DEVELOPMENTAL SCREENING USING CAREGIVER REPORT: AN EVALUATION OF SCREENING TOOLS AND CHILDHOOD DEVELOPMENTAL DELAYS IN SOUTH AFRICA

by

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Bismillah hir Rahman nir Rahim

In the name of Allah, most Gracious, most Merciful

“Whoever follows a path in the pursuit of knowledge, Allah will make easy for her a path to Paradise” – Prophet Muhammed (peace be upon him)

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PUBLICATIONS AND RESEARCH OUTPUTS

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2. Detecting developmental delays in infants from a low-income South African community: Comparing the outcome of the Bayley Scales of Infant and Toddler Development III (BSID-III) and PEDS tools. Paper presented at The International Society for Early Intervention Conference, Sydney, Australia, June 2019.
3. Characteristics of development in young children in South Africa. Paper presented at IASSIDD Europe Congress, Amsterdam, July 2021.
4. Detecting developmental delays in infants from a low-income South African community: comparing BSID-III & PEDS tools. Paper presented at the 3rd Gauteng Health Early Childhood Intervention (ECI) conference, Johannesburg, June 2019.
5. Application of the Bayley Scales of Infant and Toddler Development (III) in South Africa. Paper presented at the CHRIB Seminar, Department of Speech-Language Pathology and Audiology, University of Pretoria, August 2018.
6. Detecting developmental delays in infants from a low-income South African community: Comparing the BSID-III and PEDS tools. Paper presented at Research Day, Department of Speech-Language Pathology and Audiology, University of Pretoria, August 2019.
7. A scoping review on the use of the Parents Evaluation of Developmental Status (PEDS) and PEDS: Developmental Milestones (PEDS-DM) screening tools. Paper presented at UP Access to Care Seminar, Department of Speech-Language Pathology and Audiology, University of Pretoria, June 2021

PLAGIARISM DECLARATION

UNIVERSITY OF PRETORIA

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DECLARATION

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Title of thesis/dissertation/mini dissertation:

Developmental screening using caregiver report: An evaluation of screening tools and childhood developmental delays in South Africa

I declare that this thesis/dissertation/mini dissertation is my own original work. Where secondary material is used it has been carefully acknowledged and references in accordance with university requirements.

I understand what plagiarism is and am aware of university policy and implications in this regard.

10 December 2021

Signature **Date**

ETHICS STATEMENT

The author, whose name appears on the tile page of this thesis, has obtained, for the research described in this work, the applicable research ethics approval.

The author declares that she has observed the ethical standards required in terms of the University of Pretoria's Code of ethics for researchers and the Policy guidelines for responsible research.

ABSTRACT

Introduction: Early childhood intervention (ECI) services are recommended to be integrated in primary healthcare (PHC) in underserved communities. Currently, developmental screenings are not routinely carried out at PHC level and there are shortages of appropriately skilled staff and resources to conduct screening, assessment and provide follow-up care. As a result, there is growing interest in parent-based screening with parental concerns often predictive of developmental delay. This research project aimed to explore the use of developmental screening tools and caregiver report from diverse low-income settings. Three study objectives were identified: the first aimed to establish a developmental profile for children under the age of three years from a low-income South African community; the second objective was to provide an overview of studies that used Parents' Evaluation of Developmental Status (PEDS), the PEDS: Developmental Milestones, and the PEDS tools in combination, to identify developmental delays in children by means of a scoping review; and lastly to compare the outcomes of two caregiver report tools – namely the Bayley Scales of Infant and Toddler Development III (BSID-III) and PEDS tools – in an at-risk infant population from a low-income South African community.

Method: Study I (Developmental characteristics of young children in a low-income South African community) utilized convenience sampling to select 353 caregivers and their infants, aged between 3-36 months from a primary health care clinic. The BSID-III was used for diagnostic developmental assessments by a speech-language pathologist (SLP) and final year SLP students. Study II was a scoping review on the use of the PEDS and PEDS:DM, as well as the PEDS tools in combination, which was conducted to provide an overview of these tools and their use to detect developmental delays globally. Five electronic databases were searched. Narrative synthesis was used during data analysis. In Study III, a cross-sectional, within-subject, comparative design was employed to determine the overall and domain-specific performance of the PEDS tools smartphone application and the BSID-III to detect developmental delays in 174 young children aged 3-18 months. Data was collected at a PHC in Mamelodi, an underserved high-risk community, in South Africa.

Results and conclusion: Developmental characteristics of young children in a low-income South African community (Study I) identified signs of developmental delay in 51.8% (n=183) of 353 children. Prevalence of developmental delay increased with age from 33.1% for children younger than 12 months to 61.7% and 66.3% for children between 13 to 24 months and 25 to 36 months of age respectively. Females were 1.82 times more likely to have no signs of a developmental delay; they were 2.301 times more likely to have no signs of delay in the motor and 2.601 times more likely to have no signs in the adaptive behaviour domains. One-third (33%) of children presented with low levels of functioning in the adaptive behaviour domain. One hundred and one (28.6%) of participants across all age groups displayed superior social-emotional ability.

In the scoping review of the use of the PEDS, PEDS:DM and PEDS tools (Study II), the search strategy identified 1468 records. Thirty articles, ranging from 2003 to 2020, conducted in both high-income countries (HIC) and low- and middle- income countries (LMIC) , qualified for final inclusion. Studies conducted in HICs primarily focus on the screening of special population groups, as well as the comparison of validated tools. Studies conducted in LMICs focused more on translations, combination of the PEDS tools, validation of the tools, and the use of an app-based tool (mHealth). High referral rates are typically obtained with the PEDS and PEDS:DM when administered in low-income settings, where at-risk populations are more prevalent, and where cultural differences are a concern.

Detecting developmental delays in infants from a low-income South African community: comparing the BSID-III and PEDS tools (Study III), the PEDS tools identified 56% (n=97), and the BSID-III 35% (n=61) of the 158 children with possible developmental delays, with an overall agreement of 65% between tests. The PEDS tools referral rate was significantly higher (p=0.004) than that of the BSID-III, as domain specific outcomes (language, motor, and social emotional) of the PEDS tools and BSID-III was compared and showed that twice the number of participants were identified as having developmental delay on the PEDS tools in relation to the BSID-III in all domains. Study III contributed to information on the developmental characteristics of young children, and evaluated tools for use in developmental screening for these children, which can inform intervention and public health policy in South Africa. Despite poor developmental screening outcomes one third of children,

in the low-income South African community, presented with superior social-emotional skills. This could possibly be attributed to familial structures and relationships. One third presented with low levels of functioning in the adaptive behaviour domain which could be attributed to cultural differences. The agreement between developmental assessment outcomes across the BSID-III and the PEDS tools was poorer than expected. The high-risk nature and young age cohort (<18 months) may have contributed to these outcomes. Findings raised concerns about the outcomes of the BSID-III or PEDS tools in isolation for screening and assessment of developmental delay in infants from LMICs like South Africa. Additionally, more research from diverse settings and LMICs at large with regards to the PEDS was identified as an outstanding need. Future research should evaluate performance of the PEDS tools mHealth version in older preschool children (between 2 and 5 years) to ascertain the influence of age. This research project identified future research needs into the validity of the PEDS tools and BSID-III for young infants and children in LMICs, that needs to be prioritised prior to large scale implementation.

KEYWORDS

Smartphone application

Developmental screening

Primary health care

PEDS

PEDS:DM

BSID-III

Speech language pathologist

mHealth

Caregiver

Community oriented primary care

Child Development

Early Childhood Intervention

Low and Middle Income Countries

South Africa

Teaming and Collaboration with Others

LIST OF ABBREVIATIONS

ECI:	Early Childhood Intervention
PHC:	Primary Health Care
PEDS:	Parents' Evaluation of Developmental Status
PEDS:DM:	Parents' Evaluation of Developmental Status: Developmental Milestones
BSID-III:	Bayley Scales of Infant and Toddler Development III
HIC:	High-income country
LMIC:	Low- and middle-income country
HIV:	Human Immunodeficiency Virus
AIDS:	Acquired Immunodeficiency Syndrome
NCF:	Nurturing Care Framework
SDG:	Sustainable Development Goal
ECD:	Early Childhood Development
ASD:	Autism spectrum disorder
CHW:	Community Healthcare Workers
SLP:	Speech-Language Pathologist
RTHB:	Road To Health Booklet
mHealth:	Mobile Health
WHO:	World Health Organization
COPC:	Community Oriented Primary Care

NDP: National Development Plan

CHAPTER 1

INTRODUCTION AND RATIONALE

1.1. Introduction

The first three years of a child's life are critical for development (World Health Organisation [WHO], 2016). Experiences in this period influence learning, behaviour, capacity, health, and well-being, as well as personal and social adjustment, across the life span (WHO, 2016). The early years of childhood development are described as a time of opportunity, dependent on the quality of stimulation, support, and nurturance that the child receives (WHO, 2016). It is, however, also a period of vulnerability to negative influences, such as environmental and biological risk factors which predispose children to developmental delay (WHO, 2016). Underserved communities in South Africa bear a high burden of poverty and disability (Richter et al., 2017), largely due to service limitations in the past (Van Der Linde & Kritzinger, 2013). Poverty has been shown to be linked to structural differences in several areas of the brain associated with school readiness skills and academic achievement; thus, poverty can have a significant influence on children's learning (Hair et al., 2015; Luby, 2015). Owing to the prevalence of various risk factors such as poverty, unemployment, crime, insufficient medical and educational services, as well as Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome (HIV/AIDS) and substance abuse, young children in South Africa are at a high risk of developmental and communication delays (Guralnick, 2013; Richter et al., 2017). The efficacy of early intervention is related to the child's age at identification (Black et al., 2017). The high prevalence of risk factors and the limited availability of professional services call for a focus on the prevention and early identification of developmental delays and disorders, and the tools needed to achieve this (Richter et al., 2017).

Various prevention strategies can be implemented to avert developmental delays. Primary prevention strategies include awareness campaigns, as well as training of parents and health care professionals (Luo et al., 2019), while secondary prevention strategies include developmental screening for early identification, assessment, and intervention (Van Der Linde & Kritzinger, 2013; Van Der Linde et al., 2015). The prevention and early identification of developmental disorders in South Africa is in line with legislation focusing on primary healthcare (PHC) (Philpott et al., 2014). The Nurturing Care Framework (NCF) describes a comprehensive government and societal level approach to childhood development, outlining principles, strategic actions, and ways of monitoring child development (Pierce, 2020). Children's developmental potential is being lost as a result of their development not being monitored. This is not a local issue but a global crisis, as outlined by global agendas such as the Sustainable Development Goals (SDGs) (Black et al., 2017). The SDGs aim to ensure that all women, children, and adolescents have an equal chance to thrive, and not simply survive (Urke et al., 2018). In all countries, national plans to support children to thrive should ensure that early childhood development (ECD) is prioritized to inform policy and programmatic implementation and achieve the SDG target (Bushnell et al., 2016). Aligned with the SDG, the NCF serves as a model for providing care and services to families and their children (Black & Trude, 2019). Nurturing care is defined as the conditions created by public policies, programmes and services - by both communities and caregivers - to promote children's good health and nutrition, ensure protection from threats, and provide them with opportunities for early learning (Pierce, 2020). To support children in need, early detection of developmental delays or disorders is essential.

Developmental screening is an important public health care priority, under the directive of ECD (Richter et al., 2017). If early identification and intervention services are provided timeously, the negative effects of risk factors can be reversed, reducing the need for remediation of developmental delays or disabilities later in life (Philpott et al., 2013). Various studies have recommended that early childhood intervention (ECI) services should be integrated into PHC in underserved communities (WHO, 2012; Slemming & Saloojee, 2013; Luo et al., 2019). PHC, one of the five health priorities for low- and middle-income countries (LMICs), has resulted in improved health care services in rural and urban areas (Visagie & Schneider, 2014). Currently, though,

developmental assessments are not routinely carried out at PHC level in South Africa and there are shortages of appropriately skilled staff and resources to conduct assessments and provide follow-up care (Slemming & Saloojee, 2013). The shortage of speech-language pathologists (SLPs) at a PHC level globally (Kamenov et al., 2021) and the insufficient number of therapists in the public hospital context result in large caseloads in the public health setting. Due to inefficiency of PHC services, patients often prefer to access the health system at secondary or tertiary health care levels, and they do not always enter the healthcare system at a PHC level as intended (Mohapi & Basu, 2012). Instead, they bypass the PHC clinic structure and attend hospitals for their initial contact visits and often receive primary level care at expensive tertiary institutions (Pillay & Mahomed, 2019). This increases staff workload at tertiary levels and may lead to over-expenditure of resources and poor-quality patient care (Mohapi & Basu, 2012). As a result, developmental screening at baby wellness visits may not be given precedence (Van Der Linde et al., 2015).

Baby wellness clinics have been identified by PHC workers as the best platform on which to implement developmental screening, as regular monitoring of a child's growth and development can co-occur (Van Der Linde et al., 2015). It has been advocated for many years that all children should undergo developmental screening using a high-quality, valid screening tool to facilitate early identification during baby wellness visits (Glascoe, 2000). Developmental screening may also create awareness of ECD and increase parent/caregiver education (Der Linde et al., 2015). This, in turn, can support responsive caregiving - a vital part of providing children with early learning opportunities in accordance with the NCF (Pierce, 2020).

1.2. Rationale

Since a shift towards family inclusion was identified as a viable way forward for service delivery approaches, collaboration with families has come to be regarded as essential in ECI (Dunst et al., 2014; Guralnick, 2011). The screening process, which could well introduce parents to ECI services, may facilitate discussion as well as help to integrate the views of parents and professionals, thus promoting collaboration. This is particularly relevant in many communities within South Africa, where various risk

factors occur while negative views of disability prevail (du Toit et al., 2021). If the screening process is supportive, trusting relationships can be established with families of children at risk. Health care workers can offer both support and education to families, thus becoming 'brokers of information' (Rossetti et al., 2020). This facilitates the process of bringing together ECI services and the families and children who need them.

Once the screening process has fostered collaboration with parents and families, the next step is assessment where indicated (Guralnick, 2001). There is a growing interest in parent-based assessment, as trends indicate that parental report of and concerns regarding their children's skills are often predictive of developmental delay. Parents or caregivers are good resources when conducting screening and diagnostic tests (Glascoe & Robertshaw, 2010), as they can report their children's strengths and weaknesses (Glascoe, 2013). Parent-administered tests may, therefore, be appropriate for the over-burdened, resource-constrained public health care system in South Africa which requires time-efficient and accurate screening tools (Van Der Linde et al., 2015).

The Road to Health Booklet (RTHB) is currently the only nationally implemented developmental surveillance or screening tool for early identification in South Africa. The revised booklet was introduced in 2010, as part of the Department of Health's initiative to improve service delivery to young children (van der Linde et al., 2015). The RTHB includes a simple monitoring chart that clinic staff can use to track a child's progress in relation to developmental milestones. This serves as a guideline of what a healthy child should be able to do at different stages of development, but it is not clear how well it is implemented (Slemming & Saloojee, 2013). A study by Van Der Linde et al. (2015) indicated that the RTHB is ineffective as it failed to identify more than half of infants at risk of delays or disorders. Due to the limited validating evidence and poor accuracy of the nationally implemented RTHB, the Parents' Evaluation of Developmental Status (PEDS) tools - a combination of the PEDS and PEDS: Developmental Milestones (PEDS:DM) - have been recommended for use in PHC contexts in South Africa (Van Der Linde et al., 2015). The PEDS tools can be used to measure mild to severe difficulties such as cognitive disabilities, as well as developmental disabilities that are more challenging to identify such as Autism

Spectrum Disorder (ASD) (Glascoe et al., 2000). The PEDS tools, a parent administered test, is reported to have high specificity (71%) and sensitivity (73%) ratings for a combination of the language (receptive and expressive) and social-emotional development domains in the South African infant population. It is inexpensive, and thus appropriate for use in the financially constrained South African PHC context (Van Der Linde et al., 2015). Another recommended tool is the Bayley Scales of Infant and Toddler Development III (BSID-III). The BSID-III is a set of norm referenced measures for assessing the development of infants and toddlers, ages one month to three years six months. The BSID-III assesses five domains: cognitive, language, motor, socio-emotional, and adaptive behaviour. The performance of a newly developed PEDS screening application will be validated against the BSID-III. This is a well-validated tool, which is currently accepted as a gold standard of developmental screening and assessment (Kwun et al., 2015; Del Rosario et al., 2021).

The PEDS tools are usually administered by trained health professionals (Brothers et al., 2008). However, there is a limited availability of healthcare professionals in South Africa (Slemming & Saloojee, 2013). Healthcare professionals who are employed in South African hospitals are often faced with difficult working conditions, including high caseloads, lack of community awareness of services, and inadequate tools (Khoza-Shangase & Mophosho, 2018). Staff and other limitations can be counteracted by using automation and mobile health (mHealth) care technology to optimize health care services and resources (Hussein et al., 2015). Automated healthcare services are conducted in the absence of a specific healthcare professional, and are advocated to improve and enhance healthcare and research, particularly to underserved areas in South Africa (Rispel et al., 2018). The use of mHealth tools is ideal to overcome barriers of access and availability of services and offers the potential to extend clinical services for early detection and thus, the prevention of developmental delays or disorders. Mobile technologies including mobile phones, portable media players, portable computers, and personal digital assistants have a range of functions and technological capabilities which make them suitable for providing individual level support to healthcare consumers (Kapoor et al., 2020).

The use of mHealth approaches as a medium of service delivery is currently being explored in various healthcare fields in South Africa. Examples include the AITA Health™ software on smartphones, used by the City of Tshwane to collect and manage health status assessment data (Hussein et al., 2015). KardioFit™ is a smartphone-based application used by cardiologists to monitor patients' blood pressure, while the smartphone-based hearScreen™ application is used for hearing screening of both children and adults (Hussein et al., 2015). By enabling PHC to reach underserved communities, mHealth approaches can improve health care in LMICs (Van Der Linde, 2015). It was suggested by Van Der Linde (2015) that a developmental screening smartphone application be explored. The PEDS tools, consisting of the PEDS and the PEDS: DM, were developed into a smart phone application using the same algorithm as the paper-based PEDS tools (Maleka et al., 2016). This screening method has enabled community health workers to conduct developmental screening (Maleka et al., 2016), and may enable them to incorporate the process as part of home-based care. Thus, it could potentially increase accessibility to screening, decrease screening costs, and establish effective referral systems to appropriate healthcare professionals for earlier intervention. The smartphone application serves to alleviate the barriers to screening, as it is quick to administer, specific training is not required to use the PEDS tools, and expensive additional resources are not required to provide or sustain services.

A description of developmental characteristics, which provides information on typical and atypical development (Chambers et al., 2016; Gasparini et al., 2017), may be used to guide implementation of early intervention services (including developmental assessment, surveillance, and intervention) to support optimal child development. Given that children in sub-Saharan Africa are at high risk of not meeting their developmental potential, and that there is a dearth of published findings on the subject, investigation into the developmental profiles of these children could have significant implications for public health policies (Wedderburn et al., 2019). It is important, therefore, to describe developmental characteristics of young children, under 3 years of age, from a low-income South African community using a gold-standard tool. This is necessary in order to create a developmental profile for this population so that the need for early intervention services, as well as the protective factors or assets in the population, may be identified more easily.

Not only is it essential to understand the developmental profile of at-risk populations, it is also vital to have an effective, inexpensive screening tool with developmentally appropriate test items and good psychometric properties (Goldfeld & Yousafzai, 2018). For a tool to be suited to a context, it should be available in local languages where it is used, validated on children of the specific population, and require minimal training (Marlow et al., 2019). The PEDS, PEDS:DM and PEDS tools may be appropriate for use in various contexts. To understand how these tools perform in isolation and in combination, as well as in different contexts, a review of studies using the three potential options for screening with PEDS tools (PEDS, PEDS:DM, and PEDS tools) is recommended from a global perspective.

It is also important to provide alternative solutions to the challenge of conducting developmental screening at a primary care level. The value of the caregiver report as a means of developmental screening in South Africa is well-established (Maleka et al., 2016; Van der Linde et al., 2016). It is, therefore, apposite to compare the PEDS tools smartphone application to a valid, reliable and accurate standardized instrument of a similar nature, as it is essential to establish the reliability and validity of any newly developed measure before it is introduced into daily practice (Robin et al., 2020).

1.3. Research questions

This research project sought to explore the use of caregiver-report developmental screening tools from a LMIC perspective in order to inform practice, particularly developmental screening, in this context. The overarching aim was to explore the value and applicability of caregiver report as a means of developmental screening in an LMIC context.

The following three research questions were formulated to answer this main aim:

I. Based on the BSID-III, what are the developmental characteristics of children aged 3-36 months in a low-income community?
II. How are the three screening options with the PEDS tools (PEDS, PEDS:DM, and PEDS tools) currently being used globally to identify developmental delays?

III. How does the performance of the PEDS tools compare to that of the BSID-III for the detection of developmental delays in young children?

1.4. Outline of thesis chapters

The outline of each chapter in this thesis is described below.

Chapter One – Introduction

Chapter One introduces information which provides the background and rationale for the study, as well as the three research questions which will be addressed as three separate studies in this thesis.

Chapter Two – Methods

The methodological aspects of the three studies are described in Chapter Two. Research aims, designs, participant sampling and selection criteria, materials, data collection procedures and analysis are discussed. Ethical considerations are also outlined.

Chapter Three - Developmental characteristics of young children in a low-income South African community

Chapter Three comprises the article titled '*Developmental characteristics of young children in a low-income South African community*'.

Chapter Four - A scoping review on the use of the Parents Evaluation of Developmental Status (PEDS) and PEDS: Developmental Milestones

Chapter Four comprises the article titled *'A scoping review on the use of the Parents Evaluation of Developmental Status (PEDS) and PEDS: Developmental Milestones'.*

Chapter Five - Detecting developmental delays in infants from a low-income South African community: comparing the BSID-III and PEDS tools

Chapter Five comprises the article titled *'Detecting developmental delays in infants from a low-income South African community: comparing the BSID-III and PEDS tools.'*

Chapter Six – General discussion, implications, and conclusions

Chapter Six summarises the findings of each research project and discusses the implications of these outcomes. Recommendations for future research are outlined, as well as the strengths and weaknesses of the current study.

CHAPTER 2

METHODS

The overarching aim of this study is to explore the value and applicability of caregiver report as a means of developmental screening in an LMIC context. The research project is comprised of three separate studies, each with its own methodology. The methods of each study are outlined below under three sections, each of which describes the following: research objectives; study design; study context; research participants; research materials; procedures for data collection; data analysis; validity and reliability of the tools used. Following these three sections, the ethical considerations which applied to all three studies are outlined.

2.1. STUDY I: DEVELOPMENTAL CHARACTERISTICS OF YOUNG CHILDREN IN A LOW-INCOME SOUTH AFRICAN COMMUNITY

2.1.1. Research objective

To describe the developmental characteristics of children aged 3-36 months in a low-income community using the BSID-III.

2.1.2. Study design

A descriptive, cross-sectional research design was employed to describe developmental characteristics of children aged 3-36 months in a low-income community, using the BSID-III.. Descriptive research designs serve to provide plentiful information that can be easily understood and interpreted, and furthermore may identify problems that subsequently result in solutions (Abutabenjeh & Jaradat, 2018). Additionally, descriptive studies are useful for identifying the prevalence or incidence of a disease or disorder in a population, or the prevalence of specific traits in a population (Aggarwal & Ranganathan, 2019; Kesmodel, 2018). This research design was thus ideal. Once the prevalence of specific delays and developmental characteristics of the chosen population were evaluated, thee association between variables (for example, gender and the prevalence of a delay) were subsequently studied.

2.1.3. Study context

One PHC clinic (Stanza Bopape clinic) in Mamelodi, an underserved community of the Tshwane district, Gauteng province of South Africa, was utilized for data collection. Mamelodi has an area of 45.19 km², with a population of 334577 people, in 110703 households (Statistics South Africa, 2011). Most community residents in Mamelodi rely on government health care facilities such as Stanza Bopape clinic. Mamelodi is rife with poverty, drug and alcohol abuse, crime, HIV, and unemployment (Statistics South Africa, 2011). Although there are schools and ECD centres in the community, there are currently no formal developmental screening services in Mamelodi (Maleka et al., 2016). This community has been identified as one of the areas where services are rendered as part of community engagement initiatives by the University of Pretoria.

2.1.4. Research participants

Participants were recruited by means of convenience sampling. A total of 353 caregivers and their children aged between 3 and 36 months were included in the study. This age range was identified as focus since one month to 36 months is the targeted age range of the BSID-III. Caregivers who were waiting in the queue at the baby wellness clinic with their children were invited to participate. Parents and caregivers needed to be proficient in Afrikaans or English. There were 353 participant dyads in total. Forty-five percent (n=158) of children were female. Home languages included Sepedi (n =172; 48.7%), isiZulu (n=52; 14.7%), Ndebele (n=34; 9.6%), Setswana (n=20; 5.7%), Tsonga (n=16; 4.5%), Venda (n=12; 3.4%), Shona (n=12; 3.4%), SiSwati (n=11; 3.1%), Southern Sotho (n=7; 2.0%), Xhosa (n=6; 1.7%), English (n=5; 1.4%), Shangaan (n=3; 0.8%), Northern Sotho (n=1; 0.3%) and Portuguese (n=1; 0.3%).

2.1.5. Research materials

The BSID-III (Bayley, 2006) is regarded as the gold standard and best measure of developmental status in infants and toddlers (Del Rosario et al., 2021; Kwun et al., 2015). These scales are norm referenced measures for assessing the development of infants and toddlers, ages 1 month to 3 years 6 months. Five developmental domains form part of the scales, namely cognitive, language, motor, socio-emotional, and adaptive behaviour. Social-emotional and adaptive behaviour domains are assessed

by means of a questionnaire completed by the primary caregiver. Cognitive, language, and motor domains are assessed by means of items administered to the child. In addition, a Behavior Observation Inventory is completed during testing. The Bayley-III Cognitive Scale contains 91 items. The Language Scale is divided into Receptive Communication (49 items) and Expressive Communication (48 items) subtests; the Motor Scale is divided into Fine Motor (66 items) and Gross Motor (72 items) subtests. The Social-Emotional Scale (35 items) and the Adaptive Behavior Scale (241 items in 10 skill areas) are completed by the caregiver. The Behavior Observation Inventory (13 items) is used to report qualitative information regarding the child's responses observed during testing. The BSID-III yields a comprehensive assessment of the child, and can be used effectively in identifying children with developmental delay and for planning appropriate interventions, monitoring progress following intervention, and developmental research (Robertson, 2010). The BSID-III covers a set of domains similar to those evaluated by the PEDS tools, and is the reference measure most commonly used in studies on the validity of developmental screening measures.

2.1.6. Procedures for data collection

Ethical clearance was obtained from the Research Ethics Committee, Faculty of Humanities, University of Pretoria (Appendix A) prior to the start of data collection. Informed consent was obtained from all participants (Appendix B).

Assessments were conducted in a quiet room at the PHC clinic. The BSID-III was used for developmental assessment. Final year SLP students (registered with a professional body), who received training to conduct the BSID-III, assisted with the assessments under supervision. Quality control and monitoring processes were implemented to ensure accuracy. Scores of the paper-based BSID-III were manually completed and captured. Caregivers whose children were identified as having delays in one or more developmental domains were issued with referral letters to the relevant health care professionals for follow-up.

2.1.7. Data analysis

All quantitative data analyses (descriptive and inferential statistics) were conducted using IBM SPSS Statistics for Windows, Version 23.0, except for the achieved power analysis that was conducted using G*Power v 3.1.9.4 (Faul et al., 2007). A logistic

regression analysis was conducted to determine the effect of gender and age on the overall and domain-specific results. We assume a linear relationship between the predictor variables (age and gender) and the log-odds of the event that the dependent variable is 1 = no signs of a developmental delay. This linear relationship can be written in the following mathematical form (with l is the log-odds, β_0 is the constant, β_1 is the coefficient for gender and β_2 is the coefficient for age): $l = \beta_0 + \beta_1(\text{gender}) + \beta_2(\text{age})$. For Study I, 5% level of significance was used, meaning that if the p-value is less than 0.05, the predictor is statistically significant. In order to compute the achieved power, the level of significance (=0.05), the sample size (= 353) and the effect size is needed. For logistic regression, the odds ratio (OR) is an unstandardized effect size statistic.

2.2. STUDY II: A SCOPING REVIEW ON THE USE OF THE PARENTS' EVALUATION OF DEVELOPMENTAL STATUS (PEDS) AND PEDS: DEVELOPMENTAL MILESTONES

2.2.1. Research objective

To provide a review of the studies using the PEDS, PEDS:DM and PEDS tools globally to identify developmental delays

2.2.2. Study design

A scoping review was conducted to review studies that used the PEDS, PEDS:DM and PEDS tools to identify developmental delays. A scoping review design was chosen as it is the ideal method of identifying and mapping out available evidence. Scoping reviews are also used to identify gaps in literature, to examine emerging evidence and to pose specific questions that can be addressed by future systematic reviews (Munn et al., 2018). The PRISMA-P protocol was utilised in this study to provide a replicable, transparent, and rigorous method for the overview and synthesis of existing literature, that is also deemed a high level of evidence.

2.2.3. Procedures for data collection

Ethical clearance was obtained from the Research Ethics Committee, Faculty of Humanities, University of Pretoria (Appendix A) prior to the start of data collection.

The procedure for this study was as follows. A search was conducted on the International Prospective Register of Systematic Reviews (PROSPERO) database to identify similar reviews. No records of studies evaluating the use of the Parents Evaluation of Developmental Status (PEDS), PEDS:DM or PEDS tools were identified. The study was then registered with PROSPERO in order to promote transparency, reduce bias, and avoid study duplication (Moher et al., 2015). Five electronic databases, MEDLINE, Scopus, PsycINFO, PubMed and Science Direct, were searched for publications meeting the eligibility criteria. All the researchers reached consensus regarding the eligibility criteria as well as the search phrases prior to conducting the database searches. DistillerSR (Evidence Partners) is the web-based software that was used to manage the scoping review data, as automated management of data helps reduce data entry errors (Moher et al., 2015). This software was used to import the initial selection of articles and to remove duplications. The titles and abstracts of articles were screened, after which full texts were reviewed using an eligibility form created from the inclusion criteria. To supplement electronic searches, reference lists of included studies were reviewed. A data extraction form was developed from the DistillerSR template and used to record data items from the final selection.

2.2.4. Data analysis

The use of the PEDS, PEDS:DM and PEDS Tools in the included studies to identify signs of developmental delays was reviewed by the researcher. Data items were examined to identify studies matched for age gender, as well as context. Due to the heterogeneity of the sample, meta-analysis was not conducted as it may result in non-meaningful summary of results (Haidich, 2010). Narrative synthesis was used. The use of narrative synthesis allows for including different forms of evidence within a review (Rodgers et al., 2009). The Newcastle-Ottawa Scale (NOS) (Wells et al., 2010) was used to evaluate possible risk of bias. Determining risk of bias is not always straightforward and requires judgement on behalf of the reviewer (Lundh & Gøtzsche, 2008). In this case, a score of 1-3 was considered to be high risk of bias, while scores of 7 and higher were considered to be low risk by the reviewer. A second rater, who was a fellow SLP, subsequently rated the articles independently of the first rater, the researcher, which increased the integrity of the process.

2.3. STUDY III: DETECTING DEVELOPMENTAL DELAYS IN INFANTS FROM A LOW-INCOME SOUTH AFRICAN COMMUNITY: COMPARING THE BSID-III AND PEDS TOOLS

2.3.1. Research objective

To compare the BSID-III and PEDS tools in an at-risk infant population from a low-income South African community.

2.3.2. Study design

A cross-sectional, within-subject, comparative research design was used to compare the outcomes of the BSID-III and PEDS tools. This study design was chosen in order to compare the outcomes of the PEDS tools against a golden standard. Cross-sectional studies are often the chosen method for validation studies, and is thus the ideal study design for the comparison of one tool with a golden standard (Kesmodel, 2018.)

2.3.3. Study context

Stanza Bopape Clinic in Mamelodi, a PHC, was utilized for data collection.

2.3.4. Research participants

Participants were recruited by means of convenience sampling. The research project included two groups of participants, one group consisting of infants/toddlers aged 0-18 months and their parents/caregivers and the other of infants/toddlers aged 19-42 months and their parents/caregivers. Parents and caregivers needed to be proficient in Afrikaans or English. There were 353 participant dyads in total, with approximately 175 participant dyads per group.

2.3.5. Research materials

The smartphone application version of the PEDS tools (a combination of the PEDS and the PEDS DM) poses 10 open-ended questions to parents/caregivers to identify their concerns. Questions address infants' and toddlers' development in global/cognitive, behaviour, receptive language, expressive language and articulation, fine motor, gross motor, social-emotional and self-help skills. The PEDS tools

smartphone application provides automated scoring, and thus eliminates the need for manual scoring. The PEDS scores were interpreted into five different paths according to the PEDS tools score guide and algorithm. The PEDS tools smartphone application was programmed to automatically score the data according to the scoring guide and algorithm for the PEDS and PEDS DM (Glascoe & Robertshaw, 2010).

The PEDS referral framework consists of the following:
Path A - When there are two or more predictive concerns about self-help, social, school, or receptive language skills, refer for audiological and speech-language testing. Use professional judgment to decide if referrals are also needed for services such as social work, occupational therapy, etc.
Path B - When there is one predictive concern, administer second stage developmental screen. If screen is failed refer for testing in areas of difficulty.
Path C - When there are non-predictive concerns, counsel in areas of difficulty and follow up in several weeks.
Path D - When there are communication barriers/difficulties between parent and administrator due to foreign language/limited language proficiency, use translator in second screen.
Path E - When there are no concerns, conduct developmental surveillance at next visit.

The PEDS: DM comprises six questions posed to parents regarding their infant's or toddler's developmental milestones. The questions in each of the age intervals differ and represent the following developmental domains: fine motor, receptive language, expressive language, gross motor, self-help, and social-emotional development. If an infant has one or more unmet milestone on the PEDS:DM, the outcome of the test is a fail (Glascoe & Robertshaw, 2010). The PEDS tools were interpreted with the PEDS, where Path A represented a fail irrespective of the PEDS: DM result; but with Paths B-E the PEDS: DM results determined the actual pass or fail.

The BSID-III (Bayley, 2006) norm referenced measures for assessing the development of infants and toddlers, ages 1 month to 3 years 6 months are regarded as the gold standard and best measure of developmental status in infants and toddlers

(Del Rosario et al., 2021; Kwun et al., 2015). Five developmental domains - cognitive, language, motor, socio-emotional, and adaptive behaviour - form part of the scales.

2.3.6. Procedures for data collection

Ethical clearance was obtained from the Research Ethics Committee, Faculty of Humanities, University of Pretoria (Appendix A) prior to the start of data collection. Informed consent was obtained from all participants.

During the data collection process for Study III, assessments were conducted by the researcher, a qualified SLP, and final year SLP students in a quiet room provided at the PHC clinic. Assessment procedures were conducted in a counterbalanced sequence, between traditional diagnostic and smartphone-based assessments alternatively. The BSID-III was used for traditional diagnostic assessment, and developmental screening was conducted by smartphone assessment using the Parents' Evaluation of Developmental Status (PEDS) application. Final year SLP students (registered with HPCSA), who received training to administer the PEDS Tools smartphone application and conduct the diagnostic assessment of the BSID-III, assisted with the assessments under direct supervision. The researcher and students who conducted the assessments did not communicate, have contact with each other, or have access to each other's assessment results, to ensure that no bias was present. Scores of the paper-based BSID-III were manually completed and captured, while scores of the PEDS tools were uploaded to the smartphone application server. Caregivers whose children obtained referral results according to the findings of the SLP were issued with referral letters to the relevant health care professionals for follow-up.

2.3.7. Data analysis

All quantitative data analysis was conducted using IBM SPSS Statistics for Windows, Version 23.0, except for the achieved power analysis that was conducted using G*Power v 3.1.9.4 (Faul et al., 2007). A logistic regression analysis was conducted to determine the effect of gender and age on the overall and domain-specific results. We assume a linear relationship between the predictor variables (age and gender) and the

log-odds of the event that the dependent variable is 1 = no signs of a developmental delay. This linear relationship can be written in the following mathematical form (with l is the log-odds, β_0 is the constant, β_1 is the coefficient for gender and β_2 is the coefficient for age): $l = \beta_0 + \beta_1(\text{gender}) + \beta_2(\text{age})$. In order to compute the achieved power, the level of significance (=0.05), the sample size (= 353) and the effect size is needed. For logistic regression, the odds ratio (OR) is an unstandardized effect size statistic. For Study III, Pearson Chi-Square as well as Fishers Exact tests were used to determine the significance between the results from the PEDS, PEDS: DM, PEDS tools and BSID III. A 5% significance level was used to determine statistical significance.

2.4. VALIDITY AND RELIABILITY

The BSID-III is a gold-standard observational measure of development for children from one month to 36 months. It has established content validity, and a panel of experts reviewed the tool to ensure its validity and reliability before it was used in Study I and III. It has been validated for a South African population (Ballot et al., 2012; Rademeyer and Jacklin, 2013) and found to be culturally appropriate without modifications. Thus, the BSID III has been successfully used in South Africa on a similar population group which made this choice of assessment tool a valid choice for this study (Donald et al., 2019).

The PEDS and PEDS:DM are both validated and reliable tools. The PEDS has a sensitivity of 91 – 97% and a specificity of 73 – 86% (Glascoe, 2013). It has also been found to have a test-retest (correlation coefficient) reliability of 0.87, which is high (Vameghi et al., 2015). The sensitivity of the PEDS:DM is reported to be 83% while the specificity is 84%, and reliability is high (test-retest, .98 - .99; inter-rater, .82 - .96) using Guttman's coefficient (Brothers et al., 2008). With regard to the PEDS tools in combination, it has a sensitivity to severe delays of 55.4% - 91.9% for children <42 months, and a sensitivity of 41.8% - 94.5% for severe delays in children aged 43 – 66 months (Sheldrick et al., 2020). The specificity of the PEDS tools is also reported to be desirable, with a specificity of 80.3 – 86.9% for children <42 months and 70.2% - 85.4% for children aged 43 – 66 months (Sheldrick et al., 2020). A recent study

conducted in South Africa also found that the PEDS tools also have near perfect inter-rater reliability (Cohen's Kappa) of .87 - .96 (Maleka et al., 2016).

2.5. ETHICAL CONSIDERATIONS

Ethical clearance was obtained from the following institutions:

- Department of Health: Tshwane research ethics committee (Appendix A)
- Research Ethics Committee, Faculty of Humanities, University of Pretoria (Appendix A)

The identified clinic was contacted and informed about the study, after which permission was sought from the clinic management to conduct the study there (Appendix C). Informed consent forms were distributed to parents/caregivers at the identified clinic (Appendix B). The data was then collected by the researcher and SLP students in their final year of study, who received training in the specific procedures of the research studies and on administering the BSID-III, under supervision of a qualified SLP and Audiologist (Shabnam Abdoola, M. Early Childhood Intervention, HPCSA no. STA0028657). Out of each group of four students, one student conducted the screening using the PEDS tools smartphone application, while three students administered the BSID-III. All the clinicians were blinded to the outcomes of the other test conducted on the participant, thus eliminating bias.

The research ethics guidelines in Ethics in Health Research: Principles, Structures and Processes (Department of Health, 2015) were followed. Compliance with national and international guidelines serve to reassure the public that the rights, safety, and well-being of the participants are protected (Department of Health, 2015). The guiding principles that were applied to the study are listed and discussed in Table 1.

Table 1. Ethical principles applied in participant selection, data collection, and analysis (Department of Health, 2015)

Principle	**Application to study**
Respect and dignity: *Respect for the dignity, safety and well-being of participants should be a primary concern in health research involving human participants. Language, beliefs,*	The researchers treated each participant and their caregivers with respect and dignity. There were no medical risks associated with the procedures of this study. All participants were

perceptions, culture and customs must be considered.	informed of their rights before informed consent was obtained and data collection commenced.
Relevance: *It is an ethical responsibility of researchers in South Africa to ensure that research is relevant to the individual needs of those who suffer from the diseases and developmental concerns under study as well as the broad health and development needs of the country. The findings of the research must contribute to improving the health status of South Africans.*	The researcher aimed to describe the performance of a smartphone based developmental screening application, so that such an application can contribute to valid developmental screening practices in the PHC context in South Africa.
Scientific integrity: *In addition to being valuable, research must demonstrate a sound methodology and a high probability of providing answers to the research questions posed. Knowledge of relevant literature must be reflected. Research methods and results must be open to peer review and scrutiny.*	The scientific integrity was scrutinized by the ethics committees of the University of Pretoria and the Gauteng Department of Health. A comprehensive literature review was conducted, and the researcher consulted with peers familiar with research in similar health care contexts. The studies were presented as articles, which were reviewed by local and international scholars before being accepted for publication.
Investigator competence: *The investigator should be suitably qualified to conduct the study, in terms of education, knowledge, certification and experience.*	The researcher is a South African qualified professional SLP and Audiologist, registered at the HPCSA, who has completed a master's degree in the ECI field of interest. SLP students (registered with HPCSA) in their final year of study received training in the specific procedures of the research studies before assisting with data collection.
Principal investigator responsibilities: *The principal investigator must submit an application to the appropriate ethics committee/s.* ***Ethical review:*** *All health-related research conducted in South Africa must be reviewed by a research ethics committee and should not commence until the ethics committee has granted approval.*	The researcher submitted this proposal to the Research Ethics Committees of the Faculty of Humanities of the University of Pretoria. Research only commenced after approval had been granted by the ethics committees.

Informed consent: *Written and verbal informed consent must be obtained from research participants. Participants must be informed about the risks and benefits of the research, understand such risks and benefits and be able to give consent to participation, without coercion, undue influence or inappropriate incentives.*	Written informed consent (Appendix B) was obtained from every parent/caregiver through the use of an informed consent form prior to data collection. All caregivers with infants 0-42 months visiting the clinic were approached, but prospective participants who did not understand Afrikaans or English were not included in the study.
Privacy and confidentiality: *A participant's right to privacy and confidentiality must be protected at all times.*	Data was numerically coded, ensuring participant confidentiality. No identifying information was obtained from participants. The data will be safely stored for 15 years at the University of Pretoria.
Inclusion and exclusion criteria: *The recruitment, selection, inclusion and exclusion of participants must be based on sound scientific and ethical principles. No person may be unjustly excluded on the basis of race, age, gender, disability, sexual orientation, education, religious beliefs, pregnancy, marital status, ethnic or social origin, language****.***	All potential participants at the clinic were asked to participate on the day of the visit. Informed consent was obtained from the parents/caregivers of the infants and toddlers Parents/ Caregivers needed to be proficient in Afrikaans or English. There was no form of discrimination, and no possible participant was unjustly excluded from the research.
Risk and benefits: *All risks/benefits of the study, even beyond the duration of the research, should be noted.*	There were no risks involved in participating in the research, and the only benefit was that appropriate referrals for early intervention were made where necessary.
Publication of results: *Investigator is obliged to publicize research results in a timely and competent manner.*	The research results were submitted in 3 articles for publication in peer-reviewed accredited journals.

CHAPTER 3

DEVELOPMENTAL CHARACTERISTICS OF YOUNG CHILDREN IN A LOW-INCOME SOUTH AFRICAN COMMUNITY

Title: Developmental characteristics of young children in a low-income South African community
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Abstract

Adequate early childhood development (ECD) is critical for later-life success. Developmental profiles of specific populations are required to support implementation of early intervention services. Three hundred and fifty-three caregivers of children with mean age 17.9 months were selected from a primary healthcare (PHC) clinic. Overall positive identification of signs of a developmental delay, with the Bayley Scales of Infant and Toddler Development III (BSID-III), was 51.8% (n=183). Logistic regression analysis determined the effect of age and gender on results. Prevalence of developmental delay increased with age from 33.1% for children under 12 months to 61.7% and 66.3% for children between 13- 24 months and 25- 36 months respectively. Females were 1.82 times (95% CI [1.16, 2.85]) more likely to have had no signs of a developmental delay; 2.30 times (95% in motor and 2.06 times (95%) in adaptive behaviour domains. One-third of children presented with low levels of adaptive behaviour functioning. One hundred and one (28.6%) participants across age groups displayed superior

social-emotional ability, possibly due to familial structures and relationships. One-third of children presented with poor adaptive behaviour function, attributed to cultural differences. This study contributes to information on developmental characteristics of children in South Africa.

KEYWORDS

Child Development; Early Childhood Intervention; Low and Middle Income Countries; South Africa

3.1. INTRODUCTION

Two hundred and fifty million children below five years of age in lower-middle-income countries (LMICs) are not reaching their developmental potential (Rasheed and Yousafzai, 2015; Zablotsky et al., 2017). A large proportion of young children in South Africa are negatively impacted by a range of social and economic inequalities, undermining their development (Atmore, 2012; Hsiao et al., 2017). Poverty and socio-cultural context increase young children's exposure to risk factors that affect their development (Joshua et al., 2015; Tran et al., 2017; Carter, 2018). Children residing in poverty-stricken contexts are at significantly higher risk for behaviour-, social-emotional-, physical- and cognitive problems as well as later academic difficulties (Cairney et al., 2016; Garcia et al., 2018).

Recent prevalence estimates of children not meeting developmental outcomes in LMICs are 35 percent (Miller et al., 2016) compared to 7 percent in a high-income country like the United States (Zablotsky et al., 2015). An estimate of 474 000 children in South Africa are living with severe delays and many more with mild- to moderate delays (Bridge, 2016). About 40 percent of delays affecting young children result from preventable causes (Bridge, 2016).

Accurate data on children not reaching their developmental potential are important for policy and resource allocation, as well as for tracking progress toward meeting global goals such as Sustainable Development Goals (SDGs) (Black et al., 2017). The SDGs aim to ensure that all women, children, and adolescents have an equal chance to thrive, and not simply survive

(Urke et al., 2018). National plans, in all countries, to support children to thrive must ensure that early childhood development (ECD) is prioritized to inform policy and programmatic implementation and achieve the SDG target (Bushnell et al., 2016). Global commitments to ECD are growing, as the number of countries with national ECD policies has increased, of which 45 percent are low- and middle-income countries. In 2020, 87 countries – four more than in 2019 – have established a national ECD policy or action plan. Some 117 countries, up from 105 in 2019, have government-owned multisectoral ECD programmes, which focus on promoting stimulation and nurturing care for young children (UNICEF, 2021). In South Africa, the National Integrated Policy for ECD represents government's commitment to making quality ECD services available to young children (Bridge, 2016). Despite this policy, financial and capacity constraints result in inadequate implementation of services outlined in the comprehensive policies that are in place (Desmond et al., 2019). Inequity, marginalization, and a lack of access to quality early intervention services remain a barrier (Camden et al., 2020; Joshua et al., 2015; Murphy et al., 2020; Samuels et al., 2012).

Studies on ECD in South Africa have previously investigated risks and protective factors for development (Donald et al., 2019) and developmental outcomes of children of mothers with depression (Christodoulou et al., 2019). Other studies conducted have described relationships between a child's cognition and later educational outcomes of children in rural South Africa (Cortina et al., 2019), and the cognitive and physical development of HIV-positive children (Sherr et al., 2018). These and other studies have focussed on at-risk populations with existing conditions in rural poverty-stricken areas, rather than a broader overview of developmental characteristics in LMICs (Ballot et al., 2012; Ballot et al., 2017; Wedderburn et al., 2019). General developmental outcomes of children in LMICs are thus unclear.

A description of developmental characteristics provides information on typical and atypical development, and a prevalence of developmental delay across and within specific developmental domains (Chambers et al., 2016; Gasparini et al., 2017). This information may be used to guide implementation of early intervention services (including developmental assessment, surveillance, and intervention) to support optimal child development. An outline of developmental characteristics may also serve as an indicator of function, which aids clinicians and parents in setting realistic expectations and facilitating timely interventions (Sumanasena et al., 2019). Describing developmental characteristics of those children who are most susceptible to poor developmental outcomes is necessary to focus assessment and

interventions, as well as to improve child health outcomes (Wedderburn et al., 2019). Given that children in sub-Saharan Africa are most at risk to not meet their developmental potential, and there is a dearth of published findings thereof, these findings could have important implications for public health policies (Wedderburn et al., 2019). This study's purpose was, therefore, to describe developmental characteristics of young children, under 3 years of age, from a low-income South African community using a gold-standard tool. This is necessary in order to create a developmental profile for this population to easier identify the need for early intervention services, as well as the protective factors or assets in the population.

3.2. AIM

To describe the developmental characteristics of children aged 3-36 months using the Bayley Scales of Infant and Toddler Development III (BSID-III) in a low-income community.

3.3. METHOD

A descriptive research design was utilized to describe developmental characteristics of children aged 3-36 months using the BSID-III in a low-income community.

Context

Data for this study were collected at Stanza Bopape primary healthcare (PHC) clinic in Mamelodi, Gauteng, South Africa. Mamelodi is one of the largest townships in the Tshwane Metropolitan Municipality, South Africa. More than a third of residents in Mamelodi live below the poverty line (Freedom House, 2017).

Population

A convenience sampling method was employed to select caregiver-infant dyads to participate in this study. Caregivers were invited to participate while waiting in the queue at the baby wellness clinic with their children. A total of 353 caregivers and their children aged with a mean of between 3-36months (SD=10.5), with SD representing standard deviation, were included in the study. This age range was focused on, as one month to 36 months is the targeted age

range of the BSID-III. Caregivers attending the baby wellness clinic, who were proficient in English or Afrikaans, were included in the study.

Apparatus

The BSID-III are norm-referenced measures for assessing development of children ages one month to 36 months. It is a valid and reliable tool used for clinical and research purposes (Rademeyer and Jacklin, 2013). The BSID-III consists of five scales: Cognition, Receptive Language, Expressive Language, Fine Motor and Gross Motor, which are assessed by direct observation; and the Social-Emotional and Adaptive Behaviour domains depend on parental or caregiver report.

Descriptive classifications of the BSID-III focus on capacities of a child, and define these as very superior, superior, high average, average, low average, borderline, and extremely low. Identification of delay in a developmental domain was defined, according to the BSID-III manual, as a score of 70-79 indicating a mild delay (borderline), and a score of <69 suggesting a severe delay (extremely low).

The BSID-III is a gold-standard observational measure of development for children from one month to 36 months. It has established content validity, and a panel of experts reviewed the tool to ensure its validity and reliability before it was used in this study. It has been validated for a South African population (Ballot et al., 2012; Rademeyer and Jacklin, 2013) and found to be culturally appropriate without modifications. Thus, the BSID III has been successfully used in South Africa on a similar population group which made this choice of assessment tool a valid choice for this study (Donald et al., 2019).

As the BSID-III has been normalised in developed countries, local practitioners should understand the nuances and should know if these tests and expected performance remain consistent for different ages within the local context (Laughton et al., 2010; Rademeyer and Jacklin, 2013). Previous developmental profile studies in South Africa, using the Griffiths Mental Development Scales, showed a lower developmental profile in children from low socio-economic groups when compared with expected norms (Laughton et al., 2010). Mean scores

on assessment measures were significantly higher than British norms in a study conducted in Cape Town, while overall scores were much higher on the BSID-III in South Africa when compared to a sample in the USA (Rademeyer and Jacklin, 2013). It is thus necessary to describe specific developmental characteristics in a particular patient population profile, to appropriately identify signs of developmental delay based on their expected developmental trajectory (Laughton et al., 2010).

Procedures

Ethical clearance was obtained from the Research Ethics Committee, Faculty of Humanities, University of Pretoria (reference number GW20160607HS). Informed consent was obtained from all participants. Assessments were conducted in a quiet room at the PHC clinic. The BSID-III was used for developmental assessment. Final year Speech-Language Pathology (SLP) students (registered with a professional body), who received training to conduct the BSID-III, assisted with the assessments under supervision. Quality control and monitoring processes were implemented to ensure accuracy.

Scores of the paper-based BSID-III were manually completed and captured. Caregivers whose children were identified as having delays in one or more developmental domains were issued with referral letters to the relevant health care professionals for follow-up.

Data analysis

All quantitative data analysis (descriptive and inferential statistics) was conducted using Statistic Package Social Sciences (SPSS) v 23 (Chicago, Illinois), except for the achieved power analysis that was conducted using G*Power v 3.1.9.4 (Faul et al., 2007). A logistic regression analysis was conducted to determine the effect of gender and age on the overall and domain-specific results. We assume a linear relationship between the predictor variables (age and gender) and the log-odds (also called logit) of the event that the dependent variable is 1 = no signs of a developmental delay. This linear relationship can be written in the following mathematical form (with l is the log-odds, β_0 is the constant, β_1 is the coefficient for gender and β_2 is the coefficient for age): $l = \beta_0 + \beta_1(\text{gender}) + \beta_2(\text{age})$. A 5% level of significance was used, meaning that if the p-value is less than 0.05, the predictor is statistically significant. In

order to compute the achieved power, the level of significance (=0.05), the sample size (= 353) and the effect size is needed. For logistic regression, the odds ratio (OR) is an unstandardized effect size statistic. Interpreting ORs are explained using an example. In this study, female was coded as a '1' and males as a '0'. If the OR is greater than 1, say OR = 2.00, then females were twice more likely than males to have no signs of a developmental delay. On the other hand, if the OR is less than 1, say OR = 0.80, then females are 20% (1 – 0.2 = 0.8) times less likely than males to have no signs of a developmental delay. Since the other predictor, age, is a continuous variable, an example of the OR for age is given. Say the OR for age is 4.9, then for every month older, the participant is nearly 5 times more likely to have no signs of a developmental delay. For the achieved power calculation, the level of significance (= 0.05), the sample size (= 353) and the effect size (OR) is needed. Since there are many OR values reported in the results section, we simply mention here that the achieved power exceeded 0.8 (which is the ideal) for all OR values in the power calculation together with level of significance (= 0.05) and the sample size (= 353).

3.4. RESULTS

A total of 353 children (45.0% females) between the ages 17.9 months (SD=10.5) were assessed at a PHC facility. Forty-five percent (n=158) of children were female. Home languages spoken included Sepedi (n =172; 48.7%), isiZulu (n=52; 14.7%), Ndebele (n=34; 9.6%), Setswana (n=20; 5.7%), Tsonga (n=16; 4.5%), Venda (n=12; 3.4%), Shona (n=12; 3.4%), SiSwati (n=11; 3.1%), Southern Sotho (n=7; 2.0%), Xhosa (n=6; 1.7%), English (n=5; 1.4%), Shangaan (n=3; 0.8%), Northern Sotho (n=1; 0.3%) and Portuguese (n=1; 0.3%).

The overall rate of children with signs of a developmental delay was 51.8% (n=183) (Table 3.1). Developmental delays identified across 12-month age groups varied between 33.1% and 66.3% (Table 3.1), with more children showing signs of developmental delay between 13 to 24 months (61.7%) and 25 to 36 months of age older (66.3%) compared to children younger than 12 months (33.1%).

TABLE 3.1 Outcome of Bayley Scales of Infant Toddler Development III (BSID-III) at various age categories

	Age categories			
	1 to 12 months (n=136)	**13 to 24 months (n=128)**	**25 to 36 months (n=89)**	**Total (n=353)**
Identification of a delay	33.1% (45/136)	61.7% (79/128)	66.3% (59/89)	51.8% (183/353)
No delay	66.9% (91/136)	38.3% (49/128)	33.7% (30/89)	48.2% (170/353)

Domain-specific outcomes (cognitive, language, motor, social-emotional and adaptive behaviour) were positive for developmental delays across domains varying between 8% for social-emotional and 58% for adaptive behaviour (Figure 3.1). A logistic regression analysis was conducted to determine the effect of gender and age on the overall and domain-specific results. Females were 1.8 times more likely to not show signs of a developmental delay compared to males (β_1 = 0.60, OR = 1.82, 95% CI [1.16, 2.85]) overall. Gender was not significantly associated with a developmental delay in the cognitive, language and social-emotional domains. However, females were 2.30 times more likely than males to have no signs of a developmental delay in the motor domain (β_1 = 0.83, OR = 2.30, 95% CI [1.14, 4.65]), and 2.06 times in the adaptive behaviour domain (β_1= 0.72, OR = 2.06, 95% CI [1.23, 3.45]). Increasing age was associated with an increased likelihood of an overall developmental delay. Every month that a participant was older, they were 6.1% less likely to have no signs of developmental delay overall (β_2 = -0.06, OR = 0.94, 95% CI [0.92, 0.96]). Age was not a significant predictor of developmental delay in cognitive, motor and social-emotional domains. Participants were also 4.7% less likely to not show signs of delay in the language domain (β_2 = -0.05, OR = 0.95, 95% CI [0.93, 0.98]) and 9.9% less likely to have no signs of delay in the adaptive behaviour domain as they get older (per month) (β_2 = -0.10, OR = 0.90, 95% CI [0.88, 0.93]).

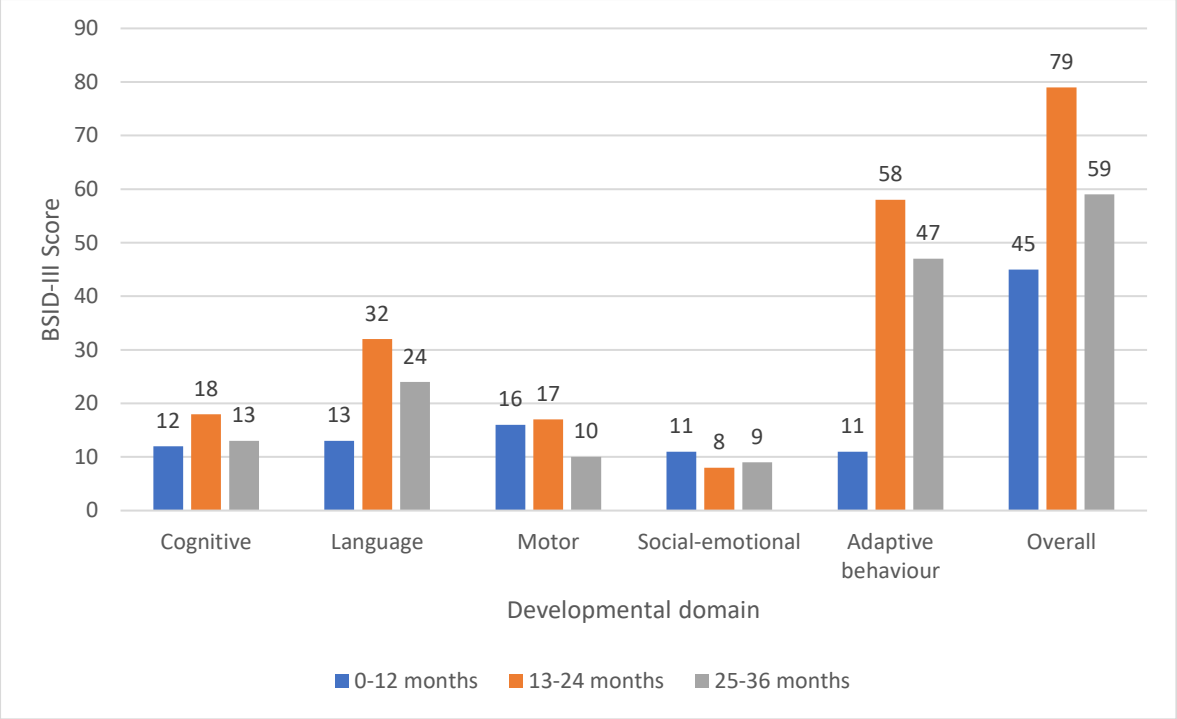

FIGURE 3.1 Overall and developmental domain-specific positive diagnoses on the Bayley Scales of Infant Toddler Development III (BSID III) (n=183)

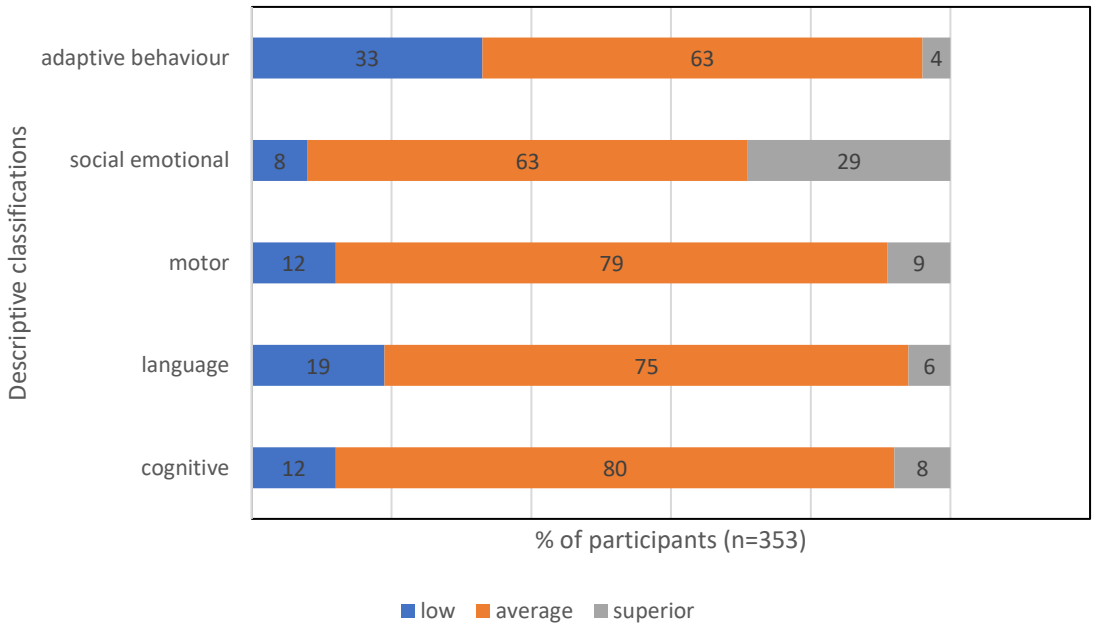

FIGURE 3.2 Descriptive classifications of development on the Bayley Scales of Infant Toddler Development III (BSID-III) (n=353) *Borderline or extremely low classifications grouped as low and indicate a developmental delay; Classifications that refer to average skills development were combined into one group (average) and those that refer to superior skills were grouped as superior*

Ages 13 to 24 months and ages 25< months have significantly more occurrences of no signs of developmental delay than age group 1 to 12 months. The oldest children in this study have the highest number of overall signs of delay (27.0%). Twenty-eight (7.9%) participants across all age groups had delays in the social-emotional domain, and 101 (28.6%) displayed superior ability in this domain. In the adaptive behaviour domain, ages 13 to 24 months and 25< months do not differ significantly from each other, with those with delays over 45%; whereas, ages 1 to 12 months differed statistically from them with identified delays of 8.1%.

3.5. DISCUSSION

This study's aim was achieved by describing the developmental characteristics of the study's population using the BSID-III. More than half (n=183; 51.8%) of young children (1-36 months) in this study were at risk of long-term developmental difficulties that warrant early intervention (Ballot et al., 2012). Positive overall identification of delays in developmental domains in the current study were greatest in children aged 25-30 months (n=280; 79.3%) as opposed to younger children. This may be attributed to the fact that it is difficult to identify developmental delays in infants (Fischer et al., 2014). There was a higher incidence of delays in older children compared to younger children (Table 3.1) with significant differences between the age groups. A similar trend was identified by Ballot et al., (2017), where the BSID-III was used to evaluate developmental outcomes of a group of very low birth weight infants (VLBWIs) in Southern Africa, and language scores decreased with age (i.e. identification of delays increased). Gender had a significant effect in this study, with males twice as likely to have delays in motor and adaptive behaviour domains than females. This is in agreement with a multi-country study where a similar trend was reported (Weber et al., 2017).

Almost twice the number of participants in the two older age groups were identified as having a delay in adaptive behaviour skills in relation to other domains (Figure 3.1). Although the BSID-III has been validated for the South African population and has been reported as culturally valid (Ballot et al., 2012; Rademeyer and Jacklin, 2013), this study found that cultural differences may have impacted children's performance on the tool. The elevated identification of delays in children aged 13-24 months and in children 25< months in the adaptive behaviour domain were likely attributed to cultural differences. Children's behaviour is often linked to caregiver expectations, as well as what is viewed as useful or of important influence in the

child's and family's life. Cultural rearing practices also play an important role in adaptive behaviour of children (Snelling et al., 2019). This sub-section of the BSID-III includes test items that are completed by parents and caregivers with relation to a child's abilities with regards to skills such as self-care, self-direction and health and safety. It is important to note that not only the rate of development, but also the activities with which the child is familiar must be taken into account; and both these may be influenced by context (Holding et al., 2008). Children from various cultural groups may not be expected to master certain skills, as they are not culturally valid or acceptable (Semrud-Clikeman et al., 2017). Furthermore, children may not need to develop certain behaviours in their specific contexts (Balton, 2019). For example, in many LMIC settings in southern Africa, children do not have stairs in their homes; therefore, items that assess motor development or adaptive behaviour based on the climbing of stairs may be inappropriate. Another study, which explored the use of the Parents' Evaluation of Developmental Status (PEDS) tools, also found that children in the low-income context of South Africa have higher referral rates with regards to adaptive behaviour (du Toit et al., 2020).

Many children in this study and more than 50% of children in a study by Ballot et al. (2017) presented with average skills in all domains. Almost a third of children in this study, however, presented with superior social-emotional skills. Similarly, higher scores in the social-emotional compared to other domains were found in a study conducted in Greece, which is classified as a high-income country (Velikos et al., 2015). In addition to social-emotional ability being derived from the parent-report questionnaires in the BSID-III, the superior social-emotional ability could be linked to strong familial relationships and extended family structures, a characteristic of many South African, especially black African families (Barbarin and Richter, 2013; Huang et al., 2017; Mampane et al., 2019; Singh et al., 2014). Extended families provide social-emotional support for one in three children, or 30%, of children in South Africa (Patel et al., 2017). Previous studies have demonstrated that increased interactions result in improved outcomes (Nuri et al., 2019; Rasheed and Yousafzai, 2015; Romeo et al., 2018).

3.6. STUDY LIMITATIONS

The current sample does not represent the spectrum of diversity across LMICs but is representative of a low-income community within South Africa; so, results cannot be generalised to all children across other socioeconomic, linguistic, and cultural groups. Although the BSID-III is valid for use in the black urban African population, further research

on the BSID-III is needed to assess a larger, more diverse group, including all age groups for which the BSID-III caters (Rademeyer and Jacklin, 2013).

Another limitation of this study is that the BSID-III has not yet been culturally adapted for the South African population. The BSID-III presented with elevated referral rates in this study. This may be attributed to a number of reasons, including the high-risk nature of the population and the young age group. Inaccuracies in parental reporting, most often used with young infants, may have contributed to the under- or over-referral results on the developmental screening measures, resulting in poorer performance than expected when compared to older children. Data for this study were also collected manually, which therefore increases the risk of data being inputted incorrectly. Additionally, while the assessors were trained to use the BSID-III, this study was limited in that no other clinical data was available to substantiate a diagnosis.

3.7. IMPLICATIONS FOR PRACTICE

This study's findings suggest that the BSID-III may be a suitable tool to describe the developmental profile of South African children, which supports previous research (Rademeyer and Jacklin, 2013). The tool has previously been evaluated in studies mostly on HIV-exposed infants and other infants at risk of developmental delay e.g. infants with low birth weight (Springer et al., 2019). Studies have mostly focused on at-risk populations in rural poverty-stricken areas (Wedderburn et al., 2019). As children in sub-Saharan Africa are most at risk of not reaching their developmental potential; understanding their development is important, and further research with a range of cultural and linguistic groups in South Africa is needed.

Clinically, understanding the developmental profile of these children will contribute to guidelines for best practice, especially regarding tailoring developmental assessment to fit the needs of this population. It is clear that the children in this study performed well in the social-emotional domain – however, a concern arose regarding adaptive behaviour functioning. This implies that more cultural consideration is needed in the assessment of adaptive behaviour, even with the use of a gold-standard tool such as the BSID-III. These studies are needed to ascertain the exact nature of expected developmental characteristics, as well as any expected developmental delay with appropriate assessment and intervention measures, across communities and population groups that are greatly influenced by cultural beliefs and practices.

3.8. CONCLUSION

This study contributes to emerging research on the understanding of developmental profiles in young children in LMICs like South Africa. Almost one-third of children in this vulnerable population presented with superior social-emotional skills, possibly due to familial structures and relationships related to the study population. One-third of children evaluated from this low-income South African context presented with low levels of functioning in the adaptive behaviour domain, possibly attributed to various factors including cultural differences. Understanding the course of healthy development and the effect of a child's settings, customs, and ethno-theories and how they interact is essential for understanding development (Marlow et al., 2019), and this study contributes to that understanding. Furthermore, this study contributes to the adjustment of guidelines regarding the identification of developmental delays in South African children, as it provides an understanding of their developmental profiles. The developmental assessment of these children may be tailored to this developmental profile to suit these children's needs. Further studies on developmental characteristics of children across LMICs are required, to tailor developmental resources and programmes and to inform intervention approaches making sustainable contributions to service delivery that are both family-centred and community-based.

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CHAPTER 4

A SCOPING REVIEW ON THE USE OF THE PARENTS EVALUATION OF DEVELOPMENTAL STATUS (PEDS) AND PEDS: DEVELOPMENTAL MILESTONES SCREENING TOOLS

Title: A scoping review on the use of the Parents Evaluation of Developmental Status (PEDS) and PEDS: Developmental Milestones screening tools

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A scoping review on the use of the Parents Evaluation of Developmental Status (PEDS) and PEDS: Developmental Milestones screening tools

Abstract

The Parents' Evaluation of Developmental Status (PEDS), PEDS: Developmental Milestones (PEDS:DM) and PEDS tools (i.e. the PEDS and PEDS:DM combined for use) are parent-reported screening tools frequently used to identify young children requiring early intervention. An ideal

screening tool for all contexts would be brief, inexpensive with appropriate test items and good psychometric properties. A scoping review was conducted to review studies that used the PEDS, PEDS:DM and PEDS tools to screen for the need for further referrals and evaluation through parent report. Thirty articles, ranging from 2003-2020, conducted in high-income countries (HIC) and lower-middle income countries (LMIC), were included from the 1468 records identified. Studies conducted in HICs (n=19) included screening of special population groups and comparing validated tools. LMIC studies (n=11) focused on translations, combination of the PEDS tools, validations of tools and use of an app-based tool (mHealth). High referral rates were obtained with PEDS (23%-41%) and PEDS:DM (12%-54%) in LMICs where at-risk populations are more prevalent and cultural differences may affect tool validity. A global dearth of research on PEDS:DM and PEDS tools exist; the review highlights factors that influence the validity and impact widespread use of the screening measures, especially in diverse populations and LMICs.

Keywords: Child development; assessment; Teaming and Collaboration with Others

4.1. Introduction

The importance of developmental screening and surveillance, typically used for early identification and monitoring from infancy to the preschool period, is universally accepted (Richter et al., 2019; Woolfenden et al., 2016). Early identification of delays is strongly linked to later academic success (Kiing et al., 2019). Screening tools are typically aimed toward parents, who are necessary partners in assessment and intervention of their children (Bindlish et al., 2018). Many developmental screening programs are currently built on basic health services, where there is ongoing contact with families, parents and children (Valla et al., 2019). Parents are an important source of information regarding their children's development and behaviour, and may provide

information that could otherwise not be observed in a clinical setting (Miller et al., 2017). Focusing on parents' concerns makes health visits more relevant, fosters collaboration, facilitates early detection, and encourages parents to adhere to professionals' recommendations (Glascoe, 2013; Glascoe & Marks, 2011). Although accuracy of parent report and their ability to evaluate child development have been questioned in the past (Stokes et al., 2011) screening for developmental delay with parent-completed tools rather than clinician-administered tools is often recommended (Mackrides & Ryherd, 2011; Ozonoff et al., 2011). Parent report measures can be completed by any caregiver of the child – and, in some cases, even the child's teacher. Teachers also have extended contact with the child in the first few years of life, and can thus be included in the screening process (Kiing et al., 2019). Parent report measures are increasingly preferred as they are quick, easy to use, and cost effective relative to formal, clinician-administered direct evaluation (Miller et al., 2017; Schafer et al., 2014).

Two of the most widely used and validated parent-completed tools are the Parents' Evaluation of Developmental Status (Glascoe, 2003) and the Ages and Stages Questionnaire (Squires et al., 1997; Mackrides & Ryherd, 2011; Sheldrick et al., 2020). The Parents' Evaluation of Developmental Status (PEDS) has demonstrated high sensitivity to severe delays when compared to other tools including the widely used Ages and Stages Questionnaire, Third Edition (ASQ-3), and the Survey of Wellbeing of Young Children (SWYC): Milestones (Sheldrick & Perrin, 2013; Sheldrick et al., 2020). The PEDS has also shown promise when investigated in different socio-economic contexts, ranging from high-income countries (Sheldrick et al., 2020) to LMICs including South Africa (Maleka et al., 2019; van der Merwe et al., 2019), Serbia (Ilić et al., 2019), and countries in Asia such as Bhutan (Wong et al., 2019) and Iran (Shahshahani et al., 2017; Vameghi et al., 2015). It is essential to prioritize healthcare in LMICs where resources and access to healthcare can be limited. Even though LMICs such as South Africa have varying contexts within the country, ranging from

higher income communities to lower income, it is still vital to understand how tools such as the PEDS are designed for specific populations within those contexts. In the case of the PEDS, it was created for use in a higher-income context, and the population of a lower-income context may thus require the tool to be adjusted or adapted across language and/or culture accordingly (Fyvie et al., 2016; Maleka et al., 2016, 2019; Vameghi et al., 2015; van der Merwe et al., 2019). Available resources also differ across economic contexts and countries. Understanding the feasibility of a tool as it applies to all contexts within a country serves to improve healthcare accessibility. In order to inform national or systemic changes within a healthcare system, it is important to know what is applicable to all communities and contexts within a greater region (Agampodi et al., 2015).

The PEDS is an evidence-based developmental screening tool that elicits and identifies parents' concerns about children's motor, language, self-help, early academic skills, behaviour and social-emotional development. The inclusion of all aspects of child development and the fact that the PEDS is a parent-completed tool may make it suitable to be used as a population outcome measure, especially in low resource settings (Limbos & Joyce, 2011; Maleka et al., 2019). The PEDS is reported to have a sensitivity of 91 – 97% and a specificity of 73 – 86% (Glascoe, 2013). In HICs, the PEDS has moderate sensitivity (74%) but low specificity (64%) when compared to the ASQ (78%) (Limbos & Joyce, 2011), but the PEDS is also reported to have higher sensitivity (78%) to mild delays among older children (43-66 months) (Sheldrick et al., 2020). In LMICs such as Iran, the PEDS is reported to have appropriate content validity (Shahshahani et al., 2017; Vameghi et al., 2015). With adequate sensitivity and specificity, the PEDS adheres to standards for developmental screening tests; and is also reliable when used by a range of professionals and individuals including community health workers (Fischer et al., 2014; Glascoe, 2013; van der Merwe et al., 2019) and teachers (Kiing et al., 2019). The PEDS is often preferred for use in developmental screening, especially in the context of child care visits as the PEDS do not require additional equipment and is

quick to administer (Shahshahani et al., 2017). The PEDS has been utilized in disadvantaged and vulnerable populations, as well as in high, middle and low income countries, and has been translated in over fifty languages (Glascoe, 2013; Woolfenden et al., 2016). In addition to the PEDS, the Parents' Evaluation of Developmental Status: Developmental Milestones (PEDS:DM) was developed and released in 2003 (Glascoe, 2003). The PEDS:DM is a tool bridging screening and diagnosis; and while it is considered to be more comprehensive than screening tools, only provides provisional diagnoses (Chunsuwan et al., 2016). While the PEDS helps to elicit and address parents' concerns using open-ended questions that elicit general concerns, the PEDS:DM provides information on the child's progress and facilitates skilled monitoring of development. The questions are more focused on specific developmental milestones, and questions differ according to the child's age. The PEDS:DM is a milestones-based checklist measure consisting of 6-8 questions, depending on the age-range which is birth to 8 years, with additional academic measures available for older children and adolescents (Glascoe, 2013). Each item taps a different developmental domain: expressive language, receptive language, fine motor, gross motor, social-emotional and self-help. With a clear scoring criteria and high sensitivity and specificity, the PEDS:DM provides accurate and reliable indicators of children's skills across domains in America (Glascoe, 2013). The PEDS:DM, also showed a moderate sensitivity for identifying signs of delays, in children from the USA and Bhutan (Soucy et al., 2012; Wong et al., 2019). The PEDS:DM is a fast test that highlights developmental milestones to parents, who can complete the PEDS:DM by reporting on or observing the behaviour elicited in their child (Chunsuwan et al., 2016; Glascoe, 2013). The PEDS:DM facilitates progress monitoring and is especially useful for clinicians who are using the PEDS and require more specific information on children's skill levels and function (Brothers et al., 2008).

Table 4.1

Example questions from the PEDS, PEDS:DM and PEDS Tools combined

	PEDS Tools Questions
PEDS Response Form Questions	**1. Do you have any concerns about how your child talks and makes speech sounds?** Select one: No ○Yes ○ A little Comments:
	2. Do you have any concerns about how your child understands what you say? Select one: No ○Yes ○ A little Comments:
	3. Do you have any concerns about how your child uses his or her hands and fingers to do things? Select one: No ○Yes ○ A little Comments:
PEDS: DM Response Form Questions	1. Can your baby poke at things with just his or her first finger? ○No ○A little ○ Yes
	2. When you say your baby's name, does he or she stop and look at you? ○No ○Sometimes ○ Most of the time
	3. How many different sounds such as "muh", "bah", "duh" or "guh" does your baby say? ○None ○1 ○ 2 or more

As illustrated by Table 1, the PEDS elicits parent concerns by posing questions probing whether they have any concerns regarding their child's development. The parent can choose between three answers: yes, no, or a little. This is followed by a 'comments' section which allows the parent to elaborate on their concerns. Conversely, the PEDS:DM is used to screen for specific developmental milestones; the example questions in Table 1 screen fine motor skills, receptive language skills, and expressive language skills respectively. The use of the PEDS and PEDS:DM combined, also known as the PEDS tools, makes use of both forms of question from the two tools, allowing for a holistic view of the child's development by gathering information on what the parent is concerned about as well as specific developmental milestones their child may or may not have reached.

The PEDS is scored according to the five PEDS-paths referral algorithms. This is a table of norms according to age distribution divided into five paths: paths A – E. Path A results in further referral due to two or more predictive concerns being present, without the need for further screening. Paths B, C, D and E recommend the use of the PEDS:DM to screen further. Thereafter, if one or more milestone on the PEDS:DM is not met, the child is referred for further evaluation. This combined approach is per the authors' guidelines (Brothers et al., 2008).

There is value in using PEDS and PEDS:DM together, as one elicits and identifies parents' concerns while the other provides information on children's actual development (Glascoe, 2013). The combination facilitates skilled monitoring of development by parents, as they are informed on what to expect from their child. Once parental concerns are identified by the PEDS, they are clarified by the PEDS:DM; and with this approach, recommendations for screening and surveillance are being fulfilled (Glascoe, 2013). A number of studies have been using the tools in combination for the following reasons: to bridge the gap between screening and diagnosis by examining domain-specific

results of the PEDS:DM to supplement the PEDS (Chunsuwan et al., 2016); to explore mobile health (mHealth) as a feasible method of developmental monitoring in LMICs (Maleka et al., 2019); to investigate whether community health workers can conduct accurate developmental screening using the PEDS tools (Maleka et al., 2016; van der Merwe et al., 2019); and to compare the performance of the PEDS tools to the Bayley Scales of Infant and Toddler Development III (BSID-III) (Abdoola et al., 2019). Combining the PEDS and the PEDS:DM elicits and identifies parents' concerns, while monitoring milestones, and screening with validated tools periodically (i.e. surveillance). Parental frustration may be decreased with the opportunity to express their concerns, with adaptive parenting encouraged for children to reach milestones appropriately. In the case of the need for further referrals and evaluation being identified when conducting the PEDS:DM, the PEDS facilitates delivering this news via affirmation of existing parental concerns. The combined use of the PEDS and PEDS:DM reportedly enhances the accuracy of responses to parental concerns and guides the responses in terms of either support or further referral (Glascoe, 2013).. The purpose of these screening tools is to identify the need for further referrals and evaluation. That is why to reduce unnecessary referrals, as well as to prioritise referrals for further evaluation, second-stage evaluation - or a tiered approach - has been recommended (Chunsuwan et al., 2016). A tiered approach may be beneficial within contexts such as LMICs where there is a high prevalence of developmental delays or disorders, even though this may take long. Selecting the most effective screening tools, and complementing parent-reported concerns with domain specific results, may reduce high referral rates and prioritize the referrals that are most at-risk (Maleka et al., 2019).

An effective screening tool for both HIC as well as LMIC would be a brief, inexpensive tool with developmentally appropriate test items and good psychometric properties (Goldfeld & Yousafzai, 2018). However, it is highly unlikely to find a one size fits all approach that can be applied to all populations across HIC and LMIC. For a tool to be fit-for-purpose at an individual

level, it should be available in local languages where it is used, validated on children of the specific population, and require minimal training (Marlow et al., 2019). As the PEDS, PEDS:DM and PEDS tools have the potential to ascribe to these characteristics, they would be considered appropriate for use in various contexts. There is evidence on the use of the PEDS with other developmental screening tools (Fischer et al., 2014; Macy, 2012), but not on the PEDS:DM or the combination of the two measures. Thus, to better understand the use of these tools in isolation and in combination, as well as in different contexts, a scoping review of the studies using the three potential options for screening with PEDS tools (PEDS, PEDS:DM, and PEDS tools) globally was conducted. A scoping review is a method of synthesising knowledge, to comprehensively summarise evidence with the aim of providing direction for future reference as well as to inform practice, programs and policy (Colquhoun et al., 2014). The purpose of this scoping review is to clarify concepts, address gaps in literature and make the information more accessible to healthcare professionals and other stakeholders who may need to use one or more of these tools in various contexts.

4.2. Method

Aim

This scoping review describes the global usage of the three screening options with the PEDS tools (PEDS, PEDS:DM, and PEDS tools) to screen for parental concerns and for further need of evaluation of developmental delays.

Eligibility criteria

Peer reviewed journal publications were selected for inclusion to obtain high quality, reliable data. English publications were selected for ease of interpretation by the researcher and no limit was

placed on the date of publication or study setting. The age range of the study population was limited to birth to eight years, as this is the age range covered by the PEDS, PEDS:DM and PEDS tools. This review considered any study that used one or more of the three options for screening with the PEDS tools in its investigation.

Material

The PEDS and PEDS:DM are both validated and reliable tools. The PEDS has a sensitivity of 91 – 97% and a specificity of 73 – 86% (Glascoe, 2013). It has also been found to have a test-retest (correlation coefficient) reliability of 0.87, which is high (Vameghi et al., 2015). The sensitivity of the PEDS:DM is reported to be 83% while the specificity is 84%, and reliability is reported to be high (test-retest, .98 - .99; inter-rater, .82 - .96) using Guttman's coefficient (Brothers et al., 2008). A recent study conducted in the HIC of the United States with a primary aim of comparing the PEDS, ASQ-3 and the SWYC, and a secondary aim of exploring the accuracy of the PEDS:DM and PEDS Tools in combination, found that these tools have reliable validity and reliability (Sheldrick et al., 2020). With regards to the PEDS tools in combination, it has a sensitivity to severe delays of 55.4% - 91.9% for children <42 months, and a sensitivity of 41.8% - 94.5% for severe delays in children aged 43 – 66 months (Sheldrick et al., 2020). The specificity of the PEDS tools is also reported to be desirable, with a specificity of 80.3 – 86.9% for children <42 months and 70.2% - 85.4% for children aged 43 – 66 months (Sheldrick et al., 2020). A recent study conducted in South Africa also found that the PEDS tools also have near perfect inter-rater reliability (Cohen's Kappa) of .87 - .96 (Maleka et al., 2016). Table 2 summarises the current available information on the psychometric properties of these three tools.

Table 4.2

Validity and reliability of the PEDS, PEDS:DM and PEDS tools

Tool	Study	Validity		Reliability	
		Sensitivity	**Specificity**	**Test-retest**	**Inter-rater**
PEDS	Glascoe, 2013	91 – 97%	73 – 86%		
	Vameghi et al., 2015			Correlation coefficient: .87	
	Sheldrick et al., 2020	Severe delays (0 – 42 months): 41.8% - 94.5% Moderate-to-severe delays (0 – 42 months): 48.8% – 69.8%Severe delays (43 – 66 months): 41.8% - 94.5% Moderate-to-severe delays (43 – 66 months): 17.1% - 70.8%	0-42 months: 75.7% - 83.1% 43 – 66 months: 64.3% - 81.3%		
PEDS:DM	Brothers et al., 2008	83%	84%	Guttman's coefficient: .98 - .99	Guttman's coefficient: .82 - .96

	Sheldrick et al., 2020	Severe delays (0 – 42 months): 49.6% - 71% Moderate-to-severe delays (0 – 42 months): 73.4% - 92.6% Severe delays (43 – 66 months): 78.3% - 93.1% Moderate-to-severe delays (43 – 66 months): 77.1% - 92.7%	0 – 42 months: 30.2% – 56.2% 43 – 66 months: 6.7% - 23.9%		
PEDS Tools	Sheldrick et al., 2020	Severe delays (0 – 42 months): 55.4% - 91.9% Moderate-to-severe delays (0 – 42 months): 44% - 65.3% Severe delays (43 – 66 months): 41.8% – 94.5% Moderate-to-severe delays (43 – 66 months): 17.1% – 70.8%	0 – 42 months: 80.3 – 86.9% 43 – 66 months: 70.2% - 85.4%		

	Maleka et al., 2016				Cohen's Kappa: .87 - .96

Information sources and search strategy

A search was conducted on the International Prospective Register of Systematic Reviews (PROSPERO) database to identify similar reviews. No records of studies evaluating the use of the Parents Evaluation of Developmental Status (PEDS), PEDS:DM or PEDS tools were identified. The current study was then registered with PROSPERO in order to promote transparency, reduce bias and avoid study duplication (Moher et al., 2015).

Five electronic databases, MEDLINE, Scopus, PsycINFO, PubMed and Science Direct, were searched for publications meeting the eligibility criteria. Searches were conducted in from the 13th to the 16th of July, using the following search phrases:

- "Parents evaluation of developmental status" AND "developmental delays"
- "Parents evaluation of developmental status" AND "developmental disorders"
- "PEDS" AND "developmental delays"
- "PEDS" AND "developmental disorders"
- "PEDS:DM" AND "developmental delays"
- "PEDS:DM" AND "developmental disorders"
- "PEDS tools" AND "developmental delays"

- "PEDS tools" AND "developmental disorders"

The use of the phrase "PEDS tools" was to identify articles wherein both the PEDS and PEDS:DM were used in combination.

Study selection and data management

All the researchers reached consensus regarding the eligibility criteria as well as the search phrases prior to conducting the database searches. DistillerSR (Evidence Partners) is the web-based software that was used to was used to manage the scoping review data, as automated management of data helps reduce data entry errors (Moher et al., 2015). This software was used to import the initial selection of articles and to remove duplications. The titles and abstracts of articles were screened, after which full texts were reviewed using an eligibility form created from the inclusion criteria. To supplement electronic searches, reference lists of included studies were reviewed. A data extraction form was developed from the DistillerSR template and used to record data items from the final selection.

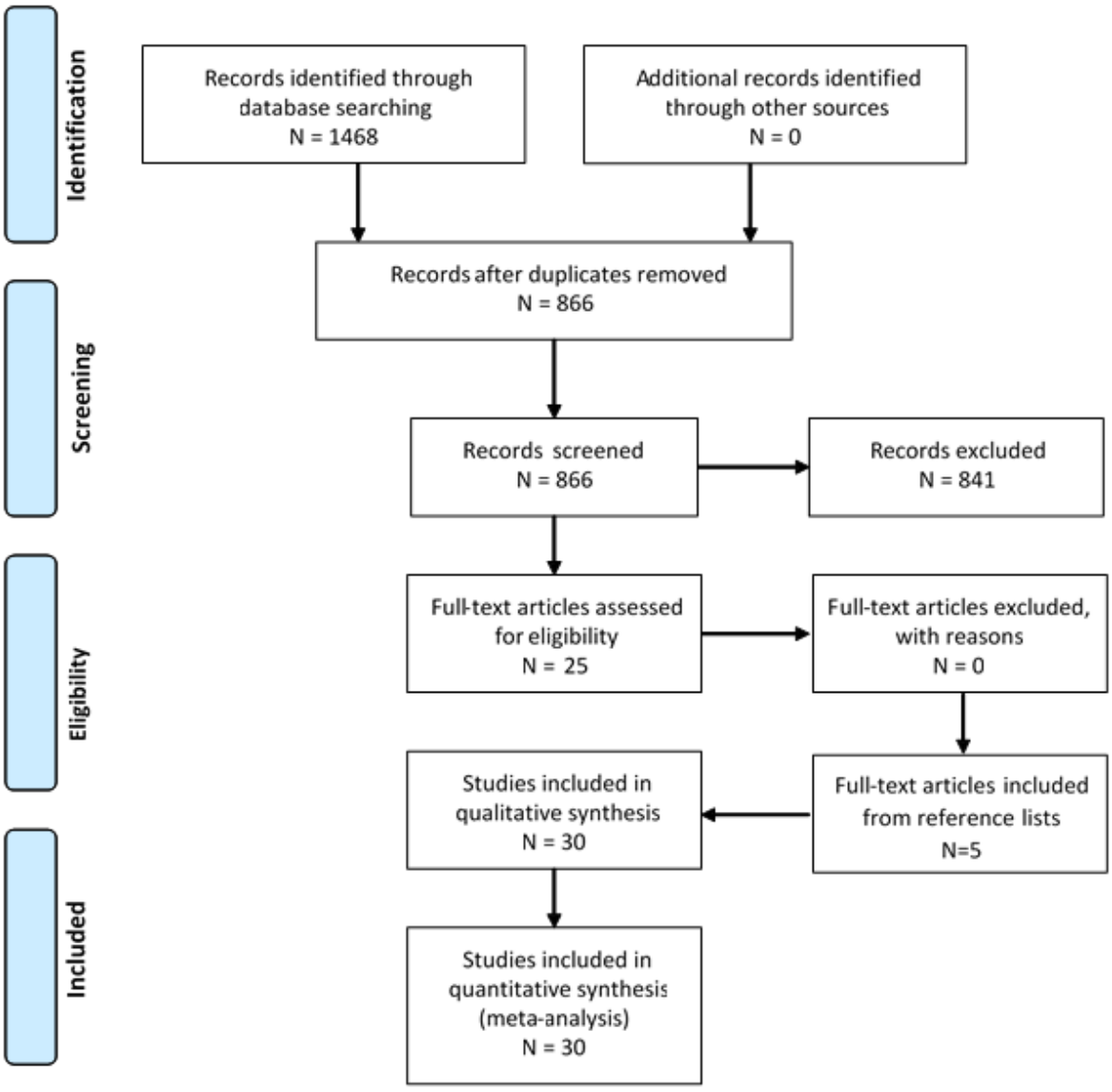

Figure 4.1: Search strategy used to identify articles for inclusion in scoping review

Data collection process and data items

The data items were selected according to the study objective and were evaluated for inclusion in the study. Data were extracted from all the eligible studies.

Data synthesis

The use of the PEDS, PEDS:DM and PEDS Tools to identify signs of developmental delays in the included studies were reviewed by the researcher. Data items were examined to identify studies matched for age gender, as well as context. Due to the heterogeneity of the sample, meta-analysis was not conducted as it may result in non-meaningful summary of results (Haidich, 2010). Narrative synthesis, the use of a narrative versus statistical summary of the results, was used. The use of narrative synthesis allows for including different forms of evidence within a review (Rodgers et al., 2009).

Meta-biases and robustness of the synthesis

To minimize publication bias, which refers to the likelihood of a study being published based on the findings of the study; all searches were conducted on five electronic databases, with no limit on setting or publication date (Song et al., 2012). Both significant and non-significant findings were reported in the studies and are included in the review. The overall risk for publication bias was thus minimal.

Risk of bias in individual studies

The Newcastle-Ottawa Scale (NOS) (Wells et al. , 2010) was used to evaluate possible risk of bias. Determining risk of bias is not always straightforward and requires judgement on behalf of the reviewer (Lundh & Gøtzsche, 2008). In this case, a score of 1-3 was considered to be high risk of bias, while scores of 7 and higher were considered to be low risk by the reviewer. A second rater, who was a fellow speech-language therapist, subsequently rated the articles independent of the first rater, the researcher, which increases the integrity of the process.

4.3. Results

Publication date ranged across 2003 to 2020 and the studies originated from both HIC and LMIC (Appendix A), including the USA, Canada, countries in Europe, Australia, countries in Asia and South Africa (Table 3). The sample was from various countries, with 1 in 3 studies conducted in HICs. In Table 3 the characteristics of the included studies are presented. The sample sizes in studies varied greatly, from 26 (Coghlan et al., 2003) to 91642 (Simon et al., 2013). Twenty-two (73%) were cross-sectional studies, only one of which had a control group. Two studies were mixed method in design, while 5 studies were prospective cohort studies and one was a retrospective cohort study. Twenty-six studies (86%) comprised non-probability, convenience or volunteer samples. Most of the studies (n=22, 73%) used the PEDS, three studies (10%) employed the PEDS:DM and five (16%) used a combination i.e. the PEDS tools (Table 3). High risk of bias was identified in two studies, while another 26 studies (84%) were rated to have low risk of bias (Appendix A). The studies by Maleka et al. (2019), with a score of 3, and Richards, Reith, Stitely, & Smith (2019), with a score of 2, were rated to have a very high risk of bias (Appendix A).

In terms of the specific contexts investigated within the countries, many of the studies conducted in HICs involved higher-income contexts (n=12, 63%). Some studies conducted in HICs focused on both high- and low-income contexts (n=6, 31%) to determine the impact of socioeconomic status on development (Simon et al., 2013). Only one study in a HIC was conducted in a specifically low-income context. Conversely, the majority of studies in the LMICs reported on low-income communities and contexts (n=7, 63%), whereas only two studies reported on high-income contexts and another two on mixed economic contexts.

Table 4.3

Summary of included studies on the use of the PEDS, PEDS:DM and PEDS tools (n=30)

	ALL	**PEDS**	**PEDS:DM**	**PEDS tools**
Studies	30	22 (73%)	3 (10%)	5 (16%)
Date range of studies	2003 – 2020	2003 - 2020	2011 - 2019	2016 - 2019
Sample size (Average +/- SD; Range)	3396+/-16671; 26 - 91642	–4377+/-19028; 26 - - 91642	95 +/-23; 66 - 124	238+/-93; 138- 406
Age (years)	0.1 - 8	0.4 - 8	0 - 8	0.1 – 3.2
Countries (n)	11 countries *11 USA* *6 SA* *3 Australia* *2 Canada* *2 Iran* *1 Serbia* *1 Israel* *1 Singapore* *1 New Zealand* *1 Bhutan* *1 Thailand*	9 countries *9 USA* *3 Australia* *2 SA* *2 Canada* *2 Iran* *1 Serbia* *1 Ukraine* *1 Singapore* *1 New Zealand*	2 countries *2 USA* *1 Bhutan*	2 countries *4 SA* *1 Thailand*
High- or low-income context (n)	14 High-income 8 Mixed 8 Low-income	13 High-income 6 Mixed 3 Low-income	1 High-income 2 Mixed	5 Low-income
Study types	22 (73%) Cross-sectional 5 (16%) Prospective cohort study 1 (4%) Retrospective cohort study 2(8%) Mixed method	17(77%) Cross-sectional 4 (18%) Prospective cohort study 1 (6%) Mixed method	2 (67%) Cross-sectional 1 (33%) Prospective cohort study	3 (60%) Cross-sectional 1 (20%) Retrospective cohort study 1 (20%) Mixed method
Comparison to other tools	4 ASQ 2 M-CHAT 1 PEDS Northern Sotho (PEDS-NS) 1 BSID-III	4 ASQ 1 PEDS-NS 2 M-CHAT	No comparisons to other tools	1 BSID-III
Person completing	17 Parent/ caregivers 5 Clinician/ health care worker 2 other	21 Parents/caregivers 1 Teacher/child care worker	2 Clinician/health care worker 1 Children	1 Parents/caregivers 3 Clinician/health care worker
Target population	18 TD*children 2 Children at risk for developmental disorder 5 Special population	18 TD children 1 Children at risk for developmental disorder 3 Special population	1 TD children 2 Special population	4 TD children 1 Children at risk for developmental disorder
Mode of completion	4 Digital (1 online; 3 mHealth) 21 Paper based	1 online 21 paper based	3 paper based	3 mHealth 2 paper based
Risk of bias	2 High risk of bias 2 Medium risk of bias 26 Low risk of bias	1 High risk of bias 2 Medium risk of bias 19 Low risk of bias	3 Low risk of bias	1 High risk of bias 4 Low risk of bias

* typically developing

As outlined by Table 3, the studies varied in sample populations. The studies conducted in HICs typically focused on the PEDS and/or PEDS:DM use in special contexts and with special populations, or the comparison of these tools with other tools of a similar nature (Table 4). A limited number of studies, with small sample sizes were conducted on the PEDS:DM and PEDS tools with no comparative studies for the PEDS:DM with other tools (Table 3). The majority of studies involved the caregiver or parent's completion of the tool (n=23, 76%). One study involved both the paediatrician and the caregiver for completion of the tool. A small number of studies required the paediatrician, childcare worker, speech-language pathologist or a clinician to complete the tool (n=5, 16%). Only one study involved the teachers of preschool children in the completion of the tool's form. Five studies compared the PEDS and ASQ. It was found that there is substantial discordance between PEDS and ASQ developmental screens (Sices et al., 2009). The ASQ showed higher sensitivity and specificity when compared to the PEDS (Limbos & Joyce, 2011; Sheldrick et al., 2020), particularly in older children (Sheldrick et al., 2020). The higher specificity of the ASQ among younger children was not statistically significant (Sheldrick et al., 2020) and in another study, the results of the test were similar in 93%, 94% and 91% of cases in fine motor, gross motor and language domains of development, respectively (Shahshahani et al., 2017).

Three studies reported on special populations; two described the utility of the PEDS (Wessel et al., 2013) and PEDS:DM (Soucy et al., 2012) in detecting warning signs of delays in children with neurofibromatosis type 1. Both of these studies were conducted in the United States. The third study, conducted in New Zealand, made use of the PEDS to measure developmental outcomes of children at age four who had been exposed to maternal antiepileptic drug use (Richards et al., 2019). In HICs, use of the PEDS in studies was often for detection of ASD and its comparison to ASD-specific tools

such as the M-CHAT (Eapen et al., 2014; Pinto-Martin et al., 2008; Wiggins et al., 2014). Five of the 20 studies conducted in HIC (Table 4) focused on factors which could potentially influence the assessment such as foster care, inter-country adoption, multilingualism, culture and low socio-economic status and the PEDS (Diamond et al., 2015; Hodges et al., 2016; Huntington et al., 2016; Kiing et al., 2012; Simon et al., 2013). Other studies focused on the use of the PEDS in contexts such as pediatric hospitals (Petersen et al., 2009) and primary care (Limbos & Joyce, 2011; Pinto-Martin et al., 2008). Referral rates of the PEDS from studies conducted in HIC ranged from 10% to 74% (Diamond et al., 2015; Limbos & Joyce, 2011). The PEDS:DM had referral rates of 68% in a study conducted in the USA, with significant delays in fine motor (35%) and gross motor (52%) skills (Soucy et al., 2012).

Table 4.4

Study type and country characteristics (n= 30)

Study types	LMICs	HICs	Total
Adaptation and translation studies	3	3	6
Population description studies	2	5	7
Comparison studies	2	6	8
Evaluation studies	4	5	9
Total	11	19	30

When compared to the studies conducted in HICs, the eleven LMIC studies have focused more on translations and adaptations, combination use of the PEDS tools, and the use of an app-based (mHealth) version of the tool. Three studies examined translations of the PEDS in two different LMIC countries- South Africa (Fyvie et al., 2016; Van der Merwe et al., 2017) and Iran (Vameghi et al., 2015). With the use of the translated tool, high referral rates were reported when participants were from underserved communities, and positive and negative correspondence was high- proving that the tool translation was accurate (Fyvie et al., 2016; Van der Merwe et al., 2017). The PEDS questions were found to have desirable content validity with no need for change

(Vameghi et al., 2015). Several studies examined the usefulness of the PEDS in detecting parental concerns in LMICs (Chunsuwan et al., 2016; Ilić et al., 2019; Shahshahani et al., 2017; Wong et al., 2019). Examining the usefulness and accuracy of a tool renders varying results, as noted in the studies included in the review (Appendix A). Four of the studies examined the potential of the PEDS tools and the utilisation of mHealth in South Africa, where a growing body of recent research has emerged from (Abdoola et al., 2019; Maleka et al., 2016, 2019; van der Merwe et al., 2019). Five studies reported adaptations and/or translations and the impact of culture and language, three of which were translation studies. Translations of the PEDS, such as in Northern Sotho, Zulu and Persian, showed desirable validity (Fyvie et al., 2016; Vameghi et al., 2015; van der Merwe et al., 2017). A study found a slight difference in referral rate with regards to translation- with a referral rate of 50% for English and 45% for the Zulu translation. This difference is suggestive of different understandings of questions in the two different languages (van der Merwe et al., 2017). A study conducted in Singapore found an increase of parents reporting concern, as "a little concern" is interpreted differently cross-culturally, and it was recommended that the word be substituted with a word like "worry" (Kiing et al., 2012). Conversely, in a HIC such as Australia it was found that the PEDS is acceptable for the reporting of developmental concerns (Coghlan et al., 2003). Referral rates in studies conducted in LMICs ranged from 23% to 41% on the PEDS (Maleka et al., 2019; Shahshahani et al., 2017), 12% to 54% on the PEDS:DM (Maleka et al., 2019; Wong et al., 2019) and 56% to 69% on the PEDS tools (Abdoola et al., 2019; Van der Merwe et al., 2019).

4.4. Discussion

The PEDS, PEDS:DM and PEDS tools were used across 11 different countries on various populations with study types including cross-sectional, prospective as well as retrospective cohort and mixed method. The 30 studies are distributed globally. Far less research is currently available internationally on the PEDS:DM and PEDS Tools compared to the PEDS. This may in part be due to

the fact that the latter are younger tools when compared to the PEDS. A large number of studies included in this review (n = 22, 73%) used the PEDS, only 3 (10%) studies used the PEDS:DM and 5 (16%) used the PEDS tools (Table 3) to identify signs of developmental delays.

In describing the use of the tools to identify need for referrals and further evaluation, there was a focus on expression of parental concern. Links between parental concern and child development; as well as the timing of concerns indicate that parents appear to be sensitive to their child's development when answering the questions on the PEDS, specifically within the special population where reported concerns of developmental delay were high (Diamond et al., 2015; Hodges et al., 2016; Ilić et al., 2019; Restall & Borton, 2010). The included studies indicate that the PEDS may be used as a tool for detecting signs of delays in special population groups. It is well-established that the PEDS is sensitive for the identification of disabilities, including learning, intellectual, language, autism spectrum and motor disorders (Glascoe, 2013).

Nineteen of the thirty studies were conducted in HICs. The PEDS and PEDS:DM are well-established in the USA since it was also developed there (Sheldrick et al., 2020). Studies in HIC initially focused on validation, and subsequently more studies conducted in those contexts were typically more towards screening of special population groups such as children with autism and comparative studies with other validated tools such as the ASQ (Morelli et al., 2014; Sheldrick et al., 2020; Woolfenden et al., 2014). The only study that involved gathering information from the teacher was also conducted in a HIC (Kiing et al., 2012). The investigation of the value of teacher input using the PEDS requires further investigation, as it shows promise (Kiing et al., 2019). The HIC studies also used the PEDS when screening for signs of developmental delays with regards to foster care, adoption and drug exposure (Diamond et al., 2015; Hodges et al., 2016; Richards et al., 2019).

Fewer HIC studies were concerned with culture and language differences (Huntington et al., 2016; Kiing et al., 2012; Simon et al., 2013) when compared to studies conducted in LMIC (Abdoola et al., 2019; Chunsuwan et al., 2016; Fyvie et al., 2016; Ilić et al., 2019; Maleka et al., 2016, 2019; Shahshahani et al., 2017; Vameghi et al., 2015; van der Merwe et al., 2019; Wong et al., 2019). Those studies that reported on cultural and language differences in HIC, however, indicated that the PEDS works equally well between cultural groups (Huntington et al., 2016) and that higher rates of positive detection of developmental delay warning signs were only present when poverty was also a factor (Simon et al., 2013). Overall, there does not seem to be an association between home language and poor performance on the PEDS (Huntington et al., 2016; Simon et al., 2013). This may be attributed to parents' ability to communicate their knowledge of their child, irrespective of the language they use to express their concerns. Cultural interpretations of the PEDS content does not seem to affect the child's performance on the PEDS – rather, it appears to affect parent report, resulting in over- or under-reporting of concerns (Kiing et al., 2012). This study recommended that small cultural adaptations should be implemented to make the PEDS content more appropriate such as the substitution of a word like "concern" with "worry" (Kiing et al., 2012). In a study assessing the use of the PEDS:DM in Bhutan, there was a greater proportion of subjects being classified as being at medium risk for developmental delay due to cultural differences (Wong et al., 2019). An example of why this was the case is the following: the self-help question "can your child get dressed by himself or herself?" was met with a "no" response by a majority of the participants. This can be attributed to the fact that Bhutanese children are dressed in traditional clothing that is more complicated in comparison to Western-style clothes, resulting in children only being able to be able to independently dress themselves at a later age (Wong et al., 2019). While different cultural groups have different expectations and may consequently observe or interpret their child's behaviour differently, children from different cultural backgrounds may perform equally well on the PEDS – such as an English- and a Spanish-speaking child (Huntington et al., 2016). This may be due to the

nature of the PEDS, as parent-report of concern for their child transcends the barriers of clinician administered tools and cultural difference. However, as findings vary in HIC and LMIC, there is a need to explore the use of the tools globally, and it is recommended to examine how they perform in different contexts.

A high maximum referral rate of 74% was found with the PEDS in one study in a HIC, which was conducted on internationally adopted children mainly from Russia and Ukraine (Diamond et al., 2015). Consistent with other research, this high referral rate may be attributed to the at-risk nature of the children being adopted from Eastern Europe. These children are known to have significantly lower levels of developmental competence in most domains compared with children adopted from other regions (Welsh & Viana, 2012). Higher referral rates are typically obtained with the PEDS and PEDS:DM when administered in low-income settings, where at-risk populations are more prevalent (Maleka et al., 2019; van der Linde et al., 2015), and where cultural differences may also potentially influence outcomes. A tiered screening approach to identifying developmental delays or disorders requires further investigation. While the PEDS is sensitive to parental concern, the sensitivity and specificity of the tool by itself does not support the use of the PEDS as a stand-alone screening tool (Wake et al., 2005). This suggests that the PEDS has potential to be used in combination with another developmental screening tool, such as the PEDS:DM, to accurately detect developmental disabilities and delays. One of the benefits thereof would be the reduction of high referral rates by potentially identifying false positives from the initial screen (Chunsuwan et al., 2016).

Translating and adapting tools, as well as adaptation of referral criteria of tests have been recommended to be more context-specific (Maleka et al., 2016; Servili & Tomlinson, 2019). Cross-culturally appropriate and affordable tools with good psychometric properties remain limited

(Goldfeld & Yousafzai, 2018). In spite of this, studies from LMICs including Thailand, and South Africa found that if not adapted, the PEDS tools may not always be appropriate developmental surveillance tools within these context due to cultural and linguistic differences (Chunsuwan et al., 2016; Dreyer et al., 2016; Maleka et al., 2019).

Other studies have reported that the PEDS tools may be feasible in the South African public health care context (Maleka et al., 2019; van der Merwe et al., 2019). There was no research found on the usage of the PEDS tools in the HIC context, however it is likely that it would perform well, as the PEDS in isolation has been used successfully in HIC school (Coghlan et al., 2003) and primary health (PHC) contexts (Limbos & Joyce, 2011). The PEDS may therefore be used successfully in combination with the PEDS:DM in these contexts, and it is recommended that future research on the use of the PEDS tools in HICs is conducted. Translation studies have also been successful in South Africa (van der Merwe et al., 2017). This is particularly important, as there is a dearth of standardized screening tools used by practitioners in LMICs such as South Africa to detect developmental delays (Sabanathan et al., 2015; van Der Linde et al., 2015). There is also a lack of consensus around which screening tools are most effective, especially where tools are used in cultures other than those in which they were created (Marlow et al., 2019; Sabanathan et al., 2015). The investigation of standardized tools suitable for a LMIC context requires more attention. The PEDS and parent-report tools have gained more attention in many LMICs, especially with regards to using it in an mHealth format. However, as findings are not consistent between and within all LMIC contexts, they cannot be generalized to diverse populations and all LMICs at large. Further research is recommended to support the PEDS, PEDS:DM and PEDS tools use for the diverse multilingual, multicultural and socioeconomic populations in various LMICs. Few studies were conducted on the PEDS:DM and the PEDS tools independently, thus indicating a need for further research.

4.5. Conclusion

Existing information on the use of the three potential options for screening with PEDS tools (PEDS, PEDS:DM, and PEDS tools) to identify a need for referrals and further evaluation was reviewed. The findings revealed gaps in the literature regarding which tools are an exact fit for specific contexts, meaning the results could not be generalised to all populations and contexts. Existing research is largely focused on the use of the PEDS in HICs. The review identified a dearth of research conducted on the PEDS:DM and PEDS tools globally and highlights factors, such as cultural interpretation, that influence the validity and impact widespread use of the screening measures, especially from diverse settings, populations and LMICs in general. Further research with these tools is recommended.

4.6. References

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4.7. Supplementary material A: Study characteristics of included studies (n = 30)

Study	Author(s)	Year of publication	Study Design	Level of evidence	Target population	Population age range	Total sample size	Location	Test platform used	Individual who completed the tool/s	Risk of bias	Study outcomes
Developmental delays in children with neurofibromatosis type 1	E Soucy, F Gao, D Guttman and C Dunn	2011	Cross-sectional study	4	Children with neurofibromatosis type 1	7 months – 8 years	66	United States	PEDS:DM; Paper-based	Parents and children	7	The PEDS:DM demonstrates the high presence of developmental delays in children with neurofibromatosis type 1 and the need for aggressive and early screening.
Comparing the results of developmental screening of 4 to 60-month-old children in Tehran using parents evaluation of developmental status and ages and stages questionnaires	S Shasshahani, R Vameghi, F Sajedi and A Biglarian	2017	Cross-sectional study	4	Children living in Tehran city	4 – 60 months	648	Iran	PEDS; Paper-based	Parent/caregiver	8	The PEDS and ASQ have acceptable agreement, thus it seems that PEDS can be used for children's developmental screening especially in child care visits.
Early identification of children with developmental delay and behavioural problems according to parents concerns in the Republic of Serbia	S Ilić, S Nikolić, D. Ilić-Stošović and Š Golubović	2019	Cross-sectional study	3	Preschool children in Serbia	3 – 7 years	289	Serbia	PEDS; paper-based	Parents	7	According to the criteria of PEDS test, this research identified 56.4% of children whose development needed to be monitored, 27.7% of children who needed to be referred for detailed diagnostic procedures, and 1.7% who needed to be included in treatment or special education support.
The outcome of a developmental screening tool (PEDS) in English and Northern Sotho: A comparative study	L Fyvie, J Anderson, C Kruger, M le Roux and J van der Linde	2016	Cross-sectional study	4	Caregivers who were literate in both English and Northern Sotho	2 – 5 years	95	South Africa	PEDS and PEDS-NS; Paper-based	Parents/caregivers	8	This proved that the PEDS-NS is an accurate translation of the PEDS. High referral rates were reported, which may be due to participants being from underserved communities. Positive and negative correspondence of the PEDS-NS was high.
Validity and reliability determination of Parents Evaluation of Developmental Status (PEDS) in 4-60 months old	R Vameghi,F Sajedi, S Shahshahani and A Biglarian	2015	Cross-sectional study	2	Persian children attending healthcare clinics	4 – 60 months	648	Iran	PEDS; Paper-based	Parents	8	This research showed that the PEDS has a good content validity and reliability and can be used for developmental screening of children in Tehran city. Because the test is brief, using it can lead to saving time and resources.

children in Tehran												All of the questions in PEDS had desirable content validity.
Parent Evaluation of Developmental Status (PEDS) in screening: The Thai experience	I Chunsuwan, T Hansakunachai and S Pornsamrit	2016	Cross-sectional study	4	Children attending 9, 18 and 30 month health checkups	9 – 30 months	266	Thailand	PEDS tools; Paper-based	Parents and pediatricians	8	Implementation of PEDS in well-child visits could enhance early detection of developmental problems, but many Thai parents were unable to mention their concerns about delayed abilities in the correct PEDS question.
Assessment of a neuro-developmental screening tool in children in Bhutan	B Wong, S Grundy, L Tshering, K Tshering and F Mateen	2019	Cross-sectional study	2	Community-dwelling Bhutanese children without diagnosed neurocognitive conditions	3 – 7 years	96	Bhutan	PEDS:DM; Paper-based	Pediatrician	7	The PEDS:DM requires further modifications and validation studies before it can be reliably implemented to assess developmental delay in children in Bhutan.
Screening for Autism spectrum disorders using the PEDS and M-CHAT	V Eapen, R Črnčec, S Woolfenden and R Blackmore	2014	Cross-sectional study	4	Parents of children aged 16 – 60 months attending childcare centers	16 – 60 months	97	Australia	PEDS; Paper-based	Parents	8	These data provide some support for tiered screening with the PEDS and M-CHAT in identifying children requiring specialized ASD assessment. Five percent of children required specialized ASD assessment based on their M-CHAT scores.
Screening strategies for autism spectrum disorders in pediatric primary care	J Pinto-Martin, L Young, D Mandell, L Poghosyan, E Giarelli and S Levy	2008	Cross-sectional study	4	Children identified at risk for ASD at their well child visits	18 – 30 months	152	United States	PEDS; Paper-based	Parents	8	The PEDS missed the majority of children who screened positive for ASD on the M-CHAT, suggesting that these two tools tap into very different domains of developmental concerns.
Developmental outcomes at age four following maternal antiepileptic drug use	N Richards, D Reith, M Stitely and A Smith	2019	Prospective cohort study	4	Children with prenatal exposure to AEDs	4 years	606	New Zealand	PEDS; Paper-based	Parents	2	Prenatal exposure to sodium valproate and lamotrigine is associated with an increased risk of concerns about emotional and behavioral development being reported by parents in a neurodevelopmental screening program.
Comparative Accuracy of Developmental Screening Questionnaires	RC Sheldrick, S Marakovitz, D Garfinkel, A Carter and E. Perrin	2020	Cross-sectional study	4	Families of children aged 9 – 42 months	9 – 42 months	1495	United States	PEDS; paper-based	Parents	8	This study found that 3 frequently used screening questionnaires offer adequate specificity but modest sensitivity for detecting developmental delays among children aged 9 months to 5 years.
Developmental Screening With Spanish-Speaking Families in a Primary Care Setting	N Huntington, K Horan, A Epee-Bounya and A Schonwald	2016	Cross-sectional study	4	Families attending an urban community health center where 75% of families are Spanish speaking	18 – 48 months	607	United States	PEDS; paper-based	Parents	7	The systematic inclusion of developmental screening as part of culturally competent primary care may aid in reducing current disparities in the identification of developmental concerns. The adjusted odds of a concern being identified was 1.5 times greater in the post-PEDS period for Developmental concerns and 2.1

												times greater for Behavioral concerns. There was no association with family language indicating that the PEDS performs equally well for English- and Spanish-speaking families.
Prioritized Surveillance of Young At-risk South African Children: An Evaluation of the PEDS Tools Referral and Response Characteristics	BK Maleka, J Van Der Linde, DW Swanepoel and FP Glascoe	2019	Retrospective cohort study	4	Children at risk for developmental delays in a primary health care setting	5 – 36 months	406	South Africa	PEDS tools; paper-based	Parents/caregivers	3	The PEDS tools must be evaluated for applicability in low-and-middle-income countries. Referral criteria must be sensitive to the demands on under-resourced health care systems. Referral criteria of the PEDS:DM in isolation as well as of the PEDS tools combined prioritizing moderately to severely affected children were modelled from the data.
Developmental Screening-Evaluation of an m-Health Version of the Parents Evaluation Developmental Status Tools	BK Maleka, J Van Der Linde, FP Glascoe, and DW Swanepoel	2016	Cross-sectional study	4	CHWs in a primary health care setting	6 – 36 months	207	South Africa	PEDS tools; app-based	CHW and SLP	7	Outcomes of the smartphone application, operated by a CHW, corresponded closely to the gold standard PEDS tools operated by a health professional.
Early detection of developmental delays in vulnerable children by community care workers using an mHealth tool	M van der Merwe, R Mosca, DW Swanepoel, FP Glascoe and J van der Linde	2019	Mixed method	4	CCWs in a primary health care setting	1 – 38 months	138	South Africa	PEDS tools; app-based	CCW	8	CCWs and mHealth-assisted developmental screening can facilitate better access to early detection and developmental surveillance for vulnerable populations. CCWs perceived mHealth screening as valuable in terms of utility, outcomes and contribution to developmental knowledge for community members and CCWs.
Interpreting parents' concerns about their children's development with the Parents Evaluation of Developmental Status: Culture matters	J Kiing, P Low, Y Chan and M Neihart,	2012	Cross-sectional study	4	Parents, teachers and child care workers of preschool children in Singapore	1 month – 6 years 11 months	1806	Singapore	PEDS; paper-based	Parents and teachers/child care workers	8	Parents' interpretation of the concept of "concern" varies across language and culture. Findings highlight the importance of evaluating a screening tool's use in local contexts before its widespread implementation to yield clinically meaningful results. The reporting of significant parental concern was considerably higher than US norms and Australian pilot figures when Western cutoff scores were applied. When cutoff scores were

												adjusted, similar patterns of reporting of high, medium, and low risk for disability could be captured.
Comparison of a broad-based screen versus disorder-specific screen in detecting young children with an autism spectrum disorder	L Wiggins, V Piazza and D Robins	2012	Cross-sectional study	4	Children evaluated for autism during 18- and 24- month well-child visits	18 – 24 months	52	United States	PEDS; paper-based	Parents	7	Findings support universal autism spectrum disorder–specific screening in addition to general developmental screening and offer considerations to encourage early identification of toddlers with autism spectrum disorder.
Socioeconomic disadvantage and developmental delay among US children aged 18 months to 5 years	A Simon, PN Pastor, R Avila and S Blumberg	2013	Cross-sectional study	4	All children aged 18 months to 5 years in the 2007 National Survey of Children's Health were categorised into three groups based on the likelihood of developmental delay	18 – 60 months	91 642	United States	PEDS; online survey	Parents	8	It was found that children who were older, male, of low birth weight, non-Hispanic black or Hispanic in a non-English-speaking household, poor or receiving more than 10 h/week of care at someone else's home were at most risk of a probable developmental delay.
Comparison of the ASQ and PEDS in screening for developmental delay in children presenting for primary care	M Limbos and D Joyce	2011	Cross-sectional study	4	Children who presented to their primary care provider for routine care	12 – 60 months	334	Canada	PEDS; paper-based	Parents	8	The findings support the guidelines of the American Academy of Pediatrics, demonstrating that both the ASQ and, to a lesser extent, the PEDS have reasonable test characteristics for developmental screening in primary care settings.
Prevalence of developmental and behavioral disorders in a pediatric hospital	M Petersen, D Kube, T Whitaker, JC Graff and F Palmer	2008	Cross-sectional study	4	Primary caregivers of children admitted to a general pediatric service	16 months – 17 years	325	United States	PEDS; paper-based	Parents/caregivers	9	This higher prevalence of developmental and behavioral disorders in hospitalized children emphasizes the need to screen for developmental disabilities at every opportunity. Strategies to implement systematic screening of hospitalized children should be examined.
Parents' concerns about their children's development at school entry	G Restall and B Borton	2009	Mixed method	4	Parents and guardians of children who entered kindergarten in one school division	36 – 60 months	290	Canada	PEDS; paper-based	Parents	7	Eliciting parent perspectives can assist to build trust and to contribute meaningfully to the identification of children at risk for poor developmental outcomes. Providers need strategies to overcome potential barriers to early identification and referral.
Detecting developmental delays in infants from a low-income South	S Abdoola, DW Swanepoel, J Van Der Linde	2019	Cross-sectional study	4	Caregivers attending the baby wellness clinic in a	3 – 18 months	174	South Africa	PEDS tools; app-based	SLP	7	A combination of tools for screening and assessment in infants in a South African PHC context may be necessary. The high-risk nature and age group

African community: Comparing the BSID-III and PEDS tools	and FP Glascoe				primary healthcare setting							may have contributed to poor agreement across tools.
Early developmental screening for children in foster care	K Hodges, M Landin, M Nugent and P Simpson	2016	Cross-sectional study	4	Children entering foster care	0 – 6 years	167	United States	PEDS; paper-based	Parents	7	These results support use of a developmental screen for children in foster care and suggest that screening be performed as early as possible to expedite necessary evaluations and referrals. Use of a developmental screening tool at foster care entry increased detection of potential DD, and the results remained consistent with screening 1 month later.
Parental perception of developmental vulnerability after inter-country adoption: A 10-year follow-up study: Longitudinal study after inter-country adoption	G Diamond, Y Seneckya, HR Reichman, D Inbar and G Chodick	2015	Prospective cohort study	4	Parents of adopted children	1 – 12 years	191	Israel	PEDS; paper-based	Parents	6	Parents perceive international adoption as being associated with a substantial risk for developmental problems. Even meticulous pre-adoption screening cannot preclude developmental problems that may appear in later childhood.
Longitudinal analysis of developmental delays in children with neurofibromatosis type 1.	L Wessel, F Gao, D Gutmann and C Dunn	2012	Prospective cohort study	4	Children with neurofibromatosis type 1	0 – 8 years	124	United States	PEDS:DM; paper-based	Clinician	6	Early developmental screening and intervention for this at-risk pediatric population is advocateda, especially in the area of gross motor function. School-age children exhibited significantly more areas of delay than infants or preschool-age children. Delays in math, reading, gross motor, fine motor, and self-help development were observed more frequently in older than younger children. Finally, analysis of 43 subjects for whom longitudinal assessments were available revealed that children often migrated between delayed and non-delayed groups in all areas except gross motor development.
Evaluation of a Zulu translation of the Parents' Evaluation of Developmental Status	M van der Merwe, M Cilliers, C Mare, J van der Linde and M le Roux	2017	Cross-sectional study	4	Caregivers of children fluent in English and Zulu	18 – 71 months	99	South Africa	PEDS; paper-based	Caregivers	8	The Zulu PEDS displayed high positive and negative correspondences, representative of an accurate translation of the English PEDS. It is recommended that the study be repeated in a

												community where the majority are Zulu home language speakers
Routine developmental screening implemented in urban primary care settings: more evidence of feasibility and effectiveness	A Schonwald, N Huntington, E Chan, W Risko and C Bridgemohan	2009	Prospective cohort study	4	Patients attending well-child care visits	6 months – 8 years	616	United States	PEDS; paper-based	Parents	6	Implementation of validated screening by using the PEDS was feasible in large, urban settings. Effectiveness was demonstrated via chart review documenting an increased rate of identification of developmental and behavioral concerns.
PEDS and ASQ developmental screening tests may not identify the same children	L Sices, T Stancin, L Kirchner and H Bauchner	2009	Cross-sectional study	4	Pediatricians and parents with children attending well-child care visits	9 – 31 months	60	United States	PEDS; paper-based	Parents	6	There was substantial discordance between PEDS and ASQ developmental screens. Clinicians need to be aware that in implementing revised AAP guidelines, the choice of screening instrument may affect which children are likely to be identified for additional evaluation.
Parents' Evaluation of Developmental Status in the Australian day-care setting: Developmental concerns of parents and carers	D Coghlan, JSH Kiing, M Wake	2003	Cross-sectional study	4	Children from day-care centres and kindergartens	18 – 36 months	26	Australia	PEDS; paper-based	Parents	7	The PEDS is acceptable to parents of Australian preschool children, with a prevalence of significant concerns that is similar to those in the USA. Further research is needed to assess what factors differentially influence whether a concern is felt in a particular domain for a particular child.
Does Parents' Evaluation of Developmental Status at school entry predict language, achievement and quality of life 2 years later?	M Wake	2005	Prospective cohort study	4	Children with significant parental developmental concerns	5.3 – 7.5. years	173	Australia	PEDS; paper-based	Parents	9	Although individual developmental concerns at school entry variably predict later academic and language scores, sensitivity and specificity values would not support use of the PEDS as a stand-alone screen to detect later problems.

CHAPTER 5

DETECTING DEVELOPMENTAL DELAYS IN INFANTS FROM A LOW-INCOME SOUTH AFRICAN COMMUNITY: COMPARING THE BSID-III AND PEDS TOOLS

Title: Detecting developmental delays in infants from a low-income South African community: Comparing the BSID-III and PEDS tools

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ABSTRACT

Detecting developmental delays is essential for early intervention, especially in low to middle income countries (LMICs), where prevalence is highest. Detection in infants is challenging; therefore, this study compares the outcome of two measures, the Bayley Scales of Infant and Toddler Development III (BSID-III) and Parents Evaluation of Developmental status (PEDS) tools. A cross-sectional, within-subject, comparative design was employed to determine the overall and domain-specific performance of the PEDS tools smartphone application and the BSID-III to detect developmental delays in 174 young children aged 3-18 months. Data was collected at a primary healthcare (PHC) clinic in Mamelodi, an underserved high-risk community, in South Africa. The PEDS tools identified 56% (n=97), and the BSID-III 35%

(n=61) of the 158 children with possible developmental delays, with an overall agreement of 65% between tests. The PEDS tools referral rate was significantly higher (p=0.004) than that of the BSID-III. The high-risk nature and age group (<18 months) may have contributed to the poor agreement across the tools. A combination of tools for the screening and assessment of developmental delay in infants in a South African PHC context may be necessary.

Keywords: Communication delays, developmental delay, primary health care, early intervention, mHealth

5.1. Introduction

Approximately 200 million children in low-and-middle-income countries (LMICs) do not reach their full potential due to developmental delays (Irwin, Siddiqi, & Hertzman, 2007). Exposure to poverty, health problems, violence, malnutrition, compromised care and stimulation, and insufficient opportunities contribute to the increased prevalence of developmental delays (Samuels, Slemming, & Balton, 2012). Developmental delay is defined as delays in speech and language development, motor development, social-emotional development and cognitive development (Demirci & Kartal, 2016). There is an established link between socio economic status (SES) and milder forms of delay, such as language or cognitive delay (Hackman & Farah, 2009; Wise, 2016); whereas an evidential link between SES and severe forms of developmental delay is not well developed (Vrijheid et al., 2000). Severe developmental delays which may have a genetic or congenital link occur across socioeconomic status groups, and irrespective of the financial status of the family (Scherzer, Chhagan, Kauchali, & Susser, 2012). Some of these severe developmental delays due to conditions such as Downs syndrome may be apparent at birth, and some through their latent nature may appear later as the child grows and develops with well-known consequences (Karmiloff-Smith et al., 2016; Hamilton, 2006). Mild delays such as language, cognitive, or motor impairment may be more subtle but also associated with poorer health status, higher rates of school failure, in-grade retention, and special education placement (Hamilton, 2006).

The long-term consequences such as the negative influence on educational achievement and later vocational outcomes, contribute to the substantial global burden of developmental delays.

The prevalence of risk factors emphasizes the importance of preventative strategies to eliminate or reduce the extent of developmental delays (Fischer, Morris, & Martines, 2014). Mild and moderate developmental delays, if not addressed timeously, can progress into developmental disorders, which limit academic and later economic success (Fischer et al., 2014). Thus, prevention, including early detection and intervention for developmental delays, serve to alleviate the burden on the child, family and society. The emphasis has shifted to *early* identification and diagnosis of delays and disabilities to reduce the impact on development, with the current focus especially aimed at infants and children from birth through three years of age (Fischer et al., 2014).

Development is often influenced by parents' expectations, which may be guided by cultural norms (Balton, 2009). Culture has various influences on child development (Yamamoto & Sonnenschein, 2016). Cultural differences in families' attitudes and coping strategies, as well as culture-specific values regarding disability; along with attitudes toward stress, may contribute to parental roles, family structure as well as child-rearing and-care practices (Rivard, Mercier, & Mello, 2016). Development is thus culturally loaded whereas growth and maturation are not, as these processes are physiological in nature.

In LMICs like South Africa, the majority (62%) of children live in rural, poverty-stricken areas, and 61% of the South African population use public health care clinics as a first point of access to medical services (van der Linde & Kritzinger, 2013). Employing screening and surveillance tools at primary healthcare (PHC) settings may facilitate early identification and diagnosis of children with developmental delays, as most infants and young children are taken to PHC facilities for immunization, providing an early opportunity for developmental screening (Brothers, Glascoe, & Robertshaw, 2008). However, the early identification and diagnosis of developmental delays is difficult as they are not easily recognized in infancy; and because infants and young children are difficult to test (Glascoe, 2000). Despite the difficulty of diagnosing developmental delay, early identification and intervention should be encouraged to maximize critical early developmental periods and reduce long-term disability. Global action to improve early childhood development (ECD) as a public health endeavor in the first 5 years of life is necessary (Sabanathan, Wills, & Gladstone, 2015). However, in LMICs, such as South Africa, access to services are often limited as there are an insufficient number of therapists, particularly in rural areas. Therapists are also disproportionately distributed between the public and private healthcare sectors; and are often not representative of the population's

cultural and linguistic diversity. These challenges make it difficult to develop and sustain early identification services (Pascoe & Norman, 2011).

Due to the dearth of human resources in rural, underserved areas, there is a need for development and use of novel, cost-effective and culturally acceptable screening and diagnostic methods that could improve timely developmental interventions for improved outcomes (Barker, Gout, & Crowe, 2011; Richter, Daelmans, Lombardi, Heymann, Boo, et al., 2017). There are many forms of developmental assessment to identify delays and initiate early intervention. Screening tools are used to identify infants at risk for developmental delay, while diagnostic assessment tools identify children who need intervention (Fischer, et al., 2014). Screening tools are less expensive, and often not lengthy. However, the results obtained may not be sufficiently detailed to diagnose developmental delay (Aylward, 2018). Screening should be as accurate as possible, to avoid both under-detection as well as over-referrals. The Road to Health Booklet (RTHB) is the only nationally implemented developmental screening tool in South Africa (Van Der Merwe, Mosca, Swanepoel, Glascoe, & Van Der Linde, 2018; van Der Linde, Swanepoel, Glascoe, Louw, & Vinck, 2015). The PEDS tools are currently being used in research, but not commercially, in South Africa (Van Der Merwe et al., 2018; Maleka, Van Der Linde, Glascoe, & Swanepoel, 2016). The PEDS includes open ended questions to elicit parents' concerns regarding their child's development and behaviors. The PEDS: DM uses more direct, close ended questions to identify whether the child has developed specific skills as per the age-appropriate developmental milestones. The PEDS tools, whilst a screening measure, also identifies areas of difficulties. The use of the PEDS tools in the South African PHC context was evaluated using the basic algorithm of the test, and it was found that the tool is very sensitive for mild to severe delays, and may thus burden the healthcare system where manpower is limited (Maleka, Linde, Swanepoel, & Glascoe, 2019). This may lead to over-referral of children in these high-risk groups. Limited healthcare resources prevent these high referral rates to be accommodated into the healthcare system (Maleka et al., 2019).

Developmental screening within a PHC setting provides an opportunity for caregivers to receive informational counselling on early development, as well as assist in early detection and intervention of developmental delay, which could take place remotely. However, tools developed in high-income countries may need to be adapted, and their costs, training requirements, and time for application may make them less suitable for use at PHC clinics in LMICs (Fischer et al., 2012). The PEDS tools is a cost-effective developmental screening

solution in PHC contexts, particularly in LMICs (Maleka et al., 2019). Although it is developed from a reliable and credible tool that is well-validated; the PEDS tools has yet to be validated based on its test performance in detecting developmental delays in infants and young children in South Africa (Glascoe, 2000; Glascoe, & Nolensville, 2013; Maleka, Van Der Linde, Glascoe, & Swanepoel, 2016). Previous research on the PEDS tools in South Africa has demonstrated the ability of community care workers to administer the tools (Maleka et al., 2016), and to thus reduce the demand on healthcare professionals in healthcare settings (Van Der Merwe et al., 2018).

Standardized tools are recommended when assessing high-risk infants, or when a more detailed assessment is needed (Rademeyer & Jacklin, 2013). Yet the current context does not always lend itself to this, as the clinician should administer these assessments. The BSID-III is a well-established diagnostic tool, which is currently a gold standard in developmental assessment (Rademeyer & Jacklin, 2013). It has concurrent validity with the Differential Abilities Scale and the McCarthy Scales of Children's Abilities. The BSID-III has been reported to be also time-consuming and costly and requires highly trained professionals to administer (Aylward, 2018). Although some concerns have been raised internationally regarding the interpretation of scores; the BSID-III has been deemed a suitable tool to be used on the black urban African population in Gauteng (Rademeyer & Jacklin, 2013). Recent studies have reported that BSID-III assessments significantly underestimate developmental delay in infants; but these findings have not been confirmed in South Africa, where the tool has not been culturally adapted for the context.

The appropriate tools for a decentralized model of detection in low-income communities can be elusive, especially in young infants where concerns have been raised with a reference standard created in high income countries. Furthermore; issues around content validity and contextual relevance of tools from high-income countries applied in low-income countries should be considered. Therefore, this study aimed to compare the BSID-III and PEDS tools in an at-risk infant population from a low-income South African community.

5.2. Method

A cross-sectional, within-subject comparative research design was employed to compare the detection of developmental delays in young children aged 3-18 months using the PEDS tools

and the BSID-III. The overall performance of the tools, as well as domain specific performance (language, motor, and social emotional) was determined. Data was collected at the Stanza Bopape PHC clinic in Mamelodi, Gauteng, South Africa. Most community residents in Mamelodi rely on government health care facilities such as Stanza Bopape clinic. Mamelodi is a low-income community with high poverty rates; and has been identified as an underserved community with a high risk population (Statistics South Africa, 2011).

Participants

A convenience sampling method was utilized to select the one hundred and seventy-four caregivers who participated in this study. Caregivers attending the baby wellness clinic with their children aged between 3-18 months were invited to participate while waiting in the queue. Caregivers who were proficient in English or Afrikaans were included in the study.

A total of 174 caregivers with infants aged between 0-18months were included in this study. 47% (n=82) of the infants were female. Home language distribution was Sepedi (47%), Zulu (15%), Ndebele (13%), Setswana (5%), Tsonga (4%), Shona (3.5%), SiSwati (2.5%), Southern Sotho (2.5%), Venda (2%), English (2%), Xhosa (1.5%), Shangaan (1.5%) and Portuguese (0.5%).

Material

The PEDS tools or mHealth version refers to the smartphone application of the combined PEDS and PEDS: DM (Maleka et al., 2016). The PEDS tools is a developmental screening tool, focusing on children's developmental milestones as well as identifying caregiver concerns by means of parental report. The developmental areas which are addressed by the PEDS include language, motor, self-help, early academic skills, behaviour and social-emotional/mental health. The PEDS consists of ten questions, focused on parental concern such as: "Do you have any concerns about how your child understands what you say?" and "Do you have any concerns about how your child behaves?" The PEDS: DM consists of questions regarding children's abilities across all developmental domains, including expressive language, receptive language, fine motor, gross motor, social-emotional, self-help and academics. The PEDS: DM consist of 6-8 questions per age interval, such as: "Does your baby look at his/her hands?" or "Does your baby put lots of sounds together that sound like talking?" (Glascoe & Robertshaw, 2009). The PEDS tools smartphone application provides automated scoring, where scores were interpreted

into five evidence-based different paths which either pass or refer a child based on the degree and nature of parental or caregiver concerns (Glascoe, 2013). Path A indicates a need for a direct referral, while Paths B-D indicate some degree of concern. These were all classified as a "refer", while Path E was classified as a "pass", as there are no concerns. When using an adapted referral criteria (ARC) (Maleka et al., 2019), the PEDS and PEDS: DM are combined, with Path A being a refer and Path B-E dependent on the PEDS: DM (two or more domains indicate a refer). Smartphone assessment was conducted using two Samsung Galaxy Pocket Plus S5301 phones running the Parents Evaluation of Developmental Status (PEDS) application.

The BSID-III is a widely used standardised assessment tool and is used as a gold standard of infant and toddler assessment (Rademeyer & Jacklin, 2013). It is a valid and reliable tool, used for clinical and research purposes (Rademeyer & Jacklin, 2013). Although designed and normed in the USA, a study to evaluate the performance of black South African urban infants on the BSID-III found it to be a suitable tool to use on this population (Rademeyer & Jacklin, 2013). Infants were assessed using the current version of The Bayley Scales of Infant and Toddler Development (version-III, BSID-III) as the diagnostic test in this study. This assessment consists of five scales: Cognition, Receptive Language, Expressive Language, Fine Motor and Gross Motor, which are assessed directly; whereas the Social-Emotional and Adaptive Behaviour domains are based on information supplied by the primary caregiver to items contained in a separate questionnaire. Diagnosis of developmental delay was defined, according to the BSID-III manual, as a score of 70-79 indicating a mild delay, and a score of <69 suggesting a severe delay.

Procedures

Informed consent was obtained from all participants. Assessments were conducted by the researcher, a qualified speech-language pathologist (SLP), and final year SLP students in a quiet room provided at the PHC clinic. Assessment procedures were conducted in a counterbalanced sequence, between traditional diagnostic or smartphone-based assessments alternatively. The BSID-III was used for traditional diagnostic assessment; and developmental screening was conducted by smartphone assessment using the Parents Evaluation of Developmental Status (PEDS) application. Final year SLP students (registered with HPCSA), who received training to administer the PEDS Tools smartphone application and conduct the diagnostic assessment of the BSID-III, assisted with the assessments under direct supervision.

The researcher and students conducting the assessments did not communicate, have contact with each other or access to each other's assessment results, to ensure that no bias was present.

Scores of the paper-based BSID-III were manually completed and captured; while scores of the PEDS tools were uploaded to the smartphone application server. Caregivers whose children obtained referral results according to the findings of the SLP were issued with referral letters to the relevant health care professionals for follow-up.

Data analysis

Quantitative data analysis was conducted using a commercially available software package, namely the Statistic Package Social Sciences (SPSS) v 23 (Chicago, Illinois). Pearson Chi-Square as well as Fishers Exact tests were used to determine the significance between the results from the PEDS, PEDS: DM, PEDS tools and BSID III. A 5% significance level was used to determine statistical significance.

5.3. Results

The PEDS tools identified 56% (n=97), and the BSID-III 35% (n=61) of the sample for possible developmental delays. When comparing the outcomes of the PEDS tools to the BSID-III, the overall agreement was 65%. The PEDS-DM and PEDS had a referral rate of 55% (n=96) and 19.5% (n=34) respectively. Maleka et al., (2019) suggested considering alternative referral criteria options to tailor the use of the PEDS tools to LMIC contexts with high prevalence of risks, which have shown lower rates of positive identification of more severe developmental delays (24%) only in their study.

Table 5.1. Pass/Refer distribution of the BSID-III, PEDS Tools, PEDS, PEDS: DM, and PEDS tools with adapted referral criteria (ARC) (n=174)

	BSID-III	**PEDS Tools**	**PEDS**	**PEDS: DM**	**PEDS Tools with ARC***
Pass	113 (65%)	77 (44%)	140(80%)	78 (45%)	130 (75%)
Refer	61 (35%)	97 (56%)	34 (20%)	96 (55%)	44 (25%)
*ARC- PEDS and PEDS: DM combined; Path A refer. Path B-E dependent on PEDS: DM (two or more domains refer)					

BSID-III, Bayley Scales of Infant and Toddler Development-III; PEDS, Parents' Evaluation of Developmental Status; PEDS-DM, PEDS-Developmental Milestones; PEDS tools, combined PEDS and PEDS: DM smartphone application

The PEDS tools and BSID III corresponded in 70.5% of cases with developmental delay, and 52.2% of cases who did not present with developmental delay (Table 5.2). Individually, the PEDS: DM and BSID-III corresponded in 70.5% of cases with a delay and 53.1% of cases without a delay; whereas the PEDS corresponded with the BSID III in 24.6% of cases with a delay and 83.2% of cases without developmental delay.

Table 5.2. Comparison of the referral rates (%) of PEDS, PEDS-DM, PEDS tools, PEDS tools ARC and the BSID-III and BSID-III (very severe only) (n=174).

	BSID-III				**BSID-III (very severe only)**			
	PEDS Tools	**PEDS: DM**	**PEDS**	**PEDS Tools (ARC)***	**PEDS Tools**	**PEDS: DM**	**PEDS**	**PEDS Tools (ARC)***
Delays	70.5	70.5	24.6	39.3	66.7	66.7	23.8	38.1
No delays	52.2	53.1	83.2	81.4	45.8	46.4	81	75.8
*__ARC__: Adapted Referral criteria - PEDS and PEDS: DM combined; Path A refer. Path B-E dependent on PEDS: DM (two or more domains refer)								

BSID-III, Bayley Scales of Infant and Toddler Development III; PEDS, Parents' Evaluation of Developmental Status; PEDS-DM, PEDS-Developmental Milestones; PEDS tools, combined PEDS and PEDS: DM smartphone application; ARC, Adapted referral criteria(Maleka, Karabo Boledi ; Van Der Linde, Jeannie; Swanepoel , De Wet and Glascoe, n.d.)

The PEDS tools referral rate was significantly higher (p=0.004) than that of the BSID-III. The referral rate of the PEDS tools dropped by 31% (from 70.5% to 39.3%) when the adapted referral criteria was implemented (Table 5.1 and Table 5.2). Participants who scored below the 2-standard deviation ("extremely low") cut-off point on 1 or more domains were identified on the BSID-III as severe failed cases (Veldhuizen, Clinton, Rodriguez, Wade, & Cairney, 2015). This approach was used to differentiate between severe and less severe delays, and then examine its' effect on the overall correspondence of the PEDS tools with the BSID-III. Using this approach, the PEDS tools and BSID-III corresponded in 66.7% of cases with developmental delay and 45.8% of cases with no delay (Table 5.2).

Table 5.3. Developmental domain–specific distribution of screening fail results on the BSID III, PEDS Tools, PEDS and PEDS: DM (n=174)

	Language (receptive and expressive)	**Motor (fine and gross)**	**Social-emotional**
BSID-III	12% (n=21)	13% (n=23)	8% (n=14)
PEDS Tools	24% (n=42)	48% (n=84)	14% (n=25)
PEDS	7% (n=12)	8% (n=14)	4% (n=7)
PEDS: DM	21% (n=37)	44% (n=77)	11% (n=20)

BSID-III, Bayley Scales of Infant and Toddler Development III; PEDS, Parents' Evaluation of Developmental Status; PEDS-DM, PEDS-Developmental Milestones; PEDS tools, combined PEDS and PEDS:DM smartphone application

Domain specific outcomes (language, motor, and social emotional) of the PEDS tools and BSID-III was compared (Aylward, 2011). Outcomes indicate that twice the number of participants were identified as having developmental delay on the PEDS tools in relation to the BSID-III in all domains (Table 5.3).

Table 5.4. Developmental domain–specific comparison of the PEDS tools, PEDS and PEDS-DM in and the BSID-III.

Developmental Domain	**PEDS**	**PEDS-DM**	**PEDS tools**
Language			
Identification of cases with delay	10%	52%	52%
Identification of cases without delay	94%	83%	80%
Motor			
Identification of cases with delay	9%	61%	61%
Identification of cases without delay	92%	58%	54%
Social-emotional			
Identification of cases with delay	0%	21%	21%

Identification of cases without delay	96%	89%	86%

BSID-III, Bayley Scales of Infant and Toddler Development III; PEDS, Parents' Evaluation of Developmental Status; PEDS-DM, PEDS-Developmental Milestones; PEDS tools, combined PEDS and PEDS:DM smartphone application

Identification of developmental delay in the language domain was significantly higher for the PEDS tools than the BSID-III (p=0.001). No statistically significant difference was noted in the social emotional domains of the PEDS tools compared to the BSID-III.

5.4. Discussion

More than a third (35%; n=61/174) of infants in the current study were identified as having a developmental delay on the BSID-III. This prevalence rate is higher than the 24% identified in Brazil (Ertem, 2012), and in agreement with reports of elevated rates in other LMICs (Ertem, 2012; Samuels et al., 2012; Maleka et al., 2016). This is not unexpected as an at-risk population was used, from a low income setting with high rates of drug and alcohol abuse, crime, HIV and unemployment (Statistics South Africa, 2011; Van Der Linde, Swanepoel, Glascoe, Louw, & Vinck, 2015). In LMIC's, children are often exposed to a combination of risk factors that limit them reaching their developmental potential (Rademeyer & Jacklin, 2013). These factors include poverty, and its associated health and social factors, in addition to various environmental and other risks. Some delays may be more influenced by these factors than others; and some as a primary effect while others as a secondary effect. The presence of risk factors, exacerbated by resource-limited settings, may increase the probability of delayed development (Van Der Linde et al., 2015).

Referral rates on the BSID-III may be elevated in the current study, as researchers have expressed their concerns about its interpretation in infants and young children. Recent studies in the United States, United Kingdom, and Australia have raised concerns that BSID-III assessments may significantly underestimate the rate of developmental delay in preterm and full-term infants (Ahn & Kim, 2017). A further limitation of the BSID-III in this study is that it has not been culturally adapted for the South African population. The BSID-III is a comprehensive test, but may be influenced by the natural uneven course of child development. The large number of test items may increase reliability, but requires a child to concentrate for a long period of time. The long duration of the test may reduce the validity of the test results (Aylward, 2018). Although test items may yield valuable information, some may be difficult

to elicit in a clinical situation. As this may not be adequate by itself to determine all the functions needed, it becomes necessary to identify the right combination of tools that best determines developmental abilities and eligibility for intervention for young children and their families. A combination of screening tools and diagnostic measures has thus been recommended, with phone screening between 3-12 months and detailed developmental assessment at 24-36 months (Aylward, 2018). Therefore, the difference between the outcome of the BSID-III and the PEDS tools smartphone application may be due to the BSID-III's underestimation of developmental delays in infants.

The high referral rate identified by the PEDS tools (56%) was consistent with findings of past research conducted in other LMIC contexts (Maleka et al., 2016; Brothers et al., 2008). Similar referral rates have also been reported with this screening tool in previous studies conducted in comparable South African communities. A referral rate of 51% was found with 142 mothers of infants aged 6-18 months in Mamelodi (Maleka et al., 2016); and of 52% with 102 mothers of young children aged 6-12 months in Olievenhoutbosch and other areas in Tshwane (Van der Linde et al., 2016). As screening isolates a small group of individuals, high referral rates can be expected. However, high referral rates further constrain limited resources to accommodate referrals in underserved communities in LMICs like South Africa. To reduce the referral rates, ongoing surveillance is recommended to initiate formal screening for those at risk for delay (Hirai, Kogan, Kandasamy, Reuland, & Bethell, 2018). Maleka et al. (2019) indicated that altered referral criteria may significantly improve the feasibility of developmental screening and surveillance in underserved PHC contexts. The use of less stringent referral criteria of the PEDS tools decreased the referral rate by 25% in infants aged 5-12 months, and by 29% in young children 13-18 months of age (Maleka et al., 2019). The adapted referral criteria, suggested by Maleka et al. (n.d.) to identify more severe delays first, may result in fewer referrals but may also result in the PEDS tools being less sensitive to mild delays. However, this type of adaptation must be investigated to avoid overburdening the constrained healthcare system in high-risk populations with limited health resources (Maleka et al., 2019).

Implementing alternative referral criteria could possibly enable referrals to be prioritized based on severity (Maleka et al., 2019), and could improve the performance of the various measures. The adapted referral criteria used to interpret the combined PEDS tools in this study indicated

poorer identification of cases with developmental delay (39.3%), but improved identification of infants without delay (81.4 %). These poor results undermine the ability of the tool to correctly identify children at risk of developmental delays whilst correctly excluding those without risks, and are insufficient for the tool to be deemed accurate (Glascoe, & Nolensville, 2013). Elevated rates of false positive results can raise concerns and anxiety for parents of children whose development is within normal range on further assessment (Sices, Drotar, Keilman, Kirchner, Roberts, & Stancin, 2008).

Most studies focusing on the use of developmental screening and surveillance tools exclude young infant age groups that were included in this study (Veldhuizen et al., 2015). Difficulties in social interaction, communication and behavior are not always clearly noticeable in children younger than 3 years (Van der Linde et al., 2016). Parental awareness of their children's development in these domains may also be better when the children are older (Van der Linde et al., 2016). As most developmental disorders are not easily identifiable among young infants, the use of standardized assessments in this age range may need to be reconsidered (Veldhuizen, Clinton, Rodriguez, Wade & Cairney, 2015). Inaccuracies in parental reporting, most often used with young infants, may contribute to the under- or over-referral results on the developmental screening measures, resulting in poorer performance than expected when compared to older children. The PEDS (in isolation) revealed poor identification of cases with delay (0-10%) for specific domains (language, motor and social-emotional). Utilizing the PEDS in combination with the PEDS: DM could facilitate improved communication with caregivers and increases the likelihood of them attending follow-up visits. The use of the combined PEDS tools is a more accurate approach to developmental screening than using the tools individually. The PEDS tools were effective in identifying communication delays in infants aged 6 months in South Africa (Glascoe, 2013). The current study also found that the combined PEDS tools demonstrated improved domain specific outcomes in language, motor and social-emotional domains.

5.5. Conclusion

Traditional assessment has both advantages and disadvantages in identifying developmental delay in infants and young children. The agreement between developmental assessment outcomes across the tools used in this study was poorer than expected. The high-risk nature

and young age cohort (<18 months) may have contributed to these outcomes. Findings raise concerns about the outcomes of the BSID-III or PEDS tools in isolation for screening and assessment of developmental delay in infants from LMICs like South Africa. Future research should evaluate performance of the PEDS tools mHealth version in older preschool children (between 2 and 5 years) to ascertain the influence of age. Further investigations into the validity of the PEDS tools and BSID-III for young infants in LMICs should also be prioritised prior to large scale implementation (Aylward, 2018).

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5.8. Disclosure statement

There are no conflicts of interest declared.

5.9. References

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CHAPTER 6

GENERAL DISCUSSION, IMPLICATIONS, AND CONCLUSIONS

6.1. Overview of research findings

The current research project entailed three studies, which aimed to describe the prevalence and nature of developmental delays in young children in South Africa, to describe the global usage of the three screening options with the PEDS instruments (PEDS, PEDS:DM, and PEDS tools) to identify developmental delays, and to compare the detection of developmental delays in young children using the PEDS tools and the BSID-III. Study I investigated the developmental characteristics of children aged 3-36 months using the BSID-III in a low-income community. Descriptions of children's domain-specific developmental characteristics in specific populations support the planning and implementation of required early intervention services. Prevalence of developmental delays in the study population increased with age from 33.1% (n=45) for children under 12 months to 61.7% (n=79) and 66.3% (n=59) for children between 13- 24 months and 25- 36 months respectively. Females were 1.82 times more likely to have had no signs of a developmental delay; 2.30 times in motor and 2.06 times in adaptive behaviour domains. One hundred and one (28.6%) participants across all age groups displayed superior social-emotional ability, possibly due to familial structures and relationships. Another third (n=116, 32.9%) presented with poor adaptive behaviour function, presumably attributed to cultural differences impacting caregiver expectations.

Children from various cultural groups may not master certain skills expected from them by measuring instruments, as the tasks are not culturally valid or acceptable (Semrud-Clikeman et al., 2017). For example, in many LMIC settings in South Africa, children do not have stairs in their homes; therefore, items that assess motor development or adaptive behaviour based on the climbing of stairs may be inappropriate. The findings

of this study contribute to the understanding of the developmental characteristics of young children in South Africa, which can inform intervention and public health policy nationally by outlining developmental profiles clinicians can expect and advocating for the need for EI services. This study also found that, if certain items are not adapted, the PEDS tools may not be appropriate developmental surveillance tools within LMICs including Thailand and South Africa due to cultural and linguistic differences (Chunsuwan et al., 2016; Dreyer et al., 2016; Maleka et al., 2019).

Study II comprised a scoping review, using the PRISMA-P guidelines. The review aimed at describing the use of the Parents Evaluation of Developmental Status (PEDS), PEDS: Developmental Milestones and the PEDS Tools. Direct comparison between studies was not possible due to heterogeneity of population characteristics and contexts. The findings indicated that there was no pattern to the use of the PEDS, PEDS:DM and PEDS tools across contexts. The PEDS is well-established globally and is often used for the screening of developmental delay. On the other hand, less research has been conducted globally on the use of the PEDS:DM and the PEDS tools combined, as well as on how these tools perform when used with children in LMIC contexts. The review did, however, identify factors that may influence the use of the screening measures such as how cultural interpretations of the PEDS content does not seem to affect performance on the PEDS, PEDS:DM and PEDS tools.

Detecting developmental delays is essential for early intervention in low- to middle-income countries. Study III compared the detection of developmental delays in young children aged 3–18 months using the PEDS tools and the BSID-III. The overall and domain-specific performance (language, motor, and social-emotional) was compared. The PEDS tools identified 56% (n = 97), and the BSID-III 35% (n = 61) of the 158 children with possible developmental delays, with an overall agreement of 65% between tests. The PEDS tools referral rate was significantly higher (p=0.004) than the BSID-III. The high-risk nature of the test population and young age group (one group infants/toddlers aged 3-18 months and the other infants/toddlers aged 19-42 months) may have contributed to poor agreement across tools. The study's cohort population came from an underserved community, and thus a number of children may have received false positive diagnoses, or a positive diagnosis according to one tool

in the absence of a diagnosis with the other tool. A combination of tools for screening and assessment in infants in a South African PHC context may improve identification and surveillance.

When considering the overarching aim of the research project, namely to explore the value and applicability of caregiver report by means of the PEDS, PEDS:DM AND PEDS tools (smartphone application) to describe the developmental characteristics of young children and to identify developmental delays in underserved communities, some general conclusions can be drawn. It has been firmly established that early identification of developmental delays is important to ensure early intervention, and to reduce the impact of delays on the child, family, and society (Ertem, 2012; Samuels et al., 2012; Scherzer et al., 2012; Richter et al., 2017; Hirai et al., 2018). Various screening options, such as the BSID-III together with the PEDS tools, have the potential to identify developmental delay (Fischer et al., 2014). However, the high referral rate on the PEDS tools as well as the poor agreement between the PEDS tools and the BSID-III may suggest that the PEDS tools are currently not optimal for the South African context. Adaptation and further development of the PEDS tools may be required to improve referral rates and to better suit the high-risk South African population. The potential use of the PEDS tools as a means for screening within existing healthcare systems, such as integration into well-child visits, must also be considered carefully with regard to its applicability (Maleka et al, 2019; van der Merwe et al., 2019). Improved, less stringent referral rates could decrease the number of children who are referred to receive services from the overburdened healthcare system in South Africa (Maleka et al., 2019). The notion of prioritised referral should also be considered. Ongoing developmental monitoring may assist with the identification of children who are most at risk of developmental delay.

The South African Government has prioritised ECD within its National Development Plan (NDP) 2030, and advocates screening on a large scale. Such a programme would also benefit from improved referral rates (National Planning Commission, 2010). The use of mHealth is encouraged as a way to reach SDG three (health and wellbeing) and four (inclusive and equitable quality education to promote lifelong learning opportunities) goals by 2030, by which time the PEDS tools may have been adapted and validated, and be used as a risk assessment tool or in combination with other tools

to facilitate developmental screening and surveillance nationally (Maleka et al, 2019; van der Merwe et al., 2019). mHealth solutions demonstrate the potential to support early identification and intervention for young children (Eksteen et al. 2019; Manus et al. 2021) and should be explored in forthcoming early development research.

6.2. Clinical implications

The conclusions drawn from studies I-III were used to describe developmental screening using mHealth technology from a South African perspective, within the NCF (Pierce, 2020). Effective developmental screening would provide additional support to professionals as well as parents, especially in vulnerable populations in LMICs. The NCF has been integrated into South Africa's new RTHB and Side-by-Side campaign (Shung-King et al., 2019). Due to the high-risk nature as well as the extended age range of children in this research project, a combined protocol including the PEDS tools and a diagnostic developmental assessment measure is recommended, with smartphone screening between 3 and 12 months and detailed developmental assessment at 24– 36 months (Aylward, 2018). The PEDS tools are appropriate for use by healthcare workers as well as community healthcare workers (CHWs) in South Africa, although they are not viable to be used in isolation at present, as indicated by their poor agreement with a gold standard tool (the BSID-III). The proposed screening opportunities are important entry points for multi-sectoral interventions, such as efficient early intervention, which are necessary to provide the required services for all families and young children in need (Black et al., 2017). Prioritised referral can also take place at these regular intervals, wherein children identified as at high risk for developmental delays during the screening process are referred for diagnostic developmental assessment (Maleka et al., 2019). Implementing such prioritised screening and surveillance would contribute to determining developmental abilities and eligibility for early intervention for young children and their families. Although the findings from the research projects are preliminary in nature, their application within this collaborative framework should be explored in future research.

Young children's development is dependent on consistent nurturing care, which ensures health, nutrition, caregiving, learning, and safety (Bamford et al., 2019). Multiple factors influence these domains of care, such as socioeconomic status and

access to healthcare. Clinically, understanding the developmental profile of children in LMICs will contribute to guidelines for best practice, as understanding these developmental profiles assists in tailoring developmental assessment to fit the needs of this population. Understanding the extent and prevalence of developmental delays in a population facilitates informed advocacy for provision of EI services for these children. The findings from study I describe the nature of expected developmental characteristics, and areas of concern. Understanding the developmental profile of a population may also aid healthcare professionals and CHWs in the identification of children at greater risk of developmental delay and indicate red flags to look out for. This allows for the identification of developmental areas that may be affected in children within communities and population groups that are greatly influenced by cultural beliefs and practices. Screening and diagnostic assessment must be adapted to be more relevant to cultural differences, and understanding developmental profiles of a population may be of assistance in that regard. Clinically, this would also aid in the promotion as well as the development and implementation of stimulation guidelines or activities for professionals and parents, using mHealth tools at various intervals (e.g. MomConnect and the RTHB health-promotion messages), implementing nurturing care, and supporting a comprehensive approach to child development. This form of information-giving, supporting responsive caregiving as per the NCF, should take place at regular intervals hand-in-hand with ongoing developmental monitoring.

Sixty-three percent of the studies included in Study II were conducted in HIC where ECD services are often available and subsidised (Engle et al., 2011). However, the results from this study highlight factors, such as cultural interpretation, that potentially influence the validity and widespread use of the screening measures. The findings contribute to evidence supporting the use of the PEDS, PEDS:DM and PEDS tools in diverse settings and populations, including LMICs. The findings of Study II show that although the PEDS can be used as a standalone measure to identify developmental delay, using the PEDS and PEDS:DM in combination as the *PEDS tools* is more advantageous, especially in the LMIC context. The PEDS tools applications could therefore be used as part of risk assessments as well as in combination with other diagnostic tools to identify developmental delay. This model of service delivery could

be applied in health as well as education and form part of ECD initiatives across the public and private sectors.

An mHealth solution could be viable in the underserved South African population, where children are at risk of developmental delays. The integration of mHealth solutions may require a deliberate and intentional strategy to prepare healthcare professionals, as suggested by Martec's Law which states that technology changes exponentially while organizations or systems change logarithmically (Wiljer & Hakim, 2019). The implication is that there is a need for training, practice, and cultural change for people to accept and effectively engage with and use these technologies (Wiljer & Hakim, 2019). Introducing screening at regular intervals provides opportunities for constructive engagement while ensuring developmental surveillance. For healthcare professionals and systems to benefit from the use of remote mHealth technology and tools, these tools should be absorbed into practice and into the culture of the systems (Wiljer & Hakim, 2019). As the PEDS tools can be used remotely, their implementation could increase access to developmental screening and surveillance, and facilitate timely referrals to healthcare professionals for early intervention. This is particularly valuable within the current climate of COVID-19 and its restrictions, especially in terms of in-person contact. With the advent of COVID-19, and more parents being faced with increased workloads, there are nevertheless opportunities for parents to provide increased support to their children. However, as parents may not always be aware of what can be expected from their child in terms of development, it is proposed that regular information sharing be promoted as well.

Routine developmental surveillance may provide parents and professionals with support and timely referrals to stimulate language, literacy, and other academic skills in diverse populations (Bamford et al., 2019). The screening process should be paired with information-giving to facilitate responsive caregiving. Following the identification of signs of a developmental delay as a result of the screening process, necessary referrals can be made to healthcare professionals for diagnostic assessment to take place. The proposed routine screenings using both mHealth and traditional diagnostic assessments would contribute to an environment that enables nurturing care, and

prioritises the provision of services to children and families. Although the results may not be significant yet, the immediate and long-term effect on human capital without further widening the digital divide should be considered (Bamford et al., 2019; Kumm et al., 2021). mHealth screening and surveillance tools have the potential to reduce disparities in service delivery between communities of varying socio-economic statuses (Kumm et al., 2021). The use of mHealth applications such as the PEDS tools or the mobile application of the RTHB (eRTHB) by various stakeholders may create larger-scale access in local settings where specialist services are poor or non-existent, and serve to facilitate better outcomes for children from vulnerable populations.

6.3. Study strengths and limitations

A critical evaluation of the research project's strengths and limitations are provided in the ensuing section.

Study strengths

- The comparative nature of Study I and Study III's designs strengthen the findings of these studies, as the statistical analysis performed allowed the researcher to establish correlations within the dataset.
- The within-subject design reduces the risk of errors and is more statistically powerful than a between-subjects design. This is because individual variation is removed, i.e. participant characteristics are controlled for.
- The cross-sectional design of Studies I and III allowed for greater flexibility during the research process, allowing adaptability where new findings arose. It considers multiple variables at one point in time and allows for relationships between these variables to be analysed.
- The scoping review of Study II provided an overview and synthesis of evidence regarding the use of the PEDS, PEDS:DM and PEDS Tools to identify developmental delays. The PRISMA-P protocol utilised in this study provided a

replicable, transparent, and rigorous method for the overview and synthesis of existing literature, that is also deemed a high level of evidence.

- Study II allowed for a focus on the current state of research regarding the PEDS, PEDS:DM and PEDS Tools and the use of these tools worldwide. This outline of current research may serve to guide future systematic reviews on the topic.

Study limitations

- The BSID-III has not yet been culturally adapted for the South African population. The BSID-III is also limited in that, while it is a comprehensive tool, it may be affected by the naturally uneven course of childhood development. Additionally, while the large number of test items may increase reliability, it requires a child to concentrate for a long period of time.
- The population sample in this project does not represent the spectrum of diversity across LMICs but is representative of a single low-income community within South Africa; consequently, results cannot be generalised to all children across other socioeconomic, linguistic, and cultural groups.
- The data collection measures used in Studies I and III were not developed in or normed for South Africa, which was a limitation in this research project. Although the BSID III and the PEDS tools were found to be appropriate for use in the South African context, the lack of standardised assessment measures for the South African population (Moonsamy et al., 2017) is generally a limitation.
- Study II was limited in that, when using a scoping review design, one does not formally evaluate the quality of evidence as is the case in a systematic review.

6.4. Recommendations for future research

Recommendations for future research emanating from the results and conclusions of this research project are discussed below.

- Scoping reviews that identify a dearth in research conducted in LMICs, such as study II, outline the need within a field. The need for research from diverse settings and LMICs in general was identified, and it is recommended that a systematic review on the validity of the PEDS, PEDS:DM and PEDS tools be conducted following the findings of study II.

- The investigation of standardised tools suitable for an LMIC context requires more attention. More specifically, the PEDS tools and their use in the LMIC context require extensive research regarding applicability and use in combination with other diagnostic tools. This includes the potential use of a combined protocol including the PEDS tools and a diagnostic developmental assessment measure. The PEDS tools have generated more interest in many LMICs, especially with regard to use in a mHealth format. However, as findings are not consistent between and within all LMIC contexts, such as the agreement of the PEDS tools with a golden standard tool, research results from one context cannot be generalised to diverse populations and all LMICs.

- It is recommended that further research be conducted to support the use of PEDS, PEDS: DM and PEDS tools for the diverse multilingual, multicultural and socioeconomic populations in various LMICs. This research should evaluate the performance of the PEDS tools mHealth version in older preschool children (between 2 and 5 years) to ascertain the influence of age. More research regarding adapting screening and assessment to be more relevant to cultural differences is also recommended. Further investigations into the validity of the PEDS tools and BSID-III for young infants in LMICs should also be prioritized prior to large scale implementation (Aylward, 2018). Future studies should compare the use of the PEDS tools to a gold standard, with a larger and more diverse population.

- Research on developmental characteristics of children across LMICs is also required, in order to tailor developmental resources and programmes and to

inform intervention approaches, making sustainable contributions to service delivery that are both family-centred and community-based. Information-giving to support responsive caregiving, taking place at regular intervals with ongoing developmental monitoring, requires more research within the LMIC context.

- There is a lack of consensus on which screening tools are most effective, especially where tools are used in cultures other than those in which they were created (Marlow et al., 2019; Sabanathan et al., 2015). The investigation of standardized tools suitable for an LMIC context requires more attention. A tiered screening approach to identifying developmental delays or disorders requires further investigation.

6.5. Conclusions

This project contributes to emerging research on developmental assessment in young children in LMICs like South Africa. These findings may assist in the adjustment of guidelines regarding the assessment and identification of developmental delays in South African children, as it provides an understanding of their developmental profiles. For allied health professionals, such as SLPs, this knowledge can be useful in a number of ways. Understanding the needs of children in a particular population allows effective advocacy for this population, particularly for timely identification of delays and prioritised referrals. This study demonstrated how developmental profiles may be influenced by familial structures and cultural differences, as exemplified by the one-third of children who presented with superior social-emotional skills as well as the children who presented with low levels of functioning in the adaptive behaviour domain in Study I. Understanding the course of healthy development and the effect of a child's settings and customs, as well as in-depth knowledge of ethno-theories and how they interact is essential for understanding development (Marlow et al., 2019), and this project contributes to that understanding. This project identified a dearth of research regarding the PEDS: DM and PEDS tools globally, and highlights factors such as cultural interpretation that influence the validity and widespread use of the screening measures. This is especially true for high-diversity settings, disparate populations, and LMICs in general. Traditional assessment has both advantages and disadvantages in

identifying developmental delays in infants and young children. The agreement between developmental assessment outcomes across the tools used in this research project was poorer than expected. The high-risk nature of the study population and young age cohort (<18 months) may have contributed to these outcomes. Although findings raise concerns about the outcomes of the BSID-III or PEDS tools in isolation for screening and assessment of developmental delay in infants from LMICs like South Africa, screening using a combination of mHealth and traditional assessment tools is recommended for use by professionals such as SLPs. Tiered screening approaches, as well as further studies on developmental characteristics of children across LMICs, are required, to tailor developmental resources and programmes and to inform family-centred and community-based intervention approaches that will make sustainable contributions to service delivery.

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APPENDIX A

Ethical Approval Letter

Tshwane research committee

Kuyasheshwa! Gauteng Working Better

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

427 Hilda Street, 4th floor, The Fields Building, Hatfield Pretoria 0001 South Africa. Tel: +27 12 451 9036
Enquiries: Dr. Molapane Chueu-Shabangu
e-mail: Molapane.Shabangu@gauteng.gov.za

TSHWANE RESEARCH COMMITTEE

CLEARANCE CERTIFICATE

Meeting: N/A

PROJECT NUMBER: 31/2016

Title: Developmental screening using mobile health technology: A South African primary health care perspective

Researcher: Shabnam Abdoola

Supervisor: Prof. De Wet Swanepoel, Dr. Jeannie Van Der Linde

Department: Speech-Language Phatholoy and Audiology, University of Pretoria

DECISION OF THE COMMITTEE

Approved

NB: THIS OFFICE REQUESTED A FULL REPORT ON THE OUTCOME OF THE RESEARCH DONE

Date: 16/08/2016

.....
Dr. Molapane Chueu-Shabangu
Chairperson Tshwane Research Committee
Tshwane Health District

.....
Mr. Pitsi Mothomone
Chief Director: Tshwane District Health
Tshwane District

NOTE: Resubmission of the protocol by researcher(s) is required if there is departure from the protocol procedures as approved by the committee.

Postgraduate Research Ethics Committee

Faculty of Humanities

University of Pretoria

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

1 July 2016

Dear Prof Vinck

Project:	**Developmental screening using mobile health technology: A South African primary health care perspective**
Researcher:	**S Abdoola**
Supervisor:	**Prof Dewet Swanepoel**
Department:	**Speech-Language Pathology and Audiology**
Reference number:	**23025914 (GW20160607HS)**

Thank you for the application that was submitted for ethical consideration.

I am pleased to inform you that the above application was **approved** by the **Research Ethics Committee** on 30 June 2016. Data collection may therefore commence.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should the actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

The Committee requests you to convey this approval to the researcher.

We wish you success with the project.

Sincerely

Prof Maxi Schoeman
Deputy Dean: Postgraduate Studies and Ethics
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail:tracey.andrew@up.ac.za

Kindly note that your original signed approval certificate will be sent to your supervisor via the Head of Department. Please liaise with your supervisor.

APPENDIX B

Information letter to caregivers of participants and consent slip

Study I and Study III

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology andAudiology

Dear Parent/Participant

TITLE OF RESEARCH STUDY: Developmental screening using mobile health technology: A South African Primary Health Care Perspective

INTRODUCTION
You and your child are invited to participate in a research study. This information leaflet will help you to decide if you want to participate. Before you agree to take part you should fully understand what is involved. If you have any questions that this leaflet does not fully explain, please do not hesitate to ask the researcher.

THE NATURE AND PURPOSE OF THIS STUDY
It is essential to conduct developmental screening at a primary health care (PHC) level, to find babies with developmental difficulties. This will help to ensure that these babies and their families can get help. By administering the PEDS tools smartphone application and the Bayley Scales of Infant & Toddler Development III, we hope to validate the mobile application for use in South African PHC contexts. Parents and their babies from birth-42 months, who are supported by primary health care at Stanza Bopape clinic in the city of Tshwane, will be asked to participate in the research study.

THE DURATION OF THIS STUDY
If you decide to participate and allow your child to participate, you and your child will be two of approximately 270 participants. The study will be conducted during 2016 and 2017. You and your child will be expected to consult with the researcher and fieldworkers once at Stanza Bopape clinic. The testing time will not take more than 60-90 minutes of you and your child's time.

EXPLANATION OF PROCEDURES TO BE FOLLOWED
This study involves answering some questions about your child's background history and development. The PEDS tools smartphone application will be conducted with you. The researcher and fieldworkers will play with your child while you are present. The Bayley Scales of Infant & Toddler Development III will be completed in a play-based assessment, which is not stressful in any way. Toys will be used to elicit the responses. You are welcome to participate and hold your child if he/she cries.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?
This research study proposal has been submitted to the Faculty of Health Sciences Research Ethics Committee, the Faculty of Humanities Research Ethics Committee and the Tshwane research ethics committee. Written approval has been granted by these committees.

WHAT ARE YOU AND YOUR CHILD'S RIGHTS AS PARTICIPANTS?
Your and your child's participation in this study is entirely voluntary. You can refuse for you and your child to participate or stop at any time without giving any reason. Your withdrawal will not affect you or your child's access to other medical care. The researcher retains the right to withdraw you and your child from the study if it is considered to be in your best interest.

RISK AND DISCOMFORT INVOLVED
There are no risks in participating in the study. No discomfort or inconvenience will be caused, and you and your child's safety and security will not be compromised by this study.

University of Pretoria
Pretoria 0002
South Africa

Tel 012 420 6485
Fax 012 420 3517

Shabnam.abdoola@up.ac.za
www.up.ac.za

POSSIBLE BENEFITS OF THIS STUDY
You will benefit directly by the study because you will receive feedback on your child's development. Therefore, if necessary, you will be referred for specialized services.

CONFIDENTIALITY
All information obtained during this study will be kept strictly confidential. Data that may be reported in articles in scientific journals will not include any information that may identify you or your child. The data collected will be stored for a minimum of 15 years at the University of Pretoria.

If you are willing to allow yourself and your child to participate in our research study, please sign the attached consent form. If you have any further questions, please feel free to contact me at (012) 420 6485.

Kind regards

Miss S Abdoola
Researcher

Prof DW Swanepoel
Supervisor

Dr J Van Der Linde
Supervisor

Prof B Vinck
Head: Department Speech Pathology & Audiology

CONSENT TO PARTICIPATE IN THIS STUDY

I confirm that I have been informed by the researcher, Miss Shabnam Abdoola, about the nature, process, risks, discomforts and benefits of the study. I have also received, read and understood the above written information (Information Leaflet and Informed Consent) regarding the study.

I am aware that the results of the study, including personal details, will be anonymously processed into research reports. I am participating willingly. I have had time to ask questions and have no objection for myself and my child to participate in the study. I understand that there are no negative consequences should I wish to discontinue with the study and my and my child's withdrawal will not affect any access to other medical services in any way.

Please indicate whether you give permission that the data may be used or future research. Herewith I give consent that the data obtained in the current study may be used for future research as well:

Yes ☐ No ☐

(Please tick the relevant block)

Parent's (participant one) name: .....
(Please print)

Parent's (participant one) signature: .....

Date.....

Child's (participant two) name: .....
(Please print)

Researcher's name: Shabnam Abdoola

Researcher's signature: ..... Date: .....

Witness's Name: .....
(Please print)

Witness's signature: ..... Date: .....

VERBAL INFORMED CONSENT

I, the undersigned, Miss Shabnam Abdoola, have read and have fully explained the participant information leaflet, which explains the nature, process, risks, discomforts and benefits of the study to the parent and child participants whom I have asked to participate in the study.

The parent participant indicates that s/he understands that the results of the study, including personal details regarding the interview will be anonymously processed into a research report. S/he understands that s/he and his/her child will be free to withdraw from the research for any reason at any time.

I hereby certify that the parent has agreed for him/herself and his/her child to participate in this study.

Parent's (participant one) name: .....
(Please print)

Child's (participant two) name: .....
(Please print)

Researcher's name: Shabnam Abdoola

Researcher's signature: ..... Date: .....

Witness's Name: .....
(Please print)

Witness's signature: ..... Date: .....

APPENDIX C

Permission Letter from Stanza Bopape Clinic

Study I and Study III

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology andAudiology

Dear Sir/Madam

REQUEST TO CONDUCT A RESERACH PROJECT AT STANZA BOPAPE CLINIC

I hereby request permission to conduct a study entitled "Developmental screening using mobile health technology: A South African Primary Health Care Perspective" at your clinic.

THE NATURE AND PURPOSE OF THIS STUDY
It is essential to conduct developmental screening at a primary health care (PHC) level, to identify babies with developmental difficulties. This will help to ensure that these babies and their families can get help. By administering the PEDS tools smartphone application and the Bayley Scales of Infant & Toddler Development III, we hope to validate the mobile application for use in South African PHC contexts. Parents and their babies from birth-42 months, who are supported by primary health care at Stanza Bopape clinic in the city of Tshwane, will be asked to participate in the research study.

Participation in this study is entirely voluntary. Participants may withdraw at any time without any negative consequences.

THE DURATION OF THIS STUDY
The PhD study will be conducted for an estimated ten month period during 2016 and 2017. I hereby request that an interview room be made available to the researcher during the data collection procedure.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?
This research study proposal has been submitted to the Faculty of Health Sciences Research Ethics Committee, the Faculty of Humanities Research Ethics Committee and the Tshwane research ethics committee. Data collection will commence only after written approval has been granted by these committees.

CONFIDENTIALITY
All information obtained during this study will be kept strictly confidential. Data that may be reported in articles in scientific journals will not include any information that may identify any participants. The data collected will be stored for a minimum of 15 years at the University of Pretoria.

If you require any information, or have any further enquiries, please do not hesitate to contact us at (012) 420 6485 (Miss Abdoola) or (012) 420 2948 (Dr Van Der Linde).

Kind regards

Miss S Abdoola
Researcher

Prof DW Swanepoel
Supervisor

Dr J Van Der Linde
Supervisor

Prof B Vinck
HoD

University of Pretoria
Pretoria 0002
South Africa

Tel 012 420 6485
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Shabnam.abdoola@up.ac.za
www.up.ac.za

Annexure 1

Declaration of intent from the clinic manager or hospital CEO

I give preliminary permission to SHABNAM S. ABDOOLA (name of researcher) to do his or her research on _____ (research topic) in

STANZA BOPAPE CLINIC (name of clinic) or

_____ (name of CHC) or

_____ (name of hospital).

I know that the final approval will be from the Tshwane Research Ethics Committee and that this is only to indicate that the clinic/hospital is willing to assist.

Other comments or conditions prescribed by the clinic or CHC manager or hospital CEO:

Signature
Clinic Manager/CHC Manager/CEO

21. 07. 2016
Date

APPENDIX D

Proof of acceptance from Journals

Journal of Child Health Care (Study I)

Journal of Child Health Care

Home

Author

Review

Submission Confirmation

Print

Thank you for your revision

Submitted to
Journal of Child Health Care

Manuscript ID
JCHC-2020-0216.R1

Title
Developmental characteristics of young children in a low-income South African community

Authors
Abdoola, Shabnam
Swanepoel, De Wet
Graham, Marien
van der Linde, Jeannie

Date Submitted
11-May-2021

Author Dashboard

Journal of Early Intervention (Study II)

Shabnam Abdoola <shabnam.abdoola@up.ac.za>

Journal of Early Intervention -Decision on Manuscript JEI-21-065.R1

Journal of Early Intervention <onbehalfof@manuscriptcentral.com> 23 November 2021 at 20:14
Reply-To: kmissal@uw.edu
To: shabnam.abdoola@up.ac.za

23-Nov-2021

Dear Miss Abdoola:

Thank you for resubmitting your manuscript, "A Scoping Review on the use of the Parents Evaluation of Developmental Status (PEDS) and PEDS: Developmental Milestones Screening Tools" (JEI-21-065.R1) to the Journal of Early Intervention. Reviewers from the Editorial Board also reviewed the first submission of this manuscript. Both Reviewers remarked on authors response to recommendations for revision. Both Reviewers want to see additional revisions, and recommended the manuscript be accepted with revisions. I concur. I will outline remaining needs below for the paper to move forward with JEI.

1) Provide a clear and strong rationale for combining the PEDS and PEDS:DM into the PEDS Tools (see Reviewer 1). I support Reviewer 1's recommendation to edit the abstract and introduction (p. 5 before Table 1) accordingly.

2) Adding items and measure details makes this a stronger manuscript. Thank you. It also raises new questions. For example, it now seems clear that the administration process and instructions are different from the PEDS and PEDS:DM. Please clarify thoroughly. If there are administration, procedural, scoring, etc. differences between two, then combining them creates questions and concerns that must be addressed in the manuscript (see Reviewer 2).

3) Please explain clearly that less research is available for the PEDS:DM and PEDS Tools compared to the PEDS (Reviewer 2).

4) I agree with Reviewer 2 that this sentence should be deleted from page 6: "It is important to note that all of these tools are merely used to identify signs of a developmental delay, rather than the diagnosis of a delay." Because all assessments have a specific purpose, please focus on the purpose of the tools – screening – rather than adding other purposes, which can be misleading and confusing to readers (see Reviewer 2). Please attend to this clarity of language throughout and refer to the PEDS Tools only as screeners.

5) The manuscript must be formatted according to the American Psychological Association Publication Manual 7th edition. I cannot send the paper forward for copy editing without proper formatting by the authors – even with positive reviews. At the current time all heading levels and spacing in the text do not comply with APA. Please present text as double-spaced throughout, with left justification and indented paragraphs per APA. Some of the references are formatted correctly, and others are not. The tables must be reformatted according to APA, including titles, spacing, and table presentation. Table 2 can be formatted as single-spaced. Please format tables to 1 page as possible. Please also format Tables and Appendix A to encompass as few pages as possible.

To revise your manuscript, log into https://mc.manuscriptcentral.com/idec-jei and enter your Author Center, where you will find your manuscript title listed under "Manuscripts with Decisions." Under "Actions," click on "Create a Revision." Your manuscript number has been appended to denote a revision. You will be unable to make your revisions on the originally submitted version of the manuscript. Instead, revise your manuscript using a word processing program and save it on your computer.

Once the revised manuscript is prepared, you can upload it and submit it through your Author Center.

When submitting your revised manuscript, you will be able to respond to the comments made by the reviewer(s) in the space provided. You can use this space to document any changes you make to the original manuscript. Please make sure this section is blinded as it is viewable to the reviewers. In order to expedite the processing of the revised manuscript, please be as specific as possible in your response to the reviewer(s). There is no word count or page limit for this response. Please do not upload your revised manuscript with your response to reviewers letter.

IMPORTANT: Your original files are available to you when you upload your revised manuscript. Please delete any redundant files before completing the submission.

Because we are trying to facilitate timely publication of manuscripts submitted to the Journal of Early Intervention, your revised manuscript should be uploaded within 90 days. If it is not possible for you to submit your revision within 90 days, we may have to consider your paper as a new submission.

Once again, thank you for submitting your manuscript to the Journal of Early Intervention and I look forward to receiving your revision.

Sincerely,
Kristen Missall, PhD, NCSP
Associate Editor, Journal of Early Intervention
kmissall@uw.edu

Reviewer(s)' Comments to Author:

Reviewer: 1

Comments to the Author
I found that the authors responded clearly to the reviewers' and editor's suggestions for revision. The aims of the paper, the process, the tools that were included, and the outcomes are much clearer. I still found that the concept of the PEDS Tools being a combination of the PEDS and PEDS DM is not totally clear. I think in the abstract (such as saying "PEDS Tools, i.e., use of PEDs and PEDS DM together") as well as adding a clarification of PEDS Tools to the paragraph on p. 5 right before Table 1 would make clearer from the beginning. The revisions have made this manuscript much stronger and a better candidate for publication in JEI.

Reviewer: 2

Comments to the Author
It has been a pleasure to review manuscript JEI-21-065.R1. In the original review, four points were discussed which will be revisited below.

1. One suggestion from the original review was to add examples of items from the PEDS and PEDS:DM. Three items from the PEDS response form and three items from the PEDS:DM response form are now included in Table 1. Being able to see the difference between the PEDS and PEDS:DM (Developmental Milestones) items is very helpful in understanding the instruments. However, a question remains. While seeing the response form is helpful, it raises a question about the process of administration for the PEDS:DM. The PEDS asks whether the parents have any concerns about various child behaviors ("Do you have any concerns about how your child talks and makes speech sounds?"). The PEDS:DM, however, asks whether the child can perform certain behaviors ("Can your child poke at things with just his or her first finger?") and is described as being obtained from parents "who can complete the PEDS:DM by report or observe as it is being administered directly to the child" (p. 5). The PEDS:DM items ask specific questions about child skills which parents may not be able to answer accurately without observing their child. This raises the question of whether filling out the form without observing the child is a possibility in completing the PEDS:DM. If so, there may be differences in scores on the PEDS:DM due to this difference in procedure. To be clear about the administration of the PEDS and the PEDS:DM, the process for administering and scoring both should be clearly described. If there are differences in the administration of the PEDS:DM, this concern should be addressed in the manuscript.

2. Another helpful addition is Table 2 from the current version of the manuscript which provides validity and reliability information for the instruments included in the scoping review when available.

3. The author(s) have also added a definition for scoping review which is helpful as this may be an unfamiliar term for many. Research from the scoping review, however, is mostly focused on the use of the PEDS with less research currently available for the PEDS:DM and PEDS tools.

4. A concern was expressed relative to wording in the prior version of this manuscript that suggested the three screening options of the PEDS could be used to identify developmental delay (p. 6 of prior version). While that wording has been changed, there is still wording that might be misinterpreted. For example, the following sentence is on p. 6: "It is important to note that all of these tools are merely used to identify signs of a developmental delay, rather than the diagnosis of a delay." This could be misunderstood and should be removed. The next sentence, however, does clarify: "The purpose of these screening tools is to identify the need for further referrals and evaluation." The latter point should be emphasized throughout.

It is the opinion of this reviewer that the changes described above in items 1 and 4 need to be incorporated into the manuscript prior to publication.

Journal of Early Child Development and Care (Study III)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Shabnam Abdoola <shabnam.abdoola@up.ac.za>

Early Child Development and Care - Decision on Manuscript ID GECD-2019-0052.R1

Early Child Development and Care <onbehalfof@manuscriptcentral.com> 3 June 2019 at 14:13
Reply-To: profrevans75@gmail.com
To: shabnam.abdoola@up.ac.za

03-Jun-2019

Dear Miss Abdoola:

Ref: Detecting developmental delays in infants from a low-income South African community: Comparing the BSID-III and PEDS tools

Our referees have now considered your revised paper and have recommended publication in Early Child Development and Care. We are pleased to accept your paper in its current form which will now be forwarded to the publisher for copy editing and typesetting.
You will receive proofs for checking, and instructions for transfer of copyright in due course.

The publisher also requests that proofs are checked and returned within 48 hours of receipt.

Thank you for your contribution to Early Child Development and Care and we look forward to receiving further submissions from you.

Sincerely,
Roy

Professor Roy Evans, PhD, FRSA

Editor,
Early Child Development and Care
profrevans75@gmail.com