Establishing concurrent validity on three domains of the Early Learning Outcomes Measure (ELOM)

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Abstract

The Early Learning Outcomes Measure (ELOM) assesses development of preschool children in five domains: gross motor development, fine motor coordination and visual motor integration, emergent numeracy and mathematics, cognition and executive functioning, and emergent literacy and language. The ELOM was developed to provide a standardised culture-fair population-level instrument for South Africa. Similar existing instruments are not standardised for South Africa and require professional administration. The ELOM is standardised for children aged 50 to 69 months and is psychometrically valid across measures of content and construct validity, reliability and cross-cultural fairness. Two studies are reported. Study one investigated the concurrent validity of the ELOM and the WPPSI-IV. Children (N = 62) enroled in the Drakenstein Child Health Study, aged 72 to 76 months (M = 75.05) were assessed on the ELOM and the WPPSI-IV. Results showed a very high correlation (r = .64, p < .001) between ELOM Total Score and WPPSI-IV Full Scale composite score, thus establishing concurrent validity of the ELOM. Fine motor coordination and visual motor integration, cognition and executive functioning, and emergent literacy and language domains correlated significantly with corresponding WPPSI-IV indices: visual spatial, fluid reasoning, processing speed, working memory, and verbal comprehension. As children in study one were older than those in the ELOM standardisation, in study two (N = 116), ELOM item ceiling effects were investigated (M = 75.82 months). No significant ceiling effects were found, thus the ELOM is valid for older ages, but revisions of Items 1, 5 and 7 should be considered.

Keywords: concurrent validity, ECD, ELOM, psychometry, WPPSI-IV

South Africa's legacy of apartheid has resulted in a significantly unequal quality of early learning opportunities, where the most disadvantaged children of colour continue to receive the poorest quality of teaching and resources in preschool programmes, which predicts substandard later academic performance (Snelling, Dawes, Biersteker, Girdwood, & Tredoux, 2019). Moreover, more than one million children in South Africa between the ages of three and five have no access to any early learning programmes, and the large majority are from poor households that cannot afford to send their children to preschools, or other early learning programmes (Hall, Sambu, Berry, Giese, & Almeleh, 2017). These children find themselves considerably disadvantaged by the time they enter Grade 1 (the first year of compulsory, free education in South Africa), when compared to the development of their wealthier peers who have been enroled in early learning programmes (Hall et al., 2017).

Inequitable education quality is recognised as a global problem and has led to the introduction of Quality Education as one of the United Nations (UN) Sustainable Development Goals. Target 4.2 of these goals states that by 2030, all girls and boys should have access to "quality early childhood development, care and pre-primary education," so that children are adequately prepared for primary education (Raikes, Britto, Yoshikawa, & Iruka, 2017, p.6). It is widely recognised that focusing on early childhood development (ECD) in low and middle-income countries is an important strategy to ensure that children's rights are upheld, and to address and reduce intergenerational poverty and inequality (Engle et al., 2007; Snelling et al., 2019). In the South African education sector, ECD is defined as "a comprehensive approach to programmes and policies for children from birth to nine years of age" which encompasses children's physical, psychological, social and emotional growth (Government of South Africa, 2019, para. 1).

Each UN country is required to implement and report on their own strategies towards achieving this goal of Quality Education and ECD. In response to Target 4.2, the South African state intends to roll out universal access to two years of ECD programmes (before starting Grade 1) by 2030, to attempt to address the evident unequal quality of education in South Africa, at a grassroots level (Kotzé, 2015). Furthermore, the National Development Plan Vision 2030 regards:

> early childhood development [as] a top priority among the measures to improve the quality of education and long-term prospects of future generations. Dedicated resources

> should be channeled towards ensuring that children are well cared for from an early age and receive appropriate emotional, cognitive and physical development stimulation (National Planning Commission, 2012, p.300).

Additionally, the early learning related goal of the National Integrated ECD Policy is:

> by 2030 to provide a universally available comprehensive quality age and developmental stage appropriate opportunities for learning for all children from birth until they enter formal school, which lay the foundations for optimal early learning, inclusion and the socio-emotional, physical, intellectual development of young children through play and other related, recognised methods for early learning (RSA, 2015, p.59).

ECD assessment tools are required to externally evaluate ECD programme quality and to identify potential problem areas in individual children's development, as well as in the ECD programmes themselves. Supportive interventions in ECD programmes within low income areas would aid in enhancing the quality of ECD within these areas, whilst also identifying possible reasons for poor enrolment rates, as well as factors that could be preventing conducive learning, such as inadequate electricity and water supply (Kotzé, 2015). Improvements to ECD programmes should be informed by assessment of the early learning outcomes of children, using ECD assessment tools (Snelling et al., 2019).

In South Africa, there are few locally, standardised ECD assessment tools, which are restricted by their affordability, need for professional administration, inability to account for differences in cultural and socio-economic backgrounds, and their need to accommodate eleven official languages (Snelling et al., 2019). The ELOM was developed to address these shortcomings of previous ECD measures in South Africa. The ELOM is the first standardised South African, psychometrically valid instrument to assess children aged 50 to 69 months from all socioeconomic backgrounds and is standardised for five South African languages (Dawes, Biersteker, Girdwood, Snelling, & Tredoux, 2016). The purpose of the ELOM is to measure early learning programme outcomes against early learning development standards that children are expected to have met before entering Grade R. The ELOM assesses development of preschool children in five domains: gross motor development, fine motor coordination and visual motor integration, emergent numeracy and mathematics, cognition and executive functioning, and emergent language and literary - using 23 items (see Appendix A). The results obtained from ELOM assessments are used to identify areas of ECD programmes that need improving in order

for children to be on par with the expected early learning development standards (Dawes et al., 2016; Snelling et al., 2019). More information about the ELOM can be found on the website: http://elom.org.za/.

Content and construct validity, reliability and cross-cultural fairness of the ELOM have been well-established. Results concluded that ELOM domains are unidimensional, internally consistent and Differential Item Functioning analyses showed that ELOM items did not discriminate against children of the same ability from different socioeconomic and language backgrounds (Dawes et al., 2016; Snelling et al., 2019). However; concurrent (criterion-related) validity and test-retest reliability have not been established in ELOM research to date (Snelling et al., 2019). These are psychometric gaps that need to be addressed.

Concurrent validity establishes the degree to which a new test compares to an established test of the same psychological construct, and furthermore determines "how well the test anticipates a criterion behavior or outcome" (Tredoux & Scott, 2002, p. 217). The current study investigated the concurrent validity of the ELOM by comparing children's performance on the ELOM with their performance on the Wechsler Preschool and Primary Scale of Intelligence (WPPSI-IV), which measures similar constructs (Canivez, 2014; Wechsler, 2012a).

The WPPSI-IV is an established, standardised intelligence test for children aged between 30 and 91 months. Test-retest reliability of the WPPSI-IV has been well-established and exhibits "excellent levels of stability over time for all age ranges" (Thorndike, 2014, p.17). Concurrent validity of the WPPSI-IV has also been well-established through comparisons with the WPPSI-III, the Differential Ability Scales, and the Bayley Scales of Infant and Toddler Development (Thorndike, 2014). However, the WPPSI-IV has not been standardised in South Africa, since it is only available in English, and thus, administrators are required to translate the instructions for non-English children. Therefore, there may be cultural bias in its administration and results, which potentially limits the ability of the WPPSI-IV to be a fair measure of intelligence in the multicultural context of South Africa (Foxcroft, 1997; Foxcroft, Paterson, Le Roux, & Herbst, 2004). There is also potential for variation in translations due to a lack of standardisation. Nevertheless, the WPPSI-IV is widely recognised as a gold-standard test which measures similar constructs to the ELOM.

To conclude, an evaluation of the ELOM and its literature reveals a lack of data on its concurrent validity. Establishing concurrent validity is important because, as a new test, it is

desirable to establish whether or not children perform similarly on the ELOM and on an established test of the same construct. This would strengthen the validity and legitimacy of the ELOM. The WPPSI-IV is a well-established test, with strong psychometric qualities, and it measures similar constructs to the ELOM. It was therefore decided that the WPPSI-IV would serve as an appropriate tool against which to assess the concurrent validity of the ELOM.

Research Aims

The primary aim of the present study was to establish the concurrent validity of the ELOM by comparing children's performance on the ELOM to core subtests of the WPPSI-IV that measure the same constructs. We investigated whether concurrent validity was demonstrated between ELOM Total and WPPSI-IV Full Scale composite scores, and between three selected ELOM domains (fine motor coordination and visual motor integration, cognition and executive functioning, and emergent literacy and language) and WPPSI-IV indices (visual spatial, fluid reasoning, processing speed, working memory and verbal comprehension). This study aimed to make a contribution to the psychometric qualities of the ELOM by strengthening its validity. The establishment of concurrent validity would mean that ELOM results can be interpreted with greater confidence, and thus with wider application and relevance.

A further objective was to establish whether the use of the ELOM could be extended to older children. We therefore investigated the range of scores and whether ceiling effects were evident on items administered to a sample of children who were considerably older than the oldest of those that participated in the ELOM standardisation.

Method

Study Design and Setting

The current study is a psychometric, correlational sub-study of the Drakenstein Child Health Study (DCHS). The DCHS is a birth cohort study based in Paarl in the Western Cape of South Africa, that has followed 1,000 mother-child dyads living in Mbekweni (a predominantly black African, isiXhosa speaking community), and TC Newman (a mixed race, Afrikaans speaking community) since March 2012. Both communities are of low socio-economic status and are characterised by multiple risk factors such as substance abuse, HIV & AIDS, and poverty (Stein et al., 2015). More information on the DCHS can be found at: http://www.paediatrics.uct.ac.za/scah/dclhs.

Participants

The DCHS mothers were recruited at 20-28 weeks' gestation at one of two primary health care clinics in the Drakenstein area. At time of recruitment, these mothers had to be over 18 years of age and needed to express no intention of leaving the area within the next year. The mothers also needed to provide written informed consent for both their and their child's participation in the research. Participants for the current psychometric study were children who were tested on both the ELOM and the WPPSI-IV during the 72-month neurocognitive testing wave of the DCHS in 2019.

Sampling procedure. Records from 150 children were provided by the DCHS. 21 records were removed because the children had not been tested on both instruments (the ELOM and the WPPSI-IV) on the same day. A further seven participants were removed because they had not fully completed the WPPSI-IV. Six participants were removed because they were noted by assessors to be tired, sick or distracted on the day of assessment. Participants over the age of 76 months were then removed, so that the sample could be closer to the age on which the ELOM has been standardised. Thus, the final sample size was $N = 62$. Six of these 62 participants were selected (using a random number generator) and manually checked for errors. No discrepancies were found in the data of these six records, and thus the accuracy of the rest of the dataset was assumed with confidence.

While the sample of $N = 62$ was used for the correlational analysis for the concurrent validity investigation, the children who were older than 76 months were re-included in the sample for the ceiling effects analysis, in order to assess a wider age range. This means that for the ceiling effects investigation, $N = 116$.

Sample size calculation. The sample size of $N = 62$ provided sufficient statistical power (greater than .80) to accurately assess concurrent validity. G*Power version 3.1.9.4 online software was used to determine sample size, with power set to .80, an effect size of .40 and significance set to .05, for a one-tailed test. This yielded a minimum required sample size of 37. (Faul, Erdfelder, Buchner, & Lang, 2009).

Sample characteristics. The sample for the concurrent validity investigation ($N = 62$) ranged in age from 72.98 months to 75.97 months ($M = 75.05$, $SD = .75$). The age distribution of the sample is visualised in the graph in Appendix B. Further sample characteristics (including sex, home language, socio-economic status, maternal education, child HIV exposure and study

site enrolment) are displayed in Table 1. Note that socio-economic status in the DCHS is constructed from several variables including education level, household income, employment status, household assets and access to resources. The quartiles in Table 1 do not correspond with national quartiles and are a relative measure specific to this sample. If national bands are used, all children in the DCHS are of low socio-economic status (Stein et al., 2015).

Measures

ELOM scores. The ELOM includes a Direct Assessment of children's performance through the administration of 23 items (see Appendix A), across five domains: gross motor development, fine motor coordination and visual motor integration (FMC & VMI), emergent numeracy and mathematics, cognition and executive functioning (CEF), and emergent literacy and language (ELL). The ELOM also includes a Teacher's Assessment of the child's social and emotional functioning (Snelling et al., 2019), but this assessment is not used in the current study. The ELOM displays face, content and construct validity. Its domains are unidimensional and internally consistent (Dawes et al., 2016; Snelling et al., 2019). In addition, Rasch's person reliability coefficients range from .63 to .75 across the five domains. Finally, Differential Item Functioning has been conducted for gender, for five socio-economic status levels, and for five languages. Results confirm that the ELOM is a fair assessment regardless of group membership (Snelling et al., 2019).

ELOM Total Score, as well as scores on three of the five domains (FMC & VMI, CEF and ELL) are used in this psychometric study. The FMC & VMI domain measures the proficiency of children's small muscle use. This includes, but is not limited to, using a pencil to draw the self (Item 7), copy a triangle (Item 6) as well as threading beads onto a string (Item 8) (Dawes, Biersteker, Girdwood, Snelling, & Tredoux, 2019). The CEF domain measures children's working memory, auditory discrimination, problem solving skills, short term memory and behavioural inhibition. This domain includes, but is not limited to, building puzzles (Item 17) and sorting cards by both color and shape (Item 14) (Dawes et al., 2019). The ELL domain measures language use, communication skills, vocabulary, comprehension and initial sound discrimination. Examples of items in this domain include answering questions about a story (Item 22), describing emotions (Item 19) and naming common items (Item 21) (Dawes et al., 2019).

Table 1

Sample Demographics

Sample Characteristics	*n* (%)
Sex	
Male	24 (38.70)
Female	38 (61.30)
Language spoken at home	
isiXhosa	45 (72.60)
Afrikaans	16 (25.80)
English	1 (1.60)
DCHS sample-specific socio-economic status quartile	
Lowest	21 (33.90)
Low-moderate	23 (37.10)
Moderate-high	10 (16.10)
High	8 (12.90)
Maternal education level	
Primary	8 (12.90)
Some secondary	38 (61.30)
Completed secondary	13 (21.00)
Some tertiary	3 (4.80)
Child's HIV exposure (maternal infection at birth)	
Not exposed	45 (72.60)
Exposed	17 (27.40)
Participant enrolment by study site	
Mbekweni	46 (74.20)
TC Newman	16 (25.80)

WPPSI-IV scores. The WPPSI-IV is an established, standardised intelligence test for children between 30 and 91 months. It has strong psychometric qualities, including test-retest reliability and concurrent validity, with reliability coefficients ranging from .70 to .90 for its various subtests and indices (Thorndike, 2014). For children between 48 and 91 months (the WPPSI-IV age-bracket most comparable to the ELOM age range), the WPPSI-IV Full Scale composite score is comprised of five Primary Index Scales: verbal comprehension index (VCI), visual spatial index, fluid reasoning index, working memory index and processing speed index (Wechsler, 2012a). DCHS children are tested on only the six core subtests of the WPPSI-IV, namely: Information, Similarities, Block Design, Matrix Reasoning, Picture Memory and Bug Search. These six core subtests contribute to the five indices, which then combine to derive Full Scale IQ (i.e. the WPPSI-IV Full Scale composite score).

The Information subtest is a component of the VCI. Through verbal and picture items, the child responds to general knowledge questions. It assesses the child's acquisition, retention and retrieval of factual knowledge from long-term memory. It measures crystallised intelligence, and verbal comprehension and perception (Groth-Marnat, 2003; Wechsler, 2012b). The Similarities subtest is also a part of the VCI. Children identify and explain why groups or pairs of objects or words are similar. It measures abstract reasoning, conceptual thinking, and verbal fluency (Groth-Marnat, 2003; Wechsler, 2012b). The Block Design subtest falls under the visual spatial index. Children use blocks to redesign a stimulus picture. It measures visual-motor coordination, non-verbal problem-solving abilities, and abstract spatial perception (Groth-Marnat, 2003; Wechsler, 2012b). Matrix Reasoning constitutes the fluid reasoning index. The child chooses the response option that best completes an incomplete matrix. This subtest requires the child to process and analyse abstract visual spatial information. It measures fluid intelligence and the ability to analyse the relationship between a whole and its parts (Groth-Marnat, 2003; Wechsler, 2012b). The Picture Memory subtest contributes to the working memory index. The child is shown a picture and must remember the stimulus by choosing it out of a set of response options. This subtest measures working memory using proactive interference (Canivez, 2014; Wechsler, 2012b). It is based on similar working memory tests such as those of Hartshorne (2008) and Makovski and Jiang (2008). The Bug Search subtest falls under the processing speed index (Canivez, 2014; Wechsler, 2012b). Children choose out of an array of insects, the one that matches the target insect. Bug Search assesses processing speed of visual information, visual-

motor coordination, planning, attention and concentration (Groth-Marnat, 2003; Wechsler, 2012b).

The five WPPSI-IV indices were thought to compare to the three selected ELOM domains. The ELOM CEF domain includes constructs measured in the WPPSI-IV indices of fluid reasoning, processing speed and working memory. Executive functioning refers to multiple higher-order cognitive processes, with fluid reasoning, processing speed and working memory existing as well-established dimensions of executive functioning (Anderson, 2002; Brocki & Bohlin, 2004; Decker, Hill, & Dean, 2007; Karasinski, 2015; Salthouse, 2005). The VCI of the WPPSI-IV is comparable to the ELOM ELL domain. Research affirms verbal comprehension and verbal fluency (both aspects of the VCI) as components of language, hence justifying the link between the ELL domain and the VCI (Maseda et al., 2014). The FMC & VMI domain of the ELOM is closely aligned with the visual spatial index of the WPPSI-IV. Carlson, Rowe and Curby (2013), as well as Decker, Englund, Carboni and Brooks (2011) have found that visual-motor coordination and visual-spatial integration are important aspects of fine motor skills. Table 2 demonstrates how the core subtests of the WPPSI-IV are comparable, via the WPPSI indices, to a specific ELOM domain, based on the justification above.

Table 2

ELOM and. WPPSI-IV Comparison

WPPSI Core Subtest	WPPSI Index	ELOM Domain
Block Design	Visual spatial	Fine motor coordination & visual motor integration
Matrix Reasoning	Fluid reasoning	Cognition & executive functioning
Bug Search	Processing speed	Cognition & executive functioning
Picture Memory	Working memory	Cognition & executive functioning
Similarities	Verbal comprehension	Emergent literacy & language
Information	Verbal comprehension	Emergent literacy & language

Socio-demographic variables. Socio-demographic variables of interest, as recorded in Table 1, included age, sex, home language, socio-economic status quartile, maternal education,

child HIV exposure and participant enrolment by study site. These variables were recorded by the DCHS and thus accompanied the dataset.

Procedure

Well-trained assessors with backgrounds in clinical or neuropsychology administered both the ELOM and the WPPSI-IV to the children at both DCHS sites. 16 children (25.80%) were tested at the TC Newman site and 46 children (74.20%) were tested at the Mbekweni site. At the TC Newman site, both tests were administered in Afrikaans. At the Mbekweni site, the ELOM was administered in isiXhosa, while the WPPSI-IV was administered in English with an isiXhosa translator present. Both the Afrikaans and isiXhosa translations of the WPPSI-IV are not officially standardised for use in South Africa, as discussed previously, but there were consensus meetings in order to standardise translations across the DCHS assessors and translators. At both sites, testing took place in a community centre, in a private room, where only the participant, researcher and translator were present.

When the child and the mother arrived at the site, they were offered food and juice before the child commenced with the ELOM. The ELOM was administered first, which took roughly 45 minutes. After completion of the ELOM, the child was given a short break, during which they were offered more food and juice, and were encouraged to make use of the restroom. There was a small play area for the child to utilise during the break. Thereafter, the child completed the WPPSI-IV, which took approximately one hour. After completion of the WPPSI-IV, a party pack for the child was presented to the child's mother as a token of gratitude for the child's participation. The mother was reimbursed for travel costs with a R100 voucher. They were thanked for their time and commitment to the study. During testing, scores were recorded with pen and paper, and then subsequently transferred onto a tablet for later digital access and statistical analysis.

Ethical Considerations

Ethical approval for the DCHS was obtained from the Faculty of Health Sciences, Human Research Ethics Committee at the University of Cape Town (401/2009, see Appendix C) and from the Western Cape Provincial Health Research committee (2011RP45, see Appendix D). Ethical approval for the current psychometric study was applied for, and granted from the Department of Psychology's ethics board, at the University of Cape Town, as per Appendices E

and F. Moreover, ethical approval for this study was granted by the DCHS, enabling the current researchers to access and analyse DCHS data (see Appendix G).

Written informed consent. Written informed consent was obtained at the time of enrolment from mothers for both their own and their child's participation in the study. Consent was then renewed after each year of participation. See Appendix H for the Year Six consent form.

Voluntary participation. At the time of recruitment, mothers were informed that participation in the DCHS was entirely voluntary and that participants could withdraw from the study at any time without penalty (Stein et al., 2015).

Confidentiality. All DCHS data is confidential, since all participants were allocated a participant ID number instead of the use of their name.

Debriefing. At the end of ELOM and WPPSI-IV testing at the 72-month testing wave, parents and children were thanked for their participation and were encouraged to ask any questions they may have had. The mother-child dyads will continue participating in the DCHS where they receive continuous support and communication.

Risks and benefits. The current psychometric study posed no additional risks or benefits to the DCHS children and their mothers. The overall risks and benefits of long-term participation in the DCHS are outlined in the consent form in Appendix H.

Data Analysis

In study one, Pearson's coefficient (*r*) was used for statistical analysis. Pearson's coefficient is a numerical value that depicts the degree of correlation between two variables and is calculated using the distance of data points from the line of best fit (the regression line) (Tredoux & Durrheim, 2013). Pearson's coefficient value (*r*) falls within the range of -1 to +1 where -1 represents a perfect negative correlation (one variable increases as the other variable decreases) and +1 represents a perfect positive correlation (where both variables either increase or decrease together). An *r* value of 0 signifies that there is no relationship between two variables (Tredoux & Durrheim, 2013).

When using Pearson correlations for psychometric tests of validity, Swank and Mullen (2017) note that "interpreting the strength of the relationship for validity coefficients is different than interpreting other bivariate correlations" (p.272). Pearson coefficients used in testing validity are frequently lower than in other applications of correlation. This is due to the fact that

the constructs that are measured by validity investigations are usually abstract or latent, resulting in complexities in measurement (Swank & Mullen, 2017). Following these authors, the following criteria were used to categorise Pearson coefficients in the current study: an *r* value less than .20 represents a low correlation, *r* between .21 and .40 represents a moderate correlation, *r* between .40 and .49 represents a high correlation, and an *r* value of .50 and above represents a very high correlation. Correlations between WPPSI-IV core subtests, WPPSI-IV indices, and ELOM domains were expected as per Table 2, but were performed as per Table 5 in the results section below. Correlations between ELOM items and WPPSI-IV core subtests were also performed, as per Table 6 in the results section below. A Pearson's coefficient was obtained for each of these correlations.

In study two, ceiling effects were investigated on the ELOM items. Ceiling and floor effects are limits of measurement where scores either tend towards the highest or lowest possible scores respectively, on a specific test. This effect restricts the ability of the item to accurately measure its respective construct and to discriminate between high performing and low performing individuals (Ho & Yu, 2014). Given the older age of the larger sample (N = 116), ceiling effects were of interest because it was expected that older children may perform better on ELOM items, thus achieving higher scores and limiting the ability of the items to discriminate between participants. Ceiling effects were analysed by creating frequency histograms in order to examine the distribution of the sample's (N = 116) performance on each of the 23 ELOM items, as well as the overall domain and total scores. A ceiling effect is demonstrated by a negatively skewed distribution of scores while a floor effect (the opposite of a ceiling effect) would be demonstrated by a positively skewed distribution of scores (Ho & Yu, 2014). Items and domains that are normally distributed indicate that there is neither a ceiling nor a floor effect.

Results

Study One: Concurrent Validity Analysis

Descriptive statistics. Descriptive statistics of the sample's (N = 62) performance on the ELOM, and its three relevant domains are presented in Table 3. Then, the descriptive statistics of the WPPSI-IV are presented in Table 4. These tables include minimums (min), maximums (max), mean scores with standard deviations (SD), as well as both skewness and kurtosis statistics with standard error (SE).

Table 3 shows a mean ELOM Total Score of *M* = 60.51, *SD* = 11.55. It is also evident that, apart from the FMC & VMI domain, which is moderately skewed, with skewness of -.68 (*SE* = .30), all other distributions have acceptable skewness and kurtosis statistics.

Table 3

ELOM Descriptive Statistics

	N	Min	Max	Mean (SD)	Skewness (SE)	Kurtosis (SE)
ELOM Total Score	62	31.86	85.45	60.51 (11.55)	-.04 (.30)	-.57 (.60)
FMC & VMI domain score	62	10.73	20.00	16.92 (2.47)	-.68 (.30)	-.54 (.60)
CEF domain score	62	2.34	18.08	10.50 (3.77)	.17 (.30)	-.65 (.60)
ELL domain score	62	2.19	19.27	9.93 (4.40)	.26 (.30)	-.55 (.60)
Valid N	62					

Table 4 presents a mean WPPSI-IV Full Scale composite score of *M* = 71.53, *SD* = 8.36. Apart from the Block Design scaled score, which is moderately skewed, with skewness of .93 (*SE* = .30), and kurtosis of 4.30 (*SE* = .60), all other distributions have acceptable skewness and kurtosis statistics.

Table 4

WPPSI-IV Descriptive Statistics

	N	Min	Max	Mean (SD)	Skewness (SE)	Kurtosis (SE)
Full Scale composite score	62	56.00	88.00	71.53 (8.36)	.16 (.30)	-.86 (.60)
VCI composite score	62	54.00	95.00	73.34 (10.21)	.20 (.30)	-.59 (.60)
Block Design scaled score	62	3.00	13.00	7.18 (1.51)	.93 (.30)	4.30 (.60)
Matrix Reasoning scaled score	62	1.00	8.00	4.68 (2.19)	-.07 (.30)	-.99 (.60)
Bug Search scaled score	62	2.00	12.00	7.15 (2.31)	.18 (.30)	-.11 (.60)
Picture Memory scaled score	62	3.00	11.00	7.27 (1.82)	-.30 (.30)	-.50 (.60)
Similarities scaled score	62	1.00	10.00	5.11 (2.32)	.31 (.30)	-.82 (.60)
Information scaled score	62	2.00	9.00	5.37 (1.98)	-.17 (.30)	-1.25 (.60)
Valid N	62					

Inferential statistics. Table 5 provides correlations between ELOM scores and WPPSI-IV scores for the sample below 76 months of age ($N = 62$). Significant correlations are starred as either $p < .05$, $p < .01$ or $p < .001$. The very high correlation ($r = .64$, $p < .001$) between the ELOM Total Score and the WPPSI-IV Full Scale composite score indicates that strong concurrent validity is demonstrated between these two measures. It was predicted, as per Table 2, that the FMC & VMI domain of the ELOM would correlate with the Block Design subtest of the WPPSI-IV. This is the case with $r = .34$ ($p = .003$), indicating a significant but moderate correlation. However, the FMC & VMI domain showed the strongest correlation with the Bug Search subtest ($r = .51$, $p < .001$). CEF was expected to correlate with Matrix Reasoning, Bug Search and Picture Memory, as per Table 2. All three of these correlations were statistically significant with r ranging from .32 ($p = .005$) to .35 ($p = .003$) demonstrating moderate correlations. However, CEF showed the strongest correlation with the Block Design subtest ($r = .37$, $p = .002$), showing a slightly higher, but still moderate correlation. The ELL domain of the ELOM was predicted to correlate with the VCI composite score (incorporating the Similarities and Information subtests of the WPPSI-IV). This very high correlation was statistically significant with $r = .50$, $p < .001$. Notably, this correlation was stronger than the ELL correlation with any individual WPPSI-IV subtest. Each of the three ELOM domains yielded a statistically significant, and high or very high correlation with the WPPSI-IV Full Scale composite score, with r ranging from .49 to .54 with $p < .001$.

To further investigate these findings, the ELOM items were individually correlated with the WPPSI-IV core subtests to examine where exactly - within each ELOM domain - the significant correlations are found (see Table 6). Although it was expected that the FMC & VMI domain (Items 5 to 8) would correlate with Block Design, it was found that only one item in this domain (Item 5) yielded a significant but moderate correlation with the Block Design subtest ($r = .30$, $p = .008$). Interestingly, Item 6 was significantly correlated with Matrix Reasoning, Bug Search and Picture Memory - three of the core subtests expected to be correlated with the CEF domain. This suggests that Item 6 (copying a triangle) could be tapping into skills of fluid reasoning, processing speed and working memory. Surprisingly, Item 7 (drawing the self) produced a significant negative moderate correlation with the Information subtest ($r = -.32$, $p = .006$) which suggests that children who showed high levels of general knowledge, performed poorly at the task of drawing themselves.

Table 5

Correlations of ELOM Domains and WPPSI-IV Subtests

		WPPSI-IV Subtests						VCI Composite Score	Full Scale Composite Score
		Block Design	Matrix Reasoning (MR)	Bug Search (BS)	Picture Memory (PM)	Similarities	Information		
		r[a] (p) CI [LL, UL][b]	r (p) CI [LL, UL]	r (p) CI [LL, UL]	r (p) CI [LL, UL]	r (p) CI [LL, UL]	r (p) CI [LL, UL]	r (p) CI [LL, UL]	r (p) CI [LL, UL]
ELOM Domain	FMC & VMI	.34** (p = .003) [.10, .54]	.39** (p = .001) [.15, .58]	.51*** (p<.001) [.30, .68]	.38** (p = .001) [.15, .58]	.22* (p = .046) [-.04, .44] [c]	.18 (p = .078) [-.07, .41] [c]	.25* (p = .025) [.001, .47]	.53*** (p<.001) [.32, .69]
	CEF	.37** (p = .002) [.13, .57]	.35** (p = .003) [.11, .55]	.35** (p = .003) [.11, .55]	.32** (p = .005) [.08, .53]	.22* (p = .041) [-.03, .45] [c]	.29* (p = .012) [.04, .50]	.32** (p = .006) [.07, .52]	.49*** (p<.001) [.28, .66]
	ELL	.25* (p = .027) [-.004, .47] [c]	.17 (p = .093) [-.08, .40] [c]	.44*** (p<.001) [.22, .62]	.37** (p=.001) [.14, .57]	.46*** (p < .001) [.24, .64]	.32** (p = .006) [.08, .53]	.50*** (p<.001) [.28, .66]	.54*** (p<.001) [.33, .70]
ELOM Total Score		.43*** (p < .001) [.20, .61]	.32** (p = .006) [.07, .52]	.48*** (p<.001) [.26, .65]	.53*** (p<.001) [.33, .69]	.39** (p = .001) [.16, .59]	.29* (p = .011) [.05, .51]	.43*** (p<.001) [.20, .62]	.64*** (p<.001) [.47, .77]

Note.

[a] r represents the Pearson correlation statistic, in *Rho*.

[b] CI stands for Confidence Interval, calculated at the 95% interval. LL stands for Lower Limit, and UL stands for Upper Limit.

[c] It is noted that these confidence intervals span across zero, so these correlations should be interpreted with caution.

*p<.05. **p<.01. ***p<.001.

The CEF domain (Items 14 to 17) was expected to correlate with Matrix Reasoning, Bug Search and Picture Memory, but through closer examination of Table 6, none of the individual CEF domain items correlate with Picture Memory. Item 17 is the only CEF item to significantly correlate with Bug Search whereas for Matrix Reasoning, both Items 15 (pencil tapping test) and 17 (picture puzzle completion) yielded a significant correlation. Unexpectedly, these two Items (15 and 17) also correlated significantly with Block Design. Collectively, these results suggest that ELOM Items 14 and 16, which show no correlations with any of the WPPSI-IV core subtests, might be measuring different constructs to those measured in the WPPSI-IV.

The ELL domain (Items 18 to 23) was expected to correlate with the Similarities and Information subtests. Items 20, 21, 22 and 23 significantly correlated with Similarities, while only Item 21 significantly correlated with Information. However, correlations between the Bug Search subtest and Items 19, 20 and 23 were significant. Notably, Item 23 (initial sound discrimination) produced significant correlations with every WPPSI-IV subtest except Information, suggesting that this Item is picking up on a wide range of intelligence constructs. It should be noted that item-by-item analyses of the gross motor development domain as well as the emergent numeracy and mathematics domain were excluded from the current study as these domains do not fall into the scope of this research.

Study Two: Ceiling Effects Analysis

The older sample of $N = 116$ was used for the ceiling effects analysis. This larger sample had an average age of 75.82 months ($SD = 1.04$). The analysis of the frequency histograms for each ELOM item, domain, and Total Score revealed that three of the 23 ELOM items did demonstrate ceiling effects: Item 1, a component of gross motor development; and Items 5 and 7, both items in the FMC & VMI domain. Most items, however, were normally distributed, or were only slightly positively or negatively skewed. The FMC & VMI domain scores were negatively skewed, indicating ceiling effects, but all other domain scores were normally distributed. Lastly, the ELOM Total Scores were normally distributed for this sample. See Appendix I for these frequency histograms.

Discussion

The current study undertook two separate psychometric evaluations of the ELOM. The first and primary investigation sought to establish concurrent validity of the ELOM with the WPPSI-IV, in order to strengthen the psychometric properties of this South African instrument.

Table 6

Correlations of ELOM Items and WPPSI-IV Subtests

		WPPSI-IV Subtests					
		Block Design	Matrix Reasoning	Bug Search	Picture Memory	Similarities	Information
ELOM Domain	ELOM Item	r (p) CI [LL, UL]	r (p) CI [LL, UL]	r (p) CI [LL, UL]	r (p) CI [LL, UL]	r (p) CI [LL, UL]	r (p) CI [LL, UL]
Gross Motor Development	1	-.12 (p=.177) [-.40, .13] [a]	-.12 (p = .175) [-.36, .13] [a]	.02 (p = .445) [-.23, .27] [a]	.19 (p = .065) [-.06, .42] [a]	-.14 (p = .140) [-.38, .11] [a]	.14 (p = .135) [-.11, .38] [a]
	2	.10 (p=.215) [-.15, .34] [a]	-.31** (p = .008) [-.52, -.06]	-.10 (p = .233) [-.34, .16] [a]	.04 (p = .393) [-.22, .28] [a]	-.14 (p = .136) [-.38, .11] [a]	-.27* (p = .018) [-.48, -.02]
	3	.08 (p=.277) [-.18, .32] [a]	-.01 (p = .456) [-.26, .24] [a]	-.16 (p = .113) [-.39, .10] [a]	-.02 (p = .427) [-.27, .23] [a]	-.18 (p = .083) [-.41, .08] [a]	-.05 (p = .358) [-.29, 21] [a]
	4	.15 (p=.127) [-.11, .38] [a]	.04 (p = .381) [-.21, .29] [a]	-.08 (p = .263) [-.33, .17] [a]	.21* (p = .049) [-.04, .44] [a]	-.08 (p = .275) [-.32, .18] [a]	-.10 (p = .229) [-.34, .16] [a]
FMC & VMI	5	.30** (p=.008) [.06, .51]	.25* (p = .026) [-.002, .47] [a]	.21 (p = .053) [-.04, .44] [a]	.23* (p = .036) [-.02, .45] [a]	.03 (p = .425) [-.23, .27] [a]	.18 (p = .086) [-.08, .41] [a]
	6	.17 (p =.097) [-.09, .40] [a]	.35** (p = .003) [.11, .55]	.32** (p = .006) [.07, .52]	.34** (p = .004) [.10, .54]	.11 (p = .198) [-.14, .35] [a]	.18 (p = .077) [-.07, .41] [a]
	7	.01	-.12	.01	.11	-.01	-.32**

		(p = .464) [-.24, .26] [a]	(p = .178) [-.40, .13] [a]	(p = .460) [-.24, .26] [a]	(p = .203) [-.15, .35] [a]	(p = .481) [-.26, .24] [a]	(p = .006) [-.53, -.08]
	8	.17 (p = .099) [-.09, .40] [a]	.12 (p = .186) [-.14, .36] [a]	.36** (p = .002) [.12, .56] [a]	.10 (p = .231) [-.16, .34] [a]	.18 (p = .079) [-.07, .41] [a]	.06 (p = .315) [-.20, .31] [a]
Emergent Numeracy and Mathematics	9	.24* (p =.031) [-.01, .46] [a]	.12 (p = .172) [-.13, .36] [a]	.30* (p = .010) [.05, .51]	.20 (p = .060) [-.05, .43] [a]	.38** (p = .001) [.15, .58]	.25* (p = .026) [-.002, .47] [a]
	10	.17 (p = .117) [-.08, .40] [a]	.06 (p = .336) [-.19, .31] [a]	.15 (p = .149) [-.10, .39] [a]	.25* (p = .039) [.002, .47]	.19 (p = .093) [-.06, .42] [a]	.15 (p = .150) [-.10, .38] [a]
	11	.19 (p = .075) [-.07, .42] [a]	.25* (p = .028) [-.01, .47] [a]	.18 (p = .085) [-.08, .41] [a]	.32** (p = .006) [.08, .53]	.30** (p = .008) [.06, .51]	.30** (p = .009) [.05, .51]
	12	.003 (p = .492) [-.25, .25] [a]	.01 (p = .479) [-.24, .26] [a]	.13 (p = .152) [-.12, .37] [a]	.09 (p = .238) [-.16, .33] [a]	.09 (p = .247) [-.17, .33] [a]	-.09 (p = .246) [-.33, .16] [a]
	13	-.01 (p = .459) [-.26, .24] [a]	.13 (p = .151) [-.12, .37] [a]	.24* (p = .032) [-.02, .46] [a]	.27* (p = .016) [.03, .49]	.24* (p = .028) [-.01, .47] [a]	.02 (p = .428) [-.23, .27] [a]
CEF	14	.14 (p = .137) [-.11, .38] [a]	-.02 (p= .450) [-.27, .24] [a]	.18 (p = .079) [-.07, .41] [a]	.05 (p = .344) [-.20, .30] [a]	.10 (p = .225) [-.16, .34] [a]	.11 (p = .208) [-.15, .35] [a]
	15	.31** (p = .008) [.07, .52]	.38** (p = .002) [.14, .57]	.13 (p = .166) [-.13, .37] [a]	.20 (p = .069) [-.06, .42] [a]	.20 (p = .063) [-.05, .43] [a]	.30* (p = .010) [.06, .51]
	16	-.12 (p = .182) [-.36, .13] [a]	.12 (p = .192) [-.14, .36] [a]	.18 (p = .087) [-.07, .41] [a]	.16 (p = .118) [-.10, .39] [a]	.01 (p = .463) [-.24, .26] [a]	.04 (p = .374) [-.21, .29] [a]

	17	.41** (p = .001) [.17, .60]	.29* (p = .011) [.04, .50]	.31** (p = .007) [.07, .52]	.21* (p = .049) [-.04, .44] [a]	.18 (p = .083) [-.08, .41] [a]	.22* (p = .042) [-.03, .45] [a]
ELL	18	.15 (p = .118) [-.10, .40] [a]	.01 (p = .486) [-.25, .25] [a]	.07 (p = .300) [-.19, .31] [a]	.20 (p = .059) [-.05, .43] [a]	.25* (p = .027) [-.01, .47] [a]	.14 (p = .138) [-.11, .38] [a]
	19	.17 (p = .094) [-.08, .40] [a]	.16 (p = .108) [-.09, .39] [a]	.48*** (p<.001) [.27, .65]	.16 (p = .115) [-.10, .40] [a]	.20 (p = .058) [-.05, .43] [a]	.22* (p = .046) [-.04, .44] [a]
	20	.12 (p = .186) [-.14, .36] [a]	.06 (p = .328) [-.20, .30] [a]	.27* (p = .017) [.02, .49]	.16 (p = .105) [-.09, .40] [a]	.25* (p = .025) [.002, .47]	.20 (p = .059) [-.05, .43] [a]
	21	.08 (p = .261) [-.17, .33] [a]	-.03 (p = .417) [-.28, .22] [a]	.24* (p = .030) [-.01, .46] [a]	.15 (p = .121) [-.10, .39] [a]	.30** (p = .008) [.06, .51]	.34** (p = .003) [.10, .54]
	22	.05 (p=.353) [-.20, .30] [a]	.32** (p = .006) [.08, .53]	.16 (p = .102) [-.09, .40] [a]	.23* (p = .035) [-.02, .46] [a]	.48*** (p<.001) [.26, .65]	.17 (p = .088) [-.08, .41] [a]
	23	.36** (p = .008) [.13, .56]	.27* (p = .041) [.02, .49]	.40** (p = .004) [.17, .59]	.45** (p = .001) [.23, .63]	.61*** (p<.001) [.42, .75]	.24 (p = .060) [-.01, .46] [a]

Note.

[a] It is noted that these confidence intervals span across zero, so these correlations should be interpreted with caution.

*p<.05. **p<.01. ***p<.001.

The second aspect of the study examined possible item ceiling effects, in order to assess the validity of the ELOM for an age group considerably older than the original sample on which the ELOM was standardised. The findings of these two psychometric investigations are discussed below.

Study One: Concurrent Validity

Using Swank and Mullen's (2017) criteria, a very high correlation was found between the ELOM Total Score and the WPPSI-IV Full Scale composite score ($r = .64$, $p < .001$) for DCHS children between the ages of 72 and 76 months. This means that strong concurrent validity of the ELOM, with the widely accepted WPPSI-IV, has been established in this sample, implying that these two tests are indeed measuring similar constructs.

Further investigations into the correlations between ELOM domains and WPPSI-IV subtests were performed. The FMC & VMI domain showed the strongest correlation with the Bug Search subtest. This suggests that the FMC & VMI domain and the Bug Search subtest are measuring similar constructs, perhaps because of the shared visual aspect. The CEF domain showed the strongest correlation with the Block Design subtest. This suggests that the CEF domain and Block Design are measuring similar constructs - potentially shared constructs of non-verbal problem solving and spatial perception (Groth-Marnat, 2003; Wechsler, 2012b). This overlap is especially seen in the similarity between ELOM Item 17 (picture puzzle completion) and Block Design. The ELL domain showed the strongest correlation with the WPPSI-IV VCI composite score. This correlation was expected since they both measure constructs of abstract reasoning, verbal fluency and verbal comprehension (Groth-Marnat, 2003; Wechsler, 2012b).

Study Two: Ceiling Effects

Ceiling effects were expected, since these older children were predicted to outperform their younger peers on which the ELOM was standardised. However, the results showed that only three items (1, 5 and 7) were subject to significant ceiling effects. Children of this age group would be expected to pass these items, so ceiling effects are not surprising. The FMC & VMI domain was the only domain that showed ceiling effects, since Items 5 and 7 contribute to this domain. Ultimately, while some items do demonstrate ceiling effects, when considered as part of their overall domain, these effects are mostly eliminated, thus making the ELOM acceptable and valid for children of this age ($M = 75.82$, $SD = 1.04$) while still retaining the ability to discriminate between weak and strong performances. Nevertheless, future revisions of the

ELOM for an older sample should consider adapting or removing Items 1, 5 and 7 (see Appendix A) to eliminate these ceiling effects. Overall, it is concluded that the ELOM can be extended for use in older children.

Limitations and Future Recommendations

The current study has successfully established the concurrent validity of the ELOM. However, test-retest reliability still needs to be investigated. It is recommended that test-retest reliability is examined in future studies to further strengthen the psychometric properties of the ELOM. Furthermore, concurrent validity of the gross motor development domain, the emergent numeracy and mathematics domain, as well as the Teacher Assessment of the ELOM, were excluded from the current study, for the sake of brevity, and thus still need to be established.

Additionally, this study did not include a diverse range of children from different socio-economic backgrounds, as it only assessed DCHS children, who are all of a low socio-economic status. The children in this sample may be developmentally compromised due to the risk factors associated with low socio-economic status, including poverty, substance abuse, and HIV exposure (Stein et al., 2015). Thus, the lack of ceiling effects demonstrated in this sample may be linked to these children's sub-standard development, and not an inherent quality of the ELOM. Ceiling effects on ELOM items may be present in a sample of children from a higher socio-economic status, who have had greater access to ECD programmes and to opportunities for developmental stimulation. It is advised that future replication of this investigation recruit a sample of children from higher socioeconomic backgrounds.

Conclusion

The establishment of concurrent validity of the ELOM has a number of beneficial implications. The fact that the children in the current sample performed similarly on the ELOM and the WPPSI-IV (as a well-established, standardised test of intelligence) means that the validity and the legitimacy of the ELOM has been strengthened, thus enabling its results to be interpreted with greater confidence. It also means that the ELOM Total Score could act as a proxy for IQ in South Africa. This is good news, given the limitations of the WPPSI-IV, which is only available in English, and is not standardised for use or for translation in South Africa. The WPPSI-IV (as well as previous ECD assessment tools) is expensive, culturally inappropriate, and thus not necessarily a fair measure of intelligence in South Africa (Foxcroft, 1997; Foxcroft et al., 2004). The ELOM, on the other hand, is well-standardised for use in South Africa, across a

broad range of languages and socio-economic backgrounds, and is culturally fair and relevant (Dawes et al., 2016; Snelling et al., 2019). Thus, the ELOM can be confidently recommended as a South African alternative to other tests, such as the WPPSI-IV.

Finally, the ELOM can contribute positively to the development of ECD programmes in South Africa, as its recommendations for programme improvement can be implemented with confidence, thus ensuring that learners are more on par with the expected early learning development standards (Dawes et al., 2016; Snelling et al., 2019). Therefore, the improved psychometric qualities of the ELOM indirectly contribute to South Africa's efforts towards reaching Target 4.2 of the UN Sustainable Development Goals (Raikes et al., 2017). As a tool used to diagnose problem areas in ECD programmes, the increased use of the ELOM will improve the overall standard of ECD, and hopefully contribute to education equality in South Africa.

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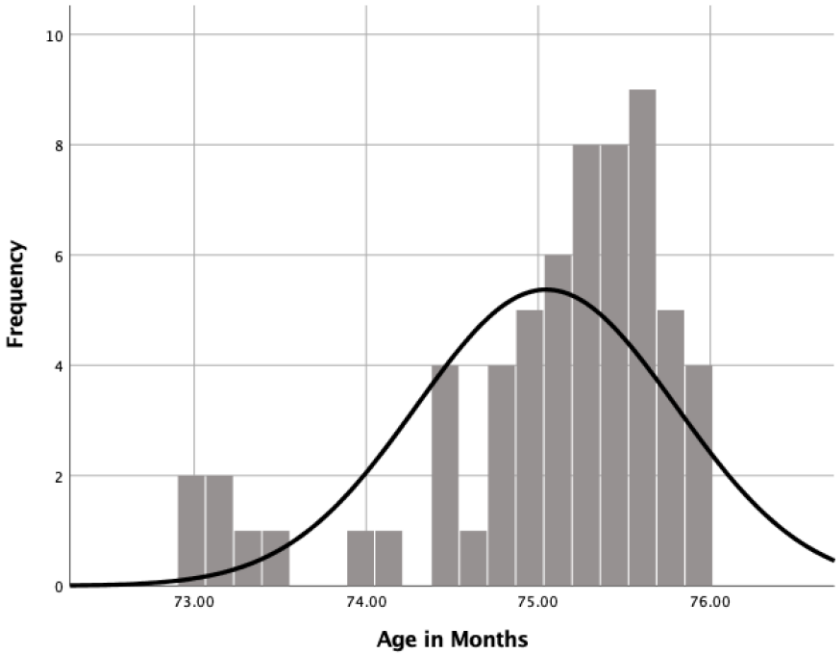
Appendix A
ELOM Items

GROSS MOTOR DEVELOPMENT	
Item 1	Stand on one leg for 10 seconds
Item 2	Catch bean bag both hands
Item 3	Catch bean bag preferred hand
Item 4	Catch bean bag non-preferred hand
FINE MOTOR COORDINATION & VISUAL MOTOR INTEGRATION	
Item 5	Copy cross & square
Item 6	Copy triangle
Item 7	Draw self
Item 8	String beads
EMERGENT NUMERACY & MATHEMATICS	
Item 9	Counting in classes
Item 10	Addition & subtraction
Item 11	Sorting & classification
Item 12	Spatial vocabulary
Item 13	Measurement vocabulary
COGNITION & EXECUTIVE FUNCTIONING	
Item 14	Dimensional change card sort
Item 15	Pencil tapping test
Item 16	Digits forward
Item 17	Picture puzzle completion
EMERGENT LITERACY & LANGUAGE	
Item 18	Expressive language: empathy
Item 19	Expressive language: self awareness
Item 20	Expressive language
Item 21	Expressive vocabulary
Item 22	Oral comprehension
Item 23	Initial sound discrimination

Appendix B
Age Distribution of Sample (N = 62)



Appendix C

Faculty of Health Sciences, Human Research Ethics Committee Approval

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30 | 08 | 19
☐ Not approved	See attached comments		
Signature Chairperson of the HREC	pp TBurgess	Date Signed	12/09/2018

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	22 Aug 2018		
HREC REF Number	401/2009	Current Ethics Approval was granted until	30 Aug 2018
Protocol title	Drakenstein Child Health Study		
Protocol number (if applicable)	Protocol v1.15		
Are there any sub-studies linked to this study?	✓ Yes ☐ No		
If yes, could you please provide the HREC Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.	Details included in appendix.		
Principal Investigator	Prof Heather Zar		
Department / Office Internal Mail Address	Department of Paediatric and Child Health Red Cross War Memorial Children's Hospital		

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

HUMAN RESEARCH ETHICS COMMITTEE
24 AUG 2018

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

1.1 Does this protocol receive US Federal funding?	✓ Yes	☐ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? **Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-enquiries@uct.ac.za)	☐ Yes	✓ No
If yes in 1.2 please complete section 1.3 below for invoicing purposes		
1.3 Annual Approval for **full committee** review	- R 3420 (inclusive of vat)	
For invoicing purposes, please provide:		
Sponsor's name		
Contact person		
Address		
Telephone number		
Email Address		

2. List of documentation for approval

1. Annual report, FHS016

3. Protocol status (tick ✓)

☐	Open to enrolment
✓	Closed to enrolment (tick ✓)
✓	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	1225
Number of participants enrolled, since last HREC Progress report (continuing review)	0
Additional number of participants still required	0

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	605

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

6. Cumulative summary of participants

Total number of participants who provided consent	1225
Number of participants determined to be ineligible (i.e. after screening)	1471
Number of participants currently active on the study	975
Number of participants completed study (without events leading to withdrawal)	0
Number of participants withdrawn at participants' request (i.e. changed their mind)	35
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	250
Unable to contact 38 Maternal withdrawal of consent 36 Mother relocated 66 Child relocated 17 Child died 24 Intrauterine death or infant death 22 Mother/ guardian unable to attend visits 30 Other 17 **TOTAL** 250	
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	None

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
Attached as appendix.

8. Protocol violations and exceptions (tick ✓ all that apply)

☐	No prior violations or exceptions have occurred since the original approval
✓	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

☐	No prior amendments have been made since the original approval

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

☐	Prior amendments have been reported since the last review and have already been approved
☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
N/A

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
✓ Yes	☐ No	☐ Not applicable
If yes, please describe:		
Mothers who have screened for mental health issues or illness have also referred. Children on the study found to have a reactive Mantoux, with illness or exposures per DOH mandatory reporting guidelines have been referred to appropriate clinic staff for follow up.		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?		
☐ Yes	☐ No	✓ Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
☐ Yes	☐ No	✓ Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.					
Agency Name		Report attached	☐ Yes	☐ No	☐ Not applicable
		DSMB report attached	☐ Yes	☐ No	☐ Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
☐ Yes	✓ No
If yes, please explain:	

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
☐	Increased
☐	Decreased
✓	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.
No new relevant literature available as yet. The study continues to work closely with the PERCH Study (Pneumonia Etiology Research for Child Health), which was launched in 2011 to investigate the risk factors for severe pneumonia through a multi-country case control study and hope to be privy to PERCH's preliminary analysis and publications.

13. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	✓ No
If yes, please explain and if necessary attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	

14. Signature

My signature certifies that the above is complete and correct.			
Signature of PI		Date	22 Aug 2018

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Appendix D

Western Cape Provincial Health Research Committee Approval

24/05/2011 14:55 0214839895 FINANCE PAGE 01/01

DEPARTMENT of HEALTH
Provincial Government of the Western Cape

COMPONENT

healthres@pgwc.gov.za
tel: +27 21 483 9976: fax: +27 21 483 9895
1st Floor, Deneys Reitz House, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za

REFERENCE: RP 45/2011
ENQUIRIES: Dr N Peer

Department of Paediatrics and Child Health
5th Floor ICH Building
Red Cross War memorial Children's Hospital
Klipfontein Road
Rondebosch
7700

Fax: **(021) 689 1287**

For attention: Professor Heather Zar

Re: Drakenstein Child Lung Health Study

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research. Please contact the following people to assist you with any further enquiries.

Paarl Hospital	**Dr Breslau Kruger**	**Tel: (021) 860 2508**
TC Newman		
Mbekweni	**Ms Marvina Johnson**	**Tel: (023) 348 8120**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (healthres@pgwc.gov.za).
3. The reference number above should be quoted in all future correspondence.

We look forward to hearing from you.

Yours sincerely

MR J LEDWABA
CHIEF DIRECTOR: HEALTH PROGRAMMES
DATE: 24/05/2011

CC **DR L PHILLIPS** **DIRECTOR: CAPE WINELANDS**

The Afrikaans or Xhosa version of this document is available on request.

page 1 of 1

Appendix E

Ethics Application to the Department of Psychology

UNIVERSITY OF CAPE TOWN

Department of Psychology
Research Ethics Committee
Rondebosch, 7701
Tel: 27 21 6503417 Fax: 27 21 6504104

APPLICATION TO CONDUCT PSYCHOLOGICAL RESEARCH

1. All applications must be submitted with the documentation outlined in the attached form.
2. All documents should be submitted electronically.
3. The University of Cape Town's Department of Psychology actively supports research as an essential academic function. It is essential that all applicants consult the UCT Code for Research involving Human Subjects (available from the UCT website).
4. In the case of research involving clinical populations, drug trials, neuroimaging, and recruitment from Groote Schuur Hospital or any affiliated medical institutions, approval must also be obtained from the Faculty of Health Sciences Research Ethics Committee (FHS REC).
5. Final responsibility for the ethical and effective conduct of the research lies with the principal investigator.

HONOURS STUDENTS:

Complete this application form, and submit it to Rosalind Adams with the formal research proposal that forms part of your research methods module in the Honours programme.

MASTER'S AND DOCTORAL STUDENTS:

Complete this application form, and submit it in electronic form to Rosalind Adams attached to the research proposal you will present to a departmental thesis committee.

DEPARTMENTAL STAFF, VISITING SCHOLARS AND POST-DOC STUDENTS:

Complete this application form, and submit it in electronic form to Assoc. Prof. Lauren Wild (lauren.wild@uct.ac.za). The application must be accompanied by a detailed proposal (maximum length 25 1.5-spaced pages).

UNIVERSITY OF CAPE TOWN
DEPARTMENT OF PSYCHOLOGY
APPLICATION FOR ETHICAL APPROVAL TO CONDUCT PSYCHOLOGICAL RESEARCH

Section A	Proposal Identification Details	To be completed by all applicants
Section B	Study Information	To be completed for all studies
Section C	Financial and Contractual Information	To be completed by all applicants
Section D	Declaration on Conflict of Interest	To be completed by all applicants
Section E	Ethical and Legal Aspects	To be completed by all applicants
Section F	Checklist	To be completed by all applicants

Section A: Proposal identification details.

1. Title of the proposal/protocol:

Establishing concurrent validity on three domains of the Early Learning Outcomes Measure (ELOM)

2. Has this protocol been submitted to any other Ethical Review Committee?		Yes ☑		No
2.1 If so, list which institutions and any reference numbers.	The protocol has been submitted to the Drakenstein Child Health Study (DCHS) for internal ethical approval			
2.2 What was/were the outcome/s of these applications?	We haven't heard back from them in an official, written capacity.			
3. Is this proposal being submitted for ethical approval for an amendment to a protocol previously approved by this committee?		Yes		No ☑
3.1 If so, what was the previous protocol's reference number?				

4. Investigator details

4.1 Principal Investigator (if a student project, the student is the principal investigator):

Title	Initials & Last Name	Department and Institution	Phone	Email	Signature	Date
Miss	K. J. Anderson	Department of Psychology, UCT	081 391 7278	katejoya@gmail.com		09-05-2019
Miss	M. L. Scott	As above	060 526 0863	meganscott7@gmail.com		09-05-2019

4.1.1 (If different to 4.1 above) UCT Principal Investigator

Title	Initials & Last Name	Department and Institution	Phone	Email	Signature	Date

4.2 Co-investigators: (if a student project, add the supervisor's name here)

Title	Initials & Last Name	Department and Institution	Phone	Email
Prof	A. Dawes	Department of Psychology, UCT	0824229940	adkinloch@gmail.com

5. Is the study being undertaken for a higher degree?	Yes ☑		No
If yes: 5.1 What degree? Honours in Psychology			
5.2 Student name: Kate Anderson & Megan Scott			
5.3 Supervisor name: Prof. Andrew Dawes			
5.4 In what department is the degree? Psychology			

Section B: Study Information (summarize the information contained in the proposal).

6. Who will act as participants in the study?

Participants for the current psychometric study will be recruited from the DCHS participants who are tested at the 78-month testing wave in the first half of 2019.

7. Estimated number of participants:

110 78-month-old children (only 60 to be used in final sample size)

8. Estimated duration of study:

Current data collection is continuously underway through the DCHS study (which has received full ethical approval). The current study will use DCHS data collected up until the end of June 2019 for analysis. Thus, data analysis should commence in July 2019. The final report for this study will be submitted by 24 October 2019.

9. Location of study (e.g. UCT, school, hospital, etc., where you will gather data from the participants):

The DCHS operates in two different sites, both in the city of Paarl, in the Western Cape of South Africa. The first site is Mbekweni, which is a predominantly black African, isiXhosa-speaking population. The second site is TC Newman, which is a mixed-race community, with Afrikaans as the dominant language. At both sites, testing takes place in a community centre, in a private room, where only the participant, researcher and potential translator are present.

10. Recruitment: Please describe how and from where the participants will be recruited. Attach a copy of any posters or advertisements to be used.

The current study will use the data from already-recruited participants who are a part of the DCHS. The DCHS mothers were recruited at 20-28 weeks' gestation at one of two primary health care clinics in the Drakenstein area in March of 2012. At time of recruitment, these mothers needed to be over 18 years of age and needed to express no intention of leaving the area within the next year. The mothers also needed to provide written informed consent for both their and their child's participation in the research. Participants for the current psychometric study will be recruited from the DCHS participants who are tested at the 78-month testing wave in the first half of 2019.

11. Vulnerable groups: Are there pre-existing vulnerabilities associated with the proposed participants, e.g., relating to pre-existing physiological or health conditions, cognitive or emotional factors, and socio-economic or legal status?

Yes ☑ No

If yes, explain briefly what vulnerability would entail in the study, and how you propose to safeguard participants' wellbeing.

Participants are children, which is classified as a vulnerable group. They are only 78-months-old and thus rely on parental consent. Informed consent has been obtained from all participants mothers as a part of the DCHS. DCHS, as the larger study with regular contact with children and their parents, do a lot to safeguard their participants well-being, especially since it is a birth-cohort longitudinal study.

12. Risks: Briefly describe the research risk associated with your study, i.e. the probability and magnitude of harms participants may experience. Minimal risk means that the probability and magnitude of harm due to participation in the research are no greater than that encountered by participants in their everyday lives.

The only risk to these children's involvement in this particular study is testing fatigue, since they are tested on both the ELOM and the WPPSI-IV in one morning with a small break in between. They might get tired and stop enjoying the 'games' they are playing with the DCHS assessors.

13. Costs: Give a brief description of any costs or economic considerations for participants.

DCHS mothers are reimbursed with a R100 voucher for the travel costs to and from the testing facilities for her and her child, so there is no financial cost for the participants.

14. Benefits: Discuss any potential direct benefits to the participants from their involvement in the project.

Mothers who are involved in the DCHS receive feedback on their child's physical and mental health and development. Children are screened for disabilities and other risks factors. Participation in the study also gives children access to more responsive and innovative healthcare.

15. Compensation: If participants are to receive compensation for participation, please provide details.

As mentioned above, mothers are given a R100 voucher to compensate for travel costs. This voucher is organised and funded by the DCHS.

16. Consent. Describe the process to be used to obtain informed consent. Where applicable, attach a copy of the information letter and consent form.

Consent for the current study is based on the written informed consent that mothers gave at the time of their enrollment in the DCHS, when they were 20-28 weeks pregnant.

17. Confidentiality. Please describe the procedures to be used to protect confidentiality of the data.

All participants are assigned a study number, and all data is linked to the study number. Thus, data is inputted based on the study number, and not the participant's name. For the current study, the data received from DCHS will include no identifying factors of specific participants.

18. Does the protocol comply with UCT's Intellectual Property Rights Policy (including ownership of the raw data)?	Yes ☑		No

Section C: Financial and contractual information

19. Is the study being sponsored or funded?	Yes		No ☑
If yes: 19.1 Who is the sponsor/funder of the study?			
19.2 Are there any restrictions or conditions attached to publication and/or presentation of the study results?	Yes		No ☑
19.3 Does the contract specifically recognize the independence of the researchers involved?	Yes ☑		No
(Note that any such restrictions or conditions contained in funding contracts must be made available to the Committee along with the proposal.)			
20. Will additional costs be incurred by the department?	Yes		No ☑
20.1 If yes, specify these costs:			

Section D: Statement on Conflict of Interest

The researcher is expected to declare to the Committee the presence of any potential or existing conflict of interest that may potentially pose a threat to the scientific integrity and ethical conduct of any research in the Department. The committee will decide whether such conflicts are sufficient as to warrant consideration of their impact on the ethical conduct of the study.

Disclosure of conflict of interest does not imply that a study will be deemed unethical, as the mere existence of a conflict of interest does not mean that a study cannot be conducted ethically. However, failure to declare to the Committee a conflict of interest known to the researcher at the outset of the study will be deemed to be unethical conduct.

Researchers are therefore expected to sign **either** one of the two declarations below.

a) As the Principal Researchers in this study Kate Anderson and Megan Scott, we hereby declare that we are **not aware** of any potential conflict of interest which may influence our ethical conduct of this study.

Signature: K. Anderson Date: 09-05-2019

Signature: M. Scott Date 09-05-2019

b) As the Principal Researcher in this study (name: _____), I hereby declare that I am **aware** of potential conflicts of interest which should be considered by the Committee:

Signature: _____ Date:_____

Section E: Ethical and legal aspects

21. Have you read the UCT Code for Research involving Human Subjects (available from the UCT website)?	Yes ☑		No

Section F: Checklist		**Tick**
Application form	1 electronic copy	☑
Covering letter and all other correspondence (e.g., ethics approval from other bodies, letters to parents, etc.)	1 electronic copy	☑
Detailed proposal, including a 200-word summary/abstract	1 electronic copy	☑
Consent/Assent form/s	1 electronic copy	☑
Participant information sheet/Debriefing form (if separate from consent form)	1 electronic copy	NA
Other documents (e.g., advertising posters)	1 electronic copy	NA

IMPORTANT NOTES:

- All applicable sections of this application form must be filled in OR justified why not.
- All applicable signatures must be sought
- All additional number of copies must be included with application
- All incomplete applications will be returned to the applicant, leading to delays in review.

Version February 2017

Appendix F

Communication of Ethical Approval from the Department of Psychology

Lauren Wild <lauren.wild@uct.ac.za> Wed, Jul 17, 12:23 PM

to me, Megan, Andy

Dear Kate and Megan

Thank you for sending me the ethical approval letters. This is all that is required, and you are welcome to proceed with your study.

Kind regards

Lauren

Appendix G

Communication of Ethical Approval from DCHS

Nadia Hoffman <nadia.hoffman@uct.ac.za> Mon, May 20, 4:34 PM

to me, Kirsty, Christopher, Megan, Andy

Dear Kate and Megan

Prof. Zar has approved your proposal to work on DCHS data. She has emphasized the importance of publication, and specified that this could be led by you as students in collaboration with your supervisors and DCHS co-authors. However, should you not be able to publish this work after graduating, the DCHS authors reserve the rights to publish the findings.

Please do let me know if you agree to the above?

The 6 year consent form is currently being reviewed by HREC as part of an amendment. The attached is the version currently used, but this will be replaced by the new version in due course.

When you are ready to submit your data request, please do so to Lesley Workman at lesley.workman@uct.ac.za. Please copy in myself and Tiffany Burd (DCHS project manager) at tiffany.burd@uct.ac.za.

Kind regards,

Nadia

Appendix H
Consent Form

DRAKENSTEIN CHILD HEALTH STUDY

CONSENT AND INFORMATION SHEET FOR MOTHERS – MAIN COHORT

June 2017

CONSENT FORM AT YEAR 6

You and your child are invited to continue to take part in a study that is being done in the Drakenstein sub-district, in collaboration with the Universities of Cape Town and Stellenbosch. We would like to thank you and your child for taking part in this study, we hope to impact child health and your participation will help us achieve that. The following information describes the study and you and your child's role for the next year. Please read this carefully and feel free to ask any questions.

Why is this study being done?

Lung infections and chest problems are common in young children. This study is being done to find out the effect of chest infections in the early years of life on the development of lung disease in children. The study will also look at a number of other factors that may affect your child's health.

You and your child will continue to attend occasional scheduled visits at your primary health care clinic and at Paarl Hospital. During these visits, we will assess the health of you and your child by using questionnaires and doing tests. Should your child get sick with a chest infection, then he/ she will be carefully investigated to try and find out the cause of this infection. This study will help us to better understand why children get chest illness and may help to improve child health.

Cognition and social emotional development are important parts of a child's overall health. By cognition we mean the way a child thinks, learns, plans and pays attention. Social emotional and social cognitive development refer to how a child learns to understand their own and others' emotions, and to reason about what other people think, believe and feel. We want to see how these factors develop over time. This study will help us understand how various other factors we look at in the main study impact on this development, and also how this development affects overall health.

What must I do if I agree to continue in the study?

If you agree to continue in this study, we will follow you and your child regularly to assess his/ her health. We will see you and your child at Paarl hospital when your child is about 6 years of age and again at about 7 years of age. We will also schedule a visit at 6 years of age and at 6 ½ years at the primary health care clinic. We will ask you some questions about your child's health, nutrition, growth and development, and any chest illnesses. We will do regular tests to watch these.

At study visits in the next year, you will be asked some questions about you and your child's health. Your child will be examined. Tests will be done on you and your child to assess whether there is any chest problem. The tests that may be done on your child are:

1. Blood tests - these will be to test for allergies or blood problems.
2. A test of the mucus from the nose (nasopharyngeal swab) to test for infection.
3. Saliva will be collected to check for germs which may cause pneumonia
4. A skin test for tuberculosis infection.
5. A urine test for smoke exposure.
6. A stool test to check what germs are in the stool.
7. A skin test if your child has a rash
8. A hearing test to see if your child may have any hearing problems

9. A formal test of school readiness and IQ will take place at 6 years.

The tests YOU will be asked to complete are:

1. Questionnaires about your socioeconomic status and your levels of emotional distress, stress, life events, social support, resilience, aggression, emotional regulation, sexual risk behaviour, impulsivity exposure to community violence, assessment of maternal parenting styles, your and your child's emotional style and empathy and drug and alcohol use. If a mental health condition or abuse is suspected, you will be referred to the appropriate local services.
2. An eye-tracking test where you will look at a computer screen showing different baby facial expressions.
3. Neurocognitive and socioemotional assessment at 6½ years. We will take a short video of you playing with your child, and of your child playing. We will then ask you to answer some questions about your child's feelings and behaviors, and about your own feelings and behaviors as well as any trauma or violence that you or your child may be exposed to. While you are doing this, we will be doing some tasks, games and puzzles with your child.

We will only share your test results with primary health care staff if it indicates that you or your child require treatment or further follow up. For some assessments, study staff may follow up with you and provide you with information on where you can seek help, if necessary.

Should your child get sick with a chest infection, wheeze or asthma then additional tests will be done to try and find out the cause of your child's illness. The tests that will be done will depend on how sick your child is and what the illness is. These tests may include:

1. Blood tests to test for infections, at the time of the illness, and again 4-6 weeks afterwards
2. A test of the mucus from the nose (nasopharyngeal swab) to test for infection
3 A skin test for tuberculosis infection.
4 A test of the mucus from the lungs (induced sputum test) for chest infection.
5 A urine test for smoke exposure

6 Chest X-ray
7 Breathing test
8 A ultrasound test of the lungs
9 A stool test to check what germs are in the stool.
10 The research team may ask you to breathe normally and cough while recording the sounds onto a smartphone. The sounds produced by your breathing/coughing will be tested and compared to the results of other tests you receive to see if in the future these sounds could help figure out respiratory problems in addition to or instead of other tests.

If your child is enrolled in the study and is admitted to hospital, he/she will be followed up in hospital by a member of the study team. The study member will ask you questions about your child's illness, and some tests may be done, including a nose swab and an induced sputum. All of these tests are usual for investigating the cause of pneumonia.

What are the benefits of my child being in the study?

You and your child will be closely followed for the first few years of your child's life. Any medical illness or problem should be found soon after it develops. Your child's growth and development will be carefully followed. If an illness or problem is found then your child will be promptly referred for treatment. If your child gets sick you will be able to take him/ her to your usual health facility, where additional tests to find out the cause of your child's illness may be done, depending on how sick your child is. If your child requires hospitalisation, then he/ she will be hospitalised at Paarl hospital as is usually done. If your child is hospitalised, then one of the study staff will see your child in hospital and additional investigations may be done to try and find out the cause of the illness. A specific focus of the study includes pneumonia, wheeze and asthma. If study staff believe that your child has any of these illnesses, your child will be referred to the clinic or hospital for treatment, depending on the severity of illness. In addition, study staff will ask questions about this illness and take specimens as detailed below. Study staff will continue to follow your child and the development of this illness as well as discuss

where to seek appropriate medical care. Therefore the study offers an opportunity for your child to receive appropriate medical care. The study will also help us to better understand the causes of illness in children, and identify the things that may harm their health. We hope that this will lead to improvements in child health. When the study is finished or if you choose to withdraw from the study, you and your child will continue to go to your usual health facility for care and study staff will no longer be involved with you or your child.

What are the risks to my child?

There are no major risks to your child. Your child may also become tired during the tasks, games and puzzles. To minimize this risk, we will take breaks whenever it seems your child is getting tired. There may also be some discomfort associated with some of the tests we will do. These tests are listed below:

(1) Blood tests

Your child may feel sore when blood samples are taken with a needle. Where possible an anaesthetic cream will be used to dull the pain from the needle. Some bruising may occur, but this is not harmful and will disappear. Only a small amount of blood (not more than 3 teaspoons) will be taken from your child at any time

(2) Nasopharyngeal swab

A sample of mucus will be taken from your child's nose, to test for germs that can cause chest infections and to monitor which germs are usually in your child's nose. Your child may experience minor discomfort when the nasal swab is done. Occasionally it can cause bleeding from the nose, but this is not serious, and usually stops by itself.

(3) TB skin test

A small injection is made on your child's arm. This is to test whether your child has TB or not, and will be done at regular visits. Your child will experience minor discomfort due to the needle, with the skin test. There may also be irritation of the skin if the test is positive (reactive). This test will need to be checked 2-3 days after the injection is given.

(4) Induced sputum

Your child will be given salt-water through a nebulizer to loosen the mucous in the lungs. Then a sample of that mucus will be suctioned, or your child will be asked to cough up the mucus. Your child may experience a little discomfort while the sputum test is done. He/ she may develop some coughing or have a small amount of bleeding from the nose after this. These are not serious. Occasionally this test can cause the airways of the lungs to close. If this occurs your child will be given medicine through an inhaler/nebulizer to open the airways.

(5) Breathing test

This test is done after a child recovers from pneumonia, and at the 4 year and 5 year visits at Paarl Hospital and should not cause any discomfort. A mask will be put on his/ her face and the air going in and out of his/ her lungs while breathing will be recorded.

(6) Stool test

This test may be done monthly on your child and then every 6 months after 1 year. Study staff will collect stool from your child's nappy if passed during a study visit. If there is no stool available, a small tube will be inserted into your child's bottom and some stool will be sucked out with a syringe. The tube is thin and bendable and is only put in 1-2 centimeters to reach stool. There is a very small chance of bleeding at the rectum right where the tube goes is.

(7) Ultrasound test of the lungs

This test will be done if your child develops pneumonia so as to better see how the infection is affecting your childs lungs. This is a very safe procedure and there are no side effects.

(8) Neurocognitive and socioemotional assessment at 6½ years.

We will take a short video of you playing with your child, and of your child playing. This will take 5 – 10 minutes. We will then ask you to answer some questions about your child's feelings and behaviors, and about your own feelings and behaviors as well as any trauma or violence that you or your child may be exposed to. This will be very safe, though you or your child may become tired. We will take lots of breaks so your child

can relax and play in between these tasks. We will provide you both with refreshments. In total, this visit will probably last about 2 hours.

(10) Hearing test

This test will assess whether your child may have hearing problems. This will be very short and there will be no pain or risk.

What are the risks to you?

There are no major risks to you. Some of the questionnaires ask for sensitive information relating to mental health and this may cause some emotional distress or discomfort. Where significant issues are identified, and if you agree, study staff will offer referral to mental health support. You may also choose not to answer certain questions and still remain in the study. You will be able to take breaks, if you need to, and you will be free to terminate or reschedule the interview should the need arise.

What happens if I get hurt taking part in this study?

This research study is covered by an insurance policy taken out by the University of Cape Town. If you suffer a bodily injury because you are taking part in the study, the insurer will pay for all reasonable medical costs required to treat your bodily injury, according to the SA Good Clinical Practice Guidelines 2006. The insurer will pay without you having to prove that the research was responsible for your bodily injury. You may ask the study doctor for a copy of these guidelines.

The insurer will *not* pay for harm if, during the study, you:

· Do not take reasonable care of yourself

If you are harmed and the insurer pays for the necessary medical costs, usually you will be asked to accept that insurance payment as full settlement of the claim for medical costs. However, accepting this offer of insurance cover does not mean you give up your right to make a separate claim for other losses based on negligence, in a South African court.

Will I be paid to participate in the study?

No, you will not be paid to participate in this study. If you agree to take part, we will reimburse your transport costs for visits that are not part of your well child clinic visits.

Will there be any cost to participate in the study?

No, there will be no cost to you.

How long will my child be in the study?

This consent form is for permission for you and your child to participate in the study from 5 to 6 years of age. We hope to continue the study for many years until your child reaches at least 10 years of age; each year we will ask you again to sign permission for you and your child to continue in the study for another year.

Will my child's participation in the study be confidential?

All information that you provide will be considered confidential, and no mention of you or your child's name will appear on the stored samples or in any publication in connection with this study. No persons other than the health care workers overseeing your child's care and the study nurses and doctors will have access to any information that identifies your child personally. All your test results will not be disclosed to anyone other than for the purpose of treating you if there is a problem.

The video material will be securely stored, and only researchers directly involved in this part of the study will have access to it. This material will also be treated as very strictly confidential. Your names will not be attached to the video. The video will give us information about how you and your child interact, and about your child's behaviour.

Mandatory reporting of abuse and/or deliberate neglect

The researcher(s) may not be able to keep confidential, information about known or reasonably suspected incidents of deliberate neglect or physical, sexual or emotional abuse of an adult or a child. If a researcher is given such information, he or she may report it to the authorities such as child welfare.

Does my child have to be in the study?

You can choose not to take part in the study. This will not affect the quality of care your child receives. You will be able to decline to participate at any time should any part of the study be unacceptable to you, you may still take part in the rest of the study.

What do I do if I have any questions?

If you have any questions about this study, you can ask study staff, the Principal Investigator, Professor Heather Zar, or the lung study doctor, Dr. Attie Stadler, at: ----------021 860 2802. The UCT's Faculty of Health Sciences Human Research Ethics Committee can be contacted on 021 406 6338 in case you have any ethical concerns or questions about your rights or welfare as a participant on this research study.

Informed Consent

1. I, _____ understand the information contained in this consent form, as explained to me in a language that I understand. I am prepared to participate in this study and give consent for my child to participate in this study.

I agree to allow study staff to access my medical and hospital records as well as those of my child during the course of the study.

2. To be completed by mother:

Child's Name:_____

Mother's Name:_____

Mother's Signature: _____

Date: _____

3. Study staff providing information: Study staff confirming consent:

Name: _____ Name: _____

Role in Study:_____ Role in Study:_____

Signature: _____ Signature: _____

Date: _____ Date: _____

4. If the mother is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the mother has given consent.

Fingerprint of mother:

Witness: I confirm that I am independent of the study and that I witnessed the entire enrolment counselling process in the home language of the mother.

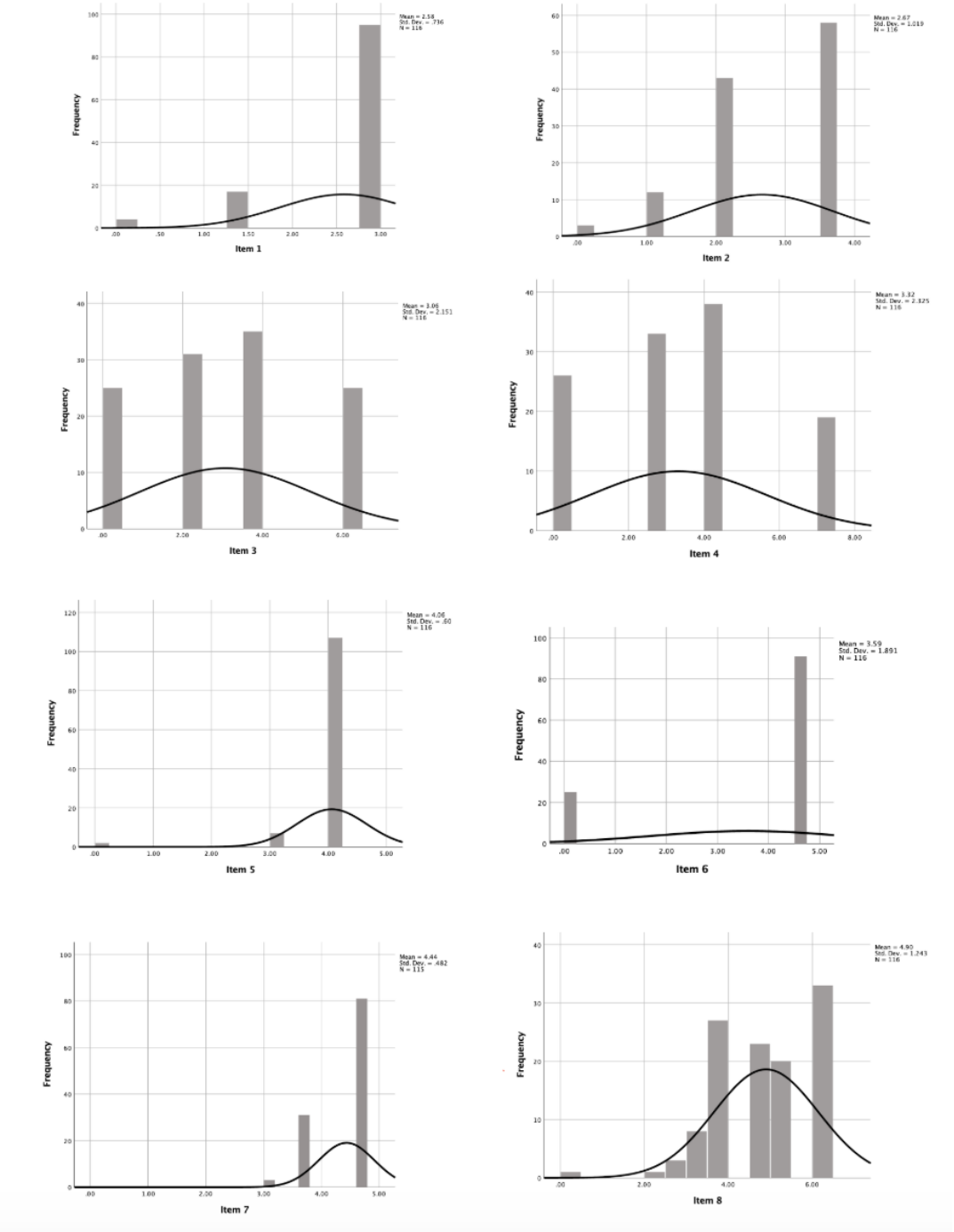
Name:_____

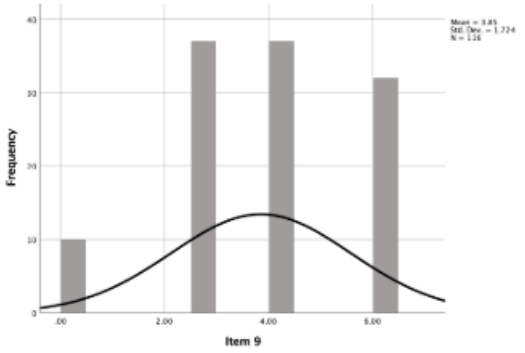
Signature: _____

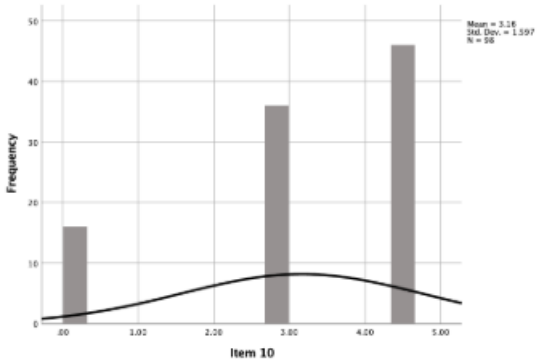
Date: _____

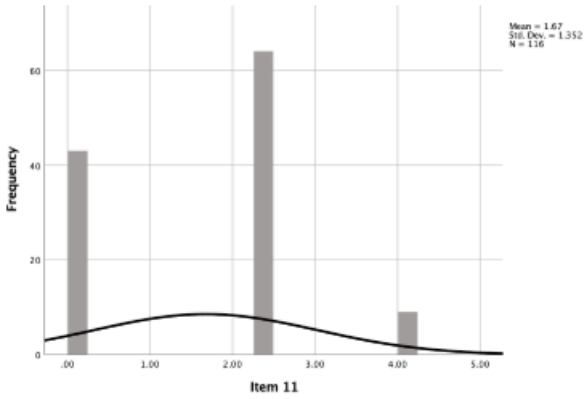
Appendix I

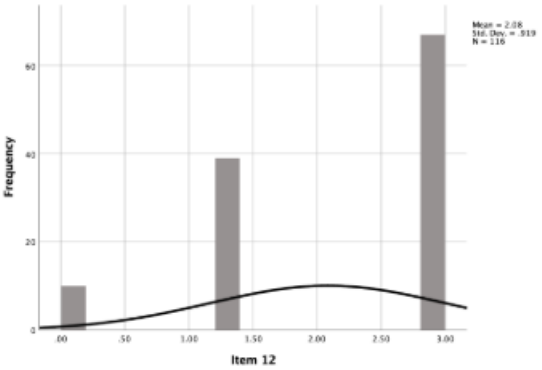
Frequency Histograms for Item Ceiling Effects

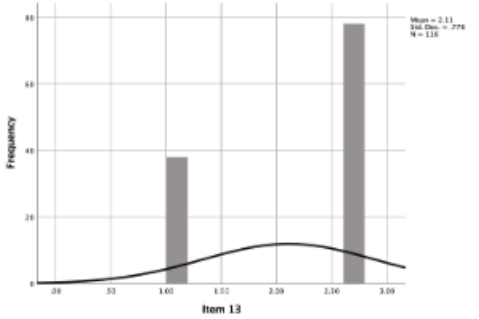



Frequency
Item 9


Frequency
Item 10


Mean = 1.67
Std. Dev. = 1.352
N = 116
Frequency
Item 11


Frequency
Item 12


Frequency
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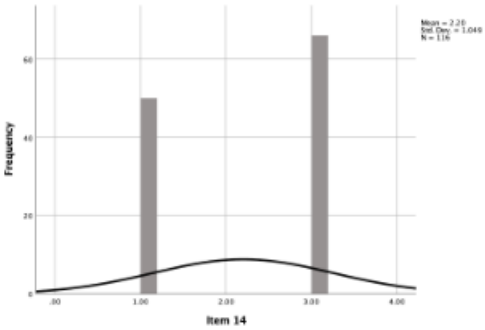
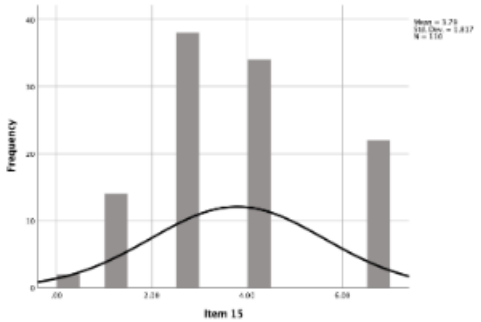
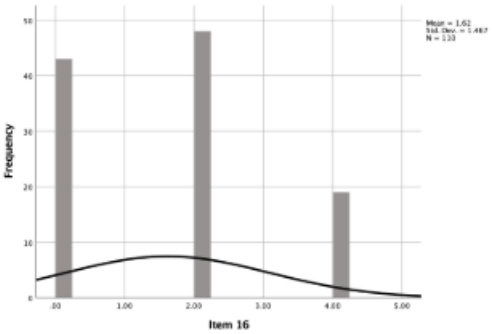
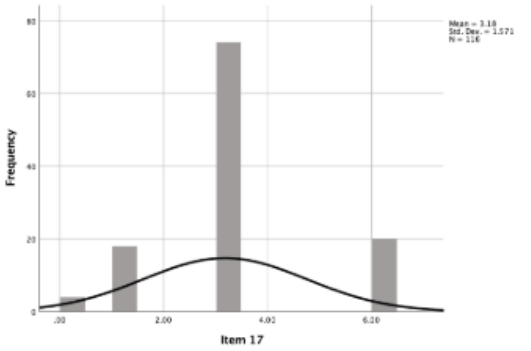
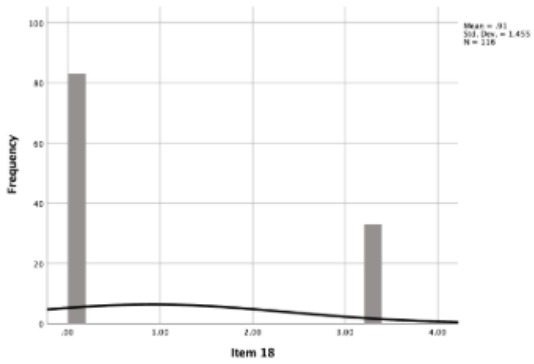
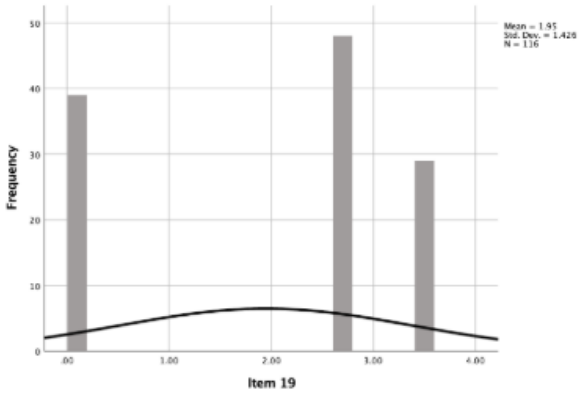

Frequency
Item 14

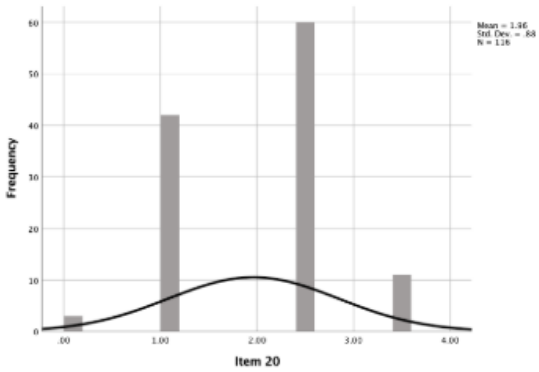

Frequency
Item 15

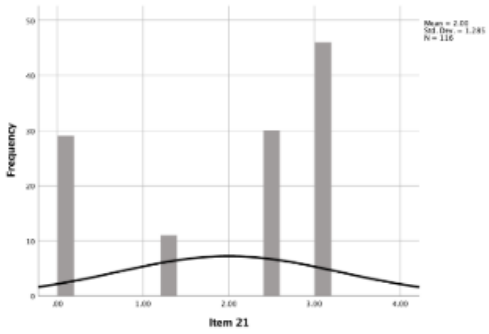

Frequency
Item 16

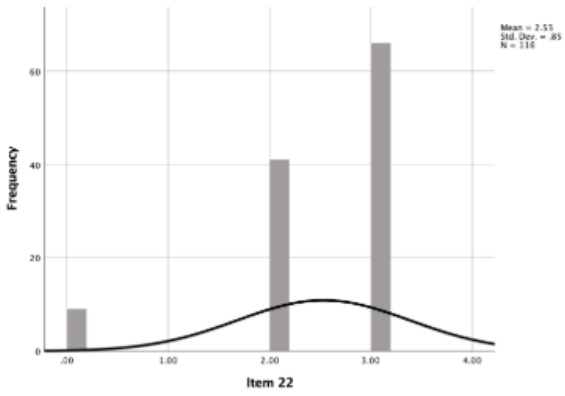

Frequency
Item 17

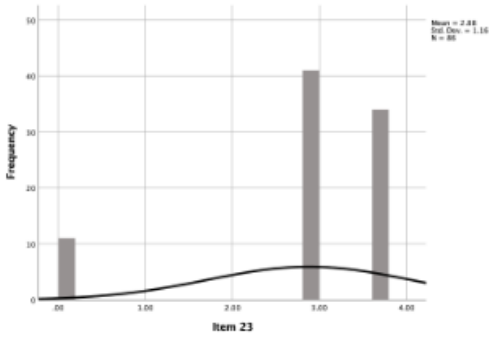

Frequency
Item 18

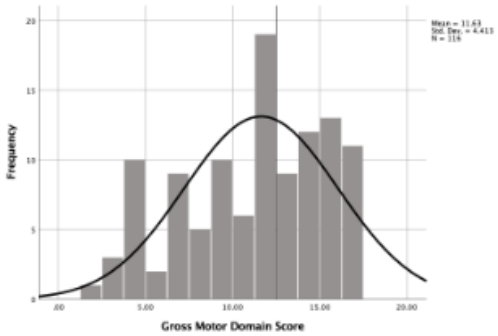

Frequency
Item 19

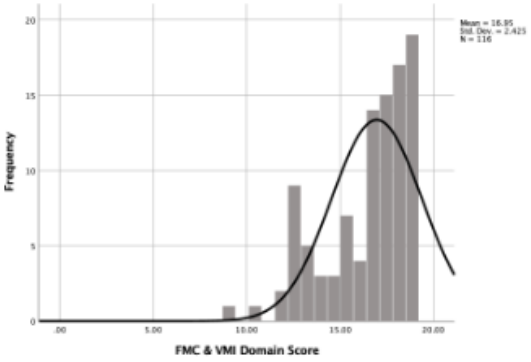

Frequency
Item 20

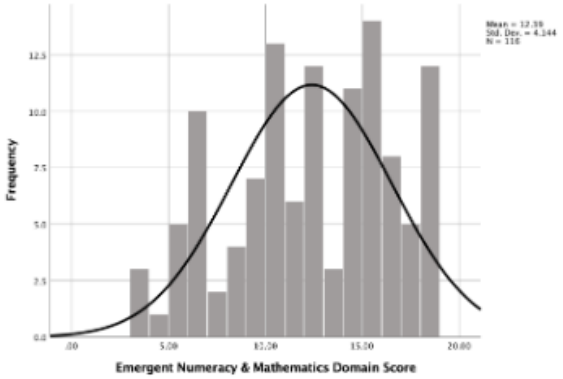

Frequency
Item 21

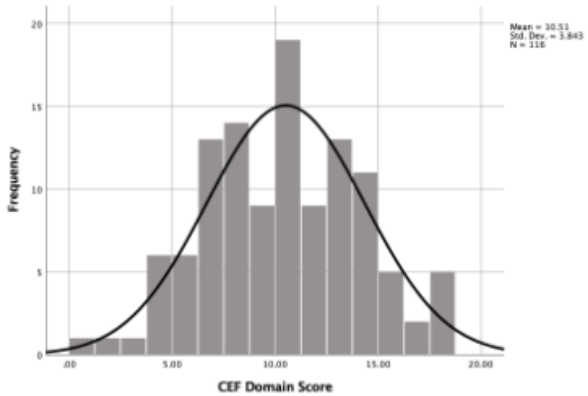

Frequency
Item 22

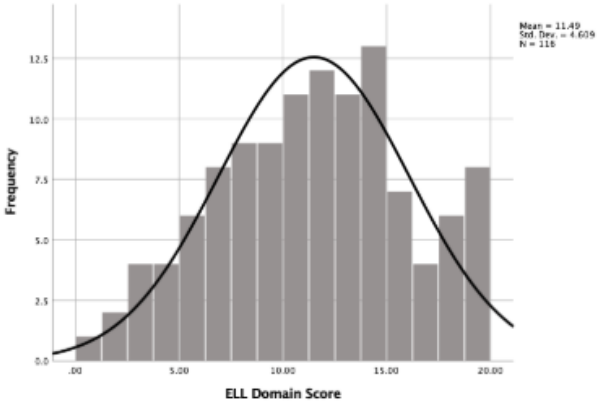

Frequency
Item 23

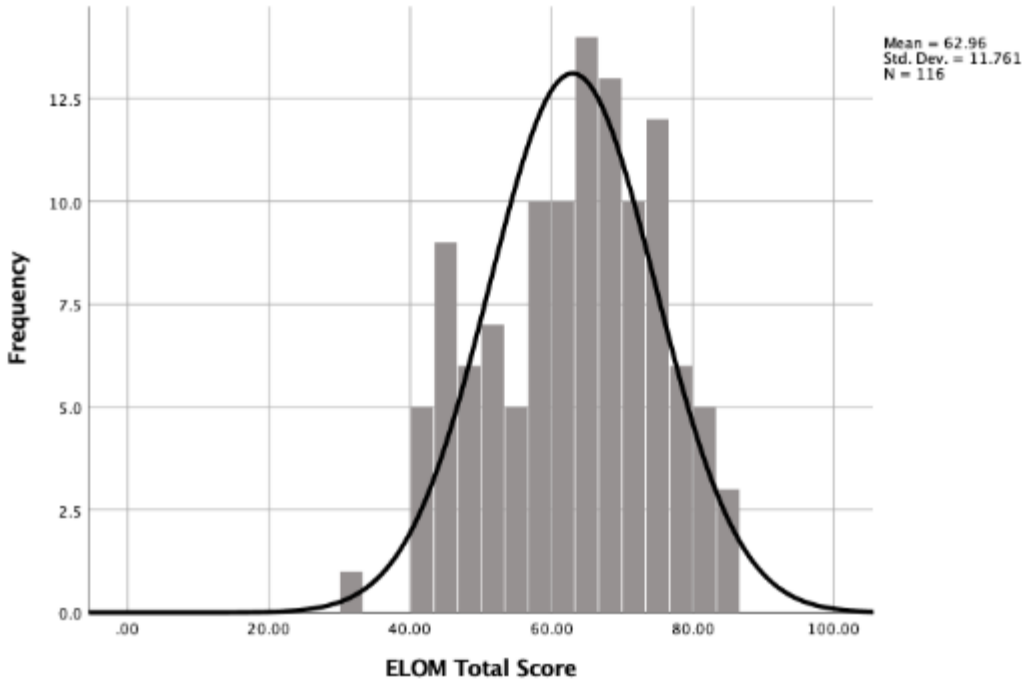

Frequency
Gross Motor Domain Score


Frequency
FMC & VMI Domain Score


Frequency
Emergent Numeracy & Mathematics Domain Score


Frequency
CEF Domain Score


Frequency
ELL Domain Score


Mean = 62.96
Std. Dev. = 11.761
N = 116
Frequency
12.5
10.0
7.5
5.0
2.5
0.0
.00
20.00
40.00
60.00
80.00
100.00
ELOM Total Score