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Health technology assessment and priority setting for health policy in Sweden

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This article describes the development of health technology assessment (HTA) in Sweden, its influence on decision making, and its link with priority setting. Sweden has a well established governmental HTA body, the Swedish Council on Technology Assessment in Health Care (SBU), and an increasing number of regional/local HTA organizations. HTA has had an impact on clinical practice and is used to some extent in policy decisions. Several initiatives have now been taken to develop processes for open priority setting of health-care services. With the establishment of a new agency to undertake reimbursement decisions on pharmaceuticals, and greater patient and public involvement in decision making, it seems inevitable that HTA will play a more important role in priority setting in the near future.

Keywords: Health technology assessment, Priority setting, Health economics, Policy analysis

INCREASING CONCERN ABOUT LIMITED HEALTH-CARE RESOURCES

In all Western countries, health care remains high on the political agenda due to major biomedical developments and a perceived gap between the demand for health services and available resources. Important contributory demand factors are the ageing population and the existence of increasingly well-educated citizens. But direct marketing by the drug industry also creates rising expectations among the public. On the supply side, increasing medical opportunities, that is, widened indications or new technology, lead to increasing consumption and rising costs for health care.

The way in which medical technology is perceived has changed over the past two decades. The imperative to embrace medical technology during the 1960s and 1970s was gradually replaced by a growing suspicion within society toward "high-tech" health care. However, politicians and the public have an ambiguous attitude toward new technology. In general, they find innovations in the biomedical field fascinating and essential for health-care improvements, but they also consider these to be the major factor behind rising health-care costs. It has also become clear that not all new technologies bring about health improvements or show a reasonable balance between patient benefits and costs. Despite the expectations prompted by medical technology and the tremendous impact that new technologies have had on health-care practice and costs, Swedish policy makers have adopted a wait-and-see attitude toward the regulation of health technology and the use of health technology assessment (HTA). The introduction of new but ineffective technology, for example, hypothermia treatment of benign hyperplasia of the prostate and rapid introduction of laparoscopic cholecystectomy without any evidence of its risks and benefit, have resulted in a greater awareness among medical professionals of the need for more scientific evidence before the introduction of new health technologies into routine care.

On a different track, the need for greater openness in priority setting in health care has been highlighted. Between 1992 and 1995, a Swedish parliamentary committee investigated the role of explicit priorities in health care, and looked at which ethical principles should guide priority setting. In

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1993, the committee presented three major principles to be used within all types of health services (11). This so-called "ethical platform" was widely discussed in the political sphere, with some public involvement, and in 1997 resulted in changes in the core section of the Health Care Act. Although people in general are mostly unaware of the ethical platform, the three principles of (i) all people are equal in dignity and value, (ii) resource allocation on the basis of need, and (iii) taking into account cost-effectiveness, are relatively well-accepted among health-care workers. However, there is still great uncertainty, even among people who are working on the development of openly acknowledged priorities, about how to use these principles in practice. A subsequent parliamentary committee analyzed the future needs of health and social care, along with the financial resources available (12). This committee concluded that, without any financial or other interventions the gap between need and available resources would continue to increase. In particular, long-term care for elderly people provided by the municipalities needs additional financial support. These two parliamentary reports contributed to increasing awareness of the need for explicit priority setting.

This article describes the development of HTA in Sweden, the organizational structure for HTA, its influences on decision making, and its link with priority setting.

CHARACTERISTICS OF THE SWEDISH HEALTH-CARE SYSTEM

To understand the process of moving from the idea of HTA to its application in daily decision making and priority setting, one has to understand some of the characteristics of the Swedish health care system. One important feature of the system is decentralized decision making, and the powerful role of the county councils and municipalities. Another is the relatively strong involvement of locally elected politicians in the policy-making process. The county councils are responsible for meeting the health-care needs of their populations and for providing publicly financed health care. In doing this, they have a high degree of autonomy; for example, they are free to make decisions concerning major investments in facilities, new technologies, organizational structures, and user fees. The municipalities are responsible for long-term care for the elderly and social services.

Sweden has twenty-one county councils including three large regions—Stockholm county council, Skåne Region, and the West Region—with over 1.5 million inhabitants in each. The size of the county councils varies between 60,000 and 400,000 inhabitants. The Skåne Region and the West Region were established at the end of the 1990s through the merger of several smaller areas. The Swedish health-care system has been in a process of transition over the past 10 years, mainly because of perceptions that it was too rigid and had a low level of responsiveness toward patients. An important component of the reforms was the decentralization of power and greater public consultation.

The issue of providing greater choice for patients and the introduction of designated units for purchasing health care were given high political priority in the early 1990s. In practice, these and other changes have proceeded slowly and the objectives of the changes have not always been clear. However, the direction of the reforms has been clear—to strengthen the position of patients and the public. For example, a patient is free to choose any health-care provider in the country, without incurring extra charges, if the waiting time for a treatment is longer than a defined period.

Although the central government has decentralized power and responsibility for health care, it still attempts to control the general direction of the system through regulation, subsidies, evaluations, and guidelines. An example of the growing conflict of power between the central/national level and the region/local level was seen in the privatization of hospitals for acute care. During 2002, there was considerable political tension between the national Social Democratic Government and the county council in Stockholm, which until the election in September 2002, was governed by a conservative-liberal coalition. In the course of 2002, a new and temporary law was introduced to prohibit Stockholm County Council from implementing its hospital privatization plans.

Another example of the changing health-care sector concerns the distribution, regulation, and financing of pharmaceuticals. Sweden participates in the European regulatory system for pharmaceuticals. Furthermore, Sweden has its own agency for controlling pharmaceuticals, the Medical Products Agency (MPA). Before October 1, 2002, when new drugs were registered—after thorough scrutiny of efficacy and safety by the MPA—the National Social Insurance Board and the drug company in question agreed upon the price of the new medication. Once a price was established, as a rule, the drug was reimbursed through the social health insurance system. That a drug was generally reimbursed without any assessment of its clinical value or its cost-effectiveness has been criticized. Over the past 10 years, pharmaceutical costs have increased, on average, by 12 percent per year, which has resulted in drug costs as part of total health-care costs increasing from approximately 8 percent in 1990 to 15.4 percent in 2000 (16). In light of these escalating drug costs, the entire system of distribution, price negotiations, and their reimbursement has been the target of several inquiries. Substantial changes are already under way. One reform is the decentralization of the financing of drugs prescribed in ambulatory care. Since 1997, the county councils have gradually been taking over funding and expenditure responsibilities from central government. An agreement for the period 2002–2004 between the county councils and the Ministry of Health and Social Affairs makes the county councils responsible for meeting the costs of prescribed drugs in ambulatory care. The money the county councils will receive from the state will cover an annual cost increase of up to 5 percent. By way of comparison,

the average drug costs for the county councils were in 2002 8 percent and in 2003 2.3 percent higher than the previous year.

INTRODUCTION OF HEALTH TECHNOLOGY ASSESSMENT

The concept of HTA is complex. It is often difficult to exactly define a health technology and categorize it. HTA is sometimes defined as applied scientific or systematic knowledge aimed at improving our ability to prevent, diagnose, and cure health problems. This involves drugs, procedures, programs, and new settings. HTA is not defined by the methodology used but by its intention to support decision making. In textbooks, HTA is defined as a form of policy research that systematically examines short- and long-term consequences of the application of health technology, a set of related technologies, or a technology related issue. In HTA, the technology is analyzed from several perspectives and includes the ethical, social, and economic consequences of that technology. The most prominent part of HTA has been to determine cost-effectiveness to improve "value-for-money" in health care.

Early HTA Initiatives

Sweden was one of the first countries to assess health technology. In fact, one of the first technology assessments was a study of the computed tomography scanner carried out in the early 1970s. Even before this study, the National Board of Health and Welfare had asked selected physicians, prominent in their specialties, to evaluate medical technology. Over the past 15 years, this informal and opinion-based approach has slowly been replaced by more evidence-based approaches. An early initiative involving economic aspects of evaluation was undertaken by the Swedish Medical Research Council (MFR), through a cost-benefit study of polio vaccinations (10). Another early initiative to conduct an economic evaluation as part of the policy-making process was undertaken in 1980 by a government committee, which carried out a cost-benefit analysis of water fluoridation. MFR was also an early player in setting up a limited research program for HTA; it also produced a review on HTA methodology in 1984 (4) and together with the Swedish Institute for Health Services Development (Spri) began a series of consensus conferences on controversial technologies or health-care practices in 1982. This series continued for over twenty years.

Those who advocated the idea of HTA in the late 1970s were greatly influenced by the work of the U.S. Office of Technology Assessment (OTA). The broad policy-oriented definition of HTA and its methodology was imported to Sweden, with representatives from the United States involved in the process of selling the concept to key people at seminars and conferences. A proposal to establish a national center for stimulating and coordinating research on medical technologies was raised in Linköping in 1982. The idea was to establish a university-based national institute for health technology assessment. This initiative failed, in part, because it was not possible at that time to obtain any financial support from the national government. However, 2 years later, the local county council in Östergötland decided, together with Linköping University, to establish the Center for Medical Technology Assessment (CMT). The center's very first project was to conduct a comprehensive assessment of the shock wave lithotriptor used to treat kidney stones (6), and its research profile continues to focus on health economic evaluations, and the evaluation of rehabilitation technologies. Ongoing projects concentrate on the evaluation of screening programs, for example, for prostate cancer, abdominal aorta aneurysm, and cervical cancer, as well as procedures related to treatment of cardiovascular diseases. Collaboration with, and financial support from, the local health-care authority are still substantial. The center is a member of the international network for HTA agencies (INAHTA).

Another active research organization, which undertakes the economic evaluation of health technologies and organizational studies, is the Institute of Health Economics (IHE) in Lund. It is a nonprofit research organization established in 1979. Today, IHE is owned by Apoteket AB (The National Corporation of Swedish Pharmacies) and conducts health-economic evaluations and analyses in the following areas:

- Evaluation of pharmaceuticals and medical technology.
- Organization and financing of health care.
- The provision of pharmaceuticals.
- Health care in developing countries.
- Traffic safety and health.

IHE also organizes courses such as health economic seminars for drug formulary committees.

Two university-based organizations with strong profiles in health economics are the Centre for Health Economics at the Stockholm School of Economics (CHE), established in 1991, and the Centre for Health Economics (LUCHE) at Lund University, founded in 1998. The research at CHE not only includes health-care economics, but also the interaction between the environment and health and the effects of income and wealth distribution on health. The research program currently includes four main areas: analysis of health-care systems, economic evaluation of health-care technologies, pharmaceutical economics, and measurement and management of efficiency and quality in health-care provision. LUCHE was established to develop the university's research capacity in the field of health economics; as early as 1980 Lund University's health economists had taken the initiative to set up a Nordic study group in health economics and in 1982, a symposium was held on pharmaceutical economics. The creation of a special center provided the network of people in

the field of health economics with a stable organization that would enhance the development of health economics as an area of specialist knowledge at the university.

Establishment of SBU

In parallel with the planning of the university center in Linköping, a proposal was developed to set up a national agency for HTA. The Swedish Council on Technology Assessment in Health Care (SBU) was created in 1987 with the basic remit to continuously update the government and health-care providers with scientific information on the overall value of medical technologies. Some county councils have more formal links with the SBU and some finance local HTA units, for example in Östergötland and Stockholm. Recently, a formal agreement was established between the SBU, the National Board for Health and Welfare and the Medical Products Agency aimed at improving cooperation in the field of assessing health technologies, transforming results into guidelines and disseminating information. The SBU has actively supported international collaboration, and, since 1986, the secretariat of the International Network of Agencies for Health Technology Assessment (INAHTA) has been located at the SBU.

The Centre for Assessment of Medical Technology in Örebro (CAMTÖ) was set up in 1999 and is financed by Örebro County Council. Its purpose is to promote health technology assessment and evidence-based medicine at the local-regional level. The center works as a network of clinicians, experienced practitioners and qualified researchers under the management of a small committee. Experts from different fields, such as epidemiology, biostatistics, health economics, health policy, and nursing have been attached to the center, serving as consultants on study design, and disseminating information to the members of the network. Examples of the topics that have been assessed include:

- Evaluation of the outcome of changes in practices, such as a higher percentage of day care, check-ups by nurses instead of doctors, referring procedures from hospitals to primary care, etc.
- Assessment of differences in practice between different health-care providers at all levels.
- The impact of systematic reviews for clinical practices at the local level.

This type of center can conduct primary research, disseminate HTA results locally, and propose new projects to the SBU.

From a Technology-Oriented to a Health Problem-Oriented Approach

During its first 5 years, assessments by SBU were technology and service-oriented. The first technology assessment addressed preoperative testing in elective surgery. Follow-up surveys in 1990 and 1991—undertaken to evaluate the impact of the first report—showed a significant decrease in routine preoperative testing, which had been recommended by the SBU. Other early reports were on dental implants, gastroscopy, and extracorporeal shock wave lithotripsy. During the 1990s, systematic literature review methodology became the fundamental method at the SBU. Increasingly, the scope of assessment came to focus on important health problems in society (e.g., back pain), and the assessment then covered all relevant preventive, diagnostic, and treatment methods. In one recent report, the SBU analyzed a great number of methods used in the management of neck and back pain, including their economic consequences, and concluded that most of the back pain methods used in Sweden were found to be either ineffective or unproven. However, this type of review takes 3–4 years from its start to the published report, a time period considered by some critics to be too long in that there is a risk that policy makers will not have the time to wait for assessment reports. On the other hand, there is a certain value in having project groups (usually approximately 7–12 people representing the clinical and research community as well as economists, epidemiologists, and other professions), working together over a long period of time on HTA. Such collaboration involves a learning process as well as a process of creating advocates for evidence-based medicine. In fact, approximately 1,000 experts have participated in SBU assessments and have become ambassadors of the results, thus playing an important role in the dissemination of the findings. It is obvious, however, that there is a conflict between being comprehensive, transparent, and evidence-based and being timely and relevant. To tackle the problem of people with limited time not being able to read reports in their entirety, the SBU has put much effort into producing short summaries of report findings for particular target groups, including the public.

A New Technology-Oriented Early Warning Program

As a response to the problem of time delay, SBU Alert—a mechanism for early identification and assessment—was established in 1997. The demand came primarily from health-care politicians. Relevant policy-oriented information on evidence and potential consequences, provided at the right time, is meant to aid health policy makers in understanding more accurately the potential impact of new technologies and to optimize their diffusion and assessment (5). To achieve this, the SBU Alert program acts as a "bridge" between medical experts, on the one hand, and policy makers and the public, on the other. It does this by identifying relevant medical technologies and producing timely information on the scientific basis of the medical effects and potential consequences for health services. The SBU produces, in cooperation with medical experts, brief assessments, which are published on the Internet and then considered for revision. The SBU Alert advisory board is composed of medical experts and is involved

in assisting in the selection of new technologies to assess; supplementing the assessments undertaken by the medical expert consultants; and taking part in information dissemination. As of February 2004, sixty-two briefs have been published and another thirty technologies have been selected for assessment.

Other relevant Swedish organizations such as the Medical Product Agency, the National Board of Health and Welfare, and health-care providers are represented on the SBU Alert advisory board. Several similar initiatives to set up units for early warning have been undertaken in other countries, including the United Kingdom, The Netherlands, Canada, Spain, France, Denmark, Switzerland, Norway, and Israel. Together, they have established the international collaborative group, EuroScan.

Increasing Interest in Priority Setting

Increasing efficiency through HTA/evidence-based medicine is one approach to handling the growing gap between the demand for and the supply of resources. Another is explicit priority setting. The National Council on Care Policy (which is a forum for dialogue between the national government, the county councils and the municipalities on health-care issues) has initiated a national program for the development of priority setting. In January 2001, the National Centre for Priority Setting in Health Care was established in Linköping. The center's mission is to pursue and stimulate the theoretical and practical development of knowledge and methodologies for priority setting.

In addition to the activities run by the center, an increasing number of projects and trials to establish systems for explicit priority setting are under way in Sweden. Such activities are currently taking place at both the national level (e.g., the National Board of Health and Welfare and the Swedish Society of Medicine), and at the local-regional level (e.g., the Östergötland county council and the West Region [Västra Götalandregionen]).

CURRENT PRIORITIES OF HTA

As all forms of technology assessment take time and consume resources, it is necessary to prioritize and pick the most policy-relevant technologies for assessment. The aim should be to identify those assessments that will offer the greatest benefit in relation to their costs and thus to maximize the benefit derived from investments in HTA. In addition to the SBU, there are several other Swedish organizations engaged in HTA; however, this section focuses on the SBU as the leading HTA agency in Sweden.

As 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, the choice of topics to undergo HTA assessment is important but very difficult. Choice involves two distinct but inter-linked processes. One is to narrow down the number of possible options (filtration); the other is to decide which fields of interest or technologies should be considered for assessment (prioritization). Broad health issues that should be subject to systematic review by the SBU originate from the Swedish Parliament, the Government (Ministry of Health and Social affairs), and health-care organizations (e.g., the executive committee of a county council). The majority of proposals to assess health technologies come from individuals working in the health field.

The SBU Board prioritizes the majority of the extensive systematic review projects after an internal filtering process. In 1999, the internal priority setting process became more explicit and structured. It starts with internal and external scanning of fields of interest. A long list of topics is discussed among project coordinators and within SBU's executive committee. A short list of topics is then presented to the SBU Board, which ranks the proposals and selects some for pilot studies. SBU staff undertake a brief literature review to ascertain whether there are scientific studies to merit a full review. Based on the results of the pilot studies, the SBU Board makes the final decision based on the following selection criteria for new systematic reviews:

- There must exist sufficient scientific data in the field.
- The subject should have a significant impact on mortality and health.
- The subject must relate to a common health problem with large economic consequences for society.
- The subject may have ethical implications.
- The subject's perceived importance should be demonstrable from an organizational or professional perspective.
- The subject is either controversial or a cause of great concern in society.

Examples of currently selected projects are:

- Hearing impairment: hearing aids in rehabilitation.
- Methods for diagnosing, preventing, and treating periodontitis.
- Osteoporosis: prevention, diagnosis, and treatment.

The process for prioritizing technologies for early assessment within the Alert program is slightly different. New and emerging technologies are identified in the following ways: through scanning scientific sources, searching the EuroScan database for information from other early warning units and medical experts, and requests from medical professionals and policy makers. SBU staff vet the proposals and present a list of technologies at each advisory board meeting. The board decides which ones to pursue in accordance with SBU Alert criteria: a technology can be considered for assessment if it is new or emerging and has been tested on patients in clinical trials. The technology should also be expected to have significance for health services in one or several respects (5). The new or emerging technology:

- may have significant economic consequences,
- may have ethical implications,

- may significantly affect health-care organization,
- is expected to entail a considerable medical breakthrough, or
- concerns a relatively large group of patients or affects a common health problem.

COLLECTION AND EVALUATION OF EVIDENCE

The collection of evidence, of course, is very different if the evaluation is conducted as primary research or if it is based on a review of the published scientific literature, as in the case of assessments by the SBU. Due to limited space, this section is limited to comments on the type of HTAs undertaken by the SBU. At the start of each project, a working group is formed. This group decides on the criteria for the project before the literature review work begins. Quality criteria for selected studies could include, for example, a shortest acceptable time of follow up, a maximum accepted percentage of dropouts, and relevant end points. Each study that meets the basic criteria is reviewed by at least two members of the group and then classified into one of three quality levels. Each assessment must include health economic aspects (e.g., cost of illness or cost-effectiveness). In many projects during recent years, the criteria proposed by Drummond et al. have been used in reviews (8). There are examples where the economic aspects have had an impact on the recommendations (e.g., assessment of advanced home care). Social and ethical aspects are also discussed within assessments. For example, decision making dilemmas could arise when the expected benefit of a treatment has to be balanced with the risk of complications. A program for early detection of cancer or other serious diseases often involves several ethical problems. After the expert group has put together the results, a draft report is sent to members of a specially selected review board who review the document. It then goes on to the SBU Board and the Scientific Advisory Committee. The Board finally approves a summary and a list of recommendations. All of the details are presented in an extensive final report.

Early assessments in the Alert program have a narrower scope. As a rule, the work involves one external expert and one reviewer. On the other hand, SBU staff and its advisory board take part in every step of the assessment. The final assessment reports are published in a standardized format on the Internet (with an abstract in English). In addition to information on the new method, reports also discuss its effectiveness, risks, cost-effectiveness, associated ethical concerns and organizational impact. In each report an evaluation of current knowledge is presented and the SBU points out potential gaps in knowledge on new technologies which may become subject to future studies. A network of nearly 4,000 people working in the health-care sector receives information on new assessments and revisions by e-mail.

DISSEMINATION OF THE RESULTS AND THE IMPACT OF HTA IN THE DECISION-MAKING PROCESS

It is difficult to provide a comprehensive account of the actual use and impact of HTA studies in policy making and clinical decision making. Therefore, it will only be possible to present a few snapshots of the possible influence of evaluations.

Examples from the National Level

In Sweden, with its decentralized health-care system, the decision-making process on medical technology takes place on several levels. First, one can identify the central (national) and local levels. At the central level are several organizations (i.e., government, government agencies, professional federations, and associations) that use evaluations in their policy work and recommendations. The clearest example of where a review of medical data and cost-effectiveness has been used in the process of policy making is in the case of the National Board of Health and Welfare's national guidelines for the treatment of coronary heart conditions.

The Department of Health and Social Affairs is regularly briefed on the work produced by the SBU. All reports are also sent to key politicians and administrators in county councils, and often, local meetings are arranged as part of the implementation process. However, it is difficult to discern how this information is actually used in the political process. There are findings that show that the SBU reports on moderately elevated blood pressure, use of neuroleptics, stomach pain, smoking cessation, and preoperative routines have had an impact on clinical practice (3). SBU staff have actively spread results through conferences, lectures, and publications. A newsletter is produced and distributed free of charge and has a circulation of 100,000 copies. In 1996, the SBU, together with four county councils in northern Sweden, developed a structure of locally based informants. Similar initiatives have subsequently been undertaken in other parts of Sweden. The network has now grown to include thirty-five informants throughout the country. The Stockholm County Council, for example, has established a local "SBU" office. A survey of clinicians and policy makers in Sweden in 1997 shows that 72 percent of politicians and 78 percent of clinicians are familiar with at least one report from SBU, while 66 percent of politicians and 78 percent of doctors have found at least one SBU report useful (13). A study in three county councils on the implementation of four SBU studies shows examples of several local activities aiming at implementing the results of the reports (13). It also shows that the implementation of results in systematic reviews is extremely complex as the results are not always clear from a policy perspective.

The effect of HTA on coverage policy decisions was studied as part of the EUR-ASSESS project. The introduction and diffusion of invasive cardiology therapy (ICT)

was investigated in five countries including Sweden (2). In Sweden, several evaluations by national agencies were produced between 1983 and 1994. These were undertaken during a period of rapid expansion of by-pass surgery. For example, a consensus conference in 1983 led to improved discussions between doctors and policy makers and was used as a basis for policy decisions, while an expert opinion report in 1986 from the National Board of Health and Welfare resulted in an expansion of open-heart surgery. The EUR-ASSESS study concluded that, in Sweden and Catalonia, recent assessment studies have influenced coverage decisions for new ICT procedures.

Examples from the Local Level

On the local level, there are political, intermediate, and individual/clinical spheres. Politicians must decide 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. At the clinical level, priorities are set between individual patients and particular patient groups, respectively. However, in practice, the system is less well defined and more complicated than this account suggests.

At the local level, there are users of nationally produced assessments and guidelines. There are also other organizations, which produce assessments and local guidelines. Sometimes the national actors like the SBU communicate directly with individual clinicians, as in the case of the report on the treatment of mild and moderate hypertension. This report was used by individuals but was also used as a basis for work on local guidelines. One of the few examples where the politicians took account of scientific evaluation occurred in the case of Östergötland County Council, when they linked their decision on a contract with private chiropractors to the scientific evidence. The CMT at Linköping University was asked to investigate whether chiropractic care, as an alternative to physiotherapy in primary health care, is cost-effective. A randomized study was carried out comparing the costs and effectiveness in the treatment of back pain through chiropractic care or physiotherapy as the primary treatment. Before the study, politicians had agreed only to a short-term contract with the chiropractors and awaited the results from the trial before making a final decision. The results, which showed that no strategy was more cost-effective in all cases, were then reported in the scientific literature (14).

Assessment of Nonpharmaceutical Technologies

Compared with other countries, decision making on investments in expensive and complicated technology is more decentralized in Sweden. This makes the influence of HTA less obvious. Despite decentralized decision making, however, there is some evidence of the impact of the assessments that have been carried out. Examples include the introduction of "high-tech" procedures such as extracorporeal lithotripsy for kidney stones, heart transplantations, and liver transplantations. These technologies, together with four different prenatal screening tests, were investigated in terms of diffusion in a European study in the early 1990s. The aim of the project was to analyze factors affecting the diffusion of innovative medical technologies (17). The study indicates that evaluations in general have had a minor role in decision making, although in Sweden, the most thorough evaluation of lithotripsy did have a clear impact on decision making (7). For transplantations, several governments as well as professional groups were willing to support the need for assessment: "The effects of the results on policies and the diffusion pattern are less easy to determine, but certainly seem to have been influential in The Netherlands and Sweden" (17).

Impact of Economic Studies

A field of increasing interest in Sweden is the introduction of new drugs. All county councils have at least one drug committee. These committees are now expected not only to consider effectiveness but also economic aspects in their recommendations. However, committees have few resources for research of their own and are dependent on other parties instead. In 1998, the Swedish Institute for Health Economics investigated attitudes toward using health economic information as a basis for their recommendations (1). The most important sources were reports from the SBU, articles in scientific journals, and recommendations from the Medical Product Agency, in that order. The most important decision criteria for the committees were (i) the therapeutic effect, (ii) the relationship between effect and costs, (iii) the relationship between effect and side effects. A 1997 review article by Jönsson on the economic evaluation of medical technologies in Sweden concluded that cost-effectiveness studies have had a limited impact on the outcomes of decisions: "This is hardly surprising since methodology and data for such studies have only recently been available and efficient use of resources just recently has risen to the top of the health policy agenda" (9). Attitudes to economic information have been investigated by Jönsson and Karlsson in a survey of 600 randomly selected decision makers in Swedish health care, of which, 70 were administrators, 70 were politicians, and the remainder were doctors in leading positions (Unpublished data, 2002). Sixty percent of those surveyed responded and 23 percent of the respondents have used economic evaluations in decision making. Over 90 percent of the respondents agree that economic aspects should influence clinical practice to some, or to a large, extent. The impact of two well-known health economic evaluations was investigated. The so-called 4-S study of cholesterol lowering was known by 47 percent of respondents, while the SBU report on hypertension treatment was known by 50 percent. Those who were familiar with these two

studies found measures on cost-effectiveness more relevant than cost-impact.

Integration of Cost-Effectiveness Information in Priority Setting

The National Board for Health and Welfare has initiated several projects on priority setting. The aim of one of the projects is to produce guidelines on heart diseases for the county councils to support local discussions on the allocation of resources and on clinical recommendations. These guidelines will include a ranked list of established health-care activities. Preliminary work in line with this plan was published in 2001 on coronary heart diseases (15). Data on cost-effectiveness played a clear role in these discussions and probably affected the outcome of the prioritization process. More comprehensive national guidelines, including priority setting for all heart-related conditions, were published during 2003. These were followed by guidelines on vertical priority setting on chronic obstructive lung disease and asthma and on venous thrombosis.

Besides this type of limited trial of explicit prioritization, not very much has happened in practice—with one exception. The drastic escalating cost of new drugs during the 1990s has, for the first time, drawn political attention to new technologies, and action is now being taken to increase the role of health economic evaluation in priority setting and decision making concerning drugs. In view of this, the Swedish Parliament passed a law in April 2002 to establish a new government agency (Pharmaceutical Benefit Board) for negotiating prices and making decisions on the reimbursement of drugs. The new agency has been operating since October 1, 2002. In the directives from Parliament, it is clear that incremental effectiveness and cost-effectiveness must be central criteria in decisions concerning the reimbursement of drugs. The new agency is now responsible for both price negotiations and decisions about a drug's inclusion in the benefit package. The agency has a staff of approximately twenty people, including health economists, who also support a decision-making committee that contains people with broad competence and experience in health care. There are two health economists among the committee's eleven members as well as two patient/public representatives. The committee meets once a month and makes decisions that are independent of the Ministry of Health and Social Affairs. All new drugs will be assessed on their clinical relevance and cost-effectiveness, based on applications from pharmaceutical companies. The committee assesses all material presented by the pharmaceutical company in its application. All relevant aspects, such as the severity of the condition, evidence of effectiveness, cost-effectiveness, and price are considered. If the company is dissatisfied with the decision made, there is an appeal mechanism. After a preliminary decision is made, representatives from the company have the opportunity to present their arguments directly to the committee. If the company is still dissatisfied with the final decision, it can appeal to an independent court. The agency will also evaluate old drugs already on the market on the same basis as new ones. Given the large number of older drugs in existence, it is uncertain how long this retrospective assessment will take.

MAJOR ACTORS IN THE SWEDISH HEALTH-CARE SYSTEM

A health-care system is always in transition. This is particularly true when new fields of interest are established. In Sweden, there is a triangle of power between the central government with its agencies, the county councils, and the medical professional groups (Table 1). The development of HTA in Sweden has seen a strong and fruitful alliance between the state, particularly the SBU, and medical doctors. In recent years, more actors have become engaged in the field and HTA is also being used more in policy making. The establishment of the new agency for the reimbursement of drugs is one example. Still, there is an issue about how to establish mechanisms within counties to support the adoption and dissemination of HTA information. In addition, sometimes there is a strong need to adapt HTA results to local conditions. The increasing interest in open priority setting may also result in greater awareness of the need for better effectiveness and cost-effectiveness data on health-care interventions.

WAYS TO IMPROVE HTA IN SWEDEN

Several reforms over the past 5 years have changed the conditions for conducting HTAs. There is now greater interest in the clinical relevance and cost-effectiveness of new drugs. That relatively little has happened to control the use of technologies other than pharmaceuticals is surprising as Sweden picked up the idea of HTA quite early on. One explanation is the decentralization of decision making in the Swedish system. This makes it difficult to control the introduction of new technology, as every county council is free to take any decision irrespective of costs. This also makes it difficult to organize expensive assessments of particular technologies as county councils compete rather than collaborate when it comes to new, prestigious technologies. There is room here for national action as it is necessary to create sources for financing primary clinical research and HTAs. The expected diffusion of small pumps for the permanent treatment of heart failure is one example that will probably have a major impact on health care in the future. There is a clear need for more collaboration and pooling of resources among county councils, government, and industry to be able to set up adequately large and comprehensive studies.

The introduction of the HTA concept dates back to the end of the 1970s. At that time, HTA was perceived as policy research. The approach was a systematic process by which

Table 1. Actors Involved in Health Technology Assessment (HTA) and Priority Setting in Sweden and Their Roles

Organizational level	HTA	Priority setting
Macro-level		
The Swedish Parliament	Sometimes takes initiatives to set up particular HTAs	Decides on basic principles for priority setting
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 some 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 (NBHW)	Produces national guidelines. Recent guidelines are based on systematic reviews made in collaboration with SBU	From 2002, priority setting recommendations are a vital part of national guidelines
SBU	Conducts comprehensive systematic reviews and produces brief assessments of new and emerging health technologies	No explicit role
Medical Product Agency	Approves marketing of new drugs based on efficacy data. Produces guidelines for drug prescription (workshop series)	No explicit role
LFN-Agency for pricing and reimbursement of drugs	Assessment of effectiveness, cost-effectiveness, and clinical relevance of new drugs	Drug reimbursement decisions
Federation of County Councils	Active actor in reforming the system for assessment and distribution of drugs. Supportive to regional and local HTA-related activities, particularly those related to drugs	Involved in production and implementation of national guidelines in collaboration with NBHW
The Swedish Medical Society	No explicit role	No formal role. Engaged in development of methods for open priority setting of health services engaging several medical specialities
Universities	Produce primary clinical research and primary HTA. Many researchers in medicine and other relevant disciplines are engaged in projects conducted by SBU and other national actors	No explicit role besides work on principles and development of methods
Other HTA org, e.g., consultants	Produce primary HTA	No explicit role
National patient organizations	Sometimes take initiative to establish and to some degree finance HTAs	Participate in formal decision-making processes as members of committees. Informal role as lobby groups
Meso-level		
County councils	Sometimes take initiatives establish HTAs. Setting up local HTA units (few examples). To a larger extent consumers of HTAs. Responsible for development of regional and local clinical guidelines	Responsible for financing and production of nearly all public health services. This involves a lot of implicit priority setting. Decide upon major investments in new medical technology. Development of open priority setting of health care is currently taking place in a few county councils
Local drug committees	Assessment of effectiveness and cost-effectiveness of drugs	Produce prescription recommendations for effective medical practice
Municipalities	No role today	Responsible for financing and production of long-term care for the elderly
Micro-level		
Clinicians	Take initiative to establish HTAs. Involved in studies. Increasingly consumers of HTA	Priority setting of individual patients. Engaged in development of clinical guidelines and moderate investments in new technology
Other professional groups	Take initiative to HTAs. Involved in studies. Increasingly consumers of HTA	Priority setting of individual patients

the direct and indirect consequences of a particular health technology were assessed. In the process, the researcher was concerned with the evaluation of safety, effectiveness, cost-effectiveness, and, where appropriate, the social, ethical, and legal impact of the application of health technology, a set of related technologies, or a technology related issue. The concept of evidence-based medicine came 15 years later, following similar lines but with more limited scope. It is

obvious that the idea of evidence-based medicine better fits the clinical sphere and has been rapidly accepted among broad groups of health professionals in Sweden. In practice, the assessments performed by the SBU over the past decade have been similar to those conducted by the Cochrane Collaboration network, with a focus on clinical effect. Additional information about economic, ethical, and social aspects has played a minor but increasing role in SBU recommendations.

The diffusion of evidence-based medicine thinking and the development of the methodology of the systematic review among clinicians and policy makers have been valuable for the development of HTA and priority setting in Sweden. However, it has become obvious that systematic reviews of existing literature have limitations from a policy-making perspective. Often decision makers need information that is not available in the international scientific literature (e.g., information that includes many more aspects and local considerations than are found in the literature). It is time to reinvent the concept of HTA and become more pragmatic; that is, to present the best available data for decision makers even if the data is based on local noncontrolled studies. At the same time, we must be aware of the conflict that exists for an HTA agency in playing a purely analytic descriptive role and playing a normative role. The problem is that policy recommendations involve value judgments, which are more or less in conflict with a strictly scientific approach to assessments. If the SBU and other HTA organizations adhere strictly to a medical and scientific-based approach, and limit their reports to information about the status of scientific knowledge, then the interest in these reports from clinicians will continue to be high but the interest from politicians will probably be low. An alternative might be to expand the interpretation of the results and focus more on complex issues such as priority setting and ethical concerns rather than just on clinical procedures. Perhaps it needs to be recognized that it is impossible to communicate across the spectrum of politicians, administrators, clinicians, and nurses with one product. Therefore, the result of the assessment must be adapted to the needs of the target group. When we communicate our results to policy makers we probably need to refer to both scientific and normative aspects of the assessment.

We also have reason to believe that more complex interventions such as health promotion activities, organizational changes, and the care of the elderly are sometimes difficult to study with methodologies used in clinical research. On the other hand, many of these interventions can be critically assessed in a more scientific way than they are today. But we have to be open to more pragmatic approaches and the methodology and criteria must be different from the assessment used on clinical procedures.

CONCLUSIONS

The Swedish system for health technology assessment has had some significant achievements. It has a well-established government body and local organizations for HTA, and the primary target groups for HTA results—policy makers and medical professional groups—are generally supportive of HTA. Still, we have few good examples that show that HTA has been used in a systematic way in policy making. Recent changes, such as the establishment of the new government agency for pharmaceutical reimbursement decisions, will certainly result in a greater impact of economic evaluations on priority setting and other types of policy making. Together with greater patient and public involvement in decision making, it seems inevitable that health technology assessment will play a much more important role in Sweden in the future.

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