**International Journal of Technology Assessment in Health Care**, **16:2** (2000), 560–575.


# HEALTH TECHNOLOGY ASSESSMENT IN SWEDEN

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Abstract

Sweden has a welfare system that is based on the fundamental principle that all citizens are entitled to good health and medical care, regardless of where they live or what their economic circumstances are. Health and medical care are considered to be public sector responsibilities. However, there is growing interest in establishing more private alternatives to public care. An important characteristic of the Swedish healthcare system is its decentralization, with a major role for county councils. County councils are now merging into larger administrative units (region). The whole Swedish system is in the process of reform, mainly because of perceptions that it was too rigid and had insufficient patient orientation. An important factor in the reforms is that power in the system will be even more decentralized and will have greater public input. This change is seen as calling for increased central follow-up and evaluation of matters such as social, ethical, and economic aspects. Although the state has decentralized control, it still attempts to control the general direction of the system through regulation, subsidy, recommendations, and guidelines. An important actor in the system is the Swedish Council on Technology Assessment in Health Care (SBU). SBU began in 1987 with assessments of health technologies, but its success has recently led policy makers to extend its coverage to dental care. Health technology assessment is increasingly visible to policy makers, who find it useful in decision making.

**Keywords:** Technology assessment, biomedical, Delivery of health care, Sweden

Sweden has a population of 8.8 million people who are concentrated mainly in the coastal regions and in the south. The country is relatively urban and highly industrialized. The Swedish rate of growth in gross national product (GNP) kept pace with the average of Organization for Economic Cooperation and Development (OECD) countries during the 1960s. After that it slowed and then became negative between 1990 and 1993, with a drop of 5%. In recent years, the Swedish economy has improved; 1998 was the first year since 1990 that Sweden has been able to diminish the state deficit. Unemployment was low for a long time, but rose to more than 8% of the total workforce in 1993 and still remains at that high level. In 1998 open unemployment (i.e., unemployed people who are not enrolled in educational programs for the unemployed or other special publicly financed programs) was 6.5% (19).

This article is an updated version of an earlier report on the role of health technology assessment in Sweden (8).

Swedes have one of the highest life expectancies in the world, closely following that of Japan and Iceland. Sweden also has the oldest population among countries in the OECD and has experienced a rapid change in the age structure. Presently, about 18% of the population is 65 years or older (17). The aging population is reflected in the high life expectancy and in the fact that the very elderly population is increasing faster than other age groups. Between 1990 and 1998 the proportion of people over age 80 increased by 17% (19).

Sweden is a constitutional monarchy in which central political power rests with an elected parliament. The 349 members of parliament are elected directly for 4-year terms by proportional representation. The government consists of ministries and about 100 central agencies. Local units of government are the county councils (*landsting*) and the nearly 300 municipalities. The county councils and municipalities have the right to levy local taxes to pay for health care and other public services. Members of the county councils and the municipalities are publicly elected every 4 years.

The responsibility for health care has rested almost completely with the county councils for the last 50 years. Since 1992, however, the municipalities have begun playing a more important role. At that time, responsibility for care of the elderly was transferred from the county councils to the municipalities. However, the county councils are still responsible for acute and geriatric care.

Several county councils in the south and southwest parts of Sweden have merged into larger administrative regions with the same responsibility as traditional county councils. This change to larger administrative regions will certainly affect the organization of healthcare delivery and the distribution of power in the system in the future.

## PRINCIPLES OF SWEDEN'S HEALTHCARE SYSTEM

The welfare policy in Sweden places a major emphasis on health and medical care, with the fundamental principle being that all citizens are entitled to good health and medical care, regardless of where they live or what their economic status is. Health and medical care are considered a public sector responsibility. About 80% of health services in Sweden are publicly financed, and about 20% of physicians' visits take place in private practice. Nearly all hospital care is provided in the public sector. Dental care is provided largely on a private basis.

National income tax is levied only on high income, and the marginal tax rate is about 55% at most. Local income tax is about 30%. Most goods and services are subject to a value-added tax. The high tax rate allows public financing of welfare benefits and health care, including outpatient and hospital services (except for some copayments), home care, long-term and nursing care, and all equipment and devices for the disabled. It also allows coverage of some of the costs of dental services and prescribed drugs. Above a certain ceiling, ambulatory care and prescribed drugs are free of charge.

The Health and Medical Services Act of 1983 completed a long period of formal decentralization, when the county councils were given further responsibility for the health of their inhabitants, including preventive care and rehabilitation. It should be noted that the authority of the county councils has long been limited in many ways. The central government has also attempted to influence the development and organization of the health service through subsidies to the county councils.

The county councils are organized in the Federation of County Councils (FCC). The FCC has a board made up of elected representatives and a central office in Stockholm. The organization handles negotiations with the national government on political and financial issues that affect relations between the national and regional level and the trade unions with respect to salaries and working conditions of healthcare personnel. The federation is not subordinated to the national government or to any of its administrative agencies.

Under the Health and Medical Services Act the county councils are required to promote the health of residents in their geographic areas and to offer the residents equal access to good medical care and medical transportation. The county councils plan the development and organization of all health services that are required to meet the needs of their populations. Healthcare legislation provides for the protection of the patient's integrity, including the right to be informed about one's state of health and the available investigative procedures and treatment options. It also includes special regulations aimed at protecting the patient's identity in file handling and in various registers.

Development of the present system of healthcare administration has been based on the understanding that the central government is responsible for most research and for physician education. For historical reasons, most education of other healthcare personnel has rested with local authorities. Today education of nurses and other professional groups has become integrated into the state universities.

## Central Administration

The central government is responsible for ensuring that the healthcare system develops efficiently and according to the overall objectives, and also in accordance with the goals and constraints of social welfare policy. The Ministry of Health and Social Affairs (*Socialdepartementet*) is concerned mainly with government matters such as legislation and guidelines for health care, social welfare services, and health insurance.

The actual work of implementing and administering the government's policy is entrusted to a number of central administrative agencies. It is their work to conduct assessments and to function as professional expert agencies. Under the Ministry of Health and Social Affairs are the National Board of Health and Welfare (*Socialstyrelsen*), the Medical Products Agency (*Läkemedelsverket*), the National Social Insurance Board (*Riksförsäkringsverket*), the National Institute of Public Health (*Folkhälsoinstitutet*), and the Swedish Council on Technology Assessment in Health Care (*Statens beredning för medicinsk utvärdering* [SBU]).

The National Board of Health and Welfare is the central supervising authority for health and social services. In addition to a central office, it has six regional units, all with the following well-defined tasks: supervision, follow-up, and evaluation of performance in all areas of health care. The National Board of Health and Welfare also serves as the center of knowledge in the field of social policy and as an expert body for the government. Control of professionals includes the educational system, various professional licensing procedures, and qualification regulations.

In 1992 the National Institute of Public Health was founded to promote healthy lifestyles in a broad sense. There are also units for health promotion activities in each county council. The institute also manages mass media programs to promote healthy lifestyles and prevent diseases, particularly those caused by smoking, AIDS, and alcohol abuse.

The Medical Products Agency is responsible for regulatory control of drugs and products closely related to drugs and drug information. The National Corporation of Swedish Pharmacies (*Apoteket AB*), owned by the national government, has the sole and exclusive right to retail drugs to the general public. The Swedish national health insurance system, state controlled and supervised by the National Insurance Board (*Riksförsäkringsverket*), is a financing instrument designed to compensate for socioeconomic inequality due to illness. The National Insurance Board is also responsible for price negotiations on pharmaceuticals.

## Healthcare Expenditure and Financing

Healthcare expenditure increased rapidly during the 1960s and 1970s, but the rate of increase was limited to about 1% to 2% during the 1980s. In the mid-1980s, when the economy

slowed, concerns were raised about the high cost of health care. Several times during the 1990s, national limits were placed on the autonomy of county councils to raise taxes.

Between 1993 and 1998 healthcare expenditures in fixed prices remained at the same level. Healthcare expenditure as a share of GNP diminished from 8.0% in 1993 to 7.4% in 1998 (21). In 1996 healthcare expenses in U.S. dollar purchasing power parities were $1,701 per capita in Sweden. This figure was higher than the expenditure in the United Kingdom (US $1,358) but much lower than that in the United States (US $3,926) (9).

During the last decade expenditures for drugs have on average increased about 12% per year, whereas expenditures for other service have decreased at the same magnitude. As a consequence, the number of healthcare employees in the public sector has declined from 425,000 full-time employees in 1988 to 271,000 in 1997 (21). However, the number of doctors and nurses has steadily increased. In 1997 there were 320 inhabitants per physician.

Patient fees represent about 3% of total revenues for public health care (21). Adult patients pay fees for each contact with the healthcare system. The fee is set by each county council and varies; for example, for general practitioner (GP) visits, 100–140 Swedish crowns (SEK) (US $13–18),[1] and for visits to specialists, SEK 120–250 (US $15–31) up to a total maximum expense of SEK 900 (US $113) within 1 year. Copayments are the same for everyone in the population except children, whose care is free. Likewise, prescribed pharmaceuticals are, with few exceptions, publicly reimbursed. Patients pay up to SEK 400 (US $50) out of pocket for the first prescription every 12 months. After an accumulated payment of 400 SEK, public funds pay an increasing share. The maximum annual patient payment for drugs is SEK 1,800 (US $226).

## Health Promotion, Primary Care, and Hospital Care

***Health Promotion and Prevention Activities.*** General preventive actions have been taken against factors such as poor eating habits, physical inactivity, tobacco smoking, alcohol and drug consumption, sexually transmitted diseases (including AIDS), the work environment, and pollution. High priority is given to maternal and child health care, and there are several programs for prevention of disease during pregnancy, childbirth, and early childhood. Several screening programs are offered for children and adults, and some of them, such as female screening programs for congenital diseases, breast cancer, and cervical cancer, and child screening programs for dental health, have a high rate of coverage.

For years, Sweden has tried to control alcohol abuse by restricting alcohol sales to special state-owned shops with limited shopping hours. However, this measure has not prevented alcohol abuse from becoming a problem in Sweden. Membership in the European Union (EU) has forced Swedish policy in this area to become more liberal. Today, rules against smoking indoors in public places and in the workplace—including hospitals—are common.

***Primary Care.*** Primary care districts have at least one local health center for outpatient care. There are about 900 health centers in Sweden (21). Care at these centers is provided by GPs, district nurses, and midwives, and, if needed, ambulatory care is provided in the patient's home. Most primary care districts also include a clinic for child and maternity health and offer mass screening and vaccination programs.

***Hospital Care.*** Nearly all inpatient care in Sweden is provided by about 80 public hospitals that are operated by the local governments (county councils). In 1998 there were 17 mostly small private hospitals for somatic care. Traditional county councils have governed an average population of 300,000 and usually have operated one specialized central county hospital with between 15 and 20 specialties, and one or more district county hospitals with at

least four specialties (internal medicine, surgery, radiology, and anesthesiology). However, the different county councils vary greatly in both size and structure (e.g., Stockholm County has nearly 2 million inhabitants and Gotland County has 57,000).

The county councils decide whether to adopt and invest in the new medical technology and equipment. However, diversity in the structure and organization of health services in different parts of Sweden has increased in recent years. In theory, the hospital tiers provide a clear hierarchy for acquisition of sophisticated new technologies. The regional hospitals are supposed to be the first to acquire a new technology, followed by the lower tiers. At each tier, a service is provided only if the population base is sufficient. Rare procedures are, in the best-case scenario, consolidated since greater experience with such procedures by medical practitioners yields better outcomes.

In some cases, the county councils' freedom of choice for patients is constrained by cooperative agreements with other county councils to provide specialized services on a regional basis. The objective of the regional system of medical services is to ensure that specific types of services are delivered at a level where they can be most efficiently provided. In all regions, the university hospital—staffed in part by the medical faculty of the university—is also the regional hospital and is responsible for highly specialized care in the region. Sweden is divided into six healthcare regions, each of which has a population of 1–2 million and is made up of two to six counties that share one or more regional hospitals that are affiliated with a medical school and function as research and teaching hospitals. Specialized services, including neurology, radiation therapy, thoracic surgery, neurosurgery, and certain types of cardiac care as well as some highly specialized services, are provided on an interregional basis (e.g., kidney transplantation is regulated by agreements among the local governments).

## Weakness in the Swedish Healthcare System

Fifteen years ago, the healthcare system in Sweden was generally considered to be rigid and characterized by long waiting times and inadequate focus on the patient. The system has improved since then, but, although new reforms are under way, waiting lists still exist. However, public confidence in the healthcare system is relatively high. A recent study showed that about 75% of the population support allocation of a greater proportion of taxes to health care (21).

The most frequently discussed weaknesses of the Swedish health services are:

- Lack of resources to care for the elderly.
- Lack of integration—despite recent reforms—between health services, social services, and health insurance (particularly sickness benefits, early retirement pensions, and occupational injury insurance), and, within the health sector, between primary care and hospital care.
- Traditional emphasis on institutional care, which may not always be effective and efficient. This emphasis has changed substantially during the past 10 years. Between 1989 and 1998, hospital beds were reduced by about 50% (19).
- Limited choices available to patients. This situation has improved, as patients are free to seek care outside the county council where they live. In practice, most people are unaware of their rights.
- Insufficient incentives for health personnel to improve productivity and efficiency in the health sector. Physician salaries and working hours are relatively low in Sweden.

The demand for health services is steadily increasing because of the growing number of elderly and of biomedical advances that allow treatment of previously untreatable conditions. These factors, together with demands for restraints on public spending, encourage further reforms.

### Reform Proposals and Implementation

In the early 1990s, a political consensus emerged to reform health services. The changes were guided by reappraising activities and were to include reallocation of responsibilities and freer market mechanisms (e.g., more competition, less bureaucracy, and more freedom of choice for users). Efforts were made to better define responsibilities, with agreements on how money should flow within the system and how patients should be cared for. Many of the new procedures that are being tested originated in the United Kingdom.

In the early 1990s, the county councils of Bohus, Dalarna, and Stockholm restructured their organizations to separate the provider and purchaser roles. In the new system, patients may choose freely among primary care centers, physicians, and hospitals, even across administrative borders. The idea was to introduce an "internal market," based on a "buy and sell" situation, to generate competition in line with the theory of incentives for improving productivity and efficiency. While the idea of introducing business concepts into health care may have sounded attractive in theory, in reality substantial problems arose, such as in caring for elderly people with a mix of somatic and social problems. The process of organizing and structuring responsibilities around these new concepts has slowed. However, today a major part of the health service has a purchaser-provider type of organization.

It is assumed that this new situation, with even further decentralization of power, creates greater demands for central follow-up and evaluation, with an emphasis on the cost-effectiveness of services. The new approach will also include tracking and evaluating the degree of goal achievement, and comparing inputs, expenditures, and results in different places and for different forms of activities, such as observing and evaluating the content and quality of activities. Quality assessment and quality assurance have become important tasks and explicit responsibilities for health professionals.

### Role of the Public in Swedish Health Care

In theory, a clear link exists between the election of public officials, the magnitude of local taxes, and the accessibility of medical services. In practice, few channels exist for citizens to directly influence health policy.

As patients, Swedish citizens pay little for health services. Hence, fees are a weak mechanism for limiting the demand for health services. A constraint on demand in the Swedish healthcare system, as in all systems, is that patients are sometimes forced to wait simply because the supply of services is insufficient. However, waiting times fell significantly between 1991 and 1993, due in part to an explicit decision by the government to guarantee access to services in another hospital or a private hospital to patients with certain conditions who had waited longer than 3 months (20). The services covered by this agreement included surgery for coronary artery disease, hip joint and knee joint replacement, cataract surgery, gallstone surgery, hernia surgery, surgery for prolapsed uterus, treatment for incontinence, and hearing aid tests. The consequence was an increase in the number of surgical operations such as hip and knee joint replacement, cataract removal, and coronary artery graft. At the end of the year in 1993 and 1994, only about 3,500 patients had waited longer than 3 months for one of these procedures. The waiting time for these same conditions is once again increasing. In 1996–97 about 13,000 patients had waited longer than 3 months for one of the selected procedures (21).

## MECHANISMS TO CONTROL HEALTH TECHNOLOGY AND IMPROVE EFFICIENCY

### Research Policies

As already noted, the central government is explicitly responsible for research and higher education. Nonetheless, some county councils, especially those connected with university

hospitals, also support research activities, particularly those aimed at improving the content and quality of services. Some local governments therefore have special research funds or personnel paid from the health budget for the purpose of assisting in research projects.

For many years, all academic activity was consolidated at the university hospitals, with their specialized wards and large outpatient departments. During the past decade, all universities have gradually focused more on primary care and health promotion. Several initiatives have been taken to develop interdisciplinary schools of public health.

The other important organizations supporting research in Sweden are the national research councils. The Medical Research Council (MRC) is the most important source of resources for medical research and for initiatives regarding government research policies. Most research funding from the MRC goes to the universities' preclinical departments, but some is allocated to clinical departments, primary care, and social medicine. During the past decade, the MRC has appointed special committees for health services research and technology assessment to stimulate such activities. Several large private foundations also support clinical research.

Sweden also has had an active pharmaceutical industry that invests heavily in health-related research. In 1980, the combined result of this industry's investment put Sweden in second place in terms of proportion of gross domestic product, behind Switzerland but considerably ahead of Germany, which was in third place (18). In 1993 approximately 50% of health-related research was financed by public sources and the other 50% was financed by industry.

Sweden also has explicit policies, as noted earlier, to encourage clinical research that can improve Swedish health services. The development of a national agency for health technology assessment (HTA) is one example. However, there is an increasing concern that clinically oriented research, which is supported by clinical activities, is losing financial support under the healthcare reforms. This problem was noted by the Swedish Parliament. An addition to the Health and Medical Services Act a few years ago expanded the research and development responsibilities of the county councils.

## Policies Toward Education and Employment of Medical Personnel

National policy in Sweden has for many years aimed at increasing the number of Swedish physicians. This policy has certainly been the case for primary care physicians, while positions for specialists trained in the use of technology-intensive methods have been relatively limited. Earlier, the National Board of Health and Welfare allocated medical posts, and this procedure largely determined where physicians worked. The board determined the number of positions in the different specialties throughout the system. This practice not only served to control health technology but also helped assure access to medical service for the entire population.

This policy has changed, and the county councils are now responsible for determining the number of positions available for doctors. Since the total volume of physicians is regulated by the number of people in medical training, which is still decided by the central government, the county councils clearly face limitations in this respect.

A similar system is applied to nurses. In Sweden, nurses comprise a greater proportion of hospital staffs than in most other countries. Trained at a high level, they perform a variety of tasks that, in other countries, would ordinarily be reserved for physicians.

## Regulation and Control of Pharmaceuticals

As a full member of the EU, Sweden participates in the European regulatory system for pharmaceuticals. Furthermore, Sweden has its own agency to control pharmaceuticals, the Medical Products Agency, which became an independent body in 1990. This

agency has a reputation for high scientific competence and reliability. When new drugs are registered—after thorough scrutiny of efficacy and safety by the European Medicines Evaluation Agency (EMEA)—the price of the new medication is agreed upon between the state (*Riksförsäkringsverket*) and the provider of the drug. The drug is then sold through the state monopoly (*Apoteket AB*), usually based on a prescription from a physician. The entire system of price negotiations for new drugs and their reimbursement is being studied, and changes are expected in the near future.

There are a few large pharmaceutical enterprises in Sweden. About 60% of drug sales in 1994 were produced by international companies.[2] Swedish companies are, however, quite successful and have considerable presence in the international pharmaceutical marketplace. Mergers of the Swedish company Pharmacia with Upjohn and of the Swedish company ASTRA with Zeneca reflect this presence. Part of their success is due to the unusually favorable level of cooperation in clinical research between the universities and industry. Sweden's population-based healthcare system and the keen interest in clinical research aimed at new therapeutic opportunities have stimulated international pharmaceutical companies to conduct early clinical trials in Sweden. Since the early 1980s, agreements between the pharmaceutical industry and the Federation of County Councils have set rules for conducting clinical studies. The agreements have been important in terms of financing clinical trials, ensuring patient safety, and improving the image of the pharmaceutical industry.

Over the past 10 years, pharmaceutical costs have increased by an average of 12% per year. This increase is due primarily to converting to new, more expensive drugs and only secondarily to increased volume and higher prices. A reformed reimbursement system is already in place. Certain drugs are subsidized only up to the price for the least expensive equivalent drug on the market. Despite resistance from patient organizations and the pharmaceutical industry, the experience is mostly positive. An even more important reform is decentralization of responsibility for financing of drugs prescribed in ambulatory care. Since 1997, the county councils have been gradually taking over the funds and the costs from the central government. From an economic incentive perspective, drugs are viewed as equal to other technologies. During coming years, cost containment and cost-effectiveness of drugs will be a major issue among physicians and healthcare managers in Sweden.

## Regulation of Medical Devices

In comparison to pharmaceuticals, medical devices have been much less regulated. Except for legislation to control sterilized disposables, electrical safety of some medical devices, and radiation safety, Sweden has had few legal rules to control the diffusion and use of medical devices. Until 1976, the main responsibility for this task rested with health personnel.

Legislation in effect since 1993 gives industry the main responsibility for "safe and appropriate" medical devices. The National Board of Health and Welfare supervised the implementation of this legislation, which was part of a general harmonization of Sweden's rules with the policies of the EU. This new legislation requires manufacturers of medical devices to report malfunctions, which enables the National Board of Health and Welfare to request technical alterations or stop the use of such devices. Sweden has participated in the development of the EU's new program on medical device regulation. This program presents a challenge for the many small manufacturers of medical devices. In the future, we expect more technology assessment of emerging medical devices.

## Systems for Quality Assurance

Policy makers in Sweden have become increasingly aware of the fact that the quality of services must be assured. Several organizations, including The Swedish Institute for Health Services Development (*Hälso-och sjukvårdens utvecklingsinstitut* [Spri]), have been active

in this field. The National Board for Health and Welfare introduced a special directive for this purpose in 1993. An extended directive followed in 1996. In addition, some of the reforms being implemented in health care include financing conditions whereby the producers of care must demonstrate the quality of the services provided and purchasers must specify their demands for services.

Today, quality indicators for some medical specialties are available. Their objective is to encourage departments to continuously monitor their own performance. Quality committees are established in most hospitals and work with different systems for quality improvement, such as Total Quality Management, which includes questionnaires to assess patient satisfaction.

National quality registers are well established in Sweden, with about 40 registers covering a range of specialties (5). These registers are financed by the central government but are run locally by professional groups.

## ASSESSMENT OF HEALTHCARE TECHNOLOGY

Although the state has decentralized the provision of health care, it attempts to control the general direction of the system through regulations, subsidies, recommendations, and guidelines, such as general guidelines on prioritization. The National Board of Health and Welfare and the Federation of County Councils, along with medical experts, are producing national guidelines for common diseases that are based on documents describing the state of the art, systematic reviews, and consensus conclusions. The first national guideline addressed diabetes. The major national organizations increase access to relevant information on healthcare issues by displaying information on the Internet.

Sweden was one of the first countries to become involved in assessing health technology (8). In fact, one of the first technology assessments was a study of the computed tomography (CT) scanner carried out in the early 1970s. Even before this study, the National Board of Health and Welfare asked selected physicians prominent in their specialties to evaluate technology to determine whether it was consistent with proven scientific knowledge and good clinical experience. This informal and expert opinion-based approach has been superseded over the past 15 years by formal HTAs.

### Development of the Swedish Council on Technology Assessment in Health Care

The Swedish Council on Technology Assessment in Health Care (SBU) was created in 1987. Its basic purpose was to continuously provide the central government and healthcare providers with up-to-date scientific information on the overall value of medical technologies, and especially new technologies. Cost containment was never the primary objective. The government did not wish to slow the introduction of new medical advancements. Rather, the goal was to improve efficiency and equity: "...all patients needing care should have access to technology which has proven its safety and efficacy" (3).

SBU is charged with assessing important technologies, and serves as a focal point and coordinating body for HTA activities in Sweden. The desired outcomes involve changing healthcare policies and practices in constructive directions. The SBU Board includes representatives from the key organizations in health care. A special independent evaluation of SBU's activities, required by the central government after the initial years of operation, suggested that it would be beneficial to formally establish SBU as a national agency. The government accepted this recommendation, and the demand for systematic reviews and other HTA activities has since increased substantially. SBU started in 1992 with a budget of SEK 12 million (US $1.5 million), and by 1999 the budget had increased to about SEK 37 million (US $4.6 million).

## Other HTA Activities in Sweden

Consensus conferences have been organized in Sweden since 1982, and have followed the model developed at the National Institutes of Health (NIH) in the United States. A conference on total hip replacement was held a few months after an NIH conference on the same subject. By 1997 the MRC and Spri had organized approximately 20 consensus conferences on a wide range of subjects. Although the Swedish conferences closely follow the NIH format, they differ in scope. In addition to focusing on the safety and efficacy of technology, the Swedish conferences also address issues related to healthcare organization, cost-effectiveness, and social and ethical considerations.

The Swedish consensus conference program was evaluated in 1985–86. Separate reports described how the consensus statements have reached and been received by physicians (7), politicians, and administrators (1). More than half the politicians and administrators indicated that they had found the statements from one or more conferences to be of practical value. In some cases, the consensus statements directly affected political decisions. Awareness of the statements was high among physicians, but only about 10% stated that a consensus statement had changed their clinical practice.

Spri was involved early in technology assessment, particularly through studies on CT scanning (22). Spri gradually developed a more comprehensive program on technology assessment when SBU was established. In 1999 the Swedish government decided to discontinue Spri.

The Institute for Health Economy (IHE), located in Lund, was established in the mid-1970s. It carries out economic evaluations and other economic analyses. IHE is owned by Apoteket AB. It has an independent role and is partially financed by research funds. Another important HTA organization is the Center for Health Economics at the Stockholm School of Economics. The center is well respected internationally. In addition to their academic courses and research, the center's staff has been engaged in several projects at, for example, SBU, and organizes courses on administration and health economics for health managers, clinicians, and administrators.

The Center for Medical Technology Assessment (CMT) was established in 1984 as an independent research institute at Linköping University, with financial support from the Östergötland County Council (the local healthcare provider). Its objective is to carry out assessment studies of medical technologies from the medical, social, economic, and ethical points of view. CMT activities consist of applied research sponsored by healthcare providers, basic research funded mainly by national research foundations, and projects externally commissioned by commercial clients. The medical technology addressed at CMT comprises preventive programs, pharmaceuticals, medical devices and procedures, and rehabilitation and habilitation technologies. CMT's budget is approximately SEK 8 million (US $1 million). It has produced a series of nearly 100 reports since its inception. Projects at CMT have resulted in several dissertations in the field of HTA.

## Identifying HTA Priorities at SBU

SBU submits to the national government an annual report that contains a review of work accomplished, plans for the future, and statements about the impact of the work. The Ministry of Health and Social Affairs notifies SBU each year about government objectives in conjunction with the upcoming year's budget. At times, this has meant that SBU studies a topic that has been discussed in the Swedish Parliament (for instance, surgery for epilepsy, the use of neuroleptics, and electronic monitoring during pregnancy).

The SBU Board has defined priorities for selecting topics to investigate:

- Methods used for the investigation and treatment of many patients;

- Expensive technologies, especially if they are of doubtful value;
- Emerging technologies that may profoundly alter routines; and
- Obsolete methods still in extensive use.

Priorities are set at SBU via discussions by the board and the Scientific Advisory Committee. Continuous contact is also maintained with other relevant bodies in Sweden. An important prerequisite for a new project is that there should be enough scientific literature to evaluate. A preliminary literature search and a search of other sources are performed (e.g., the Cochrane database and INAHTA files). The SBU Board makes the final decision and appoints a chairman and members for the project group.

## Selected SBU Projects

SBU's studies are not merely assessments of medical evidence; they also analyze relevant factors in Swedish society and evaluate the context and the technology from several standpoints, including social and economic aspects. Several SBU reports discuss assessment problems and propose methods to solve them (6;10). SBU has also published a report recommending priorities for assessment (11). Systematic literature reviews are the fundamental methods used at SBU. Close contact is maintained with the Cochrane Collaboration.

The first technology assessment addressed preoperative testing in elective surgery (12). The study team reviewed the literature and found little justification for routine use of preoperative x-rays, electrocardiograms, and laboratory tests. A survey of practice revealed considerable variations: some hospital departments always performed such tests, while others never did. An economic analysis showed that the cost of preoperative investigations in Sweden totaled SEK 726 million (US $91 million). SBU recommended that preoperative routines not be used in the absence of specific indications. An extensive "marketing" effort was used to convince surgeons and anesthesiologists to follow this recommendation. Follow-up surveys in 1990 and 1991 to evaluate the impact of the report showed a significant decrease in routine preoperative testing. The actual savings in economic terms, besides the increase in quality of care, was SEK 50 million (US $6.25 million) per year, or five times the annual budget of SBU at the time.

Another full-scale assessment addressed the problem of back pain (13). The report analyzed back pain, including its economic consequences in Sweden. The literature was reviewed to determine the efficacy of commonly used treatments. Most of those in use in Sweden were found to be either ineffective or of unproven effectiveness. An important finding was the impact of early movement and rehabilitation on the patient's recovery. In addition, back pain was examined from the standpoint of working conditions. Back problems were found to be related to both physical and psychosocial conditions. The report recommended a cautious approach to diagnosis and treatment and further research on the efficacy of proposed technologies. It also recommended systematic approaches to studying working conditions to reduce the problem of back pain in Swedish society. This report was widely disseminated and led to a renewed discussion on back pain throughout Sweden. An updated report on methods used to treat back pain will be published in 2000.

Another example of SBU's work is the thorough evaluation of treatment for mild to moderate hypertension, for which some patients are overtreated and some are undertreated (15). Although many expert committees have formulated recommendations concerning this condition, the earlier literature reviews did not critically appraise treatment outcomes in relation to the resources needed by different types of patients.

A major study completed in 1996 concerned the rationale for using radiotherapy for cancer (16). A group of oncological specialists and economists evaluated the voluminous literature on efficacy and cost-effectiveness. In addition, an extensive survey was carried out

to document the use of radiotherapy. The study showed that the practice of radiotherapy in Sweden was in accordance with findings presented in the scientific literature. Future studies should assess various treatment methods and examine the impact on patients' quality of life and well-being.

The SBU studies on the appropriateness of coronary artery bypass graft (CABG) surgery in Sweden, using methods developed by the Rand Corporation, found, for example, that rates of appropriate use are high. Other SBU reports have addressed stroke (1992), percutaneous transluminal coronary angioplasty (1992), magnetic resonance imaging (1992), early detection of diabetic retinopathy (1993), traffic accidents (1994), mass screening for prostate cancer (1995), bone density measurement (1995), estrogen treatment (1996), the scientific basis of prevention, including the role of vitamins (1997), community intervention programs (1998), and home care (1999).

In response to the increasing number of questions concerning the benefits of psychiatric care, SBU started to review psychiatric procedures in Sweden by identifying those that needed evaluation (14). The first report on the use of neuroleptic drugs was published in 1997. It concluded that neuroleptics are useful for treating schizophrenia and schizophrenia-like conditions. However, neuroleptic therapy is frequently accompanied by serious, sometimes permanent, side effects. In Sweden, neuroleptics are frequently prescribed for indications not supported by scientific evidence of patient benefit. Furthermore, high doses are often prescribed, although the effects achieved have not been shown to be better than when standard doses are used. New, more expensive drugs have also been increasingly used despite a lack of evidence of their superior effects or milder side effects.

Since its inception, SBU has published about 50 reports. In 2000, about 20 projects are in progress. Every project involves 10 to 15 people. Each project takes 2 to 3 years to complete. There are usually two or three SBU staff members in the project group; the remainder are physicians and other healthcare workers, health economists, administrators, and usually one layperson. Early in the process, the project group participates in a 2-day seminar on critical evaluation of the scientific literature and the principles of an SBU project. Later the group has several seminars on quality criteria and findings.

In addition, each year SBU arranges at least three or four major conferences that introduce or conclude new projects. The agency also organizes courses, seminars, and lectures by foreign experts. Since October 1996, the secretariat of the International Network of Agencies for Health Technology Assessment (INAHTA) has been located at SBU.

Apart from the abovementioned activities, SBU is now establishing a system for early warning of emerging health technologies (2). An Internet-based information system called Alert is under development. The target group so far includes politicians, leading officials, and chief medical officers. Technologies that require organizational or structural changes or that may have far-reaching economic consequences should be of greatest interest to this group.

SBU aims, with support from other national organizations, to present its own evaluation of current knowledge and point out possible gaps in the knowledge regarding new technologies that may become subject to future studies. The main principle is that assessments of the technologies' consequences are made with reference to existing data, documented experience, and general considerations. Only in exceptional cases is there a question of collecting primary data.

SBU plans to cover 100–150 medical technologies in the database during the first 5 years. A panel of experts with broad experience in health care and nursing will examine and support SBU in its work to select relevant technologies and to make the consequence analyses. As of early 2000, about 25 assessment reports have been published. SBU already cooperates with corresponding national organizations within the INAHTA network. Several new units have also been established for the purpose of making early assessments of medical technology. SBU is a member of the international collaborative group Euro-Scan.

### Attitudes Toward HTA in Sweden

The growing visibility of healthcare evaluation, along with the work of SBU and others, has given the field of technology assessment in health care great visibility in Sweden among healthcare professionals, politicians, and the general public. The tremendous work of evaluation that needs to be done has become a continuing topic of discussion. Generally, the government is positive and supportive about the development of HTA in Sweden, and it has continually increased SBU's budget since SBU was established. Expectations may be inflated, since many politicians and administrators hope that effective HTA can improve efficiency and reduce healthcare costs.

County councils support HTA to a varying extent. They usually act through the Federation of County Councils to support studies locally, and they expect that results from such studies will influence local practices. Some councils have a more formal liaison with the SBU's central office. Others, like Östergötland, Örebro, and Skåne, support local HTA units.

The Swedish Medical Society and the Swedish Medical Association (which are both represented on the SBU Board) are very supportive of HTA activities. Other health professions (nurses are represented on the SBU Board) also support the idea of HTA. Surveys show that most physicians in Sweden are aware of SBU's existence.

### Efforts to Change Policy or Practice in Swedish Health Care

The aim of HTA in Sweden has been to influence the way health services are administered and delivered. Although it is a governmental agency, SBU does not have formal power to directly change practice. Its only means to promote change has been through education and dissemination of information. One important mechanism in this regard is the project groups themselves, which involve a number of key persons in Swedish health care.

Although implementation of the results of SBU assessments was not a primary goal when the agency was created, SBU disseminates its results through conferences, lectures, and publications. With the increasing number of projects, the SBU staff has not had sufficient time for this activity. The central government has emphasized that other governmental or private bodies must participate in this activity. Cooperation with professional bodies, administrators employed by the county councils, the media, and other interested parties is necessary. Such activities divert time and effort from the primary goal of assessment.

Nonetheless, SBU has taken steps to promote the dissemination of results. During the last 6 years, a newsletter with a circulation of 80,000 copies has been produced and distributed free of charge. It describes the results of current projects and contains interviews with project leaders, members of the SBU Board, and other key actors in the field. The international scope of HTA is emphasized. The newsletter also contains summaries of important studies recently published in large international medical journals that may be of interest in routine medical work.

The results of some SBU projects have been presented at regional conferences, arranged jointly by the health service's regional board and SBU. Special "ambassadors" have been appointed to promote the dissemination of project findings. The first SBU ambassadors were appointed in the north region, with the assistance of the local health administration. Now there are approximately 30 SBU ambassadors in different regions of the country. They are mainly clinicians who work part-time, meeting groups of doctors and administrators. They are furnished with material from SBU and take part in special educational programs.

## CONCLUSIONS

Sweden's approach to HTA is a result of its own history and culture. Health services play an important role in society as a whole. Although the fundamental objective of health services

is humanitarian, it is essential to view this sector and the technology it possesses from a broader perspective. Health services act within a structured balance of different societal sectors necessary to the development of the overall social safety net. Health services also play an important, but often neglected, role in the overall economic development of nations. From a societal perspective the health sector: a) represents a considerable share of society's resources; b) employs a relatively high proportion of the work force; c) constitutes the basis for industrial development of pharmaceuticals, medical equipment, and medical devices; and d) has a potential to grow out of control.

The volume of health services and their costs, effectiveness, and appropriate technology are therefore of critical importance not only to a health status of a population but also to the social and economic development of a nation. It is in this broader context that technology assessment in health care has evolved in general, and in Sweden in particular.

Despite a generally high level of public confidence in the Swedish health system, several major reforms took place during the 1990s. With services decentralized to the county and municipal levels, the public is increasingly involved in decision making in the system. One result, already discernible, is the people's growing interest in choosing a healthcare provider.

During the past decade, Sweden has gradually developed a greater commitment to HTA as part of healthcare reforms. At the time of an earlier review sponsored by the Office of Technology Assessment (4), no organization in Sweden was dedicated to the assessment of medical and healthcare technology. Currently, several well-established institutions, including SBU, are engaged in this activity for the purpose of improving health care. In addition, the importance of health services and clinical research is being recognized as a key activity for improving the quality of care. Pressure to support clinical research in Sweden came first from the technology assessment community, and additional support came from clinicians who were experiencing difficulties in financing clinical research as a result of cost cuts. Several initiatives were taken at the local level to strengthen support of clinical research.

The Swedish system for HTA, still under development, has had some significant achievements. It has a respected governmental body and local organizations for HTA. It has communicated the need for HTA to the medical profession. The primary target groups for HTA results—policy makers and clinicians—are generally supportive as long as they are reached by clear messages. A common issue concerns the development of national structures for implementing results from HTA, systematic reviews, and clinical research.

Technology assessment in health care was explicitly introduced in Sweden as an activity with two objectives: a) to speed up the diffusion and use of medical technologies with proven safety, efficacy, and effectiveness, so that there would be broad and equitable access to technology for every patient; and b) to monitor technologies that have not yet been scientifically assessed and/or whose policy implications in terms of costs or social and ethical aspects are not yet fully understood.

Based on experiences in Sweden, we conclude that successful assessments must meet the following requirements:

1. Policy makers and clinicians must have a strong awareness of and interest in HTA.
2. Data must be available about the technology in question, preferably from methodologically rigorous studies, and especially from randomized trials.
3. Systematic reviews must be done with a high degree of integrity. All related studies, including clinical and economic studies, must be identified and thoroughly and critically reviewed to reach credible conclusions. An essential part of this process is the committed involvement of expert professionals who are willing to interact continuously and to review results critically.
4. The results must be assessments that are scientifically and clinically credible and are presented in a logical manner.

5. Assessments must be presented in a manner and a language that make them easily accessible and understood by the medical profession, policy makers, and the general public.
6. Results must be timely and accompanied by clear-cut policy options or straightforward recommendations to clinical and/or policy decision makers.
7. Results must be accompanied by a strategy for strong and fairly long-lasting implementation efforts directed at target groups.

In terms of the impact of assessments, SBU has come to realize that implementing the results takes nearly as much effort as carrying out the assessment itself. Assessment results need to be "marketed" to both professionals and the public. The experience of HTA in Sweden shows that it is possible to identify technologies and assess them in a way and a time frame that can affect their adoption and use. However, SBU will increase its flexibility and timeliness by setting up the SBU Alert system and will take part in establishing an international network for scanning new health technologies.

Any technology assessment agency needs to assess its impact, not only to justify its expenditures but also to improve its own activities. An issue discussed in Sweden is that assessment results do not necessarily influence routine clinical practice. Better methods of disseminating assessment results are needed, in conjunction with methods of quality assurance.

HTA is increasingly visible to policy makers, who find it useful in decision making. The extension of HTA into psychiatric care and dental care is an indication of its growing acceptance. In view of growing patient choice, it seems inevitable that the public will become increasingly involved in healthcare decision making. In Sweden, the public already has, in principle, direct input into the level of expenditures on health care through its elected county councils. In practice, public involvement in policy processes and treatment decisions is low. We see growing interest in these issues, and HTA can be helpful in this development.

A general problem for HTA in Sweden, and elsewhere, is the large number of unevaluated technologies. Even if more funds were available, there is a limit to resources such as research sites and well-trained researchers in a small country like Sweden. This limit restricts the annual output. The only solution for Sweden is international collaboration and openness to HTA activities in other countries. While Sweden is ready to carry out its share of the work, it must cooperate with others in this task. For this reason, HTA in Sweden has become increasingly international in focus. Swedish experts participate in a variety of international activities and are attempting to contribute to the development of permanent international structures to share information and coordinate activities. SBU has taken an active part in the EUR-ASSESS and HTA-Europe projects. Currently SBU runs the EU-sponsored project to establish a European Collaboration Network on HTA. While many practical problems still need to be overcome, and international structures and cooperative networks are needed to be effective, international cooperation is considered a high priority in Sweden.

## NOTES

[1] 1 U.S. dollar = 8 Swedish crowns.

[2] After 1994 there are no statistics showing the distribution of drug sales by Swedish and international companies.

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