Common Data Elements for Precision Neuropsychology

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What is a Common Data Element (CDE)?

A variable that is defined, collected, and recorded in the same way across multiple datasets

Developed/vetted by experts in the field

Name	Definition	Query / Instructions	Provenance	Value Set	Resource
PX011601_Biological_Sex_Assigned_Birth	The indication of the biological sex assigned to an individual at the time of birth. This usually aligns with a person's anatomical sex, chromosomal sex, and phenotype.	What was your biological sex assigned at birth? Participants (or proxy) indicate the biological sex assigned at birth. It can be self-administered or interviewer administered.	All of Us Research Program Participant Provided Information (PPI) Version: December 17, 2018	Female Male Intersex None of these describe me (optional free text) Prefer not to answer	PhenX

Why use CDEs?

Can be used to promote research and clinical practice with regard to:

- **Quality** – validated instruments & measures
- **Clarity** – unambiguously defined data elements, less need for ongoing local oversight
- **Reproducibility** – from rigorous comparison of data and results
- **Efficiency** – off-the-shelf data elements with existing variable dictionaries
- **Cost** – Many are open-source

Valid sharing & comparing of data allows for:

- Aggregation of data to increase statistical power
- Access to larger and more diverse samples
- Variable harmonization across studies

NIH says so

- "NIMH expects that applications submitted for funding after May 1, 2015 will incorporate these measures in all research proposed that involves human participants." NOT-MH-15-009
- "NINDS strongly encourages researchers who receive funding from the Institute to use the NINDS Common Data Elements (CDEs) or document how they will ensure their data collection is compatible with the CDEs…Justification must be clearly provided in the plan if any general CDE or disease-specific (as available) will not be used." Terms of Award for all clinical trials
- NIMH Data Archive (NDA)

Towards Precision Neuropsychology

Lack of large-scale representative databases with *clinical* data

- Incorporate other aspects of the NP evaluation:
  - Demographics
  - Medical history
  - Presenting complaints
  - Psychiatric symptoms
  - Dimensional ratings of everyday functioning and disability

Variable assessment of similar constructs

- Develop standardized, empirically-grounded evaluation of relevant constructs using modern psychometrics

Pragmatics

- Collect data securely without disrupting clinical practice

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CDEs in NP

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Study Aims

NAN Clinical Research Grant 2018

NIMH R01 - National Neuropsychology Network (NNN; R01MH101854)

Implement an accessible and secure web-based platform for collecting clinically relevant information (proposed as CDEs) and **relaying it to providers** in a time-sensitive manner, while simultaneously aggregating cumulative and item-level data into a **database repository**

Projected outcomes:

(1) identifying a set of individual-level variables with transdiagnostic relevance for a range of neuropsychiatric syndromes

(2) establishing a structured, evidence-based clinical protocol for evaluating these variables

(3) creating an accessible infrastructure for efficiently collecting patient information, and communicating it succinctly to providers

(4) creating a database repository for ongoing clinical data collection

(5) establishing the feasibility of this procedure in a real-world clinical setting

National Neuropsychology Network (NNN)

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- Medical history
- Presenting complaints
- Psychiatric symptoms
- Everyday functioning and disability

(2) establishing a structured, **evidence-based clinical protocol** for evaluating these variables

Structured History Protocol in Neuropsychology (SHiP-NP)

Proposed procedures:

- Step 1: Enrollment
  - Patient is sent appointment confirmation with a unique link embedded (link may be personalized according to their GUID but no other PHI linked to it), inviting them to access and complete forms online prior to appt.
- Step 2: Forms completion
  - Apply branched logic, CATs, forced response paradigms, etc. so patients complete only relevant and necessary items, in a correct format, prior to clinic appointment.
- Step 3: Clinical output
  - Clinician identifies their patient based on GUID and downloads clinical report output(s)
- Step 4: Deidentified data aggregation and storage for research purposes

Identifying relevant CDEs from existing CDE initiatives

Name	Abbreviation	# of Elements	CDE Resource
Standardized Asthma Outcomes for Clinical Research	Asthma CDEs	10 (adults), 25 (children)	NHLBI, NIAID
Chronic Low Back Pain CDEs	cLBP	40	NCCAM
Early Detection Research Program	EDRN	1,600	NCI
eyeGENE	eyeGENE	200	NEI
Rare Diseases Registry Program (RaDaR)	GRDR	75	GRDR
Quality of Life Outcomes in Neurological Disorders	Neuro-QOL	500	NINDS
NIDA Substance Abuse Electronic Health Record Data Elements	NIDA EHR	80+	NIDA
NIH Toolbox for Assessment of Neurological and Behavioral Function	NIH Toolbox	4 batteries of tests, each with 5-24 tests	NIH
NINDS Common Data Elements	NINDS CDEs	10,000 unique variables, 550+ instruments	NINDS
Consensus Measures for Phenotypes and eXposures	PhenX	23,000+ variables, 689 protocols	--
Patient Reported Outcomes Measurement Information System	PROMIS	50 item banks	NIAMS

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PhenX

Proposed CDEs:

<u>Core Demographics</u>

Current age
Sex
Gender identity
Race
Ethnicity
Marital status
Educational attainment
Annual family income
Child-reported parental educational attainment

<u>Additional</u>

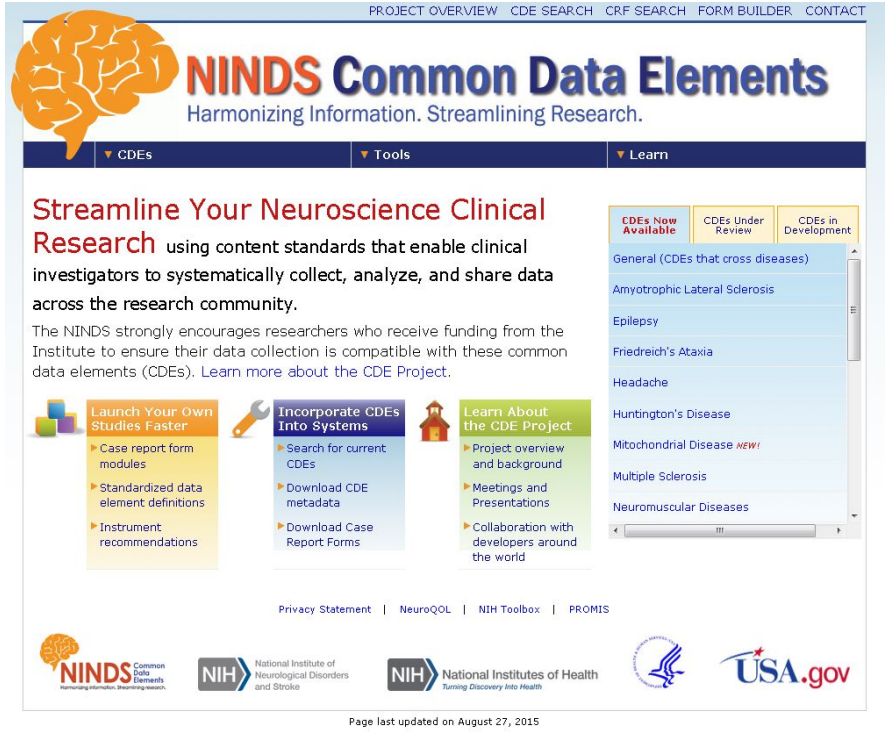
Handedness
Generational status
- Language fluency/proficiency

Social determinants of health

- Online resource of standard phenotypic & environmental exposure measures
- Protocols selected by Working Groups of domain experts using a consensus process
- 730 measures addressing 25 domains

Hamilton et al., 2011 - https://www.phenxtoolkit.org/index.php

NINDS CDEs



Developed with expertise from close to 1000 specialists worldwide, incl. representatives from NIH institutes (17+), federal and state agencies, non-profits, and Pharmaceutical/Laboratories/Companies

Proposed CDEs:

Prior and Concomitant Medications

- Drugs with known cognitive side effects (e.g., narcotic analgesics, benzodiazepines, anticholinergics, sedatives/hypnotics, and/or certain anti-epileptic drugs).

Medical History

- Disease-specific supplementary CDEs for head injury, seizures or epilepsy, stroke/CVA, cancer

Family Medical History

http://www.commondataelements.ninds.nih.gov/

Neuro QoL

Calibration testing in US general population and clinical samples using 2-PL IRT (Gerson et al., 2012)

Validated using Barthel Index, Lawton ADLs, Karnofsky Performance Status Scale (KPSS), Oral Digit Symbol Modalities, Digit Symbol Coding, Global Health Related QoL, EuroQoL-5D, PROMIS Global Health Scale, FACIT Pain + addn'l measures specific to stroke, Parkinson's disease, Epilepsy, MS, ALS (Cella et al., 2011; Victorson et al., 2014; Cook et al., 2015; Miller et al., 2016)

~10mins for all proposed banks

Score produced on the same common (Theta) metric, converted to a T-distribution + SE

Estimates of meaningful change over time available

	Adult Domains	SF # items
Mental	Cognitive Function	8
	Emotional and Behavioral Dyscontrol	8
	Positive Affect and Well- Being	9
	Stigma	8
Physical	Fatigue	8
	Lower Extremity Function - Mobility	8
	Upper Extremity Function – Fine motor, ADLs	8
	Sleep Disturbance	8
Social	Satisfaction with Social Roles and Activities	8

	During the past **TWO (2) WEEKS**, how much (or how often) have you been bothered by the following problems?	**None** Not at all	**Slight** Rare, less than a day or two	**Mild** Several days	**Moderate** More than half the days	**Severe** Nearly every day	**Highest Domain Score** (clinician)
I.	1. Little interest or pleasure in doing things?	0	1	2	3	4	
	2. Feeling down, depressed, or hopeless?	0	1	2	3	4	
II.	3. Feeling more irritated, grouchy, or angry than usual?	0	1	2	3	4	
III.	4. Sleeping less than usual, but still have a lot of energy?	0	1	2	3	4	
	5. Starting lots more projects than usual or doing more risky things than usual?	0	1	2	3	4	
IV.	6. Feeling nervous, anxious, frightened, worried, or on edge?	0	1	2	3	4	
	7. Feeling panic or being frightened?	0	1	2	3	4	
	8. Avoiding situations that make you anxious?	0	1	2	3	4	
V.	9. Unexplained aches and pains (e.g., head, back, joints, abdomen, legs)?	0	1	2	3	4	
	10. Feeling that your illnesses are not being taken seriously enough?	0	1	2	3	4	
VI.	11. Thoughts of actually hurting yourself?	0	1	2	3	4	
VII.	12. Hearing things other people couldn't hear, such as voices even when no one was around?	0	1	2	3	4	
	13. Feeling that someone could hear your thoughts, or that you could hear what another person was thinking?	0	1	2	3	4	
VIII.	14. Problems with sleep that affected your sleep quality over all?	0	1	2	3	4	
IX.	15. Problems with memory (e.g., learning new information) or with location (e.g., finding your way home)?	0	1	2	3	4	
X.	16. Unpleasant thoughts, urges, or images that repeatedly enter your mind?	0	1	2	3	4	
	17. Feeling driven to perform certain behaviors or mental acts over and over again?	0	1	2	3	4	
XI.	18. Feeling detached or distant from yourself, your body, your physical surroundings, or your memories?	0	1	2	3	4	
XII.	19. Not knowing who you really are or what you want out of life?	0	1	2	3	4	
	20. Not feeling close to other people or enjoying your relationships with them?	0	1	2	3	4	
XIII.	21. Drinking at least 4 drinks of any kind of alcohol in a single day?	0	1	2	3	4	
	22. Smoking any cigarettes, a cigar, or pipe, or using snuff or chewing tobacco?	0	1	2	3	4	
	23. Using any of the following medicines ON YOUR OWN, that is, without a doctor's prescription, in greater amounts or longer than prescribed [e.g., painkillers (like Vicodin), stimulants (like Ritalin or Adderall), sedatives or tranquilizers (like sleeping pills or Valium), or drugs like marijuana, cocaine or crack, club drugs (like ecstasy), hallucinogens (like LSD), heroin, inhalants or solvents (like glue), or methamphetamine (like speed)]?	0	1	2	3	4	

DSM-5 Level 1 &2 Cross-Cutting Symptom measures

Level 1: 23 Likert-type scale questions of specific symptomatology during the past 2 weeks across 13 mental health domains

Clinically useful, good test-retest reliability in DSM-5 Field Trials across US and Canada (Narrow et al., 2013; Clarke et al., 2014; Clarke & Kuhl, 2014)

Participants who screen positive on the Level 1 assessment receive the DSM-5 Level 2 measures

- Suicidal ideation
- Recent drug use

https://www.psychiatry.org/psychiatrists/practice/dsm/educational-resources/assessment-measures

DSM-5 Level 1 &2 Cross-Cutting Symptom measures

	Domain Name	DSM-5 Level 2 Cross-Cutting Symptom Measure	SF # items
I.	Depression	PROMIS Depression—Short Form	8
II.	Anger	PROMIS Anger—Short Form	5
III.	Mania	Altman Self-Rating Mania Scale	5
IV.	Anxiety	PROMIS Anxiety—Short Form	7
V.	Somatic Symptoms	PHQ-15 Somatic Symptom Severity	15
VI.	Suicidal Ideation	None	
VII.	Psychosis	None	
VIII.	Sleep Problems	PROMIS—Sleep Disturbance—Short Form	8
IX.	Memory	None	
X.	Repetitive Thoughts and Behaviors	adapted Florida Obsessive-Compulsive Inventory [FOCI] Severity Scale Part B	5
XI.	Dissociation	None	
XII.	Personality Functioning	None	
XIII.	Substance Use	adapted NIDA-modified ASSIST	10

PROMIS® SFs (Cella et al., 2010)

Reliability and Validity: IRT + CTT; content, cross-sectional, clinical, temporal validation studies*

Comparability: Standardized T for common metrics across conditions

Inclusiveness: General sample + DIF testing across known groups and population characteristics

*Cella et al., 2016; Pilkonis et al., 2011, 2014; Reeve et al., 2007; Riley et al, 2010; Shalet et al. 2016
http://www.healthmeasures.net/explore-measurement-systems/promis/

Additional CDEs and other data sources

World Health Organization Disability Assessment Schedule 2.0 (WHO-DAS 2.0)

In-Use Clinic History Forms

- Prior NP Testing
- Legal history
- Academic performance
- Military history
- Birth/developmental complications
- Current/Past psychiatric treatment

Protocol reviewed by NP experts

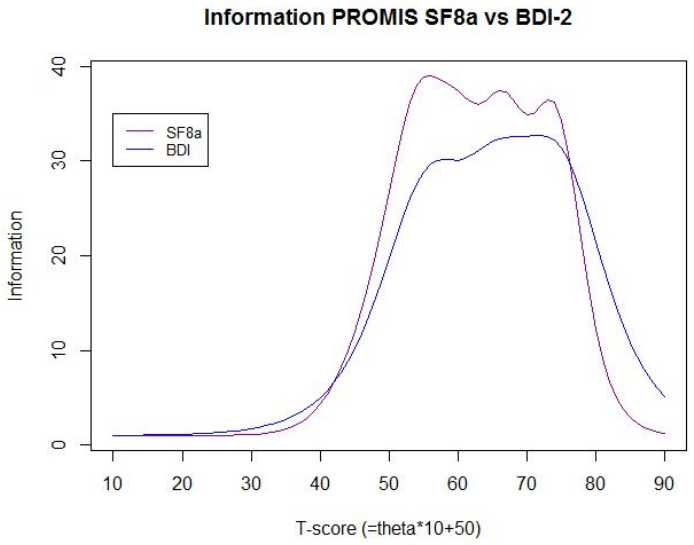
In the past 30 days, how much difficulty did you have in:						
Understanding and communicating						
D1.1	Concentrating on doing something for ten minutes?	None	Mild	Moderate	Severe	Extreme or cannot do
D1.2	Remembering to do important things?	None	Mild	Moderate	Severe	Extreme or cannot do
D1.3	Analysing and finding solutions to problems in day-to-day life?	None	Mild	Moderate	Severe	Extreme or cannot do
D1.4	Learning a new task, for example, learning how to get to a new place?	None	Mild	Moderate	Severe	Extreme or cannot do
D1.5	Generally understanding what people say?	None	Mild	Moderate	Severe	Extreme or cannot do
D1.6	Starting and maintaining a conversation?	None	Mild	Moderate	Severe	Extreme or cannot do
Getting around						
D2.1	Standing for long periods such as 30 minutes?	None	Mild	Moderate	Severe	Extreme or cannot do
D2.2	Standing up from sitting down?	None	Mild	Moderate	Severe	Extreme or cannot do
D2.3	Moving around inside your home?	None	Mild	Moderate	Severe	Extreme or cannot do
D2.4	Getting out of your home?	None	Mild	Moderate	Severe	Extreme or cannot do

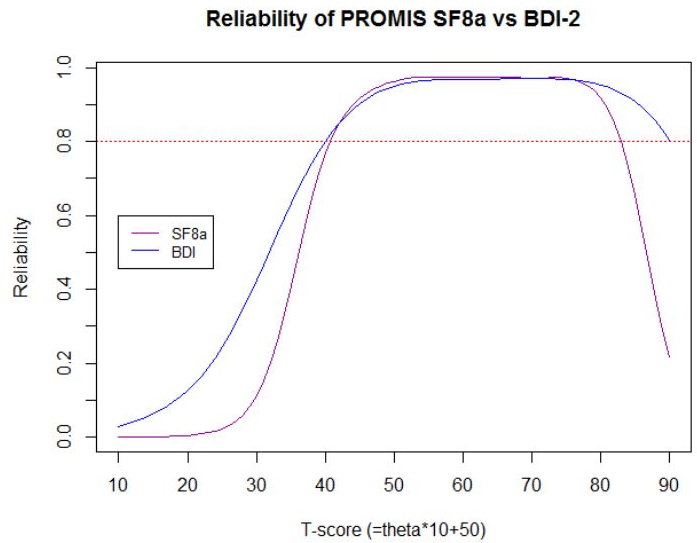
https://www.who.int/classifications/icf/whodasii/en/

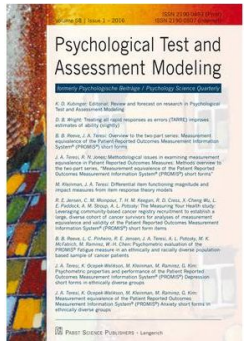
Comparative Utility of PROMIS-SF

PROsetta Stone®
Linking Patient-Reported Outcome Measures

Legacy Test	Raw score *r* (disattenuated *r*)	α
PROMIS Depression		.98
BDI-2	.89 (.92)	.96
PHQ-9	.84 (.89)	.91
CES-D	.90 (.94)	.93
PROMIS Anxiety		.98
MASQ-GA	.85 (.91)	.89
GAD-7	.86 (.91)	.93
PANAS	.89 (.93)	.97
PROMIS Sleep Disturbance		.95
PSQI	.72 (.86)	.74
PROMIS Anger		.96
BPAQ	.59 (.65)	.84







Psychological Test and Assessment Modeling, Volume 58, 2016 (1), 31-35

Overview to the two-part series: Measurement equivalence of the Patient Reported Outcomes Measurement Information System® (PROMIS®) short forms

Bryce B. Reeve[1,2] & Jeanne A. Teresi[3,4,5]

Cella et al., 2010; Choi et al., 2014; Schalet et al., 2014; Levin et al., 2015; www.prosettastone.org

Potential Barriers to Use

Patient privacy and data security

- 21 CFR Part 11, FISMA, and HIPAA-compliant environment
- Protocols transmit only de-identified data
- Access to data restricted only to users who have sufficient privileges within each clinic
- Formal risk assessment by UCLA Office of Compliance in progress

Patient accessibility

- Can complete in clinic using ipads if unable to complete at home

Legacy measures have legacy

- Similar or improved validity of proposed methods with fewer items and lower cost
- Linking tables available

Protecting the field

- Not meant to eliminate the need for clinical interviews or self-report forms, but to guide these processes more efficiently; allow for more time spent on more relevant clinical needs

Change is hard – lack of inertia in NP community

- Implementation
- Practicality for clinician AND patient
- Cost (FREE!)

Clinical application

Results can be reviewed prior to appointment and incorporated into clinical considerations throughout the rest of the evaluation

Automated flagging of items that may require clinical follow-up prior to appointment (e.g., suicidality, drug use) or influence test selection (e.g., bilingualism)

NeuroQoL, DSM-5, and WHODAS2.0 questionnaires automatically scored, normed, and organized in a data summary sheet (eliminating human error)

CDEs can be derived by:

- Raw data output (similar to current History Form) OR
- Auto-populated narrative report form

PRE-ASSESSMENT SUMMARY SHEET

Name:				Tested:	
MRN#		Examiner(s):	--	Education:	
DOB:	--	Age:	--	Supervisor:	
Gender:	--	Primary ICD-10:	--	Hand:	

ShiP-NP			
Form completed by:	*Patient/Other Name*	*Other realtionship*	*## hrs/week spent together*

Clinical Concerns

- **Bilingual in English and LANGUAGE**
- **Endorsed use of DRUG over the past two weeks**
- **Currently taking MEDICATION TYPE**
- **INFORMANT NAME holds conservatorship for this patient**
- **Prior neuropsychological evaluation completed on DATE**

Patient Questions: *Text*

Demographics

Place of Birth:	*MM/DD/YYYY*		Generational Status:	*Born in U.S./Born outside U.S./etc*		
Marital Status:	*Married/Single/Divorced*		Language Fluency:	*English*	*L2*	*L3*
Sex:	*Male/Female*		Age of Acquisition:	##	##	##
Handedness:	*Right/Left*		Education in L2:	--	*Formal edu completed*	
Ethnicity:	*(Not) Hispanic/Latino*	*Specifier if Y*	Proficiency:		##	
Race:	*Asian/Black/White/etc*	*Specifier if Y*				

Prior Neuropsychological Testing

Date:	*MM/DD/YYYY*	Provider:	*Name*	Location:	*Institution Name*

Educational History

Highest level completed:			College/Major:		Performance:
Grade Failures:	*Y/N*	*Grades failed, If Y*		*Reason*	
Special Services:	*Y/N*	*If Y, Type of service received*		*Grade/Age service received*	

Military History

Branch:	*Army/Navy/Marines/etc.*	Rank:	*X-#*	Discharge:	*Honorable/Dishonorable*
Physical Injury:	*Y/N*	*If Y, description*			
Substance Exposure:	*Y/N*	*If Y, description*			

Medical History

Medical Conditions:

Self-Report		
Neuro-QoL CATs, v1.0	T	%
Cognition		
Emotional and Behavioral Dyscontrol		
Fatigue		
Lower Extremeity Function - Mobility		
Upper Extremeity Function - Fine Motor		
Sleep Disturbance		
Stigma		
Satisfaction with Social Roles & Activites		

WHODAS 2.0	Simple Score	IRT-Based %
Overall Score		
Understanding & Communicating		
Getting Around		
Self-Care		
Getting Along With People		
Life Activities		
Participation in Society		
Satisfaction with Social Roles & Activites		

DSM Cross-Cutting Symptom Measures

Level 1	Raw Score	Rating
Depression		
Anger		
Mania		
Anxiety		
Somatic Symptoms		
Suicidal Ideation		
Psychosis		
Sleep Problems		
Memory		
Repetitive Thoughts & Behaviors		
Dissociation		
Personaltiy Function		
Substance Use		

Level 2 (*if applicable)	Raw Score	T	Rating
Depression			

Notes: Populated variables indicated in red; Templated text indicated in black and conditionally appears based on endorsement of relevant variables (e.g., Epilepsy template appears only if Epilepsy Hx is endorsed).
**** indicates items to be edited by provider (i.e., as in smart-phrasing)*

ShiP-NP Clinical Output Report

Report prepared for: [RequestorName] **Pt GUID:** ##### **DOT:** ##/##/####

CLINICAL NOTES:
Any flagged items endorsed here

- Patient is fluent in English and [LANGUAGE]
- Patient endorsed use of [DRUG TYPE] for [FREQUENCY] over the past two weeks.
- Patient is currently taking [MEDICATION TYPE] , a medication that may impact cognitive function.
- Patient reportedly completed prior neuropsychological testing on ##/#### by [PROVIDER] at [LOCATION].

Name: [FIRST NAME] [LAST NAME]
MRN: ***
DOB: ##/##/####
Age: ##
Referral Source: ***
Providers: [RequestorName]

Referral Diagnosis: ***
ICD-10 Code: ***

Dates of Service:
*** *96116, Neurobehavioral status exam with psychologist, first hour*
*** *96138, Neuropsychological testing with technician, first 30 min*
*** *96139, Neuropsychological testing and scoring with technician, additional 30 min*
*** *96132, Professional integration of patient data, first hour*
*** *96133, Professional integration of patient data, additional 30 min*

Reason for Referral:
[TITLE] [LAST NAME] is a [AGE]-year-old, [HANDEDNESS]-handed, [RACE], [SEX] with a medical history of [ALL ENDORSED MEDICAL CONDITIONS]. [PRONOUN-SHE/HE] was referred for neuropsychological testing by ***, for assessment of [PRONOUN-HIS/HER] cognitive and emotional functioning and to assist with treatment planning.

ShiP-NP Clinician Output Report

Report prepared for: Jane Doe, Ph.D. **PtID: 12345** **DOT: 04/24/2019**

CLINICAL NOTES:

- Patient is fluent in English and French.
- Patient endorsed use of Marijuana for several days over the past two weeks.
- Patient reportedly completed prior neuropsychological testing on 09/2010 by Dr. Smith at Cedar's Sinai Hospital.

Name: Jane Doe
MRN: ***
DOB: 01/01/1989
Age: 30
Referral Source: ***
Providers: Jane Doe, Ph.D.

Referral Diagnosis: ***
ICD-10 Code: ***

Dates of Service:

*** *96116, Neurobehavioral status exam with psychologist, first hour*
*** *96138, Neuropsychological testing with technician, first 30 min*
*** *96139, Neuropsychological testing and scoring with technician, additional 30 min*
*** *96132, Professional integration of patient data, first hour*
*** *96133, Professional integration of patient data, additional 30 min*

Reason for Referral:

Ms. Doe is a 30-year-old, right-handed, White, female with a medical history of epilepsy, head injury, diabetes, high blood pressure. She was referred for neuropsychological testing by *** for assessment of her cognitive and emotional functioning and to assist with treatment planning.

Note: The following information was obtained during an interview with Ms. Doe and from a review of available medical records. The patient was informed of the nature and purpose of the clinical evaluation, the status of the examiner (***), and limits of confidentiality prior to the clinical interview and administration of neuropsychological tests.

History of Present Illness:

Ms. Doe reported a history of epilepsy, diagnosed in 2004. She reportedly experienced her first seizure at age 9. She denied history of febrile seizures. Her current seizure semiology is reported as follows:

1) Aura/Warning: No
   Semiology: "Unresponsive with blank stare"
   Length of seizure: 5 seconds
   Post-ictal recovery: 0 minutes

Research applications

Data are deidentified using GUID and aggregated for future analysis

- Local clinical data can be used for program evaluation/clinic outcomes
- Exported to central repository (i.e., NDA) for future analyses

Additional deliverables:

- Data dictionary, “User’s manual” for implementation, IRB/Compliance templates, Patient forms and instructions, Clinical output resources

Summary

Establishing a set of CDEs for NP is necessary to propel efforts towards a more precise neuropsychology

- Formulate shared clinical protocols
- Generate comparable data points across sites

Ship-NP provides a proposed set of empirically-grounded CDEs with transdiagnostic relevance for a range of NP syndromes

Clinically: Long-term outcomes may result in lower costs of NP assessment and increased access for patients

Empirically: Long-term outcomes may allow for large-scale data analyses that could yield clearer understanding of individual and cultural differences in NP presentations, complex interactions of neurocognitive dysfunction with psychopathology and daily functional abilities

Future directions

Development/refinement based on user recommendations

Open-sourcing and integration with EMRs

Additional CDEs

- BOAT

Translation and expansion

- Other languages
- Ex-US development
- Pediatric version

Thank you!

lcavanagh@mednet.ucla.edu

https://www.sistat.ucla.edu/NNNWeb/index.html