Clinical validity of hearScreen™ smartphone hearing screening for school children

Faheema Mahomed-Asmail [1]

De Wet Swanepoel [1,2,3]

Robert H Eikelboom [1,2,3]

Hermanus C Myburgh [4]

James Hall [1]

1. Department of Speech-Language Pathology and Audiology, University of Pretoria, Pretoria, South Africa

2. Ear Science Institute Australia, Subiaco, Australia

3. Ear Sciences Centre, School of Surgery, The University of Western Australia, Nedlands, Australia

4. Department of Electrical, Electronic and Computer Engineering, University of Pretoria, Pretoria , South Africa

Acronyms and abbreviations:

dB: Decibel

Hz: Hertz

SD: Standard Deviation

SLM: Sound level meter

MPANL: Maximum permissible ambient noise level

ETSPL: Equivalent threshold sound pressure level

Address for correspondence:

Ms Faheema Mahomed-Asmail

Department of Speech-Language Pathology and Audiology, University of Pretoria

Room 3-25, Level 3

Corner Lynnwood and University Road

Phone: +27 12 420 2490

Email: faheema.mahomed@up.ac.za

ABSTRACT

Objectives

The study aimed to determine the validity of a smartphone hearing screening technology (hearScreen™) compared to conventional screening audiometry in terms of (1) sensitivity and specificity, (2) referral rate and (3) test time.

Design

1070 school-aged children in grade 1 to 3 (8 ±1.1 average years) were recruited from five public schools. Children were screened twice, once using conventional audiometry and once with the smartphone hearing screening. Screening was conducted in a counterbalanced sequence, alternating initial screen between conventional or smartphone hearing screening.

Results

No statistically significant difference in performance between techniques was noted, with smartphone screening demonstrating equivalent sensitivity (75.0%) and specificity (98.5%) to conventional screening audiometry. Whilst referral rates were lower with the smartphone screening (3.2 vs. 4.6%) it was not significantly different (p>0.01). Smartphone screening (hearScreen™) was 12.3% faster than conventional screening.

Conclusion

Smartphone hearing screening using the hearScreen™ application is accurate and time-efficient. Utilising commercially available, off-the-shelf, hardware provides an inexpensive solution that laypersons with limited training can operate since tests and interpretations are automated.

INTRODUCTION

Unidentified hearing loss has a substantial impact on a child's speech and language development, educational attainment and socio-emotional development (Joint Committee on Infant Hearing 2007; World Health Organisation 2013). As a result a child's risk for failure and drop-out from school is significantly greater (WHO 2013). Most children who present with a hearing impairment at birth are potentially identifiable by newborn and infant hearing screening (Cunningham & Cox 2003; Joint Committee on Infant Hearing 2007). In developing areas of the world, where more than 80% of persons with hearing loss reside, there are limited prospects of early detection for hearing loss (Skarżyński & Piotrowska 2012; WHO 2013) due to a

number of barriers. Thus close to 20% of permanent moderate or greater bilateral, mild bilateral and unilateral impairments, remain to be identified around the time of school entry (Bamford et al. 2007).

School-entry hearing screening, if available, is the first point of access for screening in most developing countries and even in some developed countries (Bamford et al. 2007; Theunissen & Swanepoel 2008). In a country like South Africa for example, where no legislation or health care mandate is in place to conduct newborn hearing screening, the recently mandated school-based screening (Intergrated School Health Policy 2012) is the first opportunity for hearing screening in most children (Theunissen & Swanepoel 2008; Meyer et al. 2012). However, effective implementation of school-based hearing screening presents a number of significant challenges (Madriz 2001; McPherson & Olusanya 2008).

The cost of hearing screening can be prohibitive due to the expense of audiometric equipment and the requirement for trained personnel to conduct the screening. Furthermore, school-based hearing screening usually takes place in an enclosed, unoccupied, furnished room where ambient noise levels often exceed permissible levels (FitzZaland & Zink 1984; Bamford et al. 2007; Lo & McPherson 2013). Furthermore, test operators usually have no feedback on the compliance of ambient noise levels during testing. As a consequence, false-positive findings occur when ambient noise masks the test signal resulting in unnecessary and costly diagnostic assessments (Lo & McPherson 2013).

A recent report of smartphone based hearing screening using the hearScreen™ application has demonstrated promise to address some of the abovementioned barriers (Swanepoel et al. 2014). hearScreen™ is a cost-effective screening option

that can be operated on an entry-level smartphone running Android[TM] OS. A supra-aural headphone can be acoustically calibrated according to international standards taking into consideration the procedures specified to determine equivalent threshold sound pressure levels (ETSPL) for non-audiometric headphones (ANSI/ASA S3.6-2010; ISO 389-1, 2009) using a type 1 sound level meter and coupler. This feature creates opportunity for smartphones to be utilized as screening audiometers with headphones calibrated according to prescribed standards. Furthermore, the hearScreen™ software application integrates noise monitoring referenced to MPANLs during testing. This provides screening operators with real-time feedback on ambient noise levels and allows frequencies to be retested where noise levels exceeds MPANLs and patients do not respond (Swanepoel et al. 2014).

hearScreen™ can be programmed according to recommended screening protocols (American Speech-Language-Hearing Association 1997; American Academy of Audiology 2011) utilizing automated test sequences based on a forced-choice paradigm to ensure reliability and ease of use (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. Additionally, the hearScreen™ application has a data storage feature utilising the connectivity available on the phone (GPRS/3G/HSDPA and Wi-Fi) to securely upload data to a cloud-based server for remote monitoring and management. An initial validation study showed no significant difference for screening outcomes using hearScreen™ and conventional audiometry (Swanepoel et al. 2014). However, the study was conducted with a modest sample size and test sensitivity and specificity was not determined.

An additional investigation is necessary to validate the smartphone hearing screening against conventional screening audiometry followed by diagnostic assessment to determine true sensitivity and specificity rates. This study therefore aimed to establish the validity of school-based hearing screening using smartphone hearing screening with the hearScreen[TM] application compared to conventional screening audiometry in terms of (1) sensitivity and specificity (2) referral rates and (3) test time.

MATERIALS AND METHODS

The research project was approved by the Research Board of the University of Pretoria, South Africa and Gauteng Department of Education, South Africa.

Participants

1070 school-aged children from grade 1 to grade 3 with an average age of 8 years (±1.1 SD; Range 6 to 12 years) were recruited from five public government schools in underserved regions of the Gauteng Province, South Africa. Demographic distribution was 50.7% female and 83.5% African (16.5% Caucasian). Only children who provided assent along with a signed consent from their parent/caregiver were included in the study. A response rate of 64.2% (1070/1667) was obtained for this study. Data were collected during a 7-month period with the exception of two vacation periods.

Test environment and screening personnel

Screening was conducted by second year audiology students from the University of Pretoria who were trained in the use of both the smartphone hearing screening and

6

conventional screening audiometry. As part of the practical block the audiology students, under direct supervision of the first author who conducted validation checks throughout, were required to complete five consecutive screening sessions. Diagnostic audiometry was conducted by the first author. Testing was conducted in a quiet room provided by the school were five stations were set up, two for conventional screening, two for smartphone hearing screening and one for diagnostic audiometry. Due to the limited number of screeners and testers available, small groups of four to six children were taken into the testing venue. Larger number of children can be screened based on the available resources. Sound in the test environment was measured with a sound level meter (RION, NA-24) for no less than five minutes prior to data collection and no less than five minutes twice during data collection during the session. Calibration was checked every four to six weeks thereafter using an IEC 60318-1 G.R.A.S Ear stimulator connected to a Type 1 SLM (Rion NL-52). Calibration checks on both screeners were carried out in order to rule out any variations to the presented pure tone signal, the values did not vary more than 1 dB HL across the multiple checks.

Equipment

Smartphone hearing screening

Data were collected with two sets of Samsung Galaxy Pocket Plus S5301 phones running the hearScreen™ Android OS application with supra-aural Sennheiser HD202 II headphones (Sennheiser, Wedemark, Germany). As the hearScreen™ application (under investigation) is not intended to be an end-user application it requires objective calibration on pre-selected smartphone models standardised for testing. Thus before data collection commenced, headphones were calibrated on the

hearScreen™ calibration function according to prescribed standards (ANSI/ASA S3.6-2010; ISO 389-1, 1998) for TDH 39 supra-aural headphones (see Swanepoel et al., 2014 for detailed description). Furthermore, the smartphone hearing screening application monitored and recorded noise levels during data collection for each child. Previously published work indicate that noise monitoring using this application on these smartphones is accurate within 1 and 1.5 dB, depending on the frequency (Swanepoel et al. 2014). Recorded noise levels consisted of the averaged ambient noise recorded by the smartphone during the pure-tone presentation (1.2 seconds duration) in the octave band corresponding to the test frequency (see Swanepoel et al. 2014). Smartphones were connected to a 3G cellular network whereby screening results were uploaded to a database at the end of each screening session.

Conventional hearing screening

Conventional hearing screening was conducted with one of two screening audiometers, a GSI Auto Tymp (Grayson Stadler, Eden Prairie, USA) or an Interacoustics Impedance Audiometer AT 235 (William Demant, Smørum, Denmark), both using Telephonics TDH 39P headphones. Audiometers were calibrated according to ISO 389-1 (1998) standards prior to data collection.

Diagnostic audiometry

Diagnostic audiometry was performed with a KUDUwave (MoyoDotNet, Johannesburg, South Africa) Type 2 Clinical Audiometer (IEC 60645-1/2). The KUDUwave is operated via a notebook computer (Acer Aspire E1-532, running Microsoft Windows 8) with the audiometer hardware encased in each circumaural ear cup and powered by a USB cable plugged into the notebook. Transducers were

insert earphones covered by the circumaural cups after insertion. A response button was connected to the KUDUwave device to record patient responses to stimuli. The KUDUwave had two microphones on the circumaural earcup that monitored the environmental noise in octave bands during testing and was visually represented in real-time within the software. Whenever the noise exceeded the maximum ambient noise level allowed for establishing a threshold as indicated by the effective attenuation level in the KUDUwave software, the audiologist waited for the transient noise to abate and then continued the testing. The KUDUwave device has been validated for accurate air- and bone-conduction thresholds in school settings utilizing the increased attenuation (insert earphones covered by circumaural earcups) and real-time noise monitoring (Swanepoel, Maclennan-Smith & Hall 2013). 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 were calibrated in accordance with ISO 389-2 and the bone oscillator according to ISO 389-3 standards.

Procedures

Each child was screened twice by the same tester, once with a conventional screening audiometer and once with the smartphone hearing screening device on the same day in the same room. Screening was conducted in a counterbalanced sequence, alternating initial screen between conventional and smartphone screening. The screener sat behind the child with the child instructed to raise a hand

upon hearing the tone (Figure 1). Screening was conducted using current recommended protocols (American Speech-Language-Hearing Association 1997; American Academy of Audiology 2011) with the exception that the screening intensity level was raised to 25 dB HL for both methods of screening (Swanepoel et al. 2014). Kram et al. (2013) indicated that the recommended criterion of 20 dB HL for referral may not be ideal for resource-limited countries. Furthermore, studies conducted in some developed and developing countries such as China, India and Africa utilized screening intensity levels of 25, 30 and even 40 dB HL (Al-Rowaily, et al., 2012; AAA, 2011; Kam et al., 2013; Lo & McPherson, 2013; Wu et al., 2014). As a resource-limited country with less than optimal test environments being utilized the screening level was set at an elevated level of 25 dB HL.
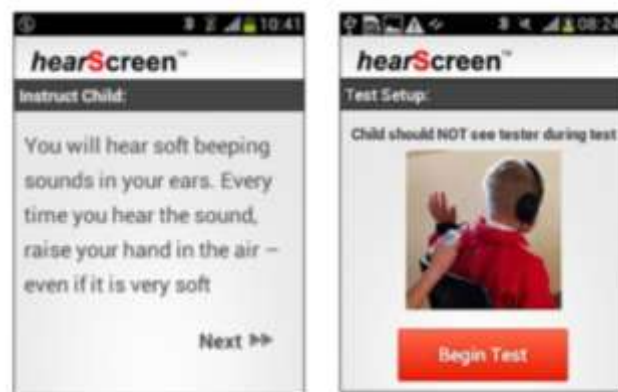

Figure 1. Onscreen hearScreen™ instructions provided to tester

Conventional screening was conducted manually whereas hearScreen™ was programmed utilizing an automated test sequence with a forced choice paradigm to ensure ease of use and minimal operator influence (Swanepoel et al. 2014). An operator placed the headphones on the child and provided the necessary onscreen instructions after filling out the child's details (Figure 1). The forced-choice paradigm requires that, after the test operator presented the test signal the child will raise a

hand upon hearing the tone, the tester will then have to indicate whether the child responded to the sound in a YES/NO response provided on the application. Based on the response the intensity and frequency changes automatically according to the programmed test protocol (See Swanepoel et al. 2014 for detailed description). Furthermore, the inter-stimulus interval of hearScreen™ is similar to conventional screening as the tester still controls when the tone should be presented allowing similar flexibility as conventional screening.

Due to the automated test sequences for hearScreen™ based upon the forced-choice response by testers, training was significantly less than for conventional screening audiometry which requires prior knowledge and skill in adjusting frequencies and intensities on the audiometer in accordance with the screening protocol.

To ensure consistency for both screening methods left ears were tested first with an initial conditioning presentation at 1 kHz at an intensity level of 35 dB HL. This was followed by presentations of 25 dB HL at 1, 2, and 4 kHz. Stimulus presentation was repeated once if a child did not respond at a specific frequency level. Once data was collected for the left ear the same procedure was repeated in the right ear. No response at 25 dB HL at any frequency in an ear constituted an initial fail. Immediately following a fail result, the child was rescreened using the same screening audiometer. hearScreen™ provided the tester with onscreen guidelines on
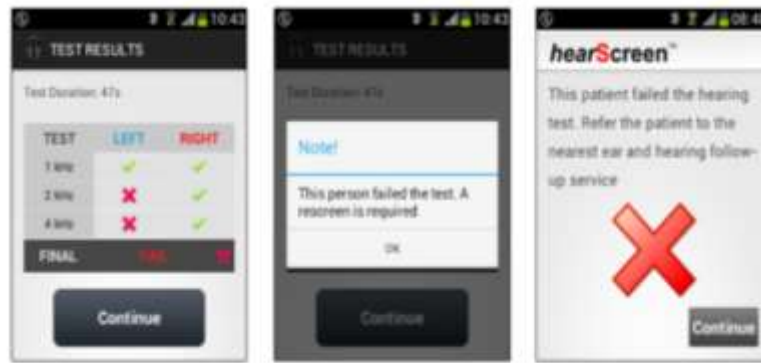
Figure 2. Rescreen and referral instructions provided by hearScreen™

when to conduct a rescreen and when a child referred (Figure 2). Average test time
for both methods were recorded, excluding instructions and preparation time. For
conventional screening the tester used a stop watch to record the time, whereas with
hearScreen™ the test time was automatically recorded by the screening application.
Furthermore, maximum permissible noise levels (MPANL) were recorded during
testing with the smartphone screening application. The MPANL's per octave band for
screening at 25 dB was 49, 57, and 61 dB SPL for 1, 2, and 4 kHz respectively
(Swanepoel et al. 2014). The ambient noise level measurements were measured
with a sound level meter (RION, NA-24) to ensure that test environment for
diagnostic testing was in accordance to those indicated in the validation study
(Swanepoel, Maclennan-Smith & Hall 2013).

Sensitivity and specificity usually requires diagnostic assessment of the entire
sample. Sensitivity for the current study was determined conventionally by
diagnostically testing each child who referred based on immediate rescreen on either
screening technique (conventional and hearScreen™). Since the current study
compared screening techniques of each child with diagnostic evaluations for
referrals on both or either screening technique, the false negatives for each

screening technique could be determined. To further investigate the possible occurrence of false negatives in children who passed both screenings a stratified sampling strategy was employed whereby every 15th child who passed both screens was tested diagnostically. In this way specificity could be determined by taking into consideration the true and false negatives for each technique. For diagnostic audiometry insert earphones were placed deeply within the external ear canal with circumaural headphones placed over the ears and the bone-conductor placed on the forehead. Children were instructed to press the response button every time they heard the tone, the KUDUwave recorded false positive results as a control. Behavioral air conduction thresholds and behavioral bone conduction thresholds were obtained at 0.5, 1, 2 and 4 kHz.

The school principal received hearing screening reports for all children tested. Based on the screening and diagnostic findings parents were provided with hearing screening reports and in the case of a referral, recommendations regarding follow-up assessments and interventions were made.

Data analysis

To evaluate the accuracy of the smartphone hearing screening, overall referral rates with the smartphone and conventional screening were compared using cross-tabulations of test outcomes for each child. Overall referral rates were obtained based on overall results following an immediate rescreen (two consecutive fail results) for each child. A Chi-square test was used to assess differences across testing with a level of $p < 0.05$ set as significant. Sensitivity and specificity were calculated separately for each screening technique with reference to conventional

diagnostic test results for each child. Sensitivity and specificity results obtained for hearScreen™ were compared to those obtained for conventional screening. Diagnostic test results revealed a hearing loss when an AC threshold greater than 25 dB at either 0.5, 1, 2 or 4 kHz was obtained. Noise level measurements recorded with hearScreen™ were averaged and compared to maximum permissible ambient noise levels (MPANL's) for the specified headphones (Swanepoel et al. 2014) at the screening level of 25 dB HL. Average test time between methods, excluding instructions and preparation time, was also determined with the paired sample t-test. Statistical analysis was conducted using SPSS (v22. Chicago, Illinois).

RESULTS

Overall referral rates were 3.2% for smartphone hearing screening and 4.6% for conventional screening (Table 1). There was no significant difference ($p > 0.01$; Chi-square test) between screening techniques for overall referral rate, across age categories or between initial and rescreen results (Table 1). Significantly more females referred ($p < 0.05$; Chi-square test) for conventional screening compared to males (Table 1). Across frequencies the highest referral rates were noted at 1 kHz for both screening techniques with no statistical difference ($p < 0.05$; Chi-square test). Average time for conducting an initial screen was significantly less ($p < 0.001$; Paired sample t-test) with the smartphone hearing screening device (mean 54.5 seconds; SD 28.3) being 12.3% faster than conventional hearing screening (mean 62.2 seconds; SD 38.1).

Table 1. Referral rates for conventional and hearScreen™ screening

Referral rate	Participants (n)	Conventional screening	hearScreen™
Overall			
Initial screen	1070	9.3%	7.4%
*Rescreen**	1070	4.6%	3.2%
Gender			
Male	528	2.8%	3.0%
*Female **	542	6.3%	3.3%
Age categories			
5 to < 7 years	221	4.1%	3.6%
7 to < 8 years	313	4.2%	2.9%
≥ 8 years	536	5.0%	3.2%
Ears			
Left	1070	3.2%	2.4%
Right	1070	3.4%	2.3%
Frequencies			
1 kHz left	1070	2.5%	1.7%
2 kHz left	1070	1.8%	1.4%
4 kHz left	1070	1.8%	1.3%
1 kHz right	1070	2.5%	1.6%
2 kHz right	1070	1.6%	1.6%
4 kHz right	1070	1.7%	1.2%

Distribution of referral rate across variables are based on final referral rate.
* Rescreen was done immediately after an initial refer result and reflects overall referral rate.
** Statistical difference obtained between females and males (p<0.05; Chi-square test) for conventional screening

Immediately following a fail result from either screening method, a rescreen was conducted using the same screening audiometer. A total of 99 children were rescreened with conventional screening and 79 children with the smartphone screening application.

One hundred and twenty-five children underwent diagnostic audiometry. 31.2% (39/125) referred on either conventional or hearScreen™ screening, and 17.6%

(22/125) referred on both screening techniques, while the remaining 51.2% (64/125) passed on both screening techniques. Only one child who referred on hearScreen™ and conventional screening could not be conditioned for diagnostic audiometry. Due to inconsistent responses, the child was excluded from data analysis. Of the remaining 124 children, 2.2% (12 male, 12 female) presented with a confirmed hearing loss (an AC threshold greater than 25 dB at either 0.5, 1, 2 or 4 kHz) when tested diagnostically. Sensitivity of the two techniques was similar with no statistically significant difference in performance (Table 2). Using a stratified sampling strategy to

Table 2. Performance of conventional compared to hearScreen™ school-based screening (n=1070)

	Conventional screening	hearScreen™
Sensitivity	75.0%	75.0%
Specificity	97.0%	98.5%
Positive predictive value	36.7 %	52.9%
Negative predictive value	99.4%	99.4%
Positive likelihood value	25.3%	49.0%
Negative likelihood value	0.5%	0.3%

diagnostically test every 15th child who passed both screening techniques revealed no false negatives in either screening technique. Six false negative cases were however identified for conventional and smartphone screening in cases where children passed on one screening technique and referred on the other. Conventional screening missed three unilateral mild-to-moderate conductive hearing losses, two bilateral mild-to-moderate conductive hearing losses and one moderate-to-severe

mixed hearing loss. Whereas, the smartphone screening application missed three unilateral mild conductive hearing losses, two bilateral mild conductive hearing losses and one mild-to-moderate sensorineural hearing loss.

Sound in the test environment measured with a sound level meter (RION, NA-24) prior to data collection and twice during data collection revealed average noise levels ranging from 42.5 to 79.6 dBA (mean 65.1 SD 9.9).

Table 3. Instances where noise level's during smartphone screening was above MPANL's

	1 kHz left	1 kHz right	2 kHz left	2 kHz right	4 kHz left	4 kHz right
Initial screen (n =1070)	7.9%	7.3%	0.2%	0%	0.1%	0.1%
Rescreen (n=79)	7.6%	6.3%	0%	0%	0%	0%

Smartphone recorded noise levels exceeded MPANL's mostly at 1 kHz (Table 3). During the initial screen noise levels exceeded MPANL's at 1 kHz in the left ear a total of 84 times (7.9%) but the screen had a fail result in only two of these instances. A similar phenomenon was noted at 1 kHz in the right ear, with only three of 78 children failing despite noise exceeding MPANL's. Only three left ears and two right ears referred on the rescreen at 1 kHz despite the present ambient noise levels. Among the referred ears, diagnostic assessment confirmed a hearing loss for two left ears and one right.

DISCUSSION

The validity of a screening protocol is determined by the degree to which results are consistent with the actual presence or absence of the disorder (American Academy of Audiology 2011). Sensitivity and specificity values support the validity of a

screening technique. Sensitivity is indicative of the accuracy of the screening tool to correctly identify individuals with the target condition whilst specificity refers to the accuracy of the screening tool to correctly identify individuals without the target condition (Margolis, Frisina & Walton 2011; Kam et al. 2014; Wu et al. 2014). In order for the smartphone hearing screening (hearScreen[TM]) to be a valid method for detecting children with hearing loss its performance must be comparable to that of conventional screening conducted manually with pure tone audiometers. Our study indicated no significant difference in sensitivity or specificity rates for smartphone compared to conventional hearing screening. Sensitivity was equivalent (75.0%) and for specificity the smartphone hearing screening was slightly higher (98.5%) than conventional screening audiometry (97.0%). This resulted in a lower referral (3.2% vs 4.6%) for the smartphone hearing screening (Table 1). Furthermore, the smartphone screening yielded a false-positive rate (1.5%) lower than conventional screening (2.9%) (Table 2) suggesting slightly improved accuracy for correctly identifying children without a hearing loss. Reduced false-positives reduces unnecessary referrals that may improve cost-effectiveness and feasibility of a screening programme.

School hearing screening specificity reported in this study by both screening techniques are comparable to those previously reported. A possible reason for the reduced sensitivity rate obtained in this study could be due to the screening level of 25 dB HL that was utilized. This slightly raised screen level was selected due to noise levels in test environment and to ensure that within the resource-limited context of developing countries like South Africa the referral rate would not create an excessive burden on the health care system. Dodd-Murphy, Murphy, & Bess (2003)

reported similar specificities to this study for educationally significant hearing loss, but high sensitivity (97.5%) was reported for a screening level of 25 dB HL when applied to known thresholds of children in three, six and nine. Sensitivity for both screening devices in our study was higher than those recently reported by Dodd-Murphy, Murphy & Bess (2014) for a 25 dB HL intensity level. The authors reported a sensitivity of 50% for children from grade one, two, three, five and seven who were screened on site, with the referral criteria set at 25 dB HL to determine minimal sensorineural hearing loss. The reason for the lower sensitivity reported by Dodd-Murphy, Murphy & Bess (2014) could be due to the fact that diagnostic evaluation was done months after the screenings. Furthermore, their study obtained a 38% sensitivity at 25 dB HL based on a retrospective analysis of known thresholds for children in grades 3, 6, 9, & 11.

We found gender effects in our hearing screening outcome with conventional screening having a referral rate for males (2.8%) significantly lower than females (6.3%). One possible contribution for this difference could be due to headphone placement affected by hair length or styles in girls that could have resulted in more low frequency leakage or standing waves. However, in contrast, previous study findings indicate that hearing loss is more common in boys due to the higher incidence of severe otitis media, noise induced hearing loss as well as genetic predisposition (Barr, Anderson & Wedenberg 1973; Axelsson, Aniansson & Costa 1987). There was no gender difference in hearing screening outcome for the smartphone hearing screening device (males 3.0%, females 3.3%). Limited findings have been reported on gender effects in school screening outcomes. Future investigations should report gender specific results to investigate this further.

There were no observable age effect in terms of referral rates. However, slightly higher referral rates were observed for the oldest age group (>9 years) utilizing conventional screening. The reason for the increase in referral rate as the age of the children increased is uncertain. In contrast the highest referral rate (3.6%) using smartphone hearing screening was evident for the youngest age group (6 < 8 years). Previous studies have reported similar findings with a decrease in referral rate as the age of children increase (Sideris & Glattke 2006; Dodd-Murphy, Murphy & Bess 2014). Younger populations typically have a higher incidence of middle ear disorders which typically lead to a higher referral rate (Swanepoel, Eikelboom, Margolis, 2014).

There was a significant difference in test time for the two hearing screening techniques. This could be as a result of hearScreen™ automatically changing to the next intensity and frequency based on the screening protocol, whereas, conventional screening required a manual change to frequency and intensity. On average, screening (excluding time taken for instructions and capturing demographic data) with the smartphone application was completed in less than a minute (mean 54.5s ± 28.3 SD) whereas with conventional screening, screening took just over a minute (mean 62.2s ± 38.1 SD). Smartphone screening was 12.3% faster compared to conventional screening. Time-efficiency with the smartphone hearing screening application may ensure screening larger numbers of children in a typical school day.

Environmental noise level is one of the most common concerns in hearing screening programs (FitzZaland & Zink 1984; American Speech-Language Hearing Association 1997; American Academy of Audiology 2011; Bamford et al. 2007; Lo & McPherson

2013). Consistent with professional recommendations (American Speech-Language Hearing Association 1997; American Academy of Audiology 2011) and to ensure test environment for diagnostic testing was in accordance to those indicated in the validation study (Swanepoel, Maclennan-Smith & Hall 2013), we used a sound level meter (RION, NA-24) to measure ambient noise levels in the test environment prior to screening. We subsequently conducted sound level measurements two more times, while data collection was being conducted on the same day. Noise levels ranged between 42.5 and 79.6 dBA (mean 65.1 SD 9.9). The ambient noise levels for this study were comparable to the ambient noise levels obtained (65.6 dBA, maximum 78.5 dBA) in the KUDUwave validation study (Swanepoel, Maclennan-Smith & Hall 2013), thus results obtained from diagnostic audiometry on-site in this study serve as a valid reference standard.

Significant variability in noise levels throughout the day is common due to children or testers leaving the room, instructions been given, the ringing of the school bell or groups of children walking pass the testing venue. The smartphone hearing screening application utilizes integrated noise monitoring referenced to MPANLs during testing. Thus hearScreen™ provides screening operators with real-time feedback on ambient noise levels to ensure compliance with standards (Swanepoel et al. 2014). We found that the recorded noise levels exceeded MPANL's mostly at 1 kHz, which may in part explain the higher referral rate at this frequency. Another factor to consider is remote frequency masking, Leibold and Neff (2011) reported that children younger than seven are at risk for remote frequency noise masking at 1kHz. The noise level monitoring function did not correct for remote frequency masking. As a result we recommend that the noise level monitoring function of

hearScreen™ be programmed in remote bands at the same time as test bands. In the case of ambient noise levels being too high a warning signal appeared on the screen, the screener was then able wait for environmental noise to subside and then conduct a rescreen. Furthermore, noise levels were recorded and uploaded with test results. Referrals could also be cross-checked with noise levels to determine if the noise may have influenced the child's response. In this study five children referred on the rescreen when noise levels were too high. Three of these children presented with a hearing loss.

The data storage feature of hearScreen™ application utilising the connectivity available on the phone allowed data to be securely uploaded to a cloud-based server for remote monitoring and management. The data was uploaded by connecting phones to a WiFi hotspot at the school. Data transmission and the cloud server is encrypted and password protected ensuring. This feature streamlined and simplified data management.

In developing areas of the world, where more than 80% of persons with hearing loss reside, there are limited prospects of early detection for hearing loss (Skarżyński & Piotrowska 2012; WHO 2013) due to barriers such as high cost of screening audiometers, operator training required to conduct conventional manual audiometric screening, over referrals due to lack of environmental noise monitoring, and poor data capturing and management (Swanepoel et al. 2014). Findings from this study indicate that a smartphone hearing screening solution like hearScreen™ may address many of these barriers. Smartphone hearing screening can provide a valid and effective screening tool incorporating quality control features for noise

monitoring, pre-programmed screening protocols allowing less training of the tester and data capturing for remote monitoring and management.

CONCLUSION

Smartphone hearing screening offers an inexpensive alternative to conventional screening audiometry with specific application to school-based screening. The application utilizes inexpensive, widely available, smartphone and headphone technology for hearing screening. Sensitivity was similar and specificity slightly better for the smartphone hearing screening device compared to conventional screening audiometry. There was no significant difference for referrals with the two screening techniques although smartphone screening had a slightly lower referral rate. The noise monitoring function along with other strategies to control ambient noise may ensure effective screening with minimal influence from noise sources. Smartphone hearing screening was slightly more time-efficient than conventional screening. The limited training required to operate the hearScreen™ software and the automated test sequences mean that it can be used by lay-persons opening up new possibilities in terms of service-delivery models. This smartphone hearing screening application therefore provides a low-cost, accurate and efficient screening solution for school-based screening that could be facilitated by non-health personnel with limited training.

ACKNOWLEDGEMENTS

REFERENCES

American Academy of Audiology. (2011). American Academy of Audiology Clinical Practice Guidelines Childhood Hearing Screening. Available from: http://www.audiology.org/resources/documentlibrary/Documents/ChildhoodScreeningGuidelines.pdf.

American Speech-Language-Hearing Association. (1997). *Guidelines for Audiologic Screening*. ASHA, 1–63.

American National Standards Institute / Acoustical Society America (ANSI/ASA) S3.6 - 2010 . *Specification for Audiometers* .

Axelsson, A., Aniansson, G., & Costa, O. (1987). Hearing Loss in School Children: A Longitudinal Study of Sensorineural Hearing Impairment. *Scand Audiol, 16,* 137-143.

Bamford, J., Fortnum, H., Bristow, K., et al. (2007). Current practice, accuracy, effectiveness and cost-effectiveness of the school entry hearing screen. *Health Technology Assessment*, *11*(32).

Barr, B., Anderson, H., Wedenberg, E. (1973). Epidemiology of hearing loss in children. *Audiology*, *12*, 226–437.

Cunningham, M., & Cox, E. O. (2003). Hearing assessment in infants and children: Recommendations beyond neonatal screening. *American Academy of Pediatrics*, *111*(2), 436–440.

Dodd-Murphy, J.D., Murphy, W., & Bess, F. H. (2003). Do school screenings identify minimal hearing loss? *Poster Presented at the Annual Meeting of the American Academy of Audiology, San Antonio, TX.*

Dodd-Murphy, J.D., Murphy, W., & Bess, F.H. (2014). School screenings and identification of mshl. *American Journal of Audiology*, 23(4), 365-373.

FitzZaland, R. E., & Zink, G. D. (1984). A comparative study of hearing screening procedures. *Ear and Hearing*, *5*(4), 205–10. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/6468778

ISHP. (2012). *Integated School Health Programme* (pp. 1–137). International Standardization Organization (ISO) 389-9 (2009). *Acoustics-Reference zero for the calibration of audiometric equipment. Part 9: Preferred test conditions for the determination of reference hearing threshold levels* .

Joint Committee on Infant Hearing. (2007). Year 2007 position statement: principles and guidelines for early hearing detection and intervention programs. *Pediatrics*, *120*, 898-921.

Kam, A. C. S., Li, L. K. C., Wu, W., et al. (2014, March 12). Automated hearing screening for preschool children. *Journal of Medical Screening.*

Leibold, L. J., & Neff, D.L. (2011). Masking by a Remote-Frequency Noise Band in Children and Adults. *Ear and hearing, 32 (5), 663- 666.*

Lo, A. H. C., & McPherson, B. (2013). Hearing screening for school children: utility of noise-cancelling headphones. *BMC Ear, Nose, and Throat Disorders*, *13*(1), 6.

Maclennan-Smith, F., Swanepoel, D. W., & Hall, J. W. (2013). Validity of diagnostic pure-tone audiometry without a sound-treated environment in older adults. *International Journal of Audiology*, *52*(2), 66–73.

Madriz, J. J. (2001). (2001). Audiology in Latin America: hearing impairment, resources and services. *Scandinavian Audiology*, *30*(Suppl. 53), 85–92.

Margolis, R. H., Frisina, R., & Walton, J. P. (2011). AMTAS(®): automated method for testing auditory sensitivity: II. air conduction audiograms in children and adults. *International Journal of Audiology*, *50*(7), 434–9.

McPherson, B. & Olusanya, B. (2008). Screening for hearing loss in developing countries. In: Audiology in Developing Countries. *Nova Scientific, New York, NY, USA.*

Meyer, M., Swanepoel, D. W., Van Der Linda, M., & Le Roux, T. (2012). Early detection of infant hearing loss in the private health care sector of South Africa. *International Journal of Pediatric Otorhinolaryngology*, *76*, 698–703.

Sideris, I., & Glattke, T. J. (2006). A comparison of two methods of hearing screening in the preschool population. *Journal of Communication Disorders*, *39*(6), 391–401.

Skarżyński, H., & Piotrowska, A. (2012). Screening for pre-school and school-age hearing problems: European Consensus Statement. *International Journal of Pediatric Otorhinolaryngology*, *76*(1), 120–1.

Swanepoel, D. W., Myburgh, H. C., Mahomed, F., et al. (2014). Smartphone hearing screening with integrated quality control and data management. *International Journal of Audiology, 53(12), 841-849.*

Swanepoel D, Eikelboom R.H, Margolis R.H. (2014). Revisiting tympanometry screening in school-entry children 5 to 7 years of age. *Journal of the American Academy of Audiology*, 25:927-936.

Swanepoel D, Maclennan-Smith F, Hall III J.W. (2013). Diagnostic pure tone audiometry in schools: Mobile testing without a sound-treated environment. Journal of American Academy of Audiology, 24 (10), 992-1000.

Theunissen, M., & Swanepoel, D. W. (2008). Early hearing detection and intervention services in the public health sector in South Africa. *International Journal of Audiology*, *47*, 23–29.

World Health Organisation. (2013). WHO | Deafness and hearing loss. Retrieved from http://www.who.int/mediacentre/factsheets/fs300/en/

Wu, W., Lü, J., Kam, A. C. S., et al. (2014). A new hearing screening system for preschool children. *International Journal of Pediatric Otorhinolaryngology*, *78*(2), 290–5.