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Five articles on health technology assessment and its application to insurance coverage decision-making in Poland

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Contents

1 Introduction

The following is a series of five articles about Health Technology Assessment and its proposed application to insurance coverage decision-making in Poland. The articles were produced under contract to the Government of Poland, Ministry of Health, Office of Foreign Aid Programmes.

The purpose of the contract is to provide inputs into the process of detailing a basic package of social insurance benefits for use in Poland. The principle recommendation of the project is to base coverage decision on cost effectiveness criteria. The outputs of the project, which are described in general terms in these articles, discuss why health technology assessment constitutes international best practice in this area and how this practice could be introduced in Poland for determining whether a treatment, drug, device or any other health technology is cost-effective.

The articles also show the limits to health technology assessment, both in scientific and policy-making terms. The effectiveness of many health technologies is not known, cost data are often lacking, and examining the full scope of social, ethical, and other impacts is challenging. As such, even the most robust health technology assessment program cannot provide, for every technology, a clear, science-based conclusion. For this and other reasons, final decisions about coverage must always remain essentially a political choice. These articles discuss the interface between health technology assessment and a proposed "coverage body", which would be a political institution charged with making the final coverage decision.

Each of the articles describes both the purpose of the article, and how the series of articles fits together. The articles are intended to be read chronologically, but each article includes a summary of the prior papers. For those uniquely interested in the conclusions of the project, those can be read in the fifth paper.

The articles refer to a series of seven working papers that constitute the scope of the outputs of this project. We encourage the interested reader to download these articles from the web site of the Polish Ministry of Health for a detailed review of health technology assessment and how it could be implemented in Poland.

2 The Need for Health Technology Assessment in Poland

By David Banta, Steven Chapman, Mieczyslaw Blaszcyk, and Krysztof Landa

The Polish health care system is seeking new ways to improve its quality and cost-effectiveness. As part of this process, the Ministry of Health, in January 2001, asked the Netherlands Organization for Applied Scientific Research (TNO) for advice on how the Netherlands and other European countries determine which treatments and health services to reimburse through health insurance and how a similar process might be able to be established in Poland.

This is the first in a series of five-articles that explain "health technology assessment", which is the emerging European and international approach to making these decisions. This article reviews the need for health technology assessment in Poland, additional articles discuss how health technology assessment is done internationally, a proposed approach for applying it in Poland, and how health technology assessment can be used to decide which technologies merit social insurance coverage.

David Banta and Steven Chapman are Senior Scientists with the Netherlands Organization for Applied Scientific Research. David Banta is past president of the International Society for Health Technology Assessment.

Miecyslaw Blaszcyk is Director of Public Health at the Ministry of Public Health.

Krzyzstof Landa is an expert in health technology assessment and formerly head of the health technology assessment department of the National Center for Quality Assurance in Krakow.

Introduction

Health technology is undoubtedly one of the most important forms of technology in society. Everyone during the course of their lives, from birth to death, has some need for health technology, either for themselves or for families and friends. Health technology touches every individual directly.

Health technology is defined very broadly. All drugs, medical devices, treatments and procedures, and even the way health care is organized in hospitals and other facilities are within the definition of health technology. Many people think of a "technology" as simply a machine, but it also includes human skills and knowledge -- the way the doctor approaches treating a patient -- or programs that encourage people to stop smoking.

This article discusses the need for assessing whether health technology, broadly defined, is working for the benefit of people in Poland. Health Technology Assessment is the dominant method used in Europe and around the world for conducting a structured analysis of a health technology to determine whether it delivers benefit and, if so, how much and at what cost. The purpose of Health Technology Assessment is to provide government, sickness funds and health care managers with the information they need to make sure that the most cost-effective health technology is being used in Poland.

Problems with Health Technology

It would be difficult to over-emphasize the importance of health technology for any society. Health technology is the tool that can lead to safer living conditions, healthier individual behaviors, and better health facilities and treatments. Unfortunately, health technology has many problems, and these problems are today more apparent than at any time in history.

From a broad perspective, people around the world have lost their belief that science and technology are always good. No longer is technological progress seen as an end in itself; it is instead a means to end. In concrete terms, hospitals only need new and often expensive machines or new treatments if they lead to one thing -- people becoming healthier.

Unfortunately, decisions made in the past -- when every new technology was thought necessary -- resulted in both populations and health care systems that have become, to a remarkable degree, essentially dependent upon technology. Elderly people are kept alive on machines when they might prefer to die. Smaller and smaller babies, often with the potential for severe mental and physical handicaps, are kept alive. Infertile couples seek new technologies in attempts to have children, including powerful drugs whose long-term effects are not known. While many societies now are questioning whether these technologies are really what they want, the cost of health care in every society is rising rapidly, often due to investments and decisions that result in little health benefit at all.

An amazing fact, after approximately 25 years of well-designed studies to determine whether health technologies provide health benefits, is that only about 20 percent of them do. In every field of medical practice, these studies have uncovered that many unproven, and even ineffective, technologies are in common use. Unsafe technologies are being applied without information of their potential harm. Technologies that are effective for some diseases and problems are being applied to other diseases and problems for which they were not intended and for which their effects are unknown.

In short, health care systems around the world are in many cases simply wasting money on health technology. This is a tragedy, because no country can afford all the health care that people might want or need. Limited health care budgets often make it impossible to purchase new technologies that are proven to produce health benefits. This creates a double problem: ineffective technologies are crowding out effective ones, and it is the users of the health care system -- those who pay for care -- who suffer.

Problems in Poland?

Is Poland purchasing and using the right health care technology? We cannot say for sure because health technology in Poland has not been systematically studied. In countries where health technology has been thoroughly studied, such as the Netherlands, Sweden, Germany, and the United Kingdom, where health care systems are advanced, problems like those described above have been found to be common.

As such, we expect that these problems exist in Poland. Further, given current financial problems, lack of access to beneficial technologies in Poland may be worse than in Western Europe. The former Soviet type system of health care had a limited tradition of evaluation of health care practice. In sum, we suspect that the problem of using ineffective technologies in Poland is likely more severe than in Western Europe.

There is some evidence from the policy level that the Polish health care system has serious problems in choosing between health technologies. For example, under Polish law, a set of services called "highly qualified services" are paid for directly by the National Ministry of Health. No explicit criteria, such as is used in for example the Netherlands, are given in the law to select such services, and there is no statement

concerning why these services -- or technologies -- are paid for centrally. One assumes that these are intended to be important technologies that require high qualifications from clinicians and hospitals and that these technologies are too expensive for sickness funds and patients to pay for directly.

So are these technologies important? Generally speaking, no, they are not. They are certainly specialized and expensive, but the list of services makes little sense in terms of benefits and costs. The list contains a number of unproven and even experimental technologies, while important technologies that should be provided to the entire population are not fully reimbursed. Although this program is being revised, the most recent statements concerning criteria for selection of technologies still do not refer to explicit methods of assessing benefits and costs.

The Problem of Pharmaceuticals

The area of pharmaceuticals furnishes many examples of poor selection of technology. The Ministry of Health has selected a "basic list" of drugs that are fully paid for and "supplemental lists", which contain presumably less important drugs, that are partly reimbursed. These lists are highly problematic in terms of benefits and costs.

Many important drugs that would be considered basic in any health care system in the world are not on the basic list; for example, iron for treating anemia and opiates for treating pain.

Drugs for the treatment of the same condition are put on different lists with no rationale. For example, the simple, cheap and effective drugs for high blood pressure are on the supplemental list, while the basic list contains more expensive drugs that should only be used after failure of the simpler drugs. The list contains a number of ineffective and even obsolete drugs.

Obviously, explicit Health Technology Assessment methods for evaluating benefits and costs have had only a limited input to these decisions. This is a pity, since information is easily available internationally to check on the logic and scientific basis of these lists.

Health Technology Assessment

In short, it is clear that at the policy level -- that is, in the Ministry of Health and in the sickness funds -- there is a need for science-based information that can help improve the use of health technology in Poland.

In other countries, faced with similar problems, a process known as Health Technology Assessment has been introduced to help policy and decision-makers choose among technologies. In the Netherlands, for example, the Ministry of Health promotes and pays for formal Health Technology Assessment studies to assist it to make decisions. These studies are used in all policy areas, from choosing among prevention programs to selecting what type and how much clinical and rehabilitation services to provide.

The Health Technology Assessment process began in the Netherlands about 1985, when problems of expensive technology had become very prominent throughout Europe. Policymakers asked themselves then, "Is there value for money in health care?" The general answer was "not enough".

European Union Framework

Every member of the European Union now has a national Health Technology Assessment body or is planning one. These bodies are taking on ever-increasing importance as providers of essential information to guide policy decisions.

The use of Health Technology Assessment requires an adequate policy framework. Such a framework must include policies toward regulation, facility and manpower planning, payment, and quality for Health Technology Assessment results to be implemented in a way that leads to beneficial effects.

Our view is that this policy framework in Poland is largely present and that new policies adopted over the past decade are increasing the ability of Poland to begin Health Technology Assessment. What is now needed is a systematic Health Technology Assessment effort to produce information that decision-makers can use.

Need For A Systematic Process

How can policy-makers decide how to choose among health technologies? How can health planning be done such that it results in a healthier population? How can coverage decisions for health insurance be made?

Under the Soviet model, these were ideological decisions. An important problem for the Polish health care system today is that such ideological decisions have not been replaced with the international-standard decision-making process. This standard is based on scientific evidence, produced through a systematic Health Technology Assessment process.

Our research has revealed the need for one or more national institutions that can support Health Technology Assessment and coordinate its development and use throughout the health care system. We recommend that links be made to other national and international bodies that have been carrying out such work for years, which would ensure the rapid development of high quality Health Technology Assessment in Poland. We recommend developing expertise in Health Technology Assessment, both in the conduct of assessments and using its results. This will require means to motivate clinicians and administrators to use Health Technology Assessment in their own decisions.

Much needs to be done, but this is an extraordinarily good time for Poland to enter this field. International and national databases make a large volume of Health Technology Assessment results available on-line through the Internet, largely free. Poland is entering the 21st century on course to become part of an integrated Europe. As part of this, Poland needs to develop its health care system so that it is modern, effective, and cost-effective. This can only be done with attention to Health Technology Assessment.

Our next articles describe how Health Technology Assessment is done and what we propose to be done in Poland.

3 How Health Technology Assessment is Done

By David Banta, Steven Chapman, Mieczyslaw Blaszcyk, and Krzysztof Landa

The Polish health care system is seeking new ways to improve its quality and cost-effectiveness. As part of this process, the Ministry of Health, in January 2001, asked the Netherlands Organization for Applied Scientific Research (TNO) for advice on how the Netherlands and other European countries determine which treatments and health services to reimburse through health insurance and how a similar process might be able to be established in Poland.

This is the second in a series of five-articles that explain the process of "health technology assessment", which is the emerging European and international approach to making these decisions. The first article reviewed the need for health technology assessment in Poland. This article reviews how health technology assessment is done internationally. Additional articles will describe health technology assessment as a tool for policy, propose an approach for applying it in Poland, and how health technology assessment can be used to decide which technologies merit social insurance coverage.

David Banta and Steven Chapman are Senior Scientists with the Netherlands Organization for Applied Scientific Research. David Banta is past president of the International Society for Health Technology Assessment.

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Introduction

In our first article, we explained why we believe that the Polish people would get more benefit from the health care system if Health Technology Assessment were used. We gave evidence that this would be so, even given the current budget for health care, in a way that meets Polish needs and demands. We stated that Health Technology Assessment was a process for answering the question, "Is there value for money in health care?"

We define health technology very broadly. All drugs, medical devices, treatments and procedures, and even the way health care is organized in hospitals and other facilities are within the definition of health technology. Many people think of a "technology" as simply a machine, but it also includes human skills and knowledge -- the way the doctor approaches treating a patient -- or programs that encourage people to stop smoking.

This article describes how Health Technology Assessment is done. Health Technology Assessment is the dominant method used in Europe and around the world for conducting a structured analysis of a health technology to determine whether it delivers benefit and, if so, how much and at what cost. The purpose of Health Technology Assessment is to provide government, sickness funds and health care managers with the information they need to make sure that the most cost-effective health technology is being used in Poland.

Taking A Broad View of Technology

Health Technology Assessment takes a broad view of technology and of technological change. As such, it studies these issues from a number of perspectives, including ethics and the social consequences to society of using health technology. The most prominent

result of Health Technology Assessment is the determination of the health benefits and financial costs of a health technology.

But Health Technology Assessment does more. It analyzes barriers that stop good technologies from being used, and incentives that keep bad technologies in place. Health Technology Assessment gives suggestions to governments, sickness funds, and health facility managers so that good health technologies are available to everyone who needs them.

Given this broad view, Health Technology Assessment is not defined by a set of methods but by what it seeks to achieve. Thus, a Health Technology Assessment of a pharmaceutical can be conducted to make a decision whether the pharmaceutical should be reimbursed by sickness funds. Further, a Health Technology Assessment of the ethical implications of gene therapy can be done to help Polish society decide whether such therapy is desirable.

Synthesizing Scientific Knowledge

How does Health Technology Assessment do this? The first thing it does is to "synthesize" the scientific literature. Health Technology Assessment does this systematically, discovering and categorizing what is known about the health benefits -- or efficacy -- and cost-effectiveness of a drug or health program. Scientific facts are used and presented in an objective manner.

Where does this scientific literature come from? Primarily from a type of study known as a prospective randomized clinical trial. Such a study conducted, say, in the Netherlands or the United Kingdom, provides basic, objective scientific information about whether a technology in fact improves health. Much of this information is of generic applicability, and as relevant to Poland as anywhere else. Some of it though is not, and why that is so needs to be analyzed and reported. In many cases, multiple studies and analyses of their limitations need to be reported together, or "synthesized"; the process of doing this is among the most important activities of Health Technology Assessment.

Health Technology Assessment is not just medical or economic studies; it goes beyond that. Health Technology Assessment describes itself as "a systematic interdisciplinary process", based on scientific evidence and taking information from doctors and economists, social scientists, public health and health services researchers, engineers, ethicists, and the values and opinions of the general public. The ultimate aim of this process is an objective synthesis of what is known about a health technology, presented in a manner that helps decision-makers.

Promoting Changes

The goal of Health Technology Assessment is change. It is not research for the sake of pure knowledge.

Health Technology Assessment, when done correctly, helps to demonstrate problems and potential solutions in health. To do this, Health Technology Assessment has a systematic priority setting process for making sure that the topics it covers are among the most important to society.

Health Technology Assessment, when done correctly, must produce its information in a timely and comprehensible manner for people who make decisions. National policy makers and politicians, hospital administrators, clinicians, and the general public are making important decisions all the time. Health Technology Assessment needs to organize itself so that its scientific syntheses are available when and how these groups need it.

Yet, even when decision-makers use Health Technology Assessment to make decisions, sometimes hospitals, doctors, or other parts of the health system do not follow those decisions. The Netherlands is now using active means to make sure that these decisions are being implemented. Much is being learned about what stops good policy from being followed. Sometimes doctors do not want to change what they do; sometimes patients do not want to receive services differently. Recently, many countries have begun to use health insurance to implement these decisions. These countries pay for what Health Technology Assessment has found to be beneficial to health and stop paying for what is not beneficial.

The Principles of Health Technology Assessment

Health Technology Assessment must be carried out with integrity, and be based on valid scientific methods. Adhering to the following basic principles does this.

1 Identify and define the policy question to be answered. This will generally require setting priorities among the thousands of potential Health Technology Assessments. Consultation with policy makers is desirable to make sure that the most important questions are being asked.

2 Formulate the specific assessment question. The question asked and the scientific measures and methods used must address the concerns of all interested parties.

3 Describe the technology, including its current state of development and diffusion. Identify alternative technologies.

4 Systematically review research evidence on the benefits or efficacy, effectiveness, safety, and costs of the technology. This is the centerpiece of the Health Technology Assessment. This collection and synthesis must be carried out using well-defined and robust methods, preferably described in what scientists call a protocol. Any new collection of data concerning the question should only be done to complement existing knowledge.

5 Consider the implications of the technology for the delivery of health care and on society as a whole.

6 Present and discuss the wider implications of the assessment.

7 Make all assumptions explicit.

8 Involve experts, users, and others in the formulation of questions, identification of problems with the data, and the reaching of judgments on the implications of the findings. However, expert opinion alone without a systematic review of existing knowledge is not a Health Technology Assessment.

9 Present conclusions, options, and, sometimes -- but only if the findings permit it -- recommendations. The scientific basis for conclusions and recommendations must be clear.

10 Fully reference all sources of information, including published literature and analytical tools, such as tables of evidence.

Challenges in Health Technology Assessment

Can Health Technology Assessment really exclusively present scientifically valid conclusions? The answer, now, is yes, if existing standards for systematic reviews are followed. If not, as has been found in the past, assessments can be incomplete and biased, tending to reflect the views of the person or people carrying out the review.

Is Health Technology Assessment really independent? Sometimes those doing assessments will come under great pressure to produce answers. Where an answer must be produced under outside presssure, attention to these principles will help ensure that answers given are as reliable and valid as possible.

Health Technology Assessment needs to follow a transparent process, making clear the extent to which good principles of assessment have been followed. Few assessments will be totally comprehensive. If not, it is necessary that the limitations of the assessment in scope, methods, and conclusions are made explicit.

How can the use of decisions based on Health Technology Assessment be ensured? This is complicated and depends on the decision, however the following methodology might help.

1 How the results of the Health Technology Assessment will be disseminated needs to be considered during the process of planning assessments. Explicit dissemination strategies need to be developed that take into account the cultural and local context of the site where the assessments will be disseminated, as well as the potential costs and benefits of the strategies.

2 Assessments should aim to involve those who will be most affected by the assessment early in the process.

3 Assessment institutions should target their dissemination efforts to specific groups and tailor the message to meet specific needs and overcome potential barriers to change.

4 Assessment institutions that are not directly responsible for implementation of technologies should increase their coordination with those that are.

5 Assessment institutions should rigorously evaluate the dissemination and implementation strategies used and base their future activities on these evaluations.

6 Assessment institutions should make recommendations clear and understandable for all target groups, including the general public, policy makers, the media and health care professionals.

In sum, Health Technology Assessment aims to highlight the facts about a health technology, such that society can choose whether that health technology should be used. This article has shown how that is done. Our next article describes how Health Technology Assessment is a tool for policy makers.

4 Health Technology Assessment as a Tool for Policy

By David Banta, Steven Chapman, Mieczyslaw Blaszcyk, and Krzysztof Landa

The Polish health care system is seeking new ways to improve its quality and cost-effectiveness. As part of this process, the Ministry of Health, in January 2001, asked the Netherlands Organization for Applied Scientific Research (TNO) for advice on how the Netherlands and other European countries determine which treatments and health services to reimburse through health insurance and how a similar process might be able to be established in Poland.

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Introduction

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Our first article gave evidence why Health Technology Assessment would produce benefits, even given the current budget for health care, in a way that meets Polish needs and demands. We stated that Health Technology Assessment was a process for answering the question, "Is there value for money in health care?"

In our second article, we explained the process by which Health Technology Assessment highlights the scientific facts about a health technology, such that society can choose whether that health technology should be used. This was shown from a broad perspective, including medical and economic realities and ethics.

This article describes how Health Technology Assessment can become an important tool for a specific set of issues facing policy and decision-makers in the health care system.

Health Technology Assessment is the dominant method used in Europe and around the world for conducting a structured analysis of a health technology to determine whether it delivers benefit and, if so, how much and at what cost. The purpose of Health Technology Assessment is to provide government, sickness funds and health care

managers with the information they need to make sure that the most cost-effective health technology is being used in Poland.

Institutionalization of Health Technology Assessment

Health Technology Assessment must become part of health policy-making -- that is, institutionalized -- if it is to be effective and achieve its goal of better health.

Every country has a structure of health policies that influence – and is influenced by – health technology. Health Technology Assessment focuses on these policies, especially those related to regulation of the health care system, quality of care, and payment for care, as the subject of its work. The driving force to improve Health Technology Assessment is to make assessments useful for policy-makers and policy-making such that better health results. Let's look at what policies interact with health technology and Health Technology Assessment.

Research and Development

Research and development policies influence health technology. New, sometimes wondrous -- or apparently wondrous -- and often highly expensive health technologies are being introduced all the time. Those working in Health Technology Assessment must be aware of these new technologies before these are introduced into the health system, so that the decision whether to introduce them and reimburse them is based on a well-founded expectation that they will result in better health.

Pharmaceuticals

Most countries regulate pharmaceuticals, biological products, and equipment for safety, and to an extent, whether they in fact improve health. In Europe, such regulations have been partially harmonized by laws of the European Union. Health Technology Assessment is an integral part of the programs implementing these regulatory programs. Regulatory agencies examine the results of Health Technology Assessment studies to reach decisions as to whether the product is to be allowed on the market.

Public Health

Many countries regulate technologies related to public health. For example, in the Netherlands, any proposed population screening program -- like for breast cancer -- must, by law, have a thorough assessment before it can be implemented on a routine basis.

Facilities and Services

A number of countries regulate the number of facilities and where they are placed; services too are regulated. For example, in the Netherlands, about 15 capital intensive services involving high technology are regulated, including radiotherapy, transplants, renal dialysis, intensive care, and cardiac and neuro-surgery. During the last 10 years, Health Technology Assessment has become part of decision-making process in such programs.

This works as follows. Generally, the government decides to regulate a certain area of services, such as radiotherapy, and requests an assessment from a Health Technology Assessment institution before reaching its decision. The government can also ask for an assessment of an existing regulation with the purpose of modifying it. In the

Netherlands, the Dutch Health Council plays this assessment role. The Health Council is a statutory advisory body that supplies scientific evidence to parliament.

Reimbursement of services -- often through social insurance, but any payment mechanism -- obviously has a great influence on what services are offered and used.

Payment Systems

In countries with some sort of system-level financial budgeting, including the Netherlands, Sweden, France, and the United Kingdom, expenditures can be directly controlled. Tight control over expenditures puts pressure on providers to reduce costs. In truth, however, Health Technology Assessment appears to have played a limited role in decision-making over expenditure controls. Nevertheless, while system-level budgeting can control costs, it does not select which technologies to provide or not provide; Health Technology Assessment can help in making that selection.

In countries without system-level budgeting, the results of any fee-for-service system (including day-rates for hospitals) gives incentives for use of technology, and otherwise leads to excessive and inappropriate health technology. The general trend in Europe is away from fee-for-service payment systems. Where fee-for-service continues, it is being increasingly linked to Health Technology Assessment.

There are many options for using payment to control health technology. For example, levels of payment can be used to stimulate the use of particular technologies -- such as prevention services -- or to discourage the use of others without proven benefit -- such as ultrasound during pregnancy.

Social Insurance

One option gaining increasing attention is to determine insurance coverage decisions based on Health Technology Assessment. In Poland, as in the Netherlands, this has generally been referred to as "defining the benefit package". Under this option, technologies are not reimbursed -- or covered -- until they are shown to be cost-effective. This option has been fully analyzed in a series of reports to the Ministry of Health by the Netherlands Organization for Applied Scientific Research.

Quality Assurance

Quality assurance includes a variety of activities, including utilization review, certification and accreditation, and evaluation of outcomes. Quality assurance has become increasingly important in recent years. The relation of quality assurance to Health Technology Assessment is not always clear. This is so because the terms "quality" or "quality assurance" have broad meanings to many people. However, a consensus is developing that quality assurance is oriented to improving health outcomes for individuals and groups. Because of this consensus, links are developing between quality assurance and Health Technology Assessment.

Education and Information

Provision of information to consumers, doctors, and other health care providers may influence the use of health technology. Certainly, many support the "empowerment" of consumers in the health care system through providing them with reliable and valid information on such aspects of technology as its efficacy -- or health benefit -- and appropriate use. Health Technology Assessment is an important source of consumer information.

Similarly, the empowerment of clinicians is increasingly important, in large part due to their current dependence on information provided by industry, particularly the pharmaceutical industry. Health Technology Assessment can be an independent and unbiased source of information for clinicians.

Improving the Polish Health Care System

This article has shown that policy-makers have a wide range of options for improving the Polish health care system using Health Technology Assessment. Regulating access to the market, facilities, services, quality, and payment systems is today however more art than science.

Health Technology Assessment can go along way toward helping policy-makers make science-based decisions. And, when coupled with systematic efforts to convince health service providers and the consumer that the technologies chosen have the highest "value for money", real change -- and change for the better -- can occur in the Polish health care system.

How can Poland win back the confidence of the general public and the doctors, nurses and managers that work within it? Making investment decisions and choices among technologies based on explicit, transparent criteria that are focused on one thing -- improving health -- is undoubtedly key. Health Technology Assessment is the internationally-recognized tool for helping decision-makers make these choices.

Has Health Technology Assessment achieved its potential to fundamentally change health systems, particularly European health systems, into the most effective and cost-effective in the world? No, not yet. But, it is systematically working to do that. The challenge is to deepen and broaden its application everywhere it is applied. We invite Poland to join in this important effort.

5 A Proposed Approach to Health Technology Assessment in Poland

By David Banta, Steven Chapman, Mieczyslaw Blaszcyk, and Krzysztof Landa

The Polish health care system is seeking new ways to improve its quality and cost-effectiveness. As part of this process, the Ministry of Health, in January 2001, asked the Netherlands Organization for Applied Scientific Research (TNO) for advice on how the Netherlands and other European countries determine which treatments and health services to reimburse through health insurance and how a similar process might be able to be established in Poland.

This is the fourth in a series of five-articles that explain the process of "health technology assessment", which is the emerging European and international approach to making these decisions. The first article reviewed the need for health technology assessment in Poland. The second article described how Health Technology Assessment is done. The third article described the role of Health Technology Assessment as an important tool for a specific set of applications by policymakers. This article proposes an approach for applying Health Technology Assessment in Poland, and the last article will demonstrate how health technology assessment can be used to decide which technologies merit social insurance coverage.

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Health Technology Assessment is the dominant method used in Europe and around the world for conducting a structured analysis of a health technology to determine whether it delivers benefit and, if so, how much and at what cost. The purpose of Health Technology Assessment is to provide government, sickness funds and health care managers with the information they need to make sure that the most cost-effective health technology is being used in Poland.

Our second article explained the process by which Health Technology Assessment highlights the scientific facts about a health technology, such that society can choose

whether that health technology should be used. This was shown from a broad perspective, including medical and economic realities and ethics.

Our third article described how Health Technology Assessment is an important tool for policy and decision-makers in the health care system. We showed that Health Technology Assessment is -- throughout Europe -- an increasingly important tool for a specific set of issues, such as regulating a technology's access to the market, and a health system's facilities, services, quality, and payment systems. We argued that Health Technology Assessment could go a long way toward helping policy-makers make science-based decisions. And, when coupled with systematic efforts to convince health service providers and the consumer that the technologies chosen have the highest "value for money", real change -- and change for the better -- can occur in the Polish health care system.

This article describes a proposed approach to Health Technology Assessment in Poland.

Health Technology Assessment -- Public or Private?

Should Health Technology Assessment be a public or private undertaking? We say that it must be rooted in the public sector.

The goal of Health Technology Assessment is a healthier population. This is fundamentally a public aim, one requiring the commitment and ownership of the public, and its leaders, particularly in the Ministry of Health. As such, we assume -- as has been the case throughout Europe -- that a national public body for Health Technology Assessment should be formed. This article gives advice on how that could be done.

But, first, why not organize Health Technology Assessment in the private sector? Many companies are prepared to pay for such assessments, and there are typically efficiency advantages to private sector involvement.

In the case of a predominantly private health care system, there may in fact be good arguments for private sector based Health Technology Assessment. For example, in the United States, health care is generally paid for and provided by private organizations. Health Technology Assessment plays an important part in these organizations. But, it is organized as part of these private providers and insurers, and, of course, it shares their priorities.

The problem with such a model is that public health priorities tend to be lost. Insurers, for example, want profits above all, not health above all. Only the public sector, committed to health above all, can be relied upon to attempt to maximize health gain within limited resources for health care. Health Technology Assessment provides the public sector with an important basis for achieving this goal.

Should Health Technology Assessment be organized in research institutions and universities? Experience has shown that researchers are mainly driven by their own curiosity, and less by public needs. Historically, universities do not reward researchers well who work on issues purely of a public interest, such as Health Technology Assessment. Universities and their staffs value primarily the scientific excellence of the research. Societal relevance is of less priority.

European Organization of Health Technology Assessment

This reasoning has led most European countries to develop or at least to begin to develop public programs and agencies in Health Technology Assessment. For example, the International Network of Agencies for Health Technology Assessment now has more than 35 member organizations, most of them public programs at either national or regional level.

In the European Union, all Member States either have such bodies or have announced plans to develop them. The public health policy of the European Union emphasizes the importance of Health Technology Assessment and states that the European Commission will stimulate and support such activities, including a network of these Member State programs.

What are the lessons from these European countries? A new Health Technology Assessment program is generally proposed and developed because of policy concern about a special -- usually very expensive -- health technology used or about to be introduced in health services. The government wants to control costs and looks to Health Technology Assessment for help.

Doctors and nurses, who are concerned about quality, generally welcome these programs. They see that investment decisions by managers are sometimes not helpful in improving the quality of care, and health.

This combination of concerns -- about costs and quality -- lead to the establishment of formal Health Technology Assessment programs. Typically, a committee located within the Ministry of Health is first formed, with limited resources and staff support, and the first assessment is conducted -- almost always selected by political concerns.

For example, in Sweden, the first Health Technology Assessment was done on computed tomography scanner -- or CT Scanner -- because it was a highly visible and expensive new technology. In these early years, assessments almost always deal with such new technologies. With time, concerns for quality and improving health status have brought new priorities, such as improved care for people with diabetes or mental problems.

Independence

How do Health Technology Assessment programs remain independent of the political motivations behind their work? Through science, as established by the quality of their reports.

Does the medical profession welcome these reports? Initially, usually not. The medical profession is typically skeptical at first, thinking the assessment recommendations political, and obviously -- like everyone -- is reluctant to change practices without being confident that recommended changes are better. Health Technology Assessment can only overcome this through science, as established by continuous concern with the reliability and validity of results and active efforts to assure the quality of assessments.

Does this mean that Health Technology Assessment needs to isolate itself from the public, the government, and the medical profession? No. Health Technology Assessment programs have discovered the value of consulting these publics early and often to ensure that their needs are addressed and that the results speak to real and important problems.

Effectiveness and Implementation

Is Health Technology Assessment immediately effective? No, unless active efforts are made to implement recommendations. Throughout the early years of Health Technology Assessment in Europe, assessments were published and distributed and did have an affect on formal policies, but there was little or no active effort to put recommendations into practice. Today, however, active efforts are underway to make sure that the recommendations of assessments are implemented.

For example, when the Swedish Minister of Health observed the great potential impact of Health Technology Assessment, special resources for the purpose of implementing recommendations were made available. The United Kingdom also now invests resources specifically for purposes of making sure that assessment results are implemented.

Beyond Committees

As indicated, a Health Technology Assessment program typically begins with a committee. Soon, however, it becomes apparent that the committee needs more resources, including staff support, and some sort of institution begins to form.

The actual form of such institutions varies widely. It could be an agency, a defined program in the Ministry, a coordinating body, or some other type of institution. Staff is not only physicians and economists, but epidemiologists, sociologists, and others. The most important issue with staff is that they be committed to scientific analysis and comfortable working in a political environment. Clear and critical thinking is a must. Formal training can of course foster this.

Because Health Technology Assessment is multidisciplinary by its nature, many different disciplines must be involved. However, all these disciplines do not need to be part of the staff of the Health Technology Assessment program. Agencies typically have a network of consultants and, in addition, may have a specially appointed group of experts to oversee the work.

In some countries, policy makers have recognized that independence of the Health Technology Assessment process is necessary to make sure results are both valid and trusted. For this reason, independent public Health Technology Assessment agencies have been established in Sweden, France, Catalonia, and other places.

Our recommendation? An independent agency is not necessary for starting a Health Technology Assessment program in Poland. Some type of Health Technology Assessment agency should however be based in the public sector and look to European models for guidance on how to develop in future.

Our next and last article proposes how Health Technology Assessment can be used in Poland to assist sickness funds in making decisions about which services to pay for -- the issue of "coverage."

6 A Proposed Health Technology Assessment Process for Making Social Insurance Coverage Decisions in Poland

By David Banta, Steven Chapman, Mieczyslaw Blaszcyk, and Krzysztof Landa

The Polish health care system is seeking new ways to improve its quality and cost-effectiveness. As part of this process, the Ministry of Health, in January 2001, asked the Netherlands Organization for Applied Scientific Research (TNO) for advice on how the Netherlands and other European countries determine which treatments and health services to reimburse through health insurance and how a similar process might be able to be established in Poland.

This is the fifth in a series of five-articles that explain the process of "health technology assessment", which is the emerging European and international approach to making these decisions. The first article reviewed the need for health technology assessment in Poland. The second article described how Health Technology Assessment is done. The third article described the role of Health Technology Assessment as an important tool for a specific set of applications by policymakers. The fourth article proposed that a public agency be assigned the task of Health Technology Assessment. This last article demonstrates how health technology assessment can be used to decide which technologies merit social insurance coverage.

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Introduction

In our first article, we explained why we believe that the Polish people would get more benefit from the health care system if a system of Health Technology Assessment was used. We defined health technology very broadly. All drugs, medical devices, treatments and procedures, and even the way health care is organized in hospitals and other facilities are within the definition of health technology. Many people think of a "technology" as simply a machine, but it also includes human skills and knowledge -- the way the doctor approaches treating a patient -- or programs that encourage people to stop smoking.

Our first article gave evidence why Health Technology Assessment would produce benefits, even given the current budget for health care, in a way that meets Polish needs and demands. We stated that Health Technology Assessment was a process for answering the question, "Is there value for money in health care?"

Health Technology Assessment is the dominant method used in Europe and around the world for conducting a structured analysis of a health technology to determine whether it delivers benefit and, if so, how much and at what cost. The purpose of Health Technology Assessment is to provide government, sickness funds and health care managers with the information they need to make sure that the most cost-effective health technology is being used in Poland.

Our second article explained the process by which Health Technology Assessment highlights the scientific facts about a health technology, such that society can choose

whether that health technology should be used. This was shown from a broad perspective, including medical and economic realities and ethics.

Our third article described how Health Technology Assessment is an important tool for policy and decision-makers in the health care system. We showed that Health Technology Assessment is -- throughout Europe -- an increasingly important tool for a specific set of issues, such as regulating a technology's access to the market, and a health system's facilities, services, quality, and payment systems. We argued that Health Technology Assessment could go a long way toward helping policy-makers make science-based decisions. And, when coupled with systematic efforts to convince health service providers and the consumer that the technologies chosen have the highest "value for money", real change -- and change for the better -- can occur in the Polish health care system.

Our fourth article argued that Health Technology Assessment should be organized in the public sector in Poland and follow models now widely established throughout Europe.

This article sets forth how sickness funds specifically can apply Health Technology Assessment for making decisions about "coverage" -- or which services to reimburse.

Legal Background

The 1999 reform of Polish health care sets out many principles for social health insurance in Poland. The most important part of that law is Article 4.3, which states, "Health services are provided to the insured according to the financial resources commanded by the Health Insurance Funds. These services should reflect the current medical knowledge and practice, and should not go above the necessary level." Article 31 defined, in general terms, the services to be provided.

While this wording sets up an attractive ideal, it does not give much guidance on how to actually decide what services are to be provided. What is "current medical knowledge and practice"? What is the "necessary level"? What are the standards for making these decisions. Who is to decide? On what basis?

This vagueness and generality is common in health insurance laws. Such terminology as services shall be "reasonable and necessary" is frequently found in health insurance laws in Europe and North America. Unfortunately, experience has shown that this wording gives little guidance on how to answer the above questions.

Such vague wording reflects the central role of physicians in health care. Physicians have long been thought to know best which treatments should be provided to patients. Evidence of many problems in health care, including the widespread application of ineffective technologies and the widespread inappropriate application of effective technologies, has brought this traditional system into question. During recent years, health insurance coverage policy has been in rapid change, especially in Western Europe, but also in the United States and Canada.

A New Standard for Making Coverage Decisions

Health Technology Assessment can apply a new standard, and a rigorous and fair process for deciding what sickness funds should pay for.

Health Technology Assessment does not discard clinical judgment and experience, which is a key part of health care. It does not imply that policy makers should just follow the results of the assessment. Coverage decisions are not only about the proven effectiveness of a treatment or service, as established in a properly done Health Technology Assessment. They can also be based on political factors, desires of the population, industry pressures, professional preferences, access issues, ethical issues, and so forth. Health Technology Assessment plays an increasingly important part in coverage decisions, but is often not the only, or even the dominant, factor.

The Netherlands Organization for Applied Scientific Research has produced seven reports describing and recommending how Health Technology Assessment can be used to, among other things, make coverage decisions. The reports document how other European countries, such as the Netherlands and Switzerland, have integrated Health Technology Assessment into their coverage decisions.

A Coverage Body and a Health Technology Assessment Body

First, we propose that two independent bodies be established. The first is the Health Technology Assessment body, which produces independent, objective, evidence-based reports about the effectiveness and, if possible, the cost-effectiveness of health technologies

The second is a Coverage Body. Such a body would be established by the government and could include a variety of different publics. This body makes decisions about which services should be reimbursed by sickness funds. These issues are discussed in detail in the seventh report of the Netherlands Organization for Applied Scientific Research.

The most important issue here is the separation of the process of Health Technology Assessment from the actual coverage decision. Health Technology Assessment is a scientific process. Coverage decision-making is a political process. Without such a separation of science and politics, the process is doomed to failure, trusted by no one.

A Proposed Model Process for Poland

The two bodies would work according to the following simplified model for a proposed Health Technology Assessment process for making health insurance coverage decisions:

1 *Identification* of the technology in question, by the Coverage Body or by the Health Technology Assessment body. The Coverage Body must determine if the technology is a potential priority for an assessment. If so, it would ask the Health Technology Assessment body for an assessment.

2 *Review scientific literature* to determine the availability of information whether the service is proven effective, and, if possible, whether it is cost-effective. If sufficient information for a Health Technology Assessment is available, the Health Technology Assessment body would propose an assessment to the Coverage Body, including a time frame for the assessment. If not, the Health Technology Assessment body would propose supporting a prospective, well-designed study, such as a randomized clinical trial, and perhaps a simultaneous cost-effectiveness analysis to develop new information. If this proposal is accepted, a delay of several years until the final decision can be expected. Naturally, the Coverage Body may reject the option for an assessment and make the decision on other grounds. It can also, depending on the characteristics of a technology and of the clinical condition to which assessment will be applied, propose temporary conditions with coverage (as can be done in the Netherlands and Switzerland).

3 *Synthesis of available information*, including that on efficacy, safety, efficiency, and social and ethical aspects, leading to a complete assessment report. Extensive expert input is sought in this synthesis process. The synthesis leads to judgments, conclusions, and (perhaps) recommendations from the Health Technology Assessment body or program to the Coverage Body. While the Coverage Body obviously needs clear indications concerning the value of a technology, whether recommendations are appropriate depends on the specific context. The Coverage Body may prefer not to have recommendations, since it has the effect of bringing pressure for a specific action. On the other hand, the Coverage Body may ask for recommendations to consider.

4 *A coverage proposal* is then developed by the coverage body. After expert review, including review by the Health Technology Assessment body, the coverage decision is made, published, and promulgated.

A Comment and a Recommendation

Finally, it is also worth noting that evolving European Union law allows Member States autonomy in making such insurance decisions on grounds such as limited financial resources, but it does require that the basis for such decisions must be transparent, objective, and verifiable. Therefore, Health Technology Assessment will be increasingly important as Poland moves toward accession to the European Union.

We recommend that the government review the reports of the Netherlands Organization for Applied Scientific Research and take the legal, regulatory, and financing steps required to establish and implement Health Technology Assessment in Poland, principally for purposes of providing inputs into insurance coverage decisions.