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Shared decision making and self-management in multiple sclerosis – a consequence of evidence

■ **Abstract** Shared decision making is increasingly recognised as the ideal model of patient-physician communication especially in chronic diseases with partially effective treatments such as multiple sclerosis (MS). Since 2001, we studied prerequisites for patient participation in decision making as well as the effects of evidence-based patient information on decision mak-

ing processes in MS. In pre-studies we found that 80 % of MS patients demand autonomous roles in treatment decisions which contrasts to a poor knowledge of risks. On the other hand MS patients are not disturbed by evidence-based, balanced complex information. MS patients can understand this kind of information and are able to transfer new abilities to other situations. Major information interests were related to symptom alleviation, diagnostic procedures and prognosis. Currently, we study the effects of a 4 hour education programme on relapse management versus an information leaflet as controls in 150 RR MS patients in a randomised-controlled trial. In a second trial including 280 MS patients we study the effects of an evidence-based decision aid on im-

muno-therapy on decisional role preference and performance in the patient physician encounter. Results at the end of 2006 will show to which extent patient education with a focus on evidence-based patient information influences participation in the decision making process. Assuming that patient education programmes will enhance self-management abilities and the sense of control over the disease with enhanced quality of life and well-being, further modules covering all aspects of MS are to be developed.

■ **Key words** informed shared decision making · evidence-based patient information · multiple sclerosis · relapse treatment · immunotherapy

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Introduction

Multiple sclerosis (MS) seems predestined for research on the enhancement of patient self-management abilities and decisional autonomy for several reasons. Firstly, the controversy on the value of immune therapies as well as on the value and kind of steroid treatment for relapses is still ongoing [5, 9]. Furthermore, health economic experts, pharmaceutical industry and opinion leaders have emphasised the problem of early treatment interruption and low adherence rates [4]. The conflicting evidence represents a typical condition in which, according to Charles [3], a shared decision making (SDM) process

between patient and physician would represent the ideal decision model. Secondly, MS is a disease of young adults in their most productive years, seldom leading to early dependency. Thus from this patient group characteristic an active role in health management is intriguing. Thirdly, MS patients' perception of their disease differs from the physicians' views as Rothwell et al. [13] have shown. Mobility restrictions appear to be less worrisome to patients than to physicians, whereas with mental disability, it is the other way round. Thus, patients might also have different views on prerequisites for decision processes than physicians. Fourthly, studies in other chronic conditions as for example diabetes have shown that enhancing self-management strategies leads

to a more rational medication regimen and improves health outcomes and quality of life [1].

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 attitudes to risk.

It is assumed that patients cannot express informed preferences unless they are given sufficient and appropriate information [5]. 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. A systematic review has shown that risk information reduces decisional conflicts and stimulates patients to be more active, although the effect on outcome of decisions is uncertain [12]. There is increasing consensus that patients' participation in medical decision making needs to be facilitated, but the impact of the information status on patients' interpersonal roles in the decision process is not clear.

Recent studies have outlined communication and information deficits in the care of patients with MS [7]. In addition, the need for balanced information and patient participation in MS decision-making has been acknowledged by the NICE MS Management Guidelines for the UK [11].

Studies on patient information in MS focused on diagnostic issues. In addition, patient information systems were developed both by pharmaceutical companies and various non-profit organisations. However, until today none of the available material fulfils the criteria for evidence-based (EBM) patient information [14] (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 initialised at an early stage of the disease, 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 fearing potentially poor courses of the

disease. This could lead to increased uptake rates and overmedication. 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. Realistic information may help to prevent patients with unrealistically optimistic expectations of the treatment from discontinuing treatment early or from failing to start medication which could benefit them.

In 2001, we started a project about shared decision-making (SDM) in MS supported by the German Ministry of Health. The project resulted in the development of two patient decision aids, based on evidence and tailored towards two major treatment decisions in MS.

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.

Decision aids are complex interventions comprising a number of separate components. The development and evaluation process therefore follows the approach of generating a continuum of increasing evidence on efficacy proposed by the UKMRC. This approach suggests five research phases: theory development, modelling of the intervention, developing the optimum intervention and study design, main trial, promoting effective implementation [8, 15].

We first looked at possible prerequisite factors for patient participation such as patients' role preferences, MS risk knowledge, perceived subjective knowledge level and information interests. As one of the latest steps we investigated the effects of evidence-based patient decision aids in randomised controlled trials.

Focus groups and survey

In a pre-study including 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 100 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, MS risk knowledge as assessed by a risk knowledge questionnaire including risk calculation abilities and emotional response to the core module of the decision aid as well as information interests [7, 8].

Table 1 Criteria for an evidence based patient information

<ul style="list-style-type: none"> • levels of evidence • clinical relevant end-points • additional graphical information • risks in absolute numbers • gain and losses • balanced and readable • patients involved in information development

Decisional role preferences

Decisional role preferences were investigated referring to five different interaction styles in the physician-patient encounter: 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.

MS risk knowledge

The mean knowledge score was 6.4 (SD = 2.4) representing 34% correct answers out of 19 questions (see Fig. 2). 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 ± 3.0 , 7.2 ± 2.6 and 5.2 ± 2.6). Secondly, patients on interferon therapies differed in their ability to calculate therapeutic effects of respective therapies from patients without treatment (mean score 7.3 ± 2.7 versus 6.1 ± 2.8). 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 $p < 0.05$).

MS information interests

Major information interests were related to alleviation of symptoms (treatment gait disorder, physiotherapy) and magnetic resonance imaging (MRI), followed by knowledge about relapses, including knowledge about steroids, and Eastern complementary medicine. By comparing different disease courses we detected considerable differences. MRI was of prominent interest for recently diagnosed RR patients. Knowledge about relapses, and Eastern complementary medicine were the first and third choices of RR patients. PP patients showed a strong interest in the treatment of gait disturbances and physiotherapy, followed by experimental therapies. Immunomodulatory therapies were among the lower half of the chosen areas in the whole cohort as well as in the subgroups. Patients with knowledge scores in the upper quartile rated the knowledge item "validity of studies" among the first three; the remaining patient groups did not mention this item among the first ten.

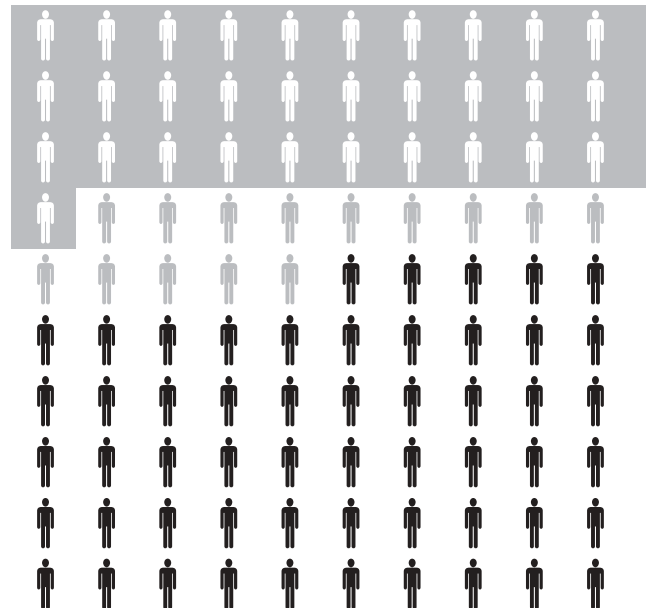


Fig. 1 Presentation form used in the example information. The proportions of the different coloured human stick Figures represent the effect of an interferon medication on disease relapses over 2 years. The 31 Figures represent patients who would not have a relapse even without medication, the black Figures represent patients who would have 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 [8])

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 immune therapies in MS. The core module explains a pharmaceutical slogan addressing the reduction of disease progression 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. 1). In contrast, common information often presents the effectiveness of a drug only in terms of relative risks.

The majority 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 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%). The differences between the two measurements of baseline and after reading the leaflet were significant for all three numeric items (control event rate, 10% to 43%, $p < 0.001$; experimental event rate, 33% to 43%, $p < 0.05$, absolute risk reduction, 21% to 41%, $p < 0.001$).

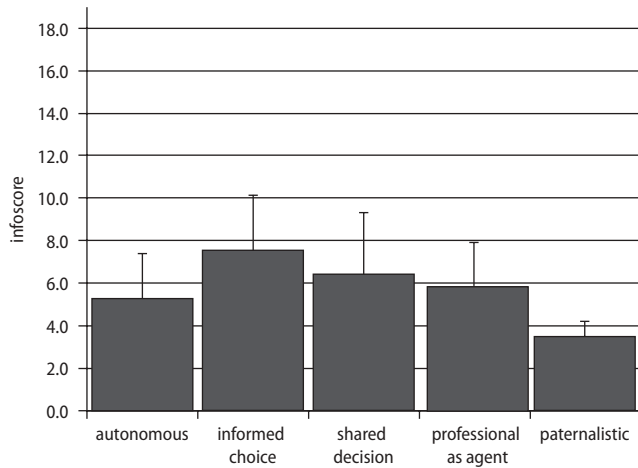


Fig. 2 Autonomy preference and knowledge scores among 168 patients with MS. Indicated is the mean knowledge score of each subgroup (\pm SD). Highest scores were among patients preferring informed choice and shared decision. MSK range 0–19, meaning that up to 19 items could be answered correctly (adapted from [7])

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. Analyses of frequencies on each of the five dimensions showed no polarised mean value with none of the mean scores being higher than ten points from zero. The most pronounced mean values were nine for “emotional arousal” and eight for “understanding” which are to be interpreted as desired responses to the information. The “certainty” scale showed a mean of minus six which can be interpreted as a minor degree of evoked uncertainty.

Interventions

■ Education programme for relapse management

Based on the pilot studies an education programme was developed. The curriculum 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 recognised

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.

■ Decision aid on immunotherapies of MS

As recommended by Coulter [5] 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 decision aid on 3 complexity levels:

Level I: Short summaries in boxes

Level II: Main text structured in:

- ⇨ overview
- ⇨ effects
- ⇨ side-effects
- ⇨ study weaknesses
- ⇨ numbers needed to treat
- ⇨ 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 focussing 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 given criteria based on his own values using a limited amount of weights.

Controlled trials

■ EBSIMS – Evidence Based Self-management in Multiple Sclerosis Relapses

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 Randomised-controlled with concealed allocation.

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 centres.

Follow-up 2 years until summer 2006.

■ ISDIMS – Informed Shared Decision In Multiple Sclerosis Therapy

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 Randomised-controlled

Primary endpoint Comparison of preferred and performed roles.

Secondary endpoints Assuming that patients might look at treatments more critically and 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 criterion 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 randomisation. 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 were videotaped to be analysed in detail. Telephone interviews directly prior to the consultation and at inter-

vals thereafter will obtain primary and secondary endpoints as well as a follow-up telephone call after 6 months.

Implementation

An implementation project for EBSIMS has already been initiated. Train-the-trainer courses are advertised at the study centre and local at MS centres 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).

Discussion

From our surveys, we conclude that a large part (80%) of MS patients demand autonomous roles in treatment decisions. On the other hand, there is poor knowledge of risks among MS patients with regard to treatment and side-effects in terms of absolute numbers. Furthermore, we could show that higher risk knowledge correlates with a preference for higher autonomy. Concerning the presentation of evidence-based patient information we could show that MS patients are not disturbed by balanced complex information stressing the scientific uncertainties of data. Furthermore, MS patients can understand this kind of information and are able to transfer new abilities to other situations. Information interests in our survey were largely influenced by disease stage and disease course, but treatment of gait disorder was the most frequently mentioned item. Our results are supported by another study also reporting symptom alleviation as the major unmet information need [16]. Assuming that carefully developed education programmes will enhance self-management abilities, further modules should focus on the information interests communicated. Thus, symptom alleviation is a major topic for advanced MS courses and diagnostics as well as prognostic information with special reference to MRI, a major theme for early MS patients.

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 above.

Preliminary data analysis from the EBSIMS trial show 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 centres in Germany.

What further factors influence decision making and especially patient participation in MS? Bekker et al. [2]

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 are thus included as moderating variables in the above mentioned RCTs.

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. However, a close correlation between patients' trust in their physicians and their preference for involvement in decision-making was recently shown [10]. This indicates that SDM is not a procedure for the health market

but an indicator of high quality patient-physician relationship.

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. whether they want to share the decision or want the doctor to decide. We think it 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.

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