

A Novel Electronic Application of Patient-reported Outcomes in Multiple Sclerosis – Meeting the Necessary Challenge of Assessing Quality of Life and Outcomes in Daily Clinical Practice

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Abstract

Multiple sclerosis (MS) has a substantial negative impact on health-related quality of life. Clinical assessments often do not include standardised, routine assessment of MS impact from the patient perspective, and communication between healthcare practitioners (HCPs) and patients can be lacking. Thus, there is a need for patient-reported outcome (PRO) measures to encourage patient-HCP communication, to help inform HCPs of matters important to patients and to aid both patients and HCPs in managing the disease. MSdialog is a web- and mobile-based software application that works with auto-injector devices and electronic autoinjectors, including the RebiSmart[®] 2.0 device (a handheld electronic Rebif[®] auto-injector with wireless data transmission capabilities, CE marked and available worldwide [excluding the US]) to collect and store real-time, point-of-administration adherence, clinician-reported outcomes and PRO data. MSdialog may provide a practical solution to support patient-proactive engagements and self-management, patient-centred care and participatory decision-making in clinical practice.

Keywords

Multiple sclerosis, patient-reported outcome (PRO), health-related quality of life (HRQoL), clinical practice, patient-provider communication

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Impact of Multiple Sclerosis on Health-related Quality of Life

Patients with multiple sclerosis (MS) suffer from myriad symptoms, including pain, fatigue, depression, bowel/bladder dysfunction and sleep disturbances. Understandably, the effects of MS on patients' vitality and physical, emotional, social, cognitive and sexual function negatively impact their health-related quality of life (HRQoL).¹⁻⁴ The relative burden of MS on HRQoL is estimated to be greater than for cardiovascular conditions, cancer, endocrine conditions, arthritis and chronic respiratory diseases.⁵⁻⁷ Compounding the negative impact of MS on HRQoL are the challenges faced by MS specialists, neurologists and general healthcare practitioners (HCPs) in managing patients with MS owing to high patient heterogeneity in terms of disease severity, comorbidities, symptoms, the impact of symptoms on HRQoL and the transient nature of symptoms. Often, standard clinical assessments do not provide enough information for HCPs to effectively manage the disease and improve HRQoL.⁸

Patient-Based Assessment

The Institute of Medicine of the US National Academy of Sciences names patient-centred care as one of six domains of healthcare quality.⁹ In patient-centred care, the patient's perspective on her/his condition is valued, and information regarding the patient's experience is considered in clinical care and treatment decision-making. The UK National Institute for Health and Care Excellence (NICE) recommends patient participation in all aspects of MS healthcare as well as self-management of general health.¹⁰ As the experience of MS varies greatly from person to person and because some treatment effects can only be identified by the individual patient, the routine assessment of disease severity and outcomes from the patient perspective is especially important for comprehensive health assessment and clinical decision-making. Enhancing HCP-patient participatory decision-making may improve patient adherence, health outcomes and satisfaction in MS.¹¹⁻¹⁴

Patient-reported outcome (PRO) instruments facilitate patient-centred care and can encourage communication between patients and physicians.^{15–18} Compared with standard clinical testing, PRO instruments more fully reflect the patient's experience of life with diseases such as MS, the patient's perception of the effects of treatment and the disease course, thereby providing a quantifiable and broader measure of the impact of disease. For example, at the clinical appointment, the patient may be asked generally, 'How are you?' Although it can be used to ask patients to reflect on their status, this type of question does not provide direction regarding specific symptoms or HRQoL aspects that may help inform disease status or how to proceed with management.¹⁹ In addition, PRO measures for MS contribute unique information that is not captured via the most commonly used measures of clinical disease severity (e.g., Expanded Disability Status Scale [EDSS], magnetic resonance imaging and relapse rate).

Additional benefits of routine PRO assessment include providing a baseline from which to tailor treatments and assess their effectiveness, screening for hidden problems and facilitating the detection of aspects of the condition that would otherwise go unrecognised (e.g., serve as an early indicator regarding the changing impact of the condition and signal the need for additional follow-up). PROs also help patients and HCPs monitor changes and responses to treatment that are meaningful to the patient.²⁰

Routine PRO assessment can also improve patient–HCP communication and patient self-management of their disease, both aspects potentially resulting in improved outcomes. Through routine self-monitoring, patients are more likely to become active in disease management and treatment decision-making, which in turn may lead to improved treatment compliance, and ultimately, improved outcomes.^{17,18,21} Furthermore, by providing patients with reference material to discuss with their HCP, PRO instruments open lines of communication between patient and HCP, enhancing rapport and interpersonal relationships.^{15,16,18,22–24} A study evaluating the relationship between HCP–patient communication and patient adherence found a 19 % higher risk of non-adherence to treatment when the patient's HCP is poor at communicating compared with HCPs who communicate well.²⁵ Thus, increasing HCP–patient communication around the full impact of disease and treatment may lead to increased treatment compliance, which in turn can result in improved patient outcomes.

To facilitate participation in patient-centred care, researchers and clinicians are becoming increasingly dependent on technological advances for PRO assessment, including web-based interventions and mobile phone applications. Recent studies have shown that these modalities are effective for health screening, education and intervention, and can even improve health outcomes.^{26–29} Studies in MS in particular have shown that patients are not only willing to utilise technology to report on their health, but that these methods are successful at obtaining valuable patient-level information.^{30–32} A recent study evaluated Internet use in 586 MS patients and found that 94 % had Internet access, with approximately one-third seeking MS-specific information.³¹ In the same study, nearly 68 % of MS patients accepted communication with their HCP via mobile phone, Internet or email. Because technology and its use will continue to advance, integrating web-based interventions in MS patient care will ultimately help improve patient outcomes.

Challenges in Assessing Health-related Quality of Life and Outcomes in Daily Practice

Despite the benefits of PRO instruments in improving HRQoL and overall patient outcomes, several obstacles exist that prevent their use in daily practice. Although PRO measures are often well accepted by patients,^{18,22}

conflicting evidence exists regarding HCP perceptions of the usefulness of these instruments.^{14,33} Barriers to the use of PRO data by HCPs may be practical (e.g., lack of financial or personnel resources for administration, scoring, collection, storage and retrieval of data; perceived time burden for HCPs and patients),^{14,34,35} methodological (e.g., how to effectively and efficiently use the information)^{33,34,36} or cultural.¹⁴ Challenges related to the utility of PRO instruments in particular include a lack of normative data for MS patients,³⁷ lack of interpretation guidelines for changes in individual patients over time,^{34,38} instruments focused on a single symptom (e.g., pain, fatigue) and a wide proliferation of instruments, thus causing confusion regarding which instrument best characterises HRQoL, especially in MS.¹⁴

It is crucial for HCPs to seek regular input from patients with regard to the experience of the disease and how it affects HRQoL in order to maximise patient outcomes.^{2,17,39} Not only are HCPs faced with challenges in terms of incorporating PROs in clinical practice, but there have been studies suggesting a lack of effective communication between HCPs and their patients with regard to factors affecting HRQoL as well as which aspects of HRQoL are most relevant.^{40,41} Therefore, there is a need to empower MS HCPs with better communication and decision-making skills and to improve attention to MS patient preferences for reception of information and involvement in health decisions.⁴²

Taking all of these factors into consideration, the present challenge is to identify a 'tool set' that meets the following criteria:

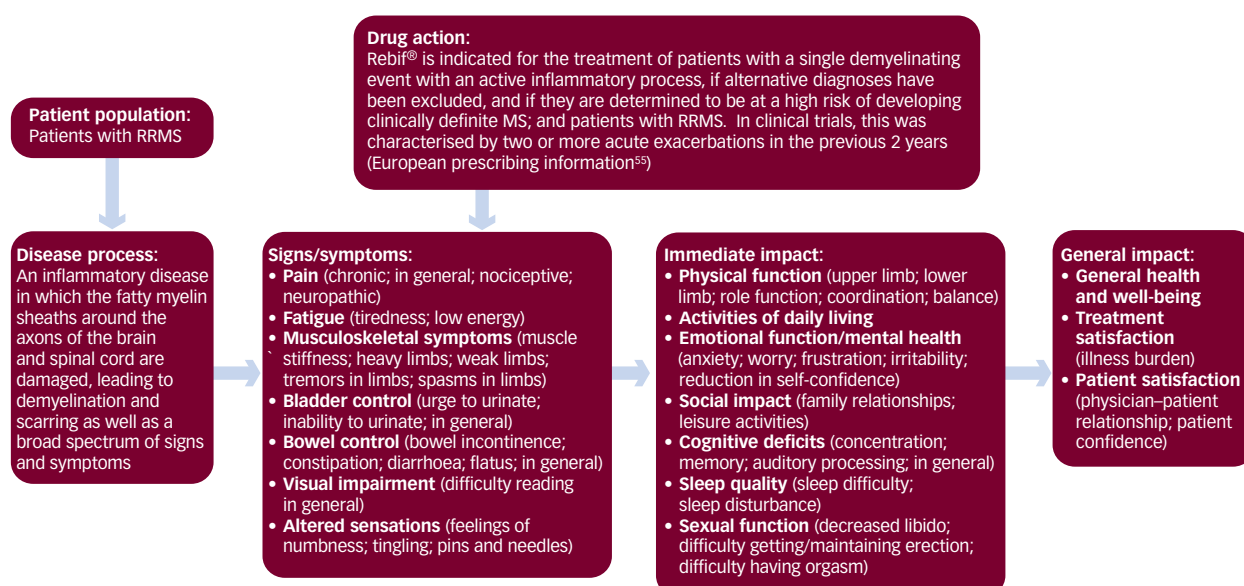
- 1) includes standardised, patient-based, reliable and valid measures;
- 2) measures MS concepts of interest;
- 3) is accepted by patients and HCPs;
- 4) is accessible and not burdensome (can be completed outside of point-of-care interaction in clinic);
- 5) is flexible to meet individual patient needs;
- 6) encourages patient participation in managing their health;
- 7) results can be interpreted by the HCP and understood by the patient;
- 8) results provide meaningful data to inform treatment and management;
- 9) results complement and expand upon standard clinical and treatment measures; and
- 10) encourages dialogue between patient and HCP.

MSdialog Background

Given the substantial disease burden and the current lack of tools to support effective and efficient patient–provider communication, a practical approach to the routine assessment of outcomes data from patients with MS is warranted.

In recent years, health information technology innovations have emerged, including electronic systems for data capture, information management, remote monitoring and management, health record integration and reporting, to close quality gaps in disease management and to help patients to achieve optimal health outcomes.^{4,43–46} Electronic data capture and reporting systems enable the routine, remote collection of data from patients in a timely, user-friendly and often cost-effective manner, and yield more accurate, readily available data with little or no delay in results reporting.

To provide MS patients and their HCPs with a secure, flexible, accurate and efficient means to capture and view outcomes data, we have developed MSdialog, an innovative, secure web- and mobile-based software application that works with suitable auto-injector devices such as the RebiSmart® 2.0 device (a handheld electronic auto-injector

Figure 1: Preliminary Hypothesised Conceptual Model for Relapsing–Remitting Multiple Sclerosis

MS = multiple sclerosis; RRMS = relapsing-remitting multiple sclerosis.

with a wireless data transmission dock, CE marked and available (excluding the US) to collect and store real-time, point of administration adherence and PRO data. Clinical outcomes data (e.g., EDSS, relapse information) may also be recorded and stored.

MSdialog is an optional companion software application to certain auto-injector devices (e.g., RebiSmart® 2.0 device), and is intended to provide a platform for HCPs, field nurses and MS patients to record, exchange and receive information on some treatment aspects and on the evolution of patients suffering from MS. Its intent is to help improve and make better use of patient visit times by facilitating patient–physician communication with appointment preparations in reviewing treatment adherence and patient perception of MS impact. The application is expected to improve efficiency by providing information in advance of a clinical visit that will help HCPs prepare and focus quickly on any patient-reported concerns. MSdialog provides HCPs and MS patients with tools to organise and track the patient’s injection history, record the patient’s general impression of MS health impacts and provide easy access to information related to the patient’s MS treatment and reported outcomes. It also offers field nurses access to select information that may enable them to deliver a higher standard of patient care.

MSdialog displays patient treatment adherence and PRO data collected at a point-in-time, or over time. It uses existing standardised PRO instruments that have been used in previous research. It was designed to be flexible in terms of the number, type and frequency of questions asked of patients, in order to reduce burden and align clinical assessments with individual patient needs. Patient-based data are transmitted electronically from the patient’s autoinjector (e.g., RebiSmart 2.0) docking station and computer/smartphone to a secure MSdialog web portal that stores data and provides options for visual display to the patient or HCP. Outcomes data collected via MSdialog belong to the patient and may be used with permission by their HCP (e.g., to prepare for patient in-clinic visits, to focus in-person discussion on major problem areas, etc.). Patient data are secured and pseudo-anonymised, and only identifiable to the patient and any HCP(s) to which she/he has granted access. MSdialog has been developed to comply with good practices and governmental regulations on data transmission and security.

The Role of Patient-reported Outcome in MSdialog

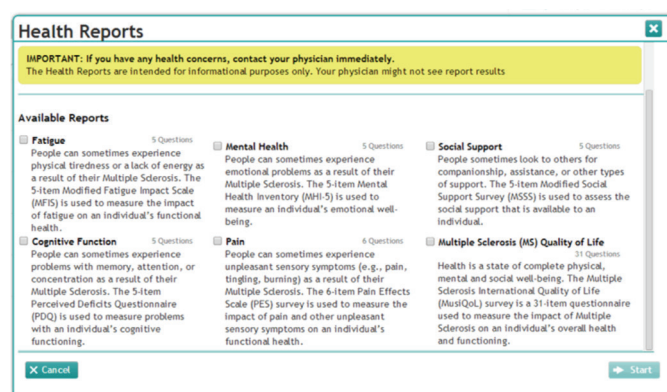
We included PRO measurement instruments in MSdialog to help engage patients in the management of their MS and facilitate communication with their HCP(s).

Initial PRO concepts to be included in MSdialog were identified through a multi-year strategic planning process that involved several structured workshops with international representation, prototype software demonstrations and input from major stakeholders via a multi-country qualitative marketing research study. This study was conducted with MS patients (n=24), clinic nurses (n=14) and neurologists (n=15) from Sweden, the UK and Canada. Participants were provided with a demonstration of the MSdialog application, and interviewers gathered feedback on the overall application and its individual features.

All participants identified the main benefit of MSdialog as providing clear and succinct information on patient status and health outcomes. Patients reported most interest in tracking their general health and well-being, pain, fatigue, cognition, life and work impact, bladder and bowel control, sexual satisfaction, mobility and visual impairment. They also reported that they would like to view reports of treatment adherence and patterns of injections. Patients reported that MSdialog would help them to accurately recall their health status over time and help them to communicate this information to their HCP; who, in turn, may develop a better understanding of the patient. Patients said that it is important to them that HCPs use the information from MSdialog. Also, patients reported that they could use the information in MSdialog to track their progress and better manage their condition. Although patients see self-monitoring as beneficial, greater importance was placed on MSdialog-facilitated information sharing with their HCP. Further, patients with MS want to use the application in their ‘own way’ and on their own schedule (daily, weekly or when experiencing issues). They indicated an interest in being able to access the system from home (PC) or while ‘on the move’ (smartphone).

HCPs (neurologists and nurses) reported that the application could provide useful information on patient outcomes to prepare for an appointment

Figure 2: MSdialog User Interface for Selection of Patient-reported Outcomes



and/or streamline discussions with the patient at the time of a clinic visit. They also reported that MSdialog information could help to engage patients in the 'ownership' and management of their condition and could be useful for assessing adherence in relation to EDSS and relapse data. Neurologists view the MSdialog as a tool to support clinic visits. They indicated that they would access information from the system just prior to or at the time of individual patient appointments. They prefer a dashboard (graphical display of output) that can be printed. Nurses indicated that their use of MSdialog would be driven by neurologist and/or patient usage. They could use the system to actively monitor patients. Nurses may help filter information or flag concerns in preparation for patient clinic visits. Like neurologists, they prefer a dashboard (graphical display of output) that can be printed.

Not surprisingly, the strongest concerns from patients and HCPs were around time and resource burden of data input and review.

Participants identified the main success factors for MSdialog: (1) focus on PROs with important clinical parameters (e.g., adherence, EDSS, relapse); (2) ensure the quality of the data; (3) provide multiple ways to access; (4) clear value proposition for HCPs; (5) ensure that patients remain in control of their own data; (6) endorsement by advocacy organisation (e.g., MS Society); (7) minimise time burden for data collection; (8) services to support application use; and (9) pilot testing.

In a follow-up study conducted in 2013, 76 MS patients, 92 MS specialists and neurologists and 40 MS nurses from the UK and Canada were asked to complete a 15-minute online questionnaire evaluating reactions to MSdialog, support for claims relating to the software features, the level of importance of each PRO and which additional PROs are considered important. The goals for this study were to determine the most important PROs for monitoring and tracking, as well as whether the claims regarding the utility and benefit of MSdialog accurately reflect target audiences. Results found patients and nurses to be generally more positive than HCPs towards MSdialog and associated claims: 87 % of patients, 76 % of nurses and 53 % of HCPs tended to have strong positive initial reactions to MSdialog. A similar trend was seen for the level of interest in using MSdialog; 83 %, 56 % and 73 %, of patients, HCPs and nurses, respectively, indicated a high level of interest. In addition, patients and HCPs were generally aligned on which PROs were considered most important for monitoring. Based on findings from this study, three core areas were considered strengths of MSdialog: 1) it provided an easy method for sharing data between patients and HCPs, 2) it enabled patients an enhanced utilisation of time with the HCP and 3) it helped engage patients in managing their disease.

Results from this research helped to identify initial PRO concepts to be included in MSdialog and informed further development of features in the MSdialog application.

Understanding of Novel Patient-reported Outcome 'Territory'

The US Food and Drug Administration (FDA) PRO Guidance,⁴⁷ European Medicines Agency (EMA) HRQoL Reflection Paper,⁴⁸ EMA Draft Guidance for the Clinical Investigation of Medicinal Products for the Treatment of Multiple Sclerosis⁴⁹ and European Health Technology Assessment (HTA) provide scientific guidelines relating to the use of PROs, primarily to support claims in medical product development and clinical research. However, MSdialog is intended for use in clinical practice, and neither specific guidelines exist for the selection and application of PRO/HRQoL measures in MS clinical practice, nor as part of a wider medical software application. NICE's (2004) Multiple Sclerosis: National Clinical Guideline for Diagnosis and Management in Primary and Secondary Care report acknowledges this gap, and indicates that there are limited data available to guide the choice of a measure for use in clinical practice. The guidelines provide some general measurement recommendations and call for a 'common approach' to a measurement system that 'checks at appropriate moments whether the person with MS has common problems' and 'does not waste the time of the person with MS or the health care professional'.

Because FDA guidelines⁴⁷ for use of PROs in clinical research are founded on principles from the field of measurement science (e.g., psychology, psychometrics), many of the same guideline recommendations apply for the selection or development and validation of PRO instruments for use in clinical practice. Thus, existing Federal guidance recommendations for the use of PROs in clinical research were considered in our PRO instrument evaluation, selection and implementation process for the initial launch of MSdialog. However, there are additional considerations when applying PROs in clinical practice. It is important to ensure that PRO instruments are suitable for administration by the patient on a repeat basis over time, outside of the clinical setting. Data collection methods, administrative modes, comparability of scores from paper and electronic instrument versions, response burden, data management, data visualisation, score interpretation and several other factors must be considered when using PROs in this context. MSdialog aims to provide a mechanism for maximising the utility of PRO in a real-life setting with patients who have MS. In this way, MSdialog presses beyond the limits of current practice into novel territory, and our experiences and lessons learned from this process are shared in the following section.

Patient-reported Outcome Instrument Evaluation, Selection and Implementation

MSdialog PRO instruments for the initial software launch include the Multiple Sclerosis International Quality of Life (MusiQoL) questionnaire and selected instruments from the Multiple Sclerosis Quality of Life Inventory (MSQLI).

Instrument Evaluation and Selection

The selection of these initial PRO measures resulted from extensive literature review, instrument evaluation and recommendations from specialists in the development, testing and application of PROs.

First, a review of published empirical literature and ongoing clinical trials (which included patient-reported symptoms and impacts as major outcome measures) was conducted to identify relevant and

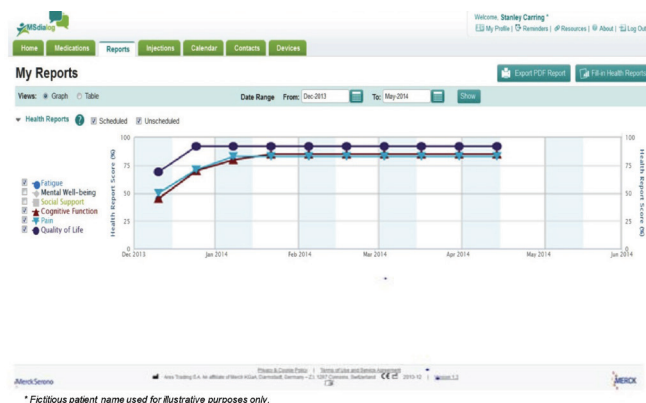
important health concepts for patients with MS (in this case, the focus was on relapsing–remitting MS).⁴ The results identified the following symptom concepts as most important and relevant to patients: pain, musculoskeletal symptoms (i.e., muscle stiffness, limb tremor/spasm, weakness in limbs), bladder and bowel concerns, fatigue, visual impairment and altered sensations (e.g., feelings of numbness). The following impact concepts were identified as important and relevant to patients: physical function, activities of daily living (ADL), emotional function, social function, cognitive function, sleep quality, sexual function, treatment satisfaction, patient satisfaction and overall QoL (see *Figure 1*). Results from this literature review informed PRO concept selection for MSdialog, although final decisions regarding concept coverage were also based on feedback from interviews and discussions with patients, physicians, nurses through the qualitative marketing study, content area experts and Merck Serono internal expert functions.

Next, an instrument evaluation was conducted to determine whether any existing measures covered the measurement concepts of key interest to Merck Serono for the initial launch of MSdialog. The instrument evaluation started with a focus on existing condition-specific instruments, since they generally are more sensitive than generic measures.^{8,50,51} Merck Serono specified several evaluation criteria for the instrument evaluation, including instrument purpose (must have a specific focus on MS, generally accepted instruments for the domain and/or have been used in MS clinical trials), content coverage, sound psychometric properties (reliable, valid, responsive to changes in the clinical condition over time), scores for subscales representing concepts of interest, potential for data visualisation, suitability for electronic administration to support remote data collection, low response burden, relevant recall period, availability across country/language translations, standardised for local populations, precedence for acceptance or favourable by regulatory agencies, conducive for use in MSdialog and easy to use by patients.

During the instrument evaluation process, the clinical development team narrowed the concept list to focus on the highest priority concepts for the initial MSdialog launch: pain, fatigue, physical function, emotional function, cognitive function, social function, general health, coping and treatment satisfaction. Two instruments emerged as meeting most of the evaluative criteria: MSQLI and MusiQoL. To arrive at a final consensus and decision, the development team conducted a confirmatory re-evaluation of the top five PRO measures (MusiQoL, MSQLI, MSQOL-54, Multiple Sclerosis Impact Scale [MSIS]-29, Hamburg Quality of Life Questionnaire Multiple Sclerosis [HAQUAMS]) based on prioritised concepts and evaluation criteria, including content coverage, psychometric properties, response burden, scores for subscales representing concepts of interest, suitability for electronic administration to support remote data collection, availability across country/language translations and low response burden. This exercise reinforced initial findings, and confirmed the selection of the MusiQoL and selected instruments from the MSQLI: Modified Fatigue Impact Scale (MFIS-5), Pain Effects Scale (PES), Modified Social Support Survey (MSSS-5), Perceived Deficits Questionnaire (PDQ-5) and Mental Health Inventory (MHI-5). Short-form versions of these instruments, when available, were selected for the initial MSdialog launch to limit response burden for patients who may complete the instruments frequently, or complete several instruments in a single administration. *Figure 2* shows the user interface for selection of PRO instruments on MSdialog.

The MusiQoL is an MS HRQoL instrument that yields an overall score and subscale scores for ADL, psychological well-being (PWB), symptoms (SPT), relationships with friends (RfR), relationships with

Figure 3: MSdialog Graph Presenting Sample Score Results for Selected Patient-reported Outcome Instruments – Patient View



family (RfA), sentimental and sexual life (SSL), coping (COP), rejection (REJ) and relationships with healthcare system (RHCS).

The instruments from the MSQLI battery yield scale scores for fatigue (MFIS-5), pain (PES), social support (MSSS-5), perceived deficits questionnaire (PDQ-5) and mental health (MHI-5).

One or more of these PRO instruments may be completed in a single administration on MSdialog. Typical average time to complete the paper version of the 31-item MusiQoL has been measured at 10 to 15 minutes, and it is estimated that the five MSQLI scales (total of 26 items) can be completed in 10 minutes or less (1 to 2 minutes per scale).

Because PRO data are visualised in a single customisable graphical display for patients, steps were taken to ensure that the MusiQoL and MSLQI scores are presented on the same metric, scored in the same direction. Raw scores were linearly transformed to a 0 to 100 metric, with higher scores representing better health (see *Figure 3* for a sample display of scores). Item-level scores for all completed instruments are available to the HCP for review.

While this development effort followed a systematic process for selection of PRO instruments for MSdialog, it also identified a need for further validation work on a few of the scales in the MSQLI. For example, there are some scales with demonstrated reliability and validity, but lacking evidence of responsiveness (sensitivity to changes in the clinical condition over time). A validation study to evaluate instrument measurement properties can address these gaps. In addition, since both the MusiQoL and MSQLI use a 4-week recall period, a validation study can evaluate instrument versions using a 1-week recall period, which may enable additional options to the user for more frequent HRQoL monitoring.

Instrument Implementation in MSdialog

Several steps were taken in order to implement the PRO instruments in MSdialog. First, applicable instrument licenses and permission to use were secured. Planned use, number of administrations, duration of data collection activity and number of translations are some of the things that need to be considered when approaching this discussion with an author/distributor.

Since the MusiQoL and MSQLI instruments were originally developed and validated in paper version, we evaluated the potential for a successful migration of these instruments to electronic administration (in this

Table 1: MSdialog Country/Language Translations for MusiQoL and MSQI Instruments

Country	Languages		
Australia	English		
Austria	German		
Belgium	French	Dutch	
Canada	English	French	
Denmark	Danish		
Finland	Finnish		
France	French		
Germany	German		
Italy	Italian		
The Netherlands	Dutch		
Portugal	Portuguese		
Saudi Arabia	Arabic		
Sweden	Swedish		
Switzerland	French	German	Italian
UK	English		

MSQI = Multiple Sclerosis Quality of Life Inventory; MusiQoL = Multiple Sclerosis International Quality of Life.

case, desktop or Smartphone). Research suggests that common minor changes (e.g., to formatting and layout of items) in migration efforts do not have a substantial effect on the performance of the instrument.⁵² Because these instruments required only minor formatting revisions to support electronic administration, cognitive interviews with a small sample of MS patients can establish that participants understand and can respond to the items in the same manner, regardless of mode.⁵³

More generally, efforts were made to align the PRO implementation with the overall regulated software development cycle for MSdialog, which included detailed functional software requirements specifying design, layout, scoring, data visualisation and quality assurance testing; interface development and human factors studies; and software registration activities. A usability study was undertaken to evaluate the MSdialog software. Neurologists and field nurses specialising in MS, as well as MS patients, completed tasks such as logging in, entering, viewing and editing data in the MSdialog system. Performance was measured by evaluating the success of each task per evaluative criteria, and by comparing user behaviour with the optimal task flows. Recommendations for design changes centred on simplifying navigation, layout, reducing complexity of data (e.g., graphs, calendars), minimising number of steps for completing tasks and adhering to principles of cognitive psychology aimed at reducing perceptual and

cognitive load (particularly for patient users). Results were used to improve MSdialog interface and navigation.

After determining country/language translation needs relevant to MSdialog initial launch, translation and linguistic validation efforts were undertaken. For each country/language, this process involved forward- and back-translation of the PRO instruments, as well as cognitive interviews with a small sample of patients who have MS in order to demonstrate conceptual equivalence and content validity of the PRO translations. This substantial effort required a strong collaboration between the MSdialog team (including software developers), instrument developers and the translation partner. In this initial launch, MSdialog offers the MusiQoL and MSQI instruments in 19 country language translations (see Table 1).

Finally, a user guide was developed for HCPs to provide an overview of MSdialog with a specific focus on the MusiQoL and MSQI instruments. The guide describes each instrument and its scoring procedures, and provides preliminary guidelines for interpretation. It is intended to support clinician and patient use of these PRO instruments on MSdialog.

Future Plans

Future plans involve launch of MSdialog outside Europe, which will require additional translation and linguistic validation efforts for each new country/language translation. Because normative interpretation guidelines are generally lacking for PRO instruments that are commonly used with patients who have MS,⁵⁴ additional research can support more extensive guidelines for the interpretation of PRO data.

Conclusion

It is crucial for HCPs to incorporate PROs into clinical practice in order to optimise patient HRQoL and overall outcomes. HCPs face challenges in utilising PRO instruments in daily clinical practice, including practical, methodological, cultural and instrument-level barriers. A 'tool set' is needed that will help engage patients in managing their disease and encouraging patient-HCP communication. MSdialog was developed to help overcome barriers in PRO use and patient-HCP communication. MSdialog is easy to use, provides longitudinal PRO and adherence data for individual patients, generates score displays that can be used by patients and HCPs and has potential to aid patients and HCPs in managing MS and optimising patient outcomes. While additional research will continue to inform how MSdialog evolves, this new software tool responds to the call for practical solutions to support patient-proactive engagements and self-management, patient-centred care and participatory decision-making in clinical practice. ■

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