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Patient-Reported Outcome Measures in Multiple Sclerosis Clinical Trials: Critical Assessment and Insights from People Living with Multiple Sclerosis

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Abstract Text:

Background: Multiple sclerosis (MS) clinical trials often include patient-reported outcomes (PROs) to quantify treatment effects not addressed by standard clinical measures. Regulatory guidance stipulates that domains measured by PROs are defined using a clinical and patient-relevant conceptual framework. However, many PROs used in MS trials were developed before this guidance.

Objectives: Examine whether PROs measuring quality of life aspects (QoL) and fatigue commonly used in MS trials satisfy current regulatory guidance by appropriately measuring outcomes relevant to persons living with MS (PLwMS).

Methods: A systematic literature review identified PROs used in MS trials. Information on domain definitions, items measured and conceptual framework were extracted. Structured interviews with expert patients (EPs) provided feedback on the PROs.

Results: The literature review (2015–2020, 26566 citations) identified 24 PROs. We selected for initial analysis, four commonly used or recently developed 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]). Seven EPs were interviewed (further results to be presented). Of the PROs, only FSIQ-RMS was based on a conceptual framework. Generally, domains were not pre-defined and included confounding items. MSQoL-54 has 12 subscales providing two domain scores (physical and mental health). Neither domains, nor a conceptual framework were defined prospectively, but the EPs liked the ability to measure an holistic impact of MS. LMSQoL was developed with patient input; EPs liked its ease of use, but no conceptual framework was specified and the domain measured (somewhere between wellbeing and quality of life) used correlation with other instruments for interpretation. The 20-item FSIQ-RMS, which assesses 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, the mFIS lacks a conceptual framework and its items (e.g. poor coordination) are not specific for fatigue.

Conclusions: These PROs generally lacked domain definitions and conceptual frameworks, limiting their validity and the interpretation of the clinical trial results. Defining domains and conceptual frameworks formally and working closely with PLwMS from the onset will yield more valid PROs measuring the symptoms and impacts of MS in clinical trials and clinical practice.

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