Implementation assessment of the 70-gene prognosis signature for breast cancer diagnostics

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Background

Constructive Technology Assessment (CTA) is a means to guide the controlled implementation of new developments in the society. We used CTA for a new diagnostic test in the Netherlands, the 70-gene prognosis signature (MammaPrint™) for node-negative breast cancer^{1,2,3}.

References: ¹ Van 't Veer et al., 2004 Nature, ² Van de Vijver et al., 2004 NEJM, ³ Bueno-de-Mesquita et al., 2007 Lancet Oncology

Methods

A multi-center, pre-post controlled prospective study from 2004-2006, using CTA. In the RASTER-study treatment advice was based on guidelines and prognosis-signature.

1. Pre-post structured surveys were conducted concerning changes in logistics and team functioning.
2. Patient centeredness was measured by questionnaires and interviews regarding knowledge, decision making and psychological impact.
3. Scenario drafting took place as a way to anticipate diffusion and possible future developments.

Results

Table 1: Physicians' treatment advice

Table 3: Patients' negative effects after test results

Hospitals	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Total
Inclusions/Signatures	172/106	124/65	194/41	103/52	86/40	59/31	40/19	37/18	27/9	27/14	18/13	13/6	6/3	4/0	4/3	812/427
Duration of implementation (months)	1.2	1.7	0.4	1.1	1.1	0.3	2.3	1.4	9.4	1.5	0.9	1.6	0.7	0.2	4.3	median 1.2 (0.2-4.4)
Prior tissue handling	dry	dry	formal n	dry	dry	dry	dry	formal	dry	dry	formal	dry	formal	formal	formal	6 formal/9 dry
Pathology lab inside/outside the hospital	in	in	out	in	out	in	in	in	in	in	out	in	out	out	in	11 inside/5 outside
Participating team members	5	5	5	6	4	6	9	10	6	5	8	7	4	7	7	median 6 (4-10)
Signature part of treatment advice?	yes	yes	yes	yes	yes	yes	yes	yes	no	no	no	yes	no	no	no	9 yes/6 no
Who decides treatment?	MDM	MDM/ onc	MDM/ surg	onc	onc	MDM/ onc	MDM	MDM/ onc	onc	MDM/ onc	onc	onc	onc	onc	onc	11 onc/2 surg/7 MDM

Table 2: Characteristics participating hospitals

Table 4: Scenario description in Rogers' adoption curve

Results

1. Median implementation-time was 1.2 months. Most changes were seen in pathology processes and adjuvant treatment decision. Physicians valued the addition of the 70-gene signature information as beneficial for patient management. (table 1, 2)
2. Patient data (n=77, response 78%): High risk and discordant clinical low/poor signature patients showed significantly more negative emotions compared to low risk patients. (table 3)
3. Original scenario (2004); discussion on validity resulted in physicians' tendency to treat according to the highest risk. (table 4)

Conclusions

CTA is appropriate for the study of early implementation of this technology. Especially to research clinical effectiveness, efficiency and patient centeredness. The CTA will be continued in the MINDACT-trial; analyzing the cost-effectiveness, updated scenarios, patients' QoL and ethical/judicial aspects.

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