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Title
Patient-reported Outcomes used in Multiple Sclerosis Trials: Critical Assessment and Insights from People Living with MS

Introduction
Regulatory guidance recommends that patient-reported outcomes (PROs) are defined by clinical and patient-relevant conceptual frameworks. Four PROs measuring quality of life (QoL) and fatigue commonly used, or recently developed for use, in MS trials were assessed as to whether they satisfy current guidance by appropriately measuring outcomes relevant to persons living with MS (PLwMS).

Methods
Information was extracted on domain definitions, items measured and conceptual frameworks from PROs measuring QoL (54-item MSQoL [MSQoL-54], Leeds MSQoL [LMSQoL]) and fatigue (Fatigue Symptoms and Impacts Questionnaire-Relapsing MS [FSIQ-RMS], modified Fatigue Impact Scale [mFIS]). Expert patients (EPs) provided PRO-related feedback through structured interviews. Seven EPs were interviewed (further interviews to be conducted).

Results
Of the PROs, only FSIQ-RMS was based on a conceptual framework. The 12-subscale MSQoL-54 provides two domain scores (physical and mental health), although these domains were not defined prospectively. However, EPs liked the ability to measure a holistic impact of MS. LMSQoL was developed with patient input; EPs liked its ease of use, but the domain (wellbeing/QoL) used correlation with other instruments for interpretation. The 20-item FSIQ-RMS, assessing physical and cognitive aspects of fatigue, was developed with patient involvement using current guidance but EPs preferred the more patient-friendly language of the 21-item mFIS. However, some mFIS items (e.g. poor coordination) are not fatigue-specific.

Conclusion
PROs lacked domain definitions and/or conceptual frameworks, limiting their validity/interpretation of results. Defining domains prospectively and involving PLwMS from the onset could yield PROs that better assess the symptoms and impact of MS in clinical trials and clinical practice.

Disclosure
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Author Details
- Presenter: Trishna Bharadia, Marlow, , United Kingdom
- Tanuja Chitnis, Brigham and Women's Hospital, Department of Neurology, Boston, MA, United States
- Piet Eelen, National Multiple Sclerosis Center of Melsbroek, Flanders, Belgium
- Birgit Bauer, Manufaktur für Antworten (UG), Abensberg, Germany
- Giampaolo Brichetto, Associazione Italiana Sclerosi Multipla Rehabilitation Center, Genoa, Italy
- Andrew Lloyd, Acaster Lloyd Consulting Ltd, London, United Kingdom
- Hollie Schmidt, Accelerated Cure Project for Multiple Sclerosis, Waltham, MA, United States
- Miriam King, Novartis Pharma AG, Basel, Switzerland
- Jenny Fitzgerald, Novartis Pharma AG, Basel, Switzerland
- Thomas Hach, Novartis Pharma AG, Basel, Switzerland
- Jo Vandercappellen, Novartis Pharma AG, Basel, Switzerland
- Jeremy Hobart, Peninsula Schools of Medicine and Dentistry, University of Plymouth, Plymouth, United Kingdom