CZECH TECHNICAL UNIVERSITY
Faculty of biomedical engineering

HTA studies for medical devices incorporating their moral ageing

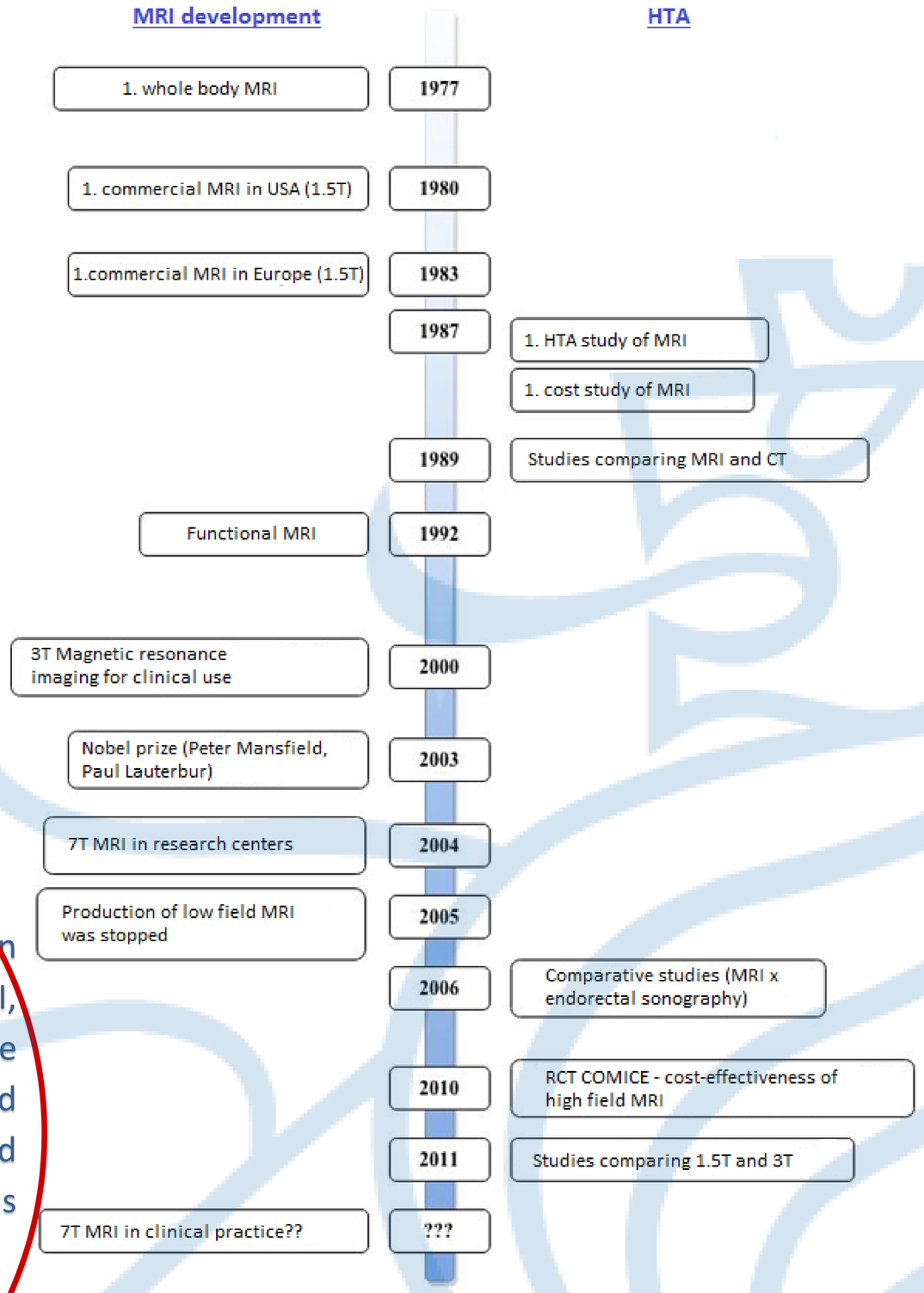
Vladimír Rogalewicz[1], Barbora Fořtová[1], Julia Šimáčková[1], Vojtěch Kamenský[1], Peter Kneppo[1]
rogalewicz@fbmi.cvut.cz, julia.simackova@fbmi.cvut.cz, vojtech.kamensky@fbmi.cvut.cz, kneppo@fbmi.cvut.cz
[1] CzechHTA, Faculty of Biomedical Engineering, Czech Technical University in Prague, Czech Republic

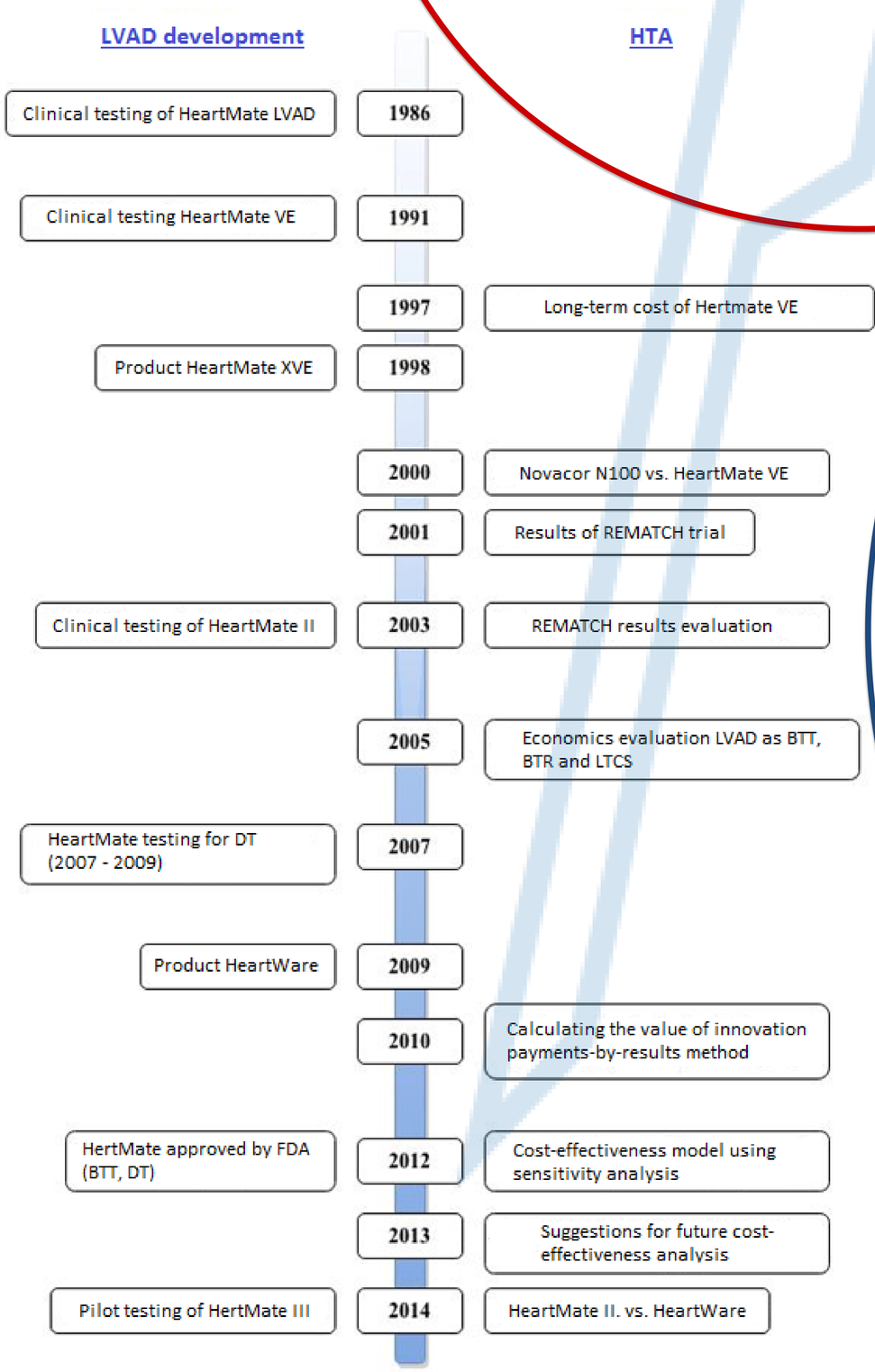
OBJECTIVES

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.

METHODS

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.





DISCUSSION

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, Gleb 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