

Smartphone-based Hearing Screening at Primary Health Care Clinics

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The hearScreen™ application is intellectual property owned, patented and trademarked by the University of Pretoria. The product is being developed for commercialization and more information is available at www.hearscreen.com

ABSTRACT

Objective: To evaluate the performance of smartphone-based hearing screening with the hearScreen™ application in terms of sensitivity, specificity, referral rates and time efficiency at two primary health care clinics.

Design: Nonprobability purposive sampling was used at both clinics. 1236 participants (mean age: $37.8 \pm \text{SD } 17.9$ and range 3 – 97 years; 71.3% female) were included in the final analysis. Participants were screened using the hearScreen™ application following a two-step screening protocol and diagnostic pure tone audiometry to confirm hearing status.

Results: Sensitivity and specificity for smartphone screening was 81.7% and 83.1% respectively, with a positive and negative predictive value of 87.6% and 75.6% respectively. Gender [$\chi^2(1, N=126) = .304, p > .05$] and race [$\chi^2(1, N=126) = .169, p > .05$] had no significant effect on screening outcome for children whilst for adults age ($p < 0.01; \beta = .04$) and gender ($p = 0.02; \beta = -.53$) had a significant effect on screening outcomes with males more likely to fail. Overall referral rate across clinics was 17.5%. Initial screening test times were less than a minute ($48.8\text{s} \pm 20.8 \text{SD}$) for adults and slightly more than a minute for children ($73.9\text{s} \pm 44.5 \text{SD}$).

Conclusion: The hearScreen™ smartphone application provides time-efficient identification of hearing loss with adequate sensitivity and specificity for accurate testing at primary health care settings.

Acronyms and abbreviations:

CHWs: Community health workers

COPC: Community orientated primary care

dB: Decibel

Hz: Hertz

MPANL: Maximum permissible ambient noise level

PHC: Primary health care

SD: Standard deviation

WHO: World Health Organization

INTRODUCTION

Hearing loss is one of the most prevalent chronic disabilities globally (WHO, 2008). It is estimated that 538 million people older than five years of age have disabling hearing loss (Stevens et al. 2011). The incidence rises to more than a billion people when including milder degrees of hearing loss (Global Burden of Disease Study 2013 Collaborators, 2015). It is unsurprising therefore that hearing loss is a leading contributor to the global burden of disease (Global Burden of Disease Study 2013 Collaborators, 2015).

The burden of hearing loss is the greatest in developing world regions such as sub-Saharan Africa, South-east Asia and Asia Pacific where more than 80% of people with hearing loss reside (Fagan & Jacobs, 2009; WHO, 2012, 2013b). Unfortunately,

hearing care services are either very limited, or totally absent in these regions (WHO, 2006; Fagan & Jacobs, 2009). Inadequate hearing care services are in large part due to the limited number of trained hearing care personnel worldwide (Goulios & Patuzzi 2008; Fagan & Jacobs 2009). A recent survey showed that there is approximately one hearing health care worker for half a million people in sub-Saharan Africa (WHO, 2013b). Additionally, hearing services in developing countries are not prioritised by health systems overwhelmed by life-threatening diseases as opposed to non-life-threatening conditions (such as hearing loss), limited resources, poor public and professional awareness as well as geographical barriers such as distance (Swanepoel et al. 2010).

The inequality between the lack of hearing services and the growing burden of hearing loss in developing world regions is significant and current hearing care efforts to reach the majority of underserved communities are inadequate (Swanepoel et al. 2010). Thus, approaches to expand and decentralise hearing services to contexts such as primary health care (PHC) clinics should be explored as a means of increasing access to care. In many developing countries PHC continues to be the only effective gateway to some form of health care (Tanser et al. 2006). This implies that if ear and hearing services are not available at PHC level, many communities in developing countries may not have any access to these services. Providing basic ear and hearing care services at a PHC clinic could increase equitable access to prevention, management, support programmes and services for hard-to-reach populations (WHO, 2013a). Including ear and hearing care in a community based rehabilitation programme and PHC clinics have also been advocated by the World Health Organisation (WHO) (WHO, 2006, 2013a).

The WHO emphasis is to provide hearing care services through PHC workers who

receive basic training in ear mopping/wicking, syringing of ear wax and prescribing treatment for common middle ear problems (WHO, 2006). A low technology approach such as performing the voice test has typically been recommended to screen hearing because audiometers are mostly unavailable at PHC clinics (WHO, 2006). The aforementioned are cost-effective interventions and can have a major impact on the burden of ear disease and hearing loss; however, using the voice test as a screening tool must be approached with caution. The voice test can yield unreliable results due to poor inter-observer variability and test-retest reliability, and is not recommended to be included in a screening programme (ASHA, 1997; Bogardus et al. 2003).

Pure tone audiometry is still recommended as the primary part of a hearing screening protocol to identify a hearing loss in children (> 5 years) and adults (ASHA, 1997; AAA, 2011). Requirements for pure tone hearing screening test entail appropriately qualified hearing health care personnel, low ambient noise levels during testing, calibrated audiometers and daily biologic checks of the audiometers to rule out distortion and intermittency (ASHA, 1997). Using these requirements as the gold standard, performing audiometry screening at PHC clinics is a challenge. There are limited numbers of qualified hearing care professionals available to perform conventional hearing screening and daily biologic checks on the audiometer. Furthermore, traditional audiological equipment and sound-treated test environments are expensive with a characteristically fixed location (MacLennan-Smith et al. 2013). The lack of controlled test environments with low levels of ambient noise can impede accurate hearing test results.

Novel telehealth approaches such as mobile health (mHealth) have, however, become available that could address some of these issues and could make identification of a hearing loss at PHC level feasible (Clark & Swanepoel 2014; Swanepoel et al. 2014; Peer & Fagan 2015; Yousuf Hussein et al. in press).

Smartphone applications for basic hearing assessments create opportunities to provide low-cost point of care diagnostics at PHC level (Kelly & Minges, 2012; Thompson et al. 2015)

The hearScreen™ application is one such technology that was developed as a low cost alternative to conventional hearing screening (Mahomed-Asmail et al. 2016). A recent report demonstrated no significant difference for sensitivity and specificity using the hearScreen™ application compared to conventional screening audiometry with more efficient testing (Mahomed-Asmail et al. 2016). hearScreen™ uses an entry-level smartphone running Android™ OS and inexpensive supra-aural headphones (Swanepoel et al. 2014). The low-cost headphones can be acoustically calibrated according to international standards allowing the inexpensive smartphone to be used as a screening audiometer (Swanepoel et al. 2014). A user-friendly interface employs pre-programmed automated test sequences with a forced-choice paradigm (Swanepoel et al. 2014). An operator with limited training can place headphones on the patient, capture demographic data, provide the onscreen instructions during the test and act on the screening outcome (Mahomed-Asmail et al. 2016). In terms of environmental noise levels, the hearScreen™ software integrates noise monitoring referenced to maximum permissible ambient noise levels (MPANLs) during testing (Swanepoel et al. 2014). Data capturing and uploading to the centralised cloud-based server, hearData, allows for remote monitoring. This

creates unique opportunity to be integrated with current community-orientated primary care (COPC) initiatives.

Integrating hearing screening at PHC clinics may allow universal and equal access to ear and hearing services (WHO, 2013a). Low-cost and user-friendly solutions for hearing screening such as smartphones offer the potential to aid prevention, early identification and management of hearing loss in underserved communities (Swanepoel et al. 2014). hearScreen™ has been investigated with success for use in schools and by community health workers (CHWs) in community-based testing (Kinkel et al. 2013; Yousuf Hussein et al. in press; Mahomed-Asmail et al. 2016). This study aimed to evaluate the performance of smartphone hearing screening in terms of sensitivity, specificity, time efficiency and referral rates at two different PHC clinics in South Africa.

MATERIALS AND METHOD

This research project was approved by the Institutional Research Board of the University of Pretoria, South Africa.

Participants

The current project was part of a larger COPC project currently underway in Gauteng (Tshwane) province (Kinkel et al. 2013). Data was collected at two PHC clinics (PHC clinic 1 and PHC clinic 2) in underserved communities in the Tshwane area where there were no prior audiology services. Data was collected during a 13-month and 6-month period at PHC clinic 1 and PHC clinic 2 respectively. PHC clinic 1 is situated

in the Pretoria West area and PHC clinic 2 is situated in the Mamelodi region.

Hearing tests were conducted once a week at each clinic.

1236 participants (PHC clinic 1 = 603; PHC clinic 2 = 633) were recruited with an average age of 37.8 years (± 17.9 ; range 3 to 97 years of age) of whom 73.6% were female and 68.2% African (Table 1). Only participants who provided signed consent (children had to provide assent along with a signed consent letter from their parent/caregiver) and who completed the screening protocol (i.e. completed a rescreen upon referral of initial screen) were included in the study.

Table 1. Demographic details of participants (PHC – Primary Health Care)

	Overall	PHC Clinic 1	PHC Clinic 2
ADULTS			
<i>n</i>	1110	498	612
<i>Male</i>	26.4% (n=293)	28.7% (n=143)	24.5% (n=150)
<i>Female</i>	73.6% (n=817)	71.3% (n=355)	75.5% (n=462)
<i>Ave Age (SD)</i>	41.2 years (SD 15.5)	43.0 years (SD 16.8)	39.7 (SD 14.2)
<i>Age range</i>	16 – 97 years	16 - 89 years	16 - 97 years
<i>Race</i>	68.2% African (n=757) 31.8% Caucasian (n=353)	29.1% African (n=145) 70.9% Caucasian (n=353)	100% African (n=612)
CHILDREN			
<i>n</i>	126	105	21
<i>Male</i>	49.2% (n=62)	49.5% (n=52)	47.6% (n=10)
<i>Female</i>	50.8% (n=64)	50.5% (n=53)	52.4% (n=11)
<i>Ave age (SD)</i>	7.5 (SD 2.9)	7.3 (SD 3.0)	8.5 (SD 2.5)
<i>Age range</i>	3 – 15 years	3 – 15 years	5 – 15 years
<i>Race</i>	31% African (n=39) 69% Caucasian (n=87)	17.1% African (n=18) 82.9% Caucasian (n=87)	100% African (n=21)

Nonprobability purposive sampling was used to screen participants at both health care clinics. At PHC clinic 1, universal screening took place by offering all individuals who visited the clinic a hearing screening free of charge. At PHC clinic 2 all

individuals who were available during the time that the services were delivered and who wanted their hearing tested were screened free of charge.

Diagnostic testing was available for confirmation of hearing loss on participants failing the screening. Diagnostic testing was also performed on a group of 111 participants who passed the screening to allow determination of screening specificity. A convenience sampling strategy was used to select these participants. One to two participants per day, who passed the hearing screening, were selected based on their availability and clinic time constraints.

Equipment

Smartphone hearing screening

Hearing screening was conducted using the hearScreen™ application (Android OS) on two smartphones (Samsung Pocket Plus S5301) connected to Sennheiser HD 202 II (Sennheiser, Wedemark, Germany) supra-aural headphones. Headphones were calibrated on the hearScreen™ calibration function according to prescribed standards (ANSI/ASA S3.6-2010; ISO 389-1, 1998) adhering to equivalent threshold sound pressure levels determined for this headphone according to ISO 389-9:2009 (Van der Aerschot et al. submitted). Calibration was performed using an IEC 60318-1 G.R.A.S. Ear stimulator connected to a Type 1 sound level meter (Rion NL-52).

hearScreen™ utilized an automated test sequence with a forced-choice paradigm to minimize operator influence and ensure ease of use (Swanepoel et al. 2014).

Screening was conducted using current recommended protocols (ASHA, 1997; AAA, 2011) with the exception that the intensity was raised to 35 dB HL for adults (>15 years of age) and 25 dB HL was used for children (3 to 15 years of age) (Swanepoel

et al. 2014). These screening intensities were to identify disabling hearing loss in children (>30 dB) and adults (>40 dB) (WHO, 2012). Furthermore typical criteria of 20 dB HL for children and 25 dB HL for adults may not be appropriate for resource-limited countries (Wenjin et al. 2014; Mahomed-Asmail et al. 2016). Lower screening intensities may result in over referral, which can overburden the health system and, in PHC contexts, may be vulnerable to false positives due to excessive ambient noise levels. In addition, studies conducted in developed and developing countries have used various screening intensity levels including 25, 30 and even 40 dB HL (AAA, 2011; Al-Rowaily et al. 2012; Kam et al. 2013; Lo & McPherson, 2013; Wenjin et al. 2014).

The smartphone hearing screening application monitored and recorded noise levels during data collection for each participant. Noise monitoring using the hearScreen™ application on these smartphones has been reported to be accurate within 1 to 1.5 dB, depending on frequency (Swanepoel et al. 2014). Recorded noise levels consisted of the averaged ambient noise recorded by the smartphone during pure-tone presentation (1.2 seconds duration) in the octave band corresponding to the test frequency (Swanepoel et al. 2014). Smartphones were connected to a 3G cellular or WiFi network whereby screening results were uploaded at the end of each session to the secure cloud-based server (hearData).

Diagnostic audiometry

The KUDUwave (MoyoDotNet, Johannesburg, South Africa) Type 2 Clinical Audiometer (IEC 60645-1/2) was used to conduct diagnostic pure tone audiometry on participants who failed the hearing screening. The audiometer hardware was contained within the circumaural ear cups and connected to a notebook (Dell

Inspiron running Microsoft Windows 7) via USB cables. Circumaural ear cups were placed over the insert earphones for additional attenuation to make hearing tests in a non-optimal environment outside a soundproof booth possible (Maclennan-Smith et al. 2013). A B-71 bone oscillator (Kimmetrics, Smithsburg, USA) was placed on the forehead with a standard adjustable spring head-band held in place on the centre of the circumaural headband with a screw fitting. The circumaural ear cups had two microphones that provided constant monitoring of environmental noise in octave bands during testing. An electronic response was connected to the headset software interface (eMoyo) that controlled the KUDUwave audiometer. The audiometer was calibrated prior to commencement of the study using a Type 1 sound level meter (Larson Davis System 824, Larson Davis, Provo, Utah) with a G.R.A.S. (Holte, Denmark) IEC 711 coupler for insert earphones and an AMC493 Artificial Mastoid on an AEC101 coupler (Larson Davis) with 2559 ½ inch microphone for the Radioear B-71 bone oscillator. Insert earphones and the bone oscillator were calibrated in accordance with ISO 389-2:1994 and ISO 389-3:1994 standards respectively.

Procedures

Testing was conducted in an examination room without sound isolation. Due to the busy nature of the clinics at times more than one participant was examined at the same time in the room.

Hearing screening and diagnostic hearing tests were facilitated by third and fourth year undergraduate audiology students from the University of Pretoria, under supervision of an experienced audiologist (first author). The audiology students had basic experience in hearing screening and were trained in the use of smartphone

hearing screening and to facilitate automated pure tone air and bone conduction audiometry during a two hour practical session prior to performing services.

Instructions were provided in English or Afrikaans. Written instructions in Sepedi were used by a non-Sepedi speaking test operator if participants did not understand English or Afrikaans. After capturing demographic information on hearScreen™, the student placed the headphones on the participant. The forced-choice paradigm required the student to indicate if the participant responded to the sound with a Yes/No response after the sound was presented (Figure 1).



Figure 1. hearScreen™ interface

Forced-choice paradigm requires the operator to select Yes/No based on the response of the participant

The student stood behind the participant with the participant instructed to raise a hand upon hearing the tone. The initial presentation level at 1 kHz was raised 10 dB above the screening level for conditioning purposes after which the screening continued on the test intensity. A 1, 2, and 4 kHz sweep was then performed at 35

dB HL for adults and 25 dB HL for children (ASHA, 1997). Stimulus presentation was repeated once if the participant did not respond at a specific intensity level. Left ears were tested first, followed by testing of right ears in the same way. Participants who responded to all the frequencies on both ears passed the screening. A two-step hearing screening protocol was followed; thus when a participant failed to respond to one or more frequencies in either ear, the results constituted an initial fail and an immediate rescreen was initiated. This standard practice is in accordance with screening guidelines (AAA, 2011; ASHA, 1997) recommending an immediate rescreen, which represents the final screening outcome (AAA, 2011). The two-step protocol was followed to minimize over-referrals. All test results were uploaded from the smartphones to the cloud-based server from where data were exported for analysis and interpretation. A diagnostic hearing test was conducted on the same day if participants failed the screening for a second consecutive time. In the case of children between the age of 3 and 4 years, the procedure was adapted to a play-based method i.e. the student conditioned the child to respond to the stimulus through a play activity such as dropping a block in a bucket when the sound was heard.

For diagnostic testing, insert earphones were placed deep in the ear canal with circumaural headphones placed over the ears to improve attenuation of ambient noise, and to minimize the occlusion effect. Air conduction audiometry was conducted for 0.25 kHz to 8 kHz. An automated threshold-seeking paradigm was utilized with a similar threshold-seeking method used in manual test configuration i.e. the modified Hughson-Westlake method. Participants were instructed to press the response button every time they heard a sound. Air conduction threshold differences between the test and non-test ear of 75 dB or greater at low frequencies (<1 kHz)

and 50 dB at high frequencies (> 1 kHz) were masked. A narrowband noise masking level of 30 dB above the air conduction threshold of the non-test ear was used. Bone conduction thresholds were determined with a continuous masking level of 20 dB above the air conduction threshold of the non-test ear (ASHA, 2005). The KUDUwave software actively monitored ambient noise levels across octave bands throughout the test procedures in both clinics.

Participants who presented with a mixed or conductive hearing loss were referred to the clinics' general practitioner for further medical intervention. Participants who presented with a sensorineural hearing loss were referred to the nearest district hospital for a hearing aid fitting evaluation.

Data analysis

Data was extracted from hearData and analysed using SPSS v23 (Chicago, Illinois). To evaluate the performance of the smartphone hearing screening, descriptive statistical measures were used to determine overall referral rates and recording times. Overall referral rates were obtained based on overall results following an immediate rescreen. A Chi-square test ($p < .05$ indicated a significant effect) was used to determine if gender, race and age had an effect on the screening outcome in children. A binary logistic regression model was used to determine the effect of age (as a continuous variable) gender, race and clinic on referral rate in adults ($p < .05$ indicated significance). Recording time differences between adults and children who passed and failed the initial screening was determined with an independent sample t-test. Recording time differences between initial and rescreens was determined with a paired sample t-test.

Sensitivity and specificity were calculated for smartphone hearing screening with reference to diagnostic test results. A hearing loss, indicated by the screening test, was confirmed by the diagnostic hearing test if the air conduction threshold at 0.5, 1, 2 or 4 kHz was greater than 25 dB for children or greater than 35 dB for adults. Frequency distributions and cross-tabulations were used to investigate screening outcomes where MPANLs were exceeded.

RESULTS

Twenty six participants (22 adults, 4 children) at PHC clinic 1 and 2 participants (2 adults) at PHC clinic 2 were excluded from the study because the screening protocol was not completed due an operator error. Two other participants were omitted from the study group at PHC clinic 2 because their date of birth was not captured. A total of 1236 participants were included in the final analysis.

The overall referral rate across clinics was 17.5% (adults 194/1110; children 22/126) (Table 2 and 3). Gender or race did not have a significant effect on screening outcomes for children [gender: $\chi^2(1, N=126)=.304, p>.05$; race: $\chi^2(1, N=126) = .169, p>.05$]; Chi square]. Whilst race did not have a significant effect on the screening outcome for adults ($p=0.66$; $\beta= -.55$; binary logistic regression), the screening outcome was significantly affected by gender ($p=0.02$; $\beta= -.53$; binary logistic regression) as more male participants failed the screening. Referral rate increased significantly with age ($p<0.01$; $\beta= .04$; binary logistic regression). More adults referred at PHC clinic 1 (20.5%) than at PHC clinic 2 (15.0%) although this difference was not significant ($p=0.41$; $\beta=-0.23$; binary logistic regression). Initial recording time was

Table 2. Referral rates for adults using smartphone hearing screening in primary health care clinics (PHC – Primary Health Care)

	Overall (n)	PHC Clinic 1 (n)	PHC Clinic 2 (n)
Overall referral	17.5% (194/1110)	20.5% (102/498)	15.0% (92/612)
<i>Initial screen</i>	20.7% (230/1110)	21.5% (107/498)	20.1% (123/612)
<i>Rescreen</i>	84.3% (194/230)	93.6% (102/107)	74.8% (92/123)
Gender			
<i>Male</i>	25.3% (74/293)	31.5% (45/143)	19.3% (29/150)
<i>Female</i>	14.7% (120/817)	16.1% (57/355)	13.6% (63/462)
Age			
<i>16-39 years</i>	9.8% (55/562)	*9.6% (22/228)	*9.9% (33/334)
<i>≥40 years</i>	25.4% (139/548)	*29.6% (80/270)	*21.2% (59/278)
Ears			
<i>Left</i>	15.9% (177/1110)	18.1% (90/498)	14.2% (87/612)
<i>Right</i>	14.6% (162/1110)	16.1% (80/498)	13.4% (82/612)
Frequencies			
<i>1 kHz left</i>	8.0% (89/1110)	7.6% (38/498)	8.3% (51/612)
<i>2 kHz left</i>	9.3% (103/1110)	9.2% (46/498)	9.3% (57/612)
<i>4 kHz left</i>	10.8% (120/1110)	14.1% (70/498)	8.2% (50/612)
<i>1 kHz right</i>	7.7% (86/1110)	7.4% (37/498)	8.0% (49/612)
<i>2 kHz right</i>	8.7% (97/1110)	8.6% (43/498)	8.8% (54/612)
<i>4 kHz right</i>	11.4% (126/1110)	13.5% (67/498)	9.6% (59/612)

significantly shorter ($44.0s \pm 15.0$ SD) for adults who passed the screening compared to adults who referred [$67.3s \pm 27.0$ SD; $t(1108) = -16.9$, $p < .05$; Independent t-test]. In children there was also a significant difference between the initial screening times for those who passed ($62.8s \pm 38.8$ SD) and those who referred [$106.4s \pm 44.5$ SD; $t(124) = -5.3$, $p < .05$; Independent t-test]. Initial screening test times were significantly shorter for adults ($48.8s \pm 20.8$ SD) compared to children [$73.9s \pm 44.5$ SD; $t(1234) = -10.9$, $p < .05$; Independent t-test] (Table 4). Rescreen test time was significantly longer (82.6 ± 49.9 SD) compared to initial test time [$67.3s \pm 27.0$ SD; $t(231) = -4.9$, $p < .05$; Paired t-test] for adult participants. There was no significant difference between initial ($106.4s \pm 44.5$ SD) and rescreen [$123.9s$

± 80.0 SD; $t(31) = -1.6$, $p > .05$; Paired t-test] times for children.

Table 3. Referral rates for children using smartphone hearing screening in primary health care

	Overall (n)	PHC Clinic 1 (n)	PHC Clinic 2 (n)	clinics (PHC – Primary Health Care)
Overall referral	17.5% (22/126)	16.2% (17/105)	23.8% (5/21)	
<i>Initial screen</i>	25.4% (32/126)	24.8% (26/105)	28.6% (6/21)	
<i>Rescreen</i>	68.7% (22/32)	65.4% (17/26)	83.3% (5/6)	
Gender				
<i>Male</i>	19.4% (12/62)	19.2% (10/52)	20% (2/10)	
<i>Female</i>	15.6% (10/64)	13.2% (7/53)	27.3% (3/11)	
Ears				
<i>Left</i>	22.2% (28/126)	21.0% (22/105)	28.6% (6/21)	
<i>Right</i>	16.7% (21/126)	16.2% (17/105)	19.0% (4/21)	
Frequencies				
<i>1 kHz left</i>	15.9% (20/126)	14.3% (15/105)	23.8% (5/21)	
<i>2 kHz left</i>	15.1% (19/126)	13.3% (14/105)	23.8% (5/21)	
<i>4 kHz left</i>	15.1% (19/126)	14.3% (15/105)	19.0% (4/21)	
<i>1 kHz right</i>	12.7% (16/126)	11.4% (12/105)	19.0% (4/21)	
<i>2 kHz right</i>	13.5% (17/126)	13.3% (14/105)	14.3% (3/21)	
<i>4 kHz right</i>	10.3% (13/126)	10.5% (11/105)	9.5% (2/21)	

Table 4. Mean test duration using hearScreen™ at both primary health care clinics

	Adults	Children
Initial screen		
<i>Mean test time (±SD)</i>	48.8s (±20.8)	73.9s (±44.5)
<i>Range</i>	24 - 192s	27 - 241s
Rescreen		
<i>Mean test time (±SD)</i>	82.6s (±49.9)	123.9s (±80.0)
<i>Range</i>	26 - 382s	30 - 320s

Diagnostic evaluations were performed on 63.8% (138/194) of the participants (4 children and 134 adults) who referred. Fifty-six participants were not tested diagnostically, mostly due to logistical reasons at the PHC clinics. In the group tested diagnostically, the average age was 48.5 years (±19.7; range 7 to 97 years), 56.1% female and 56.9% African. Of the 138 participants tested diagnostically, 87.6%

(121/138; 4 children, 117 adults) presented with a confirmed hearing loss. Diagnostic evaluations were also performed on 10.8% (111/1020) of participants who passed the screening. These had an average age of 38.0 years (± 14.9 ; range 6 to 70 years), 78.2% female, and 77.2% African. Sensitivity and specificity for the screening was 81.7% and 83.1% respectively (Table 5). False positive and false negative results accounted for 10.8% (27/249) and 6.8% (17/249) of cases respectively.

Table 5. Test performance for hearScreen™ at primary health care clinics (n=249). Participants' hearing status was confirmed by diagnostic testing (PHC – Primary Health Care)

	Overall (n=249; 44.5% pass; 55.4% refer)	95% Confidence intervals	PHC Clinic 1 (n=99)	PHC Clinic 2 (n=150)
Sensitivity	81.7%	74.3 - 87.4	88.8%	75.0%
Specificity	83.1%	74.1 - 89.6	77.7%	85.1%
Positive likelihood ratio	4.86%	3.13 – 7.54	4.0%	5.0%
Negative likelihood ratio	0.22%	0.15 – 0.31	0.14%	0.29%
Positive predicative value	87.6%	81.0 – 92.6	91.4%	83.8%
Negative predicative value	75.6%	66.6 – 83.3	72.4%	76.8%

Smartphone noise levels only exceeded MPANLs in 2.4% (left ear) and 6.3% (right ear) of thresholds tested at 1 kHz in children and only one instance at 2 kHz. In the adult population noise levels only exceeded MPANLs in 0.2% (left ear) and 0.1% (right ear) of instances tested at 1 kHz.

DISCUSSION

This study evaluated the performance of smartphone-based hearing screening following a two-step screening protocol with hearScreen™ at two PHC clinics in South Africa. The performance of a screening test depends on the sensitivity and specificity of the technique. Sensitivity and specificity across adults and children for hearScreen™ at PHC clinics was 81.7% and 83.1% respectively. These are the first results of smartphone hearing screening at PHC clinics reported to date. While sensitivity is somewhat better to a recent reported sensitivity of 75.0% using the same software for smartphone hearing screening in a school-based context (Mahomed-Asmail et al. 2016), the specificity (98.5%) of the recent study was considerably higher than the current study. The variation in specificity values between the two studies can be attributed to differences in the populations and disease prevalence. Mahomed-Asmail's et al. (2016) study focused on young children (mean age 8 years \pm 1.1; range 6 to 12 years) with an overall referral rate of only 3.2%. In contrast, the current study population comprised mostly (89.8%) adults (mean age 37.8 \pm 17.9; range 3 to 97 years) and had an overall referral rate of 17.5%. Previous studies performed in PHC contexts using a hand-held combination otoscope and audiometer demonstrated lower specificity (60% - 80%) and slightly higher sensitivity (94%) compared to current study findings (Lichtenstein et al. 1988; Ciurlia-Guy et al. 1993; McBride et al. 1994). These studies differed however in terms of screening protocol (500 – 4000 Hz vs. 1000– 4000 Hz), screening level (40 dB HL vs. 35 dB HL) and different population ages. A number of the studies (Lichtenstein et al. 1988; Ciurlia -Guy et al. 1993; McBride et al. 1994) included elderly persons (above 60 years) whilst the average age in the current study was 41.2 years (15.5 SD).

Increasing age had a significant impact on referral rate in the adult population. These results reflect the familiar patterns of nonlinear increase of hearing loss with age and compare well to other epidemiology studies (Cruickshanks et al. 1998; Cruickshanks et al. 2003; Lin et al. 2011; Roth et al. 2011). These results are also comparable to a recent study performed in a community setting indicating that 25.0% of adults older than 45 years failed the hearing screening (Yousuf Hussein et al. in press).

The majority of referrals in children occurred at 1 kHz. In contrast, the majority of referrals in adults were seen at 2 kHz and 4 kHz. This suggests a sloping pattern of loss and is typical of age-related hearing loss (Cruickshanks et al. 1998; Lin et al. 2011). In addition to age, environment factors (e.g. noise exposure, ototoxic medication, socio-economic status) and health co-morbidities (e.g. cardiovascular disease) could also have predisposed a higher referral rate in this selected population (Agrawal et al. 2009; Lin et al. 2011). Many of the individuals screened visited the PHC clinic for management of prominent diseases and conditions such as diabetes, tuberculosis, HIV/AIDS, hypertension and malaria, all from which hearing loss can arise (Araújo et al. 2012; Seddon et al. 2012; Assuiti et al. 2013; Van der Westhuizen et al. 2013). It was, however, beyond the scope of this study to establish relationships between the abovementioned risk factors and hearing loss at PHC level.

More adult females (73.6%) than males (26.4%) were screened. This could be expected as South African women are more likely to visit a health care worker/ clinic than men (Statistics South Africa, 2013). Male participants were, however, more likely to fail the screening. These results compare well to other epidemiology studies that show men have a greater risk of hearing loss (Cruickshanks et al. 1998).

A leading cause for increased referral rates in community-based hearing tests is environmental noise. The hearScreen™ application provides a quality control feature which monitors noise levels during testing. In the current study ambient noise levels did not demonstrate a significant effect on screening outcome. Previous studies using the same application showed that recorded noise levels exceeded MPANLs mostly at 1 kHz for 25 dB HL, which is the screening intensity for the child protocol (Yousuf Hussein et al. in press; Mahomed-Asmail et al. 2016). The 1 kHz stimulus is typically more susceptible to ambient noise than 2 and 4 kHz whilst the 25 dB HL screening level is more susceptible than the 35 dB HL screening level employed for adults in this study.

Average test time for the initial smartphone hearing screening, excluding time taken for instructions and capturing demographic information, was less than a minute for adults (48.8s ± 20.8 SD) and just over a minute for children (73.9s ± 44.5 SD). This compares well with recent hearScreen™ studies performed in a community context and in a school-based context (Yousuf Hussein et al. in press; Mahomed-Asmail et al. 2016). These average test times are shorter than conventional hearing screening (Sideris & Glatke, 2006; Wenjin et al., 2014; Mahomed-Asmail et al. 2016). Shorter test times could facilitate more efficient hearing screening at PHC level.

The high referral rate (17%) in this study demonstrates the need for hearing services at PHC clinics. Smartphone hearing screening by minimally trained personnel could be seen as the initial phase in the attempt to increase access to early detection of hearing loss at a PHC level. A limitation of the current study, however, was that screening was performed by audiology students with basic experience in hearing screening and not by minimally trained community members or clinic staff. A recent study, however, has demonstrated that CHW's can be trained to successfully

perform hearing screening using this smartpone technology at primary care level (Yousuf Hussein et al. in press). The current study revealed some operator errors which reduced the data available to the study. Upgrades to the software that insist that the date of birth be entered, and not allowing the operator to exit the software if a rescreen is indicated, are recommended.

The burden of hearing loss is a global dilemma, particularly in developing world regions where the majority of hearing-impaired persons reside. The growing burden of hearing loss and the lack of hearing services are particularly significant in underserved communities worldwide where there is a pervasive shortage of hearing care personnel. Mobile technology is a gateway to expand and decentralize hearing services to PHC level where persons with minimal training could perform hearing screening. PHC detection could be followed by air conduction threshold testing using similar technology, as recently demonstrated, which could reduce false-positive referrals (van Tonder et al. in press; Sandstrom et al. in press). Additionally, smartphone audiometry opens the door for new possibilities at PHC such as monitoring programmes for ototoxicity in treatment for tuberculosis. Using smartphone technology in conjunction with automated tympanometry or tympanic membrane image-analysis to detect otitis media or ear canal obstructions may further optimise the referral system in resourced-constrained communities (Myburgh et al. 2016). Integrating smartphone technology could therefore increase access to PHC hearing care in terms of decentralised detection and point-of-care diagnostics whilst future opportunities may also extend to interventions i.e. self-fitting, or preset hearing aids (WHO, 2013; Keidser & Convery, 2016). The current study demonstrates that, as a step towards increased access in underserved areas, smartphone-based hearing tests using calibrated headphones at PHC clinics can

provide simple, time-efficient screening with adequate sensitivity and specificity for children and adults.

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