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Abstract

Many of the available disability outcome measures used in clinical trials of multiple sclerosis are insensitive to change over time, inadequately validated, or insensitive to patient-perceived health status or quality of life. Increasing focus on therapies that slow or reverse disability progression makes it essential to refine existing measures or to develop new tools. Major changes to the expanded disability status scale should be avoided to prevent the loss of acceptance by regulators as a measure for primary outcomes in trials that provide substantial evidence of effectiveness. Rather, we recommend practical refinements. Conversely, although substantial data support the multiple sclerosis functional composite as an alternative measure, changes to its component tests and scoring method are needed. Novel approaches, including the use of composite endpoints, patient-reported outcomes, and measurement of biomarkers, show promise as adjuncts to the current disability measures, but are insufficiently validated to serve as substitutes. A collaborative approach that involves academic experts, regulators, industry representatives, and funding agencies is needed to most effectively develop disability outcome measures.

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