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OBJECTIVES:
Health Technology Assessment developed out of pharmacoeconomy; its methodology fits best for drugs. Medical devices have their specificities that affect significantly all processes they are involved in [1,2]. The differences between medical devices and drugs from the perspective of HTA [3] have led to a special methodology [4]. However, the main challenge remains how to calculate the effects (outcomes) of a particular device. The generally used QALY concept is not suitable for medical devices, as they frequently do not directly affect the quality of life and/or life years of the patient. The efficiency of a device depends not only on the device itself, but also on how it is used (the skill and experience of the surgeon, organization of work on the clinic, etc.). Instead of the QALY gain, its effect can be rather 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 evaluated directly.

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 multiple-criteria decision analysis. 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.

METHODS:
The possibilities of MCDA have been studied recently. Frequently discussed approach is a total replacement of CEA with MCDA [5,6]. However, this approach challenges serious consideration of cost data [7]. 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. This approach gives us the possibility to assess medical devices according to their technical data, which was impossible in the standard pharmaeconomic methodology.

See our poster [8] for more details.

References
5. Baillie, R: Question is not whether but how to use MCDA. ISPOR 16th Annual European Congress, Dublin (2013) http://www.ispor.org