Don’t throw the baby out with the bathwater: Creating developmentally-appropriate PROMIS early childhood parent report instruments

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• 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 approach¹
   - **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 model²
   - **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

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

Literature & measure review

Expert input

38 semi-structured concept elicitation interviews

41 cognitive interviews

Draft item pools

Revise item pools

Field testing

Develop/revise domain frameworks

Revise item pools

Calibration & norming

Final item banks
## PROMIS Early Childhood Domains

### Global Health

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<tr>
<th>Physical Health</th>
<th>Mental Health</th>
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<td>- Physical Activity</td>
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<td>- Self-regulation</td>
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Key Considerations¹

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. 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 domains¹

• e.g., what does “well-being” look like for 1-5yr olds?
  – Positive Health Framework²
  – Model of Child Well-Being³
  – Positive Indicators of Child Well-Being Framework⁴
  – Head Start Early Learning Framework⁵

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

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

*PROMIS Parent-Proxy (5-17yrs) item is from the Life Satisfaction instrument.
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Questions?
ECHO
Environmental influences on Child Health Outcomes
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EXTRA SLIDES
# Global Health Domain Framework

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<thead>
<tr>
<th>Domain</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Global Health</td>
<td>Overall evaluation of an individual's physical, mental, and social health.</td>
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</table>
# Physical Health Domain Frameworks

<table>
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<tr>
<th>Domain</th>
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<tbody>
<tr>
<td>Physical Activity</td>
<td>General physical activity behaviors and associated intensity and physiological symptoms.</td>
</tr>
<tr>
<td>Sleep Disturbance</td>
<td>Assessment of sleep quality pertaining to delayed sleep, sleep onset, and sleep continuity</td>
</tr>
<tr>
<td>Sleep-related impairment</td>
<td>Assessment of the impact of poor sleep on daytime functioning, routines, and mood.</td>
</tr>
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## Mental Health Domain Frameworks

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<tbody>
<tr>
<td>Anger/Irritability</td>
<td>Angry mood (Irritability, grouchiness) and behavior (frustration, tantrums, and management of angry behavior)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>Fear (fearfulness, panic), anxious misery (worry/dread), hyperarousal (tension, nervousness), social/separation anxiety (fear/distress when separating from caregivers, in unfamiliar situations)</td>
</tr>
<tr>
<td>Depressive Symptoms</td>
<td>Sad/withdrawn, negative views of self (self-criticism, worthlessness, low self-esteem), anhedonia (loss of interest, inability to engage in play, lack of enjoyment)</td>
</tr>
<tr>
<td>Positive Affect</td>
<td>Moods and feelings associated with momentary positive affective experiences (contentment, calmness, pride, love, happiness, energy).</td>
</tr>
<tr>
<td>Engagement</td>
<td>Emotional, behavioral, and cognitive curiosity and interest (eagerness, persistence, positive self-concept)</td>
</tr>
<tr>
<td>Self-regulation</td>
<td>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)</td>
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# Social Health Domain Frameworks

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<tbody>
<tr>
<td>Family Relationships</td>
<td>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</td>
</tr>
<tr>
<td>Peer Relationships</td>
<td>Positive peer interactions, sociability (getting along well with others), and empathic behaviors</td>
</tr>
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