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HEALTH POLICY, HEALTH TECHNOLOGY ASSESSMENT, AND SCREENING IN EUROPE

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Abstract

Objective: To present a summary of the papers in this volume, illustrating the links between health technology assessment (HTA), health policies and specifically policies toward prevention and screening, and implementation of screening tests in the case of three screening methods: mammography screening for breast cancer, screening for prostate cancer, and routine use of ultrasound in pregnancy.
Method: To commission papers from eight European countries based on a set of questions to be answered, as well as a paper synthesizing the scientific literature on the three screening procedures.
Results: Indicate that few of the countries examined have developed effective links between HTA, health policy, and implementation related to screening procedures. Only Sweden and the Netherlands appear to have developed such links. In the other countries, HTA has a limited role in determining health policy. It also seems to be uncommon for countries to have a specific prevention strategy.
Conclusion: The major conclusion is that countries of Europe need to develop HTA as part of prevention policies.

Keywords: Preventive services, health technology assessment, Mammography, PSA testing, Ultrasound, Europe

The papers presented in this issue have examined three screening procedures in the countries of Austria, Belgium, Germany, Greece, Italy, the Netherlands, Sweden, Switzerland, and the United Kingdom. In each case, the author(s) have sought assessments of the screening procedures carried out within the country that might supplement the international literature and help explain the extent of use of the screening procedure in the particular country. They have also examined policies toward screening in general and toward the three screening procedures. Finally, they have presented available evidence of the extent of use of the screening procedure in the country in question.

The aims of this paper are: a) to analyze common patterns in the nine countries' approaches to assessing and managing mass screening; and b) to delineate differences in approach where they seem interesting and important from an international perspective.

GENERAL OBSERVATIONS

The first observation is that the population of the nine countries described enjoys essentially universal access to healthcare services (1). Some countries (Sweden, the United Kingdom, and Italy) cover any individual living in the country. Other countries manage, through a mix of public and private funding and services, to cover close to 100% of the population.

The second observation is the complexity and diversity of the healthcare systems of the countries described. For the outsider, European healthcare systems are sometimes described as if they are quite similar in their organization and financing. In fact, each country has a healthcare system that has evolved over time, with decisions based on social and cultural preferences. The different countries have quite different health systems (1). Mechanisms for dealing with such issues as costs of health care and needs for assessment of health technology vary considerably.

Finally, given this diversity, it is perhaps no surprise that the situation with regard to the three screening procedures differs remarkably from country to country. Perhaps the only important general observation is that health technology assessment (HTA) has had relatively little overall impact on the extent of use of these three screening procedures.

THE HEALTH SYSTEMS OF THE EIGHT COUNTRIES

A key factor in organizing health services is the source of the funds. There are four key sources of funds for health care: taxation, contributions to social insurance schemes, voluntary subscriptions to private insurance schemes, and out-of-pocket payments (6). Social health insurance and taxation are compulsory, while voluntary insurance and out-of-pocket payments are voluntary. All countries of Europe rely on all four sources of funding, but the voluntary methods of funding are relatively unimportant except in some sectors such as dentistry. Part of out-of-pocket payments are copayments, which are being used more often in attempts to both raise more money and to reduce the demand for health care.

European countries may be classified by the predominant type of statutory financing that characterizes their healthcare systems:

- Healthcare systems that are predominantly insurance based;
- Healthcare systems that are predominantly tax based; and
- Healthcare systems that are insurance based but in a state of transition toward a tax-based system.

In this project, Sweden and the United Kingdom have tax-based systems; Austria, Belgium, Germany, the Netherlands, and Switzerland have insurance-based systems; and Greece and Italy are in transition to a tax-based system (6).

In the HTA-Europe project, it was observed that governments may have more control over health services in tax-based systems (1). In addition, they may have more policy concern about the health care that is delivered when it is paid for directly from the government budget. There may then be a relationship between the establishment and prominence of HTA in a country and the method of payment. The European Union countries with tax-based systems generally have national agencies for HTA and have given a degree of prominence to HTA in their policy making. The countries with insurance-based systems generally do not have national agencies and have not given HTA the same prominence as the countries with tax-based systems (1).

Some countries have a rather open system, with a relative lack of controls, while others have a more closed and controlled system. Germany is an example of a country with a rather open system of care, with many sickness funds paying for care. The German system is not very regulated, and hospitals are rather free to develop services as they like. Still, different

pressures, including concerns about costs, are bringing proposals for new types of payment and regulation.

The Netherlands also has a rather open system. It also has multiple payers for care and largely private providers, but the system is rather heavily regulated. Policies concerning health technology, including screening, are highly developed.

At the other extreme is the system of Sweden, which is a public system paid for with public funds. The private sector plays a relatively unimportant role in health care. Based on this spectrum, one might expect Sweden to have active policies toward HTA and toward screening, and that is in fact the case.

The United Kingdom is a tax-based system, with an active HTA policy and a national mechanism for assessing screening that is intended to influence national policy toward screening (3).

The Netherlands has gone the furthest of the insurance-based systems in this regard, with active policies toward screening. Switzerland also uses HTA actively in policy making, particularly in decisions concerning inclusion of technologies in the basket of services covered by sickness funds, but it does not have a coherent policy concerning screening. The other countries presented here have not developed HTA to a high level and do not have active policies toward screening.

SPECIFIC ASSESSMENTS OF SCREENING

The three screening methods presented here were assessed by systematic review of the international scientific literature as part of this project (7). Briefly, the conclusion was that mammography screening is justified in women over the age of 50, while neither prostage-specific antigen (PSA) screening for prostate cancer or routine ultrasound screening in pregnancy can be justified by the evidence of benefit.

Only Sweden, the United Kingdom, and the Netherlands have carried out formal national assessments of screening procedures, including the three cases analyzed in these papers.

In Sweden, prevention is considered an important part of national health policy. Sweden also has an effective policy toward HTA, with a well-established national HTA program. Assessments of the three screening interventions analyzed in these papers have been carried out. Mammography screening has been recommended and has been implemented by the counties in Sweden. Each county program differs a bit, with some, for example, encouraging screening for women over the age of 40. PSA screening was assessed and was not recommended, but opportunistic screening seems to be common. An assessment of ultrasound screening in pregnancy found a lack of evidence for its effects on morbidity or mortality of the newborn, but recommended routine use of two scans in all pregnancies. Thus, in Sweden assessment and policy are well linked, although practice does not always follow policy guidelines.

The United Kingdom has an active and apparently effective program for implementing HTA into policy decisions, as well as administrative and clinical decisions. The HTA program includes an active policy concerning the assessment of screening methods. The assessment of screening is implemented through the National Screening Committee, established in 1997. The three screening issues examined in this paper have all been assessed within the context of the U.K. Department of Health. In the case of mammography screening, the assessment was done more than 10 years ago and was followed by the implementation of a national screening program for breast cancer. In the case of prostate cancer screening, the HTA program has supported two systematic reviews that have concluded that screening should not be carried out. In general, this recommendation has been accepted in the United Kingdom. Use of ultrasound has been assessed by the National Screening Committee.

In the Netherlands, a national prevention policy, including assessment of screening, has been formulated. There is a national law requiring scientific assessment of screening before implementation into Dutch health care. The assessment and implementation of screening for breast cancer is an excellent example of the interaction of health policy, assessment, and implementation of mass screening. However, although ultrasound in pregnancy has been assessed and no evidence has been found to support its routine use, there is no formal policy toward such screening, although use of ultrasound in normal pregnancy is essentially universal. In the case of screening for prostate cancer, formal assessments have been done and no group carrying out assessment has recommended such screening, but PSA screening is reported to be growing rapidly. The second two cases point up the difficulties of dealing with opportunistic screening, where diagnostic technologies are used in normal populations for screening purposes when they visit clinical facilities for other reasons.

In the other countries, some assessments have been done. Since none of these countries have a national public program for HTA, it cannot be a complete surprise that they also lack visible publicly funded assessments done for the purposes of affecting policy. However, in Italy a surprising amount of assessment has been carried out, considering the lack of a formal national program for HTA.

An alternative approach to assessment may be consensus programs, used in a number of countries historically, but apparently going out of favor in relation to HTA. In consensus development, generally speaking, groups of experts are brought together to assess technology and make recommendations concerning implementation. A big problem with such groups is that they seldom carry out thorough systematic reviews of the scientific literature (2). Conclusions are generally based on the pre-existing knowledge and opinions of the experts chosen and may be biased.

One alternative source of assessment is consensus conferences or reports. Consensus reports dealing with breast cancer screening have been published in Italy, Belgium, and Austria, coming to similar conclusions in all cases. The extent to which these reports were based on a careful synthesis of scientific literature is not clear. What is clear is that in all three cases, the reports were based on physician consensus without involvement of others such as policy makers, economists, or the general public.

Another alternative source of assessment is voluntary organizations such as cancer societies, as in the case of Austria's Cancer Aid. While this appears to be an authentic consumer-oriented group, its opinions are based on the opinion of experts such as oncologists. One must be somewhat skeptical in considering such assessments. Obviously, a cancer society has a bias in approaching the question of cancer screening. It actively seeks means to attack cancer, and its very life depends on such means. This may lead a cancer society to be biased in favor of public programs dealing with cancer, including screening. Nevertheless, such private organizations may be an important source of assessments.

There is no lack of research on the screening tests chosen in these countries. A surprising amount of prospective research has been carried out or is under way in these countries. Such research may be initiated by local investigators, but usually also has local funding, which indicates a degree of interest in the evaluation of screening and perhaps may indicate a degree of policy interest as well. Thus, even those countries that do not have formal programs for HTA do show considerable, and perhaps increasing, interest in activities generally associated with HTA.

POLICIES TOWARD SCREENING

When a new technology such as a screening test moves out of the laboratory or the research clinic and begins to enter everyday healthcare practice, governments, institutions, and practitioners must decide whether to invest in the technology and whether it should

be extensively diffused. Since the populations of the countries discussed in this volume have extensive financial coverage for health care, decisions regarding adoption and use of health technology are not very much constrained by references and incomes of individuals. Collective constraints, however, have been introduced as a matter of public policy in every country. In many cases, these have been introduced because of rising costs or because of obvious problems with efficacy and safety of healthcare technology. The introduction of constraints continues, although it began more than 20 years ago.

The Netherlands has the most active and visible policy constraint specific to screening. In the Netherlands, a 1996 law states that all proposals for population screening must seek approval from the Minister of Health before they are launched. A specially appointed national committee assesses each proposal and advises the Minister of Health concerning such aspects as efficacy and cost-effectiveness. The minister then decides whether to implement the screening program.

Constraints are often indirect. A common form of indirect constraint on health technology is financial and involves decisions by government or an insurance fund about the budget or fees to be permitted. Decisions about fees include whether to reimburse for the use of the technology at all, and if so, how much. Fees can be coupled with conditions, such as that the technology may only be reimbursed when carried out by a certain specialist.

Beginning in the mid-1980s, insurance coverage has been increasingly based on HTA in a number of European countries. For example, in the Netherlands prospective assessments are done for the purposes of influencing coverage policy through the Fund for Investigational Medicine. In 1992, a special committee was asked to advise the government on how to define the basic benefit package (4). The committee acknowledged serious problems of ineffective and cost-ineffective technologies and overuse of effective technologies in the Dutch healthcare system. It proposed the use of four screens to define the basic benefit package. First, is the care necessary, meaning (for example) is it necessary to assure normal function or to protect life? Second, is the intervention proven to be effective by controlled clinical trials? Third, is the care efficient, meaning is it shown to be cost-effective by a formal analysis? Is the cost reasonable when compared with the benefits? Fourth, is it possible to leave the care to individual responsibility? For example, the committee concluded that *in vitro* fertilization and homeopathic medicines could be left to individual responsibility. The committee concluded that applying these four screens in selecting technologies to be included in the benefit package would result in a rather extensive benefit package without excessive costs. While this scheme has not actually been put into practice, it has affected thinking on this issue and has furnished general guidance to policy makers in the Netherlands.

Among the insurance-based systems examined in this issue, only the Netherlands and Switzerland actively couple HTA and coverage decisions, although Germany is rapidly developing such an explicit coupling in coverage decisions in the ambulatory care sector. The other countries generally seem to follow the historical method of determining the benefit package: to pay for what physicians do. Thus, generally speaking, the screening procedures described here are paid for even when they have not been shown to have benefit. Nonetheless, constraints are beginning to develop, particularly in the case of routine ultrasound screening in pregnancy. HTA is becoming more prominent, and coverage is also increasingly seen as an opportunity for rationalization of health care.

A final issue with financial constraints is that screening tests are generally also used for diagnostic purposes. Unless the test is totally worthless, coverage is not an effective way of controlling such tests. If the test is reimbursed as a diagnostic test, the physician may decide to carry out opportunistic screening, in which an asymptomatic person is tested while (for example) visiting a physician for other reasons to determine if a particular problem is present. This applies to all three screening tests examined in this series of papers. All are

paid for as a diagnostic tool, and all three are often used as screening tests outside the context of a national policy or program for screening. Controlling this practice is extremely difficult. Even in Sweden, with its active assessment programs and its vigorous health policy, PSA screening is out of control.

SPECIFIC OBSERVATIONS CONCERNING MAMMOGRAPHY SCREENING

Mammography screening seems to be effective for women over the age of 50, although a recent re-analysis of the trials has raised questions about this conclusion (5). Nonetheless, at this time, the weight of the evidence indicates benefits from mammography screening (7), and there is certainly an international consensus favoring the practice. Given this fact, it is surprising that so few countries have active policies concerning its implementation. Among these nine countries, only Sweden, the United Kingdom, and the Netherlands have implemented such a policy. Italy has a new policy toward mammographic screening, but the extent of implementation is unknown. Other countries such as Switzerland and Belgium are apparently moving to develop such a policy.

These decisions are not generally based on a formal assessment process. In Italy, a consensus paper developed by several organizations working together and apparently only involving physicians was the stimulus for the national policy. In Belgium, a prevention conference was held that has given impetus to the idea of mammography screening. In Austria, a consensus report on breast cancer developed by oncologists has given the issue some prominence, but no action has yet been taken.

From an assessment point of view, another important issue with mammography screening is that it has not been shown to be of benefit in women under the age of 50. Nonetheless, it is often used in such women, generally in opportunistic screening. In Sweden, however, some areas have formal screening programs that are also addressed to women under the age of 50.

Quality assurance is a significant issue in mammography screening. The x-ray technology must be adequate and must be monitored for such potential problems as excessive radiation exposure. The reading and interpretation of the mammography pictures must be carried out by adequately trained personnel, and their performance needs to be monitored. According to the papers in this volume, among the countries studied, the Netherlands, the United Kingdom, and Sweden have active national efforts directed to the quality of mammography. In addition, Switzerland has a long tradition of efforts in improving the technical quality of mammograms. Recently the professional societies have agreed on quality improvement programs through mandatory continuous education.

As in the other cases, the links between assessment, policy making, and screening are distressingly weak. Despite credible international assessments, most countries do not attempt to assure that women at risk of breast cancer who could benefit from mammography screening actually are screened.

SPECIFIC OBSERVATIONS CONCERNING ULTRASOUND SCREENING IN PREGNANCY

Ultrasound screening is a method that has spread into almost universal use, despite a lack of assessment showing benefit. Perhaps this is because ultrasound screening is appealing, apparently safe, and relatively cheap.

In fact, in Sweden a formal assessment found lack of benefit for the newborn but concluded that the practice was acceptable because of clinical considerations, its widespread use, its safety, and the demand for it from patients and physicians.

Nonetheless, concerns about ultrasound have grown. In some countries, as many as nine scans or more have been done in normal pregnancies. If nothing else, this is a significant financial issue. Therefore, several countries have taken steps to limit the number of scans to two or three. For example, in Belgium the number of ultrasound examinations reimbursed was reduced to three. The same is the case in Germany. These decisions were not based on a formal assessment but seemed to be motivated primarily by fiscal concerns. In Switzerland, an attempt to limit the number of scans led to active consumer protests, which have stimulated a vigorous evaluation effort. The sickness funds currently cover two ultrasound examinations in a low-risk pregnancy.

In short, assessment and use of ultrasound as a screening tool in pregnancy are essentially uncoupled. Assessment has some influence on health policy, which is seeking to limit the number of scans provided in a number of countries.

SPECIFIC OBSERVATIONS CONCERNING PSA SCREENING

PSA screening has been formally assessed in a number of countries. As far as is known, no public assessment program in the world has supported such screening. All such assessments have found significant questions concerning such screening, especially the lack of evidence of health benefit. Nevertheless, it is supported by many physicians, especially urologists, and is rapidly growing in a number of countries, probably in all countries examined in this issue.

What are the forces encouraging PSA screening? Prostate cancer is one of the most important causes of mortality in men. Screening has been successful in other cancers, and it is logical to believe that screening could also have a place in the early detection and treatment of prostate cancer. Many physicians are obviously either not convinced by the lack of evidence of benefit from formal assessments of PSA screening or are not aware of the facts. At the same time, many expert urologists support such screening in articles and presentations. Consensus meetings, urological groups, and clinical guidelines (mainly those produced by urologists) have supported such screening. And lurking in the background is industry promotion of a profitable product.

Policy making and assessment have been generally well linked in this case. No country described in this issue has a positive policy toward PSA screening for prostate cancer. Nonetheless, the PSA test is available and is paid for. It is then used with increasing frequency in opportunistic screening.

In summary, PSA screening is a method of screening that has not been shown to be of benefit and that certainly is associated with an elevated risk of harm to patients and growing financial costs. How to prevent the spread of such a screening procedure is a serious question for health policy.

DISCUSSION

The application of HTA to the area of mass screening of the population is a very important part of health policy, and it will grow in importance as more screening tests become available. Implementation of HTA is needed in this area, as in other areas of health care, to assure health benefits with reasonable risk and costs. The field of HTA has illustrated that it can identify technologies and produce assessments in a timely fashion. The screening procedures discussed here have all been formally assessed in a number of countries.

The papers illustrate that technology assessment has begun to become an important part of healthcare policy making in many countries. In the Netherlands, the United Kingdom, Switzerland, and Sweden, HTA has attained a degree of maturity and has a growing influence on health policy decisions.

One major problem is the response of policy makers. Despite the 20-year history of the field, many policy makers do not see the importance of assessment. In fact, policy is often made with little or no reference to assessment and to a scientific analysis of benefits, risks, and costs. Furthermore, the cases may indicate that policy is overly negative, and that policy makers are more interested in constraining technology and have limited interest in promoting beneficial technologies such as mammography. Another problem is that clinical providers have generally not been influenced by technology assessment, in part because of the complex mechanisms that influence clinical practice.

Technology assessors have not yet learned how to reach out to the general public or how to systematically convey the results of HTA to the lay mass media. As illustrated by the cases of ultrasound screening in pregnancy and PSA screening, the public seeks technologies that are not proven to be of benefit. One reason for such behavior, of course, is uncertainty about the outcome and fears of the consequences of disease.

Much of the potential of technology assessment has not been realized. Even when good assessments are done, their impact on policy making has been modest. Perhaps the main accomplishment of the last 10 years is to demonstrate that such assessments can be done. In essentially all the countries discussed in this issue, technology assessment activities are spreading. Such activities seem certain to continue and grow in importance.

This issue reveals some common problems and differing approaches used in nine European countries that are similar in many ways. It is perhaps surprising to find so much diversity in a relatively small geographic area. Sharing information between countries of their experiences, as in this area of screening, is highly desirable. As indicated in the HTA-Europe project, European-wide and even global sharing of such experiences can be highly valuable (1).

One purpose of this project was to illustrate the value of an established network for HTA. With relatively little effort and with a small financial investment, it has been possible to examine the situation with screening in nine countries. Perhaps this is a model that could be used much more in the future.

Health technology is international. Efforts to understand its benefits, risks, and costs must also become increasingly international. The current explosive development of information technologies and increase in access to the Internet is an opportunity to deliver the messages about results of HTA to decision makers at all levels from national policy makers to practitioners. An effort needs to be made to assure the diffusion of adequate information on the conclusions from HTA studies to patient groups and the general public. Such dissemination strategies are necessary to avoid the spread of confusing, superficial, or even clearly false information by growing numbers of commercially driven Web sites. A systematic information strategy is needed as part of HTA on the European level and elsewhere.

REFERENCES

1. Banta HD, Oortwijn WJ (eds). Special section: Health technology assessment in the European Union. *Int J Technol Assess Health Care*. 2000;16:299-435.
2. Council on Health Care Technology, Institute of Medicine. *Improving consensus development for health technology assessment: An international perspective*. Washington, DC: National Academy Press; 1990.
3. Department of Health. *The first report of the National Screening Committee*. London: The Department of Health; 1998.
4. Dunning A, Chairman. *Executive summary: Choices in health care: A report by the government Committee on Choices in Health Care* (in English). Rijswijk: Ministry of Welfare, Health and Cultural Affairs; 1992.
5. Gotzsche P, Olsen O. Is screening for breast cancer with mammography justifiable? *Lancet*. 2000;55:129-134.

6. Saltman RB, Figueras J. *European health care reform: Analysis of current strategies*. Copenhagen: World Health Organization, Regional Office for Europe; 1997.
7. Woolf S. 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.