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Clinical and economic assessment of medical devices

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Summary

Resources for health care are inevitably limited; thus, it is necessary to make decisions on a regular basis, what health care will be reimbursed from the public health insurance, and what care will be behind the limits of possibilities of the particular society. Since 1980s, methods of health technology assessment (HTA) have been developed, and HTA has become a standard policy in evaluating pharmaceuticals worldwide. A desirable application of the same methodology to medical devices appeared extremely difficult, though. A possible solution is an application of the multiple-criteria decision analysis (MCDA). We recommended two MCDA methodologies for completion of HTA studies in medical devices, the first suitable for the national regulator, while the other corresponding to the needs of individual hospitals (within so-called hospital-based HTA). The results of the second approach led to an interest in establishing HTA units in large Czech university hospitals. Furthermore, the presented study deals with particular, but important issues concerning HTA in medical devices. These include pricing, public procurement, allocation (diffusion) across the country and different types of hospitals, and early HTA (definitely interesting for the industry). Thus, the study based on original results of the CzechHTA team from the Faculty of Biomedical Engineering covers all aspects of the technical and economic assessment of medical devices specified for the conditions of Czech health care system.

Souhrn

Zdroje, které jsou k dispozici pro zdravotní péči, jsou nutně omezené; je tedy nutné pravidelně přijímat rozhodnutí, jaká péče bude hrazena z veřejného zdravotního pojištění, a jaká péče již překračuje možnosti dané společnosti. Od 80. let 20. století jsou vyvíjeny metody pro hodnocení zdravotnických technologií (HTA), které se celosvětově stalo standardní metodou pro hodnocení léčivých přípravků. Ukázalo se však, že žádoucí využití stejných postupů pro zdravotnické prostředky je mimořádně obtížné. Možným řešením je využít metod vícekriteriálního hodnocení (MCDA). Pro vytváření studií HTA jsme navrhli dvě metodiky založené na MCDA; první z nich je vhodná pro národního regulátora, druhá odpovídá potřebám jednotlivých nemocnic (v rámci HTA zaměřeného na nemocnice, HB-HTA). Výsledky druhého přístupy vedly k zájmu o vytvoření oddělení HTA ve velkých českých fakultních nemocnicích. Předložená práce se dále zabývá konkrétními, ale důležitými otázkami v oblasti HTA pro zdravotnické prostředky. Sem patří otázky cenotvorby, pořizování zdravotnických prostředků ve veřejné sféře, rozmístění přístrojové techniky v rámci státu a podle typu nemocnic a tzv. včasné hodnocení (které je rozhodně zajímavé pro průmysl). Práce založená na originálních výsledcích skupiny CzechHTA na FBMI tak pokrývá všechny otázky technicko-ekonomického hodnocení zdravotnických prostředků, a to konkretizované pro podmínky českého zdravotnického systému.

Keywords

medical device, health technology assessment, HTA, cost-effectiveness, MCDA, pricing, technology diffusion, early assessment

Klíčová slova

zdravotnické prostředky, hodnocení zdravotnických technologií, HTA, nákladová efektivita, vícekriteriální hodnocení, tvorba cen, rozmístění zdravotnické techniky, včasné hodnocení

Content

List of abbreviations

AHP	analytic hierarchy process
C/E	cost-effect ratio
CEA	cost-effectiveness analysis
CTU	Czech Technical University
CUA	cost utility analysis
FBME	Faculty of Biomedical Engineering
HB-HTA	hospital-based health technology assessment
HRQOL	health related quality of life
HTA	health technology assessment
HTAi	Health Technology Assessment international
IKEM	Institute for Clinical and Experimental Medicine
ISG	interest sub-group
MCDA	multiple-criteria decision analysis
MD	medical device
MRI	magnetic resonance imaging
QALY	quality-adjusted life year
TOPSIS	Technique for Order of Preference by Similarity to Ideal Solution

1. Introduction

1.1 Limited health care resources and health technology assessment

The second half of 20th century witnessed an unprecedented development in health care. Its technological basis increased both in knowledge and investment in technology, apparatus and drugs. New inventive drugs, innovative medical devices, pioneering surgical and therapeutic techniques and, last but not least, rapid propagation and easy accessibility of information led, for the first time in human history, to the situation that health care had to be limited due to economic reasons.

The economic view of health care funding is rooted in three fundamental observations [1]:

1. Resources are scarce in relation to human wants.
2. Resources have alternative uses.
3. People have different wants.

Already in 1996, Victor R. Fuchs said in his presidential lecture delivered at the meeting of the American Economic Association: *"This economic point of view stands in stark contrast to the romantic and monotechnic points of view that I found prevalent among health professionals and health policymakers. The romantic point of view refuses to accept the notion that resources are inherently scarce; any apparent scarcity is attributed to some manmade problem, such as capitalism or socialism, market failure or excessive government interference."* [1]

Once we agreed that resources for health care are limited, it is necessary to make decisions on a regular basis, what health care will be paid for and what care will be behind the limits of possibilities of the particular society. The tool theory offers for answering such questions is health technology assessment (HTA). It is a multidisciplinary applied field that evaluates and assesses health technologies and interventions in the context of clinical, ethical, economic, social, legislative, organizational and other parameters, the domains of the rating [2, 3].

Medical technologies vis-à-vis HTA include drugs, diagnostic tests including indicators and reagents, devices, equipment and supplies, medical and surgical procedures, support systems, and organizational and managerial systems used in prevention,

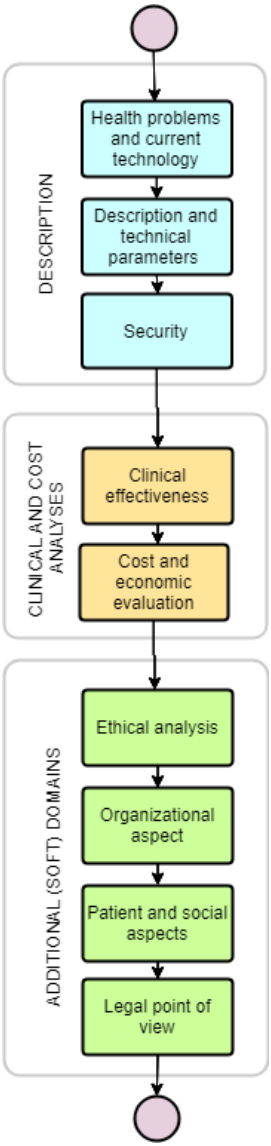

Fig. 1. Domains of the HTA Core Model (after [8])

screening, diagnosis, treatment and rehabilitation [4]. Health technology assessment is the systematic evaluation of properties, effects or other impacts of health technologies. The main purpose of HTA is to inform policymaking (in the broad sense) in health care [2, 5]. Therefore, HTA must always be based on findings and outputs of research and application of scientific methods.

1.2 The HTA Core Model

The EUnetHTA HTA Core Model is a methodological framework developed by the EUnetHTA European network (see https://www.eunethta.eu) to standardize HTA reports within the EU in order HTA studies could be conducted in a structured, uniform format [6, 7]. The HTA Core Model is a registered trademark; its use is subject to a licence. It uses a multidisciplinary approach, and its main objective is to support international collaboration in HTA information production and sharing the results. The model has a structure consisting of nine evaluation domains. Each domain provides tools for tracking the technology description, utilization and impacts from many angles. Figure 1 shows the individual domains of the HTA Core Model [8] and their structure.

2. Specificities of medical devices affecting HTA methodology

Since the beginning of 1990s, HTA has become a standard policy in evaluating pharmaceuticals worldwide. As a

rule, the cost-utility analysis (CUA) is used relating costs to "life years in full quality" gained, so-called QALYs, a patient self-reported quality-of-life parameter. We described QALYs, their definition, application, and the criticism of the QALY concept in [9].

However, application of the same methodology to medical devices (MDs) appeared challenging [10-12]. The following list [13] is a modification and completion of Drummond´s reasons, why assessments of MDs differ from that of pharmaceuticals [11]:

- many MDs are diagnostic,
- often the outcome cannot be separated from the treatment,
- MDs may have multiple applications,
- short life cycles, frequent modifications,
- existence of "learning curves",
- dynamic pricing,
- non-existence of a steady-state period to evaluate the device in a randomized controlled trial,
- impossibility of blinded studies,
- the efficacy depends on how the device is used (e.g. the skill and experience of the staff),
- implementation of a new therapy involving a device can have wider economic implications,
- equivalent clinical evidence may not be available for all products,
- MD´s prices are likely to change over time, as new upgraded products enter the market.

The problem of the necessity of a modified HTA methodology to be applied in MD has not been adequately studied for a long time. However, in the years 2013-2015, four EU FP7 projects (MedtecHTA, ADVANCE-HTA, INTEGRATE-HTA, AdHopHTA) focused on MDs [14], which moved the topic to researchers´ spotlight [15-17] including the earlier published results [10, 11, 18-20]. The most topical problems in MD assessment were summarized in recent papers [12, 17, 21-23].

A possible solution may be application of the multiple-criteria decision analysis (MCDA) [24, 25]. It enables us to take into consideration more parameters, and to weight them according to expert opinion preferences. The parameters can comprise not only clinical outcomes, quality of life and/or life years of the patient (particularly QALYs), but also technical data [13, 26].

In a short time it appeared that the question was not whether to use MCDA, but how to do it [27]. There were two development lines. In the first, MCDA was taken as the main and only method used in device assessment, while the other recommended staying with the application of the cost-effectiveness analysis (CEA), i.e. the relation of costs and suitably quantified effects (outcomes) of the intervention. The later method that allows for a separation of costs and effects has been slowly prevailing [28].

3. HTA for medical devices (CzechHTA results)

Our CzechHTA research team at the Faculty of Biomedical Engineering (FBME), CTU in Prague, has been developing HTA methods for MDs since 2009. In 2014 we published a comprehensive analysis how to apply HTA to MDs, including the methodology for MCDA application [18, 29]. This methodology included two approaches for two distinct situations.

The basic structure of the evaluation process is common for both approaches. The process consists of four steps:

1. formulation of the problem;
2. formation of the expert panel;
3. selection of assessment criteria;
4. evaluation of individual variants, their prioritization and/or ordering.

While the first approach (developed by Ilya Ivlev and his colleagues) is a detailed (but slow) process based on a carefully selected expert panel and finding a firm consensus using the Delphi method [30, 31], the other one (developed by Ivana Juřičková-Kubátová and her colleagues) was tailored to be appropriate for a rapid operative decision-making under time pressure [26, 32] (see Figure 2 for its process analysis).

Both methods were repeatedly applied to various MDs, mostly as master thesis projects in the study program Systematic Integration of Processes in Health Service at FBME CTU. Before continuing in the theory, I´ ll show the basic principles on two examples from these theses.

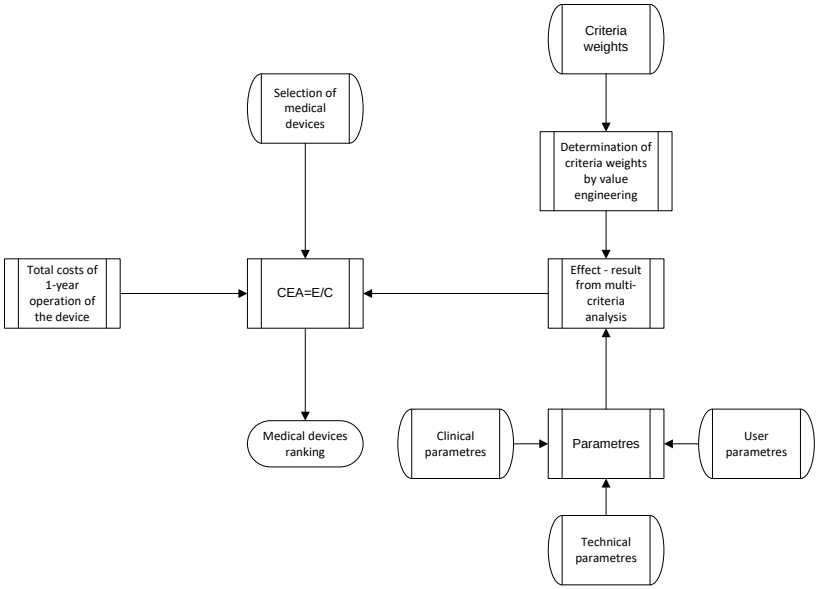

Fig. 2. Flowchart of the MD evaluation process [18, 26]

3.1 Example 1: A rapid MCDA application: selection of a C-arm for specific conditions of a particular hospital [33]

The CEA (the ratio of the costs and the effects) combined with MCDA methods (used for quantification of the effects) was used to select a C-arm suitable for the Cardiac Centre of the Institute for Clinical and Experimental Medicine (IKEM) in Prague. Five systems were compared (three Philips and two Siemens). Cost data were collected from two Prague hospitals (the Královské Vinohrady University Hospital and the IKEM) where the particular systems were operated. Only direct medical costs were taken into account, when the costs of individual variants were determined as an average cost of one examination over the device lifetime.

The effects were evaluated by MCDA methods. Non-standardly (due to research reasons), four methods were applied (combinations of two methods for criteria weight determination and two methods for variant evaluations according to the individual

criteria) to evaluate the effects; their results were eventually compared.

Six evaluators for MCDA were chosen ad hoc (included cardiologists, interventional radiologists and biomedical engineers from hospitals and suppliers). Six criteria were selected for the comparison: monitor size, resolution, angulation, depth of C, exposition time, user comfort (radiation dose and service speed, originally chosen, were removed due to ambiguity). Two methods (awarding points and Saaty´ s method) were used to determine criteria weights. In the next step, again two methods (TOPSIS and the weighted sum method) were used to determine values of individual criteria.

Only minor differences (where the devices proved almost identical) were observed between individual MCDA methods. As the result, one of five examined C-arms was recommended as the most cost-effective (for concrete results see [33]). This result was confirmed by pair-wise calculated incremental cost-effectiveness ratios (ICERs) to have a better view of the differences between the variants.

3.2 Example 2: a ranked list of MRI systems [31, 34]

The objective of the study was to make up a ranked list of MRI systems for (contributory) regional hospitals in the Czech Republic.

For the purpose of developing the expert group using the methodology described in [35], sixty potential experts (physicians, biomedical engineers, radiological assistants, medical physicists, etc.) in 34 Czech health facilities operating MRI systems were asked to fill out a web-based questionnaire. Nineteen (31.7%) potential experts responded. The qualitative composition in terms of the jobs and positions of the potential experts who responded corresponded to the composition of the potential experts to whom the questionnaire was sent. The expert group was selected based on eight criteria, and each expert was given a weighting factor regarding the importance of their judgments.

The list of key specifications that play the most important roles in selecting MRI systems for purchase by hospitals were defined based on the literature review (see [31]). Specific values for the default specifications were obtained from a report published

by the ECRI Institute [36] and from the MRI manufacturers and official suppliers in the Czech Republic.

A set of 13 MRI systems and 14 key default specifications that play the most important roles when hospitals select MRIs were defined. Each expert provided a matrix of pairwise comparisons of the criteria and comparisons of the MRI systems with respect to each criterion. Judgments of the experts were combined according to their weighting factors.

Several MCDA methods were compared to select the best variant (device) and the MRI ranked list. It was shown that the AHP best suited the former task, while the TOPSIS method is best for generation of the ranking of all variants. Concrete results (purchase recommendation of particular MRIs and a ranked list of all 13 assessed systems) can be found in [31] and [34]. The study was carried out in 2015; thus, it does not comprise newer models of MRI systems.

3.3 Methodology for the rapid MCDA

The above described example (Chapter 3.1) has all typical features of the method. Let us suppose that a hospital wants to select a MD that would suit them best, when a handful of producers and models are available. They create an ad hoc expert panel, usually comprised of the hospital employees. It is recommended that the panel always comprised physicians, economists and biomedical engineers, while other professions may be involved if appropriate.

The expert panel first defines criteria that will be considered for the device selection. Usually a larger list of technical, operational and clinical criteria is created. Value engineering methods are used to determine the weights of importance for individual criteria. A shorter list of criteria with the highest weights is selected to be used in the assessment of the variants. A MCDA method is used to choose the most suitable variant.

Kubátová [37] used the sensitivity analysis to recommend the most convenient methods. She recommended application of Saaty´s matrices for the value engineering (criteria prioritization) step, and the TOPSIS method for the MCDA (variant selection) step.

3.4 Multiple-criteria decision analysis supporting the selection of MDs under uncertainty

Ivlev [29, 31] suggested a more sophisticated, but time demanding process (see the example in Chapter 3.2). Its main characteristic is finding consensus among the expert panel members, when the analytic hierarchy process (AHP) and the Delphi method are used to identify experts' preferences and for expert consensus building.

The appropriate panel composition remains a controversial issue requiring critical reflection. The principal problems are (i) the size of the panel, (ii) the expertise of the panellists, (iii) the consistency of the panel, and (iv) whether the selection of panellists should be internal or external. Ivlev et al. recommended a solution [35] stressing the formal side of panellists' expertise, and used it in practice [31]. However, this method does not fully correspond to the current requirements on health care system management in the Czech Republic. Although it is definitely less dependent on personal preferences of those creating the panel, the criteria require a revision and redefinition closer to the Middle European standards [18].

On the contrary, application of the AHP has been advocated and encouraged by many researchers worldwide [38-40]. It seems to be the best possible method suggested for MD selection up to now, although it is not fully rationalized [41]. However, if combined with the Delphi method to reach consensus, it is quite time consuming, as the example showed.

3.5 Utilization of the MCDA methods for HTA studies

The methods described in 3.3 and 3.4 can be used to quantify effects of medical interventions. Then, these values can be used in a cost effectiveness analysis (CEA), the core method of HTA studies.

In HTA studies for drugs, QALYs are traditionally used for measuring the effects. In that case, QALYs are expressed as a product of the health related quality of life (HRQOL) and the life expectancy, when the HRQOL values are based on patient self-assessment. QALYs were considered to be the utility values (CEA was then called cost-utility analysis), which enabled an interpretation within the economic utilitarian theory. Let us remark that

QALYs are also a MCDA method involving in a simple way two variables (HRQOL and life expectancy) [9]. However, the concept of QALYs have been criticized from different angles. The main reasons are as follows [9]:

1. The HRQOL values are neither stable nor robust;
2. Some applications of QALYs in HTA are not in agreement with our moral intuition; the idea of justice in health care among the general public differs substantially from the approach based on QALYs;
3. The definition of QALYs is based on the assumption of a linear relation between the life expectancy and its quality given a fixed value of QALY; this assumption is probably not correct.

Moreover, QALYs appeared unsuitable for assessment of medical devices, above all the expensive equipment that is used repeatedly in many patients (e.g. imaging devices, operation robots, radiotherapy accelerators). We discussed the reasons in detail in Chapter 2. Let us stress now, that such devices are usually expensive technologies requiring the perspective of the hospital or region as a whole. Thus, the primary goal of HTA studies is not maximization of the cost-effectiveness ratio, but a decision about procurement and/or incorporation of the device. The clinical benefit is not expressed in terms of quality of life, but in the rate of diagnostic yield. Most of the problems can be overcome if we use MCDA methods and replace QALY values with a multiple-criterial complex variable.

MCDA can combine outcome parameters of the particular therapy with related technical and operational characteristics. It is straightforward that other parameters than the quality of life are important in case of diagnostic devices. MCDA allows to choose the best suited parameters.

There is a drawback of the MCDA approach. The CUA results in the costs of one QALY. It is a simply interpretable variable that allows a comparison of very different interventions (for example answer the question when a consultation with a physician is better (read: more cost-effective) than administration of antidepressants). This allowed to set a cost-effectiveness threshold in such a way that an intervention was considered cost-effective if its cost-effect ratio (C/E) was below the threshold, and ineffective, if

C/E was above the threshold. Interventions that were cost-effective were reimbursed, while the ineffective were refused to be reimbursed [42]. This approach was criticized for an alleged violation of human rights, and was banned in the United States and in German. At present, the cost-effectiveness threshold is legally applied only in Slovakia, although it is unofficially used in many countries incl. the Czech Republic [42]. In the Czech Republic, such unofficial threshold is considered at three-fold GDP per capita (a little above CZK 1.2million at present).

Application of most MCDA methods does not allow for such a general comparison of all interventions, but only direct comparisons within one study are possible. However, we do not consider it a drawback due to the controversy of QALYs and due to a special character of cost-effectiveness reports for MDs.

4. Hospital-based HTA

The original purpose of HTA was to inform the (national) regulator. In last 15 years, a different application of HTA methods has been more and more used: a support to strategic decisions at the level of a hospital [43]. However, this application called hospital-based HTA (HB-HTA) has different goals and uses different tools than classic HTA studies. HB-HTA provides information on a local level, and thus it is typically used in the field of strategic planning or decisions, purchase and operation of expensive medical devices, and for general organizational solutions in hospitals [44].

In Czech hospital environment, HB-HTA proved useful above all in medical devices management [13, 45]. In this area, HB-HTA studies have been welcomed in Czech hospitals, while the general HTA has been rather disregarded at the national level [46].

In 2006, an "interest sub-group" (ISG) was created at HTAi, which started a more systematic approach to the issue. This ISG noticed that "*...the tendency is not the result of any reduced role for HTA as a support to policy decision making (macro level), but it is related to the increasing consciousness that health technologies' value should be judged in connection with specific organizational contexts.*" [47] The ISG recognized four models of HB-

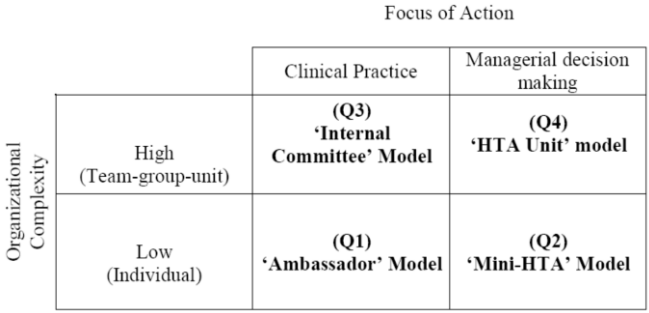

Fig. 3. HTA organizational models [47]

HTA organizational models [47]. For HTA organizational forms depending on the organizational complexity and the focus of action see Fig. 3.

Some Czech hospitals showed interest in HB-HTA implementation, above all on the managerial level. These tendencies are most progressed in the Motol University Hospital and in the General University Hospital in Prague. Both hospitals consider implementation of the HTA Unit model; up to now, the hospital managements collaborated in numerous pilot studies (e.g. [45, 48-51]). Some pilot studies were created also for other hospitals (e.g. [52-55]). The listed studies present some of the reports produced in collaboration with the CzechHTA group at FBME CTU; they are focused on medical devices management and many of them show possible applications of MCDA methods.

HB-HTA appears to be a promising field of application of HTA methods, especially if applied to medical devices [56-59].

5. Procurement and price issues of medical devices

Let us finish the paper with two chapters that will provide only limited solutions, but present a challenge for future research in MD (technical and economic) assessment. First, there is the vast area of MD purchasing, where above all the problems of price transparency and MD diffusion appear important. These problems will be discussed in this chapter. Second, the procedures called broadly "early assessment" were recommended quite recently and will be discussed in the next chapter. They suggest moving the MD assessment period to the late development

phase, which would allow launching the product to the market with a preliminary assessment. However, it is still in the stage of academic research.

5.1 Medical device procurement

Procurement of expensive medical devices is a sensible issue. It is much more urgent and topical in the Czech Republic, where (due to general economic situation) costs of MDs (in terms of purchase prices and operational costs) represent a much greater share of health care budgets than in the West. However, the purchased systems differ from each other, and prices are mostly kept confidential. The procurement of MDs has been broadly discussed [60-62], while the concerned professionals do not dispose with sufficient amount of reliable information on prices and other parameters necessary in the process of MD purchasing. In the Czech Republic, there is a visible interest of the national authorities to make the MD procurement more transparent. These efforts cover three areas:

- rules for MD public procurement, tools supporting public procurement,
- MD price analysis,
- regulation of MD allocation.

After the period of a quite wild situation with MD procurement in Czech hospitals within European operational programmes in the first decade of this century [19], it was clear that this field needs some support and probably also some kind of regulation. Within the CzechHTA group, Donin with colleagues recommended a comprehensive method for MD procurement tracking in the Czech Republic [61, 63]. Their method was created to assess procurement efficiency and to provide information to different actors during MD purchases in future. The core of their system is created by data from public procurement databases and related e-marketplaces completed with data from other open sources. Over this database they suggested several standard MCDA-based reports that enable to analyse the procurement data and to formulate hypotheses about procurement efficiency [63].

5.2 Price transparency and analysis

The above described system collects quite extensive data about realized MD procurements, while the most important parameter is the purchase price. Unfortunately, this very piece of data is usually unavailable. Next to the unwillingness of producers as well as health care facilities to disclose the realized prices, there are a few objective reasons why the prices are not directly comparable, including

- different configuration of the equipment,
- possible inclusion of extra software, spare parts and/or consumables,
- training options,
- prolonged guarantee,
- above-standard service agreement,
- dynamic price development, etc.

However, frequent doubts about the effectiveness of MD procurement procedures affecting health care budgets and unexplained variations in MD prices [19, 64, 65] led to debates concerning the transparency of MD prices. In 2007 the U.S. Congress was discussing the bill of Transparency in Medical Device Pricing Act [66]. Senator Grassley introduced and justified the bill saying: "*Hospitals have no way of knowing what a fair market price for a medical device is, because in this one industry there is a veil of secrecy over pricing information.*" As a result, hospitals "*are involved in one-sided negotiations with medical device manufacturers. …Many hospitals pay absurdly more than others for the same medical device*" [64]. His words hold true still today.

Donin, Barták and Kneppo [67] suggested a novel method for MD price estimation. They recommend to search open sources (public-procurement databases, scientific papers, HTA studies, professional reports, and Internet) for price data and subject them subsequently to critical assessment incorporating the reliability of the information. They provided a self-contained methodology and applied it to the tomotherapy equipment as a case study.

5.3 Medical devices allocation

Doubts have been expressed not only about the pricing, but also about the necessity of MD installations. There is a suspicion that some medical equipment were purchased just to increase the prestige of the respective hospital or to fulfil ambitions of a surgeon, without a real need rooted in the health care process. Such practices may lead to differences in health care accessibility, but also to overconsumption of some treatment modalities, and ineffective spending. Such a situation was discussed e.g. in relation to MRIs [68, 69] or da Vinci robots [70-72].

A too dense allocation (diffusion) of medical devices can lead to excessive requirements on the health care budgets. The problem is not only in the procurement costs, but above all in regular operational costs for staffing, maintenance, spare parts, consumables, etc. The availability of a new modality gives rise to its more frequent utilization, when some interventions may be unnecessary. At present we do not fully understand the factors potentially driving adoption and diffusion of medical devices [22]. A solution is often seen in a kind of regulation. This is also the way chosen by the Ministry of Health of the Czech Republic that established the Board for Medical Devices Allocation (the "MD Board") as a consultative body of the Minister (see [73]).

The original idea of an equal coverage of the country (based either on the distance or on the population density) appeared inadequate. First, the type of the health care facility should be taken into account (e.g. the centres of highly specialized care with the minimum requirements on equipment defined by legislation); second, there may be operational limitations (e.g. staffing and quality management may be the reason for MRI installation preferably more pieces in larger centres than densely in the country). This is in contradiction with the MD Board´ s rule of procedure, when individual applications are decided in the order they were delivered. Even if the Board members try to do their best, this procedure does not allow for a systematic approach. There is a real challenge for the academy to draft and put through intermediate plans for individual modalities, and the future installations should be then guided by such plans. Even then the MD Board may fulfil an important coordination role.

6. Early HTA

Due to specificities of MDs (see Chapter 2), especially a narrow time window of unchanged MD stable operation due to learning curves, incremental innovations and dynamic pricing, carrying out HTA studies for MDs is a quite challenging task, and their results have only a very limited time validity [16]. Prof. IJzerman and his colleagues of University of Twente, NL recommended to do the first HTA study still during the MD´ s development [74-76]. Although their primary objective was to maximize the return on investment and societal impact of R&D, researchers from academia suggest that such early HTA might affect the introduction of new medical devices to the market, and be interesting for customers (health care facilities) as well as the national regulator [77].

The early HTA reports are rarely disclosed, as they contain sensitive market information. Thus, it is not clear, how much they are utilized by MD producers. Markiewicz et al. [78] tried to answer this question, however in the specific Dutch market.

The academically interesting topic of early HTA has not found much utilization in practice yet. There are still more questions than answers. A possible way beneficial for MD developers may be utilization of existing HTA reports covering MDs close to that under development, and to complete missing data with results from mathematical models [79].

7. Conclusions

Although it may seem unethical, due to financial requirements on budgets, economic considerations must be incorporated into decision-making in health care. Since medical devices consume a fair share of the health care budget, economic and cost analyses are an important part of clinical engineering.

Based on research results of the CzechHTA team at the CTU Faculty of Biomedical Engineering in Kladno, we can formulate the following conclusions:

1. HTA and cost analyses can provide different stakeholders with valuable information. It is worthwhile to work towards implementation of HTA structures in the Czech Republic. Establishing a HTA agency and accepting national HTA guidelines would be beneficial also for a comprehensive assessment of medical devices.

2. Special methods are necessary above all for the assessment of outcomes (effects) of MDs. MCDA methods have been proved to suit well this purpose; as an added value, they allow incorporation of technical and medical (diagnostic and therapeutic) criteria next to generally used (patient-self-reported) quality of life and life expectancy (expressed as QALYs). Also the HTA Core Model must be adapted if used for MDs.

3. HTA reports describing MDs find its application both at the national regulator´ s level and at the level of individual hospitals or their consortia. Hospital-based HTA has established itself during last 15 years. It is used above all by hospital management for strategic decisions incorporating medical devices. In the near future, HTA units will appear in the largest hospitals, focused strongly on planning, purchase and operation of medical devices, which will be viewed as a collaboration opportunity for academia.

4. Procurement of medical devices (incl. public procurement, price transparency, MD allocation strategy) presents a handful of open problems that are topical and urgent. The best possible price estimation and strategic recommendation concerning numbers and allocation of individual expensive modalities belong to the main challenges faced by the researchers.

5. Early assessment of medical devices already in the late development phase seems to be a promising solution to the problems with MD assessment. The methodology of such reports should be prepared in collaboration with MD producers. It would also be beneficial to harmonize regulatory, reimbursement and evaluation processes for MDs.

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