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**TNO report**

**PG/VGZ 2002.003**

**Working Paper 3**

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**HTA methods, the purchase of highly qualified  
services, and other policy concerns**

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Project name	Standard of health services purchased in the national health insurance system (contract nr. 3.4.1.41) - Poland
Project number	011.41053

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Gorterbibliotheek

05 APR 2002

Postbus 2215 - 2301 CE Leiden

Searchnummer:

19.231



## Summary

In the transition of the Polish health care system to a social insurance system similar to that of many Western European countries, many issues have arisen. A number of such issues concern the basic of making decisions in Polish health care.

Under the Soviet model of health care, decisions were made based on socialist ideology and central planning. A new basis is needed. Following the lead of other European countries, Poland wishes to gain information on how decisions can be guided by health technology assessment. Some key problems in Poland include:

- 1 Attempts to set standards on safety and quality;
- 2 The basis of coverage, that is, the definition of the benefits package;
- 3 Payment for highly qualified services.

Health policy makers in European Union countries (and Switzerland) have addressed these and related problems, especially using Health Technology Assessment (HTA) and linking it to regulatory and reimbursement decisions. Using HTA actively would result in standards being set based on effectiveness and cost-effectiveness, coverage decisions being based (in part) on systematic evidence of effectiveness, and highly qualified services being regulated and reimbursed based on effectiveness. This paper focuses on highly qualified services as a case of linking national policy to HTA, considering both regulation and reimbursement.

### Health Technology Assessment

HTA may be defined as “a structured analysis of a health technology, a set of related technologies, or a technology-related issue that is performed for the purpose of providing input to a policy decision” (Banta, EUR-ASSESS glossary).

HTA is a form of policy research that systematically examines short- and long-term consequences of the application of health technologies. The goal of HTA is to provide input to decision making in policy and practice. The essential properties of HTA are this orientation to decision making and its multidisciplinary and comprehensive nature (Banta, Introduction to EUR-ASSESS).

Health technologies are the drugs, devices, procedures, and the organisational and support system within which health care is delivered.

HTA takes a broad view of technology and of technological change and carries out analyses of such issues from a number of perspectives. The field includes studies of ethical and social consequences of technology; factors speeding or impeding development and diffusion of health technology; the effects of public policies on diffusion and use of health technology and suggested changes in those policies; and studies of variation in use of technologies. The most prominent part of HTA is to determine, insofar as possible, the benefits and financial costs of a particular technology or group of technologies. The main goal of such studies is to improve “value for money” in health care.

Given this broad context, HTA is not defined by a set of methods but by its intent. A technical assessment of a pharmaceutical or medical device carried out by a program as

part of a regulatory decision can be considered HTA. Likewise, an ethical analysis concerning gene therapy done to clarify its implications before deciding whether to provide it can be considered an HTA. The most frequent activity in HTA is a synthesis or systematic review of available information, especially on efficacy and cost-effectiveness, to assist different types of policy decisions. A prospective randomised clinical trial or prospective cost-effectiveness study done for policy reasons, as in the Netherlands or the United Kingdom, is also a technology assessment. On the other hand, clinical research or even clinical trials done solely for the purpose of increasing scientific knowledge are not technology assessments.

Technology assessments are useful to a wide range of decision makers in health care, including government policy makers, insurance companies and other payers, industry, planners, administrators, clinicians, and patients.

### **A Theoretical Orientation to Health Technology Assessment and National Decisions**

Obviously, an important role for the Ministry of Health of Poland in the new structure is to improve the health of the population, within limited resources available for health care. Such a task requires attention to the inputs of care, that is, health technologies.

All too often, national planning decisions concerning health and health care are reactive to pressures and events instead of being “pro-active” in seeking to improve health care to the benefit of the population. Concerning technology, this often means that HTA is coupled to decisions as to whether to give in to pressure to buy new machines or provide new services. While HTA in such a context can undoubtedly be useful to policy makers, there are alternatives in which HTA may make a greater contribution to health of the population. HTA may be integrated into all health policy decisions so that the health care system gives more health benefit to the population. Such an integrated model will be discussed in more details in the body of the report.

#### ***Highly Qualified Services***

In the Health Insurance Act of 1997, Article 31a(1)(7) provides that highly qualified services shall be paid for centrally. The wording of the law is as follows: “highly-qualified medical procedures: the list, principles and procedure of providing these services will be announced by an ordinance of the Minister of Health and Social Welfare, following a consultation with the Chief Medical Council. These services are financed by the central budget”.

No further definition of highly qualified services is provided in the Act. There is no statement as to why some procedures are to be financed centrally, and there is no indication of what type of process should be followed to define such services.

A list of highly qualified services has been published periodically and these services are paid for from public funds, although they are sometime reimbursed as well from the sickness funds, leading to duplications in payment. The selection of the list is carried out by the Department of Public Health in the Ministry of Health and the Minister of Health makes the final decision. The procedure of selection is not transparent and few people know how or why a service is put on the list or removed from it.

During 2000, discussions were held in the Ministry of Health as to what the rationale for this program should be, what limitations there should be, what indications or other requirements there would be, etc. Guidelines for the program were developed in mid-2000. These guidelines are apparently in the process of implementation, but further steps are necessary to improve the list and to develop a sound and transparent procedure.

The 2000 guidelines includes criteria for highly qualified procedures:

- 1 Financing to come from only one source (the Ministry of Health);
- 2 The service should be "beyond regional character";
- 3 High unit price of a service;
- 4 The possibility of identification of the population demand for the service;
- 5 High level of technical complexity;
- 6 High index of effect/cost;
- 7 Susceptibility to monitoring the process of service delivery.

The focus of this report will not be specifically on this program, since it is changing. The focus will be on the use of HTA in such a program, Point 6 apparently refers to effectiveness and cost-effectiveness, which requires specific studies in the HTA field. This is an important development for the future.

The approach of most of the remainder of this report is to illustrate the use of HTA in such decisions. Through a series of case studies from different countries, the use of HTA in highly specialised services will be introduced.

#### ***Other Uses of HTA at the Central Level (Ministry of Health)***

The uses of HTA at the Central Level vary depending on the health care system of the country, as well as by the priorities felt by policy makers in a particular country. For example, a number of countries provide public health and preventive programs from the central budget. Preventive activities are weak in Poland. Because the TNO team feels that this area should be developed in Poland, some examples in this area are also provided.

Another area often regulated at the central level and sometimes paid for is organ transplants. Therefore, this area will also be considered specifically.

Some countries do actually set health care and health priorities based on population needs, as implied by the theoretical model above. Therefore, one example will be provided of such an approach.

Lastly, a major concern for national health policy makers today is the quality of services provided. HTA is aimed, in large part, at improving quality. However, HTA does not generally have the ability to implement. One possibility is to implement HTA through the developing programs of quality assurance.

This report also includes two appendices. The first concerns principles of costing, and will be of interest to those who seek specific understanding of the "cost" part of Health Technology Assessment. The second is the transcript of the conference that took place concerning this Working Paper, in May 2001.



## Contents

<b>1</b>	<b>HTA Methods, Highly Qualified Services, and Other Policy Concerns — 9</b>
1.1	Introduction — 9
1.2	“Highly Qualified Services” — 9
<b>2</b>	<b>The Case of the Netherlands — 11</b>
2.1	The Case of Computed Tomography (CT) Scanning in the Netherlands — 13
2.2	The Case of Magnetic Resonance Imaging (MRI) in the Netherlands — 14
2.3	The Case of Neonatal Intensive Care in the Netherlands — 15
2.4	Other Prominent Assessments in the Netherlands — 16
<b>3</b>	<b>Introduction of the CT Scanner to Sweden — 19</b>
<b>4</b>	<b>Introduction of the Magnetic Resonance Imaging (MRI) Scanner to Canada — 21</b>
<b>5</b>	<b>The Introduction of Lithotripsy to France — 23</b>
<b>6</b>	<b>Renal Dialysis in the United States — 25</b>
<b>7</b>	<b>Centrally Planned Organ Transplant Services – The Case of the Netherlands — 27</b>
<b>8</b>	<b>Centrally Planned Prevention and Screening Services and Their Relation to Health Technology Assessment — 29</b>
<b>9</b>	<b>Centrally Planned Prevention and Screening Services and Their Possible Relation to Health Technology Assessment – The Case of the Netherlands — 31</b>
<b>10</b>	<b>HTA and Policies toward Screening in the United Kingdom — 33</b>
<b>11</b>	<b>Quality Improvement and Health Technology Assessment — 35</b>
<b>12</b>	<b>A Theoretical Model of Health Technology Assessment and Planning — 37</b>
<b>13</b>	<b>Discussion — 39</b>
<b>14</b>	<b>References — 41</b>
	<b>Appendices</b>
<b>A</b>	Principles of Costing
<b>B</b>	Presentations and Discussion at Seminar – May 2001





# 1 HTA Methods, Highly Qualified Services, and Other Policy Concerns

## 1.1 Introduction

Other reports have described the background of Poland and the Polish health care system, so this report will not repeat that material.

What is very clear is that the Polish health care system has changed dramatically in recent years. The main change has been to move away from the centralised model of the Soviet system and the development of decentralised administration. With this change, the role of the Ministry of Health has also changed dramatically, so that it is becoming an instrument for policy development and leadership rather than the head of a centralised health care bureaucracy. A great deal of decision-making is now delegated to other parts of the health care system.

At the same time, the Polish Ministry of Health retains an overall responsibility for public health, that is, assuring a healthier population within the limited resources available for health care. Such a role requires having an overview of the most important health problems and what may be done to ameliorate them. It requires knowledge of available health technologies and their potential costs and benefits. It means setting priorities between different policies and between different technologies.

A possible misunderstanding must be addressed from the beginning. Many policy-makers expect HTA to control or help control health care costs. However, while individual HTAs can help reduce expenditures on specific technologies (and increase expenditures on others), controlling costs is fundamentally a task for budgets. Most European systems now have more-or-less fixed budgets for a year of care, especially hospital care. This means that CHOICE is the key word through the health care system. HTA is a tool to help choice. That is its role in relation to cost-containment.

To develop its new role, the Ministry of Health needs sources of information that will guide future developments. Health technology assessment (HTA) is such a source of information. It is because of this that the Polish Ministry of Health has asked TNO to advise it on how to link HTA with different policy areas, focusing on health benefits coverage. This report focuses on a related area, those decisions that are still made in the Ministry of Health, or those decisions that may be made in the future.

## 1.2 “Highly Qualified Services”

The Health Insurance Act of 1997 provides that the Ministry of Health will pay for certain services called “highly qualified” in the Act. The meaning of this term is not entirely clear, and it is neither defined in the Act, nor in an Ordinance from the Ministry of Health. In fact, essentially any health service could be put on the list of highly qualified services at this moment, since there have been no clear criteria for the list.

Scanning the 1998 list makes it clear that any rational basis for the list does not exist. The list does, in fact, mostly deal with very specialised services, but the list includes established technologies as well as a number of experimental services. For example,

radiotherapy, a fully established procedure, is listed, as is cochlear implants for deafness. On the other hand, treatment of Gaucher's Disease, a rare genetic disorder, with cytostatics is on the list; this is an experimental treatment.

During 2000, discussions were held in the Ministry of Health as to what the rationale for this program should be, what limitations there should be, what indications or other requirements there would be, etc. Guidelines for the program were developed in mid-2000. These guidelines are apparently in the process of implementation, but further steps are necessary to improve the list and to develop a sound and transparent procedure.

The 2000 guidelines includes criteria for highly qualified procedures:

- 1 Financing to come from only one source (the Ministry of Health);
- 2 The service should be "beyond regional character";
- 3 High unit price of a service;
- 4 The possibility of identification of the population demand for the service;
- 5 High level of technical complexity;
- 6 High index of effect/cost;
- 7 Susceptibility to monitoring the process of service delivery.

Another recent change is that as part of the new "compulsory act on health insurance", which has been in effect for two months, the Ministry of Health, after consultation with doctors and nurses associations, will define a list of health services, pharmaceuticals, and other medical technologies which have a high price and for which special medical qualifications are necessary. The Minister of Health will take advice from a "confidential committee" that will make a judgement about the need for access to these highly qualified services, and then propose a list of them for reimbursement. It is not clear that this is a change in policy. The most important question, in terms of this project, is whether effectiveness or cost-effectiveness, with assume a broader role than in the past.

The focus of this report will not be specifically on this program, particularly since it is changing. The focus will be on the use of HTA in such a program, Point 6 apparently refers to effectiveness and cost-effectiveness, which requires specific studies in the HTA field. This is an important development for the future.

In the section that follows, a number of case studies from different countries will be presented to illustrate how HTA is carried out in similar cases, and how it is used in making the actual decision.

## 2 The Case of the Netherlands

The Article 18 program of the Netherlands is similar in some ways to the highly qualified services, and will therefore be presented at some length.

The Hospital Provisions Act of 1971 is the major health-planning tool in the Netherlands. (Bos, 2000). The law gives the government the power to regulate all building of hospitals and care institutions. The main goal is to enable the Minister of Health to regulate and co-ordinate the creation of inpatient facilities and outpatient services throughout the country, to ensure the population's maximum access to health care. The provincial health authorities had the responsibility for implementing this plan. Article 18 of the law related specifically to the planning of supraregional, high-technology medical facilities (as stated in other papers from this project, the law has been changed, but the Article 18 part has remained essentially unchanged). The law requires hospital authorities that want to provide these services to seek direct approach from the Minister of Health. When the minister decides that a specific technology or medical service should be regulated through Article, a planning document is published containing general planning guidelines, an estimate of the need for that service, quality criteria to be met by hospitals, and other pertinent points. The minister asks the Health Council, a national body set up to provide scientific advice to the government, to report on the technology's scientific state of the art, safety and efficacy aspects, cost-effectiveness, and appropriate use. Article 18 generally deals with expensive, technically sophisticated services that will be located in only a few facilities, for which the need can be expressed quantitatively and that are not considered experimental. Originally, Article 18 regulation as used mainly to control the diffusion of technologies by limiting the number of facilities (e.g. computed tomography (CT) scanners, linear accelerators and dialysis machines) and the number of procedures, with a focus on cost-containment. But gradually the government began to use this tool as a planning instrument, to ensure proper geographic distribution, to promote concentration of facilities, and to enhance expertise and quality, with the emphasis on cost-effectiveness and appropriate use. Emphasis in the Article 18 program shifted from merely controlling the purchase of equipment to regulating neonatal intensive care, and in vitro fertilisation (IVF). Since 1984, with the introduction of the global budget system for hospitals, the government no longer attempts to regulate the volume of procedures, since this has become part of the negotiations over the annual budget between hospitals and insurers.

Article 18 regulation has also become more flexible. Regulation is first applied for a period of 4 years and then either removed or renewed, even for an indefinite period. The regulation is lifted when the technologies comes to be considered a standard procedure no longer restricted to selected institutions (e.g., CT scanners, magnetic resonance imaging (MRI), nuclear diagnostics, and cardiac angiography).

Article 18 originally applied only to community hospitals, since university hospitals then fell under the authority of the Ministry of Education and Science. But beginning in 1985, the Ministries of Health and Education and Science began to co-operate to ensure smooth functioning of the Article 18 program. In 1990 the Scientific Education Act and the Hospital Provisions Act brought the academic hospitals under the authority of the Minister of Health, as far as health care was concerned.

The co-ordination between Article 18 and payment decisions has also become more effective. Since Article 18 approval implies money to perform the service, reimbursement decisions tend to follow such approval. For a number of technologies, specific budget parameters have been calculated for use in budget negotiations (e.g., for bone marrow transplantation). In recent years, Article 18 regulation has been coupled to evaluation activities under the Fund for Investigational Medicine. The aim here is to ensure that new technologies under assessment are not widely diffused throughout the health care system before the results of assessment are known and interpreted.

While the research fund bears the cost of evaluative research, Article 18 is used to deny other hospitals the use of the new technology. Such cases are decided formally by the Minister of Health after advice from such bodies as the Health Insurance Council and the Health Council, as in the case of lung transplantation.

In general, Article 18 works well. It has prevented oversupply and stimulates effective use of the technologies concerned. Hospitals that ignore the regulations are subject to sanctions and will not be reimbursed by insurance agencies. The procedure is, however, rather bureaucratic and time-consuming. Only a minority of the thousand of technologies offered by the health care system is controlled under this program (approximately 3% of total health care costs and 9% of hospital costs). In recent years, the Ministry of Health has concentrated on a more flexible and effective approach to control health technology. A new Law on Specific Medical Services, introduced in 1998, focuses on quality of care and appropriate use, rather than on cost containment. There is a close relation with assessment of technology (Bos, 2000).

The Table shows the status of the program in 1996. It can readily be seen that almost all of the procedures are important in health care, are established by HTA, and are provided in relatively limited numbers, meaning that they need to be centralised. HTA has been progressively integrated in the program since the mid-1980s, so that all technologies on the list have had specific HTAs carried out before implementation. The Health Council has a specific program for HTA in relation to Article 18.

Type of Service	Controlled since	Present Status	Total Program Cost (million NLG)
Renal dialysis	1976	Regulation continued	525
Kidney transplantation	1976	Regulation continued	330
Radiotherapy	1979	Regulation continued	180
Computed tomography	1984	Regulation lifted 1988	-
Nuclear medicine (diagnostic and therapeutic)	1984	Regulation lifted 1988	-
Genetic screening	1984	Regulation continued	24
Cardiac angiography	1984	Regulation lifted 1991	-
Cardiac surgery	1984	Regulation continued	450
Interventional cardiology (PTCA, implantable defibrillator)	1984	Regulation continued	145
Neurosurgery	1984	Lifted for simple procedures in 1991	170

Type of Service	Controlled since	Present Status	Total Program Cost (million NLG)
Neonatal intensive care (including ECMO)	1984	Regulation continued	120
In vitro fertilisation	1988	Regulation continued	40
Heart transplantation	1994	Regulation continued	10
Liver transplantation	1991	Regulation continued	14
Lung and heart-lung transplantation	1991/1996	Regulation continued	6
New candidates for Article 18:			
Bone Marrow transplantation (allogeneic and autologous)	1994		54
Pancreatic transplantation	1994		2

Source: Bos (2000)

The new law, the Law on Specific Medical Procedure, has other implications: the legislation's focus on quality of care with specific technologies, and with their ethical, legal, and societal aspects. HTA will play an even more prominent role in the new process. Regulation by the central health authorities will be limited to the period of assessment and introduction of new technologies. Once a technology is established, planning and diffusion should be controlled by the providers and the insurance agencies through the system of negotiating budgets and outcome.

## 2.1 The Case of Computed Tomography (CT) Scanning in the Netherlands

Dutch radiologists learned about CT scanning at the yearly Radiological Society of North America Congress in the early 1970s. Leading radiologists argued that the Netherlands should take part in the clinical development of CT scanning from the very beginning. Several scanners were purchased by specialised hospitals and clinics (Bos, 1995).

The Minister of Health then requested the Health Council to report on the state of the art of CT scanning. Specifically, the Council was asked to consider the evidence of clinical benefit of CT and the necessity of regulating the diffusion process through Article 18 regulation. Radiologists, strongly supported by the Dutch company Philips, argued that CT should not be withheld from eligible patients.

The Health Council published its first report after six months, based on a comprehensive review of the evidence (1976). The main conclusions were as follows:

- 1 CT scanners should be regulated under Article 18 because of the high cost, speed of technological development, and special expertise needed;
- 2 CT scanning is of great potential value to neuroradiology (brain, central nervous system);
- 3 The value of CT scanning for other parts of the body is not defined yet;
- 4 CT scanners should, for the time being, be restricted to teaching hospitals.

However, the Ministry of Health failed to act, and diffusion of CT scanners proceeded rather rapidly, so that there were 37 scanners (2.6 per million population) by 1981, without planning or co-ordination, and despite two other reports from the Health Council proposing further evaluation, as well as co-ordination and planning (Health Council, 1977; 1981). The Ministry finally acted in 1981, publishing a decree to regulate CT scanners so that no more scanners could be installed by general hospitals until a definite plan for diffusion was published. During the next few years, only university hospitals, exempt from the regulation, were able to buy scanners. Further regulation in 1984 restricted the number of scans nationally to 130,000, which was less than the number being provided at that time, so that no more scanners could be purchased. In fact, the number of scanners was 45 in 1984, and was only 46 in 1987. Radiologists and Philips ardently opposed this regulation, which was finally totally lifted in 1989.

This case illustrates that assessment for regulatory purposes is possible, even very early in the development. However, assessment is not enough. The government must be prepared to take advice and to act. In the late 1970s and early 1980s, there was no tradition of HTA in the Netherlands, which main explain the lack of action. Regulation in this case was addressed primarily to cost-containment, and was successful in that aim, perhaps, but the government and Article 18 regulation were unpopular in certain circles, especially radiologists.

## **2.2 The Case of Magnetic Resonance Imaging (MRI) in the Netherlands**

The Philips Company was one of the first to enter the MRI market, installing a prototype machine in its factory in 1981 (Bos, 1995). This machine was made available without cost to radiologists from four university hospitals. A second prototype was installed in the university hospital in Leiden in 1982 as a test site for inpatient MRI studies. In 1983, the other university hospitals approached the Ministry of Education and Science for permission to purchase MRI scanners. The Minister of Education and Science approached the Ministry of Health to develop a careful policy for the introduction of MRI scanners. The failures of assessment and planning in the case of CT scanning were definitely on the minds of top policy makers.

The Health Council was asked to report on the state of the art of MRI. The Health Council presented its report in January 1984 (Health Council, 1984). The new technology was considered to be very promising, but its exact application was not defined. The Council proposed that three hospitals co-operate in an assessment. In mid-1984, the Ministers of Health and Education and Science announced the policy. Four university hospitals could operate MRI scanners while they co-operated in an assessment, but the hospitals would have to furnish the services out of existing budgets. In a break-through agreement, the sickness funds and private insurance companies decided that they would pay half the operating costs in the four selected hospitals. In the meantime, Article 18 regulation prevented other hospitals from purchasing MRI scanners.

The evaluation was completed in 1989, demonstrating considered clinical benefit, especially in scanning of the brain and spinal cord. On the basis of this evaluation, the government gave permission for six more scanners, four in university hospitals and two

in national oncology (cancer) centres. Extra money was provided to finance these scanners.

In 1991, the Minister of Health decided to end restrictions on MRI, freeing hospitals to acquire scanners if they could finance them from existing budgets. By 1993, there were 33 MRI scanners, with predictions that there would be 80 to 90 scanners by early in the 21<sup>st</sup> century.

In this case, learning from the case of CT scanning, government regulation and payment was used creatively to assure careful evaluation before diffusion. The precedent set in this case has been followed very often since that time. A standard model in the Netherlands is now to announce Article 18 regulation of a new technology and only allow its use in hospitals participating in the evaluation. The evaluation is generally funded by the Investigational Medicine Fund, a fund set up to support HTA for policy purposes.

## **2.3 The Case of Neonatal Intensive Care in the Netherlands**

Modern, sophisticated neonatal intensive care began to develop around 1970. Regional neonatal intensive care units (NICUs) were established in the university hospitals and some paediatric hospitals. By 1978, there were 31 fully equipped intensive care units available, including a number of small units in regional hospitals. In 1979, when the situation with neonatal intensive care had become critical, the Minister asked the Council to assess the scientific development of neonatal intensive care and report on the future need for NICU facilities. The main concern was proliferation of NICUs and the possibility of poor quality of care.

The Health Council made its recommendations in 1982. The Council recommended the following: (Health Council, 1982):

- 1 Neonatal intensive care should be restricted to 10 fully equipped supra-regional centres (8 university hospitals and 2 non-university centres).
- 2 The future need (1985-1990) for neonatal ICU in the Netherlands was calculated to be 140 Intensive Care (IC) beds and 228 High Care (HC)/Medium Care (MC) beds.
- 3 The minimum size for a centre was put at 10 IC, 12 HC and 10 MC beds.
- 4 Neonatal intensive care should be concentrated in these 10 centres by means of legal regulation, by applying article 18.

In 1983 this policy was stated, but it had to wait till 1987 before the Ministry of Health published a planning document in which the 10 centres were actually named. Between 1986 and 1991 the Minister of Health made the development of these NICU centres one of his priorities, approving the building of new facilities and increasing the budgets of these centres.

Although during these years the capacity of the NICU centres had almost doubled, it became clear that the shortage was not resolved. Therefore the Minister again requested the Health Council in 1989 to report on future developments in intensive care. This report was ready in 1991 (Health Council, 1991). It contained a survey of the use of NICU facilities in the Netherlands, which showed that the demand for neonatal IC was growing. It also contained an assessment of the effectiveness of NICU (improving survival and preventing handicaps). Finally, the need for NICU was estimated to be

165-202 IC beds (at 80% occupancy) in the 1990-1995 period, to be realised in the existing ten centres.

This time the Minister of Health did not take long to act: in January 1993 a new Planning Document was published which set the future need for NICU at 168 beds (at 90% occupancy rate). Peripheral hospitals that provide NICU on a small scale, but had not been authorised under Article 18, would have to terminate this type of care, but some were allowed to continue until the capacity in the 10 centres was expanded (Bos, 1995).

In 1990, Extracorporeal Membrane Oxygenation (ECMO) was introduced in the Netherlands in the Nijmegen University Hospital, after several years of animal experimentation. Although the first treatments seemed successful, there was a doubt over the long-term results of ECMO. The Health Council, in its 1990 annual report, found that initial results were favourable, but that ECMO had significant complications and about 10 percent of survivors showed mental and physical disability. The Council stated that ECMO should be considered an “experimental therapy” and recommended its use only in cases of severe neonatal respiratory failure in selected NICUs. The Council strongly recommended a prospective HTA. The Ministry of Health followed these recommendations. In 1991, four centres applied for funding of a ECMO from the Fund for Investigational Medicine. Two centres were selected. In 1993, the Minister of Health restricted the use of ECMO by applying Article 18 regulation, and ECMO was only allowed in the two centres involved in the HTA. The study found significantly better survival in neonates with serious respiratory distress and no difference in short-term morbidity in ECMO-treated babies at a cost of about US\$25,000 per baby. The Minister then decided, about 1995, to license ECMO and cover it for reimbursement, restricted to two national centres. The initial estimate of need for ECMO was a minimum of 24 patients a year, rising over time.

Assessment studies have played an important role in the development of NICU centres in the Netherlands. Two assessment reports issued by the Health Council (in 1982 and 1991) were the basis for the policy pursued by the Minister of Health. The prospective HTA on ECMO led to policies toward regulation and coverage consistent with the results of the assessment.

## **2.4 Other Prominent Assessments in the Netherlands**

In 1985, three prominent HTA projects were initiated by the government and the Sickness Funds Council to study heart transplantation, liver transplantation, and in vitro fertilisation (IVF). The assessments were comprehensive, covering efficacy and safety, social, economic, and ethical aspects of the technologies. The research was carried out in two university hospitals. Final reports were completed in 1988 and 1989. Based on these reports, the Ministry of Health and the Sickness Funds Council decided to cover heart transplantation and IVF, while further research on the long-term survival of liver transplant was organised. At the completion of the assessment on liver transplant, it was also covered. These three technologies were regulated under Article 18 during the research, and they continue to be regulated under Article 18 to the present (Bos, 2000).

The lack of expertise and experience in HTA in the Netherlands led the Ministry of Health to ask the Steering Committee on Future Health Scenarios (STG) to recommend a long-term policy on medical technology. In its 1987 report, the STGG raised the



possibility of developing an “early warning system” for future health technology. The main policy conclusion was that if the Netherlands wished to have greater control over the development and diffusion of health technology, it would have to create a co-ordinated system for identifying technologies and assessing their benefits, risks, financial costs, and social implications (Banta and Gelijs, 1987).

The government of the Netherlands has gradually followed this advice. The Health Council has “scanned” future technology since 1988, producing annual reports for the government. In 1988, the government and the Sickness Funds Council set up the National Fund for Investigational Medicine to give national support to HTA. This Fund was primarily for the purpose of advising on specific technologies based on HTAs supported by the Fund. In 1991, the Health Council published a report titled “Medical practice at the crossroads”, in which it observed that inappropriate use of both established and new medical procedures and technologies is widespread in the Netherlands. The main conclusion of the report is that large and unexplained variations in medical practice point to the inefficient use of resources, which can no longer be ignored. This report has stimulated great debate among the medical profession and policy makers, led to considerable interest in the issue of HTA in the Dutch Parliament, and has caused further policy changes, which are ongoing. Perhaps the most interesting change at this moment is that a “platform” for national co-ordination of HTA is being established as part of the National Organisation for Science.

The use of HTA in reimbursement decisions in the Netherlands, including defining the benefit package, has been described in Working Papers 1 and 4.



### 3 Introduction of the CT Scanner to Sweden

The computed tomography (CT) scanner was introduced to Sweden in 1973, the same year that the United States acquired its first scanner. Planners in Sweden did not view the introduction of CT scanning to Swedish hospitals as a simple case of adding another machine. They viewed CT as a technology that would partially replace the other diagnostic tests, so that these could be allocated fewer resources. Therefore, when the first head scanner was installed by the Karolinska Hospital in Stockholm, an evaluation was immediately mounted to rationalise further purchases of CT scanners.

The research team, which worked from the Swedish Planning and Rationalisation Institute (SPRI), carried out a study weighing the costs of the CT head scanner against those of cerebral angiography and pneumoencephalography at various levels of examinations. The basic question was this: How many angiographic and/or pneumoencephalographic examinations would have to be replaced at a given hospital by CT scanning in order for the costs of the scanner to be economically justified? Only equipment, hospital, and personnel costs were included in the analysis, although other costs and benefits, including medical and psychological value of the innovation, were listed. The cost-effective level for installation of CT scanners was determined to lie somewhere between the levels of the regional and central general hospitals (Jonsson, 1980). Since some of the large central hospitals did almost as many brain examinations as the smallest regional hospital, the evaluation did not recommend specific hospitals to receive CT scanners. Instead, the evaluation published charts that county councils could use to graph specific levels of usage of angiography and pneumoencephalography at a given hospital in order to determine whether replacement of these modalities with a CT scanner would be cost-effective.

The success of the Swedish evaluation was probably due in large part to its timeliness. The county councils needed information to help their decision-making. The information was available when it was needed, and it was credible. Most Swedish hospitals waited for the report and followed its recommendations. Only two scanners had been installed in Sweden by the time the report was released. By December 1978, Sweden had eight head scanners, all but one at regional hospitals, and six total body scanners, two of which were located at the largest central hospital. An important factor was that the county councils expected the CT scanners to pay for themselves from replaced procedures. Hospitals therefore received only a small additional budget when they purchased a scanner.

By May 1978 Sweden had only 1.6 per million scanners, while the USA had 4.8 scanners per million (Gaensler et al, 1982). This is surprising, considering that Sweden originated the specialty of neuroradiology and has been a leader in radiology and radiotherapy. One might have predicted that such medical and scientific leadership could have led to rapid diffusion of an exciting medical innovation such as CT scanning.

While the CT scanner has continued to diffuse in Sweden, it has been continually monitored and has never been out of control, as it was in some other countries. There is no doubt that the HTA had a significant and positive impact on the decisions to purchase and pay for scanners.



## 4 Introduction of the Magnetic Resonance Imaging (MRI) Scanner to Canada

MRI was introduced to Canada as a research tool in 1982. The first clinical uses began in 1985. The provincial governments were generally sceptical of the value of MRI. CT scanners had diffused rather rapidly into Canada, and since the images with MRI and CT scanning were similar, they wished to be assured that the MRI scanner was truly important (Battista et al, 1995).

Initial diffusion of MRI scanners was restrained by the global budgeting system of Canadian hospitals. It was difficult for hospitals to buy MRI scanners without additional funds. The national and regional concerns about levels of health care spending had tended to promote scepticism about new technology. In addition, a severe recession in the late 1980s led to further concerns about such high technology.

In 1988, the first technology assessment body was established in Canada, in the Province of Quebec, known as the Quebec Council of Evaluation of Health Technology (CETS in its French acronym). Subsequently, other provinces have established such bodies, although all provinces do not yet have them.

In the province of Quebec, a 1990 report to the Ministry of Health and Social Services (MHSS) noted that MRI's "diagnostic superiority" remained unproven and recommended that MRI be considered as a service specific to university centres. Projected demand was estimated to require eight units in the province, of which three were operating and three were under construction when the report was published. The report also proposed several general approaches to new technology including 1) a systematic selection and follow-up of patients receiving MRI to ensure that only those in which MRI would be the first choice of diagnostic investigation were in fact receiving it, thus reducing waiting lists to a minimum, 2) payment and budgeting mechanisms based on general categories of diagnostic services rather than specific modalities, and 3) modelling to establish an optimal distribution of MRI technology (CETS, 1990).

The relation between the assessment of MRI scanners and other factors is difficult to separate. However, it is clear that Canada has many fewer scanners on a population basis than the United States.



## 5 The Introduction of Lithotripsy to France

Extra-corporeal shock wave lithotripsy (ESWL) became commercially available in 1982. Two lithotripters were acquired by French centres, one in Paris and one in Lyon (Weill, 1993)

Because this was a high-priced machine, the French government preferred to purchase a French product if one was available. However, although French companies had begun to develop a lithotripter in 1980, it was not yet available. This aspect of industrial policy was important in the French policy toward lithotripsy.

Purchase of lithotripters was prevented by national regulations concerning high technology. To purchase a large machine for routine use in France requires that it be listed on the "health map." In addition, because of the high costs, grants from the Ministry of Health were essential. The government encouraged evaluation of lithotripsy in centres in Paris and Lyon as a basis for further decision-making. The Paris evaluation will be described.

The Paris lithotripter was located in the Assistance Publique (Public Hospitals) of Paris. The AP set up an autonomous structure, the "CIEL", involving 10 urologists, at the Necker Hospital. Each urology service within the AP had access to the lithotripter one day every 2 weeks. The shared site made multicenter evaluation possible, and all users of the machine were involved in the evaluation. The evaluation gave a wealth of information concerning the outcomes of lithotripsy. In summary, lithotripsy was able to lead to the removal of almost 100% of stones without surgical intervention.

Based on these evaluations, after some discussion, the government added lithotripsy to the health map in June 1986. By that time, the French lithotripters were approved and ready for marketing. Since that time, the number of lithotripters has been regulated, so that France now has a modest number of lithotripters in relation to some other countries (Weill, 1993) Because of this and other experiences, the French government decided to establish a national agency for health technology assessment (ANDEM) in 1990.





## 6 Renal Dialysis in the United States

Treatment for permanent kidney failure is the only medical condition that entitles nearly all Americans to treatment paid for by the federal government under the Medicare program. Congress passed the bill leading to the end-stage renal disease (ESRD) program in 1972. The program has grown tremendously, from 10,000 treated in 1973 to more around 200,000 in 2000, with costs in recent years of more than US\$ 1 billion per year. Because of its expense and visibility, the ESRD program has been subject to many changes in reimbursement, as well as many studies. In comparison with other diseases, a large amount of data is collected on ESRD (Tunis and Gelband, 1995).

Outpatient hemodialysis is the dominant treatment under the ESRD program, with more than 82 percent of patients treated in this way. Kidney transplant would be the preferred treatment for as many as  $\frac{3}{4}$  of new ESRD enrollees, but the supply fall far short of the demand, so only about 20 percent of current ESRD beneficiaries have had transplants.

ESRD and its treatment have been the subject of many studies, as already stated. From its beginnings, renal dialysis was obviously life saving. Without treatment, patients with ESRD had a short life expectancy. Thus, efficacy was obvious, and no controlled trials were ever conducted of this technology. On the other hand, many cost-effectiveness studies have been carried out, and have influenced policy in many ways. For example, studies of the cost-effectiveness of centre-based versus outpatient dialysis and of transplant versus hemodialysis have been carried out. In the case of transplant, the first year costs for a successful transplant have been found to be about US\$56,000, while the average dialysis patient has costs of US\$32,000 a year but in later years the cost of a transplant patient is only US\$64,000, so the costs are even after 3 years, and after that transplant is clearly less costly, as well as more cost-effective, since patients on transplant have a better quality of life. Such studies have led to active policy changes to encourage outpatient dialysis and transplant. In addition, advanced age was once considered a contraindication to transplantation, but studies showed that the outcomes of transplantation in the elderly have generally good results. Likewise, diabetic patients were once excluded from transplant, but studies have shown good results, and they are now included (Tunis and Gelband, 1995). When erythropoietin, a drug used to treat anemias caused by ESRD, came onto the market in 1989, it was subjected to both efficacy and cost-effectiveness studies before it became a routine.

Finally, studies of incentives of different payment schemes have been carried out more-or-less continuously, based on research. The findings of these studies have generally been implemented in the program.

Thus, Medicare's ESRD program might be viewed as a continuing experiment in how government policies can affect medical care and how HTA can interact with government policies. Reimbursement has been driven by the desire to create a fair reimbursement system that neither induces excessive government spending nor harms the quality of care furnished to Americans. Since the ESRD program is similar to the highly qualified services program of Poland, at least in concept, the lessons from this experience are interesting in the Polish context.



## 7 Centrally Planned Organ Transplant Services – The Case of the Netherlands

Organ transplants are one of the “highest” technology services that make up health care. To provide high quality transplants requires fresh organs carefully matched to the recipient’s immune system; expert transplant services, including highly trained surgeons and nurses; risky chemicals to suppress the body’s immune response; and careful monitoring of the patient’s status in an ongoing process that lasts as long as the patient lives. To provide such a service requires careful planning. To illustrate this area, the case of the Netherlands will be used.

The first whole organ transplants were with the kidney. Renal transplant as a therapy for end-stage kidney failure began after the development of renal dialysis in the 1950s and 1960s. Dialysis was introduced in the Netherlands in 1963 and began to be covered by insurance as part of the benefit package in 1967. The first renal transplant was performed in 1966, using a living twin donor (Bos, 2000). This followed years of experimentation, much of it in the United States. Kidney transplantation using kidneys from cadavers began in the Netherlands in 1967. The results of kidney transplants steadily improved in the early years based on continued evolution of the procedure and ongoing monitoring and assessment.

A key step was made possible by the typing and matching of human tissues on the basis of human leukocyte (white blood cell) antigens, especially fostered in the Netherlands by Dr. Johannes Josep van Rood. Van Rood advocated matching cadaveric donor kidneys to suitable recipients on the European scale, from which sprang, in 1967, the Eurotransplant organisation, the first international organisation of this type in the world. In 2000, Eurotransplant was responsible for the matching and exchange of all cadaveric donor organs, including a large proportion of all tissues (cornea, bone, heart valve, and ligament) in the Netherlands, Belgium, Luxembourg, Germany, Austria, and Slovenia. In 1999 there were 12,000 patients on the waiting list for organs; 1,635 cadaveric donors were involved and 5,128 organ transplants were performed. Eurotransplant has continually evaluated its own services and has depended on HTA studies for improvements in transplants.

Other organ transplants, liver, heart, and pancreas, were introduced in the Netherlands in the 1980s. By that time, HTA was a field beginning to become visible in the Netherlands, as mentioned above. Two of the first HTAs commissioned by the government and the Sickness Funds Council involved heart and liver transplants. Article 18 regulation was used to prevent diffusion of these transplants until assessments were completed. When the assessment was completed, the sickness funds and private insurance bodies covered the technologies, based on the assessments.

Lung and heart-lung transplantation were introduced to the Netherlands in the early 1990s. The decision to cover the cost under social insurance was made on the basis of HTA, despite considerable pressure from physicians and patients (Bos, 2000). Pancreas and lung transplantations have been assessed in recent years and both are now covered as part of the insurance benefit package. Provision of such transplants is also regulated under Article 18, so that the procedures cannot be provided without an institutional “license”.

The policy has been to restrict the number of transplant centres for reasons of quality and efficiency. Quality standards have also been developed as part of the regulatory process. At present there are eight kidney centres, two heart centres, three liver centres, and one lung centre. A national committee monitors transplantation outcomes and development of indications.

Allogenic bone marrow transplantation began in 1968 in the Netherlands, and autologous bone marrow transplantation in 1980. Both therapies have been thoroughly assessed over the years. Recently, an assessment was started concerning bone marrow transplantation for breast cancer. The Health Insurance Council defines the indications for which the therapy is reimbursed under the social insurance benefit package. The Health Council carries out periodic reviews of scientific developments in the field of transplants.

Most recently, in 2001, the Steering Committee for Organ Transplants evaluated 2 requests for a licence:

- Small intestine transplants. License granted to 1 academic hospital. Evaluation after 1 year).
- Heart transplants of children. Evaluated by a committee of the Health Council. Minister of Health has decided to grant a license for 1 or 2 centres. The Committee advised licensing 2 academic centres.

The field of transplants in the Netherlands is noted for its monitoring of technological developments coupled with HTA, and a creative use of regulation and payment to assure high quality, accessible services to the entire Dutch population.

## 8 Centrally Planned Prevention and Screening Services and Their Relation to Health Technology Assessment

Generally speaking, in health care systems based on social insurance, the government does not directly pay for care, but instead oversees the health care system, provides standards, and “steers” the system by its policies. Exceptions to this rule include the Polish highly qualified services program or the US Medicare ESRD program.

However, public health is generally an exception to this rule. Government recognises that public health services, including preventive services, are not generally encouraged by private services, so have taken a special role in this area. All European countries have national policies concerning prevention, often based on recommendations of the World Health Organisation. Important questions remain:

- 1 Are there in fact effective and cost-effective preventive services that have not been implemented?
- 2 Are prevention services, as well as public health in general and health promotion, subjects of HTA?
- 3 Are policies responsive to HTA results?
- 4 Do formal policies in fact affect the behaviour of insurance companies, administrators, and clinicians?

These questions were considered by a special European Working Group on Prevention (Banta, in press). It has often been that there are relatively few proven interventions in the prevention field. The Working Group demonstrated that this impression is not correct. Based on systematic reviews carried out by others (Canadian Task Force; Schaapveld and Hirasings, 1997; University of York; US Preventive Services Task Force), the group developed a list of more than 70 interventions that have been found effective. Few studies of health promotion were found, however. And cost-effectiveness has seldom been rigorously studied.

The health technology assessment agencies, members of the International Network of Agencies for Health Technology Assessment (INAHTA), have developed a large database of their own studies, including those in the field of prevention. The database has many assessments of prevention, showing that HTA has in fact dealt with prevention. However, the interventions assessed are almost entirely within health care. Other types of interventions, such as tax policies, are seldom the subjects of assessments carried out by the HTA agencies.

The Working Group also selected 8 areas of prevention:

- Genetic aberrations and congenital malformations;
- Detection of treatment of hypertension;
- Cigarette smoking/lung cancer;
- Counselling and sexual behaviour;
- Cervical cancer screening;
- Colorectal cancer screening;
- Detection of excessive drinkers;
- Traffic injuries.

An exhaustive literature review demonstrated that there was at least one effective intervention in each of these areas. A survey was then carried out in the 15 members of

the European Union, plus Switzerland and Norway, to determine if HTAs had been carried out and if they had influenced health policy. Countries with active HTA programs, such as Sweden, the Netherlands, France and the United Kingdom, had assessed essentially all of these areas. Coverage otherwise varied considerably. The area with the least assessment attention was colorectal cancer screening. Interventions outside of health care had been assessed, but not by HTA agencies. These assessments were generally carried out by other parts of the government, such as the Ministry of Transportation.

These assessments had also influenced policy, however, "policy" quite often consisted of statements from the Ministry of Health or professional bodies without backing from formal policies such as regulation or payment. Again, the countries with active HTA programs also generally had more active policies toward prevention.

Documenting the actual extent of use of the preventive interventions in the different countries was more difficult. Generally speaking, data were not available, and when it has been collected, it was not comparable to that from other countries. Therefore, little can be said about the actual extent of use of preventive interventions.

In summary, there is a body effective preventive interventions. It should be remembered that only 8 areas, perhaps 10 percent of all possible areas, were examined. Policy responses to information indicating effectiveness of interventions were disappointing. There seems little doubt that aggressively implementing policies toward prevention could have a very positive effect on the health of the population in most European countries.

## 9 Centrally Planned Prevention and Screening Services and Their Possible Relation to Health Technology Assessment – The Case of the Netherlands

In the Netherlands, the government has taken a special responsibility for prevention. As already described in Working Paper 1 for the project, the Netherlands has actively developed HTA and has sought to involve the results in HTA in all policy decisions, as well as decisions by managers and clinicians. The field of prevention is no exception (Banta and Oortwijn, 2001).

The Dutch government has given a strong endorsement to prevention. Policy papers also state that any prevention or screening program should be evaluated as to its effectiveness, efficiency, and for its ethical, legal and social acceptability. Health problems are chosen as priorities for policy on the basis of criteria such as the burden of disease and the availability of effective and acceptable preventive interventions. Research is mainly aimed at assuring such results, and consulting international data and experience is common. Prospective research can also be supported, when appropriate. Programs are generally not paid for centrally, although they can be, but the services are provided by sickness funds and insurance companies under guidelines provided by the government.

It is often said that the number of preventive interventions that have been proven to be effective and/or cost-effectiveness is very limited. This statement is not true. As already indicated, there are at least 70 specific interventions (for more detail and references to this literature, see Banta D, in press).

As part of its prevention policies, the Ministry of Health initiates or supports screening programs carried out by public or private organisations. The Parliament passed a law on population screening in 1996. The purpose of this law is to protect the population against screening that may be harmful to physical or mental health. The law states that all proposals for population screening must seek approval from the Minister of Health before they are launched. The law defines population screening as medical examination of individuals that is offered to the whole population or a specific subcategory of the population with the aim of detecting diseases or risk factors. Examples of mass screening in the Netherlands include PKU screening of neonates, hypothyroidism screening in neonates, breast cancer screening by mammography and cervical cancer screening. The law requires that all proposals for population screening should be presented to a special committee based at the Dutch Health Council. The committee advises the Minister of Health on the screening proposal's safety, effectiveness, appropriateness, ethical aspects, etc., as well on implementation issues. The Minister then decides whether to allow the screening program. The law also includes a provision requiring an assessment by the Health Council committee of any research on screening.

Thus, in the Netherlands, the Ministry of Health has been active in promoting disease prevention and screening. HTA is fully integrated into this effort. In the screening area, the Netherlands may be the only country in the world with a national law requiring an HTA before a screening program can be implemented.

Such assessment and steering is necessary because of the poor performance of the health care system of most countries in the area of prevention (see Banta, in press). In European Union countries, only the United Kingdom, Sweden, France, and the Netherlands have made prevention a high priority. Likewise, as discussed in Working Paper 1 from this project, the Polish government has not made prevention a high priority and generally has not tried to promote or organise prevention programs. TNO suggests that this area deserves more attention from Polish policy makers.



## 10 HTA and Policies toward Screening in the United Kingdom

The United Kingdom is another leader in HTA that has linked HTA to policy decisions. During the mid-1990s, policy concerns about screening continually surfaced in the United Kingdom (National Screening Committee, 1998). One important question that was repeatedly asked was, does a particular screening program confer more benefit than harm for the population in terms of lives saved or suffering avoided? This issue was obviously of key importance, since it was easy to demonstrate that there were more than 300 screening programs in the United Kingdom, including many still in the research stage. At the same time, many screening programs had been introduced by Health Authorities to meet a variety of local needs, each with their own arrangements and protocols.

The evaluation of screening was made a high priority in the UK because of these factors (Gray, 2001):

- 1 There was concern about the unplanned drift of new tests into screening practice;
- 2 The population that might benefit from, or be harmed by, a screening program is easy to identify;
- 3 The evidence base on which decisions could be made is strong with both randomised trials and systematic reviews of screening;
- 4 A high value was placed on protecting the public from the harmful effects of screening; and
- 5 Small changes in screening policy could have large resource consequences in a time in which resources are constrained and value for money must be maximised.

To meet these goals, a National Screening Committee (NSC) was installed in 1997. The main role of the NSC is to advise on:

- 1 The case for implementing new population screening programs not presently purchased by the National Health Service;
- 2 Implementing screening technologies of proven effectiveness but which require controlled and well-managed introduction;
- 3 The case for continuing, modifying or withdrawing existing population screening programs, in particular, programs inadequately evaluated or of doubtful effectiveness, quality, or value.

One of the first tasks undertaken by the NSC was the development of an inventory of screening programs, identifying all the programs that people wish to introduce as well as those currently being offered. The results of this inventory demonstrated that of the many programs being delivered to the public, only 4 were both evidence-based and had a good quality management program.

Another important task undertaken by the NSC was to develop a framework for screening and its evaluation (NSC, 1998). This then was the basis for the introduction of a handbook from the NSC on population screening programs. One part of the handbook was a recommended format for systematic reviews concerning screening programs.

Finally, the NSC identified programs where current guidance exists, programs where there is an explicit policy not to offer (prostate cancer screening, neuroblastoma screening), and areas under current review or with a plan for review.

Information on the NSC program, including the handbook itself, is available on the Department of Health website (<http://www.open.gov.uk/doh.nsc.hnsch.htm>).

## 11 Quality Improvement and Health Technology Assessment

The quality of medical and health care is becoming an increasingly visible public issue in a number of countries. Issues identified with poor quality include many common to HTA: ineffective technologies, lack of use of effective technologies, cost-ineffective choices, overuse of effective technologies, and insufficient attention to safety issues.

The objective of quality assurance is to “improve the outcome of all health care in terms of health, functional ability, patient well-being and consumer satisfaction” (World Health Organisation, 1988). HTA should support such activities, with its emphasis on efficacy (health outcomes).

Assessment of quality requires standards for good or poor quality. Using standards to evaluate quality of care requires criteria by which to judge how a health condition or disease has been diagnosed or treated (Banta and Luce, 1993). The development of such criteria, if they are to be valid, must be based on knowledge about (at least) the efficacy and safety of the health technology(s) involved. Therefore, that HTA and quality improvement should be closer linked seems obvious. HTA's main role here is to provide the evidence for setting criteria of quality.

One major problem with quality improvement activities is that they often have tenuous links to health outcomes. The usual classification of quality improvement refers to the structure, process and outcomes of care. Evaluating structure (such as number of hospital beds or numbers of nurses per bed) requires the assumption that care will be better with better staff, better physical facilities, etc. This further requires that available knowledge allows one to identify what is good in terms of staff, physical structure, etc. This is often not the case. Process is the evaluation of the actual activities of providers, but requires specifying which activities are appropriate, which should mean having specific knowledge about the links between certain health care processes and health outcomes. However, the assessment of process has generally been limited to evaluating the extent to which care conforms to accepted norms of care rather than linking them with outcomes. Assessment of outcomes is the evaluation of end results of health care in terms of health, including recovery and restoration of function. The main problem here is that outcomes can be very difficult to evaluate in the ordinary clinical setting, especially because of the long-term nature of such evaluation.

In practice, evaluation by structure predominates, with a poor empirical base to support its activities. In short, structural standards have generally not been linked to health outcomes. Process standards are closer to the clinical situation, and are often used as well, but they also have often not been evaluated, although this is a field of active development.

It is often said that quality improvement activities are growing rapidly in Europe. The only area of visible growth, aside from HTA itself, is in accrediting and licensing programs (see Working Paper 5), especially those dealing with hospitals. Otherwise, there is a plethora of approaches, most carried out in a very decentralised manner in many institutions. What seems clear is that quality improvement activities are far behind HTA in national and regional implementation, meaning that there are relatively few national agencies and programs. This fact surely impedes the links between HTA

and quality improvement. Nonetheless, such links seem almost certain to grow, given the serious policy concerns that have led to these two related fields.

## 12 A Theoretical Model of Health Technology Assessment and Planning

HTA, as it has developed, deals mostly with health technology. Typically, a new technology is being considered as part of health care, so an HTA is carried out to examine the efficacy and cost-effectiveness of the technology. At the completion of the HTA, a policy decision is made concerning whether the technology should be incorporated into health care or not.

This is a passive approach to health planning, what one might call a “technology driven” model. The model is undoubtedly useful, especially to policy makers who often do in fact make specific decisions on specific technologies. However, such an approach does not fully utilise the potentials of HTA for improving the health of a population. Such observations have led to the concept of “needs based HTA” (Feeny et al, 1986).

One approach to needs-based HTA was proposed by Feeny et al (1986) as involving the “technology assessment iterative loop” (see Figure 1).

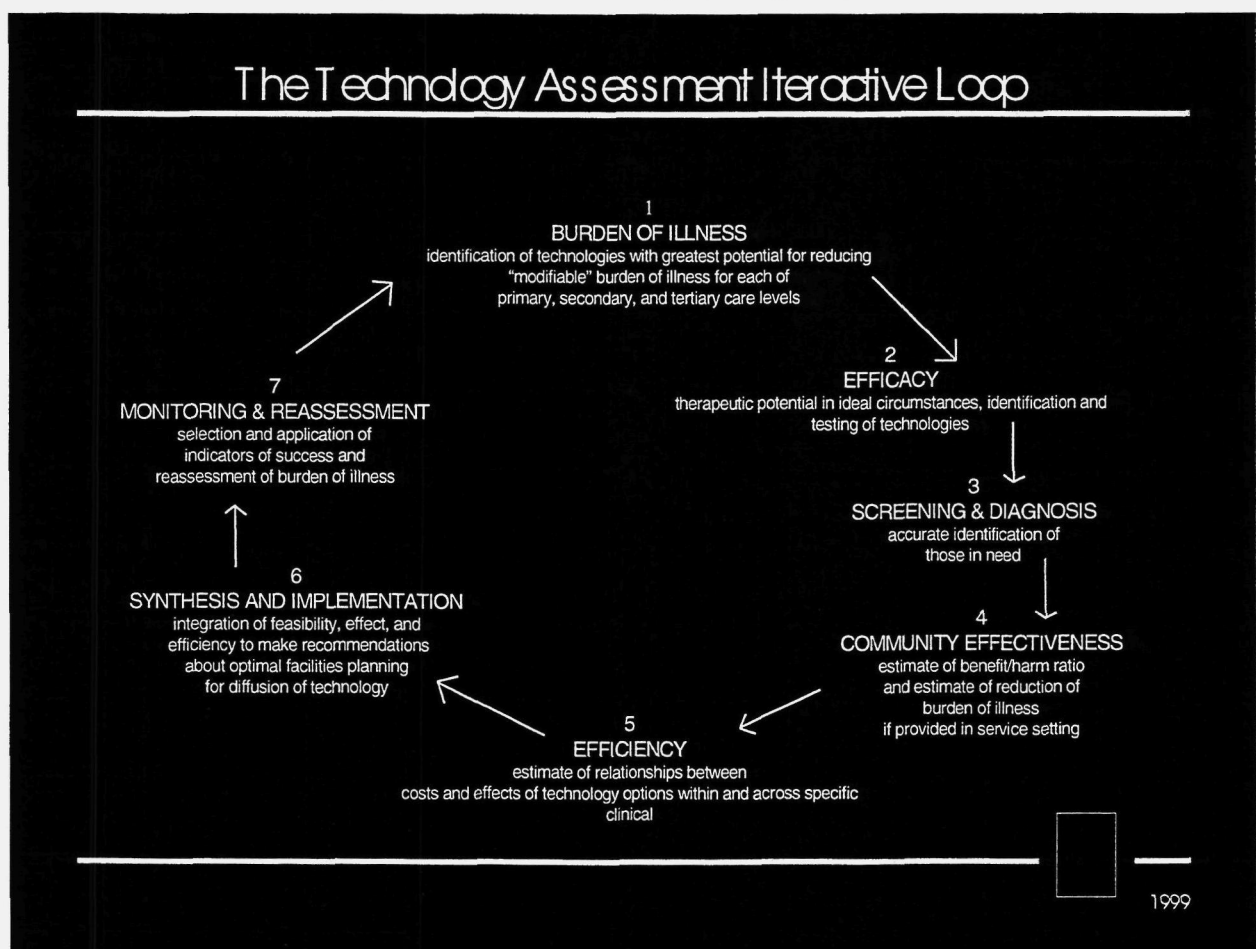


Figure 1: Feeny et al (1986)

In this model, assessment begins with determining the current levels of morbidity and mortality for specific conditions. Then the modifiable burden of disease is determined, based on having health technology that has the potential to provide accurate diagnosis

and efficacious prevention, cure, or palliation. Resources should then be made available to assess these potential technologies, or for those that are already known to be effective, to assure the development and diffusion of applications of these technologies in the primary, secondary, and tertiary care levels of the health system. Examinations of efficacy show the therapeutic potential in ideal circumstances. Screening and diagnosis leads to an identification of those in need. Community effectiveness needs to be estimated, since effectiveness will be less than the efficacy of the technology would indicate when it is implemented at the community level. For example, the availability of well-trained staff must be ascertained, and training programs implemented if necessary. Costs can then be estimated, in relation to the effects. Synthesis of all this information leads to conclusions (and possibly recommendations) concerning how to approach the particular disease or problem. The program can then be implemented at the community level. Finally, monitoring and reassessment leads back around the loop so that the program may change based on ongoing research and evaluation.

Such a model is in fact being used more and more frequently by HTA agencies and by some governments. An example in the HTA field is the examination of back pain in Sweden described in Working Paper 4. Broader assessments are much more common now than they were 5 years ago. For example, mental health services are being assessed in the Netherlands, the United Kingdom and Sweden.

Government has also begun to use such planning tools. The Netherlands approach to prevention described above is a good example. The United Kingdom is another example. In 1999, the UK published a White Paper titled "Saving Lives: Our Healthier Nation" in which the "main killers" in the UK, cancer, coronary heart disease and stroke, accidents and mental health are made high priorities for policy making, including specific funding. The government commissioned the UK Cochrane Centre and the NHS Centre for Reviews and Dissemination to prepare a document presenting evidence concerning the efficacy of different approaches to ameliorating the results of the diseases and problems in question. More than 1,000 systematic reviews concerning interventions were found and are summarised in a large report (Cochrane Collaboration, 2000). The interventions recommended included clinical health care and prevention and screening, also covering such societal interventions as changing tax policy to influence cigarette smoking and high design to prevent traffic injuries. This effort is an excellent example of beginning from the burden of disease and planning approaches to these diseases based on HTA.

## 13 Discussion

This report has summarised some approaches to national health policymaking based on HTA. The experience presented here should be relevant to the Polish program of highly qualified services and to other priorities programs. The key issues for national health policy making in Poland include maximising health with limited health care resources, setting priorities among possibilities for action (that is, making choices), and controlling certain areas of technology, such as highly specialised services and commonly used drugs and medical equipment. HTA can assist in these policy areas.

An important national policy in Poland and a focus of this paper (and in Working Paper 1) is the program of highly qualified services does not have a clear purpose or goal, although the situation is changing. Since its inception, however, the existing program has been based on tradition and on lobbying or influence, and not on principles such as those found in HTA. However, recent guidelines being developed for this program seem found. These guidelines depend on analyses such as those found in HTA. For example, the rationale of highly qualified services needs to be clear. Examples of such principles would be to include technologies that are addressed to important health needs, that should be centralised for reasons of quality and inability of the population and sickness funds to pay directly for the services, and that have been shown to be efficacious and cost-effective.

Likewise, Poland has not emphasised health planning based on HTA. A specific example from disease prevention has been presented here. Disease prevention seems quite undeveloped in Poland, and deserves much more attention. If the situation changes, HTA should be a clear and visible part of policy making in this area.

The cases presented in this report are “real life” cases taken from a number of countries, although focusing on the experience in the Netherlands. Some clear lessons are as follows:

- 1 The main motivation in national health policy making is the health of the population. In brief, the question is: which beneficial services can be provided within existing resources?
- 2 Answering the question concerning health benefits requires a systematic process of health technology assessment. Such HTA must be scientifically and clinically credible. The HTA results must also be presented in a form understandable to policy makers.
- 3 Timeliness is key in HTA addressed to national health policy making. An assessment that is completed after the decision has already been made is of little benefit.
- 4 Policy makers must learn to ask for HTA and rely on its results. While there are many steps that those working in HTA can take to try to have their results used, the actual action depends on the policy maker. Again, HTA that is not used for policy making is of little benefit.
- 5 Assuring the integration of HTA into policy decisions at the national level requires an organised approach to HTA. All of the cases presented in this report involve assessments carried out by agencies and programs affiliated with the national government. In Europe, almost all members of the European Union have realised that they need HTA results to help their decisions and that excellent, timely results depend on organisation. Furthermore, HTA programs that are not funded by public funds have limited incentives to examine problems of national policy making.

- 6 For HTA to be successful, it requires not only organisation, but also resources. Such resources certainly include money. But other resources, such as highly-motivated and well-trained people, are also very important.

It is also important to recognise the limits to formal policy-making. Most health care decisions are made in the clinic or the physician's office. Formal policies are a "blunt tool" for rationalising health care. It is possible to say "yes" or "no", but it is not possible to fine-tune the health care system from the Ministry of Health. This truism has a number of implications. From the standpoint of HTA, it means that assessment must also become part of administrative and clinical decisions. Policies to assure such a development are also part of the role of the Ministry of Health. The final end is a "culture of assessment" extending into every clinical setting and into every lay journal dealing with health care addressed to the general public.

These considerations are part of what has led to the rapid growth in HTA activities in the European Community and other parts of the world. Some evidence of the impact of HTA is presented in the methodological appendix that forms part of this report. The approaches to the problems of national health policy making and their successes are part of the evidence that has led TNO to recommend development of a national, publicly-funded program of HTA affiliated with the Polish Ministry of Health.



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## A Principles of Costing

This appendix concerns the principals and practice of how to estimate unit price data for HTA purposes when such data is not readily available.

It describes general considerations about two ways of collecting evaluation cost data, the top-down model and the bottom-up model respectively. It is not intended to be comprehensive. Instead the ambition is to give some of the most common techniques about how to handle pricing problems. Examples are given on how to find practical solutions to costing problems. The text is intended to be used to accompany the cost-effectiveness studies performed by the project and presented in Working Papers Six and Seven.

To a large extent the Polish health care lacks short and long-term activities to generate data necessary to study the cost-effectiveness as a routine tool for monitoring and planning. The principal way to do this is to establish an administrative system that make the patient the unit of accounting, which is also beneficial for the insurance system in general. The second best method is to do special estimations of cost-effectiveness, which uses the accounts whenever possible and collect first hand information for the rest.

The appendix is concerned with how to use the *accountant's perspective* (costs are shown to the financier to account for where they were consumed and how much) and the *evaluator's perspective* (costs are shown to the decision-maker for what purpose they were used and why). The difference between the two perspectives frequently causes problems between economists and accountants. The main problem is that the accountancy perspective fails to recognise the opportunity cost principle, which is crucial to the evaluator.

Two basic approaches are possible to establish unit prices. The top-down method is characterised by macro-oriented data collection, which is approximated for more detailed real data. We make approximations or simplifications in the cost estimates by using data from a higher aggregation level than the actual. The economists can often give a very good picture of the resources used (time and/or money), but there are a number of problems how to handle the so called overhead-cost which is not directly connected to the treatment but for one or another reason is measured on a level higher than the level of analysis. The top-down method is characterised by low measurement precision. In many cases the handicraft of doing guesswork so that the analysis will serve its purpose takes a great deal of skill, and the use of the top-down approach is mainly done for academic purposes.

Secondly, the bottom-up method has become more useful. The basic idea is that (for instance) the cost per patient in a certain treatment is built up from a number of great and small decisions about the use of different health care resources, and summarised to a total cost, which will be different for each patient. It is also more intuitive since most accountancy work uses this principle.

Classifying costs according to types of illnesses are difficult because of the large variety of diagnosis/treatment combinations. Thus, many countries have adopted a compromise between the two approaches, the concept of diagnose-related groups (DRGs) to monitor

the costs of the (hospital based) health care. It has mainly been used in a financial and cost-containing sense, but properly used it would also help the evaluative work and can be used as bases for decisions of future allocation of resources. A number of descriptions of these principles are available. This part of the report uses the Australian Refined DRG system (AR-DRG) as an example.

Another issue in the collection of data for unit prices is the method of analysis. RCT, randomised controlled trials statistically is the most recommended way of how to judge whether an exposure causes or prevents a disease. RCT has then become the major gold standard of any health care investigation. However, in many cases unit prices are not possible to get from RCTs only and other, observational studies are used. In the HTA literature they often pass under the name of modelling studies. The techniques used are taken from a number of disciplines like epidemiology, statistics or operations research, all specialised in processing quantitative data. In the HTA area especially Decision analysis, Extrapolation and Markow models are common and each one is discussed briefly in this report.

This appendix ends with a few methodological issues of how to adapt recorded data into an evaluator's perspective. The special case of hospital costs and primary care costs are discussed.

The main conclusion from this appendix is that the Polish health care, as well as the Polish insurance system would benefit from the sustainable development of HTA based analysis and that such a development would increase the volume of good health care to a reduced cost to government and the insurance.

## **A.1 Introduction**

The Polish government is reviewing opportunities to improve the function of the health care sector by applying HTA techniques. The centerpiece of health technology assessment is cost-effectiveness or cost-benefit analysis. The issue of assessing effectiveness and benefits is covered in all reports, and the Methodological Appendix. The issue of costs is less well understood and its treatment overall in the projects reports is less extensive than that relating to the assessment of effectiveness or benefits.

This appendix is intended to analyse cost data in a generic way such that the knowledge can be applied in a diverse manner, including to the issues of highly qualified services, other policy concerns, and the recommendations put forward in the final Working Papers.

Many health care systems around the world have been developed from the perspective of the doctor. The main interest has been to provide health care for single patients in need, and the cost for doing this has been a secondary matter. However, in the highly specialised and technological health systems of today, scarce resources limit the actions possible, and they are also scrutinised and challenged from other competing sectors of society.

Current accounting systems take the clinic as the basis for costing. Yet, evaluators of health costs have agreed that truly understanding costs requires using the patient as the basis for costing. Much of the complication of costing today, as will be presented below,

is rooted in attempting to understand costs on the basis of the patient within systems who use other bases for cost.

This appendix will start with general considerations about the two obvious ways of collecting evaluation cost data, the top-down model and the bottom-up model respectively. It is not intended to be comprehensive. Instead the ambition is to give some of the most common techniques how to handle pricing problems and to provide a reference guide for the costing activities undertaken in the assessments presented in working paper six.

#### **A.1.1 *The Polish Problem of Health Care Costing***

Policy decisions about how to use resources for health technology would benefit from being based on universal HTA methodology and data. It would help comparisons of the effectiveness of different procedures between hospitals or regions. A general HTA methodology would also facilitate comparisons over time as a consequence of the general consistency.

A universal HTA methodology is now available for Poland in Polish as a result of this project. However, methodology is not enough – also reliable data is necessary. The Polish health care system should now initiate short and long-term activities to generate data necessary to study the cost-effectiveness as a routine tool for monitoring and planning. The principal way to do this is to establish an administrative system that makes the patient the unit of accounting. Since many countries already have accounting systems built up for other purposes this is not the common way, and the second best method is to do special estimations of cost-effectiveness, which uses the accounts whenever possible and collects first hand information for the rest.

#### **A.1.2 *Data for HTA Purposes***

There are several sources to search for economic data. There are typically two aspects of costing. One is the *accountant's perspective* – costs are shown to the financier to account for were they were consumed and how much. The other is the *evaluator's perspective* – costs are shown to the decision-maker for what purpose they were used and why.

The difference between the two perspectives frequently causes problems between economists and accountants. The accountancy perspective fails to recognize the opportunity cost principle, which is crucial to the evaluator.

Specially trained professionals can provide generic data by applying a set of simple, practical rules. These data can be used as proxies in different evaluation situations.

### **A.2 The Structure of Evaluative Costing**

An economic or HTA evaluation, with a purpose to form a basis for decisions how to use resources needs to be done using what is called a true resource perspective. Only the actual resources used are taken into account.

In this text we will consider the two basic methods, the top-down and the bottom-up approaches. First we will give some definitions:

- **Direct costs** Costs, directly resulting from treatment activities, for instance the cost of a painkiller pill.
- **Indirect costs** Costs for facilitating treatment, but not directly resulting from treatment, for instance, ward management.
- **Variable cost** Costs which vary with the volume of the treatment – the more treatment, the more cost.
- **Fixed cost** Costs which do not vary with the volume of the treatment and which will prevail, at least for some time, if treatment for one patient is not given.

Table 1. Examples of cost concepts

	Direct costs	Indirect costs	Total costs
<b>Variable costs</b>	Diagnostics, pharmaceuticals, surgical operations, meals, consumables, consultants	Water and electricity consumption,	Total variable costs
<b>Fixed costs</b>	(Permanent care staff) maintenance, general cleaning	Rents, management, hospital library	Total fixed costs
<b>Total costs</b>	Total direct costs	Total indirect costs	Total costs

From Laprè and Montfort: *Bedrijfseconomie van de gezondheidszorg* (adapted)

Sometimes it is also useful to distinguish between variable **patient related costs** and **patient unrelated cost**. The former is directly attributed to one specific patient and can also vary between patients, for instance costs for blood tests, but the latter is the same for all patients, like the cost for a bed. Still, both belong to the categories of variable costs as well as direct treatment costs.

The problem with this categorisation of costs is that sometimes a certain type of cost can be categorised into two or more alternatives. In the table above, according to the accrual based costing, the same cost will appear in the books for permanent staff if one patient is treated or not. The reason is that permanent staff is not fired or transferred to other wards according to short term variations in patient load. Accordingly the cost should be regarded as fixed.

### A.3 The Top-Down Method

The top-down method is characterised by macro-oriented data collection, which approximate for more detailed real data. We make approximations or simplifications in the cost estimates by using data from a higher aggregation level than the actual.

An example. In most cases we wish to estimate the cost of treating one patient with one method compared to another method. Then the “cost per patient” is relevant and only secondary, for instance “cost per day” or “cost per visit”.

The simplest approximation is also the most macro-oriented. We may know the cost per year of all hospitals in the country. We also know the number of patients treated in

hospital care. We then divide the annual cost by the number of patients and get the average cost per patient.

This is of course the crudest possible estimate. Firstly, it does not recognise a difference between small hospitals in the countryside and a big university hospital. The latter has higher specialised staff and also a large cost for education of medical students. If we take the costs for the different types of hospitals and divide by the number of patients in the different hospitals we will find a pattern of higher cost per patient in a university hospital than in others. The following list types of hospitals whose cost per patient is likely to systematically differ.

- University hospitals;
- Specialist hospitals;
- Basic hospitals;
- Mental hospitals;
- Long-term hospitals;
- Geriatric hospitals;
- Nursing homes;
- Hospices.

Secondly, it does not recognise differences between the care of different illnesses. A gall bladder operation will take a few days and a severe long-term illness may take the whole year (and more). The annual cost per patient would be higher in hospitals with more chronic patients than for instance hospitals specialised in surgical operations.

Thirdly, it does not recognise differences between regions or other geographical boundaries. A rural area will be organised in another way than urban areas. This will also reflect in the costs of treating a patient.

To summarise: As soon as costs can be assumed to be markedly different between the alternatives studied there is a case for a closer approximation. The level of approximation needs to get lower in the macro/micro dimension. The three obvious dimensions are:

- **Regional structure** (Union), Country, Region, Local authority, Hospital ...;
- **Geographical structure** Rural, Suburban, Central ...;
- **Specialty structure** Internist, Surgery, Oncology ...

Even more detailed are the categories of:

**Illness structure** Cholera, Typhoid, Salmonella, Shigellosis ... (ICD-10);

**Treatment structure** Pharmaceutical, Surgical, Radiation, ...;

**Approach structure** Causal, Symptomatic, Palliative ...;

**Population structure** Elderly, Children, Fertile women ...

Thus, it has to be discussed how far the approximation to true costs can and must be done. In the example above the first national level approximation is of little use if we compare treatments of a very defined sub-diagnosis with two different treatment methods, like moderate hypertension with two different ACE drugs. On the other hand, if we evaluate a law for organ donations it may be fully sufficient to use a national cost per patient.

## A.4 The Distribution of Overhead Costs

In many cases much is known about details of a treatment. Professionals can often give a very good picture of the resources used (time and/or money), but there are a number of problems how to handle the overhead-cost which is not directly connected to the treatment. A typical example is the cost for blood tests in a hospital. Many hospitals do not collect data to the patient level. Only the ward or the clinic will be charged an annual internal price for blood tests according to the number of tests performed for this ward/clinic. In principle, with modern computer technology, it would be both feasible and also efficient to charge the patient's bill for the exact number of tests. Then patients using many blood tests would be charged more heavily than those with fewer blood tests would. This would in turn lead to a deeper knowledge from a professional point of view what is and what is not necessary to produce a good output – a healthy patient, than just an average number, the same for all, regardless if the patient benefited from the blood test or not.

The other situation is that it may be impossible to actually tell how much of an overhead should be allocated to a specific patient. In the field of accounting four different methods can be found to distribute indirect costs over the available "products". This kind of calculation is aimed to calculate the *total* cost for a specific product or department. This means that both the fixed costs and the variable costs are included in the analysis.

There are four variants:

- **The partial calculation.** This method divides the total costs of a specific period by the total produced carriers of costs.
- **The equivalent method.** This method is a refinement of the partial calculation.
- **The depot method.** This method allocates indirect cost by defining "depots" of direct costs.
- **The cost-place method.** This is activity-based costing.

## A.5 The Bottom-Up Method

The top-down method is characterised by low measurement precision relative to the bottom-up method. The basic idea is that the cost per patient in a certain treatment is built up from a number of great and small decisions about the use of different health care resources, and summarised into a total cost, which will be different for each patient. It is also more intuitive since most accountancy work uses this principle.

Usually, the bottom-up method follows a chronological order:

- Contacting or being approached by the health care;
- Information collection including testing;
- Diagnosis procedure;
- Treatment;
- Monitoring;
- Recuperation;
- Rehabilitation;
- ...



Each of the above items also is a summary of more basic elements. The treatment activity could be summarised from:

- Hospital treatment;
- Primary care treatment;
- Pharmaceutical treatment.

**Hospital treatment**, in turn may be summarised (for a certain cancer treatment) from:

- Internal Medicine treatment;
- Oncology consultancy;
- Chemotherapy treatment;
- Radiotherapy treatment;
- Antibiotics treatment;
- Supporting treatment e.g. anti-emetica, wig.

And obviously the **Internal Medicine treatment**, except for direct oncology, may consist of

- supply of bed;
- supply of clothing;
- supply of food;
- general nursing;
- general material.

And the deductive process could be driven further and further until the basic Tayloristic time and motion concepts, where every body movement was registrated and timed with a stopwatch.

## A.6 DRG-grouping

Classifying costs according to types of illnesses are difficult because of the large variety of diagnosis/treatment combinations. Thus, many countries have adopted the concept of diagnose-related groups (DRGs) to monitor the costs of the (hospital based) health care. It has mainly been used in a financial and cost-containing sense, but properly used it would also help the evaluative work and can be used as bases for decisions of future allocation of resources. A number of descriptions of these principles are available. The following shows the Australian Refined DRG system (AR-DRG) and follows closely the text of the Australian report (1).

The format of each AR-DRG consists of four alphanumeric characters, where:

- The first character indicates the broad group to which the DRG belongs;
- The second and third characters identify the adjacent DRG within the major diagnostic category (MDC), and the partition to which the adjacent DRG belongs;
- The fourth character is a split indicator that ranks DRGs within adjacent DRGs on the basis of their consumption of resources.

Different letters of the alphabet have been used to signify the broad group to which the DRG belongs, while the number '9' has been used to identify Error DRGs. The first number in the list looks as follows:

*Table 1. Sample of Australian DRG groups.*

A01Z	Liver Transplant
A02Z	Multiple Organs Transplant
A03Z	Lung Transplant
A04Z	Bone Marrow Transplant
A05Z	Heart Transplant
A06Z	Tracheostomy Any Age Any Cond
A40Z	Ecmo - Cardiac Surgery
A41Z	Intubation Age<16
B01Z	Ventricular Shunt Revision
B02A	Craniotomy + Ccc
B02B	Craniotomy + Smcc
B02C	Craniotomy - Cc
B03A	Spinal Procedures + Csc
B03B	Spinal Procedures - Csc
B04A	Extracranial Vascular Pr +Csc
B04B	Extracranial Vascular Pr -Csc
B05Z	Carpal Tunnel Release
....	....

DRG codes with numbers two and three, e.g. B02A, B02B and B02C - may be taken to relate to the same adjacent DRG.

In order that the second and third characters of each AR-DRG number may also be used to identify the partition to which the adjacent DRG belongs, three separate ranges - 01 to 39, 40 to 59 and 60 -99 have been used to indicate the surgical, other and medical partitions respectively. For example, the three AR-DRGS numbers P76D, I09B and O40Z reveal that the first is part of a medical partition, the second is part of a surgical partition, and the third is part of an 'other' partition.

Finally, the fourth character of each AR-DRG has been used as a split indicator to identify the relative importance of DRGs within an adjacent DRG in terms of resource consumption. Any one of a number of values may be used:

- A highest consumption of resources within the adjacent DRG;
- B second highest consumption of resources
- C third highest consumption of resources
- D fourth highest consumption of resources
- Z no split for adjacent DRG

The meaning of this split indicator may be gathered from the names of DRGs. For example, the three DRGs in the tenth adjacent DRG of the medical partition in MDC 01 (diseases and disorders of the nervous system):

B69A	TIA and Precerebral Occlusion W Catastrophic CC
B69B	TIA and Precerebral Occlusion W Severe CC
B69C	TIA and Precerebral Occlusion W/O Catastrophic or Severe CC (1)

For further details, please refer to the Australian Refined Diagnosis Related Groups version 4.1, Definitions Manual, Volumes 1 -3.

## A.7 Methodological and Technical Considerations

### A.7.1 *Methods and Models*

There are a number of methods available for the quantitative analyst. The basic requirement of a good analytical method is that it should provide evidence of high validity and reliability.

Among many professionals there is a fundamental difference between medicine and economics about the necessity of “correct” data. Many health care professionals have learned that the gold standard of measurement is the randomised controlled experiment or trial (RCT). Every other data collected by other methods is of inferior standard. This draws on the correct notion that RCT statistically is “the most direct evidence on which to judge whether an exposure causes or prevents a disease” (Hennekens and Buring 1987) and in this sense the RCT certainly is a gold standard.

For instance the quality of evidence from different types of studies was graded by Spitzer, (3):

- I** — Evidence obtained from at least one properly randomised controlled trial (RCT).
- II-1** — Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
- II-2** — Evidence obtained from comparisons between times or places with or without intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin in the 1940s) could also be regarded as this type of evidence.
- III** — Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

However, there is a problem that the RCT design in many cases covers a limited and special population and can not simulate the true health care situation. “The choice of study design best suited for investigation of an issue at a given time is influenced by particular features of the exposure and disease, logistic considerations of time and resources, as well as results from previous studies and gaps in knowledge that remain to be filled” (Hennekens and Buring 1987). Besides, the usefulness of the study results very often is not the immediate statistical cause/effect results but the conclusions drawn about future health effects or effects in a wider population. The conclusion is then that the superiority of the RCT is very much dependent on the term “properly” under I: above. High quality observational studies are well in line with high quality RCTs in terms of evidence of efficacy. The difference in quality lies probably more in the difference in research and model design (BMJ 2000).

Thus, for HTA studies the uncritical use of RCT models often is inferior to other designs. A more elaborate research discussion is necessary, especially about the methods, technologies and techniques of gathering data for resource allocation purposes. Especially the notion of *accuracy* needs to be discussed.

The important problem of data quality makes the modelling approach vulnerable. The well-known saying about “garbage in, garbage out” was originally attacking the

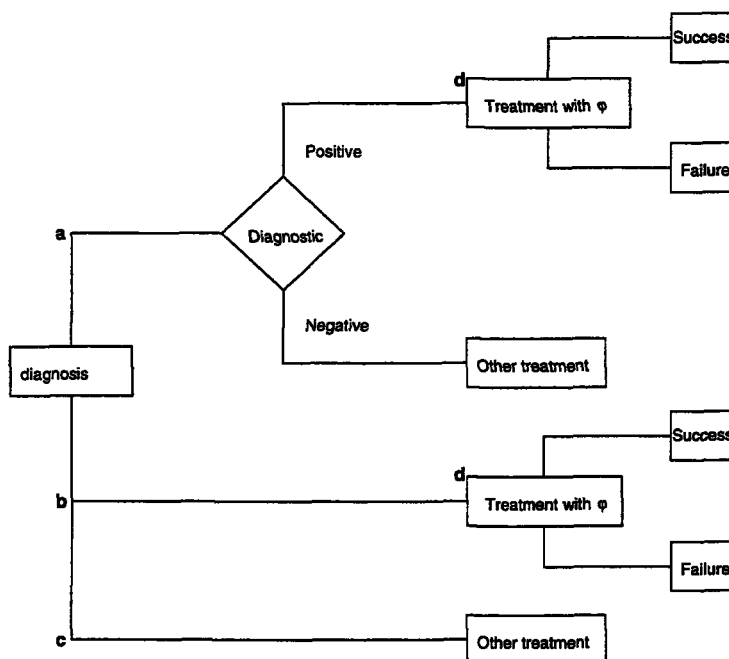
statistical discipline for using low quality data, but it is certainly also applicable to modelling in general.

Modelling involves a number of techniques, but is obviously also a way of describing a certain way of working. In fact, all research activities include some kind of modeling. Even the specification of the research problem is of course a model (of reality). The techniques used are taken from a number of disciplines like epidemiology, statistics or operations research, all specialised in processing quantitative data. In the HTA area the following modelling techniques are common.

#### A.7.2 *Decision Analysis*

Originally decision analysis was used to predict the likely outcome of single cases, regardless if it was applied in health care, legal issues or other. But there is no principal difference to use this type of modelling also for making choices of policy decisions based on evaluated options. The analysis is generally made as a decision tree.

*Figure 2. Decision tree (example)*



In the tree the different nodes are connected to:

- a the type of node (chance, choice, end);
- b the number of observations passing the node (no. of patients, percentage) or probabilities;
- c typically the cost of passing the node;
- d typically the outcome of passing the node (e.g. treatment result, quality of life).

By feeding the starting node with a suitable number of patients, software applications can estimate the number of patients going into different alternatives, including total costs and outcomes, and as a result the decision analysis will present the most favourable cost-effective alternative and breakpoints to the other alternatives. The

model can also be fed with different kinds of variability measures to facilitate a sensitivity analysis.

The decision tree can give a good representation of different alternatives, their probabilities, costs and outcomes. The drawback is that when the model gets complex the different branches do too. Also, small variations between alternatives have to be defined in the model as distinct mathematical variants, which sometimes do not reflect real life.

A consensus statement of when and how to use decision analysis has been taken in Pharmacoeconomics:

“A good decision analytic model for the economic evaluation of health technologies is one that:

- is tailored to the purpose for which it is to be used;
- is useful for informing the decisions at which it is aimed;
- is readily communicated (Consensus statement 2000).

To conclude, the decision tree models are simple, convenient and very clear if the number of branches are small. However, it is important that decision models can be transparent, internally consistent, reproducible, informative and explicit in calculation of uncertainty. Unfortunately, with the software available for these techniques the transparency becomes obscured to some extent by the automated production of output. In the following publication it is consequently difficult to check the reproducibility.

#### A.7.3 *Extrapolation*

Very often the analysis of health technologies incorporate an element of long term prediction or an element of aggregation to a broader population than the one actually analysed. A cost-effectiveness analysis typically involves a costly treatment procedure with short-term restoration of health but also including effects after many years. The immediate cost has to be compared to effects over a long time.

In the discussion about preventive screening for coeliac disease (gluten intolerance) for instance, the effects of proper testing, diet instructions and follow ups lead to short term results in terms of better wellbeing and bowel functioning. But the results of the screening most likely also, among other things, lead to fewer cases of miscarriages and lymphomas, and on the very long term to less frequent osteoporotic fractures.

The analysis, whether it is a RCT or an observational study, can not wait until these long-term effects appear. The only way to reach a policy decision of screening is to make a model of the pros and cons, the likely costs and health outcomes. This ideally should be done using a prediction interval (a confidence interval with extra compensation for future uncertainty) technique from statistics inference analysis. The technique commonly used is regression analysis with a sample of patients to make this prediction interval. For a closer discussion see e.g. Altman (1991). The advantage with this kind of statistical projection is that the strength of the analysis is demonstrated to the decision-maker. Also, the technique of discounting costs and benefits is easily done when the time perspective is clear and well defined.

A point of concern is that the prediction interval in many cases looks like a trumpet. That is, it widens very quickly if the data analysed is of poor quality. From a certain

point of view then the analysis is more precise. However, from an economic point of view future costs and benefits should not only be reduced compared to those of today, but could sometimes also be accepted with a larger prediction interval which makes the interpretation of the analysis more of a political matter than it was originally intended.

#### **A.7.4**     *Epidemiological Models (Markow Models)*

Models based on epidemiological analysis are often focusing on cohort analysis, that is analysis of a certain group of people followed over time. The techniques involved are often referred to as “survival analysis”, population pyramids, transition statistics, relative risks and odds ratios. Especially the Markow models have come to great use in economic modelling.

Markow models means to make use of decision trees like the one above but doing it in a cyclic iterative way. The end of a certain branch is fed into the beginning of the tree to start a loop. The number of loops is decided in the parameters of the model and usually all end stages, except the final death, are used to feed the loop. The advantage of using this type of model is that several treatment cycles can be analysed in the same model and the dynamic properties of population changes can be followed over a longer time.

The detailed discussion of the applicability of these techniques has to be left out, but the epidemiological concepts may also in many cases be used for economic purposes, especially to follow and value health outcomes over time in a certain population or defined subgroup of a population.

However, it has to be checked carefully for the variability or uncertainty of the data. Economic analyses often make use of the individual observation to assess group average behaviour. In most cases the economic uncertainty is rather small on individual level. Epidemiological data often use population-based data to draw inference into individual level. Relative risks, for instance is generally expressed with just one or two digit certainty which means that going back to population level, for economic purposes would impose quite a large statistical error of up to 10 %. Still, in many cases it is better to know the uncertainty than to have to rely on data with totally unknown validity or reliability, which is often the HTA case.

### **A.8     What Data Is Needed and What Can Be Used?**

#### **A.8.1**     *Valuation of Marketed Goods and Services: Charges vs. Costs*

It has been pointed out before that charges can not automatically be trusted to reflect resource use or *real cost* from the evaluator's point of view. The analyst should not uncritically adopt charges or other prices as stated in accounts or other financial records. Sometimes they should be adapted (or rejected completely). There is no simple rule how to identify situations when suspicions should be raised that there would be a difference between charges and costs. From a professional economic point of view some important aspects would be:

- **Fixed cost elements**

The problems of fixed cost elements are covered in length in the *overhead cost* section

- **Third party payments**

Every insurance system, and also to a large extent tax funded systems, builds on the fact that risks are distributed among the policy holders/taxpayers. That means in practice that what you pay in premiums may be higher, or lower than the resources you actually use for your healthcare. To which degree your premiums cover the real (marginal) cost of your treatment might sometimes need to be checked, especially when the policyholder is believed to be far away from the average.

- **Taxes and subsidies**

A variation of the above problem is when the government impose taxes on certain consumption or when some consumption is promoted by the government for instance by subsidising buildings or other capacity to free or reduced cost. This latter could be the case for instance when research activities are done in a university area or when a screening campaign is given for free to a group of the population.

- **Monopoly**

When one hospital is the only health care unit in an area, when the political control is fragmentary and where it is no or little choice to another health care unit, this will probably lead to high charges and low production compared to a situation with more competition between hospitals. The real resources used for treatment are then less than what the charges say, either they are presented directly to the patient or via an insurance.

It is important to recognise that the presence of a monopoly or any of the other market failures is not the important issue, but the degree of deviation the monopoly will create from the real resource cost. If it is just a few percent and the political control of the management is good then the monopoly will not cause serious problem. Thus, in practice, the important question to raise is if it is believed to make considerable difference? Only experience and thorough investigation can tell.

#### A.8.2 *What About Productivity Costs?*

It does not seem to be a large discussion about measuring the costs of being away from work to participate in treatment activities. But very often a considerable part of the results of health care also can be measured as better ability to perform work, either in the household or in paid work. It has long been a common technique to show this benefit as a measure of the value of the health care. In many cases the largest contribution to the value comes from such productivity improvements. However, in many cases the leisure is not counted at a value comparable to working hours. This technique has often been called “slave calculus” by many since the dominating value of the treatment is valued as the ability to work. The consequences of this kind of policy analysis would also be that the health care would prioritise the younger generations in contrast to the retired people, a fact that is contrary to the needs of many elderly.

To summarise, “The convention of dividing costs into direct and indirect has caused discussion and confusion. Some economists have gone into details about the actual value of lost production, supplying techniques for valuing complex corporate

organisations where individual productivity can be hard to assess (e.g. in teamwork). Also, the salary as a measure of productivity has been criticised. In most cases, however, it has become the standard to value lost productivity to the patient's salary, sometimes gross of income tax, sometimes net of tax, depending on whose values are to count, the society's, the company's or the patient's."

The simplistic division of direct and indirect costs sometimes has led to analytical errors and even flaws in decision making. Despite a resistance to change habits, a movement is going on to get out of this logical straitjacket (2, p. 23-24).

But if they need to be calculated, how should that be done? The first measure to use would then be the *average income of all citizens* in Poland. The average income of the *working population* in Poland would give a somewhat higher value and further, the income of the *full time workers* in Poland would give an even higher. What to choose is to a large extent a matter of the purpose of the investigation. If the household situation is reflected the first choice would be more appropriate than the last. On the other hand, if the short-term loss of time is of concern the latter would be better.

Secondly, there must be a choice of what cost to measure, *gross of tax* or *net of tax*. How much of the taxes should be included? In many countries the tax imposed on a hospital for hiring labour would amount more than 40 %. It is then of great importance to motivate the choice between what the employee gets in his pocket and the cost to the employer (i.e. what he has to pay).

Furthermore, some costs are not paid in the form of salary tax but as a premium for later retirement pension. It can then be discussed how much of this cost should be seen as a real cost and how much should be seen as a transfer of costs from one point in time to another.

In many cases the simple choice of net or gross of tax will be too simplified. The Appendix on Methodology then gives a technique for how to use demand and supply elasticity to find the correct point somewhere in between.

### A.8.3 *Valuation of Non-Marketed Goods and Services*

Non-marketed goods and services are such that can not be valued separately but has to go with something else. The (dis-)value of pollution is one often-cited example, the value of increased or decreased personal primary sensations like pain, loss or distortion of your sense of smell, eyesight, hearing. These sensations are not costs but the maximum value of activities (costs) avoiding getting the effects can be valued.

#### *The value of time*

Some economists claim that we should not only assess the monetary values but also the value of time spent in different activities. The reason is that in many cases they are not exchangeable. The busy executive director of a successful organisation says "I don't care about the money, but I have no time to go to the doctor". If you can not pay your way out of a busy situation you should also value the time, besides the money.

In the early days of health economics a number of attempts were done to assess the time people put into different activities, and how much they valued these activities. In a perfect world all people work in balance to their leisure and there is no desire to change



this balance. That means that the marginal rate of substitution (MRS) is the same. That, in turn means that the value per unit of working hours (basically the salary) is the same as the value per unit of leisure time. Otherwise there would be a noticeable strive among people to change the balance. This means that the value of leisure should be the same per time unit as the pocket income from the employer.

There is one exception to this, and that is when some time is so valuable that it has no alternative value (opportunity cost). There is sometimes a value of time, which may be so high that no monetary compensation could be enough. This situation is probably rather uncommon, but unfortunately health care would probably also be one of the sectors of society where you could possibly find it. This should then be left to the ethicists to discuss instead of making a senseless economic value.

But for normal circumstances some researchers hold that leisure should be zero valued, with the argument that leisure is of no market value. "It is not productive". That, in turn would mean that what you do in your leisure would be of no difference to you. If you read a story to your grandchild or sitting in the doctor's waiting room would not matter to you. If you ask people what they would prefer, and how much they would like to be compensated if they should choose the inferior choice they would certainly be able to provide a sensible answer. The value of leisure is certainly greater than 0.

Also, the value of home production should be considered. This production could be of higher or lower value than leisure alone, but also higher or lower than market production (that is, receiving monetary salary).

The conclusion is not that "time is money", but certainly that time has value, and most often also that time has monetary value.

### *The value of life*

Another case where the cost may be estimated as the value of the effect achieved is the value of a lost life. That could be activities for decreasing operation mortality, decrease neonatal mortality or traffic safety. All these activities and others involve the use of resources to save lives. In most cases the value of these resources are no problem to define and quantify, but sometimes there may be greater problem. Also, the value of a lost life is essential to assess at the effect side of an evaluation.

Jones-Lee et al. (1985) estimated the value of avoiding one statistical life in traffic to be \$1.6 mln in 1985 (about \$2.4 mln in 2001). The study analysed the willingness to pay, in terms of raising policies or taxes for building safer roads.

But in many cases a value is needed to estimate premature death of a number of years. If a person dies at the age of 65 instead of 80 we would say that the loss is 15 years, at the age of 50 it would be a loss of 30 years. The corresponding cost of avoiding such an event would be the same, at maximum.

Let us make the assumption that no year is more valued than any else, that is, all 80 years have the same nominal value. However, the value of losing 30 years is not double the loss of 15 years, because of the general economic principle of discounting (see the Appendix on Methods). Therefore we need to find a nominal value, the same for all

years of life, which, as a sum of all life costs, gives the discounted value of the entire life.

Thus, assume that the length of life is 80 years. There is an annual value  $C_y$  that in a consecutive discounted series of 80 years will sum to a value of  $L = \text{fl.5 mln}$  according to the formula:

$$L = \sum_{y=1}^{80} \frac{C_y}{(1+i)^y}$$

This nominal value for one year,  $C_y$  can be estimated to about \$100.000. Every lost year up to 80 from the year of death are then discounted to present value and then summed to a total value of the lost number of years.

Neither is this way of calculating costs free of objections. With a more elaborate database of percent of the population by age and elaborate data of probability of death in each age group the cost per lost year of life would be different, but the principle would be the same.

## A.9 Hospital Costs

One problem is that many of the necessary cost items are not known. Like in many other countries, it is also quite clear that appropriate unit costs can not be produced in a routine accounting fashion until radical changes is done of the administrative hospital systems.

The question is then, what can be learned from other countries? Are there ways to translate the extensive work already done to a Polish setting? This problem is somewhat similar to the problem of comparing the price of pharmaceuticals in different countries. The area has been subject to an extensive research over years, and some important results have come out. But it is also clear, even from a theoretical point of view, that prices in one country are not possible to mechanically translate to other countries. There will always be a part that is not possible to explain from simple rules of thumb.

This study proposes that the following process:

- 1 A long-term process should be initiated from the government to record costs in a way that can improve the function of the health care.
- 2 A medium-term process should be initiated to produce translations of international cost data for Polish purposes. This activity has to be iterative in nature, striving to better performance by learning by the process itself. Every attempt to adapt international prices should be checked and followed up to adjust weights to next period of time (next year).
- 3 A short-term process should be started to find price "corner-stones", unit prices of general importance. The principles of this report and the Appendix on Methods should be used. The list below proposes a start of such basic prices, and the ambition should be that of the Dutch principles for cost research in health care (Oostenbrink et al.):
  - Hospital day in a medicine clinic;
  - Hospital day in a general surgery clinic;
  - Surgery theatre cost per minute;

- The price per hour to the hospital of one doctor;
- The price per hour to the hospital of one nurse;
- Typical cost per day and m<sup>2</sup> of hospital building.

The item 1. above does not require a great need of resources. However, it requires administrative and legislative input to ascertain that work is started, going on and finishes with the desired results.

Item 2. requires bilateral comparisons between Polish unit cost and corresponding cost from another country, for instance the Australian DRG system. These comparisons should be expressed as ratios of the same kind as currency exchange rates. It is recommended that they are developed from the most basic cost elements. Another approach would be to build prices, which can be used from time to time when needed. The Dutch health care produced such lists (Oostenbrink et al.).

As an example, let us use the common DRG group listed in the Australian data, *F20Z Vein Ligation & Stripping* and translate these costs to the Polish situation, to be used in evaluations instead of using Polish bottom-up calculated prices.

The total Australian cost is 2,079 AUD (Australian dollar) for such a procedure (see appendix 2) or 3,934 PLN. The error we impose by using this simple technique is that we will only consider the demand and supply of money of the two countries. This, in turn, reflects mainly patterns of trade. That means that the approximation will disregard other differences like labour/capital supply and demand, like for instance differences in salary structure or differences in general technology level. If Australian doctors are in the top ten percent of the income spectrum and Polish doctors only in the top twenty it would create an error. If that error can be neglected or if it is large enough to compensate for depends on the importance of the cost of the stripping procedure related to other parts of the study. A guiding figure from the Netherlands states that about 50% are staff costs.

If needed, the next narrowing step would thus be to adjust different procedures for differences in salary levels, and maybe also for differences in technology costs. The price of a vein ligation and stripping would be cheaper in Poland because of the cheaper labour cost. In the ligation example prices are classified into direct and overhead. The direct cost part to a large extent consists of salary. A simple procedure would then be to make an adjustment of direct cost according to the salary percentage of total health care costs in the two countries – data that would be available in most countries from the national central bureau of statistics.

Making the approximation more precise would also require more detailed data from the health care sector, and with a system mainly not using accounts at department level this is an issue for general administrative development. In this case the advantage of adopting prices from other countries would decrease or disappear compared to building own prices in a bottom-up system.

Typically the accounts for a hospital department would appear as follows:

**Annual costs for XYZ Department**

<b>Cost units</b>	<b>Direct costs</b>
Direct salary	
Salary taxes	
Pensions	
Direct material	
Equipment	
Patient administration	
External service (Sold)	
<b>Total direct costs</b>	<b>Σ</b>
	<b>Transferred (or Indirect) Costs</b>
General administration	
Blood supply	
Radiology	
Pathology	
Bacteriology	
Chemical laboratory	
Clinical laboratory	
Patient meals	
Bed service	
Laundry	
Cleaning	
Maintenance and rent of buildings	
Energy	
...	
<b>Total transferred costs</b>	<b>Σ</b>
<b>Total direct and transferred costs</b>	<b>Σ Σ</b>

**A.9.1 Generic Costs for Staff**

The cost for staff is generalised to the salary cost per hour. This cost should reflect the cost to the employer, including salary tax and pension funds, and only in exceptional cases the actual pocket salary of the employed.

In cases where staff cost is a major part of the study adaptations should be made for the turnover of staff. Consider the following example.

A nursing home has a large turnover due to a stressful working situation, which in turn leads to “burnout” syndromes. About 20 % of the staff finish their employment every year. Still the total amount of employed people is maintained, which means that also 20 % new employees enter the nursing home every year. The cost for advertisement, employment, training and friction in production is considerable for this new staff. In the annual accounts is clearly visible that this nursing home has a higher cost per treated patient than similar homes. It takes, however, a special investigation to show the turnover. In the accounts is no sign of irregularities. The nursing home has the same number of staff as other comparable homes.

Sometimes it should be recognised that a number of staff shares their work between two or more departments. Only the effective number of hours should be counted. The same goes also for part time workers.

#### A.9.2 *General Cost for Material and Equipment*

The cost for equipment, diagnostic, treatment and assistive material varies to a large extent depending on the specific care and department. In many cases these costs are included in the direct cost of the department, especially if the department has a low technology level like a geriatric department or a nursing home. However, if the department is highly technical this part will take a larger percentage of the total costs. The Dutch study shows a material and equipment cost of 20 – 25% of the total cost.

#### A.9.3 *General Costs for Supporting Departments*

There are two ways that supporting department cost can be assigned. First, the cost of the laboratory can be distributed equally, or as a percentage (e.g. by total cost, number of patients, number of patient days or number of beds) among the treatment departments or wards. The other way is to make an estimate of the laboratory charge for the particular *treatment* and instead disregard formal percentage accounts from the above table. Such charges can be collected from DRG lists of the Australian type. The price estimates would then come via different principles but would still give a better estimate than pattern cost of the percentage type.

#### A.9.4 *Rents*

Costs for expensive equipment, vehicles or buildings might need a special consideration. If, say, a certain part of a building is used and has other possible utilisation it has an opportunity cost and should be included in the total cost. However, typically buildings have different opportunity cost in short and long term view. If a patient is treated one day instead of another the building space would maybe not be used for something else. It would be empty. In this case there is no opportunity cost. On the other hand, if a group of patients will be treated in another hospital instead of this one, the space could be used for other purposes, by a decision from the management. The latter is more of a long-term change of resources. According to the economic textbooks in very long-term all resources are variable (and thus have an opportunity cost).

For our purpose this is the first consideration to make, but also there is an interpretation of the purpose of the study. If the study compares costs of treatment with one drug compared to a similar, the question of financing building space would probably be of minor influence. However, if the decision to be made involves also financial decisions it becomes partly something else than a pure HTA study. Then building rents and maintenance could well be included.

If such building rent would be included it should be included with its interest value which is the cost of the loan. The repayments are not a cost of the money but the repeated instalments to escape from the loan.

The same technique could in principle be used for the periodical cost of expensive equipment. Using cash money is not without cost even if it seems to be a “free” resource. Even if the equipment (e.g. an electric wheelchair) has been paid for by ordinary cash withdraws from a bank account, the opportunity of leaving the cost for other purposes is lost. Thus, the cost of using the money for the purpose of buying a wheelchair would be equal to the lost interest or the cost of lending the money. This cost could be taken from any bank.

#### A.9.5 Administration

If the opportunity cost principle is applied on overhead costs, the same discussion will arise. If a patient is not treated one day instead of another the only cost that could be avoided is the very close bedside administration – that is very little. If a patient's entire treatment episode is avoided the administration of registration and discharge is avoided, as well as the paper work of patient record, test referrals etceteras. This type of administration is generally done at the ward. General hospital administration will not be affected other than large parts or whole departments are affected. This latter type of overhead can be excluded as well as general hospital book-keeping, library service, organisational administration and research activities. Also when research is done on patients this activity should be separated and excluded from the general treatment activities.

### A.10 Primary Care Costs

If hospital costs are difficult to measure and estimate the primary care costs are even worse. This is due to two major shortcomings. First it is a matter of definition when the treatment of one illness starts and stops, the so-called *episode of illness*. The statistics do not tell much about repeated visits to the doctor. Children see the doctor 2 to 3 times a year in average, mainly for single reasons. People over 65 see the doctor 5 to 10 times a year, with diffuse symptoms with increasing age. In some countries the median age of primary care patients is 70 years or more. Sometimes also elderly people visit the doctor for more than one reason at one visit. Obviously the doctor's problem of defining a illness related cause to the visit is great and the statistics, if any, will be less defined and accurate.

Secondly, the bookkeeping in primary care is less developed then in hospitals. The reason for accurate accountancy is not as important as in a hospital department where total resources need to be accounted for in a precise way to allow for financial inspection. The primary care units frequently do not at all register any cause, or categorise patients into symptom groups.

New methods for (outpatient) description and analyses of complex patterns of health service delivery are needed, and some studies have been done about the "total episode of care". In a Swedish study the construction of total episodes of care has been constructed using case registers (Heibert-Arnlin M, André B, Ivarsson B, Lindmark J. Analysing Swedish psychiatry by using the total episode of care concept).

"The aim has been to illuminate the benefits of the total episode of care as a tool for better understanding of costs, quality and distribution of services in the population."

The study defines *Episode of care* as all contacts that a patient has with the health care for a specific health problem, between a starting and an end point. That means also that the time frame has to be broad enough that the episode of illness can be defined. If the time frame is very small only a small part of the episodes can be identified. If it is too large, more than one year, there will be trouble identifying not only the patient characteristics but also the production characteristics. Doctors and other staff leave. Treatment technology changes, partly from the information care staff get from previous treatment of the same patient but also from new general knowledge from the health care sector.

In the Swedish study data about all encounters a patient had during the totality of care were collected from the case registers kept by two services (patients encounters in outpatient care with doctors, nurses, psychologists etc, number of days in inpatient care. Four aggregated diagnoses were used, *schizophrenia*, *mood disorders*, *crises* and *anorexia*. In order to test the episodes for epidemiological purposes, episode data were related to the population in different parts of the reception areas. Cumulative incidence were calculated as well as prevalence for different time windows. Cost data, specific for each visit, were collected in case registers, so the total cost for every single episode could be estimated.

A number of new measures were constructed; total length of episode expressed in episode days (episode duration); total number of encounters in out- and inpatient care per episode (one inpatient day was regarded as one encounter); number of contacts in relation to episode duration (contact intensity); number of outpatient encounters in relation to the sum of out- and inpatient encounters (outpatient ratio).

The results show that aggregation of visit/encounter data to episodes of care can illuminate aspects of the care in a way that adds on to knowledge retrieved by encounter data alone. Episode analysis also reveals that the two services have systematically different offers to make their patients when they fall ill. The episode concept (not surprisingly) is more related to long-term commitment from health care staff. Future analyses of total episodes of care could benefit from registration outcome measures of some kind, either by severity of illness or by some quality-of-life instrument.

“As data on episodes of care relate to consumption of care for specified individuals for a specific health problem episodes of care give the possibility to describe what groups or categories of patients that resources are spent on. For example it is possible to describe how many persons in a selected community, specified for age and gender, who will turn ill a specific year and hence use the psychiatric services (*ceteris paribus*). It will be possible to forecast how many of these that will end their treatment and also how many that will have an ongoing episode of care. To all these data it will be possible to connect information about costs.”

Information based on episodes of care was also used to follow up and evaluate changes in the health care systems. Effects of changing medical technologies will be easily recognised, as they probably will influence the way that episodes are constructed. The study also recommended that the episode concept should be used to analyse also other types of “diagnoses” than the four used. From a HTA point of view the Polish primary care system would benefit greatly from attempts to build organisational and administrative systems to be able to follow the episode of illness concept rather than the visit/encounter concept.

## A.11 Conclusions

This appendix concerns the principals and practice how to estimate unit price data for HTA purposes when such data is not readily available. At best such prices can be used generically, that is in several applications without a need for adaptation. However, generic prices can not uncritically be used and there is a need for concern in some special cases. The ambition is that the most important cases are covered by this report.

The basic cause to confusion about unit prices lies in the fact that economic data is collected for two distinctly different purposes. The first is the accountant's perspective where data is *accounted for*. Where did the money go and how much? This recording is different from the evaluator's approach which answers to the question -Where did the money go and why? The difference sometimes makes a clear difference, especially when treating overhead cost.

Basically, two ways are possible of calculating unit prices from other data, the top-down method and the bottom-up method. The former uses the principle of approximation and the latter the principle of component building. A mixed approach is the DRG-grouping which aims to calculate average unit prices for a specific treatment or treatment episode.

Neither the extreme top-down approach nor the extreme bottom-up approach will give good unit prices. The optimal solution is to lie in the compromise between lack of discriminative ability vast and expensive data collection. The right level of aggregation is a matter of the purpose of the study.

Likewise, there is no absolute value in a special type of methodology to study unit prices. Often there is a sharp dividing line between RCTs and the so-called modelling studies (here mainly Decision analysis, extrapolations and Markow chains). The gold standard from an epidemiological point of view, the RCT is at its best very precise, but if necessary, a well-performed observational study can give better economic data than a poor or biased RCT.

Thirdly, the report concludes that unit prices have to be checked in some situations against recorded charges. Charges are mainly overestimations of the real resource use and they sometimes need to be reduced. Some special guidelines have been issued when dealing with parts of unit prices which concerns the value of time or the value of life so that these values are not ignored or disregarded.

Finally, some practical considerations are given about the cost issues of hospitals and primary care.

#### Recommendations:

- The Polish health care would benefit from performing national HTA studies, and not rely too much on unit prices from abroad.
- A long-term commitment should be made by authorities to initiate, maintain and develop the HTA work in such a way that generic unit prices could come into routine use.
- Polish evidence base medicine experts would benefit from establishing a clearing-house for the collection and development of national unit prices in health care.



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## **B Presentations and Discussion at Seminar – May 2001**

A seminar was held at the Ministry of Health, Warsaw, in May 2001, with specially invited guests with an interest in health care efficiency and cost containment. Minister Opala chaired the seminar.

Two introductory speeches were given by Prof. Banta and Dr. Brodin, TNO, followed by invited discussion contributions as well as contributions from the floor. The following is a transcript of the major parts of the seminar.

**Min. Opala:** Thank you for coming to our conference concerning standards in health insurance.

It is a problem that is differently perceived by various groups. Why are there no standards? Since they exist in many countries, we should be able to implement them within our system, too. It only requires choosing whose footsteps to follow. But we know the problem is methodologically and politically difficult and complex. Running away from it is a usual practice for fear of suggesting limiting access and amount of health services delivered. It is associated with political failure of the idea whose implementation is anyway inevitable.

**Dorota Salaj:** Good morning, my name is Dorota Salaj. I am the director of the bureau of foreign aid programs. This project is funded by World Bank and led by TNO Company from Holland. It has wide European and world experience.

The work we are about to present to you has been undertaken by many groups of professionals from various medical specialties, regional sickness funds, and the association of sickness funds. The aim of the project is to develop a common language to allow different groups to communicate in this area. I hope that TNO's rich experience will help us to join everyday practice of European Union in terms of standards, which we will deal with today.

With this conference we would like to open a series of meetings with health professionals on that subject.

**Prof. Banta:** Honourable Minister of Health, Ladies and Gentlemen.

As you have heard, TNO has been selected to carry out this project for the Polish Ministry and my role is Chief Design Consultant for the project. As someone who has worked in all the countries of the EU and a number of countries in Eastern and Central Europe. In fact in 1991, I was here in Warsaw for the first time with the first World Bank mission on health care and we made many recommendations at that time which we are probably going to make now. So it is interesting for me to come back to Poland, very interesting, after ten years and see the changes.

As you have heard, what I have been asked to do in this presentation is to give a general background to our thinking on the subject and, at the same time, to tell you what in fact is happening in the European countries individually and also within the European Union and the European Commission. The project, in my way of interpreting it, has one main aim that is to suggest policies, which can improve health care in Poland.

Improve to me means that quality should be improved, that is that people seeking health care should get more health benefit from the health services. At the same time, of course, you hope and we hope that the services will be given more efficiently or more cost effectively. The main policy tool we have been asked to focus on is health technology assessment or, perhaps, a better known name is evidence-based medicine. The main implementation tool is health insurance coverage policy or standards for coverage. Here, I have put down from my experience from some European countries some important issues concerning health technology.

Of course, all countries are facing rising cost for health care and limited resources. Poland is in no way unique in this regard. And this presents those who pay for care and Ministry of Health with very serious problems: problems of choice, problems of changing policies. And those problems are made worse or fostered by a very rapid technological change in health care. The change in health care technologically speaking during the last twenty years has truly been phenomenal. But the next twenty years I am sure, and all experts say so, will bring even more rapid technological change. This rising costs and visibility of technology has led a lot of people to look at the content of health care. This has brought forward the problems of efficacy and effectiveness of health care.

Efficacy here means the health benefits of the care, and generally is taken to mean benefits under ideal circumstances such as in a well-organised clinical trial in the best medical centre. Effectiveness is what is actually seen when the technology is spread throughout the system to the entire population. When the staff is perhaps not so well trained, supporting facilities are not so good, the standards of care are not so good, and so forth. At any rate, what we have found, the more we look at health care and medical care, the more problems we find with efficacy and effectiveness. In the material that you have been given today, just as one illustration we put in tables on obstetric care which have been developed in Europe under the lead of the Oxford conference centre and the Oxford perinatology centre.

You will see there, that these investigators, these obstetricians had been able to make a long list of common obstetrical procedures, which by best evidence appear to be useless and even harmful. And others, which are, as well, useless, also you can separate and identify those procedures that by scientific evidence are very beneficial and should always be offered. Then, in the middle are those procedures, which evidence is not so good, where at the end of the day, we have to say, we don't know or we don't know yet. The more we examine health care the more we find that this is the case with all of the health care.

So far the care provided by physicians has been looked at much more than care provided by other providers, such as nurses, physiotherapists and so forth. We are fairly well along the road of examining medical practice, yet still there are many procedures, which have been in use in medical practice for decades, which have not been examined, in some cases probably not even then identified outside the medical profession. Therefore, although we are well on the road, we still have a long way to go. But I think, that realising, that there is because of lack of effectiveness, a lot of waste of funds in the health care system gives fantastic opportunities for the future for removing those services which are without benefit or are harmful and replacing them with new services. Then of course if the services are not effective, they are costly, and so we have

enormous problems of cost-effectiveness in the system. And the quality of care cannot be good if so much ineffective technology is being offered.

In addition we have increasing population demands. We have spent enough time in Poland now to know you have the same issue in Poland. Certainly, in Western Europe, populations which twenty years ago were rather passive in seeking health care and doing what doctors told them to do, today are questioning and demanding, which puts more pressure on the system. And finally, the population is ageing, so we see more chronic illnesses, we see more frail, elderly people, we see rapidly rising needs for care.

I want to first define technology, because sometimes people interpret technology as meaning machines and equipment and this is not correct. Technology is defined in a very broad sense: systematic application of scientific and other knowledge to valued ends, or practical tasks. So health care technology, as you can see, does include equipment and machines, but it also include drugs, pharmaceuticals, biologics and procedures carried out by health care professionals, such as physiotherapy massage is a technology and the organisational supportive systems within which these clinical services are provided. So machine is a technology, a procedure using a machine is a technology, but the system, say the system for the care of diabetics, is also a technology.

This just illustrates the types of technology, the drugs and biologics, equipment and machines, physical techniques, procedures which are a combination of technologies, the physical techniques, the machines and also very often drugs and then systems, such as system of care for people with diabetes, or with emergencies or with other problems. And the purpose of health technology spans everything that is done in the health care, prevention and health promotion, screening, diagnosis, treatment, rehabilitation and supportive care.

I want to introduce the field of health technology assessment. Technology assessment, the term technology assessment was first used about 1967 in the US Congress for analytical techniques that look at the social consequences of technology. So applying this to health or health care we see the application of technology assessment. In health is particularly concerned with efficacy and safety of health care technology and financial costs of course are also a key issue.

As I said, the term technology assessment was first used about 1967, health technology assessment was first used and described about 1975, also in the Office of Technology Assessment of the US Congress. This idea of pulling together, of analysing technology and using the results of these analyses, of these studies for policy making purposes, then spread to Europe.

And, as I will point out later, it is now becoming to be common in all Western European countries. In fact there is a rather vigorous technology assessment centre in Poland, which we have been working with. Krakow is part of the National Centre for Quality Assurance, so probably many of you are generally familiar with this idea, and I have to say, that, as far as we can tell, from our experience so far, that centre has done a very good start toward having a high quality assessment studies that are well tied in to other European networks.

A full, comprehensive technology assessment would take in, all of these aspects of technology, technical safety, for example: is the machine safe, electrically speaking, it does not shock or harm the patients or physicians who use it. Technical effectiveness: does it do, what it is supposed to do, for example, does a drug, that says is an anticoagulant, does it actually anticoagulate the blood. Clinical safety: is it safe in use, or does harm to patients. Effectiveness and efficacy, clinical effectiveness and efficacy I have already described. Cost, I think you are generally familiar with. Cost-effectiveness puts these concepts together. It can be done in a sort of array. From this side efficacy and effectiveness, and on this side we have cost. And then you can say: well we think that cost are more less in balance, we are getting a good return for the cost or there can be a formal cost-effectiveness analysis carried out by a skilful health economist. And finally social consequences, ethical, legal, social and cultural dimensions which sometimes are very important.

A process of a health technology assessment is carried out in one of the agencies for health technology assessment. Again, as I have mentioned before, almost all Western European countries now have national agencies for health technology assessment. We network continually, we share methods and this is a rather common method for carrying out a health technology assessment or from now I'll say HTA, because it's easier.

Well, first of all we have to identify what technologies are needed to be assessed, and there are literally thousands that need to be assessed. Therefore it is necessary to set priorities. There are quite a number of experiences in trying to identify technologies that need to be assessed, for example in the Netherlands, physicians working for sickness funds as advisors were asked to list, or send list of technologies, they had questions about from their own experience or had heard from other physicians that they might be questionable. And this simple letter resulted in about one thousand five hundred questions, specific technologies, that physicians themselves wondered if they were any of benefit at all. So it is not difficult to identify technologies that need assessment, but it is difficult to make an entire comprehensive list, and then it is necessary, as I have said, to set priorities between those. Then one goes on to scientific literature to find out if there is an evidence base, if there have been randomised control trials concerning that particular technology. In general, newer technology is evaluated better than older technology. Randomised trials had only been applied in medicine beginning in the late forties, and it was probably only twenty years ago that they became relatively common. So those technologies that were already in place twenty years ago tend to be not as well evaluated as newer technologies.

Today we are doing a fairly good job of evaluating new technologies. So these studies are identified and pulled together in a synthesis document. Once we know what is known, it is almost always necessary to get more information, this might be a prospective clinical study, could be a study on cost, because cost are generally not very well covered in literature or could concern other aspects that might be important such as social and ethical. Then all of this information is put together in a final synthesis-conclusion, which could be very simple: the technology does not work or there is no evidence that it works or it could be very complicated, such as the technology works very well for this group of patients, but has no effect on that group and so forth. In some instances recommendations are also required. Then these findings are given back to the people who need them and there is evaluation of their use and feedback into the system.

As I have said, one of the tools which we are going to recommend in this project, or in fact we were requested by the Polish Ministry to look at that is coverage for health insurance. When you think about this process, it more or less is a process that needs to be followed in coverage decision making. Identification might be the question from the sickness fund or a question from the doctor: "Would you pay for this technology if I began to provide it". Then the literature search and synthesis goes on. In the case of coverage there seldom would be time to do a very detailed clinical study. So a final synthesis and conclusion is reached and then, a coverage body would decide if the technology should be covered or not and if so under what circumstances. One of the coverage decisions that could be made is that the technology would be covered, but only with the requirement of additional data collection, such as a data bank. So, coverage decisions are not just "yes-no", but have a lot of complexity built into them.

This is what task a national agency would usually take on. It needs to know a lot about a whole status of the population, health policy structure, problems in existing policies and needs for change in policies, and the situation of the health technology in the country. There have to, of course, be interactions with policy makers, and the agency need to go through this process I have already shown you of identifying and studying the technologies to come to conclusions and maybe also suggest changes in policy.

What I have found throughout the world and certainly in Europe, and Poland, is that countries do have policy structure, and HTA can be linked to that policy structure, can be used in the policy system. Research and development leads to certain technologies that can be funded in certain directions or can not be funded in certain directions. The HTA policy itself is kind of health policy that can affect health care. All countries, including Poland have a regulation on registration of pharmaceuticals, and this is based on health technology assessment sometimes very well and sometimes not very well. But it is based on some sort of assessment. Of course, there is a European system for registration of pharmaceuticals and the Polish law on pharmaceuticals is in the process of being harmonised with that law for entry into the European Union. Likewise, medical equipment is regulated in some way.

I think there is no regulation of medical equipment in Poland at the moment, but there is a law somewhere in development and there is a European Union regulation for medical equipment. Planning and regulation for technological investments, I am going to say more about it in a moment, so right now I am going to skip it. There can be a full system for medical equipment, such as having centres for spare parts and maintenance and repair, which in 1991 Poland had a very well developed system. I must say I do not know the situation today. The payment system has many consequences, and I will also go into that, particularly into coverage. Quality assurance, you have a National Centre for Quality Assurance in Poland, and the standards for quality assurance, should certainly be based on HTA and consistent with what is known from HTA.

Informational strategies means basically pulling together information and furnishing it to policy makers, to managers and to clinicians to try to affect decisions on all levels in the system, and finally education and training.

Before I go further into these policies, I just want to say a few words about the situation with European health care systems because we have seen in the last fifteen years a tremendous convergence in the way European health care systems are organised,

administered and operated. And I suppose the changes in Poland in the last ten years are also very much based on these developments in Western Europe.

First of all, it is now pretty much universal in the fifteen members states of the European Union that there is a publicly financed system of care with payments by third party players under defined contracts with competing providers of care and some competition between payers of care. Sounds very much to me like where Poland is moving. The system allows for cost containment, it allows for setting prospective budgets for care for a year, it allows setting prospective hospital budgets for a year. Those are very common tools that are used for cost containment. It also allows decentralisation of decision making. The providers, clinical physicians are left relatively free and autonomous in these systems, within the framework of the system. Patients have more and more choice. There is extensive choice for patients under these systems. The governments' ministries of health have stepped away from direct controls from the system to a certain extent, and the role of the payers for care- sickness funds, insurance companies is being increased.

So now I want to go on with these two policies. We were asked in the terms of reference of our project there were two areas that we were asked to analyse and go into specifically: one is certificate of need, and the other was coverage policy or defining a benefit to the policy. So, certificate of need is actually a term from the United States, it is not much used in Europe, but the idea of certificate of need is quite common. In our report we will describe the Dutch system in detail, how these decisions are made. The general goal of these kinds of programs, those kinds of regulations is to promote a regionalised system of care, so that when the patient goes to the primary care, the appropriate services are there, and when the patient is referred to secondary care, the appropriate services are there, when the patient is referred on to a large hospital the more expensive technological services are there.

And generally speaking, there will be a forth, very high layer of very specialised care, sometimes specialised centres, such as heart and cancer centres. Actually, this is for efficiency reasons, that is that the services should be both close to the patient, as close as possible, should not be centralised in one area, and certainly, should not be excessive. But there is also a strong quality reason for having this policy: it is summed up by the term "practice makes perfect". For highly technological services, hospitals and doctors who provide the services more, have higher quality and you can measure it very easily for example by mortality in higher surgery such as heart surgery.

Surgeons and hospitals that have low volumes of care in highly technological procedures do worse than those in centralised procedures. And this is very clear. It is not a beneficial policy to allow services to be spread throughout the system, wherever anyone can get the money to provide them. One of the most interesting pieces of information in this regard is to compare the state of New York in the US, which has a strong certificate of need program, with the state of California, which has none. And you can calculate more or less how many people are being killed by the health care system in California, people who would live if they happened to have a surgery in New York.

This regulation is implemented, as I said to improve efficiency and quality. The regulation is typically a part of hospital regulation, hospitals have licenses and in fact, the first form of certificate of need limited hospital beds and even could force the

closing hospitals. And then there is usually a separate section, which deals with technologies, and generally speaking, 10 or 15 technologies, or technological areas are regulated directly by the Ministry of Health. This sort of regulation is possible in any sort of system. The Netherlands is really a private system, hospitals are private, doctors for the most part are in private practice, but they are regulated under the Hospital Provisions Act. 15 years ago these decisions were made largely on political or other grounds. But this was very insufficient method of guiding the decisions. It was recognised clearly.

In the Netherlands for 15 years these decisions have been based on HTA and there is a special HTA office for answering questions or for evaluating this particular program. Flexibility in these programs is very important and they have to be evaluated continually or they can become a major blockade to progress.

Here's a list of services regulated in the Netherlands, when you'd look at other countries such as France, you'd find a very similar list. These are expensive technologies, generally expensive on a unit basis. They are technologies that are not provided at very high rates to the population, so they are natural to be centralised and they are highly technological, so if they are not provided at high rates, the results are not expected to be as good as if they were widely spread. So major imaging devices, such as CT, MRI, and positron emission topography are subject to this regulation. Radiation therapy meets all the criteria, all the major transplants: kidney, heart, lung, liver, pancreas and bone marrow and also renal dialysis, so there are renal dialysis and transplant centres under the law. Some form of surgery: eye, neurosurgery, not simple neurosurgery and cardiac surgery along with cardiac catheterisation, angioplasty, lasers and so forth. So we have cardiac centres and these procedures can only be provided in these centres. Intensive care in the Netherlands is neonatal intensive care, genetic screening and counselling and in vitro fertilisation.

I am going to move on to payment and HTA. The first thing to recognise is that in any system of payment, any system at all, there is money in the system, and the money must go to the hospitals and the physicians, and these methods of payment and amounts of payment lead to certain practices, in other words there are incentives to do certain things and disincentives-not to do certain things in any system. What you would like to do, is to design the system so it gives incentives for doing good things and gives disincentives for doing bad things - this is not an easy task of course. It has been shown, particularly in the Netherlands and several other Western European countries that rising expenditures for care are very much related to incentives for certain technologies. They are particularly linked to fee-for-service payments, to specialists. When attempts have been made to control the incomes of specialists they provided more diagnostic tests, which increased their income, and so there has been an enormous inflation of cost because of favouring these diagnostic procedures in the payment system.

This is one very prominent example of incentives in the system, which are not appropriate. These rising expenditures can be addressed by prospective fixed budgets and the fixed budgets can control cost and they also control the technology, technology coming into the system. But they have a major problem, and that is that they basically stop progress. All cost are controlled, all technologies are controlled, and the danger than, under this sort of budgetary control is that we will just end up with a stagnant primitive system. And we want to make change, make room for new and beneficial, cost effective technology. So my way of looking at this is that, HTA does not control



cost, not at all, it is a research tool, and cannot control cost. The way to control cost is through budgetary means. Having done that, HTA can guide the choices that have to be made which quite often are very difficult, so old technology can be removed and new, beneficial technology can be admitted.

Now I have come to the specific issue of coverage, which is the other issue, our project will focus on. Health systems generally provide predefined packages of benefits. In some systems this package is explicitly defined, that is, it is listed. These are the things that we provide. In some systems it is implicit. It has never been listed, but everyone has more or less a good idea as to what it is. Up until fairly recently, that package was defined by medical doctors. For example, the US Medicare law says that usual and customary services will be provided. That is the entire definition. The Dutch law is quite similar: what physicians do is paid for. But this has led to a lot of problems, including lack of benefits of care and cost-effectiveness. And so there has been a process of change to define these benefit packages through HTA. To sum that up, that means that new technology is not admitted to the package until it has shown to be effective and possibly cost-effective, and old technology is removed from the package when it has shown to be ineffective or very expensive for the benefit gain.

One tie in here to the Polish experience is the growing use of contracts. For these purpose contracts particularly between health insurance funds, national payers, sickness funds and those who provide care. These contracts become more and more detailed all the time, they can spell out volumes of services, payment regulations, budget and cost-effectiveness which is, of course to me the most interesting part.

Well, different countries in the European Union take different approaches to this, but there is a lot of similarity in the way the countries are going. All countries in the EU are developing HTA, the most advanced are Sweden and the United Kingdom, then at sort of medium level, Netherlands, France, Spain, Italy, and least developed: Belgium, Portugal, Luxembourg, Austria. The EU about two years ago published a health policy paper, which was intended to lay out health policy guidelines, health policy pillars in the EU at the European level for the next ten to twenty years. As you probably know, harmonisation of health systems is excluded from the competence of the EU totally at the moment and focus of this health policy paper is on information. The problem of ineffective and cost-ineffective practice, technology is very clearly acknowledged in this paper and the solution is said to rest on information at the European level.

In other words, HTA, evidence based medicine, cost effectiveness is being made major tool for health policy in Europe in the future. The policy paper has now been considered for about two years, it was revised after the Commission all resigned and presented again in stronger form. It is now in its final discussions in the EU Parliament, it has been accepted by the European ministers and probably by the end of this year at the latest, this health policy line will be totally accepted and there will be an established HTA centre or office at the European level. This will be based, I can say almost surely, on a network of national programs. This will not be a national agency such as the Drug Agency in London, it will be some sort of co-ordinating centre, probably located in one of the existing HTA programs.

The network co-ordinator at the moment is in the Swedish agency and this might continue to be a very good place to leave that. But the important thing for Poland in this regard is that most likely you will be legally required to have HTA capacity in the

Ministry of Health for purposes of networking, passage of information, so even if you didn't think it was a good idea, I think you'll want to get into that anyway.

But I am sure you all think it is a good idea, so this is really not too much of an issue. Now as far as the coverage activity, this has also been developed rather fast European countries over the last fifteen years. It started, as far as I know, in the Netherlands in 1985 with commissioning large HTA studies to help coverage decisions on some new technologies. The first ones were heart transplant, liver transplant and in vitro fertilization. Other countries followed suit rather fast. Today, I'd say probably Switzerland is the furthest ahead, in explicitly defining the benefit package and Netherlands is next. France, Spain, Italy and Germany are the countries that are working very hard in this direction.

It is a typical experience that countries have gone through, sickness funds have gone through. This was the experience in both Switzerland and Netherlands, I know that, because I was there consulting with these programs. They first think: all we have to do is list all the practices and procedures in health care, throw out those that don't work, explicitly recognise those that do and then we have a basic benefit package. But the problem with that, as I have tried to indicate already, is that if you take this circle as all the health care, there are very large areas, which are not defined, not evaluated at all.

And observers of the system have pointed to such areas as long term care, chronic disease care, primary care and so called ancillary services such as physiotherapy, where relatively little evaluation has been done. So we have a long way to go to reach the goal of having a truly explicit basic benefit package. So in a pragmatic way, what countries have done is to put up a barrier to new technologies entering the system.

You see here, the new technology is seeking to come in, so at that point an evaluation is required, before a coverage decision can be made. And this results in a positive list, these procedures are definitely paid for, they have been shown to be effective and cost-effective. Of course, part of that list may very well be the amount of payment as well. But the important thing is, they have been put on the list, they have been recognised by the coverage body as a benefit to the individual patient and to the patient population. And if the technology is evaluated and found not to be a benefit it can also be put on the negative list. Now, probably many of you know, that a number of countries already have positive and negative lists for pharmaceuticals, so pharmaceuticals are rather easy here to actually make a basic benefit package. The Netherlands for example has negative and positive lists, Spain has a negative and positive lists.

It is easy to identify pharmaceuticals because they are registered and they generally have been fairly well evaluated. Prevention has been generally pretty well identified and pretty well evaluated. Emergency services are I think relatively easy to identify. What is still left, is a large body of services, which have not yet been looked at very carefully. So the result is that Switzerland said: this is our basic benefit package. That was the definition. What is provided is the basic benefit package and then we will begin a process of screening everything that wishes to come in. The Netherlands has done more or less the same, but has added the "looking at the old". So now we are systematically going into these practice areas. I mentioned before the experience with the sickness funds, doctors, 1500 procedures were identified, a 125 high priorities were identified, and those are presently being assessed, and many of them are being removed and put on a negative list. We no longer pay for these procedures.

The process is something like this. This is from a Dutch policy report, which was published six or seven years ago. The commission was chaired by the most prominent professor of cardiology in the Netherlands, professor Dunning, and the commission was basically mainly physicians from outside the government and they recommended the system along these lines. The technology should enter the assessment and coverage process like this and decision should be made: is this important or is it potentially important. If it is trivial, we are not interested in it. Important for health- if it is, we want to know effectiveness, we can look at effectiveness through existing literature, and if that is insufficient, we have to organise prospective randomised clinical studies.

So one of the things Dutch government did was to set up a special fund for such prospective clinical studies. Then if it is effective, we want to know: is it cost-effective and that means an explicit, well-organised analysis of cost-effectiveness. In fact in the Dutch system, the fund I have referred to, generally is stimulating studies that simultaneously look at effectiveness and cost-effectiveness.

So these two screens, these two funnels: effectiveness and cost-effectiveness tend to come together more than this picture implies. And then finally, there are some services that could be cost-effective, but the payers chose not to pay for them. For example, homeopathic drugs are thought by many people to be cost-effective but the payers, the sickness funds in the Netherlands have decided not to pay for them because they are not very expensive and it is felt that people can afford to pay for them themselves if they wish to have homeopathic drugs.

So this is a kind of a quick look on how the Dutch are organising this system. I think it is quite likely, that we will that Poland follow rather closely the way the Dutch model works. Of course trying to adapt that to the Polish situation and discuss problems in how this would be adapted, how it could be adapted to the Polish situation but the main lines I have laid out here I am pretty certain we will follow in our final report.

I think this is a very interesting time for Poland because we do have quite a lot of information now, information on the assessment of the technologies which is in most cases readily available through the Internet, usually free and we have a lot of information from the coverage bodies themselves. I have brought all the coverage documents from Switzerland to the colleagues here in the Ministry and the in HTA centre and we can get other documents from the other countries so we can see what decisions other people have made. So I think this system could be developed in Poland rather fast, in other words you can take advantage of the 15 years experience in other countries such as the Netherlands, Switzerland to jump really up to what I would call modern standards.

I just want to point to one final issue and that is that no one should think that once the coverage decision is made the problem is solved. The technologies enter into coverage process. Of course, generally speaking they can't be provided, unless they are being covered. Once they are covered, they go into hospitals and clinics. Managers are making decisions as to purchasing machines, allowing certain services to be offered and then clinicians are actually deciding what to provide under what circumstances. There are a lot of other forces that are driving decisions. In the clinician area you have preferences both by doctors and by patients. You have patients' demands, you have professional standards, you have industry pressure, you have media, so there is also need to consider this, what you may say, downstream effect.

Coverage is a powerful tool, but there are other things that need to be done, and I think one of the things you need to begin to think about is how HTA can interact not only with the coverage decisions but also with the managerial decisions and the clinical decisions. You can call this the macro-level, and here we have the meso-level, and here we have the micro-level. I would tend to think that the level of the clinical decisions is probably most important of those, although it is very difficult to steer or to control.

This system, that I have presented to you today I think offers advantages to all parties. For the government or for the payers of care there is control of cost in such a system and certainly is improved quality of care. For providers of care there is improved quality, and there is also access to new, cost-effective technologies, which providers like and of course they wish to provide such services. For patients there are guaranteed benefits: they know what they are entitled to, there is less ineffective and harmful technology and there are better outcomes. Well, I am personally convinced that Poland should generally follow this line. Dziękuję bardzo.

**H. Brodin:** Minister, Ladies and Gentlemen.

I would like to show some of the details of the standards of services that need to be developed during this work and where we need your help. Let me start by showing a very practical example from the Netherlands. In our institute in TNO about one year ago we were approached by a German producer of rehabilitation technologies. Let us call him „Herr Director Holz”. That is not his real name. He asked us to do a cost effectiveness study of a new knee brace he had developed. He wanted it to be listed among the procedures that the Dutch insurance would pay for. Let us pretend that this Herr Director Holz came to the Polish government instead and asked the same question.

A knee brace is a stocking for knee injuries and this was a specialty of his firm, this company of his. He has a home page. This is not his home page; this is one of his competitors. We are of course cautious about the identity of Herr Holz. These are other type of knee braces that he makes. And he already has nine different types of knee braces paid for in the Dutch system.

Now he has this new fantastic thing. I have an English version of this device. For me it is a compression knee brace with one bilateral spiral stay and an adjustable strap. Of course, if that is going to be paid for, he has to ask for it somewhere. Where does he call? Does he call the Ministry, does he call the insurance office, or does he call some kind of HTA agency to do this kind of thing.

Who will speak to him, would it be technicians, would be doctors, would it be an economist. And what kind of answer will he get. The obvious answer is: “sorry you have already nine of them, we have no money”. Another answer could be “you have already ten or nine of these, and you need to provide some extra information to prove that this is actually something that is better than the others. Because otherwise it is of no use for us.

So, probably Herr Director Holz will get a very professional reception. And he will be asked to motivate this proposal with information about cost and effect. And he will be asked to specify if there are any problems with these knee-braces or other any adverse effects of any kind. He will be asked to provide information about the efficacy, the

safety, the effectiveness and the cost-effectiveness. And those concepts need to be defined to him so he knows what he is going to provide.

The information that he has to provide should be compared to the already existing technologies, which are the other nine knee braces he had. The instructions also tell him how the documentation should be done. What methods and techniques to use and some specific information, for example what discount rates to use, which is special for these long term treatments. This information has to be specified. And he will also be told that he should not be too creative when he provides the information. No fancy stuff.

Now, that was maybe not the information Herr Director Holz wanted, because it seems obvious that he has to do a lot of work. He realises that he is far from meeting the requirements and he has to prove his case in some kind of way. The information he has already is one article in a magazine called „Rehabilitation And Quality of Life” which is financed by the Association of Rehabilitation Companies. It is not peer reviewed. He also has tested these knee braces on six patients and all six reported that they were satisfied with the brace. And that is not considered to be a very straight evidence of a good technology.

So, he is recommended to ask a Polish professional HTA bureau for help. It is an independent bureau. It is unbiased, and it is probably funded by standardised fees. The bureau is well acquainted with the Polish rules for these standards of services and designs are studied according to the issued guidelines. Now, director Holz's company is very small and this is a new technology that he introduces. But the same principles, as Prof. Banta told us, go for pharmaceutical companies, go for big producers of equipment, and of the assisted devices for instance, wheelchairs, etc. This example just gives the principle, properties, I would say, for the health technology assessment.

Half a year later, Herr Director Holz returns to this standards of services office and delivers the requested positive information, because of course it was a very good knee brace. What happens then is that this study is reviewed by someone, somewhere in the authorities. Probably there will be some price negotiations about what is actually paid for in this knee brace, whether it is not over-financed. Then there will be some kind of registration. There needs to be some information sent to some insurance companies or the people who can prescribe these rehabilitation activities. So everyone knows what is going on, and knows what is possible, and what is not possible.

Now let us go over to the principal issues. The example of Herr Director Holz shows that there are a number of things you need to consider when we are building up this system.

We start with the development, the inventions of the technologies. That could be initiated by patients and consumers, that could also come from professions, hospitals, or it can be a collaboration between hospitals and the industry. Next step in the process is the assessment of how this technology is working. Does it really do what it is set to do and so on? And that has to be done by information of different kinds, and they will also be provided by professions or directly from the technology itself and used by the health technology assessment procedure.

I am not specifying how this is done, because it could be done in many ways. That is one of the questions we need your input for. It could be one office in every insurance

company, it could be a central office for doing this HTA or it could be done by private firms under contract with the government or whatever. This is not what we would like to prescribe, but more ask about. Also the price negotiating part needs to be discussed and evaluated. The government has an important role for creating and maintaining the policy in these cases and to collect, store and disseminate the information about these things.

And then we have the use, which is based on the policy of course but also filtered by the health care providers who sometimes are very closely connected to the professions, of course. And then we have the insurance company and we have the supervisors of the insurance, which are doing a kind of control of the system, that everything works as it should work.

So we have basically two problems and one solution. The problems are what I talked about before. The producers of the HTA studies, how they are to be done and how they are to be read. And we need some kind of common Polish guidelines for this procedure. And we will propose three different areas for these guidelines. And they follow very much the same funnels that Prof. Banta already talked about. And that is that we have the European draft guidelines of HTA. We will also recommend this for macroeconomic guidelines in Polish, which is a project but could fairly easily, be adopted to the whole area of HTA. Thirdly, we have a report in our project of how to use the HTA methodology and that is also produced during this project and will be presented later this year.

So, when to sum up the methodological part of these things –We have already some information, we have the international literature of course, we have the European guidelines, we have the Polish guidelines. But then of course, the most important resource of information in this case is what you can provide yourself and the competence that you can build in Poland and the competence you can already utilise for this purpose combined with for instance the evidence based medicine competence that you already use, so to say. We will later in the project ask key persons in different areas about how we should proceed with this methodological part. But that is the thing we have to discuss and we will come back to you about that, and I hope you will be able to give us some interesting answers. Thank you.

## **Discussion**

The discussion following the speeches focused on the implementation problems of the proposed HTA based system changes. The following is a summary of the important discussion elements.

### **Grabowski:**

Together with Director Kozierkiewicz we represent Minister of Health for negotiating this project. The title is „Standards of Health Services purchased in the Polish National Health Care System. There are many different opinions about standards, often contradictory, superficial, or even totally mistaken. The perfunctory review would undoubtedly show that standard is understood as meaning requirement concerning health services, sometimes as requirement for highest level achievement, as something what is demandable, quote: “what the insured person is eligible for”. Another term that recently came into being in our system is “product”, with specified minimum

requirements to be contracted by sickness funds. And as I understand it should specify raised requirements for service provider expenditures.

Medical practice should be based on standards, credible and reliable scientific data. Standard should prove useful when the financial and other resources are limited and one must make wise choices. They should be adapted to our experience, potential, organisational solutions, health insurance system, and economic or cultural conditions. Have we succeeded so far? We can recognise three approaches to standards issue:

- 1 Standards of products, with the whole process of creating them, and quite broad practice in using them;
- 2 Standards of conduct, also in the process of creating;
- 3 This project just being realised, which answers some other needs.

Products standards project started in 1999 and aims at specifying the subject of contract to a maximum possible extent, especially in relation to minimum requirements for these products to be purchased in the system. These standards were supposed to raise the available quality requirements. In terms of process structure and outcome the product standards did quite well when it comes to description of structural requirements. The practice of using was different in different sickness funds. Some of them undoubtedly treated standards very seriously, analysed them in details, adapted to their needs and then required and controlled the use of them. Some of sickness funds more declared than actually used and required standards.

These standards did say very, very little about the process of providing health service, what actually takes place, how should the insured or the patient benefit from it. This was undoubtedly weakness of these standards.

Here you have a list of requirements concerning consultation within these standards of products. It deals with personnel qualifications, requirements for the place the services are delivered in, the range of diseases available for treatment in a particular place, range of available procedures, minimum medical equipment and minimum clinical experience in treatment of particular diseases.

The process of creating product standards here in the Ministry was relatively short, a few months, with 280 people working in 42 groups, many known experts among them. Did the product standards prove useful later on? It is of course an issue to be discussed, in our opinion more action is required, more steps need to be taken in order for these standards to be more functional.

What is the main problem about these standards? Why don't they give much hope for being more useful to the health care system? There was a division made of the diseases and the procedures into certain specialties and products, but there was no connection found between them.

It leads to difficulties in determining the relevance between the disease and the procedure. These standards are useless in such cases and need to be reconstructed. They are actually useful in the moment of contracting services, but much less practical during service provision, because there no obligation for the provider that certain service should be provided in the context of certain health problem.

They set requirements of a structural type; this is surely their advantage, because it prevents accidental providers from entering the system.

The issue of standards of conduct was undertaken in the Ministry of Health. There were six topics chosen, chronic and some acute diseases, the standards are aimed at basic level of health care – POZ, because it is a place of serious competence disputes and difficulties in defining what a patient is eligible for. These tasks are not finished yet.

In the documents available so far, we can surely find many valuable recommendations coming from scientific societies, academic centres and other professionals. The most crucial problem for us is whether one or the other standardisation process is beneficial for reaching agreement among those with specialist knowledge and a payer, and on the third side with a patient. In our opinion the answer is no, and therefore we should continue the standardisation process. Our proposition is standards guaranteed in health insurance system, where we assume to reach equality in accessibility to certain chosen services, where we would be able to define the rights of the insured, where in some time we would be able to put certain obligations on the payer and the service provider, where finally we will only support effective therapeutic procedures.

Of course we are trying to do so in concordance with what is going on in Europe in order not to invent anything new and so that our solutions were in line with European experience. It is usually assumed to “freeze” status quo of health services and build standards on that basis by choosing the services worth being defined a standard. The conceptual, legal and organisational framework needs to be defined and constructed, based on tested solutions. The crucial issue is whether health technology assessment needs to be applied for the whole process. These new standards should resemble recommendations. They should recommend most cost-effective solutions to health problems.

Here we have an example taken from TNO materials. It concerns cardiology, diagnosis acute myocardial infarction. Medical procedures are listed; two rules for patient's transport are given with approximate time of supplying anticoagulant treatment. This doesn't provide all info about AMI treatment, but this surely contains recommended procedures, although by no means necessarily complete. We do not assume the created list of services will be complete – the plan contains bringing out some proposition until the end of this year. It will then be subjected to a wide discussion. This very list is not intended to solve the problem of co-payment. For instance, if some procedures are found on the list, it doesn't mean that those not found on the list are paid out-of-pocket by a patient. Undoubtedly the mechanism for adding procedures to the list would be pretty efficient way of improving communication between payers and specialists, usually involved in clinical trials. Up to now it is pretty difficult to mutually motivate costs of such trials and procedures.

All users can have influence on standards of services in the health insurance system, specialists, payers, service providers, especially management, institutions responsible for health policy and sometimes insurance. It is a plot of sometimes very contradictory interests. Our task is to define the mechanism, its methodology, consensus procedures, role of certain institutions and their range of responsibility, the sequence of taking subjects, legal system, and later the practice in using the standards. We would like to leave the meetings and ad hoc system for the more systematic approach to creating



standards, led on the country level with an axis around the health technology assessment.

We have our goal: to have good standards? What do we mean by that?

Undoubtedly these must be standards that deal with important medical problems, because it is not worth effort to deal with unimportant issues, for getting a standard is costly, time-consuming and pretty difficult. We have to acquire the skill of determining what is important. These standards should be compatible with current state of medical knowledge; there should be an undisturbed flow of information between the scientific world and the world that finances health services. It should also as possible take into account the balance between individual and public interest.

Medical professionals should accept it, so it means you. You should be involved in creating these standards. They should also be possible to implement under our local circumstances. If we follow the described pattern we will not disturb current financing of health services by sickness funds, and help keep their financial stability.

Such a standard should be useful to all users of the system. Is there a requirement for legal regulation in order the standards come into being in the health care system? Undoubtedly yes, because we have much standardisation experience so far. If we plan to move to more practical actions in future, they should have the legal basis and be an obligation to all users of the system.

**Piróg:**

I am the consultant for this project. I would like to make, with the Minister's acceptance, a provocation to enable so long expected decision. For ten years now, we fight the myths of health, which we have created ourselves. The package, the law on guaranteed services, health insurance. We work hard on the myth called privatisation, by our side there was another myth created: the myth of the worst reform introduced by this government.

We have to work on the system to make what we planned to. The project we are talking about now is the most advanced. We intend to no longer use the name "health benefits package" understood as a list of what the insured person is eligible for and what not, because of the lack of money within the system.

The other issue is diagnosed related patient groups, national health account and health priorities identification.

I believe that the package issue was very efficiently discredited in the 80s, when it was identified with what is indispensable to survival, synonymous to and secured by "cards". This means I would be offered the amount in order for me not to die. Another interpretation of the package is the one after 1992 law on health guaranties by the state. Somehow "father during child delivery" proved substandard, but "drunk person in emergency room" unfortunately was standard. We have now possibility to refrain from creating another myth, concerning health technology issue. So the decision what is patient eligible for is simply based on effectiveness, it should be effective therapeutically and economically. We need an institution working on behalf of the Minister of Health in order to select those technologies. And we can find best examples,

Holland for instance. All those, who see their best interest in providing public funding for effective procedures, should help make the necessary decisions. Different groups present different level of preparation for this thing to happen. Surely health professionals gathered here are prepared, they will disseminate the info into their environments. Representatives of the payer are another example. And still another myth: "the funds are bad", also weak, even if they are right, they are afraid to speak out loud. The society is relatively weaker, also because those who are supposed to disseminate information, who are less professional and actually need explanation and education, do not attend such conferences.

Those who represent the most powerful media do not attend such conferences. And if they would, they receive very bad information, which I expect to bring either resistance or fear, or another myth. Unsigned material that served as a written basis for this project's press conference. And what do we find on the third page? Keep in mind such a clear and good lecture by professor Banta in the context of what we find here. "It is also important to acknowledge that efficacy, safety, and cost-effectiveness are not the only reasons to cover a specific technology. Other factors, such as politics, professional opinions <there should definitely be quotation marks, especially after such a magnificent word "expert">, and population demands, also play an important part. In a democracy, such factors are both inevitable and appropriate". Fortunately democracy doesn't equal stupidity, so it would have been better if that material never saw daylight. Only after its correction we can move on to benefits decisions and creating an institution, agency, public health institute to deal with health technology assessment issues. I asked to cross out the word "political" from the title of my speech, and so it was done accepted by the Minister, who said anything is political. True, and we surely have to make this inevitable political decision.

**Prof. Nizankowski:**

Magical thinking has a long history. Here we have an amulet used to treat all diseases 3000 years B.C. I think that this way of thinking still has many supporters. Greeks called it "panacea", it has been sought after by medicine ever since. Today we know nothing like this exists, but the approach is still "en vogue". What types of "panacea" were proposed for Polish health care system?

Minister Piróg was talking about myths; it's the same as magical thinking. For instance the belief that once we introduce sickness funds, all our troubles will be gone.

Another candidate is the famous basic benefits package. Now we are in the phase of magical thinking about standards. They will do all for us, we write them or translate them, and Polish health care will be magnificent. Privatisation is one more candidate lined up in a queue so everybody started talking about.

What are the opinions on basic benefits package?

Well, so far it assumed a dichotomised division into included and excluded procedures. Those included are funded by sickness funds or the Ministry; those excluded may be financed through patient himself or additional insurance.

It was obviously assumed that the inclusion into package should be based on current scientific evidence on clinical and cost effectiveness of particular therapeutic or diagnostic procedure, so in one word – HTA.

Let us take a closer look.

First element: effectiveness assessment. It is associated with calculating the value of NNT – Number Needed to Treat, which says how many patients need to undergo a particular procedure in order to avoid one consequence – the end point (e.g. heart attack). Now how do we determine the criterion for inclusion into basic benefits package? Should it be 65 patients for 5 years or 30 patients for 6 years? We deal with a continuous parameter and there is no straightforward answer to what is effective and what not. We sometimes ask which method is more effective, what is the probability of such case. EBM and HTA can provide these answers.

Next question is the uncertainty level. If one procedure parameter is within the range of the other procedure parameter, then it means they are both equally effective. If the score is shifted in relation to the other in one or the other direction means that one is more effective than the other. Let us look at trombolitic treatment in infarction. But this uncertainty range is quite broad; one can have doubts if this mean value is true. It narrows down with every analysed trial, yet there is quite a number of procedures for which no such analysis is available, usually because of lack of data. Another example is xylocaine use in early infarction. Every trial brings to a conclusion that it may be better to use placebo. But still, all outcomes touched one, so there was some margin for beneficial action.

Let's look on the other side – cost-effectiveness analysis. First one must bear in mind that such an economic analysis may be performed from many different perspectives, say hospital, service provider, payer or sickness fund. The analysis may look quite differently if we consider social perspective, i.e. expenses through social insurance system. Where do we take cost data? We can use good American or European literature and find effectiveness of particular medical procedure. In case of costs we have to base on our local cost data. Modelling is one of the methods, i.e. accepting some assumptions about the standard procedure and associated costs. Another method is actual monitoring of cost, which requires much more effort and is more difficult than modelling.

We still have discounting to be considered, for both costs and consequences, if anything is delayed in time. We have the uncertainty in economic analysis, too. And we can take attempt to estimate it by means of sensitivity analysis.

So now please, tell me: can you make decision based on such data? HTA gives some clues, advice, and only after confronting it with certain values one can say yes or no. That type of decision-making is not a part of HTA; it forms a separate element, indispensable in terms of making final decision.

Basic benefits in the model I am describing assume that some procedures receive 100% reimbursement, while other are not publicly funded at all. Now comes a question: where is the borderline? If excluded procedures are being performed, who will decide to withdraw from publicly financing them? It seems much better if we differentiate funding amount so that some procedures receive more reimbursement, while other –

less. Of course that inevitably means the need of co-payment from a patient. We have a dilemma, what should be done with the mass amount of procedures we perform each and every day in our hospitals and clinics. Are we able to analyse them in a couple of months? Unreal.

In my opinion HTA should lead to determining particularly effective procedures and those that make more harm than good and should unequivocally be excluded from use. On the other hand those beneficial could form a group of particularly high cost-effectiveness, which should be financed in a way that promotes their use. We will also have a whole group of procedures with unclear effectiveness, which should be financed in a way to impede their use – passive-financing system. This could be payment “per capita”.

Modifying use of procedures through adequate payment system allows to continuously working on the package, not with one effort of doubted quality. It also allows allocating the resources according to economic growth of the country. It is an evolution shift to more rational medicine. That approach also could allow certain control during provision of services and implementing any necessary changes. Naturally, it also minimises political resistance. The Greeks not only invented panacea, but also rational approach to any problem. Let the latter lead rather than the first.

#### **Min. Opala:**

We have presented our partners, Dutch company TNO. We are certain it is irrelevant to put effort into creation of completely new ideas. We should rather adapt solutions in accordance to our potential and needs. We are aware that Poland is one of the weakest countries when range of financing is considered. But we also know very well that the more resources are scarce, the more important their rational allocation. Many comparisons show there is no direct association between quality of health services and level of health, and the amount of money spent in the system. If system is changing, is rationalised, one may say the only reason is to increase availability of possibly best quality health services. One can define it differently; the goal is to allow equal access to basic services.

Adequate rational allocation of resources and education form rational social basis in this field. I think we choose European model, with open list of currently financed procedures, determining requirements on the basis of both current knowledge and within the realms of possibility. I think of a dynamic system, in which anything that didn't pass the exam is excluded, and anything new is added, if confirmed by sufficient data and estimated worth implementing.

It is also a safe solution, first because it doesn't limit access to health services market as it is. It rather rationalises, puts in order, and in some sense cleans up by throwing away what is doubtful or unnecessary and by cautious adding what newly emerges.

Our situation is generally good. Two days ago I met national consultants, particularly the group most often applying for treatment abroad. The conclusion was simple; nowadays in Poland we are able to perform everything. Only exceptional are the cases when we would have to treat abroad. It may only be due to lack of very highly specialist devices that we are unable to buy or it is not economically sound. I can say we do make a change. The money, up till now spent on treatment abroad, can be allocated in Poland,

if a highly qualified specialist is necessary, we will bring him to Poland and teach our specialists at the same time.

Some time ago we didn't expect a doctor to be obliged to make decisions resulting in allocation of public money. Now it is particularly important especially when we consider market forces of new technologies coming into market and highly organised system of aggressive marketing activities.

**Czczot:**

I represent branch sickness fund. All of this we heard is really unavoidable, but with every time the position of sickness funds is getting more difficult when faced with applications for new technologies reimbursement. We also have this question: should we reimburse it from public funds? It is getting more and more common. Maybe we could get back to the period when scientific trials were publicly financed and some criteria for implementing new technologies were also partially elaborated. Even if there is little anxiety of what may happen in the system, it is important to notice that these changes are inevitable. Undoubtedly the majority of sickness funds would opt for more systematised procedures.

**Zbigniew Wronkowski (Oncology Center):**

We basically do not start from point zero, it is obvious that most of us is already involved in standardisation process. In many cases standards are readily available in oncology. I cannot imagine a future situation when standards are not precise and obligatory. In many countries when a doctor applies for money, he or she has to convince to fulfil obligatory standards. In case the standards are not kept, the eventual court trial will surely be lost. Many countries, including Finland, have standards for carcinoma of the uterine cervix detection that could serve as a standard for us. We are well on the way to having standards, and it is time to make standards more precise so they could help those who treat and those who are treated.

**Konstanty Radziwiłł (the secretary of Main Medical Committee):**

When speaking about improving quality of health care in Poland, we all express our deepest interest. Minister of Health on one side, sickness funds representatives on another, interested in, to say shortly, not paying for pointless or not cost-effective procedures, and finally representatives of medical self-governments, legally responsible for quality of health care. I wouldn't like to create another myth. It is totally obvious the doctors should do only what is effective and good, and should be refrained from doing things that are ineffective or in contradiction to current knowledge.

But, here in this room, the standards are understood in a little different way, more to improve budget than quality of doctor's work. In time standards elaboration would lead to implementing new, more cost-effective technologies, and get rid of the maximum possible number of ineffective ones. Drug issue in Poland is a good example. But there is still another issue: what is the conclusion, final aim of it all? I have an impression from Prof. Niżankowski lecture, that health technology assessment is just a prelude, an opinion and not a decision itself. To make a decision, one must apply values. The question arises what values and who would make the final decision. Because naturally the proposed institution for HTA will not make decisions. Nowadays in Poland these

decisions are actually made by sickness funds. And there is a fear that these decisions will be based on values not fully compatible with other participants' ones. The recent debate on recognising multiple sclerosis a chronic disease with drugs reimbursed according to some special rules, could serve as a good example. Some countries try to cope with the problem, for instance Holland or Croatia, have already formed institutions gathering representatives of payers, the state, politicians and patients. In a multilateral discussion process they reach a consensus on values to be applied to certain medical problem. Homeopathy is another example, with numerous pressures to withdraw its public financing.

It seems that we should foresee such an institution; otherwise the whole issue may be actually trivialised to some fiscal values estimation, although full effective and cost-effectiveness evaluation will be performed.

**Michał Tandala (Silesian Medical Academy):**

I was very pleased with what I heard from the Minister, that it is not about basic benefits package but rationalising health care expenditures. The package should be treated as one of the elements of the rationalisation. Maybe these standards should be determined by level of health care, different for basic and for specialist levels. It is obvious that great medical progress has to be somehow financed. It would be better if the rules were set at an early stage, so that was known if part of these costs could be taken by the health care system. I would personally think of it as the best solution. Or part of the costs could be covered by institutions responsible for scientific progress – less beneficial solution. I would like to appeal no longer cost thinking be used while negotiating contracts with sickness funds. Let us try to talk in purposeful categories, especially when highly specialist procedures are considered. The standards are just the first stage in evolution of a concept. After we elaborate them, we must implement, which could be relatively easy because of the role of payment system. Important issue is the control of implementation process and the standards themselves. Implementation control is the potentially costly element. It would be better if crucial expenses didn't go to cover it. I have mixed emotions after this meeting, because in some cases the way problems were presented was extremely superficial. I also hope the help from the company will be highly competent, and not such as could be expected from the form of presentation we experienced today.

**Pan Professor (name unheard):**

We are interested in processes and systemic solution that would more objectively secure health needs of the society independently from the amount of resources spent and ideas of various political groups. I agree with the Professor, that the company's presentation was nothing new to us, especially in sickness fund. Financial abilities of particular sickness funds differ from one another, they interpret their role differently. I think Minister of Health should be more active in diminishing the differences. The lectures, we have heard, it was theory, what we need now is practice. Our health care reform receives good marks from different foreign institutions: the chief of Health Insurance Supervision Office in Germany, American, European Union or French institutions. I must admit we have never heard of such an acceptance from politicians. It seems it is a long way from theory into practice, and sometimes this practice may be presented sooner, without repeating the theory.

If we today speak about co-financing, this must be accepted by the society, not necessarily politicians. Can we have co-payments nowadays? Yes, we can. We do it. Our patients co-finance health programs and participate in costs of some drugs. It has full legal basis for this, without a big sign: basic benefits package.

Maybe today it is not so necessary to educate medical professionals, because they have to learn anyway. I am surprised at us say: the sickness fund paid, or didn't pay, or will pay, some press conferences are held. In US if a doctor makes a mistake in an insurance form, the hospital will not get the money. And it is not the fault of insurance, but the person who made mistake. If we lack clear and well-defined criteria, than arguments diffuse to the outside world. And one must say that information failed when it comes to health care reform.

Will doctors be satisfied with setting limits to spending public money? They will not, because nobody likes being controlled. This leads to a conclusion that medical environment cannot be a reliable source of info about the current changes. You should for info from the society and not the doctors.

Accessibility to services is fully monitored by sickness funds. In sickness funds we have various info on medical issues concerning patient and doctor. If this info was used to make standards, the empiric period could be definitely shortened. There is one obvious problem – too many decision centres. Pharmacoeconomics in Poland is the best example, someone is creating reimbursement lists, someone else sets prices, still different person negotiates prices of imported drugs, and the payers have no influence on the process, because nobody asks.

I hope there will be another meeting soon, when we will discuss how join our forces to actually improve accessibility, information and utilisation of funds.

**Adam Troślewski (Consulting Services Agency):**

I would like to congratulate on taking up the subject. In my opinion the standardisation is required because of the need of civilising the relation between a payer and a service provider. For instance the problem relates to low precision of chronic care definition resulting in many sickness funds withdraw from financing chronic care services. Less officially my colleagues from sickness funds say they do not want to allow shifting responsibilities from social insurance and social help to them. There will be pressures on adding technologies to the package from the insured, service providers and suppliers. The second pressure is associated with, thank God, dynamic development in medicine. The result of this pressure will be in strong thrust to add new technologies. What we need is a civilised, formalised, uniform procedure, which is much more important than current financial potential. I understand we plan for ten or more years ahead. I am afraid one of the obstacles could be our roots deep in the budgetary system. We have to build some sort of consensus, and not force to certain solutions. Doctors, nurses and directors have to understand that "golden freedom" is an attractive but also abstractive term. It is also important to prevent the situation when a doctor prescribes, patient nods, and then throws the prescription away because he has got not enough money.

**Janusz Cykowski (assistant to deputy Adam Wędrychowicz):**

The subject of today's seminar is very up to date, especially when we consider finalising work on amendment to the law on general health insurance in the Sejm. It is recognised that introducing a system like this requires "sizing" and "costing" of all available medical procedures. Therefore it seems very important to ask what values and criteria should be used in the process. They should definitely be described in legal acts. Nowadays the general health insurance law sets out certain directions, for instance that range of services should be determined by medical knowledge on one hand and available resources on the other. There is also a term "limits of necessary need" (granice koniecznej potrzeby). Deputy Wędrychowicz proposed to delete this term, as nobody is able to determine what these borders actually are.

**Bohdan Hazan (gynaecologist, Institute of Mother and Child):**

We ourselves create standards. Unfortunately they all have this primary sin of disregarding financial situation. These standards have some legal impact, too. They should be flexible and have the necessary level of generalisation. Some standards may need to be modified in different regions of the country. The actions should not be aimed at eliminating but putting in order, systematising, so that public funds were spent in the optimal way.

**Mateusz Kuczawski (monthly „Puls”, Institute of Mother and Child, oncological surgery):**

The important question is the acceptance of our idea by medical professionals. We have to admit our professional groups reluctantly look at standards, which may cause problems. It is most important to know how to sell the info and ideas.

So there are two basic potential problems: how to verify procedures and how to gain acceptance. I hope next meeting will be more detailed.

One of the persons spoke about regional differentiation of standards. I believe the basis of the reform is equal burden for all patients regardless the region they live in. Concluding the standards should be the same for all country, all procedures centrally assessed and calculated.

**Marek Wójtowicz:**

Our colleagues from Holland should work on unifying terminology. We say standard, they say medical technology, and it seems we speak more or less about the same. But not quite, because technology is a dynamic process of producing a treatment procedure, and as we understood the term it was more about equipment, personnel and housing requirements. I understand the examples from gynaecology and obstetrics are not intentionally from just one field and next time we will have more examples from different medical specialties.

**Min. Opala:**

I see the conference proved we still do not speak the same language. Despite all our efforts to clarify terms we still sometimes do not understand one another. I think these



materials will be delivered to you with adequate comments in order to clarify what our goals are. The question remains on who should set the standards. As for now it is usually determined by sickness funds. This is definitely not the way, it should not be up to the payer to determine standards, he can reject it, argue with it, but never determine. I must say I do not like distancing from what we have to go through together.

## B.1 Transcript of the Conference

Good morning dr Banta, dr Łanda, dr Exter. I'd like to welcome you warmly on behalf of the Secretary of Health prof Łapiński. And it's really pleasure and honour for us to have you with us. I'd like to say that this project is of extreme importance for us and that we are, do our best to implement it as soon as possible. I am definitely sure that this conference will enable us to understand where are the problems. The floor is yours, please.

GRABOWSKI: Chciałem powitać wszystkich uczestników naszej konferencji, aczkolwiek spodziewaliśmy się jakby większej frekwencji bo temat jest bardzo ważny, ale myślę, że pozostali dołączą w trakcie. Moje nazwisko Grabowski, jestem wicedyrektorem systemów informacyjnych, zajmuję się tym projektem od początku, od okresu negocjacji aż do teraz, w ramach grupy roboczej i w związku z tym chcę powiedzieć państwu, że jest to, dzisiejsza konferencja jest pointowaniem jednego z siedmiu zadań tego projektu. Projekt dotyczy przede wszystkim zastosowania oceny technologii medycznej w podejmowaniu jakby racjonalnych decyzji z zakresu standardów gwarantowanych w systemie powszechnego ubezpieczenia zdrowotnego. I były również poboczne tematy, między innymi system licencjonowania szpitali, materiał znajdziecie państwo na stronie informacyjnej Centrum, wprowadzie jeszcze w wersji angielskiej, ale zostanie on przetłumaczony. W każdym bądź razie dzisiejsze spotkanie jest poświęcone przedstawicielom Kas Chorych, aby przedstawić postępy zastosowania oceny technologii medycznej w świecie, w Europie szczególnie dla różnych systemów ochrony zdrowia, przedyskutować aspekty metodologiczne oraz aspekty prawne tej problematyki. Podobne spotkania odbyły się w obszarze zainteresowań osób zajmujących się polityką lekową dla, była jedna konferencje bez sprecyzowania uczestników i generalnie staramy się jak najszerszej prezentować ów projekt. Pierwsze wystąpienie będzie dotyczyło oceny technologii medycznej w Europie. Pan prof. David Banta ma ogromne doświadczenie i ogromny udział w wielu projektach w wielu krajach europejskich i światowych, również o charakterze ponadnarodowym uczestniczył w wielu organizacjach międzynarodowych, przewodniczył wielu z nich i myślę, że możemy liczyć na taką syntetyczną ocenę jak rzecz przebiega w Europie, i zapraszamy serdecznie.

Dr Banta

Thank you. Ladies and gentlemen. As you know, I've been asked to present you the basis of our project, which is coming close to an end. It has about two more months until it is completed. The project is carried out by TNO - the Netherlands Organisation of Applied Scientific Research. The co-ordinator of the project Steve Chapman is here in the front row and I'm the chief technical consultant for the project. The project really, in my mind, has one main aim and that is to improve the quality of care or help improve quality of care in the Polish healthcare system. The main policy tool as you have already heard is health technology assessment. So I'm going to begin by giving you a

brief thing, a brief briefing on health technology assessment. What it is and how it's been used in different countries. The main implementation tool for the Polish health insurance system and the Polish healthcare system indeed is coverage policy or standards policy based on health technology assessment. So I will also give you an idea of what other countries are doing. And in particular our contract calls for us to develop a detailed and robust process for the making of coverage decisions. So I'm going to introduce that to you today. It's quite complicated so I can only give you an idea. Those who are interested, of course copies of the report will be available in English and Polish within two months from now and I apologise that this will go very fast. I was a little worried about even being able to show you and hold up a slide like this and say 'Well, the slide shows...' but at least you get a kind of overview. And I'll make a few comments also about the European Union, which in this regard, which I understand, are of great interest to you. I believe, it was two days ago I saw in one of the English language newspapers that Poland was expected to become a member of the EU in 1995 and I suppose this is very much on the minds of everyone at the top, at the upper levels of Polish society for sure. // Well, to begin this is the overview of the project as is laid out in the contract between TNO and the Dutch Ministry of Health and also described in the terms of reference for the project. There are seven work packages described. The first work package is a description and analysis of the present situation and possibilities for the future. That paper is not totally finished but has been translated. I think it's here. There will be some minor changes, but only minor at this point. So you can essentially consider it final. You may find some small mistakes so far, but otherwise this paper will not be changed. Work packages 2 to 4 concern different applications of health technology assessment. 2 will deal with pharmaceuticals and health technology assessment and coverage decisions. We had a meeting yesterday on pharmaceuticals and that will be one basis for that report, which I'm in the process of pulling together now. Work package 3 will deal with HTA and top policy decisions, particularly those from the Ministry of Health, so highly specialised services would be an important example of the use of health technology assessment at that level. And work package 4 is what we're talking about today, which is the use of health technology assessment in general coverage decisions to finding a benefit package setting standards for coverage. Work package 5, in the contract, is labelled certificate of need but Prof Den Exter, I believe, convinced the Ministry that it should be broader and concern licensing in general. So certificate of need still is the part of this project but now has a broader kind of base into licensing of facilities and manpower. Work package 6 is the process itself which I'll also present today, that is the process of making coverage decisions and how HTA can fit into that process. As I've heard, recent discussions are very consistent with what we're presenting which is very good to hear because this may mean that the report is actually useful and will be used. And work package 7 is a synthesis of all the other reports and recommendations for the future and I will also give you our thinking on the recommendations as of today. As I've said, none of these, except for word package 1, is final and we would very much value your comments and criticisms at this stage.

I'm not sure how technology is used in Polish nor how it translates, but when we use the word technology in Western Europe, we're using a very broad definition. Sometimes people think of technology as only equipment and machines, but in fact technology refers to applied knowledge or applied science and therefore, healthcare technology or health technology has been defined as the drugs and devices, yes but also but also medical surgical procedures used in health care and the organisational and supportive systems, within such care, within which such care is provided. So this is just to illustrate the types of technology that we might, we might talk about. Drugs and biologics, equipment and machines, physical techniques, for example is physiotherapy -

a technology when a person is only using his or her hands, yes, physiotherapy is a technology; procedures which is usually a combination of technologies and systems. Systems are of more and more importance because what we're finding now in healthcare is that we have a growing body of effective clinical technologies, which are not being applied effectively in practise. So there is more and more attention to the system as a technology. How do you put together these beneficial technologies into the system that actually contributes to people's health? I personally think this is the big challenge of the day in healthcare. We've made enormous progress on the clinical side but the healthcare benefits and cost effectiveness have not improved in the way they should have done. This is a system problem. The purposes of health technology are also broad and complex: prevention health promotion, screening, diagnosis, treatment, rehabilitation and supportive care. Technology assessment also has a broad definition. It's a formal policy research and it's addressed, in the broad sense, toward social consequences or social implications of health technology. In health technology assessment the major outcome we're looking for, the major use of technology is health benefit for patients, that is improved health outcome. So that is the main consideration in health technology assessment as well. That's said. I have to go on and say that the policy makers, and sickness funds, I suppose, also, are, maybe even more concerned with cost and therefore costs and cost effectiveness are also very important central parts of health technology assessment. The most important word in this definition is policy. This is not academic research. This is not research as published in specialised medical journals that we hope someone in the future will use. This is research done for today. Tomorrow it should lead to change right away and if it doesn't, there's something wrong with the process of health technology assessment and how it's being used. This is very practical research and, as I say, it should immediately be taken up into health policy, into practice and so fort. // This shows the different dimensions that you might run into in the particular health technology assessment. We'd like to talk of a comprehensive health technology assessment, which will include all of these elements. Probably less than half of technology assessments done today are comprehensive in this sense. They're usually done for the immediate purposes of the context so efficacy, effectiveness pretty much is always part of the consideration and cost, cost effectiveness also, but we can't forget that, particularly for drugs and devices, there are very important technical consideration: drug purity – does the drug really do what it is supposed to do in terms of the body? and equipment - is the equipment safe?, does it actually work?, does it produce pictures that are reliable?, and so fort. This is in the background and clinicians, I think, have the tendency to forget how important this technical aspect is. And, on the other side, there are also important ethical, legal, social and cultural issues, which depending on the technology may be extremely important to include. // A process of health technology assessment looks something like this. There's an identification of the technology, which needs to be assessed and a priority setting process because there is never enough money, there are not enough analysts, computers and so fort, to do thorough assessments on everything. So priorities have to be set, literature search then and synthesis. Literature search these days is quite interesting and that's were the main advantage for Poland comes at this moment. I entered this field about 1975 and there was essentially no systematic information at all. When we looked at health technology we had to begin from the beginning. We had to try to find randomised trials and other kinds of studies, but from those days there's been an enormous development of systematic reviews. Many people here will have heard or used the Cochrane Collaboration which has developed huge worldwide effort to review all healthcare, pull together all randomised trials and in some cases other kinds of evidence dealing with efficacy and effectiveness. The Cochrane library is available on

the Internet for a not very large subscription fee and the abstracts from the Cochrane reviews are free on the Internet. So most people these days will immediately go to the Cochrane library to see if there is a review and I would say in the majority of cases you will find a review in the issue that's of great importance to you today. And there are also many other international sources of information: the international network of agencies on health technology assessment, which is called INATA. INATA now has now 35 members which are national and regional HTA public agencies which share information and likewise there is a free database of HTA reports available through York, England and for the most part those reports can be, can be acquired free or at least for modest charge. The UK has a number of free databases on health technology assessment, evidence based medicine, systematic review and the National Library of Medicine in the United States also has free databases. There are others as well. So this is an enormous advance and makes it possible to really base coverage decisions and other important policy decisions on health technology assessment. So literature search these days first looks for a systematic review and if there is one, would check it for validity and update it and that might very well be enough. However, when one looks at that systematic review it will usually only deal with the efficacy, effectiveness and you probably want information on other aspects as well. That's where the original data collection comes in. It's almost always necessary to do some sort of economic data collection in the particular place. Even the international literature, if it exists, may not apply to your situation. When this is all pulled together, there's a final synthesis, coming to conclusions and maybe recommendations depending on what's needed. The information is disseminated and implemented and then there is a process of evaluation and feedback. The all, all member states of the European Union either have national HTA bodies or are in the process of developing them or perhaps, I might say, discussing developing them. The leaders in this field, I would say, are Sweden, the Netherlands, France and the UK and other, other countries that come not far behind are Spain and Italy. Outside the UK Norway and Switzerland are extremely active. So there are within the European Union tremendous efforts in this, in this direction and all of these agencies have endorsed this kind of process and most of them use it. // Now I just want to say a bit about how health technology assessment interacts with health technology in the policy sense. When the new procedure, drug or equipment is ready to be implemented, there may be other processes back here like regulation, but an important event is the coverage decision. Will we pay for this technology or will we not? And that's a very important point in the implementation of the technology. It gives any society a very clear cut decision point and very important decision point. But it's also very important to realise that making that decision is not the end of the process. What coverage can do is keep out the ineffective technology or technology which has not yet been assessed or force an assessment. But for those effective technologies, in general, the coverage process will not prevent overuse, will not guarantee appropriate use, will not guarantee appropriate placement and so fort. That goes to managers and then ultimately to clinicians, clinical physicians. So there is still a need for policy development in every country beyond the coverage process. For example there are many forces acting on clinicians: general preferences, demands of patients, what the media says, in particular, professional standard which may not be in accord with an assessment, opinions and so fort. So there are many factors, which come in there. The technology assessment is only one of those factors. There was a very active development in way it is influenced, how managers and how clinicians act with regard to evidence, evidence based medicine, evidence based health care. I'm not really going to talk about that today. I just want you to register that this is a very important issue that needs to be thought about.

When I come to the recommendations, I'll come back to this point, you'll see that we are going to recommend development of a national agency or program of health technology assessment for Poland but based on the agencies that are existing in Western Europe. I can say that these are the kinds of functions, which have been undertaken. The national HTA program needs to monitor the health status, the health policy and health technology in, in the country. It needs to interact with policy makers to know what the problems are from the standpoint of policy making. And then the next stage you recognise as the process of HTA itself, identify technologies, set priorities, synthesise the evidence, fund or possibly stimulate regional research, reach conclusions, suggest changes in policy with regard to the technology and then evaluate the results and feed them back. This is very important to have the national agency to coordinate and oversee all assessment efforts in the country. This is not to say at all, that all assessment should be under the funding or supervision of the Ministry of Health, but it's very important to have this kind of coordination of efforts and to assure that the assessment is available for different policy purposes including the coverage decisions, including making of contracts between providers and insurance funds. // Every country has a set of health policies and what health technology assessment has done from its earliest beginnings is to identify the policies that exist or in many cases suggest changes in policies or new policies and then has made links with that, with that policy area. Information, such as that from health technology assessment does not change behaviour or has very slow and late effects on behaviour. It's necessary to find other means to change behaviour and policies are a very important one. // From the standpoint of the policy maker implementation of the policies can be very much improved by linking to an assessment. In some areas such as pharmaceutical regulation health technology assessment is absolutely essential for the policy implementation and in other areas policies are better carried out by linking to HTA. Payment in particular is an example of that and in fact this coverage process which we're describing in our project is probably the most active and an actively growing area in Europe: the use of, of HTA for coverage decisions, for defining health benefits, for defining the specific terms of contracts and so forth. And another actively growing area is linking all the quality assurance activities with health technology assessment.

This just gives a, an overview of some of the policy areas that can be thought about. Research and development - you can use health technology assessment to define areas that have priorities and research for example in technology development. Policies toward health technology assessment itself, regulation of pharmaceuticals for safety and efficacy which all countries do in some way or another, regulation of medical equipment for safety and efficacy. I'll just say here briefly that probably most of you know that when you join the European Union you will automatically become part of the drug pharmaceutical regulatory process of the European Union and that Polish law will have very little effect at that point. Polish efforts will fall completely, more or less completely, under European law. Maybe I'm overstating, if I am professor Den Exter can correct me later on. And the same thing applied to the regulation of medical equipment. 15 years ago when I went to the Netherlands, the Netherlands had one of the strictest regulatory programs for pharmaceuticals in the world that has now totally been taken over by the European program and the Netherlands no longer has such a strict regulatory program. The emphasis, I must say, of the European regulatory program is access to the market. There is not an emphasis on public health. The national program, certainly the Dutch program in 1985 to 1990 had its main emphasis on public health preventing harm, assuring efficacy. That is no longer the case. The major emphasis now is trade and innovation. So more and more emphasis goes to reimbursement as a second line to all and I'll come back to this point later on. Payment system I've already

mentioned quality assurance, informational strategies. The information can be aggressively marketed to physicians, to managers, and also to the general public, we shouldn't forget the general public in this and HTA should have some part to play in professional training and education.

Here's one specific area, which we will be dealing with in this project and that is regulating numbers and placement of health technologies. The general goal here is to promote or develop original system where services are available at the appropriate level, in other words, a general practitioner would not be expected to carry out coronary angiography. The services should be, should be placed in appropriate institutions accessible to the public and of high quality. This has to do with both efficiency and quality. Regulation is typically part of hospital regulation. That's the case in the Netherlands. Usually 10 to 15 technologies are directly regulated in this way. Regulation is possible in any kind of system, either public or private. The decisions are more and more based on health technology assessment and should be. That means that the decisions are scientifically sound and are credible to all parties. The program needs to be flexible and able to change in rather quickly and there should be an ongoing evaluation of results. And this is the Dutch list of technologies, which have been regulated in, in recent years under this kind of program. What this means is that they're put on this list and only a hospital that receives a licence is able to purchase and use the, the equipment or to provide the services that are listed here. So you see the major imaging devices are actually computer tomography and, I think, magnetic resonance. Imaging both have been removed from the regulatory list after being on it for about twenty years. It wasn't thought necessary any more to directly regulate these technologies. Radiation therapy is directly regulated, all the major organ transplants, some types of high technology surgery such as neurosurgery and cardiac surgery, neonatal intensive care, genetic screening and counselling and in vitro fertilization. Though, in the Netherlands in 1985, when I first lived there these decisions were made on rather arbitrary grounds. I would say probably the most important factor was that a particular prestigious professor or perhaps a friend of the Prime Minister would advocate his institution should have this particular machine and then he would get it. That was probably the main, the most important factor in these decisions. Today these decisions are made completely on the basis of health technology assessment and I think the, the image of this program, the value that is put on it has increased enormously in these 15 years because now the program is considered to be credible and mostly fair, not entirely of course. Nothing is totally fair. // Now I've come to the issue of most interest, I suppose, to this audience and that is the question of coverage and health technology assessment. Well, health systems generally provide the defined, more or less defined package of benefits. This package of benefits may be implicit. You won't find a list of coverage services in the UK or in Sweden, but still there is a set of benefits, which are provided as part of healthcare. Under the social insurance this lists tend to be more explicit, in particular toward specialty services and probably they become most explicit when specialists are paid fee for service and so the coverage becomes very much a tool to control specialty medical care. But it's important to realise that this definition of a benefit package is not dependent on fee for service. It fits into every kind of system and every kind of payment system. In the past, going back about 25 years, in the United States for example the so-called package was defined entirely by medical doctors. The doctors did something and insurance paid for. So there were essentially no national standards. Physicians could do what they liked and be paid. There were many, many abuses, problems of efficacy, problems of safety, overuse, really serious problems of quality, waste and so the process began to link these decisions to scientific medicine not to opinion of, of clinicians and that's where HTA was more or less invented and

used for the first time in, in the policy decisions, particularly by the Blue Cross Blue Shield Association in the United States. This idea spread to Europe about 1995 and is now quite far advanced in a number of countries. In my opinion the country which has gone the farthest is Switzerland with the Netherlands not too far behind and other very active countries are Spain, Germany. It's not coming as an issue in Italy and with a totally different kind of system and payment system – Sweden and UK are also very much involved in influencing the benefits through HTA. One, there are two specific ways that health technology assessment is used here. One is that new technology is not admitted to the benefit package until it's shown to be effective and that usually means by well controlled clinical trials, in particular randomised control clinical trials. More and more cost effectiveness is brought in to these decisions as well. At the same time probably a great deal of present day healthcare is ineffective or not cost effective though there is a process particularly in the Netherlands of going back to see what doctors do and remove old obsolete technologies from the benefit package. // In our report of work package 6 I looked for standards or principles for defining a basic benefit package and I've found from a national meeting in the United States these statements which I thought were quite good. In defining a basic benefits package first it is appropriate for insurance and sickness fund clients to define criteria that limit the services they will provide to pay for. That is there is no intrinsic obligation for clients to pay for anything that anyone might want. Second, if plans are to accomplish these limitations the language they use must be as precise as possible, not just legally precise, but comprehensible to members. Words such as necessary, appropriate and investigational will not work. That has definitely been shown. Specific criteria are necessary. Here I'll just mention that, in my opinion, and I don't know what professor Den Exter thinks about this specifically, I hope he'll tell us, but the Polish health insurance law is very vague on this point. It in fact does use terms such as necessary and appropriate and therefore is, in my view, insufficient to make progress in health insurance. Because, third, because the natural incentive of the patients is to expand rather than to contract, the interpretation of language and because the courts will tend to interpret any ambiguity or misunderstandings in favour of the patient, and here I would say this is exactly what UNO's told us, unless it's precise, we will interpret in the best, we will take the patient's point of view not the point of view of the client, or the society. If the criteria are to achieve the objective of unambiguous communication between plant, position and member, they should be defined narrowly. A plan can easily expand the criterion, either formally by adding specific inclusions afterward. // And then the report goes on to propose specific wording for health plans. Health plans are required to cover health interventions within the specified benefit categories if they meet the following criteria. One: the intervention is used for a medical condition. Two: there is sufficient evidence to draw conclusions about the intervention's effects on health outcomes. Three: the evidence demonstrates that the intervention can be expected to produce its intended effects on health outcomes. Four: the intervention has expected beneficial effects on health outcomes, outweighs its expected harmful effects. And five: the intervention is the most cost effective method available to address the medical condition. So we are basically I would say proposing that the Polish insurance system would use similar more precise language of course appropriate to your own context and so forth, but to me, to my way of thinking and interpretation, this wording is a very good basis for accomplishing what you would wish to accomplish. // Now there's a short term problem and there's a long term problem. This is a picture I drew just to indicate what healthcare looks like. Healthcare is generally not very well defined and I suppose all of you know that. There are huge areas in here which are not made up of specific procedures but just some sort of general thing having to do with care, long term

care, mental healthcare, old people's care, long term care, even primary care. So if this can ever be defined in the benefit package, it's going to take a long time. And for the most part these areas have not been assessed. It is only beginning now in most of these areas. I have done reviews now in physiotherapy and occupational therapy in the last several years. Physiotherapy is something more than a thousand specific interventions, it has about one thousand randomised trials, so the data base for assessment is completely inadequate in most areas as to make a decision whether an intervention is effective or not. Occupational therapy has no scientific bases at all, I would say. That does not mean however that we should stop paying for it at all, that is impossible. People are seeking occupational therapy, occupational therapists are providing therapy, they probably do some good, but it comes not from the scientific, but much more pragmatic point of view. So this is a long term problem: to define and assess these areas. Prevention is relatively well defined. Not promotion however. Drugs: quite well defined in general. Emergency care - probably. So there are some areas where a lot of progress can be made very quickly, prevention: no question, a basic benefit package for preventive services can be developed very quickly, but for the rest, no - it is going to take a very long time. And countries such as Switzerland and the Netherlands have come against this problem, so they have taken a pragmatic approach, which is to put a barrier here. Here comes a new technology and they say: we do not pay for it until it has been assessed and shown to be a benefit or maybe a cost-benefit. And that is a major change in the last few years in Europe. Over here the Netherlands also said we want to remove the old technologies, gradually take out the old obsolete technologies which have questionable benefit or no benefit and so there is a very active process of defining priorities, going through assessment, quite often finding original research which has never been done. This is a very long process. At the moment there is a list of 125 high priority technologies being examined for five years, but the total list was about two thousand. So this is going to take a long time to work through. A start can be made here, and this can be done for the new, can be done rather quickly. For the rest, I am afraid, it is necessary to assume that the services are more or less effective until the evidence can be gathered. Of course, as I said, the international experience gives the basis for these changes in many cases rather quickly. And I think Dr. Landa will describe the experience we have been gathering up together in Cracow. Is that right, Dr. Landa? You will be telling what you are doing. We have a contract with the centre in Cracow to in three months examine around two hundred technologies, using basically international information. We are going to demonstrate what can be done with not huge amounts of money and smart people who work hard in not very long periods of time. This is just to show you what can be done. This can be done in short term, but there is still the long term issue that remains. I think since I have passed 45 minutes and I am supposed to finish in one hour, I think I am not going to show you all the slides of the process that we are going to propose. It would take me several hours to explain all of this process. I just want to show you that we have it. We have it done starting from the coverage demand and going through a series of slides. For example here is a compilation of existing information, indicating at each step how to carry out that step. Here's the synthesis with the discussion of all the implications. Conclusions, review, and then we come to coverage process. The most important thing about this process to me is that all this above is essentially a scientific process it is not a political process. The coverage decision is a political process, so at this point this moves out of technology assessment into policy making. And I believe strongly that all this process should be in a separate organisation, probably a separate site, under separate auspices, has to have integrity, has to base on the best clinical science, and then a coverage report or assessment report is the result. I believe there should be a coverage body, which considers this evidence in



relation to other factors. I would not try to list what are those other factors, but they could be such I said before. The prime minister's brother in law is a physician, and says we have to provide this. I have seen it all over the world. The newspapers bring so much pressure, the coverage body says: we have to cover this, we understand it is not useful. People really believe that this technology is useful, so the coverage body says: we have to include it. So this is truly political. So this is the way coverage body will act, and yesterday on seminar we gave on pharmaceuticals someone asked: would sick funds be involved in these decisions. To me the coverage body is a body that represents the stakeholders in a health care system and definitely the sick funds should be there. I would like to see the general public there as well. This is a kind of thing the coverage body would do. It looks at the coverage report, it considers all the other factors that may play and it comes to a decision. The decision may be: no. We do not cover the technology. We just say: no. No is no. Yes. No. We might say no, we want a further assessment, so then there is a further assessment done which might be an original study. It is quite often done in the Netherlands or in the UK. The information is not there in the scientific literature, so the government funds a prospective study to answer the question. And no decision is made until that assessment is completed. The decision may be "yes", just "yes", we cover the technology or it can be yes with different conditions, such as limited numbers, we might say, yes we cover but only in three sites of the country. Or we cover but only in hospitals which have certain trained surgeons, trained nurses, certain supportive services. Or there can be different conditions put on the coverage, defined indications: it is only available to people between certain ages, certain severity of the disease. Defined setting, defined skills or it can be covered, but with the requirement for the data collection. Switzerland uses this quite a lot, setting up a data base for further experience which the providers are then required to contribute to, so reassessment can be done later on. I have here a simplified process, which would possibly fit the Polish situation, which has really four steps, covering these other important steps. We tried to implement that in Cracow and it is similar to what we will hear here from doctor Łanda. I want to come to this European issue. I mention this point. As I said the EMEA does not allow members of the European Union to assess and regulate pharmaceuticals outside of that program. Once the drug is approved by the EMEA it is on the market in all countries of the EU and there is no choice. This will be the case for Poland too. // The Union does accept that member states have substantial autonomy in the area of pharmaceutical prices and pharmaceutical reimbursement. So what you can have, a list of reimbursed drugs that is completely appropriate and acceptable and that is, in fact, what the Netherlands has and other European countries have. However, under EU rules there has to be a process which is transparent, objective and verifiable and Poland does not have such a process so there's a, there's a great need here for development and HTA can fit just, just here. Another part of the European Union, which I will just briefly mention, is that the European Union has begun since the Maastricht and Amsterdam Treaties to develop a public health policy. The public health policy cannot in any way be related to harmonisation of the health systems of Europe. The member states have rejected that so one of the pillars of this public health policy is information for decision making and within that health technology assessment has been picked out as a key factor. This policy paper is now being implemented. It has been totally accepted and there probably will be within the next year or so a European health technology assessment program legally established and funded by the European Union which Poland could then be required to participate in as one of the requirements for the accession. This is my guess, as to what's gonna happen. // I want to end with the few cases because I was asked, 'Does HTA actually have anything to do with cost or cost containment?', so I want to show you very quickly some of the ways that, that HTA

could cut cost or improve quality or both. This is a long list of obstetrical procedures, which obstetricians and epidemiologists have agreed are not efficacious. As you can see it says: forms of care that should be abandoned. So they should be taken out of the benefit package, I would say, and I'm not going to try to read all this list. I just want to indicate to you that you could, for example, today or next week remove these from the benefit package and that would improve quality and also save a lot, a lot of money. One of these cases I'll focus on a little bit for, a little bit deeper. This is a very common obstetrical technology – electronic field monitoring which has been considered standard practice in obstetrics since about 1972. It was accepted as a routine in the United States before any randomised trial was published. First randomised trial was published in 1976 but by that time, as I said, it was already considered standard practice. In 1979 the National Institute of Health put out a much publicised report that said there was no improvement over listening auscultation. Nonetheless it continued to be sold and accepted. During the 80s there were multiple RCT I think now there were 12 randomised trials with 50 or 60 thousand patients in total and there apparently is no or very little benefit if any. Yet the technology continues in widespread use. The number of systematic reviews and reports from different countries have come to the conclusion that there probably is no benefit from this technology, yet it continues in widespread use. Here's a famous drug example, which I think is similar to a lot of hormone treatments today in the pharmaceutical area - a synthetic oestrogen which was used from the 1940s in complicated pregnancies, in threatened miscarriage, threatened abortion. There were randomised trials in the 1950s showing no benefit. The drug continued to be used. In 1970 cancer in the ES daughters, cancer of vagina was found in the ES daughters, that is women who had been exposed to the drug in the uterus and after that it stopped being used very quickly in many countries. Nonetheless it still goes on being used in many other countries. I have no idea of the situation in Poland. I don't think it's used in all of the Western Europe, but it's used all over the world. Otherwise there were 250 thousand Dutch women exposed to the ES and about 3 million American women exposed to the ES and there are probably here many such cases today that we don't know about yet. No benefit and great harm. Use the case of low back pain which in Sweden was found to be the most expensive one, problem for the health care system, so they, the agency looked to see what procedures were being used in medical care for low back pain, for acute low back pain and chronic low back pain. So you can see bed rest which still is used although not as much as it used to be. There's strong evidence against using rest in back pain. It actually does harm, but that's very clear. Traction there's some evidence in favour in acute back pain, strong evidence against in chronic and otherwise there is either no evidence or evidence against. So basically medicine, healthcare, doctors doesn't know what to do about back pain. Well, something is done and is mostly useless or in some cases quite, quite harmful. Here's a specific case where the Swedish agency wanted to find out what the financial implications of one technology assessment were. They looked at preoperative routines such as doing chest X-rays, electrocardiograms and blood chemistries and also haematologies before routine surgery. They found no evidence in the literature that this was useful, that it led to any benefit at all. In fact, in the majority of cases the surgeon didn't even look at the test. They publicised these results very much. The practice gradually was abandoned and they were able to show that the saving was about 130 million Swedish crowns a year or about 20 million dollars, which is more than the budget of the HTA agency from this one case. This practise has now been totally abandoned in Sweden and is being abandoned in other countries. So, I'm just trying to illustrate to you, I think we're still just on the surface of things. We have many, many things to do to improve the quality of healthcare. Personally, I have no doubt that

Poland or any country at Poland's level of development or higher can provide all cost effective services within available resources but it requires health technology assessment to do that. // Finally, this is what we are considering as recommendations. First: change the health insurance law to bring in efficacy, effectiveness in coverage decisions, but we don't recommend changing the law to bring in cost, cost-effectiveness at this time for two reasons. One is, we don't believe the methodology of cost, cost-effectiveness is reliable enough and secondly Poland has no the expertise to bring in cost in a legal sense. There should be more attention to cost – yes, but as part of the coverage process. Recommendation two: we strongly support establishing the national HTA program affiliated to the Ministry of Health. Third: we recommend that a specially appointed coverage body representing important stakeholders be developed. And recommendation four is professor Den Exter's recommendation having to do with licensing, which we accept, but I think he will discuss it so I won't say anything more about it. Well, I'm sorry I have taken a few minutes more than I should have taken, but anyway thank you very much.

GRABOWSKI: Dziękujemy panu profesorowi i zapraszamy do wysłuchania wystąpienia pana prof. Dextera, który będzie mówił o aspektach prawnych związanych z oceną technologii medycznej z procesem włączania w system gwarantowanych świadczeń zdrowotnych. Myślę, że bardzo ważne są różne konsekwencje, które pojawiają się dla naszego kraju w momencie braku tego typu rozwiązań w przyszłej Unii Europejskiej. Myślę, że warto nad tym się głębiej zastanowić.

Den Exter

In terms of Monty Python's 'Flying Circus' now something completely different, I would say. Although I have to stick on the subject health technology assessment. What I would like to do this morning is I read the report, the proposal you already received and I made some remarks on it from a legal perspective and these remarks I would like to share with you. One of the main questions for lawyers is what you can see the title: 'What's law got to do with it?' Well, it wouldn't be a surprise to hear from a lawyer that it has quite a bit, quite a lot to do with law. For instance, and I'll focus on these four topics I would like to address. And to start with the identification and the review of technologies. It concerns legal issues and the legal considerations involved. They primarily concern what are the consequences of new or already existing technologies to patient's rights. And I think most countries do have some examples of technologies which interfere or have also consequences to the rights of patients. I mentioned a few, for instance the ACMO case – a hard lung device for neonats I understood and this deals with questions concerning, for instance, about a starting the procedure, to continue the procedure and finish the procedure, then should we finish the procedure for such a device. And, as you already guess this concerns questions about life and death and the particularly involved is the right to health here involved. Already existing example, another one, concerns the in vitro fertilisation, which more recently raised some new questions about what to do with the rest cells. Can we use it for research purposes and what kind specific purposes we can use it? And also, at least in the Netherlands, there are question about or actually it was well developed for infertile couples or one of the persons is infertile and now can we also use it for homosexual couples and not only for heterosexual couples. So this raises the issue of discrimination. What, for what kind of reasons can we exclude certain persons, for instance, from in vitro fertilisation technology. The other example was already yesterday mentioned – the drug for multiple sclerosis – the interferone- $\beta$  case and what we see here is the question raised concerns about access to healthcare. In what respect do these patients have the right to this kind

of this specific drug when or not included in the basic benefit package? Some other examples, the final one, about genetic engineering. What to do with the human genome? The what kind of interventions on the human genome and on what condition is it allowed, for instance for therapeutical or diagnostic purposes. Now these are some specific examples. Of course it should be mentioned that not always legal issues today are not always in force. I took these examples because these are well more explicit. And the question raised concerns what I mentioned, first of all the issues of patients' rights, the fundamental rights which are mentioned as right to life or human dignity and integrity, access to healthcare and more classical examples of informed consent the protection of medical sensitive data. And the analysis of these questions should be then in what kind of or what kind of infringements of human rights are involved when introducing such a new technology or more positively, would it be conformed to the national, national or international law to introduce such technologies. So it means that from a legal point of view the assessment should focus, in this respect, on what are the relevant sources of law. First of all, we look at the national patients' rights legislation, if it exists or it is more spreaded, for instance find in the national constitutions, but also in health insurance legislation or specific patients' rights law and even we look at the professional codes of conduct. Well, such an analysis should include or will conclude in whether or not there is a violation of, of patients' rights to when we introduce or exclude such a technology. And for instance, but it could also be the case that introducing such a technology could also mean strengthening of patients' rights, for instance, strengthening access to healthcare services. So it can also have positive aspects. But what is the case that in most cases national legislation is fakely defined, fake norms, so it is not quite clear in what respect such a new technology could be considered according to the national law. So therefore, another consequence is that national legislation is not applicable or because the technology at, or technology developed was not or sorry, the legislation developed was not even considering this kind of technology. So, in that, for that reason, but also for other reasons we are not only focusing on national legislation but we also have to consider the consequences of international law. And when I speak about international law I mean international treaties binding or not binding, but probably the most relevant are the binding treaties concerning human rights. And I mentioned some examples. For instance about European Convention of Human Rights. It is a very fundamental rights and also ratified by Poland. More recently we have, the countries of the Council of Europe adopted the biomedicine convention and this is particularly of relevance to medicine, to healthcare because this convention includes all the rights, are the most important rights of patients that are involved and so they should also be taken into consideration. When we concern, when we look to the more international level, then we find the ILO convention, the conventions of the International Labour Organization which are dealing with social security. And this is of relevance in case of excluding or limiting the scope of healthcare services in the benefit package. Since all the countries that have ratified this kind of conventions guarantee a certain limit of healthcare services within the basic benefit package. So from a legal perspective we do look to both the national and international legal norms and in most cases there's a kind of, there is a certain overlap in the provisions because most national law has been taken into account the international legal norms, but there can also be a conflict of norms and that is one of the legal issues that is the most problematic. I will not further discuss it but only as an indication what kind of legal issues can be raised in this kind of research. // Secondly, the previous speaker already mentioned the ES case, a very famous case, also in the Netherlands. So it means that besides the patients' rights development and which has to be taken into consideration. Do we have to focus on safety and liability issues as in the

ES case. It means for instance, and particularly for accession countries that we do have to consider, we do have to implement the relevance directives concerning the product liability, but also the general product safety directive. Both directives need to be implemented in national law and they are aimed to ensure adequate protection of victims of defective products. It means for instance the development of a so called Rapex procedure, it means the kind of recall system in, of products in case it has been identified as a defective product. This should be developed and of course, the development of certain liability rules in case of damages. So these are the two topics that are included. Certainly they are not all of them but I only put two legal issues that are of relevance. // A third remark concerned the coverage process. It was mentioned in the report, as coverage decisions are primarily political decisions made by the administrative body, the coverage body that could be the Ministry of Health. As a consequence of such a decisions most countries develop a kind of list of services that are included or excluded, but also we do see that there is also they use clinical guidelines in order to specify the criteria. So clinical guidelines defining the medical and the social criteria, probably social criteria included. And in practice these guidelines are also used for such kind of coverage decisions. Well, this raises the question of limiting access to healthcare because using these criteria can mean that a certain, that a patient is excluded from this kind of technology. And that raises, what I said, the question of: 'Can you limit access to healthcare by means of such guidelines?' Well, that's from a legal perspective a very difficult question and no court has already dealt with these questions in several countries, but it appeared that there is not a single line to see in how these kind of rules were dealt with. But what we can say is that first of all there is a kind of abstract review and it means that the court will only deal with these questions, review these questions by means of whether these decisions are according to the principles of proper administration. Are they made according to the principles of proper administration? This means for instance: are they, these decisions, are they published, are they motivated and the provision of reciprocity or they cannot work in the past. And of course the most important the rights and the prohibition of non-discrimination. // When I mentioned that the coverage decision is political process then I also have to say in return from the perspective of patients it means that it is a collective right to participate. It means that patients or citizens are entitled to participate in the planning and a kind of also, in the evaluation of health services. This, this raises the issue of patients' participation or patient empowerment, so strengthening patients' rights by, for instance, participating in all kinds of healthcare decisions, in decision making. And it is not an invention in theory but it is also the agreed in one of the latest Council of Europe recommendations and it's said that, because this recommendation also ratified by Poland mentioned that, to member states will do everything to develop and integrate a concept of collective rights promoting citizen participation. What does it mean for HTA? For instance, it could mean to ensure citizen participation in coverage decision making and not only informing patients but also participating in the decision making process itself. And secondly, also to include some structures and to develop patients' rights. But at the same time, when you develop patients' rights it means that you have to guarantee, to ensure some procedures that they can claim these rights. And this can mean for instance, that's implied role of the court, that when you develop such patients' rights, it means that in case of not or not yet developed aid technologies you can request for coverage decision by the court. And it was already discussed yesterday that we see a kind of acceleration, speeding up of the HTA process due to this kind of legal procedures. Secondly is that after when these technologies have been included in the coverage package or the benefit package, then we see that in case of non-availability, that patients or the insured enforce their rights because it's an entitlement

based on the law. And when we say that we include HTA research and based on this research we can come to a coverage decision, it appeared even more difficult to exclude technologies based on HTA because when they are mentioned in the basic benefit package then it's even more difficult than to exclude them from that package because, for instance, of HTA research. // So that brings me to some conclusions. First of all, it was mentioned that legal HTA is primarily concerns patients' rights and more specifically the implications, the violations of, of possible violations, I should say, possible violations of patients rights. Secondly, that absence of legal assessment may cause legal but also social and financial problems. Particularly when a technology has already been developed, but afterwards it is concluded that there are certain legal problems with implementing it and it's extremely difficult to not to continue this kind of research. So therefore, it should be included in a very brief early stage. And secondly, the post, the judicial reviews always afterwards it's can mean that certain unwelcome, political unwelcome decisions can interfere this process. And that is particularly the case when we see the cases on the co-payments, introducing co-payments in the social health insurance scheme. Finally, to develop an HTA system, could, should consider patient involvement in the coverage decision making process. And this is one of the recommendations based on that Council of Europe recommendation since it is considered that patients involvement in early stage can, well can include or strengthen the acceptability of certain unwelcome decisions. Thank you.

Dr Łanda:... partnera TNO, w tymże projekcie, który to partner jest odpowiedzialny za realizację trzech zadań. Właściwie jednego w całości i dwóch zadań, w realizacji dwóch zadań jesteśmy tutaj tylko pomocni. Proszę państwa, chciałem kilka słów powiedzieć o samym projekcie, o analizach efektywności, o analizach opłacalności, od ewentualnych generalnych zmianach w systemie refundacji. Proszę państwa, kiedyś byłem proszony przez panią Minister Cegielską o wytłumaczenie pani Minister w ciągu trzydziestu minut na czym polega ocena technologii medycznych i na czym polega farmakoekonomika. Otóż pozwoliłem sobie przedstawić taki obrazek ogrodu i powiedziałem, że te roślinki, które są w tym ogrodzie są to technologie medyczne, które są aktualnie finansowane i używane w danym systemie służby zdrowia. Proszę państwa, powstaje pytanie, czy możemy w tej chwili odróżnić rośliny, które przynoszą plony, które są korzystne dla społeczeństwa od roślin, które są chwastami a następnie kolejnym pytaniem jest, czy potrafimy te rośliny, które przynoszą plon, te plony porównać i określić, które z nich są bardziej wartościowe, które są mniej wartościowe. No oczywiście finansowanie tych technologii medycznych to jest praca ogrodnika. Czyli należałoby oczywiście usunąć chwasty czyli technologie medyczne, które są defakto szkodliwe. Należałoby proszę państwa również promować te technologie, które są najbardziej efektywne oraz te, które są najbardziej opłacalne. Proszę państwa to są niektóre leki o nie udowodnionej skuteczności działania, których nie zarejestrowano w Stanach Zjednoczonych. To jest oczywiście tabela z książki „Receptariusz szpitalny” prof. Jacka Spławińskiego. Jak państwo widzicie sporo z tych leków, które w Stanach Zjednoczonych nie zostały zarejestrowane w Polsce jak najbardziej mają się dobrze. Proszę państwa 14 preparatów o nie udowodnionej skuteczności z pokazaniem wielkości ich sprzedaży w roku 97 i miejsca, które zajmowały na liście 100 najlepiej sprzedawanych leków w Polsce. Tutaj jak państwo widzicie wiele z tych leków jest oczywiście, ma się bardzo dobrze również dzisiaj, również ich sprzedaż jest bardzo wysoka również dzisiaj. Tutaj „niakalcid nasal” w dawce 100 jednostek został rok później w roku 98 wycofany z rynku ale proszę państwa jeśli chodzi o inne preparaty jak mówiłem, one są wciąż sprzedawane. Oczywiście powstaje pytanie również jeżeli

dzisiaj byśmy zrobili takie zestawienie, które leki najlepiej sprzedawane w Polsce są lekami o udowodnionej skuteczności, a które są lekami o nie udowodnionej skuteczności to proszę państwa jestem przekonany, że okaże się to jak w 97 roku, że mniej więcej co czwarty, co piąty lek jest lekiem o nie udowodnionej skuteczności i nie powinien być defakto finansowany ze środków publicznych. Proszę państwa, oczywiście sens stosowania technologii medycznych. Technologia powinna być stosowana, technologia powinna być finansowana jeżeli przynosi więcej korzyści niż szkód. Czyli jeżeli wiemy, że w badaniach klinicznych, w wiarygodnych badaniach klinicznych oczekiwany efekt korzystny przeważa oczekiwane ryzyko związane z zastosowaniem danej technologii. Jeżeli technologia przynosi więcej szkód niż korzyści to jest technologią nie efektywną a właściwie jest technologia szkodliwą. I mamy również proszę państwa technologie o nieznanym efektywności, nie przebadanej bądź przebadanej w badaniach o niskiej wiarygodności. Proszę państwa jak duży jest odsetek poszczególnych rodzajów tych technologii na rynku. Z 226 procedur położniczych, które udało się wypisać na podstawie obserwacji pracy na oddziałach położniczych w Wielkiej Brytanii w roku 89, udało się znaleźć doniesienia naukowe dotyczące prawie połowy z nich, co się okazało, że proszę państwa 1/3 z nich są to procedury o wątpliwej wartości a nawet przynoszące szkodę. Jak te dane wyglądają w aktualnej, na dziś jeśli chodzi w ogóle o kraje, w tym kraje wysoko rozwinięte. Proszę państwa, książka „Evidence Based Health Care” podstawowy podręcznik chyba menadżerów w krajach wysoko rozwiniętych, menadżerów zdrowia. Jeżeli to jest 100% technologii używanych, stosowanych w danym kraju, to mniej więcej taki jest odsetek technologii o udowodnionej efektywności. Taki jest odsetek technologii, które przynoszą więcej szkód niż korzyści, czyli my wiemy, że to są technologie szkodliwe, pomimo to są stosowane a wiele z nich wciąż jest finansowanych ze środków publicznych. Tyle jest proszę państwa technologii o nieznanym efektywności aktualnie. Proszę państwa z pewnością państwo znacie nazwisko Cochrane, ogromna organizacja międzynarodowa Cochrane Collaboration, która wytwarza przeglądy systematyczne, systematic reviews, które są jak gdyby Cochrane Library czyli biblioteka Cochrane's, jest w tej chwili traktowana jako jedno z najważniejszych źródeł informacji dotyczącej efektywności. Otóż Archie Cochrane powiedział „ponieważ zasoby zawsze są i będą ograniczone powinny być rozsądnie spożytkowane jedynie na te świadczenia zdrowotne, których efektywność została wykazana w prawidłowo zaprojektowanych badaniach naukowych” Proszę państwa, jaką wagę w innych krajach przywiązuje się do analiz efektywności. Zobaczcie państwo, że jeśli chodzi o Stany Zjednoczone, już w 62 roku poprawka Cafoyvera i Harrisa do Konstytucji mówi, że która zezwala na rynku amerykańskim wyłącznie leków efektywnych. Ta analiza efektywności dokonywana jest przez FDA. Musimy pamiętać proszę państwa, że analiza efektywności to są de facto dwie rzeczy. Po pierwsze rozróżnienie co jest efektywne a co jest nie efektywne, co jest szkodliwe, czyli to jest pierwszy podział i pierwsze zróżnicowanie, natomiast drugim zróżnicowaniem jest wśród tych technologii efektywnych, o udowodnionej efektywności powstaje pytanie, która z nich jest lepsza, bardziej efektywna i o ile, i czy jesteśmy w stanie w ogóle tą różnicę w sposób istotny stwierdzić. Proszę państwa na czym polega analiza efektywności. Otóż gromadzi się wiarygodne doniesienia naukowe dotyczące danej technologii medycznej danego leku, ocenia się wiarygodność tych badań a następnie użyteczność wyników poprzez analizę istotności statystycznej oraz istotności klinicznej. Nie mogę oczywiście nic państwu na ten temat powiedzieć natomiast chciałbym kilka najważniejszych rzeczy tutaj poruszyć. Oczywiście istnieje coś takiego jak złoty standard jeśli chodzi o badania kliniczne w dziedzinie chociażby terapii w tym momencie. Proszę państwa, najważniejszym kryterium wiarygodności jest randomizacja, zaślepienie próby, czyli wtedy kiedy pacjent nie wie co otrzymuje, w

której grupie jest, czy w kontrolnej, czy w badanej porównanie z placebo, mierzone punkty końcowe, o tym za chwilę będę prosił państwa mówić. I teraz jest taki artykuł prosił państwa, ukazał się w piśmie, w czasopiśmie internetowym „Bandolier” tu jest odsyłam państwa do referencji ewentualnie. Oni zbadali i badali badania kliniczne, czyli chcieli się dowiedzieć jaki wpływ mają błędy metodologiczne w badaniach klinicznych na obserwowane wyniki. I zobaczcie Państwo do jakich wniosków doszli; pierwszym wnioskiem było to, że przeszacowanie następuje zawsze w kierunku wykazania potwierdzenia skuteczności, którą bada się zainteresowanym. Zawsze na korzyść tej interwencji oczywiście, która leży w obszarze zainteresowań badacza i prosił państwa o 41% są przeszacowane wyniki badań, parametry względne tych badań, jeżeli randomizacja została niewłaściwie przeprowadzona, o 30% jeżeli randomizacja została tylko i wyłącznie nie właściwie opisana w publikowanym doniesieniu naukowym. To są prosił państwa straszne liczby, dlatego że często obserwowane różnice, jeśli chodzi o ryzyko względne są rzędu 10%, 20% , powstaje w tym momencie pytanie, jeżeli badanie jest nie wiarygodne to czy mamy prawo, czy powinniśmy wyciągać jakiegokolwiek wnioski z tego badania. Moim zdaniem, jeżeli badanie jest niewiarygodne, nie powinniśmy w ogóle z niego korzystać. W ogóle nie przechodzimy do analizy wyników. I tu prosił państwa było pokazane, jeżeli podzielimy badania dotyczące przeszczepów elektrostymulacji nerwów to prosił państwa badania randomizowane wskazywały na to, że jest to bezużyteczna technologia w leczeniu ostrego bólu, natomiast jak widzicie państwo badania randomizowane wykazywały, że jest to świetna technologia. Prosił państwa, śmiem twierdzić, że jeżeli ktoś robi badania obserwacyjne jest w stanie wykazać praktycznie wszystko, zarówno pozytywny wynik, jak i negatywny wynik. Dopiero badania randomizowane, wyniki tych badań możemy traktować jako dowody naukowe. Do tych badań nie randomizowanych należy podchodzić bardzo ostrożnie, i to są oczywiście metody niwelowania tego przeszacowania, natomiast w tej chwili nie będziemy o tym mówić. Prosił państwa pojedyncza ślepa próba a wtedy kiedy pacjent nie wie czy jest w grupie kontrolnej czy w grupie badanej. Podwójnie nie wie pacjent, nie wie lekarz, który podaje czy ordynuje dany lek. I maskowanie, potrójna ślepa próba, wtedy nie wie również ten kto analizuje wyniki. Prosił państwa, okazuje się, że jeżeli badania, że parametry względne będą przeszacowane w kierunku wykazania skuteczności interwencji aż o 17% w przypadku braku zaślepienia próby. I tak wyglądają prosił państwa wyniki. Badania były pogrupowane, były zgrupowane w dwóch grupach niezależnie od tego czy były randomizowane czy nie, tylko jedynym kryterium podziału było zaślepienie próby. Jak państwo widzicie, zaślepienie tutaj, ta różnica jest nieistotna statystycznie więc nie wiadomo czy akupunktura pomaga czy nie pomaga, natomiast ta prosił państwa w badaniach nie zaślepionych, ta różnica jest istotna statystycznie i można powiedzieć, że akupunktura jak najbardziej jest technologią efektywną. Hierarchia badań w medycynie, oczywiście najbardziej wiarygodne są duże badania randomizowane, małe badania randomizowane, i teraz prosił państwa tutaj postawiłbym taką granicę. Tu jest prosił państwa ogromna przepaść jeśli chodzi o można powiedzieć charakter dowodowy wyników tych badań. Tutaj mamy nie randomizowane ze współczesną grupą kontrolną, z historyczną grupą kontrolną, kohortowe, kliniczno - kontrolne, rejestry, opis historii przypadków, opis pojedynczego przypadku. Prosił państwa polityką pewnego, jednego z krajów zachodnich zadano pytanie; który z trzech programów zdrowotnych dotyczących prewencji raka sutka chciałby finansować ze środków publicznych. Oczywiście ci politycy nie wstrzymali się na długo z decyzją i wszyscy bardzo chętnie głosowali nad tym, ja bym chciał, żeby Państwo się zastanowili, który z tych programów warty byłby finansowania. Program a; eliminuje 33% ryzyka śmierci z powodu raka sutka. Program b; zapobiega śmierci z



powodu raka sutka jednej na 1600 kobiet poddanych rocznie mammografii przez 7 lat. Program zdrowotny c; zwiększa szansę, że kobieta nie umrze w ciągu następnych 7 lat z powodu raka sutka, z 99,82% do 99,88%. Powiem państwu jakie były odpowiedzi tychże polityków, otóż znaczna większość chciała finansować program zdrowotny „a”, niewielu chciało finansować program zdrowotny „b”, a praktycznie nikt nie chciał finansować programu zdrowotnego „c” i konsternacja tych polityków była bardzo duża kiedy okazało się, że są wyniki tego samego programu zdrowotnego. Proszę państwa po prostu są prezentowane te wyniki tego programu zdrowotnego, są prezentowane w różny sposób. Tu mamy relative risk reduction, tu mamy number needed to treat, tu mamy absolute risk reduction. To jest proszę państwa język evidence based medicine, jeśli chodzi o terapię, w tej chwili nie będziemy oczywiście mogli przejść do poszczególnych parametrów, natomiast na kursach EBM których w Krakowie prowadzimy, oczywiście bardzo dokładnie omawiamy metodologię i korzystanie z tychże parametrów. Chciałbym tylko wspomnieć o jednym parametrze, który również wczoraj był przypominany tutaj przez pana dyrektora Kułagę, czyli NNT liczbę pacjentów, której należy podawać dany lek w określonym czasie, na przykład przez rok, ażeby zapobiec jednej śmierci, jednemu wynikowi negatywnemu. I proszę państwa jeżeli teraz będziemy lek „x”, mamy dwie grupy, to jest grupa badana, w której jest 20 osób, to jest grupa kontrolna w której jest 20 osób również, w tej grupie podajemy przez powiedzmy rok, podajemy lek „x”. Tej grupie przez rok podajemy placebo, czyli glukozę w kapsułkach na przykład, prawda, proszę państwa po roku co się okazuje, w grupie, która otrzymywała placebo zmarły 4 osoby, w tej grupie na 20 osób umarło 2 osoby. Z tego oczywiście wynika, że musimy podawać lek 10 osobom bo na 10 osób tutaj umierały dwie, tutaj na 10 osób umiera jedna. W takim razie, żeby zapobiec jednej śmierci musimy leczyć tutaj 10 osób. To tak tylko na marginesie. Proszę państwa, placebo jest również skutecznym lekiem, w każdym systemie służby zdrowia lekarz ma do dyspozycji cały wachlarz leków o skuteczności placebo. I tak powinno rzeczywiście być, natomiast proszę państwa chciałem zaznaczyć tylko jedną rzecz, że nieetyczne, niemoralne jest stosowanie leków o efektywności placebo tam gdzie istnieje inne leczenie, którego efektywność jest udowodniona. Proszę państwa rzeczywiste czyli pierwszorzędowe punkty końcowe w porównaniu do drugorzędowych punktów końcowych. I zobaczcie państwo, że nie interesuje nas w tym momencie efekt fizjologiczny jaki moglibyśmy osiągnąć za pomocą stosowania powiedzmy enkainidu. Oczywiście enkainid wpływa na zmniejszenie skurczów dodatkowych, natomiast proszę państwa ten lek powoduje wzrost śmiertelności w grupie chorych, która go otrzymuje w porównaniu do grupy, która otrzymuje placebo. Czyli ten lek proszę państwa jest lekiem szkodliwym. Proszę się również przyjrzeć tym pozostałym lekom. Proszę państwa profesor Egon Jonson, dyrektor SBU, szwedzkiej agencji rządowej HTA powiedział: „w dłuższej perspektywie czasu żadnego kraju nie stać na finansowanie technologii nieefektywnych”. Krótko, proszę państwa różnica pomiędzy farmakoekonomiką a oceną technologii medycznych. Farmakoekonomika zajmuje się jednym rodzajem technologii czyli lekami. Ocena technologii medycznych, nie tylko lekami ale również procedurami diagnostycznymi, chirurgicznymi, sprzętem i wieloma innymi o których mówił prof. Banta. Tak bym mniej więcej, tu jest napisane na moim komputerze FE czyli farmakoekonomika, tutaj tego akurat nie widać. w każdym razie, ocena technologii medycznych jest szerszym obszarem można powiedzieć. Kilka proszę państwa słów na temat definicji, gdyż nimi będę się za chwilę posługiwał. Otóż ja rozumiem bezpieczeństwo jakiegoś leku czy terapii jako potencjalny wpływ szkodliwy technologii. Czy to jest ryzyko związane z jej stosowaniem. Ocena tego ryzyka czy też ocena tej terapii, działanie niepożądane czy powikłania. Skuteczność, jest to wpływ korzystne technologii natomiast efektywność proszę państwa to jest

porównanie bądź zestawienie tej skuteczności, tego korzystnego wpływu z tą oceną ryzyka. Jeśli chodzi o analizę opłacalności czyli efektywności kosztowej oczywiście, składają się z dwóch elementów. Z jednej strony jest to ocena efektywności z drugiej strony jest to ocena kosztów. Nie można prosić państwa ograniczać się tylko i wyłącznie do kosztów bezpośrednich ale też trzeba wziąć pod uwagę koszty pośrednie, i ma to szczególnie znaczenie w technologiach nielekowych. O innych kosztach powiem państwu później, natomiast efektywność tak jak mówiłem państwu wcześniej jest to porównanie tej korzyści z bezpieczeństwem, z potencjalnym ryzykiem. Tu proszę państwa taki przykład, który robimy na ćwiczeniach z zakresu evidence-based medicine w Krakowie. Porównujemy dwa leki, lek „a” i lek „b”. I te proszę państwa leki są rzeczywiście, to są dane jeśli chodzi o koszty, są to dane sprzed trzech lat. Ale przypuszczam, że relacje między tymi dwoma lekami są wciąż zachowane, są to proszę państwa leki, które znajdują się w tej chwili na liście leków refundowanych. I zobaczcie państwo, mamy tutaj parametry z dwóch grup, czyli możemy wnioskować o efektywności, mamy również koszt. Nie wiem, czy wszyscy zdajemy sobie sprawę, ale koszt uratowania jednego życia za pomocą leku „a” wynosi ok. 120, ok. 120 tysięcy złotych. Oczywiście przy tych uproszczonych założeniach jakie tutaj prezentuję. To oczywiście jest bardziej skomplikowane w rzeczywistości niż w prezentowanym to jest tym ćwiczeniu. Natomiast proszę państwa, za pomocą leku „b”, z tej samej grupy notabene, koszt uratowania jednego życia wynosi ok. 18 no powiedzmy 20 tys. złotych. Powstaje oczywiście pytanie w jakim zakresie one powinny być refundowane. Wydaje się, że z punktu widzenia społecznego, oczywiście jeżeliby nasi politycy postanowili należałoby promować stosowanie tego leku ustanawiając wyższy na przykład tutaj, wyższą stawkę refundacyjną, natomiast ten na niższym poziomie, jeżeli w ogóle. Są oczywiście różne rodzaje analiz ekonomicznych, chciałem tylko powiedzieć, że najczęściej stosowaną jest analiza efektywności kosztów. A to jest proszę państwa schemat, bardzo ogólny schemat, w jaki sposób dokonujemy analiz opłacalności w biurze standaryzacji, otóż oczywiście sprecyzowanie problemu, określenie tutaj wszystkich najważniejszych tutaj opcjonalnie sposobów postępowania, i potem proszę państwa opracowujemy strategię wyszukiwania, tak żeby dotrzeć do wszystkich wiarygodnych badań klinicznych, które są dostępne w medycznych bazach danych, w analizach musimy oczywiście odnaleźć pełne teksty, analizujemy ich wiarygodność, przypisujemy odpowiednie wagi odpowiednim badaniom w zależności od stopnia ich wiarygodności, dokonujemy metaanalizy, czyli sumujemy wyniki tych badań, które oczywiście są homogenne, i analizujemy skuteczność powikłania, czyli efektywność. Jeśli chodzi o koszty oczywiście musimy zidentyfikować źródła danych kosztowych, te dane kosztowe musimy zebrać a następnie je zanalizować. Dopiero to pozwala nam na przeprowadzenie cost-effectiveness, a w niektórych przypadkach wykonujemy analizę break even point . Dlatego, jeżeli mamy do czynienia z kosztami zmiennymi i z kosztami stałymi to oczywiście dla porównywanych technologii może się okazać, że w zależności od tego ile świadczeniodawca danych procedur tygodniowo czy miesięcznie wykonuje inny rodzaj technologii może mu się bardziej opłacać. To jest taki przykład strategii wyszukiwania, tu jest akurat dla nie trzymania moczu, wysiłkowego nie trzymania moczu u kobiet, nie będę w tej chwili wchodził w szczegóły, to były baza danych, które przeszukaliśmy jeśli chodzi o wysiłkowe nie trzymanie moczu poczynając jak państwo widzicie od Cochrane Library . Tutaj dwie rzeczy, dwa podzbiory można powiedzieć główne; czyli Cochrane Database of Systematic Reviews i Cochrane Controlled Trial Register . Również przeszukaliśmy bazy związane ze specjalistycznymi pismami medycznymi. Współczynnik wiarygodności określamy zgodnie oczywiście z kryteriami wiarygodności badań klinicznych, zgodnie z zasadami EBM . Wyniki, wyniki są prezentowane przy użyciu tych parametrów, które są, jeśli

chodzi o efektywność, wyniki są prezentowane przez nas za pomocą parametru języka, tego zunifikowanego języka EBM, z podaniem stopnia istotności statystycznej. Tutaj proszę państwa my założyliśmy, że nie będziemy obliczać kosztów całkowitych wykonywania danej technologii, dlatego, że koszty całkowite są obarczone dużym ryzykiem błędu szczególnie w sferze kosztów niemierzalnych bądź trudno mierzalnych. Co się okazuje proszę państwa, że jeżeli będziemy analizować najważniejsze opcje postępowania, najważniejsze opcjonalne technologie, to nie musimy liczbowo określać kosztów niemierzalnych i trudno mierzalnych. Najczęściej są to koszty wspólne. Nie są to koszty różniące tej technologii, stąd również wnioskowanie o koszcie całkowitym, o różnicach kosztów pomiędzy tymi technologiami, możemy w tym momencie pominąć te koszty trudno mierzalne i niemierzalne zupełnie prawidłowo wnioskując o różnicy kosztów całkowitych. Tak to mniej więcej proszę Państwa wygląda. Są koszty różniące prawdą, no nie wiem na przykład koszt znieczulenia około operacyjnego, może być różny dla różnych technologii ale na przykład koszt hospitalizacji, jeżeli pacjent jest hospitalizowany przez dwa dni w przypadku pierwszej technologii i dwa dni w przypadku drugiej technologii to niezależnie w tym momencie od poziomu referencyjności szpitala jest to koszt wspólny, prawda, bo defakto zakładamy, że pacjent może być hospitalizowany w tym samym szpitalu. Oczywiście przeprowadzamy, pokazujemy wyniki analizy ekonomicznej i jeszcze chciałem powiedzieć, że oczywiście analizy cost-effectiveness mogą być robione z różnych punktów widzenia. Jak do tej pory robiliśmy analizy cost-effectiveness z punktu widzenia świadczeniodawcy oraz płatnika. Mamy w tej chwili również zamówienia na analizy również z punktu widzenia społecznego pacjenta ZUS-u, ale do tego dojdzie prawdopodobnie w przyszłym roku. Tu jest taki przykład jednego z raportów oceny technologii medycznych, i jest to porównywanie niektórych chirurgicznych metod leczenia wysiłkowego nie trzymania moczu u kobiet. Najczęściej proszę państwa manipulacją jeśli chodzi o analizy cost-effectiveness jest po prostu nie ujmowanie w porównaniu technologii, która może być zagrażająca jeśli chodzi o opłacalność, czyli jeżeli ja bym chciał, jeżeli mam technologię „a, b c i d”, to powiedzmy jeżeli moja jest drugą, jeśli chodzi o opłacalność w kolejności jest inna bardziej opłacalna, najprostszą rzeczą żeby wykazać, że moja jest bardziej opłacalna po prostu nie uwzględnię tej najbardziej opłacalnej w mojej analizie. To jest bardzo powszechna praktyka, dlatego to co należałoby wymagać od analiz opłacalności to jest przedstawienie wszystkich, najpierw przedstawienie wszystkich możliwych opcji, a następnie uzasadnienie, szczegółowe uzasadnienie wyboru dlaczego te technologie będziemy porównywać a te odrzucimy, nie uwzględnimy w tym porównaniu. I tutaj były proszę państwa trzy operacje: plastyka przedniej ściany pochwy z podszyciem cewki szwami Kellego, operacja Marshall-Marchetti-Krantz, operacja metodą Burcha. Takie były proszę państwa wyniki, jeśli chodzi o koszty to jak państwo widziecie najtańszą, najmniej kosztowną technologią okazała się plastyka przednia pochwy, drugą w kolejności jest tutaj TVT, natomiast jeśli chodzi o skuteczność czyli odsetek w tym momencie trwałych wyleczeń z nie trzymania tego, z nie trzymanie wysiłkowego moczu jak państwo widziecie po zrobieniu metaanalizy wiarygodnych badań klinicznych, które zciągnęliśmy z baz danych na całym Świecie jest TVT w porównaniu z najmniej skuteczną czyli z plastyką przednią. Jak teraz są dalej prezentowane wyniki. Otóż wiecie państwo co to jest iloraz współczynników, jest to opłacalność, współczynnik cost-effectiveness to jest jednej metody podzielony przez cost-effectiveness drugiej metody. Jak państwo widziecie niezależnie od tej, niezależnie od kosztów wspólnych, których wartościowo nie określamy, niezależnie od tej wielkości zawsze proszę państwa TVT będzie metodą bardziej opłacalną od plastyki przedniej pochwy. Oprócz tego jest to technologia bardziej skuteczna. Tak są przedstawiane wnioski jeśli chodzi o

ten opis i jak państwo widziecie dla kosztów wspólnych, dążących do zera i następnie do kosztów wspólnych dążących do nieskończoności. Niezależnie od wielkości tych kosztów wspólnych, na korzyść plastyki przedniej, korzyść TVT jest zawsze dosyć znaczna. Inny raport tutaj porównanie innych terapii guzków krwawniczych, trzy metody: ligatura Barona, operacja sposobem M. Morgana, metoda Longo Stapler. Tutaj oczywiście była znacznie większa ilość technologii, dlatego że technologia to nie jest tylko metoda. To jest również, czyli technologia to nie jest tylko i wyłącznie preparat, jakiś lek, nazwa handlowa czy międzynarodowa. Technologia medyczna to jest dany lek stosowany w danej dawce, daną drogą podawania, w określonej postaci, jednostce chorobowej, w określonym stanie klinicznym, w takiej a nie innej dawce jak już mówiłem i w celu uzyskania takiego a nie innego efektu zdrowotnego. To jest bardzo ważne aby tym efektem zdrowotnym był pierwszorzędowy punkt końcowy, czyli obniżenie śmiertelności, zmniejszenie zachorowalności bądź chorobowości, bądź poprawienie jakości życia. To są trzy czy cztery można powiedzieć główne, główne obszary pierwszorzędowych punktów końcowych. Tych technologii było sporo, ponieważ dodatkowym czynnikiem różnicującym była możliwość wykonania poszczególnych operacji z różnym rodzajem znieczulenia. System. Można tu zaproponować dwustopniowy system oceny technologii, nowych technologii, farmaceutyków i innych technologii medycznych w Polsce. Pierwszy poziom dotyczyłby analizy efektywności dla leków i ocena bezpieczeństwa dla parafarmaceutyków, drugi poziom to ocena efektywności kosztowej, która mogłaby być dokonywana na poziomie płatnika bądź państwa. Jak to mniej więcej wygląda na świecie. Otóż jeżeli jakaś technologia, jak mówi tutaj pan prof. Banta przedstawiał. Że mogą to być nowe technologie, które wchodzi na rynek, ale mogą to być technologie, które w tej chwili są na liście leków refundowanych, które należałoby przejrzeć pod kontem najpierw efektywności, czy w ogóle jest to technologia, lek o udowodnionej efektywności czy też nie, następnie jaka jest siła tej interwencji czyli w porównaniu z innymi opcjami, o ile bardziej on jest efektywny o ile mniej efektywny. A następnie dopiero przechodzimy do opłacalności, czyli zestawienie efektywności z kosztami. Jeżeli technologia czy nowa czy stara chce wejść na rynek oczywiście najpierw jest oceniane jego bezpieczeństwo lub efektywność. I tym zajmuje się oczywiście w Polsce komisja rejestracji w Stanach Zjednoczonych FDA. Teraz jeżeli technologia jest efektywna bądź bezpieczna jest technologią zarejestrowaną i można ją sprzedawać na danym obszarze. Jeżeli nie to jest oczywiście zakaz stosowania. Następnie proszę państwa technologie zarejestrowane, jeżeli producent na przykład jest zainteresowany tym, żeby ta technologia była refundowana, czyli żeby była współfinansowana ze środków publicznych, jest, mógłby być zobowiązany do przedstawienia analizy efektywności w porównaniu z innymi opcjami, czyli rzeczywiście jeżeli chcemy, żeby ten lek ma być refundowany to czym on jest lepszy od tych do tej pory, które są refundowane. Albo oczywiście można pójść dalej i powiedzieć o ile on jest bardziej opłacalny w takim razie od tych technologii stosowanych do tej pory, aktualnie refundowanych. I tym mogłaby się zajmować komisja refundacji do pomocy mogłaby mieć agencję HTA, bądź jakiś Polski NICE, w tym momencie technologie byłyby refundowane bądź byłyby to technologie zarejestrowane ale nie refundowane. Tam jeszcze jest problem oczywiście z limitami. Jeśli chodzi o zadanie szóste tego projektu w którym uczestniczymy z TNO, zajmujemy się tworzeniem szkieletu dla listy świadczeń gwarantowanych i co chcielibyśmy dzięki temu osiągnąć. Po pierwsze chcieli byśmy pokazać jakie kategorie w liście świadczeń gwarantowanych występują a następnie chcieli byśmy pokazać jak wygląda wpis dla 200 do 300 technologii medycznych, lekowych nielekowych, diagnostycznych, terapeutycznych, z różnych specjalności także chcielibyśmy tutaj zachować pewien balans, aczkolwiek wybór ten

jest można powiedzieć dosyć przypadkowy. Chociaż ostatnio prof. Banta zalecił nam przeprowadzenie pewnych analiz dla grup leków i dla leków wymienionych czy też stawianych w wątpliwość przez Prescrire francuskie. I my to oczywiście zrobimy, jeszcze ten projekt ma przed sobą dwa miesiące, w tej chwili weźmiemy się za leki, które Prescrire wymieniło tutaj w swoim opracowaniu. Generalnie rzecz biorąc lista świadczeń gwarantowanych ma dwie główne kategorie. Pierwsza kategoria jest to ocena efektywności, tutaj dokonujemy proszę państwa odpowiedzi tylko i wyłącznie na jedno pytanie, czy technologia jest o udowodnionej efektywności czy jest szkodliwa, czy też jest technologia o nie udowodnionej efektywności. Drugi stopień oceny to są analizy opłacalności. I teraz jest sześć podkategorii jeśli chodzi o efektywność. Technologie, która jest , która wchodzi do, zostaje poddawana ocenie, może trafić do jednej z sześciu grup. Do technologii o udowodnionej efektywności w badaniach randomizowanych, udowodnionej efektywności nie wymagane są badania randomizowane, na przykład insulina w cukrzycy. Udowodnionej szkodliwości w badaniach randomizowanych, udowodnionej szkodliwości gdzie nie wymagane jest badanie randomizowane, może trafić do kategorii, w której znajdują się technologie zarówno skuteczne i jest oczekiwany ten efekt korzystny tej technologii oraz są to technologie obciążone dużym ryzykiem na przykład coronarografia, albo niektóre sposoby leczenia w onkologii. I również jest kategoria dla sporej grupy technologii stosowanych w tej chwili w Polsce o nie udowodnionej efektywności. Jeśli chodzi o drugi etap oceny to oczywiście tylko i wyłącznie technologie, które są, mają udowodnioną efektywność oraz te, które są zarówno skuteczne jak i obciążane dużym ryzykiem, one przechodzą do dalszego etapu oceny, rzeczywiście siły tej interwencji a następnie porównanie tej siły interwencji poszczególnych opcji i oceny kosztów pośrednich i bezpośrednich związanych z ich stosowaniem. I tu oczywiście mamy trzy rodzaje, trzy subkategorie czyli największa opłacalność, średnia opłacalność i niska opłacalność. Jeśli chodzi, jakby to, jak, jak, tłumaczy się wyniki raportów oceny technologii medycznej na wpisy do tych kategorii. Otóż mogę to powiedzieć na przykładzie raportu dotyczącego, chirurgicznego metod leczenia guzków krwawniczych. Otóż tam się okazało, że najbardziej opłacalną metodą jest obligatura Barona czyli założenie na szypułę guzka krwawniczego prostej gumki. On tu po prostu obsycha i odpada. Natomiast drugą metodą jeśli chodzi o opłacalność okazało się stapler Longo . To jest akurat wycięcie i połączenie błony śluzowej bez naruszania tkanki samego guzka. Proszę państwa, jakie są z tego wnioski. Otóż z drugiej strony muszę tu jeszcze jedną rzecz powiedzieć, otóż ligatura Barrona ta gumka okazuje się technologia bardzo tania ale skuteczną tylko i wyłącznie, tam było badane w 70%, ok. 70% chorych jest rzeczywiście na trwałe wyleczonych. Ale 30% chorych jest dalej nie wyleczonych. I teraz jeśli chodzi o największą opłacalność to rzeczywiście ligatura Barrona ta gumka wędruje do tej kategorii. Natomiast stapler Longo wędruje do tej kategorii, ale jak to się przekłada teraz na system ubezpieczeniowy. Otóż wydaje się, że jeśli chodzi o powszechne ubezpieczenie zdrowotne to mogłoby powstać takie zalecenie, że ligaturę Barrona będziemy oferować wszystkim pacjentom w drugim i trzecim stopniu zaawansowania guzków krwawniczych jako technologie pierwszego rzutu. Natomiast w przypadku niepowodzenia będziemy pacjentom finansować stosowanie staplera Longo. Natomiast jeśli by doszło w Polsce do stworzenia, do powstania rynku ubezpieczeń dodatkowych, to pacjenci, którzy wykupują ubezpieczenia dodatkowe mogliby wtedy mieć stosowany stapler Longo jako technologię pierwszego rzutu, ale to jak mówię za dodatkową opłatą. W tej chwili nie jest to w ogóle usystematyzowane. Trzeba również powiedzieć proszę państwa, że analizy opłacalności to nie wszystko. I zdecydowanie decyzje o refundowaniu, finansowaniu technologii medycznych powinni podejmować tutaj politycy, również

przedstawiciele zainteresowanych grup społecznych i innych instytucji. Proszę państwa HTA czy farmakoeconomika to tylko jeden element tej układanki. Politycy powinni określić możliwości strukturalne, preferencje pacjentów, system prawny, dostępne środki wreszcie. I dopiero na tej podstawie podejmować decyzje o finansowaniu bądź nie i zakresie finansowania poszczególnych technologii. Tutaj rolą osób, które zajmują się tego typu analizami jest tylko i wyłącznie przedstawienie pewnego materiału, pewnych wiarygodnych danych, z drugiej strony należy bardziej uważać i pamiętać o tym, że analizy farmakoeconomiczne mogą być zmanipulowane. I tutaj system, system oceniania oceny wiarygodności, oceny tychże analiz jest koniecznością. Również te kryteria będą rzeczą bardzo istotną, o których tutaj mówili moi przedmówcy, dlatego, że te kryteria są wymagane przez Unię Europejską. Czyli jasne przejrzyste kryteria dokonywania, podejmowania decyzji o finansowaniu takich a nie innych technologii są pewną koniecznością. To też trzeba będzie bardzo uważać, żeby nie znalazły się tam różnego rodzaju zapisy, powiedziałbym niewłaściwe, otwierające furtkę do korupcji. Jeszcze chciałbym takie jedno hasło prawie na zakończenie państwu przedstawić. Otóż szczególny nacisk jak sądzę, co jest w tej chwili bardzo nie doceniane przez decydentów, należy szczególny nacisk położyć na analizę opłacalności procedur diagnostycznych. Procedury diagnostyczne to jest, to jest proszę państwa klucz do skarbcza. To jest, tym się właśnie otwiera skarbonkę ze środkami publicznymi. Napędzanie, niewłaściwe napędzanie badań diagnostycznych powoduje również następne finansowanie niepotrzebne leczenie. I takich przykładów oczywiście mamy wiele natomiast czas nie pozwala mi w tej chwili o nich powiedzieć i o przykładach takiego działania. Proszę państwa tu jest przykład kilku wpisów do , na listę świadczeń gwarantowanych. Na przykład wziąłem tylko zastosowanie interferonu beta. I to tylko w jednej postaci stwardnienia rozsianego sclerosis multipleks. Dokonaliśmy analizę efektywności stosowania interferonu beta w stwardnieniu rozsianym. Oczywiście z tego interferonu beta powstało ponad 30 technologii medycznych. Każdą z nich należy traktować oddzielnie. I teraz zobaczcie Państwo, że interferon beta 1a, stosowany jak mówiłem, to jest proszę państwa dotyczy zapisu, opisu technologii medycznych czyli interferon beta 1a, stosowany podskórnie w dawce takiej i takiej przez 36 miesięcy w celu, to jest bardzo ważne, w celu zmniejszenia częstości zaostrzeń stwardnienia rozsianego rzeczywiście ma udowodnioną efektywność. Jest innym pytaniem do którego na razie nie wchodzimy ponieważ jest to pierwszy stopień oceny, czy to jest interwencja silna czy to jest interwencja słaba, czy to jest interwencja znacznie silniejsza od placebo, czy bardzo blisko, troszkę tylko prawda lepsza od placebo. Ba, powstaje pytanie jaka jest relacja pomiędzy tą interwencją a innymi opcjami postępowania. Ale zobaczcie państwa co się dzieje dalej. Otóż interferon beta 1a podskórnie w takiej i takiej dawce przez 36 miesięcy, ale stosowany w celu opóźnienia tej progresji niesprawności bardzo mi przykro ale ma efektywność nie udowodnioną. Jest technologią o nie udowodnionej efektywności. I dalej, interferon beta 1a stosowany podskórnie w takiej dawce w celu zmniejszenia częstości zaostrzeń udowodniona, natomiast jeśli chodzi o opóźnienie progresji, niesprawności nieudowodniona. To jest tylko proszę państwa tak jak mówię dla postaci wtórnie wstępującej stwardnienia rozsianego, zachęcam państwa do lektury całego, całej analizy szczegółowej, jeśli Państwo oczywiście chcielibyście to analizą służyć. Na tym dziękuję.

Grabowski: Dziękujemy bardzo, to bardzo konkretne wystąpienie dotyczące problematyki metodologicznej co oczywiście pokazuje skalę szczegółowości tych analiz, które na koniec przekładają się na proste pytanie i prostą odpowiedź tak lub nie, prawda. Ja rozumiem, że podstawowym problemem, który się pojawia, to taka

organizacja ewentualnego systemu uzgadniającego ocenę technologii medycznej w wyborze świadczeń gwarantowanych w systemie ochrony zdrowia, która z jednej strony nie byłaby biurokratycznym koszmarem, drogim systemem, tylko przynosiła maksymalną korzyść, która jest wielce prawdopodobna. I myślę, że warto nad tym się zastanowić. Zapraszam do dyskusji na ten temat. Aczkolwiek nasi goście nie mają zbyt wiele czasu bo zbliża się odlot samolotu, także zachęcam. Proszę bardzo.

NN: Jestem kierownikiem katedry medycyny społecznej i zapobiegawczej również ekspertem Światowej Organizacji Zdrowia i wreszcie pełnię konsultanta krajowego w dziedzinie zdrowia publicznego. Muszę powiedzieć, że bardzo jestem zadowolony, że mam okazję uczestniczyć w tym spotkaniu, to są bardzo ważne dla polskiego systemu opieki zdrowotnej, jak rozumiem dyskusje, propozycje, przyjęcia pewnych rozwiązań i tutaj bardzo dziękuję naszym gościom z Holandii za interesujące informacje. Ja króciutko przekartkowałem te materiały, które dostaliśmy dzisiaj z jednej strony widzę tam bardzo wiele wartościowych zaleceń i krytyczną ocenę polskiego dotychczasowego systemu, chociażby refundacji leków. Bardzo podobają mi się wskazówki, które zwracają uwagę na konieczność zintensyfikowania prewencji i przeznaczenia, zwrócenia na to i większej uwagi i kierowania większych środków, z drugiej strony to chyba jest materiał w tej chwili jeszcze roboczy dlatego, że jest tam wiele błędów, połączeń języka polskiego z angielskim w tych samych zdaniach, jest sporo jakiś niezręczności edycyjnych, językowych nie wiem skąd one się wzięły, myślę, że to powinno zostać dopracowane i wtedy powstanie naprawdę wartościowy materiał, który warto byłoby upowszechnić, żeby dotarł do szerszego grona i decydentów ale i do środowisk akademickich, żeby trafił na uczelnie i wreszcie do środowisk związanych chociażby z kasami chorych, które podejmują tutaj ważne decyzje. To taka moja generalna uwaga, natomiast jeszcze miałbym może jeszcze uwagę do wystąpienia pana doktora Łandy ale to może za chwilę ktoś inny zabierze głos.

Grabowski: Ja chciałbym jeszcze uzupełnić inne informacje, że jeszcze inne podręczniki w tym projekcie są przewidziane w tym jeden no bardzo metodologicznie zorientowany podręcznik, który jak sądzę może stanowić bardzo dobre źródło informacji jak to zorganizować tego typu przedsięwzięcie i on jest też ważny. Pojawi się też podręcznik dotyczący systemu licencjonowania świadczeniodawców jak ten problem jest rozwiązany w Holandii i jakie rekomendacje dla nas grupa TNO widzi i myślę, że te podręczniki wszystkie one są bardzo wartościowe i rzeczywiście tu przychylam się do opinii, że one powinny być lepiej zredagowane i lepiej przetłumaczone i rozumiem, że to do Steve'a Chapmana kierujemy te uwagi bo on jakby zarządza projektem, myślę, że rzeczywiście jest pewnego rodzaju problem. Po prostu trzeba znaleźć osobę, która będzie w stanie pod względem językowym i merytorycznym dobrze wypełnić to zadanie. Zachęcam do jakiś szczegółowych pytań jeśli Państwo jakieś macie i jeszcze jakiś głód informacji bo to unikalna okazja.

NN: W takim razie skoro nikt nie zabiera w tej chwili głosu to może ja bym zadał tutaj koledze z Krakowa takie pytanie; z bardzo dużą też uwagą śledziłem pana wystąpienie, bardzo mi się podobało, ale proszę mi odpowiedzieć na takie pytanie. Te analizy efektywności kosztowej, które pan prezentował dzisiaj. Czy one były oparte na podstawie informacji zebranych, to znaczy zebranych to tak ale, na podstawie badań wykonanych w Polsce i na podstawie polskich analiz ekonomicznych, myślę i o zabiegach chirurgicznych, które pan przedstawił. Bo jeżeli weźmiemy dane dotyczące skuteczności poszczególnych zabiegów leczniczych czy skuteczności leków, uzyskane za granicą, jeżeli weźmiemy koszty zebrane w Holandii, w Kanadzie, w Stanach

Zjednoczonych, w Anglii, tylko spróbujemy to przenieść, przewartościować to na złotówki polskie, to wnioski z tego wynikające będą wielce dyskusyjne. Ja myślę, że w tego typu analizach trzeba dysponować polskimi danymi. Dotyczącej efektywności kosztowej, choćby zabiegów chirurgicznych i również dość rzadko prezentowano badania dotyczące skuteczności leczniczej oparte na reprezentatywnym i wystarczająco dużym materiale. W związku z tym moje pytanie raz jeszcze powtarzam, czy te analizy, które pan prezentował były oparte na polskich danych uzyskanych w naszym kraju.

Łanda: Dziękuję za to pytanie, oczywiście zapomniałem o niektórych rzeczach tutaj wspomnieć, naprawdę bardzo się spieszyłem i myślę, że Państwo mi to wybaczyć. W każdym razie jeśli chodzi, takie jest na świecie ogólna przyjęta procedura, że jeśli chodzi o wyniki dotyczące skuteczności czy efektywności różnego rodzaju technologii medycznych lekowych i nie lekowych, to wyniki jeśli chodzi i efektywność pomiędzy poszczególnymi krajami rzeczywiście można je przenosić z kraju na kraj i prawdopodobnie, nie wiem, aspiryna, czy jakieś betablokery tak samo będą działały w populacji amerykańskiej jak i w populacji polskiej. Być może są różnice, generalnie rzecz biorąc z pewnością uważa się, że jeśli chodzi o wyniki badań klinicznych, badań trzeciej fazy to można te wyniki przenosić pomiędzy krajami. Myślę tu przede wszystkim o krajach średnio i wysoko rozwiniętych. Oczywiście tym bardziej te wyniki można przenosić i można je uogólniać, jeżeli one są zrobione nie tylko na podstawie jednego badania klinicznego ale jeżeli są zrobione na podstawie badań klinicznych, metaanalizy badań klinicznych z różnych krajów. I teraz to co myśmy zrobili to dla każdego z naszych raportów jest zrobiona metaanaliza. Na początku jak mówiłem już, opracowujemy strategię wyszukiwania, przeszukujemy za jej pomocą wszystkie dostępne bazy danych, odnajdujemy doniesienia naukowe, których następnie wiarygodność określamy i te najbardziej wiarygodne, na podstawie tych najbardziej wiarygodnych robimy, dokonujemy pewnego sumowania, metaanalizy. I tyle jeśli chodzi i efektywność, to są dane nie polskie, zwykle mogą być również polskie ale nie tylko polskie, w każdym razie są to dane sumaryczne na podstawie najbardziej wiarygodnych badań klinicznych z całego świata. Jeśli chodzi o analizę kosztów zdecydowanie ten obszar, ta część analizy opłacalności absolutnie nie jest transformowalna pomiędzy żadnymi krajami. Nawet pomiędzy Polską a Czechami nie można takich danych przenosić bezpośrednio. Myśmy również tego nie zrobili i dokonaliśmy sami analizy kosztów. Jak my to robimy. Oczywiście, że nie mamy aż tak ogromnych środków, żeby robić badania powiedzmy całego rynku ale dobieramy sobie pewną próbę. Na przykład 5 szpitali o różnym poziomie referencyjności, mamy informacje od pewnych kas chorych, mamy również informacje, tak jak mówiłem nie tylko od szpitali specjalistycznych ale jakiś szpitali powiedzmy rejonowych i dokonujemy tutaj analizy kosztów na podstawie polskich danych. Zdecydowanie tak, czyli prosimy kontakty, które mamy wśród świadczeniodawców o wypełnienie tabeli kosztowych i następnie albo te dane uśredniamy i one się nie wiele różnią, albo dajemy je w wartościach granicznych dokonując następnie analizy wrażliwości. Ja jeżeli państwo jesteście zainteresowani tym żebym ja przesłał te raporty Państwu, ja proponuję o kontakt po prostu e-mailowy ze mną, zgłoszenie takiego zapotrzebowania ja z przyjemnością państwu tego typu analizy mogę przesłać. Mój adres e-mailowy, jeżeli mogę w tej chwili podać to jest Krzysztof\_Łanda@poczta.onet.pl, lub jeszcze drugi adres może; xlanda@mp.pl, mp to skrót od medycyny praktycznej, oczywiście nie odpłatnie możemy jeden, dwa, trzy egzemplarze różnych raportów państwu wysłać.



Grabowski: Chciałem tą informację tylko uzupełnić, że wszystkie te projekty i produkty są z zakresu public domei, jak rozumiem z natury rzeczy będą udostępniane. Nie jest to tak, że to jest własność kogokolwiek konkretnego. One będą po prostu wystawione w formie elektronicznej na stronie internetowej, być może Centrum Systemów Informacyjnych, być może Ministerstwa Zdrowia. Wśród projektów finansowanych przez Bank Światowy projekt priorytetu polityki zdrowotnej, w którym to projekcie jest podręcznik jak liczyć koszty, bodajże dla programów polityki zdrowotnej i jest tam dość szczegółowo to krok po kroku przedstawione, także można zorientować się na ile są to dokładne analizy aczkolwiek problematyka liczenia kosztów w Polsce to myślę jest temat na wielodniową dyskusję.

Grabowski: Natomiast ja mam takie pytanie, trzeba by się dobrze zastanowić o to, że miałyby ta centralna instytucja zajmujące się problematyką HTA robić. Jakie miałyby zadania, funkcje spełniać. Wydaje się, że dość jakby jest oczywista jej pierwsza funkcja, to znaczy ocenianie gotowych już raportów, ocen technologii medycznych, natomiast wydaje się, że gdyby taka instytucja miała powstać niezależnie od tego gdzie ona ewentualnie miałyby być umieszczona to ona powinna również licencjonować ośrodki, które by takie raporty tworzyły. To znaczy, prowadzić rodzaj ratingów, systematycznie oceniać jakość tych raportów, eliminować te ośrodki, które produkują raporty nierzetelne. I taką funkcję powinna pełnić i pewnie powinna pełnić trzecią funkcję określającą programy szkoleniowe dla ludzi, którzy by w ogóle w tym systemie działali. Natomiast ja widzę trzy takie funkcje, nie wiem jak inni uczestnicy, ale generalnie wydaje się, że żadna z tych funkcji nie jest wbrew pozorom bardzo kosztowna, prawda, bo to nie powinno być tak, że to ta instytucja generuje te raporty, prawda, bo raporty w gruncie rzeczy może wygenerować każdy, z tym że jeśli każdy będzie to robił to będą one tragicznej jakości, w związku z tym oczywiście musi być to wszystko przemyślane i dobrze zorganizowane, co na ten temat myślicie.

Łanda: Chciałbym tylko jedną rzecz zauważyć, że dokonywanie analiz opłacalności nie jest sprawą prostą i jest sprawą bardzo kosztowną. Biorąc pod uwagę ilość technologii, nowych technologii pojawiających się na rynku każdego roku, obawiam się, że nie powinno to być, dokonywanie tego typu analiz nie powinno obarczać budżetu państwa, ale powinno obarczać tych, którzy aplikują o finansowanie nowych technologii ze środków publicznych. To jest rzeczywiście bardzo kosztowny proces, u nas jeśli chodzi o biuro standaryzacji mniej więcej trzy, cztery osoby obserwują jedną taką analizę trzy, cztery miesiące.

Grabowski: Inne pytanie, jaka ma być marchewka, prawda. Bo skoro trzeba wydać pieniądze aby taki raport przygotować to co właściwie ma być na końcu korzyścią z faktu wydania tych pieniędzy, bo ja właściwie rozumiem, że może być korzyść marketingowa oto jest raport technologii medycznej, jest on lepszy niż inne technologie, prawda, lub włączenia do koszyka. Ale co oznacza w praktyce owe włączenie do koszyka. To jest bardziej pytanie do Kas Chorych, myślę niż do eksperta, pana doktora Landy czy do ministerstwa. Co Kasy Chorych mogłyby zaoferować tym świadczeniodawcom, żeby ten mechanizm napędzić, żeby promować tego typu działania.

NN: Ale koszyk świadczeń nie będą Kasy Chorych tworzyć, jeśli ma być w ogóle koszyk świadczeń to ministerstwo będzie. To w związku z tym to co pan dr Landa mówi, to Kasy Chorych nie mają pieniędzy na to, żeby płacić za ocenę czy wybór programu. W związku z tym wydaje mi się że mimo wszystko zależy tutaj od

Ministerstwa Zdrowia by pewne ogólne rzeczy. Ja uważam, że to co pan dr Landa przedstawia to są powijaki tego co się, bo poza Krakowem nie wiem czy są ośrodki, które tego typu świadczą usługi i dlatego moim zdaniem jest to, stawiamy pierwsze kroczki w dziedzinie, która jeśli wejdziemy do Unii Europejskiej będzie wymagalna.

Grabowski: Nie, ja nie sugerowałem, że kasy chorych będą tworzyły koszyk, bo to nie o to chodzi tylko jeśli już ten koszyk powstanie to jak on będzie pracował. Jak to z tymi faktami, z tymi zgromadzonymi świadczeniami miało działać. W moim przekonaniu, prostym takim mechanizmem jest to aby tworzyć na przykład kolejkę oczekujących, prawda, tych świadczeń, badać jaka jest dostępność. Skoro wybieramy już jakąś grupę świadczeń i uznajemy, że one są efektywne, skuteczne pod względem finansowym no to wtedy dbajmy żeby dostęp do nich był najlepszy. Wydaje się że to wtedy jest taki impuls dla wszystkich, że warto się ubiegać o tą pozycję wśród tych standardów, prawda, warto o to jakby zadbać. Być może jakieś inne mechanizmy byłyby tu do pomyslenia.

Łanda: Na całym świecie są dwie drogi, jest formalna i nie formalna wykorzystywania wyników analiz opłacalności. Jeśli chodzi o drogę formalną to są różnego rodzaju struktury, również sposoby, takie jak tworzenie receptariuszy, tworzenie listy świadczeń gwarantowanych, to są sposoby kontraktowania, analizy opłacalności wykorzystywane są przy tworzeniu standardów postępowania, wreszcie lista leków refundowanych razem z limitami, które są mechanizmem, jeżeli w tym momencie większy ciężar ponosi pacjent tym bardziej jak gdyby mechanizm działa negatywnie, jeśli chodzi o, zmniejsza używanie danej technologii. Natomiast są również bardzo powszechnie wykorzystywane nieformalne sposoby wykorzystywania analiz opłacalności w celu racjonalizacji a może powiedzmy bardziej brutalnie ograniczenia kosztów czy farmakoferapii czy w ogóle kosztów opieki zdrowotnej, jeśli chodzi o, mogę podać przykład Kaiser Permanente. Oni wykorzystują wyniki analiz opłacalności, analiz efektywności do informowania świadczeniodawców z którymi kontraktują. Sama informacja, że dana technologia jest znacznie bardziej efektywna od tamtej i że taka, ta technologia jest bardziej opłacalna od innych alternatyw powoduje wzrost częstości świadczenia, stosowania danego leku. I jest to przyznam się szczerze mechanizm bardzo skuteczny o ile świadczeniodawcy i pacjenci mają zaufanie do takiej instytucji, która rekomenduje taką a nie inną technologię.

Grabowski: Kto powinien płacić za raporty, jeśli okaże się, że technologia jest nie skuteczna?

Łanda: Ja myślę, że tutaj powinni przede wszystkim płatnicy zainteresować się technologiami, które już w tej chwili są refundowane, które już są w tej chwili świadczone. Bo tu chodzi jak gdyby o tworzenie listy negatywnej. Za nowe technologie, za analizy tego typu powinni płacić przede wszystkim ci, którzy ubiegają się o ich finansowanie ze środków publicznych.. Natomiast za stare technologie częściowo producenci ale częściowo w wielu tutaj przypadkach kasy będą zainteresowane, wydaje mi się że za zapłacenie analizę efektywności czy efektywności kosztowej, dlatego, że oszczędności, które są związane z takim raportem kilkadziesiąt bądź kilkasetkrotnie przewyższają koszt opracowania samego raportu.

NN: Ja myślę, że tu jest jeszcze jedna dosyć ważna sprawa, mianowicie kto ma wykonywać tego typu analizy. Z mojego rozeznania wynika, że w Polsce jest grupa kilkudziesięciu dobrze przygotowanych osób, które mają formalne studia zagraniczne,

pewne doświadczenia również pewne publikacje w tej dziedzinie. Istnieje, wydaje mi się realna możliwość stworzenia poza krakowskim kilku centrów, które mogłyby tego typu działalność ekspercką świadczyć. I w Łodzi widzę takie możliwości i z całą pewnością w Warszawie, myślę że to byłoby korzystne dla całego systemu dlatego, że pewien monopol jest nie bezpieczny. Dlaczego nie chce w tej chwili tutaj szczegółowo uzasadniać? Tutaj powinna wyjść inicjatywa od kierownictwa resortu, bo to jest w interesie całego dobra publicznego całego społeczeństwa, żeby promować skuteczne i opłacalne kosztowo technologie medyczne, jak również różne inne działania lecznicze. Także to wydaje mi się jest realne stworzenie tego typu, formalnych czy nie wiem czy niekoniecznie sformalizowanych bardzo grup eksperckich, które mogłyby tego typu działania prowadzić. Chce przypomnieć, że co najmniej kilkanaście osób z Polski skończyło studia podyplomowe na Uniwersytecie w Yorku, w Wielkiej Brytanii. Chyba najlepszym tego typu, przynajmniej jednym z najlepszych na Świecie, a przynajmniej najlepszym w Europie, w ośrodku, w którym tego typu badaniami i działalnością ekspercką się zajmuje, dziękuję.

Łanda: Jeśli mógłbym. Wydaje mi się, że w czasach globalizacji nie powinniśmy się w ogóle tylko ograniczać do rynku polskiego i polskich ekspertów, którzy robiliby tego typu analizy i myślę, że jeżeli będzie taka potrzeba, jeżeli jest to działalność rzeczywiście opłacalna i racjonalna dla systemu, z pewnością znajdzie się bardzo wiele również firm międzynarodowych i zagranicznych, które chciałyby tego typu analizy dla, na polskie zamówienia i w oparciu o polskie dane kosztowe przeprowadzić.

Grabowski: Ja myślę, że to jest problem kryteriów które by opisywały jakość tych analiz, że ona jest dobra lub zła, prawda. I jaka ma być konsekwencja faktu, że ktoś produkuje złe analizy, dokonuje nierzetelnych zestawień, przeszukań, porównań i co z tego ma wynikać, jaka jest pętla zwrotna wykrycia takiego faktu.

NN: No tak ja myślę, zgadzam się z panem. Myśl, że takie możliwości są by zlecać te analizy za granicą, czasem to byłoby wskazane przy bardzo kontrowersyjnych problemach gdzie środowiska eksperckie są już podzielone z różnych powodów i z powodu również formalnych i nie formalnych nacisków i wtedy wydaje mi się, że warto byłoby skorzystać z ekspertyz zagranicznych, które trzeba jednak zdawać sobie sprawę, że będą one znacznie droższe. Bo godzina pracy dobrego eksperta to jest nie wiem 200\$ a w Polsce jak państwo doskonale wiecie można te rzeczy kupić taniej i nie koniecznie będą one gorszej jakości no i to jest rzecz do rozważenia. Na pewno wszyscy się tutaj zgodzimy, że tego typu ekspertyzy są konieczne i przede wszystkim rzeczywiście powinny być finansowane przez producentów leków i technologii nowych, którzy chcą uzyskać wejście na rynek, nie koniecznie ich refinansowanie na przykład w przypadku leków ale dopuszczenie do obrotu w ogóle. Bo możemy sobie wyobrazić, że technologie i gotowi są zapłacić sami klienci, czy pacjenci ale chodzi o to żeby zezwalać na stosowanie technologii o nie udowodnionej skuteczności czy niebezpiecznych dla zdrowia i tutaj jest obowiązująca na świecie praktyka w wielu krajach, że rzeczywiście te koszty pokrywają zainteresowani, których na to zresztą stać. To są globalne koncerny, które mają ogromne wolne środki finansowe. Byłoby to korzystne i dla naszego państwa i dla instytucji naukowych i eksperckich, które tym się zajmują.

Grabowski: Rozumiem, że lista tematów nam skończyła się, lista tematów do poruszenia, dziękuję serdecznie wszystkim uczestnikom, którzy znaleźli trochę czasu i

mam nadzieję, że w przyszłości jeżeli będziemy organizować tego typu spotkanie możemy również na państwa liczyć, dziękuję bardzo.

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