ECHO

Environmental influences on Child Health Outcomes

A program supported by the NIH

Don’t throw the baby out with the bathwater:

Creating developmentally-appropriate PROMIS early childhood parent report instruments

Courtney K. Blackwell, PhD

Research Assistant Professor

ckblackwell@northwestern.edu

Northwestern Medicine®

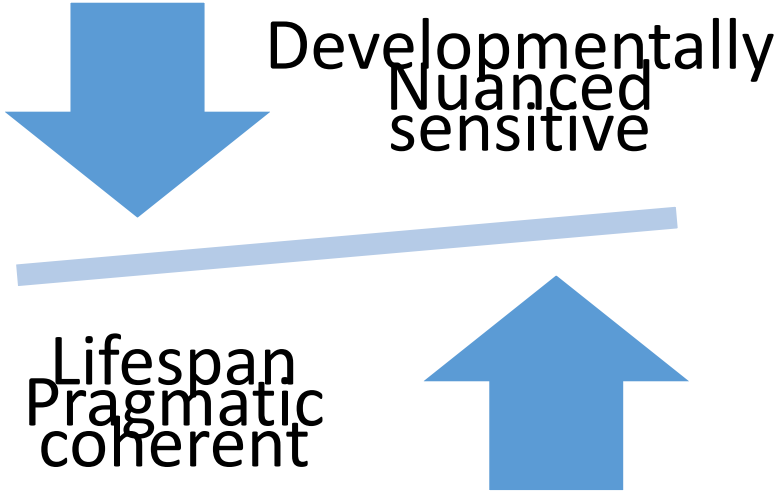
Feinberg School of Medicine

COI

- I have nothing to disclose.

Background

- Most pediatric health measures are downward extensions of adult versions → **lifespan coherence**
- Traditional early childhood measures emphasize depth and developmental nuance → **wide range of normative variation**



Objective

- Integrate developmental considerations into person-reported outcome (PRO) measurement development…
- …to create new PROMIS early childhood parent report measures (ages 1-5yrs)…
- …that are both *developmentally-sensitive* **and** *lifespan coherent*

Methods

- Combine:

(1) Pragmatic strengths of PROMIS mixed-methods approach[1]

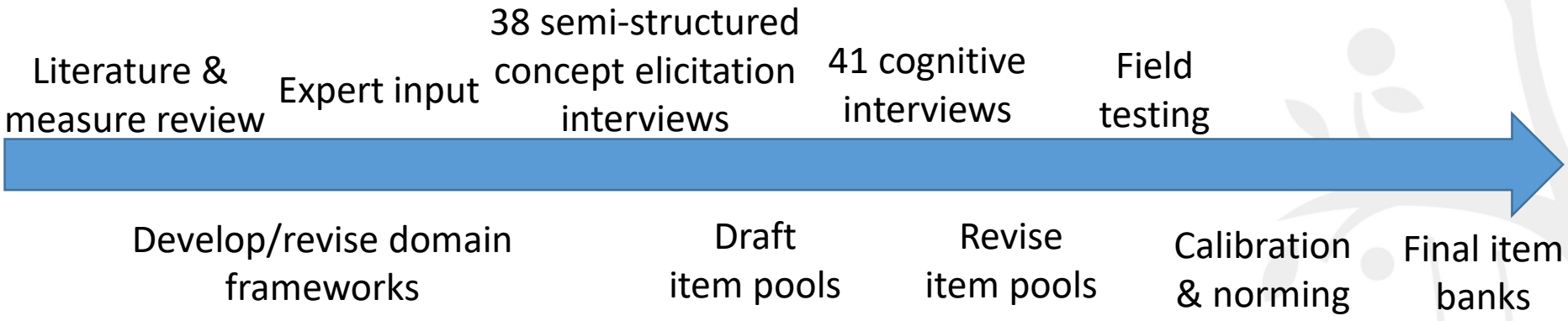
  - Approach: low burden, EHR integration
  - Models & Framework: WHO, domain experts, extant literature
  - Designs: cross-disease, relevant to policy and practice, real-world application
  - Measures: Strong psychometrics, norm benchmarking, lifespan coherence

(2) Depth and nuance of developmental specification model[2]

  - Approach: developmental-sensitivity, typical/atypical variation
  - Models & Framework: Multidimensional Assessment Profile (MAPS)[3]
  - Designs: disease-specific, real-world application
  - Measures: less severe/potentially worrisome items, conceptually and psychometrically grounded

[1]Glasgow, 2013; Glasgow & Riley, 2013; [2]Wakschlag et al., 2010; 2015; 2017; [3]Biedzio & Wakschlag, 2019; Wakschlag et al., 2014

Process Overview



PROMIS Early Childhood Domains

Global Health

Physical Health	Mental Health	Social Health
- Physical Activity - Sleep Disturbance - Sleep-related Impairment	- Anger/Irritability - Anxiety - Depressive Symptoms - Positive Affect - Engagement - Self-regulation	- Family Relationships - Peer Relationships

Key Considerations[1]

1. Engage interdisciplinary content experts to identify meaningful and relevant constructs
2. Balance developmental expression with lifespan consistency
3. Emphasize observable features across the typical/atypical spectrum
4. Integrate behavioral context into conceptual frameworks
5. Identify concept relevance differences within early childhood
6. Ensure feasibility and relevance for clinical and research application

[1]Blackwell CK, Wakschlag LS, Krogh-Jespersen S, Bevans K, Lai JS, Forrest CB, Cella D. Pragmatic health assessment in early childhood: The PROMIS® of developmentally-based measurement for pediatric psychology. Journal of Pediatric Psychology. Under review.

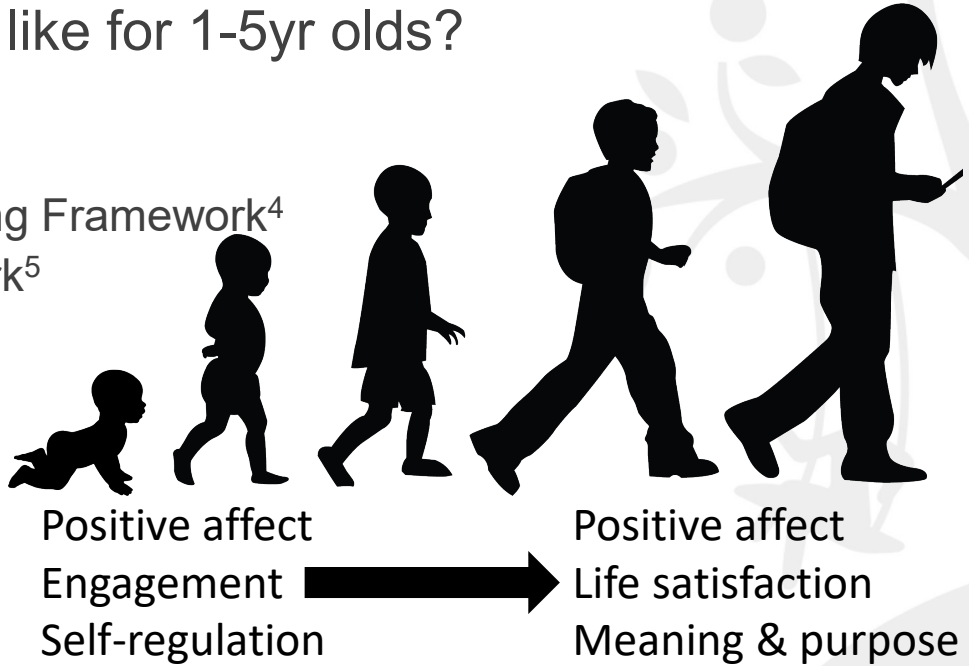
1. Engage interdisciplinary content experts to identify meaningful and relevant constructs

- Academic and clinical expert review and revisions of domain frameworks
  - e.g., expand definition of Anxiety to include social/separation anxiety because salient feature for early childhood
- Parent expert input via concept elicitation interviews
  - e.g., relevance of Peer Relationships for very young children

    "Right now at 13 months, he's been developing more socially than when he was younger…He seems to notice that the kids are around his age [be]cause he seems to go crawl towards them, or be by them."

2. Balance developmental expression with lifespan consistency

- Developmental translation of latent constructs to meaningful terms for early childhood across domains[1]
- e.g., what does “well-being” look like for 1-5yr olds?
  - Positive Health Framework[2]
  - Model of Child Well-Being[3]
  - Positive Indicators of Child Well-Being Framework[4]
  - Head Start Early Learning Framework[5]



[1]Wakschlag et al., 2010; [2]Forrest, Blackwell, & Camargo, 2018; [3]Moore, Bethell, Murphy, Martin, & Beltz, 2017; [4]Lippman, Moore, &, McIntosh, 2011; [5]Office of Head Start, 2015

3. Emphasize observable features across the typical/atypical spectrum

- Shift from parent *proxy* to parent ***report***
  - Aligns with FDA guidance[1] & parent feedback:

    "I can't even think about how I would know if this kid is worrying or not."

[1]US DHHS, 2009

4. Integrate behavioral context into conceptual frameworks

- Expands normative variation and enhances identification of clinically concerning behaviors
  - e.g., “My child was inconsolable when separating from me or other parent in a **familiar** [an unfamiliar] setting.”
- Consider environmental barriers/facilitators
  - Physical Activity items remains context-independent to maximize generalizability to general pediatric population

5. Identify concept relevance differences within early childhood

- Some domains required age-based items to fully capture developmental expression of constructs
  - e.g., Peer Relationships empathic behavior items for 3-5yr olds
  - e.g., items requiring verbal skills
- Items originally intended for 1-2yr olds generally worked for 3-5yr olds but not vice versa
  - e.g., “My child became angry quickly” v. “My child had a hot/explosive temper.”
- DIF by child age

6. Ensure feasibility and relevance for clinical and research application

- Brief, efficient, clinically-meaningful
- Translatability review
- Short forms and CATs

Example Developmental Adaptations

Domain	PROMIS Parent-Proxy (5-17yrs)	PROMIS EC Parent Report (1-5yrs)	Key Considerations
Depressive symptoms	My child felt too sad to eat.	My child seemed uninterested in eating food he/she usually likes.	(1) Expert input; emphasize anhedonia
Engagement*	My child's life is filled with things that interest him/her.	My child actively explored the world around him/her.	(2) Developmental expression
Sleep-related Impairment	My child got mad easily because he/she was sleepy.	When my child didn't sleep well, he/she got mad easily.	(3) Observable features
Anxiety	My child felt worried.	My child seemed fearful or worried **when out in public**	(4) Context
Anger/ Irritability	My child felt mad.	My child acted cranky. (all ages) My child acted grumpy. (3-5yrs)	(5) Differences within early childhood
ALL	Short forms, CAT, translatability	Short forms, CAT, translatability	(6) Feasibility & relevance

*PROMIS Parent-Proxy (5-17yrs) item is from the Life Satisfaction instrument.

Acknowledgements

ECHO PRO Core: Katherine Bevans, PhD; **David Cella**, PhD (MPI); **Matthew Davis**, MD; **Christopher B. Forrest**, MD PhD; **Richard Gershon**, PhD (MPI); **Aaron Kaat**, PhD; **Bradley Scott Marino**, MD, MPP, MSCE; **Jin-Shei Lai**, PhD; **Megan York Roberts**, PhD; **Lauren S. Wakschlag**, PhD; **Donna Woods**, PhD

Expert Consultants: Christina D. Bethell, PhD; **Sara Bufferd**, PhD; **Kristin Buss**, PhD; **Rachel Flynn**, PhD; **Jody Ganiban**, PhD; **Sheila Krogh-Jespersen**, PhD; **Joan Luby**, MD; **Ann S. Masten**, PhD; **Megan McClelland**, PhD; **Amanda Nili**; **Koraly Perez-Edgar**, PhD; **Amelie Petitclerc**, PhD; **Daniel Pine**, MD; **Northwestern University Institute for Innovations in Developmental Sciences (DevSci)**

Funding: Research reported in this publication was supported by the Environmental influences on Child Health Outcomes (ECHO) program, Office of The Director, National Institutes of Health, under Award Number U24OD023319 (Person Reported Outcomes Core).

Questions?

ECHO

Environmental influences
on Child Health Outcomes

A program supported by the NIH

EXTRA SLIDES

Global Health Domain Framework

Domain	Definition
Global Health	Overall evaluation of an individual's physical, mental, and social health.

Physical Health Domain Frameworks

Domain	Definition
Physical Activity	General physical activity behaviors and associated intensity and physiological symptoms.
Sleep Disturbance	Assessment of sleep quality pertaining to delayed sleep, sleep onset, and sleep continuity
Sleep-related impairment	Assessment of the impact of poor sleep on daytime functioning, routines, and mood.

Mental Health Domain Frameworks

Domain	Definition
Anger/Irritability	Angry mood (Irritability, grouchiness) and behavior (frustration, tantrums, and management of angry behavior)
Anxiety	Fear (fearfulness, panic), anxious misery (worry/dread), hyperarousal (tension, nervousness), social/separation anxiety (fear/distress when separating from caregivers, in unfamiliar situations)
Depressive Symptoms	Sad/withdrawn, negative views of self (self-criticism, worthlessness, low self-esteem), anhedonia (loss of interest, inability to engage in play, lack of enjoyment)
Positive Affect	Moods and feelings associated with momentary positive affective experiences (contentment, calmness, pride, love, happiness, energy).
Engagement	Emotional, behavioral, and cognitive curiosity and interest (eagerness, persistence, positive self-concept)
Self-regulation	Recognition and regulation of emotions and behaviors in service of one's own goals and in response to environmental demands and expectations adaptability, coping, frustration tolerance)

Social Health Domain Frameworks

Domain	Definition
Family Relationships	Positive interactions, experiences, and connectedness with caregivers and family that reflect mutual feelings of warmth and affection and caregiver/family sensitivity, trust, dependability, and support
Peer Relationships	Positive peer interactions, sociability (getting along well with others), and empathic behaviors