

Real-life versus hypothetical decision making: Opt-in and opt-out treatment decisions in multiple sclerosis

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Abstract

Background: Patients' decisions in relation to treatment depend on individual values and relevant outcomes. Presenting possible decisions by way of defaults (opt-in or opt-out) has been used to achieve desired outcomes. Our objective was to assess the impact of defaults in patients with multiple sclerosis (MS) during the decision process related to the initiation of treatment with disease modifying drugs (DMD). **Methods:** MS patients were requested to accept or reject DMD treatment using either the (1) opt-in condition, where they were told that the leading treatment guideline is not to start DMD treatment after the diagnosis of MS; (2) the opt-out condition where the default was to start DMD treatment; and the (3) neutral condition that required patients to choose whether to be treated or not, with no prior information. **Results:** One hundred and sixteen relapsing-remitting MS patients consistently chose to fulfill their inclinations to start early DMD treatment. In the neutral condition 64.5% chose to initiate DMD treatment. In the opt-out condition, 81% conformed to treatment, while 19% opted-out. In the opt-in condition, 39.3% conformed not to start treatment, while 60.7% opted-in ($p = 0.004$).

Conclusion: Taken together these findings reveal that patient-physician reciprocation increases by 28.3% the rate of MS patients choosing to change the default they were presented with.

INTRODUCTION

Multiple sclerosis (MS) is a lifelong disease leading to significant disability in young adults. Treatment decisions in the context of MS are often undertaken with the perspective of long term outcomes. The last decade introduced new immunomodulatory disease modifying drugs (DMD) into the therapeutic MS arsenal, all aimed at relapse reduction and decreased disease activity. There is strong clinical evidence that initiating DMD treatment early in the disease course will positively affect outcome. The introduction of these drugs emphasizes the complex decision making that neurologists and MS patients are engaged in. The availability of a range of DMD treatments raises the need to achieve the "right" decision while keeping in mind the life-long consequences. This combined with myths and misconceptions about the course of MS makes every decision a complex challenge for each patient, and more so at the cross-road of initiation of DMD treatment. In parallel, the treating neurologist presenting treatment options to the patients is required to decide on the appropriate therapy for each individual MS patient. This

requirement is near impossible at a time when no clear advantage has been demonstrated for any of the DMD and when no specific predictive marker or test for tailored best treatment is available. Moreover, treatment optimization is also limited by a differing side-effects profile of the available DMD and the overwhelming body of information presented to MS patients at the junction where they are requested to decide on acceptance of long-term treatment.¹⁻³

Social psychologists have long been interested in decision making and several insights are relevant to the patient-physician dialogue concerning treatment. When faced with momentous and not trivial decisions subjects are reluctant to decide and tend to both avoid deciding and to rely on factors which should not affect the choice.⁴ Moreover the role that patients play in decision making has shifted from physician paternalism towards informed autonomous relationships.⁵⁻⁷ The shift in -patient-physician- relationship placed treatment decision making in the center of this dialogue. One of the main themes in the study of decision making suggests that there are techniques that may result in better outcomes for patients.

For example, defaults may be best applied when strong clinical evidence suggests a treatment option to be correct for most people but preserving patient choice is appropriate. Alternatively, the use of environments that explicitly facilitate the optimal construction of preferences is most appropriate when choice depends on a patient's ability to understand and represent probabilities and outcomes.⁸ Many demonstrations show that respondents' preferences, even for substantively important decisions, are influenced by factors which should not affect the choice such as the wording in which "survival" versus "mortality" data is presented.⁹

We are facing a time of progressively more complex treatment options in MS, where data require continuous updating, and preferences and values become highly relevant. Patients are overwhelmed by information through media such as the internet, personal contact with other patients, family physicians and patients' organizations while very few information sources are based on rigorous guidelines or are evidence-based. Moreover, health messages on television and other mass media have the potential to significantly influence patients' health-related knowledge and behaviors, though little is known about their ability to comprehend such messages.¹⁰ Involvement in treatment decisions becomes ever more imperative. Development of modular programs for all relevant decisions in MS to increase patients' self-management and to extend their individual approach with the disease is needed. Still, it remains a challenge to adequately assess decision quality.¹¹

Thus, the present study was designed to specifically evaluate the role of defaults in MS patients' treatment decisions in real-life. The results were expected to aid both treating neurologists and patients in this crucial junction of disease management through utilizing the process of decision making towards better physician-patient cooperation.

METHODS

Subjects

Patients followed at Sheba University Hospital MS Center were recruited to participate in the study during the period January, 2008 to December, 2009 according to the following eligible criteria: (1) a confirmed diagnosis of relapsing-remitting MS according to the McDonald's criteria¹² and (2) considering immunotherapy with DMD. We

excluded patients under 18 years of age, patients with cognitive impairment and patients who had already participated in other studies related to informed decision making. Patients were randomized when they confirmed an appointment with their physician. Enrollment took place consecutively until the planned sample size was achieved.

Protocol

Randomization was carried out by concealed allocation using computer generated random numbers. The concept of "opt-in" and "opt-out" was developed for studying decisions and in medical practice refers to the following: a) Opt-in: the condition in which the patient has to actively request participation in an intervention not offered to patients; b) Opt-out: the condition in which the patient has to actively request removal from an intervention offered to all patients. The ratio for randomization was 2:1:1 (neutral, opt-in, opt-out). The study was approved by the Sheba Medical Center IRB committee. This was part of a larger survey aimed at assessing response and confrontation to DMD in MS. We recruited patients not yet receiving medication, who were deciding about initiating DMD treatment. We asked respondents during a scheduled visit to our center to endorse a short questionnaire that focuses on whether they would accept DMD treatment using one of three options as follows:

Opt-in condition: patients were told that treatment guidelines in our center are *not to start* DMD treatment after MS diagnosis; they were given a choice to confirm or change that decision.

Opt-out condition: patients were told that treatment guidelines in our center are *to start* DMD treatment after MS diagnosis; they were given a choice to confirm or change that decision.

Neutral condition: patients were required to choose whether to be treated or not, with no prior option or information as to the guidelines used in our center. In the opt-in and opt-out conditions a "no decision" answer was unacceptable.

Participants were told the information they received was standard information in our center. We estimated that the great majority of patients will adhere to the default condition presented to them, as shown by previous authors when studying complex and complicated decisions.¹³

We assumed that if inclinations concerning early DMD treatment are strong, defaults should have only a minor effect.

Statistical Analysis

Data were analyzed using a paired-samples and independent-samples approach. The two-tailed t-test and nonparametric test were undertaken to evaluate for differences between the evaluations for qualitative parameters. Examination of differences between the categorical parameters was based on the Pearson Chi-square and contingency coefficient tests. All tests applied were two-tailed, and p value of 5% or less was considered statistically significant.

The data was analyzed using the Statistical Analysis System software.¹⁴

RESULTS

There were 116 consecutive MS patients who participated in the study. Randomization to the three option conditions was in a 2:1:1 ratio. Thus, 62 patients were randomized to the neutral condition (no default), 28 to the opt-in condition and 26 to the opt-out condition. Mean age for the total sample was 32.3 ± 5.4 years, there were 75 women and 41 men. Mean disease duration was 1.4 ± 0.8 years and neurological disability quantified by the Expanded Disability Status Scale (EDSS) mean score was 2.2 ± 0.4 , for the whole sample. There were no differences in these variables between the 3 option arms.

In the neutral condition 64.5% (40/62) chose to initiate DMD treatment and a minority 27.5% (17/62) indicated that they would not choose to start treatment. It is of interest to note that only 8% (5/62) of patients were unable to decide and returned a non-endorsed questionnaire despite encouragement by the research staff to complete the assignment.

In the opt-out condition, wherein patients were required to choose to conform with the recommendation to initiate DMD treatment, 81% (21/26) indeed conformed while only 19% (5/26) opted-out (refused the offered treatment option). The proportion of patients who opted to decline treatment in the opt-out arm was not significantly different from the neutral group ($p = 0.071$). Thus, in comparison to the neutral condition more patients (16.5%) had in fact “adhered” to the center’s guideline to initiate treatment.

In the opt-in condition, wherein patients were required to choose to conform with the recommendation *not* to accept early treatment,

only 39.3% (11/28) conformed, while the majority – 60.7% (17/28) opted-in (requested DMD treatment). Thus, in comparison to the neutral condition more patients (11.8%) had in fact “adhered” to the center’s guideline not to initiate treatment. In comparison to the neutral condition a similar proportion of patients requested treatment. However, in order to achieve this proportion the majority (60.7%) of patients had to “actively” opt-in, that is to change the presented default to start treatment and this change was significant ($p = 0.004$). This may imply that the “declared” physician position not to start early treatment had only a minute influence on patients’ choice. (See Figure 1, flow-chart, for details of the study results.)

DISCUSSION

Decision research has repeatedly shown that the process of deciding is often difficult and even enigmatic. When faced with a decision that may impact our future significantly many of us circumvent the need to decide. The impediment to decision-making may often be the cost of making a decision. Since people consider this question aversive, there is some utility to defaults, which allow people not to make choices as forming a preference is cognitively costly.¹⁵ In this context it should be pointed out that the assumption that people have reached a decision is frequently mistaken. Instead of expressing well-articulated preferences, the preference in regards to a medically significant decision is not well formed, suggesting the possibility that decisions are often constructed in response to the pertinent question. As a result, the form of the question influences its answers.^{16,17}

One virtue of this work is that it uses a sample of patients for whom the choice to be made has important consequences. In that sense this is a valuable field study. The findings of the present study clearly demonstrates that the acknowledged difficulty in decision making attributed to the lay public does not hold true for MS patients faced with real-life decisions. Our patients actively participated in the decision making process and specifically chose the active option to start DMD treatment. Only a small minority of 8% of patients in the neutral condition could not make a definite choice, while all patients that were presented with the default conditions (either opt-in or opt-out) made a definite choice. It is conceivable that the guidelines presented to the patients in the default conditions had swayed the

doubting patients into a clear-cut decision. While the neutral condition revealed that the majority of patients are inclined towards early treatment for MS, the opt-out default increased patients' treatment choice moderately as *a priori* their inclination was towards treatment. The increase in choosing treatment by 20.3%, compared with the opt-in condition, is not negligible. This may imply that the "declared" physician position (as revealed by the guidelines presented to the patient) to initiate treatment had influenced patients only moderately, as the majority did not have to make an "active" choice, that is a change from the presented default. This may be due to a combination of physician recommendations and "natural" propensity of subjects not to choose. In addition, the ceiling effect - i.e. the already high rate of patients inclined to start DMD in the neutral condition - makes a change towards accepting treatment only of moderate effect size. On the other hand, in the opt-in condition more than half of the patients had indeed acted "against"

the recommendations of our center's physicians gravitating towards DMD treatment. The default had a dramatic impact, demonstrating increase in active choice for treatment, being trice as high when opting-in (60.7%) as when opting-out (19%). The opt-out condition, the current practice in our center, did not differ significantly from the neutral condition. The opt-in condition was significantly lower than the neutral preference for active treatment, suggesting that patients are inclined towards early DMD treatment. Taken together our findings demonstrate that the rate of patients choosing to change the default they were presented with was 28.3% (the cumulative percentage of patients who made an active choice to change either one of the default conditions presented to them, Figure 1), a considerable number compared to preferences the neutral condition established. Recently, Giordano and colleagues¹⁸ reported that patient preferences regarding treatment decisions have not been adequately surveyed, particularly in people suffering from MS. Using the Italian

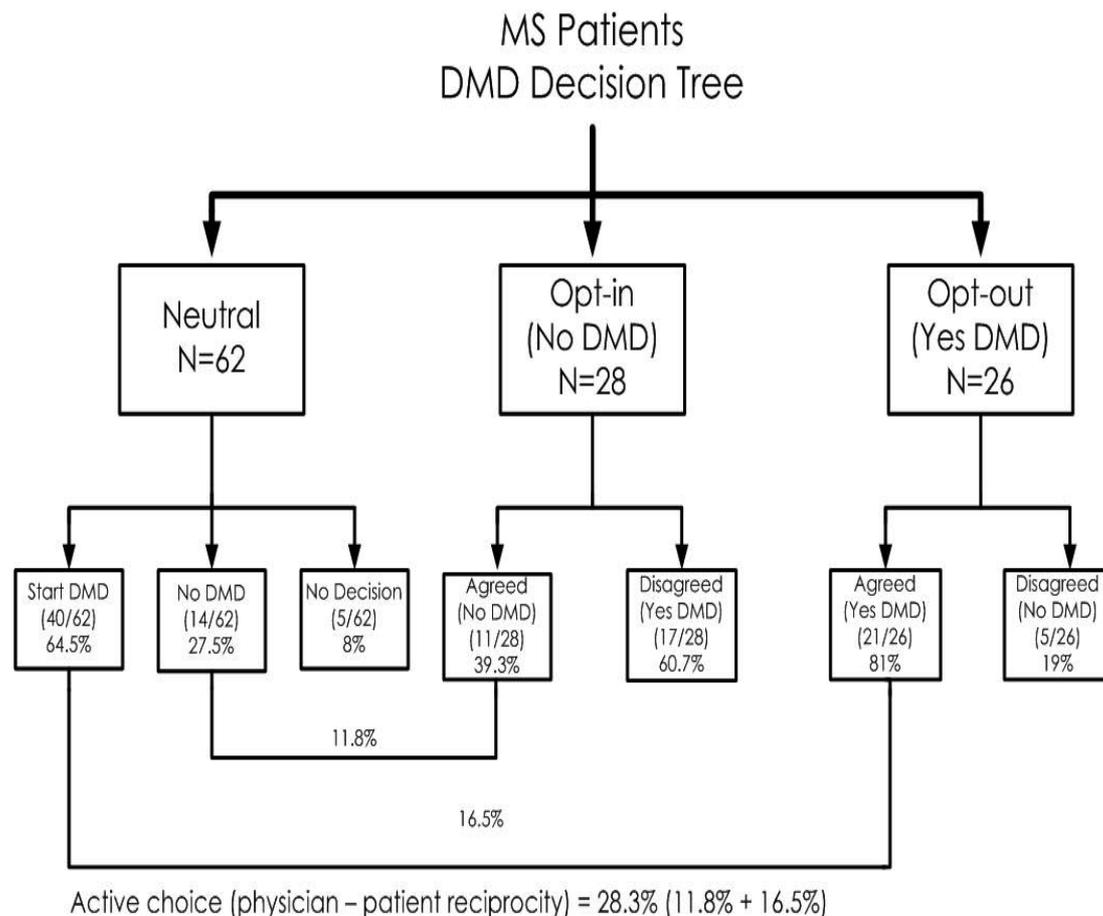


Figure 1. Detailed flow-chart of the study results. DMD = Disease modifying drugs

version of the Control Preference Scale with 140 people with MS, who varied in clinical and general a collaborative role (physician-patient) was preferred by 61% of patients, followed by passive (33%) and active (6%) roles. These data are similar to our opt-in condition results emphasizing the role of definitive guidance in aiding patients' decisions.

Social psychology demonstrates that subjects' choice is influenced by opt-in versus opt-out presentation of decision algorithms. Defaults not only make a difference in what is chosen, they can also make decisions easier. Moreover, default decisions are optimal when subjects have a strong propensity to procrastinate.¹⁹ This factor is particularly relevant to healthy subjects presented with complex and affectively loaded decisions. The impact of defaults have been emphasized in the general public by several unintended "natural experiments" in which governmental and public organizations randomly assign people to one program and then give the chance to choose among a set of alternative ones - examples include assignment to health care plans, the adoption of privacy policies and organ donation, where the stakes are high.⁴ These "natural" experiments show that defaults have a substantial role in determining what is chosen. In most cases, the majority of people choose the default option to which they were assigned.¹³ However, it has not been conclusively demonstrated that in real-life situations wherein patients have to commit a major disease related act (start treatment or undergo surgery), defaults play a significant role. A growing literature has examined how these findings may be placed within the context of the therapeutic relationship. Researchers involved in these studies suggest that many patients do not seek the level of involvement which the bioethics literature suggests they should wish. The strong preference for a shared role - physician-patient cooperation - suggests that involved patients wish to understand their disease and the choices available to them, and to be involved in aspects of decision-making that will affect their quality of life. However, they are willing to leave much of the responsibility for tasks that require expertise to the treating physician.^{15,19} Our findings indeed support the collaborative reciprocal dynamics involving both physician recommendations and patients' revealed preferences. The defaults presentation had swayed nearly one in three patients from their "neutrally" revealed choices. This highlights the role that physicians' recommendations and professional guidelines play in medical decisions.

In conclusion, this study evaluated a unique sample of participants, facing an important medical decision. Moreover, the impact of defaults is an important subject of current research and adding to our knowledge of the magnitude of their effects "in the field" is valuable. Unlike lay persons required to decide on important medical matters, MS patients take a stand preferring early treatment moderately swayed by defaults presentation.

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