

Development and Usability Testing of a Patient-based Digital Tool to Understand Early Signs of Changes in Multiple Sclerosis Symptoms and Progression: Your MS Questionnaire



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Introduction



WHY?

There is an unmet need as discussion of symptoms between plwMS and HCPs can be unstructured and lead to uncertainty in recognizing subtle worsening of MS¹



HOW?

Your MS Questionnaire (YMSQ) was developed with input from plwMS, patient advocacy groups and HCPs and is **based on the MSProDiscuss™**, a physician-completed digital tool



WHAT?

YMSQ is a **patient-completed questionnaire** that asks information on relapses, symptoms and impacts experienced within the past six months. The purpose of this questionnaire is to **facilitate a discussion between HCPs and plwMS**, to better understand patient history, symptoms and impacts experienced by the patient

Objective

- To develop a patient-based tool, Your MS Questionnaire (YMSQ), that is completed by plwMS
- To evaluate the usability of Your MS Questionnaire (YMSQ) in helping both plwMS and HCPs in clinical practice, and to understand whether the plwMS have experienced any changes in their disease

1. Davies F et al. Int J MS Care. 2016.

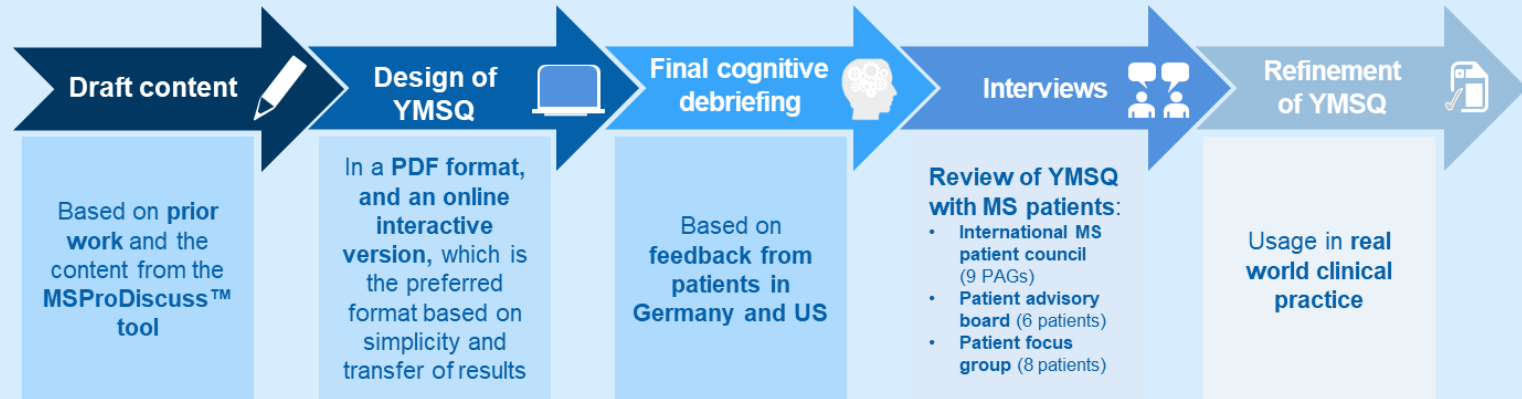
HCP, health-care professionals; MS, multiple sclerosis; MSProDiscuss, Multiple Sclerosis Progression Discussion; plwMS, people living with MS; YMSQ, Your MS Questionnaire.

Methods

Development of YMSQ

- YMSQ was designed based on MSProDiscuss™ to capture the experience of plwMS regarding changes in their MS symptoms and its impact on daily living over the past 6 months
- The questions were identified as relevant through qualitative and quantitative research with experienced HCPs and using inputs from plwMS and patient organizations
- YMSQ was initially developed as a paper version, however, later due to COVID-19 pandemic and to support telemedicine, plwMS were provided the option to complete an online or paper version prior to the consultation

Fig. 1: Development of YMSQ



YMSQ was developed using inputs from plwMS, patient organizations, and HCPs

Methods (contd.)

Fig. 2: YMSQ layout

Your MS

This questionnaire asks about your MS in the past 6 months, including any relapses, your symptoms and their impact on your daily life. This information will help you have a focused discussion with your doctor about your MS and any changes you have experienced over the past 6 months. If possible, ask a family member, partner or carer for help and input when completing the questionnaire.

What is your age?

Please mark one box per question to give your answer

1. Your MS

1.1 In the past 6 months have you had any relapses (periods of time where your symptoms were worse and then got better)? Yes No Go to question 2

1.2 If yes, how many relapses? 1 2 3+

1.3 If yes, how well did you recover from your most recent relapse? Fully (10%) Nearly full (75%) Partially (50%) A little (25%) Not at all (0%)

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2. Your symptoms

a) Have you experienced any of the following symptoms in the past 6 months?

	No	Yes
2.1 Problems with your vision	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Muscle weakness or muscle spasms	<input type="checkbox"/>	<input type="checkbox"/>
2.3 Problems walking or getting around	<input type="checkbox"/>	<input type="checkbox"/>
2.4 Problems with coordination or balance	<input type="checkbox"/>	<input type="checkbox"/>
2.5 Pain	<input type="checkbox"/>	<input type="checkbox"/>
2.6 Numbness or tingling	<input type="checkbox"/>	<input type="checkbox"/>
2.7 Bladder control or bowel problems	<input type="checkbox"/>	<input type="checkbox"/>
2.8 Problems with your speech	<input type="checkbox"/>	<input type="checkbox"/>
2.9 Problems concentrating or remembering things	<input type="checkbox"/>	<input type="checkbox"/>
2.10 Feeling tired or fatigued	<input type="checkbox"/>	<input type="checkbox"/>

b) Did you experience these symptoms during any relapses you had in the past 6 months?

	No	Yes
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

c) Did the symptoms come and go or were they there most of the time?

	Symptoms came and went	Symptoms were there most of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

d) If symptoms were there most of the time...

	Did they get better?	Did they stay the same?	Did they get worse?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. How MS impacts your life

How much have your MS symptoms over the past 6 months affected you? Not at all A little Moderately A lot I can't do this because of my MS

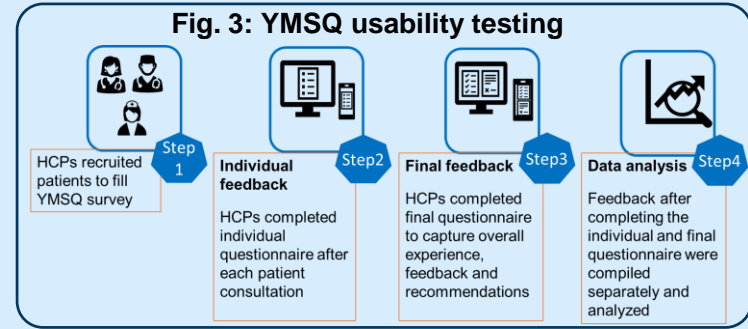
3.1 Getting around	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Washing, bathing or dressing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.3 Completing everyday tasks (for example, housework or driving)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.4 Doing hobbies or leisure activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.5 At work (paid or volunteering)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> I cannot answer Q3.5 because I do not work for reasons unrelated to my MS					
3.6 Being intimate or having sex	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.7 Emotionally (for example, feeling low, anxious or worried)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Are there any specific symptoms that you would like to focus on when you meet with your doctor? If so, please circle/mark the relevant question number(s) in this questionnaire, or write the relevant question number(s) in the box below.

YMSQ usability testing: A two-part HCP survey

- **Individual questionnaire (15 questions):**
 - After every patient consultation, collected feedback for usability and usefulness, comprehensibility, patient and HCP satisfaction, and usability in conjunction with MSProDiscuss™
- **Final questionnaire (15 questions):**
 - After 40 patient consultations (a minimum of 10), collected in-depth feedback on usefulness, integration into clinical routine and recommendations for improvement areas
- HCPs had option to provide their response in four categories: strongly agree, agree, disagree, strongly disagree

Fig. 3: YMSQ usability testing



Results

- Usability testing of YMSQ is ongoing with HCPs across 8 countries. Until data cut-off for interim analysis (12 Feb 2021), nine HCPs from four countries (US, China, Spain and Italy) completed the testing based on 168 MS patient consultations where YMSQ was used

Fig. 4: Distribution channels for YMSQ

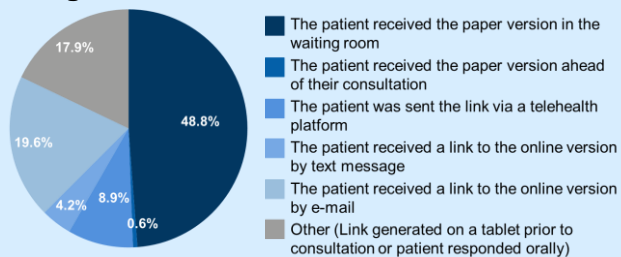


Fig. 5: Completion status of YMSQ*

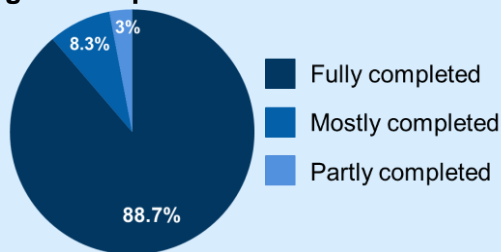
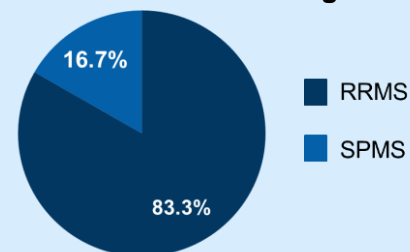
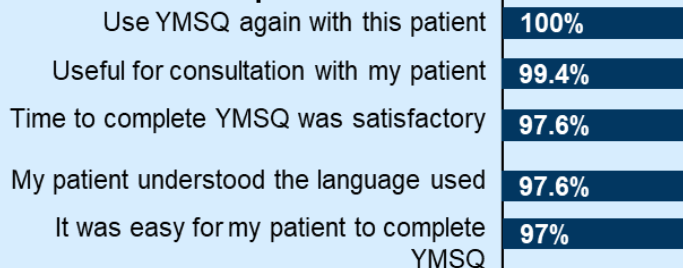


Fig. 6: Patient distribution according to YMSQ



- The majority of HCPs agreed or strongly agreed that YMSQ was useful in their practice and was easy for plwMS to use and understand (**Fig. 7**)
- The use of YMSQ positively influenced the clinical practice; it was helpful in engaging patients with their MS
- The majority of HCPs (80%) were willing to integrate the YMSQ in addition to MSProDiscuss™ in routine clinical practice

Fig. 7: HCPs' feedback based on the 168 individual questionnaires^a



^aData represents the responses falling under the categories 'strongly agree' and 'agree'.

*'Mostly' refers to >50% of the questionnaire, while 'Partly' refers to <50% of the questionnaire.

HCP, healthcare professional; MS, multiple sclerosis; RRMS, relapsing-remitting MS; SPMS, secondary progressive MS; YMSQ, Your MS Questionnaire; US, United States

Conclusions

- YMSQ was developed with input from plwMS, patient advocacy groups and HCPs, based on the MSProDiscuss™, a physician-completed digital tool
- YMSQ facilitates discussion between plwMS and HCPs on changes in MS symptoms and ways in which they impact daily activities within past six months, enabling holistic approach to MS patient management
- Based on initial results from the usability testing of YMSQ in real-world clinical practice, HCPs found it useful and are willing to use it again on the same patients
- When completed before consultations, YMSQ may benefit plwMS and HCPs by enabling a better-structured conversation, a better-informed consultation, with potential uses in telemedicine

The tool is freely available online at www.yourms.com

Disclosures

TZ has received compensation for consulting and lecturing from Alexion, Biogen, Celgene, Novartis, Roche, Sanofi, and Teva and for research from Biogen, Novartis, Roche, Teva, and Sanofi. **EA** received compensation for consulting from Actelion/Janssen, Alexion, Bayer, Biogen, Celgene/BMS, EMD Serono/Merck, Genentech/Roche, Genzyme, Novartis, Sanofi, and TG Therapeutics and for research from Biogen, Genentech/Roche, Novartis, TG Therapeutics, Patient-Centered Outcomes Research Initiative, National Multiple Sclerosis Society, National Institutes of Health, and Rocky Mountain MS Center. **VB** received compensation for consulting, lecturing and advisory board from Biogen, Celgene, EMD Serono, Genzyme, Novartis, Roche, Sanofi, and Teva Neuroscience, for site PI from Biogen Idec, EMD Serono, Novartis, Sanofi-Aventis, and Teva Neuroscience. **JB** received compensation as a speaker and advisory board member from Bayer Schering, Biogen-Idec, Novartis, Merck Serono and Sanofi-Genzyme. **OH** received consulting fee from Biogen, Merck, Novartis, Roche, Sanofi, for research from Biogen, Novartis, Sanofi and as speaker from Merck, Novartis, Roche, Sanofi. **COG** received consulting fee from Novartis, Alexion, Roche, for research from Alexion and as speaker from Novartis, Roche. **RRC** has received compensation for consulting services and speaking fees from Biogen, Roche, Novartis, Bayer, Merck, Sanofi, Genzyme, Teva Pharmaceutical Industries Ltd, and Almirall. **MT** has received compensation for consulting from Novartis, Biogen, Merck, Roche, Sanofi, and for research and as salary from Biogen, Merck, Novartis, Roche. **PV** received compensation for consulting and/or research and registration, travel, and accommodation for meetings from Biogen, Roche, Novartis, Sanofi, Teva, Merck, Celgene, Imcyse and AB Science. **SN** received compensation as speaker from Accord Therapeutics, Biogen, Genentech, Genzyme, Mallinckrodt, and Novartis. **AM** received compensation for consulting from Novartis, Genetech, Biogen, Alexion, EMD Serono, BMS, for research from Alexion, Novartis, Biogen, as speaker from Alexion, EMD Serono, BMS, Genetech. **YX** has nothing to disclose. **JV, MK, MM, BS, TH** are employees of Novartis. **GG** received consulting fee from AbbVie, Actelion, Atara Bio, Biogen, Celgene, Sanofi-Genzyme, Genentech, GlaxoSmithKline, Merck-Serono, Novartis, Roche and Teva, for research from Biogen, Roche, Merck, Merck-Serono, Novartis, Sanofi-Genzyme and Takeda.

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