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Standard of health services purchased in the national health insurance system in Poland

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Summary

In the transition of the Polish health care system to a social insurance system similar to that of many Western European countries, many issues have arisen. A number of such issues concern the basis of making decisions in Polish health care.

Under the Soviet model of health care, decisions were made based on socialist ideology and central planning. A new basis is needed. Following the lead of other European countries, Poland wishes to gain information on how decisions can be guided by health technology assessment. Some key problems in Poland include:
1 Attempts to set standards on safety and quality;
2 The basis of coverage, that is, the definition of the benefits package;
3 Payment for highly qualified services.

Health policy makers in European Union countries (and Switzerland) have addressed these and related problems, especially using Health Technology Assessment (HTA) and linking it to regulatory and reimbursement decisions. Using HTA actively would result in standards being set based on effectiveness and cost-effectiveness, coverage decisions being based (in part) on systematic evidence of effectiveness, and highly qualified services being regulated and reimbursed based on effectiveness. This paper focuses on defining the benefit package by using HTA. In brief, the standards for inclusion of a service in the benefit package would be based in large part on HTA.

Technology Assessment

HTA may be defined as "a structured analysis of a health technology, a set of related technologies, or a technology-related issue that is performed for the purpose of providing input to a policy decision" (Banta, EUR-ASSESS glossary).

HTA is a form of policy research that systematically examines short- and long-term consequences of the application of health technologies. The goal of HTA is to provide input to decision making in policy and practice. The essential properties of HTA are this orientation to decision making and its multidisciplinary and comprehensive nature (Banta, Introduction to EUR-ASSESS).

Health technologies are the drugs, devices, procedures, and the organisational and support system within which health care is delivered.

HTA takes a broad view of technology and of technological change and carries out analyses of such issues from a number of perspectives. The field includes studies of ethical and social consequences of technology; factors speeding or impeding development and diffusion of health technology; the effects of public policies on diffusion and use of health technology and suggested changes in those policies; and studies of variation in use of technologies. The most prominent part of HTA is to determine, insofar as possible, the benefits and financial costs of a particular technology or group of technologies. The main goal of such studies is to improve "value for money" in health care.

Given this broad context, HTA is not defined by a set of methods but by its intent. A technical assessment of a pharmaceutical or medical device carried out by a program as

part of a regulatory decision can be considered HTA. Likewise, an ethical analysis concerning gene therapy done to clarify its implications before deciding whether to provide it can be considered an HTA. The most frequent activity in HTA is a synthesis or systematic review of available information, especially on efficacy and cost-effectiveness, to assist different types of policy decisions. A prospective randomized clinical trial or prospective cost-effectiveness study done for policy reasons, as in the Netherlands or the United Kingdom, is also a technology assessment. On the other hand, clinical research or even clinical trials done solely for the purpose of increasing scientific knowledge are not technology assessments.

Technology assessments are useful to a wide range of decision makers in health care, including government policy makers, insurance companies and other payers, industry, planners, administrators, clinicians, and patients. This report concerns standards for making coverage decisions by the sickness funds and the national government.

This report includes a "Methodological Appendix" which discusses the basics and methods of HTA in some details. The Methodological Appendix is background for Working Papers 2, 3 and 4 and will be provided with each of those reports. Therefore, these Working Papers will only deal with HTA at a general level in their text.

The Basis of Defining the Polish Health Benefits Package

The 1999 reform in Polish health insurance is spelled out in a detailed law. Perhaps the most important provision in the law is Article 4.3, which states, "The health services are provided to the insured according to the financial resources commanded by the Health Insurance Funds. These services should reflect the current medical knowledge and practice, and should not go above the necessary level." Article 31 defined, in general terms, the services to be provided.

If the benefit package is to be based on HTA, this wording may not be sufficient, legally speaking. How does one define "current medical knowledge and practice"? How is the "necessary level" to be defined? While the idea that services should be effective may be implicit in such wording, a number of countries have found that such wording does not satisfy legal requirement for precision of definition. The Netherlands and the United States, for example, have found themselves hampered by similar general wording in their health insurance legislation. In Switzerland, in contrast, the health insurance law was changed to address this problem. For this reason, and others, the Swiss coverage process in relation to HTA will be described in some detail in this report.

Links Between Health Benefits Coverage and HTA

From the beginning, organised health care systems and payment plans have had to describe a package of benefits. Traditionally, these have been defined by what doctors do. In other words, doctors have determined what they thought to be effective, and the system has provided payment for application of these technologies.

Evidence of many problems in health care, including the widespread application of ineffective technologies and the widespread inappropriate application of effective technologies, has brought this traditional system into question. During recent years,

coverage policy has been in rapid change, especially in Western Europe (and the United States and Canada).

The growth in the field of HTA has led to an important alternative to the traditional system, which is to determine benefits coverage through a process of HTA. This is not to discard clinical judgement and experience, which is a key part of health care. Nor is it to say that policy makers should just follow the results of HTA. Coverage decisions are not only about effectiveness, but may be based on political factors, desires of the population, industry pressures, professional preferences, access issues, ethical issues, and so forth. The difference is that HTA plays an increasingly important part in coverage decisions, but is often not the only, or even the dominant, factor.

The main problem with HTA in relation to coverage is the lack of scientific information on which to base such decisions. Despite 25 years of development in HTA, many technologies have not been assessed, or even identified. Such areas as long-term care, mental health care, chronic disease care, and care for the elderly have not been well-characterised, and the body of evidence concerning efficacy, effectiveness and safety of interventions in these field is lacking. Therefore, for the time being, an assumption that most of health care is efficacious must be made, while beginning to strengthen decision-making in selected areas of care. Typically, insurance begins with pharmaceuticals, preventive procedures, and specialised medical care, where the evidence base is better than in other areas of health care.

A partial solution to this problem will the described in Working Papers 6 and 7, so will not be introduced further in this report. Instead, this report will present, in addition to the case of Switzerland, some cases of technology and technological decision making to indicate, in real-world terms, just how HTA can be used in coverage decisions.

Contents

1 Introduction

Other reports have described the background of Poland and the Polish health care system, so this report will not repeat that material.

What is very clear is that the Polish health care system has changed dramatically in recent years. The main change has been to move away from the centralised model of the Soviet system and the development of decentralised administration. With this change, the role of the Ministry of Health has also changed dramatically, so that it is becoming an instrument for policy development and leadership rather than the head of a centralised health care bureaucracy. A great deal of decision-making is now delegated to other parts of the health care system.

To develop its new role, the Ministry of Health needs sources of information that will guide future developments. Health technology assessment (HTA) is such a source of information. Following the lead of other European countries, Poland wishes to gain information on how decisions can be guided by health technology assessment. Some key problems in Poland include:

1 Attempts to set standards on safety and quality;
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3 Payment for highly qualified services.

Health policy makers in European Union countries (and Switzerland) have addressed these and related problems, especially using HTA and linking it to regulatory and reimbursement decisions. Using HTA actively would result in standards being set based on effectiveness and cost-effectiveness, coverage decisions being based (in part) on systematic evidence of effectiveness, and highly qualified services being regulated and reimbursed based on effectiveness. This paper focuses on defining the benefit package by using HTA. In brief, the standards for inclusion of a service in the benefit package would be based in large part on HTA.

2 The 1999 Reforms in the Polish Health System

The 1999 reform in Polish health insurance is spelled out in the 1997 Health Insurance Act. Perhaps the most important provision in the law is Article 4.3, which states, "The health services are provided to the insured according to the financial resources commanded by the Health Insurance Funds. These services should reflect the current medical knowledge and practice, and should not go above the necessary level." Article 31 defined, in general terms, the services to be provided.

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Eddy (1996) summarises the lessons from this international experience as follows (although he gives particular emphasis to the issue from the United States perspective):

"First, it is appropriate for plans to define criteria that limit the services they will provide or pay for. That is, there is no intrinsic obligation for plans to pay for anything that anyone might want.

Second, if plans are to accomplish these limitations, the language they use must be as precise as possible – not just legally precise, but comprehensible to members. This has several implications. An immediate one is that the unadorned words "necessary," "appropriate," and "investigational" will not work. They have been tried and they have failed. New benefit language will have to lay out specific criteria, and probably should illustrate the criteria with specific examples. Another implication is that the language should be kept as simple as possible, searching for clear lines and using common words to the greatest extent possible. Still another implication is that when there are no clear lines or when common words can be misinterpreted, specific inclusions or exclusions should be used liberally to address any services that might be ambiguous or controversial.

The third lesson is that because the natural incentive of patients is to expand rather than contract the interpretation of the language, and because the courts will tend to interpret any ambiguity or misunderstandings in favour of the patient, if the criteria are to achieve the objective of unambiguous communication between plan, physician, and member, they should be defined narrowly. A plan can easily expand a criterion, either formally by adding specific inclusions, or informally by simply paying for services that fall outside the criterion. However, plans cannot move in the other direction; they cannot expect to win if they withhold coverage for services that fall within a liberal or even ambiguous interpretation of the criteria."

3 Coverage Decisions in Switzerland

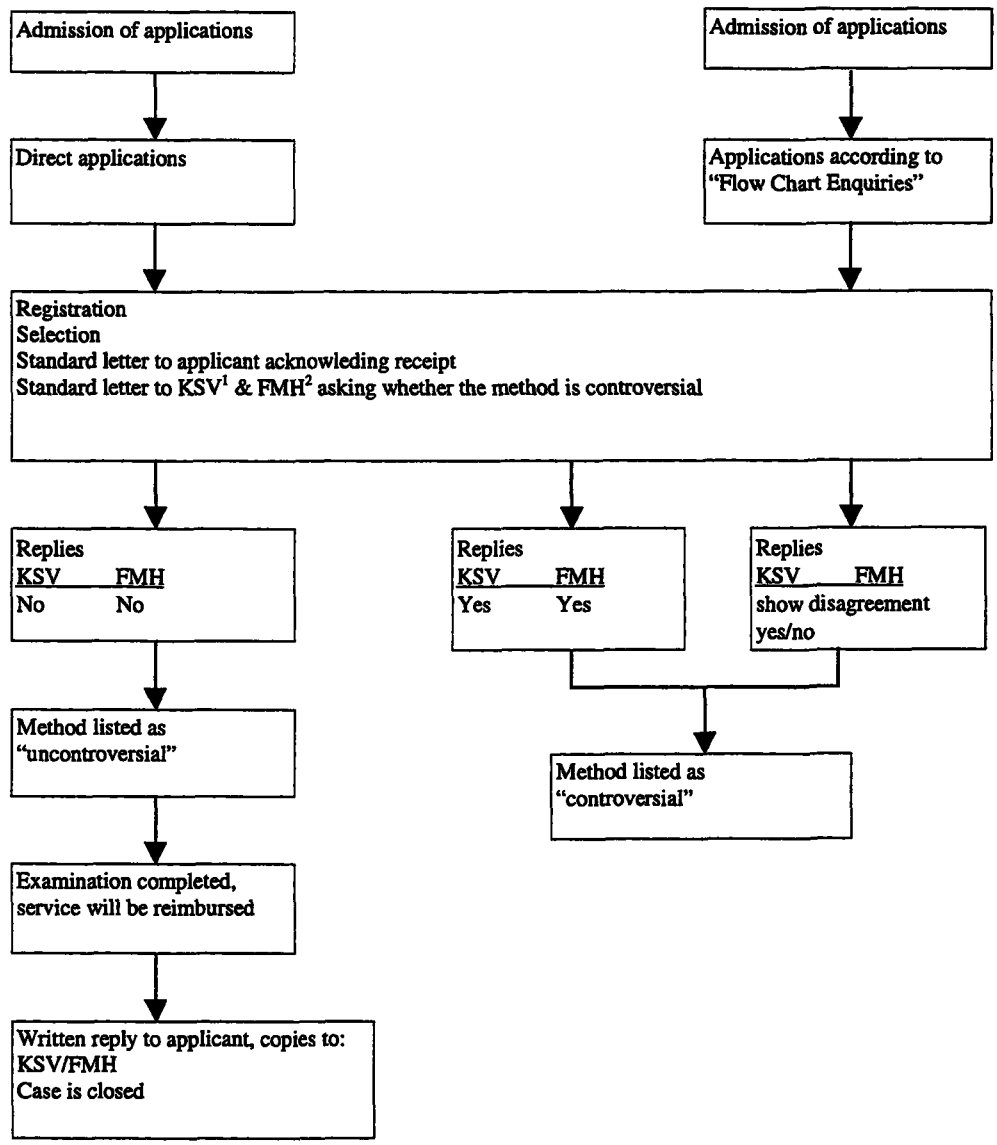
The case of **Switzerland** will be used to show how these lessons may be applied in practice. Switzerland has a mixed social and private system of health care. Each canton (state) has its own health law, and the health care administration is highly decentralised. Since 1996 the entire population has a choice between different health plans, including health maintenance organisations, which compete with each other, especially on the basis of additional packages of benefits. An estimated 35% of the population is covered by semi-private or private insurance schemes supplementing the compulsory insurance, but this number is falling. Hospitals are generally private/non-profit, but receive part of their budgets from government. The cantonal governments plan their own health services.

Switzerland has carried out more and more HTA for coverage decision making since the mid-1980s. This experience convinced Swiss policy-makers of the necessity for a formal process to define a basic benefit package (see Cranovsky et al, 1997). At a meeting on 30 August 1990, the Federal Commission for Health Insurance Benefits asked the Swiss Federal Social Insurance Office (BSV) to establish a list of criteria to be met when applying for recognition of medical services as reimbursable. The proposed procedure was approved by the Commission in 1992 and subsequently implemented. Beginning in 1992, a manual was developed to guide applicants in gathering the required documentation in accordance with recognised principles of medical and economic evaluation of medical services. The draft manual has been through several revisions and is still a draft, but is available in German, French and English (Swiss Federal Office of Social Security, 1998).

On 1 January 1996, a new law introduced compulsory basic health insurance with specially regulated cantonal subsidies for basic sickness insurance coverage. The 1996 law provides for a list of approved medical procedures for basic health insurance. However, that does not mean that all medical and health care procedures are listed. In the case of physician and hospital care, all diagnostic and therapeutic procedures are reimbursed unless it has been expressly established that their effectiveness, appropriateness, and cost-effectiveness are not (or not yet) proven ("negative list"). There are approved lists for other health services, such as drugs, laboratory procedures, and preventive procedures.

All requests for the inclusion of new procedures in the positive lists are submitted directly to the Federal authorities by interested parties (see Figure 1). The health insurers (KSV) and the Swiss Medical Association (FMH) are asked if the procedure is established or controversial. A limited synthesis of appropriate literature is carried out by the BSV staff or contracted experts at the same time. If both state that the procedure is established, it is generally covered (the Federal Coverage Committee make the decision).

Figure 1. Flow chart for individual technologies



[1] KSV = Swiss Health Insurer's Association
[2] FMH = Swiss Medical Association

If either or both organisation states that the procedure (the technology) is controversial, there is an organised process of assessment and gathering opinions before a coverage decision is made (see Figure 2). The process begins with discussions of the needs for information with the applicant, including a visit by BSV staff to the applicant's facilities. The assessment information must be produced by the applicant; generally speaking, one or more experts in HTA will be commissioned to participate in the process. An information synthesis on known efficacy, effectiveness, and safety is carried out, as well as collection of information on economic aspects, drawn from the scientific literature and Swiss and foreign reports. Where appropriate, information on legal, ethical, and other social aspects may be required. If information is available from Swiss registries, data on utilisation, outcome, side effects, cost, manpower considerations, and technical aspects, are also parts of the process. The documentation to be submitted to the BSV includes three parts:

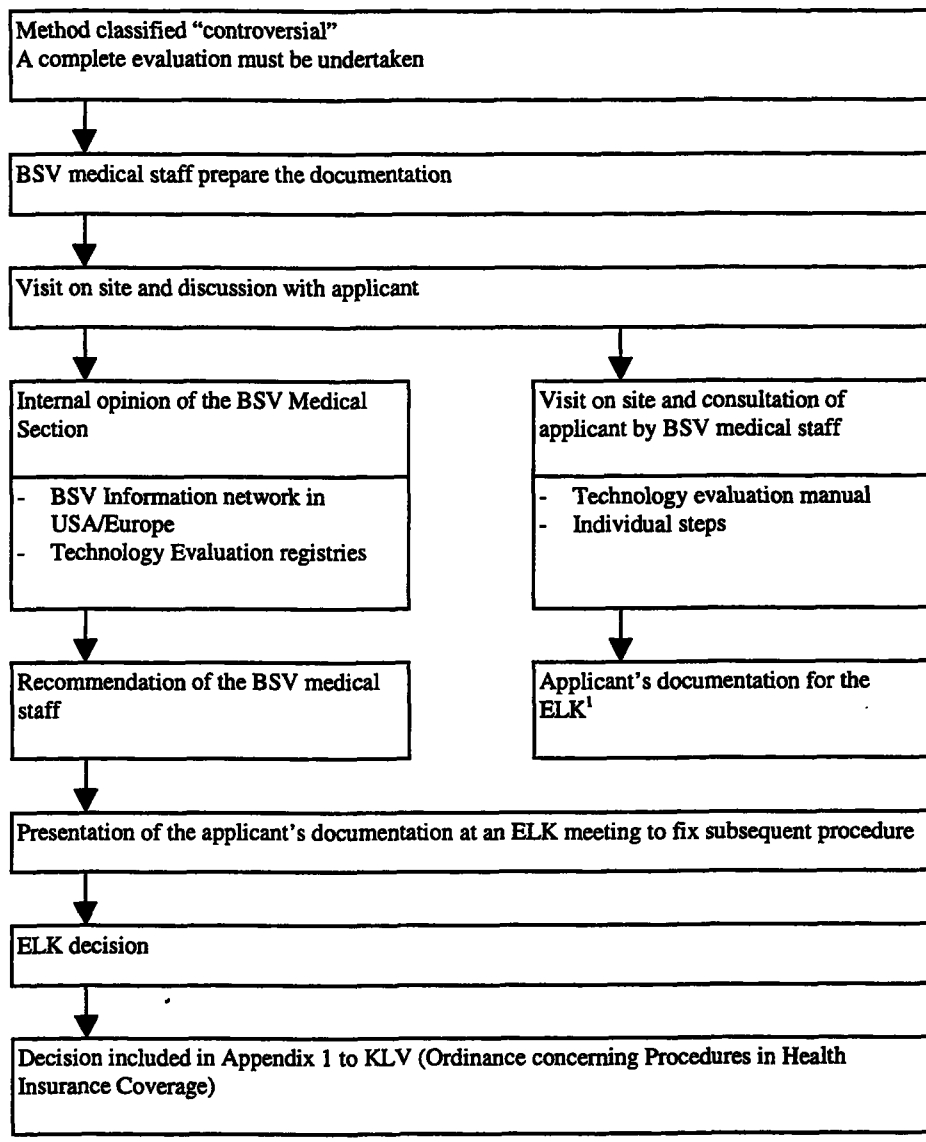
1 Part 1 – Medical documentation – including efficacy/effectiveness and safety;
2 Part 2 – Economic documentation – a cost computation for the service in question;
3 Part 3 – Discussion and justification of the application in view of the effectiveness, appropriateness and efficiency of the method.

The manual lays out evaluation principles in these steps:

1 Designating the technology. A standard name for the technology must be used, accompanies by complementary information to clarify the indication. In the case of different indications or complex procedures, these must be differentiated.
2 State of medical knowledge. This section describes the method or technology, how it has been developed, and a current description. A description of the frequency of use and results and evolution of the technology would generally be required.
3 State of clinical practice in Switzerland. Documentation of the use of the technology in Switzerland must be provided. It is important to compare Swiss experience with relevant experience of other countries.
4 Presentation of own experience. This step outlines the major points of a medical justification for an application for reimbursement. The presentation should include:
    1 Indication for the service;
    2 Effectiveness of the service;
    3 Appropriateness of the service;
    4 Safety of the service;
    5 Comparison of the service with alternative treatments in terms of effectiveness and appropriateness;
    6 The global needs for Switzerland must be estimated on the basis of epidemiological and demographic data. Problems for the patient should be described. The consequences in terms of follow up services and subsequent treatment should also be covered.

An appendix should include a thorough bibliography, photocopies of 3-5 key publications in full, illustrations and photographs, and (perhaps) video or audio recordings.

Figure 2. Flow chart for individual technologies



[1] ELK = Federal Commission for Health Insurance Benefits

The manual also describes "fundamental principles of the economic evaluation of technologies." A series of tables describe what should be done:

1 Cost breakdown;
2 Cost components;
3 Cost calculations;
4 Setting costing rates.

The manual also includes many examples of technologies, model forms and letters, and so forth.

While experts may be contracted to do all or part of this work, the Federal Office of Social Insurance has the responsibility for producing a report detailing its conclusion. Then a specially appointed Federal Coverage Committee makes the final decision.

The Federal Coverage Committee has a number of options. It can say "no" to coverage, it can say "no" but ask for a further assessment, or it can say "yes" to coverage. It can also say "yes" conditionally. One option frequently used, particularly in the case of expensive or complex medical procedures, is to say "yes", but only if the procedure is carried out by specially qualified professionals in determined settings. Another option is to say "yes", but only for certain medical or health indications. A final option used fairly frequently is to require further data collection, particularly by setting up a registry to collect information on technical, medical and economic aspects of the technology. The aim of this conditional coverage is to carry out a thorough HTA and make the revision of coverage after a stated period of time.

The manual devotes considerable attention to "Services performed on the orders or on behalf of a physician." In this section, specific procedures to be reimbursed in a number of fields are detailed. The fields include physiotherapy; occupational therapy; nursing care outside the hospital; speech therapy; preventive measures; special maternity services; dental treatment; medical supplies and equipment; spas; and routine and emergency transportation costs.

As noted above, a complete positive list for pharmaceutical coverage is available separately.

Concerning medical specialty services, those services that have been examined are listed, giving the coverage decision. For example, in internal medicine, positive decisions include hyperbaric oxygen treatment (for specific indications); acupuncture (with a time limitation); rabies vaccination (in case of an animal suspected to be rabid); obesity treatment (with indications); transplantation of donor bone marrow in several cases, but not in the case of multiple myeloma; hemodialysis and peritoneal dialysis in home or hospital; enteral tube feeding or parenteral nutrition at home, as necessary; and insulin pump therapy under defined conditions. Technologies not covered include oxone injection therapy; medical eurhythmics; cellulotherapy with fresh cells; serocytotherapy; and certain defined obesity treatments.

An interesting incident in Switzerland focused on routine ultrasound screening in pregnancy. After an assessment showing no evidence of benefit, the Federal authorities proposed to withdraw reimbursement for the procedure. Swiss obstetricians and patients, assisted by industry, lobbied actively against the proposal. The media made it a

prominent issue, implying that the Federal authorities did not care about the health of foetuses and babies. The final outcome was that the Swiss authorities withdrew the proposal, but required that a special data collection effort be carried out involving a registry to determine the implications and possible benefits of the screening. This proposal was acceptable to doctors and patients, and the study is underway.

The Swiss authorities have been able, in a relatively short period of time, to change the health insurance law to make the powers of the Federal government explicit and to strengthen the basis of coverage decision-making. In time, an entire defined benefits package may be possible, but that time is sometime in the relatively far future. In the meantime, Swiss policy-makers also have no doubt that this approach has improved the quality of health care while making it simultaneously more cost-effective. In short, the Swiss experience indicates that basing coverage decisions on HTA is an essential part of making the health care system more cost-effective, especially in a system based on social health insurance.

The Swiss experience is highly relevant for Poland. The Swiss system is a complex, but workable system for basing decisions on HTA. In Working Paper 6, a model assessment process is presented. Such a model must be adapted to local circumstances in Poland. The Swiss system is one positive example to show how this can be done.

4 The Coverage Process in the Netherlands

The **Dutch** health care system and the relation of HTA to coverage decisions was discussed in Working Paper 1 and will only be summarised here. Some results of this process are presented later in the section.

The issue of efficacy/effectiveness of health technology became an issue in the Netherlands in the early to mid-1980s. In 1982, the Sickness Funds Council was confronted with patients who demanded that the costs of heart and liver transplantation that had been performed a broad would be reimbursement by the sickness funds. The debate stimulated by this case led to a 1983 government paper, "Limits to the Expansion of the Benefit Package" (Grenzen aan de groei van her verstrekkingenpakket). The paper stated that in the future all major new medical technologies were to be assessed for their efficacy and cost-effectiveness and would be admitted to the benefit package according to their priorities. A serious problem was the lack of expertise in assessing efficacy and cost-effectiveness in the Netherlands.

In 1985, three major evaluations were begun on liver and heart transplantation, plus in vitro fertilisation, funded by the Sickness Funds Council and the Ministry of Health. The actual evaluations were carried out in three university hospitals. The final reports in 1988 and 1989 led to coverage decisions with defined conditions of use. All three technologies were covered.

The lack of expertise and experience in evaluation in the Netherlands led the Director General of Health to ask the Steering Committee for Future Health Care Scenarios (Stuurgroep Toekomstscenario's Gezondheidszorg) for advice on a long-term policy on health technology assessment (HTA). A project on future health care technology under the direction of a specially-appointed committee met from 1985 to 1987 and developed a comprehensive overview of future health care technology, including recommendations for the development of HTA and its use in policy decisions.

In 1988, the government responded to this report with a report "Limits to Care" (Grenzen van de Zorg) that was presented to the Parliament. The government requested advice on limits to health care from three important councils, all of which pointed to HTA as an important tool for establishing the border between effective and ineffective care, as well as establishing the border between affordable care and non-affordable care. The Sickness Funds Council emphasised that HTA could help break the automatic addition of new technology to the health care benefit package.

In 1988 the Sickness Funds Council and the Ministry of Health, in co-operation with the Ministry for Education and Science, established the "National Fund for Investigational Medicine" (Fonds Ontwikkelingsgeneeskunde) with a budget of 36 million guilders (about US$20 million) a year. Projects under this fund may evaluate new or established technologies, examining efficacy, cost-effectiveness, social, ethical, and legal implications, depending on the policy decisions that may be taken. In practice, projects have mainly dealt with new technologies proposed for the benefit package. Proposals were initially solicited from the medical faculties ("bottom-up approach"), but evaluations showed that these proposals were often not high priority, so the program has gradually changed to emphasise commissioned research on important topics ("top-down approach"). In addition, the government has from time to time requested for

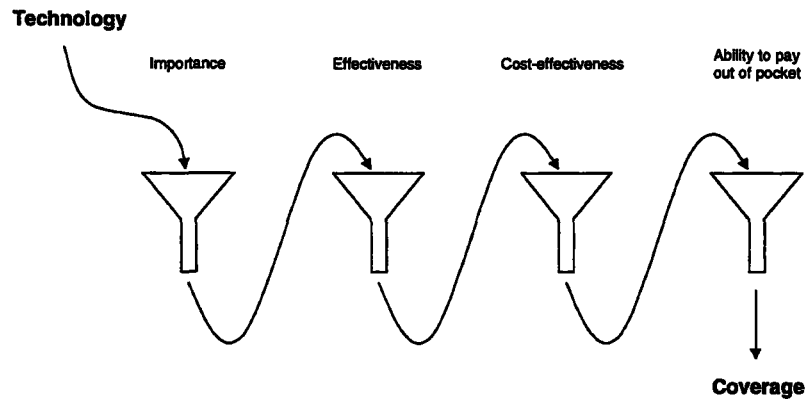
support for a study of a technology of policy importance, such as lung transplantation. Recently, a large part of the Fund has been moved to the National Organisation for Science (NOW), but its principles remain similar. Results of the evaluations have generally had great influence on health policy, especially coverage decisions.

Another important report was published by the Sickness Funds Council in 1991: "Limits to the Growth of the Benefit package: Third Advice" (Grenzen aan de groei van het verstrekkingspakket: derde advies). The report stated that efficiency was an important criterion for inclusion of a new technology in the benefit package and that technology assessment could evaluate this aspect of a technology. The central point in this report concerned inclusion of essential services in the benefit package. The Council concluded that the legal basis for controlling development of the benefit package was insufficient, since the law defines help by medical specialists and general practitioners as "insofar as this help is considered usual by the medical community". The report also acknowledged that legal policies were not enough to assure the appropriate definition of limits to care. Consensus forming and clinical protocols were seen as two possibilities for going beyond formal policies.

By the 1990s, then, HTA and coverage had become an important health policy issue in the Netherlands. In 1989, a special commission was appointed with the task of analysing choices in health care. One of the key sections of its 1992 report dealt with how to define the basic benefit package (Dunning, 1992). In its report, the committee acknowledged serious problems of ineffective and cost-ineffective technologies and overuse of effective technologies in the Dutch health care system. It proposed the use of four screens or "sieves" or "funnels" to define a basic benefit package, which are depicted in Figure 3. First, is the care **necessary**, meaning (for example) is it necessary to assure normal function or to protect life? Second, is the interventions proven to be **effective** by controlled clinical trials? Third, is the care **efficient**, meaning is it shown to be cost-effective by a formal analysis? Is the cost reasonable when compared to the benefits? Fourth, is it possible to leave the care to **individual responsibility**? For example, the committee concluded that in vitro fertilisation and homeopathic medicines could be left to individual responsibility (although, in fact, as already noted, in vitro fertilisation is fully covered as a benefit). The committee concluded that applying these four screens in selecting technology to be included would result in a rather extensive benefit package without excessive costs.

However, this model has in fact not been fully applied. There are practical problems in trying to apply the model. As the report itself acknowledged, information on effectiveness and cost-effectiveness is often lacking, requiring prospective studies. Such studies may take years. Another problem is that coverage policy is a **macro** policy, which has limited effects at the bedside of the patient. Other policies must be developed to influence medical practice, such as clinical guidelines and protocols. Another problem is that there are thousands of health technologies. No comprehensive list of technologies has ever been made for all of health care, much less an assessment. As one insurance executive noted, "We must take as a basic assumption that those things that doctors do now are effective. Otherwise, we have to assess everything in health care in a short period of time, which is impossible" (Cranovsky et al, 1997). Such areas of health care as mental health care, home health care, chronic disease care, and nursing home care are examples of huge areas of activity that are essentially not affected by coverage policy.

Figure 3 Basic Benefit Package criteria in the Netherlands



Faced with these problems, the Sickness Fund Council and the Ministry of Health have followed a pragmatic policy, based on assessing new technologies before they enter the benefits package.

The following is a description of some experiences with the National Fund and its relation to health policy decisions, including coverage decisions. The typical study supported by the National Fund runs for 3 years, although there may be a longer follow-up. After completion of the study, it is forwarded to the College voor Zorgverzekeringen (CVZ - Council for Health Insurance, former Sickness Funds Council), which makes a recommendation to the Minister of Health. The Minister may follow this advice or may not. The process of recommendation and decision-making takes another 18 months or so. Therefore, it is only possible to describe the outcome of studies begun years ago.

Technologies following into the general category of "advanced medical care" are treated in a special way. Prohibition, temporary prohibition (while an HTA is done), and not very strong regulation by favouring certain specific interventions are all possible. The Investigational Medicine Fund prospectively evaluates these technologies, usually by a randomised controlled trial with a simultaneous cost or cost-effectiveness analysis. During the assessment process, placement of the technologies is regulated by a "certificate of need" program (detailed in Working Papers 1 and 5), the so-called "Article 18" program, after its Article in the Hospital Provisions Law.

These studies were initiated during the period 1991-1995:

- Diagnosis of infertility.
- Extra Corporal Membrane Oxygenate (ECMO) of neonates (part of regulated neonatal care under art 2 WMBV (former art 18). Effectiveness for indications under

study was proven. The decision was made to reimburse this type of care. Concentration of care in 2 centres was recommended.

- Use of Recombinant Granulocyte-Macrophage Colony-Stimulating Factor During and After Remission Induction Chemotherapy in Patients Aged 61 Years and Older With Acute Myeloid Leukaemia (AML). This treatment was not found to be effective. A general guideline for use of growth-factors in oncology was adapted.

- Lung transplantation (also a regulated technology under art 2. WBMV. Effectiveness was proven, although high cost was noted. Reimbursed beginning 1 January 1998.

- Paediatric cochlear implantation. Found to be cost-effective in 1996. The technology was not reimbursed until 2000 because of controversy (see the case of cochlear implants below). In 2001 the Health Council published a report on CI, in which it was advised to restrict CI to 2 academic hospitals.

Other policy decisions based on assessment have also been made:

- Physiotherapy. A limited number of visits are reimbursed. Supplemental insurance is allowed.
- Plastic surgery. Limited coverage, mainly focusing on functional limitations. No coverage for "esthetic" reasons. Great activity in private hospitals).
- Dental care. Limited for adults. Supplemental insurance is allowed.
- Contraceptives. Decision to continue reimbursement. An ongoing discussion about whether they could be paid for by people themselves.
- In Vitro Fertilisation. Covered with age limitation and limitations on the number of attempts.

In addition, in 2001, the Steering Committee for Organ Transplants of the CVZ evaluated 2 requests for a licence:

- Small intestine transplants. License granted to 1 academic hospital. Evaluation after 1 year).
- Heart transplants of children. Evaluated by a committee of the Health Council. Minister of Health has decided to grant a license for 1 or 2 centres. The Committee advised licensing 2 academic centres.

During the last year or so, reports on the following technologies have been finalised, discussed by the CVZ, and recommendations have been made to the Ministry. The impact of these evaluations on policy is not yet known.

-Thalamus stimulation
-Laprascopic surgery of pancreas carcinoma
-Cervical cancer screening
-Radiotherapy of bone metastases
-Pre-surgical orthopedic treatment
-Post-traumatic dystrophy
-Treatment of capsulitis
-Prevention of restenosis by means of stenting
-Craniomandibular dysfunction
-Decontamination liver transplantation

-MEDx training and chronic back-neck pain
-Somatistatin scintifigraphy
-Reno-vascular hypertension
-Sleep apnea syndrome
-Combination therapy for arthritis

At the same time, old technologies have been assessed. The approach to old technology has been quite interesting. A quasi-Delphi study was carried out, in which hundreds of physicians, most working for or with Sickness Funds as employees and advisors, were asked to suggest health technologies that might be ineffective or outmoded. The resulting list had more than 1000 candidates for assessment. In the Delphi study, they were asked to prioritise this list, eventually coming to 125 candidates. Those 125 technologies are presently being assessed by a process in which the scientific literature is reviewed to determine if evidence for efficacy and/or cost-effectiveness is sufficient to answer the question as to whether coverage should be continued. If the evidence is sufficient to continue coverage, that is the recommendation. If the evidence is sufficient to lead to a presumption of limited efficacy and/or cost-effectiveness, the recommendation is to remove the technology from the benefit package (by a "negative list"). If the evidence is not sufficient, a prospective study is generally mounted to determine whether access to the technology should be continued or discontinued.

In time, then, more and more of health care will be assessed. But the full definition of a basic benefit package will take many years, as can be readily seen. The main focus of the Fund and the Health Council is on expensive and complex technology that may be subject to explicit policy decisions.

The Netherlands experience illustrates some important points. First, it shows the difficulty of developing a basic benefit package based on efficacy and cost-effectiveness, particularly in the short-run. Second, it shows that coverage decisions can be based on such considerations. This is an important finding, because it means that services can be dropped or forbidden entry to the benefit package in such a way as to both enhance health benefits and save money simultaneously. Dutch policy makers have no doubts about the value of this approach to defining the benefit package.

5 The Impact of HTA on Coverage Decisions – The Case of Cochlear Implants

Cochlear implantation (CI) was developed during the last 30 years and was first introduced to Europe in 1984. Today, CI is a widely accepted treatment for deafness. More than 10,000 implantations have been performed worldwide (Cranovsky et al, 1997). In Europe, nearly all countries are involved in CI and there are more than 130 active CI clinics in European Union countries. Nonetheless, the technology is controversial, especially in the cases of prelingually deaf children and of severely impaired older persons. Members of the deaf community and organisations representing them have brought pressure against coverage of the technology, especially in the case of children. A recent doctoral dissertation from the Netherlands analyses the issue concerning children in great detail (Reuzel, 2001) The basic issue is whether deafness is viewed as a pathological disorder to be eradicated or a feature of a specific cultural minority. In the latter case, CI might not be favoured, especially not for young children. The controversy has led to considerable confusion and discussion, including among health insurance authorities. One result has been a number of clinical and cost-effectiveness studies.

In 1997, the situation with cochlear implants in six European countries was reviewed (the Netherlands, Switzerland, Spain (and the province of Catalonia), Germany, United Kingdom, and France (Cranovsky et al, 1997). This overview showed that there are major differences from country to country both in policy and practice, with indications for implantation and subsequent rehabilitation and social integration of deaf people. Full coverage of CI treatment for all qualifying patients is available in the six countries, as well as others, such as Scandinavian countries. However, in most of these countries, CI is limited in some way, mostly by limited budgets or by restrictions on patient selection criteria. The major discrepancy internationally concerns young children.

HTAs concerning CI have been carried out in all of the 6 countries. However, these studies have varied greatly. In France, UK, Germany, and the Netherlands, prospective primary data collection has been carried out. In Catalonia, only retrospective data analysis has been done. And in Switzerland and Spain the approach has been through consensus conferences. These HTAs have had considerable impact on both general health policy and on coverage/reimbursement decisions in the six countries.

Because of continuing controversy, additional studies have been commissioned or set up. Hopefully, these will clarify the situation with CI. At the same time, the device itself is being modified and improved. There is an international consensus that long-term surveillance of the technology and prospective reassessments are necessary. The most pressing issue, however, is resolution of the conflict between medical and cultural views of deafness. Perhaps this issue can only be addressed by each country individually.

6 The Impact of HTA on Coverage Decisions – The Case of Percutaneous Transluminal Coronary Angioplasty (PTCA)

In 1997, as part of the EUR-ASSESS report, members of the group from Catalonia (Spain), Greece, the Netherlands, Sweden, and Switzerland decided to develop a case study of coverage of invasive cardiological therapy, a widespread, expensive, and developing technology (Cranovsky et al, 1997). In this case, only the material on PTCA will be presented.

PTCA was introduced in Europe from 1980 to 1983. At that time, it was regarded as a partial substitute for coronary artery bypass grafting (CABG). Substitution did take place fairly rapidly in university cardiac centres, but CABG continued to be the most-used therapy in nonuniversity centres. By the early 1990s, indications for PTCA expanded: multi-vessel PTCA, PPPTCA combined with thrombolysis in acute myocardial infarction, and PTCA combined with stenting. These more complex procedures were again pioneered in university centres. The expansion of indications caused a 5- to 10-fold increase in PTCA during the 10-year period, while the number of CABG procedures doubled in most countries. PTCA has surpassed the number of CABG procedures in a number of countries, including France, Belgium, Germany, the Netherlands, Spain, and Switzerland, and the same phenomenon was expected in almost all European countries.

A number of HTA studies have been carried out and usually affect planning and payment strategies. Some countries have regulations for technologies such as PTCA, and HTA was been coupled into such decisions.. The Article 18 program in the Netherlands is one such example. There have also been studies of appropriateness of PTCA, but this has not led to payment linked to appropriate PTCA indications.

Some countries have specific coverage policies linked to HTA. However, the case also points out some difficulties: 1) the boundaries of "experimental technologies" and the nature of the information required for a technology to be accepted as proven are generally not explicit; 2) conditions guaranteeing quality of care are not generally addressed; and 3) when coverage is established according to a broad category of services, the possibility exists of including a mix of procedures where the safety and short/long-term efficacy and cost-effectiveness of some of the procedures are not known, as in the case of expanded indications of PTCA. This leads to problems. The technology is accepted for some indications that are considered proven, but other indications are the subject of research, which also needs to be taken into account. The most usual result, as already indicated, is that technologies are used beyond the accepted indications. This points out the need for other actions, such as active dissemination of information to the medical profession.

Although HTA studies are just one factor among a group of interacting forces in the establishment of coverage policy decisions, those countries with established HTA programs that have carried out studies of PTCA have used such studies as a basis for coverage policy decisions. The main problem remains as already stated: a coverage decision can state that the treatment is only accepted for certain indications, but the medical profession tends to use it for additional indications. With today's state of the

art, it is very difficult to control or influence such practice. Possibilities include clinical guidelines and patient/consumer education programs (Cranovsky et al, 1997).

7 The Impact of HTA on Coverage Decisions – The Case of PSA Screening for Prostate Cancer

In 1999-2000, as part of the HTA-EUROPE report, the relations between policies toward prevention and screening, HTA, and actually screening practices were explored in 9 countries, Austria, Belgium, Germany, Greece, Italy, the Netherlands, Sweden, Switzerland, and the United Kingdom, using several cases. Prostate specific antigen (PSA) was one of the cases. In each country, one or more experts in HTA gathered information and described and analysed the situation in their own country (Banta et al, 2001).

The body of evidence concerning PSA screening is very large, and a number of synthetic reports (HTAs) have also been carried out (Banta, Oortwijn and Cranovsky, 2001). As far as is known, no public HTA assessment program in the world has supported such screening. In addition, the International Network of Agencies for Health Technology Assessment (INAHTA) produced a report based on work in a number of HTA agencies. This report also did not support PSA screening. The main issue is lack of proven health benefit from screening (and treatment, when cancer is found). Nevertheless, such screening is supported by many physicians, especially urologists, and is rapidly growing in a number of countries, including all of those mentioned above.

What are the forces that encourage PSA screening? Prostate cancer is one of the most important causes of mortality in men. Screening has been successful in other cancers, and it logical to believe that screening could also have a place in the early detection and treatment of prostate cancer. Many physicians are obviously not convinced by the lack of evidence of benefit from formal assessments of PTA screening or are not aware of the facts. Lurking in the background is industrial promotion of a profitable product.

Policies toward screening for prostate cancer are consistent with HTA in all of the countries covered in this section. The technology is not covered by social health insurance or by national health systems (the UK and Sweden). No country covered in this section has a positive policy toward PSA screening for prostate cancer. Nonetheless, the PSA test is available and it is paid for (as a diagnostic test). It is then used with increasing frequency in "opportunistic screening", that is, screening that is done when a man visits a physician for other reasons. Payment may be denied if it is requested for "PSA screening", but diagnosis using PSA is covered, since PSA is considered a standard diagnostic procedure for demonstrating the presence of prostate cancer and following its course.

So PSA screening is a procedure that has not been shown to be of benefit. It is associated with elevated risk of harm of patients (mainly because of radical surgery) and growing financial costs. Although coverage policy is based on HTA, it has not been very successful in preventing the adoption and use of this technology. How to prevent the spread of such a screening procedure, which is another case of "expanding indications", is a serious question for health policy.

8 The Case of Routine Pre-operative Testing in Sweden

In Sweden controls over health technology include the regionalised system of care; training and control over health care professionals, and the nature and orientation of the Swedish population. Although the state has decentralised control over the system, it still attempts to control the general direction of the system through both regulation and subsidy (Jonsson and Banta, 1995).

The Swedish government created the Swedish Council for Technology Assessment in Health Care (SBU) in 1987 and confirmed its permanent mandate in 1992. The Council was envisioned as an organisation to both assess important technologies and to serve as a focus and co-ordinating body for activities in Sweden. The Board of the Council was made up of representatives of all important organisations in health care. The permanent Council began to function in 1992 with a budget of 12 million SEK (US$1.5 million).

The first technology assessment of SBU concerned preoperative investigations in elective surgery (SBU, 1989). The study team reviewed the literature and concluded that there was little justification for routine use of preoperative x-rays, electrocardiograms, or laboratory tests. A survey of practice revealed considerable variations in use of such tests, but some hospital departments always perform such tests, while others never perform such tests. An economic analysis showed that the cost for complete preoperative investigations in Sweden totalled 726 million crowns (about US$90 million). SBU recommended that preoperative routines should not be used in the absence of specific indications. An extensive 'marketing' effort was used to convince surgeons and anaesthesiologists of the wisdom of these recommendations.

Follow-up surveys of practice were done in 1990 and 1991 to evaluate the impact of the report. The evaluation in 1990 showed a significant decrease in routine preoperative testing that continued in the 1991 measurement. The actual saving in economic terms was 50 million crowns per year, or 5 times the yearly budget of SBU at that time (Jonsson and Banta, 1995). The value of the increase in quality of care could not be quantified.

Since the Swedish report, pre-operative routines have been examined by HTA agencies in France, the Basque Country (Spain), Catalonia (Spain), the United Kingdom, and the Netherlands. In 1999, the International Network of Agencies for Health Technology Assessment produced a synthesis report based on six reports from these agencies (Lopez-Argumedo and Asua, 1999). The results were similar to those of the Swedish report.

The interest of this case for Polish sickness funds is that the practice of routine pre-operative testing is not justified. The entire amount of money spent on this technology could be saved without any loss of health benefits. Such practices could be put on a "negative list" that would not be reimbursed. If such a list were developed in Poland, this case would be an obvious candidate for listing.

9 The Case of Back Pain in Sweden

Another full-scale assessment carried out by SBU concerned the problem of back pain (SBU, 1991). Most commonly used treatments in Sweden were found, through literature review, to be either ineffective or unproven. However, early movement and rehabilitation were found to have a positive impact on recovery. Moreover, the SBU report found that back problems were related to both physical and psychosocial working conditions. The report recommended a cautious approach to diagnosis and treatment, and more research on the efficacy of proposed treatments. It also recommended systematic approaches to changing individuals' working conditions so as to reduce the problem of back pain. Extensively publicised, this report led to a renewed discussion of the disorder throughout Sweden.

The main interest of this report for the Polish situation is the extensive list of interventions that are either ineffective or unproven (see table). Back pain is the most expensive medical condition in Sweden (including costs of unemployment, sick leave, etc.), and treatment costs are high. Only paying for those treatments proven and/or funding evaluations of commonly used treatments for proof of efficacy could lead to considerable savings.

10 Policy Tools for Controlling Technology in Addition to Coverage Policy

One of the strongest lessons from the cases presented here is that coverage policy, while quite important in itself, often cannot control health technology. The most important reason is that effective technology is used for indications where it may not be either effective or cost-effective.

This is a difficult issue to deal with. One lesson to be learned, however, is that formal policy-making has limits in controlling those in the health care system, including physicians. The most important approach to this problem so far devised is **to involve clinicians in HTA.** Clinicians do tend to follow the results of HTA when they have been involved in the process of HTA. Aside from the fact that clinical judgement and experience is an important contributor to HTA, this is the most important reason for arguing that clinicians need to be involved in HTA activities.

This is perhaps done most effectively in Sweden, where the Swedish Council of Technology Assessment in Health Care (SBU) depends on outside groups, predominantly clinical experts, to carry out its larger assessment. The general process is as follows:

1 A technology is identified for assessment, often in consultation with clinical experts or medical societies;
2 A group of experts is set up to carry out the assessment. Although predominantly clinicians, such groups usually include at least one economist and other non-medical experts. SBU selects the membership of the group, in consultation with outside groups and individuals;
3 A staff person from SBU participates in the group, often acting as chair;
4 The group is required to take a one-week course in HTA and evidence-based medicine before beginning the assessment. Part of this course is the presentation of standards to be used in the assessment. For example, conclusions are expected to be evidence-based;
5 The main source of information is the scientific literature. An expert documentalist/librarian is available to each group to assist it in identifying and acquiring such literature;
6 Additional information can be collected with agreement between the group and SBU. For example, surveys or small studies of economic implications can be supported by SBU;
7 Extensive external review of draft materials is required;
8 The draft report cannot go to the Council until the SBU staff is satisfied with it. The Council itself may also demand changes.

These groups do not actually make recommendations to policy makers. That is the role of the Council itself, which acts as a board of directors of SBU and which is made up of important stake-holders in Swedish health care (ministry of health, county councils, medical society, nursing society, etc.). Thus, the science of the assessment is separated from the policy decision. This is important for a number of reasons, including the fact that those doing the assessment often stand to gain or lose from policies concerning the technologies that they assess.

Experience has shown that these groups are generally strong advocates for the findings of the assessment. Since they are mostly respected clinical experts, they have considerable influence among clinicians. In addition, during its 14-year history, SBU has produced a fairly large number of physicians who have some expertise in HTA. This may be the most important reason that Sweden is on the road to developing a "culture of assessment" in its health care system.

Another policy worth discussion is **disseminating and implementing HTA results.** Until fairly recently, neither HTA agencies nor others with information that should be used by clinicians have paid much attention to this issue. However, as organisations have realised that the results of assessments may have delayed or no impact on practice, dissemination and implementation have moved onto the agenda (Granados et al, 1997).

The issue of dissemination and implementation is very complex. The EUR-ASSESS report on this subject gives general guidance (Granados et al, 1997). There is little empirical research on the effectiveness of dissemination and implementation strategies on changing the behaviour of policy makers. However, there is considerable empirical literature on dissemination and implementation for health care professionals. There are also a number of systematic reviews of this literature.

The main issue is that producing more information does not necessarily foster rational decision-making. Dissemination and implementation must go beyond the optimistic view and information will be used by decision-makers. The complexity of policy formation and clinical decisions makes it difficult to generalise about the effectiveness of a specific strategy used to implement a specific recommendation in a specific setting. Still, general principles have been defined. One is that barriers to behaviour change must be assessed and strategies should be designed to overcome these barriers. The nature of the message and its manner of presentation are also important. The reader is referred to Granados et al (1997).

A final important issue is that of **clinical guidelines.** Clinical guidelines have received a great deal of attention in recent years and are one of the most important of the new policies that attempt to change health care practice. A recent issue of the International Journal of Technology Assessment in Health Care (Caro, 2000) considers this issue in some detail, focusing on the future. Available research has shown that a framework of barriers prevents physicians from following guidelines. The majority of these barriers are related to physician attitudes. Thus, widespread use of guidelines requires changing physician beliefs, through either persuasion or coercion. This points again to the importance of involving clinicians in HTA activities.

11 Discussion

This report has illustrated that coverage decisions can certainly be based on HTA. HTA is already linked to coverage policy in a number of European countries. The case of Switzerland has pointed to some real-life changes and considerations that are involved in linking HTA and policy.

The most striking lesson to come from the cases, however, is the difficulty in controlling technology through coverage policy. If the technology is found to be ineffective, that is, if the evidence of benefit is lacking, reimbursement can be totally withheld. However, in most cases, a new health technology will be found to be efficacious and even cost-effective for some indications. In general, efficacious technology gives benefit only to certain subgroups of people. It is necessary to specify the benefit expected, the health problem leading to use of the technology, the population affected, and conditions of use under which the technology is applied (OTA, 1978)

The issue of benefit is fairly clear-cut. However, the scientific literature focuses on mortality. It may be difficult to find evidence of improvement of symptoms or morbidity, and information on quality of life is often completely lacking. Yet physicians often use the term "quality of life" to describe the benefit gained by patients. The medical literature often presents data such as shrinkage of a tumour and assumes that this improves quality of life. This practice is generally not justified. Another common failing is the use of "surrogate endpoints," where an intermediate outcome such as a change in the blood level of a chemical is used as the outcome measure rather than actual health benefit for the patient. This practice is also highly questionable (Liberati et al, 1997).

A technology's efficacy can only be evaluated in relation to the diseases or medical conditions for which is is applied. Obviously, one would not spend much time evaluating the efficacy of plaster cast applications for controlling hypertension. In general, however, the specification of medical problems is complex and can lead to controversy. For example, hysterectomies have been performed for a variety of medical conditions, including pre-malignant states and localised cancer, descent or prolapse of the uterus, and obstetric catastrophes. They may also be performed as prophylaxis to avoid later possible cancer or pregnancy. If efficacy has been assessed for one disease or condition, it cannot be assumed that the procedure will have similar efficacy for others.

The population affected can be important in several ways. Sometimes, enough uniformity of effect exists to permit careful generalisations. For example, the earliest clinical trials of treatment of hypertension were carried out in men. Could it be assumed that the results would apply to women as well? It is often difficult to organise clinical trials involving children. But children may react to treatments such as drugs in entirely different ways than adults. Therefore, the population that can be expected to benefit must be specified.

Conditions of use can also be important in several ways. The outcome of a health technology is partially determined by the skills, knowledge, and abilities of physicians, nurses, and other health personnel, and by the quality of the drugs, equipment, institutional settings, and support systems used in the applications. Cardiac surgery, as a

commonly cited example, often results in better outcomes when conducted by skilful, well-trained surgeons who frequently perform such operations than when conducted by surgeons who rarely use that technology.

The point is that when efficacy is demonstrated and specified in these four dimensions, a coverage decision will generally be positive. However, the tendency is then for clinicians to use the technology on other populations, on patients with other conditions (or less severe conditions), or in settings where the quality of the procedure cannot be expected to be optimal. While coverage can deal with this problem to a certain extent, every aspect of the technology cannot be specified for every technology under all conditions. And if it were, how would the outcomes be monitored and assured? Furthermore, coverage often gives high financial incentives for providing new procedures. There are then a number of reasons for a physician to provide a service for indications that are not specified, and little to prevent it, other than the professional ethics and concerns of the clinician.

Lastly, it is important to consider briefly the situation with European law. Does the law allow limitations of health benefits for such purposes as assuring cost-effectiveness? In the case of pharmaceuticals, the European court has explicitly held that negative lists, pharmaceuticals that will not be reimbursed in a particular Member State, are legal, since Member States have a legitimate interest in controlling the health budget. However, evolving European law requires that the basis for such decisions must be transparent, objective, and verifiable. Therefore, HTA plays an increasingly important role in such decisions.

This report has given some examples of methods that are being devised to address this problem. The general lesson is that basing coverage on HTA is not particularly difficult. But this is usually only the beginning of the story.

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