Patient-reported outcomes in the spotlight

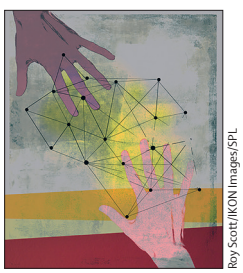
The importance of patients' perspectives on their disease status and quality of life is well recognised as an essential part of research studies and neurological practice. How best to incorporate patient-reported outcomes (PROs) in clinical studies and, eventually, into clinical practice remains a matter of debate. The use of PROs is especially challenging for neurological diseases, considering that patients are usually old, fragile, with comorbidities, and often have cognitive or communication impairments. The Patient Reported Outcomes Initiative for Multiple Sclerosis (PROMS) has been launched to tackle this challenge for patients with this disease. Expectations are high because efforts to enable uptake of PROs could be greatly enhanced by a common strategic agenda, and PROMS' achievements could also influence clinical research in other subspecialties.

Although clinicians acknowledge the importance of PROs to facilitate understanding of treatment effects or compare treatment options, patients are frustrated that functional domains that matter most to them are often not addressed. Regulatory authorities recognise that current research outcomes (eg, the Expanded Disability Status Scale, relapse rate, and MRI features) do not fully capture the lives and experiences of people with multiple sclerosis; Healthcare Technology Assessment agencies aim to integrate the patient voice in coverage decisions; and pharmaceutical companies have acknowledged the importance of including PROs in the lifecycle management of experimental therapies. Practical issues include how to capture the pertinent data (eg, by use of technology), the need for a clear definition of which between-group differences and within-subject changes are clinically meaningful, and understanding of how domains of interest purportedly assessed by a PRO measure are affected by unrelated contextual factors (eg, how marital issues or depression might affect self-reported disease status).

In recognition of the need for a common strategic agenda and roadmap shared by all relevant stakeholders to tackle these issues and facilitate the uptake of PROs into decision-making processes, the PROMS initiative was born—a project aiming to provide a unified view on and maximise impact of patient input on the health, healthcare, and quality of life of people affected by multiple sclerosis. The Multiple Sclerosis International Federation, the Italian Multiple Sclerosis Society, and the European Charcot Foundation launched PROMS on Sept 12, 2019, at the 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis, held in Stockholm, Sweden. The strategic priorities of PROMS are centred around the validation and development of PROs that matter most to people with multiple sclerosis; implementation and support of initiatives aimed at validating and harmonising PROs across cultures; and translation of standardised data into a performance measure that captures the results most important for improving long-term wellbeing.

The PROMS initiative aims to learn from best practices of other ongoing relevant initiatives. For example, the European Charcot Foundation has experience providing a joint approach to coordinate existing initiatives in multiple sclerosis (such as MS Brain Health, MS in the 21st Century, Neuro-Compass, and ParadigMS Foundation); and the MULTI-ACT project, launched in 2018, is facilitating a collaborative approach to develop brand new tools to assess the value of research in neurology from the patients' perspective—the impact of research in multiple sclerosis will be assessed as a first step. PROMS could also learn from established initiatives that focus on patients' priorities in neurological research. For instance, the James Lind Alliance has been facilitating partnerships between patients, carers, and clinicians to set research priorities since 2004. Also, a Dutch initiative with a similar ethos for patient advocacy in Parkinson's disease—ParkinsonNet, established in 2004—is trying to include patients in health-care decisions and make specialist-care choices easily available for all patients with the disease. The model has already begun to spread, with adjustments made for cultural and system-specific needs to enable implementation in Germany and the USA.

Several previous initiatives have faltered, in most cases due to the lack of appropriate infrastructure and shared means of aligning efforts and results. There is a need for a global approach, across countries, stakeholders, and disciplines. A goal to accelerate shared learning is by no means an easy one, but will be essential to maximise the potential benefits of patient involvement in neurological research. With PROMS planning to deliver results in July, 2022, this goal can hopefully begin to be realised soon. ■ *The Lancet Neurology*



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For more on **PROMS** see https://www.msif.org/news/2019/09/12/global-initiative-places-the-patient-voice-front-and-centre-in-ms-research-and-care/

For more on the **ECF MS Initiative** see https://www.charcot-ms.org/research-initiatives/multi-stakeholder-initiatives

For more on **ECTRIMS 2019** see https://www.ectrims-congress.eu/2019.html

For more on **MS Brain Health** see https://www.msbrainhealth.org/

For more on **MS in the 21st Century** see *J Neurol* 2013; **260:** 462–69

For more on **Neuro-Compass** see https://www.neuro-compass.education/en-gb/home/

For more on the **ParadigMS Foundation** see http://paradigms.foundation/

For more on the **MULTI-ACT initiative** see https://www.multiact.eu

For more on the **James Lind Alliance** see http://www.jla.nihr.ac.uk/

For more on **ParkinsonNet** see **Editorial** *Lancet Neurol* 2014; **13:** 525 and http://www.parkinsonnet.info/media/15290577/rompen_on_the_move__2015__parkinsonnet_concept.pdf