



National Institute
of Nursing Research

BIOMARKERS AS COMMON DATA ELEMENTS FOR SELF-MANAGEMENT AND SYMPTOM SCIENCE RESEARCH



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Purpose of this Webinar

- **Define** common data elements (CDE)
- **Describe** ongoing initiatives at NIH regarding the development of CDEs
- **Review** NINR's efforts and processes in developing Biomarker CDEs for self-management and symptom science research
- **Discuss** and obtain feedback on proposed biomarkers as CDEs



Common Data Elements

A data element that is common to multiple data sets across different studies

- Universal
- Domain-specific
- Required
- Core



Benefits of CDEs

- Accelerate study start-up
 - Easily accessible tools
 - Encourage focused, simplified data collection
- Improve data quality
- Facilitate data sharing and aggregation
 - Standard definitions, common forms
- Facilitate specifications for common report templates (e.g., DSMBs)
- Encourage common measures



Examples of Current NIH CDE Initiatives

Name	Acronym	Brief Summary	Subject Area	Resource Contact
National Ophthalmic Disease Genotyping Network	eyeGENE	eyeGENE – CDEs have been developed for collecting phenotypic data associated with > 30 inherited ophthalmic diseases (https://eyegene.nih.gov/)	Ophthalmology	NEI
QOL in Outcomes in Neurological Disorders	NeuroQOL	A core set of quality of life questions that address chronic neurological disorders (http://www.healthmeasures.net/)	Neurological Disorders	NINDS
Common Data Element (CDE) Resource Portal	CDE Resource Portal	This portal provides access to information about NIH-supported CDEs, as well as tools and resources to assist investigators developing protocols for data collection. (https://www.nlm.nih.gov/cde/)	Cognitive, emotion, motor, sensory function	NLM
NINDS Common Data Elements	NINDS CDEs	A core set of data elements for use in NINDS-funded studies, including core and supplementary sets of CDEs for use in disease-specific studies (https://www.commondataelements.ninds.nih.gov)	Neurological disorders	NINDS
Consensus Measures for Phenotypes and eXposures	PhenX	Standard measures related to complex diseases, phenotypic traits and environmental exposures for inclusion in genome-wide association studies (https://www.phenxtoolkit.org/)	Genome-wide association studies	NHGRI
Patient Reported Outcomes Measurement Information System	PROMIS	A system of item banks measuring patient-reported health status for various domains of physical, mental, and social health across clinical populations (www.nihpromis.com/)	Physical, mental, and social health	NIAMS
Common Data Repository for Nursing Science	cdRNS	The NINR, is a leading supporter of clinical studies in symptom and self-management research. To harmonize data, NINR is spearheading an effort to develop CDEs in nursing science. (https://ninr-public-prod.cit.nih.gov/)	Symptom and Self Management Science	NINR

History of CDEs at NINR

- 5 Symptom Science Centers funded in 2012
- 2014 Meeting with Center PIs, defined CDEs for Symptom Science
 - Symptoms – Pain, Sleep, Fatigue, Cognition, Affect
 - CDEs presented at Regional Conferences
 - Paper Published, 2015 JNS
- 2015 Meeting with Center PIs, defined CDEs for Self-Management
 - CDEs presented at Regional Conferences
 - Paper Published, 2016, JNS
- 2016 Center Meeting focused on Biomarker
 - 2017 Paper in Review



NINR CDEs for Symptom Science

Topic	CDE
Pain	PROMIS-pain
Fatigue	PROMIS-fatigue
Sleep disturbance	PROMIS +additional duration question
<i>Affective-mood</i>	PROMIS Positive Affect & PROMIS Depression
<i>Affective-anxiety</i>	PROMIS Anxiety
<i>Affective-well being</i>	Psychological well-being scale SF-36
Cognitive	PROMIS applied cognition and general concerns
Demographics	Ethnicity, Race, Educational level, Date of birth, Gender



NINR CDEs for Self-Management Science

Topic	CDE
Activation	Patient Activation Measure® (Hibbard)
Self-regulation	Index of Self-Regulation (Yeom)
Self-efficacy for Managing Chronic Conditions	Self-efficacy for Managing Chronic Disease (Lorig)
Global Health	PROMIS SF v1.1 - Global



Process for Selection of Biomarkers for CDEs

- Conceptual definitions of constructs were decided
- Strengths and weaknesses of each biomarker proposed were discussed including whether the biomarker chosen would resonate across both symptom and self-management science
- Minimum set proposed



Considerations for Selection

- Burden on subjects
- Cost of collection, storage and assay
- Feasibility of collection, storage and assay
- Level of of data/dimensions captured
- Appropriate for use across different populations and cultures



Recommended Biomarker CDEs

Biomarker	Recommended Sample Source	Recommended Assay Type/Technique
Cytokines <ul style="list-style-type: none"> • Interleukin-1beta (IL-1b) • Interleukin-6 (IL-6) • Interleukin-10 (IL-10) 	Plasma, serum, or White Blood Cell supernatant	Enzyme Linked Immunosorbent Assay (individual assay kits or multiplex array)
HPA Axis Markers <ul style="list-style-type: none"> • Free Cortisol 	Saliva, collected at a specified time of day for all participants, or three or more times at day for one or more days to determine cortisol area under the curve (AUC)	Enzyme Linked Immunosorbent Assay
Neuropeptides <ul style="list-style-type: none"> • Brain-derived Neurotrophic Factor (BDNF) 	BDNF may be measured in plasma, serum or white blood cells isolated from serum	mRNA: quantitative polymerase chain reaction (qPCR) Protein: Enzyme Linked Immunosorbent Assay
Genetics <ul style="list-style-type: none"> • Single Nucleotide Polymorphisms 	Plasma, serum, saliva, or white blood cells isolated from serum	DNA: either whole genome or exome sequencing or candidate genotyping via Taqman or other assays

Comments and Questions

Biomarker

Cytokines

- Interleukin-1beta (IL-1b)
- Interleukin-6 (IL-6)
- Interleukin-10 (IL-10)

HPA Axis Markers

- Free Cortisol

Neuropeptides

- Brain-derived Neurotrophic Factor (BDNF)

Genetics

- Single Nucleotide Polymorphisms

- Are we missing any key areas for the development of biomarkers for self management and symptom science?
- What other areas do you see a fit for CDE's?
- What methods can we use for *communicating* use of CDEs?
- How might we best facilitate collaborations for use of CDEs?



Send your Comments or Suggestions

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