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Research Article

Referral Criteria for Preschool Hearing Screening in Resource-Constrained Settings: A Comparison of Protocols

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Purpose: This study aimed to describe and compare the performance of two screening protocols used for preschool hearing screening in resource-constrained settings.
Method: Secondary data analysis was done to determine the performance of two protocols implemented during a preschool hearing screening program using mobile health technology in South Africa. Pure-tone audiometry screening at 25 dB HL for 1000, 2000, and 4000 Hz in each ear was used by both protocols. The fail criterion for the first protocol (2,147 children screened) constituted a no-response on one or more frequencies in either ear. The second protocol required two or more no-responses (5,782 children). Multivariate logistic regression models were used to investigate associations between outcomes and protocol, age, gender, and duration.
Results: Fail rates for the one-frequency fail protocol was 8.7% (n = 186) and 4.3% (n = 250) for the two-frequency fail protocol. Children screened with the two-frequency fail protocol were 52.9% less likely to fail (p < .001; OR = 0.471; 95% confidence interval [0.385, 0.575]). Gender (p = .251) and age (p = .570) had no significant effect on screening outcome. A percentage of cases screened (44.7%) exceeded permissible noise levels in at least one ear at 1000 Hz across both protocols. True- and false-positive cases did not differ significantly between protocols. Protocol type (p = .204), gender (p = .314), and age (p = .982) did not affect the odds of being a true-positive result. Average screening time was 72.8 s (78.66 SD) and 64.9 s (55.78 SD) for the one-frequency and two-frequency fail protocols, respectively.
Conclusions: A two-frequency fail criterion and immediate rescreen of failed frequencies significantly reduced referral rate for follow-up services that are often overburdened in resourced-constrained settings. Future protocol adaptations can also consider increasing the screening levels at 1000 Hz to minimize the influence of environmental noise.

Hearing loss is a significant health problem and, if undetected, can have a detrimental impact on the speech and language development, educational attainment, and social–emotional development of children (Joint Committee on Infant Hearing of the American Academy of Pediatrics et al., 2013; Wilson et al., 2017). A systematic analysis for the Global Burden of Disease Study in 2016 indicated that 15.5 million children under the age of 5 years had hearing loss (Global Research on Developmental Disabilities Collaborators, 2018). The prevalence of childhood hearing loss is substantially higher in low- and middle-income countries (LMICs) than in high-income regions due to increased environmental risk factors such as infectious diseases (Emmett, Robler, Wang, et al., 2019; Wilson et al., 2017).

Newborn hearing screening services in LMICs are very scarce and potentially complex to initiate due to the requirement of specialized equipment and as many births occur outside of health facilities (Olusanya & Newton, 2007). Furthermore, even when newborn hearing screening is available, it does not identify late-onset, acquired, or many cases of progressive hearing loss (Bamford et al., 2007; Dodd-Murphy et al., 2014; Wilson et al., 2017). Approximately 60% of

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childhood hearing loss is due to preventable causes such as otitis media, noise exposure, ototoxicity, and vaccine-preventable infections such as measles, mumps, rubella, and bacterial meningitis (Emmett, Robler, Gallo, et al., 2019; Emmett, Robler, Wang, et al., 2019; Harlor et al., 2009; Wilson et al., 2017). Hearing screening in young children, for instance in preschool or school settings, can serve (McPherson et al., 2010; Skarzyński & Piotrowska, 2012) to identify the need for the further audiological assessment to detect and treat hearing loss (Bamford et al., 2007; Dodd-Murphy et al., 2014; Harlor et al., 2009; Talbot et al., 2012).

There are various challenges to the implementation of population-based hearing screening in the educational settings. These include variable protocols for testing and referral criteria, less than ideal test conditions, limited human and technology resources, competing national health priorities, and poorly integrated electronic data management systems (Bamford et al., 2007; Prieve et al., 2015; Stenfeldt, 2018). As a consequence, children in resource-constrained settings are rarely screened for hearing loss (Harris & Dodson, 2017; Levy et al., 2018; Mulwafu et al., 2016; Swanepoel & Clark, 2019; Wilson et al., 2017). Some of these challenges may be overcome by incorporating mobile health (mHealth) technologies and community-delivered hearing health care as these have the potential to decentralize and increase access to services in resource-constrained settings (Emmett, Robler, Wang, et al., 2019; Jayawardena et al., 2020; Manus et al., 2021; Suen et al., 2019; Swanepoel, 2020; van Wyk et al., 2019; World Health Organization [WHO], 2021; Yancey et al., 2019). mHealth technology, such as the validated hearScreen application (hearX Group), offers an inexpensive and mobile alternative to conventional evaluations by utilizing calibrated headphones on low-cost smartphones, employing a simple user interface (Mahomed-Asmail et al., 2016; Sandström et al., 2016; Swanepoel, 2020; Swanepoel & Clark, 2019; van Tonder et al., 2017; Yousuf Hussein et al., 2016, 2018). Key enabling factors in these mHealth supported screening models are the utilization of community health workers (CHWs) and automated screening applications with preset protocols and advanced quality control measures that enable CHWs with minimal training to undertake screening (Dawood et al., 2020; Eksteen et al., 2019; Manus et al., 2021; O'Donovan et al., 2019; Swanepoel, 2020; van Wyk et al., 2019; WHO, 2021).

However, key questions still exist in planning hearing screening programs in resource-constrained settings such as the targeted hearing loss and protocol considerations (e.g., intensity levels and fail criteria) to minimize false positives and over referrals to resource-constrained health facilities. Paramount to the success of any hearing screening program is an established referral pathway that ensures follow-up services that enable identification of hearing loss and intervention (de Kock et al., 2016; WHO, 2021). Current protocols (American Academy of Audiology, 2011; American Speech-Language-Hearing Association, 1997) for screening programs of children 3 years of age or older typically recommend screening at 20 dB HL across 1000, 2000, and 4000 Hz in each ear and a fail result constituting a no-response at one or more frequencies. A typical variation includes a slightly higher screening level of 25 dB HL to minimize the influence of environmental noise on screening outcomes (Allen et al., 2004; Bamford et al., 2007; Meinke & Dice, 2007). A previous study investigating protocols used for school-based screening reported 25 dB HL to be most appropriate in resource-constrained settings (Mahomed-Asmail et al., 2016). However, no comparative studies have investigated the effect of adjusting a protocol with a single frequency fail criterion to a two or more frequencies fail criterion. Especially in resource-constrained settings, where referral rates and false-positive screening outcomes burden pressurized health facilities, the performance of a two-frequency fail protocol should be investigated and compared to the performance of a one-frequency fail protocol in the field. The aim of this study was to compare a screening protocol using a single-frequency fail criterion to a screening protocol using a two-frequency fail criterion for preschool screening in a resource-constrained setting facilitated by CHWs.

Materials and Method

A community-based hearing screening program for preschool children by CHWs was implemented using mHealth technologies in preschools in partially informal townships of the Western Cape, South Africa (Eksteen et al., 2019). During the course of the screening, two protocols (both screening at 25 dB HL for 1000, 2000, and 4000 Hz in each ear) that differed in fail criterion were used: (a) one-frequency fail protocol: No response at one or more frequency across both ears constituted a fail result; and (b) two-frequency fail protocol: No response at two or more frequencies across both ears constituted a fail result. The two different protocols were nonrandomized, and the first protocol was adapted and changed after referral rates were reported to burden the public health audiology clinics where children who failed the screening were referred to for diagnostic testing. A retrospective secondary data analysis was conducted using the data obtained through the implemented screening program. Institutional review board clearance for the study was obtained from the University of Pretoria (HUM020/1019).

Participants

All preschools located within the area of Khayelitsha and Mitchells Plain, Western Cape, South Africa, were contacted and were provided with the option of participating in this study. Preschool principals were contacted through quarterly preschools' forums organized by local nongovernmental organizations in the community (Eksteen et al., 2019). Informed consent letters were given to the principals of preschools by CHWs to distribute to the children between the ages of 4 and 7 years attending these preschools (Eksteen et al., 2019). All children who returned a signed parental consent form were included in the study (n = 7,929). All preschool children screened from October 1, 2017, until

February 25, 2018, were tested using the one-frequency fail protocol (n = 2,147), and children were tested with the two-frequency fail protocol from February 26, 2018, until November 30, 2018 (n = 5,782).

Four CHWs were appointed and trained to conduct the hearing screening of all children included in the study at their preschools. None of them had previous formal training in hearing health care. The CHWs received practical training on using the equipment and assessing a child's responses over a period of 5 days (Eksteen et al., 2019). The training was conducted by a qualified audiologist, who also supervised screening in the field for 2 days. Weekly meetings were chaired by the audiologist during which retraining was done as needed. Emphasis was placed on techniques such as testing arhythmical, allowing some time without presenting a tone to ensure no false-positive responses and spending enough time to condition a child before starting the test.

Equipment / Apparatus

Screening audiometry was conducted with the hearScreen application and its cloud-based data management service mHealth Studio (hearX Group). This application utilizes automated test sequences with prespecified screening protocols for interpretation of results. The hearScreen application was operated on a Samsung A3 smartphone (Android OS, v8.0) connected to circumaural Sennheiser HD280 Pro headphones (Sennheiser), calibrated according to prescribed audiometry standards (ISO 389-1:2017; International Standardization Organization, 2017). Calibration was performed using a GRAS RA0039 artificial ear using an RION NL-52 sound-level meter, complying with ISO 60318-1:2009 (International Standardization Organization, 2009) and ISO 60318-2:2017 (International Standardization Organization, 2017). The application has been validated to record and monitor environmental noise using the smartphone microphone to monitor when maximum permissible ambient noise levels (MPANLs) during testing are exceeded (Swanepoel, Myburgh, et al., 2014). The MPANLs, at the screening level of 25 dB HL, were 56, 69, and 68 dB SPL for 1, 2, and 4 kHz, respectively (Madsen & Margolis, 2014).

Data collected by the smartphone were automatically uploaded through cellular networks at the end of each test to the cloud-based data management system (mHealth Studio, hearX Group). This electronic platform (mHealth studio) is synchronized between cloud and mobile versions that host the point of care hearing screening application and associated data. The mHealth application and server security is ensured through use of local data encryption at rest using AES-256bit (Eksteen et al., 2019).

Audiological assessments at the first-line follow-up included threshold audiometry using the hearTest smartphone application (hearX group) and otoscopy (Welch Allyn otoscope). The hearTest application was operated on the same smartphone used for screening. The threshold determination sequence follows the Threshold Ascending method as specified in ISO 82531:1.5 (van Wyk et al., 2019). This application has been validated to record reliable air-conduction hearing thresholds (van Tonder et al., 2017).

Screening Procedure

CHWs screened the hearing of children at preschools using the hearScreen application with calibrated circumaural headphones. The headphones were connected to the smartphone and calibrated before screening commenced. Only participants who returned signed parental consent forms, and gave assent, were screened. Participants were instructed by the CHWs in a group, in their native language, to raise their hands when they heard a sound. The action of raising their hand when a sound was heard was practiced in the group. Each child would then be called by the CHW to be screened individually. Screening was conducted in the quietest area of the preschool where space is allowed.

The predetermined protocol was selected on the mHealth hearing screening application, and the details of the participant were entered on the application. The selected criterion for the two different protocols are described in Table 1.

The CHW, sitting behind the participant, played a conditioning tone at 40 dB HL at 1000 Hz in the left ear, which was the automated first step of the screening process. Within the conditioning feature of the application, the CHW had the option to increase intensity and switch ears where the tone would be heard. During the training and retraining of the CHWs, the goal of conditioning and the indications to increase the conditioning intensity level were discussed. Another feature of the application was that the test could be "paused" and the option of "talk forward" could be selected. This enabled the CHW to talk to the child through the smartphone's microphone into the headphones to either re-instruct, praise, or motivate the child. Once the CHW felt confident that the participant understood the instructions, the screening test was initiated.

Ambient noise was monitored continuously throughout testing at each frequency. MPANLs specify the maximum ambient noise level allowed in a testing room to ensure that thresholds obtained are not elevated. If the ambient noise exceeded MPANLs at any frequency, this was displayed and therefore warned the CHW who could then move to a quieter space or reduce background noise before continuing the test. Noise levels were automatically recorded, and testing was completed even if noise levels could not be reduced adequately (van Wyk et al., 2019).

A sweep test was performed at the intensity level of 25 dB HL at 1000, 2000, and 4000 Hz, in that order. Left ears were tested first. The CHW presented the stimuli at random intervals and could indicate on the smartphone screen whether a sound was heard or not. In case a sound was not heard, the automated protocol presented the sound once again to confirm a no response. If the child heard the sound, the automated protocol would confirm the response. An immediate rescreen was done for the specific frequency/frequencies that were failed following a fail result.

Once the test was complete, the application immediately calculated and displayed the results at each frequency

Table 1. Selected criterion for screening protocols.

Criterion	One-frequency fail protocol	Two-frequency fail protocol
Frequencies tested per ear (Hz)	1000, 2000, 4000 Hz	1000, 2000, 4000 Hz
Screening intensity (dB HL)	25	25
Fail criterion: no. of no-responses across both ears	1 or more frequencies	2 or more frequencies
Immediate rescreen	At frequencies failed during initial test	At frequencies failed during initial test

and an overall "pass" or "fail" result. The final screening result was automatically uploaded to a cloud-based server via a mobile network for data management. The result of the immediate rescreen was considered to be the overall or final result and would be considered for referral to a first-line follow-up. Results were communicated directly via text messages to parents/caregivers of participants.

If the overall screening result was a "fail, " the participant was seen by an audiologist for a first-line follow-up at the child's preschool a week or 2 weeks later, depending on the availability of the audiologist. Follow-up testing included otoscopy and automated air-conduction threshold pure-tone audiometry at 0.5 to 8 kHz starting at an intensity level of 40 dB HL until a minimum response level, using the hearTest application to determine degree and configuration of hearing loss. A threshold was determined by the minimum intensity at which the participant reliably responded twice. The results of the air-conduction audiometry, in conjunction with otoscopy, were used to identify the presence of hearing loss and confirm the screening result. Criteria constituting hearing loss was a pure-tone average (500–4000 Hz) of 25 dB HL or greater in the better ear. If the child had a hearing loss as indicated by this first-line follow-up conducted by the audiologist at the child's preschool, they were referred to a public health audiology clinic for further testing and intervention (Eksteen et al., 2019). Children who were difficult to condition, and therefore not tested successfully at the first-line follow-up, were also referred to a public health audiology clinic for further testing. These cases were excluded from the study analysis investigating true-positive rate.

Data Analysis

Data were extracted from the secure cloud-based server to a Microsoft Excel 2016 sheet for statistical analysis using Statistical Package for Social Sciences SPSS (Version 26; IBM Corp., 2019). The overall referral rate was calculated as the number of children who failed an immediate rescreen after they presented with a "fail" at the initial screen. The true-positive rate was calculated as the number of children who failed the screening test and presented with a hearing loss confirmed at the first-line follow-up.

Descriptive statistics were used to compare the protocols in terms of sample gender and age, screening duration, referral rate, and true-positive rate. Descriptive statistics were used to determine the incidence of exceeded MPANLs during screening. The Shapiro–Wilk test was used to test for normality (Field, 2018). Not all variables were normally distributed, and therefore, nonparametric tests were used, as nonparametric tests have been shown to be as powerful, or almost as powerful, as their normal theory counterparts (Gibbons & Chakraborti, 2010). A p-value cutoff was set at .05 and indicated the level of significance throughout this study. The two-proportion z test was used to compare referral rate, true-positive rate, and false-positive rate between the two protocols. Two multivariate logistic models were built. The dependent variable, which is dichotomous, was screen result (see Model 1) and final result (after a follow-up hearing test; see Model 2). The covariate (continuous independent variable) was age, and the factors (categorical independent variables) were gender (females benchmarked against males) and protocol (Protocol 2 benchmarked against Protocol 1). A multiple linear regression model was used to estimate the association between test duration and protocol, age, and gender.

Results

A total of 7,929 preschool children received hearing screening over 16 months. Approximately half (50.4%) were female and mean age was 5.8 years (0.64 *SD*) ranging from 4.1 to 7.3 years of age. The number of children screened using the one-frequency fail protocol was 2,147; the two-frequency fail protocol was used on 5,782 children. Table 2 depicts the characteristics of the sample for the two protocols.

For the one-frequency fail protocol, the overall referral rate (i.e., after immediate rescreen of the 23.0% [n = 493] of children who had failed the initial screen) was 8.7% (n = 186; see Table 3). For the two-frequency fail protocol, the overall referral rate (i.e., after immediate rescreen of the 13.6% [n = 786] of children who had failed the initial screen) was 4.3% (n = 250; see Table 3). The overall referral rate across the different protocols was significantly different between tests (two-proportions z test).

Multivariate logistic regression demonstrated no significant effect of gender (p = .251) and age (p = .570) on screening outcome but a highly significant effect of protocol used. Compared to children tested with the one-frequency fail protocol, those tested with the two-frequency fail protocol were 52.9% less likely to fail (p < .001; OR = 0.471; 95% confidence interval [0.385, 0.575]).

Environmental noise exceeded MPANLs at 1000 Hz mainly across both protocols. A certain percentage (44.7%)

Table 2. Participant characteristics according to protocol.

Demographics	Number and percentage	One-frequency fail protocol	Two-frequency fail protocol
Children screened	*N*	2,147	5,782
Male	*N*	1,073	2,857
	% within protocol	50.0%	49.4%
Female	*N*	1,074	2,925
	% within protocol	50.0%	50.6%
Age in years	*M* (*SD*)	5.6 (0.57)	5.8 (0.65)
	Range (min–max)	4.1–6.9	4.2–7.3

of cases screened had exceeded MPANLs in at least one ear at 1000 Hz across both protocols.

Seventy children (16.1% of the total number of children who failed screening) were not tested at the first-line follow-up (due to absence on the day of testing [$n = 60$] or being unable to test [$n = 10$]; see Table 4). Of the children who underwent a follow-up test at their preschool, 42.2% (155/367) had confirmed hearing loss and were therefore considered true-positive cases (see Table 4). There was no significant difference between screening protocol performance (true and false-positive cases) between the two protocols (see Table 4). Multivariate logistic regression analysis evaluating the effect of protocol, age, and gender on the final outcome of the follow-up hearing assessment demonstrated no significant effect.

Average time to conduct the screening test was 72.8 s (78.66 *SD*) for the one-frequency fail protocol and 64.9 s (55.78 *SD*) for the two-frequency fail protocol, including the immediate rescreen if this was conducted. A multiple linear regression model for test duration, $F(716.667)$, $p < .001$, explained 26.6% of the variation (adjusted $R^2 = .266$), with only screening outcome significantly affecting test duration. Overall, test duration was 141.75 s longer for those who failed compared to those who passed ($p < .001$; $B = 141.75$; 95% confidence interval [136.53, 146.98]). Gender ($p = .314$), age ($p = .052$), and protocol ($p = .329$) were not significant predictors.

Discussion

The recommended criterion for referral of hearing screening should be evidence-based and consider specific contextual resources to ensure an ethically responsible approach to screening (Allen et al., 2004; Kam et al., 2014; Mahomed-Asmail et al., 2016). This study compared two screening protocols utilized in an mHealth-supported hearing screening program facilitated by CHWs. The protocol with a single frequency fail criteria screening at 25 dB HL across 1000, 2000, and 4000 Hz had a significantly higher referral rate compared to the two-frequency fail protocol. This protocol requiring two or more no-responses at any frequencies across both ears had a higher true-positive rate, lower false-positive rate, and shorted screening duration, but which were not statistically significant.

Referral rate influences the sustainability of a screening program and should not be excessively high; otherwise, health care systems might be overburdened (Allen et al., 2004; Bamford et al., 2007; Mahomed-Asmail et al., 2016; Olusanya, 2008), especially in an LMIC where resources are limited (Allen et al., 2004; Kam et al., 2014; Swanepoel &

Table 3. Referral rates across screening protocols.

Screening referrals	Ears	Number and percentage	One-frequency fail protocol	Two-frequency fail protocol	*z*-test stat *p* value
Children screened		*N*	2,147	5,782	
Overall screen referral rate		*N*	186	250	7.532
		% within protocol	8.7%	4.3%	< .001*
Referral rate at 1000 Hz	Left	*N*	73	148	2.020
		% within protocol	3.4%	2.6%	.043*
	Right	*N*	70	171	0.698
		% within protocol	3.3%	3.0%	.485
Referral rate at 2000 Hz	Left	*N*	46	119	0.234
		% within protocol	2.1%	2.1%	.815
	Right	*N*	59	131	1.248
		% within protocol	2.7%	2.3%	.212
Referral rate at 4000 Hz	Left	*N*	64	104	3.248
		% within protocol	3.0%	1.8%	.001*
	Right	*N*	73	101	4.465
		% within protocol	3.4%	1.7%	< .001*

*Statistically significant difference at a 5% level of significance.

Table 4. Screening performance for children who attended follow-up hearing assessments.

Screening performance	Number and percentage	One-frequency fail protocol	Two-frequency fail protocol	*z*-test *p* value
	N	186	251	
True positive	*N*	60	95	1.208
	% within protocol	32.3%	37.9%	.227
False positive	*N*	97	115	1.310
	% within protocol	52.2%	45.8%	.190
Unable to be tested	*N*	6	4	1.128
	% within protocol	3.2%	1.6%	.259
Not tested at first-line follow-up	*N*	23	37	0.713
	% within protocol	12.4%	14.7%	.476

Clark, 2019; Wu et al., 2014). Previous studies reported referral rates of 6.7% (Mahomed-Asmail et al., 2016), 7.6% (Dodd-Murphy et al., 2014), and 9.3% (Wu et al., 2014). Employing a protocol with two or more frequency fail criteria to decrease referral rate was confirmed in this study to be useful in reducing false positives (Allen et al., 2004). The referral rate for the one-frequency fail protocol was significantly higher (8.7%) than the two-frequency fail protocol's referral rate (4.3%). An immediate rescreen reduced the number of referrals across both protocols, corresponding with the findings from a previous study (Mahomed-Asmail et al., 2016), and so confirms recommendations that an immediate rescreen should be employed routinely in screening programs (Allen et al., 2004; Kam et al., 2014; van Wyk et al., 2019).

Acute otitis media and otitis media with effusion are reported to account for the majority of hearing loss in preschool children with hearing impairment (Wu et al., 2014) and are known to be high in LMICs (WHO, 2021; Yousuf Hussein et al., 2018). Therefore, transient conductive hearing losses secondary to otitis media is likely to increase the referral rate. Based on the target disorder set out in this study (pure-tone average [500–4000 Hz] of 25 dB HL or greater in the better ear), abnormal middle ear function causing a child not to respond to pure tones at 25 dB HL warranted referral for a diagnostic audiological evaluation.

Based on findings from studies that indicated significantly higher referral rates in children younger than 4 years of age (Cedars et al., 2018; Kam et al., 2014; Wu et al., 2014; Yousuf Hussein et al., 2018), this study only included preschool children between the ages of 4 and 7 years. We did not find an impact of children's age on screening results, in contrast to other studies that included children younger than 4 years of age (Cedars et al., 2018; Kam et al., 2014; Sideris & Glattke, 2006; Wu et al., 2014; Yousuf Hussein et al., 2018). In a study by Manus et al. (2021), where children 4 years and older were screened, age also did not have an impact on screening outcome. In agreement with other studies, gender did not have an impact on screening results (Cedars et al., 2018; Kam et al., 2014; Wu et al., 2014).

Overreferrals contribute to the burden faced by follow-up services, as well as reducing credibility with parents and physicians (Dodd-Murphy et al., 2014; Mahomed-Asmail et al., 2016). Compared to a study by Wu et al. (2014), where 18.8% of children who had positive screen results were diagnosed with hearing loss, the percentage of true-positive cases in this study is high. This might be due to the referral criterion of the screening or the fact that children who failed the first-line follow-up still had to be seen for a comprehensive diagnostic audiological evaluation, including wax removal, tympanometry, and bone-conduction audiometry. We did not find an impact of protocol or children's age or gender on the final outcome after a follow-up hearing assessment. Despite not being significantly different, the higher true-positive rate for the two-frequency fail protocol (37.9%) compared to that of the one-frequency fail protocol (32.3%) is a factor to consider for community-delivered screening in a resource-constrained setting.

Duration of screening per protocol was another factor evaluated as time efficiency facilitates screening of larger numbers of individuals over a shorter period of time, contributing to the cost effectiveness of the program and avoiding disturbances of the child (Śliwa et al., 2011). Longer test durations were associated with failed screening outcomes across both protocols, probably due to the immediate rescreen or re-instruction of children struggling with the task (Eksteen et al., 2019). The two-frequency fail protocol's mean duration of screening was 8 s shorter than the one-frequency fail protocol. The difference between the protocols was not proven to be significant.

Noise poses a challenge to reliable screening in uncontrolled environments, such as educational settings (Allen et al., 2004; Kam et al., 2014; Levy et al., 2018; McPherson et al., 2010; Sideris & Glattke, 2006). It is critical to be able to monitor noise levels throughout community-based hearing screening (van Wyk et al., 2019) and is an advantage of recent mHealth screening apps (Paglialonga et al., 2019). In this preschool study, real-time ambient noise measurements by the smartphone indicate that test performance is likely affected when testing at 25 dB HL, especially at 1000 Hz in support of previous reports (Al-Rowaily et al., 2012; Levy et al., 2018; Mahomed-Asmail et al., 2016; Swanepoel, Myburgh, et al., 2014; Yousuf Hussein et al., 2016). To address this potential influence, increasing the screening intensity at 1000 Hz from 25 to 30 dB HL should be considered in future studies. A lower rate of false positives due to noise, at the risk of missing milder losses likely due to

transient middle-ear effusion, may be a trade-off to consider in resource-constrained contexts.

Employing validated mHealth technologies that support CHWs, government and community screening programs can improve capacity for effective large-scale hearing screening (Emmett, Robler, Wang, et al., 2019; Jayawardena et al., 2020; Shinn et al., 2019; Suen et al., 2019; Swanepoel, 2020). In order for CHWs to deliver such care with new technologies, it is important that screening protocols are selected appropriately to maximize true positives and minimize excessive referral rates tailored to contextual health care system capacity. This study demonstrated that a protocol that includes a two-frequency fail criteria had an acceptably low referral rate and a high true-positive rate. Limitations of the current study included that sensitivity and specificity for these protocols could not be determined, and the study design was not a randomized controlled trial, and so type of facility and time varied between the protocols and may have influenced the impacts thereof. For resource allocation in screening programs, however, the referral rate provides valuable metrics to plan services. Future studies comparing otoacoustic emission screening outcomes to pure-tone audiometry screening in these communities would be of interest as a potential tool to screen children younger than 3 years of age too.

Conclusions

A protocol employing a two-frequency fail criterion and immediate rescreen of failed frequencies significantly reduced referral rate for follow-up services that are often overburdened in resourced-constrained settings. Future protocol adaptations can also consider increasing the screening levels at 1000 Hz to minimize the influence of environmental noise. Using validated mHealth screening technologies operated by CHWs that employ optimized screening protocols can support scalable screening programs in resource-constrained settings.

Author Contributions

Susan Eksteen: Conceptualization (Equal), Data curation (Lead), Formal analysis (Lead), Funding acquisition (Equal), Investigation (Equal), Methodology (Equal), Project administration (Lead), Writing – original draft (Lead), Writing – review & editing (Equal). **Robert H. Eikelboom:** Methodology (Equal), Supervision (Equal), Writing - Review & Editing (Equal). **Stefan Launer:** Funding acquisition (Lead), Supervision (Equal), Writing - Review & Editing (Equal). **Hannah Kuper:** Supervision (Supporting), Writing - Review & Editing (Equal). **De Wet Swanepoel:** Conceptualization (Equal), Data curation (Equal), Formal analysis (Supporting), Funding acquisition (Equal), Investigation (Equal), Methodology (Equal), Supervision (Lead), Writing - Original Draft (Equal), Writing - Review & Editing (Equal).

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