

Early phase Technology Assessment of nanotechnology in oncology

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ABSTRACT

To perform early Technology Assessment (TA) of nanotechnology in oncology. The possibilities of nanotechnology for detection (imaging), diagnosis and treatment of cancer are subject of different research programs where major investments are concerned. As a range of bio- nanotechnologies is expected to enter the oncology field it is relevant to consider the various aspects involved in especially early TA. This article provides two cases of early assessment of (predecessors of) nanotechnologies: Microarray Analysis and Photodynamic Therapy implementation, which methodology can be extrapolated to other nanotechnologies in oncology.

Constructive Technology Assessment (CTA) is used for the introduction of technologies that are still in a dynamic phase of development or in an early stage of diffusion. The selection of studied aspects in CTA is based on: clinical aspects (safety, efficacy, and effectiveness), economic (cost-effectiveness), patient related (QoL, ethical/judicial and psychosocial), organizational aspects (diffusion and adoption) and scenario drafting. The features of the technology and the phase of implementation are decisive for choices and timing of the specific aspects to be studied.

A framework was drafted to decide on the relevant aspects. In the first case, early implementation of Microarray Analysis; clinical effectiveness, logistics, patient centeredness and scenario drafting were given priority. Related to the diffusion-phase of Photodynamic Therapy however other aspects were evaluated, such as early cost-effectiveness analysis for possible reimbursement. Often CTA will result in a mixed method design. Especially scenario drafting is a powerful instrument to predict possible developments that can be anticipated upon in the assessment.

CTA is appropriate for the study of early implementation of new technologies in oncology. In early TA small series often necessitate a mix of quantitative and qualitative methods. The features of nanotechnology involved are decisive for the selection of CTA aspects, most likely: safety -especially possible interactions with other technologies-, ethics, cost-effectiveness and patient centeredness.

Key words: *Early Technology Assessment, nanotechnology, oncology.*

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Note: 70-gene prognosis signature, performed by Agendia, Amsterdam; MammaPrint™ Agendia's 'MammaPrint diagnostic service' is cleared by the Food and Drug Administration as a medical device and is ISO-17025 accredited, utilizing a custom designed array chip "MammaPrint™".

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