

HEALTH TECHNOLOGY ASSESSMENT AND SCREENING IN SWEDEN

Egon Jonsson

Swedish Council for Technology Assessment in Health Care (SBU)

H. David Banta

Netherlands Organization for Applied Scientific Research (TNO) and SBU

Tore Scherstén

SBU

Abstract

Objectives: To describe health technology assessment (HTA) and policies concerning three screening procedures in Sweden.

Methods: The main source of information was reports from the Swedish Council for Technology Assessment in Health Care (SBU) and other governmental reports, supplemented by the professional literature.

Results: Prevention is emphasized in the healthcare services of Sweden. Specifically, screening is encouraged and supported when it is deemed beneficial. Sweden has a strong orientation toward evidence-based health care and HTA. Since its inauguration in 1987, SBU has fostered the use of HTA in making policy and clinical decisions in Sweden. Government policy in Sweden is to encourage services that are beneficial and cost-effective and discourages services that are not. Screening is no exception to this general rule. The three cases examined in this paper—mammography screening, PSA screening, and routine ultrasound screening in pregnancy—have all been formally assessed in Sweden. Assessments have been an integral part of policy making concerning these and other preventive measures. Mammography screening has been widely implemented. However, as in other countries, screening is often carried out in an opportunistic fashion, so that PSA screening, in particular, is carried out more in Sweden than can be justified by the evidence.

Conclusions: Mammography screening is promoted and is completely available to the target group. PSA screening is discouraged, but not with complete success. Ultrasound in pregnancy is widely used, not because of good evidence of impact on mortality and morbidity among newborns, but because it increases the detection rate of congenitally malformed fetuses and because of evidence of positive effects on the management and planning of deliveries, as well as because of psychological and ethical implications of the technology. HTA is an important part of health policy making in Sweden.

Keywords: Health technology assessment, Screening, Mammography, PSA, Ultrasound in pregnancy

In this paper, the experiences of Sweden with mass screening are examined, using three cases: mammography screening for breast cancer, prostate-specific antigen (PSA) screening for prostate cancer, and routine ultrasound use in pregnancy. The aim of the paper is to elucidate the links between health policies (including policies toward prevention and screening) and health technology assessment (HTA).

THE HEALTHCARE SYSTEM OF SWEDEN

All Swedes are entitled to health and medical care. Health care is considered a public sector responsibility. The national health insurance system is a state-controlled and supervised financing instrument designed to create equity in health care. Hospitals are public and most physicians are employed in the publicly run hospitals and within the primary health services.

The Swedish healthcare system is decentralized. The state is responsible for ensuring that the system develops efficiently and according to overall objectives, in the context of the goals and constraints of social welfare policy (3). At the top level of the state system is the Ministry of Health and Social Security. At the second level are a number of relatively independent administrative agencies, including the National Board of Health and Welfare, the central supervising authority for health and social services. The central government has decreasing control over the organization of services, with a concentration of systems for follow-up and evaluation (17).

The healthcare system has several levels, the uppermost being the Federation of County Councils. The system has regional, county, and local levels. The seven regions, made up of about three counties each, share one or more regional hospitals. The counties generally have one highly specialized central hospital. The local level consists of primary care districts with at least one local healthcare center.

The hallmark of the Swedish healthcare system is its regionalized hospital system. The hospitals are operated by the county councils, so it is the counties that invest in new health technology and decide whether to adopt a new technology. In addition, the budgetary authority of the counties constrains the services offered by the hospitals. The regionalized system, with its four hospital tiers, provides a clear hierarchy for acquisition of sophisticated new technologies.

The county councils have the basic responsibility of paying for health services. Almost 80% of health services are financed by tax revenues (17). Nonetheless, patients pay directly for services, with subsidized levels of fees. There is also an annual limit of patient costs. Since the 1990s, the financial resources in the Swedish health services have been shrinking. In real terms, expenditure reductions of almost 10% have been achieved. The emphasis during this period has been on better use of available resources.

POLICIES TOWARD HTA IN SWEDEN

Sweden was one of the first countries to become engaged in HTA, and it was the first country in Europe to have a national program for HTA. The Swedish Council for Technology Assessment in Health Care (SBU) was established in 1987. SBU was envisioned as an organization that would both assess important technologies and serve as a coordinating body for activities in Sweden.

Unlike some other HTA programs, SBU depends on researchers and specialists working in the health services to carry out its assessments, assuring contact with problems encountered in the daily routine of medical services and encouraging use of the results of assessment throughout the system. Indeed, HTA has achieved a high degree of acceptance in Swedish health care. One could truly say that Sweden is developing a "culture of assessment." HTA is increasingly valued by policy makers (including members of Parliament), clinicians, and even the general public.

SWEDISH POLICIES TOWARD PREVENTION

Prevention is emphasized in the Swedish healthcare services, and such emphasis is increasing. The emphasis extends from the central government, which evaluates the outcome of

services, through the county councils, which have the responsibility of striving to achieve a good standard of health in the population, to the primary care level (17).

Prevention has a long tradition in Sweden. Primary prevention, along with elements of organized or opportunistic screening (e.g., to lower maternal/child mortality or to prevent tuberculosis), were frequent and forceful features of the healthcare system in the 19th century. In the 20th century several prevention programs (e.g., for polio, caries, and accidents to children and at work sites) were introduced and extended to more or less formal screening activities. During the last 50 years, numerous screening programs for prevention of disease have been introduced, although few of these may be defined as mass screening of the entire population of the country. Rather they have been introduced and assessed in certain regions of the country, for example, screening for hypertension, alcohol abuse, chlamydia, colon cancer, and prostate cancer. Other programs have included essentially the entire target population, such as screening with ultrasound examination during pregnancy, PKU screening for newborns, screening of 4-year-old children for physical and mental disorders, screening for cervical cancer, breast cancer, and preoperative screening procedures. In the case of screening for cervical cancer, there is no randomized controlled study that would provide conclusive evidence about its effectiveness; however, there is longitudinal data in support of its benefit. Thus, the incidence and mortality in cervical cancer increased rapidly from 1958–67. Thereafter both incidence and mortality have decreased significantly, and it is generally thought that organized screening for cervical cancer, introduced in 1965, is the main reason for these trends.

By policy, many preventive services are free to the population. Children and young people under 20 do not pay patient fees. In children's clinics, vaccinations, health checks, and consultations are provided free of charge to all children under school age. Expectant mothers are provided regular check-ups and prenatal care without charge. All children and young people up to the age of 19 years receive free dental care, and the emphasis is on prevention (17).

Preventive services are evaluated like any other health technology. Specifically, the Swedish view is that health investigations (screening) for early detection of serious diseases in the general population (i.e., of symptom-free individuals) are meaningful if they are cost-effective and the healthcare system can offer a beneficial treatment to the patient.

In recent years, SBU has evaluated a number of preventive services. In 1998 SBU published a report on smoking cessation methods, which concluded that questions to patients regarding their smoking habits, followed by clear recommendations to stop smoking and advice on nicotine replacement agents, is cost-effective when done routinely. On the other hand, many other interventions, including hypnosis, acupuncture, and drug therapy (other than nicotine replacement), have not been shown to be effective (16).

Another recent study examined community interventions aimed at reducing the burden of cardiovascular disease. The study examined projects that focus on entire populations, projects that address multiple risk factors concurrently, programs that compare the effects of interventions with trends in a control population, and programs directed at individuals without cardiovascular disease (primary prevention). The study found no conclusive scientific evidence that would support starting new, large-scale community intervention programs aimed at preventing cardiovascular disease (13).

A final example was a study of antioxidants as disease prevention. The study concluded that the scientific literature shows that a dietary intake that includes an abundant supply of antioxidants, mainly from fruits and vegetables, may help prevent a variety of diseases. However, there is no scientific evidence to show that supplemental antioxidants, beyond those found in a balanced diet including fruits and vegetables, would prevent disease. Furthermore, controlled studies have shown that high doses of beta-carotene and vitamin E supplements have caused serious negative effects in smokers (14).

Many screening methods have also been evaluated in Sweden. Some examples are given in the cases that follow.

BREAST CANCER SCREENING WITH MAMMOGRAPHY

Burden of Disease

Breast cancer is the most common cancer among Swedish women and constitutes about 25% of all female cancers. About 5,000 new cases per year will appear and between 1,200 and 1,500 patients per year will die of the disease. In addition, a few men, fewer than 50 per year, develop breast cancer (11).

The age-standardized incidence of breast cancer in Sweden has increased from 65 per 100,000 women in 1961 to 115 per 100,000 in 1994. The increase has been on average 1.4% a year for the last 20 years. Part of this increase can be attributed to the spread of mammography screening during the same period. Despite this increased incidence, the age-standardized mortality rate of the disease has decreased and is now less than 30 per 100,000.

Several of the prospective trials of mammography screening have been carried out in Sweden (19). The two-county study (Dalarna and Ostergotland), begun in 1977 using single-view mammography to screen every 20 to 36 months, invited 134,867 women aged 40–74 years. The results in 1985 showed a 31% reduction in the breast cancer mortality rate among the invited women (18). The Malmo study partially confirmed these results, showing a decrease of the mortality rate of 21% in the age group of 55–70 years after an average follow-up period of 8.8 years (1). Finally, a study from Stockholm, published in 1991, showed a decrease in the mortality rate for screened women in the age group of 40–64 years of 29.5% and of 43% for the age group from 50–64 years (2).

The Swedish Cancer Foundation initiated an overview of all the Swedish studies (4). Individual data from these studies were collected and analyzed. The synthesis of individual data was considered valid because the structure of the Swedish studies was similar. The results were based on a follow-up from 1977 to 1993. They showed a statistically significant decrease in the breast cancer mortality rate of 29% for the invited women in age groups of 50–59 and 60–69. In other age groups, no significant decrease in the mortality rate was shown (10). The latest analysis of these data confirmed the earlier results with one addition (5): after an average screening time of 7 years and follow-up time of 12.8 years, a decreased mortality risk of 23% was shown for women in the age group from 40–49 years. Overall, Swedish studies based on a comprehensive program for breast cancer screening with mammography indicate that screening of women age 40–74 years decreases the mortality rate from breast cancer. The effect is smallest in the younger ages.

Assessments of Breast Cancer Screening in Sweden

Four assessments based on critical literature review have been performed in Sweden by the National Board of Health and Welfare in cooperation with the Swedish Planning and Rationalization Institute (SPRI) in 1986, 1990, 1993, and 1998 (6;7;8;9). Based on these assessments, the National Board of Health and Welfare has recommended that mammography should be offered to women age 40–74 years, with an interval of 18 months for women age 40–54 and 24 months for those older than 54 years.

Quality Assurance in Breast Cancer Screening in Sweden

In 1993 the National Board of Health and Welfare issued a general advisory report for quality assurance in health care. This was followed by a Parliamentary amendment to the 1982 National Health Act stating that quality assurance should be an integrated part of

all health services. The National Board of Health and Welfare has recommended specific measures to assure quality in breast cancer screening.

The board recommended establishment of a regional quality control council with representatives of all involved specialties. This council has been established, and has a broad range of responsibilities, including education and training in relevant areas. For quality assurance, the following parameters are reported:

- Number of women invited;
- Number of participating women;
- Number of women receiving a needle biopsy;
- Number of women that had an operation (diagnostic or therapeutic);
- Number of women with a diagnosis of breast cancer;
- The fraction of women with invasive cancer < 15 mm;
- The fraction of women with lymph node metastases;
- The distribution of stages following UICC standards;
- Number of women with interval cancer defined as diagnoses between two screening episodes with negative results of the preceding mammography; and
- Number of nonparticipating women with breast cancer.

The quality of x-ray equipment and radiation protection are also emphasized by the National Board (9). Extensive documentation on the outcome and quality of the program is available through the National Board of Health and Welfare (9).

Mammography Screening in Sweden

The assessments and recommendations from the National Board of Health and Welfare have strongly influenced the policy of the county councils toward mammography. When the first guidelines from the National Board of Health and Welfare were published in 1986, only five counties (of 26) were offering screening for breast cancer to part of or the whole female population. After the publication of the guidelines, a rapid increase in establishing local programs was seen. In 1992, active screening was performed in 22 counties. In 1997, all counties offered screening with varying age limits and time intervals (9).

In 1996–97, 1.3 million women were invited for screening and just over 1 million accepted (80%). Participation was highest in the rural areas and lowest in the three larger cities.

SCREENING FOR PROSTATE CANCER

Burden of Disease

Prostate cancer is a significant health problem in Sweden with an increasing incidence rate. Because the cancer causes few symptoms until it extends beyond the prostate capsule, more than 50% of patients already have local extracapsular cancer growth or distant metastases at the time of clinical diagnosis. This fact, together with the substantial morbidity associated with progression of prostate cancer, such as urinary tract obstruction and severe bone pain from metastases, has contributed to stimulate the interest in early detection through screening.

Prostate cancer is the most common cancer in Swedish men, accounting for 27% of all male cancer. The incidence increased from 1,540 cases diagnosed in 1960 to 5,340 cases in 1992 (12). This annual increase amounts to 1.2% per year for 20 years. No cases have appeared before the age of 40 years, and 73% of all diagnoses cases have been 70 years

or older. The diagnosis has been verified cytologically or histopathologically in 99% of cases.

The mortality rate from prostate cancer is increasing in Sweden. Between 1981 and 1993 the age-standardized increase was about 20% (12). Survival observations in men with prostate cancer and studies of prevalence of prostate cancer in men who died of other causes than prostate cancer support the assumption that a substantial number of patients have biologically mild disease that does not appear likely to progress to life-threatening metastatic disease.

Swedish Assessments of Screening for Prostate Cancer

SBU published a critical and systematic review of mass screening for prostate cancer in 1996 (12). The study group arrived at four conclusions:

1. There are no compelling reasons to recommend mass screening aimed at detecting early forms of prostate cancer;
2. From a scientific viewpoint, the same reservations apply to the value of opportunistic screening as apply to mass screening;
3. There is no sufficient reason at this time to recommend large randomized trials as a means to assess the total effects of mass screening on prostate cancer; and
4. Effective screening for prostate cancer is an objective that is attainable through further research.

Based on this review, SBU concluded that routine screening for prostate cancer could not be recommended because of lack of evidence regarding benefits and considerable risk of adverse effects. In addition, the costs of a program were not considered to be in reasonable proportion to the healthcare costs of the disease itself and the effects achieved (12).

The Present Situation in Sweden

The recommendation from SBU has been followed by the county councils. No county or municipality has organized screening programs for prostate cancer. The extent of opportunistic screening in Sweden is not known. It is thought to be relatively common and increasing in rate.

ULTRASOUND SCREENING DURING PREGNANCY

Ultrasound examination during pregnancy was introduced nearly 25 years ago. In the beginning, the technology was used mainly in cases of suspected morbidity or fetal malformation. As ultrasound technology has advanced, the indications for the examination have expanded, so that all pregnant women in Sweden are now offered an ultrasound examination at least once in their pregnancy. However, in contrast to other European countries, routine ultrasound is not carried out specifically with the idea of fetal diagnosis, such as to search for anomalies.

Assessment of Ultrasound in Sweden

In 1998, SBU published a comprehensive report on ultrasound in pregnancy in Sweden (15). Some of the conclusions of the report are as follows:

- There is no scientific evidence to show that routine ultrasound examination creates a biological risk for the mother or the fetus;
- It has not been proven that routine ultrasound examination during pregnancy reduces prenatal mortality or reduces morbidity among newborns;

- Prenatal ultrasound examination influences the management of the pregnancy and the planning prior to delivery in a positive way; and
- Routine prenatal ultrasound examination increases the detection rate of the congenitally malformed fetus.

It was further concluded that, although it has not been proven that routine ultrasound examination during pregnancy reduces perinatal mortality or morbidity among newborns, it increases the detection rate of congenitally malformed fetuses and influences the management of the pregnancy and the planning procedures prior to delivery in a positive way. On the basis of these findings, the report recommended screening and stated that scientific evidence, along with psychological and ethical aspects, suggests that fetal diagnostics should be routinely offered as part of screening.

Because the technology is not used routinely to diagnose fetal abnormalities in Sweden, it is recommended that such diagnostic examination should be routinely offered as part of screening. Since this is not done routinely now, this requires additional training and quality assurance. In addition, the report recommends that the ethical, organizational, and educational consequences in this context should be investigated (15). The report also recognizes that being informed that the fetus is malformed may traumatize parents, so psychological care is particularly important.

The Present Situation in Sweden

An average of slightly more than two ultrasound examinations are performed per pregnant woman, including examinations performed on medical indications (15). More than 95% of women who deliver have undergone routine ultrasound examination. There is no reason to believe that the number of examinations will increase in the future.

DISCUSSION

Sweden has emphasized prevention and screening in its health services for many years, and evaluation has been emphasized in this context for years. For example, the breast cancer screening case discussed above shows that randomized studies of mammography screening were organized in Sweden as early as the late 1970s.

Nonetheless, a major change has been seen in Sweden during the last few years. With the reduction in resources for health care, prevention has been seen as an increasingly important strategy. Scarce resources require that all technology be carefully evaluated before diffusion. In the case of prevention, this imperative is particularly important, since cost-effective preventive programs will produce health and may even save resources, at least in the short run, while programs that are not cost-effective will merely waste resources. Therefore, promoting cost-effective prevention and screening in Sweden is a high priority in Sweden today.

With the formation of SBU in 1987 and the increasing emphasis on evidence-based medicine in all services, HTA is an increasingly important part of health policy making in Sweden. Cost containment in Sweden depends on budgets for health care; HTA is not involved at this level. HTA has had a more positive slant: to ensure that beneficial and cost-effective technologies are diffused rapidly into the healthcare system.

Thus, acceptance of HTA is not a problem in Sweden, neither in clinical services nor in public health and preventive services. In early years, assessments tended to focus on expensive, new medical equipment, as in other countries. However, with time, assessments have expanded to take in such subjects as back pain and mental healthcare. More recently, prevention and screening are increasingly important subjects.

A great challenge for HTA is to assure use of its results. Dissemination of information is time-consuming and expensive and may have only moderate effects. Every assessment needs its own specific strategy for implementation of its results. However, the Swedish government has consistently praised SBU's attempts to disseminate its results. In 1999, SBU received a substantial increase in its budget with the charge to expand its dissemination activities. Nonetheless, better dissemination methods are needed. One possibility that has not yet been realized is to link HTA closely to quality assurance activities, which are also growing in Sweden.

This problem is less acute in preventive services, where formal policies have more influence. There generally are few pressures in favor of expanded preventive services, as there often are with clinical services. Therefore, assessments can have more influence, as illustrated with the cases in this paper. Still, the growing use of opportunistic screening, as in the case of PSA for prostate cancer, is a reason for concern. As in other countries, Sweden has no clear-cut method for dealing with this problem.

CONCLUSIONS

HTA is an increasingly important part of health policy making in Sweden. This is perhaps especially true in preventive services, including screening, where county councils tend to make explicit resource allocation decisions favoring certain preventive programs.

One pervasive problem in HTA in Sweden, as in other countries, is the large number of technologies that could be assessed. This points out the importance of international collaboration in this field.

REFERENCES

1. Andersson I, Aspegren K, Janson I, et al. Mammographic screening and mortality from breast cancer: The Malmo mammographic screening trial. *BMJ*. 1998;297:943-948.
2. Frisell J, Eklund G, Hellstrom L, et al. Randomized study of mammography screening: Preliminary report on mortality in the Stockholm trial. *Breast Cancer Res Treat*. 1991;18:49-56.
3. Jonsson E, Banta HD. Health care technology in Sweden. In *Health care technology and its assessment in eight countries*. Washington, DC: US Government Printing Office; 1995:209-239.
4. Laird N, Mosteller F. Some statistical methods for combining experimental results. *Int J Technol Assess Health Care*. 1990;6:5-30.
5. Larsson LG, Nystrom L, Wall S, et al. The Swedish randomized mammography screening trials. An analysis of their effect on the breast cancer related excess mortality. *J Med Screening*. 1996;3:129-132.
6. National Board of Health and Welfare. *Mammography screening for early detection of breast cancer in Sweden*. Stockholm: National Board of Health and Welfare; 1986.
7. National Board of Health and Welfare. *Uppfoljning och kvalitetsaskring. Allmannarad*. Stockholm: National Board of Health and Welfare; 1990.
8. National Board of Health and Welfare. *Morfologisk diagnostik av brostcancer. Principer och kvalitetssakring. Allmannarad*. Stockholm: National Board of Health and Welfare; 1993.
9. National Board of Health and Welfare. *Mammography screening for early detection of breast cancer in Sweden*. Stockholm: National Board of Health and Welfare; 1998.
10. Nystrom L, Rutqvist L, Wall S, et al. Breast cancer screening with mammography: Overview of Swedish randomized studies. *Lancet*. 1993;341:973-978.
11. Stenbeck M, Rosen M, Holm LE. Cancer survival in Sweden during three decades, 1961-1991. *Acta Oncol*. 1995;34:881-891.
12. Swedish Council on Technology Assessment in Health Care (SBU). Mass screening for prostate cancer. *Int J Cancer Suppl*. 1996;9:1-72.
13. Swedish Council on Technology Assessment in Health Care (SBU). *Community intervention: Cardiovascular disease. Summary and conclusions*. Stockholm: SBU; 1997.

14. Swedish Council on Technology Assessment in Health Care (SBU). *Preventing disease with antioxidants: Summary and conclusions*. Stockholm: SBU; 1997.
15. Swedish Council on Technology Assessment in Health Care (SBU). *Routine ultrasound examination during pregnancy: Summary and conclusions*. Stockholm: SBU; 1998.
16. Swedish Council on Technology Assessment in Health Care (SBU). *Smoking cessation methods: Conclusions*. Stockholm: SBU; 1998.
17. The Swedish Institute. *The health care system of Sweden*. Fact Sheets on Sweden, May 1999.
18. Tabar L, Faberberg C, Gad A, et al. Reduction in mortality from breast cancer after mass screening with mammography: Randomized trials from the Breast Cancer Screening Working Group of the Swedish National Board of Health and Welfare. *Lancet*. 1985;1:829-832.
19. Woolf SH. The accuracy and effectiveness of routine population screening with mammography, prostate-specific antigen, and prenatal ultrasound: A review of unpublished evidence. *Int J Technol Assess Health Care*. 2001;17:275-304.