Common Data Elements in the Assessment of Military-Related PTSD Research Applied in the Consortium to Alleviate PTSD

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ABSTRACT Introduction: Driven by the need to share data, sufficiently power studies, and allow for cross-study comparisons of medical and psychiatric diseases, the President's National Research Action Plan issued in 2013 called for the use of state-of-the-art *common data elements* (CDEs) for research studies. CDEs are variables measured across independent studies that facilitate methodologically sound data aggregation and study replication. Researchers in the field of military-related post-traumatic stress disorder (PTSD) have suggested applicable CDEs; however, to date, these recommendations have been conceptual and not field-tested. The Consortium to Alleviate PTSD (CAP) – an interdisciplinary and multi-institutional, military-related PTSD research consortium funded by the Departments of Defense and Veterans Affairs – generated and applied CDEs that can be used to combine data from disparate studies to improve the methodological and statistical capabilities of study findings. We provide a description and rationale for the CAP CDEs and details about administration with two main goals: (1) to encourage military-related PTSD researchers to use these measures in future studies and (2) to facilitate comparison, replication, and data aggregation. Materials and Methods: The CAP compiled mandated (core) and optional CDEs based on the following criteria: (1) construct applicability to military-related PTSD; (2) precedence (use) in prior, related research; (3) published and strong psychometric evidence; (4) no cost (public domain); and (5) brevity, to limit participant burden. We provided descriptive statistics and internal consistency reliabilities for mandated measures from an initial cohort of around 400 participants enrolled in CAP studies. Results: Mandated CDEs in the CAP were found to have very good internal consistency reliability. Conclusion: Although further research is needed to determine the incremental validity of these CDEs, preliminary analyses indicated that each mandated measure has very good internal consistency reliability. Investigators designing military-related PTSD research should consider using these field-tested CDEs to facilitate future data aggregation. Feedback based on empirical evidence or practical concerns to improve these CDEs is welcome.

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INTRODUCTION

The National Institutes of Health (https://www.nlm.nih.gov/cde/) recommend the use of *common data elements* (CDEs) to standardize, integrate and share data from federally funded clinical trials and epidemiological studies. A CDE is "a combination of a precisely defined question (variable) paired with a specified set of responses to the question that is common to multiple datasets or used across different studies."[1] CDEs promote interoperability between different data collection systems and facilitate valid meta-analyses. CDEs also create uniform data collection procedures, which improve the efficiency and quality of data collection and analysis.[1]

Post-traumatic stress disorder (PTSD) researchers, particularly those who study military and veteran populations, have sought to identify CDEs to maximize consistency in instrumentation across studies. A working group comprised of content experts from the Department of Veterans Affairs (VA), the Department of Defense (DoD), and the National Institute of Mental Health (NIMH) generated a consensus-based list of CDEs for eight PTSD-related constructs and domains, including: (1) demographics; (2) exposure to stressors and traumatic events, including lifetime exposures; (3) potential stress moderators; (4) PTSD screening; (5) PTSD symptoms and diagnosis; (6) PTSD-related functioning and disability; and (7) mental health history.[2] A second working group of VA and DoD content experts generated a list of CDEs for military operational stress research, which included indicators of dysfunction, resilience, and growth, as well as subthreshold and diagnosable psychopathology.[3] The recommendations of these two consensus panels provided a foundation on which military stress and trauma research could build.

A National Research Action Plan jointly issued by the Departments of Defense, Veterans Affairs, Health and Human Services, and Education in 2013 directed federal agencies to develop a coordinated plan to improve the prevention, diagnosis, and treatment of mental health conditions affecting post-9/11 military service members, veterans, and their families.[4] The Consortium to Alleviate PTSD (CAP), which was established in 2013 as an interdisciplinary and multi-institutional, military-related PTSD research consortium jointly funded by the VA and DoD, provided an optimal context to apply CDEs. The CAP is comprised of randomized clinical trials, biomarkers studies, and epidemiological studies on trauma, PTSD, and related problems for service members, veterans, and their families. The CAP established centralized research cores to plan and oversee studies to maintain uniformity in assessments, namely a Coordinating Center and an Assessment Core. Each study funded by the CAP follows uniform best practices for clinical trials design, human subjects' protection, data security, storage, archival access, and data analysis guidelines established by the Coordinating Center and Cores. The CAP Assessment Core, working with individual study investigators, generated a set of CDEs using the working groups' suggestions and our experience generating and fielding an initial set of CDEs to ensure the comparability of metadata for the South Texas Research Organizational Network Guiding Studies on Trauma and Resilience, also known as the STRONG STAR Consortium. The constructs and domains addressed were: (1) primary and secondary PTSD endpoints; (2) lifespan and warzone exposure to potentially traumatizing events; (3) depression symptom severity; (4) anxiety depression severity; (5) alcohol use; (6) nicotine use; (7) sleep; (8) head injury; (9) suicidal ideation and parasuicidal behaviors; and (10) functional impairment. In this paper, we describe the mental and behavioral health CDEs used in the CAP and the procedures used to administer and sequence measures to provide researchers with field-tested guidelines. Creating and field testing biomarker CDEs are no less important[5]; however, a description of the biological CDEs we have generated for the CAP is beyond the scope of this paper. We also provide descriptive information (means, *SD*, percentages) and the internal consistency reliabilities for the main CDEs, based on available CAP study participants (see Tables 1 and 2). These results are provided as a basis of comparison and to provide information about the reliability of key CDEs in active duty and veteran research participants.

The following criteria guided the selection of CDEs for the CAP: (1) construct and content applicability to military-related PTSD; (2) precedence (use) in prior, related research; (3) published psychometric evidence; (4) no cost (available in the public domain); and (5) brevity, to limit participant burden. To further reduce the burden on participants, we generated a tiered system of CDEs for CAP studies. One set of core measures was mandated in all studies and the second set was optional. The latter entailed a menu of specific measures that were nonetheless required if a study was testing or exploring a specific additional domain.

The descriptive statistics and internal consistency reliability findings were calculated from an initial group of around 400 CAP study participants assessed at baseline prior to enrolling in one of seven studies. More information about CAP studies can be found on the CAP website, www.ConsortiumToAlleviatePTSD.org, and all clinical trials are registered at ClinicalTrials.gov. Each of the studies underwent Institutional Review Board (IRB) reviews as well as review and approval by the U.S. Army Medical Research and Materiel Command Human Research Protection Office, (USAMRMC HRPO).

The mandated core measures described below are grouped in order of administration. Table 1 consists of self-report scales administered by study staff prior to an interview with an independent evaluator. Table 2 includes CDEs administered by independent evaluators that assess exposure to potentially traumatizing events, culminating in the determination of the Criterion-A event used to assess PTSD symptoms according to the fifth edition of the

TABLE I. Core CDEs with Brief Administration Details and Descriptive Statistics for an Initial Consortium to Alleviate PT Cohort[a]

Measure	Domain	Time to Complete (Minutes)	Included in PhenX Toolkit	Descriptive Statistics from CAP
Demographics and Military Service Characteristics Form	Demographic Information	5	Yes	**Age** (n = 400); M = 38.6 (SD = 7.9) **Military status** (n = 412); active duty (59%); veterans (19%); retired (17%); other (5%) **Ethnicity** (n = 412); Hispanic (26%) **Race** (n = 412); Caucasian (56%), African American (28%), other (10%), Native American (2%), Pacific Islander (2%), Asian (1%)
History of head injuries (modified DVBIC)	Brain injury	5–10	No	**Number of head injuries**: **While deployed** (n = 414), M = 2.0 (SD = 3.7) **While not deployed** (n = 416), M = 1.2 (SD = 4.6)
DRRI-2 Combat Experiences Subscale	PTE exposure during active combat	5	Yes	n = 406, M = 42.6 (SD = 17.0) range: 17–94 Cronbach's alpha = 0.93
DRRI-2 C Postbattle Experiences Subscale	PTE exposure to aftermath of combat	5	Yes	n = 408, M = 39.0 (SD = 15.0) range: 13–78 Cronbach's alpha = 0.93
Life Events Checklist for *DSM-5*	Criterion A	5	Yes	Conservative Lifetime Trauma Exposure Index (sum of "happened to me," and "witnessed it" items) n = 401, M = 11.0 (SD = 5.2), range: 0–26
Patient Health Questionnaire-9	Depression (suicidality)	2	No	n = 412, M = 16.6 (SD = 5.5), range: 0–27 Cronbach's alpha = 0.84
Depressive Symptoms Index – Suicidality Subscale	Suicidal Ideation	<1	No	n = 411, M = 1.1 (SD = 1.8), range: 0–9 Cronbach's alpha = 0.88
Generalized Anxiety Disorder Screener	Generalized anxiety	2	No	n = 404, M = 15.2 (SD = 4.9), range: 0–21 Cronbach's alpha = 0.89
Alcohol Use Disorders Identification Test self-report version	Alcohol use	5	Yes	n = 409, M = 4.4 (SD = 5.7), range: 0–40 Cronbach's alpha = 0.88
Quick Drinking Screen self-report version	Alcohol use	1	No	n = 409 **Drinking days per week** M = 1.3 (SD = 1.7), range: 0–7 **Number of drinks** M = 2.2 (SD = 3.9), range: 0–48 **Times of five or more drinks** M = 0.6 (SD = 1.7), range: 0–14 **Greatest number of drinks in one day**M = 2.3 (SD = 3.9), range: 0–48
Fagerström Test for Nicotine Dependence	Tobacco use	1	Yes	n = 82, M = 3.1 (SD = 2.9) range: 0–18
Fagerström Test for Nicotine Dependence-Smokeless Tobacco	Tobacco use	1	No	n = 50, M = 2.8 (SD = 2.2) range: 0–8
Veterans RAND 12-Item Short Form Health Survey	Health symptoms/ impairment	2	Yes, 36-Item Form	n = 401 **Physical component summary** M = 38.1 (SD = 11.6), range: 13.7–61.0 **Mental component summary** M = 28.9 (SD = 11.5), range: 1.0–60.1
Brief Inventory of Psychosocial Functioning	Interpersonal/ occupational functioning	1	No	n = 404, M = 26.5 (SD = 10.0) Range: 0–49 Cronbach's alpha = 0.81
Insomnia Severity Index	Sleep problems	2	Yes	n = 394, M = 19.3 (SD = 6.0), Range: 0 – 28 Cronbach's alpha = 0.89
PROMIS Sleep Disturbance and Sleep-Related Impairment short forms	Sleep problems	2	No	n = 401 (t-scores) **Sleep Disturbance** M = 32.3 (SD = 5.6), range: 8–40 Cronbach's' alpha = 0.88 **Sleep-related impairment** M = 28.1 (SD = 6.9), range: 8–40 Cronbach's' alpha = 0.90
STOP Sleep Apnea Screening Questionnaire	Sleep apnea	<1	No	n = 331, M = 2.4 (SD = 1.1), range: 0–4

Self-report scales administered prior to interview with an independent evaluator. PTE, potentially traumatic event.
[a]Measures are listed in recommended temporal order.

TABLE II. Core CDEs with Brief Administration Details and Descriptive Statistics for an Initial Consortium to Alleviate PTSD Cohort[a]

Measure	Domain	Time to Complete (Minutes)	Included in PhenX Toolkit	Descriptive Statistics from CAP
CAPS-5	PTSD Severity/Diagnosis	45–60	Yes	n = 391 M = 36.8 (SD = 10.1), range: 0–66 Cronbach's alpha = 0.83
Self-Injurious Thoughts and Behaviors Interview	History of suicidal/non-suicidal self-injury	1–20	Yes	**Proportion of "yes" responses to each category's gate question** n = 353 Suicidal ideation, 56% Suicide plan, 26% Suicide gesture, 5% Suicide attempt, 31% Thoughts of non-suicidal self-injury, 9% Non-suicidal self-injury, 9%
PTSD Checklist for *DSM-5*[b]	PTSD Severity/Diagnosis	5	Yes	n = 397 M = 51.3 (SD = 14.0), range: 0–80 Cronbach's alpha = 0.92

Measures administered by independent evaluators.
[a]Measures are listed in recommended temporal order.
[b]The PTSD Checklist is a self-report measure that should be administered following the Independent Evaluator interview to ensure appropriate Criterion-A anchor has been selected.

Diagnostic and Statistical Manual of Mental Disorders (*DSM-5*).[6] In Tables 1 and 2, we provide descriptive statistics and internal consistency reliability findings of the measures. The optional CDEs are listed in Supplementary Table 1 along with some brief administration-related information.

CORE MANDATED CDES FOR THE CONSORTIUM TO ALLEVIATE PTSD

Pre-Interview Measures

Demographics and Military Service Characteristics Form

This form is used to gather demographic (race, gender, age) and military service information (e.g., military grade or rank).

History of Head Injuries

We used a modified version of the Defense and Veterans Brain Injury Center 3-Item Screening Tool (DVBIC 3)[7,8] to assess head injury. The form was modified to capture the number of injuries and index symptoms resulting from the worst injury, and capture ongoing symptoms following the head injury. We also added questions about head injuries sustained outside of deployment.

Deployment Risk and Resiliency Inventory-2 (DRRI-2) Combat Experiences Subscale and Postbattle Experiences Subscale

The DRRI-2[9] is a suite of 17 subscales that assess varied deployment-related risk and resilience variables. Scores on the DRRI-2 have demonstrated strong internal consistency reliability and criterion-related validity.[8] We used the *Combat Experiences* and *Postbattle Experiences* subscales to index exposure to potentially traumatic deployment experiences.

Life Events Checklist for *DSM-5* (LEC-5)

The LEC-5 assesses 16 potentially traumatic life events.[10] For the CAP, we added an additional write-in item and two questions about military sexual trauma. The psychometric properties of the LEC-5 have not been published, but the measure is nearly identical to the original LEC, which has demonstrated convergent validity and test-retest reliability.[11]

Patient Health Questionnaire-9 (PHQ-9)

The PHQ-9[12] is a widely used and well-validated instrument for measuring the severity of depressive symptoms. Scores on the PHQ-9 have demonstrated high internal consistency[13] and have been shown to correlate strongly with scores on other measures of depression.[14]

Depressive Symptom Index – Suicidality Subscale (DSI-SS)

The DSI-SS[15] was used to evaluate current suicidal ideation. The DSI-SS is a self-report measure of suicidal ideation that focuses on ideation, plans, perceived control over ideation, and impulses for suicide. A systematic review found that scores on the DSI-SS had evidence of excellent internal consistency and concurrent validity.[16]

Generalized Anxiety Disorder Screener (GAD-7)

The GAD-7[17] was used to assess anxiety symptoms. Scores on the GAD-7 have been shown to have high internal

consistency[18] and reliably discriminate between anxious and non-anxious diagnostic groups.[12]

Alcohol Use Disorders Identification Test (AUDIT) Self-Report Version

The AUDIT[19] was used to identify harmful patterns of alcohol consumption and to index the severity of these problems. The AUDIT is a screening measure with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems). Scores on the AUDIT have good internal consistency as well as sensitivity and specificity.[20,21] The AUDIT's time-frame is the last 12 months. Therefore, for trials without long-term follow-up, the AUDIT was administered only at baseline. For studies with long-term follow-up, the AUDIT was administered at baseline and final follow-up.

Quick Drinking Screen (QDS) Self-Report Version

The QDS[22] was used to measure alcohol consumption by probing frequency and quantity of alcohol consumption. The QDS has been validated against the Timeline Follow-back daily estimation index of alcohol use, and it shows good psychometric properties.[22,23] The QDS's time interval was modified (i.e., "last 2 weeks") to align with the measures of depression and anxiety (PHQ-9 and GAD-7).

Fagerström Test for Nicotine Dependence

The Fagerström[24] is a self-report measure that assesses severity of nicotine dependence. Questions probe both quantity of nicotine use and pattern of use (e.g., time to first cigarette in morning). The Fagerström scale has demonstrated test–retest reliability and convergent validity.[24,25]

Fagerström Test for Nicotine Dependence – Smokeless Tobacco (FTND-ST)

The FTND-ST is a modified version of the Fagerström Test that focuses on smokeless tobacco use. Scores on the FTND-ST have demonstrated convergent validity with biochemical indices of nicotine use.[26]

Veterans RAND 12-Item Short Form Health Survey (VR-12)

The VR-12 is an index of overall mental and physical health and the impact of health on functioning, developed from the longer VR-36.[27] Items are sampled from each of the eight health domains from the VR-36. Also, there are two summary scales: a physical component summary and a mental component summary. The VR-36 has been widely used, distributed, and documented in the Veterans Health Administration.

Brief Inventory of Psychosocial Functioning (B-IPF)

The B-IPF is a self-report instrument measuring respondents' level of functioning in seven life domains[28] over the past 30 days. The B-IPF has demonstrated concurrent validity, and the full 80-item IPF from which it was created has strong test–retest reliability and internal consistency.[28] The CAP assesses one item from each domain. This 7-item version has demonstrated strong internal consistency.[29]

Insomnia Severity Index (ISI)

The ISI[30] is a self-report measure that assesses perceived severity of insomnia. Scores on the ISI have demonstrated high internal consistency and convergent validity.[31]

Patient Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance and Sleep-Related Impairment Short Forms

The PROMIS *Sleep Disturbance and Sleep-Related Impairment* short forms[32] are self-report measures of past-week sleep disturbance and sleep-related impairment, derived from the larger PROMIS item banks.[33] Scores on each measure have shown strong reliability and construct validity.[32]

Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen

The STOP[34] was administered to screen for sleep apnea. The STOP was developed and validated in 211 pre-operative surgical patients. Individuals answering "yes" to two or more of the questions were advised that they may be at risk for having sleep apnea and to speak with their primary care provider.

Interview-Administered Measures

Health Questionnaire

For the CAP, we rationally generated a measure of medical and mental health care history and diagnoses, medical board and disability status, medications, and caffeine use. The version of the Health Questionnaire used at follow-ups also probed military status changes and any important new life events or changes since the time of the last assessment.

Selection of Index Event Interview

We developed an interview and set of procedures to guide service members and veterans to identify a Criterion-A index traumatic event among various potential lifespan and war-zone experiences. Participants identified the worst and most currently distressing event endorsed on each of the measures assessing potentially traumatic events (LEC-5, DRRI-2 Combat Experiences and Postbattle Experiences Scales). At the start of the interview, participants were reminded about these worst and most currently distressing events. They were then asked to identify and describe in greater detail the most distressing event among these three. If the event met the Criterion-A definition of a traumatic event, that event was used to index the Posttraumatic Stress Disorder Checklist for *DSM-5* (PCL-5, described below) and the Clinician Administered PTSD Scale for *DSM-5* (CAPS-5, described below). If the Criterion-A experience represented a series of events, the participant was asked questions to help him or

her choose a specific event (e.g., "Which experience gets in the way of your life the most?"). At the end of the interview, the interviewer wrote down a description of the Criterion-A event so that it could be typed according to the scheme developed by Stein et al[35] for future research purposes (see Litz et al[36]). Participants were asked the following question to further aid in subtyping the event for future research: *What were the worst parts of this event?* Response options included: *(1) you thought that you could be seriously injured or killed; (2) you thought that someone else could be seriously injured or killed; (3) the sights, sounds, and smells of the event (e.g., seeing dead bodies); (4) a friend or unit member was killed; (5) you acted in ways that violated your own moral code or values;* and (6) *someone else acted in ways that violated your own moral code or values.*

For future research purposes, we also asked participants to provide feedback about the process of narrowing down their lifespan and warzone experiences to a single event. The questions asked were as follows: (1) *How hard was it to try to narrow down to a single event what is the worst and most currently distressing?* (0 = *Not hard at all* to 10 = *Extremely difficult*); and (2) *about how many different events could have been selected as the worst and most currently distressing?*

CAP epidemiological and pilot studies that did not include clinical interviews relied exclusively on self-report questionnaires to obtain information about Criterion-A index traumatic events. In these instances, participants completed the DRRI-2 Combat Experiences and Postbattle Experiences Scales, as well as the LEC-5, identifying worst events from each measure. Then participants were asked to identify and briefly describe the worst overall event and answer several questions to determine Criterion-A status. Finally, participants were instructed to complete the PCL-5, with their symptom reports indexed to this event.

The Clinician-Administered PTSD Scale for *DSM-5* (CAPS-5)

The CAPS-5[37,38] is a structured diagnostic interview and the gold standard for assessing PTSD. The CAPS-5 uses a single 5-point ordinal rating scale to measure symptom severity. Symptom-severity ratings combine information about symptom frequency and intensity obtained by the interviewer. Consistent with its predecessor, the CAPS-5 has been shown to have excellent psychometric properties.[37,39]

The CAPS-5 is administered by trained and certified masters- or doctoral-level independent evaluators blind to treatment status at the beginning and end of interventions for all participants. Interviews are randomly selected for review on twice monthly calibration calls to establish interrater reliability and to prevent rater drift. The inter-rater reliability of CAPS-5 case decisions is excellent ($N = 78$; *Cohen's kappa* = 0.90) and the correlation of severity scores between raters is excellent ($r = 0.98$). The kappa was based on comparisons of decisions about the presence or absence of PTSD by an independent evaluator with an expert evaluator co-rating audio-taped interviews. The correlation coefficient was calculated using the total sum CAPS-5 severity score by the independent evaluator and the expert evaluator.

Self-Injurious Thoughts and Behaviors Interview (SITBI) Short Form

The SITBI[40] is a structured interview assessing the historical presence, frequency, and characteristics of self-injurious and suicidal thoughts and behaviors. The short form version of the SITBI was administered at baseline by an independent evaluator, who instructed the participants to answer the questions based on their entire lifetime. Scores on the SITBI have shown high interrater reliability, test–retest reliability, and concurrent validity.[39]

Self-Report Measures Indexed to a Traumatic Event

The PTSD Checklist for *DSM-5* (PCL-5)

The PCL-5[41] is a self-report measure, selected for its dimensional sensitivity, with higher scores reflecting greater PTSD severity. Scoring is based on how much the patient has been bothered by PTSD symptoms in the past month. The PCL has excellent psychometric characteristics for screening and as a secondary indicator of PTSD symptom severity.[39,42]

Administered at Follow-up Intervals

Independent Evaluator Blind Form

This form measures the independent evaluator's best guess about the treatment that the participant received, level of confidence in this guess, and how unblinding could potentially have occurred. The form was used at treatment completion and follow-up for all CAP trials that include independent evaluation of outcomes.

OPTIONAL CDES FOR THE CONSORTIUM TO ALLEVIATE PTSD

The following optional CDEs were recommended in the event the following domains were assessed: (1) co-occurring psychiatric disorders; (2) anger and aggressive behaviors; (3) sexual functioning; (4) somatic complaints; (5) post-deployment and veteran risks and resources, and trait resilience; and (6) treatment outcome credibility and expectancy. These measures are described below in the order of administration as presented in the mandated CDEs above.

Interview-Administered Measures

Mini International Neuropsychiatric Interview (MINI)

The MINI 7.0 is a short, structured clinical diagnostic interview designed to cover the major psychiatric disorders in *DSM-5* and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10). The MINI was used to assess the full spectrum of

psychiatric disorders, or investigators used specific modules. The MINI was also used to assess conditions that would exclude participants. The MINI cannot be used to determine severity of various psychiatric problems, but rather, to determine caseness.

Self-Reported Measures

Patient Health Questionnaire – 15 (PHQ-15)

The PHQ-15[14] is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. Scores on the PHQ-15 have demonstrated excellent internal reliability and good convergent validity.[14]

Sexual Function and Satisfaction Measures (Version 2.0) from the Patient Reported Outcomes Measurement Information System (PROMIS)

The PROMIS questionnaires are a system of reliable measures of patient–reported health status for physical, mental, and social well–being. One of the PROMIS instruments is the revised *Sexual Function and Satisfaction Measures* version 2.0.[43] This instrument provides scores on 11 different subdomains of sexual function over the past 30 days. All subdomain scores are expressed as *t* scores (mean = 50, standard deviation = 10). Scores on the measure have demonstrated convergent validity and strong internal consistency.[43]

Revised Conflict Tactics Scale (CTS) Physical Assault & Psychological Aggression Subscales

The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family,[44] and over time it has become the most widely used instrument to assess intimate partner violence.[45] The revised CTS (CTS2)[45] has fewer items. For CAP studies, only the *Physical Assault* and *Psychological Aggression* subscales (20 items) of the CTS2 were used. Scores on the instrument have demonstrated good internal consistency and construct and discriminant validity.[46]

The Dimensions of Anger Reactions-5 (DAR-5)

The DAR-5[47] was specifically developed for war veterans, and it measures anger frequency, intensity, duration, aggression, and interference with social functioning. Respondents indicate the degree to which each of five items describes their feelings or behavior over the last 4 weeks. The original DAR has shown good psychometric properties.[47–49]

Response to Stressful Experiences Scale (RSES)

The RSES[50] is a trait measure of resilience. It assesses cognitive, emotional, and behavioral resilience. Respondents endorse the degree to which statements describe them, both during and after stressful events in their lives. Scores on the RSES have demonstrated good internal consistency, convergent validity, and test–retest reliability.[50]

Deployment Risk and Resilience Inventory-2 (DRRI-2) Post-Deployment Life Events, Post-Deployment Support, and Post-Deployment Family Experiences, and Unit Support Subscales

These DRRI-2 scales were used to assess post-deployment factors that may affect recovery. To allow repeated measurement, the Post-Deployment Support, Post-Deployment Family Experiences, and the Unit Support subscales were modified to use an "in the past month" time frame. The Unit Support subscale is applicable only to current service members.

Administered Following Explanation of Treatments and at Follow-up Intervals

Credibility and Expectancy Questionnaire (CEQ)

The CEQ[51] was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies. The CEQ assesses whether the person cognitively understands how the therapy works (credibility) as well as whether the person effectively believes that the therapy will work for him or her personally (expectancy). Scores on the CEQ have demonstrated strong internal consistency and test–retest reliability.[51]

Self-Report Measures Indexed to a Traumatic Event

Trauma-Related Guilt Inventory (TRGI)

The TRGI[52] was developed to assess guilt feelings and attitudes about a specific traumatic event. The TRGI is scored into three scales (Global Guilt, Distress, Guilt Cognitions) and three subscales (Hindsight-Bias/Responsibility, Wrongdoing, and Lack of Justification). Scores on the TRGI have demonstrated consistently high internal consistency, convergent validity, and test-retest reliability.[52] An abbreviated 16-item version of the TRGI was used in the CAP studies.

Post-traumatic Cognitions Inventory (PTCI)

The PTCI[53] is a self-report questionnaire that measures trauma-related thoughts and beliefs and is comprised of three subscales (Negative Cognitions About the Self, Negative Cognitions About the World, and Self-Blame). Scores on the measure have demonstrated high internal consistency, convergent and discriminant validity, and test-retest reliability.[53]

DISCUSSION

CDEs allow researchers to compare research participant characteristics and outcomes for studies conducted by different investigators and with different study populations. CDEs also allow researchers to combine data from multiple studies to increase power, overcome sampling biases, and test research questions with metadata. In this paper, we described the CDEs generated and fielded for the CAP. We sought to share these measures to promote uniform methods (1) to assess PTSD and related-constructs and (2) to measure

PTSD outcomes in epidemiological studies, biomarker studies, pilot studies, and clinical trials of military-related PTSD.

Many of the measures we employed in our CDE set are updated versions of CDEs recommended by Kaloupek et al.[2] However, we have added to these recommendations in several ways. We included measures of head injury, depression, anxiety, suicidal and self-injurious behavior, alcohol and nicotine use, trauma-related cognitions and guilt, resilience, psychosocial functioning, sleep problems, treatment expectancies, and interpersonal conflict and anger. We believe that these additions provide better coverage of mental and behavioral health problems that are commonly comorbid with PTSD. They also equip researchers with a wider array of variables that potentially moderate and/or mediate variability in PTSD outcomes in clinical trials.

To date, no one has provided evidence to support the incremental explanatory validity of CDEs for PTSD research. Although the CAP-CDE domains were generated using a sound set of assumptions and the measures we chose were evidence-based, the explanatory and incremental validity of the set of domains and measures we selected is an empirical question. Researchers need to determine how well measures of comorbid conditions and problems account for PTSD outcomes and the relative potency (e.g., area under receiver operating curve) of the collection of predictor variables.

CONCLUSIONS

This paper is the first to provide a list of military-related PTSD CDEs that are being fielded successfully in a large, government-funded research consortium. We hope that other studies use these CDEs to facilitate data aggregation and valid comparability across trials. The set of CDEs we recommend is not static and should be shaped by future empirical testing and practical field testing in other contexts.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Military Medicine* online.

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REFERENCES

1. Sheehan J, Hirschfeld S, Foster E, et al: Improving the value of clinical research through the use of common data elements. Clin Trials 2016; 13(6): 671–6. doi:10.1177/1740774516653238.
2. Kaloupek DG, Chard KM, Freed MC, et al: Common data elements for posttraumatic stress disorder research. Arch Phys Med Rehabil 2010; 91 (11): 1684–91. doi:10.1016/j.apmr.2010.06.032.
3. Nash WP, Vasterling J, Ewing-Cobbs L, et al: Consensus recommendations for common data elements for operational stress research and surveillance: report of a federal interagency working group. Arch Phys Med Rehabil 2010; 91(11): 1673–83. doi:10.1016/j.apmr.2010.06.035.
4. Department of Defense, Department of Veterans Affairs, Department of Health and Human Services, Department of Education: National Research Action Plan: Responding to the Executive Order "Improving Access to Mental Health Services for Veterans, Service Members, and Military Families (August 31, 2012)." Washington, DC, Departments of Defense, Veterans Affairs, Health and Human Services, and Education, 2013. Available at https://www.ninds.nih.gov/sites/default/files/NRAP_AUG2012_508C.pdf; accessed January 26, 2018.
5. Lehrner A, Yehuda R: Biomarkers of PTSD: military applications and considerations. Eur J Psychotraumatol 2014; 5. doi:10.3402/ejpt.v5.23797.
6. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, 5th edn, Arlington, VA, American Psychiatric Association, 2013.
7. Schwab KA, Baker G, Ivins B, Sluss-Tiller M, Lux W, Warden D: The Brief Traumatic Brain Injury Screen (BTBIS): investigating the validity of a self-report instrument for detecting traumatic brain injury (TBI) in troops returning from deployment in Afghanistan and Iraq. Neurology 2006; 66(5)(Supp. 2): A235. [Abstract].
8. Schwab KA, Ivins B, Cramer G, et al: Screening for traumatic brain injury in troops returning from deployment in Afghanistan and Iraq: initial investigation of the usefulness of a short screening tool for traumatic brain injury. J Head Trauma Rehabil 2007; 22(6): 377–89. doi:10.1097/01.HTR.0000300233.98242.87.
9. Vogt D, Smith BN, King LA, King DW, Knight J, Vasterling JJ: Deployment Risk and Resilience Inventory-2 (DRRI-2): an updated tool for assessing psychosocial risk and resilience factors among service members and veterans. J Trauma Stress 2013; 26(6): 710–7. doi:10.1002/jts.21868.
10. Weathers FW, Blake DD, Schnurr PP, Kaloupek DG, Marx BP, Keane TM: The Life Events Checklist for DSM-5 (LEC-5). National Center for PTSD, 2013. Available at https://www.ptsd.va.gov/professional/assessment/te-measures/life_events_checklist.asp; accessed February 5, 2018.
11. Gray MJ, Litz BT, Hsu JL, Lombardo TW: Psychometric properties of the Life Events Checklist. Assessment 2004; 11(4): 330–41. doi:10.1177/1073191104269954.
12. Kroenke K, Spitzer RL, Williams JB, Löwe B: The Patient Health Questionnaire Somatic, Anxiety, and Depressive Symptom Scales: a systematic review. Gen Hosp Psychiatry 2010; 32(4): 345–59. doi:10.1016/j.genhosppsych.2010.03.006.
13. Cameron IM, Crawford JR, Lawton K, Reid IC: Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care. Br J Gen Pract 2008; 58(546): 32–6. doi:10.3399/bjgp08X263794.
14. Kroenke K, Spitzer RL, Williams JB: The PHQ-15: validity of a new measure for evaluating the severity of somatic symptoms. Psychosom Med 2002; 64(2): 258–66. doi:10.1097/00006842-200203000-00008.
15. Metalsky GI, Joiner TE: The Hopelessness Depression Symptom Questionnaire. Cognit Ther Res 1997; 21(3): 359–84. doi:10.1023/A:1021882717784.
16. Batterham PJ, Ftanou M, Pirkis J, et al: A systematic review and evaluation of measures for suicidal ideation and behaviors in population-based research. Psychol Assess 2015; 27(2): 501–12. doi:10.1037/pas0000053.
17. Spitzer RL, Kroenke K, Williams JB, Lowe B: A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006; 166(10): 1092–7. doi:10.1001/archinte.166.10.1092.
18. Löwe B, Decker O, Müller S, et al: Validation and standardization of the Generalized Anxiety Disorder Screener (GAD-7) in the general population. Med Care 2008; 46(3): 266–74. doi:10.1097/MLR.0b013e318160d093.

19. Babor TF, Higgins-Biddle J, Saunders J, Monteiro M: AUDIT: The Alcohol Use Disorders Identification Test: Guidelines for Use inPrimary Care, 2nd edn, Geneva, Switzerland, World Health Organization, 2001. Available at http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.505.4146&rep=rep1&type=pdf; accessed February 5, 2018.
20. Saunders JB, Aasland OG, Babor TF, De La Fuente JR, Grant M: Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO collaborative project on early detection of persons with harmful alcohol consumption-II. Addiction 1993; 88(6): 791–804. doi:10.1111/j.1360-0443.1993.tb02093.x.
21. Reinert DF, Allen JP: The Alcohol Use Disorders Identification Test: an update of research findings. Alcohol Clin Exp Res 2007; 31(2): 185–99. doi:10.1111/j.1530-0277.2006.00295.x.
22. Sobell LC, Agrawal S, Sobell MB, et al: Comparison of a quick drinking screen with the timeline followback for individuals with alcohol problems. J Stud Alcohol 2003; 64(6): 858–61. doi:10.15288/jsa.2003.64.858.
23. Roy M, Dum M, Sobell LC, et al: Comparison of the quick drinking screen and the alcohol timeline followback with outpatient alcohol abusers. Subst Use Misuse 2008; 43(14): 2116–23. doi:10.1080/10826080802347586.
24. Heatherton TF, Kozlowski LT, Frecker RC, Fagerström KO: The Fagerström Test for Nicotine Dependence: a revision of the Fagerström Tolerance Questionnaire. Addiction 1991; 86(9): 1119–27. doi:10.1111/j.1360-0443.1991.tb01879.x.
25. Meneses-Gaya ICD, Zuardi AW, Loureiro SR, Crippa JADS: Psychometric properties of the Fagerström Test for Nicotine Dependence. J Bras Pneumol 2009; 35(1): 73–82. doi:10.1590/S1806-37132009000100011.
26. Ebbert JO, Patten CA, Schroeder DR: The Fagerström Test for Nicotine Dependence-Smokeless Tobacco (FTND-ST). Addict Behav 2006; 31(9): 1716–21. doi:10.1016/j.addbeh.2005.12.015.
27. Kazis LE, Selim AJ, Rogers W, Ren XS, Lee A, Miller DR, R.A.N.D: Veterans, 12-Item Health Survey (VR-12): a White Paper Summary, 2008. Available at https://www.researchgate.net/publication/237314426_Veterans_RAND_12_Item_Health_Survey_VR12_A_White_Paper_Summary; accessed August 23, 2018.
28. Marx BP: Development and validation of a PTSD-related impairment scale [final research report]. Boston, MA, Boston VA Research Institute, 2013. Available from the Defense Technical Information Center website at www.dtic.mil/cgi-bin/GetTRDoc?AD=ADA585414; accessed February 6, 2018.
29. Erb SE, Kearns J, Bovin MJ, et al: (2015). Psychometric properties of the Brief Inventory of Psychosocial Functioning. Poster session presented at the 31st Annual Meeting of the International Society for Traumatic Stress Studies, New Orleans, LA.
30. Morin CM: Insomnia: Psychological Assessment and Management. New York, NY, Guilford Press, 1993.
31. Bastien CH, Vallieres A, Morin CM: Validation of the Insomnia Severity Index as an outcome measure for insomnia research. Sleep Med 2001; 2(4): 297–307. doi:10.1016/S1389-9457(00)00065-4.
32. Yu L, Buysse DJ, Germain A, et al: Development of short forms from the PROMIS™ sleep disturbance and sleep-related impairment item banks. Behav Sleep Med 2012; 10(1): 6–24. doi:10.1080/15402002.2012.636266.
33. Buysse DJ, Yu L, Moul DE, et al: Development and validation of patient-reported outcome measures for sleep disturbance and sleep-related impairments. Sleep 2010; 33(6): 781–92. doi:10.1093/sleep/33.6.781.
34. Chung F, Yegneswaran B, Liao P, et al: STOP questionnaire: a tool to screen patients for obstructive sleep apnea. Anesthesiology 2008; 108(5): 812–921. doi:10.1097/ALN.0b013e31816d83e4.
35. Stein NR, Mills MA, Arditte K, et al; for the STRONG STAR Consortium: A scheme for categorizing traumatic military events. Behav Modif 2012; 36(6): 787–807. doi:10.1177/0145445512446945.
36. Litz B, Contractor A, Rhodes C, et al; for the STRONG STAR Consortium: Distinct trauma types in military service members seeking treatment for posttraumatic stress disorder. J Trauma Stress 2018; 31(2): 286–95.
37. Weathers FW, Bovin MJ, Lee DJ, et al: The Clinician-Administered PTSD Scale for DSM–5 (CAPS-5): development and initial psychometric evaluation in military veterans. Psychol Assess 2018; 30(3): 383–95. doi:10.1037/pas0000486.
38. Weathers FW, Blake DD, Schnurr PP, Kaloupek DG, Marx BP, Keane TM: The Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). National Center for PTSD, 2013. Available at https://www.ptsd.va.gov/professional/assessment/adult-int/caps.asp; accessed February 6, 2018.
39. Bovin MJ, Marx BP, Weathers FW, et al: Psychometric properties of the PTSD Checklist for Diagnostic and Statistical Manual of Mental Disorders–Fifth Edition (PCL-5) in veterans. Psychol Assess 2016; 28(11): 1379–91. doi:10.1037/pas0000254.
40. Nock MK, Holmberg EB, Photos VI, Michel BD: Self-Injurious Thoughts and Behaviors Interview: development, reliability, and validity in an adolescent sample. Psychol Assess 2007; 19(3): 309–17. doi:10.1037/1040-3590.19.3.309.
41. Weathers FW, Litz BT, Keane TM, Palmieri PA, Marx BP, Schnurr PP: The PTSD Checklist for DSM-5 (PCL-5). National Center for PTSD, 2013. Available at https://www.ptsd.va.gov/professional/assessment/adult-sr/ptsd-checklist.asp; accessed February 6, 2018.
42. McDonald SD, Calhoun PS: The diagnostic accuracy of the PTSD Checklist: a critical review. Clin Psychol Rev 2010; 30(8): 976–87. doi:10.1016/j.cpr.2010.06.012.
43. Weinfurt KP, Lin L, Bruner DW, et al: Development and initial validation of the PROMIS® sexual function and satisfaction measures version 2.0. J Sex Med 2015; 12(9): 1961–74. doi:10.1111/jsm.12966.
44. Straus MA: Measuring intrafamily conflict and violence: the Conflict Tactics (CT) Scales. J Marriage Fam 1979; 41(1): 75–88. doi:10.2307/351733.
45. Straus MA, Douglas EM: A short form of the Revised Conflict Tactics Scales, and typologies for severity and mutuality. Violence Vict 2004; 19(5): 507–20. doi:10.1891/vivi.19.5.507.63686.
46. Straus MA, Hamby SL, Boney-McCoy S, Sugarman DB: The Revised Conflict Tactics Scales (CTS2) development and preliminary psychometric data. J Fam Issues 1996; 17(3): 283–316. doi:10.1177/019251396017003001.
47. Forbes D, Alkemade N, Mitchell D, et al: Utility of the Dimensions of Anger Reactions-5 (DAR-5) scale as a brief anger measure. Depress Anxiety 2014; 31(2): 166–73. doi:10.1002/da.22148.
48. Forbes D, Hawthorne G, Elliott P, et al: A concise measure of anger in combat-related posttraumatic stress disorder. J Trauma Stress 2004; 17(3): 249–56. doi:10.1023/B:JOTS.0000029268.22161.bd.
49. Novaco RW, Swanson RD, Gonzalez OI, Gahm GA, Reger MD: Anger and postcombat mental health: validation of a brief anger measure with US soldiers postdeployed from Iraq and Afghanistan. Psychol Assess 2012; 24(3): 661–75. doi:10.1037/a0026636.
50. Johnson DC, Polusny MA, Erbes CR, et al: Development and initial validation of the Response to Stressful Experiences Scale. Mil Med 2011; 176: 161–9. doi:10.1176/appi.ajp.2014.13040502.
51. Devilly GJ, Borkovec TD: Psychometric properties of the credibility/expectancy questionnaire. J Behav Ther Exp Psychiatry 2000; 31(2): 73–86. doi:10.1016/S0005-7916(00)00012-4.
52. Kubany ES, Haynes SN, Abueg FR, Manke FP, Brennan JM, Stahura C: Development and validation of the Trauma-Related Guilt Inventory (TRGI). Psychol Assess 1996; 8(4): 423–44. doi:10.1037/1040-3590.8.4.428.
53. Foa EB, Ehlers A, Clark DM, Tolin DF, Orsillo SM: The Posttraumatic Cognitions Inventory (PTCI): development and validation. Psychol Assess 1999; 11(3): 303–14. doi:10.1037/1040-3590.11.3.303.