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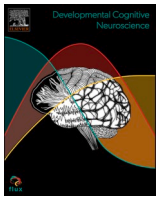

Capturing the complexity of child behavior and caregiver-child interactions in the HEALthy Brain and Child Development (HBCD) Study using a rigorous and equitable approach

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ABSTRACT

The HEALthy Brain and Child Development (HBCD) Study, a multi-site prospective longitudinal cohort study, will examine human brain, cognitive, behavioral, social, and emotional development beginning prenatally and planned through early childhood. This article outlines methodological considerations and the decision-making process for measurement selection for child behavior, parenting/caregiver-child interactions, and the family/home environment for HBCD. The decision-making process is detailed, including formation of a national workgroup (WG-BEH) that focused on developmentally appropriate measures that take a rigorous and equitable approach and aligned with HBCD objectives. Multi-level-observational and caregiver-report measures were deemed necessary for capturing the desired constructs across multiple contexts while balancing the nuance of observational data with pragmatic considerations. WG-BEH prioritized developmentally sensitive, validated assessments with psychometrics supporting use in diverse populations and focused on mechanistic linkages and prediction of desired constructs. Other considerations included participant burden and retention, staff training needs, and cultural sensitivity. Innovation was permitted when it was grounded in evidence and filled key gaps. Finally, this article describes the rationale for the selected constructs (e.g., temperament, social-emotional development, parenting behaviors, family organization) and corresponding measures chosen for HBCD visits from early infancy through 17 months of age.

The HEALthy Brain and Child Development (HBCD) Study is a national consortium study that aims to better understand how brain and child development is affected by exposure to various adverse and protective environmental, social, and biological factors during pregnancy and after birth. This study is enrolling over 7000 diverse pregnant individuals and their children at 27 sites across the U.S. and following them from pregnancy through early childhood (Nelson et al., this issue). Specific goals of the HBCD Study include characterizing typical neurodevelopmental trajectories of young children; identifying key developmental windows during which exposure to substances, poverty, other stressors, and protective influences have the greatest impact on neurodevelopment; and assessing the impact of early caregiver-child relationships on risk and resilience pathways, all within an equitable lens. The purpose of this article is to describe the conceptualization, methodological considerations, and decision-making processes involved in selecting specific constructs and measures under the broad umbrella of "child behavior and caregiver-child interaction" for HBCD.

1. WG-BEH: Child Behavior and Caregiver-Child Interactions Workgroup

The selection of protocols administered within HBCD is driven by multiple workgroups composed of HBCD investigators who are experts in specific domains. The workgroups are overseen by the HBCD

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Consortium Administrative Core (HCAC) and Steering Committee. The Child Behavior and Caregiver-Child Interactions Workgroup (WG-BEH) was formed to select constructs and assessments related to child behavior, parenting and caregiver-child interactions, and the family and home environment. Initial selection of domains within the WG-BEH purview were developed with HCAC input but ultimately decided upon by the WG-BEH chairs and members.

1.1. Decision making principles

WG-BEH decisions were guided by several overarching principles. Given the large coverage area that could be subsumed under the domains of "child behavior" and "caregiver-child interactions," the workgroup selected specific constructs and measures to align with the HBCD Study design (see Fig. 1) that were also (1) responsive to study aims; (2) measurable during early childhood in a developmentally meaningful way (birth to 5 years); (3) pragmatic for implementation in a large national consortia; (4) relevant and valid for families from diverse cultural and sociodemographic backgrounds; (5) distinct from those being identified by other workgroups (e.g., neurocognition, caregiver mental health); and, (6) that allowed continuity with the Adolescent Brain Cognitive Development (ABCD) Study (abcdstudy.org), when developmentally appropriate and relevant (Morris et al., 2020). In addition, WG-BEH prioritized constructs that have (1) established neural correlates; and/or (2) documented sensitivity to the effects of in utero substance exposures and other prenatal and postnatal environmental exposures; and/or (3) potential relevance for modifying/moderating exposure effects on developmental trajectories. In prioritizing domains, WG-BEH was cognizant of including measures that assess protective and promotive factors as well as those that assess risk and areas of concern. Following an iterative process of discussions and review, WG-BEH selected essential domains of study that could be assessed within the study design.

1.2. Measure selection decisions

WG-BEH identified measures that mapped onto the chosen construct domains. Measure selection was also guided by a number of principles, including that chosen assessments (1) were valid with diverse populations and during the relevant ages of assessment; (2) could be repeated across time to detect changes in development and/or caregiver-child relationships; (3) were available and validated in English and Spanish or could be translated; (4) were feasible to administer in a variety of settings; (5) minimized participant and investigator/staff burden (i.e., costs, time, equipment, training, managing complexity of required data collection) without sacrificing construct validity; and (6) when possible, could be administered remotely and/or flexibly to accommodate family needs. Some measures were specifically adapted for use in HBCD when existing measures were prohibitively long or complex, and newer measures were considered to assess important constructs for which established measures were not available. Each measure was assigned two to three subject matter experts (SMEs) from WG-BEH. SMEs were responsible for incorporating the measure into the HBCD protocol at multiple stages (e.g., adapting for HBCD usage, presenting to the Steering Committee for review and protocol adoption, overseeing ongoing data quality).

1.3. Considerations for diversity, equity, and inclusion (DEI)

HBCD's core values statements include supporting participation of families from all sociocultural backgrounds to reflect the rich diversity of families in the United States (https://hbcdstudy.org/values/). Assessing child behavior and caregiver-child interactions across diverse participants from different cultural, geographic, and experiential backgrounds is essential for achieving HBCD scientific goals. WG-BEH strived to include culturally sensitive assessments, or those that measure child behavior and caregiver-child interaction in a way that represents the perspectives of participants from varied cultural backgrounds (Mikkonen et al., 2022). In addition, it is important that such assessment tools are valid, meaningful, and function equitably across racial and ethnic groups.

DEI considerations were central to deliberations when selecting and adapting measures for use in HBCD. Diverse cultural backgrounds and changes in societal arrangements have expanded what was once considered the traditional definition of family; for example, family members may not live together, and children may be cared for by extended family or non-family members at various times. In addition, past research on parenting and parent-child relationships has had a strong history of gender bias, with a focus primarily on mothers and heterosexual parents (Patterson, 1992, 2006). Thus, as often as possible,

Fig. 1. Timeline of HBCD Study Visits 1–5.

measures were edited so that terms such as mother, father, and parent were adapted to apply to a variety of caregiving environments and to include non-biased language and gender inclusiveness (e.g., "caregiver"). WG-BEH also examined the ableist assumptions (e.g., Bottema-Beutel et al., 2021) of commonly used assessments of parents and children and adapted the administration of the observational assessments to be inclusive of caregivers and children with a range of abilities. Additionally, caregiver-report measures needed to be accessible to people with different reading levels, access to technology, and digital literacy.

The most recent U.S. Census indicated that, after English, Spanish was by far the most common language spoken in the U.S. (U.S. Census Bureau, 2020). While it would be ideal to include families who speak all languages in HBCD, the consortium decided to limit participation to English and Spanish speakers. This decision was made to ensure that individuals who speak the two most common languages have access to all aspects of the study, including recruitment materials, consent forms, measures, and bilingual research staff. Unfortunately, translating all materials and hiring staff fluent in multiple languages would present significant logistical challenges and reduce the likelihood of study-wide success.

To facilitate adherence to HBCD's core DEI values, all WG-BEH recommended measures were reviewed by the HBCD DEI workgroup (WG-DEI). Both the WG-DEI and WG-BEH include scholars who have studied diverse families and communities, and members with lived experience of various languages and cultures. The WG-BEH also consulted with experts within HBCD and the broader field of child development regarding antiracist measures and inclusion of those who have been historically underrepresented in research (Iruka et al., 2022; Zgierska et al., 2024). The WG-DEI provided feedback around gender bias, nuclear family assumptions, ableist assumptions, racially or culturally biased items, and use of coded language (Murray & Slopen, this issue). In response to DEI concerns, WG-BEH SMEs consulted with measure creators when possible to obtain permission and ensure that the proposed changes did not threaten measure validity. In rare instances of disagreement or unresolved DEI issues concerning measures within WG-BEH, various steps were taken: the measure creator was consulted; alternative measures were explored; and/or an anonymous poll was administered to workgroup members, and, if the majority voted in favor of the measure, it was presented to the HBCD Steering Committee for final decision.

1.4. Inclusion of observational measures

WG-BEH concluded that both caregiver-report and observational measures were essential for assessing child behavior and caregiver-child interactions (Morris et al., 2020). Caregiver reports are invaluable and have the advantage of ease of administration and leveraging of caregivers' historical knowledge of their children's development and functioning across a range of contexts. Observational assessments provide ratings of child behavior that complement caregiver reports, which can be prone to bias due to caregivers' difficulty objectively rating behavior (Briggs-Gowan et al., 1996; Hay et al., 1999; Morris et al., 2020; Wakschlag et al., 2005). Observational measures provide a more standardized assessment of the child's development and may add precision in detection of prenatal exposure effects, despite the added burden in terms of time, cost, and training (Massey et al., 2020). The ecological validity they afford and their unique capacity to capture families' lived experience is also critical for advancing an equitable and anti-racist science (Iruka et al., 2022; Weisleder et al., in preparation).

Unfortunately, observational assessment has had limited traction as big data approaches have gained momentum for large-scale neurodevelopmental consortia. This may be due in part to their relative burden for data acquisition (e.g., often done in a laboratory or home setting requiring a lengthy family visit) and time intensive coding (e.g., extensive training and coding time that is 3–4x longer than the observational paradigm itself). Recognizing the need to balance pragmatics with developmentally sensitive methods, WG-BEH proposed including a series of standardized observational assessments adapted for HBCD to efficiently capture caregiver-child interactions and child behavior, which will then be coded by a centralized coding team. This ensures that observational data will be available for public release in a timely fashion, in parallel to the rigor and quality of the neural data (Morris et al., 2020).

1.4.1. One-pass coding

Traditionally, observational coding is a lengthy process that includes extensive training and a multi-pass approach, requiring hours to code each task. This approach is not tenable for use in a large national consortium, with its large sample size, and imperative for rapid public release of data. Thus, a WG-BEH subgroup developed an adapted coding scheme that retains the "essence" of constructs captured by established, validated codes while distilling them to a simpler form that would enable a reliable "one-pass" coding method (Morris et al., 2020). This approach requires sacrificing some nuance while ensuring that observational methods could be incorporated into the core HBCD protocol. While not common, there is precedence for one-pass coding to be used successfully in developmental research (Crnic et al., 2005; Stevenson and Crnic, 2013).

In one-pass coding, coders rate activities during a single video viewing, without pausing or replaying, requiring simplification and reduction in the number of codes. A master coder model is used to ensure coder reliability, with 20 % of videos double coded. A specialized training manual is being developed to generate bias awareness and reduce implicit bias in the coding process. This approach is employed at initial coding to reliability and in a standard monitoring and discussion process throughout the data collection period.

1.4.2. Equity in observational assessment

Recent heightened awareness of structural and methodologic inequities "baked into" psychological and other research methods, as well as implicit bias, has propelled the field to re-examine traditional measures within the lens of anti-racism, cultural humility, and equitable assessment towards more a more inclusive and representative science (Iruka et al., 2023; Kamboukos et al., 2022; Nketia et al., 2021; Smith et al., 2023; Stern et al., 2022). WG-BEH consulted with leading experts in culturally responsive and anti-racist developmental science (Amso and Lynn, 2017; Iruka et al., 2023, 2022; Nketia et al., 2021; Tamis-LeMonda and Kahana-Kalman, 2009) to operationalize coding for HBCD. For example, traditional codes, such as caregiver "intrusiveness," that rely on coder inference and may have differential meaning and predictive validity across racial ethnic groups and contexts, (Benito-Gomez, 2022; Diemer et al., 2021) were replaced with codes, such as "directiveness," that focus only on observed caregiver behaviors.

2. Domains of assessment

The following sections describe the three overarching domains within the purview of WG-BEH: (1) child behavior; (2) parenting and caregiver-child interactions; and (3) family and home environment, and the specific corresponding measures chosen for HBCD Study visits 3–5. As visits 1–2 occur during pregnancy and the neonatal period, respectively, no WG-BEH assessments are administered at these visits. Visits 3–5 cover child ages 3–17 months, with staggered age ranges. Though HBCD will extend beyond these ages, current protocol development is still underway for visits 6 and beyond, so not discussed here. Table 1 provides an overview of current WG-BEH measures and the timing of visits. Assessments include caregiver reports and observational assessments, each described in detail below as the applicable domain is discussed.

3. Domain one: Child behavior

Socioemotional development is a foundational component of early childhood; thus, a primary goal of HBCD is to acquire data on child socioemotional development and mental health, as reflected in the measures chosen for this domain.

3.1. Socioemotional problems

Early problems regulating emotions and behavior have been linked to developmental delays and behavioral problems across the lifespan, with as many as 20 % of children in the U.S. being diagnosed with a mental health disorder by the age of 3 years (Dougherty et al., 2015; Stephenson, 2021). Interactions between genetic predispositions and early life experiences, including prenatal exposures, can disrupt healthy brain development and increase the risk for mental health problems, which often manifests as dysregulation (Belsky and De Haan, 2011; Van den Bergh et al., 2018). A critical goal of HBCD is to track brain development and associated functioning across infancy and childhood, with the goal of identifying specific early life vulnerabilities and resiliencies and changes in brain functioning that are associated with mental health.

Irritability has been identified as a transdiagnostic construct underlying many mental health problems, an indicator of early neurodevelopmental vulnerability (Wakschlag et al., 2018), and a robust predictor of lifespan mental health disorders and functional impairment (Klein et al., 2021; Sorcher et al., 2022; Wakschlag, 2023). Therefore, irritability was chosen as a focal construct during these early visits and is assessed both observationally and through caregiver report. At later developmental stages, WG-BEH plans to incorporate additional measures to capture a broad range of emerging mental health problems.

3.1.1. The Early Regulation in Context Assessment (ERICA)

The ERICA (Krogh-Jespersen, Kaat, et al., 2022) is an adaptation of the well-established Disruptive Behavior Diagnostic Observation Schedule (DB-DOS), a standardized developmental-clinical observation paradigm, which has been validated in multiple independent and diverse early childhood samples and has demonstrated sensitivity to exposure effects and predictive, clinical, and mechanistic utility (Frost et al., 2018; Lind et al., 2014; Massey et al., 2020; Quiñones-Camacho et al., 2020; Wakschlag et al., 2008). The ERICA was chosen because it is non-proprietary, efficiently elicits variability in child and caregiver behavior, and is easily adapted to different developmental stages through use of appropriate emotion-eliciting activities from infancy through preschool age. Each age-based version consists of five brief activities that the caregiver and child are asked to do together. For example, an activity that elicits frustration might include getting cleaned up (wiping child's face and hands) for an infant or completing a challenging puzzle task for a toddler. An activity that elicits enjoyment might include blowing bubbles or playing with fun toys. By including a range of activities, the ERICA allows observation of the amount and quality of children's emotions and social engagement, as well as how these are managed within the caregiving relationship. The ERICA paradigm and codes were adapted for use in HBCD, weighing the following considerations: (1) relevance to core HBCD constructs; (2) ease of administration across multiple sites; (3) feedback from focus groups with diverse caregivers; (4) codes that could be meaningfully applied from early infancy through preschool age; (5) potential for behavioral reduction and simplification; and (6) bias reduction and enhancement of cultural humility (Weisleder et al., in preparation). Specific codes for child behavior, parenting behavior, and caregiver-child interaction are described below in relevant content sections.

The ERICA *Irritability* code assesses the child's capacity to regulate frustration in the face of varied motivational demands. It captures intensity and recovery from frustration, demands and transitions. Ratings factor in the intensity, duration, context (e.g. "out of the blue" or developmentally appropriate in response to a challenging task), and child's ability to recover.

Table 1
WG-BEH domains, constructs, and measures.

	Visit 3 (3–9 months)	Visit 4 (9–15 months)	Visit 5 (10–17 months)
Child Behavior			
Temperament	IBQ-R	–	IBQ-R/ECBQ
Irritability	MAPS-TL infant	–	MAPS-TL infant/ toddler
Regulation	–	–	ecPROMIS Self-Regulation
Peer relationships	–	–	ecPROMIS Peer Relations
Observational assessment	ERICA*	Play/BI*	–
Parenting and Caregiver-Child Interaction			
Caregiver-child relationship	ecPROMIS Caregiver-Child	–	ecPROMIS Caregiver-Child
Socialization goals	FCM*	–	–
Observational assessment	ERICA*	–	–
Family Environment			
Quality	–	HOME21	–
Family relationships	–	FAD	–
Disorganization	–	CHAOS	–

Note: Visits 1 and 2 (prenatal and neonatal periods) have no child behavior or parenting focused measures. Visits 4–5 (and 6 noted elsewhere) are subject to change. All questionnaires are offered remotely; *indicates the measure is administered at the in-person visit. IBQ-R: Infant Behavior Questionnaire – Revised; ECBQ: Early Child Behavior Questionnaire; CBQ: Child Behavior Questionnaire; MAPS-TL: Multidimensional Assessment Profiles, Temper Loss; ecPROMIS: Early Childhood version of the Patient-Reported Outcome Measurement Information System; ERICA: Early Regulation in Context Assessment; Play: Semi-Structured play task; BI: Behavioral Inhibition; FCM: Family Culture Matters; HOME: Home Observation for Measurement of the Environment; CHAOS: Confusion, Hubbub, and Order Scale; FAD: Family Assessment Device.

3.1.2. The Multidimensional Assessment Profiles, Temper Loss Scale (MAPS-TL)

The MAPS-TL (Wakschlag et al., 2012; Wiggins et al., 2023) is a caregiver-report survey that assesses child atypical irritability. The MAPS-TL captures irritable behavior and mood in a developmentally sensitive manner, including frequency, expression, context, and qualitative features (e.g., "wake up fussy," "break or destroy things during tantrums"). Versions for infants (<1 year old) and toddlers/preschoolers (1–5 years) are administered (Krogh-Jespersen, MacNeill, et al., 2022; Wakschlag et al., 2012).

3.2. Socioemotional competence

Socioemotional competence refers to a young child's ability to express and regulate emotions and behaviors, as well as form positive relationships with others (Eisenberg and Fabes, 2006), which are foundational for lifelong physical and mental health, and academic achievement (Murray et al., 2015; Shonkoff et al., 2012). Thus, the WG-BEH felt strongly that including measures of promotive or positive socioemotional experience were integral to understanding child development.

3.2.1. The ERICA

Two aspects of socioemotional competence are assessed with the ERICA (see Section 3.1.1). (1) *Positive Affect* measures the child's intensity and modulation of expression of positive affect, such as playfulness, joy, and enthusiasm. Low-level indicators include brief smiles or excited movements, whereas high-level positive affect may be seen through laughing, clapping, or bright sustained smiling. (2) *Social*

Engagement measures the extent to which the child is responsive to and initiates interactions with the caregiver. Behaviors can range from looking with interest to engaging in back-and-forth play in an infant/toddler, to initiating and sustaining conversation, sharing information, and engaging in back-and forth conversation in an older child. They do not include attempts to be soothed by, or irritable/angry behaviors towards the caregiver.

3.2.2. The Early Childhood version of the Patient-Reported Outcome Measurement Information System (ecPROMIS®)

The ecPROMIS offers clinicians and researchers a brief, efficient, and precise way to evaluate young children's well-being (Blackwell et al., 2020; Lai et al., 2022; Park et al., 2022). The PROMIS initiative developed item banks that have been normed to the U.S. population, providing scores in the common T-score metric (Cella et al., 2022, 2007; Sherlock et al., 2022). The ecPROMIS caregiver reports include a *Self--Regulation-Flexibility* scale and *Peer Relationships* scale. The *Self--Regulation-Flexibility* scale assesses young children's cognitive flexibility, or the ability to adapt in response to environmental demands, changes, and expectations (Blackwell et al., 2022; Murray et al., 2015). The *Peer Relationships* scale measures young children's positive peer interactions, sociability (getting along well with others), and empathic behaviors.

3.3. Temperament

Temperament shapes how children perceive and respond to their social world. Temperament is conceptualized as constitutionally based individual differences in reactivity and self-regulation that emerge in infancy, are relatively stable, and underlie expressions of stress reactivity, emotionality, and sociability (Gartstein and Rothbart, 2003; Stifter, 2016). Temperament is related to differences in brain development (Filippi et al., 2020; Pérez-Edgar and Fox, 2018; Salzwedel et al., 2019) and can be shaped by maternal mental health and early life exposures (Davies et al., 2021; McGrath et al., 2008). The behavioral inhibition temperament profile (e.g., highly fearful or behaviorally inhibited) is the most potent specific risk factor for anxiety disorders later in life (Chronis-Tuscano et al., 2009; Goldsmith et al., 2022). Others (e.g., high positive affect, well-regulated) are related to positive relationships with caregivers (Planalp et al., 2017, 2019) and lower behavioral inhibition in adolescence (Moore et al., 2022). For these reasons, temperament was determined to be a critical socioemotional domain and is assessed using both observational and caregiver report measures.

3.3.1. Rothbart behavior questionnaires

Caregiver reported child temperament can be measured using developmentally appropriate questionnaires originally developed by Rothbart and colleagues. There are multiple parallel versions that show strong reliability and validity, relevant for the infancy (Gartstein and Rothbart, 2003; Putnam et al., 2014), toddlerhood/preschool (Putnam et al., 2006), and preschool/middle childhood (Putnam et al., 2006; Rothbart et al., 2001) periods. Each is also available in a very-short form that is easily administered online, reducing the burden for caregivers (Putnam et al., 2006, 2014). The very-short form questionnaires provide scores for three overarching temperament domains: Surgency/Extraversion, Negative Affect, and Effortful Control. The full versions also include a scale reflecting Behavioral Inhibition, a particularly salient temperament characteristic that shows unique relations to brain development (Planalp et al., 2023) and emerging anxiety (Chronis-Tuscano et al., 2009). Thus, the broad domains of infant/child temperament are measured in HBCD using the very short forms plus the Behavioral Inhibition scale from the long form.

3.3.2. Laboratory temperament assessment

To supplement caregiver report, observed behavioral inhibition (BI) is collected using the Laboratory Temperament Assessment Battery (Lab-TAB; (Goldsmith, 1999; (Planalp et al., 2017)) Stranger task, which WG-BEH termed the "friendly unfamiliar adult" for HBCD protocols. In this task an unfamiliar adult approaches a child, either while the child is seated in a high-chair (9–12 months) or playing on the floor (12 + months), as might occur when a caregiver and child are sitting in a doctor's office or receiving visitors in the home. Coding of bodily, facial, and verbal fear behaviors will be completed in a similar manner to ERICA "one-pass" coding by the ERICA coding team.

4. Domain two: Parenting and caregiver-child relationships

Longitudinal investigations, such as HBCD, that track the contribution of parenting and caregiver-child relationship quality to child outcomes must reliably elicit and measure relevant, developmentally appropriate parenting constructs at different child ages.

4.1. Parenting behaviors

Although the specific parenting behaviors that promote healthy child development may manifest somewhat differently as children grow, there is general consensus that positive and effective parenting is characterized by warmth and acceptance of the child, provision of structure, and encouragement of age-appropriate autonomy (Skinner et al., 2005). In contrast, hostile, coercive, unpredictable, and neglectful parenting deleteriously affects the caregiver–child relationship and undermines the child's healthy development (Glynn and Baram, 2019; Martoccio et al., 2022; Patterson, 2016; Pinquart, 2017). Socialization models posit that caregiver responsiveness during infancy and early childhood, coupled with clear caregiver expectations and contingent discipline appropriate for the child's developmental stage and the family context (e.g., clear parental guidance and limit setting; Baker and Brooks-Gunn, 2020; (Morawska et al., 2019)), promotes internalization of caregiver expectations, resulting in increasingly self-regulated behavior (Bugental, 2006; Grusec et al., 2000).

4.1.1. The ERICA

The ERICA (see Section 3.1.1) includes three codes assessing parenting behavior. (1) *Responsive Behavior* measures the caregiver's contingent, sensitive responses to the child with acknowledgment, warmth/affection, concern, encouragement, and/or reassurance. Responsive behavior may include encouraging or warm affect (smiling, warm tone of voice), comforting child's distress, terms of endearment/expressions of affection directed toward child or loving touches. (2) *Irritable Behavior* assesses the caregiver's irritable, frustrated, and/or angry affect and behavior in response to the child. Irritability can range from frowning, scowling, and sighing on the lower end, to harsh, negative comments, yelling, and rough handling of the child on the higher end. (3) *Directive Behavior* assesses the extent to which the caregiver directs the child's activities or places demands on their behavior. Examples include limit setting, commands, moving the child's hands toward a task, or repeatedly directing child's attention.

4.1.2. Semi-structured play activity

Given evidence that caregiver responses to child distress and non-distress have different sequelae (Leerkes et al., 2012), WG-BEH felt it important to include a paradigm that assessed caregiver-child interaction during an unstructured, playful context. Structured play paradigms are widely used to assess caregiver and child behaviors relevant to child cognitive, emotional, and behavioral functioning. In this task, the caregiver and child sit on a mat with a standard set of age-appropriate toys and are asked to interact as they typically would at home. The length of the task has varied between published studies; WG-BEH limited the task to 5 minutes to reduce study burden. This paradigm (or ones similar to it, e.g., the 3-bags task) has successfully been used in several previous large-scale studies, including those with families from socioeconomic and racially diverse backgrounds (e.g., Fuligni and

Brooks-Gunn, 2013; Gustafsson et al., 2012; NICHD Early Child Care Research Network, 1999), and to assess the behaviors of many different types of caregivers (e.g., multigenerational co-parents; fathers and father-figures) (e.g., Barnett et al., 2012; Mills-Koonce et al., 2015; Cabrera et al., 2007).

4.2. Caregiver-child relationships

In infancy, caregivers and infants together co-regulate their interactions, with caregivers interpreting and appropriately responding to infants' affective and physiological cues (Beeghly et al., 2016; Beeghly and Tronick, 2011). Importantly, self-regulation is thought to be a product or extension of co-regulation, whereby children learn and strengthen self-regulation skills through responsive interactions with caregivers (Murray et al., 2015). Co-regulation and connectedness in early development lay the foundation for successful self-regulation of physiology, behavior, attention, and emotion, and the development of social emotional competencies throughout the lifespan (Feldman, 2009; Murray et al., 2015). The caregiver-child relationship also provides an early model of relationship building, and children with positive parental relationships have better relationships with peers and others (Ladd and Kochenderfer-Ladd, 2019).

4.2.1. The ERICA

The ERICA (see Section 3.1.1) includes the dyadic code of connectedness. *Connectedness* is a measure of mutual enjoyment, back-and-forth interactions, shared attention, and cooperative communication between the caregiver and child. It assesses how well dyads shift behavior and emotion in response to each other to stay in synchrony and engage with each other and/or the same activity (e.g., joint attention to same toy). If conflict or distress arises, this code assesses how well the dyad works together to resolve the conflict/distress and return to a state of emotional equilibrium.

4.2.2. The ecPROMIS

The ecPROMIS (see Section 3.2.2) includes a *Caregiver-Child Interactions* scale. This brief caregiver report questionnaire assesses the degree to which infants and young children develop close and trusting relationships with their caregivers.

4.3. Socialization goals

Socialization goals are qualities that caregivers value and desire to see in their children as they develop. Research has established the importance of studying socialization goals as both a means for understanding caregiving beliefs and practices and as a window into the broader cultural contexts of parenting/caregiving (Ng et al., 2012; LeVine, 2003). Recent work has emphasized the importance of taking a dimensional and dynamic approach, recognizing that caregiver goals can change over time, as children develop (Tamis-LeMonda and Kahana-Kalman, 2009).

4.3.1. Family Culture Matters (FCM)

The Family Culture Matters (FCM) is a Q-sort activity that captures a caregiver's values, desires, and socialization goals for their child. The FCM was adapted for HBCD from a socialization goals measure developed by Tamis-LeMonda and colleagues (Ng et al., 2012). The caregiver is asked to sort a set of 15 qualities (e.g., "to be kind," "to be a leader," "to be obedient") in order of importance to them for their child, with one blank card to capture any additional important qualities not listed. They first sort the qualities into three groups of five (very important; important; not as important), and then rank order qualities within those groups. The 15 qualities fall within five broader goal categories: Achievement, Self-Maximization, Proper Demeaner, Connectedness and Honesty/Decency. For example, the value "to be obedient" may reflect cultural constructs such as filial piety, which emphasizes the respect for and deference to elders, and familism, which underscores the importance of family loyalty and cohesion, and is categorized under Proper Demeaner. The FCM is administered immediately following the ERICA. The FCM will facilitate examination of connections between structured observations of caregiver-child interaction and culturally informed values reported by caregivers that may shape early relationship patterns.

5. Domain of assessment: Family and home environment

Research on a child's family environment has identified key family and home characteristics that support a child's achieving age-appropriate social, emotional, and cognitive skills (Evans, 2004; Lehrl et al., 2020). Home environments that are organized and rich in learning materials and stimulation, provide ample opportunities for curiosity and play, provide appropriate supervision and monitoring, and have safe, predictable routines are associated with positive developmental outcomes (Bradley and Corwyn, 2002; Shonkoff, 2003; Wachs, 2000; Whiteside-Mansell et al., 2007). Family relationships that are warm, responsive, engaging, and cohesive are also associated with more optimal developmental outcomes across development from early childhood into adolescence (Goodrum et al., 2020; Lucia and Breslau, 2006). Conversely, characteristics such as household confusion and unpredictability have been directly and indirectly linked with poor executive functioning, academic achievement, and socioemotional adjustment (Andrews et al., 2021; Evans et al., 2005; Larsen and Jordan, 2020; Matheny Jr et al., 1995) even after controlling for socioeconomic status and parenting practices (Dumas et al., 2005; Evans et al., 2005). Therefore, assessment of children's contexts and experiences in the home was considered a necessary element for inclusion in HBCD. The final domains included in the protocol were selected because of cross-cultural evidence of association with child development (Bradley and Corwyn, 2005). Further, to reduce the potential for bias in assessment, the WG-BEH was thoughtful to select instruments that have demonstrated utility and validity across various cultural groups in the US.

5.1. The Home Observation for Measurement of the Environment (HOME) Inventory

The HOME (Bradley and Caldwell, 1988) measures characteristics of the household learning environment (e.g., provision of materials and household organization) and quality of family relationships the child experiences. The HOME is one of the most widely used measures of the quality and quantity of support available to a child in the home environment and has been used for a wide variety of sociocultural groups (Bradley, 2015). The HOME-21 is a modified version of the HOME-Short Form (Bradley et al., 2014; Mott, 2004), which uses multi-response caregiver reports that were reworded from the original dichotomous observer ratings. Items on the HOME-21 reflect items from the Infant/Toddler and Early Childhood HOME scales of Acceptance, Variety, Learning Materials, Language Stimulation, and Physical Environment. WG-BEH chose the HOME-21 (Lansford et al., 2023) over the original HOME to reduce overlap with other assessments and reduce the need for additional training, reliability, and certification. Importantly, the HOME-21 has been revised to reflect changes in: (1) family composition and gender roles, where items were reworded to be gender-neutral and inclusive of diverse family structures, (2) discipline, where item scoring reflects changes in acceptance of spanking, and (3) technology, where revisions to the types of devices available in homes were made and items were added to capture access to information (the use of a computer in the home and internet access). The tool covers an age range from infancy through age 17 and has strong content, concurrent and discriminant validity and has been examined for income, gender, and racial biases (Bradley, 2015; Lansford et al., 2023; Whiteside-Mansell et al., 2009).

5.2. The McMaster Family Assessment Device (FAD)

The Family Assessment Device (FAD) measures the structural and organizational properties of families and patterns of family interactions (Epstein et al., 1983; Miller et al., 1985). The FAD consists of seven scales, but to minimize burden, only the short form of the General Functioning scale (GF6 +) was chosen for use in HBCD as it has strong correlations with each of the other subscales (Boterhoven de Haan et al., 2015). This caregiver-report measure assesses the overall healthy functioning of the family, such as emotional supportiveness between family members and acceptance of one another. It has strong test-retest, concurrent, and discriminant validity; has been widely used in both research and clinical practice; is valid for families with young children (Staccini et al., 2015), and has high internal reliability (Mansfield et al., 2015).

5.2.1. The Confusion, Hubbub, and Order Scale (CHAOS)

The CHAOS assesses household routines, as well as confusion, disorganization, and noise in the child's immediate living environment (Dumas et al., 2005; Matheny Jr et al., 1995; Wilhoit et al., 2021). Although the original CHAOS scale used a dichotomous true/false response set (Matheny Jr et al., 1995), recent studies, including a validated Spanish translation (Sánchez-Mondragón and Flores Herrera, 2019), adopted Likert scales to reflect normative nuance in household chaos (Andrews et al., 2021; Marsh et al., 2020; Wilhoit et al., 2021). The CHAOS scale has been used mostly with families of infants and toddlers, but also in studies with school-aged children and adolescents (Marsh et al., 2020).

6. Pilot testing

Pilot testing the planned protocol was essential for ensuring high quality data collection and the feasibility and acceptability of the proposed measures with the HBCD population. Piloting also allowed for refinement of measures prior to main study launch. SMEs were responsible for evaluating any missingness patterns and determining whether variability at the item- and scale-level aligned with expectations. They then reported any errors to the HBCD Data Coordinating Center (HDCC) and brought any concerns about measure performance to WG-BEH for discussion.

Piloting of the observational assessments involved iterative refinement. Every site completed at least two pilots of each observational assessment protocol (i.e., semi-structured play/BI/ERICA-FCM). Pilot videos were reviewed by SMEs to monitor quality and provide ongoing training and feedback to sites (e.g., camera placement, adherence to protocol), as well as to make iterative changes to protocol to enhance standardization across sites, ease of administration and comfort for families. Modifications that were made based on piloting included adjusting the order of tasks (e.g., adding a recovery activity to avoid two stressful activities back-to-back), streamlining and simplifying caregiver instructions, and developing revised guidance for managing child distress.

7. Other considerations

There was some content overlap between WG-BEH and WG-Social and Environmental Determinants (WG-SED), which was tasked with measuring environmental stressors (Cioffredi et al., this issue), and WG-Neurocognition and Language (WG-NCL; Kable et al., this issue). The constructs selected for inclusion by WG-BEH capture elements of the child, family and home not measured by other workgroups. Many of these constructs are specific to socioemotional contexts (e.g., emotionally salient situations), and caregiver-child relationships within the home itself.

Additional constructs and measures were considered by WG-BEH but ultimately not included in the HBCD protocol. Some assessments, such as those that measure infant-caregiver attachment security, were deemed prohibitively difficult to administer in this study's context, given the complexity of protocol administration and coding and the need to conduct lengthy laboratory (e.g., for the Strange Situation paradigm; Ainsworth et al., 2015) or home visits (the Attachment Q-sort; Vaughn and Waters, 1990; Waters and Deane, 1985). The Disturbances of Attachment Interview (Smyke and Zeanah, 1999) and the Attachment Relationship Inventory (Spruit et al., 2021) were considered, but ultimately excluded because they are either typically administered by trained clinicians or utilized as part of clinical assessment, with low base rates of attachment disorders in population-based samples. The Brief Infant Toddler Social Emotional Assessment (BITSEA; Briggs-Gowan et al., 2002) was also considered, but WG-BEH is electing to administer the Child Behavior Checklist (CBCL; Achenbach and Rescorla, 2000) in future visits for continuity with ABCD.

8. Future visits

At the time of this publication, WG-BEH is actively planning for visits 6, 7 and 8 and has proposed several additional measures for piloting. In the domain of child behavior, these include the CBCL for Ages 1½ −5 (CBCL 1.5–5; Achenbach and Rescorla, 2000) to assess a broad spectrum of behavioral and emotional problems in young children, the electronic versions of the Modified Checklist for Autism in Toddlers, Revised with Follow-Up (M-CHAT-R/F; Attar et al., 2023) a widely-used screener for risk of autism in toddlers, and a modified version of the Preschool Age Psychiatric Assessment (Egger et al., 2019), a clinical interview with caregivers to assess child psychiatric symptoms and diagnoses. In the domain of family and home environment, this includes the addition of the brief Questionnaire of Unpredictability in Childhood (QUIC-5; Davis & Glynn, 2024). WG-BEH also plans to re-administer many of the measures from visits 3–5 described in this paper at future visits.

9. Conclusion

The HBCD Study has the potential to elucidate complex mechanisms of risk and resilience pathways. Characterizing child behavior, the caregiving environment, and caregiver-child-interactions within a nuanced developmental context is essential for understanding brain-behavior associations in early life. Doing so in the context of prenatal and early adversity is critical, as these exposures can alter developmental trajectories with potential lifelong implications in unknown ways. Given the goal of the HBCD Study to reveal how child development is affected by various adverse and protective social and environmental social exposures, WG-BEH took a rigorous and equitable approach to ensure the collection of high quality, developmentally appropriate, and culturally sensitive measures of child behavior, caregiver-child interactions, and the family and caregiving environment. Such an approach enhances the likelihood that the findings from the HBCD Study will maximally inform the development of preventative approaches to optimize developmental outcomes across early childhood and, consequently, the lifespan.

CRediT authorship contribution statement

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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