Specificities of Medical Devices Affecting Health Technology Assessment Methodology

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Abstract. Health Technology Assessment developed out of pharmacoeconomy; although it is routinely used for all health technologies incl. therapeutic interventions, preventive measures etc., its methodology fits best for drugs. Medical devices have their specificities that affect significantly all processess, where they are involved. The differences between medical devices and drugs from the perspective of HTA have led to a special methodology used by NICE. However, the main challenge remains to be how to calculate and express the effects (outcomes) of a particular device. The generally used QALY concept is not much suitable for medical devices, as they frequently do not directly affect the quality of life and/or life years of the pacient. The efficiency of a device depends not only on the device itself, but also how it is used (the skill and experience of the surgeon, organization of work on the clinic, etc.). Its effect can be lower radiation, more comfort for the clinician or the patient, better image resolution. We recommend to calculate standard CEA, where the effects are evaluated by means of a combination of value engineering methods and multiple-criteria decision analysis, while costs are evaluted directly (ideally by the micro-costing method). The paper discusses specific features of medical devices, and provides example of a solution.

Keywords: HTA methodology · medical devices · multi-criteria decision analysis · output research

1 Introduction

Health Technology Assessment (HTA) comprises a number of methods for assessing effectiveness, appropriateness and cost of health technologies, i.e. drugs, biologics, devices, equipment and supplies, medical and surgical procedures, support systems, and organizational and managerial systems. It can inform us, which care is efficient from the point of view of the society as a whole [1,2]. 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. It relates costs to gained "life years in full quality", so-called QALYs. Such analyses are used not only in OECD countries, but all over the world, even in countries as Bolivia, Ghana, Indonesia or Kazakhstan.

For biomedical engineers, the name may be rather confusing. The word *technology* is used in much wider sense that engineers are used to. In English, *technology* is an equivalent for two expressions, as they exist in German and other European languages: *Technik* and *Technologie*. While engineers usually understand *Technik*, the meaning in HTA is *Technologie*. Therefore, we will speak about *medical devices* (sometimes equipment or apparatus) if we address just the subject of interest of biomedical engineers, and the word *technology* will be reserved for the general concept.

Medical devices can be divided to those applied to a single patient, and those used repeatedly. While the former group allows assessment of clinical outcomes similarly to drugs, the situation is much more complex in the latter group. These are usually expensive technologies requiring the perspective of the hospital or region as a whole. Thus, the main goal of HTA studies is not maximization of 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. An important issue is also the moral lifetime of the device; rapid upgrades pressurize the researchers into assessing devices immediately, without much experience, and in a shorter time, which does not allow for sufficient clinical experience.

CUA is a special case of the evaluation called cost-effectiveness analysis (CEA) [3]. In CEA we relate outputs measured in various units (not necessarily in QALYs) to costs. Hence, we have a theoretical tool to deal with medical devices. Nevertheless, it is questionable which parameters should be used as outputs (called often effects in CEA). The multi-criteria decision analysis can be a solution.

Measurement of effects in interventions based on medical devices has been recently given attention. Special sections were organized e.g. at the 2013 HTAi Annual Meeting in Seoul, or the 2013 ISPOR Annual European Congress in Dublin. Next to drugs, also therapeutic interventions (e.g. surgery procedures) seem to have no problem with QALYs. The question arose whether the situation with medical devices is singular. The answer is "no", as also other diagnostics (e.g. laboratory methods) have hit similar limitations. Maybe only diagnostic devices have problems, and the line is between diagnostic and therapeutic methods. Nevertheless, at present we deal with medical devices as a group, and try to find modifications of pharmacoeconomic analyses useful in assessment of medical devices generally.

2 Differences Between Drugs and Devices

Recently, Santos, Tavares et al. published a series of papers describing specificities of medical devices from the point of view of product development process [4,5]. They point out above all that medical devices create a regulated industry, similarly to automotive or nuclear industries, which is a very dynamic branch with permanent changes and short lifetime of products. Manufacturers have many obligations even after selling the device, namely post-market surveillance and adverse event reporting. In case of adverse events, they should take an action. Moreover, the field is very sensitive to ethical and economic issues. Similar problems appear if we decide to submit medical devices to HTA methods.

HTA was used mainly for pharmaceuticals for a long time. With raising prices of instrumentation, the need of cost analyses appeared also in medical devices. From the beginning it was obvious that although the general HTA methods can be applied equally, there are a number of inherent characteristics specific to the technology, which makes the assessment of the (effectiveness and cost-effectiveness) evidence of medical devices somewhat more challenging to assess [6]. In 2009, *Value in Health* published two papers summarizing arguments for equal or different character of drugs and medical devices in economic evaluations [7,8].

While Taylor and Iglesias [7] stand up for equal approach, Drummond et al. [8] listed main problems that a researcher meets when assessing medical devices. The following list is a slight modification of their reasons, why assessments of medical devices differ from assessments of pharmaceuticals:

- many medical devices are diagnostic, hence the outcome cannot be separated from the treatment and, moreover, most such devices have multiple applications;
- due to a short lifetime of medical devices, their frequent modifications, and the existence of "learning curves", there is unlikely to be a substantial steady-state period, during which the device could be evaluated in a randomized controlled trial;
- in addition, it is usually difficult or even impossible to undertake blinded studies with medical devices;
- the efficacy of a device depends not only on the device itself, but how it is used (e.g. the skill and experience of the surgeon);
- implementation of a new therapy involving a device can have wider economic implications;
- equivalent clinical evidence may not be available for all products, making comparisons difficult;
- prices are likely to change over time, because new better products enter the market, or because of the ways, in which procurement takes place in many health care systems.

Both papers [7,8], as well as papers by Santos et al. [4,5], discuss the need to reconsider the regulatory regimens of medical devices that are not as developed as those of pharmaceuticals. In their current status, at least in Europe and North America, these regimens provide unclear incentives to R&D, licensing, price competition, and generation of robust clinical evidence.

The situation mirrors in special methodology for HTA studies focused at medical devices. The most detailed handbook was published by NICE in 2011 [9]. Nevertheless, the number of HTA studies focused on medical devices is much smaller as compared with drugs or therapeutic procedures. The exceptions seem to be DaVinci robots and a comparison of different kinds of stents [10], both therapeutic applications with an effect to individual patient´s quality of life. Thus the uncertainty concerning the methods applied to medical devices outcome evaluation probably causes that medical devices are more scarcely assessed.

3 Multi-Criteria Decision Analysis

A solution to the situation could be the utilization of multi-criteria decision analysis (MCDA). It enables to take into consideration more parameters, and to weight them according to expert opinion preferences. The parameters can comprise technical data, clinical information, and quality of life and life years of the patient (particularly QALYs).

The possibilities of MCDA have been studied recently. Frequently discussed approach is a total replacement of CEA with MCDA [11,12]. However, this approach challenges serious consideration of cost data [13]. Instead, we recommend maintaining CEA as the main tool, and utilizing MCDA only for evaluation of technology outcomes (effects). Thus, the value used for decisions will be the ratio of outcomes evaluated by means of MCDA, and costs in their natural expression. Next to MCDA, also value engineering methods can be used [14]. The TOPSIS method proves to be the best for evaluations for device procurement by medical facilities (clinics, hospitals), while analytic hierarchy process was chosen for strategic decisions at the state or region governmental level [15].

This approach gives us the possibility to assess medical devices according to their technical data, which was impossible according to standard pharmacoeconomic methodology. For example, different brands of lung ventilators were assessed using CEA, where the outcomes were calculated by means of MCDA taking into consideration technical data, namely the respiratory rate, tidal volume, expiratory volume per minute, inspiratory flow, inspiratory pressure, PEEP, power input 240 V, and output. It is obvious that these parameters affect significantly the result of the clinical intervention, and hence it is justified to take them into consideration in ventilators assessment.

4 Conclusions

The specificities of medical devices make standard HTA studies difficult, and in many cases practically impossible. Especially the problems with carrying out large randomized controlled trials can be hardly overcome. Even so, we wish to introduce new medical devices into the diagnostic and therapeutic process, and make it possible for patients to enjoy the benefits new equipment can bring them. Moreover, many decisions are taken at the hospital level. The lack of information can cause uneconomical purchases or operation of medical devices [16]. Any possibility to carry out a (partial) evaluation of costs and outputs of the medical device can be very beneficial. We offer an option to do it using MCDA.

Although MCDA brings many new problems (one of the biggest is the composition of the expert panel), it gives the possibility to consider different types of data at the same time. In medical devices, technical data are of extraordinary importance. Thus, even in cases when the standard CUA/CEA is feasible, we may successfully utilize application of MCDA in the outcome research, and end with HTA studies that are much more comprehensive.

Baltussen [11] stresses that today the question does not ask whether to use MCDA, but how to do it. It is reasonable to keep costs and benefits (outcome, effects) of technologies separated. The costs can be calculated traditionally, basically by the micro-costing method from the health care provider. The outcomes of medical devices can comprise technical and clinical data with patient reported quality of life, and provide us with the most complex view of technology benefits.

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