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Recommendations for the Use of Common Outcome Measures in Pediatric Traumatic Brain Injury Research

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Abstract

This article addresses the need for age-relevant outcome measures for traumatic brain injury (TBI) research and summarizes the recommendations by the inter-agency Pediatric TBI Outcomes Workgroup. The Pediatric Workgroup's recommendations address primary clinical research objectives including characterizing course of recovery from TBI, prediction of later outcome, measurement of treatment effects, and comparison of outcomes across studies. Consistent with other Common Data Elements (CDE) Workgroups, the Pediatric TBI Outcomes Workgroup adopted the standard three-tier system in its selection of measures. In the first tier, core measures included valid, robust, and widely applicable outcome measures with proven utility in pediatric TBI from each identified domain including academics, adaptive and daily living skills, family and environment, global outcome, health-related quality of life, infant and toddler measures, language and communication, neuropsychological impairment, physical functioning, psychiatric and psychological functioning, recovery of consciousness, social role participation and social competence, social cognition, and TBI-related symptoms. In the second tier, supplemental measures were recommended for consideration in TBI research focusing on specific topics or populations. In the third tier, emerging measures included important instruments currently under development, in the process of validation, or nearing the point of published findings that have significant potential to be superior to measures in the core and supplemental lists and may eventually replace them as evidence for their utility emerges.

Key words: children; infants; outcome assessment, TBI

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Note: With the exception of the first and second authors, all other working group members have been listed in alphabetical order, and each has contributed significantly to the overall preparation of this manuscript.

Introduction

The purpose of the Common Data Elements (CDE) Traumatic Brain Injury (TBI) Outcomes Workgroup was to address the need for a common set of outcome measures for TBI research across agencies and populations (Thurmond et al., 2010). However, during the development of the original Outcomes CDE (hereafter referred to as the "original CDE"), the failure to include measures that would be appropriate for children and infants was a notable limitation. Therefore, an additional workgroup was formed to specifically address this gap. As with the original CDE Workgroup, physicians, neuropsychologists, psychologists, and others with specific expertise in pediatric TBI outcomes research, including physical and occupational therapists and speech-language pathologists, were recruited to participate in the Pediatric CDE Workgroup. Further information regarding the background of the TBI CDE initiative and the methods used by all workgroups to arrive at CDE recommendations is detailed by Miller, Duhaime, Odenkirchen, and Hicks (*in press*).

Selection of TBI Outcome Domains and Measures

In selecting outcome *domains*, the Pediatric CDE Workgroup sought to preserve the focus that was established by the original CDE Workgroup, consider outcomes at multiple levels, and select measures of import to stakeholders, scientists, and practitioners. Of the original CDE domains, we included global outcome, recovery of consciousness, perceived health-related quality of life, neuropsychological impairment, physical functioning, psychological status, and TBI-related symptoms. The number of domains was expanded to also include measures related to academics, daily life skills/adaptive functioning, family/environment, language and communication, social cognition, and social competence/role participation. Finally, a subset of measures that could be used with infants and toddlers was included, given their unique developmental issues. When possible, measures were identified that spanned a wide age range to avoid the need to change measures between childhood and adolescence. Spanish translations that have been standardized are noted. (The Pediatric CDE Workgroup also recognizes that other translations including Spanish exist but have not been validated.) As with the original CDE, we sought a set of measures that collectively could cover the continua from acute to long-term outcome and from mild to severe TBI. These domains are further described in Table 1.

Factors of importance in selecting outcome measures within the domains

Consistent with the intent of the original CDE, measures in the pediatric subset were selected to maximize the ability of clinical researchers to: 1) document the natural course of recovery after TBI; 2) enhance the prediction of later outcome; 3) measure the effects of treatment; and 4) facilitate comparisons across centers/studies.

The Pediatric CDE Workgroup divided into smaller subgroups based on interests and expertise to identify sets of measures and detailed characteristics of potential measures for each domain. Measures were identified using the following criteria: 1) sufficient representation in the scientific literature and/or widespread use among the pediatric TBI clinical and research communities in diagnosis, outcome measurement and, prediction, or treatment effectiveness; 2) evidence of sound psychometric properties including construct validity, internal consistency, sensitivity to change, test–retest reliability, and intra-/inter-rater agreement; 3) well-established normative data; 4) applicability across a range of injury severity, functional levels, and developmental levels; 5) availability in the public domain; 6) ease of administration; 7) brevity; and 8) continuity with the original CDE measures where practicable. Whenever possible, the panel considered factors that would render the measures appropriate for international use, such as the availability in different languages and validation in different ethnic groups. For measures of health-related quality of life, activity/participation, and psychological function, consideration was also given to flexibility of formats (e.g., telephone interview versus in-person administration or self versus proxy respondent). Finally, for standardized, performance-based neuropsychological measures, the availability of alternate forms to minimize practice effects was given careful consideration.

Distinguishing core, supplemental, and emerging outcome measure recommendations

In accordance with other CDE Workgroups, three tiers of CDE were recommended: Core, Supplemental, and Emerging (Miller et al., *in press*, Thurmond et al., 2010). First, well-established core measures covering outcome domains relevant to most TBI studies were included. Core measures were selected with the idea that many of these could be applied across large TBI studies, either as a comprehensive battery or in addition to other outcome measures selected by the investigator when practicable. *As with all CDEs, the use of these recommended measures should be tempered by the specific study objectives, design, and target populations; they should not be viewed as prescriptive or required for inclusion in research studies. The goals of the research studies should remain paramount when selecting appropriate outcome measures.* In the second tier, supplemental measures were recommended for consideration in pediatric TBI research focusing on specific topics or populations. For example, a study in which language and communication, physical functioning, or neuropsychological outcome is of particular interest may draw upon measures from the supplemental list that target functions not tapped specifically by the core. In the third tier, emerging measures include important instruments currently under development, in the process of validation, or nearing the point of published findings with pediatric TBI. These instruments are potentially superior to some measures currently in the core and supplemental lists or examine a novel construct within a domain.

General process for selecting common data elements

Each member of the panel selected one or more outcome domains based upon interest and expertise. Subgroups of panel members developed initial lists of potential measures within each domain and provided information on the criteria detailed previously. The potential measures were discussed among the entire panel via a series of conference calls, and a more limited set of measures for each outcome domain was selected for further discussion among the panel at a face-to-face meeting in Houston in March 2010. In preparation for the meeting, all panel members assisted in

Table 1. Outcome Domains and Descriptions

Domain	*Description*
Academics	Children with TBI have been found to have significant academic difficulties characterized by school failure and deficits in academic achievement such as reading, mathematics, and written language.
Adaptive and Daily Living Skills	Adaptive and daily life functioning consists of multiple domains and involves the ability to "adapt" to (e.g., adjust, vary, fit one's behaviors/actions) and manage one's surroundings to effectively function in home, school, and community life. This domain also includes children's functional activity and activity limitations.
Family and Environment	This domain includes moderators of outcome related to family and environment as well as the consequences to family.
Global Outcome	Global outcome measures summarize the overall impact of TBI incorporating functional status, independence, and role participation.
Health-Related Quality of Life	TBI may create significant limitations in multiple areas of functioning and well-being, often reducing perceived quality of life with regard to multiple generic and disease-specific dimensions.
Infant and Toddler Measures	Childhood and adolescence represent a wide range of developmental levels and even most pediatric measures are inappropriate for infants and toddlers. Therefore, limited special measures are included for this age range.
Language and Communication	Deficits in language comprehension and expression and in speech articulation are common after TBI. Measures of language use in context (pragmatics) are particularly sensitive to TBI effects.
Neuropsychological Impairment	Objective measures of neuropsychological functions such as attention, memory and executive function are very sensitive to the effects of TBI and often affect everyday activities.
Physical Functioning	Children with TBI (particularly severe TBI) may manifest difficulties in physical or neurological functioning including cranial or peripheral nerve damage, impairment in motor functioning, or in strength and/or coordination, or impairment in sensation. These impairments may contribute to difficulties in performing day-to-day activities safely and independently.
Psychiatric and Psychological Functioning	In the context of pediatric TBI, psychological/psychiatric variables are behavioral and emotional constructs related to positive or negative functioning. These variables may be pre-morbid or post-traumatic in occurrence. Etiologies are both biologic and environmental.
Recovery of Consciousness	Measures, such as the duration of coma, level of consciousness and rate of recovery are sensitive to TBI severity. As such, these measures are significant predictors of functional outcome and play a key role in treatment and disposition planning.
Social Role Participation and Social Competence	Participation is defined by the World Health Organization (WHO) as "involvement in life situations"(ICF, 2004*) and commonly includes engagement in endeavors within one's community. TBI affects many areas of participation including productive activities, recreation, social pursuits, and family role function.
Social Cognition	Social cognition refers to the cognitive processes necessary for successful social interaction. A growing body of literature has documented impairments in this domain after TBI, in some cases independent of other cognitive impairments.
TBI-Related Symptoms	TBI-related symptoms include somatic (e.g., headaches, visual disturbances), cognitive (e.g., attention and memory difficulties) and emotional (e.g., irritability) symptoms. They are commonly reported after mild TBI and may persist in some cases at all levels of TBI severity.

*See http://www.who.int/classifications/icflen/ (last accessed July 27, 2011).

composing a series of tables detailing relevant information on general administration characteristics, psychometric properties, and advantages and limitations of each of the potential measures.

As with the original CDE meeting in March 2009, the primary objective of the meeting was to further examine, refine, and limit the list of potential outcome measures using the information collected and reviewed. In accordance with other CDE working groups, a final set of measures was selected and organized into the three tiers described previously, after further discussion of the relative advantages and limitations of each measure. Selection of the final measures for each level of CDE was accomplished by Workgroup consensus. When disagreements arose regarding the selection of some measures, extensive discussion of the relevant merits and disadvantages of the measures continued (often spanning several conference calls and e-mail exchanges) until a consensus was achieved. In rare instances when the group was unable to reach consensus, more than one measure was included along with the considerations for the use of each.

Description and selection of core, supplemental, and emerging CDE

Consistent with the original CDE objective, the Pediatric CDE Workgroup sought to select a single measure (or at most a limited set of measures) that best covered each domain. Brevity, ease of administration, and purchase cost influenced the selection of Core measures, because the intent was to recommend measures that could feasibly be administered in a variety of settings and across a range of age and post-injury functional levels. Availability of tests in Spanish or other languages was also considered. Measures with established reliability and validity for children with TBI were prioritized when available for these core measures. In three cases, two "comparable" or at least widely used measures were selected (i.e., in the core measures of domains: infant and toddlers, memory, and physical functioning) because a choice could not be reasonably made between them based on psychometric properties, specifics of the domain they assess, or other important characteristics.

The rationale behind creating a set of supplemental measures was to recommend additional measures in each domain that could be considered for more in-depth outcome assessment within a certain domain or for patients at a specific functional level. Additionally, measures of psychological and/or family functioning or substance abuse were included here because of their importance, depending upon the study design, functional level, recovery phase, or target population. Other reasons for inclusion in this category included the probability of ceiling effects outside of rehabilitation populations (e.g., including the Pediatric Evaluation of Disability Inventory for children in the acute recovery phase, but the Bruininks-Oseretsky Test of Motor Proficiency-2 for children further along in their recovery), the requirement for specialized training (e.g., Language Sample, K-SADS-P/L), normative data limitations, and cost.

The third tier – emerging measures – filled existing gaps in measurement of TBI-related sequelae in children. Additionally, some of these measures may better facilitate comparison across patient groups (e.g., to allow comparison with different neurologic disease populations, inclusion of a broader age range, more comprehensive sampling of domains of function, etc.). Emerging measures require ongoing consideration to progress to becoming supplemental or core CDE measures, as evidence accumulates regarding their psychometric characteristics, normative data, and utility in pediatric TBI research.

As with the original CDE, the efforts of the Pediatric CDE Workgroup reflect a dynamic tension between the desire to maintain consistency among a stable set of measures and the desire to adopt new, improved measures as they become available. The selection of recommended outcome measures is an evolving process and recommendations may change with additional evidence and discussion regarding the current CDEs. Therefore, the Pediatric CDE Workgroup advises the reader to consult the CDE website (http://www.nindscommondataelements.org) for any updates to this listing, particularly with respect to emerging measures.

Recommendations for TBI Outcome Measures

Recommended CDEs (all three tiers) are summarized in Table 2, which is provided as an overview of how specific measures fit into each domain. Each measure is described in more detail in the text that follows. The reader is also referred to http://www.commondataelements.ninds.nih.gov for additional supplemental information on each measure, including the number and description of items and subscale structure, range of scores, administration time, training requirements, and information on the appropriate age range and population for its use. If Spanish translations, validated Spanish versions, or alternate forms are available, they are noted. Some measures may appear more than once because: they may span multiple domains, or a subscale was singled out for inclusion in another tier different from where the full measure was listed. In this case the complete measure is described only once for brevity.

Core Data Elements

Academics

Child behavior checklist-school competence (CBCL). With two sets of parent forms, the CBCL spans the ages of 1.5 to 5, and 6 to 18 years. There are corresponding teacher report forms at both age ranges allowing for broad coverage. The CBCL School Competence subscale (Achenbach, 1991) asks parents to rate their child's performance in several academic subjects from failing to above average, and children with TBI have been rated as having lower academic performance than typically developing children (Ewing-Cobbs et al., 2004; Fletcher et al., 1990). Administration time is <5 min for this subscale. Translated Spanish versions of the complete CBCL measure are available.

Adaptive and daily living skills

Pediatric evaluation of disability inventory (PEDI™). The PEDI is a norm-referenced assessment used primarily in acute and post-acute rehabilitation settings to examine functional skills and caregiver assistance in three subdomains: mobility, self-care, and social functioning (Haley et al., 1992). It has been used in many studies with children with TBI and other acquired brain injuries, and has established evidence of reliability, validity, and responsiveness to change during inpatient rehabilitation and post-discharge follow-up (Bedell, 2008; Coster et al., 1994; Dumas et al., 2001 a, b,2004; Fragala et al., 2002; Haley et al., 1992, 2003; Khoteri et al., 2003; Nichols and Case-Smith, 1996; Tokcan et al., 2003; Ziviani et al., 2001). The PEDI is recommended for children in acute and rehabilitation settings and for post-discharge follow-up. The self-care and mobility subdomain scales are recommended as core measures of adaptive/daily life functioning and physical functioning, respectively. The social functioning scales are recommended as supplemental measures of social role participation/social competence. Although they did not include children with TBI, translated Spanish versions of the PEDI are available that have demonstrated validity (Gannotti and

Table 2. Listing of the Core, Supplemental, and Emerging Measures for Each Domain

Domain	*Core*	*Supplemental*	*Emerging*
Academics	Child Behavior Checklist (CBCL-School Competence scale)	1. Woodcock-Johnson, 3rd Edition (WJ-III) 2. Gray Oral Reading Test, 4th Edition (GORT-4)	1. Comprehensive Test of Phonological Processing (CTOPP) 2. KeyMath-3 Diagnostic Assessment 3. Test of Word Reading Efficiency (TOWRE)
Adaptive and Daily Living Skills	1. Pediatric Evaluation of Disability Inventory (PEDI™ – Self Care subscales) or 2. Functional Independence Measure for Children (WeeFIM™)	Vineland-II	1. Adaptive Behavior Assessment System-Revised (ABAS-2) 2. Mayo-Portland Adaptive Inventory-4 (MPAI-4)
Family and Environment	Family Assessment Device – General Function subscale (FAD - GF)	1. FAD (full version) 2. Family Burden of Injury Interview (FBII-interview format) 3. Conflict Behavior Questionnaire/ Interaction Behavior Questionnaire (CBQ/IBQ)	1. Family Burden of Injury Interview (FBII self-report version) 2. Child and Adolescent Scale of Environment (CASE)
Global Outcome	Glasgow Outcome Scale-Extended (GOS-E Peds)	PedsQL	Pediatric Test of Brain Injury
Health-Related Quality of Life	PedsQL (generic core)	None	1. Patient-Reported Outcomes Measurement Information System (PROMIS) 2. Neuro-QOL
Infant and Toddler Measures	1. Mullen Scales of Early Learning or 2. Bayley Scales of Infant and Toddler Development-III (full, not screen) 3. Brief Infant Toddler Social Emotional Assessment (BITSEA) or 4. CBCL	None	1. Shape School 2. Trails-P
Language and Communication	1. Wechsler Abbreviated Scale of Intelligence (WASI- Vocabulary subtest) 2. Caregiver Unintelligible Speech Rating	1. Comprehensive Assessment of Spoken Language (CASL) 2. Clinical Evaluation of Language Fundamentals (CELF-4) 3. Goldman-Fristoe Test of Articulation 4. Peabody Picture Vocabulary Test, 4th Edition (PPVT-4) 5. Percentage of Consonants Correct-Revised (PCC) 6. Verbal Motor Production Assessment for Children (VMPAC)	NIH Toolbox measure(s)

(*continued*)

Table 2. (Continued)

Domain	*Core*	*Supplemental*	*Emerging*
		7. Language Sample 8. Test of Language Competence-Expanded (TLC-E)	
Neuropsychological Impairment			
Attention/Processing Speed	WISC-IV/WPPSI-III Processing Speed Index	1. Conners' Continuous Performance Test-Revised (CPT-2) 2. Test of Everyday Attention (Tea-Ch)	1. Flanker Test 2. NIH Toolbox measure(s)
Executive Functioning	Delis-Kaplan Executive Function System (D-KEFS) Verbal Fluency	1. Delis-Kaplan Executive Function System (D-KEFS) Trail Making Test 2. Behavioral Rating Inventory of Executive Function (BRIEF) 3. Contingency Naming Test (CNT)	1. Test of Executive Control (TEC) 2. Test of Strategic Learning (TOSL) 3. Functional Assessment of Verbal Reasoning and Executive Strategies – Student Version (FAVRES-S) 4. NIH Toolbox measure(s)
General Intellectual	WASI	None	None
Memory	1. Rey Auditory Verbal Learning Test (RAVLT) or 2. California Verbal Learning Test for Children (CVLT-C)	1. Wide-Range Assessment of Memory and Learning-Revised (WRAML-2) 2. Test of Memory and Learning-Revised (TOMAL-2)	NIH Toolbox measure(s)
Motor/Psychomotor	None	1. Grooved Pegboard	NIH Toolbox measure(s)
Visual-Spatial	None	1. WISC-4/WPPSI-3 Block Design 2. Beery VMI	None
Physical Functioning	1. WeeFIM or 2. PEDI mobility subscale	1. Gross Motor Function Measure (GMFM-88, GMFM-66) 2. Peabody Developmental Motor Scales, 2nd Edition 3 Bruininks-Oseretsky Test of Motor Proficiency-2 (BOT-2)	1. PROMIS (mobility and upper extremity domains) 2. Neuro-QOL (mobility/ambulation domain) 3. NIH Toolbox measure(s)

(*continued*)

Table 2. (Continued)

Domain	*Core*	*Supplemental*	*Emerging*
Psychiatric and Psychological Functioning	1. CBCL Problem Behaviors or 2. Strengths and Difficulties Questionnaire	1. Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL) 2. Screen for Child Anxiety Related Emotional Disorders (SCARED) 3. Short Mood and Feelings Questionnaire (SMFQ) 4. UCLA PTSD Index 5. Alcohol, Smoking, and Substance Abuse Involvement Screening Test (ASSIST) 6. Children's Affective Lability Scale (CALS) 7. Children's Motivation Scale (CMS) 8. Modified Overt Aggression Scale (MOAS)	None
Recovery of Consciousness	1. Children's Orientation and Amnesia Test (COAT) 2. Galveston Orientation and Amnesia Test (GOAT)	None	None
Social Role Participation and Social Competence	1. PedsQL (Social subscale) 2. Strengths and Difficulties Questionnaire (Peer Relations and Prosocial Behavior subscales)	1. Child and Adolescent Scale of Participation (CASP) 2. Social Skills Rating Scale (SSRS) 3. Child Behavior Checklist (Social Competence scale) 4. Vineland-II (Socialization scale) 5. PEDI Social Functioning Scales	None
Social Cognition	None	None	1. Interpersonal Negotiation Strategies (INS) 2. Reading the Mind in the Eyes Test-Child Version 3. Video Social Inference Test (VSIT)
TBI-Related Symptoms	Health and Behavior Inventory (HBI)	Post-concussion Symptom Inventory (PCSI)	None

Cruz, 2001; Gannotti et al., 2001; Wren et al., 2008). Administration time is ~45–60 min.

Functional independence measure for children (WeeFIM™). The WeeFIM is a standardized assessment that measures independence in activities of self-care, sphincter control, transfers, locomotion, communication, and social cognition. It is part of the Uniform Data System for Medical Rehabilitation. It has extensive evidence of reliability, validity, and responsiveness to change during inpatient rehabilitation for children and youth with TBI (Chen et al., 2005; Massagli et al., 1996; Ottenbacher et al., 1996, 1997, 2000; Rice et al., 2005; Swaine et al., 2000; Ziviani et al., 2001), with established normative data (Msall et al., 1994). The WeeFIM is the pediatric downward extension of the FIM™ (Granger, 1998), which was recommended as a core measure for adults with TBI (Wilde et al., 2010), but scoring criteria are somewhat different to account for developmental differences. The full 18-item WeeFIM (13-item motor scale and 5-item cognitive scale) is recommended as a core measure of adaptive/daily life functioning for children in acute and rehabilitation settings and post-discharge follow-up. The motor scale (8 self-care and 5 mobility items) is also recommended as a core measure of physical functioning. A Spanish translated version is available from the publisher. Administration time is ~20–30 min.

The Pediatric CDE Workgroup selected both the PEDI and the WeeFIM as core measures for use in acute and post-acute rehabilitation settings because both measures have been extensively studied and used. The PEDI is more comprehensive and therefore takes more time to administer, but is less expensive. The WeeFIM is briefer and is compatible with the FIM, which was recommended as a core measure for adults with TBI (Wilde et al., 2010); however, use of the WeeFIM, unlike the PEDI, requires credentialing, and there are propriety restrictions placed on its use. Researchers and clinicians should select the tool that best matches their goals, needs, and resources.

Family and environment

McMaster family assessment device (FAD-general function subscale). The 12-item general function scale of the FAD (FAD-GF) (Epstein et al., 1983) has demonstrated reliability and validity and has been used to assess global family functioning in numerous studies of children with TBI and their families (Barney and Max, 2005; Taylor et al., 1999; Yeates et al., 2004). It is available free of charge. The Pediatric CDE Workgroup recommends using the general functioning subscale as a core measure, and the FAD-full scale is recommended as a supplemental measure. Administration time is ~5 min.

Global outcome

Glasgow Outcome Scale – extended pediatric revision (GOS-E Peds). The GOS-E Peds (Beers et al., 2005) was developed to provide an age-appropriate, valid measurement of outcome necessary to complete randomized clinical trials in infants and children <17 years of age with TBI. The original semi-structured interview was modified to include a developmentally appropriate interview to classify TBI outcome in the youngest patients. A recent validity study has established the concurrent, predictive, and discriminant validity of the GOS-E Peds (Beers et al., In Press). Administration time is ~5–15 min.

Health-related quality of life

Pediatric quality of life inventory (PedsQL generic core). The PedsQL generic core (Varni et al., 1999, 2001, 2003) is composed of 23 items measuring the health dimensions of physical, emotional, social, and school functioning, and also generates summary scores for physical health and psychosocial health as well as a total score. Child self-report forms have been designed and validated for ages 5–18 years and parent proxy report forms are available for children ages 2–18 years. It has been used in pediatric TBI (Aitken et al., 2009; Calvert et al., 2008; Curran et al., 2003; Erickson et al., 2010; McCarthy et al., 2005, 2006, Moon et al., 2010; Slomine et al., 2006) and has been translated into over 48 languages including Spanish. Administration time is ~ 5 min.

Infant and toddler measures

Mullen scales of early learning. This instrument is a comprehensive measure of development that is composed of five scales: gross motor, visual reception, fine motor, expressive language, and receptive language (Mullen, 1995). This norm-referenced test is appropriate for children from birth to age 68 months. It has strong psychometric properties and has been used with a variety of populations including children with TBI (Keenan et al., 2007). Administration time is ~15–60 minutes depending upon the child's age.

Bayley scales of infant and toddler development, 3rd Edition (Bayley-III). The Pediatric CDE Workgroup recommends the Bayley-III (Bayley, 2005) as an appropriate alternate measure to the Mullen scales of early learning (Mullen, 1995) which is also cited as the core measure in this domain. The Bayley-III is a comprehensive measure for assessing infant development, and is normed on a large demographically representative sample of infants/toddlers ages 1 to 42 months. The core battery consists of five scales: three child-assessed scales (cognitive, motor, language) and two scales that derive information from parent questionnaires (social-emotional and adaptive behavior). Earlier versions of this measure have been used extensively in studies assessing outcome after early brain injury (Badr, 2009; Badr et al., 2006; Barlow et al., 2005; Beers et al., 2007; Bonnier et al., 2007; Ewing-Cobbs et al., 1998b, 1999; Landry et al., 2004; Prasad et al., 1999, 2002). The Bayley-III also has strong psychometric properties (Bayley, 2005). The Pediatric CDE Workgroup recommends using the full version of the Bayley-III rather than the screening version. Administration time is ~30–90 min depending upon the child's age.

CBCL. The CBCL parent, teacher, and youth self-report questionnaires (Achenbach, 1991) have been widely used to assess emerging and persistent behavior problems following pediatric TBI. The CBCL can be used with toddlers and children ages 18 months to 5 years. Administration time is ~10 min for the early childhood version.

Brief infant toddler social emotional assessment (BITSEA). The BITSEA (Briggs-Gowan and Carter, 2006) is a 42-item parent or caregiver report form that assesses social or emotional behavior problems and competencies of children ages 1 to 3 years. This screening test is based on the Infant Toddler Social Emotional Assessment (ITSEA). The BITSEA yields a problem total score and a competence total score. There are two versions, a parent form and a childcare provider form that are available in several languages including Spanish. The BITSEA was primarily included as a core measure to cover children ages 12–18 months, an age range not assessed by the CBCL. Administration time is ~7–10 min.

Language and communication

Wechsler abbreviated scale of intelligence-vocabulary subtest (WASI-Vocabulary subtest). The WASI (Wechsler, 1999) is a brief estimate of general intelligence for persons ages 6 to 89 years. The Pediatric CDE Workgroup recommends using the vocabulary subtest as a brief measure of language functioning. Although the WASI does not have specific sensitivity to mild injury severity, it has been shown to be sensitive to a range of neurologic conditions including moderate-to-severe TBI (Gamino et al., 2009; Wechsler, 1999). Other Wechsler vocabulary scales have been used to measure language in children with TBI (Catroppa and Anderson, 2004; Prigatano and Gray, 2008). Administration time is ~15 min.

Caregiver unintelligible speech rating. This is a simple but predictive parent/caregiver rating of the child's speech intelligibility in real-life spontaneous speech (Campbell, 1999; Coplan and Gleason, 1988). It is most appropriate for children <60 months of age. It has been shown to have high sensitivity and specificity for identifying children with speech delay/disorder (Coplan and Gleason, 1988). Administration time is ~1 min.

Neuropsychological Impairment

Attention and processing speed

Wechsler intelligence scale for children, 4th edition (WISC-IV)/Wechsler preschool and primary scale of intelligence, 3rd Edition (WPPSI-III) processing speed index. This measure of processing speed and sustained attention is based on the coding and symbol search subtests of the WISC-IV (Wechsler, 2003a), which has extensive normative data and excellent psychometric properties (Flanagan and Kaufman, 2004; Prifitera et al., 2005; Sattler and Dumont, 2004; Wechsler, 2003b). The WISC-IV was designed for use with children ages 6:0–16:11 years. The same subtests are also normed on the WPPSI-III (Wechsler, 2002) for children ages 4:0–7:3 years. As a measure of information processing rate, these indices from the WISC-III and WISC-IV are highly sensitive to the effects of TBI and its severity (Allen et al., 2010; Donders, 1997; Donders and Janke, 2008; Tremont et al., 1999; Yeates and Donders, 2005). It has been used in different languages, cultures, and ethnic groups. The WISC-IV Spanish version was designed to assess Spanish-speaking children in the United States and is available from the publisher (Wechsler, 2004). Administration time for the coding and symbol search subtests is ~ 5 min.

Executive functioning

Delis-Kaplan executive function system verbal fluency test (D-KEFS VF). The D-KEFS VF (Delis et al., 2001) creates a phonemic fluency condition wherein the child is asked to verbalize words beginning with a designated letter according to specific rules, a semantic fluency condition in which the child is asked to verbalize exemplars of specific categories, and a semantic switching condition in which the semantic category switches, thus increasing the demand on executive function. The D-KEFS VF can be given to children ≥8 years of age. The D-KEFS VF was selected as a core measure because verbal fluency has been shown to be sensitive to TBI severity (Strong et al., 2010) and to focal left frontal lesions (Levin et al., 2001), and because all of the D-KEFS tests were standardized on normative data for 1750 typically developing children (Delis et al., 2001). Additionally, consideration was given to maintaining consistency with the adult CDE core measure of this domain (Wilde et al., 2010). The integration of verbal fluency with semantic fluency and the switching condition also potentially enhances the usefulness of the D-KEFS VF as a measure of executive function. Alternate forms of this test are available and administration time is ~10–15 min.

General intellectual ability

WASI. The WASI is a brief estimate of general intelligence for persons age 6:0–89 years (Wechsler, 1999). The Pediatric CDE Workgroup recommends using the two-subtest version of this instrument (i.e., vocabulary and matrix reasoning) (Wechsler, 1999). Although the WASI does not have specific sensitivity to mild injury severity, it has been shown to be sensitive to a range of neurologic conditions including moderate-to-severe TBI (Nosarti et al., 2007; Wechsler, 1999). Administration time for the vocabulary and matrix reasoning subtests is ~15 min depending upon ability level.

Memory

Rey auditory verbal learning test (RAVLT). This measure of word list learning is brief, available in the public domain, and covers a wide age range (5 years to older adult). The RAVLT is one of the most widely studied measures of cognition, has extensive normative data (Ivnik et al., 1992; Mitrushina et al., 2005; Schmidt, 1996), has been translated into many different languages (including Spanish), and has been used in diverse cultures and ethnic groups. It has sound psychometric properties and is sensitive to several neurologic conditions including TBI. The RAVLT was selected, in part, to maintain consistency with the adult CDE core measure of this domain (Wilde et al., 2010). Alternate forms are available and administration time is ~10–15 min.

California verbal learning test-children's version (CVLT-C). The CVLT-C (Delis et al., 1994) is a brief measure of verbal learning that is structured similarly to the RAVLT; however, the CVLT-C was specifically designed to deconstruct learning strategies and processes that allow for the identification of unique, disorder-specific profiles. The CVLT-C can be administered to children ages 5 to 16 years and there are now normative data available for 4- year-old children (Goodman et al., 1999). It has sound psychometric properties and has been shown to be sensitive to neurologic conditions including pediatric TBI (Donders and Hoffman, 2002; Donders and Minnema, 2004; Donders and Nesbit-Greene, 2004; Hoffman et al., 2000; Mottram and Donders, 2005, 2006; Roman et al., 1998; Salorio et al., 2005; Warschausky et al., 2005; Yeates et al., 1995). A Spanish version has also been developed (Rosselli et al., 2001). Administration time is ~10–20 min.

Both of the previous memory measures have been used extensively, so the Pediatric CDE Workgroup recommended either the RAVLT or CVLT-C as a memory measure for the core. The RAVLT offers several advantages. 1. It is consistent with the original CDE Workgroup recommendations (Wilde et al., 2010). 2) It is available free of charge. 3) It is being used as the validation measure for the memory instruments proposed by the NIH Toolbox. In contrast, the CVLT-C provides a more comprehensive set of indices to allow for the identification of disorder-specific profiles of deficits in learning strategies and processes and has a wider age range (down to age 4 years with supplemental normative data) with a substantial degree of validation in pediatric TBI research. Therefore, the Pediatric CDE Workgroup recommends that researchers and clinicians select the one measure of episodic memory that best matches their goals, needs, and available resources.

Motor and psychomotor functioning

No core measure was identified for this domain in an effort to maintain consistency with the core recommendations of the original Adult CDE Workgroup (Wilde et al., 2010). See Supplemental measures.

Visual–spatial functioning

No core measure was identified for this domain in an effort to maintain consistency with the core recommendations of the original Adult CDE Workgroup (Wilde et al., 2010). See Supplemental measures.

Physical functioning

WeeFIM (motor scale). Information about the complete measure has been described previously. The motor scale (8 self-care, 5 mobility items) was primarily selected as one of two options for core measures in this domain to assess motor function in the acute recovery phase.

PEDI mobility subscales. Information about the complete measure has been described previously. The mobility subdomain of this measure was selected as an alternative to the *WeeFIM* as a core measure of physical functioning in the acute recovery phase.

See section on adaptive and daily living skills regarding comparison of these measures for selection.

Psychiatric and psychological functioning

CBCL problem behaviors subscale. The CBCL parent, teacher, and youth self-report questionnaires (Achenbach, 1991) have been widely used to assess emerging and persistent behavior problems following pediatric TBI. The CBCL is designed for use with children ages 6 to 18 years. Subsets of items from the CBCL have also been analyzed to characterize sleep problems (Beebe et al., 2007), post-traumatic stress symptoms (Gragert et al., 2010), and ADHD (Chapman et al., 2010). Administration time for this subscale is ~10 min, and Spanish translations are available.

The strengths and difficulties questionnaire (SDQ). The SDQ (Goodman, 1997) is a brief, 25-item behavioral screening questionnaire for children ages 4 through 16 years (11 through 16 years for self-report) that is widely used in epidemiological, developmental, and clinical research (Carlsson et al., 2008; Clover, 2006; Goodman et al., 2000; Johnson et al., 2005; Olsson et al., 2008). Parent, teacher, and self-report versions are available. It has adequate concurrent and discriminant validity (Goodman, 1997), predictive validity (Goodman et al., 2000), and other critical psychometric properties (Goodman, 2001; van de Looij-Jansen et al., 2010). Extended versions assess the child's problems with respect to chronicity, distress, social impairment, and burden for others. Scoring and report generation is available online. The SDQ is available free of charge in a variety of languages (Klasen et al., 2000; Koskelainen et al., 2001; van Widenfelt et al., 2003). This measure is available in Spanish translation and many other languages. Administration time is ~ 5–10 min.

The Pediatric CDE Workgroup has recommended both the CBCL and SDQ as part of the CDE. Both have acceptable psychometric properties and translations in multiple other languages. The two measures are highly correlated (Goodman and Scott, 1999). When both the SDQ and the CBCL were compared to a semi-structured interview, the SDQ was significantly better than the CBCL at detecting aspects of inattention and hyperactivity, and was comparable at detecting internalizing and externalizing symptoms. The CBCL has been very broadly used to assess behavioral difficulties following pediatric TBI and there is some evidence that it is responsive to behavioral treatments for TBI (see Wade et al., 2006). However, the SDQ is increasingly used in studies of TBI outside of the United States, considerably shorter than the CBCL, and available without cost. Therefore, it may afford a useful alternative for those seeking a less intensive and costly measure. It is unclear whether the factor structure for the SDQ, derived outside of the United States, is comparable to United States samples, raising potential concerns about subscale analyses (Dickey and Blumberg, 2004).

Recovery of consciousness

Children's orientation and amnesia test (COAT). The COAT (Ewing-Cobbs et al., 1990) was designed to be used specifically with children after TBI and is administered at bedside to assess recovery of orientation and memory in children ages 3 to 15 years. The duration of post-traumatic amnesia (PTA) is defined as the number of days until COAT scores reach the cutoff for age-normed performance on 2 consecutive days. The items administered vary by age. The general orientation (7 items) and memory (4 items) questions are administered to all ages. Temporal orientation (5 items) is assessed only for ages 8–15 years because of the unreliability of scores and limited developmental data for younger children. The duration of PTA as measured by the COAT is related to acute indices of injury severity and to both long-term cognitive and functional outcomes. The COAT is also used during the sub-acute stage of recovery to estimate whether the child has attained age-appropriate orientation and is able to participate in standard psychometric assessments. Administration time is ~ 5–10 min.

Galveston orientation and amnesia test (GOAT). The GOAT (Levin et al., 1979) is administered to prospectively assess the duration of post-traumatic amnesia for subjects ≥16 years of age. The GOAT consists of 10 items that allow prospective assessment of recovery of orientation to person, place, and time, and provides a retrospective estimate of the duration of its utility in predicting both sub-acute and long-term functional and neuropsychological outcomes. Administration time is ~ 5–10 min. A Spanish translation is available.

Social role participation and social competence

PedsQL social subscale. The social subscale of the PedsQL measures childrens' perception of how well they get along and form friendships with peers. A detailed description of the complete measure appears previously.

SDQ-peer relations and prosocial behavior subscales. These subscales of the SDQ measure the child's perception of the quality of his or her peer interactions. A detailed description of the complete measure appears previously.

Social cognition

No core measure was identified for this domain.

TBI-related symptoms

Health and behavior inventory (HBI). The HBI (Ayr et al., 2009) is a 20-item rating scale that measures the frequency of 20 common post-concussive symptoms. Each symptom is rated on a scale from 1 (never) to 4 (often) based on its frequency over the past week. The scale's construct validity has been established through factor-analysis of cognitive and somatic symptoms. It has been used primarily with 8- to 15-year-old children and adolescents, but can be adapted to younger children and older adolescents. Both parent and child forms are available, including a parent form for rating pre-injury symptoms retrospectively. The HBI was selected as a core measure based on its sound psychometric characteristics, validity in distinguishing mild TBI from other injuries, and availability in the public domain. The scale has been used to investigate the outcomes of mild-to-severe TBI, and it is sensitive to various markers of injury severity (Fay et al., 2010; Hajek et al., 2011; Moran et al., In Press, Taylor et al., 2010). Administration time is ~ 5–10 min.

Supplemental Data Elements

Academic abilities

Woodcock-Johnson III tests of achievement (WJ-III). The WJ-III assesses a broad range of academic abilities (Woodcock et al., 2001). It is composed of two batteries (standard and extended) for a total of 22 subtests. There are two parallel forms as well as a Spanish translated version of this measure (Schrank et al., 2005). The WJ-III is extensively normed and has strong psychometric properties. The following subtests are recommended: letter-word identification, reading fluency, passage comprehension, word attack, calculation, math fluency, applied problems, spelling, writing fluency, and writing samples. The earlier version of this measure (Woodcock et al., 1989) was used in several outcome studies (Fay et al., 2009; Taylor et al., 1999, 2002; Yeates and Taylor, 1997). Subtests of the current revision of this measure have been used in pediatric TBI outcome studies (Ewing-Cobbs et al., 2006 a, b, 2008; Taylor et al., 2008). Administration time is ~ 5 min per subtest.

Gray oral reading test, 4th Edition (GORT-4). The GORT-4 (Wiederholt and Bryant, 2001) assesses oral reading fluency (rate and accuracy) as well as comprehension. This measure has strong psychometric properties, and has been found to be sensitive to reading difficulties in children with TBI (Ewing-Cobbs et al., 2006b, 2008). Administration time is ~ 20–30 min.

Adaptive and daily living skills

Vineland adaptive behavior scales, 2nd edition (VABS-II). The VABS-II is a comprehensive norm-referenced measure of adaptive and daily life functioning that taps four broad domains: communication, daily living, socialization and motor skills (Sparrow et al., 2005). There is also an optional maladaptive skills scale. The VABS-II is recommended as a supplemental measure. The VABS-II and the original VABS (Sparrow et al., 1984, 2005) have established evidence of reliability and validity and have been used in many pediatric TBI studies primarily for studying long-term sequelae, family functioning, and school adaptation (Hawley, 2004; Josie et al., 2008; Max et al., 1998; Taylor et al., 2002; Yeates et al., 2004). The VABS-II can be used with a broad age range of individuals (infancy to 89 years) and test procedures (i.e., age range allows for establishing accurate basal level) and is useful when working with low cognitive functioning populations such as those with severe TBI. Both caregiver interview and rating scale are available, but the rating scale is recommended. Administration time is ~20–60 min. A validated Spanish version of this test is available.

Family and environment

FAD-full scale. The 53-item FAD has been used in numerous studies with children with TBI and their families and has established evidence of reliability and validity (Epstein et al., 1983). The general functioning scale (FAD-GF) measures the family's overall health and pathology and was recommended as a core measure. The other six scales assess the six dimensions of the McMaster Model of Family Functioning: Problem Solving; Communication; Roles; Affective Responsiveness; Affective Involvement; and Behavioral Control. The complete FAD was also recommended as a supplemental measure for family members of adults with TBI (Wilde et al., 2010). The full scale takes ~10 min to administer and is free to use.

Family burden of injury interview (FBII). The FBII is a structured interview measuring injury-related stress and has been used in numerous studies of recovery following TBI (Taylor et al., 1999, 2001; Wade et al., 1998, 2003, 2004). The reliability and validity of this measure have been reported previously (Burgess et al., 1999). The FBII has been broadly used internationally; however, reliability and validity for the translated versions are lacking. A self-report version (recommended as an emerging measure) also exists but existing data are awaiting psychometric analyses. Administration time is ~ 20 min. The briefer self-report version is recommended as an emerging measure (discussed subsequently). Both versions are freely available.

Conflict behavior questionnaire (CBQ)/interaction behavior questionnaire (IBQ). Parent–adolescent communication and conflict behavior have been assessed using a 20-item short form of the CBQ, which is also known as the Interaction Behavior Questionnaire (IBQ) (Prinz et al., 1979; Robin and Foster, 1989). The CBQ is reliable and discriminates between distressed and non-distressed families. The CBQ/IBQ has been shown to be responsive to changes in family interactions as a consequence of family-centered treatments for pediatric TBI (Wade et al., 2008). Administration is ~ 5 min and the questionnaire is in the public domain.

Global outcome

Pediatric quality of life inventory. See Health-Related Quality of Life subsection of the Core Data Elements section for details on the complete measure.

Health-related quality of life

No supplemental measure was identified for this domain.

Infant and toddler measures

No supplemental measure was identified for this domain.

Language and communication

Comprehensive assessment of spoken language (CASL). The CASL (Carrow-Woolfolk, 1999) is an individually administered assessment of language processing skills (comprehension and expression) in four language categories (lexical/semantic, syntactic, supralinguistic, and pragmatic) for children and young adults ages 3 to 21 years. The CASL was selected as a comprehensive measure of language function and has been used in studies of pediatric TBI (Taylor et al., 2008; Turkstra et al., 2008). Its constituent tests also may be administered individually. Administration time is ~ 30–45 minutes for the core battery.

Clinical evaluation of language fundamentals, 4th edition (CELF-4). The CELF-4 (Semel et al., 2003) is a measure of language performance for children and young adults ages 5 to 21 years. The measure provides composite scores including: core language, receptive language, expressive language, language structure, language content, language memory, and working memory indexes as standard scores. An earlier version was used in studies of pediatric TBI (Hanten et al., 2009; Taylor et al., 2008). As the CELF-4 is available in a Spanish translation (Wiig et al., 2005), it was included as an alternative to the CASL when norms for Spanish-speaking children and adolescents are needed. Administration time is ~ 30–45 min.

Goldman-Fristoe test of articulation, 2nd edition (GFTA-2). The GFTA-2 (Goldman and Fristoe, 2000) is a standardized measure that assesses an individual's ability to produce 39 consonant sounds of Standard American English. The GFTA-2 provides information on an individual's speech-sound production skills in single words, sentences, and a controlled conversational context. Normative data are based on a national sample of 2350 examinees ages 2–21 years of age who were stratified to match the United States Census data on gender, ethnicity, region, and socioeconomic status as determined by the mother's education level. The GFTA-2 was selected as a supplemental test to provide more specific information on the speech articulation errors of children who failed the core caregiver unintelligible speech rating measure. The Sounds-in-Words section takes ~ 5–10 min to administer.

Peabody picture vocabulary test-4 (PPVT-4). The PPVT-4 (Dunn and Dunn, 2007) is a measure of receptive vocabulary skills and is often used as a screening test of verbal ability. It includes normative data for children and adults ages 2.6 to 90 years. It was standardized on a sample of 3500 subjects that matched the United States Census for gender, race/ethnicity, region, socioeconomic status, and clinical diagnosis for special education placement. At present, the PPVT-4 is normed on English-proficient subjects only, but a Spanish version of the PPVT-4 is under development. A Spanish version of the previous revised edition (i.e., PPVT-R), the Test de Vocabulario en Imágenes Peabody (TVIP) is currently available for Spanish-speaking children and adolescents (Dunn et al., 1986). Administration time is ~15 min.

Percentage of consonants correct (PCC). The PCC is a metric expressing the percentage of consonant sounds produced correctly in spontaneous speech, giving equal weight to speech-sound omissions, substitutions, and distortions (Shriberg et al., 1997). The PCC is derived from a conversational speech sample, which is more linguistically rich and ecologically valid than standardized articulation measures, particularly for young and severely impaired children (Campbell and Dollaghan, 1994; Campbell et al., 2007, 2009). PCC normative data are available for individuals from age 18 months to 21 years (Campbell et al., 2007; Shriberg et al., 1997). The PCC was selected as a supplemental measure to provide more detailed information about a child's consonant production skills in an extended conversational context. The measure has been used to investigate the longitudinal speech outcomes of children with moderate-to- severe TBI (Campbell et al., 2007). Administration time is ~ 15–20 min for sample collection and 60 min to transcribe.

Verbal motor production assessment for children (VMPAC). The VMPAC provides information about the integrity of the motor speech system in children (Hayden and Square, 1999). This standardized measure assesses three major areas of function: 1) global motor control; 2) focal oromotor control; and 3) sequencing of speech sounds. Normative data are available for individuals aged 3 to 12 years. The VMPAC was selected to identify children who have speech motor control deficits that affect the recovery and development of normal speech production. It has been used to examine the speech outcomes of children with various neurological deficits, including TBI. Administration time is ~ 30 min.

Test of language competence-expanded edition (TLC-E). The TLC-E (Wiig and Secord, 1989) was designed as a test of pragmatic language use, including production of context-appropriate sentences and comprehension of idioms. Although some of the idioms are no longer in current usage, the TLC-E has shown discriminant validity for children and adolescents with TBI in previous research (Dennis and Barnes, 1990; Hallett, 1997; Towne and Entwisle, 1993). Administration time is ~ 45–60 min.

Language sample. Language sample analysis is a nonstandardized method for evaluating communication skills. It is primarily used in research only because it is highly labor intensive. Two main transcription conventions and software programs are used: Systematic Analysis of Language Transcripts (Miller and Chapman, 2004) and CHAT, the coding language of the Child Language Data Exchange System (MacWhinney, 2000). Language sample analysis has been found to discriminate between children and adolescents with and without TBI in several studies (Biddle et al., 1996; Brookshire et al., 2004; Campbell and Dollaghan, 1990, 1994, 1995; Campbell et al., 2009; Chapman et al., 1992, 1997, 1998, 2004, 2006; Coelho et al., 2005; Dennis et al., 1994; Ewing-Cobbs and Barnes, 2002; Ewing-Cobbs et al., 1998a; Wilson and Proctor, 2002; Youse and Coelho, 2005). Content validity is high, as samples are taken with relevant partners (e.g., parents). Language samples often are more sensitive to group differences than are standard language measures. Administration time is ~ 5–10 minutes. Transcription and data analysis times vary depending upon the length of the sample, analysis software used, and type of analysis conducted.

Neuropsychological Impairment

Attention and processing speed

Connors' continuous performance test-revised (CPT-2). The CPT-2 (Conners, 2004) is a computerized test of sustained attention and response inhibition. It can be administered to persons from 6 to >55 years of age. The test takes 14 min to administer and requires the respondent to press a key in response to all letter stimuli excluding the 'X.' The CPT-2 is used frequently in evaluations of attention deficit/hyperactivity disorder, but has more limited use in pediatric TBI research.

Test of everyday attention for children (TEA-Ch). The TEA-Ch (Manly et al., 1999) is composed of nine tasks intended to measure attention processes in children and adolescents ages 6:0–16:11. The subtests can be combined to assess three main attention factors: 1) focused (selective) attention, 2) sustained attention, and 3) attentional control/switching. This measure has been shown to be sensitive to children with severe TBI (Anderson et al., 1998). There will be a new version of the measure available in 2012 with United States norms for use with persons aged 5–25 years. Administration time for the TEA-Ch is ~ 60 min.

Executive functioning

D-KEFS trail making (D-KEFS TM). The D-KEFS TM (Delis et al., 2001) consists of a visual cancellation condition, motor speed condition, and three conditions of a timed connect-the-circle visuomotor task based on the original Trail Making Test (Reitan and Wolfson, 1992). The procedure provides a contrast between the condition involving switching between numeric and alphabetic sequences that emphasizes executive function and the simpler conditions restricted to alphabetic sequencing or numeric sequencing without switching. Trail making tests have been shown to be sensitive to TBI in children (Bauman Johnson et al., 2010; Sroufe et al., 2010). The D-KEFS TM was selected as a supplementary test because it has been standardized on 1750 typically developing children ≥8 years of age, allowing comparison with D-KEFS Verbal Fluency and providing age-based percentile scores. Administration time is ~10–15 min.

Behavior rating inventory of executive function (BRIEF). The BRIEF is a behavioral rating scale of executive functions with forms for parents and teachers for children 5:0 to 18:11 years old (Gioia et al., 2000, 2003; Guy et al., 2004). A self-report form is available for the 11–22-year age range. It consists of behavioral regulation and metacognition indexes that have been identified by factor analysis of individual subscales. The three overall indexes (general executive composite, metacognition index, behavioral regulation index) have been shown to be sensitive to TBI severity and outcome (Chapman et al., 2010; Chevignard et al., 2009; Conklin et al., 2008; Donders et al., 2010; Gioia and Isquith, 2004; Gioia et al., 2002, 2010; Karunanayaka et al., 2007; Maillard-Wermelinger et al., 2009; Mangeot et al., 2002; Merkley et al., 2008; Muscara et al., 2008a, b; Nadebaum et al., 2007; Power et al., 2007; Sesma et al., 2008; Vriezen and Pigott, 2002; Walz et al., 2008; Wozniak et al., 2007). The BRIEF was selected as a supplemental measure to provide an evaluation of everyday executive function and because of its standardization on a large number of typically developing children, thus providing age-based standard scores. Administration time is ~10 min.

Contingency naming test (CNT). The CNT (Taylor et al., 1992) asks the child to name a series of colored shapes (circle, square, triangle) by their color or shape depending upon the rule specified in each of the four parts of the test. The CNT taps flexibility in response to the switching of the relevant responses. The child is given up to five trials to learn the rule; the criterion is errorless performance on one trial or completion of the five trials. Errors, self-corrections, and response latency are scored as is an index of cognitive flexibility. The CNT has been used primarily with children and adolescents 6 to 16 years old, but it could be given to older adolescents. Part 4 can be omitted for young children. The CNT was selected as a supplemental measure based on its good psychometric features, its sensitivity to TBI in children, and its availability in the public domain. The CNT has been used to study short- and long-term outcomes of moderate-to-severe TBI in children (Anderson et al., 2002; Muscara et al., 2008a) and it has been shown to predict social problem-solving skills. Administration time is ~15–20 min.

General intellectual

No supplemental measure was identified for this domain.

Memory

Wide range assessment of memory and learning-revised (WRAML-2). The WRAML-2 (Sheslow and Adams, 2003) is a measure of verbal and visual learning abilities in children, adolescents, and adults ages 5:0–90 years. The memory battery includes indices of: 1) verbal memory; 2) visual memory; 3) attention and concentration; and 4) working memory. The WRAML-2 also assesses delayed and recognition memory of verbal and visual materials. The WRAML-2 and its predecessor have been found to be useful in studies of pediatric TBI (Donders and Hoffman, 2002; Farmer et al., 1999; Williams and Haut, 1995; Woodward and Donders, 1998). The full battery requires ~1 h for the core subtests. This measure is currently not available in Spanish. Administration time is ~60 min for the core battery.

Test of memory and learning-revised (TOMAL-2). The TOMAL-2 (Reynolds and Voress, 2007) is a measure of verbal and visual learning abilities in children, adolescents, and adults aged 5–59 years. The TOMAL-2 includes three core index scores that can be completed in ~30 min: 1) verbal memory; 2) nonverbal memory; and 3) composite memory. The TOMAL-2 has supplementary composite indices including 1) verbal delayed recall; 2) learning; 3) attention and concentration; 4) sequential memory; 5) free recall; and 6) associate recall. Validation and normative data were obtained from a sample of >1900 children including several ethnic groups. The TOMAL-2 and its predecessor have been found to be useful in studies of pediatric TBI (Alexander and Mayfield, 2005; Lowther and Mayfield, 2004; Ramsay and Reynolds, 1995; Reynolds and Bigler, 1996). Administration time is ~ 30 min for the core battery.

As both measures (e.g., WRAML-2 and TOMAL-2) have excellent psychometric properties, researchers and clinicians are encouraged to select the one measure that best suits their needs.

Motor and psychomotor functioning

Grooved pegboard test (GPT). The GPT (Mathews and Kløve, 1964) is a manipulative dexterity test that has proven to be a sensitive indicator of brain functioning, with diminished performance noted even following milder injury. It is readily available, easy, and brief to administer. One drawback is that performance can be influenced by peripheral injury, such as arm or hand fracture, or problems with visual acuity. The GPT was selected to maintain consistency with the adult CDE core measure of this domain (Wilde et al., 2010). Administration time is ~ 5–10 min.

Visual–spatial functioning

WISC-IV / WPPSI-III block design. This Wechsler subtest is a brief measure of the ability to analyze and synthesize abstract visual information and visuoconstructive ability. This subtest can be administered to children 2:6–7:3 years (WPPSI-III) (Wechsler, 2002) and ages 6:0–16:11 years (WISC-IV) (Wechsler, 2003 a, b) and also to adults in studies of TBI that cross wide developmental levels (Prigatano and Gray, 2008; Prigatano et al., 2008). Administration time for this subtest is ~10–15 min.

Beery-Buktenica developmental test of visual–motor integration, 6th edition (Beery™ VMI). The Beery VMI (Beery et al., 2010) is a measure of visual–motor integration assessed through the copy of a series of increasingly challenging geometric figures. Normative data are available for children and adolescents aged 2 to 18 years. Adult normative data are also available. A short form is often used for children aged 2 to 8 years. Administration time is ~10–15 min.

Physical functioning

Gross motor function measure (GMFM-88, GMFM-66). There are two versions of the GMFM available, the GMFM-88 (Russell et al., 1989) and GMFM-66 (Russell et al., 2000). The GMFM-88 is the original criterion-referenced measure consisting of 88 items grouped in 5 dimensions of motor function: 1) lying and rolling; 2) sitting; 3) crawling and kneeling; 4) standing; and 5) walking, running, and jumping. The GMFM-66 is derived from the GMFM-88 using Rasch analysis. Responsiveness to change in motor function using the GMFM-88 after pediatric TBI has been demonstrated in multiple studies (Kuhtz-Buschbeck et al., 2003; Linder-Lucht et al., 2007; Thomas-Stonell et al., 2006) and the GMFM-66 as well as the GMFM-88 have recently demonstrated sensitivity and discriminant validity, with excellent test–retest reliability, for use in children and adolescents with TBI (Linder-Lucht et al., 2007). The GMFM was validated with children and adolescents from 5 months to 16 years of age and is appropriate for children with motor skills at or below those of a 5-year-old child without motor disability. Administration time for the GMFM-88 is 45–60 min; less for the GMFM-66. The test is free to use. Spanish and German translated versions are available.

The Peabody developmental motor scales, 2nd edition (PDMS-2). The PDMS-2 (Folio and Fewell, 2000) is an early childhood motor development program that provides in-depth assessment and training or remediation of gross and fine motor skills. The assessment is composed of six subtests that measure interrelated motor abilities that develop early in life. It is designed to assess the motor skills of children from birth through 5 years of age. Reliability and validity have been determined empirically. The normative sample consists of 2003 persons residing in 46 states. The PDMS-2 can be used by occupational therapists, physical therapists, diagnosticians, early intervention specialists, adapted physical education teachers, psychologists, and others who are interested in examining the motor abilities of young children. Subtests include reflexes, stationary, locomotion, object manipulation, grasping, and visual–motor integration. The subtests yield quotients for gross motor, fine motor, and total motor skills. Administration time is ~ 45–60 min.

Bruininks-Oseretsky test of motor proficiency, 2nd edition (BOT-2). The BOT-2 (Bruininks and Bruininks, 2006) is an eight-subtest standardized measure that assesses gross and fine motor proficiency including fine motor precision, fine motor integration, manual dexterity, bilateral coordination, balance, running speed and agility, upper-limb coordination, and strength, to yield four motor composites and one comprehensive measure of overall motor proficiency. It can be used with children, adolescents, and young adults 4 to 21 years of age. The BOT-2 is psychometrically sound and has been used successfully in discriminating among populations. It provides normative interpretation of subtest and composite scores, provides a profile analysis for individuals, and is increasingly used with children with TBI. Both the original and second editions have been increasingly used (Chaplin et al., 1993, Gagnon et al., 1998, Gagnon et al., 2004 a, b; Wallen et al., 2001). The BOT-2 requires 15–20 min (short form) or 45–60 min (complete battery) to administer.

Psychiatric and psychological functioning

Schedule for affective disorders and schizophrenia for school-age children: present and lifetime version (K-SADS-

P/L). The K-SADS-P/L (Kaufman et al., 1997) is a semi-structured interview that uses a systematic inquiry to assess symptom presence. Suggested verbal prompts assist in clarifying presence and severity of symptoms. The interview ascertains both lifetime and current diagnostic status according to DSM-IV criteria. It is administered to children and adolescents aged 6 to18 years. Administration time is ~75 min.

Screen for child anxiety related emotional disorders (SCARED). The parent and child versions of the SCARED (Birmaher et al., 1997, 1999; Hale et al., 2005; Monga et al., 2000) are 41-item self-report questionnaires measuring symptoms of DSM-IV defined anxiety disorders except for obsessive-compulsive disorder. It is available in multiple languages (e.g., German, Italian, and Chinese) and has been used in different cultures (Su et al., 2008; Weitkamp et al., 2010). Administration time is ~ 10 min.

Short mood and feelings questionnaire (SMFQ). The SMFQ (Angold et al., 1995; Costello and Angold, 1988) provides a brief assessment of core depressive symptoms and a screening measure for depression in child psychiatric epidemiological studies, with parallel versions for children and adolescents aged 6–17 years, and their parents. Administration time is ~ 5 min.

UCLA PTSD index for the DSM-IV. The UCLA PTSD Index for DSM-IV (Steinberg et al., 2004) is a set of self-report and parent-report instruments that screen for exposure to traumatic events and DSM-IV PTSD symptom criteria in school-age children (7–12 years) and adolescents (≥13 years). A parent-report version is available, as is a Spanish translation. These instruments provide brief (20 min) screening generating information about trauma exposure and resulting PTSD symptoms.

Alcohol, smoking, and substance use involvement screening test (ASSIST). The ASSIST (WHO ASSIST Working Group, 2002) was developed by the World Health Organization (WHO); has been validated in nine countries; and is easily administered, reliable and valid. Recently completed work indicates that the ASSIST is sensitive to change and specifically to the effects of a brief intervention (Humeniuk et al., 2008). Administration time is ~ 5–10 min.

Children's affective lability scale (CALS). The CALS (Gerson et al., 1996) is a 20-item parent report measure developed to assess affect regulation in children and adolescents aged 6 to 16 years. It was normed with school children in regular education classrooms and with children hospitalized in a psychiatric facility. Internal consistency reliability, split-half reliability, and two-week test–retest reliability were excellent. Staff inter-rater reliability in the psychiatric sample was acceptable. Higher CALS scores were observed in an inpatient psychiatric sample than in either an outpatient or a normative sample. A principal components factor analysis yielded two components for the normative sample. Administration time is ~ 5 min.

Children's motivation scale (CMS). The CMS (Gerring et al., 1996) is a 16-item parent report measure developed to evaluate level of motivation in children ages 6 to 16 years. The study population consisted of a normative sample of 290 school children and a clinical sample of 165 child and adolescent psychiatric patients. Test–retest, internal consistency, and inter-rater reliability were fair to good for both samples. Validity of the CMS was demonstrated by its ability to differentiate clinical from normative samples according to the level of motivation, by a significant correlation of the CMS with an independent measure of withdrawal, and by its lack of correlation with an independent measure of depression. Principal components analysis identified a three-component structure. Administration time is ~ 5 min.

Modified overt aggression scale (MOAS). The MOAS (Kay et al., 1988) is a version of the original Overt Aggression Scale (Yudofsky et al., 1986) that has been revised to improve psychometric properties. The MOAS is a rating scale measuring aggressive behaviors in children and adults in four domains: physical aggression against 1) objects, 2) self, 3) others, and 4) verbal aggression. Administration time is ~ 5 min.

Recovery of consciousness

No supplemental measure was identified for this domain.

Social role participation and social competence

Child and adolescent scale of participation (CASP). The CASP is a parent/guardian report measure that assesses participation in home, school, and community settings (Bedell, 2004, 2009; Ziviani et al., 2010). It includes 20 items that broadly examine children's participation compared to children of the same age. Items address social and leisure activities, school activities, and independent and daily living activities such as self-care, family and household chores, shopping, money management, transportation use, and work. The CASP has been used in studies with children and youth with TBI in the United States and worldwide (Bedell and Dumas, 2004; Galvin et al., 2010; Wells et al., 2009; Ziviani et al., 2010). Reliability and validity evidence have been reported (Bedell, 2004, 2009). Administration time is ~ 5–10 min.

Social skills rating scale (SSRS). The SSRS (Elliott et al., 1988) measures positive social behaviors in the domains of 1) cooperation, 2) empathy, 3) assertion, 4) self-control, and 5) responsibility, while also providing problem behavior scales of externalizing and internalizing problems, and hyperactivity. An academic competence scale is also available from teacher report. The instrument is appropriate for use with children and adolescents aged 3–18 years. Administration time is ~ 25 min.

CBCL social competence subscale. See Psychiatric and Psychological Functioning section of core measures for a detailed description of the complete measure.

VABS-II socialization subscale. See Adaptive and Daily Living Skills section of supplemental measures for a detailed description of the complete measure.

PEDI social function subscales). See Adaptive and Daily Living Skills section of core measures above for a detailed description of the complete measure.

Social cognition

No supplemental measure was identified for this domain.

TBI-related symptoms

Post-concussion symptom inventory (PCSI). The PCSI (Gioia et al., 2009) is a rating scale measure of post-concussive symptoms in physical, cognitive, emotional, and sleep domains. It has three different self-report forms for children and adolescents of different ages (ages 5–7, 13 items; ages 8–12, 25 items; ages 13–18, 26 items) and one 26-item form for parents and teachers. Each symptom is rated on either a 3-point Likert scale (for 5–7- and 8–12- year old children) or 7-point Likert scale (for parents and teachers of adolescents aged 13–18 years). The factor structure of the scale has been examined. Although the age range of this inventory is more limited than for the core measures, the PCSI was selected as a supplemental measure because of its sound psychometric characteristics, promising indications of validity in distinguishing mild TBI from other injuries, applicability to younger children, and availability in the public domain. It was selected as a supplemental rather than a core measure because, compared to the Health and Behavior Inventory, it has less empirical validation. Administration time is ~ 10–15 min.

Emerging Data Elements

Academics

Comprehensive test of phonological processing (CTOPP). The CTOPP (Wagner et al., 1999) assesses three skills related to reading: phonological awareness, phonological memory, and rapid naming. The first level, developed for individuals aged 5 and 6 years (primarily kindergartners and first graders), contains seven core subtests and one supplemental test. The second level, for individuals age 7 to 24 years (persons in second grade through college), contains six core subtests and eight supplemental tests. To date, one subtest of this task has been used in at least one study on outcome from childhood TBI (Ewing-Cobbs et al., 2008). Administration time is ~ 30 min.

KeyMath 3 diagnostic assessment. The KeyMath-3 (Connelly, 2007) evaluates understanding and application of mathematical concepts and skills. The 10 subtests are grouped into three factors: 1) basic concepts, 2) operations, and 3) applications. This measure has good psychometric properties and has potential to elucidate mathematical skills in children with TBI. To date, there are no published studies on this task with children with TBI. Administration time is ~ 30–90 min depending upon the child's age.

Test of word reading efficiency (TOWRE). The TOWRE (Torgesen et al., 1999) assesses reading development by examining two aspects of word reading skills: the ability to accurately recognize familiar words and the ability to decode new words (nonsense words) quickly. The test is composed of two subtests, lasting 45 sec each. Each subtest has two forms (A and B) that are of equivalent difficulty. The test is normed for individuals aged 7 to 24 years.

Adaptive and daily living skills

Adaptive behavior assessment system®, 2nd edition (ABAS-II). The ABAS-II is a comprehensive norm-referenced measure of adaptive functioning (Harrison and Oakland, 2003). The ABAS-II and original ABAS have been used often with children and adults (infancy to 89 years) with developmental and intellectual disabilities (Harrison and Oakland, 2000, 2003; Rust and Wallace, 2004). The ABAS-II has four domain composite scores (conceptual, social, practical, and general adaptive composite) and 10 skill area scores (communication, community use, functional academics, health and safety, home or school living, leisure, self-care, self-direction, social, and work). Motor skill area scores are available on the two forms appropriate for children up to age 5 years. Although the ABAS-II has evidence of reliability and validity (Harrison and Oakland, 2003; Rust and Wallace, 2004), there are limited published studies in children with TBI (Catroppa et al., 2009; Muscara et al., 2009; Yeates et al., 2010). A Spanish translated version of this measure is available from the publisher. Administration time is ~ 15–20 min.

Mayo–Portland adaptability inventory, 4th edition (MPAI-4). The MPAI-4 broadly taps multiple domains such as daily and community living skills (e.g., self-care, household activities, work), behavioral, cognitive, emotional, physical, and social functioning. The MPAI-4 has established reliability and validity evidence for use with adults with TBI, is frequently used with adults with TBI in rehabilitation and community settings, and therefore was recommended as a supplemental measure for adults with TBI (Malec et al., 2003; Wilde et al., 2010) The MPAI-4 was modified for use with children and youth with TBI and acquired brain injury in inpatient and outpatient rehabilitation settings. It has preliminary evidence of validity and reliability and clinical utility based on one study with a sample of children and youth with acquired brain injury from one hospital (Oddson et al., 2006). Potential limitations in scoring were reported, such as underestimating extent of disability in younger children (Oddson et al., 2006). The MPAI-4 is available in multiple languages. Therefore, the MPAI-4 is recommended as an emerging measure for youth with TBI and youth with TBI transitioning to adulthood. A Spanish translated version is available (http://www.tbims.org). Administration time is ~ 20–25 min.

Family and environment

FBII—self report. In contrast to the FBII Interview, the FBII self-report can be completed in ~ 5 min and can be completed by parents and other guardians of children with TBI of all ages. Data on ~ 300 families of children with TBI have been collected worldwide and are awaiting further psychometric analyses (Burgess et al., 1999). Administration time is ~ 5 min.

Child & adolescent scale of environment (CASE). The CASE is an 18-item parent report inventory that examines the extent of physical, social, and attitudinal environmental problems that could hinder children's participation in home, school, and community settings. Problems identified include negative attitudes of others, inadequate or lack of resources (i.e., information, finances, supports, services, programs, transportation, or equipment) and crime or violence in the community. The CASE is a developing instrument with evidence of reliability and validity and has been used in a number of studies with children and youth with traumatic and other acquired brain injuries (Bedell, 2004, 2009; Bedell and Dumas, 2004; Galvin et al., 2010; Wells et al., 2009; Ziviani et al., 2010). The CASE is an adaptation of the Craig Hospital Inventory of Environment Factors (CHIEF) (Whiteneck et al., 2004) which has been used primarily with adults with TBI and other disabling conditions, and more recently with children with disabilities (Law et al., 2007). The CASE was selected over the CHIEF because the CASE has been used in a number of studies specific to children and youth with TBI and acquired brain injury (Ziviani et al., 2010). The CASE can be administered in ~ 5 min.

Global outcome

Pediatric test of brain injury (PTBI). The PTBI (Hotz et al., 2010) is specifically designed for use in children and adolescents 6 to 16 years of age who are recovering from TBI. The PTBI is presented in an interview format with the focus on cognitive and academic skills. This measure was selected as an emerging measure based upon its specific use and validation in children with acquired brain injury or TBI and its potential usefulness across the spectrum of recovery. Administration time is ~ 30 min.

Health-related quality of life

Patient-reported outcomes measurement information system (PROMIS). The PROMIS (Ader, 2007) is a new measurement system that is part of the NIH Roadmap for Medical Research to improve the clinical research enterprise, and it was included as an emerging element for the original CDE. The PROMIS network has developed and tested a large bank of items measuring patient-reported outcomes over several domains in children including: anxiety, asthma, depressive symptoms, fatigue, mobility, pain, peer relations, and upper extremity functioning. Item banks have been calibrated allowing the test to be administered as a computerized adaptive test or as short forms to ensure brevity. Researchers can select domains of functioning relevant to their specific research question. The PROMIS is designed as a generic measure that is to be used across all medical populations. Administration time varies depending upon domain selection.

Neuro-QOL. The Neuro-QOL is a patient-reported outcome measurement system funded through a contract method by the National Institute on Neurological Disorders and Stroke (NINDS) (Miller et al., 2005; Perez et al., 2007). The Neuro-QOL for children assesses the following domains: anger, anxiety, applied cognition, depression, fatigue, pain, social relations, and stigma. A significant number of PROMIS items are embedded in the Neuro-QOL domains. The Neuro-QOL was designed to be a common outcome variable across all clinical trials research sponsored by the NINDS, and was also included in the original adult CDE as an emerging measure. Spanish translations are available. Administration time varies.

Infant and toddler measures

Shape School. The Shape School test (Espy, 1997) is a measure of inhibition and executive control for children ages 3 to 6 years. This task utilizes a story book format and familiar concepts such as colors, facial expressions, and shapes, to assess inhibition as well as switching. Shape School has been found to be sensitive to developmental changes in executive functions. This measure has excellent potential to elucidate emerging executive functions in young children. Administration time varies depending upon the child's age.

Trails-preschool (Trails-P). The Trails-P (Espy and Cwik, 2004) was developed for children ages 3 to 5 years as a downward extension of the Trail Making Test (Reitan and Wolfson, 1992). This preschool measure uses a storybook format to assess psychomotor speed, complex attention, and executive functions. Children stamp dogs in order of size and then bones in order of size. Reversal and distraction conditions are included as well. This measure has been found to capture development changes in executive functions. To date, there are no published studies using this measure in children with TBI. Administration time varies depending upon the child's age.

Language and communication

No emerging measure was identified for this domain.

Neuropsychological Impairment

Attention and processing speed

Flanker task. The Eriksen Flanker Test (Eriksen and Eriksen, 1974) is a computer-based measure of response inhibition. In the neutral condition, the participant is presented arrow stimuli one at a time and is required to make a response on the keyboard (e.g., press a key on the left side of the keyboard for an arrow pointing to the left). The stimuli can be "flanked" by arrows that are either facilitating/congruent (pointing in the same direction as the target stimulus) or incongruent (pointing in opposite direction to target stimulus). Differences between the incongruent and neutral reaction times are used as a measure of response inhibition or cognitive control; longer reaction times are associated with poorer cognitive control (Levin et al., 2004). Currently, there are no normative data available and the measure has not been standardized. Administration time varies depending upon the task version used.

Executive functioning

Tasks of executive control (TEC). The TEC (Isquith et al., 2010) is a standardized computer-administered measure that integrates two neuroscience methods commonly used to tap working memory and inhibitory control: an n-back paradigm that parametrically increases working memory load and a go/no-go task to manipulate inhibitory control demand. The TEC was standardized on a large and representative sample and has demonstrated reliability and concurrent validity with clinical populations including those with mild TBI. Administration time is ~ 20–30 min.

Test of strategic learning (TOSL). The TOSL (Chapman Submitted) is a measure of higher-order verbal reasoning that assesses the ability to extract meaning from complex information at two levels. At a basic level, TOSL measures the ability to learn important facts from texts. At a higher level, TOSL measures the ability to derive global, abstracted meanings from explicit text through gist reasoning. The TOSL provides two core scores relevant to measuring ability to abstract meaning from complex information. One score examines gist reasoning ability through written summaries coded for abstracted ideas, and the other measures fact learning through probe questions that require explicit short answers. TOSL has been used extensively in the 7 to 20-year age range in normal and clinical populations including those with acquired brain injury. Administration time is ~ 15–20 min.

The TOSL was selected as an emerging measure because, although not yet published, it provides a functional measure of the strategies a student uses to understand and encode meaning from information that is much like what is encountered in the classroom and everyday life. The TOSL provides a measure of cognition that is not available in typical standardized tests that rely on multiple choice answers. The validity of the TOSL as a measure of higher order cognitive function has been established in prior studies conducted across 15 years of research in cognitive neuroscience (Chapman et al., 2012; Gamino et al., 2010). Moreover, gist reasoning ability as measured by the TOSL has been associated with frontally mediated measures of executive function such as working memory, concept abstraction, cognitive switching, and fluid reasoning.

Functional assessment of verbal reasoning and executive strategies – student version (FAVRES-S). The FAVRES-S (MacDonald, In Press) assesses a child's ability to verbally reason and execute strategies using written and oral responses. This measure yields standard scores as well as reasoning subscale scores of: 1) getting the facts; 2) eliminating irrelevant material; 3) weighing facts; 4) flexibility; 5) predicting consequences; and 6) a total reasoning score. This measure includes items that are similar to everyday life (e.g., planning an event, scheduling, making a decision, and problem solving). The FAVRES is sensitive to impairments in high-functioning individuals (MacDonald, 1998). The adult version of the FAVRES has been shown to discriminate well those with TBI from typically developing individuals (MacDonald and Johnson, 2005) and also has been validated in relation to return to work (Isaki and Turkstra, 2000; MacDonald and Johnson, 2005). Administration time is ~ 60 min.

General intellectual

No emerging measure was identified for this domain.

Memory

No emerging measure was identified for this domain.

Motor and psychomotor functioning

No emerging measure was identified for this domain.

Visual–spatial functioning

No emerging measure was identified for this domain.

Physical functioning

PROMIS mobility and upper extremity functioning domains. See Health-Related Quality of Life subsection of the Emerging Data Elements section for details on the complete measure.

Neuro-QOL mobility/ambulation domain. See Health-Related Quality of Life subsection of the Emerging Data Elements section for details on the complete measure.

Psychiatric and psychological functioning

No emerging measure was identified for this domain.

Recovery of consciousness

No emerging measure was identified for this domain.

Social cognition

Interpersonal negotiation strategies (INS). The INS (Yeates et al., 1990) is a measure of social problem-solving ability through a semi-structured interview in which participants are presented scenarios depicting social conflicts. Participants are asked questions addressing four problem-solving steps: defining the problem, generating alternative strategies, selecting specific strategy, and evaluating outcome. The original sample included 95 children and adolescents aged 6 to 16 years from the Northeast United States. The INS interview and scoring system has demonstrated internal reliability and predictive validity with pediatric TBI research (Janusz et al., 2002; Yeates et al., 1991) and has been used in other pediatric TBI studies (Hanten et al., 2008). Administration time is ~ 30 min.

Reading the mind in the eyes test:child version. This test assesses the ability to recognize emotions and mental states in photographs of eyes of adults (Baron-Cohen et al., 2001). Developed for use in autism, it also has been used in TBI (Tonks et al., 2007, 2008). Social cognitive functions, including emotion recognition, are increasingly recognized as factors in psychosocial outcome studies of typically developing children and adults. This measure is considered emerging because of its limited use in studies of children with TBI. Currently, there are no normative data available and the measure has not been standardized. Administration time is ~ 20 min.

Video social inference test. This measure assesses ability to make social inferences (e.g., familiarity judgments, sarcasm comprehension, and detection of social behavior violations) in video vignettes (Turkstra, 2008). It was developed for use with adolescents with TBI (Stronach and Turkstra, 2008; Turkstra et al., 2001) and has been used with adults with TBI (Turkstra, 2008). Social cognitive functions, including emotion recognition, are increasingly recognized as factors in psychosocial outcome studies of typically developing children and adults. Currently, there are limited normative data available and the measure has not been standardized. Administration time is ~ 20 min.

TBI-related symptoms

No emerging measure was identified for this domain.

Measures that span multiple domains

National Institutes of Health toolbox (NIH toolbox: cognitive, emotional, motor, sensory). The NIH Toolbox is part of the NIH Blueprint for Neuroscience Research initiative. It seeks to assemble brief, comprehensive assessment tools that will be useful in a variety of settings with a particular emphasis on measuring outcomes in epidemiologic studies and clinical trials across the lifespan. The ultimate goal is to help improve communication within and among fields of biomedical research to advance knowledge by using common data elements. The battery will examine various cognitive (episodic memory, language, processing speed, working memory, executive functions, attention), emotional (negative affect, positive affect, stress and self efficacy, social relationships), sensory (vestibular, audition, olfaction, taste, vision and somatosensation) and motor functions (dexterity, strength, locomotion, endurance, balance). The battery is designed to measure these domains in individuals ages 3 through 85 years, will be available at a nominal cost, and will take no more than 2 h to administer. The battery has gone through extensive work to identify and pre-test the constructs to be measured. Validation has been completed, and norming will be soon underway (please see http://www.nihtoolbox.org for additional information).

Future Issues and Research Needs

The Pediatric CDE Workgroup identified several challenges and areas where additional research would enhance outcome measurement in TBI. First, selection of measures that span a wide age range is complicated given the dramatic developmental changes that occur in this spectrum of age. Second, as indicated in the discussion on emerging measures, there is a need for further validation and testing of measures such as the NIH Toolbox to specifically evaluate their utility in TBI. Third, measures that specifically address impairments in infants and toddlers are quite limited, and measures that do exist for this age range may require further testing in infants and toddlers with TBI. Fourth, research could benefit from the establishment of normative data that span broader age ranges, take into account multiethnic and multiracial diversity, and are available via multiple equivalent forms, as well as being available in Spanish and other foreign languages. Consideration needs to be given to additional brief measures in the domain of neurological functioning. Fifth, the Pediatric CDE Workgroup acknowledged the need for additional measures of executive functioning, prospective memory, and social cognition that keep pace with theoretical developments in clinical neuroscience. Finally, psychosocial and moderator variables (e.g., socioeconomic status, family environment, gender, duration and intensity of treatment, genetics and epigenetic factors) are particularly relevant in studies of pediatric TBI, and researchers are urged to consider the impact of variables on outcome (e.g., see the *Psychosocial Adversity Index* as detailed in Wade and Gerring).

Summary

In accordance with other CDE Workgroups, three tiers of CDE for pediatric TBI outcomes were recommended: 1) core measures covering outcome domains relevant to most TBI studies that could be applied either as a comprehensive battery or in addition to other outcome measures selected by the investigator; 2) supplemental measures for consideration in TBI research focusing on more specific topics or subpopulations; and 3) emerging measures, which include promising instruments currently under development, in the process of validation, or nearing the point of published findings that have significant potential to be superior to some measures currently in the core and supplemental lists. The selection of the CDE measures is intended to facilitate comparison of findings from large-scale research efforts designed to document the natural course of recovery from pediatric TBI, enhance the prediction of outcome, and/or measure the effects of treatment; however, *these measures are neither intended as prescriptive nor should they to be considered required elements of a research project*. The Pediatric CDE Workgroup acknowledges that although these measures were chosen after substantial review of available evidence and discussion among the group, any selection of CDE is a dynamic process that must accommodate some shift and evolution in the measures within each category as new evidence emerges and selected measures continue to be tested.

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Author Disclosure Statement

The following authors report a financial conflict of interest as an author or co-author of assessment instruments recommended by the Workgroup from which royalty income is/will be generated:

Vicki A. Anderson (Test of Everyday Attention for Children). Note that Dr. Anderson was not involved in the discussions regarding the inclusion/exclusion of this measure.
Sandra B. Chapman (Test of Strategic Learning)
Gerard Gioia (Behavior Rating Inventory of Executive Function and the Tasks of Executive Control)

The following authors report conflicts of interest inasmuch as they are authors or co-authors of the assessment instruments recommended by the Workgroup, but they report no financial conflicts of interest in connection with these instruments:

Sue R. Beers (Glasgow Outcome Scale-Extended Pediatric Revision)
Gary Bedell (Child and Adolescent Scale of Participation and the Child and Adolescent Scale of Environment)
Linda Ewing-Cobbs (Children's Orientation and Amnesia Test)
Joan P. Gerring (Children's Affective Lability Scale and the Children's Motivation Scale)
Lyn S. Turkstra (Video Social Inference Test)
Shari L. Wade (Family Burden of Injury Interview)
Keith O. Yeates (Health and Behavior Inventory and Interpersonal Negotiation Strategies)

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Stephen R. McCauley, Elisabeth A. Wilde, Thomas F. Campbell, , Harvey S. Levin, Linda J. Michaud, Mary R. Prasad, and Bonnie R. Swaine.

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