

Supplement
Gulf War Illness (GWI) Common Data Elements Project
Summary Recommendations

The GWI Common Data Elements (CDE) Working Group members developed common definitions, terminology, and standardized data sets tailored to GWI research. This document represents the progress accomplished to date in developing the initial version of a resource that will standardize the collection of GWI research data.

As assessment tools are validated in GWI research, the instruments, case report forms, laboratory measures, and guidelines will be updated in the list of CDEs. Recognizing that extensive data collection in research presents a significant burden for investigators and study participants, the data elements in each domain are designated with the terms Core, Supplemental-Highly Recommended, Supplemental, or Exploratory.

The GWI CDEs are listed in the following domains and areas:

Symptoms Assessment

Baseline/Covariate
Fatigue
Post-Exertional Malaise
Sleep
Pain
Quality of Life
Functional Status/Activity
Exercise Challenge Studies

Systems Assessment

Neurological
Neuropsychological
Neuroimaging
Autonomic
Endocrine/Neuroendocrine
Immune
Biomarkers

Deployment Exposures and GWI Risk Factors

Additional descriptions of the GWI Common Data Elements are listed under the Gulf War Illness Research Program on the DoD CDMRP website:

https://cdmrp.army.mil/gwirp/pdfs/GWI%20CDE%20Draft%20Version%201_0.pdf

Many of the instruments listed on the tables can be found on the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH) Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) CDE website:

<https://www.commondataelements.ninds.nih.gov/Myalgic%20Encephalomyelitis/Chronic%20Fatigue%20Syndrome>

**Department of Veteran Affairs / Department of Defense
 Congressionally Directed Medical Research Programs
 Gulf War Illness Common Data Elements (CDE)
 Summary Recommendations**

GW I Common Data Elements: Baseline/Covariate

Instrument Name	Classification Core, Supplemental---Highly Recommended, Supplemental, or Exploratory
General Core	Supplemental—Highly Recommended
Demographic Information for Baseline GWI	Supplemental—Highly Recommended
Adult Employment and Education History	Supplemental—Highly Recommended
Past and Current Illnesses	Supplemental—Highly Recommended
Family Health History	Supplemental—Highly Recommended
Questions from DePaul Symptom Questionnaire	Supplemental—Highly Recommended
Symptom Checklist	Supplemental—Highly Recommended
Physical Examination Form	Supplemental—Highly Recommended
Laboratory Test Results	Supplemental—Highly Recommended
Medication/Other Treatments	Supplemental—Highly Recommended
Kansas Case Definition of GWI	Core
CDC Case Definition of GWI	Core

Source: VA/DoD GWI Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements: Post-Exertional Malaise Table 1.

Instrument Name	Classification
DePaul Symptom Questionnaire 5-item Post Exertional Malaise sub-scale	Supplemental

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements: Post-Exertional Malaise Table 2.

Instrument Name	Classification
Study baseline Type of exertional stimulus (e.g., physical exercise, cognitive, emotional, orthostatic) and detailed methodological description of steps that were taken to keep the stimulus as standardized as possible across study participants.	Supplemental— Highly Recommended
Study baseline 5-item post-exertion malaise sub-scale of the DePaul Symptom Questionnaire.	Supplemental
Study baseline Physical activity behavior of participants via self-report or accelerometry (especially when physical exercise is used as the exertional stimulus).	Supplemental
Study baseline Characterization of chronic symptoms using the questionnaires receiving the highest recommendation from each symptom module (e.g., fatigue, pain sleep, quality of life, etc.).	Supplemental
Study baseline Characterization of health using the measures receiving the highest recommendation from each system module (e.g., neuroimaging, autonomic, immune).	Supplemental
Prior to and following the exertional stimulus Administration of questionnaire(s) with instructions and item phrasing that are designed to capture immediate (e.g., immediately before and after the exertional stimulus) and/or day-to-day changes (i.e., before and 24hr, 48hr, 72hr, etc. after the exertional stimulus), but that are also representative of GWJ symptoms. For instance, the Profile of Mood States is a good example because it uses instructional language that is appropriate for capturing immediate and day-to-day changes (e.g., circle the number that best describes how you feel RIGHT NOW?), but also provides data on a symptom that is representative of GWJ (i.e., mood disturbance).	Supplemental
Prior to and following the exertional stimulus Functional measures of physiology (e.g., central nervous system, autonomic, immune) and behavior (e.g., physical activity, cognitive performance, pain sensitivity) that may be correlated with symptom changes.	Supplemental

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWI Common Data Elements: Fatigue

Instrument Name	Classification
Fatigue Severity Scale	Supplemental
Checklist of Individual Strength – Fatigue (CIS)	Supplemental
Multidimensional Fatigue Inventory (MFI)	Supplemental—Highly Recommended
PROMIS Fatigue Short Form	Supplemental
Quality of Life in Neurological Disorders (Neuro QoL)	Supplemental
Modified Fatigue Impact Scale	Supplemental
POMS Fatigue	Supplemental

Source: VA/DoD GWI Common Data Elements Version 1.0, 3/2019

GWI Common Data Elements: Sleep

Instrument Name	Classification
Sleep Questions for All Studies---Case Report Form	Exploratory
Sleep Assessment Questionnaire-Moldofsky	Exploratory
Pittsburgh Sleep Quality Index	Supplemental—Highly recommended
Stanford Sleepiness Scale	Exploratory
Sleep Disorders Screening Checklist	Exploratory
Holland Sleep Disorders Questionnaire	Exploratory
Epworth Sleepiness Scale	Supplemental—Highly recommended
Nonrestorative Sleep Scale	Exploratory
Global Sleep Assessment Questionnaire	Exploratory
Restorative Sleep Questionnaire	Exploratory

Source: VA/DoD GWI Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements: Pain

Instrument Name	Classification
Brief Pain Inventory (BPI)	Supplemental
Fibromyalgia Impact Questionnaire - revised	Exploratory
McGill Pain Questionnaire Short Form version2	Supplemental—Highly recommended
Faces Pain Scale - revised	Exploratory
Pain Frequency - Severity - Duration	Exploratory
Neuropathic Pain Symptom Inventory	Exploratory
PROMIS Pain Behavior Short Form	Exploratory
PROMIS Pain Interference Short Form	Exploratory
Visual Analog Scale	Supplemental
Widespread Pain Index (ACR)	Supplemental

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements: Quality of Life

Instrument Name	Classification
Short-Form 36 item Veteran Health Survey (VR-36) Physical Component Summary (PCS) Score Mental Component Summary (MCS) Score	Core
Short-Form 12 item Veteran Health Survey (VR-12)	Supplemental
Short-Form 8 item Veteran Health Survey (VR-8)	Supplemental
NIH Neuro-QoL (PROMIS)	Exploratory
World Health Organization Well-Being Index (5)	Exploratory
World Health Organization Well-Being Index (10)	Exploratory
EuroQoL	Exploratory
Health Related Quality of Life (HRQoL)	Exploratory

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements: Functional Status

Instrument Name	Classification
Karnofsky Scale	Supplemental—Highly Recommended
World Health Organization Disability Assessment Schedule (WHODAS)	Exploratory
Short-Form 36 item Veteran Health Survey (VR-36) or Short-Form 36 item Health Survey (SF-36) Physical Component Summary (PCS) Score Mental Component Summary (MCS) Score	Core
Bell CFIDS Disability Scale	Supplemental—Highly Recommended

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements: Exercise Challenge Studies

(Formerly Cardiopulmonary Exercise Testing (CPET))

Instrument Name	Classification
GWJ Exercise Challenge Studies Prior to instrumentation and testing Exercise pre-participation health screening, including assessment of physical activity behavior via questionnaire, accelerometry or both.	Supplemental—Highly recommended
Participant height, body weight, and age	
24 hour recall of drug or supplement use	
Whether or not participant arrived at the laboratory in a fasted state	
Atmospheric conditions in the testing environment (i.e., barometric pressure, mmHg, humidity, %, and temperature, C°)	
Heart rate and blood pressure	
Gulf War Illness symptom severity questionnaires	
During testing Oxygen consumption, carbon dioxide production, ventilation via indirect calorimetry (resting and during exercise)	Supplemental—Highly recommended
Heart rate	
Rating of perceived exertion (6-20 scale)	
Blood pressure	
Exercise intensity (% of estimated maximum)	
Workload (rpm and watts for cycling studies, speed/% grade for Treadmill studies)	
Immediately after testing Reason why exercise was stopped by participant (e.g., target testing duration complete, breathlessness, muscle pain, fatigue, other) or test administrator (e.g., contraindications to exercise)	Supplemental—Recommended
Blood lactate	
Prior to instrumentation and testing Participant expectations for effects of exercise on psychological and physical health outcomes	Supplemental—Recommended
Muscle pain in exercising muscles	
Blood lactate (resting and during exercise)	
Collection of physiological and perceptual measures during active recovery/cool down	

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements: Neurological

Instrument Name	Classification
Neurological—Case Report Form (CRF)	Supplemental—Highly recommended

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements: Neuropsychological

Instrument Name	Classification
Word Reading Subtest of the Wide Range Achievement Test (WRAT-4)	Supplemental—Highly recommended
Continuous Performance Test -3 (CPT3)	Supplemental—Highly recommended
Wechsler Adult Intelligence Scale-IV (WAIS-IV) Recommended tests: Digit Spans, Block Design	Supplemental—Highly recommended
Profile of Mood States (POMS)	Supplemental—Highly recommended
Davidson Trauma Scale (DTS) - PTSD	Supplemental—Highly recommended
Delis-Kaplan Executive Function System (D-KEFS) Recommended modules: Color-Word-Interference Test, Trail Making Test, Verbal Fluency	Supplemental—Highly recommended
California Verbal Learning Test - Second Edition (CVLT-II)	Supplemental—Highly recommended
Rey-Osterrieth Complex Figure Test (ROCF)	Supplemental—Highly recommended
Finger Tap Test	Supplemental
Grooved Pegboard Test	Supplemental
Hopkins Verbal Learning Test (HVLT)	Supplemental
Brief Visual Memory Test (BVMT)	Supplemental
PTSD Checklist for DSM-V (PCL-5)	Supplemental
Center for Epidemiological Studies Depression Scale (CES-D)	Supplemental
Clinician Administered PTSD Scale (CAPS-5)	Supplemental
Structured Clinical Interview for DSM-V (SCID-5)	Supplemental

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements: Neuroimaging

Instrument Name	Classification
Diffusion Tensor Imaging (DTI)	Supplemental—Highly recommended
Electroencephalography (EEG)	Supplemental—Highly recommended
Functional Magnetic Resonance Imaging (fMRI)	Supplemental—Highly recommended
Low-resolution Electromagnetic Tomography (LORETA)	Supplemental—Highly recommended
Magnetic Resonance Spectroscopy (MRS)	Supplemental—Highly recommended
Magnetoencephalography (MEG)	Supplemental—Highly recommended
Positron Emission Tomography (PET)	Supplemental—Highly recommended
Quantitative Electroencephalography	Supplemental—Highly recommended

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements Module: Autonomic

Instrument Name	Classification
Compass - 31	Supplemental—Highly recommended
Modified Orthostatic Symptom Grading Scale— Case Report Form	Exploratory
Passive Standing Test—Case Report Form	Exploratory
Heart Rate Variability	Exploratory
Tilt Table Test	Exploratory
Romberg Test	Exploratory
Sudomotor Test	Exploratory
Pupilometry Test	Exploratory

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements: Endocrine/Neuroendocrine

Instrument Name	Classification
Neuroendocrine Labs Cortisol Diabetes Thyroid Sex Hormones Other Endocrine	Supplemental—Highly recommended
Neuroendocrine/Hypothalamic Symptoms	Supplemental—Highly recommended
Reproductive and Hormonal History	Supplemental—Highly recommended
ASA Dietary Survey	Supplemental
Dietary Supplements	Supplemental

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements: Immune

Instrument Name	Classification
Medical History—Case Report Form	Supplemental—Highly Recommended
Immune System Onset Type	Supplemental—Highly Recommended
Rome IBS Criteria	Supplemental
Physical Examination—Case Report Form	Supplemental—Highly Recommended
Laboratory Tests—Case Report Form	Supplemental—Highly Recommended
NK Cell Assay Test	Supplemental

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements Module: Biomarkers

Instrument Name	Classification
OMICS: Microbiome/ Microorganisms Proteome/ Proteins Metabolome/ Metabolism Genome/ Epigenome Gene expression/ Transcriptome miRNA profiling Multiplex vs. SRM assays Bioinformatics Pathways Interconnect Omic data	Exploratory
NON-OMICS: Protein array analysis Cytokine measurements Chemokine measurements Flow-cytometry measurements of immune cells Autoantibody analyses Individual protein quantification Biomarkers of autonomic system dysfunction Blood chemistry Elements from detoxification pathways Exosomes	Exploratory
Biomarker Guidelines	Supplemental—Highly recommended
Biomarkers- Related Sample and Medication Questions	Supplemental—Highly recommended
Biomarker Reference Table	Supplemental—Highly recommended

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019

GWJ Common Data Elements: Deployment Exposures and GWJ Risk Factors

Instrument Name	Classification
Deployment Exposures and GWJ Risk Factors Questionnaire	Supplemental—Highly recommended

Source: VA/DoD GWJ Common Data Elements Version 1.0, 3/2019