An Open-Source Smartphone Otoacoustic Emissions Test for Infants

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abstract

OBJECTIVE: Universal hearing screening is essential for early identification of infants with hearing loss, yet there is a lack of low-cost, scalable equipment suitable for resource-constrained settings. Here we test a low-cost smartphone device for infant hearing screening.

METHODS: Infants aged 0 to 6 months were recruited from 3 ambulatory clinics at Seattle Children's Hospital with a high prevalence of hearing loss. We compared results from a low-cost open-source distortion product otoacoustic emission (OAE) probe and smartphone app with results from a commercially available OAE device. Hearing status was confirmed using newborn hearing screening, diagnostic testing, or both. Primary outcomes were referral rate as well as sensitivity, specificity, positive predictive value, and negative predictive value compared with known hearing status.

RESULTS: Among N = 76 infants, the mean age at screening was 3.1 ± 1.9 months and 13% had hearing loss. Referral rates were 24% and 26% for the smartphone and conventional devices, respectively. Both devices demonstrated 100% sensitivity (95% CI, 0.69–1.00) and negative predictive value (95% CI, 0.94–1.00). Specificity was 88% (95% CI, 0.78–0.95) and 85% (95% CI, 0.74–0.92) for the smartphone and conventional devices, respectively. Positive predictive value was 56% (95% CI, 0.31–0.78) for the smartphone and 50% (95% CI, 0.27–0.73) for the conventional device.

CONCLUSION: The smartphone-based OAE device effectively screened hearing in high-prevalence infants. Thus, smartphone-based OAE detection may be a promising low-cost solution to the challenge of building scalable universal newborn and infant hearing screening programs in resource-constrained settings.

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Nada Ali conceptualized the study, designed the data collection instruments, coordinated data collection, carried out the initial analyses, drafted the initial manuscript, and critically reviewed and revised the manuscript. Justin Chan conceptualized the study, collected data, provided technical supervision, carried out the initial analyses, and critically reviewed and revised the manuscript. Anna Meehan conceptualized the study, collected data, and critically reviewed and revised the manuscript. Brent Collett and Sarah Benki-Nugent conceptualized the study and critically reviewed and revised the manuscript. Shyam Gollakota conceptualized the study, provided technical supervision, and critically reviewed and revised the manuscript. Juliana Bonilla-Velez and Randall Bly conceptualized the study, supervised data collection, and critically reviewed and revised the manuscript. Emily Gallagher conceptualized the study, coordinated data collection, supervised the study, and critically reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

WHAT'S KNOWN ON THIS SUBJECT: Universal newborn hearing screening is an effective strategy to enable early childhood development. However, a lack of scalable and cost-effective technology is a barrier to implementing universal hearing screening programs in low-resource settings.

WHAT THIS STUDY ADDS: The work presented here investigates a smartphone-based device in an infant cohort and compares its test characteristics and results with a commercially available otoacoustic emission device for the application of infant hearing screening.

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INTRODUCTION

The World Health Organization (WHO) estimates that there are over 400 million people—including 34 million children—living with disabling hearing loss.[1] This represents approximately 5% of the world's population and makes hearing loss the third leading cause of years lived with disability globally.[2] This large population underscores the urgent need for prioritizing public health interventions to address hearing loss.

In 2017, WHO called for the global development and implementation of screening programs in high-risk populations, including infants and young children.[3] Identifying and intervening at an early age is crucial to avoid the negative effects of unaddressed hearing loss on pediatric language, psychosocial, and neurocognitive development.[4–7] However, there remains an inequitable distribution of the prevalence of hearing loss, with the greatest burden in low- and middle-income countries (LMICs) in South Asia, Asia Pacific, and Sub-Saharan Africa.[2,8,9] This inequity is further magnified when examining the capacity for early hearing detection and intervention (EHDI) for pediatric hearing loss in low-resource settings.[10] A recent survey highlighted the inequity in newborn hearing screening globally, with 114 of 196 countries screening fewer than half of infants.[11] Countries with the least developed hearing screening programs diagnosed hearing loss at an older age compared with countries with higher screening rates (34.9 months compared with 6.9 months), and also suffer the highest burden of hearing loss.[11]

Universal newborn and infant hearing screening is an important strategy to facilitate EHDI that is supported nationally and internationally by WHO, the American Academy of Pediatrics, the National Institutes of Health, and the Joint Committee on Infant and Hearing Screening.[12–15] However, implementing universal screening in resource-limited settings raises many challenges. Factors such as cost, high out-of-hospital birth rates, and limited hearing care awareness can limit the scalability of screening programs in these settings.[16,17] Proposed solutions to address challenges to EHDI in LMICs have included targeted screening based on hearing loss risk factors and using behavioral screening in infants,[18,19] such as a low-cost calibrated mechanical noisemaker.[20] These methods, however, cannot detect hearing loss in children without risk factors or who cannot participate in behavioral screening. Universal screening using physiological tests such as otoacoustic emissions (OAE) and automated auditory brainstem response (AABR) remain the gold standard.[12] OAE and AABR devices cost thousands of dollars per unit, which limits the ability of financially strained governments and health systems in resource-constrained settings to scale their use for universal screening. OAE screening detects otoacoustic emissions, quiet sounds generated by the hair cells of the cochlea in response to a sound stimulus. OAE testing does not require a behavioral response from the patient and is therefore useful in infants. The test requires an unblocked ear canal and is ideally performed with a seal around the ear canal in a quiet and still patient.

Innovations and implementation strategies suited specifically for universal newborn and infant hearing screening in resource-constrained settings are limited. Mobile technology has significant potential as a low-cost approach to reducing the cost of these programs. To address this gap, we evaluated test characteristics for a recently developed off-the-shelf distortion product OAE (DPOAE) probe for smartphone-based hearing screening with limited clinical testing in a broad cohort aged 0 to 20 years.[21] To further test the suitability of this device for infant hearing screening, we examined screening accuracy of this smartphone device in an infant cohort, with known hearing status and high prevalence of hearing loss, and compared test characteristics with a commercially available DPOAE device.

METHODS

Study Design

Study participants were recruited from ambulatory craniofacial medicine, otolaryngology, and audiology clinics at Seattle Children's Hospital and an audiology clinic at the University of Washington's Institute on Human Development and Disability. These clinics were chosen because of the relatively high prevalence of both hearing loss and risk factors for hearing loss, given the need to have patients with expected abnormal results in a relatively small cohort. On the dates of study recruitment, all infants and their caregivers attending these clinics were approached.

Infants were eligible if they were aged younger than 6 months, had at least 1 patent ear canal, and were accompanied by a primary caregiver able to provide written informed consent. Infants were excluded if they had otorrhea on the date of the clinic visit, had anatomy precluding ear insert use (ie, aural atresia, ear canal stenosis), or were a ward of the state. The Seattle Children's Hospital institutional review board reviewed and approved the research protocol (STUDY00002817).

Study Procedures

Study coordinators with minimal prior clinical experience conducted OAE measurements following training by an otolaryngologist or audiologist. Study coordinators were undergraduate and graduate students, one of whom had prior work experience as a medical assistant. None had prior experience working with infants. Training was approximately 60 minutes and included operating the smartphone and conventional OAE devices, choosing the appropriate ear tip size, and inserting and removing the device probes into the ear canal. The consent process

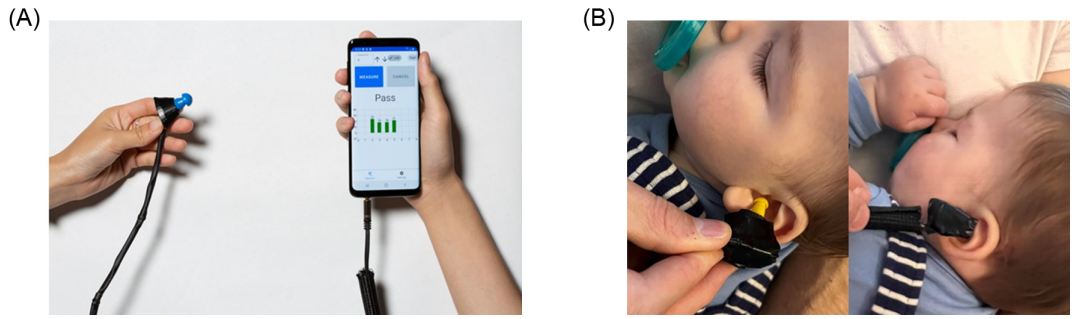

FIGURE 1.
Smartphone system. (A) An off-the-shelf otoacoustic emission probe connects to a phone through an audio jack. The otoacoustic emission measurement is performed on a custom software application with a simple user interface. (B) A generic ear tip is placed on the otoacoustic emission probe and inserted into the external auditory canal.

and OAE measurements were completed in a private room in the clinic. Approximately half of the infants underwent OAE testing with a commercial device followed by the smartphone device, whereas the other half underwent testing in the reverse order.

For smartphone testing, we used an open-source DPOAE probe that included off-the-shelf earphones and microphones, with a material cost of $10, and a custom software application to conduct single-step hearing screening. A probe attached to a 3.5-mm audio jack of a Samsung Galaxy S9 and a generic ear tip[22] was placed on the probe head prior to being inserted into the subject's ear canal (Figure 1). Two pure tones—*f1* and *f2* at a ratio of 1.2—through separate earphone speakers were then played from the smartphone into the ear canal. The resultant emitted DPOAE signal from the inner ear was measured by a microphone on the probe. Infants were tested in positions most convenient to their caregiver—either supine on the examination table or held in the caregiver's arms—while either awake or asleep.

Two commercially available conventional OAE devices were used based on location: Bio-logic AuDX Pro (Natus) or 39500 Series OAE Hearing Screener (Welch Allyn). Testing with the commercially available OAE device was also done in a single step. All devices, smartphone and conventional, were calibrated to emit *f1*/*f2* at a 65/55-dB sound pressure level, respectively.[23,24] Given the variable size and shape of infant ear canals, our software performed in-ear calibration to automatically adjust the sound levels of *f1* and *f2* based on their recorded sound levels in the ear. Measurements were obtained for *f2* of 2, 3, 4, and 5-kHz frequency bands. For the smartphone, we considered a "passed" screen to be one where DPOAEs exceeded a signal-to-noise ratio (SNR) threshold of 5 for at least 3 out of 4 frequencies based on previously reported testing.[21] For the conventional devices, the manufacturer-determined SNR threshold was 6. The result of smartphone or conventional testing was considered a "refer" if the infant did not meet or exceed the SNR threshold for at least 3 out of 4 frequencies in at least 1 ear. Testing both the smartphone and conventional device on 1 infant was completed in approximately 5 minutes.

Analysis

Demographic characteristics, medical history, physical examination, and hearing status were ascertained using caregiver interviews and confirmed using medical record review where possible. Hearing loss risk factors were defined according to the Joint Commission on Infant Hearing.[15] The infant's hearing status was determined by reviewing the medical record for results from their newborn hearing screening and, for infants who did not pass the newborn hearing screen, diagnostic brainstem auditory evoked response (BAER) performed by an audiologist. The BAER was generally obtained before 3 months of age, and the test date closest to the study date was used to determine known hearing status. No additional diagnostic hearing assessments were performed as part of the research procedures, but data from these tests were used when obtained as part of routine clinical care.

Study data were collected and managed using Research Electronic Data Capture electronic data capture tools hosted at Seattle Children's Hospital.[25,26] Primary outcomes included referral rate, sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV). Referral rate was defined as the proportion of infants that did not pass OAE testing out of all infants tested. The outcomes for the smartphone and conventional devices were each calculated using known hearing status for all infants that completed testing with both devices.

RESULTS

Between March 2022 and October 2022, we approached the legal guardians of 248 infants (Figure 2). A total of 128 infants were enrolled, for a consent rate of 51.6%. One infant was withdrawn from the study by their caregiver

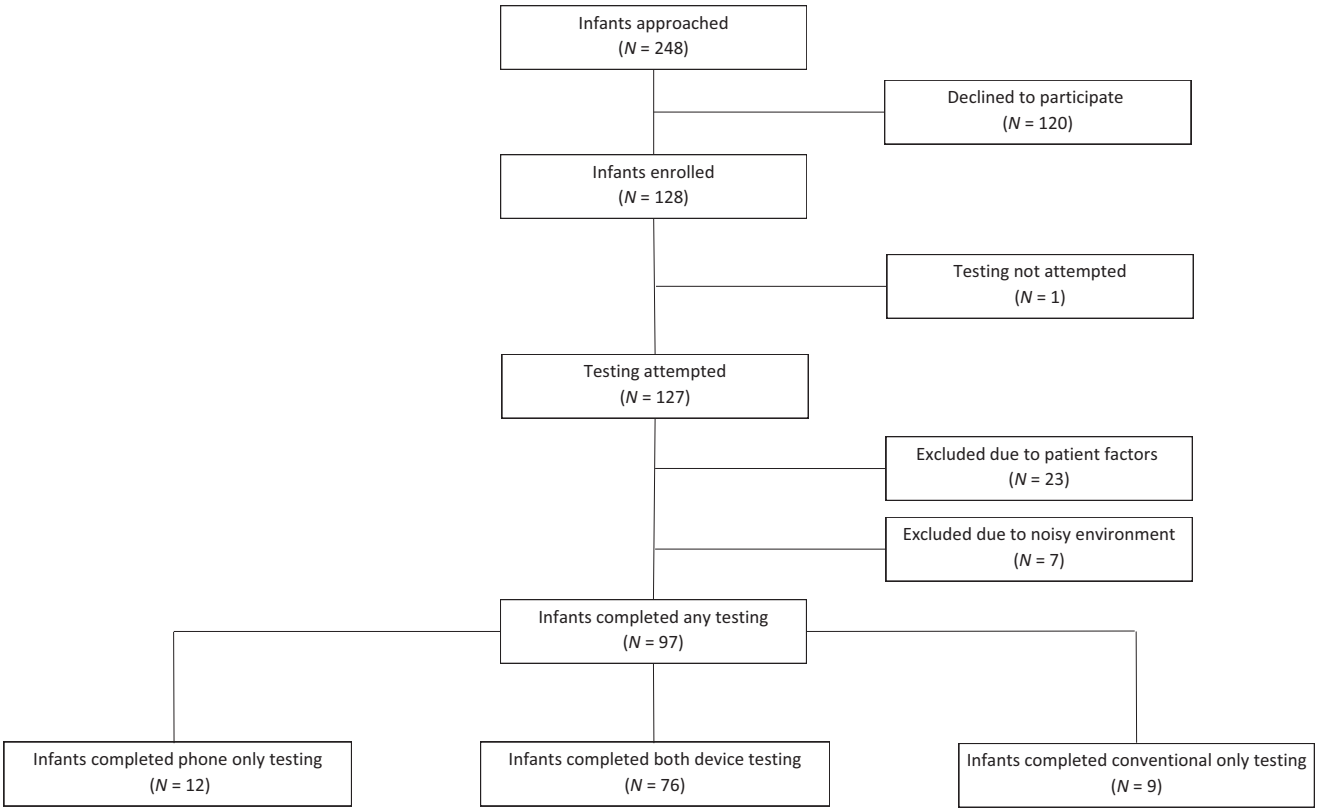

FIGURE 2.
Study subject recruitment and enrollment overview.

prior to attempting testing. Among 127 infants on which testing was attempted, 23 were excluded due to patient factors (ie, inability to keep probe well seated in the ear canal, active or fussy infant) and 7 were excluded due to a noisy environment. A total of 12 infants completed only smartphone testing, 9 infants completed only conventional testing, and 76 infants completed testing with both devices. Infants ranged in age from 9 days to 5 months and 29 days with a mean age of 3.1 ± 1.9 months (Table 1). Of these infants, 41% were female and 59% were male. The majority were full term, although over one-third had at least one known hearing loss risk factor such as a congenital infection, ototoxic exposures, low birth weight, premature birth, birth trauma, family history, craniofacial malformation, or maternal history of gestational diabetes or pre-eclampsia.[15]

Per EHDI protocol for newborn hearing screening, infants who refer (ie, do not pass) on 2 hearing screens undergo diagnostic testing with BAER. In our cohort, 18% of infants had their hearing status determined by BAER. The prevalence of abnormal hearing status in at least 1 ear was 13%, with 5% sensorineural, 4% conductive, and 4% mixed type (Table 2). Otoscopy was performed prior to OAE device testing as a part of routine clinical care on the date of testing in 20% of infants. A clear auditory canal, intact tympanic membrane, and aerated middle ear was visualized for 13 out of 14 infants on which otoscopy was performed as a part of routine clinical care.

TABLE 1. Demographic Characteristics of Infants Who Completed Both Smartphone and Conventional Testing

Characteristics	n (%)
Total infants	76 (100)
Chronological age at testing	
≥4 wk	8 (11)
1–2 mo	11 (14)
2–3 mo	8 (11)
3–4 mo	10 (13)
4–5 mo	9 (12)
5–6 mo	30 (39)
Sex	
Female	31 (41)
Male	45 (59)
Gestational age at birth	
Preterm, <37 wk	8 (11)
Full term, ≥37 wk	68 (89)
Known hearing loss risk factor	
Yes	26 (34)
No	50 (66)

Abbreviation: n, sample size.

TABLE 2. Hearing Assessments and Otologic Examination Findings for Infants Who Completed Both Smartphone and Conventional Testing

Ear and Hearing Assessments	n (%)
Total infants	76 (100)
Type of hearing assessment	
Newborn hearing screen	62 (82)
Diagnostic brainstem auditory evoked response performed by audiologist	14 (18)
Hearing assessment within 30 d of testing	
Yes	18 (24)
No	58 (76)
Hearing status	
Abnormal in at least 1 ear	10 (13)
Sensorineural	4 (5)
Conductive	3 (4)
Mixed	3 (4)
Normal in both ears	66 (87)
Otoscopy on date of testing	
Yes	15 (20)
No	61 (80)
Otoscopy, ear canal	
Clear auditory canal	14 (18)
Partial cerumen	0 (0)
Cerumen impaction	1 (1)
Otoscopy, middle ear	
Intact tympanic membrane, middle ear aerated	13 (17)
Intact tympanic membrane, middle ear effusion	1 (1)
Tympanic membrane perforation	0 (0)
Tympanic membrane not visualized	1 (1)

Abbreviation: n, sample size.

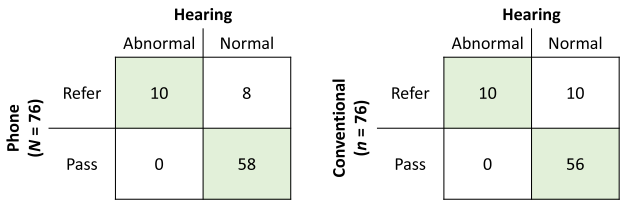

FIGURE 3.
Two-by-two tables comparing the accuracy of the smartphone device and the conventional device in correctly identifying known hearing status in infants that completed testing with both devices.

Figure 3 displays a two-by-two table comparing the accuracy of the smartphone device and the conventional device in correctly identifying known hearing status in infants that completed testing with both devices. Table 3 summarizes the test characteristics for the devices.

Among the 76 infants that completed testing with both smartphone and conventional devices, there was a 24% referral rate for the smartphone and a 26% referral rate for the conventional device. Using known hearing status as the gold standard, the sensitivity for both devices was 100% (95% CI, 0.69–1.00). Specificity was 88% (95% CI, 0.78–0.95) and 85% (95% CI, 0.74–0.92) for the smartphone and conventional devices, respectively. We also calculated NPV and PPV using a hearing loss prevalence of 13%. PPV was 56% (95% CI, 0.31–0.78) and 50% (95% CI, 0.27–0.73) for the smartphone and conventional devices, respectively. For both devices, NPV was 100% (95% CI, 0.94–1.00).

TABLE 3. Test Characteristics. Sensitivity and Specificity of Smartphone Otoacoustic Emission and Conventional Otoacoustic Emission Compared With Known Hearing Status for Infants That Completed Testing With Both Devices

Test Characteristics	Smartphone	Conventional
Total infants tested, n	76	76
Abnormal hearing status, n (%)	10 (13)	10 (13)
Refer, n (%)	18 (24)	20 (26)
Pass, n (%)	58 (76)	56 (74)
Sensitivity (95% CI)	1.00 (0.69–1.00)	1.00 (0.69–1.00)
Specificity (95% CI)	0.88 (0.78–0.95)	0.85 (0.74–0.92)
Positive predictive value (95% CI)	0.56 (0.31–0.78)	0.50 (0.27–0.73)
Negative predictive value (95% CI)	1.00 (0.94–1.00)	1.00 (0.94–1.00)

Abbreviation: n, sample size.

DISCUSSION

Our study serves as proof of concept for a promising low material cost smartphone-based DPOAE device for infant hearing screening. The smartphone OAE showed high sensitivity and high specificity in infants when compared with known hearing status, which reinforced the findings of the initial all-ages cohort[21] and demonstrated similar test characteristics as the commercially available devices. Our device was 100% sensitive for hearing loss with a 100% NPV, making it an accurate screening method for detecting hearing loss in infants. The smartphone device demonstrated good specificity in a 1-step screening protocol, with a PPV reflective of the relatively high prevalence (13%) of hearing loss in our study.[27] This PPV is acceptable for a screening device and is higher than published values of 1.5%–22.2% for universal newborn and infant hearing screening programs utilizing OAE measurements in a lower risk population.[28]

There are challenges to implementing universal hearing screening programs for newborns and infants in low-resource settings.[29] Among these are transient ear conditions complicating result interpretation for OAE-based screening, challenges with device usability, human resource limitations, and device cost.

In our study, a referral rate of about 25% highlights a high false positive rate that is a major limitation of any OAE-based screening. The smartphone-based and conventional OAEs had similar test completions and referral rates.

In general, OAE screening is particularly prone to false positives due to transient ear canal and middle ear conditions leading to obstruction of the signal from the meatus to the inner ear (ie, middle ear fluid or blood, canal edema from birth trauma, relatively narrow medial external auditory canals, and cerumen impaction).[30] In this study, we used the available otoscopic findings from routine clinical examinations to assess middle ear pathology likely to impact OAE results, although these were available for a minority of infants. Although otoscopy at the time of the test has utility, there is considerable interobserver variability in interpretation of middle ear findings, even among experts.[31,32] Real-time otoscopy was beyond the scope of this study and is impractical for universal hearing screening programs. Future study protocols may incorporate impedance testing to allow for the most objective measure of ear canal and middle ear status in infants that may influence OAE measurement.

We conducted our proof-of-concept study in a high-prevalence population for infant hearing loss, which is not a typical target population for a screening test. Our study sample had a hearing loss prevalence of 13%. In contrast, according to 2020 national Centers for Disease Control and Prevention EHDI data, the prevalence of permanent hearing loss among newborns and infants is estimated to be 1.8 per 1000 screened cases.[27] This high hearing loss prevalence introduces spectrum bias, as the test characteristics of both devices are likely to vary based on population characteristics of each unique testing setting (i.e, primary care clinics, well-baby nurseries, specialty clinics such as ours, etc). Although our study population was not the intended use population, it allowed us efficiency in assessing clinical efficacy of low-cost smartphone-based screening prior to future validation in a general infant population in an intended use limited resource setting. The relatively low prevalence of hearing loss in a general infant population would have made piloting the smartphone device unfeasible within our study's time and resource constraints. A validation study is needed to show equivalence for high-throughput newborn hearing screening in a general population.

A strength of this study was that device testing was completed by study coordinators with minimal prior clinical experience, suggesting that smartphone-based infant hearing screening may be successfully carried out by non–hearing care specialists in the future, which is vital to the success of widespread universal screening programs. An important next step will be to evaluate interrater reliability and usability of the smartphone OAE device by lay users. Although the smartphone device presented here has low material cost, future work will also examine the overall cost and cost-effectiveness of implementing screening programs using this technology in a low resource setting.

Approximately one-fourth of infants did not complete testing that was attempted in our study, possibly due to several factors, including the age of the infants and long clinic visits due to the medical needs of these patient populations. An additional limitation of this study protocol is the inability to perform diagnostic evaluations on the same day as OAE-based hearing screening.

Prior studies have suggested a potential role for smartphone technology in newborn and infant hearing screening.[33] Other studies have described technical specifications for such devices geared for adult ears.[34,35] However, newborn and infant hearing screening poses unique challenges that further amplify the importance of studies such as ours that test specifically in an infant population.

The specifications of the smartphone probe and software used in our work are available open source, which we chose to do to maximize access.[21] The device is neither US Food and Drug Administration cleared nor registered. However, the device was fabricated in a research laboratory. Although the fabrication plans and software are available open source, there may be variability in the assembly and usage of the device before it is commercially produced.

CONCLUSION

The overarching goal of this work was to generate a strong evidence base for low-cost infant hearing screening, thereby supporting the adoption and integration of infant hearing screening programs in low resource settings using cost-effective and scalable equipment. In this study, the smartphone device effectively screened for hearing loss in a high-prevalence cohort, although validating in the general population was beyond the scope of this work. Future validation studies are recommended, and our findings suggest that smartphone-based OAE detection is a promising low-cost solution to the challenge of building scalable infant hearing screening programs in resource-constrained settings. The work presented here establishes an evidence base to support future validation of the smartphone device for hearing screening in an intended use setting and population.

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