SMARTPHONE-BASED DEVELOPMENTAL SCREENING BY COMMUNITY HEALTH CARE WORKERS

By

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ABBREVIATIONS

PHC: Primary Health Care
CHW: Community Healthcare Workers
SLP: Speech-Language Pathologist
PEDS: Parents’ Evaluation of Developmental Status
PEDS:DM: Parents’ Evaluation of Developmental Status: Developmental Milestones
RTHB: Road To Health Booklet
mHealth: Mobile Health
WHO: World Health Organization
COPC: Community Oriented Primary Care
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ABSTRACT

Developmental delays are more prevalent in lower income countries such as South Africa. However, access to developmental screening is severely limited. This study evaluated an mHealth version of a standard developmental screening tool, Parents Evaluation Developmental Status (PEDS) and PEDS: Developmental Milestones (PEDS:DM) for use by community health workers (CHWs) in terms of (1) correspondence with conventional paper-based testing by a speech language pathologist (SLP) and (2) inter-rater reliability compared to an SLP.

CHWs were trained in a primary health care (PHC) setting to administer the newly developed smartphone application version of the PEDS tools. A quantitative cross sectional, within subject research design was followed, by implementing a survey method. One SLP and two CHWs recruited 207 caregivers who were attending a baby wellness clinic. Caregivers were tested by one CHW using the smartphone application of the PEDS tools, a qualified SLP simultaneously recorded and scored the PEDS tools on the same participants.

High positive (100%) and negative correspondence (96%) was found between the paper-based PEDS tools and the smartphone application PEDS tools and between the SLP and CHW. Almost perfect (Cohen’s Kappa) inter-rater agreement between conditions was demonstrated ($\kappa=0.873$ to $\kappa=0.961$).

Outcomes of the smartphone application, operated by a CHW, corresponded closely to the gold standard PEDS tools operated by a health professional. Trained CHWs can conduct accurate developmental screening using the smartphone version of the PEDS tools. The smartphone version of the PEDS tools could be used as part of the Community Oriented Primary Care (COPC).

**Keywords:** Community health worker; smartphone application; developmental screening; primary health care; PEDS; PEDS:DM; speech language pathologist; mHealth; caregiver; community oriented primary care
1. RESEARCH PROPOSAL

1.1 Motivation, background, and research problem

It is estimated that at least 200 million children in developing countries are not reaching their full potential due to developmental delays (Irwin, Siddiqi & Hertzman, 2007). Of the 18.7 million children in South Africa, the majority are living in rural, poverty stricken areas (Van der Linde & Kritzinger, 2013). Children living in poverty are at an increased risk of a developmental delay (Van der Linde & Kritzinger, 2013). Consequently many South African children may not achieve developmental milestones at the expected age levels (Strasheim, Kritzinger & Louw, 2011).

Developmental delays are detected by using developmental screening measures. Early detection through developmental screening leads to assessment and early intervention (Lynn, Newton & Rae-Grant, 2012) which can minimise the developmental delay as neural plasticity allows infants and young children to learn new skills (Berk, 2004). Consequently future delays can be prevented (Berk, 2004). Screening measures can also be used in developmental surveillance, to monitor children who are at risk of developing a disability (World Health Organization [WHO], 2012).

Currently in South Africa the only implemented developmental screening tool is integrated as part of the Road to Health Booklet (RTHB) (Van der Linde, Swanepoel, Glascoe, Louw & Vinck, 2015). This tool is, however, not a standardized developmental screening tool and although it has high specificity (95%), it has low sensitivity (25%) (Van der Linde et al., 2015). This means that the RTHB developmental screen may fail to detect developmental delays, which could result in infants in need of early intervention services remaining undetected. Therefore, the RTHB developmental screen should be replaced or modified in order to improve early identification of infants and young children at risk of a developmental delay (Van der Linde et al., 2015). The accuracy of screening measures is of great concern, given their importance in the life of a child and his or her family (Macy, 2012). Any screening measure should therefore have a large supporting body of evidence reporting on its validity, reliability, and accuracy (Macy, 2012).
The Parents’ Evaluation Developmental Status (PEDS) and Parents’ Evaluation of Developmental Status: Developmental Milestones (PEDS:DM), i.e PEDS tools, are parent informant screening tools. The PEDS tools constitute evidence-based screen that elicits and addresses parents’ concerns about children's language, motor, self-help, early academic skills, behaviour, and social-emotional/mental health (Glascoe & Nolensville, 2013). The PEDS tools are effective in identifying developmental delays regardless of the parents' level of education, income, and race, and age of the child. The PEDS tools could be used as a developmental screening package in the underserved South African community. It could be a cost effective, quick way of identifying children with developmental delays (Glascoe & Nolensville, 2013).

In South Africa the implementation of early communication intervention services in Primary Health Care (PHC) is limited. This may be due to the lack of health policy on how to implement early communication intervention in PHC and low levels of awareness among the public and health professionals (Van der Linde & Kritzinger, 2013). PHC facilities have already been identified by audiologists as viable platforms for early identification of hearing loss (Swanepoel, Hugo & Louw, 2005). Since current service delivery is still limited, a proposal has been put forward that the South African PHC system be re-engineered in order to improve access to healthcare and advance the early identification of diseases. Making use of community health workers (CHWs) have been identified as one of the ways of improving PHC services so that patients can receive an early diagnosis and routine care can be given to children (Bam, Marcus, Hugo & Kinkel, 2013). CHWs who are properly trained, equipped, and supported can take on a range of tasks, including developmental screening (Tulenko et al., 2013). CHWs can extend care to underserved communities. They are highly accessible and provide low cost services. CHWs who speak the local language and identify with the local community convey health messages more effectively (Tulenko et al., 2013). In developing countries, CHWs can work effectively in the primary health setting to deliver developmental screening to the underserved community using the Mobile Health (mHealth) approach (Källander et al., 2013).

mHealth is a medical and public health practice supported by mobile devices such as mobile phones, patient monitoring devices, personal digital assistants, and wireless devices (World Health Organization [WHO], 2011). The technology that has been
used to transform communication, entertainment, and commerce is now poised to alter how health care is delivered (West, 2012). The utilization of mobile phone networks in many low and middle income countries results in the transformation of the way health services and information are accessed, delivered, and managed (WHO, 2011). Mhealth will improve health care in low and middle income countries by enabling health care to reach underserved communities and contribute to rapid improvement in the way healthcare is delivered in the community based setting (Leon & Schneider, 2012).

A study that compared the feasibility of implementing a surveillance system which would be used to monitor and evaluate CHWs, using paper-based and mobile phone methods, concluded that mobile phone surveillance of CHWs was feasible and appropriate. The study demonstrated the benefit of immediate access to data in order to monitor the activities of CHWs (Leon & Schneider, 2012). Furthermore, the removal of pen-and-paper-based forms resulted in increased convenience and efficiency of data collection, transfer, and storage. Cutting out paper was reported as saving costs of paper as well as transport and storage. Rapid access to data allowed for real-time monitoring and rapid analysis and sharing of data (Leon & Schneider, 2012). Thus, mHealth would be a cost effective and efficient way of delivering developmental screening to the underserved community.

The WHO (World Health Organization) conducted a survey completed by 114 of its member states. The majority of the member states (83%) reported offering at least one type of mHealth service (WHO, 2011). WHO supports the use of mHealth in member states to maximize its impact (WHO, 2011). Connectivity and onsite capturing make mHealth a powerful tool for developmental screening. In addition, mHealth serves as a data collection tool for research and disease surveillance, management in administration, planning, monitoring, and evaluation of services. MHealth can also be used to support clinical service delivery (Leon & Schneider, 2012).

It is clear that CHWs using mHealth in the PHC setting may provide a way to deliver developmental screening to underserved South African communities. Caregivers visit the PHC settings regularly for their children’s immunizations and regular health check-ups. It is thus, an appropriate platform to conduct developmental screening
The following research question is posed: What is the agreement in developmental screening outcomes by CHWs using a smartphone-based version of the PEDS tools compared to a health professional using the conventional paper-based version?

1.2 METHOD

1.2.1. Research Aim
To evaluate developmental screening by CHWs using a smartphone-based version of the PEDS tools.

1.2.2. Sub Aims
- To determine the correspondence between conventional testing using paper-based methods by the SLP and testing using a smartphone application by the CHW
- To evaluate developmental screening in terms of inter-rater reliability between the SLP and CHW.

1.2.3. Research Design
A quantitative cross sectional, within subject research design will be used for this study, by implementing a survey method (Gideon, 2012).

1.2.4 Ethical Considerations
The researcher will by all means abide to ethical, legal, and regulatory standards of research involving human research participants. The researcher will submit the research proposal for consideration, comment, guidance, and approval to the Faculty of Health Sciences and Humanities’ Research Ethics Committees as well as to the Tshwane District Department of Health prior to data collection. (World Medical Association [WMA], 2013). Written permission to conduct research will be obtained from the chief executive officer at Stanza Bopape clinic, the targeted institution where the research will take place. Written informed consent will also be obtained from all the research participants (WMA, 2013).
The data collection, handling, and storage process will protect respondents’ anonymity. The researcher will protect the health, dignity, integrity, right to self-determination, privacy, and confidentiality of research participants (Curtis & Drennan, 2013). The researcher will at all times treat participants with beneficence and non-maleficence, justice, due consideration of plausibility and implausibility, veracity as well as with fidelity and respect (Moule & Hek, 2011).

1.2.5. Reliability and validity

In this research study a credible and standardized instrument will be used to collect data. The set of PEDS tools was standardized in 2012 on 47,531 families in the United States and Canada (Glascoe & Nolensville, 2013). The PEDS tools have been validated and deemed reliable on more than 4,500 children across various settings (Glascoe & Nolensville, 2013). The PEDS tools present with content validity, construct validity, concurrent validity and predictive validity (Kumar, 2011). They have a high test - re-test rate and inter-rater reliability. High sensitivity and identify 74%-80% of children with developmental and social-emotional/mental health disabilities. Furthermore, the set of tools has high specificity of 70% to 80% (Glascoe & Robertshaw, 2010).

1.2.6. Research Participants

1.2.6.1 Sampling Procedure

A convenience sampling method will be used to select CHWs as research participants. CHWs based at Stanza Bopape clinic utilise smartphone applications as part of their service delivery (i.e. health registrations and general risk surveys). CHWs will be trained on administering the smartphone-based version of the PEDS tools as part of an outreach programme. After training, 3 CHWs will be recruited as volunteers to participate in the study.

Convenience and disproportionate stratified sampling will be utilized to select participants. Every caregiver attending the clinic with their child or children will be presented with the opportunity to voluntarily participate in the study until the sample size is reached. The caregivers will be divided according to the age groups of their children and each age group will be equally represented (Gerrish, Lacey & Cormack, 2010). The stratified sample age groups will be: 6-18 months 69% (n=142) and 19-
36 months 31% (n=65). Caregivers who do not have children between the ages of 6 months and 36 months and who are not proficient in English will be excluded from the study. The researcher will approach the immediate next participant, should any caregiver decline to participate in the study.

1.2.6.2 Sample Size
A total of 250 participants will be recruited. The participants will be selected over a five week period, during which time 8 participants will be targeted per day. The 250 participants will be interviewed by the CHW using the smartphone application PEDS tools. Simultaneously, the researcher will be recording and scoring the PEDS tools for the same participants. The researcher will record responses on the paper based PEDS tools for 125 (50%) of odd-numbered participants. Furthermore, the researcher will record responses on the smartphone application PEDS tools for 125 (50%) of even numbered participants.

1.2.7 Material and Apparatus
In this study, the PEDS and PEDS:DM combined will be regarded as a unit and referred to as the PEDS tools for reporting purposes. The PEDS tools constitute a developmental screening tool by parental report and will be used to collect data. Many developmental screening tools have been developed and validated internationally (Van der Linde et al., 2015). The DENVER-II was evaluated in 58 research studies between 1971 and 2010 (Van der Linde et al., 2015). However, the reported sensitivity and specificity ratings of the PEDS tools were higher than those of the DENVER-II (Van der Linde et al., 2015). Tools that have been available longer tend to have been investigated or utilized in more studies, but this does not necessarily mean they are better or more rigorous in detecting delay/disability (Macy, 2012). The Ages Stages Questionnaire has an expensive material kit, whereas the PEDS tools only have questionnaires. Hence, the PEDS tools were deemed more appropriate for the developing South African context (Van der Linde et al., 2015).

The PEDS tools focus on developmental and behavioural screening (Glascoe & Nolensville, 2010). The PEDS tools questionnaire will be administrated face-to-face, in the form of an interview (Gideon, 2012). The advantage of the selected face-to-face survey method is that it will be useable with respondents who cannot read or
write (Gideon, 2012). The PEDS elicits parents’ concerns about children's language, motor, self-help, early academic skills, behaviour, and social-emotional/mental health. The PEDS consists of ten questions, for example: Do you have any concerns about how your child understands what you say? Do you have any concerns about how your child behaves? The PEDS:DM is indicative of children's skills across all developmental domains: expressive language, receptive language, fine motor skills, gross motor skills, social-emotional development, self-help, and academics. The PEDS:DM consists of 6-8 questions, for example: Can your child walk without falling much? Does your baby drink (not suck) from a cup? (Glascoe & Robertshaw, 2010).

The PEDS tools screening age is from birth to 8 years. However, for the purposes of this study, the age range will be from 6 months to 36 months. The PEDS tools provide information regarding children’s progress and facilitate skilled monitoring of development (Glascoe & Nolensville, 2010). The PEDS tools elicit parents’ concerns about development, behaviour, and mental health.

The PEDS tools will be developed into a smartphone application, using the same algorithm as the conventional paper-based PEDS tools. Two Samsung Neo Trend smartphones (Android OS 4.4.1) will be used to install the PEDS tools application. The PEDS tools application will be developed by the University of Pretoria, and evaluated and pilot-tested by 2 SLPs working with 8 caregivers. The PEDS tools will be conducted using a smartphone equipped with an application of the PEDS tools, and demographic questions will also be asked. Recording of responses will be done on the smartphone application as well as manually on the traditional paper-based PEDS tools. The smartphone application PEDS tools will provide easy-to-use automated scoring which eliminates the need for manual scoring. Patient data will be stored in a safe online database.

The PEDS scores will be allocated into five different paths according the PEDS score guide and algorithm. Caregivers’ concerns will be classified into predictive concerns for developmental problems on the one hand and non-predictive concerns on the other hand. Two or more reported predictive concerns will be deemed a response requiring a referral, conventionally labelled “a refer”. Furthermore, the responses to the PEDS:DM will be interpreted as follows: when milestones are not achieved, the results will be deemed a refer (Glascoe & Robertshaw, 2010).
A training module and the PEDS tools brief scoring and administration guide will be used to train CHWs on how to administer the PEDS tools. The training session will last one hour. A projector and a laptop will be used as tools during the training.

1.2.8 Data Collection

1.2.8.1 Research Setting
This research study will take place at Stanza Bopape, a government PHC facility in Mamelodi, Gauteng Province, South Africa. Due to office space shortages at the clinic, a private mobile office will be set up. The clinic in Stanza Bopape provides PHC services to a wide spectrum of people residing in Mamelodi, an underserved township. There are currently no formal developmental screening services in Mamelodi. It is a township burdened by high levels of unemployment, poverty, informal dwelling, HIV, crime, and alcohol and drug abuse. Most of the residents in Mamelodi rely on health care services provided by government facilities and as a result the Stanza Bopape clinic has high traffic volumes (Statistics South Africa [STATS], 2011).

1.2.8.2 Data Collection Procedure
On the day of data collection, the researcher will arrive at Mamelodi clinic at 07:00am. The researcher will report to management upon arrival. The researcher and the CHWs will approach caregivers who are in a queue for immunization and/or other health services. The researcher and the CHW will explain in detail to the potential participants the purpose of the study and what is expected from them and issue them with an information letter and a consent form to sign.

The CHW and researcher will proceed to the mobile office with one participant at a time and the PEDS tools will be administered. The testing CHW will interview the participant using the smartphone PEDS tools application. The CHW will record responses on the smartphone application, while the SLP (the researcher) records the responses of the same participant. The SLP will alternate the use of the paper based PEDS tools and the PEDS tools as a mobile application, i.e. with every second person the mobile application will be used. The SLP and the CHW will not communicate with each other during testing or view each other’s responses. They will be strategically positioned in such a way that they will not be able to view each
other’s results. Recording of responses will be done on the smartphone application by the SLP and CHW as well as manually on the traditional paper-based PEDS tools by the SLP. The smartphone application PEDS tools will provide automated scoring, and thus eliminate the need for manual scoring.

The scores of the CHW will automatically be sent to a secure server upon completion. The scores of the SLP from the mobile application will also be sent to the server upon completion. Furthermore, the scores of the paper based PEDS tools will be captured and uploaded to the same server.

Caregivers whose children obtain “refer” results according to the results of the SLP will be issued with referral letters to the relevant health care professional for follow-up. At the end of each interview the researcher will thank the respondent for participating in the study and issue the respondent with juice or fruit for the child. At the end of the day the researcher will thank the CHW and proceed to management to report departure.

The researcher will pack away all research instruments and apparatus as well as response forms. They will be stored in a secure locked room.

1.2.8.3 Data Processing and Analysis

Raw data collected using the paper based PEDS tools will be recorded on a paper-based scoring sheet with coding and then immediately captured to a secure server. The data will then be captured onto an Excel spreadsheet and data cleaning and decoding will take place. Data collected using the smartphone application PEDS tools will be stored electronically and automated scoring will take place. Thereafter, the data will be sent to a secure server. Comparative data analysis will be done using Statistics Package Social Sciences (SPSS) v22 (Chicago, Illinois) (William & Wagner, 2014). Pivot tables will be utilized to determine correspondence between the outcomes of the PEDS tools, to calculate positive and negative correspondence (Healey, 2015).

Cohen’s Kappa coefficient will be used to establish the inter-rater agreement between the paper-based and smartphone application PEDS tools as well as between the SLP and CHW. Inter-rater agreement will be classified according to the Landis and Koch-Kappa’s Benchmark Scale into poor (κ=<0.0), slight (κ=0.0-.20),
fair (κ=0.21-0.40), moderate (κ=0.41-0.60), substantial (κ=0.61-0.80), almost perfect (κ=0.81-1.00) (Gwet, 2014; Shrout, Spitzer & Fleiss, 1987).

1.2.9 Budget

Table 1: Research Budget

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<th>Total Cost</th>
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2. RESEARCH ARTICLE

TITLE: DEVELOPMENTAL SCREENING – EVALUATION OF A MHEALTH VERSION OF THE PEDS TOOLS

Authors: Boledi K Maleka, Jeannie Van Der Linde, Frances Page Glascoe and De Wet Swanepoel

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Note: This article was edited in accordance with the editorial specifications of the Journal of telemedicine and e-Health. The article may differ from the editorial style of the rest of this document.

2.1 Abstract

Background: Developmental delays are more prevalent in low-income countries and access to developmental screening is severely limited.

Introduction: This study evaluated an mHealth version of a standard developmental screening tool, Parents Evaluation Developmental Status (PEDS) and PEDS: Developmental Milestones (PEDS:DM) for use by community health workers (CHWs) in terms of (1) correspondence with conventional paper-based testing by a speech language pathologist (SLP) and (2) inter-rater reliability compared to an SLP.

Method: CHWs were trained in a primary health care (PHC) setting to administer the newly developed smartphone application version of the PEDS tools. One SLP and two CHWs recruited 207 caregivers who were attending a baby wellness clinic. Caregivers were tested by one CHW using the smartphone application of the PEDS tools, a qualified SLP simultaneously recorded and scored the PEDS tools on the same participants.

Results: High positive (100%) and negative correspondence (96%) was found between the paper-based PEDS tools and the smartphone application PEDS tools
and between the SLP and CHW. Almost perfect (Cohen’s Kappa) inter-rater agreement between conditions was demonstrated ($k=0.873$ to $k=0.961$).

**Conclusion:** Outcomes of the smartphone application, operated by a CHW, corresponded closely to the gold standard PEDS tools operated by a health professional. Trained CHWs can conduct accurate developmental screening using the smartphone version of the PEDS tools.

### 2.2 Introduction

Developmental screening is vital in establishing early detection and timely referral to early intervention services (Conatser, James & Ledingham, 2013; Fernell et al., 2014). Early intervention is beneficial in that stimulation could still have an effect on brain growth and recovery (Sonnenschein, Conover & Shizgal, 2003). During the first three years of a child’s life rapid brain development occurs, which is essential for future growth, development and progress. Early intervention aims to ensure and enhance children’s personal development and resilience. Children with disabilities who receive good care as well as developmental opportunities during early childhood are more likely to become healthy, productive adults. This can potentially reduce the future costs of education, medical care and social spending (World Health Organization [WHO], 2012). Ultimately, future delays can be prevented by means of early intervention (Groak, Eidelman, Maude, Croak & Eidelman, 2011).

Early intervention is especially important in developing countries, such as South Africa, where the prevalence of developmental delays are high (Van der Linde et al., 2015). To detect developmental delays developmental screening measures can be employed (Lynn et al., 2012). Currently there is no coordinated developmental monitoring and surveillance system in place within either the public or private sector in many countries like South Africa. Developmental screening is conducted by nurses in PHC clinics that are often understaffed and underresourced (Van der Linde et al., 2015). A comprehensive developmental screening approach is required for appropriate care and support including early identification, assessment and early intervention planning, provision of services, and monitoring and evaluation (World Health Organization [WHO], 2012). The only implemented developmental screening tool in South Africa is integrated as part of the road to health booklet (RTHB). This tool is not standardized and has been shown to have low sensitivity (25%). There is a
clear need for an efficient developmental screening tool to improve early detection of developmental delays at community levels (Van der Linde et al., 2015).

The PEDS tools, a standardized and validated measure, have recently been considered for use in PHC contexts of South Africa (Van der Linde et al., 2015; Glascoe & Robertshaw, 2010). Ideally a tool that is quick, reliable and which could be used by frontline health workers such as CHWs could ensure widespread access to early detection. The number of SLPs and other healthcare professionals are limited and overburdened with high caseloads in secondary and tertiary health centers (Van der Linde & Kritzinger, 2013). In South Africa, the use of smartphone applications is part of the community oriented primary care (COPC) initiative using CHW and mHealth initiatives to deliver continuous, comprehensive, integrated and informed healthcare services to underserved communities. A developmental screening like the PEDS tools in an App format could function as part of the COPC initiative whereby CHWs conduct the smartphone application PEDS tools remotely during home visits (Bam et al., 2013).

Identification and assessment of children with disabilities in high-income countries often involves teams of highly trained professionals (World Health Organization [WHO], 2012). The PEDS tools for example is usually administered by parents or trained developmental health professionals (Brothers, Glascoe & Robertshaw, 2008). However, in low and middle income countries such comprehensive expertise is often inaccessible and poor parental literacy skills may pose a challenge (World Health Organization [WHO], 2012). In some countries, CHWs are trained and supported by professionals to strengthen capacity and improve the quality of interventions (World Health Organization [WHO], 2012) (Bam et al., 2013; Tulenko et al., 2013). CHWs can extend care to underserved communities, drawn from local communities. They speak the languages and identify with the local community to convey health messages more effectively (Tulenko et al., 2013). CHWs can therefore be uniquely positioned for early detection of developmental concerns if the right tools that are simple, cost and time efficient are available (Bam et al., 2013). The PEDS tools could potentially be used in the form of a mobile phone-based assessment for developmental screening by CHWs. CHWs using mHealth tools has been proposed as an important way to improve access to health care services for early detection and subsequent care for community members (Bam et al., 2013; Hussein et al.,
This study therefore aimed to evaluate developmental screening in terms of (1) correspondence between conventional testing using paper-based methods by the SLP and testing using a smartphone application by the CHW and (2) inter-rater reliability between the SLP and CHW.

2.3 Methods

2.3.1 Participants
Data were collected at Stanza Bopape Clinic, a government PHC facility in Mamelodi, Gauteng Province, South Africa. Due to office space shortages at the clinic, a private mobile office was set up. CHWs were trained on administering the smartphone-based version of the PEDS tools as part of an outreach program. Three CHWs were asked upon completion of the training to volunteer to participate in the study. Two female CHWs with five years CHW experience assisted with recruiting participants. One male CHW who had six years CHW experience in the PHC setting and no tertiary qualifications was administering the smartphone PEDS tools. All the CHWs daily utilise smartphone applications in the PHC setting as part of their service delivery (i.e. health registrations and general risk surveys) (Bam et al., 2013).

A convenience and disproportionate stratified sampling method was utilized to select 207 caregivers who were waiting in a queue at a baby wellness clinic at Stanza Bopape Clinic (Bernard, 2012). Caregivers who were not proficient in English were excluded from the study. Caregivers attending the clinic with their child or children were asked to voluntarily participate in the study. Mothers were 88% (n=182) of respondents, 7% (n=15) other family members and 4% (n=9) were fathers. Sepedi was 44% (n=90) of the caregivers’ first language, 15% (n=30) were Tsonga, 12% (n=24) were Zulu speakers and 29% (n=63) had other languages as their first language. Caregivers were divided into a stratified sample according to the age groups of their children. The age groups were 6-18 months 69% (n=142) and 19-36 months 31% (n=65). The mean was 1.937 and standard deviation was 1.3549, 99.9% (n=206) of children screened were black and 0.5% (n=1) were other.

2.3.2 Material and Equipment
In this study, the PEDS and PEDS:DM combined, are referred to as the PEDS tools for reporting purposes. The PEDS tools are a developmental screening tool by
parental report which was used to collect data. The PEDS elicits parents’ concerns about children's language, motor, self-help, early academic skills, behaviour and social-emotional/mental health. The PEDS consists of ten questions, such as: Do you have any concerns about how your child understands what you say? Do you have any concerns about how your child behaves? The PEDS:DM is indicative of children’s skills across all developmental domains; expressive language, receptive language, fine motor, gross motor, social-emotional, self-help and academics. The PEDS:DM consist of 6-8 questions, such as; Can your child walk without falling much? Does your baby drink (not suck) from a cup? (Glascoe & Robertshaw, 2010).

An hour training session on administering the PEDS tools on a smartphone application was provided to the CHWs in person utilizing a training module of the PEDS tools and the PEDS tools guide to administration and scoring. The PEDS tools were developed into a smartphone application, using the same algorithm as the conventional paper-based PEDS tools. Two Samsung Neo Trend smartphones (Android OS 4.4.1), were used to install the PEDS tools application. The PEDS tools application was developed by the University of Pretoria, evaluated and piloted by two SLPs on eight caregivers. Screenshots of the PEDS tools application are presented in figure 1.

Figure 1 Screenshot of the PEDS tools application. (a) Example question; (b) response options; (c) Results screen; (d) Results description.
2.3.3 Data collection

CHWs were trained and thereafter, caregivers were interviewed by the CHW using the smartphone application of the PEDS tools, simultaneously a qualified SLP was recording and scoring the PEDS tools on the same participants. The SLP completed the PEDS tools, based on caregiver responses, using either the smartphone application or conventional paper-based version in a counter-balanced manner. The CHW only administered the smartphone version. In order to eliminate bias, the SLP and the CHW did not communicate, make contact or view each other’s records during testing. The PEDS tools were administered concurrently by the SLP and CHW to ensure the context and caregiver responses, as elicited by the CHW, were similar.

Scores of the paper-based PEDS tools completed by the SLP were manually captured and uploaded to the same server as 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.

2.3.4 Data Analysis

The Statistic Package Social Sciences (SPSS) v22 (Chicago, Illinois) was used for statistical calculations and analysis (William & Wagner, 2014). Frequency distributions, cross tabulations and descriptive statistics depicting the mean,
standard deviation, minimum and maximum values were used to analyse data. Pivot tables were used to calculate positive correspondence which determined the proportion of positive screen outcomes correctly identified and negative correspondence which measured the proportion of negative screen outcomes that were correctly identified. Positive and negative correspondence was calculated for paper-based and smartphone application PEDS tools as well as for the results obtained by the CHW and the SLP (Healey, 2015). Cohen’s Kappa coefficient was used to establish the inter-rater agreement between the paper-based and smartphone application PEDS tools as well as between the SLP and CHW. Inter-rater agreement was classified according to the Landis and Koch-Kappa’s Benchmark Scale into poor ($\kappa$<0.0), slight ($\kappa$=0.0-.20), fair ($\kappa$=0.21-0.40), moderate ($\kappa$=0.41-0.60), substantial ($\kappa$=0.61-0.80), almost perfect ($\kappa$=0.81-1.00) (Gwet, 2014; Shrout et al., 1987).

2.4 Results
A total of 207 children were assessed using the PEDS tools by the CHW and the SLP. Half of the children (51%) were assessed using the paper-based PEDS tools (odd-numbered participants) and the other half (49%) were assessed using the smartphone application (even-numbered participants) by the SLP. Referral rates were similar when the outcome of the CHW and the SLP were compared. Similar referral rates were also yielded when the paper-based outcomes were compared to the outcomes of the application (Table 1). The SLP and the CHW also found similar referral rates across age categories (Table 2).

<p>| Table 2: Distribution of PEDS tools outcome for CHW and SLP (n=207 children) |
|---------------------------------------------------------------|----------------|----------------|----------------|----------------|</p>
<table>
<thead>
<tr>
<th>CHW (n=207)</th>
<th>SLP (n=207)</th>
<th>SLP - Paper-based (n=105)</th>
<th>SLP - App (n=102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pass</td>
<td>40%</td>
<td>42%</td>
<td>41%</td>
</tr>
<tr>
<td>Refer</td>
<td>60%</td>
<td>58%</td>
<td>59%</td>
</tr>
</tbody>
</table>

App, application
High positive and negative correspondence was found between the paper-based PEDS tools and the smartphone application PEDS tools, as well as between the SLP and CHW (Table 3). Higher positive and negative correspondence was noted in the younger 6-18 months age group (Table 3). High Inter-rater agreement between conditions varied from $\kappa=0.873$ to $\kappa=0.961$ (Kappa score; Table 4).

### Table 3: Age specific outcomes of the PEDS tools (n=207 children)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>CHW (n=142)</th>
<th>SLP (n=142)</th>
<th>CHW (n=65)</th>
<th>SLP (n=65)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pass</td>
<td>49%</td>
<td>49%</td>
<td>22%</td>
<td>26%</td>
</tr>
<tr>
<td>Refer</td>
<td>51%</td>
<td>51%</td>
<td>78%</td>
<td>74%</td>
</tr>
</tbody>
</table>

### Table 4: Correspondence of the PEDS tools

<table>
<thead>
<tr>
<th>Condition</th>
<th>Positive Correspondence</th>
<th>Negative Correspondence</th>
<th>Overall Correspondence</th>
</tr>
</thead>
<tbody>
<tr>
<td>SLP vs CHW (n=207)</td>
<td>99%</td>
<td>97%</td>
<td>95%</td>
</tr>
<tr>
<td>Smartphone vs Paper-based (n=105)</td>
<td>100%</td>
<td>96%</td>
<td>100%</td>
</tr>
<tr>
<td>Smartphone vs Smartphone (n=102)</td>
<td>98%</td>
<td>98%</td>
<td>100%</td>
</tr>
<tr>
<td>SLP vs CHW (6-18 months) (n=142)</td>
<td>100%</td>
<td>99%</td>
<td>100%</td>
</tr>
<tr>
<td>SLP vs CHW (19-36 months) (n=65)</td>
<td>98%</td>
<td>88%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Vs, versus

### Table 5: Inter-rater agreement (Cohen’s Kappa) for the CHW using the AB and the SLP using conventional PB and AB versions of the PEDS tools

<table>
<thead>
<tr>
<th>Condition</th>
<th>$\kappa$ Value</th>
<th>Standard Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHW-AB and SLP-PB/AB (n=207)</td>
<td>.960</td>
<td>.020</td>
</tr>
<tr>
<td>CHW-AB and SLP-PB (n=105)</td>
<td>.961</td>
<td>.027</td>
</tr>
<tr>
<td>CHW-AB and SLP-AB (n=102)</td>
<td>.959</td>
<td>.029</td>
</tr>
<tr>
<td>CHW-AB vs SLP-PB/AB (Age 6-18 months) (n=142)</td>
<td>.986</td>
<td>.014</td>
</tr>
<tr>
<td>CHW-AB vs SLP-PB/AB (Age 19-36 months) (n=65)</td>
<td>.873</td>
<td>.071</td>
</tr>
</tbody>
</table>

AB, Application based; PB, Paper-based
2.5 Discussion

The smartphone-based version of the PEDS tools developed for this study operated by CHWs corresponded exactly with the paper-based version completed by a SLP in 99% of instances (n=207). Agreement was therefore almost perfect ($\kappa=0.960$; Cohen’s Kappa) between test outcomes by a CHW using the application and results obtained by a health professional (SLP) using conventional paper-based testing. Previous studies have reported that CHWs can provide high-quality care and bridged the gap between patients and healthcare providers (Collinsworth, Vulimiri, Schmidt & Snead, 2013). Furthermore, CHWs were found to fulfil a crucial role in smartphone-based hearing screening and management of non-communicable diseases (Hussein et al., 2015) (Tsolekile, Puoane, Schneider, Levitt & Steyn, 2014). It has also been reported in a South African study that a trained lay telehealth clinic facilitator was effective in capturing reliable images of the eardrum for accurate asynchronous diagnosis by an otolaryngologist (Biagio, Swanepoel, Adeyemo, Hall & Vinck 2013). CHWs who are part of the COPC initiative are frontline health workers that are more accessible and cost effective than SLPs and other healthcare practitioners (Bam et al., 2013). The PEDS tools smartphone application, when used by users with different levels of training, was demonstrated to be reliable. CHWs who receive appropriate training are able to effectively administer developmental screening using the smartphone-based PEDS tools application.

Outcome on the PEDS tools application corresponded with those found on the conventional paper-based PEDS tools (Table 3). The PEDS tools smartphone application was accurate and maintained the integrity of the conventional PEDS tools. Developmental screening by CHWs utilizing a smartphone-based version of the PEDS tools could be beneficial in underserved South African communities, where children are at an increased risk of developmental delays (Van der Linde et al., 2015). The use of a developmental screening tool like the PEDS tools operated from a smartphone could ensure availability of developmental screening services and referrals to appropriate healthcare professionals for earlier intervention. The RTHB screening done by nurses in South Africa has limitations (Van der Linde et al., 2015). The PEDS tools may offer an advantage and decentralise current screening initiatives from clinics to homes.
The use of smartphone applications in healthcare has been shown to improve access to PHC services (Hussein et al., 2015). The use of the PEDS tools as part of the COPC initiative would assist in early developmental delay detection using smartphones occasional home visits of CHWs. Caregivers would receive informational counselling on early development and early intervention remotely. Furthermore, test results can be sent to a cloud-based service whereby the information would be accessible and safe. In addition, caregivers would be provided with referral appointments.

A high referral rate was obtained by both the SLP and CHW in the sample population. A possible reason for this may be due to the children being from a high risk population (Van der Linde et al., 2015). Similar referral rates have been reported in a previous study conducted in other South African underserved communities (Van der Linde et al., 2015). In contrast, a study conducted on a global scale, including data from 11 countries, depicted a lower referral rate of 34% (Woolfenden et al., 2014).

The high referral rate noted in the above mentioned South African contexts maybe problematic as the already overburdened health care system may not be able to provide effective and accountable services to all, should developmental screening be implemented on a large scale. The PEDS tools referral algorithm may need to be adapted for the South African underserved population to ensure that moderate to severe developmental delays are detected as well as referred and that mild developmental delays are followed up by means of developmental surveillance. This could be implemented to obtain more reasonable referral rates. A validation of the application should be done evaluating the smartphone PEDS tools against a PEDS tools as a diagnostic gold standard tool. Furthermore, it should be determined if caregivers will be able to effectively administer the PEDS tools smartphone application. Since the PEDS tools was administered by the SLP and CHW, the accuracy of the smartphone-based version was not determined on a group of participants with varying knowledge on child development. It is therefore recommended that the PEDS tools smartphone application should be evaluated when administered by caregivers themselves as well as various health professionals such as nurses, occupational therapists, paediatricians and general practitioners.
2.6 Conclusion
Almost perfect agreement between conventional testing using the paper-based PEDS tools and the PEDS tools as a smartphone application was found. Furthermore, almost perfect inter-rater agreement between the SLP and CHW was reported. CHWs who have been trained successfully conducted developmental screening using the smartphone version of the PEDS tools. COPC initiatives may be a viable platform to render smartphone-based developmental screening to high risk communities. CHWs can conduct developmental screening in high risk communities easily with the smartphone application and results can be integrated into a telehealth framework to provide appointments, reminders, informational counselling and even early tele-intervention services. This makes early detection of developmental delays in underserved communities possible towards preventative measures and early initiation of necessary interventions.

2.7 Acknowledgements
The researchers would like to acknowledge Stanza Bopape Clinic management and staff for supporting this research project. We also thank all the caregivers for participating in the study. The researchers acknowledge Frances Glascoe for making the paper-based PEDS tools available for use in this study. Information regarding the PEDS tools application can be obtained from the authors.

2.8 Disclosure statement
No competing financial interests exist
3. DISCUSSION AND CONCLUSION

3.1 Discussion of results

The study set out to evaluate developmental screening by CHWs using a smartphone-based version of the PEDS tools. The study evaluated developmental screening in terms of inter-rater reliability between the SLP and CHW.

The PEDS tools and PEDS online have been used widely internationally and have been shown to be effective in identifying developmental delays regardless of the parents' level of education, income, race and age of the child (Coghlan, Kiing & Wake, 2003; Brothers et al., 2008). The smartphone-based version of the PEDS tools developed for this study and operated by CHWs corresponded exactly with the paper-based version completed by a SLP in 99% of instances (n=207). A high referral rate was obtained by both the SLP and CHW. Similar referral rates have been reported in a previous study conducted in other South African underserved communities (Van der Linde et al., 2015). This may be due to the children being from a high risk population (Van der Linde et al., 2015). In contrast, a study conducted in over 11 countries globally, reported a lower referral rate of 34% (Woolfenden et al., 2014).

The high referral rate noted in the South African context may be problematic as the already overburdened health care system in South Africa would not be able to render services to all the referrals, should developmental screening be implemented on a large scale. The PEDS tools referral algorithm may need to be adapted for the South African underserved population to ensure more reasonable referral rates.

A lower agreement in older children, whilst it is still an almost perfect inter-rater agreement (κ -0.873), suggests that more referrals may yet appear in older children. The increased discrepancy could be due to the test questions being more complex with the increase of age. The Cohen’s kappa agreement was found to be almost perfect (κ=0.960; Cohen’s Kappa) between test outcomes obtained by a CHW using the smartphone application and results obtained by the SLP using conventional paper-based testing. It has been found that CHWs provide high-quality care and bridge the gap between patients and healthcare providers (Biagio et al., 2013). Furthermore, CHWs were found to fulfil a crucial role in smartphone-based hearing screening and
the management of non-communicable diseases (Hussein et al., 2015; Collinsworth et al., 2013). It has also been reported, in a study conducted in South Africa, that a collaborative process between a trained hearing telehealth clinic facilitator and a lay person was equally effective for asynchronous diagnosis by an otolaryngologist compared with conventional face-to-face otoscopy (Woolfenden et al, 2014). This suggests that training and supervision of CHWs increases their effectiveness (Biagio et al., 2013). CHWs who receive appropriate training may be able to effectively administer developmental screening using the smartphone-based PEDS tools application.

The use of smartphone applications in healthcare has been shown to improve access to PHC services (Hussein et al., 2015). The PEDS tools application could function as part of the COPC initiative if CHWs conduct the smartphone application PEDS tools remotely during home visits (Bam et al., 2013). This would assist in early developmental delay detection for the reason that caregivers would receive informational counselling on early development and early intervention could take place remotely. Furthermore, the PEDS tools application test results can be sent to a cloud-based application where the information would be accessible and safe. In addition, caregivers would be provided with referral appointments.

### 3.2 Clinical application

A model of service delivery using the PEDS tools applications could be used as part of the COPC initiative. Developmental screening by CHWs utilizing a smartphone-based version of the PEDS tools could be highly beneficial in the underserved South African community, whose children are at risk of developmental delays (Van der Linde et al., 2015). It could ensure access to developmental screening, as well as referrals to appropriate healthcare professionals for earlier intervention. The use of smartphone applications in healthcare has been shown to improve access to PHC services. CHWs who are part of the COPC initiative are more accessible and cost effective than SLPs and other healthcare practitioners (Bam et al., 2013; Tulenko et al., 2003). CHWs who receive appropriate training will be able to effectively administer developmental screening using the smartphone-based PEDS tools application.
3.3 Study limitations and strengths

The following study limitations were found:

- The set of PEDS tools was administered by one SLP and one CHW, but the accuracy of the smartphone-based version was not determined for a group of participants with varying degrees of knowledge about child development. It should be determined more comprehensively if caregivers and other health professionals will be able to administer the PEDS tools smartphone application effectively.
- The research was conducted in the township PHC setting and therefore, it cannot be generalised to other contexts such as urban and rural areas.
- Screening was conducted in English which is a second language of the CHW and caregivers, this may have an impact on their performance. However, English is accepted as the language of learning and teaching in the community.
- A validation study of the PEDS tools application should be done evaluating the smartphone PEDS tools against the PEDS tools as a diagnostic gold standard tool on a larger scale.

The following study strengths were found:

- The PEDS tools smartphone application was developed from a standardized, reliable and credible tool (Glascoe & Nolensville, 2013).
- The study was conducted in an area whereby there are currently no formal developmental screening services. Important services were rendered in the context.
- The PEDS tools smartphone application provided automated scoring and as a result, it was quicker for the CHW to conduct the smartphone application PEDS tools, furthermore scoring and capturing errors were eliminated.
- The PEDS tools are an affordable tool in comparison to other developmental screening tools such as the DENVER and the ages and stages. Thus, the PEDS tools are a relevant tool to use in the developing South African context.
3.4 Recommendations for future research

As this was the first time the PEDS tools smartphone application was developed and evaluated, more studies will be necessary to validate the PEDS tools application. A validation study on the application should be conducted on a large scale. In addition, there is an opportunity to conduct a study of the PEDS tools being administered by caregivers themselves vs the professional SLP as well as other health professionals who work in the early intervention sphere. The performance of the caregivers should be compared to the performance of an SLP. It is therefore recommended that the PEDS tools smartphone application should be evaluated when administered by caregivers themselves as well as various health professionals such as nurses, occupational therapists, paediatricians, and general practitioners. Caregiver self-screening and health professionals screening should be done to determine the outcome of the PEDS tools smartphone application.

A similar study should be conducted in rural areas, to determine whether the results of the PEDS tools application will be replicated in different demographic environments. In addition, a similar study should be conducted in other South African official languages, to determine whether the results will be replicated in different languages.

3.5 Conclusion

Almost perfect agreement was found between conventional testing using the paper-based PEDS tools and the PEDS tools as a smartphone application. Furthermore, almost perfect inter-rater agreement between the SLP and CHW was reported. CHWs who have been trained successfully conducted developmental screening using the smartphone version of the PEDS tools. COPC initiatives may be a viable platform to render smartphone-based developmental screening to high risk communities. CHWs can conduct developmental screening with ease in high risk communities with the smartphone application and results can be integrated into a telehealth framework to provide appointments, reminders, informational counselling, and even early tele-intervention services. This makes early detection of developmental delays in underserved communities possible, increasing the possibility of preventative measures and early initiation of the necessary interventions.
4. REFERENCES


Fernell, E., Wilson, P., Hadjikhani, N., Bourgeron, T., Neville, B., ...Taylor, D. (2014) Screening, intervention and outcome in autism and other developmental disorders:
the role of randomized controlled trials. *Journal of Autism and Developmental Disorders, 44*(8), 2074-2076.


Lynn, D., Newton, H.B., Rae-Grant, A.D. (Eds.). 2012. *The 5-Minute Neurology Consult*. Lippincott Williams & Wilkins. USA


5. APPENDICES
APPENDIX A: Procedure Information Letter and Informed Consent Form – Research Participants
PARENT/CAREGIVER AND COMMUNITY HEALTH WORKER (CHW) INFORMATION LEAFLET & INFORMED CONSENT FORM

Title of the research study: Smartphone-based developmental screening by community health care workers.

INTRODUCTION
You are invited to volunteer to participate in a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved.

WHAT IS THE PURPOSE OF THIS TRIAL?
It is important to develop a developmental screening program in the underserved South Africa. With a community health worker and a speech language therapist administering the PEDS tools, we hope to compare the reliability of community health worker conducting developmental screening using a smart phone application PEDS tools. All parents/caregivers visiting Stanza Bopape Clinic with babies from 6 months to 36 months, will be asked to participate in the research study.

WHAT IS THE DURATION OF THIS TRIAL?
If you are a parent/caregiver and you decide to participate in the study, you will be one of 250 parents/caregivers. The study will be conducted during 2015. The testing time will not take more than 15 minutes of your time. CHWs will receive training and will participate in the study throughout data collection phase of the study.

EXPLANATION OF PROCEDURES TO BE FOLLOWED
This study involves a CHW asking some questions with regard to your child’s development and background history, as the parent/caregiver you will be required to answer the questions truthfully. The community health worker will also ask some demographical information. The community health worker will record responses on a smart phone PEDS tools and the speech-language therapist will be recording responses on either a paper-based administered PEDS tools or on the smart phone application PEDS tools.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?
This research study Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee as well as the Faculty of Humanities’ Research Ethics Committee, University of Pretoria and written approval has been granted.

© University of Pretoria
The study has been structured in accordance with the Declaration of Helsinki (last update: October 2008), which deals with the recommendations guiding doctors and allied health care professionals in biomedical research involving human subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT IN THIS RESEARCH STUDY?
Your participation in this trial is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect you or your child's access to other medical care. If it is detected that you did not give an accurate history and or did not follow the guidelines of the trial and the regulations of the trial, you may be withdrawn from the trial at any time.

MAY ANY OF THESE PROCEDURES RESULT IN DISCOMFORT OR INCONVENIENCE?
Since the PEDS tools are conducted in an interview form, no discomfort or inconvenience will be caused by the research study.

WHAT ARE THE RISKS INVOLVED IN THIS RESEARCH STUDY?
No risks are involved when participating in the research study. The benefit in participating in the study is that you will receive feedback on your baby’s general development based on your parental concerns and therefore, if necessary, you will be referred for the specialized services. CHW will be trained on using the PEDS tools.

CONFIDENTIALITY
All information obtained during the course of this trial is strictly confidential. Data that may be reported in scientific journals will not include any information which identifies you or your child in this research study. You and your baby's name will not be used and the results will be kept confidential. Data will be securely stored, electronically and on hardcopy, for a minimum of 15 years at the University of Pretoria.

Please indicate whether you give permission that the data may be used for 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)
INFORMED CONSENT FOR PARENTS/CAREGIVERS AND CHWs

I, hereby confirm that I have been informed by the investigator, Ms Boledi Karabo Maleka about the nature, conduct, benefits and risks of the research study titled: “Smartphone-based developmental screening by community health care workers”. I have also received, read and understood the above written information (Patient Information Leaflet and Informed Consent) regarding the research study.

I am aware that the results of the study, including my and my child’s personal details regarding date of birth, initials and diagnosis will be anonymously processed into a research report.

I may, at any stage, without prejudice, withdraw my consent for my participation in the trial. I have had sufficient opportunity to ask questions and (of my own free will) declare that I am prepared to participate in the trial.

Parent/Caregiver(s) Name

(Please print)

Parent/Caregiver(s) Signature

Date

Child’s Name

(Please print)

Community Health Worker Name

(Please print)

Community Health Worker Signature

Date

Investigator’s Name

(Please print)

Investigator’s Signature

Date

Witness’s Name

(Please print)

Witness’s Signature

Date
VERBAL PATIENT INFORMED CONSENT

I, the undersigned, Boledi Karabo Maleka, have read and have explained fully to the parent/caregiver or CHW, named _____________________________ and/or is/her relative, the patient information leaflet, which has indicated the nature and purpose of the research in which I have asked the parent/caregiver or CHW to participate. The explanation I have given has mentioned both the possible risks and benefits of the trial and the alternative treatments available for his/her child’s illness or to the CHW. The parent/caregiver or CHW indicated that he/she understands he/she will be free to withdraw from the research at any time for any reason.

I hereby certify that the parent/caregiver or CHW has agreed to participate in this trial.

Parent/Caregiver Name _____________________________

(Please print)

Community Health Worker Name _____________________________

(Please print)

Community Health Worker Signature _____________________________

Date __________________

Investigator’s Name _____________________________

(Please print)

Investigator’s Signature _____________________________

Date __________________

Witness’s Name _____________________________

(Please print)

Witness’s Signature _____________________________

Date __________________
APPENDIX B: Permission Letter - CEO Stanza Bopape Clinic
Dear Sir/Madam

REQUEST TO CONDUCT A RESEARCH PROJECT AT STANZA BOPAPE CLINIC

I, hereby request your permission to conduct a research project titled: ‘Smartphone-based developmental screening by community health care workers’ at your clinic. I, Boledi Karabo Maleka am a Masters student at the University Of Pretoria.

This research study is essential as we are comparing developmental screening conducted by community health care workers to the same screening conducted by a speech-language therapist. Firstly community health care workers will have to be trained on the administration of the developmental screening tool that will be used for data collection. After the training of community health care workers, the researcher and the community health care worker will be approaching parents and caregivers that are in a queue waiting with their children aged 6 months to 36 months, for either immunization and or to be attended by a health professional. A paper-based and a smart phone mobile application of the same developmental screening tool, will be conducted in English on the parents and caregivers. For all participants, participation is voluntary and they may withdraw from the study at any time without any negative consequences. Written informed consent will be obtained.

The research project will run for an estimated five week period. I, hereby request that an interview room be made available to the researcher to assist in the data collection. The research proposal has been submitted to the Faculty of Health Sciences Research Ethics Committee as well as the Faculty of Humanities’ Research Ethics Committee, University of Pretoria. Data collection will only commence when approval by these committees have been obtained. The research report will be made available to you upon request.

If you require any information or have additional queries, please do not hesitate to contact us at 012 420 2948 (Ms Van Der Linde) and 072 662 83 62 (Ms Karabo Maleka)

Kind Regards,

Boledi Karabo Maleka
Student

Prof D W Swanepoel
Supervisor

Jeanie Van Der Linde
Supervisor

HEAD: Dept. of Speech-Language Pathology and Audiology

© University of Pretoria
I, M. T. Matome, hereby grant Boledi Karabo Maleka permission to conduct research at Sianza Bopape Clinic.

Request Authorized

2015/02/12

Date
Declaration of intent from the clinic manager or hospital CEO

I give preliminary permission to [NAME OF RESEARCHER] to do his or her research on [RESEARCH TOPIC] in [NAME OF CLINIC] or [NAME OF CHC] or [NAME OF HOSPITAL].

I know that the final approval will be from the Tshwane/Metsweding Regional 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:

[PLEASE SHARE FINDINGS WITH THE CLINIC STAFF]

[Signature]
Clinic Manager/CHC Manager/CEO

[Date]
APPENDIX C: PEDS tools Questionnaire
1. Parent/Caregiver provides consent to allow for PEDS testing as well as all data collection requirements.

   YES  NO

2. State Tester

3. State Facility

4. Child first Name

5. Child Last Name

6. Child Identity Number

7. Child Gender

   MALE  FEMALE

8. Child Date of Birth
9. Duration of Pregnancy

10. Respondent First Name

11. Respondent Last Name

12. Respondent relationship

13. Difficulty communicating with respondent

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>
PEDS Response Form

Child’s Name ___________________________ Parent’s Name ___________________________
Child’s Birthday ___________________________ Child’s Age __________ Today’s Date __________

Please list any concerns about your child’s learning, development, and behavior.

Do you have any concerns about how your child talks and makes speech sounds?

Do you have any concerns about how your child understands what you say?

Do you have any concerns about how your child uses his or her hands and fingers to do things?

Do you have any concerns about how your child uses his or her arms and legs?

Do you have any concerns about how your child behaves?

Do you have any concerns about how your child gets along with others?

Do you have any concerns about how your child is learning to do things for himself/herself?

Do you have any concerns about how your child is learning preschool or school skills?

Please list any other concerns.

**Peds DM Form C (5-7 months)**

<table>
<thead>
<tr>
<th>Question</th>
<th>No</th>
<th>A little</th>
<th>Yes</th>
<th>No</th>
<th>Sometimes</th>
<th>Yes</th>
<th>No</th>
<th>Sometimes</th>
<th>Yes</th>
<th>No</th>
<th>A little</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>When your baby is holding a toy in each hand, does he or she look from one hand to the other?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>When you say things like, “Come here”, does your baby hold out his or her arms?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your baby “talk” or make sounds when he or she holds a toy or sees a pet?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If your baby is lying on her back can she pass a toy from one hand to the other?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If you try to give more food than your baby wants, does he keep his lips closed or turn away?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>When you play gentle tickling games with your baby, does he or she enjoy this?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Form D (8-10 months)**

<table>
<thead>
<tr>
<th>Question</th>
<th>No</th>
<th>A little</th>
<th>Yes</th>
<th>No</th>
<th>Sometimes</th>
<th>Most of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can your baby poke at things with just his or her first finger?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>When you say your baby’s name, does he or she stop and look at you?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How many different sounds such as “muh”, “bah”, “duh” or “guh” does your baby say?</td>
<td>None</td>
<td></td>
<td>1</td>
<td>2 or more</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can your baby get around on hands and knees or by scooting on his or her bottom?</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your baby try to get to toys that are out of reach?</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your baby like to play peek-a-boo?</td>
<td>No/Never tried</td>
<td></td>
<td></td>
<td>A little</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
### Peds DM Form E (11-13 Months)

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can your baby make squeeze toy squeak – or try to?</td>
<td>No, A little, Yes</td>
</tr>
<tr>
<td>When you say things like, &quot;Where's your bottle?&quot; does your baby look</td>
<td>No, Sometimes, Most of the</td>
</tr>
<tr>
<td>around for his bottle?</td>
<td>time</td>
</tr>
<tr>
<td>Does your baby put lots of sounds together that sound like talking?</td>
<td>No, Sometimes, Yes</td>
</tr>
<tr>
<td>If you hold only one of your baby's hands, can he or she take a few</td>
<td>No, A little, Yes</td>
</tr>
<tr>
<td>steps?</td>
<td></td>
</tr>
<tr>
<td>Can your baby drink (not suck) from a cup?</td>
<td>No/Don't know, A little, Yes</td>
</tr>
<tr>
<td>Does your baby look for new things to play with and try to figure out</td>
<td>No, A little, Often</td>
</tr>
<tr>
<td>how they work – like busy boxes or squeezing toys?</td>
<td></td>
</tr>
</tbody>
</table>

### Form F (14-15 Months)

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can your child unwrap food or a toy that has been loosely wrapped?</td>
<td>No, Sometimes, Most of the</td>
</tr>
<tr>
<td>If you hold out your hand and ask your child to give you something,</td>
<td>time</td>
</tr>
<tr>
<td>does he or she give you something even if it is not the right thing?</td>
<td>No, Sometimes, Most of the</td>
</tr>
<tr>
<td>If you offer your child something she likes, does she nod or say &quot;yes&quot;?</td>
<td>time</td>
</tr>
<tr>
<td>Can your child walk without falling much?</td>
<td>No, Falls a lot, Doesn't fall</td>
</tr>
<tr>
<td>Does your child take off his or her own shoes if you undo the laces or</td>
<td>often</td>
</tr>
<tr>
<td>buckles?</td>
<td></td>
</tr>
<tr>
<td>Does your child watch other children do things and then try to copy</td>
<td>No/Don't know, Not very often,</td>
</tr>
<tr>
<td>them?</td>
<td>Often</td>
</tr>
</tbody>
</table>
**FORM G (17-19 months)**

<table>
<thead>
<tr>
<th>Can your stack blocks?</th>
<th>No/Don't have blocks</th>
<th>1-2 blocks</th>
<th>3 or more blocks</th>
</tr>
</thead>
<tbody>
<tr>
<td>How many of these body parts can your child point to if you say, “Where are your eyes?” “Where is your nose?” “feet?” “hair?” “mouth?” “ears?”</td>
<td>None</td>
<td>1</td>
<td>2 or more</td>
</tr>
<tr>
<td>Does your child try to get your attention by pointing to things?</td>
<td>No</td>
<td>Sometimes</td>
<td>Most of the time</td>
</tr>
<tr>
<td>Does your child try to jump, even if both feet don’t leave the ground?</td>
<td>No</td>
<td>Feet stay on the ground</td>
<td>One or both feet off the ground</td>
</tr>
<tr>
<td>When you are dressing your child, does he or she help by holding out an arm or lifting a foot?</td>
<td>No</td>
<td>Sometimes</td>
<td>Most of the time</td>
</tr>
<tr>
<td>When around other children, does your child try to do things with them, such as feeding or kissing them, or even pushing or taking toys?</td>
<td>No</td>
<td>Not very often</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**FORM H (20-22 months)**

<table>
<thead>
<tr>
<th>Does your child try to scribble with crayons or markers?</th>
<th>No/Never tried</th>
<th>Sometimes</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>How many of these body parts can your child point to if you say, “Where are your eyes?” “Where is your nose?” “feet?” “hair?” “mouth?” “ears?”</td>
<td>None</td>
<td>1</td>
<td>2 or more</td>
</tr>
<tr>
<td>If you ask your child, “What's this?” and showed things like a spoon, cup, doll, truck, box, crayon, cookie, chair, or light, how many names for these or other things does he or she say?</td>
<td>No</td>
<td>Feet stay on the ground</td>
<td>One or both feet off the ground</td>
</tr>
<tr>
<td>Does your child try to jump, even if both feet don’t leave the ground?</td>
<td>No</td>
<td>A little</td>
<td>Yes</td>
</tr>
<tr>
<td>When you are dressing your child, does he or she try to put an arm through a sleeve or a leg into pants?</td>
<td>No</td>
<td>Not often</td>
<td>Yes</td>
</tr>
<tr>
<td>Does your child watch people’s faces for clues to how they are feeling? Can he or she tell if someone is mad, sad, or happy?</td>
<td>No</td>
<td>Not often</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### FORM J (23-25 months)

<table>
<thead>
<tr>
<th>Question</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Option 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your child try to scribble with crayons or markers?</td>
<td>No/Never tried</td>
<td>Sometimes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>How many of these body parts can your child point to if you say, “Where are your eyes?”... “Where is your nose?”... “feet?”... “hair?”... “mouth?”... “ears?”</td>
<td>None</td>
<td>1-2</td>
<td>3 or more</td>
<td></td>
</tr>
<tr>
<td>If you ask your child, “What’s this?” and showed things like a spoon, cup, doll, truck, box, crayon, cookie, chair, or light, how many names for these or other things does he or she say?</td>
<td>None</td>
<td>1-2</td>
<td>3-4</td>
<td>5 or more</td>
</tr>
<tr>
<td>How does your child get up a set of stairs?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your child try to help when it is time to put things away?</td>
<td>No</td>
<td>Sometimes</td>
<td>Most of the time</td>
<td></td>
</tr>
<tr>
<td>Does your child use two toys together such as taking a doll for a ride in a toy car, having a truck carry things, or having a doll take a pet for a walk?</td>
<td>No</td>
<td>Sometimes</td>
<td>Yes, used two toys together</td>
<td></td>
</tr>
</tbody>
</table>

### FORM K (2 years 2 months-2 years 4 months)

<table>
<thead>
<tr>
<th>Question</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Option 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your child try to scribble with crayons or markers?</td>
<td>No/Never tried</td>
<td>Sometimes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Show your child a book and say, “Point to the front”, or “Where’s the front”. Try again with the “back,” “top,” and “bottom.” How many did your child know?</td>
<td>No</td>
<td>Some</td>
<td>All</td>
<td></td>
</tr>
<tr>
<td>If you ask your child, “What’s this?” and showed things like a spoon, cup, doll, truck, box, crayon, cookie, chair, or light, how many names for these or other things does he or she say?</td>
<td>None</td>
<td>1-4</td>
<td>5-7</td>
<td>8 or more</td>
</tr>
<tr>
<td>When your child tries to run, does each foot leave the ground a little, even if he or she falls often?</td>
<td>No</td>
<td>Sometimes</td>
<td>Most of the time</td>
<td></td>
</tr>
<tr>
<td>Does your child try to help when it is time to put things away?</td>
<td>No</td>
<td>Sometimes</td>
<td>Most of the time</td>
<td></td>
</tr>
<tr>
<td>Does your child try to join in when other children play?</td>
<td>No</td>
<td>A little</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
**FORM M (2 years 10 months - 3 years 2 months)**

<table>
<thead>
<tr>
<th>Question</th>
<th>No</th>
<th>Sometimes</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can your child scribble with a crayon or marker without going off the page much?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Point to pictures of the cats and balls and say, <em>Show me something big. Now show me something little.</em> What does your child know?</td>
<td>No</td>
<td>Sometimes</td>
<td>Yes</td>
</tr>
<tr>
<td>When your child talks to other people, how much do they understand of what he or she says?</td>
<td>None</td>
<td>Not much</td>
<td>About half</td>
</tr>
<tr>
<td>Can your child stand on each foot for a second?</td>
<td>No</td>
<td>Only one foot</td>
<td>Yes</td>
</tr>
<tr>
<td>Can your child slip his or her shoes on?</td>
<td>No</td>
<td>Yes, mostly on the wrong feet</td>
<td>Yes, mostly on the right feet</td>
</tr>
<tr>
<td>Can your child play well with a group of children? If so, for how long?</td>
<td>No, or less than 5 minutes</td>
<td>5-10 minutes</td>
<td>15-20 minutes</td>
</tr>
</tbody>
</table>
Black boxes are a fail, white box is a pass. If a child fails any one of the questions the child fails the whole PEDI:DM test.

How Form A to M is structured:

1. Fine motor = refer to occupational therapist
2. Receptive language = refer to speech-language pathologist
3. Expressive language = refer to speech-language pathologist
4. Gross motor = refer to occupational therapist
5. Adaptive behaviour (self help) = refer to occupational therapist
6. Social emotional = refer to speech-language pathologist

Interpretation:

Start with PEDI:

PATH A = FAIL irrespective of the outcome of the DM

PATH B = Conduct DM: if the DM is a pass the child pass, if child fall child has to be referred for testing (Q1,4, 5 refer to occupational therapist; Q2,3, 6 refer to speech-language pathologist)

PATH C= Conduct DM: if the DM is a pass the child pass, if child fail child has to be referred for testing (Q1,4, 5 refer to occupational therapist; Q2,3, 6 refer to speech-language pathologist)

PATH D = Conduct DM: if the DM is a pass the child pass, if child fail child has to be referred for testing (Q1,4, 5 refer to occupational therapist; Q2,3, 6 refer to speech-language pathologist)

PATH E = Conduct DM: if the DM is a pass the child pass, if child fail child has to be referred for testing (Q1,4, 5 refer to occupational therapist; Q2,3, 6 refer to speech-language pathologist)
APPENDIX D: Training Module
Welcome

Community Healthcare Worker (CHW) administering the PEDS tools i.e PEDS and PEDS:DM using a smart phone application for the purposes of a research project.

Background

Benefits of developmental screening?

- Developmental delays are detected by using developmental screening tools, early detection leads to early intervention of any developmental delays (Korczak & Seewald, 2012).
- Developmental screening in South Africa would be beneficial because children with emerging risks or with established risk for a developmental delay would be identified early and further referred to the relevant health professionals for assessment and intervention services.
- Developmental screening works promote child development and have a preventive function, they prevent further delay in development (Van der Loo, 2011).

How to Administer PEDS: Parents’ Evaluation of Developmental Status

By: T. Tseko, T. Mothoane

Procedure for the day

- The researchers and the CHW will approach parents and caregivers that come in to receive their children for their health check-ups or other health services. The researcher and the CHW will in detail explain to the potential participants the purpose of the study and what is expected from them and issue them with an information letter and a consent form to sign.

- The CHW and researcher will proceed to an interview room with the participant at a time and the PEDS tools will be administered. The CHW will introduce the participant using the smartphone PEDS tools application. The CHW will record responses on the smartphone application, while the speech-language therapist record the responses of the same participant.

Procedure for the day cont.

- The speech-language therapist will randomize the use of the paper-based PEDS tools and the PEDS tools in a mobile application, i.e. every second person themobile application will be used. The speech-language therapist and the CHW will communicate during training or view each other’s responses. They will be strategically positioned in such a way that they will not be able to view each other’s responses.
Procedure for the day cont..

- The scores of the CHW will be sent automatically upon consent in a secure server. The scores of the speech-language therapist will also be sent in the server upon consent. The scores of the paper-based Peds tools will be entered and uploaded to the server.
- Referral letters will be provided to parents whose child/children fails the screening (based on the findings of the speech-language therapist). At the end of each interview, the researcher will thank the respondent for participating in the study and give the respondent a fruit or snack for the child.

What does the Peds tools response form look like?

- You will use the response form on the smart phone application to record response. Responses will be recorded as either YES/NO/A Little. You must also note the parents comments.
Examples of Parents' Concerns:

- Expressive Language: He can't talk plainly.
- Receptive Language: She doesn't seem to understand us.
- Gross Motor: He's clumsy, falls a lot, awkward, late to walk.
- Fine Motor: She can't write well, messy eater.
- Global/Cognitive: Slow and behind, can't do what other kids can.
- Other: Trouble hearing, seeing, health problems, family issues.
- Social/Emotional: He's mean, she's bossy, doesn't have friends.
- Behavior: He won't mind me, temper tantrums.
- Academic/grade level: Trouble in school, doesn't know ABC's.
- Self-Help: Can't get dressed by himself.

I used to be worried but now I think he's doing OK.

Scoring: Mark the Score Form

- Mark the box to show the kind of concern.
- Even if there are several different kinds of issues under the same category, only check the box once (e.g., tantrums, hyperactivity, biting—all just get a single check under behavior).
- When parents answer "a little" to indicate the degree of concern, view this as a "yes".

Scoring: Alert

Parents don't always answer the question asked so be sure to focus on the categories of concern, not the type of question asked.

Scoring: Add your concerns too

- If you have a concern about a child, you can add checks to the boxes.
- However, don't remove or ignore the parents' concerns.

Scoring: Summary

- Total the number of concerns in the shaded boxes into the large shaded box at the bottom.
- Total the number of concerns in the unshaded boxes into the large unshaded box at the bottom.
• The Interpretation Form has space on the right to record your decisions, referrals, advise, etc. This provides a longitudinal record of services provided—helpful for audits, etc.

• Five questions are on the Peds:DM. A different form will be used according to the child’s age.

Clip of Peds:DM Items (29 - 33 Months)

Peds:DM Recording Form
For tracking development and recording decisions

Peds:DM Recording Form: Growth Chart Section
Delayed and passing responses are recorded on the Growth Chart for monitoring strengths and weaknesses in each domain over time.

Specific Decisions
This is a clip from the Peds:DM Recording Form showing space for notes on performance, parental concerns, clinician responses, etc.
For existing PEDS users wishing to add the PEDS:DM, the back of the PEDS:DM Recording Form includes the PEDS Score Form and a revised PEDS+PEDS:DM Interpretation Form. This form shows when the PEDS:DM is needed and how its results can inform decisions on developmental and behavioral needs.

Case example

Russell, age 30 months

This is the PEDS Response Form showing the PEDS questions and Ms. Richard's responses.

This clip from the PEDS+PEDS:DM score form shows issues raised at prior and current visits, and that the behavior concern does not predict developmental problems at this age (unshaded boxes), but the concern about listening does (shaded boxes).

Clip from the PEDS+PEDS:DM algorithm showing Path B, and the appropriate response to a single predictive concern.

Path B is associated with a moderate (but not high) risk level. Additional screening is wise in order to rule out delays.

PEDS:DM Items at 2 - 5 to 2 - 8 years
Here is Russell’s PEDS:DM Growth Chart showing past and present performance (top row of colored in boxes) and revealing adequate development in all domains.

ROLE PLAY
Practice Examples: Amy

Practice Examples: Billy
Practice Examples: Roger

He’s very coordinated and very fast!
Lots of instincts

He just doesn’t seem interested in even watching other kids

He is very independent

He’s too young for that sort of stuff

We spend a lot of time playing and talking with him and this seems to be helping some. I do wonder about his hearing sometimes though.
References
Approval Certificate Amendment
(to be read in conjunction with the main approval certificate)

Ethics Reference No.: 102/2011

Title: Researching the development, application and implementation of Community Oriented Primary Care (COPC). A study in Gauteng (Tshwane) and Mpumalanga Province

Dear Prof Johannes Hugo

The Amendment as described in the documents received on 3/11/2014 was approved by the Faculty of Health Sciences Research Ethics Committee on the 28/01/2015.

Please note the following about your ethics amendment:

- Please remember to use your protocol number (102/2011) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics amendment is subject to the following:

- The ethics approval is conditional on the receipt of 6 monthly written Progress Reports, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research

Yours sincerely

Professors Werdele (CW) Van Staden
MBChB, NMed(Psych), MD, FCPSych, FTCL, UPLM
Chairperson: Faculty of Health Sciences Research Ethics Committee

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles, Structures and Processes 2004 (Department of Health).

Tel: 012-3541329  Fax: 012-3541367  Fax2 Email: 0866515624  E-Mail: fhesethics@up.ac.za
Web: http://www.up.ac.za/healthethics  H W Snyman Bld (South) Level 2-34  Private Bag X 323, Arcadia, Pta, S.A., 0007

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APPENDIX F: Ethical Clearance Letter Faculty of Humanities
30 January 2015

Dear Prof Vinck

Project:
Smartphone-based developmental screening by community health care workers

Researcher:
K Maleka

Supervisor:
Dr J van der Linde

Department:
Speech-Language Pathology and Audiology

Reference:
23081814 (GW2015-03HS)

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 29 January 2014, conditional to written permission being granted by:

- the Ethics Committee of the Faculty of Health Science
- the Gauteng Department of Health
- the CEO of the Stanza Bopape Clinic

Please note that data collection may not commence prior to proof of above permissions being submitted and subject to final approval by this Committee. To facilitate the administrative process, please respond to Ms Tracey Andrew at tracey.andrew@up.ac.za or Room HB 7-27, at your earliest possible convenience.

Sincerely

[Signature]

Prof. Karen Harris
Acting Chair: Research Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: karen.harris@up.ac.za

Research Ethics Committee Members: Prof KL Harris (Acting Chair); Dr L Boixland; Dr JEH Grobler; Prof B Hogmey; Ms H Klopper; Dr C Panebianco-Warren; Dr C Puttenell; Prof GM Spies; Dr Y Giliis; Prof E Taljaard;
APPENDIX G: Ethical Clearance Letter Tshwane Research Committee
Meeting: N/A

PROJECT NUMBER: 10/2015

Title: Researching the development, application and implementation of community Orientated Primary Care (COPC), A study in Gauteng (Tshwane and Mpumalanga province)

Researcher: Karabo Maleka
Co-Researcher:
Supervisor: Prof. J. Hugo
Department: Health Science

DECISION OF THE COMMITTEE

Approved

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

Date: 23/04/15

Mr. Peter Shwamba
Chairperson Tshwane Research Committee
Tshwane 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.