

Engaging people with MS in decision-making: the concept of evidence-based patient information



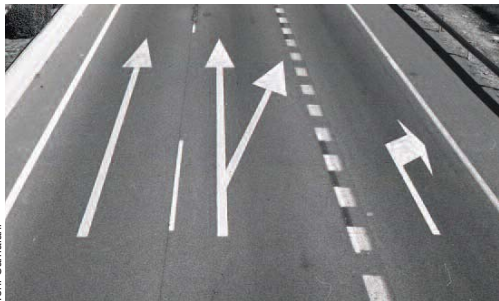
Sascha Köpke and Christoph Heesen, Institute of Neuroimmunology and Clinical MS Research, Hamburg, Germany

With newer, more potent MS drug therapies on the horizon, treatment decisions for both people with MS and their health professionals are about to become a lot more complex. It is more important than ever that people with MS have the information they need to make informed decisions in partnership with their health professionals. Health professionals need to communicate effectively with people with MS in order to quantify the risks and benefits of the various treatment options; to understand an individual's values; and ultimately to facilitate treatment decisions that will improve an individual's quality of life. In the following article, Dr Köpke and Dr Heesen explore how evidence-based patient information can engage people with MS in decision-making and demonstrate how the application of the evidence based patient information and shared decision-making not only increase knowledge and satisfaction in people with MS, but also improve quality of life and disease management.

Introduction

In 2009, reports about rising numbers of people with MS developing progressive multifocal leukoencephalopathy (PML) while undergoing treatment with natalizumab (Tysabri), painfully highlighted two neglected issues relating to MS immunotherapy decision-making. Firstly, that information about benefits and side-effects of treatments based on large clinical trials need to be communicated clearly and transparently. To achieve this, information about efficacy and side-effects of drugs need to be collected systematically and updated regularly. Ideally this information needs to carry an expiry date to indicate currency of the information. Unfortunately, this is rarely the case. The second point the PML cases illustrated was that treatment decisions are only reasonable with strong involvement of patients'. The decision-making process requires a thorough and transparent reflection of personal values and preferences, perceived threat of MS, as well as perceived benefit and harm of treatment options. Again, this is rarely carried out in a structured way in daily practice.

The example of natalizumab and PML nicely reflects the paradigm shift discussed in modern medicine based on the concepts of evidence-based medicine and shared decision-making.



Toni Camatiani

What is evidence-based patient information?

Evidence-based patient information is based on the concept of evidence-based medicine established in the early 1990s by a group led by the Canadian physician and epidemiologist David Sackett. Evidence-based medicine has often been misinterpreted as 'cookbook medicine' – undermining physicians' clinical expertise by providing recommendations via practice guidelines. On the contrary, in one of the early descriptions of evidence Sackett claimed:

"Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice, it cannot result in slavish, cookbook approaches to individual patient care."³ There are many clinical situations where no convincing evidence exists or where the evidence that does exist is conflicting - but decisions still have to be made. Evidence-based medicine suggests that clinical decision-making with individual patients requires an integrative process. Evidence-based medicine thereby embraces the concept of sharing decisions between physicians and patients, which in 1997 was defined by the Canadian sociologist Cathy Charles as shared decision-making (SDM). A main tenet of evidence-based patient information is that evidence is made available and presented in a clear and easily comprehensible format.

Bunge and colleagues summarised the main elements of evidence-based patient information in 2010⁴ and explained how the principles of evidence-based patient information help patients and clinicians to make informed decisions. In order to achieve informed decision making, Bunge and colleagues proposed that relevant treatment effects need to be communicated in absolute numbers (as absolute risk reductions and/or numbers needed to treat). Here, referring to cohorts of 100 or 1000 people is helpful. Presentation of relative risk reductions should be avoided as these are not intuitively understood and usually overestimate treatment effects.

The principles of evidence-based patient information also dictate that patient-relevant outcomes such as relapses ought to be communicated. Outcomes of questionable relevance and surrogate markers such as MRI measures should be given less emphasis. Findings should also be presented graphically. Benefits and harms should be presented equally in the same format. Figure 1 shows how these aspects can be incorporated using interferon treatment as an example. Above this, open questions should be clearly addressed. Language should be kept simple and medical or technical terms should be avoided or explained in simple terms. And crucially, patients should be involved in the development of the information.

It has also been demonstrated that patients better understand information presented in the form of numerical data, presented

verbally, and through the use of diagrams, graphics, and charts. Other criteria such as providing information on the developmental process of the information, or equal presentation of positive and negative treatment effects using patient oriented outcomes, are based on ethical guidelines such as the GMC guidelines⁵. Some central aspects of evidence-based patient information, such as presenting the quality of evidence, giving information about the development process, or including pictures and drawings, lack the evidence to support their effectiveness as yet.

There are several ways of providing patients with evidence-based patient information. It usually involves more than just written information. Ideally, it will be a staged process such as providing an information brochure in addition to group education sessions – a process proposed by the Medical Research Council and referred to as ‘complex interventions’⁶. Trials evaluating programmes of evidence-based patient information therefore, should not only show that patients are better informed and satisfied with the information, they should also show how they lead to more involvement in decision-making and better individual health management. There should also be evidence of

increased quality of life, improved health status, and cost effectiveness as a result of such programmes and they should be easy to implement in daily routine.

Current evidence on effectiveness of evidence-based patient information in MS

MS is an unpredictable condition with respect to many aspects including diagnosis, prognosis, and the effectiveness of drug therapies. Since 2003 our group has been developing evidence-based patient information projects to help people with MS make informed decisions. Our approaches ranged from two-page information flyers to complex programmes with comprehensive information materials and group education programmes on areas such as relapse management.

Figure 1: Effects of interferon: number of patients with relapses within two years



The EBSIMS programme: an evidence-based self-management programme in MS relapses

Relapses are recognised as a significant source of anxiety and uncertainty for people with MS particularly in relation to their significance as prognostic markers, disease progression, and the use of steroids to treat and facilitate recovery. To address some of these issues, in 2004 we developed a patient education programme on relapse management in MS. The programme consists of two parts, a preparatory 30-page brochure and a four hour educational programme providing evidence-based patient information on relapses and relapse therapy. Participants also work with decision trees and have group discussions. The group allows participants to reflect on their preferences and also to hear and discuss participants' experiences with relapse management.

In a multi-centre randomised-controlled trial in Germany involving 150 patients with relapsing remitting MS and high disease activity, the programme was compared to a one-page standard information leaflet*. Based on strong treatment recommendations in Germany favouring intravenous corticosteroid therapy which is not in line with the current best evidence⁸, it was hypothesised that the education programme would lead to altered treatment decisions as a result of the greater patient autonomy and shared-decision making it encourages. The study participants were divided into two groups; one group received the education programme while the other group did not. In the intervention group, 78% of relapses were treated with oral or no corticosteroids compared to 56% in the control group (absolute difference of 22%, see figure 2).

Patients' risk knowledge as well as perceived autonomy of treatment decision-making was significantly higher in the education programme group. People who received the programme also reported less visits and less telephone calls to physicians. Quality of life, disability status, and adverse events of corticosteroid therapies were comparable between groups. Interestingly, people in the education programme group had less relapses during the two years of study follow-up, while in the two years before the study, relapse rates were comparable between groups.

A subsequent implementation study trained 31 health care professionals, who later performed the programme within their institutions. People who participated in these programmes

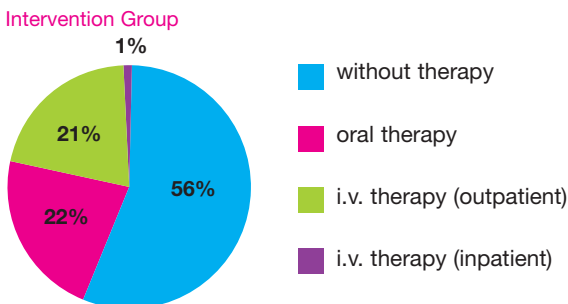
showed increased risk knowledge and increased decision-making autonomy preferences. The implementation study confirmed that patients appreciate evidence-based patient information about relapse management and view evidence-based patient information and presentation of scientific uncertainty as a chance for decision-making autonomy.

A further multi-centre study (ISDIMS – informed shared decision making in MS immunotherapy) assessed the efficacy of a 120-page evidence-based patient information booklet and decision aid on decision-making about immunotherapy⁹. In this study, 305 German MS patients were recruited to a trial investigating the effects of the evidence-based patient information compared to standard material from a German self-help organisation. However, this study did not produce the expected result in that it did not change decision-making behaviour. This could be explained by the fact that most of the participants recruited reported a preference for having a very active role in treatment decisions prior to commencing the education programme. However, while there were no effects on the primary endpoint, people who received the education programme appeared to reflect more deeply on the information they were presented with.

Our more recent research addressed issues facing people newly diagnosed or still in the diagnostic process. This period can be characterised by feelings of vulnerability and uncertainty. The question of whether or not an earlier diagnosis is beneficial for individuals with MS is still a matter of some discussion. In this pilot study an evidence-based patient information leaflet was developed for distribution to people with symptoms suggestive of MS as well as a cohort of people with a recently confirmed diagnosis of MS. It aimed to engage people in decision-making about diagnostic testing in MS. Results of the study showed that early communication of a possible MS diagnosis and the related uncertainties was highly valued by both groups¹⁰.

Based on these results, another evidence-based patient information programme for patients with early or suspected MS has been developed (PEPADIP – patient education program about diagnosis, prognosis and early MS treatment). This four hour interactive education programme, supplemented by a 60 page booklet, gives information about areas such as predictive markers of disease course and early initiation of disease modifying drug treatment. In this ongoing randomised controlled trial, we have recruited 190 patients from seven German academic centres. The education programme is being compared to a stress and coping group education session of similar length. The primary endpoint is 'informed choice' measured by integrating risk knowledge, attitude towards immunotherapy and actual therapy uptake. Role preferences, control beliefs, anxiety and depression, decisional conflict and satisfaction will also be

Figure 2: Relapse therapies in the EBSIMS trial



measured. We expect the programme to enhance the sense of control and lead to more informed choices about immunotherapies. Results are expected by the end of 2011.

The above mentioned ISDIMS programme has also been expanded by adding a two part six hour interactive group session to the updated brochure. A trial called PEPIMS – patient education about immunotherapy in MS, evaluating the programme with patients in rehab clinics is also ongoing.

European perspective - the AutoMS study

Earlier research has pointed to differences in autonomy preferences between German and Italian MS patients¹¹. Thus a recently started European initiative (AutoMS – autonomy preferences, risk knowledge and decision-making performance in MS performance in MS patients) aims to establish common tools to assess decision-making quality in centres from six European countries and an Australian partner. The study has been initiated by the groups of Christoph Heesen in Hamburg and Alessandra Solari in Milan as part of the activities of the special interest group for patient education within RIMS, the network of European MS rehabilitation centres. AutoMS will study role preferences and aim to identify any correlating cultural factors. It will also try to develop a European consensus for a risk knowledge questionnaire for relapsing remitting MS. Furthermore, based on the “Theory of Planned Behavior”¹², the group aims to develop a new tool to be known as the “Planned Behaviour in MS Questionnaire (PBMS)” to assess patients’ perceptions and thus better describe patients’ decision-making. Finally, AutoMS will refine an observer-based rating tool assessing patient-physician interaction during consultations¹³ as a potential outcome parameter in studies aimed at enhancing shared decision-making. All the instruments produced will be harmonised between the participating countries and linguistically validated in the target languages.

Conclusions

Patients are increasingly encouraged to be partners in medical decision-making and MS is a paradigmatic condition for a shared decision-making approach. Different studies since 2002 have shown that people with MS appreciate unbiased communication of scientific uncertainties to enhance involvement in decision-making. Increased satisfaction with health care through an increase in risk knowledge has consistently been shown in our studies and other clinical settings when evidence-based patient information concepts are applied¹⁴. Ultimately, these interventions should not only show increased knowledge and satisfaction but also increased quality of life and improved disease management. The above summarised EBSIMS trial exemplified how evidence-based patient information can change health behaviour. As an increasing number of MS treatment options emerge, patients’ involvement in treatment decisions becomes increasingly important. Well informed patients may also be better able to recognise and communicate side-effects which must be reported in international databases.

In the developed countries we should now see doctors working with expert patients. However, to get the best out of that relationship healthcare providers need to take account of different preferences in terms of the role patients want to play in decision-making about treatments. There will always be different models of behaviour, determined by different factors such as medical condition, cultural and personal factors. While trust in a physician seems to be redundant in purely autonomous patients and might be blind in patients preferring paternalistic counselling, a trusting patient-physician relationship is also a prerequisite for enabling shared decision-making¹⁵.

In the UK, NICE gave a grade A recommendation for an information pack specific for newly-diagnosed MS patients. However this recommendation was not based on evidence derived from the MS research area, but mainly on evidence from stroke and cancer patients¹⁶. In view of the above mentioned activities, it is hoped that the provision of evidence-based patient information in MS will soon be better supported by evidence more sensitive towards the specific needs of people with MS.

References

- 1 Heesen C, Kleiter I, Nguyen F, et al. Risk perception in natalizumab-treated multiple sclerosis patients and their neurologists. *Mult Scler* 2010; [In press].
- 2 Barratt A. Evidence based medicine and shared decision making: the challenge of getting both evidence and preferences into health care. *Patient Educ Couns* 2008; 73:407-412.
- 3 Sackett D, Rosenberg W, Gray J, et al. Evidence based medicine: what it is and what it isn't. *BMJ* 1996; 312:71-72.
- 4 Bunge M, Mülhhauser I, Steckelberg A. What constitutes evidence-based patient information? Overview of discussed criteria. *Patient Educ Couns* 2010; 78:316-328.
- 5 General Medical Council. Consent: patients and doctors making decisions together. [Cited 2010; August 26] Available from: URL: HYPERLINK "http://www.gmc-uk.org/static/documents/content/Consent_2008.pdf" www.gmc-uk.org/static/documents/content/Consent_2008.pdf
- 6 Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008; 29:337.
- 7 Köpke S, Kasper J, Mülhhauser I, et al. Patient education program to enhance decision autonomy in multiple sclerosis relapse management: a randomized-controlled trial. *Mult Scler* 2009;15:96-104.
- 8 Köpke S, Heesen C, Kasper J, et al. Steroid treatment for relapses in multiple sclerosis - the evidence urges shared decision-making. *Acta Neurol Scand* 2004;110:1-5.
- 9 Kasper J, Köpke S, Mülhhauser I, et al. Informed shared decision making about immunotherapy for patients with multiple sclerosis (ISDIMS): a randomized controlled trial. *Eur J Neurol* 2008;15:1345-1352.
- 10 Heesen C, Schäffler N, Kasper J, et al. Suspected multiple sclerosis - what to do? Evaluation of a patient information leaflet. *Mult Scler* 2009;15:1103-1112.
- 11 Giordano A, Mattarozzi K, Pucci E, et al. (2008). Participation in medical decision-making: attitudes of Italians with multiple sclerosis. *J Neurol Sci* 2008; 15:86-91.
- 12 Ajzen I. Perceived behavioral control, self-efficacy, locus of control, and the theory of planned behavior. *J Appl Soc Psychol* 2006;32:665-683.
- 13 Elwyn G, Edwards A, Wensing M, et al. Shared decision making: developing the OPTION scale for measuring patient involvement. *Qual Saf Health Care* 2003; 12:93-99.
- 14 Coulter A, Ellins J. Effectiveness of strategies for informing, educating, and involving patients. *BMJ* 2007;335:24-27
- 15 Kraetschmer N, Sharpe N, Urowitz S, et al. How does trust affect patient preferences for participation in decision-making? *Health Expect* 2004; 7:317-326.
- 16 National Institute for Health and Clinical Excellence. Multiple sclerosis: management of multiple sclerosis in primary and secondary care. NICE Clinical Guideline 8. London: NICE; 2003.

