Health economics and health technology assessment in Central and Eastern Europe: a dose of reality

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Published online: 24 June 2012
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Introduction

It is an opinion widely shared, at least among health economics (HE) and health technology assessment (HTA) experts, that the need for HE and HTA is increasing due to two main factors. One is the more and more serious budget constraints of the recession, the other increasingly demanding policy makers and funders who require greater evidence for new and existing therapies. But is this really the case? Are policy makers and funders aware of the potentials and limitations of HE and HTA? If they are convinced and committed to use HE and HTA results, is there sufficient capacity at national level to provide the required HE and HTA evaluations both in terms of quantity and quality? Are these methodologies and results recognised or valued during the decision making process?

More than 20 years ago, in the early 1990s when the political systems in Central and Eastern European countries changed from socialism to democracy, many of us believed that HE and HTA would spread quickly around the region. We thought HE and HTA institutions and university departments would be established and that this development would be boosted further by the pure fact of EU enlargement incorporating all new member states. We had a dream that more and more resource allocation decisions related to drug reimbursement and public health would be based on results, provided nationally, from HTA and HE.

At that time we had no doubt that, due to sustainable economic growth, fresh money would be allocated to different parts of health care systems under the title of “resource allocation”. Our methodology was set to assist decisions under this economic condition. Various projects funded by the European Commission, and worldwide (INAHTA) and European networks (EunetHTA) pushed things further. However, this dream is still sluggish in coming to fruition. Still today, the role of HE and HTA is very limited in the new member states. Only two countries, Poland and Hungary, have established HTA offices and some university departments of HE. In the following, we will see what has been achieved so far, look at possible explanations for this slow development, and discuss the main issues still waiting to be resolved.

Health care financing and drug budgets in recession

The economic conditions of CEE countries differ. Poland enjoys economic growth and stability while others are in recession. In Hungary, for instance, the drug reimbursement budget of the National Health Insurance Fund Administration has been cut drastically. The 2011 amount of 376 billion HUF (€1.3 billion) was reduced to 277 billion HUF (€0.94 billion) in 2012 and, apart from this reduction, the government is planning to decrease the subsidy of pharmaceuticals further by 77 billion to 200 billion HUF (€0.68 billion) for the year 2013. That means a budget cut of almost 50 % (47 %) within 2 years (the real value is even lower due to the effect of inflation). There are, at least in theory, three possible scenarios in this situation. One is that the government will set the prices of the drugs (price cut) as is happening in Greece. However, there might be some side effects of this solution strategy:

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medicines that are no longer eligible for reimbursement might become unavailable at the decreased price, creating shortage. This might lead to politically sensitive situations, for instance where life-saving drugs are involved, as has already happened with blood-thinner and oncology medications and asthma inhalers in Greece. There are already some signs that it may be difficult to decrease prices further. Blind bidding has been introduced in Hungary and, as a result, some cancer drugs are out of stock or pharmacists cannot order as many units as they need. Therefore, we assume that further significant price decreases in Hungary are not very likely, whilst a 10–20 % reduced price will not impact much on the size of the drug reimbursement budget cut. The second scenario suggests that the projected impacts will be much higher co-payments and patient payments. The third scenario is to try to spend better, to get better value for the budget spent on health care and drugs. This is a very attractive scenario, especially if the consequences of the financial crisis on patients (more limited access to medical care and worsening outcomes) are taken into consideration. However, we have difficulty in implementing this concept due to the shortage of basic epidemiologic data, information on patient access and outcomes in the countries of this region. Patient access is related to equity; however, measuring equity in health care is a true challenge, not least because there is no consensus on how to define and measure this concept. Whatever happens, economic growth or recession, the consequences are likely to remain unknown, simply because we do not collect data and do not measure outcomes. Although statistics and registries in this region do exist, most of the data are self reported, often with poor or unknown validity as there are no quality checks. Local data would be needed for evaluation of the transferability of HE and HTA results from other jurisdictions to CEE countries.

Poland: HTA assisted decision making

The Agency for Polish Health Technology Assessment (AHTAPol) (Agencja Oceny Technologii Medycznych, AOTM) was created in 2005 to advise the Ministry of Health (MoH) on reimbursement decisions. In 2007, the first version of HTA guidelines was published and the first set of reimbursement recommendations were issued. In 2009, AHTAPol became an independent legal entity with its own budget, operating at national level under the supervision of MoH. A new channel of financing was opened to fund AHTAPol: manufacturers are obliged to pay a fee after every submitted reimbursement application, the fee for which cannot be higher than 150,000 PLN (€34,884). In 2010, the average was €22,100/submission. The main body of AHTAPol is the President who, based on

the position of the Transparency Council, prepares a recommendation concerning reimbursement of a given health technology. The Transparency Council consists of 20 members appointed by MoH and is a successor to the Consultative Council, which worked as advisory body to the President of AHTAPol from 2007 until February 2012.

The AHTAPol team consists of 60 qualified employees and the annual budget is €2.45 million. The current version of HTA guidelines was published in January 2010 [1]. HTA guidelines explain how to prepare the HTA reports that are submitted to MoH and then transferred to AHTAPol, where the process of appraisal takes place and recommendations are issued. There is a standardised format for recommendations: statement, justification, objective, health problem, description of technology, alternative technology, efficacy, safety, relation of cost to health effects, impact on payer budget, recommendation from HTA institution from other countries, course of preparing the recommendation.

These methodological guidelines are similar to guidelines from other countries. One important issue is that the threshold of $3 \times \text{GDP per capita/QALY}$ or LYG has been published in the Reimbursement Act [2] and is taken into consideration in the appraisal process of the HTA reports and then in the recommendations issued by the President of AHTAPol.

Between 1 January 2007 and 31 May 2012, 421 reimbursement recommendations were made. Recommendations of the Transparency Council and meeting proceedings are publicly available from the AHTAPol website. From June 2012 all other materials (HTA dossier submitted by the applicant, assessment reports, comments on the assessment reports sent within 7 days after publication) will also be published on the AHTAPol website.

The review of AHTAPol recommendation for drug therapies issued in 2008 [3] showed that the number of positive and negative recommendations was 88 and 63, respectively. Altogether 151 drug therapies with distinct indications were used for the purpose of the study, using the checklist by Raftery [4] for evaluation. Reasons for negative recommendations were: insufficient clinical data (32 cases), poor efficacy or safety (19 cases), unacceptable cost-effectiveness/cost-utility ratio (9 cases), an unacceptable budget impact (2 cases) and risk of off-label use (1 case). From the 88 positive recommendations, 33 were classified as for use with major restrictions, 40 with minor restrictions and 15 without restrictions. The comparison of 67 recommendations issued in 2008 in Poland with the Scottish Medicinal Consortium's decisions [5] showed that, among clinical reasons, inappropriate comparators was the most frequent cause of negative recommendations and rejections in Scotland; however, in Poland safety concerns were the most oft-cited reason for rejection. This

is an interesting result but unfortunately no further explanation is available. What could explain this difference? Patient safety is part of the first three hurdles, as EMA registration acknowledges and guarantees that patient safety is acceptable based on data from clinical trials. Other sources of patient safety information are patient registries, from where real-world data can be extracted. However, data from registries are rarely available when recommendations are made for the first time about the new drug. Decision makers in Poland presumably have different concerns and policies on safety when interpreting safety data of the EMA registered drugs. Safety could be the most important concern, and reducing safety risk as close to zero as possible is one possible HTA and decision-making approach. However, this is a trade-off and we have to give up a certain amount of benefit if we refuse to accept risk. Generally, the concept here is to consider risk/harm and benefit when calculating outcome. This is only a general rule, which is not always applicable, as decisions have to be made differently from case to case, taking into consideration legal issues, ethical, cultural concerns, patient preferences and other factors. In terms of economic reasons, poor economic data and unacceptable budget impacts were mentioned more frequently in Poland, and insufficient justification of treatment costs in relation to benefit was the main reason for negative suggestions in Scotland [5].

Czech Republic

An HTA Agency has not yet been established, and there are no officially accepted guidelines for HTA or HE. The Czech Health-Economy Society issued the second version of “*Guidelines for conducting health economic analyses*” in 2011 [6]. However, those have not been officially accepted and published by the authorities of the MoH and/or the State Institute for Drug Control (Státní Ústav Pro Kontrolu Léčiv SUKL). These guidelines describe types of analysis, with preference given to cost-effectiveness and cost-utility analysis (CEA and CUA), comparator, and modelling techniques. The guidelines are aligned strongly to ISPOR methodology and follow a descriptive, methodological approach. The recommended discounting level is 3–5 %. In terms of costing it is stated that all relevant costs must be included in the analysis. HE analysis has to be a standard part of any company submission, which requires (1) incentive (bonus) to basic level reimbursement; (2) “second level” reimbursement; or (3), if products are assessed as single technology, they should not be included in reference groups (including innovative drugs). No specific type of health economic analysis is required, but CEA and CUA are preferred. Recently SUKL tends to prefer CUA with cost/QALY as outcome. No guidance has yet

been published to support this approach. From January 2008 until November 2011 (valid amendment to Act 48/1997 version), cost containment was applied and only cost-saving interventions were (by law) considered cost-effective. In reality, a number of interventions with cost/QALY above $3 \times$ GDP per capita/QALY (especially in oncology) were granted reimbursement during this period. The valid amendment requires a comparison with a current standard, funded from public sources. It defines cost effectiveness as cost saving or with incremental costs, which are in the range “of incremental costs per effect of similar interventions publicly funded”. No explicit or implicit willingness-to-pay (WTP) threshold has been published or even established; however, ongoing discussions over the past 18 months indicate a consensus of CZK 0.9–1 million/LYG (€34,901–38,779), based on a hemodialysis model, and acceptance of $3 \times$ GDP per capita as being cost-effective in terms of cost/QALY. These data, however, have not been published, although they were discussed on several occasions. A budget impact analysis is an integral part of any submission that has an impact on public expenses.

Hungary

Named after the European Transparency Directive and Technology Appraisal Committee (TAC), the Transparency Secretariat (TS) was formed in 2004 at the National Health Insurance Fund Administration (NHIFA) and Ministry of Health to assess the therapeutic value or clinical benefits of drugs and to compare them with existing therapies in order to prepare decisions on reimbursement applications. Also in 2004, the National Institute for Strategic Health Research of the Ministry of Health (NISHR) was established to assist with decision making in four major areas of health policy and financing: medical informatics and information policy, health economics, health services research, and HTA. Regarding the latter, the Office of Health Technology Assessment (OHTA) has the task of providing an organizational framework for technology assessment that serves as the basis for the medicine subsidy approval policy of the NHIFA, and performing the related medical and economic assessment duties. This development is well supported by the Act No. CLIV of 1997 on Health, which clearly states among the basic principles that healthcare services have to be evidence-based and cost-effective. In 2010, the MoH became part of the Ministry of National Resources (Nemzeti Erőforrás Minisztérium), which was renamed the Ministry of Human Resources (Emberi Erőforrások Minisztériuma) in May 2012, as state secretariat and OHTA became part of the National Institute for Quality and Organisational

Development in Healthcare and Medicines GYEMSZI (Gyógyszerészeti és Egészségügyi Minőség és Szervezetfejlesztési Intézet) and re-named Technology Appraisal Head Department (TAHD) (GYEMSZI Technológia-értékelő Főosztály). TAHD carries out technology appraisals, a formal procedure including the evaluation of the submitted economic dossier that is a legally required part of each company submission. In 2002, the Ministry of Health released guidelines for conducting health economic analyses that determine the methodological issues of health economic evaluations [7]. A description of these guidelines was published in the *EJHE* at 2002, but there are major differences between the official Hungarian and the English versions. Of these differences, the most important is that no threshold was set in the guidelines published by the MoH; however, an explicit threshold of 3.2 million HUF (€10,811) was presented in the publication by Szende et al. [8]. The guidelines expired in 2004, but were extended until 2006. Since then there have been no official guidelines in Hungary. During 2007–2008, advisors from an HTA consultancy agency and a university were invited to create a checklist to evaluate the methodological quality of the company submissions for reimbursement. The health economics and technology assessment community was not involved in this process. This checklist is used for internal TAHD evaluation of the submitted economic dossiers of the pharmaceutical companies, and this checklist changes from time to time, according to the head of TAHD. This checklist is not available to the pharmaceutical companies, researchers or the general public.

TAHD staff, which consists of four physicians, six economists, and one engineer with some training of HE and HTA, prepare the evaluation report. Evaluation reports made by TAHD are submitted to TAC. Recommendations or reimbursement decision details are not publicly available.

Between 2004 and 2010, altogether 997 company submissions were received by OHTA and evaluated by its staff. The scope of evaluations covered drugs from 2004, medical devices from 2007 and medical and health care technologies (such as valves, pacemakers etc.) from 2010. Companies have to pay a contribution fee, which is, for instance in the case of drugs, normal procedure and amounts to 1.5 million HUF (€5,068) per submission. In 2004, 20 % of these submissions contained HE analysis, while in 2010 this rate was more than 80 %.

A small-scale study was conducted in 2006 with 25 drugs undergoing a “normal” evaluation process during a randomly selected period during 2005 to investigate the current practice of decision making in drug reimbursement. Twenty-five submission dossiers of medicines were reviewed, including (1) the economic dossier submitted by companies, (2) evaluation by the governmental HTA

agency; (3) the opinion/guidance of professional bodies, and (4) summaries and decrees made by the NHIFA, Department of Reimbursement.

The main aim of this research was to investigate whether the size of the target population, the budget impact and health economics evidence were clearly available or not. (These are required by the official methodological guidelines.) In 48 % of cases, the OHTA did not accept the estimated size of the target population, and the number of patients in the target population was not available in 16 % of cases. Estimation of the budget impact for Hungary was not available in 64 % of cases. Although the Hungarian guidelines on health economic analyses requires the use of local data, this criteria was not fulfilled in 92 % of cases. The results of health economics analysis from other countries were applied without any adaptation to the Hungarian reimbursement authority. What is even more notable is that the size of the target population remained unknown in 64 % of cases [9].

In Hungary, 50 economic dossiers submitted by pharmaceutical companies and market licence holders for reimbursement of pharmaceuticals in 2007 and 2008 were evaluated in order to identify the most common methodological problems. The aim of this study was to develop a relevant Hungarian checklist for the critical appraisal of economic evaluations. The results of this study have not yet been published [10]. Between January and June 2008, the official resolutions of 29 pricing and reimbursement submissions were analysed. The average length of pricing and reimbursement was 172 days (from 43 to 534 days). The authors concluded that transparency directives were implemented only partially in Hungary, stating that “The appropriate use of scarce public health care resources cannot be justified in case of positive decisions and there is no remedy for negative reimbursement decisions.” [11].

Other Central and Eastern European Countries

The idea of implementing HTA-based reimbursement practices has emerged from time to time in other countries in Central and Eastern Europe, such as Bulgaria, Croatia, Romania, Slovak Republic and Serbia. Some elements of HTA are in place in these countries; however, no comprehensive and transparent system exists.

HE and HTA; politics, health policy and financing

The main question here is, what is the value of HE and HTA for politicians and policy makers? As we see, HE and HTA are still not seen as useful and valuable tools by decision makers. In Poland and Hungary quite a lot of

activities are ongoing; however, it is difficult to judge the value of these materials due to the fact that reports are not available for the public.

There is an important question related to the previous issue, touched on by Buxton et al. [12] who ask, “What values do the public want their health care system to use in evaluating technologies?” The authors express their concern that, because the current economic evaluation may not be consistent with society’s health values, the public would not naturally choose the most efficient allocation of resources and maximise the QALY gained.

Methodological issues

Epidemiology of various diseases, disease severity, mortality and costs of diseases and treatments are essential for health economic analysis, for modelling or even model adaptation.

In these countries valid data are rarely available. The same can be said for the standard practice of different diseases. This is important because identifying treatment comparators is one of the first steps in health economic analysis. In Polish guidelines, the primary comparator is the existing practice: “It is the procedure that will likely be replaced by the assessed technology in medical practice” [1]. Standard or existing practice can be described as the most frequently used, the cheapest, the most efficient, compliant with the standards and guidelines from clinical management. This comparator description is from the Polish guidelines, but we are wondering whether “or” or “and” are supposed to be read in between items of the characteristic of the good comparators. If we are free to choose (and we would want to sell something to the HTA agency), we would choose the most frequently used and cheapest drugs as comparators, forget efficiency for a while, and have a good chance to show that our drug is more cost-effective. If we want to show a good budget impact analysis result, we might make a different choice. The choice of the “most efficient” option is a difficult one. We have to prove that the drug has the best clinical efficacy/safety characteristics. As discussed above, safety concerns are the most often cited reason for rejection in Poland. “Most efficient” is supposed to mean most cost-effective, or at least a drug with favourable costs and treatment outcome. Treatment outcome can be extracted from clinical trials (efficacy) or from real local practice (effectiveness). Effectiveness data could come from registries and from studies, and should be adjusted by risk and categories of disease severity, the amount of co-morbidity, compliance, and so on. In no country are all these inputs readily available when needed. These data, and guidance for their use, should be provided by an agency financed

through a central budget, as is the case in a number of other European countries. In the absence of such data, we definitely need, at the very least, more coherence through transparency, the chance to learn from submission to submission, and we should preferably use the same or similar data and methodology.

Another important issue is cost. There is an unknown difference between official retail price lists and the real costs of products, due to the business practices of pharmaceutical companies. This difference is not known, but we can assume that it is significant. As long as this practice exists, no really valid health economics analysis can be done in this region.

Transparency, accountability

Most cost-effectiveness, cost-utility analyses and budget impact studies have been performed in Canada, the US, UK, Northern Europe, The Netherlands, Germany, and France. These countries differ considerably from Central and Eastern European countries in GDP per capita, health and social care systems, demography, morbidity, health status of the population in question, comparator medications, standard practice, prescription behaviour of doctors, reimbursement mechanisms of medications and financing of health care institutions, price level, unit costs, and direct and indirect costs. Thus, transferability of these health economic results to jurisdictions of Central and Eastern Europe is rather limited. Furthermore, there are noticeable limitations in terms of HTA capacity (number of professionals and budget to generate new country-specific HTA results) in the Central and Eastern European region. Hence it is essential to find out how these published results can be made more transferable and more useful.

For this purpose, a wide spectrum of deterministic factors has to be analysed, such as country-specific guidelines (both professional and financing), financing mechanisms and incentives derived from this, patient data, access to health care facilities, etc.

To make studies from other countries more transferable is essential. This activity needs a high level of coordination and cooperation among key players. Good epidemiology data and cost data (cost-book) are needed of course, but until we have such data we should at least try to be coherent, using the same data and the same concept of analysis in different HTA materials submitted by companies. That is why the full economic dossier and evaluation report should be available publicly at the end of the decision-making process, or at least within an acceptable time frame. In CEE countries, very few bits of data that fall under company confidentiality and are still sensitive data when the acceptable time period is finished are used. The

same can be said for economic models established under the “one size fits all” concept. More and more local model adaptations are seen, with sometimes 100 or more assumptions, but the model structure is usually not described, and the transferability of the key assumptions and applicability of the results are not known. Models are sometimes not documented appropriately and are not, or only partially, available, and HTA agencies and funders accept this behaviour. We think this is unacceptable when discussing taxpayer-financed health care systems. All important information about the models and adaptations must be made publicly available.

This would be very helpful to all key players. Pharma companies nowadays are wondering and trying to find out what is required from the MoH and funders in order to have their drugs reimbursed. They invest significant resources into this exercise. Most would be willing to invest more to create better economic dossiers. This is hardly new for them as this is what they are used to in many other countries. Clear incentives from policy makers and funders would assist in the transfer of company knowledge to other jurisdictions, in this case to Central and Eastern European countries. Incentives and motivation is the key to transferability, we should not forget that. If there is no requirement for high quality HE and HTA studies and reports, these will not be created and delivered. The opportunity to learn from previous HE and HTAs would speed up the learning cycle of HE and HTA professionals, and more and better materials would be created. Appraisal would be easier and quicker for the same reason.

And finally, three more thoughts

The first concerns affordability, the second the impact of threshold value, and the third the relationship between appropriateness of transferability and the outcome of the medical treatment or the health care system in general.

With respect to affordability, Culyer [13] stated: “Affordability lacks an economic definition. It is sometimes used to convey an absoluteness about purchasing plans (particularly in the negative, as in “we can’t afford that”). This is an absoluteness and denial of trade-off possibilities that will not appeal to many economists. In the present context, however, the meaning relates to a judgement (after all relevant trading-off has been done) that something is not “worth” the purchase. In the context of health care purchasing by public bodies on behalf of whole communities, it may mean that benefits forgone in the shape of other public programmes or private consumption are judged to be higher than the benefits to be gained from the programme (or the size of programme) under consideration”. We assume that affordability is related to the

impact of threshold value. Vermer et al. [14] highlighted that the role of the threshold value for a QALY has been given little consideration—this could be one of the causes of country-specific differences in cost-effectiveness. The authors state that this issue should be taken into consideration in transferability checklists.

Fixed cost-effectiveness thresholds might result in different affordability through different threshold values in different areas and treatments in the health care system.

Another, largely ignored, issue is the relationship between health economic analysis or transferability process and the outcome achieved. The appropriateness of the HE and HTA analysis or the transferability method checklist can only be justified by the results in practice—we have to know the outcome. Interestingly enough, this relationship became apparent during the recent health care reform in Hungary. One of the important elements of this reform from the point of view of this paper is the permit for insurers to sell private health insurance products. Various packages are available in the market already. The importance of the quality of health care services, the usefulness of the pay-for-performance concept and method are being recognised by both insurers and providers. We assume that cost-effectiveness, and health economic analysis in general, will become more recognised as a useful tool.

In summary

A lot has happened in HE- and HTA-assisted decision making in a group of countries in Central and Eastern Europe, especially Poland and Hungary. We have some achievements so far, and have gained a significant amount of experience. In the beginning, we understood HE and HTA as technical tools. Of course technical tools are important, but today we recognise much more the importance and challenges of societal perspectives, values, expectations and other more complex institutional and system culture-backed issues on which the whole castle of HE and HTA should be based. It could be said that in the first two decades we learned how to analyse, and tried to transfer technical details; now more is needed in order to make these elements function well.

Acknowledgments The authors are grateful to Ildikó Kaposi (American University in Kuwait), Jana Skoupa (Pharmaprojects, Czech Republic) and Imre Boncz (Pécs University, Hungary) for their contribution.

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