

## Informed shared decision making in multiple sclerosis—inevitable or impossible?

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Received 29 January 2006; received in revised form 10 May 2006; accepted 15 May 2006

Available online 2 April 2007

### Abstract

Patients and health authorities increasingly claim active roles in health care decision making processes. As immune therapies in MS are partially effective MS is a prototypic condition for a shared decision making process. The treatment of acute relapses and the initiation, change or withdrawal of so called disease-modifying treatments are key decisions in MS management. We developed two decision aids following the phased approach of the framework of increasing evidence for complex interventions for these key decisions. In prestudies we found that 80% of MS patients demand autonomous roles in treatment decisions which contrasts with a poor knowledge of risks. On the other hand MS patients are not disturbed by evidence-based, balanced complex information. MS patients do understand this kind of information and are able to transfer new abilities to other situations. Currently we study the effects of a 4-hour education programme on relapse management versus an information leaflet in controls in 150 MS patients. In a second trial with  $n=298$  MS patients we study the effects of an evidence-based patient information on immunotherapy on decisional role preference and performance in the patient physician encounter. Results in early 2007 will show to which extent patient education with a focus on evidence-based patient information influences participation in the decision making process.

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**Keywords:** Informed shared decision making; Evidence-based patient information; Multiple sclerosis; Relapse treatment; Immunotherapy

### 1. Introduction

There has been a considerable change of attitudes in the patient–doctor relationship during the last 50 years. Patients and health authorities increasingly claim active roles in health care decision making processes [1]. In 1997 the concept of shared decision making (SDM) was introduced by medical sociologists [2]. As pointed out by Charles, SDM is not the preferable concept in every clinical decision making situation. However, especially in chronic conditions with only partially effective treatments and considerable side-effects it seems an ideal concept. A central feature of SDM is the two-way exchange of information between physician and

patient. In this exchange process both parties have their competencies. At best, both have their insights into the evidence, physicians and patients add their experience and patients their personal values and attitudes to risk. Elwyn et al. [3] have described communicational prerequisites for SDM. They introduced the concept of equipoise, which means that the decision process starts from a point where each option to act has the same value. Within the SDM process the patient is required to define the prioritized criteria and to weigh the different kinds of chance and risk against each other. In this way the uptake of any option is justified.

According to the criteria defined by Charles, multiple sclerosis (MS) is an ideal candidate for SDM since the controversy on the value of immune therapies is still ongoing [4].

Recent studies have outlined communication and information deficits in the care of patients with MS [5–7]. In addition, the need for balanced information and patient

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Table 1  
Criteria for an evidence-based patient information (examples)

|  |
|--|
| Levels of evidence                           |
| Clinical relevant endpoints                  |
| Additional graphical information             |
| Risks in absolute numbers                    |
| Benefits and losses                          |
| Balanced and readable                        |
| Patients involved in information development |

participation in MS decision making has been acknowledged by the NICE MS Management Guidelines for the UK [8].

Studies on patient information in MS have focused on diagnostic issues [7,9,10]. In addition, patient information systems have been developed both by pharmaceutical companies and by various non-profit organisations [11]. However, until today none of the available material fulfils the criteria of evidence-based (EBM) patient information [12] (see Table 1). In particular, the benefits and losses of interventions are not communicated adequately in numbers such as numbers-needed-to-treat or numbers-needed-to-harm.

Since immune therapies are increasingly started while the disease is at an early stage the question about the early need for information and its influence on decision processes becomes more urgent. On the one hand, at this early stage information may evoke disturbance and anxiety in patients viewing potentially bad courses of the disease. This could lead to increased uptake rates and overmedicalisation. On the other hand, information potentially helps patients to develop realistic expectations concerning the treatment options. These are prerequisites for an elaborated decision making process [13]. Realistic information may help to prevent patients with unrealistically optimistic expectations of the treatment from stopping treatment early or from failing to take up medication which could help them.

It is axiomatic that patients cannot express informed preferences unless they are given sufficient and appropriate information [14]. Carefully developed information about the prognosis of the disease and the effects of medications including the knowledge of risks are important prerequisites for decisional competencies. Evidence-based information may enable patients to participate in the decisional encounter with the physician more autonomously.

It has been hypothesised that evidence-based risk communication increases the sense of control, alleviates anticipatory reflection and induces a reflection on personal values leading to a two-way exchange between physicians and patients [14,15]. A systematic review has concluded that risk information reduces decisional conflicts and anxiety, enhances knowledge, satisfaction with the decision making process and realistic expectations and stimulates patients to be more active, while the effect on outcome of decisions is uncertain [16]. And the impact of evidence-based knowledge on patients' interpersonal roles in the decision process is not clear.

Our project on shared decision making (SDM) in MS was started in 2002 at the Department of Neurology and

Department of Health Sciences, University Medical School Hamburg Eppendorf supported by the German Ministry of Health. We identified two important treatment decisions in the area of MS management, suitable for an exemplary implementation of measures to facilitate patients' involvement in the decision making process:

1. The decision on treatment of acute relapses: high-dose steroids intravenously versus oral steroids or no steroid treatment.
2. The decision on immunotherapy: whether to initiate, to delay or refrain from a so called 'disease-modifying' therapy, as well as to change, to interrupt or to continue immunotherapy.

We decided to address these two sets of decisions by developing two different interventions with decision aids. This paper outlines the process of development. Since decision aids are complex interventions composed of various components affecting different aspects of the decision making context the development has to undergo a stepwise process. A phased evaluation approach as proposed by the UK Medical Research Council [17] has been used. This includes both qualitative and quantitative methods. In this approach, controlled trials and implementation studies represent the last sequence of a continuum of increasing evidence. In the beginning, underlying theories have to be analysed and evidence of the treatments has to be reviewed systematically (phase-1). Then modelling of the intervention is required conceiving and testing the components of the intervention (phase-2). Furthermore, exploratory trials should be conducted to check methods for the following main trial, e.g. outcome parameters, survey methods, design, sample size (phase-3). Thorough performance of the first three phases of the continuum will permit to study efficacy and effectiveness of an intervention in a randomized controlled trial (phase-4). Implementation of proven interventions into routine care can be investigated under less controlled conditions (phase-5).

The report of developing two interventions for key decisions in the Multiple Sclerosis follows these five phases of the MRC framework.

## 2. Phase-1

### 2.1. Theoretical foundation of the development process

Reviewing the literature and research concerning the concept of SDM and SDM outcome measurement we found a need for additional conceptual specifications [18,19]. Following the existing components of the concept [2,3] we analysed the exchange of information and information processing performed by physician and patient using the communication theory of Luhmann [20]. Based on this analysis we began to study the role of uncertainty in medical communication [21]. This led to the development of an

instrument (described in phase-3) to operationalise the extent to which uncertainty is perceived by patients.

Charles [22] defines SDM as a communication process offering the choice of participating more or less actively. A specific and recognizable involvement of the patient is not considered essential. What is omitted in this definition is, in our view, crucial to the process of SDM: the reason for offering patient participation. This is the “equipoise-condition” [3] which asserts that scientific evidence alone can never lead to an individual treatment decision. This condition needs to be taken into consideration in the methodology used to assess the extent of SDM performance (see phase-3).

Criteria for evidence-based patient information have been described [12,14]. But apart from these formal criteria there has been no discussion how to measure quality of decision aids [23]. Since there is a dramatic increase in decision aid development in the last decade leading to 350 decision aids listed in the Cochrane library the need for a concept of quality is urgent. Developers of DAs ought to make transparent and explicit their analytical reasoning for making predictions about how DAs can be expected to achieve their goals [23–25]. Consequently, quality assessment should ascertain the rationale behind the combination of goals, methods and intended mediating mechanisms (described in phase-3).

## 2.2. Background of MS treatment decisions

### 2.2.1. Relapse treatment

High-dose methylprednisolone (MP) has been proposed as the standard therapy for MS relapses, although recommendations and actual prescription practice are inconsistent [26–28]. On the other hand, from studies a 1% chance of serious adverse events (such as depression, psychosis, gastrointestinal bleeding, thrombosis) can be expected. Furthermore, glucocorticosteroids (GC) induce at least transient cognitive deficits [29]. Despite predominantly paraclinical evidence for the superiority of high-dose over low-dose and oral GC treatment, there seems to be a trend, especially in Germany, towards a “hit hard and early” approach [11]. Recently, it has been shown that high-dose oral GC are as safe and effective as intravenous therapy [30]. There is ongoing discussion whether GC therapy leads to lasting therapeutic effects other than a short-term benefit in the speed of functional recovery [27]. Also there remains uncertainty about the preferable route, dosage, duration, and effectiveness of (GC) therapy for the acute relapse. Relapses are of major importance for patients with RRMS. There is a high level of anxiety and uncertainty associated with the unpredictable occurrence and the possible long-term effects of relapses [31]. Patients tend to feel obliged to submit themselves to early intervention with GC, but feel ambivalent and distressed about this obligation. This becomes especially evident when the relapse (and consequent treatment) starts on a weekend or during a holiday. This stands in contrast to the uncertainty that remains with respect

to route, dosage, duration, and effectiveness of GC therapy for the acute relapse.

### 2.2.2. Immunotherapy

Partially effective immunomodulatory and immune suppressive treatments are increasingly advocated among the MS population but are on the other hand disputed among experts ([4] and letters). With the three trials on very early treatment patients with clinically isolated syndromes are increasingly early in their disease course confronted with a therapeutic decision. It has been shown that many patients stop treatment early [32], partly due to unrealistic expectations of the treatment [13]. Inadequate decision making processes might be another reason for early discontinuation as for example too early decisions while patients have not yet accepted that they have MS or while they are still within a relapse.

## 3. Phase-2: modelling and piloting

In a focus group prestudy with  $n=56$  patients the hypothesis was generated that MS knowledge, autonomy preferences and information interests might be largely influenced by disease course and stage. We thus randomly selected 113 (sonst ist nicht klar, wies zur 213 kommt) relapsing-remitting (RR) and 100 primary-progressive (PP) MS patients from our MS database of 1374 patients. The response rate of the survey was 79% (169 out of 213). We analysed decisional role preferences [33], MS risk knowledge as assessed by a risk knowledge questionnaire including risk calculation abilities [34], and emotional response to the core module of the decision aid [35].

### 3.1. Decisional role preferences

Decisional role preferences were investigated referring to five different interaction styles in the physician–patient encounter as for example described by Degner [34]: a paternalistic style, a professional as agent style, a shared decision style, an informed choice style and a concept of pure autonomy. 79% (132 out of 168) of patients preferred active roles (i.e. autonomous, informed choice or shared decision) in medical decision making (see Fig. 1). Since a paper–pencil version of the instrument was associated with missing and invalid values, we provided a card sorting version in further studies.

### 3.2. MS risk knowledge

The mean knowledge score was 6.4 (SD 2.4) representing 34% correct answers out of 19 questions. MS risk knowledge scores were associated with the actual relevance of such knowledge for a single patient. The highest risk knowledge score was seen in patients with a recent (max. 1 year) MS diagnosis, followed by RR and PP patients (mean score  $8.2 \pm 3.0$ ,  $7.2 \pm 2.6$  and  $5.2 \pm 2.6$ , ANOVA,  $p=.001$ ). Secondly, patients on interferon therapies differed in their ability to

calculate therapeutic effects of their therapies from patients without these therapies (mean score  $7.3 \pm 2.7$  versus  $6.1 \pm 2.8$ , ANOVA,  $p = .002$ ). Emphasising the impact of risk knowledge in the decision making process we found that decisional role preference was significantly associated with knowledge. Participants preferring informed choice or shared decision making showed higher knowledge compared to the three other groups (ANOVA  $p = .024$ ).

3.3. Evidence-based information — effects on numeracy and acceptability

The core module tested in this study represents the basic concept of a more comprehensive decision aid about immuno therapies in MS. The information refers to an advertising slogan of a pharmaceutical company, promising a “37% reduction of disease progression”. The numbers were taken from one pivotal study of interferon- $\beta$  [36]. The core module explains the slogan by giving the control event rate, the experimental event rate and the absolute risk reduction. This is explained by using three pictograms with 100 differentially coloured human stick figures (see Fig. 2). In contrast, common information often presents the effectiveness of a drug only in terms of relative risks. Nevertheless, the chosen graphical representation is still a simplification as it does not illustrate random distribution and side-effects. Additionally the core module provides information about the time frame and the difficulties of study endpoints (i.e. relapse rate and disability), relevant aspects for the critical appraisal of clinical MS studies.

Most of the study-participants were apparently not familiar with relative risk statements as they are usually presented. At baseline assessment 134 of 169 (79%) failed to complete a question on the absolute risk reduction concerning disease progression during interferon treatment in

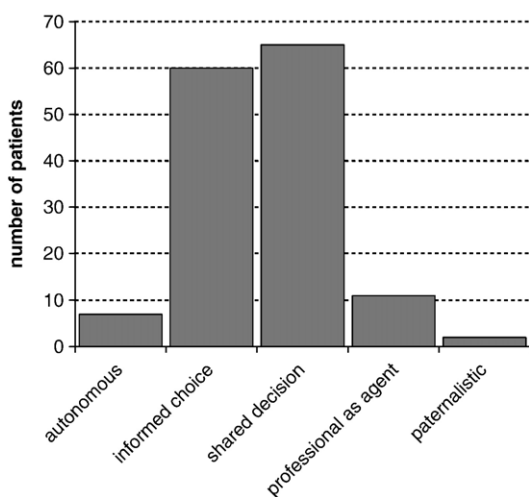


Fig. 1. Autonomy preferences among 168 patients with MS. Indicated is the first choice decision making style. Highest priorities were shared decision and informed choice (adapted from [34]).

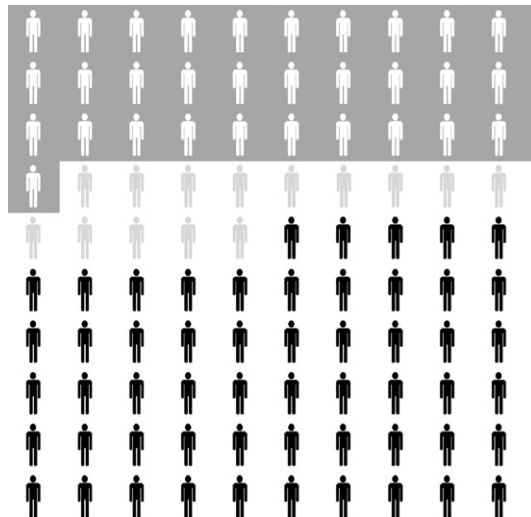


Fig. 2. Presentation form used in the example information. The proportions of the different coloured human stick figures represent the effect of an interferon medication on disease relapses over 2 years. The 31 figures represent patients who would not get a relapse even without medication, the black figures represent patients who would get a relapse despite medication, the 14 grey figures represent patients who will benefit from therapy by not relapsing in the study time window (adapted from [35]).

general within a range of 10% around the correct value. After reading the information, the number of correct answers for this item increased from 35 to 70 (21% to 41%). Still 99 (out of 169) participants were not able to answer this item correctly. The differences between the two measurements of baseline and after reading the leaflet were significant for all three numeracy items: control event rate, 10% to 43%,  $p < .001$ ; experimental event rate, 33% to 43%,  $p = .043$ , absolute risk reduction, 21% to 41%,  $p < .001$ . Results of four patients, which just repeated the earlier presented values, were not counted as correct answers.

Five dimensions were regarded as relevant for emotional appraisal of evidence-based medical information: grade of familiarity with the information, subjective understanding, relevance, emotional arousal, and certainty (see Fig. 3). These dimensions were presented by labelling the extreme poles with pairs of adjectives: “unfamiliar” versus “already familiar with the information”, “complete understanding” versus “no understanding”, “highly relevant” versus “not relevant”, “did evoke my interest” versus “did not evoke my interest” and “wary” versus “encouraged”. Responses were converted to percentages, which represented the proportion of the distance between the two poles. Scores were projected onto a scale of minus 50 to plus 50. Analyses of frequencies on each of the five dimensions showed no polarised mean value with none of the mean scores being higher than 10 points from zero. The most pronounced mean values were 9 for “emotional arousal” and 8 for “understanding” which are to be interpreted as desired responses to the information. The “certainty” scale showed a mean of minus 6 which can be interpreted as a minor degree of evoked uncertainty.

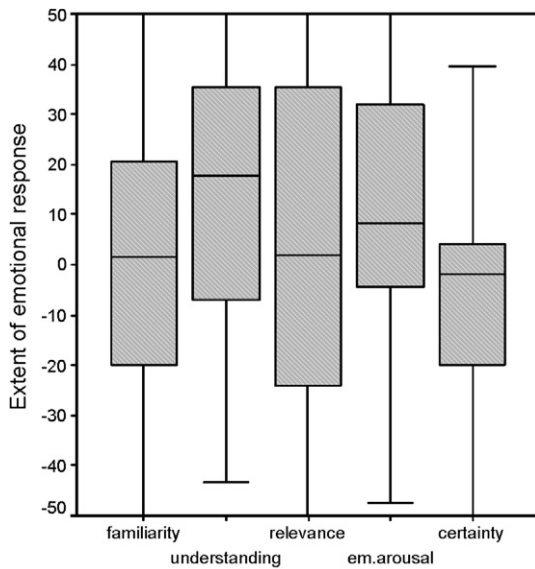


Fig. 3. Emotional response to the risk information ( $n=127$ ). The figure shows the emotional responses on the five selected dimensions. Median, interquartile range and extreme values are presented, as they resulted from the assigned Visual Analogue Scales (VAS) (adapted from [35]).

### 3.4. Development of interventions

#### 3.4.1. Education programme for relapse management

Based on the pilot studies (see Sections 3.1–3.3) an education programme was developed. The final version consists of a 4-hour course, led by a trained MS nurse and a patient, and a 40-page brochure which was mailed to the participants prior to the course. The educational programme is supplied with presentation material as well as with a card system leading through the programme and ensuring standardisation. The programme is divided into 5 parts: 1. information on relapses (definition and differentiation of relapses and fluctuations, evidence for the prognostic relevance of relapses), 2. evidence and clinical reality of steroid treatment, 3. personal strategies and behaviour options, 4. reflection on disturbing information, 5. evaluation of the course. The major objective is to communicate the numerous uncertainties of treatment for MS relapses and to increase the number of recognized options for the treatment of relapses. In this way the programme is intended to empower participants to find their own management strategies. Oral self-medication is mentioned as a treatment option but not as the preferable treatment.

#### 3.4.2. Decision aid on immunotherapies of MS

As recommended by Coulter [14] patients were involved in all steps of the evaluation beginning with the selection of the contents and finishing in readability tests of the final version of the brochure. Initially three versions (short–medium–extended) were presented. In pilot studies patients preferred the most extensive version. Thus we chose to construct the brochure on 3 complexity levels:

Level I: Short summaries in boxes

Level II: Main text structured in:

- ☒ overview
- ☒ effects
- ☒ side-effects
- ☒ frequently asked questions

Level III: Detailed information for “experts”

In addition, patients are given the opportunity to classify themselves according to disease course and activity. Treatment options and their evidence are displayed according to this classification giving patients the opportunity to focus their reading on their concrete situation. The presentation of each treatment is highly structured focusing on absolute numbers for relapse-free and progression-free patients, and absolute numbers for side-effects.

The decision aid includes a work sheet presenting an overview of decisional criteria to be taken into account. The patient is instructed to weigh the importance of the given criteria based on his own values using a limited amount of weights.

### 4. Phase-3: exploratory trials

We extracted eight disjunctive qualities of decisional uncertainty out of interview material from patients suffering different chronic diseases. This leads to the development of a 50-item questionnaire covering these aspects (Qualities of Uncertainty in Chronic Conditions, QUICC). The QUICC was pretested in an MS outpatient sample with acceptable psychometric properties [21]. As a revised version (30 items) it is included in the ISDIMS trial (see below, phase-4) of the decision aid on immunotherapy. The instrument is intended to reflect the stage of awareness of disease related uncertainties as a pattern. This pattern is aimed to change as a result of an elaborated decisional process.

We participated in a group uniting ten German research projects on SDM in order to develop an appropriate questionnaire to assess participation in medical decision making. The resulting instrument is a 24-item questionnaire assessing whether patients perceive the steps of an SDM process according to Elwyn [3] in the decisional encounter [37]. The instrument (Partizipative Entscheidungsfindung, PEF) is included in the ISDIMS trial (see below) for validation.

It is expected that the degree of understanding the underlying equipoise condition should be an SDM measure independent of the actual involvement. Using a five-stimuli ranking item, we ask patients for their understanding of the reason for the offer of participation. Equipoise so far underwent only qualitative evaluation and is also included for further validation in the ISDIMS trial (see below).

As a result of our theoretical work in decision aid quality assessment we developed a tool to support a reviewer to systematically assess the quality of a given decision aid [23].

## 5. Phase-4: controlled trials

### 5.1. EBSIMS — Evidence-based Self-management in Multiple Sclerosis Relapses — outline and baseline data of a randomized controlled trial [38]

#### 5.1.1. Study synopsis

*Hypothesis:* there will be more autonomous management of relapses in trained patients including delaying or refraining from treatment and possible oral self-medication with an increased feeling of control.

*Intervention:* relapse management course (intervention group) versus a leaflet on steroid treatment in the control group.

*Design:* randomized-controlled trial (RCT).

*Primary endpoint:* number of refusals of steroid treatment and number of oral self-medications.

*Secondary endpoint:* kind of treatments, treatment effects, disability, side-effects.

*Inclusion criteria:* relapsing-remitting MS, 2 relapses within the previous 24 months and no major cognitive deficit.

*Number of participants:* 150 patients in 3 centers.

*Follow-up:* 2 years until summer 2006.

### 5.2. ISDIMS — Informed Shared Decision in Multiple Sclerosis Therapy — outline of a randomized controlled trial [39]

#### 5.2.1. Study synopsis

*Hypothesis:* EBM information leads to more patients achieving their preferred roles in the physician encounter. Thereby those who want to participate in the decision making will have a greater chance to really do so if they are provided with the EBM information. Furthermore, patients who received the intervention are expected to prefer more autonomous roles.

*Intervention:* evidence-based patient information booklet versus standard information from self-help organisations.

*Design:* randomized-controlled.

*Primary endpoint:* comparison of preferred and performed roles [33].

*Secondary endpoints:* assuming that patients might look at treatments more critically and might delay or refuse treatment when provided with the EBM information we will assess the number of patients on any treatment at the study end.

*Inclusion criterium:* MS patients facing a therapeutic decision which means initiation or change as well as possible ending of treatment.

*Number of participants:* 280 patients in Germany.

*Follow-up:* 6 months.

*Study conduct:* patients facing a therapeutic decision have been addressed all over Germany through newspapers, websites and self-help group publications. If a telephone interview made them eligible (screening) they were

instructed to make an appointment with their personal MS physician which was the prerequisite for randomization. Four weeks before this appointment the information material was mailed to the patients. In the subgroup of patients presenting at the MS outpatient clinic in Hamburg appointments for therapeutic decisions have been videotaped to be analysed with the OPTION instrument [40]. Telephone interviews directly prior to the consultation and at intervals thereafter will obtain primary and secondary endpoints as well as a follow-up telephone call after 6 months.

## 6. Phase-5: implementation

An implementation project for EBSIMS has already been initiated. Train-the-trainer courses are advertised at the study center and local MS centers in Germany. Furthermore, the validated information material is posted stepwise on the website of the MS Network Hamburg, an initiative of different health professionals in the MS field and patients to improve communication and management strategies ([www.ms-netz-hamburg.de](http://www.ms-netz-hamburg.de)).

## 7. Discussion

Informed shared decision making theoretically seems the ideal approach for MS treatment. In a modelling and piloting phase we studied possible prerequisites of SDM in MS. It is not entirely clear whether patients really want to participate, whether they really do share decisions or whether they just want to feel they are involved. We also do not yet know which other factors are necessary for the decision making process.

We found that MS patients claim active roles. Hypothetical role preferences might not anticipate patients' behaviour in real life decisions as Entwistle et al. [41] have shown in hysterectomy decision making processes. Nevertheless, control preferences reflect a sense of control if the desired role is an active one. This may yield positive effects on disease outcome, if only on psychological factors, regardless whether this hypothetical preference may lead to a real autonomous decision or not.

Overall, risk knowledge was low in our survey but we asked for proportions of treatment benefits. More importantly higher risk knowledge was associated with a higher degree of claimed decisional autonomy. We showed that numeracy competence could be increased through well-prepared evidence-based patient information. A number of questions remain unresolved, in particular concerning the presentation of the possible effects of treatment options. For example, is the knowledge of absolute risks necessary for decision processes from the patient perspective? Recently, Halvorsen et al. [42] have suggested that treatment decisions seem to depend more on the type of disease to be prevented and the costs involved than on the communication of effect sizes as numbers-needed-to-treat. On the other hand, it has been repeatedly shown that presentation of absolute risks increases

the proportion of patients who have a realistic perception of benefits and risks [43]. Agreement between chosen treatment and patient values could be increased by giving patients percentage estimates of risk, leading to an enhanced treatment adherence. We therefore think that information about risks and uncertainties which includes communicating absolute numbers should be made available for patients.

Information deficits and unmet information needs have been repeatedly acknowledged in MS [7] despite a large array of information sources such as the Internet. This raises the question whether there is a lack of valuable information from the patient perspective or if there is another hidden deficit behind this demand. The uncertainty of the disease itself, the lack of highly effective treatments and maybe also the lack of personal support might all be addressed through the complaints about information deficits. Nevertheless, our results show that a critical presentation of effectiveness data does not elicit anxiety among patients. So we do not think that MS patients are unable to share scientific uncertainties with their physicians.

In summary we conclude from phase-1–3 of our development process:

- 80% of MS patients demand autonomous roles in treatment decisions.
- There is a poor knowledge of risks among MS patients with regard to treatment and side-effects in terms of absolute numbers.
- Higher risk knowledge correlates with a preference for higher autonomy.
- MS patients are not disturbed by evidence-based, balanced complex information.
- MS patients do understand this kind of information and are able to transfer new abilities to other situations.

To clarify to what extent decisional role preferences predict decisions in real life and to weigh the impact of scientific risk information on patient role preferences and autonomy two RCTs were started as outlined in Section 5 of this paper.

Preliminary data analysis from the EBISMS trial shows an increased knowledge about relapses and the evidence of current drug application concepts. As a result, an implementation study has begun as part of the process of transferring the programme to other MS treatment centers in Germany.

Which further factors influence decision making and especially patient participation in MS? Prosser et al. [44] have shown that therapy initiation among MS patients depends on risk attitudes as assessed by a standard gamble question. Risk-seeking patients were less likely to choose treatments compared to risk-averse patients supporting the suggestion that personal factors have a large impact on decisional processes. Janssens et al. [45] could show that risk perception for the further disease process is a major determinant for depression in early MS. Bekker et al. [46] recommended measures of reasoning, affect and information processing as possibly important factors influencing the

effect of an intervention with an information tool. Thus, a well-balanced evidence-based information tool is clearly only one factor enabling patient participation in health care. Risk attitudes, uncertainty perception, self-efficacy and depression measures are thus included as moderating variables in the abovementioned RCTs.

When MS is at an advanced stage with cognitive deficits and/or altered decision making abilities and emotional reactivity [47] or psychiatric symptoms participation in decision making may seem impossible. On the other hand MS seldom leads to frank dementia. Studies in psychiatric diseases have shown improved adherence to medication and disease management when patients are involved in medical decision making [48]. Further studies are needed to clarify the impact of decision making abilities and emotional reactivity on MS treatment decisions.

It could be argued that SDM is more an ethical or health-economical concept than a strategy with a proven impact on health indicators such as quality of life. Recently, a close correlation between patients' trust in their physicians and their preference for involvement in decision making has been shown [49]. This demonstrates that SDM is not a procedure for the health market but an indicator of high quality patient–physician relationship.

Apart from the ongoing discussion about modulating factors of the decision making process cultural attitudes towards the patient–physician relationship and even a philosophical viewpoint on the freedom of will must be determinants of patients' and physicians' attitudes to involvement strategies. There is thus on the one hand the perspective in which patients are seen as ill people who need help, in which trust is understood as acceptable dependency [50] and on the other hand the perspective that no one can decide on a health issue of someone else [51]. In the commentary of McNutt [51] on SDM physicians are characterized as navigators in a process of decision making in which patients are considered pilots. Certainly, not every patient wants to share every medical decision, but we think at least patients should make their preferred interaction model explicit, i.e. if they want to share the decision or want the doctor to decide. We think it is essential that a shared decision making process based on validated evidence-based information should be available for those who want it. Studies should analyse how many and which patients will use this approach.

## Acknowledgement

We thank the German Ministry of Health and Social Security for sponsoring the study.

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