final reports of the G-BA (including all comments made and the decision and its substantiation and the comments of the theme groups) are publicly accessible through the internet. The decisions of the G-BA are laid down in the 'Bundesgesetzblatt'.
The Netherlands	MoH, based on recommendations of the CVZ.	Not transparent. MoH generally follows CVZ recommendations, but has discretionary power. MoH considers criteria necessary care and whether individual should carry the costs. The decision of the MoH may be limited to a particular indication or require permission for treatment. Moreover, decisions are needed at the institutional level, certainly when extra investments are necessary.	Not transparent without process information from Ministry. CVZ assessment is basis of decision process. Other information will likely be used in difficult or controversial decisions.	Decisions resulting in changes to the ZVW are published in the official journal of the state ('Staatscourant'). Decisions that require changes in the regulations ('beleidsregels') will result in updates from the NZa.
Sweden	County councils.	Decisions are typically implicitly made. Advisory committees often prepare them. A few county councils aim to develop more explicit methods.	SBU reports. The influence of assessment is not clear. It partially depends on ties of county councils with HTA organizations.	Decisions become visible in agreements for finance and production of health services.
Switzerland	EDI, following advices of the ELK and the BAG, and, if desired, an advice of the EGK.	Not transparent. The recommendations of the ELK and the decisions of the Minister are not published extensively – expect for short press releases.	Not clear. Yet, the role of HTA studies and data on cost-effectiveness is believed to be relatively small, compared to that of data on effectiveness.	Decisions are documented in Annex 1 of the KLV and published in the 'Amtliche Sammlung des Bundesrechts' (without much further explanatory commentary).
United Kingdom	The Appraisal Committee of NICE.	The Appraisal Committee meets twice to draw conclusions about evidence. Patient and clinical experts attend the meetings and offer their view. Consultees and commentators comment on planned decisions.	The Appraisal Committee considers evidence and comments of stakeholders. The appraisal includes costs and effects, but also priorities, need, balance of benefits and costs, available resources, uncertainty, and the long term NHS interest of innovation.	Documented in the Final Appraisal Document, which concludes a Technology Appraisal. Technology Appraisal documents are disseminated and distributed as full reports, quick reference guides, and lay versions.

Table 11-4 Comparison of systems for priority setting at technology level: outputs and implementation

Country	Appeal and dissent	Implementation and communication	Monitoring and reappraisal	Evidence of impact of the decision
Australia	Unsuccessful applicants are invited for debriefing at MSAC. There is no independent review mechanism to appeal MSAC recommendations and MoH decisions.	Through Medicare, which involves fee setting and provision of an item description for MBS listing, by DoH and consultative bodies (approved by MoH prior to publication). The state is responsible for delivery.	Reappraisal dates are not defined.	Medicare's corporate governance program must ensure proper functioning. Activities include audits and activities to prevent inappropriate practices by medical practitioners, consumers, pharmacists or public authorities.
Belgium	The system does not have its own formal appeals procedure.	The mutualities are legally required to reimburse any service included in the nomenclature. The institutions of the fourth hurdle system are not involved in formal support mechanisms to ensure the implementation of decisions. Generally, physicians who provide, at the expense of the compulsory health insurance, unnecessary or unnecessarily expensive benefits may be imposed sanctions.	Reappraisal dates are not defined. From an overall perspective, decisions are in a sense reviewed by the Committee for the Permanent Assessment of the Nomenclature, which advises on the modification and simplification of the nomenclature and on the introduction of new benefits.	There are no official processes for measuring the impact of a given decision by the fourth hurdle system.
Canada	No special formal appeals procedures were found in the provinces. The system has a 'CHA dispute avoidance and resolution process', which commits governments to actively participate in ad-hoc federal, provincial and territorial committees on CHA issues. It should improve fairness, transparency, and timeliness of dispute resolving.	Implementation belongs to the responsibility of the provinces. CADTH has a facilitating role in the development of guidelines by the provincial medical associations, to enable the incorporation of HTA results into these guidelines. On the provincial level, changes in the benefits package are communicated to the medical profession and published on the internet.	Reappraisal dates are not defined. Reappraisal of decisions may be triggered by HTA prioritization in CADTH or by a change in the 'standard of care' whereby the existing technology becomes the comparator in an HTA.	The impact of CADTH reports on technology decisions is not evaluated structurally.

Country	Appeal and dissent	Implementation and communication	Monitoring and reappraisal	Evidence of impact of the decision
France	UNCAM's decision can be disapproved by MoH (within 1 month, on legal aspects). Majority trade-union organizations have right of opposition to avoid collective agreements to which the profession concerned would be opposite.	Regional insurance funds implement decisions by concluding local contracts with health care professionals according to fixed budgets and national agreements. HAS distributes health information to professionals and the public. Guidelines may be developed.	Reappraisal dates are not defined. HAS and UNCAM together decide on a yearly work program regarding existing benefits.	UNCAM's tasks include local implementation of health care priorities and monitoring of quality of health care delivered.
Germany	The system does not have its own formal appeals procedure. The only way to appeal against G-BA decisions is through legal complaints (which is generally not successful however).	Implementation does not take place until agreement is reached on the specification of quality aspects and the reimbursement fees. There is no formal procedure to communicate the decisions to the different parties involved in the implementation of new services. This rather happens through informal mechanisms within the joint self-governing structure. Once a technology is excluded by the G-BA, the statutory sickness funds are not allowed to cover it.	There is no systematic reappraisal mechanism in place. Yet, any of the organizations represented in the G-BA (sickness funds, doctors, hospitals, patients) can request a reappraisal by the G-BA, which decides on the prioritization of these requests.	There are no official processes for measuring the impact of a given decision by the fourth hurdle system.
The Netherlands	The system does not have its own formal appeals procedure. Resubmission with additional or new evidence is feasible. Generally, the original decision stands until further notice. Several changes to the benefits package have been (partly) reversed in recent years (i.e., IVF, skin flap plastic surgery). Court cases are possible, just like 'no' decisions in the pharmaceutical branch have been challenged in court.	Implementation involves completing administrative steps: include in DBC system, instructions and pricing. Associations of medical specialists may be instrumental in implementing it in practice. CBO may be asked to make or revise care protocols or guidelines. The macro budget ceiling may slow down or block implementation, especially within the A (budgeted) segment of care.	No information or protocol found for reappraisal. Technologies in existing DBCs come in scope as comparator when requests for new DBCs or modifications are handled. Monitoring is feasible through the DBC Information System.	No information found about plans to measure the impact of decisions by the fourth hurdle system.

Country	Appeal and dissent	Implementation and communication	Monitoring and reappraisal	Evidence of impact of the decision
Sweden	The system does not have its own formal appeals procedure.	Because influence of HTA on local decisions is not obvious, the central government promotes use of HTA indirectly, e.g. by guideline development.	There are no formal dates set for reappraisal.	CAMTÖ was established to explore trends in health care and assess differences between providers. It assists in dissemination of HTA results locally, and proposes new projects to the SBU.
Switzerland	The system does not have its own formal appeals procedure.	The 'Krankenkassen' must reimburse all the medical services carried out by authorized health care providers, but may not reimburse services that have been excluded. There are no formal support mechanisms to ensure the implementation of decisions. Generally, health care providers must restrict themselves in providing care considering the interests of the insured and the purpose of the treatment. Otherwise, care may be excluded from reimbursement, while reimbursements paid wrongfully may be reclaimed and sanctions may be imposed.	There are no official procedures to review decisions on the inclusion of medical specialist care in the benefits package. Neither is there a general system for identifying when to reappraise technologies.	There are no official processes for measuring the impact of decisions by the fourth hurdle system.
United Kingdom	Consultees have the right to appeal. Appeals will be considered when ground for appeals is appropriate.	Health professionals and organizations must take NICE guidance fully into account. NHS must provide funding for services that Technology Appraisals recommend.	When NICE publishes its recommendations, it also indicates when it will be considered for review.	The Health Care Commission tests implementation of NICE guidance, by performing reviews, audits and assessment. NHS organizations are also compared against standards.

Chapter 12 Case studies

In the preceding chapters we described and compared the systems for reimbursement decisions in the different countries. The procedures, we concluded, are made more transparent and the appraisal of collected evidence is increasingly explicit. HTA is introduced in the procedures to refine the way the health basket is defined, as it makes explicit whether the evidence is strong and supports the entitlement of the service. Services should only be added to the entitlements if the evidence for the safety, clinical effectiveness, and cost-effectiveness is believed to be strong. Transparency, consistency, and procedural elements have become more and more important to make legitimate decisions.

The decision processes, however, are probably far more complex than their descriptions might suggest (Scott, 1998). The procedures as described in the former chapters did not yet pay attention to the practical skills that underwrite the decision process. Often formal procedures work thanks to measures that are not envisaged in the procedures. Some of these measures might even be prohibited by the procedures.

To describe the practical skills we conducted three case studies. We selected three medical services that were assessed recently: deep brain stimulation (DBS) for Parkinson patients, transurethral microwave therapy (TUMT) for patients with an enlarged prostate and position emission tomography (PET). To reconstruct the way in which the decisions about reimbursement were made, we analyzed the assessment reports and interviewed physicians, representatives of the medical industry, and policy makers by telephone.

12.1 The case selection

We selected deep brain stimulation (DBS) as our first case study. DBS is a form of functional surgery – it involves the implantation of one or two electrodes in the brain. These electrodes emit electric pulses which interfere with abnormal electrical signals in the brain. As a result, involuntary shaking of hands or abnormal spasm can be prevented. This kind of surgery is indicated in patients with Parkinson's disease for whom the standard treatment with drugs has failed. For this particular case prospective informants could be easily identified. DBS involves a technology that is developed by one particular organization, Medtronic. Medtronic produces and delivers the electrodes and the neurostimulator in all the eight countries. Medtronic was willing to share with us their information about the reimbursement of DBS. In addition, the project leader of a current international RAND study was willing to introduce us to the members of an international expert panel. The physicians in this panel know the international literature about DBS very well. Moreover, several of these experts are well informed about the reimbursement decisions concerning DBS. Some of them were even involved in the application procedures for reimbursement.

As our second case study we selected transurethral microwave thermotherapy (TUMT). TUMT is one of the minimal invasive treatments for patients with an enlarged prostate that causes problems with

urinating. Again the technology that is used in this particular treatment made it easier to collect data about the reimbursement of the treatment in the eight countries. The company which developed the technology for TUMT is well informed about the reimbursement status of TUMT in these countries. Besides, this company – Prostalund – has national representatives in five of the eight countries of our study (Belgium, Germany, Sweden, Switzerland, and United Kingdom). TUMT was also a convenient case for us as the project leader of a recent international study on therapeutic protocols was willing to introduce us to the members of an expert panel. Since few patients are treated with TUMT and very few physicians know the details about reimbursement decisions, the expertise of the physicians in this panel is unique.

Positron emission tomography (PET) is our third case. PET scanning is an imaging procedure that is used to characterize the metabolism, the biochemical processes, and the blood flow in organs. It can detect pathologic processes invisible for other, more classical, imaging techniques. In case of cancer it is used to detect the radiopharmaceutical uptake. Although PET is a diagnostic device, it is assessed as (part of) a treatment. The recommendations focus upon whether PET imaging would result in better patient outcomes. PET is a well documented case. The International Network of Agencies for Health Technology Assessment (INAHTA) has examined the clinical use of PET, including the assessments since 1997 (Adams et al., 2006; Hastings & Adams, 2006). PET is an interesting case because the decisions of the Belgium Health Care Knowledge Centre (KCE) and the Medical Services Advisory Committee (MSAC) have been discussed explicitly in the literature (Ware et al., 2004). Such debates are rare – hardly any assessments have been criticized publicly. Illustrative is the recent appeal against the NICE Appraisal Consultation Document Alzheimer. It was the first formal appeal NICE got since it was founded (see also Chapter 10).

12.2 DBS

DBS is a new technology for which funding was sought. The first formal application for reimbursement was done in Australia in 2001. France and the UK followed in 2002, Canada in 2005 (Medical Services Advisory Committee, 2001a; ANEAS, 2002; National Institute for Health and Clinical Excellence, 2002; National Institute for Health and Clinical Excellence, 2003; Ontario Health Technology Advisory Committee, 2005a).⁶³ The ANAES made a progress report and NICE conducted a rapid assessment. These were not meant to be assessments of the evidence. As NICE warns: “it (the rapid assessment) should not be regarded as a definitive assessment of the procedure”. The Australian MSAC and the MAS in Canada conducted a complete HTA procedure.⁶⁴

⁶³ In Belgium, Germany, Sweden and Switzerland, as far as we know, no formal HTA assessments were done.

⁶⁴ Both reports were made by HTA experts. The Australian report was prepared with assistance from the Centre for Health Program Evaluation and the Centre for Clinical Effectiveness Monash University. That reviewed four HTA reports and 30 studies, which were selected out of 629 studies. To contrast, the NICE only reviewed seven studies and the MSAC report.

12.2.1 *The evidence*

The first three assessments were negative about the evidence of the efficacy and safety of DBS (Medical Services Advisory Committee, 2001a; ANEAS, 2002; National Institute for Health and Clinical Excellence, 2002). According to MSAC, ANAES, and NICE no conclusions could be drawn on the efficacy and the safety of DBS due to deficiencies in the studies available (see Table 12-1). Further studies were said to be needed to establish the efficacy and safety of DBS.

Table 12-1 The recommendations of the health agencies about DBS

MSAC (2001)	Any conclusions regarding the effectiveness of DBS over medical therapy cannot be determined because of major methodological problems and poor quality of reporting in each of the studies used in the HTAs. More randomized controlled studies which look at long-term effectiveness and take full account of patients' quality of life are required in order to make a valid assessment of effectiveness (Medical Services Advisory Committee, 2001a).
NICE (2002)	Only one very small randomized controlled study was found. No studies were found comparing DBS with its comparator (treatment with drugs) (National Institute for Health and Clinical Excellence, 2002).
ANEAS (2000)	The lack of properly designed trials hampers the assessment of the efficacy and safety of DBS. We cannot draw conclusions from existing clinical trials on the theoretical advantages of stimulation, i.e. its efficacy compared with lesional surgery or with optimum medical therapy, the possibility of bilateral stimulation without increasing the complications, and its reversibility (ANEAS, 2002).

12.2.2 *Expert advice*

In case of DBS the physicians – presented in the procedure as clinical experts – were convinced about the effects. According to the British neurological association, who reviewed the whole procedure, DBS could be seen as an established practice. NICE strongly relied on the opinion of this panel. Being ‘an established practice’, NICE felt ‘no need to postpone the application of DBS’ (National Institute for Health and Clinical Excellence, 2002; National Institute for Health and Clinical Excellence, 2003). In France, the literature review was submitted to a committee of experts and members of the medical associations for neurology, psychiatry, and neurosurgery. The ANAES expert panel concluded that DBS is effective. Based on their advice the ANAES concluded in their report: “According to the current state-of-the-art, deep brain stimulation is feasible” (ANEAS, 2002). As this case shows, the health agencies could only partially ensure that scientific evidence supports the reimbursement of medical procedures. Both NICE and ANEAS did not want to wait for better information. It was perceived more appropriate to take a timely decision on the basis of the available evidence. In this particular case the advice of clinical experts has outweighed the conclusions of the technical assessment report. The alternative was to postpone reimbursement until sufficient levels of effectiveness and cost-effectiveness had been demonstrated. Regarding the clinical experience this options was perceived to be inappropriate – lack of evidence does not necessarily mean lack of effect.

12.2.3 *The working of the procedure*

To understand the interaction between evidence and clinical expertise that might explain why and how the formal HTA procedures work, it is particular relevant to have a closer look at the assessment report of the Ontario Health Technology Advisory Committee (OHTAC). The Canadian OHTAC assessed DBS in 2005 – three years after the first assessment in Australia. In their report the OHTAC summarized and interpreted the earlier assessments. According to the OHTAC (Ontario Health Technology Advisory Committee, 2005a), the other assessments led to the following conclusions:

1. NICE. “Safety and effectiveness data adequate to support DBS in patients with PD who have become refractory to standard medical treatment, providing for consent, audit, and clinical governance”.
2. ANAES. “DBS is feasible; however, benefit-risk ratio not adequate for indications proposed. Recommend involvement of expert centres for further assessment”.
3. MSAC. “The review by the Australian MSAC recommended interim funding, provided subjects participate in a long-term RCT”.

Examining the way the agencies refer to studies and other assessment reports, we see how the deficiencies of the studies and the need for further studies are placed in the background. The different health agencies, starting with a large amount of articles and reports, reorganize them around their claims. After the HTA reports are published, fellow agencies judge them taking into account what was previously published and the reputation and competence of the agencies. Although the MAS does not deny the deficiencies of the studies – in fact, they do mention the deficiencies in their report – they focus on the positive conclusions the other agencies have drawn to support public funding (Ontario Health Technology Advisory Committee, 2005a). Due to this the status of claims altered from inconclusive evidence into undisputed decisions (Valckenburg et al., 2003). In other words, the health agencies construct consistent evidence, which is so nicely shown in this case. They make case evidence-based policy to work – while doing this, they intermingle different kinds of evidence (research evidence, professional evidence, and stakeholder participation) into a hybrid form that supports their decision.

12.2.4 *Recommendation*

In this case all four health agencies advised their governments to support public funding. According to the MSAC interim public funding should be supported for a specific group of patients, i.e. patients who do not respond to medical therapy anymore (Medical Services Advisory Committee, 2001a). More information should be obtained on adverse events and longer-term patient outcomes within three years to support permanent funding. Like the MSAC, the ANEAS made further evaluations a condition for reimbursement. Only specialists who are involved in evaluating the technique were allowed to perform DBS in France (ANEAS, 2002). Similar conditions were set in Canada. According to the OHTAC, DBS should only be provided in centers that offer multi-disciplinary expertise (Ontario Health Technology Advisory Committee, 2005a). Although NICE did ask physicians to participate in a trial, they did not set

additional conditions. The 'normal arrangements' for consent, audit and clinical governance should be sufficient (National Institute for Health and Clinical Excellence, 2003).

12.2.5 Implementation

In this particular case the clinical experts who advised the health authorities about the interpretation of the evidence were also closely involved with the controlled implementation of DBS. According to our respondents, the number of centers that should be allowed to treat patients should be limited. DBS, they say, is more effective if done in an expert center. Only the surgeons in expert centers could have enough experience with the treatment to do it precise. Less precision will make the treatment less effective and might lead to more complications making the treatment less safe and more expensive. For this reasons, the physicians in the UK, France, and Belgium consider the development of expertise centers.⁶⁵ In other words, the physicians did not perceive the reimbursement application as a (fourth) hurdle. In fact, the reimbursement application was seen as a chance to improve the quality of care.

A good illustration is the PDsurg trial in the UK (National Institute for Health and Clinical Excellence, 2002). The trial was both an opportunity for the physicians to treat more patients as it was a possibility for the NHS to define the number of maximum treatments. Before the trial the NHS paid for a limited amount of treatments. The UK panel member we interviewed was first allowed to treat 5 patients. When the trial started the NHS gave extra funding for this trial. As a result more patients could be treated.

12.2.6 Lessons to be learnt

Since lack of evidence does not necessarily mean lack of effect, it is perceived inappropriate to postpone reimbursement until sufficient levels of effectiveness and cost-effectiveness are demonstrated. Formal HTA procedures can only partially ensure that scientific evidence supports the reimbursement of medical procedures. In fact, the health agencies intermingle different kinds of evidence (research evidence, professional evidence, and stakeholder participation) into a hybrid form that supports a decision. The interpretation of the evidence and the role of experts should be analyzed in this regard.

12.3 TUMT

TUMT is one out of a couple of new treatments for benign prostate hyperplasia (BPH). The first assessment was done in Canada in 1996 (Canadian Coordinating Office for Health Technology Assessment, 1996). TUMT was assessed in Germany in 1998 (Pientka, 1999), in Switzerland in 2001 (personal communication), and again in Germany in 2002 (personal communication). In Canada, Germany, and Switzerland, a complete HTA was conducted. The Swedish SBU published an HTA alert (Swedish Council on Technology Assessment in Health Care, 2002). Like in the DBS case, this alert was

⁶⁵ Belgium has no formal expert centers, but most physicians refer their patients to one of the ten hospitals that were closely involved in the development of the treatment. As a result of the complex reimbursement procedure (including a peer review of the medical record), only specialized physicians prescribe these types of pharmaceuticals.

based on a relatively small sample of studies. Note: the alternatives for surgery are diverse – in the other countries other alternative minimal invasive treatments for DBS have been assessed.

12.3.1 Evidence

The first assessment was negative about the efficacy of TUMT. The latter assessments, however, were positive about the scientific evidence, at least about the safety and the effects in the first half year after the treatment. TUMT has, in contrast to other minimal invasive therapies for BPH, proven to be effective in good clinical studies.

Table 12-2 The evidence about TUMT

CCOHTA (1996)	Other treatments are available but are unproven (e.g., hyperthermia) (Canadian Coordinating Office for Health Technology Assessment, 1996).
German Association for Urology (1999)	The strength of evidence pertaining to TUMT in relation to its safety and effectiveness is strong enough (Pientka, 1999).
SBU (2002)	There is good scientific documentation concerning the effects of the method in the short term. There is poor scientific documentation concerning patient benefits in the long term. From a patient perspective, however, it is unclear how to balance these effects (Swedish Council on Technology Assessment in Health Care, 2002).

12.3.2 Recommendation

Both the German G-BA⁶⁶ and the Swiss Federal government decided not to reimburse TUMT. The strength of evidence pertaining to TUMT in relation to its safety and effectiveness was said to be strong enough, but they missed data about the number of patients who needed to be treated again. The evidence was perceived to be incomplete as no data was available about the clinical effects over a longer period. In Sweden, TUMT was already reimbursed at the time the SBU assessed its effectiveness, appropriateness, and efficiency. It seems that TUMT has implicitly been added to the entitlements. In contrast to Germany and Switzerland, TUMT is much more embedded in the Swedish health care. Although the treatment has been diffused to other countries, most treatments are done in Sweden where the technology was developed. According to a representative of Prostalund, 1,000 patients per year are treated in Sweden. In Germany, the estimated number of treatments is 400 and in Switzerland the estimated number is only 10 patients.⁶⁷

⁶⁶ As an illustration, we present the following quote: “Die Wirksamkeit der Niedrig-Energie-TUMT und der Sichtlaser-Prostatektomie ist zwar in guten klinischen Studien nachgewiesen worden: Allerdings fehlen Daten zur Langzeitwirkung und zum Stellenwert im derzeitigen Therapiespektrum” (Pientka, 1999).

⁶⁷ We also asked the panel member about the estimated number of treatments in their country. They have similar estimates. It must be stressed, these numbers are only estimates.

12.3.3 *Re-application*

In 2002, the first long-term clinical outcomes of TUMT were published (Ekstrand et al., 2002). For this study 371 patients with BPH were treated with TUMT at the Karolinska Hospital in Sweden. They were followed for one up to six years after the treatment. According to the researchers, the long-term clinical data show that TUMT treatment gives a good success-rate, with reduction of symptoms. A re-application could be done.

In Switzerland, however, no re-application has been done. According to our respondents, there was no need to do so. This may be explained as follows. In 2004, a new federal medical tariff, known as TarMed, was introduced in Switzerland. TarMed replaces local healthcare-funding arrangements made by the Swiss cantons with a single federal scheme. The federal tariff for TURP is, according to the representative of Prostalund, rather low. There is no federal tariff for TUMT as it is not covered by the mandatory basic plan of Swiss health insurance, but the federal tariff for TUMT will, it is expected, not be higher than the tariff for surgery (TURP). In other words, the decision to reimburse TUMT will cost physicians money. Physicians will probably be paid less for a TUMT if the Swiss ELK would decide to reimburse the treatment. The reimbursement of TUMT seems to be not an issue anymore, as patients are able and willing to pay for the treatment themselves.

In Germany, the G-BA did start a re-application procedure in 2002. This procedure was never finished. The re-application took already four years, but that did not cause any problems. In fact, the reimbursement status of TUMT is not an issue in Germany. Patients are willing to pay for the treatment themselves. Like in Switzerland, physicians will probably be paid less for a TUMT if the G-BA would decide to reimburse the treatment. In the private market patients pay around €2,000 for a treatment which leaves about €800 for the physician as honorarium. If the TUMT was paid via the DRG system a physician would probably get €300 for a treatment⁶⁸ which leaves hardly any honorarium for the physicians.

12.3.4 *Sponsors*

The German procedure clearly demonstrates how the position of physicians in the procedures has become less prominent. With the introduction of specialized agencies such as NICE and IQWiG physicians and medical industries are no longer involved in collecting and reviewing the evidence. NICE and IQWiG utilize independent contractors to do the assessments. As a result physicians who were once experts have become stakeholders – who are consulted at the end of the procedure.

⁶⁸ The debate about TUMT and TURP is in Germany also an element in controversies about the profession of urologists. The BAG is forcing urologist to work in one system, aiming to make urologists' services only available in hospitals and not in an ambulatory care setting. In this controversy about urology in ambulatory care, TUMT plays a role. Those who favour the hospital as the best place for urological treatments prefer TURP. Those who favour treating patients outside the hospital prefer TUMT as it can be done in an office. There is no need to conduct this treatment in an operation room, and thus in a hospital.

The GB-A conducted the assessments via in-house committees. The German Association for Urology was asked, according to our German member of the 'TUMT' expert group, to review the evidence themselves. They wrote a systematic overview of the literature about the effectiveness and the safety of minimal-invasive therapies for BPH for the GBA.

Minimal invasive treatment of BPH was one of the first assessments of IQWiG. IQWiG decided to start a new procedure to assess the evidence about TUMT. They hired independent contractors to conduct the assessment. Consequently, the physicians that wrote the first paper about the effectiveness and the safety of minimal-invasive therapies for BPH were not involved any more, not as evaluators at least. Instead, they will be asked to comment on the report after it has been finished. They have become stakeholders. The shift in the position of physicians from expert to stakeholder explains their critique on the new procedure. According to the physicians, the new procedure leaves hardly any room for their opinion and their experiences in practice. "After they will at last publish their report, we will have only six weeks to give a reply and we never know what they do with our remarks". If we see the example as a request to intensify the participation of stakeholders, we would misunderstand the way the procedure works.

It is illustrative to compare the German with the Swiss procedure on this particular point. The HTA report for the Swiss federal government has, in contrast to the HTA report for IQWiG, been written by Medalliance GmbH – a consultancy firm specialized in the reimbursement procedures of the healthcare systems in the German-speaking countries. A reimbursement application dossier is one of their products. The Swiss government does not utilize independent contractors to conduct the assessment. In this case the supplier of the technology Prostalund did the application and provided an assessment report. Prostalund hired a consultancy firm to prepare the application. Prostalund is, in this particular case, both the HTA expert, the clinical expert, and stakeholder. They are closely involved with the studies to collect evidence about the safety, clinical efficacy, and cost-effectiveness, the pay for the assessment report and they have the right – as stakeholder – to comment on the report and on the recommendations about reimbursement.

12.3.5 *Lessons to be learnt*

Integrated assessment and decision procedures are established in clinical areas where medical professionals used to be autonomous. Physicians, who were once autonomous experts in Germany, have become stakeholders when IQWiG was created. Consequently, stakeholder involvement is not always guaranteed or systematically embedded in the procedures. This may cause problems when decisions have to be implemented. If the procedure does not meet stakeholder expectations, or is considered unfair, we observe a tendency to work around formal ways.

12.4 PET

The scientific evidence of PET has been assessed in several countries. In Australia (2000, 2001, 2006), Belgium (2005), Canada (2001, 2003 (2x), 2004 (2x)), France (2005), Germany (2003), and the United

Kingdom (2004) a formal application was done to determine whether PET belongs to the health-insurance (or national health service) coverage entitlements (Medical Services Advisory Committee, 2000b; Comite d'Evaluation et de Diffusion des Innovations, 2001; Institute For Clinical Evaluative Sciences, 2001; Medical Services Advisory Committee, 2001b; Medical Services Advisory Committee, 2001c; Perleth et al., 2003; Federaal Kenniscentrum voor de Gezondheidszorg, 2005; Ontario Health Technology Advisory Committee, 2005b; Medical Services Advisory Committee, 2006b; Medical Services Advisory Committee, 2006a). In Sweden and Switzerland, as far as we know, no formal HTA assessments were made.

The MSAC did the first assessment in 2000. As the MSAC was done relatively early in the development of this diagnostic service, several re-applications were needed. The MSAC re-assessed PET in 2001 and 2006 and new re-assessment might be needed in the future. The latest first assessment was done in Belgium. According to the Belgian KCE the late timing of the evaluations is the main reason why Belgium is one of the countries with the highest number of PET per million people in the world at the time of the evaluation. Despite the fact that the scans were already used and the images were already reimbursed, the KCE started an assessment procedure.

12.4.1 *The evidence*

The assessments were not very positive about the evidence of the efficacy of PET. They perceived the existing evidence as limited or sparse. PET is assessed as (part of) a treatment, although it is a diagnostic device. The question is not whether PET is an accurate diagnostic device. The question is whether PET would lead to more effective medical treatments, for example for cancer patients (see Table 12-3). Therefore, the conclusions focus upon whether PET imaging would result in better patient outcomes. However, most studies focus on the accuracy of the PET images in comparison to conventional images.

12.4.2 *Recommendation*

At the moment the assessments started PET scans were already diffused in clinical practice (see Table 12-4). Both MSAC and the KCE acknowledged that because the technology was already in use the scope of this particular assessment might need to be broader than usual. The questions of the KCE have a broader scope. They also concern the organization of care and the problems to control the budget impact. The KCE formulated the purpose of the appraisal of PET: (...) the main objective of this HTA report is to formulate practical recommendations to the health authorities about planning, organization, financing, research and development of PET in Belgium. In this context, it is important to consider the ethical aspects, such as accessibility and patient preferences (Federaal Kenniscentrum voor de Gezondheidszorg, 2005).

Table 12-3

Australia	There is currently insufficient evidence on the clinical and cost-effectiveness of PET to warrant unrestricted funding. Despite this, the evidence suggests that PET is safe, potentially clinically effective and potentially cost-effective for the indications reviewed. MSAC recommended PET receives interim funding in clearly specified clinical scenarios (Medical Services Advisory Committee, 2000b).
Belgium	The existing evidence for clinical indications for PET is often still limited to level 2 or 3, according to the grading system we adopted. Very often, there is only evidence for diagnostic accuracy of PET (level 2 - sensitivity and specificity) and only for some indications there is also evidence for an effect of PET on diagnostic thinking (level 3). For some rare indications, it is obviously difficult to obtain a solid evidence base, as it takes long to gather the data (Federaal Kenniscentrum voor de Gezondheidszorg, 2005).
Canada (ICES)	Despite the availability of PET scanning for almost three decades, the number of methodologically high quality studies (and the numbers of patients within those studies) is distressingly small. It is also possible that publication bias (the preferential publication of studies that show a benefit of PET scanning) may limit the evidence considered in this report. These two factors combine to make any conclusions about the usefulness of PET scanning less definitive than one would like (Institute For Clinical Evaluative Sciences, 2001).
Germany (G-BA)	Overall quality of quality and validity of available evidence can be described as sparse. The main constraints were: lack of generalisability due to the limited number of participants, high risk of systematic bias due to design issues and limited reporting quality. Most of the papers evaluated diagnostic accuracy and only few assessed the value of PET in the clinical management (Perleth et al., 2003).

Table 12-4 Diffusion of PET scans in different countries

Country	Year of assessments	Numbers of scans in 1997	Numbers of scanners in 2003 (pet scans per 1 million)
Australia	2000, 2001, 2005	3	13 (0.65)
France	2002, 2005	3	50 (0.83)
Germany	2002	2	80 (1.0)
Belgium	2005	2	13 (1.26)
UK	2005	0	16 (0.28)

Source: (Asua & Conde Olasagasti, 1999).

The KCE concluded the existing number of scanners to be sufficient and explicitly advised the government not to increase the number of scanners. Its report claims: “With the current evidence, there is no medical or scientific justification for more PET scanners in Belgium. For the reimbursed indications, a number between 7 and 9 PET scanners should be sufficient (in 2003, almost 12,000 PET scans were reimbursed) (Federaal Kenniscentrum voor de Gezondheidszorg, 2005). In addition, the KCE warns the national insurance for an uncontrolled increase of the expenditures. In their own words: “The National Health and Disability Insurance (RIZIV/INAMI) risks to be confronted with an uncontrolled increase in budgetary outlays for PET scanning if it leaves the door open for additional PET scanners for the sake of emerging indications” (Federaal Kenniscentrum voor de Gezondheidszorg, 2005). There is, as we said before, much uncertainty over whether the health agencies should give recommendations because of the

need to separate expert advice, based on the scientific evidence, from decision making, which must inevitably take other factors into consideration. In this particular case, the KCE is quite explicit about the budgetary constraints and the strategic direction of their decision.

12.4.3 *Legitimacy*

The reports of the MSAC and the KCE have been fiercely criticized (see the quote). According to the critics the MSAC did not properly follow the procedure. The Department of Health, they said, re-invented the procedure by establishing a new committee. This committee, they continued their critique, re-wrote the assessment reports. Not only did the committee include new evidence, they also included broader policy issues. In the perceptions of the critics, the committee repeated the work of the MSAC to include new evidence and new interpretations that fitted better with the recommendations the government already wanted to make.

“The pivotal finding of the Supporting (scientific) Committee that PET was “clinically effective” was altered by the Steering (policy) Committee to the finding that PET was “potentially clinically effective”. This change appears to have occurred without any documented authorization by the Supporting Committee (the only committee which undertook detailed evaluation of evidence) or MSAC (which had ultimate responsibility for making decisions about the evidence) (Ware et al., 2004).

The MSAC could easily contest this critique. As they explained, the MSAC did follow the procedure (Van der Weyden & Armstrong, 2004). In Australia, and in most other countries, an expert committee is charged with the preparation of the final assessment report. They cannot rewrite the assessment of the evidence, but they can include other sources. Moreover, it is their task to formulate recommendations to the minister. No HTA researcher and no policy maker would see it as a failure of the agencies to follow the procedure properly if they would include other considerations than only the evidence. If we, however, agree that scientific evidence can only partially ensure support for the reimbursement of medical procedures, we might also define the state as a stakeholder. Like the experts have become stakeholders, the state might also be seen as a stakeholder. In any case, the re-definition of the role of stakeholders, experts and stakeholders should be carefully considered.

12.4.4 *Lessons to be learnt*

To assess a service that is already introduced does not seem to be very effective (Ross, 1995; Drummond & Weatherly, 2000). Most applications concern new services that have not been introduced to health care yet. With the existing procedures no technologies, as far as we know, have been identified for exclusion. The decisions focus on the inclusion of services – not the exclusion. Consequently, if governments want to have the option to exclude certain services, the services should be assessed before they are introduced into health care or at least before they are in widespread use.

12.5 Conclusions

The decision processes are more complex than their descriptions might suggest. Services, we said in the introduction of this chapter, should only be added to the entitlements if the evidence about its safety, clinical effectiveness and cost-effectiveness is strong. As has become clear in all three cases, the agencies have to deal with inconclusive evidence. In all three cases the evidence is incomplete and/or inconclusive. On the efficacy of DBS no conclusions could be drawn due to deficiencies in the studies available. TUMT has proven to be effective in good clinical studies, but the evidence was perceived to be incomplete as no data was available about the clinical effects over a period of a couple of years. The evidence was perceived to be limited and even sparse because it remained unclear whether PET would lead to more effective medical treatments.

In this chapter, we described some crucial measures to deal with inconclusive evidence that are not envisaged in the procedures. First, neither agencies nor the governments did apply a single and uniform criterion for the evidence that is considered acceptable for decision-making. The differences between the DBS and the TUMT case epitomize this practical rule. The evidence of the efficacy of DBS was inconclusive, but the clinical experts perceived DBS as an established practice that should be part of the health basket. In case of TUMT, the assessments were positive about the scientific evidence, at least about the safety and the effects in the first half year after the treatment. The health authorities, however, decided not to reimburse TUMT. Only in the TUMT case, the long-term clinical effects were made into a criterion.

Examining the way the agencies refer to studies and other assessment reports, we also demonstrated how the status of claims can alter. After the HTA reports are published, fellow agencies judge them, taking into account what was previously published and the reputation and competence of the agencies. In the case of DBS they focused on the conclusions the other agencies have drawn namely to support public funding. Thereby the deficiencies of the studies and the need for further studies were placed on the background (Ontario Health Technology Advisory Committee, 2005a). Due to this work the status of claims altered from inconclusive evidence into undisputed decisions.

Second, the health authorities have to weigh the need for enough data against the need to make an early decision. Services have to be subject to extensive research before they can be assessed.⁶⁹ A service should, however, be assessed before it is introduced into health care or at least before it is in widespread use (Pels, 2003). To assess a service that is already introduced does not seem to be very effective (Ross, 1995; Drummond & Weatherly, 2000). None of our respondents could give us an example of a service that was unlisted. Even in Australia, where a new list is made every year, only services have been excluded

⁶⁹ The availability is, for example, mentioned as an important criterion in the application manuals. As illustrated by the Swiss 'Manual for the standardization of clinical and economic evaluation of medical technology'. It states: "The application procedure for reimbursement of a new medical service requires a minimum amount of information which will enable the Federal Office of Public Health to assess the new service in terms of its effectiveness, appropriateness/safety and efficiency" (Swiss Federal Office of Public Health, 2005).

that had become obsolete. Almost all, if not all, applications concern new services that have not been introduced to health care yet.

Last, but certainly not least experts play a vital role in the interpretation of evidence. As said before, expert committees are often charged with the preparation of the final assessment report. They might also be involved in formulating recommendations. The experts' observations of the effects of treatments in daily practice are highly valued. Their advice might even outweigh the assessment, as the DBS case has shown. As clinicians they have a vital and direct state in the results of their observations. Especially the possible risks of treatments is a powerful impetus to careful observation and experimentation (Scott, 1998). The experts, however, do not only advise the health authorities about the interpretation of the evidence, they can also be involved with the (controlled) implementation of services. In the DBS case the physicians did not perceive the reimbursement application as a hurdle. Instead the reimbursement application was seen as a chance to improve quality of care.

The position of physicians, which seems to be so crucial, is becoming less prominent in the procedures. With the introduction of specialized agencies such as NICE and IQWiG physicians and medical industries are no longer involved in collecting and reviewing the evidence. NICE and IQWiG utilize independent contractors to do the assessments. As a result physicians who were once experts have become stakeholders – who are consulted at the end of the procedure. Such a change requires adaptation of these stakeholders to their new role.

Also in this study we started with the assumption that if the reimbursement decisions are properly ordered – that is to say if the procedures are in place and the criteria are well defined – the expansion of the benefits package would be transparent and entitlements would only exist when the service is effective and efficient. This is, as the case studies have shown, not the case. No HTA researcher and no policy maker, however, would see it as a failure of the agencies to follow the procedure properly if they would include other considerations than only the evidence about the safety, efficacy and cost-effectiveness of the medical procedures. The procedures and the criteria that are used to explicitly define the benefits package are themselves heterogeneous, complex, and we might even say messy (Lehoux et al., 2004; Rotstein & Laupacis, 2004; Mol, 2006; Raad voor de Volksgezondheid en Zorg, 2006).

Chapter 13 Discussion

This report aimed to answer the research question “What procedures and criteria are used by countries that are relevant comparators to the Netherlands, to determine whether specific services of medical specialist care belong to the health insurance (or national health service) coverage entitlements?”. This question represents several sub-questions:

- Who decides on benefits to medical specialist care?
- What assessment procedure underlies the decisions?
- Is the decision procedure transparent and consistent?
- How is the assessment procedure embedded in the decision-making procedure?
- Can stakeholders participate in the assessment or decision-making process?
- Are decisions about inclusion made in a timely manner?
- What is the effect of procedures and criteria for specific technologies and conditions?

These questions have different layers. First, they point to descriptive information about the features of systems for decisions on medical specialist care, i.e., to questions about the different steps of the procedure (the assessment, the decision, and the implementation of the decision). These questions also point to different conceptions on where to lay the boundary between ‘recommendation’ and ‘decision making’ – or in a greater scheme, between science and policy. It is the boundary between science and policy that bothers policy makers: if we employ HTA researchers to do the assessment, will they also interpret the evidence? If so, do they decide upon the benefits to medical specialist care? And what room will be left to the central or local government to decide upon the benefits to specialist care? Our analysis has regard to both levels.

13.1 From assessment to decision

Reviewing the information about assessment and decision-making in nine countries, we found that the procedures differ in many details. In Chapter 11, we showed how these differences are related to fundamental choices on health care regulation. At one end of the spectrum, we find countries that rely on indirect steering for health care decisions. This occurs in several countries with a health insurance system where governments have delegated responsibilities to insurers, the medical profession, or local authorities (e.g., France, Germany, Belgium). Similar modes of regulations exist in some countries with national health services (Canada, Sweden) where local authorities and the medical profession have to reach agreements on benefits and tariffs. The assessments in these countries are seen as an indirect instrument to steer the decisions others (insurers, local authorities, or hospitals) have to make. The assessment could be conceptualized as a communicative instrument – it is an aid to inform the decision makers about the evidence. The managerial process gives legitimacy to decisions.

At the other end of the spectrum lie the countries where decisions on the benefits package are made by the government or governmental agencies (e.g., Australia, UK, the Netherlands). In these countries, the decision maker is independent of the key actors in the system. These countries rely on direct steering for health care decisions. The central government or the governmental agencies are responsible for the appraisal. Hence, the assessments are shaped towards the needs of the central decision-maker. The governmental agencies that are responsible for the assessment appraise the evidence to titrate the information to the decision. Here we can speak of an integrated assessment and decision procedure, whereby the legitimacy of a decision needs to be derived from proper assessment and proper interpretation of the evidence within legal boundaries.

13.2 Explicit assessments and procedural justice

Our report demonstrates that the room for improving transparency and consistency of the decision-making process is not just served by improving methods for assessment, but that it is also important to specify what procedures will be followed in evidence appraisal. Since there are typically no documents that guide value judgments, it is inherent that the system becomes more ambiguous and less formalized than refined and detailed instructions for assessment suggest.

There seems to be a trend towards explicit assessments. Most agencies publish their assessment reports on their website. In our study, the Swiss BAG is the only exception. Moreover, the appraisals seem to become more explicit. The most visible example is the Australian MSAC, which started to document their decision process by publishing the minutes of the appraisal committee. Another example is the SBU. The Swedish government cannot integrate the assessments with the appraisal, as the local authorities decide on the benefits in their county. The SBU, however, started to promote the use of assessments indirectly by guideline development and visitations for example. Moreover, some Swedish county councils strive for openness in decision-making, being concerned about the fact that on basis of the same information different decisions were made across counties on the reimbursement status of a service.

The procedures developed by UK's NICE serve as an example to most other countries, both in terms of content and procedural aspects. NICE is an independent organization: as decision maker it is independent of key actors in the system. HTA consultants, using state-of-the-art techniques, perform assessments. The evidence is next appraised in a separate procedure by NICE. The considerations in the appraisal are made public, so that the procedure is transparent and it can be confirmed if a decision is consistent with legal principles. To ensure that evidence is looked upon from various perspectives, stakeholders participate in the process, further attributing to the legitimacy of decisions.

The review of the procedures in nine countries suggests that most countries are continuously working on improving their systems for decision making. Decision makers seem aware of the scientific state of the art in HTA and update the requirements for assessment accordingly. Legitimacy, we found, gets more and more important and the procedures derive this legitimacy from explicit assessments and procedural justice.

13.3 Timeliness versus relevance

The case studies presented in Chapter 12 indicate that in spite of the strengthened and formalized methods for assessment, the appraisal of collected evidence remains difficult. Evidence, we demonstrated, is typically inconclusive. Especially in medical specialist care, the question is not so much what kind of information should guide decisions, but how this information can be made available. Compared to the area of pharmaceutical care, it seems more difficult to collect information.

The lack of data thus critically impacts on the procedure. In most drug reimbursement systems it is the decision-maker who specifies what type and quality of information must be made available in an application for reimbursement, and the applicant, typically a manufacturer, is responsible for collecting and reporting that information. Data collection is part of the process of product development – data which then is appraised by the decision-maker or a scientific body. In medical specialist care, in contrast, typically an HTA agency funded by the government collects information. This commonly involves a literature review of available evidence, rather than the use of specific requirements for reimbursement dossiers. Primary data collection in a national setting for the purpose of supporting reimbursement decisions is not common, and, if new studies are performed, they are often paid for by the government. For example, NICE pays for HTA in the UK, and MSAC pays for Australian HTAs done by contract researchers. Overall, the role of HTA in decisions is less formal in medical specialist care than it is in pharmaceutical care.

In strategies for dealing with the lack of evidence, a second issue is relevant: timeliness of decisions. Can we afford to wait for perfect information, or is it more appropriate to make a timely decision now on basis of available information? Most countries opt for the latter, feeling it inappropriate to implement a system of not reimbursing an intervention as long as sufficient levels of effectiveness and cost-effectiveness have not been demonstrated (the standard mode of regulating pharmaceutical benefits). So, a tradeoff is made between timeliness and relevance of information. This also explains why most countries have a non-restrictive policy that allows for funding of treatments in spite of insufficient evidence. Therapies may be expensive, but the targeted disease may be too severe to withhold therapies. Reimbursement may then for example be offered on a conditional temporary basis, in anticipation of re-evaluation. In this respect, also the scope of assessment procedures should be considered. Should all new services be evaluated prior to reimbursement? Or can we also rely on post-launch evaluations aimed at defining appropriate use?

There is yet another reason to make a timely decision on basis of available information. To assess a service that is already introduced does not seem to be very effective (Ross, 1995; Drummond & Weatherly, 2000). Most applications concern new services that have not been introduced to health care yet. With the existing procedures, no technologies, as far as we know, have been identified for exclusion. The decisions focus on the inclusion of services – not the exclusion. Consequently, if governments want to have the option to exclude certain services, the services should be assessed before they are introduced into health care or at least before they are in widespread use. But at that moment evidence is limited. Most

countries therefore appear to have rather modest expectations of the role of assessments in decision-making, which also explains why often no stringent definitions of criteria are used and why no threshold values for positive or negative decisions have been specified. This may be perceived as a weakness of assessment programs. However, it is doubtful whether procedures can be improved by using more stringent requirements. If decision-makers would use strict definitions to evaluate if available evidence substantiates a positive reimbursement decision, the outcome would often be negative. The problem then becomes that absence of evidence would yield the same outcome as evidence that demonstrates that a treatment is not effective or cost-effective. However, lack of evidence does not necessarily mean lack of effect. Treatments therefore should not necessarily be abandoned just because their benefits have not yet been scientifically assessed, because of potentially detrimental effects on innovation that are not in the interest of patients or society.

The question is not so much about what assessment criteria should be and how thresholds values can be defined, but rather how the decision-making procedure can deal with incomplete evidence, considering potentially detrimental effects on innovation when evidence does not substantiate a positive reimbursement solution. In this respect, it is important to consider the modes of finance for procedures that do not get a positive reimbursement decision yet. One solution is to offer an interim positive reimbursement status and request additional reimbursement. This seems to be the only solution in countries where treatments can only be financed on a fee-for-service basis. If health care is financed using fixed budgets, providers have more autonomy to explore innovations, which may be less burdensome on the system.

13.4 Involving stakeholders

In any case, in developing a system it seems crucial that it is clear at forehand how the system may cope with decisions on services where evidence is incomplete. Experts, we demonstrated, play a role in the interpretation of (incomplete) evidence. The experts' observations on the effects of treatments in daily practice are highly valued. In situations where evidence is scarce, decision-makers might to a large extent rely on expert advice. It is therefore not surprising that in all countries clinical experts are involved in the decision-making procedure, with responsibilities varying from a limited role in commenting on a draft assessment report to preparing the report and formulating recommendations. The role of other stakeholders varies more between countries.

In countries where decisions are made in negotiation between insurers, local authorities and/or the medical profession, stakeholder involvement is inherently at a high level. In countries where decision makers act autonomously, stakeholder involvement is not always guaranteed or systematically embedded in the procedures. This may cause problems when decisions have to be implemented. If the procedure does not meet stakeholder expectations, or is considered unfair, we observe a tendency to work around formal ways. This problem may occur when integrated assessment and decision procedures are established in clinical areas where medical professionals used to be autonomous. In Germany for example, physicians, who once were autonomous experts, have become stakeholders when the G-BA was created. It is

understandable that this transition is a bit difficult, especially when one considers that Germany has no strong HTA tradition. Still, the re-definition of experts as stakeholders should be carefully considered.

13.5 Conclusions

Countries throughout the world are relentlessly improving their systems for decision-making on the reimbursement of medical specialist care. This is typically done by updating the requirements for the assessments according to the state of the art in HTA. The objective of the systems for priority setting is more or less the same across countries, which is to guarantee high-quality health care while controlling cost. Another shared characteristic is that the assessment agencies apply similar criteria, typically taking into account both clinical and economic considerations.

Next to the similarities, the analysis presented in this report also revealed significant differences between the systems for priority setting. These differences concern the methods for assessment and appraisal and the distinction between assessment and appraisal. The methods for assessment have varying levels of formalization: in some countries agencies perform a literature review to collect information on a technology, while in other countries standards are offered for types of information that needs to be made available by applicants. The methods for appraisal also differ in level of formalization. In most countries, the appraisal of the assessment remains implicit. Only the evidence is collected and summarized, and no policy recommendations are included. The decision on the benefits package depends on the stakeholders (medical professionals, local authorities, and/or insurers) reaching consensus on the added value of a new therapy. It is not clear to what extent the provided information is actually used in the decision-making process. The legitimacy of the decisions is expected to result from consensus and/or the democratic mandate of elected decision makers. Australia and the UK are notable exceptions though. Here an explicit appraisal process follows the assessment reports. Both MSAC and NICE recommend whether a new therapy should be reimbursed. Both the guidelines for the procedural steps and the documents leading to the decision are published on the internet. The legitimacy of decisions should result from transparency, consistency of decisions, and stakeholder involvement.

A common trend between all countries is the growing focus on explicit assessments and procedural justice, which lends a broader legitimacy to the decision-making process. The procedures suggest that services should only be added to the entitlements if the evidence about its effectiveness and cost-effectiveness is strong. However, a more nuanced picture emerged from the case studies. It appeared that, while the aim is to use state-of-the-art assessment procedures, countries often need to base decisions on limited evidence about the (cost-)effectiveness of a new medical technology. Especially in medical specialist care, it is often difficult to collect information. Decision makers simply cannot afford to wait for good information, as it is perceived inappropriate to hamper access to services that are seen as clinically effective but for which the sufficient levels of effectiveness have not been demonstrated. Considering it unethical to postpone a decision until new studies have been done, most agencies rely on expert judgment about the new technologies and grant technologies a temporary positive reimbursement status. The experts' advice about whether a new therapy should be part of the benefits package is considered relevant

additional information, showing that subjective assessments are still accepted when objective assessments are lacking. This reintroduces exactly the kind of uncertainty that formalized assessment procedures aim to prevent. It is recommended therefore that, when striving for updating the requirements for the assessments according to the state of the art in HTA, countries should at least consider how to deal with these kinds of uncertainty in the design of the decision-making procedures. When a procedure is being established, not just requirements for assessments should be dealt with, but the process for decision-making should also be considered. The role of stakeholders in the procedures seems crucial.

To conclude, the transparency and consistency of the decision-making process benefits significantly from improved methods for assessment. However, it is equally important to specify what procedures will be followed in the evidence appraisal. Legitimacy is often obtained from consensus among stakeholders. Since there are typically no documents that guide value judgments, it is inherent that the system becomes more ambiguous and less formalized than refined and detailed instructions for assessment suggest. So, despite formalized procedures, the expansion of the benefits package might never be as transparent as hoped.

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