

Parkinson's Disease Version 2.0 NINDS CDE Project Other Non-Motor Subgroup Summary

The purview of the Other Non-Motor Subgroup focused on non-motor features of Parkinson's disease (PD), excluding cognition and psychiatry. This included four primary categories each with sub-categories:

1. **Autonomic dysfunction**

- Gastrointestinal
- Urinary
- Sexual
- Thermoregulatory
- Cardiovascular
- Respiratory

2. **Sleep dysfunction**

- Diagnosis of sleep disorders
- Sleep methods
- Overall sleep quality
- Insomnia
- Excessive daytime sleepiness
- Obstructive sleep apnea
- REM sleep behavior disorder
- Restless legs syndrome

3. **Sensory dysfunction**

- Vision impairment
- Olfaction impairment
- Pain

4. **Other non-motor dysfunction**

- Fatigue
- Nutritional status
- Weight loss/weight change

In these various categories, instruments, procedures, and diagnostic criteria were recommended in the form of a Notice of Copyright (NOC) with a focus on symptom specific scales. A corresponding guidance document provides further information on the recommendations.

The subgroup reviewed and updated the recommendations from v1.0 by revising the guidance document, removing or updating NOCs from v1.0, as well as adding new recommendations. The subgroup first reviewed the NINDS CDE PD v1.0 recommendations, removing some, and updating others by adding new information or changing the classification. Subgroup members reviewed with current validity, reliability, and feasibility in mind. The work was divided among the subgroup members based on area of expertise. The members then recommended new instruments, procedures and diagnostic criteria based on advances in the field since the v1.0 recommendations were published.

Five ad hoc members were consulted in updating the recommendations for the autonomic, sexual dysfunction, urinary dysfunction, and gastrointestinal subject areas.

In total, 59 instruments were recommended by the subgroup members and consultants with classifications including Supplemental – Highly Recommended (S-HR), Supplemental, and Exploratory.

When looking at several scales/instruments that addressed the same subject area, the members considered any redundancy or overlap, and chose the best scales based on use and validation among research in the field. In some cases, scales were recommended even if they had not been validated or designed for use in PD because non-motor symptoms have not been well studied and few PD-specific measures exist. The subgroup did not focus on non-specific non-motor questionnaires and instead evaluated symptom specific scales.

The subgroup also developed a table at the end of the guidance document that outlines the current available instruments and organizes the recommendations based on the sub-category and type of instrument (screening instrument, rating scale, diagnostic criteria and instrument, required instrument).

The subgroup did not focus on subpopulations within PD.

Summary of Recommendations

The subgroup recommendations include a guidance document with associated Supplemental CDEs and the following scales/instruments. All recommendations are in the Outcomes and End Points Domain/ Other Non-Motor Subdomain.

Instrument/Scale Name	Category	Classification
Composite Autonomic Symptom Scale (COMPASS-31)	Autonomic	S-HR
Scale for Outcomes in Parkinson's Disease Autonomic (SCOPA-AUT)	Autonomic	Supplemental
Orthostatic Hypotension Questionnaire (OHQ)	Cardiovascular	S-HR
Orthostatic Symptom Grading Scale	Cardiovascular	Supplemental
Fatigue Severity Scale (FSS)	Fatigue	Supplemental
Parkinson's Disease Fatigue Scale (PFS-16)	Fatigue	Supplemental
Constipation Severity Scale (CSS)	GI	Supplemental
Drooling Rating Scale (DRS)	GI	Supplemental
Drooling Severity and Frequency Scale (DSFS)	GI	Supplemental
Gastrointestinal Symptoms in Neurodegenerative Diseases Scale (GIND)	GI	Supplemental
Munich Dysphagia Test - Parkinson's Disease (MDT-PD)	GI	Exploratory
Quality of Life in Swallowing Disorders (SWAL-QOL)	GI	Supplemental
Radboud Oral Motor Inventory for Parkinson's Disease (ROMP)	GI	Supplemental
Rome III/IV Constipation Module	GI	Supplemental
Sialorrhea Clinical Scale for Parkinson's Disease (SCS-PD)	GI	Supplemental
Swallowing Disturbance Questionnaire (SDQ)	GI	Supplemental
The Gastrointestinal Dysfunction Scale for Parkinson's Disease	GI	Supplemental
The International Parkinson and Movement Disorder Society Non-Motor Rating Scale (MDS-NMS) (GI Domain)	GI	Supplemental
The Swallowing Clinical Assessment Score in Parkinson's Disease (SCAS-PD)	GI	Supplemental

Instrument/Scale Name	Category	Classification
Non-Motor Symptom Questionnaire (NMS-Quest) (PD-NMS)	Multiple symptom categories	Supplemental
The International Parkinson and Movement Disorder Society Non-Motor Rating Scale (MDS-NMS)	Multiple symptom categories	S-HR
Mini Nutritional Assessment (MNA)	Nutritional Status	Supplemental
Brief Pain Inventory (BPI) Short Form	Pain	Supplemental
King's Parkinson's Disease Pain Questionnaire (KPPQ)	Pain	Exploratory
King's Parkinson's Disease Pain Scale (KPPS)	Pain	Supplemental
Numeric Rating Scale (NRS)-Box 21 Scale	Pain	Supplemental
The International Association for the Study of Pain (IASP) Definitions for Pain	Pain	Supplemental
International Restless Legs Syndrome Study Group Severity Rating Scale (IRLS)	Restless Legs Syndrome	S-HR
The International Restless Legs Syndrome Study Group Diagnostic Criteria	Restless Legs Syndrome	S-HR
Female Sexual Function Index (FSFI)	Sexual Health/Function	Supplemental
International Index of Erectile Function-5 (IIEF-5)	Sexual Health/Function	Supplemental
Actigraphy (with Sleep Diary)	Sleep	Supplemental
Berlin Questionnaire	Sleep	Supplemental
Epworth Sleepiness Scale (ESS) - Adult Version	Sleep	S-HR
Innsbruck REM Sleep Behavior Disorder Inventory (RBD-I-5)	Sleep	Supplemental
Insomnia Severity Index (ISI)	Sleep	Supplemental
Karolinska Sleepiness Scale (KSS)	Sleep	Supplemental
Mayo Sleep Questionnaire	Sleep	Supplemental
Multiple Sleep Latency Test (MSLT) and Guidelines	Sleep	S-HR
Parkinson's Disease Sleep Scale 2nd Version (PDSS-2)	Sleep	S-HR
Pittsburgh Sleep Quality Index (PSQI)	Sleep	Supplemental
Polysomnography (PSG) and Guidelines	Sleep	S-HR
Scale for Outcomes in Parkinson's Disease-Sleep (SCOPA-Sleep)	Sleep	S-HR
Stanford Sleepiness Scale (SSS)	Sleep	Supplemental
STOP-BANG Questionnaire	Sleep	Supplemental
The American Academy of Sleep Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria	Sleep	S-HR
The REM Sleep Behavior Disorder (RBD) Questionnaire – Hong Kong (RBDQ-HK)	Sleep	Supplemental
The REM Sleep Behavior Disorder Single-Question Screen (RBD1Q)	Sleep	Supplemental
The REM Sleep Behavior Disorder (RBD) Screening Questionnaire (RBDSQ)	Sleep	Supplemental

Instrument/Scale Name	Category	Classification
Brief Smell Identification Test (Brief-SIT)	Smell	Supplemental
Hyposmia Rating Scale (HRS)	Smell	Exploratory
Sniffin' Sticks	Smell	Supplemental
University of Pennsylvania Smell Identification Test (UPSIT)	Smell	Supplemental
International Consultation on Incontinence Modular Questionnaire-Overactive Bladder (ICIQ-OAB)	Urology	Supplemental
International Consultation on Incontinence Questionnaire Bladder Diary (ICIQ-Bladder Diary)	Urology	Supplemental
International Prostate Symptom Scale (IPSS)	Urology	Supplemental
Neurogenic Bladder Symptom Score (NBSS)	Urology	Supplemental
Pelli Robson Test	Vision	Supplemental
Visual Impairment in Parkinson's Disease Questionnaire (VIPD-Q)	Vision	Exploratory

The subgroup's recommendations include other standards from the Movement Disorders Society, American Academy of Sleep Medicine, International Association of the Study of Pain, among others.

The large number of "other" non-motor features in PD means that it is not feasible to address them all in every clinical or research situation. Fluctuation of symptoms, both motor and non-motor, is common in PD. The instruments selected by the subgroup are not designed to address these fluctuations. For more information regarding potential issues with a specific other non-motor feature, please see the guidance document.

There are few validated or PD-specific measures for non-motor features. Areas in need of further research and development include appropriate screening measures, scales that cover the full breadth of non-motor features, and measures that address and assess symptom fluctuation. Development of a clinical history case report form may be considered in future iterations of the project.