

APPENDIX: Example of a systematic evaluation of a decision aid using MATRIX

Title of the DA: Immunotherapy in multiple sclerosis

A. Appropriateness of goals

Consider publications referring to the background theory, modelling of the DA and exploratory trials, to identify the goals of the DA.

Kasper J, Köpke S, Mühlhauser I, Heesen C. Evidence-based patient information about treatment of multiple sclerosis. A phase one study on comprehension and emotional responses. *Patient Educ Couns.* 2006;62: 56-63; **Kasper J**, Kuch C, Heesen C. Shared decision-making als Interaktionsstil: eine konstruktivistische Perspektive. In: Scheibler F, Pfaff H (editors) *Shared Decision Making. Der Patient als Partner im medizinischen Entscheidungsprozess.* Juventa, Weinheim, München 2003: 34-45; **Heesen C.** 2004 ISRCTN25267500: Informed Shared Decision making In Multiple Sclerosis immunotherapy (ISDIMS). A randomised controlled trial to investigate the effects of an evidence-based decision aid on decision-making about immunotherapy in multiple sclerosis. Available from: <http://controlled-trials.com/isrctn/trial/ISDIMS> (Accessed at 07-18-2007); **Heesen C**, Kasper J Segal J Köpke S Mühlhauser I. Decisional role preferences, risk knowledge and information interests in patients with multiple sclerosis. *Mult Scler.* 2004;10: 643-650; **Heesen C**, Schwickert Y, Kasper J, Köpke S, Scheunemann D, Meyer G, Mühlhauser I. Immuntherapien der Multiple Sklerose. Broschüre für Patienten, Hamburg (2004) Available from: www.uke.uni-hamburg.de/kliniken/neurologie/downloads/klinik-neurologie/ISDIMS_Komplett_08.pdf (Accessed at 07-18-2007); **Kasper J**, Geiger F. Der evidenz-basiert informierte Multiple Sklerose Patient – Risikokommunikation zwischen Arzt und Patient. *Der Klinikarzt.* 2007; 36: 43-47; **Steckelberg A**, Berger B, Köpke S, Heesen C, Mühlhauser I. Kriterien für evidenzbasierte Patienteninformationen. *Z Ärztl Fortbild Qualitätssich.* 2005 99: 343-351; **Heesen C**, Berger B, Hamann J, Kasper J. Empowerment, Adhärenz, evidenzbasierte Patienteninformation und partizipative Entscheidungsfindung – Schlagwörter oder Wegweiser? *Neurol Reha.* 2006;12:235–241; **Heesen C**, Segal J, Reich C, Hämäläinen P, Broemel F, Niemann S, Simon U, Gross R, Kasper J. Acceptability of patient information on cognitive symptoms in MS. *Acta Neurol Scand.* 2006;114:268-72; **Kasper J**, Köpke J, Mühlhauser I, Heesen C. Informed shared decision making in multiple sclerosis immunotherapy: A randomised controlled trial to evaluate a patient decision aid. 4th International Shared Decision Making Conference May 30th – June 1st, 2007, Freiburg.

A1: Does an explicit rationale for the selection of the goals exist?

Yes. Evidence based information is used to promote patients' autonomy supporting decisions suitable to their values and preferences (Kasper 2006).

A2: Are the goals precisely worded?

Yes (Kasper 2007)

A3: Are the goals defined in terms of measurable dimensions?

Yes (Kasper 2007, Heesen 2004)

B. Appropriateness of effect mediators

B1: List the particular goals of the DA into the left column.

B2: Identify the effect mediators and allocate them into the upper row.

B3: Within each **cell** of the matrix, frame questions to explore the mediating mechanisms by which the effect mediators are expected to achieve the goals.

B4: Answer your questions and ascertain the mediating mechanisms:

Goals (precise and measurable)	Categories of <i>effect mediators</i>					
	Contents: Comprehensive (90 pages), evidence based, treatment options exhaustively...	Structure: Structured according to the course of disease and the level of difficulty (three levels)...	Complexity: High complexity: information on clinical studies, measurement, study design, level of evidence...	Setting: Postal delivery before consultation with the neurologist...	Presentation: 100 figures pictograms in ordered form mainly used for risk communication...	Media: Leaflet, working sheet...
1. patients realize role preferences in decision making	a	b	c	d	e	f
2. patient autonomy in the physician patient encounter is enhanced	g	h	i	j	k	l
3. decisions are informed (evidence based)	m	n	o	p	q	r

Questions (examples)

a: Does a rationale exist that such a comprehensive information promotes patients' ability to realize their preferred role in decision making?

The mediating mechanism is plausible. The authors found evidence for a pronounced interest of the target group for comprehensive material (Kasper 2006). Patients with best risk knowledge had highest autonomy preferences (Heesen 2004). However, reliable evidence for this mechanism seems to be lacking...

e / k / q: Is the style to communicate risks and treatment effects using pictograms suitable? Using 100 figures pictograms for risk communication is a common approach.

The use of graphical illustration of probabilities and reference amounts when communicating benefits and harms of medical options enhances informed decision making (Steckelberg 2005). However, different kinds of illustration (e.g. bar charts or stick figures) and different styles of pictograms (for instance sorted or unsorted) exist. The authors do not provide the evidence supporting their choice...

m: Is the content of the DA likely to enhance patients' knowledge?

This is evident from the authors' preliminary studies. The authors found that patients with multiple sclerosis are able to comprehend the information and to transfer their numeracy competence to other issues (Kasper 2006). However, a considerable proportion of patients were not able to understand the core module tested in their preliminary study. Therefore, the comprehensibility of the information presented in the DA can be challenged...

C. Efficacy and effectiveness

C1. Are the outcome measures patient relevant and do they represent the particular goals of the DA?

Yes... (Heesen 2004)

C2. Are the dimensions of goals operationalised appropriately?

Yes. E.g. the primary endpoint was the frequency of coincidence of patients' control preference and actually performed role in the encounter (Kasper 2007). This dimension is assessed using the Degener Control Preference Scale....

C3. Are the outcome measures considered completely (e.g. side effects)?

Not applicable (RCT not published yet)

C4. Are the designs and methods (randomisation, allocation, blinding etc.) of the studies evidentiary?

Yes... (Heesen 2004)

C5. To which extent and referring to which outcomes is the DA effective?

Results of RCT do not indicate that the DA is effective to enhance patient autonomy or the processes of realizing role preferences and decision making (Kasper 2007)...

C6. Is the DA effective under uncontrolled conditions (reproducibility, external validity)?

Not applicable (RCT not published yet)

C7. Do the data on effectiveness of the DA support the intended mediating mechanisms?

No. The authors discuss a Hawthorne effect in their RCT as a possible cause for the missing differences between the study groups. Both groups got an unusual degree of attention by the measurement telephone calls. However, this hypothesis is not proven yet...