

**Updated Criteria for the Diagnostic Procedure for Parkinson's Disease Dementia on  
Level I and their Validity in Deep Brain Stimulation Cohort**

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## **Updated Criteria for the Diagnostic Procedure for Parkinson's Disease Dementia on Level I and their Validity in Deep Brain Stimulation Cohort**

### **Introduction**

Parkinson's disease (PD) is a neurodegenerative disorder characterized by a gradual and progressive onset of motor symptoms, including rigidity, bradykinesia, and resting tremors, which eventually extend to both motor and non-motor impairments ([Postuma et al., 2015](#)). Beyond these hallmark features, cognitive decline is a critical aspect of the disease trajectory, culminating in Parkinson's disease dementia (PDD) in a substantial subset of patients ([Meireles & Massano, 2012](#)).

The diagnostic criteria for PDD ([Dubois et al., 2007](#)), first formalized in 2006, were heavily influenced by frameworks established for Alzheimer's disease (AD) owing to the absence of PD-specific biomarkers that could facilitate a biologically grounded diagnostic system. Although these criteria provided a valuable initial foundation, they lacked the specificity required to capture the distinct pathophysiological and cognitive features of PD-related dementia ([Emre et al., 2007](#); [Yamashita et al., 2023](#)).

An important feature of the original criteria was the provision of an algorithm that allowed for flexibility in test selection ([Dubois et al., 2007](#)). Specifically, clinicians could choose between months reversed or seven backwards for attention assessment, lexical fluency or clock drawing for executive function evaluation, MMSE pentagons for visuospatial ability, and three-word recall for memory assessment. The availability of multiple operationalization options for PDD enhances the ability to examine the psychometric properties of the construct. Agreement across different criteria allows for the parallel computation of inter-rater reliability, which, in turn, facilitates the calculation of construct validity ([Conway et al., 1995](#)) further strengthening the diagnostic framework for PDD.

Subsequent advancements have introduced the concept of Parkinson's disease mild cognitive impairment (PD-MCI), refining the understanding of cognitive dysfunction in PD ([Litvan et al., 2012](#)). The PD-MCI criteria, published in 2012, have propelled progress in diverse areas, enabling improvements in clinical characterization, identification of genetic correlates, therapeutic interventions, clinical trial design, and the assessment of progression

risk to PDD ([Aarsland et al., 2021](#); [Hoogland et al., 2017, 2019](#)).

Currently, efforts are focused on refining the PDD diagnostic framework to improve its consistency and applicability in both research and clinical contexts across multiple centers ([Kulisevsky et al., 2024](#)). Our prior investigations have underscored the importance of employing rigorous psychometric methodologies to differentiate PD-MCI from PDD, particularly given that a diagnosis of PDD remains a contraindication for deep brain stimulation (DBS) ([Bezdicek et al., 2016](#); [Deuschl et al., 2006](#)).

The present study evaluates the diagnostic concordance between the original Level I PDD criteria, as established by the Movement Disorder Society (MDS) Task Force ([Dubois et al., 2007](#); [Emre et al., 2007](#)) and criteria inspired by the recent call for change ([Kulisevsky et al., 2024](#)) within a PD cohort selected for DBS. **Furthermore, both sets of criteria are compared to PDD diagnosed on Level II. The study aims to address following research objectives (RO): 1) to estimate prevalence of PDD in patients considered for DBS, 2) to characterize variability in PDD diagnosis depending on PDD criteria, 3) to evaluate concordance between different sets of PDD criteria, and 4) identify factors that account for variability in PDD diagnosis between criteria.**<sup>1</sup> By addressing these objectives, this study seeks to validate the revised PDD criteria and evaluate their relevance in the context of DBS eligibility, thereby contributing to the refinement of cognitive assessment protocols in PD.

## Methods

### Participants

This study retrospectively analyzed clinical data from a cohort of patients with PD considered for treatment via DBS of subthalamic nucleus at the General University Hospital in Prague. All patients were diagnosed with idiopathic PD by a movement disorder specialist according to the MDS Clinical Diagnostic Criteria for PD ([Postuma et al., 2015](#)). Clinical

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<sup>1</sup> JM: It is a good practice in science to explicitly specify research objectives, questions or hypotheses to streamline the process. The idea is to create a (literal) line going theory -> objective -> estimand -> estimate -> interpretation (in light of theory presented before with maybe a special focus on mismatches between theory and results/estimate). Check whether the changes make sense to you.

records spanning August 2014 to February 2025 were examined. All participants underwent neuropsychological evaluation conducted by a trained clinical psychologist as part of standard preoperative cognitive assessments for DBS eligibility at the General University Hospital in Prague.

Ethical approval for the study protocol was obtained from the Ethics Committee of the General University Hospital in Prague. Informed consent was secured from all patients prior to their neuropsychological assessments, in adherence to ethical research guidelines.

### **Neuropsychological Assessment**

Cognitive performance was evaluated at both Level I (abbreviated assessment) and Level II (comprehensive assessment) according to the standard MDS neuropsychology battery for Parkinson's Disease Mild Cognitive Impairment (PD-MCI) Bezdicek et al. (2017). Level I was assessed using the Mini-Mental State Examination (MMSE) (Folstein et al., 1975; Stepankova et al., 2015) and the Montreal Cognitive Assessment (MoCA) (Kopecek et al., 2016; Nasreddine et al., 2005), both of which provide measures of global cognitive functioning. The neuropsychological assessment at Level II covered five cognitive domains, each evaluated through specific tests as follows: attention and working memory assessed using Trail Making Test Part A (TMT-A) (Bezdicek et al., 2012; Reitan, 2004), Prague Stroop Test – Dots (PST-D) (Bezďíček et al., 2021), Letter Number Sequencing (LNS) (Wechsler, 1997), WAIS Digit Span Backward (WAIS DSB) (Wechsler, 1997), and WAIS Corsi Block Backward (WAIS CB) (Wechsler, 1997); executive function evaluated via the Tower of London (ToL) (“Specific Impairments of Planning,” 1982), Categorical Verbal Fluency (CF) (Benton et al., 1989), Trail Making Test Part B (TMT-B) (Reitan, 2004), subtests from the Prague Stroop Test – Words (PST-W) and Colors (PST-C) (Bezďíček et al., 2021); language measured with the WAIS Similarities subtest (Wechsler, 1997) and the Boston Naming Test (BNT-60) (Kaplan et al., 1983); memory examined using the Rey Auditory Verbal Learning Test (RAVLT) (Frydrychová et al., 2018; Rey, 1964) for immediate and delayed recall (including List B and recognition trials), and the Brief Visual Memory Test–Revised (BVMTR) (Benedict, 1997; Havlík et al., 2020), including delayed recall and forced choice recognition; visuospatial function assessed through the Judgment of Line Orientation Test (JoLO) (Benton et al., 1983),

Clock Drawing Test (CLOX) ([Royall et al., 1998](#)), and the Grooved Pegboard Test (GPT) ([Klove, 1963](#)).

In addition to the core cognitive assessments, tasks such as the Clock Drawing Test (CDT) and Letter Fluency tasks were included to capture domain-specific impairments. The classification of Parkinson's Disease Dementia (PDD) based on Level I criteria was determined using established scoring thresholds from Dubois et al. ([Dubois et al., 2007](#)) with corresponding MoCA equivalents.

To assess functional impairment, the Functional Activities Questionnaire (FAQ) ([Bezdicek et al., 2011](#); [Pfeffer et al., 1982](#)) was administered. Additionally, neuropsychiatric status was evaluated using the Beck Depression Inventory-II (BDI) ([Beck et al., 1996](#); [Ciharova et al., 2020](#)) and State-Trait Anxiety Inventory (STAI) ([Mullner et al., 1980](#); [Spielberger et al., 1983](#)). Psychotic symptoms were assessed through structured psychiatric interviews conducted by a trained psychiatrist.

### **Theoretical and Empirical Estimands**

Following the framework of Lundberg et al. ([2021](#)), in this section we link our research objectives to theoretical (i.e., targets of inference) and empirical (i.e., observable data) estimands. Whereas, the theoretical estimand, consisting of unit-specific quantity and the target population, represents the quantity one would compute to address a research objective under ideal conditions (e.g., data from the whole population or ideal experimental manipulations), the empirical estimand represents the quantity one can compute with the data at hand. The population of interest across our theoretical estimands is a population of patients with PD worth consideration for DBS treatment.<sup>2</sup> The theoretical estimand related to our RO1 is the prevalence of PDD in patients screened for DBS and theoretical estimand related to our RO2 is the variance of prevalence estimates due to the measurement process. To estimate these quantities, we calculate the proportion of patients with probable PDD (defined below) according to each tested criterion resulting into a set of prevalence estimates. Theoretical estimand related to our RO3 is a set of population-wise contingency tables of probable PDD diagnosis

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<sup>2</sup> JM: This will have to be stated better.

assigned by different PDD criteria and metrics derived from these tables. Our empirical estimands consist of matrixes derived from pairwise Receiver Operating Characteristic (ROC) curve analyses. Finally, the theoretical estimand related to our RO4 is a set of PDD criterion components that, if observed to change, substantially change probability of a probable PDD diagnosis. We approach this RO from an exploratory point of view and evaluate the importance of each PDD criteria component by observing change in empirical estimands for RO1-3 when stratified by different operationalization decisions.<sup>3</sup>

### Operationalization of Parkinson's Disease Dementia

In this study, we applied three distinct sets of diagnostic criteria for **probable**<sup>4</sup> PDD at Level I. The first set was based on the original framework (Dubois et al., 2007), which utilized the Mini-Mental State Examination (MMSE) as a global cognitive screening tool, supplemented by assessments of attention, executive function, visuospatial abilities, and memory. The second set of criteria was drawn from the recent call for change of dementia diagnostic guidelines (Kulisevsky et al., 2024), which advocate for more sensitive cognitive domain assessments in the context of Parkinson's disease (PD). This updated approach incorporated specific items from the Montreal Cognitive Assessment (MoCA) to better detect PD-related dementia. The third approach applied the Czech version of the shortened Montreal Cognitive Assessment (sMoCA) (Bezdicek et al., 2020), a time-efficient modification designed to ascertain whether equivalent cognitive impairments could be reliably identified using a reduced testing protocol. Lastly, the fourth approach followed the Level II battery protocol, which is commonly used in the evaluation of PD-MCI. **The Level II methodology, including the use of a regression-based normative scoring approach, has been detailed in a prior study (Bezdicek et al., 2017). Refer to Table 1<sup>5</sup> to a summary of the components**

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<sup>3</sup> JM: Will need to work on wording here, but the idea hopefully comes across.

<sup>4</sup> JM: We should unite the terminology. Most importantly, I reckon, we should differentiate between “probable PDD” (what is implied by meeting all the criteria within an operationalization) and “PDD” (the latent state of patient's cognition); and to use consistently the following trifecta - “criterion,” “operationalization” and their “component”.

<sup>5</sup> JM: Placeholder until we make the table proper.

**and scoring thresholds of each diagnostic criterion. All non-cognitive criteria of probable PDD (i.e., diagnosis of PD that developed before dementia and absence of Major Depression, delirium or other abnormalities that obscure diagnosis were established by an independent neurological and psychiatric assessments and held true for all patients in the sample).**

[Insert Table 1 here]

For each of these diagnostic approaches, we applied two operationalization strategies based on deficits in Instrumental Activities of Daily Living (IADL). First, we utilized FAQ item 9, which approximates the pill questionnaire from the original criteria (Dubois et al., 2007) **employing a cut-off score of 2 points or higher**. Second, we applied the entire Functional Activities Questionnaire (FAQ) as suggested in the call for change (Kulisevsky et al., 2024), **employing a cut-off score of 7 points or higher based on Czech normative data (cite it).**<sup>6</sup> These methodologies resulted in a total of 66 operationalizations, which were distributed across different diagnostic criteria: 4 MMSE-based, 60 MoCA-based, 2 sMoCA-based, and 0 based on the Level II battery<sup>7</sup>.

## Statistical Analyses

For sample description, we summarized continuous variables using mean, standard deviation, median, minimum, and maximum values. Categorical variables were summarized by the number of patients in each category. To address study objectives, we started by repeatedly assigning each patient the diagnosis of probable PDD based on each PDD operationalization listed in Table 1 resulting in a 204 (patients)  $\times$  66 (operationalizations) matrix where each cell indicates whether a patient (row) meets criteria for probable PDD according to an operationalization (column). PDD prevalence estimates were then computed as  $\frac{N_{PDD}}{N_{total}}$  separately for each operationalization to address RO1.

To address RO2-4, a set of two class cross-tabulations with associated statistics was computed for each pair of operationalizations via the `confusionMatrix()` function from the

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<sup>6</sup> JM: I am pretty sure Kulisevsky et al. did not suggest cut-off  $FAQ \geq 7$  We ought to locate the Czech normative study Ondrej bases this value on.

<sup>7</sup> JM: Need to add Level II operationalization and allow the `stopifnot()` test code above. My job.

R package *caret* (Kuhn, 2008). For each pair of operationalizations, the analysis was repeated twice such that each variables of the pair served once as the reference and once as the predictor. Following measures were used to evaluate pairwise concordance between different operationalizations of PDD criteria: 1) Cohen's  $\kappa$  with its 95% confidence interval (CI) computed via the `cohen.kappa()` function from the R package *psych* (William Revelle, 2024); 2) Accuracy (i.e., the proportion of correct predictions, both true positives and true negatives, among the total number of cases) with its 95% CI; 3) Sensitivity/Recall (i.e., the proportion of true positives); and 4) Specificity (i.e., the proportion of true negatives).<sup>8</sup>

Finally, the No Information Rate (NIR) was calculated for each pair of operationalizations. NIR is the accuracy that could be obtained by always predicting the majority class and in our case it is equivalent to the complement of the PDD prevalence estimate according to the reference operationalization. Accuracy of prediction was subsequently compared to the NIR via a one-sided Exact Binomial Test as implemented by the `binom.test()` R stats function. Reference/predictor pairs associated with  $p < .05$  were considered to show significantly better accuracy than NIR. In other word, for reference/predictor pairs associated with  $p < .05$ , we conclude that knowing the probable PDD status according to the predictor operationalization helps to estimate the probable PDD status according to the reference operationalization and the two opeartionalizations thus show substantial concordance.

Data wrangling and visualizations were done in the *tidyverse* package (Wickham et al., 2019) and tables were formatted in the *gt* package (Iannone et al., 2024). All analyses were conducted with the R (version 4.3.3) software environment for statistical computing (R Core Team, 2024). The software code supporting this article is available at <https://github.com/josefmana/DemCr1t.git>.<sup>9</sup>

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<sup>8</sup> Unlike Cohen's  $\kappa$ , Accuracy, Sensitivity and Specificity are not symmetrical, i.e., their value depend on which variable is considered reference and which is considered predictor. Consequently, we report these values twice for each pair of operationalizations. Note that the Sensitivity of a reference/predictor pair corresponds to the Positive Predictive Value if their roles were reversed. The same relationship holds true between the Specificity and the Negative Predictive Value.

<sup>9</sup> **JM: Do not forget to make it public before submitted!**



## Results

### Sample Description

A total of 204 patients were included. Demographic and clinical characteristics of the sample are summarized in Table 2. ...<sup>10</sup>

[Insert Table 2 here]

### Prevalence Estimates

Operationalization-wise prevalence estimates are presented in Table 3. On average, estimated prevalence was 6.00% (SD = 3.45, Md = 3.94, range 2.00-16.75). Notably, the prevalence estimate was substantially lower when FAQ item 9 was used as a criterion of IADL deficit (M = 3.09%, SD = 0.48, range 2.00-3.94) compared to using total FAQ score criterion (M = 8.90%, SD = 2.56, range 3.50-16.75) as demonstrated also in Figure 1.<sup>11</sup>

[Insert Table 3 and Figure 1<sup>12</sup> here]

### Criteria Concordance

Results of the analyses of prediction Accuracy, Cohen's  $\kappa$ , Sensitivity and Specificity are presented in Figure 2, Figure A1, Figure A2 and Figure A3 respectively. Numerical results are available ...<sup>13</sup>

**In this section, we need to discuss among ourselves what and how to report such that the results give enough information, the most important information and are readable as well.**

[Insert Figure 2<sup>14</sup> here]

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<sup>10</sup> JM: Give some brief impressions from the Table 2 here. E.g., evaluate sex proportion, age, (we are missing education for some reason) etc. with general PD population (e.g., from some meta-analysis). Maybe say a word or two about mean cognitive profile or its spread.

<sup>11</sup> JM: For oneself - work on the code here, it ain't good.

<sup>12</sup> JM: For thyself - add description.

<sup>13</sup> JM: ... as some kind of Supplementary Table, ideally html but Excel file would work as well.

<sup>14</sup> JM: For thyself - add description.

## Discussion

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**Table 1**

group	type	glob	glob_t	atte	atte_t	exec	exec_t	memo	memo_t
mmse	mmse1	mmse	26	mmse_7	4	cloc	2	mmse_3words	3
mmse	mmse2	mmse	26	mmse_7	4	cloc	2	mmse_3words	3
mmse	mmse3	mmse	26	mmse_7	4	vf_s	10	mmse_3words	3
mmse	mmse4	mmse	26	mmse_7	4	vf_s	10	mmse_3words	3
moca	moca1	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	1
moca	moca2	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	1
moca	moca3	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	1
moca	moca4	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	1
moca	moca5	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	2
moca	moca6	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	2
moca	moca7	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	2
moca	moca8	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	2
moca	moca9	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	3
moca	moca10	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	3
moca	moca11	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	3
moca	moca12	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	3
moca	moca13	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	4
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moca	moca19	moca_total	26	moca_7	3	moca_cloc	2	moca_5words	5
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moca	moca23	moca_total	26	moca_7	3	vf_k	11	moca_5words	1
moca	moca24	moca_total	26	moca_7	3	vf_k	11	moca_5words	1
moca	moca25	moca_total	26	moca_7	3	vf_k	11	moca_5words	2
moca	moca26	moca_total	26	moca_7	3	vf_k	11	moca_5words	2



**Table 2**

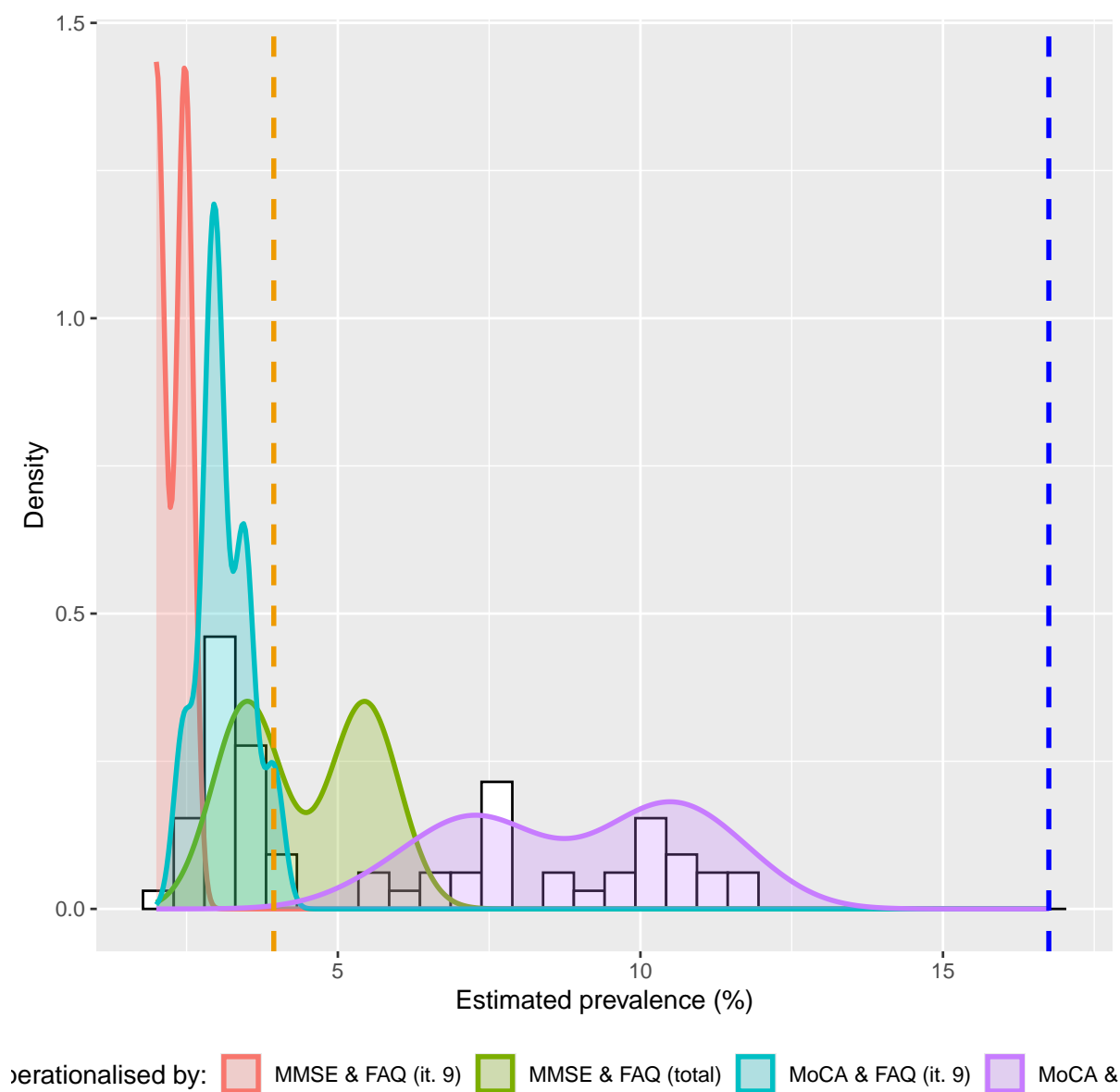
*Table 2 Sample description. Demographic, clinical and cognitive characteristics of the sample.*

	N	Md	Min-max	M	S
Demographics					
Sex of Participants (Male, Female)	126 (62%)	-	-	-	-
Age of Participants (in Years)	203	60	34-73	58.96	8.3
Clinical					
Type of PD: Akinetic-rigid, Tremor-dominant; Axial	32/107	-	-	-	-
Hoehn Yahr stage (range 0-5)	2/8/66/33/14/2	-	-	-	-
PD duration (in years)	162	10	1-25	10.71	4.3
asym_park	66 (51%)	-	-	-	-
L-DOPA (in mg)	138	1607	0-4138	1697.58	670
UPDRS III off state	135	35	10-81	37.43	13.5
UPDRS III on state	135	14	2-45	15.97	8.3
MMSE					
MMSE (range 0-30)	203	27	15-30	26.69	2.3
MMSE 7 (range 0-5)	1/2/8/20/34/139	-	-	-	-
VF S (number of words per minute)	202	15	1-34	14.95	5.3
Clock Drawing (range 0-2)	26/91/86	-	-	-	-
MMSE pentagons (range 0-1)	187 (92%)	-	-	-	-
MMSE (range 0-3)	5/14/60/124	-	-	-	-
MoCA					
MoCA (range 0-30)	203	24	9-30	24.07	3.4
sMoCA (range 0-16)	203	11	1-16	11.26	2.3
MoCA 7 (range 0-3)	1/2/29/171	-	-	-	-
VF K (number of words per minute)	204	16	0-29	15.50	5.3
MoCA (range 0-3)	24/83/96	-	-	-	-
MoCA (range 0-1)	164 (81%)	-	-	-	-

**Table 3**

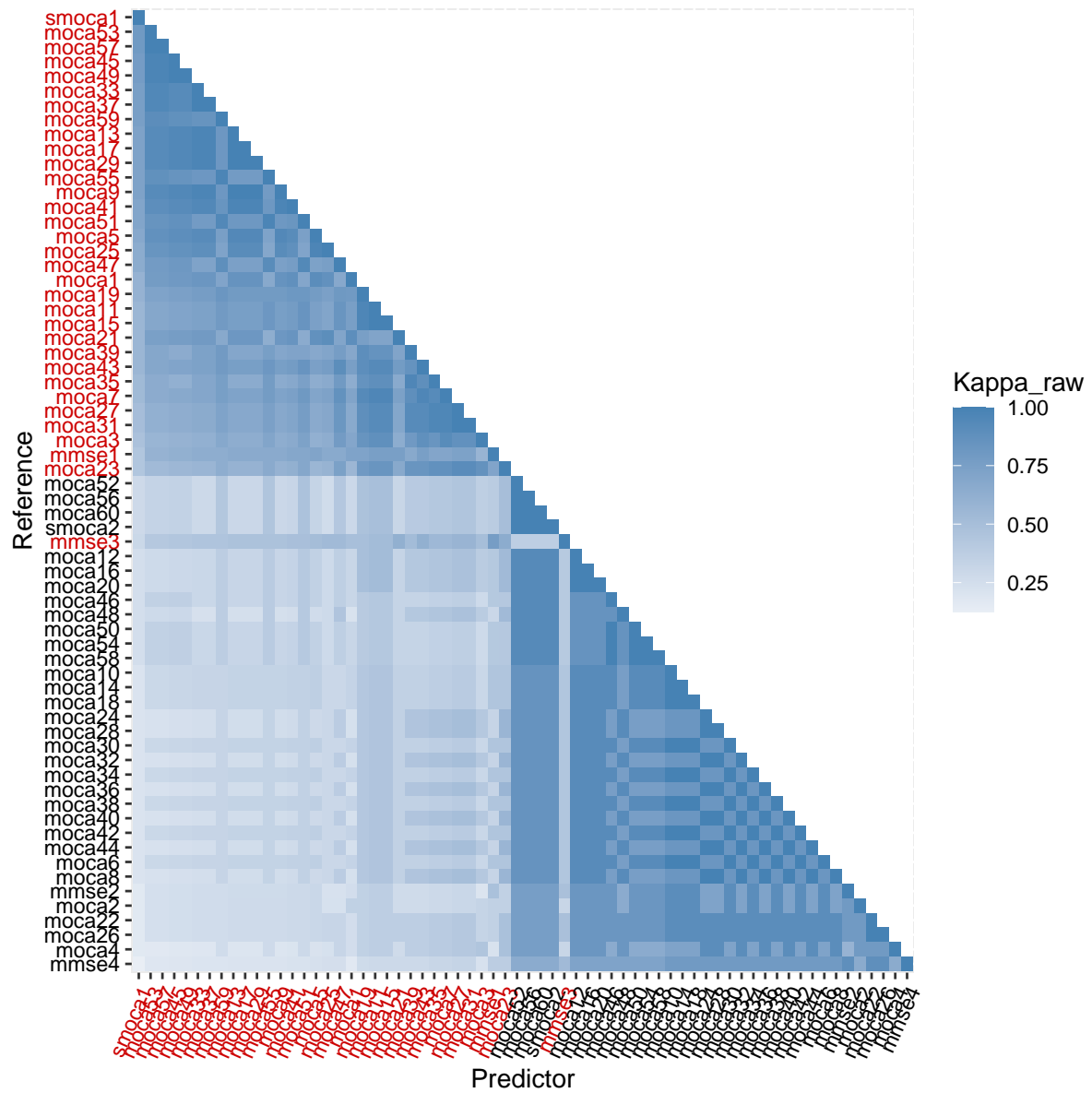
*Table 3 Estimates of prevalence. Estimates of the prevalence of probable PD-D in the sample.*

				Impaired cog
Global deficit	Attention	Executive function		
sMoCA (range 0-16) < 13	-	-		
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 3		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 3		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 3		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 3		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	VF K (number of words per minute) < 11		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	VF K (number of words per minute) < 11		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 3		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 2		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 2		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	VF K (number of words per minute) < 11		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 3		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 2		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 3		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 3		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 2		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	VF K (number of words per minute) < 11		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 3		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 2		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 2		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 2		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	VF K (number of words per minute) < 11		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	VF K (number of words per minute) < 11		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	MoCA (range 0-3) < 3		MoC
MoCA (range 0-30) < 26	MoCA 7 (range 0-3) < 3	VF K (number of words per minute) < 11		MoC

**Figure 1**



### Figure A1



### Figure A2

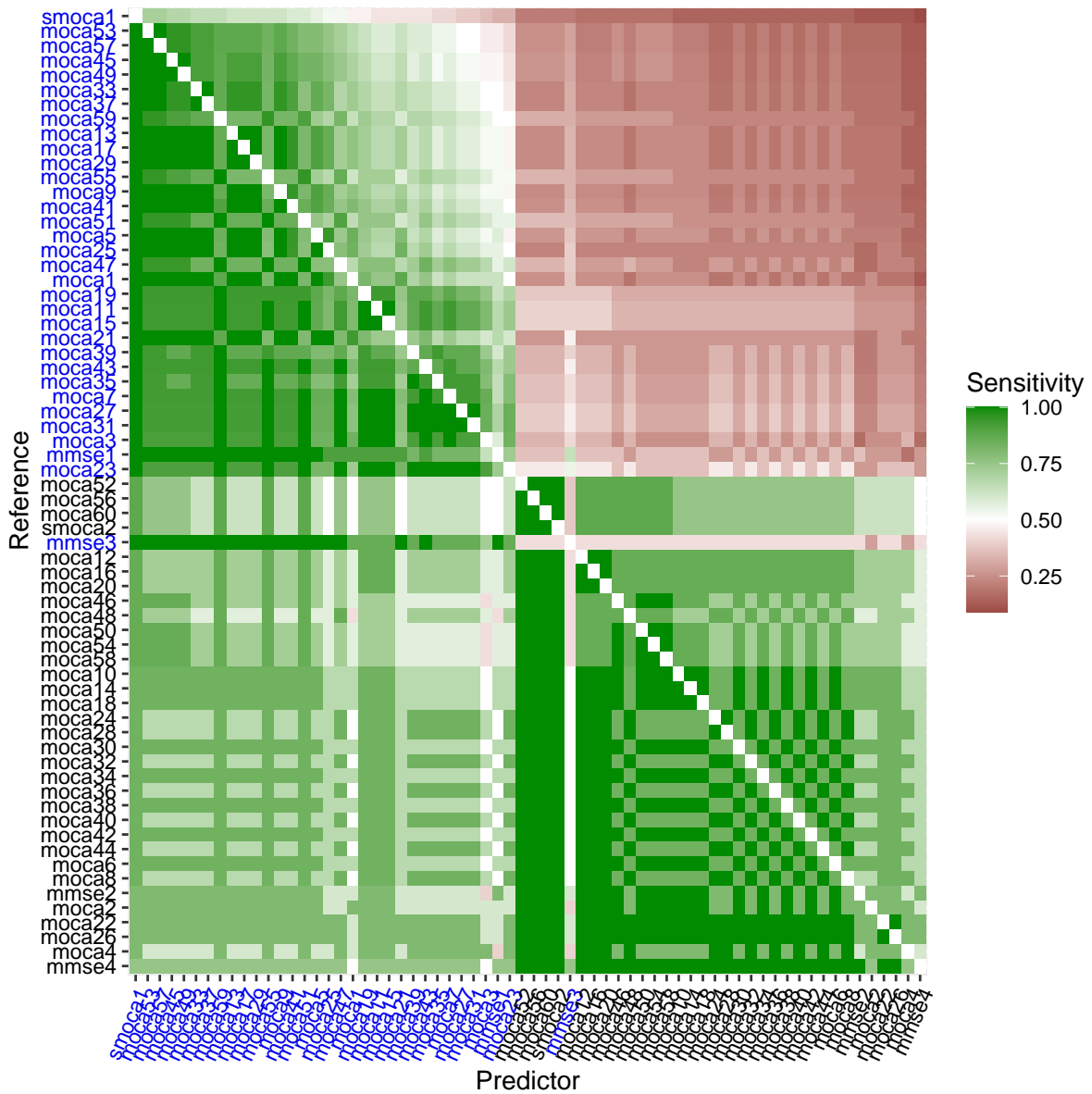


Figure A3

