Scenario drafting as a tool to perform early cost-effectiveness analyses: the case of the 70-genes prognosis signature in breast cancer

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Abstract

Background:

Health policy challenges arise when a promising new technology is in its early development phase and certain stakeholders find reason to speed up implementation in clinical practice. Broad clinical implementation and performing a Technology Assessment (TA) for policy decision making may be premature in the absence of prospective data of the actual benefits. However, if we wait to perform a TA, it might very well be that worthwhile technology is withheld from the public. We used scenario drafting as a tool for the evaluation of a new diagnostic test in the Netherlands, the 70-gene prognosis signature (MammaPrint(TM) for node-negative breast cancer patients. The early implementation of this genomic test is supported by a controlled introduction study; a Constructive Technology Assessment (CTA). Diffusion scenarios, which are commonly applied in industry to anticipate on future development, for instance by Shell, have been applied in this study. Scenarios can be used to monitor the implementation process through the various diffusion phases and can support and identify the need for evaluation or even interfere through formal decision making.

Methods:

We described the development of diffusion phases as suggested by Rogers in 2003. Each diffusion phase of the scenario process, new scenarios are integrated in a (probabilistic) Markov type decision model. Each time, it is calculated whether, based on existing knowledge, the technology is cost-effective and whether (and which) additional evidence is required to support this decision in the future.

The first scenario was written before the prognosis signature was introduced in the Netherlands (mid-2004). A second revised scenario was drafted based on the first experiences in a feasibility study in the Netherlands (MicroarRAy PrognoSTics in Breast CancER (acronym RASTER-study)) (mid-2005). The third scenario was written alongside the MINDACT trial (Microarray In Node-negative Disease may Avoid ChemoTherapy), a randomized, international multicenter trial (mid 2008). This third scenario, consisting of 10 alternatives, was first checked by experts of the 70-gene signature, followed by a questionnaire send to breast cancer specialists, and finally validated in a discussion workshop among 50 breast cancer experts of Europe.

Results:

Although not considered very likely at the time of starting the study in the Netherlands, the first scenario regarding the effects on a discussion on validity of the 70-gene signature proved
to be realistic, especially in Europe. The qualitative scenarios alternatives are quantitatively used in the cost-effectiveness analysis model of the 70-gene signature.

Conclusions:

Scenario drafting can be used as a tool in forecasting new, still dynamic technologies, in order to provide the decision maker with an early view on the potential and likely cost-effectiveness of a technology in clinical practice.

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