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Review

APPROACHES FOR HEALTH TECHNOLOGY ASSESSMENT IN EUROPE: SITUATIONAL ANALYSIS

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Summary

Health technology assessment (HTA) is a process, which should answer the question "Is a given health technology/medication worth its price for the value it provides?" In the spirit of the amendments to the Bulgarian Health Insurance Act and institutionalization of HTA, our team prepared this situational evaluation aiming to throw light on the practices and approaches to HTA in European countries. As a whole, we can identify two types of agencies that perform it: those servicing the population of an entire nation or a region, and those working at the level of hospitals or a network of hospitals. All the agencies studied have two common characteristics. First, they were created with a non-profit purpose and second, all of them are financed by public funds in a variety of ways. It also becomes clear from the comparative analysis performed that the ways HTA is conducted in Europe differ from country to country. Irrespective of the variations, the common aspiration is that the value for a patient, to which the approved health technologies contribute, should be greater than the price to be paid for them. Bulgaria is may be the last EU state to implement HTA in its domestic legislation and this also gives the advantage of having and using the experience of the other countries. Establishing an independent structure, which is appointed to prepare local health technologies assessment would result in transparent decision-making, participation of all concerned parties and optimization of the budget for medicines regarding the effectiveness/benefit ratio, as well as expenses.

Key words: health technology assessment, cost effectiveness, HTA agencies, agencies for HTA

Introduction

Health technology assessment (HTA) is a multidisciplinary science whose role is, by detailed analyses, to study the medical, social, ethical and economic effects of the development, distribution and use of various health technologies [1-3]. The purpose of HTA is to serve as bridge between the world of science and the world of decision-making [4]. The process develops very rapidly worldwide and we see a rapid growth determined by the necessity of managerial, clinical and political decisions. The amplification of HTA is also due to the evolution of the methods of assessment in social

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and applied sciences, including clinical epidemiology and health economics. The decisions healthcare managers and politicians have to make become more and more important because the costs of wrong resolutions get higher and higher [5-10].

Health technology assessment is a process, which should make judgments if a particular health technology/medication is worth its price for the value it provides. It is a more sophisticated type of pharmacoeconomic studies [11]. In the spirit of the amendments to the Bulgarian Health Insurance Act and the institutionalization of HTA, our team prepared this assessment, aiming at throwing a light on the practices and approaches to HTA in European countries.

Assessment of the health technologies in Europe – review

Types of HTA agencies

As a whole, we can identify two types of agencies: ones servicing the population of an entire nation or region (national or regional ones), and others working at the level of healthcare institutions or a network of hospitals. The latter type facilitates the decisions of hospital management and the management of clinical activities. The addressees of national and regional agencies are the various management levels, at which decisions in the field of healthcare are made. On the one hand, the agencies aim at facilitating the process of decision-making at macro level, which affects large groups of people with health insurances with relevant funds. On the other hand, a part of the work of the agencies is directly related to the micro level in the process of making medical decisions at patient level, i.e. decisions made by clinicians when using a particular health technology. The users of the output data, resulting from the activity of the agency, may expect a different effect from its work and the dissemination of the data obtained is diverse [12-19].

Financing of the HTA agencies

All studied agencies have two common characteristics. First, they were set up as non-profit organizations. Second, all of them are supported by public funds and the ways of financing vary. The main source of financing is the budget for healthcare of each country. This is true for the health care systems financed directly from taxes, as well as for those, whose funding comes mainly from contributions of employers and contributions from individuals. Besides financing by the budgets for health care, some agencies receive additional resources from various public and private funds [20-21].

For example, "Haute Autorité de Santé" (HAS) in France is subsidized by the government (10%). HAS also receives payment for accreditations performed (15%), contributions from health insurances (31%), fees from producers of medicinal products (7%) and revenues from the pharmaceutical industry (34%), which are in the form of taxes on promotional activities [22-23].

The financial resources of the HTA agencies in Europe vary from a little less than 1 million euros annually for most of the agencies, to more than 10 million euros for the national agencies of Holland, Great Britain, and IQWiG in Germany. Even after the relative share of the population serviced by a given agency has been taken into consideration, the range is still quite wide (US$ 0.02 to US$ 0.89 per capita of the population) (Table 1) [24].

The variations in financing may be explained to some extent by the differences in the concepts for HTA. In some countries, the assessments of the agencies are mainly of the secondary type, usually a result of cooperation with experts from the academic field and clinicians in the capacity of consultants. In other countries, the HTA programs finance not only secondary assessments but also a big part of the primary studies, which have been considered significant for the relevant healthcare system.

Activities of the HTA agencies

Depending on the activities of the European HTA agencies, they may be classified into two categories.

Category 1: Organizations focusing mainly on the production and distribution of HTA reports. These include CEDIT (France), SBU and CMT (Sweden), NCCHTA (Great Britain), Ludwig Boltzmann Institut für HTA – LBI-HTA (Austria), Medical Technology Unit – MTU (Switzerland); Agencia de Evaluación de Tecnologí as Sanitarias in Spain, and Deutsche Agentur für HTA (DAHTA) in Germany. All of them were established in the 1980s and 1990s. DAHTA was officially established in 2000, but the project leading to its establishment had produced their first HTA reports in the 1990s. Besides assessing the already registered health

Table 1. HTA agencies in Europe and their financing

Agency	Country	Established	Role	Annual budget (US$, mln)	Serviced population (mln)	HTA budget per capita of population (US$)	Permanent staff (headcount)	Consultants (headcount)
CEDIT	France	1982	Regional	0.34	11.0	0.03	11	yes/no
CMT	Sweden	1984	Regional	1.5	n.a.	n.a.	17	5-8
SBU	Sweden	1987	National	6.8	9.0	0.75	33	300
LBI-HTA	Austria	1990	National	0.93	8.0	0.12	10	yes/no
CAHTA	Spain	1991	Regional	2.4	7.0	0.34	45	150
MTU	Switzerland	1992	National	n.a.	7.6	n.a.	6	60
OSTEBA	Spain	1992	Regional	0.3	2.1	0.14	5	40
AETS	Spain	1994	National	0.6	46.1	0.01	11	80
FinOHTA	Finland	1995	National	2.0	5.1	0.39	18	65
VSMTVA	Latvia	1995	National	0.05	2.3	0.02	8	yes/no
AETSA	Spain	1996	Regional	0.9	7.5	0.12	15	yes/no
NCCHTA	UK	1996	National	21.6	59.8	0.36	36	yes/no
DACEHTA	Denmark	1997	National	3.8	5.4	0.7	15	yes/no
NHSC	UK	1998	National	1.2	50.0	0.02	7	yes/no
AVALIA -1	Spain	1999	Regional	0.35	2.7	0.13	7	yes/no
MTV-Aarhus	Denmark	1999	Regional	n.a.	n.a.	n.a.	n.a.	n.a.
DAHTA	Germany	2000	National	1.5	80.0	0.19	8	yes/no
ZonMw	Netherlands	2001	National	13.5	16.0	0.84	7	yes/no
MTV-Odense	Denmark	2001	Hospital	n.a.	n.a.	n.a.	n.a.	n.a.
A.Gemeli	Italy	2001	Hospital	n.a.	n.a.	n.a.	n.a.	n.a.
KCE	Belgium	2002	National	3.1	10.3	0.3	35	yes/no
NHS QIS	UK	2003	Regional	0.8	5.1	0.16	15	yes/no
NOKC	Norway	2003	National	4.0	4.5	0.89	30	100
ROHTO	Finland	2003	National	n.a.	5.1	n.a.	n.a.	n.a.
UETS	Spain	2003	Regional	0.8	6.0	0.13	10	yes/no
IQWIG	Germany	2004	National	17.0	80.0	0.21	70	yes/no
AHTAPol	Poland	2005	National	3.6	38.2	0.09	40	yes/no
HAS	France	2005	National	1.0-60.0	65.0	0.01-1.2	17	225

technologies, some of those agencies also deal with the processes of identifying newly arisen technologies.

Category 2: Organizations and institutions of a larger scope that involve, but are not limited to only producing HTA reports. For example, the Belgian Federaal Kenniscentrum voor de Gezondheidszorg – Centre Fédéral d'Expertise des Soins de Santé (KCE) is responsible for facilitating decision-making as a result of its work in the field of HTA, preparing guidance for treatment and conducting research in the field of healthcare. Other agencies with a wider scope of activities include the Spanish agencies of autonomous regions – AETSA, AVALIA-t, CAHTA, OSTEBA, SCS, UETS, the Danish Centre for Evaluation and Health Technology (DACEHTA, the German IQWiG, and the Polish Agencja Oceny Technologii Medycznych (AHTAPol) (Table 2).

Norway

In Norway, the activities of the agency are even wider as a result of merging several functions. The Nasjonalt Kunnskapssenter for Helsetjenesten (NOKC) was established in 2004 by incorporation of the former agency for HTA-SMM, HELTEF – the foundation for scientific research in the field of health care, and the Scientific Department at the Ministry of Health and Social Policy. NOKC is also responsible for monitoring the level of satisfaction of patients

Table 2. Review of the institutions performing HTA and analysis of their activities (Europe)

Agency (country)	Established	HTA reports	Review of future technologies	Educational role
CEDIT (F rance)	1982	+	+	
CMT (S weden)	1984	+		
SBU (S weden)	1987	+	+	
LBI -HTA (A ustria)	1990	+	+	+
CAHTA (Spain)	1991	+		+
MTU (Switzerland)	1992	+		
OSTEBA (Spain)	1992	+	+	+
AETS (Sp ain)	1994	+	+	+
FinOHTA (Finland)	1995	+		+
VSMTVA (Latvia)	1995	+		
AETSA (Spain)	1996	+	+	+
NCCHTA (UK)	1996	+		
DACEHTA (Denmark)	1997	+	+	+
NHSC (UK)	1998		+	
AVALIA -t (Spain)	1999	+	+	+
DAHTA (Germany)	2000	+		
ZonMw (Netherlands)	2001	+		
K CE (Belgium)	2002	+		
NHS QIS (UK)	2003			+
ROHTO (Finland)	2003	+		+
UETS (Spain)	2003	+		+
IQWIG (Germany)	2004	+		
NOKC (Norway)	2004	+	+	+
AHTAPol (Poland)	2005	+		+
HAS (Finland)	2005	+	+	
HIQA (Ireland)	2007	+		+

and healthcare professionals.

Germany

Gemeinsame Bundesausschuss – G-BA was founded in 2004 and is responsible for assessment of the technologies in both outpatient and inpatient health care that are reimbursed by the German SHI system. (Table 3). In addition to decisions for reimbursement, G-BA is also accountable for issuing directives on the organizatin and quality assurance of the healthcare system. As a consultant in this activity, G-BA works with representatives of the social health insurance fund (SHI), contractual partners from outpatient and inpatient healthcare, and independent consultants and representatives of patients' organizations.

The German Institute of Quality and Efficiency in Healthcare (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen – IQWiG) performs assessments, including ones ordered by G-BA. Nowadays, IQWiG produces HTA reports for medications, procedures,

Table 3. Criteria for reimbursement is some European countries

Categories	Germany	Denmark	Spain	France	Hungary	Italy	Netherlands	Poland	England and Wales
Medical activity									
Inpatient	A; CE; Ex; N	B; N	C; E; N; S	N; E; S	C; E	A; N; B	C; E; N	ns	B; C; N
Outpatient	CE; Ex; N	B; N	C; E; N; S	N; E; S	C; E	A; E; N; B	C; E	ns	C; E; N
Rehabilitation	CE; Ex; N	B; N	N	N	ns	A	A	ns	E; N
Continuous nurse care	C	N	N	N	ns	A; E; N; B	ns	ns	E; N
Auxiliary care	A; Ex	N	C; E; N	N	ns	C; E	ns	ns	E; N
Medical products for outpatient use									
Medications, etc.	E; N	B; CE; N	B; N; U	C; E; I; S	B; CE; E; N; S	C; E	B; CE; I	C	B; CE; E; N; S
Devices, etc.	E; U	U	CE; E; S	E; U	ns	N; C	C	N; C	E; N; S

Abbreviations
Criteria: A – appropriateness; B – budget; C – cost; CE – cost/effectiveness ratio; E – efficiency; Ex – expediency; I – innovation; N – need; S – safety; U – usefulness; ns – not specified

organizational matters (e.g. maximum allowable volumes of procedures), and recommendations for clinical behavior.

France
In France, there are three institutions dealing with decisions in reference to reimbursement. The decisions for reimbursement and price formation are closely related, but different committees are responsible for making these decisions.

A special committee of HAS advises the Ministry of Health as to whether a particular type of consumable or medicine should be reimbursed by the public fund. The Medication Committee (Commission de la Transparence) consists of representative of the social health funds, the Government and contractual partners of outpatient and inpatient medical care, clinicians and experts in the field of pharmacology. The Consumable Committee ("Commission d'Évaluation des Produits et Prestations") includes academic experts and representatives of the social health funds, the industry, the Government, clients and patients [22]. After some health technology has been approved for inclusion in the reimbursement list, another committee ("Comité Économique des Produits de Santé – CEPS") sets the price after negotiations with the producers. Finally, the social health funds set the percentage of reimbursement (Union Nationale des Caisses d'Assurance Maladie – UNCAM) (Table 3).

Conclusions

The comparative analysis presented in this paper shows that the ways of conducting HTA in Europe differ. Irrespective of the differences, the idea they share is that the value of approved health technologies for patients should be larger than the price to be paid. The health authorities in the various countries have found a modus operandi depending on the needs and expectations of society. At the same time, the development in the healthcare systems is very dynamic, i.e. evolution of the process of health technology assessment has not ended.

Bulgaria may be the last EU state to introduce HTA but this also may give the country the advantage of having the experience of the other countries, and use this experience.

The establishment of an independent structure, which can prepare local health technologies assessment, including data transfer and adaptation of practices of other countries, preparation of manuals for making HTA reports and guidance for those structures [25], would result in transparent decision-making, participation of all stakeholders and optimization of the budget for medicines regarding cost-effectiveness ratio and expenses.

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