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INTRODUCTION: MASS SCREENING, HEALTH TECHNOLOGY ASSESSMENT, AND HEALTH POLICY IN SOME EUROPEAN COUNTRIES

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Abstract

Objective: The series of papers in this issue was developed to examine the use of health technology assessment in policies toward prevention—specifically toward mass screening—in European countries. The papers actually examined three screening strategies: mammography screening for breast cancer, prostate-specific antigen screening for prostate cancer, and routine ultrasound in normal pregnancy.
Methods: Papers were sought from the member states of the European Union, plus Switzerland. Ultimately, nine acceptable papers were received, and were reviewed, revised, and edited.
Results: Screening is an accepted strategy in many countries for reducing the burden of disease through early detection and intervention. In part, this is because of successful screening programs that have been evaluated and implemented in many countries. At the same time, unevaluated and even useless and harmful screening programs—unjustified medically or economically—are widespread. Health technology assessment could help assure that only effective and cost-effective screening programs are implemented.
Conclusion: The main conclusion is that screening is an important preventive strategy. Any screening program, however, should be carefully assessed before implementation.

Keywords: Health policy, Health technology assessment, Screening

This series of papers concerns mass screening. Screening is the application of a test to detect a potential disease or condition in a person who has no known signs or symptoms of that disease or condition (6). The goal of screening is the early detection of disease or risk factors of disease so that intervention can reduce morbidity and mortality from the involved disease. Screening has been associated with substantial reductions in morbidity and mortality (12). Screening programs that have been shown to improve the health of the population in many

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countries include those for phenylketonuria and congenital hypothyroidism in newborns, for cervical cancer in women (Papanicolaou testing), and for hypertension in adults. At the same time, much useless and potentially harmful screening is done throughout the world. In part because of the successes of some programs of screening, it is considered a popular strategy for improving population health.

Screening has been subject to increasing evaluation in many countries during the past several decades as part of an increasing attention to the possible benefits, risks, and costs of health technology (4;5;6;7;8;9;10;12). Many screening programs in widespread use have been found to be of unproven effectiveness (12). Different countries have begun to develop screening programs based in part on recommendations in favor or against specific screening tests. Screening tests of unproven effectiveness can cause definite harm and are often expensive, especially when performed on large numbers of people.

The purpose of this series of papers is to examine some screening technologies in a number of European countries (using a broad definition of health technology, both a specific screening test and a screening program are technologies). Specifically, the relations between health technology assessment, health policy, and mass screening will be examined.

BACKGROUND

Beginning about 1990, some individuals involved in health technology assessment (HTA) in Europe began to discuss the possibilities of better communication and cooperation among those doing such work, especially those working in national and regional public agencies. These discussions led to the EUR-ASSESS project, which attempted to lay the groundwork for such improved cooperation and aimed at actual coordination of work (2). The EUR-ASSESS project involved almost all the member states of the European Union, plus observers from other countries.

Some key figures in EUR-ASSESS made contact with the staff of the Directorate General V (DGV) of the European Commission, which has the responsibility for implementing the public health provisions of the Maastricht and Amsterdam treaties. Improving coordination of HTA had already been highlighted in a report to the DGV, which made several recommendations relevant to HTA, including the following (1):

> The Community should coordinate technology assessment throughout the Union.

The HTA-Europe project developed from a recommendation in the EUR-ASSESS project:

> While there is certainly value in diversity, the existing diversity is not understood or documented. The relationship between HTA and the health system in different countries has hardly been examined. Resources should be devoted to studying the relationships between HTA and health systems in the member states of the European Union.

A proposal to the DGV based on this recommendation was presented in 1996 and was approved and funded in early 1997. Most members of the steering committee of the EUR-ASSESS project became members of the steering committee for the project. Ultimately, a representative of every member state was identified, and authors were commissioned for each member state to address the EUR-ASSESS recommendation. Switzerland also joined the project on a self-pay basis. These papers have been published separately (3).

The Swiss participants were particularly interested in the issue of HTA and prevention, focusing on the issue of screening, and offered supplemental funding to carry out an activity in this area. During the first meeting of the steering committee in Paris in March 1997, representatives from each country were asked to state if they were interested in becoming part of a related project on screening. Those interested became part of a separate project.

METHODS

The main method of this project consisted of identification and descriptions of mass screening programs in different countries in Europe. Each of those interested in the screening issue was asked to write a report on screening in his or her own country, focusing on three questions: a) What formal assessments of screening had been carried out in their country?; b) What formal policies had been developed to deal with screening, and how were these related to assessments (in particular, was there evidence that assessments had had an impact on health policy)?; and c) What was the present state of screening in the country (focusing on whether assessments and policies had affected the nature and extent of screening)?

Representatives from each member country met in Barcelona in June 1997 to discuss feasibility of the project. It was decided that it was not feasible in the time frame of the HTA-Europe project, and especially given the lack of resources, to study the complete scope of screening procedures. Instead, it was decided to examine three screening procedures.

After considerable discussion, three cases were chosen to illustrate different types of procedures:

1. Mammography screening for breast cancer, a screening procedure that has been rather thoroughly assessed in different countries, both by prospective research (including randomized clinical trials) and by synthetic systematic reviews of the literature. Generally speaking, mammography screening is seen as effective and cost-effective. Therefore, the case would seek to discover if this international literature and the consensus that has grown up around it had influenced decision making in each country. In short, was mammography screening actively supported and promoted by the medical community, policy makers, and the population in that particular country?
2. Routine ultrasound in pregnancy, a screening procedure that has been in use for a number of years in many countries. However, assessments in some countries have come to the conclusion that such screening had not been shown to be of benefit and could not be recommended (12). The key task in this area, therefore, was to analyze the situation in each country, and especially to discover if the international literature and assessments in the country had influenced health policy and practice.
3. Screening for prostate cancer, focusing on the use of prostate-specific antigen (PSA). Screening with PSA is a newer screening procedure that has not been shown to be of benefit and could be harmful. Nonetheless, there are indications that it is spreading rapidly into practice in a number of countries. Therefore, the task here was to document this spread, if possible, and to attempt to determine the factors that had led to the spread. In particular, were there local activities or assessment that had encouraged PSA screening in that particular country?

The authors were asked not to deal with the international assessment literature. Instead, Dr. Steven Woolf, who had worked with the U.S. Prevention Task Force in studies of screening, was commissioned to synthesize the international literature on these three cases. Dr. Woolf's paper follows this introduction. Dr. Woolf's paper was circulated to the representatives during the development of their papers so that they had the benefit of its analysis.

Reports were drafted during the period from June through December 1997. In December 1997, a workshop was held in Zurich, with the support of the Swiss partners, to discuss the three cases in light of these reports. While no published report resulted from this workshop, authors were asked to take the key points from the discussions into account in revising their reports, and the general discussion helped in the development of the paper that concludes this series of reports.

Following the workshop, it was apparent that a number of excellent reports had been developed. Therefore, the authors of the reports were invited to prepare publishable papers based on their reports. Papers were received beginning in late 1998, and were reviewed, revised, and edited. Because publication was delayed, authors were given an opportunity

to update their papers in early 2000. The final discussion paper published here was based primarily on these papers.

None of the HTA-Europe funding was used to support this project, although all participants were members of HTA-Europe. Therefore, although the screening project was initiated in the framework of HTA-Europe, it was not actually a formal part of HTA-Europe. The authors received no funding from outside sources for their participation (except for travel to the Swiss workshop). The work of overseeing the project, editing the papers, and analyzing the results was supported by the Netherlands Organization for Applied Scientific Research (TNO). TNO also funded the paper by Dr. Woolf. The results of the screening project were not reviewed by the steering committee for HTA-Europe. Neither the steering committee nor DGV of the European Commission has any responsibility for the papers and discussion presented here.

HEALTH TECHNOLOGY ASSESSMENT

HTA is analysis of the implications of health technology that is intended to influence decision making. An important focus of such analysis is the question of health outcomes; that is, what benefits are gained by the population from health technology? For policy makers, the key question is often framed as "value for money in health care." For more than 10 years, member states of the European Union have been developing this field. Some have institutionalized it in their health systems, where it continues to gain a more important role.

The development of HTA has been guided by awareness of the goal of health care: to improve the health of individuals and the population. While health care has become increasingly effective during the last decades, evidence has gradually emerged of many ineffective technologies, as well as overuse and inappropriate use of health technologies. This evidence has fueled the debate on healthcare reforms and has stimulated the field of HTA. Now about 20 years old, the assessment field developed as a tool for policy makers to help shape the course of technological change in health care.

There are also important related activities, including evidence-based medicine and the Cochrane Collaboration. The United Kingdom has probably been the leader in developing and funding these activities in Europe.

HTA in Europe

HTA is organized and implemented in a somewhat different manner in each country. One of the main determinants of such differences is the nature of the health system of the country. Some countries, such as Sweden, Spain (and several provinces, including Catalonia), and France, have a public agency for assessment of health technology. Others, such as the Netherlands and Switzerland, implement HTA primarily in relation to payment for health care through sickness funds and insurance companies. The United Kingdom has embedded HTA in the R&D programs of the National Health Service and the Department of Health in an attempt to bring HTA into all administrative and clinical decisions.

The heterogeneity and diversity that exists in HTA in Europe stimulates an exchange of experiences within Europe. There is no one right way to do HTA or to use it to improve the performance and quality of health services. Although the method of HTA is well known, the questions to be answered and the scope of HTA vary considerably among the countries.

European healthcare systems are quite diverse. For example, some systems are hospital- and specialist-oriented, while others emphasize primary care. HTA is very much influenced by national, regional, and local contexts. This diversity can be very valuable when those from different countries and regions share methods and results.

While HTA has a growing importance in Europe, it is only one means aimed at achieving important goals. HTA is fundamentally an exercise in rationality. Human and political

behavior is not necessarily rational. HTA does not by itself determine decisions, which are actually made in human and political processes. Therefore, HTA is no more than an aid in the difficult task of making healthcare decisions.

Health Policy and HTA

In recent years a great deal of attention has been paid to the possibility of assessing the benefits, risks, and costs of technologies before they come into general use and employing the results of these assessments to guide technology adoption and use. For various reasons the effects of technology assessment have been limited in these nations, especially when the forces of the healthcare system lead to behavior that differs from what is seemingly desirable. For example, powerful incentives are embodied in payment for healthcare. Physicians may be paid highly for doing endoscopies, and studies showing that endoscopy is overused will probably have little effect on practice as long as use is well (and perhaps excessively) rewarded. This situation underlines the importance of the structure of the healthcare system and the nature of policies on technology adoption and use.

Choices among technologies have to be made—this occurs at different levels of healthcare systems. Some choices are made at the national or regional policy level, as when laws and regulations prevent the purchase of equipment or the provision of certain services. Most choices, however, are at the operational level of clinical practice: made by hospital administrators, heads of clinical departments, and healthcare providers working day to day. While hospitals are the most visible part of the healthcare system, HTA also can be effectively used at the level of primary care. The ability to influence these choices and the means through which that influence is exerted are prominent health policy issues.

Policy making can be either formal (such as laws and regulations) or informal. Policy making is based on a number of different factors, including preferences, values, and evidence. Every country and its regions or provinces have a structure of health policies that influences—and is influenced by—health technology. While these policies have mostly not been developed with the idea of channeling health technology development and diffusion, they affect technology. From its beginnings, HTA has focused on these policies, especially policies related to regulation, quality, and payment for care, as a target for its work. The primary philosophy has been to try to develop assessments useful for policy makers and policy making.

A number of countries have specific policies concerning screening, including its assessment. All countries have policies that influence screening. Screening tests must often pass some sort of regulatory assessment of their safety and efficacy, especially in the case of screening using medical equipment. Screening tests must be paid for, and in Europe, such payment is largely collectivized (therefore, a key question is whether a specific screening test is part of the benefit package of health insurance or a national health program). And screening may be subject to quality standards related to technical and laboratory issues, professional competence, and communication of results.

ASSESSMENT OF SCREENING

Assessment of screening is complex, as indicated in the paper by Dr. Steven Woolf that follows this introduction. However, as with all health technology, the primary question is whether the procedure improves health outcomes for individuals and population groups. If the answer is no, the screening program should not be implemented. If the answer is unknown, implementation is dubious. If the answer is yes, a number of other questions need answers, including whether cost-effectiveness is reasonable. In this series of papers, the focus is on the question of health outcomes.

The key question concerning screening and health outcomes is the following: Is there evidence that early detection is beneficial, and do persons identified with early-state disease through screening have better health outcomes than those who come to clinical attention without screening? Therefore, it is not enough to know that a screening test actually identifies early diseases or conditions at a specific point of development of disease. There must also be an effective intervention, usually a treatment. This treatment itself must be scientifically assessed. In short, the effects on health of the screening intervention need to be addressed.

The most reliable test of a screening program is a randomized controlled trial (RCT), in which an experimental group is screened and treated in accordance with screening results and a control group is followed in the usual way without screening. A classic RCT of screening was a study of mammography screening for breast cancer carried out in New York City in the 1970s, which was made up of women enrolled in the prepaid group practice, the Health Insurance Plan of Greater New York (11). The RCT showed clear benefit for mammography screening. This RCT began the assessment of mammography screening and led to the implementation of mammography screening in many countries, despite controversies concerning age groups for screening, risk factors, and frequency of screening.

DISCUSSION

The benefits and risks of health technology have come under increasing scrutiny during the past few years. Prevention activities, including screening, must be examined as carefully and critically as other health technologies. Prevention activities can be useless and harmful, just as can other healthcare activities, and prevention activities have other possibly negative consequences, such as financial costs.

Screening certainly can be scientifically assessed for efficacy (health benefits), as well as for other effects, such as cost-effectiveness. The number of such assessments is increasing rapidly. A key question is whether these assessment influence health policy and practice. The papers in this issue examine this question in nine European countries.

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