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Development and validation of an early childhood development scale for use in low-resourced settings

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| 6 | Development and Validation of an Early Childhood Development Scale for Use in Low- |
| 7 | Resourced Settings |
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Abstract

Background: Low-cost, cross-culturally comparable measures of the motor, cognitive, and
socioemotional skills of children under 3 years remain scarce. In the present paper, we aim to
develop a new caregiver-reported early childhood development (ECD) scale designed to be
implemented as part of household surveys in low-resourced settings.
Methods: We evaluate the acceptability, test-retest reliability, internal consistency, and
discriminant validity of the new ECD items, subscales, and full scale in a sample of 2,481 18- to

30 36-month-old children from peri-urban and rural Tanzania. We also compare total and subscale

31 scores with performance on the Bayley Scales of Infant Development (BSID-III) in a subsample

32 of 1036 children. Qualitative interviews from 10 mothers and 10 field workers are used to

33 inform quantitative data.

Results: Adequate levels of acceptability and internal consistency were found for the new scale and its motor, cognitive, and socioemotional subscales. Correlations between the new scale and the BSID-III were high (r > .50) for the motor and cognitive subscales, but low (r < .20) for the socioemotional subscale. The new scale discriminated between children's skills based on age, stunting status, caregiver-reported disability, and adult stimulation. Test-retest reliability scores were variable among a subset of items tested.

40 Conclusions: Results of this study provide empirical support from a low-income country setting
41 for the acceptability, reliability, and validity of a new caregiver-reported ECD scale. Additional
42 research is needed to test these and other caregiver reported items in children in the full 0 to 3
43 year range across multiple cultural and linguistic settings.

44 Keywords: Early child development, low-income countries, measurement, validation, 0-3

Background

| 47 | Mounting evidence suggests the importance of investing in early childhood development |
|----|--|
| 48 | (ECD) for enhancing the economic, health, and educational status of individuals, communities |
| 49 | and nations [1-4]. Over the past several decades, a number of well-validated tools have been |
| 50 | developed for measuring individual children's motor, cognitive, language, and social functioning |
| 51 | during the first years of life (e.g., Griffiths Mental Development Scales, Denver Developmental |
| 52 | Screening Test, Bayley Scales of Infant and Toddler Development). These direct assessments |
| 53 | are typically done by clinically trained personnel and provide detailed information on |
| 54 | individuals' developmental status that can be used for informing clinical decisions, |
| 55 | understanding developmental processes, or testing the efficacy of early interventions [5]. |
| 56 | Despite their utility in capturing rich data, individual-level assessments are limited in |
| 57 | their ability to provide estimates of population-level developmental status for several reasons. |
| 58 | First, many of these assessments are quite costly in terms of their copyrights, the time they take |
| 59 | to administer, as well as the resources necessary to train assessors, making them impractical for |
| 60 | use at scale [6]. Second, the majority of existing developmental assessments have been created |
| 61 | with one particular – primarily high-resourced, Western – cultural context in mind. Although |
| 62 | great advances have been made recently in developing new tools for non-Western, low-resourced |
| 63 | settings (e.g., the Malawi Developmental Assessment Tool, the Inter-American Development |
| 64 | Bank's PRIDI tool, the Developmental Milestones Checklist, the East Asia and Pacific Early |
| 65 | Child Development Scales), the utility of these assessments for making generalizations outside |
| 66 | of the context in which they were developed is unknown [7-8]. Finally, many comprehensive |
| 67 | developmental assessments have focused primarily on motor, cognitive, and language |
| 68 | development, while neglecting to integrate early manifestations of social, emotional, and |

regulatory competence. Although many socioemotional skills vary in importance and
developmental determinants cross-culturally, research has increasingly shown the early
emergence of a core, basic set of these capacities to be strongly related to later-life outcomes in
diverse parts of the world [6, 9-13].

73 In recent years, several new tools have been developed to address these limitations and 74 provide comprehensive population-level data in older children (e.g., UNICEF's Early Childhood 75 Development Index for 3- and 4-year-olds, the Early Development Index for school-aged 76 children) [14, 15]. Still, no such scale exists for the under three age period, when children's 77 brains and bodies are developing most rapidly and are most susceptible to intervention [16]. 78 Given that target 4.2 of the Sustainable Development Goals aims to "ensure that all girls and 79 boys have access to quality ECD," measuring children's developmental status at the population 80 level is of important policy relevance [17]. Internationally validated and valid tools would 81 provide a new opportunity for global ECD advocates to quantify children's needs across 82 countries and regions, to make more informed decisions regarding policies and resource 83 allocation, and to monitor progress in achieving global goals congruent with the post-2015 84 agenda [18].

In this study, we describe the development of a set of caregiver-reported items for quickly and easily measuring the motor, cognitive, and socioemotional skills of children under three living in low-resourced settings, collectively known as the Caregiver-Reported Early Development Index (CREDI). Our focus on a caregiver report format allows us to address several practical and conceptual challenges of using direct assessment with large groups of infants and toddlers. Compared to direct assessments, caregiver reports require limited training and implementation time, provide a more generalizable perspective on children's skills and

92 behaviors across time and setting, are more appropriate for capturing socioemotional skills, and 93 are less likely to be biased against children who are unfamiliar with clinical assessments, who are 94 shy with strangers, or who do not understand verbal instructions [5]. In particular, the CREDI is 95 designed to be 1) simple and clear enough to be answered by a caregiver with minimal formal 96 education, 2) short enough to be feasibly integrated within large-sample household data 97 collection efforts, 3) sufficiently "culturally neutral" to allow for cross-context comparison, and 98 4) adequately aligned with "gold standard" direct assessment measures of proven clinical and 99 developmental utility. In creating the CREDI, our ultimate aim is to generate a new tool that will 100 serve to provide conceptually rich, developmentally informed, population-level data on global 101 progress in alleviating ECD-related inequities and meeting target 4.2 of the SDGs. In the present 102 paper, we detail the initial validation of the CREDI using qualitative and quantitative data among 103 18- to 36-month-old children in peri-urban and rural Tanzania, including evidence of the 104 individual items' and overall scale's acceptability, reliability, and validity. We conclude by 105 describing the implications of this generative work for future validation and expansion efforts. 106 Methods 107 **Study sample**

The sample for the present study was comprised of children 18 to 36 months who had previously participated in a neonatal vitamin A supplementation trial in the Morogoro region of Tanzania (registered at anzetr.org.au as ACTRN12610000636055) [19], as well as the person in the household who reported to spend the most time caring for that child (i.e., their primary caregiver). This particular area of Tanzania was selected over alternate study locations due to its 1) track record and infrastructure for conducting high-quality early childhood research, and 2) similarity to the broader population of Tanzania with regard to its high prevalence of poverty and malnutrition, mix of peri-urban and rural settings, and cultural diversity. Newborns were eligible for the original vitamin A study if they were able to feed orally, were born within the past 72 hours, were not already enrolled in other clinical trials, their family intended to reside in the study area for at least six months post-delivery, and their caregivers provided written informed consent. Notably, results of the original vitamin A trial revealed no detectable impacts on children's developmental outcomes [19], suggesting that randomization in the original study should not have affected the results of the present analysis.

122 For the original trial, a total of 20,104 randomly selected children living in Morogoro 123 region were enrolled. For the follow-up study, sampling was restricted to children from the 124 original trial living within the Ifakara Demographic Surveillance Site (IHI DSS). No other 125 exclusion criteria (e.g., based on disability or health status) were applied. Given this, the sample 126 is representative of the greater Ifakara area, with all eligible children in Ifakara town and the 127 surrounding villages being equally likely to be selected for participation. In keeping with the aim 128 of the study to validate the CREDI for children 18-36 months, only those within this age range 129 were selected, with the specific age of the child varying non-systematically based on the timing 130 of initial recruitment to the vitamin A study and the timing of the CREDI assessment (38% 18-131 23mo, 25% 24-29mo, and 38% 30-36mo). Children in the present sample were found to be 132 comparable to those sampled from the 2015-2016 Tanzanian national Demographic Health 133 Survey (DHS) in rates of stunting (43.3% vs. 43.8%, respectively; [20]. Compared to the 134 Tanzanian average, mothers in this sample were more likely to have attended primary school 135 than those in the DHS (87.9% vs. 61.9%, respectively), but less likely to have completed 136 secondary school or higher (7.3% versus 23.4%).

137 Ethics

All study protocols were approved by institutional review boards (IRBs) at the Harvard School of Public Health, the National Institute of Medical Research of Tanzania, and the Ifakara Health Institute. Caregivers provided written consent for their own participation and the participation of their children after a field worker read the consent out loud and answered any questions. All study staff were trained and monitored in IRB-approved procedures for identifying participant needs and, as necessary, providing referrals to local physical and mental health services.

145 Item development phase

146 Multiple steps were taken to develop the ECD items analyzed in this study. First, we

147 reviewed the ECD measurement literature to help us to define 1) the purpose of the scale, 2) the

age-appropriate developmental domains and constructs to be covered by the scale, and 3) the

validation plan. Second, and based on the literature review, we built an inventory of existing

150 measurement tools from high-, middle-, and low-income country contexts (see Appendix A), and

151 identified gaps in their coverage of our age-specific domains and constructs. Third, we selected,

adapted, and/or created an initial set of items based on the following criteria:

153 Each item must:

154 1) have evidence for face, construct, and/or criterion validity for representing one of the core

- 155 ECD domains¹
- 156 2) be developmentally appropriate for children 18 to 36 months²

¹ Although not representative of the core ECD domains, one item – whether the child was frequently too sick to play – was borrowed from the MICS ECDI and included alongside the motor items to test its utility in the <3 age group. This health item was tested in the qualitative and quantitative pilots but not included in reliability or validity analyses of the total CREDI scale.

² In several cases, items appropriate for younger ages (down to 12 months) were included to assess their suitability for older children living in an under-studied, at-risk sample.

| 157 | 3) be reportable by a primary caregiver on a yes/no response scale (i.e., the item cannot be task- |
|-----|---|
| 158 | based, cannot be rated on a continuous scale ³ , and must be sufficiently concrete that a |
| 159 | caregiver would already be familiar with the specified behavior/skill in the child) |
| 160 | 4) be simple in wording to allow for easy translation and comprehension by caregivers with |
| 161 | minimal formal education |
| 162 | 5) have the potential to discriminate between individuals (i.e., indicate a high likelihood of |
| 163 | variability in response) |
| 164 | 6) not be subject to severe social desirability (i.e., a caregiver will not feel compelled to respond |
| 165 | in a particular way in order to please the assessor or avoid shame/embarrassment) |
| 166 | 7) be culturally neutral (i.e., involve skills, behaviors, objects, ideas, or terminology that are |
| 167 | common across contexts) |
| 168 | Each of these three phases was led by the study authors, with results reviewed by a group |
| 169 | of advisory team members who represented multiple backgrounds (e.g., research, practice, |
| 170 | policy), fields (e.g., health, nutrition, psychology, education), and geographical contexts (e.g., |
| 171 | United States, sub-Saharan Africa, Asia, Latin America). Advisory group members provided oral |
| 172 | and written feedback on study procedures and materials via bi-monthly conference calls, formal |
| 173 | surveys, and informal communications (e.g., emails, one-on-one meetings). |
| 174 | Finally, all items were translated and back-translated to/from Swahili by bilingual |
| 175 | Tanzanian and American study staff. Discrepancies in translation were resolved based on the |

³ In the case of items of child behavior traditionally measured using Likert response scales (e.g., never/sometimes/often/always), we integrated "frequency anchors" into the questions themselves to indicate the prevalence of behavior necessary to achieve a "yes" versus a "no" response (e.g., "Does the child get along well with other children *most of the time*?"). These frequency anchors were selected to discriminate between adaptive vs. non-adaptive behavior for each item.

176 consensus of a committee comprised of CREDI team members, local staff, and bilingual177 Tanzanian community members.

178 Qualitative pilot phase

179 To provide preliminary feedback on the initial set of items, we conducted a series of 180 "cognitive" (qualitative) interviews in December of 2013 with 10 caregiver-child pairs in and 181 around Ifakara, Tanzania (mean age of children = 28.2 months, range = 20-35 months). A local 182 female research scientist with a Master's degree in human development was recruited based on 183 her previous experience conducting qualitative research in the study community. The 184 interviewer conducted interviews one-on-one with caregivers in children's homes using a semi-185 structured interview protocol designed to elaborate each item's acceptability, clarity, and 186 applicability, as well as the comprehensiveness and redundancy of the scale as a whole [21, 22]. 187 Specifically, the interviewer asked the caregiver (all of whom happened to have been mothers) to 188 respond to each item based on her child's ability or behavior. The interviewer then asked one or 189 more in a series of seven follow-up questions designed to elicit the caregiver's perceptions of the 190 item, her thought process in responding to the item, and/or her suggestions for improving the 191 item. At the end of each interview, the caregiver was also asked to give her general impressions 192 of what positive ECD means to her, the acceptability of the scale, and whether she had any 193 suggestions for improving the scale. (For the full interview protocol, contact the first author.) 194 The results of these interviews were used to provide preliminary information regarding the 195 overall acceptability of the scale, as well as to identify items that required further adaptation or 196 elimination prior to larger-scale quantitative testing.

197 Quantitative pilot phase

198 Following the qualitative phase, we conducted a full quantitative pilot from January to 199 October of 2014 in 2,481 caregiver-child pairs, of which 2,320 (93.5%) included mothers, 68 200 (2.7%) included fathers, and 93 (3.8%) included other family members (e.g., grandparents, 201 aunts). Child-caregiver pairs who participated in the qualitative pilot portion of the validation 202 study were excluded from participation in the full quantitative pilot phase. Of the 4,356 children 203 randomly selected for a home visit, 2,481 (57.0%) completed the visit, 558 (12.8%) were 204 temporarily away, 1,204 (27.6%) had permanently moved, 60 (1.4%) had died, and 53 (1.2%) 205 had caregivers who refused to participate. The characteristics of those who completed the home 206 visit versus those who were invited but did not complete the home visit are shown in Appendix B 207 and indicate relative similarity across the groups. Each caregiver-child pair was visited in their 208 home, invited and consented to participate, and interviewed using all items on the CREDI. 209 Caregivers also reported on cognitive stimulation using six items from UNICEF's Multiple 210 Indicator Cluster Survey ECD module capturing adult-child interactions [14] and children's 211 physical and mental disability using six items from the Ten Questions screener [23]. Stimulation 212 items reflected whether an adult household member had engaged the child in six different 213 activities (e.g., reading, counting, playing, singing) over the preceding three days. Children were 214 grouped into low (0-2 activities), moderate (3-4 activities), and high (5-6 activities) stimulation 215 categories for analyses. Disability items reflected children's difficulty with seeing, hearing, 216 moving, and learning. Children were considered to have a disability if their caregiver answered 217 "yes" to any of the six screening items.

Home visits were completed by eight male, secondary school-educated field workers with previous experience conducting field-based research with families and children in the local area. Field workers were selected based on their performance as data collectors in the original vitamin

221 A study and participated in a two-day training on the CREDI and other study visit procedures. 222 All workers were also monitored by the study coordinator in the field on a bi-weekly basis to 223 ensure continued adherence to study protocols. During the home visits, field workers rated their 224 perceptions of caregivers' understanding of and honesty in responding to the CREDI items. 225 They also recorded any questions or concerns stated by the caregivers during the interview. At 226 the end of the visit, field workers measured children's height to the nearest 0.1 cm. Children less 227 than 24 months were measured using a Seca length board, whereas those 24 months or older 228 were measured using a portable Seca stadiometer. Field workers measured height twice in a 229 row, and if the two values differed by more than 0.2 cm, they repeated the measurement a third 230 time, taking an average of the two closest values. Table 1 shows descriptive statistics for this 231 sample.

Table 1. Descriptive characteristics of the quantitative pilot sample

| | Ν | Mean/% | SD | Min | Max |
|---|------|--------|------|-------|-------|
| CREDI ^a | | | | | |
| Total Score (n=44 items) | 2481 | 0.64 | 0.17 | 0.07 | 0.98 |
| Motor (n=5 items) | 2481 | 0.63 | 0.24 | 0.00 | 1.00 |
| Cognitive (n=19 items) | 2481 | 0.64 | 0.29 | 0.00 | 1.00 |
| Socioemotional (n=20 items) | 2481 | 0.64 | 0.15 | 0.10 | 1.00 |
| Bayley Scales of Infant Development-III | | | | | |
| BSID Cognitive | 959 | 60.50 | 8.67 | 30 | 81 |
| BSID Receptive Communication | 950 | 25.78 | 7.00 | 5 | 42 |
| BSID Expressive Communication | 947 | 30.06 | 8.58 | 3 | 46 |
| BSID Fine Motor | 955 | 40.56 | 6.55 | 12 | 62 |
| BSID Gross Motor | 960 | 57.00 | 5.56 | 34 | 70 |
| BSID BOI - Caregiver | 1033 | 1.51 | 0.35 | 0 | 2 |
| BSID BOI - Assessor | 1033 | 1.56 | 0.25 | 0 | 2 |
| Child and Family Characteristics | | | | | |
| Child female | 2481 | 45.6% | | | |
| Child age (months) | 2481 | 27.07 | 6.08 | 17.03 | 37.08 |
| Child height-for-age z-score | 2177 | -1.82 | 1.28 | -5.99 | 4.94 |
| Child stunted (HAZ<-2) | 2177 | 43.3% | | | |

| Child any disability | 2481 | 1.9% | | | |
|---|------|-------|------|------|------|
| Proportion of stimulation activities conducted (out of 6) | 2480 | 0.49 | 0.16 | 0.00 | 1.00 |
| Maternal educ - No school | 2481 | 4.6% | | | |
| Maternal educ - Primary school | 2481 | 86.2% | | | |
| Maternal educ - Secondary school | 2481 | 7.3% | | | |

236 Note: ^a CREDI mean scores represent proportion of correct responses on the scale or sub-scale.

- 237 Scores calculated based on the final set of 44 items only.
- 238

Approximately 60 percent of caregiver-child pairs were selected by a computer-generated 239 240 random number draw before their home visit to be invited to an additional clinic visit, which 241 occurred one to six days after the home visit. Of the 1,478 children randomly selected for a 242 clinic visit, 1,037 (70.2%) completed the visit, 224 (15.2%) agreed to the visit but did not show 243 up, 57 (3.9%) refused the visit, and the remainder (10.8%) were not scheduled due to logistical 244 reasons (e.g., caregiver or child was ill, no clinic appointments were available). The 245 characteristics of home visit participants who completed the clinic visit versus those who did not 246 complete the clinic visit are shown in Appendix C and indicate relative similarity across the 247 groups. During the clinic visit, a female nurse with training in child development and research 248 re-administered a subset of 11 CREDI items (selected for their conceptual diversity) and 249 conducted an adapted and translated version of the Bayley Scales of Infant Development (BSID-250 III) [24] with the child, including all direct assessment subscales as well as the Behavior 251 Observation Inventory (BOI). The BSID-III was chosen as the comparison metric for the present 252 study due to its acceptance as a "gold standard" clinical assessment with strong reliability and 253 validity, its complementary direct assessment format, and its previous use by our team in 254 Tanzanian ECD research [25-27]. 255

Because the BSID-III was originally developed in the United States, field and research
staff completed a detailed adaptation process over the period of several weeks to improve its

257 applicability within the Tanzanian context. Details of the training, adaptation, and psychometric 258 properties of the BSID-III can be found in Sudfeld et al. [28]. Briefly, six nurses were trained to 259 administer the BSID-III by two American PhD-level psychologists over a three-week period, 260 after which four nurses were selected as study staff based on quantitative ratings of their 261 performance and knowledge. Study nurses were each monitored by the local study coordinator 262 on a biweekly basis to ensure quality and to avoid assessor drift. To enhance cultural 263 applicability, unfamiliar images and terminology within 13% of BSID-III items (n=30) were 264 replaced using more culturally relevant stimuli (e.g., changing a picture of an apple to a banana) 265 based on local expert consensus. To maintain functional equivalence, replacement stimuli were 266 selected to be of similar size, style, and complexity to original stimuli. Raw scores were used for 267 analyses due to lack of Tanzania-specific age-norms. At the end of the clinic visit, nurses 268 recorded mothers' questions and any problems that may have precluded full completion of the 269 visit (e.g., child was sick or uncooperative).

270 Data from the quantitative pilot phase were used at the item level to understand 271 individual items' distributional properties, including pass/fail rates and levels of non-response 272 (i.e., "don't know" answers). Test-retest reliability was assessed for the 11 CREDI items tested 273 in both the home and clinic visit. Additional tests of reliability and validity were performed for 274 items that were identified to have sufficient variability (i.e., that did not show evidence for floor 275 or ceiling effects). Specifically, internal consistency was captured within each of the three 276 CREDI domains/subscales using Cronbach's alpha. Discriminant validity was assessed by 277 comparing CREDI total and subscale scores across a set of child and family characteristics, 278 including child age, gender, stunting status (height-for-age z-score of <2SDs below the WHO 279 standard) [29], caregiver-reported disability, caregiver-reported cognitive stimulation in the

280 home, and maternal education (which was collected at children's births as part of the original

vitamin A study). Finally, concurrent validity was assessed by correlating each CREDI subscale

score with the corresponding BSID-III raw score. Psychological field standards (e.g., Cicchetti,

283 1994) [30] were used as the basis for determining acceptability of the items' and subscales'

reliability and validity.

285 Field staff interviews

At the end of the quantitative pilot phase, 10 qualitative "exit" interviews were conducted with field staff (including 6 field workers, 3 nurses, and 1 field supervisor) to identify areas of confusion, difficulty, or lack of clarity in the CREDI based on their experiences over nine months of data collection.

290

Results

291 Item development & qualitative interviews

292 Review of the literature and consultation with ECD experts resulted in the identification 293 of three primary domains - motor, cognitive/language, and socioemotional skills - and 12 294 constructs or subdomains for inclusion in the CREDI (see Table 2). Based on a review of 295 existing ECD measurement tools (see Appendix A) and the process of identifying conceptual 296 gaps, an initial set of items was developed by the core research team. Whereas many of these 297 items were highly similar to questions from existing ECD assessments, a substantial number -298 particularly from the socioemotional domain, where the largest conceptual gaps were identified -299 were completely novel. Following a round of revisions to the items by the ECD expert team, a 300 total of 92 items were submitted for initial qualitative pilot testing. Following qualitative 301 interviews, 22 items (n=7 from motor, n=8 from cognitive, and n=7 from socioemotional) were 302 dropped from the CREDI for the following reasons: the item was too easy/hard for children of

| 303 | this age group $(n=10)$, the item was redundant with another item $(n=8)$, the item was confusing |
|-----|---|
| 304 | and could not be easily clarified (n=3), and the item was culturally inappropriate and could not |
| 305 | be easily adapted (n=1). Of the remaining 70 items, 15 (n=1 for motor, n=7 for cognitive, and |
| 306 | n=7 for socioemotional) were adapted prior to the quantitative pilot based on suggestions from |
| 307 | cognitive interview participants and additional consultation with local experts. These |
| 308 | adaptations primarily involved the addition of examples to improve item clarity, such as |
| 309 | changing "Does the child know any numbers?" to "Does the child know any numbers (e.g., one, |
| 310 | two, three)?" In several instances, words relating to culturally specific objects (e.g., toys) were |
| 311 | removed or replaced. |

313 **Table 2**. Domains and constructs of the CREDI

| | DOMAINS | Motor | Cognitive | Socioemotional |
|-----|------------|----------|------------------------|-------------------------------|
| | CONSTRUCTS | 1) Fine | 1) Expressive language | 1) Early executive function & |
| | | 2) Gross | 2) Receptive language | effortful control |
| | | | 3) Preacademic | 2) Emotion regulation |
| | | | skills/knowledge | 3) Externalizing symptoms |
| | | | 4) Reasoning & problem | 4) Internalizing symptoms |
| | | | solving | 5) Reactivity & soothability |
| | | | | 6) Social competence |
| 315 | | | | |
| | | | | |

316

317 Acceptability

318 Cognitive interviews revealed that 10/10 caregivers were cooperative with and felt

319 pleased by the items, and 9/10 felt that "there were no right or wrong answers." (One mother of a

- 320 20-month-old child reported, "I was uncomfortable when you asked me things which my child
- 321 cannot do, as she is too young.") Field workers' average ratings of whether the caregivers
- 322 understood the questions during the quantitative pilot was 3.85 (SD=0.28) and whether they
- 323 appeared to answer truthfully was 3.77 (SD=0.36) on a scale of 1 (No, not at all) to 4 (Yes, all

questions). In addition, exit interviews of field staff identified no problems with items' demand
characteristics, with the exception of a socioemotional item capturing whether the child "gets
along well with other children most of the time" that was reported by 5 of the 11 field workers as
eliciting problems with social desirability.

328 Item analysis

329 Results of item analyses to understand the completeness, distribution, and relative 330 difficulty of each item as measured during the quantitative pilot home visit can be found in 331 Appendix B. Results revealed that 25 of the 70 items (n=10 for motor, n=8 for cognitive, n=7 332 for socioemotional) showed evidence of ceiling effects, with pass rates of >95%. In general, 333 these items tended to represent more basic developmental skills that may be more appropriate for 334 children <18 months (e.g., walking, achieving object permanence, saying one word, showing 335 affection). These items were removed from the final subscales used for reliability and validity 336 analyses. Figure 1 summarizes the item selection process. Figures 2 to 4 show score 337 distributions by age.

338

<< Figures 1-4 here >>

339 "Don't know" responses were infrequent across the CREDI, with an average of 1.8% of 340 the sample responding "don't know" for any given item during the home visit. In comparison, 341 among 1,037 BSID-III assessments, 9.9% were incomplete and an additional 10.1% were 342 flagged by nurses as challenging or unreliable due to children's illness, injury, 343 uncooperativeness, or distraction. Of the items that were most frequently answered as "don't 344 know," the majority were also acknowledged as unclear in the qualitative interviews due 345 translation difficulties (e.g., inability to find an equivalent word or set of words for "distracted"

in Swahili) or lack of a concrete behavioral marker (e.g., ambiguity of what it means to showsympathy or concern).

348 Reliability

349 A total of 26 items were excluded from the original 70-item set due to ceiling effects 350 (n=25) and the lack of conceptual fit with a specific developmental domain (n=1, "too sick to 351 play"). Cronbach's alpha coefficients calculated in the final set of 44 items suggested acceptable 352 internal consistency / inter-item reliability for motor (α =.68), cognitive (α =.90), and 353 socioemotional (α =.68) items. Kappa coefficients were used to capture the reliability of 354 responses from the same caregiver to 11 items administered at both the home and clinic visits 355 (see Table 3). It should be highlighted that the Kappa statistic was originally developed as a 356 measure of inter-rater reliability, where two raters directly observe or assess the same individual 357 at the same time. In the case of the present study, our Kappas capture both test-retest reliability 358 (with an average time between study visits of 3.17 days [SD=2.11]) and inter-rater reliability 359 (between male home visitors and female clinic nurses). Given this, they represent both true 360 variation in children's skills over time, as well as multiple potential sources of measurement 361 error. As such, we might expect our Kappas to be lower than those used simply to capture inter-362 rater reliability. Indeed, results indicate differential reliability, with 2 items showing moderate 363 reliability (Kappa ≥ 0.40), 6 items showing fair reliability (Kappa ≥ 0.20), 2 items showing slight 364 reliability (Kappa ≥ 0.00), and 1 item showing poor reliability (Kappa ≤ 0.00). Additional analyses 365 revealed no consistent evidence for systematic differences in mean scores across home and clinic 366 visits (see Table 3) or for substantial differences in Kappa values based on the time delay 367 between the home and clinic visit (contact first author for detailed results).

368

369 Table 3. Test-retest reliability of 11 select items across data collection contexts with same

370 caregiver reporter (n=962)

371

| | Mean Score | | Difference | % | |
|---|-------------------|---------------------|------------|-----------|--------|
| | Home Interview | Clinic Interview | in means | Agreement | Kappa |
| Does the child walk several steps without the support of a person or object (e.g., wall or furniture)? | 0.99 | 0.99 | 0.00 | 99.3% | 0.663 |
| Does the child know the names of at least two body parts (e.g., arm, eye, or nose)? | 0.67 | 0.65 | 0.02 | 80.4% | 0.563 |
| Does the child say five or more words (e.g., names like Mama or objects like cup)? | 0.91 | 0.93 | -0.02 | 90.4% | 0.335 |
| When asked what common objects (like a cup or a knife) are for, does the child explain correctly? | 0.34 | 0.20 | 0.14 | 74.4% | 0.363 |
| Does the ever child kick, bite, or hit other children or adults? ^r | 0.45 | 0.31 | 0.14 | 68.0% | 0.333 |
| Does the child pick up a small object like a rock with just his/her thumb and a finger? | 0.78 | 0.84 | -0.06 | 78.0% | 0.276 |
| Does the child get along well with other children most of the time? | 0.92 | 0.97 | -0.05 | 92.2% | 0.241 |
| When the child is upset, is he/she able to calm down by him/herself? | 0.45 | 0.59 | -0.14 | 60.0% | 0.213 |
| Does the child pay attention when someone is talking to him/her? | 0.90 | 0.95 | -0.05 | 87.8% | 0.156 |
| Does the child follow simple directions (e.g., "Stand up or Come here")? | 0.98 | 0.99 | -0.01 | 97.7% | 0.144 |
| Is the child sometimes impatient or unwilling to wait or hold still when you ask him/her to? ^r | 0.38 | 0.48 | -0.10 | 49.4% | -0.020 |
| Average | 0.71 | 0.72 | -0.01 | 79.8% | 0.297 |

372

373 Notes: CREDI mean scores represent proportion of correct responses on the item. ^r indicates item

that was reverse coded.

375

376 Validity

377 Table 4 shows the results of tests of discriminant validity for CREDI scores based on

378 child and family characteristics. These results show significantly higher total CREDI scores for

379 children who were older, non-stunted, non-disabled, and from high-stimulation households at the

time of data collection. Effect sizes for these differences ranged from small ($d\approx 0.20$ SD) for

381 stunting, to large (d>0.50SD) for age, disability, and stimulation. No significant (p<.05)

382 differences were observed for CREDI scores across gender or maternal education with the

383 exception of socioemotional scores, which were highest for children of non-educated mothers

384 (*d*≈0.20SD).

385

| 386 | Table 4. | CREDI mean scores (SE) by subgroup (n=2,481) |
|-----|----------|--|
| 387 | | |

| | Total | Motor | Cognitive | Socioemotional |
|--|--|---|--|-------------------------------|
| Child age | | | C | |
| $18-24 \text{ mo}^{a}$ (n=934) | 0.50 (0.005) | 0.45 (0.008) | 0.44 (0.007) | 0.57 (0.005) |
| $>24-30 \text{ mo}^{b}$ (n=614) | 0.67 (0.005) | 0.67 (0.010) | 0.69 (0.008) | 0.65 (0.005) |
| $>30-36 \text{ mo}^{\circ} (n=933)$ | 0.76 (0.004) | 0.82 (0.007) | 0.79 (0.005) | 0.71 (0.004) |
| dif | F(2, 2478) = 965.00 ** | F(2, 2478) = 560.63 ** | F(2, 2478) = 860.93 ** | F(2, 2478)=234.26** |
| | a <b: d="1.00**</td"><td>a<b: d="0.78**</td"><td>a<b: d="1.03**</td"><td>a<b: d="0.52**</td"></b:></td></b:></td></b:></td></b:> | a <b: d="0.78**</td"><td>a<b: d="1.03**</td"><td>a<b: d="0.52**</td"></b:></td></b:></td></b:> | a <b: d="1.03**</td"><td>a<b: d="0.52**</td"></b:></td></b:> | a <b: d="0.52**</td"></b:> |
| | b <c: d="0.51**</td"><td>b<c: d="0.50**</td"><td>b<c: d="0.41**</td"><td>b<c: d="0.39**</td"></c:></td></c:></td></c:></td></c:> | b <c: d="0.50**</td"><td>b<c: d="0.41**</td"><td>b<c: d="0.39**</td"></c:></td></c:></td></c:> | b <c: d="0.41**</td"><td>b<c: d="0.39**</td"></c:></td></c:> | b <c: d="0.39**</td"></c:> |
| | a <c: d="1.51**</td"><td>a<c: d="1.28**</td"><td>a<c: d="1.44**</td"><td>a<c: d="0.92**</td"></c:></td></c:></td></c:></td></c:> | a <c: d="1.28**</td"><td>a<c: d="1.44**</td"><td>a<c: d="0.92**</td"></c:></td></c:></td></c:> | a <c: d="1.44**</td"><td>a<c: d="0.92**</td"></c:></td></c:> | a <c: d="0.92**</td"></c:> |
| Child gender | | | | |
| Male (n=1,349) | 0.64 (0.005) | 0.64 (0.008) | 0.63 (0.007) | 0.64 (0.004) |
| Female (n=1,132) | 0.64 (0.005) | 0.64 (0.009) | 0.64 (0.007) | 0.64 (0.004) |
| dif | t(2479) = -0.70 | t(2479)=0.08 | t(2479) = -1.34 | t(2479)=0.31 |
| , | d=0.03 | d=-0.00 | d=0.06 | <i>d</i> =-0.01 |
| Child stunting | | | | |
| Non-Stunted (n=1,222) | 0.66 (0.005) | 0.66 (0.008) | 0.66 (0.007) | 0.65 (0.004) |
| Stunted (n=955) | 0.62 (0.006) | 0.62 (0.010) | 0.60 (0.008) | 0.65 (0.005) |
| dif | t(2175)=4.79** | t(2175)=3.46** | t(2175)=6.09** | t(2175)=0.86 |
| , | d=-0.19** | d=-0.13** | d=-0.25** | <i>d</i> =-0.04 |
| Child disability | | | | |
| No disability $(n=2,434)$ | 0.64 (0.003) | 0.65 (0.006) | 0.64 (0.005) | 0.64 (0.003) |
| Any disability (n=47) | 0.53 (0.032) | 0.45 (0.050) | 0.48 (0.047) | 0.60 (0.025) |
| dif | t(2479)=4.43** | t(2479)=4.73** | t(2479)=4.45** | t(2479)=1.81+ |
| · | d=-0.65** | d=-0.69** | d=-0.65** | d=-0.27+ |
| Stimulation | | | | |
| Low stimulation ^a (n=847) | 0.63 (0.005) | 0.62 (0.10) | 0.63 (0.008) | 0.64 (0.005) |
| Mod stimulation ^b $(n=1,498)$ | 0.63 (0.005) | 0.65 (0.08) | 0.62 (0.006) | 0.64 (0.004) |
| High stimulation ^{c} (n=135) | 0.75 (0.011) | 0.77 (0.021) | 0.81 (0.014) | 0.68 (0.014) |
| dif | F(2, 2477)=29.57** | F(2, 2477)=17.41** | F(2, 2477)=41.00** | F(2, 2477)=3.65* |
| | a <b: d="0.02</td"><td>a<b: d="0.09+</td"><td>a<b: d="-0.02</td"><td>a<b: d="0.03</td"></b:></td></b:></td></b:></td></b:> | a <b: d="0.09+</td"><td>a<b: d="-0.02</td"><td>a<b: d="0.03</td"></b:></td></b:></td></b:> | a <b: d="-0.02</td"><td>a<b: d="0.03</td"></b:></td></b:> | a <b: d="0.03</td"></b:> |
| | b <c: d="0.67**</td"><td>b<c: d="0.45**</td"><td>b<c: d="0.80**</td"><td>b<c: d="0.22*</td"></c:></td></c:></td></c:></td></c:> | b <c: d="0.45**</td"><td>b<c: d="0.80**</td"><td>b<c: d="0.22*</td"></c:></td></c:></td></c:> | b <c: d="0.80**</td"><td>b<c: d="0.22*</td"></c:></td></c:> | b <c: d="0.22*</td"></c:> |
| | a <c: d="0.68**</td"><td>a<c: d="0.54**</td"><td>a<c: d="0.77**</td"><td>a<c: <i="">d=0.25*</c:></td></c:></td></c:></td></c:> | a <c: d="0.54**</td"><td>a<c: d="0.77**</td"><td>a<c: <i="">d=0.25*</c:></td></c:></td></c:> | a <c: d="0.77**</td"><td>a<c: <i="">d=0.25*</c:></td></c:> | a <c: <i="">d=0.25*</c:> |

Maternal education

| No education ^a (n=113) | 0.63 (0.016) | 0.61 (0.029) | 0.61 (0.022) | 0.67 (0.015) |
|---------------------------------------|--|--|--------------------------|---------------------------|
| Primary school ^b (n=2,138) | 0.64 (0.004) | 0.65 (0.026) | 0.64 (0.005) | 0.65 (0.003) |
| Secondary school ^c (n=181) | 0.61 (0.013) | 0.63 (0.022) | 0.61 (0.019) | 0.62 (0.012) |
| dif | <i>F</i> (2, 2429)=2.63+ | F(2, 2429)=1.36 | <i>F</i> (2, 2429)=2.29+ | <i>F</i> (2, 2429)=4.36** |
| | a <b: <i="">d=0.14</b:> | a <b: d="0.20</td"><td>a<b: <i="">d=0.19</b:></td><td>a<b: <i="">d=-0.04</b:></td></b:> | a <b: <i="">d=0.19</b:> | a <b: <i="">d=-0.04</b:> |
| | b <c: d="-0.18+</td"><td>b<c: <i="">d=-0.08</c:></td><td>b<c: <i="">d=-0.14</c:></td><td>b<c: <i="">d=-0.19*</c:></td></c:> | b <c: <i="">d=-0.08</c:> | b <c: <i="">d=-0.14</c:> | b <c: <i="">d=-0.19*</c:> |
| | a <c: d="-0.04</td"><td>a<c: <i="">d=0.12</c:></td><td>a<c: <i="">d=0.05</c:></td><td>a<c: <i="">d=-0.24*</c:></td></c:> | a <c: <i="">d=0.12</c:> | a <c: <i="">d=0.05</c:> | a <c: <i="">d=-0.24*</c:> |

Note: ** p < .01, * p < .05, + p < .10; CREDI mean scores represent proportion of correct responses on the scale or sub-scale; *d* indicates effect size of standardized mean differences as represented by Cohen's *d*

| 393 | Figure 5 shows the correlations between the CREDI and BSID-III subscales. Linear |
|---------------------------------|--|
| 394 | bivariate correlations between the CREDI motor items and the BSID-III fine and gross motor |
| 395 | subscales were $r=.50$ and $r=.51$, respectively. Correlations between the CREDI cognitive items |
| 396 | and the BSID-III cognitive, receptive communication, and expressive communication subscales |
| 397 | were $r=.68$, $r=.69$, and $r=.73$, respectively. All of these correlations were significant at the |
| 398 | p<.001 level. Correlations between the CREDI socioemotional items and the BSID-III BOI were |
| 399 | much smaller, at $r=.16$ ($p<.001$) for the caregiver-reported BOI and $r=.09$ ($p<.01$) for the |
| 400 | examiner-reported BOI. |
| 401 | |
| 401 | << Figure 5 here >> |
| 401 | << Figure 5 here >> Discussion |
| | |
| 402 | Discussion |
| 402 403 | Discussion The primary aim of the present study was to describe initial evidence for the |
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| 402 403 404 405 | Discussion The primary aim of the present study was to describe initial evidence for the acceptability, reliability, and validity of the newly developed CREDI as a measure of ECD designed for feasible use within standard household surveys in low-resourced settings. Results |
| 402 403 404 405 406 | Discussion The primary aim of the present study was to describe initial evidence for the acceptability, reliability, and validity of the newly developed CREDI as a measure of ECD designed for feasible use within standard household surveys in low-resourced settings. Results of our initial validation effort in Tanzania suggest that the CREDI tool may provide a valid |

disabled children, and children from more versus less cognitively stimulating households, while
showing evidence for equality across gender and maternal education within a large quantitative
sample. Collectively, the items also showed adequate criterion validity with the BSID-III motor,
cognitive, and communication subscales, which are "gold standard" direct assessments of

414 children's early developmental status often used in clinical settings by highly trained staff.

415 In addition to showing positive evidence for validity, the CREDI was found to be an 416 acceptable tool for use in low-resourced settings. It was well understood by respondents and 417 quick to implement (taking an average of 20 minutes to administer in total) by trained field staff 418 with the equivalent of a secondary education. Furthermore, initial findings suggest that the 419 caregiver report format may be advantageous for use with young children in low-resourced 420 settings in order to avoid problems with non-compliance (e.g., due to unfamiliarity with testing 421 situations, fear of unfamiliar adults, child illness, etc.) that were found to affect the quality and 422 completeness of nearly 20 percent of BSID-III direct assessments.

423 Although the CREDI as a whole shows promise as an acceptable and valid measurement 424 tool, test-retest reliability was also low for many individual items, and particularly for those that 425 qualitative interview respondents noted were difficult to translate or lacking in examples, 426 benchmarks, or behavioral markers. Given that no systematic differences were found based on 427 the interviewer, setting, or time between visits, these results suggest that further adaptation is 428 needed to make items as concrete as possible and reduce respondent "guessing." Additional 429 reliability testing, qualitative work, and empirical analysis (e.g., item response theory) are also 430 warranted in future work to ensure that items' interpretation is occurring similarly across time, 431 context, respondent, and assessor.

432 In addition, these results revealed a relatively weak correspondence between the 433 socioemotional items and the BSID-III BOI. This low correlation was not particularly surprising 434 given that 1) the BOI was not designed as a measure of socioemotional functioning, per se, and 435 2) our aim in developing the socioemotional items was to capture a large breadth of important 436 but potentially non-overlapping developmental constructs. Our review of the literature and 437 consultation with ECD experts revealed that the vast majority of previous measurement tools 438 (like the BSID-III) have focused on young children's motor and cognitive development, with far 439 fewer options for capturing social, emotional, and higher-order cognitive processes like self-440 regulation and executive function that are increasingly being shown by the literature to predict 441 later life outcomes [31-33, 10, 12]. Given that our socioemotional items showed adequate 442 reliability and validity in other ways (e.g., internal consistency, discrimination by age, caregiver-443 reported stimulation, etc.), we are confident that their inclusion represents an important advance 444 over previous work in this age group. At the same time, we acknowledge the need for further 445 validation against alternative socioemotional measurement approaches (e.g., the Ages and Stages 446 personal-social and socio-emotional scales, observer ratings of child behavior during assessment) 447 and clinical diagnoses, as well as examinations of predictive validity over time in diverse 448 settings, particularly given a lack of understanding of these early skills cross-culturally. 449 Additional research is also needed to explore the somewhat counterintuitive finding that less 450 educated caregivers report the highest levels of socioemotional development for their children. 451 Despite the strengths of this study, the research presented also has several important 452 limitations that must be addressed through future work. First, and most importantly, our focus 453 on a single geographic context substantially limits the generalizability of these results. Second, 454 the number of qualitative interviews conducted in this study was quite small, and focused only

455 on mothers. Third, as is noted previously, our lack of a "gold standard" metric against which to 456 compare our socioemotional items limits our understanding of their concurrent validity. Fourth, 457 our additional measures of context and disability were limited and coarse, and may not have been 458 suitable for fully describing the risks and challenges faced by children. Finally, the cross-459 sectional nature of our data collection effort precludes our ability to draw conclusions about the 460 CREDI's long-term predictive validity. To address these limitations, we plan to continue 461 validation of the CREDI using 1) a large number of geographically, linguistically, and culturally 462 diverse contexts, 2) different types of caregivers, 3) a wider range of locally-generated 463 comparison and diagnostic metrics, and 4) longitudinal data. In particular, additional qualitative 464 and quantitative work is currently underway in multiple countries to improve the clarity and 465 objectivity of items in an attempt to improve test-retest reliability. Based upon the results of 466 these ongoing and future efforts, we hope to finalize and disseminate the CREDI as an open-467 source tool for governments, agencies, and organizations to quantify developmental status at a 468 population level and track progress in alleviating ECD-related disparities around the world.

469

Conclusions

470 Given growing justification for and investment in the promotion of positive development 471 in the first 1000 days of life, providing a tool for quantifying and monitoring early 472 developmental outcomes – particularly for the 89 percent of children under five globally who 473 live in low- and middle-income country contexts – is critically important [34]. Designed as a 474 comprehensive, caregiver-reported assessment of ECD for children under three, the aim of the 475 CREDI is to provide low-cost, large-scale data that will facilitate decision making regarding 476 intervention and resource allocation, and track global progress in alleviating early developmental 477 disparities. The results of the present study suggest that overall, the CREDI worked well for

| 478 | capturing ECD behaviors and skills in 18- to 36-month-old children within Tanzania. Additional |
|-----|---|
| 479 | research in diverse linguistic and cultural contexts and younger age groups is needed to ensure |
| 480 | the CREDI's utility prior to full dissemination. |
| 481 | |
| 482 | Abbreviations |
| 483 | BOI: Behavior Observation Inventory |
| 484 | BSID-III: Bayley Scales of Infant Development (III) |
| 485 | ECD: Early Childhood Development |
| 486 | CREDI: Caregiver-Reported Early Development Index |
| 487 | |
| 488 | Declarations |
| 489 | Ethics approval and consent to participate: Primary caregivers provided informed consent for |
| 490 | their own participation, as well as the participation of their children. All study protocols were |
| 491 | approved by institutional review boards (IRBs) at the Harvard School of Public Health, the |
| 492 | National Institute of Medical Research of Tanzania, and the Ifakara Health Institute. |
| 493 | Consent for publication: Not applicable |
| 494 | Availability of data and material: The datasets generated and analyzed during the current |
| 495 | study are not publicly available due to their ongoing analysis but are available from the |
| 496 | corresponding author on reasonable request. |
| 497 | Competing interests: The authors declare that they have no competing interests. |
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500 Author contributions: DM conceptualized and designed the study, developed the data 501 collection instruments, conducted the preliminary analyses, drafted the initial manuscript, and 502 approved the final manuscript as submitted. CS assisted in the conceptualization and design of 503 the study, developed portions of the data collection instruments, reviewed and revised the 504 manuscript, and approved the final manuscript as submitted. DB led the cultural adaptation of 505 the BSID-III and training of data collectors, reviewed and revised the manuscript, and approved 506 the final manuscript as submitted. AM assisted in the development of the data collection 507 instruments, translated study materials, coordinated and supervised data collection, critically 508 reviewed the manuscript, and approved the final manuscript as submitted. GA assisted in the 509 development of the data collection instruments, translated study materials, coordinated and 510 supervised data collection, critically reviewed the manuscript, and approved the final manuscript 511 as submitted. TW conducted the interviews with field staff, analyzed, translated and summarized 512 the resulting qualitative data, critically reviewed the manuscript, and approved the final 513 manuscript as submitted. WF oversaw the design and conceptualization of the study, reviewed 514 and edited the data collection instruments, critically reviewed the manuscript, and approved the 515 final manuscript as submitted. GF assisted in the design and conceptualization of the study, 516 developed portions of the data collection instruments, led the study sampling, conducted the final 517 analyses, reviewed and revised the manuscript, and approved the final manuscript as submitted. 518 Acknowledgements: The authors would also like to express gratitude to the field staff and 519 study participants who made this research possible.

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Figure Captions

- 627 **Figure 1**. Item selection tree.
- **Figure 2**. Proportion children passing each motor item, by age (n=2,481)
- **Figure 3**. Proportion children passing each cognitive item, by age (n=2,481)
- **Figure 4**. Proportion children passing each socioemotional item, by age (n=2,481)
- 631 **Figure 5**. Histogram of CREDI distribution and local polynomial graph of the relation between
- 632 CREDI and BSID-III subscale scores (line w/ 95% CI)