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Shared Decision Making Resources

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A Novel Tool to Improve Shared Decision Making and Adherence in Multiple Sclerosis: Development and Preliminary Testing

Nananda Col, Enrique Alvarez, Vicky Springmann, Carolina Ionete, Idanis Berrios Morales, Andrew Solomon, Christen Kutz, Carolyn Griffin, Brenda Tierman, Terrie Livingston, Michelle Patel, Danny van Leeuwen, Long Ngo, and Lori Pbert

Abstract

Background. Most people with multiple sclerosis (MS) want to be involved in medical decision making about disease-modifying therapies (DMTs), but new approaches are needed to overcome barriers to participation. Objectives. We sought to develop a shared decision-making (SDM) tool for MS DMTs, evaluate patient and provider responses to the tool, and address challenges encountered during development to guide a future trial. Methods. We created a patient-centered design process informed by image theory to develop the MS-SUPPORT SDM tool. Development included semistructured interviews and alpha and beta testing with MS patients and providers. Beta testing assessed dissemination and clinical integration strategies, decision-making processes, communication, and adherence. Patients evaluated the tool before and after a clinic visit. Results. MS-SUPPORT combines self-assessment with tailored feedback to help patients identify their treatment goals and preferences, correct misperceptions, frame decisions, and promote adherence. MS-SUPPORT generates a personal summary of their responses that patients can share with their provider to facilitate communication. Alpha testing (14 patients) identified areas needing improvement, resulting in reorganization and shortening of the tool. MS-SUPPORT was highly rated in beta testing (15 patients, 4 providers) on patient-provider communication, patient preparation, adherence, and other endpoints. Dissemination through both patient and provider networks appeared feasible. All patient testers wanted to share the summary report with their provider, but only 60% did. Limitations. Small sample size, no comparison group. Conclusions. The development process resulted in a patient-centered SDM tool for MS that may facilitate patient involvement in decision making, help providers understand their patients' preferences, and improve adherence, though further testing is needed. Beta testing in real-world conditions was critical to prepare the tool for future testing and inform the design of future studies.

Keywords

shared decision making, communication, multiple sclerosis, adherence, patient preferences, values clarification, image theory, chronic disease

Introduction

Multiple sclerosis (MS) is a chronic, progressive disease of the central nervous system with unpredictable neurologic manifestations that can affect many dimensions of health (e.g., physical, emotional, social). Disease-modifying...
Difficult trade-offs among personal values (e.g., efficacy versus risk) can induce negative emotions that may lead people to avoid or delay decision making or to choose the default option. Physicians often make assumptions about what matters to patients, but those assumptions are often incorrect. A variety of approaches have been developed to help patients clarify their values with respect to a treatment decision, but these approaches typically rely on preference items selected by the developer or physicians, which may not be relevant to patients.

Patients need trusted, up-to-date information to engage in SDM, but the amount and essential elements of that information are undefined. Too much information can interfere with decision making and result in people focusing on only part of the information, screening out information or options based on initial impressions, settling on the first option that appears satisfactory, or using contextual cues to make a choice. SDM provides a framework for identifying the types of information needed to facilitate decision making (e.g., list all options, describe positive and negative features, describe natural history without treatment). However, SDM offers little guidance on how to manage a wide range of options and features or how to present information to patients.
patients to support decision making. In contrast, image theory describes how people make complicated value-laden decisions involving multiple options. Image theory depicts decision making as a two-step process. The first step involves focusing on the negative attributes of the options to screen-out options that are incompatible with one’s values and goals. The next step involves examining the pros and cons of each remaining values-compatible option to choose the best one. Validated in multiple settings and endorsed for SDM, image theory informed the design of the SDM tool.

Adherence to DMT is critical to achieve full treatment benefits, yet adherence is low, ranging from 41% to 95%. SDM may improve adherence, but the evidence is inconclusive. A recent review concluded that SDM can improve adherence to DMTs, based in part on a study showing that patients who did not feel well-informed by their neurologist were more likely to be non-adherent. SDM may improve adherence to DMTs by helping MS patients and providers choose a DMT that is more consistent with the patient's treatment goals, preferences, and lifestyles.

The objectives of this study are to 1) describe the development of a patient-centered SDM tool that also targets adherence; 2) describe patient and provider responses to the tool; and 3) discuss challenges in development and implementation.

Methods

Overview

This study is part of a larger mixed-methods study (the MS Decisions Study) to develop and evaluate web-based SDM tools for MS patients. The patient-centered design process was guided by formative work, relevant theory (Table 1), and SDM guidance. We previously developed and validated a preference tool to assess patient treatment goals for MS and patient preferences for the attributes of DMTs. That preference tool served as the nucleus for MS-SUPPORT.

All patient-facing content was co-written and iteratively revised by people with MS and reviewed by experienced providers for scientific accuracy. As part of our development process, people with MS iteratively assessed the tool's usability (alpha testing); patients and providers iteratively assessed the tool within the context of a clinical MS appointment during beta testing. This study was approved by the New England Independent Review Board. All participants provided written (online) informed consent.

Previous Work Identifying Patients’ Goals and Preferences

Cognitive mapping informed the design of the values clarification modules, using previously published methods. In brief, we used the nominal group technique to identify and prioritize patient treatment goals, preferences for DMT attributes, and factors driving a change in treatment. We used card sorting coupled with hierarchical cluster analysis and multidimensional scaling to create a cognitive map that organized preference items into meaningful clusters. These clusters comprised the lists of goals and preferences included in the values clarification modules and were independently validated.

The SDM Tool: MS-SUPPORT

MS-SUPPORT is an interactive, online decision aid designed to encourage patient-provider collaboration and promote treatment adherence. The tool emphasizes patient engagement, patient-provider communication,
SDM, healthy lifestyles, and treatment adherence. Design features include accessibility on multiple platforms, scalability, encryption, HIPAA compliance, and various options for dissemination and clinical integration. Content can be rapidly updated online. The tool employs principles of effective communication including positive framing, side-by-side comparisons, graphics, plain language, highlighting important information, and a user-driven path. The average reading level is grade 6.9. The tool was created using customized Qualtrics software.

MS-SUPPORT guides users through a series of structured, interactive modules (Figure 1). It provides personalized feedback based on the patient’s stated goals, preferences, needs, situation, adherence, and health behaviors, generating a concise summary that is emailed to the patient to share with their provider (Figure 2). Sharing can be accomplished by printing or emailing the summary, copying it into the electronic patient portal, or using a mobile device. MS-SUPPORT also generates and emails a comprehensive personal report to the patient that includes information on the topics of interest selected by the patient. Patients do not have to complete all the modules at once; they can log back in later to complete the tool.

General Tool Design and Rationale. The introductory section of the tool is designed to set the emotional tone, build trust, and promote engagement. It assesses the patient’s role preference in the decision-making process (using the Control Preferences Scale) and provides tailored feedback about the importance of engagement and communicating their preferences with their provider.

Values Clarification Exercises. Multitiered values clarification exercises help the user identify and prioritize their MS treatment goals and preferences for DMT attributes by asking the user to select the most important broad goals (or attributes) from a list. Next, the user rates the importance of conceptually related but more specific items within those broad goals (or attributes). Last, additional preference items can be added by the user. Once this exercise is completed, MS-SUPPORT generates a succinct summary of the patient’s goals and preferences and explains how to use goals and preferences to guide decisions. Other preference modules follow a similar design. Values clarification exercises precede discussion of specific DMT options in order to minimize the premature elimination of options that might seem incompatible with one’s values (keeping with image theory).

Defining the Scope and Key Content Messages. During formative work, we became aware of information gaps and misperceptions about MS and DMT that could interfere with informed decision making. To more systematically identify common patient misconceptions and information gaps about DMTs, we convened a very small convenience sample of patients and providers. The sample included five patient advisers who were peer-to-peer educators (e.g., moderating MS blogs and/or support groups) and five experienced MS providers (three medical doctors, one physician assistant, one registered nurse) from different parts of the United States. Advisers independently answered the question, “In your opinion, what do you think are the most important misperceptions and information gaps that interfere with good decision-making about DMTs?” After responding to the question, each respondent was shown responses from previous respondents to stimulate new ideas. They were also asked for suggestions for correcting those gaps and misperceptions (Table 2). Responses guided the content and scope of the tool. For example, because patients did not clearly distinguish between symptom management and slowing disease progression, the tool addressed symptoms as well as DMTs. Because of the many misconceptions regarding lifestyle and DMTs, which could affect symptoms and disease progression, a lifestyle module was included.

Presenting Decisions. DMT decisions were classified as either starting, stopping, or switching treatment, depending on current DMT use. Options were presented to balance the general risks, benefits and inconveniences of DMTs as a class against the risks, benefits and inconveniences of not taking DMTs. The attributes of specific DMTs were subsequently compared. Different graphic representations, including balance scales and flow charts (Figure 3), aided comprehension.

Comparing Options. A simplified table compares the effectiveness and risks of specific DMTs. Using an iterative design process, we initially developed a table comparing each treatment’s relative risk estimate for each benefit and risk, in accordance with SDM guidance. Despite numerous revisions, we abandoned this approach due to persistent misinterpretation by the testers. Indeed, the scientific evidence does not support head-to-head comparisons among DMTs at this time. Cross-DMT comparisons are confounded by differences in each trial’s comparison group. Providing general information about a treatment’s effectiveness on different outcomes by using
**Figure 1** Content diagram of MS-SUPPORT. *Summary individualized based on patient responses. Summary and content e-mailed to patient.*
Summary of your responses and preferences  4/11/2018

RRMS since 2007
Symptoms began: 2004
**Can walk** Couple miles without stopping
**Assistive devices used:** None
**0 falls** last month

**MS symptoms:** 0 means not at all bothersome, 10 means most bothersome
- Pain: 1
- Fatigue: 4
- Thinking: 6
- Weakness: 6
- Numbness/tingling: 9
- Spasticity: 1
- Arms: 1
- Legs: 1
- Vision: 1
- Bladder: 5
- Bowel: 1
- Balance: 5
- Heat sensitivity: 1
- Sex: 1

Not depressed// No anxiety
**Preferred role:** Make the final selection myself after seriously considering my doctor's opinion

**Goals for MS treatment**
1. Avoid flare-ups or progression
2. Finding the best medication
3. Disability concerns

**Specific goals:** keep the brain healthy (avoid brain atrophy), maintain clear thinking, better balance (for example, avoid falling), avoid or slow progression of MS, avoid flare-ups

**Important DMT features**
1. Effectiveness
2. Confidence in the treatment
3. Serious side-effects
4. Brain health
5. Managing symptoms

**Specifics:** ability to prevent underlying disease progression, effectiveness in preventing further disability, feeling better while on treatment, effectiveness in preventing new or enlarging MRI lesions, my other health conditions.

**Current DMT:** Tecfidera® (dimethyl fumarate)
**Past DMT:** Copaxone® (glatiramer acetate), Rebif® (interferon b-1a), Tysabri® (natalizumab), Rituxan® (rituximab)

**Why stopped:** Copaxone: It was not stopping my relapses or progression// Rebif: It was not stopping my relapses or progression// Tysabri: JC Virus Positive// Rituxan: I kept getting sick //

**Interested in changing DMT:** Yes because I am getting continuous infections and feel like it is time for a change

**Adherence:** 0 missed DMT doses.
**Challenges taking DMTs as prescribed:** When your routine is messed up.
**Able to give injections:** Yes, I can do it myself

**Lifestyle:** No tobacco use, Up to one drink a day, Perceived weight: Somewhat overweight, Not enough regular exercise: exercises only 3 times/week. Interested in changing now: lose weight; Interested in changing later: exercise more

**Questions for provider:** What new medication can I change to that will work differently from Tecfidera

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*Figure 2*  Sample overall summary generated by MS-SUPPORT.
Table 2  Summary of Identified Misperceptions and Information Gaps about MS (Based on Responses from a Convenience Sample of 10 Experienced Providers and Patient Peer Educators)
Respondents were asked to respond to: In your opinion, what do you think are the most important misperceptions and information gaps that interfere with good decision making about DMTs?

<table>
<thead>
<tr>
<th>Misperception or Gap</th>
<th>Proposed Solutions Offered by Respondents*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expectations about DMTs</td>
<td>Education, let them know, even when they feel good, they need to stay engaged; use MRI to illustrate the disease ticking away. Show proof that it's working—no new lesions, present DMTs as an insurance plan to protect them from the future but won't improve their QoL now by treating their symptoms. Explain that DMTs are not used to treat these symptoms. If newly diagnosed and no disability, redefine cure to mean stop the disease dead in its track. Don’t want to oversell what they can do, but don’t become therapeutic nihilists. May be a problem only with patients not in the MS loop [lacking specialty MS care]. Especially as we get more DMTs, don’t throw in the towel.</td>
</tr>
<tr>
<td>DMTs don’t make you feel better/don’t improve or cure daily MS symptoms.</td>
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<tr>
<td>Expect DMTs to help with symptoms that are gradually worsening (e.g., optic neuropathy, spasticity, walking impairment).</td>
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<tr>
<td>Associate DMT with being a cure.</td>
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<tr>
<td>If one DMT doesn’t work, why bother to try another. This is also a problem among the medical community (perception of therapeutic equivalence among DMTs, reluctance to move people onto a different treatment). Not knowing that there are DMTs available now.</td>
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<tr>
<td>Not understanding that adherence to treatment matters and affects how well the treatment works, even though there’s no immediate negative repercussion when they miss it. (Some patients may think it’s OK as long as they don’t tell their neurologist.)</td>
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<tr>
<td>Believe that steroids used during a relapse prevent underlying damage.</td>
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<tr>
<td>Understanding risks and side-effects</td>
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<tr>
<td>People don’t understand numbers very well, especially when talking about risk (e.g., what a risk of 1/20,000 v. 1/10,000 means, how to compare it to other risks in our lives). Patients tend to focus on the fact that the risk is there, not on how likely it is, they magnify rare risks and imagine the worst possible case scenario.</td>
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<tr>
<td>Fear about being involved in research. Anything seeming like research or not proven has negative perception. “Are you putting me into a study?”</td>
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<tr>
<td>There are safety concerns and confusion about interpreting risk. For example, with Tysabri, people think they will get PML, and the patient has already written off a medication because they perceive a potential adverse event as one that they will get. Risk numbers mean different things to different people. What risk of PML is acceptable? People have different risk tolerance. Why introduce the risk of a potentially fatal disease into a condition that is not fatal? Framing matters—if going to sports stadium that holds 70,000, and know that 7 will be shot and killed by a sniper, would I go to the game? Need to reframe to reflect risks of not treating. First identify why patients are hesitant from a safety perspective. Talk about a medication; if the patient is not open to it, ask why they are hesitant, what makes them nervous about it. People may say, “I read you get PML or get seizures on this med.” Be aware that people get information from lots of different sources. One provider uses brain atrophy data (not drug specific) to discuss the rate of brain atrophy with and without treatment (0.4 v. 0.1). Address cultural differences.</td>
<td></td>
</tr>
<tr>
<td>Misperception or Gap</td>
<td>Proposed Solutions Offered by Respondents*</td>
</tr>
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<td>--------------------------------------------</td>
</tr>
<tr>
<td>Misunderstand flu-like symptoms, think of them as nausea, vomiting. People confuse having JCV antibodies with having PML.</td>
<td>Refer to MS consortium guidelines—recently updated, p 20, talks about importance of being on DMT and brain atrophy. Explain that just because the risk is listed doesn’t mean it will happen. PML freaks people out the most. Use risk stratification posters . . . use visual charts to put in perspective, what is your risk of your becoming disabled and progressing if you don’t go on treatment. People are misinformed about safety risk . . . talked about risk tolerance—referring to “big” risks.</td>
</tr>
</tbody>
</table>

Perceptions of DMT efficacy
The efficacy of DMTs is related to its mode of administration and/or frequency; drugs taken more frequently are thought to be more effective. Drug can’t be effective if only taken for 6 months. IV meds are stronger than oral meds and get into the body better. Perceptions that pills are the least effective. People thought that Avonex, a weekly IM DMT, was a long-acting form of interferon (e.g., depot form) therefore stronger. Be clear about efficacy and what influences it. That mode of administration is independent of efficacy.

Understanding of MS
Believe their immune system is underactive or weak instead of being overactive, medication side effects not withstanding (“I have a weak immune system”). Believe an injury caused their MS, so they don’t have “real MS” or need treatment. People looking for “why me?” Explain that MS results from an overactive immune system.

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Perceptions that MS is only a white matter disease (not knowing that lesions can occur in grey matter); thinking that no enhancing lesions mean no progression.

Disease monitoring
People think that MRIs involve radiation exposure, leading to avoidance of periodic MRI due to perceived risk.

Difficultly forecasting adaptation to new situations
Patients don’t think they can’t administer injections, and then have no trouble with them.

Fear of intermittent self-catherization.
Fear of adaptive equipment—think that once I use it, I’m giving in to my progression.

Be clear that MRIs do not involve radiation exposure.

Talk about hurdles, fear of injectable meds, how most people easily adapt.
<table>
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<tr>
<td><strong>Preparation needed for decision making about DMTs</strong></td>
<td>Help people prepare for the visit, give simple pointers, such as list all meds, bring a friend/family. Bring a friend to the visit.</td>
</tr>
<tr>
<td>Not understanding the need to prepare in advance to be involved in decision making about DMTs.</td>
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<tr>
<td>Expect that all the information that is given to patients during the visit will 'stick' and have an impact.</td>
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<tr>
<td>Expect their MS doctor to make them feel better, get rid of their pain, etc.</td>
<td></td>
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<tr>
<td>Underestimate how much their overall physical and mental health affects how they feel on a day-to-day basis. If I feel good, all is OK.</td>
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</tr>
<tr>
<td><strong>Lifestyle: exercise, diet, psychosocial</strong></td>
<td>Explain the benefits of exercise.</td>
</tr>
<tr>
<td>Thinking that you shouldn’t exercise with MS—stems from the idea that “I have MS and therefore I’m fragile and need to be more sedentary/If I push myself too hard, I’ll push myself into a relapse.”</td>
<td>Transiently, exercise may worsen fatigue, but overall the benefits and gains from exercise outweigh that transient feeling.</td>
</tr>
<tr>
<td>Exercise will worsen fatigue.</td>
<td>Explain that heat sensitivity is a QOL issues, not related to progression.</td>
</tr>
<tr>
<td>Getting hot can cause damage/If I have heat exposure, that’s causing new lesions, relapse, new damage.</td>
<td>Complementary medicine is challenging. Patients get bombarded by friends, social media, especially dietary. We don’t know what the best diet is. Social media can be a curse... read something online, think that’s going to be me. Some have distrust of traditional meds, especially pharma, think that there’s a cure out there that doesn’t involve profit. Remind people that MS is varied, there is no right magic bullet for everyone. People with MS tend to die from heart disease, cancer, stroke, so overall wellness matters. See NMSS refs. Actuarial tables show that life expectancy is about 7 years shorter.</td>
</tr>
<tr>
<td>Paleo diet and other extreme diets will cure MS/reverse/stall.</td>
<td>There may not be good data about how affects how the DMT works, but it may well affect adverse drug reactions and adherence. Ask about smoking. Give feedback about how it affects the course of MS. Talk about the benefits of maintaining positive social relationships.</td>
</tr>
<tr>
<td>Thinking that what’s good for one person must be good for you. Not understanding that making risky lifestyle choices (binge drinking, smoking, huffing) could interfere with how the DMT works and/or side effects. Patients may not disclose “closet habits” to doctor.</td>
<td></td>
</tr>
<tr>
<td>Not understanding that smoking accelerates MS progression. Think that psychosocial stress causes disability, and/or relapse, therefore the patient has to isolate oneself from psychosocial stressors because it will make their MS worse.</td>
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</tr>
</tbody>
</table>

**Table 2 (continued)**

DMT, disease-modifying therapy; IM, intramuscular; IV, intravenous; MRI, magnetic resonance imaging; MS, multiple sclerosis; QoL, quality of life; ADR, adverse drug reaction; JCV, John Cunningham virus, NMSS, National Multiple Sclerosis Society; PML, Progressive multifocal kukoencephalopathy.

*These include the specific responses and/or thoughts offered by respondents.*
There are many ways that a DMT can influence your life. The figure below compares the risks of taking a DMT to the risks of NOT taking a DMT.

**No DMT**
- More disability
- More relapses
- Costs of MS progression
- Brain lesions accumulate

**DMT**
- Less disability
- Rare serious risks
- Longer survival
- Fewer relapses
- Fewer MRI lesions
- Costs of DMTs
- Possible side effects

All DMTs help prevent relapses, disability associated with relapses, and reduce the number of brain lesions. Some are more effective than others.

*DMTs usually do not improve the symptoms of MS. There are other ways to manage day-to-day symptoms of MS. DMTs may help prevent future complications.*

- DMTs are available in different forms—pills, injections, or intravenous infusions (an IV).
- Dosing options range from daily to yearly.
- Like all medications, they each have potential side effects. Some DMTs can lead to flu-like symptoms for up to a day or two, some can cause injection-site reactions, some can increase your risk of infections.
  - Most of these side-effects are not severe, **many patients never get these side-effects**, and in many patients these side-effects get better over time.
- Some medications for MS have rare but severe potential side effects, such as liver failure, PML (progressive multifocal leukoencephalopathy, a viral disease), or leukemia.

**Your 4 options:**
- Continue current DMT
- Change to another DMT
- Stop using a DMT
- Make my decision later

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**Figure 3** Screen shots from MS-SUPPORT. Examples of presenting decisions in MS-SUPPORT.
a check mark system within the comparison table (Figure 4) proved useful and acceptable to patient and providers.

**Encouraging Adherence.** We developed an adherence module that explains the benefits of adhering to DMTs and addresses individual barriers to adherence. Reasons for nonadherence and strategies for remediation were compiled based on a targeted literature review and formative work (e.g., misperceptions about DMTs). This compilation was transformed into self-assessment instruments, each iteratively revised by patients and providers. These instruments assessed the number of recently missed DMT doses, reasons for past nonadherence, and anticipated barriers to future adherence. Tailored feedback addressed problem areas, provided practical tips and resources, and summarized patient responses.

**Alpha and Beta Testing**

**Participants.** Participants included non-pregnant, English-speaking patients between the ages of 21 and 75 who self-identified as having MS, were not enrolled in a clinical trial of an MS medication, and had access to the Internet. Beta testing was further limited to patients with an upcoming appointment with their MS provider within 12 weeks.

We initiated an online participant panel for this study in January 2015 composed of participants who were referred to the study (opt-in) through multiple methods, including referrals by participating providers, patient advisers, support groups, and private Facebook groups. All referrals were facilitated by patient advisers or participating providers to ensure that only subjects with a diagnosis of MS were included. Alpha-testers were identified through the patient panel; beta-testers were referred from patients or participating providers.

**Data Collection.** Potential participants were emailed invitations to review and evaluate MS-SUPPORT between October 1, 2017, and May 1, 2018. Invitations included a web link to a secure website that directed the participant though the eligibility screener, informed consent document, and baseline questionnaire. Questions assessed sociodemographics, current and previous DMT use, adherence, and self-reported knowledge about MS and treatment options. For beta-testers, we also asked for the date of their upcoming provider appointment and provider name. Eligible participants were emailed a unique, nontransferable link to the MS-SUPPORT tool that included evaluation questions. Beta testing subjects were emailed a second evaluation on the day of their scheduled provider appointment. Participants received
an incentive payment ($25 online gift card) after each completed evaluation.

Assessments

Alpha testing included online evaluation and structured video-conference interviews. Assessments addressed overall evaluation (“I would recommend it to others with MS”), usability (“It was easy to use,” “It was easy to read,” “It was well organized,” “It kept my interest,” “It contained the right amount of information”), trust in the information (“I trusted the information provided,” “It presented unbiased information”), patient-provider communication (“It addressed topics that are important in communicating with my doctor”), values clarification (“It helped me understand the things that matter most to me about my MS”), knowledge (“It helped me understand the importance of taking DMTs as prescribed,” “It makes me more likely to take my medications as prescribed”), and suggestions for improvement.

Beta testing additionally evaluated the use of the tool in the context of a clinical visit with an MS provider. Beta-testing questions also addressed preparedness for the clinical visit (e.g., “It will help me make the most of my next MS doctor’s visit”), decision making (“It prepared me to make better decisions about MS”), communication (“It will help me talk to my doctor about what matters most to me”), stage of decision making, preparation (It will help me prepare for my next MS appointment”), and role preferences (“It helped me think about how involved I want to be in MS decisions” and the validated role preference scale). Survey response options used a 5-point Likert-type scale (“strongly disagree,” “somewhat disagree,” “neither agree nor disagree,” “somewhat agree,” “strongly agree”). After their provider appointment, we assessed SDM-relevant items from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician and Group Survey for Merit-based Incentive Payment System and their experience sharing their summary with their provider. Questions addressed their provider’s interest in reviewing the summary, whether the summary helped them talk to their provider about their preferences, challenges encountered, and whether MS-SUPPORT affected the quality of the visit, decision making, and motivation to make lifestyle changes. Likert response categories were “not at all,” “very little,” “somewhat,” “a lot,” or “a great deal.”

Participating providers were emailed a brief online survey just after interacting with a patient participant. An incentive payment of $50 was offered for each completed provider survey. We asked providers questions about patient-provider communication, the usefulness of the patient summary, and the patient’s preparation for the visit.

Results

Alpha testing included 14 patients with MS, of whom 11 completed the online evaluation and 9 participated in a video-conference interview (Appendix 1). A separate sample of 40 patients were invited to participate in beta testing (Appendix 1), of whom 15 completed the screening process and evaluations (Appendix 2). Those who did not complete the screening process were slightly younger and more likely to be white, male, and less educated than participants.

Alpha Testing

We iteratively revised the tool’s content, design, and tailoring algorithms during alpha testing until all identified problems were addressed and satisfactory usability ratings were obtained. This process resulted in shortening passages, removing inessential or repetitive elements, correcting programming errors, introducing skip patterns, tiering information, offering less important information as optional drill-downs, and emailing information of interest to the user upon completion. Findings are shown in Appendix 3. Because MS-SUPPORT underwent substantial revisions during alpha testing, we focus on beta testing finding.

Beta Testing

It took patients an average of 62 minutes (adjusting for outliers; range 18-496) to complete the tool. Twenty-five percent completed the tool within 36 minutes, including the evaluation module and any breaks the patient may have taken. All15 patient beta-testers wanted to share their summary with their provider, but only 8 did (7 brought a printed copy [3 out of 8 patients requested that the printout be mailed to them due to challenges printing it themselves], 1 used their smartphone; 2 reported verbalizing the summary to their provider after forgetting to bring the report with them). Many logistical problems reported by patients were due to a single programming error that prevented patients from sharing their summary with their provider and which was corrected during beta testing. All who shared their summary reported that they (not their provider) initiated discussion about the summary. All patients agreed or strongly agreed that the
report was easy to share, that they felt comfortable sharing it, and that their provider seemed interested in reviewing their report during the visit. Most of their providers asked them questions about the report. Six of seven patients agreed or strongly agreed that “the summary report helped me talk to my provider about my preferences” (the remainder neither agreed nor disagreed).

Patient evaluations after viewing MS-SUPPORT (before the clinic visit) were favorable (Figure 5). Higher ratings were reported on topics that were applicable to everyone (e.g., trust in the information, preparing for appointments, communication) as compared to topics that were more relevant to those with specific issues (e.g., severe symptoms) or behaviors (e.g., nonadherence). “Not applicable” was not a response option and all participants received the same evaluation questions. MS-SUPPORT improved 6 of 15 participants’ stage of decision making (Figure 6).

Patient evaluations after the clinic visit suggested that the tool helped most patients with decision making, communication, and preparation (Appendix 4). Patients who shared their summary (compared to those who did not) reported higher evaluations of their providers and higher CAHPS metrics (Appendix 5).

**Provider Evaluations**

Fourteen patient participants were associated with 12 different providers. Four of these providers (all neurologists) completed six evaluations of MS-SUPPORT (one provider saw three participating patients). Four of these evaluations reflected visits where the patient shared their personal summary. Providers reported that it took an average of 5.25 minutes (range 1-10 minutes) to review the summary. All providers would recommend MS-SUPPORT to a colleague. Most reported that MS-
SUPPORT improved the quality of care provided, the efficiency of the visit, and their knowledge of and interaction with the patient (Appendix 6). Evaluations were more positive for the four encounters in which patients shared versus did not share their personal summary.

Discussion

The patient-centered design process described succeeded in guiding the design and delivery of a feasible and potentially effective SDM tool for MS. Having patients with MS guide all stages of development added substantial complexity to the design process but increased the tool’s patient-centeredness. The development process adhered to SDM guidelines and included recommended alpha testing with patients and beta testing in “real-life” conditions. Additional design processes and theoretical frameworks were needed to address challenges that were not readily addressed by SDM guidelines. Image theory was instrumental in structuring information. Despite the large amount of information and options included in the tool, all testers felt MS-SUPPORT contained the right amount of information. The pilot alpha and beta testing included in the development process was instrumental in developing the intervention and guiding subject recruitment, intervention delivery, and sample size calculations for future studies and dissemination. Pilot testing that encompasses recruitment and delivery strategies has been called for in other areas and is especially valuable for SDM tools, where dissemination challenges persist.

Disseminating the tool to patients through patient-referral networks was feasible, required no effort by providers, and helped deliver the tool to patients who lack MS specialty care. However, delivering MS-SUPPORT to patients just in time to prepare for a clinical appointment was challenging. Providing the tool too early resulted in patients forgetting to bring their summary with them to the appointment while providing it too late did not give patients enough time to review MS-SUPPORT. Timely reminders might help overcome these challenges.

An unexpected finding was that all patients wanted to share their personal summary with their provider and all who did reported it was easy to share. However, implementation challenges were encountered. Despite offering
several options for sharing the report, most patients relied on manual printing instead of the patient portal, even though the latter facilitated delivery via the electronic health records (EHRs). Participants lacked familiarity with utilizing patient portals in this manner (portals are typically used to view laboratory results or schedule appointments). Sending reminders before the HCP visit and helping patients access and use their patient portal should help. Embedding the tool directly into an EHR should obviate many logistical problems encountered, making it possible to trigger access to the tool prior to upcoming appointments and incorporate the summary page into the patient’s EHR, but was beyond the scope of this project.

We designed MS-SUPPORT to improve adherence by targeting factors that contribute to nonadherence. These factors include poor patient-provider communication, patient attitudes and beliefs about health and illness (e.g., difficulty perceiving the benefits of DMTs on frequently occurring relapses or disability progression), high treatment costs and provider co-pays, limited access to MS specialists and specialized treatment centers, and restricted formularies. The self-assessments and patient feedback were intended to motivate patients to learn ways to surmount adherence obstacles. Informing providers about their patient’s adherence behaviors through the summary page may help providers address patient’s adherence challenges (many DMT nonadherent patients do not tell their provider) and help them select DMTs to which patients can more easily adhere. MS-SUPPORT helped people understand the importance of adherence and improved adherence expectations, which is strongly associated with actual adherence. However, actual adherence was not assessed.

This study builds upon a growing body of educational tools for MS. These include a decision aid for managing MS relapse, a booklet for women with MS considering motherhood, an information aid for newly diagnosed patients, a DMT booklet, and an interactive tool that compares DMTs. MS-SUPPORT offers the additional functionality of connecting patients to their providers to improve patient—provider communication, SDM, and adherence to treatment.

By helping patients understand their own goals and values and share them with their provider, MS-SUPPORT may help providers comply with the American Academy of Neurology’s recommendation that providers assess patient preferences for DMTs. Combining preference assessment with the other key elements of SDM should enhance the effectiveness of this recommendation in improving care. The other SDM elements include the following: 1) informing patients when they need to be involved in making a decision; 2) explaining why their preferences matter; 3) assessing patients’ desired level of involvement in decision making; 4) helping interested patients be more involved in decision making; and 5) assuring patients of their provider’s support for their decision.

SDM tools such as MS-SUPPORT can help with most of these elements, but only providers can demonstrate their support for patients to participate in SDM. Providers thus play an important role in either encouraging or impeding patient involvement. Training providers in SDM and providing SDM tools that can be used in clinical practice should help providers create opportunities for patients to discuss their needs and preferences and engage in partnership building.

Our pilot testing has many limitations that diminish internal and external validity, notably small sample size and lack of a control group. We relied on self-report, which may have led to a tendency for more favorable responses. Including only patients with an upcoming appointment may have resulted in selecting patients with more active disease. Many participants were relatively well-educated, though less-educated people and people with lower health literacy were included. Lower educational levels may prevent understanding of health information and compromise participation in SDM, but does not necessarily predict response to tools designed to overcome literacy barriers. We did not confirm a diagnosis of MS but our referral sources made incorrect diagnoses unlikely. Participating providers likely represented higher performing providers who were willing to engage in SDM, which could bias their responses. Our pilot testing was not designed to establish the impact of the tool but rather to improve the tool and guide future evaluation in a larger and more diverse sample.

The positive response from both patients and health care providers to the tool during beta testing establishes the feasibility of the SDM intervention and procedures for dissemination and clinical integration in real-life conditions. The process of developing the MS-SUPPORT tool can be applied to developing decision tools for other health conditions.

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**Supplemental Material**
Supplementary material for this article is available on the *Medical Decision Making Policy & Practice* website at [https://journals.sagepub.com/home/mpp](https://journals.sagepub.com/home/mpp).
References


