Parkinson’s Disease Version 2.0 NINDS CDE Project
Quality of Life Subgroup Summary

The Parkinson’s Disease (PD) Version 2.0 Quality of Life Subgroup determined that they would continue to use the defined purview from the version 1.0 recommendations:

Health-Related Quality of Life

The introduction to this section is adapted from the MDS Guidelines on Quality of Life Measures with permission of the Chair, P. Martinez-Martin (Martinez-Martin et al., 2011).

The term “quality of life” (QoL) has been used loosely to refer to a broad spectrum of patient reported outcome measures. In the context of clinical research, there is general agreement that emphasis should be placed on the narrower and more specific construct of Health Related Quality of Life (HRQL).

HRQL focuses on the impact of disease and treatment on patients, assessed from their perspective and including physical, emotional and social aspects (Schipper et al., 1996; Martinez-Martin, 1998; Den Oudsten et al., 2007). It also involves a combination of objective functioning and subjective perceptions of health (Den Oudsten et al., 2007; Hunt, 1997). For some authors, HRQL focuses on health status, level of impairment, disability, and, to a lesser extent, handicap (Doward & McKenna, 2004). In summary, HRQL refers to the dimensions of QoL that are affected by health status and by health care.

Health status (HS) is a closely related concept that refers to perceived health in terms of physical and mental symptoms, disability, and social dysfunction related to the health condition. It is different from HRQL in that it lacks subjective judgments and reactions. HS may influence and predict HRQL but should not be considered a part of HRQL (Den Oudsten et al., 2007).

In practice, instruments measuring HRQL assess the physical, emotional and social well-being and satisfaction related to health, combining objective functioning and subjective perceptions and judgments. Whereas, instruments aimed at measuring HS focus mainly on the impact of disease on physical, mental, and social functioning but do not include judgments and reflections about well-being and satisfaction with health.

The subgroup’s approach was to select existing instruments from the PD v1.0 Project that were validated and expand the development of CDEs to incorporate newly validated scales based on their prior knowledge and literature reviews. The available medical literature was searched for all generic quality of life instruments that had been used to evaluate PD and for all disease specific PD HRQL scales. Instruments were divided among members for review. Each instrument was reviewed by a primary and secondary reviewer. Instruments recommendations were then discussed by the whole subgroup. A summary table of the recommendations is included below.

The subgroup determined that there are no differential applications to subpopulations. Additionally, there were no issues encountered that were unique to PD when developing the CDE standards.

In comparison to other PD standards, the Quality of Life Subgroup is aware of the Movement Disorder Society recommendations which were developed several years ago. These were incorporated. The subgroup acknowledges that there may be other standards, but these were not referenced in developing the recommendations.

The subgroup determined that some of the scales require further validation in PD (e.g., PROMIS and SEIQoL). Additional psychometric information is also needed for some of the recommended measures (e.g., minimally important change or clinically important change scores) which is particularly true for the generic measures.

References

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Martinez-Martin P, Jeukens-Visser M, Lyons KE, Rodriguez-Blazquez C, Selai C, Siderowf A, Welsh M, Poewe W, Rascol O, Sampaio C, Stebbins GT, Goetz CG, Schrag A. Health-related quality-of-life scales in Parkinson's disease: critique and recommendations. Mov Disord. 2011 Nov;26(13):2371-80.

Schipper H, Clinch JJ, Olweny CLM. Quality of life studies: definitions and conceptual issues. En: Spilker B (Ed.).Quality of life and pharmacoeconomics in clinical trials, 2nd edit. Philadelphia: Lippincot-Raven Publishers, 1996; 11-23

Subdomain	Instrument Name	Classification	Purpose, Other Information, Instrument Use
Quality of Life/Patient Reported Outcomes	EuroQoL-5 Dimension Questionnaire (EQ-5D)	S-HR	Indicated for studies as a Generic Health-Related Quality of Life measure
	Parkinson's Disease Quality of Life Questionnaire (PDQL)	Supplemental	
	Parkinson's Disease Quality of Life Scale (PDQUALIF)	Supplemental	
	Parkinson's Disease Questionnaire (PDQ-39)	S-HR	Indicated for studies requiring a Parkinson's Disease-Specific Health-Related Quality of Life measure
	Parkinson's Impact Scale (PIMS)	Supplemental	
	PROMIS Item Bank v1.2 - Global Health	Supplemental	PROMIS is widely used, but these measures have not been specifically validated in PD. As additional data is collected in PD, these may be moved to Supplemental – Highly Recommended. Indicated for studies requiring a Global Health-Related Quality of Life (HRQOL) measure. Provides extensive comparison data to other disease areas.
	PROMIS-29 Profile	Supplemental	
	Quality of Life in Neurological Disorders (Neuro-QOL)	S-HR	Highly recommended for studies of psychosocial functioning, quality of life, outcome, and long-term adjustment studies
	Scales for Outcomes in Parkinson's Disease-Psychosocial (SCOPA-PS)	Supplemental	
	Schedule for the Evaluation of Individual Quality of Life (SEIQoL)	Exploratory	Developed as an individualized measure that allows for the respondent to choose the most important domains to be evaluated. Has not been used in PD.
	Schedule for the Evaluation of Individual Quality of Life - Direct Weighting (SEIQoL-DW)	Supplemental	
	Short Form 36-Item Health Survey (SF-36)	S-HR	Indicated for studies as a Generic Health-Related Quality of Life measure
	World Health Organization Quality of Life Assessment (WHOQOL-BREF)	Supplemental	

Supplemental – Highly Recommended (S-HR)