The Uniform Data Set (UDS): Clinical and Cognitive Variables and Descriptive Data From Alzheimer Disease Centers

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Abstract: A Clinical Task Force, composed of clinical leaders from Alzheimer's Disease Centers (ADC), was convened by the National Institute on Aging to develop a uniform set of assessment procedures to characterize individuals with mild Alzheimer disease and mild cognitive impairment in comparison with nondemented aging. The resulting Uniform Data Set (UDS) defines a common set of clinical observations to be collected longitudinally on ADC participants in accordance with standard methods. The UDS was implemented at all ADCs on September 1, 2005. Data obtained with the UDS are submitted to the National Alzheimer's Coordinating Center and represent a unique and valuable source of data to support and stimulate collaborative research.

Key Words: Alzheimer disease, mild cognitive impairment, nondemented aging, standard assessment protocols, data set

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The National Institute on Aging (NIA) of the National Institutes of Health (Bethesda, MD) established the Alzheimer Disease Centers (ADCs) program beginning in 1984. Currently 29 ADCs are funded by the NIA. The ADCs support a comprehensive approach to Alzheimer disease (AD), including research on basic disease mechanisms, clinical and neuropathologic diagnosis, course, and treatment as well as educational initiatives for professional and lay audiences. Although the ADCs share common components and features, each ADC developed unique research questions and methods. As a result, the content and administrative procedures for research protocols used to assess dementia at each ADC vary widely, as does the implementation of diagnostic criteria for mild cognitive impairment (MCI) and AD.

The advantages of using a consistent set of evaluation procedures to characterize ADC participants were quickly recognized. The Consortium to Establish a Registry for Alzheimer's Disease (CERAD) brought the ADCs together in a coordinated effort to use standard assessment methods to gather reliable clinical and neuropsychologic data from individuals participating in research studies at each site.[1] Although the CERAD protocols were well received and translated into 11 languages other than English, they were designed simply to provide clinicians with the minimum information needed to describe the clinical features of individuals with AD. The CERAD data thus were relatively limited and inadequate for many evolving research questions, including those that now focus on MCI. Moreover, the CERAD batteries often were modified (sometimes substantially) at individual sites to comply with local preferences.

To address this heterogeneity and to promote data sharing, the Executive Committee of the ADC Directors, with the support of the NIA, developed a Minimum Data Set (MDS) in 1997 and established an Interim Data Coordinating Center under the direction of Denis Evans at Rush University Medical Center, Chicago, IL.[2] The list of items in the MDS was limited largely to basic demographic and clinical information about ADC participants at their most recent ADC evaluation. The

MDS was successful as an inventory of ADC research participants but did not include many important variables (eg, neuropsychologic test scores), nor did it obtain longitudinal data from participants or specify uniform methods for data collection. There thus remains a critical need for standard and reliable assessment protocols, administered in a uniform manner, to obtain a database for MCI and AD that will foster and support collaborative research.

METHODS

In 1999, the NIA funded the National Alzheimer's Coordinating Center (NACC; UOI AG016976) under the direction of Walter Kukull at the University of Washington in Seattle, WA. In collaboration with the Steering Committee (Elizabeth Cochran, MD; Dennis Dickson, MD; Bernardino Ghetti, MD) of the ADC Neuropathology Core Leaders, NACC developed a Neuropathology Data Set (NDS) to capture the neurodegenerative, vascular, and other pathologic features of ADC participants who came to autopsy. The NDS, which complements the MDS for purposes of limited clinicopathologic correlative studies, was implemented in December 2001; neuropathologic data on over 9000 individuals now have been entered into this data set. In accordance with the data sharing policies of the National Institutes of Health, public access is available for the MDS and the NDS.

The primary goals for NACC were to develop a database that captured and integrated data on all ADC participants and promoted collaborative research among the ADCs. Data needed to be sufficiently comprehensive to allow phenotyping of each individual's cognitive, behavioral, functional, and medical status, yet not too burdensome for routine and broad implementation. Furthermore, the protocol had to include detailed guidelines for administration with standard definitions and terminology so that findings at all ADCs could be compared. To achieve these aims, expansion of the MDS was necessary to define a common set of clinical observations on all ADC participants, collected longitudinally in a uniform manner. Other goals were to improve clinical assessment and diagnosis, track change over time, provide data in support of current projects, and stimulate research. This newly developed data set was intended to be the standard clinical protocol used by all ADCs.

To develop the protocol, in June 2002 the ADCs elected a 5-member Clinical Core Steering Committee (John C. Morris, Charles DeCarli, Norman Foster, Neill Graff-Radford, Elaine Peskind). The NIA then chartered a Clinical Task Force (CTF), consisting of the elected Clinical Core Steering Committee members and 5 additional members appointed by the NIA (Helena Chui, Jeffrey Cummings, Steven Ferris, Douglas Galasko, Sandra Weintraub). Nonvoting members included Creighton Phelps and Marcelle Morrison-Bogorad from the NIA, Dan Mungas (University of California, Davis, as representative of the ADC Data Core Leaders), and Walter Kukull, Erin Ramos, Duane Beekly, and Tom Koepsell from NACC. The mandate of the CTF was to expand the MDS to include longitudinal clinical and cognitive data on all ADC participants, obtained by standard methods and characterized by uniform diagnostic criteria. This new Uniform Data Set (UDS) was designed to provide data to support collaborative research initiatives, such as the NIA's Genetic Consortium for Late Onset AD (U24 AG026395; Richard Mayeux, PI) and the Alzheimer's Disease Neuroimaging Initiative (U01 AG024904; M. Weiner, PI). The CTF first convened in October 2002, to address its mandate.

The CTF adopted the following principles to guide the development of the UDS: (1) dementia remains a clinical diagnosis, and the instrument should provide sufficient information for an experienced clinician to determine the presence or absence of dementia and judge its cause or causes; (2) the initial protocol focuses on the characterization of nondemented aging, MCI, and mild AD; (3) included in this characterization is an assessment of whether an individual's cognitive and functional abilities have declined from previously attained levels, and thus informants are required for all individuals, including nondemented controls; (4) assessments are to be obtained annually; (5) the assessment protocol must provide sufficient data to address research questions but also should capitalize on commonly used criteria, measures, and scales to minimize the burden of implementation at each ADC; and (6) UDS data are collected in a standard and uniform manner. The NIA requires that all eligible ADC research participants be evaluated with the UDS protocol and that their data be submitted to NACC. After implementation of the initial version of the UDS, the CTF plans to develop additional modules to better characterize other individuals seen at ADCs, including those with more severe AD and with non-AD dementia, and to provide translations of the instrument for participants not fluent in English. Periodic revisions also are planned as further experience accumulates and in response to the needs of investigators.

The CTF surveyed all ADCs to determine the most frequently used clinical diagnostic criteria, scales for the clinical and behavioral features of AD, and neuropsychologic measures to evaluate cognitive function. The CTF then reviewed these measures for their psychometric properties and compatibility with the UDS goals. Published clinical diagnostic criteria[3–10] were adopted and additional guidance provided to clarify interpretation and aid uniform implementation across centers. The UDS protocol classifies participants with MCI into amnestic and nonamnestic, single and multiple domain categories.[9]

Individual components for the UDS (Table 1) were selected in accordance with 2 aims: (1) to provide an experienced clinician with sufficient clinical information to determine the presence or absence of dementia and, when present, its possible cause or causes; and (2) to serve as a research database for studies of AD and MCI in comparison with nondemented aging. Demographic information for participants (Form A1) and their

TABLE 1. The UDS Initial Visit Packet (Available at http://www.alz.washington.edu) (Version 1.1, September 2005)

Introduction
Form Z1: Form checklist
Form A1: Subject demographics
Form A2: Informant demographics
Form A3: Subject family history
Form A4: Subject medications
Form A5: Subject health history
Form B1: Evaluation form—Physical
Form B2: Evaluation form—Hachinski Ischemic Scale (Rosen et al[11])
Form B3: Evaluation form—Unified Parkinson's Disease Rating Scale (UPDRS) (Fahn and Elton[12])—Motor Examination
Form B4: Global staging—Clinical Dementia Rating (CDR) (Morris[13])
Form B5: Behavioral assessment—Neuropsychiatric Inventory Questionnaire (NPI-Q) (Kaufer[14])
Form B6: Behavioral assessment—Geriatric Depression Scale (GDS) (Sheikh and Yesavage[15])
Form B7: Functional assessment—Functional Assessment Questionnaire (FAQ) (Pfeffer et al[16])
Form B8: Evaluation—Overall Appraisal
Form B9: Clinician judgment of symptoms onset
Form C1: Neuropsychological Battery
Form D1: Clinician diagnosis—Cognitive Status and Dementia
Form E1: Imaging/Labs

TABLE 2. Neuropsychological Battery (UDS Form C.1) (Available at http://www.alz.washington.edu)

General Dementia Screen
Mini-Mental State Examination (Folstein et al[17])
Verbal Episodic Memory
WMS-R Logical Memory IA—Immediate (Wechsler and Stone[18])
Attention
Digit Span—Forward (Wechsler and Stone[18])
Digit Span—-Backward (Wechsler and Stone[18])
Semantic Memory/Language
Category Fluency (animals; vegetables) (Morris et al[1])
Boston Naming Test (30 item, odd numbered) (Goodglass and Kaplan[24])
Psychomotor Speed (also tests visuospatial function)
WAIS-R Digit Symbol (Wechsler[19])
Trailmaking Test Part A (Armitage[20])
Executive Function
Trailmaking Test Part B (Armitage[20])
Delayed Verbal Episodic Memory
WMS-R Logical Memory IIA—Delayed (Wechsler and Stone[18])

informants (Form A2) covers basic descriptive data, including the frequency and type of exposure of the informant to the participant. The family history for the participant (Form A3) focuses on dementing illnesses experienced by the participant's first degree relatives. A medication inventory (Form A4) records all medications (including nonprescription drugs, vitamins, and supplements) taken by the participant within 2 weeks of their ADC visit. The health history (Form A5) records information about disorders that potentially could contribute to dementia (eg, stroke) or influence cognitive assessment (eg, depression). The physical examination of the participant (Form B1) records vital signs and evaluates visual and auditory function, and the neurologic examination (Form B8) describes findings indicative of central nervous system disorders.

In choosing among the many available structured and semistructured dementia assessment scales, preference was given to those that would best serve to phenotype participants and were already in use in many ADCs. The Rosen modification of the Hachinski Ischemic Scale (Form B2) records the presence of features that may suggest cerebrovascular contributions to cognitive status.[11] Similarly, the Unified Parkinson's Disease Rating Scale (Form B3) captures information that may point to extrapyramidal disorders as either comorbid or causative factors for dementia.[12] Behavioral features of dementing illnesses are assessed with the Neuropsychiatric Inventory Questionnaire (NPI-Q) (Form B5; Cummings et al[21]; Kaufer et al[14]), administered to the informant, and with the 15-item Geriatric Depression Scale (GDS) (Form B6; Sheikh and Yesavage[15]; Yesavage[22]), administered to the participant. The informant's observations about functional impairment for the participant is recorded with the Functional Assessment Questionnaire (FAQ) (Form B7; Pfeffer et al[16]). The clinician's overall assessment of the presence or absence of dementia and, when present, its severity are operationalized with the Clinical Dementia Rating (CDR) (Form B4; Morris[13]). The opportunity to use established training and reliability protocols for the Unified Parkinson's Disease Rating Scale, the Neuropsychiatric Questionnaire, and the CDR was an additional factor leading to the inclusion of these scales in the UDS.

A CTF subcommittee under the leadership of Sandra Weintraub selected the measures included in Neuropsychological Battery (Form C1) (Table 2). It was the intention of the CTF to keep the battery brief, requiring about 30 minutes, while including at least 1 test designed to measure each major cognitive domain. Nevertheless, some cognitive domains (eg, nonverbal memory and visuospatial function) are sparsely covered because consensus was lacking for specific measures that had sufficient brevity, wide usage, and well-studied psychometric properties. Some of the tests included in the battery are administered as part of the UDS under special arrangements with copyright holders.

Drafts of the UDS were presented to the ADC clinicians, neuropsychologists, data managers, and administrators at the ADC Directors' Meeting in March 2003 and again in April 2004. The working version of the UDS was formally adopted by the ADC Directors in September 2004. With the determination of the individual clinical and cognitive variables, NACC then developed the UDS Data Forms and Coding Guidebook, which details the administration and scoring for each measure. These forms were piloted at several ADCs in May and June 2005. The final UDS Initial Visit Packet (Version 1.1) was implemented at all ADCs on September 1, 2005. Standardization and training meetings were held for ADC physicians and neuropsychologists (November 2005) and data managers (January 2006).

A web-based data submission system and database for collecting and storing data from the ADCs has been

developed by NACC.[23] To promote data sharing in a manner similar to the MDS and NDS, a mechanism for public access to the UDS is being developed. Information about the UDS forms, data element dictionary, training procedures, data system, quality assurance, and public access (MDS and NDS) can be obtained at http://www.alz.washington.edu.

The UDS is administered as a standard instrument, separate from protocols already in use at the individual ADCs. An ADC may continue to administer separately its site-specific protocols to maintain fidelity with data obtained before implementation of the UDS and to address research questions for which the UDS is not the appropriate instrument. Mapping from site-specific instruments to the UDS, however, is not permitted. Occasionally, forms cannot be completed or may have missing data because of participant variables such as fatigue during administration or physical disability. Provision has been made to document such circumstances. Otherwise, complete data collection is expected for each subject annually. Forms Z1, A1, B4, B9, C1, D1, and E1 must be submitted on an individual participant to permit inclusion in the NACC database.

RESULTS

The NACC has received UDS data from 3309 participants who were evaluated at the ADCs from September 1, 2005, through June 30, 2006. Descriptive cross-sectional data are presented here to illustrate the potential utility of the UDS for research studies.

The characteristics of the nondemented, MCI, and AD participants are shown in Table 3; in addition, there were 115 individuals diagnosed with "Cognitive Impairment, Not MCI," and 206 individuals diagnosed with non-AD dementia. Participants were highly educated and predominantly white, particularly the nondemented participants. There were proportionately more men in

TABLE 3. Demographic Characteristics for UDS Participants With a Clinical Diagnosis of Normal Cognition, MCI, or Probable/Possible AD

	Normal (N = 1322)		MCI (N = 617)		Prob/Poss AD (N = 1149)	
	n	%	n	%	N	%
Age at visit (y)†						
< 59	90	6.8	26	4.2	62	5.4
60-64	105	7.9	53	8.6	58	5.0
65-69	208	15.7	71	11.5	99	8.6
70-74	261	19.8	131	21.2	179	15.6
75-79	289	21.9	149	24.2	263	22.9
80-84	207	15.7	109	17.7	282	24.5
85-89	101	7.6	52	8.4	154	13.4
90-94	49	3.7	21	3.4	41	3.6
≥ 95	12	0.9	5	0.8	11	1.0
Mean Age (SD)	74.0 ± 9.5		74.9 ± 8.8		76.7 ± 9.2	
Education (y)*						
≤ 7	8	0.6	26	4.3	65	5.7
8-11	27	2.1	43	7.0	101	8.9
12	185	14.1	132	21.6	321	28.3
13-15	270	20.7	115	18.8	201	17.7
16-17	385	29.5	152	24.8	246	21.7
≥ 18	432	33.0	144	23.5	200	17.7
Mean Education (SD)	15.7 ± 2.8		14.5 ± 3.7		13.8 ± 3.8	
Sex						
Male	488	36.9	302	49.0	503	43.8
Female	834	63.1	315	51.0	646	56.2
Race						
White	1191	90.1	496	80.4	928	80.8
Black/African American	109	8.3	87	14.1	148	12.9
Am. Indian/Alaska Native	1	0.1	2	0.3	2	0.2
Hawaiian/Pac. Islander	0	0.0	0	0.0	1	0.1
Asian	7	0.5	10	1.6	15	1.3
Others	7	0.5	20	3.3	51	4.4
Unknown	7	0.5	2	0.3	4	0.3
Hispanic						
No	1245	94.2	544	88.2	1043	90.8
Yes	45	3.4	50	8.1	90	7.8
Unknown	32	2.4	23	3.7	16	1.4
Primary Language						
English	1272	96.2	560	90.8	1063	92.5
Spanish	32	2.4	40	6.5	68	5.9
Others	18	1.4	17	2.7	18	1.6

*Missing education data for 35 individuals.

TABLE 4. Primary Dementia Diagnoses in 1355 Demented Individuals in the UDS Sample

Diagnosis	%
Probable AD	71.3
Possible AD	9.3
Dementia with Lewy bodies	5.5
Frontotemporal dementia	4.3
Primary progressive aphasia	2.4
Vascular dementia	1.6
Corticobasal degeneration	1.2
Undetermined etiology	1.2
Parkinson disease	1.0
Progressive supranuclear palsy; Huntington disease; Prion disease; cognitive dysfunction/ medications; cognitive dysfunction/medical illness; depression; major psychiatric illness; hydrocephalus; others	Each < 1.0

the MCI and AD groups than among nondemented participants. More than 80% of the participants with dementia had a primary diagnosis of AD (n = 1355; 1149 with probable or possible AD, 206 with non-AD dementia), consistent with the clinical and scientific interests of the ADCs and with the initial focus of the UDS (Table 4).

The possible range of scores for selected UDS scales and tests are shown in Table 5. Lower scores represent "best" performance for the CDR Sum of Boxes, GDS, and FAQ; for all other measures, higher scores represent best performance. Table 6 shows the group frequencies for selected subitems of the NPI-Q and mean group performances on the CDR Sum of Boxes, GDS, and FAQ.

Raw values from the performance of 1322 nondemented, MCI, and AD participants on the UDS Neuropsychological Battery do not constitute normative values, which must await additional UDS data collection to achieve a sufficient sample size that permits appropriate adjustment for age and education. As expected, however, AD subjects had lower scores than nondemented participants on all tests. ADC participants with AD predominantly are those in the milder stages of dementia, although the UDS sample includes individuals with all degrees of dementia severity.

TABLE 5. Possible Range of Scores for Selected UDS Tests

	Minimum	Maximum
CDR Sum of Boxes	0	18
GDS Total Score	0	15
FAQ Total Score	0	30
MMSE (WORLD)	0	30
Logical Memory-Immediate	0	25
Digit Span Forward-No. Trials Correct	0	12
Digit Span Forward-Length	0	8
Digit Span Backward-No. Trials Correct	0	12
Digit Span Backward-Length	0	7
Category Fluency-Animals	0	77
Category Fluency-Vegetables	0	77
Trail Making Test-Part A	1	150
Trail Making Test-Part B	1	300
WAIS-R-Digit Symbol	0	93
Logical Memory-Delayed	0	25
Boston Naming Test-(30 Odd Numbered)	0	30

The neuropsychologic performance of MCI individuals was intermediate between normal and AD participants. Although original criteria for MCI emphasized amnestic deficits,[7] revised criteria[9] allow impairment in other cognitive domains and do not require memory impairment. In the 617 individuals with MCI, amnestic, single domain MCI (memory only) was reported in 44% (n = 274), but 24% (n = 145) had nonamnestic MCI (93 with a single nonmemory cognitive deficit, and 52 with multiple nonmemory cognitive deficits). Another 32% (n = 196) had amnestic, multiple domain MCI (memory impairment with at least one other cognitive deficit). Although these preliminary data are cross-sectional and limited to the UDS sample, it seems that at least some MCI individuals in the UDS sample begin without memory impairment and perhaps as many as 40% have multiple cognitive deficits.

CONCLUSIONS

The UDS has been successfully implemented at all ADCs as a standardized assessment of research participants. It capitalizes on commonly used instruments, definitions, and diagnostic criteria and incorporates the observations of a knowledgeable informant. Despite some initial concern about the feasibility of identifying a knowledgeable informant for each participant, particularly for those without dementia, this has not proven to be an important barrier. Furthermore, there is the distinct advantage of providing the clinician with informant observations to determine whether an individual has declined from previous cognitive abilities, in addition to evaluating their performance on the neuropsychologic measures.

The UDS is designed to be administered longitudinally and thus will track cognitive and functional decline in impaired individuals and the onset of cognitive change in those who were initially nondemented. Because data will be available from a very large number of carefully characterized older adults, it will be a unique and valuable resource to address questions about normal cognitive aging, dementia risk, prodromal disorders such as MCI, and progression of AD.

The UDS also has important limitations. It is not intended for the initial or routine evaluation of patients with cognitive dysfunction. Although incorporating features of the UDS might enhance assessments in clinical practice, the selection of the UDS components, including the tests in the neuropsychological battery, were driven by research priorities for AD and MCI rather than for differential diagnosis. The neurologic examination and laboratory assessment also is limited and may not include all appropriate procedures for patients receiving a full dementia evaluation. The UDS is designed primarily to

TABLE 6. Frequency of Selected NPI-Q Subitems and the Mean (SD) of the CDR, GDS, and FAQ for UDS Participants With a Clinical Diagnosis of Normal Cognition, MCI, or Probable/Possible AD

	Normal (N = 1322)		MCI (N = 617)		Prob/Poss AD (N = 1149)	
	n	%	n	%	n	%
NPI-Q*						
Delusions						
No	1155	99.0	541	96.3	857	81.6
Yes	12	1.0	21	3.7	193	18.4
Apathy						
No	1126	96.5	472	84.0	559	53.2
Yes	41	3.5	90	16.0	491	46.8
Irritability						
No	1070	91.7	422	75.1	641	61.1
Yes	97	8.3	140	24.9	409	38.9
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
CDR Sum of Boxes	1322	0.1 (0.5)	617	1.4 (1.2)	1149	7.5 (4.6)
GDS Total Score†	1275	1.4 (2.0)	588	2.3 (2.5)	935	2.5 (2.5)
FAQ Total Score‡	1243	0.4 (1.6)	583	3.6 (4.8)	1119	17.8 (9.0)
MMSE Score§	1312	29.0 (1.2)	607	27 (2.8)	1086	18.8 (>0)

*NPI-Q data missing for 155 Normal, 55 MCI, and 99 Prob/Poss AD individuals.
†GDS data missing for 47 Normal, 29 MCI, and 214 Prob/Poss AD individuals.
‡FAQ data missing for 79 Normal, 34 MCI, and 30 Prob/Poss AD individuals.
§MMSE data missing for 10 Normal, 10 MCI, and 63 Prob/Poss AD individuals.

assess neurodegenerative causes of dementia and is inadequate to assess other dementing illnesses, such as rapidly progressive dementia or vascular dementia.

There also are limitations to these data. Individuals assessed at ADCs agree to participate in longitudinal research studies at academic medical centers and hence are unlikely to be representative of the general population of older adults. The UDS sample intentionally includes fewer individuals with severe dementia than would be found in a community or institutional setting. Consequently, these data should not be construed to reflect the general distribution of findings in individuals with AD in the community.

There may well be better scales for the clinical, behavioral, and functional features of MCI and AD and better tests of specific cognitive domains than the measures included in the UDS. The UDS is far from comprehensive; additional modules are planned that will better characterize non-AD dementias. Translations of the UDS for non-English speaking individuals also are needed. Nonetheless, the UDS will provide an increasingly valuable source of data for exploratory and explanatory research and will stimulate new collaborative research that previously was impossible.

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