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HTA studies for medical devices incorporating their moral ageing

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As a consequence of the steady technological development, Health Technology Assessment seeks how to address the issue of moral obsolescence in medical devices. Due to specificities of medical devices (short lifetime, learning curve, limited approval process, steady technological development, etc.), it is desirable to take account of moral aging in HTA studies focused on devices. Methods that could be used to evaluate innovations that are brought by a new generation of instruments are not well defined yet. The main result of this study is a suggestion how to measure the value of innovations using the outcomes of a multi-criteria decision analysis.

MRI development HTA 1. whole body MRI 1977 1. commercial MRI in USA (1.5T) 1980 1983 1.commercial MRI in Europe (1.5T) 1. HTA study of MRI 1. cost study of MRI Studies comparing MRI and CT 1992 Functional MRI 3T Magnetic resonance 2000 imaging for clinical use Nobel prize (Peter Mansfield, 2003 Paul Lauterbur) 7T MRI in research centers 2004 Production of low field MRI 2005 was stopped Comparative studies (MRI x 2006 endorectal sonography) RCT COMICE - cost-effectiveness of 2010 high field MRI 2011 Studies comparing 1.5T and 3T 7T MRI in clinical practice??

First, the history of innovations and their incorporation in HTA analyses was studied for three typical devices (MRI, left ventricular assist device – LVAD, stents) with the focus on delays in the particular analyses. Second, based on a literary review, a recommendation was formulated for assessment of devices in the case when innovations appear rapidly after each other.

HTA

Clinical testing of HeartMate LVAD 1986 Clinical testing HeartMate VE 1991 Long-term cost of Hertmate VE 1997 1998 Product HeartMate XVE 2000 Novacor N100 vs. HeartMate VE 2001 Results of REMATCH trial 2003 Clinical testing of HeartMate II REMATCH results evaluation Economics evaluation LVAD as BTT, 2005 BTR and LTCS HeartMate testing for DT 2007 (2007 - 2009)Product HeartWare 2009 Calculating the value of innovation 2010 payments-by-results method HertMate approved by FDA Cost-effectiveness model using

2012

2013

2014

sensitivity analysis

Suggestions for future cost-

effectiveness analysis

HeartMate II. vs. HeartWare

(BTT, DT)

Pilot testing of HertMate III

LVAD development

Current methodologies for medical device assessment do not consider their moral ageing and/or innovations. It is demonstrated that older generations of devices are often being assessed when substantial innovations are already available, without taking them into consideration. Evaluations of innovations should meet the following conditions:

- The change from the original type is concretely indicated.
- This change has a clear consequence (e.g. clinical effects).
- This consequence is quantifiable.

However, such a result can be achieved only rarely, especially in the field of medical devices when the result depends on multiple variables. Classic CEA is usually difficult to apply. Two possible approaches were selected: MCDA applied to the effect side of the CEA (a modification of the method suggested by *Rosina et al.*) [1], and the headroom method [2].

References

[1] ROSINA, Jozef, Vladimír ROGALEWICZ, Ilja IVLEV, Ivana JUŘIČKOVÁ, Cleb DONIN, Nikola JANTOSOVÁ, Jakub VACEK, Radka OTAWOVÁ and Peter KNEPPO. Health Technology Assessment for medical devices. Lékař a technika. 2014, vol. 44, no. 3, pp. 23-36

[2] COSH, Emma, Alan GIRLING and Richard LILFORD. Investing in new medical technologies: A decision framework. Journal of Commercial Biotechnology [online]. 2007, vol. 13, no. 4, pp. 263–271