Diagnostic accuracy of non-specialist *versus* specialist health workers in diagnosing hearing loss and ear disease in Malawi

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Abstract

Objective: To determine whether a non-specialist health worker can accurately undertake audiometry and otoscopy, the essential clinical examinations in a survey of hearing loss, instead of a highly skilled specialist (i.e. ENT or audiologist).

Methods: Clinic-based diagnostic accuracy study in Malawi. Consecutively sampled participants ≥18 years had their hearing tested using a validated tablet-based audiometer (hearTest) by an audiologist (gold-standard), an audiology officer, a nurse and a community health worker (CHW). Otoscopy for diagnosis of ear pathologies was conducted by an ENT specialist (gold-standard), an ENT clinical officer, a CHW, an ENT nurse, and a general nurse. Sensitivity, specificity and kappa (k) were calculated. 80% sensitivity, 70% specificity, and kappa of 0.6 were considered adequate.

Results: 617 participants were included. High sensitivity (>90%) and specificity (>85%) in detecting bilateral hearing loss was obtained by all non-specialists. For otoscopy, sensitivity and specificity were >80% for all non-specialists in diagnosing any pathology except for the ENT nurse. Agreement in diagnoses for the ENT clinical officer was good (k=0.7) in both ears. For other assessors, moderate agreement was found (k=0.5).

Conclusion: A non-specialist can be trained to accurately assess hearing using mobile-based audiometry. However, accurate diagnosis of ear conditions requires at least an ENT clinical officer (or equivalent). Conducting surveys of hearing loss with non-specialists could lower costs and increase data collection, particularly in low and middle-income countries, where ENT specialists are scarce.

Keywords: Hearing loss, Community Health Worker, Epidemiology, Prevalence, Diagnostic accuracy

Introduction

Data on the prevalence and causes of hearing loss are lacking in many low and middle-income countries

(LMICs). A systematic review of studies conducted in sub-Saharan Africa found only eight published studies from the region [1]. Recent WHO estimates suggest that approximately 5% of the global population – or 466 million people – have disabling hearing loss (hearing loss of moderate or greater degree in the better ear) [2]. The estimates provide evidence that hearing loss is very common, however, many of the studies contributing to these estimates were conducted more than 10 years ago [3]. Only approximately half (24 of 42) of the studies were conducted in LMICs, where the majority (>80%) of people with hearing loss reside. In 2017, the World Health Assembly passed a new resolution on hearing loss which called for member states to collect country-specific data on the prevalence and causes of hearing loss [4].

In low-resource settings, there are several challenges in conducting an all-age population-based survey of the prevalence and causes of hearing loss. The cost of surveys is a significant barrier – which is driven by the large sample size required, the high costs of specialist equipment, and the costs of human resources to carry out the survey.

One way to reduce the costs of a survey and increase data collection could be to develop a rapid survey method. A rapid method is appropriate when data are needed quickly, and there are substantial barriers (in terms of time and cost) to conducting a full epidemiological survey [5]. This type of method has been developed for assessing the prevalence and causes of avoidable blindness (RAAB – rapid assessment of avoidable blindness). The components that make the RAAB survey rapid are (i) a focus on people aged 50+ based on evidence that >80% of blindness is experienced by this age group, reducing the sample size required; (ii) a simplified examination protocol which reduces the time taken to undertake the survey; (iii) automated data-entry and analysis. A similar survey protocol could be possible for surveys of hearing loss.

This paper forms part of a wider study to develop a rapid assessment of hearing loss (RAHL) survey method. Hearing loss prevalence increases rapidly with age, and >70% of hearing loss is experienced by those aged 50+.[6, 7] Focussing on people aged 50+ can help to simplify the current examination protocol recommended by WHO.[8, 9] This WHO protocol recommends expensive objective tests such as otoacoustic emissions (OAE) and auditory brainstem response (ABR) testing for children <4 years, and audiometry for people 4 years+.[9] To help establish the causes of hearing loss, otoscopy (ear examination), tympanometry (test of middle ear function), and data on clinical history are recommended for all ages.

Focussing on people aged 50+ means the protocol for assessing hearing can be simplified to audiometry alone; OAE and ABR are objective screening tests that are more suitable for the paediatric population.[10-12] A growing body of evidence suggests that mobile-based audiometry can be used instead of more expensive portable audiometers, which helps to reduce costs and improve logistics.[13, 14] Assessing the exact causes of hearing loss is more complex.[1, 6]

Hearing loss is often described by type, of which there are two main categories: sensorineural (problem in cochlear or auditory nerve) and conductive (problem in outer or middle ear). In a clinical setting, for conductive hearing loss, causes can often be established through clinical history, visualisation of the tympanic membrane through otoscopic examination, alongside the results of audiometry and tympanometry.

For sensorineural hearing loss, a similar battery of tests is used to determine possible causes, however the exact causes are often undetermined. This is because there are a multitude of sometimes overlapping risk factors such as noise exposure, ototoxic drugs, ageing and infectious diseases. In a survey setting, where portable and low-cost equipment is key, otoscopic examination is an essential part of the protocol, however interpretation is subjective and causes of sensorineural hearing loss cannot be established through this method. The utility of tests such as tympanometry and tuning forks for use in a prevalence survey is not well-understood. These tests may be useful in determining type, and in the diagnosis of otitis media, however the evidence on this is not clear-cut.[15, 16] Therefore the essential tests for a rapid survey of hearing loss include audiometry and otoscopy.

Many LMICs lack adequate human resources to meet the demand for ear and hearing services.[18] If specialist ear and hearing professionals (Ear Nose and Throat specialists (ENTs), and audiologists) do exist, then conducting a survey may disrupt needed service delivery, limiting the opportunity for their involvement in surveys. These factors have all contributed to the lack of prevalence data. There is potential for non-specialist health workers to be involved in ear and hearing assessments in surveys of hearing loss. However, evidence is lacking as to whether the key assessments (audiometry and otoscopy) can be reliably conducted by a non-specialist. In Malawi, training Community Health Workers (CHWs) in primary ear and hearing care improved their knowledge and ability to detect people who potentially have ear or hearing issues in their community.[17] However, the skills of CHWs in making an accurate diagnosis have not yet been examined.

This study aimed to determine whether a non-specialist health worker can accurately undertake audiometry and otoscopy, the essential clinical examinations in a survey of hearing loss, instead of a highly skilled specialist (i.e. ENT or audiologist).

Methods

Sample

A clinic-based diagnostic accuracy study was conducted in Malawi in May-August 2018. All individuals aged ≥18 years presenting to the ENT and Audiology departments at Queen Elizabeth Central Hospital (QECH), Blantyre, were invited to participate using consecutive sampling until the target sample size was reached. Based on an estimated proportion of either hearing loss/ear disease in patients presenting to clinic of 50%, a sample size of 300 was required to allow us to detect 80% sensitivity/specificity to +/- 8% accuracy for both audiometry and otoscopy.

Data collection tools

Data were collected using a standardised questionnaire on Open Data Kit (ODK) – a cell phone-based data collection platform.[19] In addition to basic demographic information from the study participants, the results of a) hearing test (audiometry) and b) ear examination were recorded. A validated mobile-based audiometry system hearTest, by the hearX group, was used to test hearing.[13, 20] HearTest was run on Samsung Galaxy Tab 3 Lite tablets, coupled with Sennheiser HD280 Pro2 circumaural headphones. Prior to the study the headphones were calibrated according to ISO standards (using an artificial ear, force gauge, sound level meter, and calibration app). Hearing thresholds at 0.5, 1, 2, 4 kHz in each ear were obtained. Audiometry testing was conducted in a single quiet clinical room, with multiple tests ongoing simultaneously. We used partitions to divide the room into four private test areas. Testers instructed the participant to raise their hand when a tone was heard, the tester would press a button on the tablet screen every time the participant responded. The minimum testing level was set to 10dB. Ambient noise was monitored continuously throughout testing at each frequency. If the ambient noise exceeded the maximum permissible ambient noise level (MPANL) at any frequency, this was displayed at the end of the test and recorded. The MPANL specifies the maximum ambient noise level allowed in testing room to ensure that thresholds obtained are not elevated.

We used otoscopy to examine ears and diagnose pathologies. Examiners were trained to choose one of the following eight mutually exclusive options for each ear: acute otitis media (AOM), otitis media with effusion (OME), chronic suppurative otitis media (CSOM), dry perforation, impacted wax, foreign body, otitis externa, other ear pathology, or normal ear examination. “Other” includes rarer complex conditions (e.g. cholesteatoma), or those that do not fit in to the above categories (e.g. non-occluding wax). These options cover the range of common middle ear conditions.

Health workers included

The study included two phases, with different cadres of health care workers involved in each. We defined specialists in this study as those that had a university degree in the field of audiology (audiologist) or otolaryngology (ENT specialist). For the non-specialist health workers, we included mid-level workers (nurses and clinical officers) and CHWs, who make up a large proportion of the health workforce in Malawi and many other LMICs.[21] A previous study in Malawi had shown that it was feasible to train CHWs in primary ear and hearing care, however their skills in making an accurate diagnosis had not been tested.[22-24]

Phase 1

Six assessors were involved in Phase 1 of the study – three to conduct audiometry, and three to conduct otoscopy on all participants.

- Gold/reference standard: The most experienced (specialist) clinician was defined as the gold standard and their results were compared to each of the other personnel. For audiometry, this was an audiologist and for ear examination – an ENT surgeon. Both have >5 years of clinical experience (Table 2).
- Index testers: Two index (non-specialist) assessors each for audiometry and ear examination were

included for comparison to gold standard.

- Audiometry: audiology clinical officer, and trained nurse
- Ear examination: ENT clinical officer, and trained CHW

Phase 2

Based on preliminary data from the phase one, which suggested that diagnostic agreement after ear examination with a CHW was low, a second study was introduced for an additional 300 participants in order to assess whether the accuracy would improve with nurses. Two types of nurses were invited to be trained for the study, one with ENT experience (hereafter referred to as an ENT nurse), and a trained general nurse. The rationale for including the two different types of nurses was to increase applicability to other LMICs, such as those in Southeast Asia where nurses receive training in ear and hearing to deliver these services at the primary level.[25] The gold standards remained the same, and new index testers included:

- Audiometry: trained CHW
- Ear examination: ENT nurse, and a trained general nurse without experience working in ENT

The comparisons are summarised in Table 1.

Table 1: comparisons in the study and which phase of the study the comparison occurred

		Gold standard testers	Phase
Index (comparison testers)	**Audiometry**		
	Audiology officer	Audiologist	1
	Nurse		1
	Community health worker		2
	Otoscopy		
	ENT clinical officer	ENT specialist	1
	Community health worker		1
	ENT nurse		2
	Nurse		2

Background on experience of health workers

Table 2 provides a breakdown of the educational background and clinical experience of the health workers included in the study.

Table 2: Education and clinical experience of the health workers involve in the study

	Education and training	Clinical experience
Audiometry		
Audiologist (gold standard)	Three year diploma in nursing and midwifery, one year diploma in Audiology and Public Health otology, Master of Clinical Audiology	General: five years clinical experience in non-ENT specific services Audiology: five years clinical experience in audiology
Audiology officer	Three year diploma in nursing and midwifery, one year diploma in Audiology and Public Health Otology.	General: six years clinical experience in non-ENT specific services Audiology: five years clinical experience in audiology
Nurse	Three year diploma in nursing and midwifery Additional ENT training: 4 day course on primary ear care, 3 month training in United Kingdom	General: 8 months clinical experience in non-ENT specific services. ENT: two years working in the ENT department
Community health worker	Health Surveillance Assistant training (2 months) and refresher. No previous experience in ENT.	General: >20 years' experience working in health centres and clinics
Otoscopy		
ENT specialist (gold standard)	Six year medical degree, five years ENT specialisation	ENT: 11 years clinical experience
Community health worker	Health Surveillance Assistant (community health worker) training (2 months) and refresher training. No previous experience in ENT.	General: >20 years' experience working in health centres and clinics
Nurse	Three-year diploma in nursing and midwifery, registered nurse. No previous experience in ENT.	General: six years clinical experience in non-ENT specific services
ENT nurse	Diploma in nursing and midwifery. Additional ENT training: four-day course on primary ear care.	General: eight years clinical experience in non-ENT specific services ENT: two years working with the ENT department
ENT Clinical Officer	Two years Medical Officer training, 18 months ENT Clinical Officer training	General: five years clinical experience in non-ENT specific services ENT: five years ENT clinical experience

Study training

All personnel were trained for 5-7 days by TB and MP on study procedures, clinical testing, and ethical considerations. Those performing otoscopy received an additional 14 hours of training over 6-7 days by a skilled ENT (WM) and audiologist (MP). This included both theoretical training using the WHO Primary Ear Care manual (intermediate level), and practical sessions under supervision.[26]

Data collection protocol

All patients underwent both audiometry and otoscopy by the gold standard assessors and index assessors on the same day. Masked outcome assessment was ensured; clinical interpretation occurred without knowledge of results from other examiners and each assessor performed the test without observation from other personnel involved in the study. Test order was quasi-randomised. Given most patients arrived at the clinic in the morning, after recruitment, each tester would commence testing on an available participant, who would then be seen by the next tester as soon as they were available.

After all examinations were complete, advice and treatment were provided by the gold standard examiner (audiologist, or ENT specialist depending on the presenting concern of the participant). No treatments were given prior to hearing testing or otoscopy, in order to replicate the survey protocol.

Data analysis

All data were analysed in Stata (version 15). For each index tester, the following analyses were conducted, comparing their results to the gold standard assessor.

For hearing assessment:

- *Sensitivity and specificity:* Using diagnostic criteria of presence versus absence of hearing loss (using a cut point of >25dB pure tone average at 1, 2, 4, 0.5kHz in the better ear, and in each ear). This definition was used to align with the WHO definitions.
- *Specific thresholds obtained:* Comparative analysis between hearing thresholds obtained by each examiner, including the average difference between corresponding thresholds and the percent correspondence (within 5 and 10dB) between thresholds obtained by different examiners. The distribution of thresholds was not normally distributed (Shapiro-Wilk test of normality), and thus non-parametric analysis was conducted (Wilcoxon signed rank tests) to determine if there were significant differences between thresholds obtained by different assessors.

For otoscopic examination:

- *Sensitivity and specificity*: Using a diagnostic criteria of normal vs abnormal ear examination. Abnormal ear examination was made up of seven main conditions in our study (AOM, OME, CSOM, dry perforation, impacted wax, foreign body, otitis externa, other).
- *Agreement in specific diagnosis of middle ear conditions*: Cohen's kappa agreement was calculated.
- *Analysis of dangerous errors*: Comparative analysis of the diagnoses made between an ENT and other

assessors to understand where agreements and possible mistakes were made, and whether these errors were potentially dangerous. In surveys of hearing loss, basic treatments are often provided, and referrals made as necessary. Treatments vary depending on setting, but typically include wax or foreign body removal, dry mopping for CSOM, and provision of medications. Appendix 1 provides details of the usual treatment that would be provided in a survey setting in Malawi. A "dangerous error" was defined as where the mistaken diagnosis could lead to (i) inappropriate treatment that may cause harm to ears or hearing; (ii) missed opportunity for treatment or referral; (iii) inappropriate referral (burden to participant).[27] The list of what was considered a dangerous error for this study is outlined in Table 3. It is important to note that in this study, the errors were not dangerous as the final treatments and diagnoses were provided by a gold standard assessor, after all examinations had been completed.

Table 3: Dangerous error definitions

	Error made	Reason dangerous
1	Normal misdiagnosed as any ear condition	Unnecessary treatment or referral
2	CSOM misdiagnosed as impacted wax or foreign body	Treatment in the field (removal by suction or hooks) may cause damage
3	CSOM misdiagnosed as otitis externa	Treatment (drops) may damage hearing
4	CSOM misdiagnosed as AOM or OME	Missed opportunity for referral
5	Otitis externa, AOM, OME, impacted wax, foreign body, misdiagnosed as CSOM	Treatment in the field incorrect and unnecessary referral

Cut-off values for sensitivity, specificity and kappa

According to McNamara et al. (2018) selecting the optimal cut-point for sensitivity/specificity depends on the purpose of the test and authors recommend for screening (as in a survey of hearing loss) that the test is highly sensitive (fewer false negatives).[28] However, for surveys it is also important that the specificity is also high, so that the prevalence is not overestimated (false positives) and too many people are referred incorrectly to services with limited capacity. Based on previous studies, a cut-off of 80% sensitivity was agreed as the target for good sensitivity, and higher than 70% specificity.[14] 95% confidence intervals (CI) were obtained. A cut-off of 0.6 (good agreement) was considered adequate for Cohen's kappa.

Ethical considerations

Ethical approval for this study was granted by London School of Hygiene & Tropical Medicine (LSHTM) and the College of Medicine Research Ethics Committee (COMREC) in Malawi. All participants received detailed information about the study purposes and procedures both verbally from the study co-ordinator and in written form on an information sheet in the local language. Informed consent was obtained by signature or thumbprint.

Results

617 people participated in the study overall – 313 in Phase 1 and 304 in Phase 2. In Phase 1, 306 participants underwent audiometry, and 308 otoscopic examination. Some participants were not examined by all assessors, so the numbers in each comparison vary (e.g. 305 for ENT clinical officer vs ENT specialist, and 308 for community health worker vs ENT specialist). In Phase 2, 302 participants underwent audiometry and 304 otoscopy.

In Phase 1, the proportion of participants with any level of hearing loss (pure tone average >25dB HL in the better ear) was 26% (95%CI=21.0, 31.4). The proportion of participants with any ear disease in either ear was 31% (left ear 20% (95%CI=16.0, 24.7), right ear 21% (16.0, 25.7)). In Phase 2, the proportion of participants presenting with any level of hearing loss was 20% (95%CI=16.0, 24.8). The proportion of participants with any ear disease in either ear was 22% (left ear 14% (95%CI=10.0, 18.3), right ear 14% (95%CI= 11.0, 18.9). The vast majority of tests were performed in appropriate levels of background noise, however ambient noise exceeded MPANLs more often at lower frequencies (500 and 1000Hz) (Appendix 2).

Regarding test order, for Phase 1, 24% of participants had their hearing tested first by the audiologist, 25% by the audiology clinical officer and 51% by the nurse. For otoscopy, ENT was the first examiner for 22%, ENT clinical officer for 37%, and the CHW for 42%. In Phase 2, 42% of participants were assessed by the audiologist first, and 58% by the CHW. For otoscopy, 55% were assessed by the ENT first, 25% by the ENT nurse, and 20% by the general nurse.

Audiometry comparison

Table 4 shows the accuracy of the index assessors at detecting any level of hearing loss compared to the audiologist (gold standard). There was high sensitivity (>90%) and specificity (>85%) for each of the CHW, general nurse, and audiology officer (Table 4). By ear, the sensitivity and specificity for the left ear was >90% for all three health workers. In the right ear, the sensitivity was 89% for the audiology officer, 90% for the nurse, and 98% for the community health worker. The specificity was 98% for the audiology officer, 91% for the nurse, and 89% for the CHW.

Table 4: Sensitivity and specificity results for hearing loss diagnosis by audiologist (gold standard) vs index assessors

	Bilateral hearing loss (PTA>25dB better ear)		**Left ear hearing loss (PTA >25dBHL)**		**Right ear hearing loss (PTA >25dBHL)**	
	Sensitivity	**Specificity**	**Sensitivity**	**Specificity**	**Sensitivity**	**Specificity**

	%	95% CI	%	95% CI	%	95% CI	%	95% CI	%	95% CI	%	95% CI
Audiology officer (n=306)	92.5	84.4, 97.2	95.6	92.0, 97.9	90.0	79.5, 96.2	97.2	94.2, 98.8	88.5	77.8, 95.3	97.6	94.7, 99.1
Nurse (n=306)	95.1	87.8, 89.6	87.6	82.5, 91.6	95.0	86.1, 99	91.9	87.7, 95	90.3	80.1, 96.4	91.0	86.7, 94.3
Community health worker (n=302)	95.0	86.1, 99.0	86.4	86.1, 99.0	93.2	81.3, 98.6	92.2	88.3, 95.2	97.9	88.7, 99.9	88.6	84.1, 92.2

Table 5 shows that there was a statistically significant difference between the mean thresholds obtained by the audiologist and other assessors (p<0.001). However, the majority of thresholds obtained by the audiologist and other assessors were within ≤5dB and ≤10dB (>69.2% and 85.1%). The audiology officer and the audiologist had the highest correlation in thresholds obtained.

Table 5: Average difference and correspondence between gold standard (audiologist) and index assessors

		500	1000	2000	4000
Right	**Audiology officer**				
Average difference	Mean	0.7	-1.1*	-0.9*	-1.8*
	SD	0.4	0.51	0.4	0.4
Correspondence (%)	+/-5dB	82.3	84.6	86.6	77.4
	+/-10dB	97.4	94.8	96.1	94.7
Left					
Average difference	Mean	6.9	0.3	-1.2*	-2.3*
	SD	109.2	0.4	5.8	0.4
Correspondence (%)	+/-5dB	77.4	85.6	86.2	76.1
	+/-10dB	93.4	97.7	96.1	91.8
Right	**Nurse**				
Average difference	Mean	-3.2*	-4.2*	-3.7*	-3.2*
	SD	0.6	0.7	0.7	0.7
Correspondence (%)	+/-5dB	69.8	73.8	70.8	69.2
	+/-10dB	88.8	89.5	90.8	88.5
Left					

Average difference	Mean	3.6*	-2.2*	-4.0*	-2.6*
	SD	6.3	9.5	9.3	7.8
Correspondence (%)	+/-5dB	72.5	79.0	72.1	76.8
	+/-10dB	88.2	91.8	90.2	92.1
Right	**CHW**				
Average difference	Mean	-3.8*	-4.0*	-4.3*	-7.2*
	SD	0.6	0.6	0.4	0.5
Correspondence (%)	+/-5dB	70.8	76.8	75.8	57.0
	+/-10dB	88.1	92.7	93.4	85.1
Left					
Average difference	Mean	-1.8*	-2.3*	-4.5*	-6.9*
	SD	8.4	6.8	8.1	9.9
Correspondence (%)	+/-5dB	70.9	83.1	78.5	58.9
	+/-10dB	90.1	96.0	94.4	83.1

*Notes: Index assessor thresholds subtracted from gold standard thresholds; *=significant difference on t-test*

Ear examination comparison

Table 6 shows the sensitivity and specificity results for normal vs abnormal ear examination and the kappa agreement values for exact cause. In general, the sensitivity and specificity were greater than 80% for both the left and the right ear, with the exception of the ENT nurse for specificity (68% left and 69% right). Agreement between the ENT clinical officer and ENT specialist was good (k=0.7) for both left and right ears. For other cadres, agreement was moderate (k=0.5) for one or both ears.

Table 6: Sensitivity, specificity and kappa results for ENT specialist (gold standard) vs index assessors in the left and right ears

	Left ear					**Right ear**				
	Sensitivity		**Specificity**		**Kappa**	**Sensitivity**		**Specificity**		**Kappa**
	%	95% CI	%	95% CI		%	95% CI	%	95% CI	
ENT clinical officer (n=305)	80.0	67.7, 89.2	96.3	67.7, 98.2	0.7	92.1	82.4, 97.4	94.6	91.0, 97.1	0.7
CHW (n=308)	86.9	75.8, 94.2	89.9	85.4, 93.3	0.6	87.5	76.8, 94.4	90.2	85.7, 93.6	0.5
General nurse	88.1	74.4, 18.3	90.8	86.6, 94.0	0.6	86.4	72.6, 94.8	89.2	84.8, 92.7	0.5

(n=303)										
ENT nurse (n=302)	97.6	87.4, 99.9	67.7	61.6, 73.3	0.5	93.2	81.3, 98.6	69.4	63.4, 74.9	0.5

Table 7 provides details on the differences and similarities in diagnoses made by the ENT specialist in comparison to the other health workers in the left and right ears. Dangerous errors are also indicated. The ENT clinical officer made fewer dangerous errors than other cadres (ENT clinical officer n=28 (4% of ears); nurse (general) n=53 (9% ears); CHW n=75 (12% ears); ENT nurse n=117 (19%).

Table 7: Differences in diagnosis between ENT and other assessors

	ENT clinical officer																	
	Left ear (k=0.7)									Right ear (k=0.7)								
ENT specialist	AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other	AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other
AOM	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0
OME	0	3	1*	0	0	0	0	8	0	0	4	1*	0	0	2	0	3*	0
CSOM	0	0	6	0	0	0	1	0	1	0	0	6	1*	0	0	2	0	0
IW	0	0	0	21	1	0	0	1*	0	0	0	0	22	1	3	0	1*	1
FB	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
OE	0	0	3	0	1	4	0	0	0	0	2	1*	0	0	3	0	1*	0
DP	0	0	1	0	0	0	2	0	0	0	0	1	0	0	0	6	0	0
Normal	1*	1*	0	5*	0	1*	1*	236	0	1*	0	0	0	1*	2*	1*	229	0
Other	0	0	0	1	0	0	0	1	1	0	0	0	0	0	0	0	0	1

	Community								
	Left ear (k=0.6)								
ENT specialist	AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other
AOM	1	0	0	0	0	0	0	1	0
OME	3	0	2*	0	0	1	3*	4*	0
CSOM	0	0	5	0	0	0	3	0	0
IW	0	0	0	23	0	0	0	0	0
FB	0	0	0	0	0	0	0	0	0
OE	0	0	4*	0	0	0	3*	1*	0
DP	0	0	1*	0	0	0	2	0	0
Normal	1*	0	0	11*	2*	1*	7*	222	3
Other	0	0	0	1	0	1	0	2	0

	ENT nurse																	
	Left ear (k=0.3)									Right ear (k=0.3)								
ENT specialist	AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other	AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other
AOM	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
OME	0	1	0	0	0	1	0	1*	1	0	0	0	1	0	0	0	0	3
CSOM	0	0	1	0	0	0	0	0	0	0	0	3	0	0	0	2	0	0
IW	0	0	0	26	0	0	1*	0	3	0	0	0	19	0	0	1*	1*	3
FB	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2*	0
DP	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0	0
Normal	3*	2*	0	10*	0	6*	17*	177	46*	1*	3*	1*	6*	1*	9*	6*	180	52
Other	0	0	0	3	0	0	1	1	0	0	0	0	5	0	0	1	0	0

	Gene								
	Left ear (k=0.6)								
ENT specialist	AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other
AOM	0	0	0	0	0	0	0	0	0
OME	0	1	0	1	0	1	0	1*	0
CSOM	0	0	2	0	0	0	0	0	0
IW	1*	1*	0	25	0	0	0	3*	0
FB	0	0	0	0	0	0	0	0	0
OE	0	0	0	0	0	0	0	0	0
DP	0	0	0	0	0	0	1	0	0
Normal	2*	2*	6*	10*	0	1*	3*	238	0
Other	0	0	0	3	0	1	0	1	0

AOM=Acute otitis media; OME=Otitis media with effusion; CSOM=Chronic suppurative otitis media;

IW=Impacted wax; FB=Foreign body; OE=otitis externa; DP=Dry perforation; k=kappa; * Dangerous error

Discussion

This study aimed to determine whether non-specialist health workers can accurately undertake audiometry and otoscopy in order to address the constraints that high cost and low availability of specialists places on population data collection efforts. We found that a trained audiology officer, CHW, and nurse are able to detect the presence of hearing loss using mobile-based automated audiometry (hearTest) to >90% accuracy. This is encouraging given that CHW- and nurse-level cadres are much more widely available in LMICs than specialist ear and hearing professionals.[22-24] In terms of otoscopy, we found that the agreement in specific diagnosis with an ENT specialist was acceptable for the ENT clinical officer but not for the CHW, and nurse-level health workers. In addition, CHW and nurses also made more “dangerous errors” in diagnoses, which could lead to mismanagement in the field, or inappropriate referral. CHW and nurses were able to detect the presence of any pathology with high accuracy, and this evidence may be useful for other applications such as community-level identification. The results of this study suggest that otoscopic examination requires greater level of experience to perform accurately. Thus, for a prevalence survey, at least an ENT clinical officer (or equivalent) cadre is required to make an accurate and safe diagnosis of ear conditions, as well as to provide some basic treatments (e.g. wax removal, ear drop application), or make a judgement about referral.

Comparison to previous studies

Several studies report varying diagnostic accuracy by non-ENT specialist cadres in high-income settings. Steinbach et al. (2002) compared diagnoses made from otoscopy between general paediatricians and paediatric ENTs and found only slight to moderate agreement (k=0.5).[29] Blomgren et al. (2003) evaluated inter-rater agreement in diagnosis of acute otitis media amongst children between general practitioners and ENTs and found kappa of 0.3.[30] Asher et al. (2005) found that 62% of children with a confirmed AOM diagnosis (on tympanocentesis) were correctly referred by paediatricians, or general practitioners after otoscopic examination in primary care.[31] Pichichero et al. (2002) found that paediatric residents correctly diagnosed AOM and OME 41% of the time.[32] The poor diagnostic agreement found in these studies suggests that accurate diagnosis of ear disease based on otoscopy is difficult and subjective. These findings concur with our study and highlight the need for a clinician with more ENT-specific experience to be involved in diagnosing causes of hearing loss, and management of ear disease in the field studies.

A small number of studies have compared agreement in diagnoses within cadres. In a study by Sebothoma et al. (2018), agreement in diagnoses between two ENTs was high.[33] Pinchichero reported that within cadres, the diagnoses were highly consistent, however data was not provided on level of agreement.[34] In another study, agreement between attending physicians was found to be moderate (kappa 0.4).[35] These studies highlight that some variation can exist even within clinicians with the same level of training, likely due to the subjective nature of the examination. However, the variation is not expected to be as pronounced as that found across cadres.

Few studies have compared diagnoses made by non-specialist health workers in LMICs. Mulwafu et al. (2017) found that training CHWs for three days using the WHO primary ear and hearing care manuals resulted in improvements in knowledge. This study also found that CHWs could identify and refer members of their community with a suspected ear disorder or hearing loss, however the accuracy of this identification was not reported.[17] Our study agrees with the finding from this study that training CHW to undertake primary ear and hearing care identification is feasible, and provides evidence on the accuracy of this exercise. In a survey of ear disease amongst school children in Kenya in 1992, ENT clinical officers were involved in ear and hearing screening, however the diagnostic accuracy of these clinicians was not reviewed in depth.[36] Therefore our study adds to the limited evidence base.

Studies comparing diagnostic accuracy of different clinical cadres in hearing testing are lacking. A study by Yousuf-Hussein et al. (2015) suggested that CHWs in South Africa could screen for hearing loss in community settings using smartphone-based hearing screening (hearScreen).[13] However, they did not make comparisons with a gold standard assessor. Several studies have described the role of "non-specialist health workers", such as nurses, in newborn hearing screening programmes, however none to date have made comparisons in the accuracy of this screening compared to a gold-standard tester.[37-39] The Joint Position Statement on Infant Hearing (2007), asserts that screening technologies that are automated are necessary to eliminate individual test interpretation, reduce effects of tester error on test outcome. The need to detect diagnostic accuracy in automated tests may seem counter-intuitive given that automated suggests that tester decisions are minimised. However, given testers still have to instruct participants, and press a button when the participant indicates they have heard, testing the accuracy of different cadres is justified. Our study provides evidence that non-specialist health workers can accurately carry out automated audiometry after training.

Strengths and limitations of the study

This study adds to the small evidence base on diagnostic accuracy of non-specialist health workers in detecting hearing loss and diagnosing ear disease. We attempted to standardise the training for non-specialist health care workers – each cadre received the same number of hours of training by the same person and used a WHO manual to deliver training.[26] The results of each examination were masked to ensure independent assessments. A wide spectrum of patients was included in the sample, which was representative of clinical practice. This helps to mitigate spectrum bias. The sample size was approximately 300 in each study, which was based on an *a priori* sample size calculation. We managed to achieve this sample size, which is a strength of our study.[40] In determining sample size we expected 50% of participants to have ear disease or hearing loss, however, only 26% of participants had hearing loss in Phase 1, and 20% in Phase 2. For ear disease these proportions were 31% and 22% respectively. However post-hoc sample size calculations suggest the sample size still provides adequate power. Our study was powered for sensitivity/specificity outcomes and was underpowered for Cohen's kappa analysis. However, the comparison of diagnosis in this study provides important indications on where common errors in diagnosis are made.

This study was conducted in Malawi, and therefore findings may not be generalisable to other settings. We tried to address this limitation by including a range of health care workers that would be common across different LMICs. For instance, not all countries have an ENT clinical officer cadre, although ENT nurses may be more common. The results for ENT nurses were quite poor in comparison to the ENT specialist, and thus further research in other settings is needed to understand whether this finding is replicable, or whether nurses in other settings may perform better. We only had one of each clinical cadre of health worker involved in the study, which also limits generalisability of our findings. There are likely to be variations in skill level across health workers within the same clinical cadre, which is another justification for further similar studies to be conducted. This limitation could not be avoided due to substantial time and resource constraints. Finally, we used the WHO-recommended definitions of hearing loss for the analysis of this study. A range of alternative definitions exists, such as that proposed by Stevens et al. (2011) which suggests a slightly lower cut-off of >20dB for mild hearing loss, and also includes unilateral hearing loss.[41] Using this more conservative definition may have resulted in a higher number of people identified as having any level of hearing loss. However, given that we also compared thresholds obtained, and considered ear-specific findings in the analysis, the impact of an alternative definition on the results of the research is unlikely to be substantial.

Implications

The lack and cost of human resources for ear and hearing services in LMICs is a barrier to conducting surveys to understand the population need. To help to overcome these barriers, our findings suggest that a nurse or CHW cadre of health worker can undertake reliable hearing assessments in the adult population using mobile-based audiometry (hearTest). However, a mid-cadre ENT health worker (e.g. ENT clinical officer) or specialist-cadre (ENT specialist), is required to make accurate and safe diagnoses in these surveys. Involving health workers below the level of clinical officer could result in dangerous errors in population-based surveys – i.e. inappropriate referral or treatment. This finding reflects the complexities of diagnosing ear conditions. The advantage of a mid-cadre ENT is that they are typically in greater supply, and less expensive than a specialist. For instance, in Malawi there are approximately 30 ENT clinical officers but only 3 ENT specialists. With the rapid development of new technologies such as automated diagnosis based on images of the ear drum through machine learning, it may be possible in future for diagnosis to be made by non-specialist cadres. In this study, health workers who conducted otoscopy were trained over 3-5 days for a total of 14 hours. To enable greater diagnostic accuracy, further training may be required, and this deserves attention in future research.

This study has implications beyond that of the development of the rapid assessment of hearing loss (RAHL) survey protocol. It can also be used to inform cadre of workers required for screening for ear disease and hearing loss in community settings. Our findings add to the evidence base, and show that non-specialists who have received training are able to accurately determine the presence or absence of ear disease (not specific diagnosis), and also to screen for hearing loss using mobile tools. This builds on previous work in Malawi that found training CHW in primary ear and hearing care is feasible.[17] This provides evidence to support further development of primary ear and hearing care programmes involving primary health care workers in LMICs. This study also found that ENT clinical officers are able to diagnose with accuracy. Given training is only 18 months for this cadre, this study provides evidence that the ENT clinical officers training programme offered in Malawi and other African countries such as Kenya should be scaled-up to other LMICs, allowing the few ENT specialist clinicians in these settings to manage more complex clinical treatments. These types of "task shifting" approaches are recommended by the WHO as a method to overcome the skills shortage for ear and hearing care in many LMICs.[26]

Conclusion

This study found that a CHW or nurse can be trained to accurately assess hearing thresholds using mobile-based audiometry. In general, the sensitivity in detecting presence vs absence of middle ear pathology using otoscopy was >80% for non-specialist cadres compared to gold standard ENT assessment. However, only the ENT clinical officer level was able to make an accurate and safe diagnosis of specific ear conditions, and thus determine the potential causes of hearing loss. Clinical officers, or other paramedical practitioners for ear and hearing care, are much more widely available and less costly than specialist medical professionals. The findings of this study suggest that non-specialist health workers can be involved in surveys of the prevalence and causes of hearing loss. For hearing assessment, CHWs or above are appropriate; and for diagnosing the causes of hearing loss, ENT clinical officers (or equivalent) or above are required. Further studies are required in other locations to understand generalisability of these findings. Conducting surveys of hearing loss with non-specialist health workers could lower the costs, and improve survey logistics, and has potential to increase data collection efforts for the prevalence and causes of hearing loss in LMICs.

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Appendix 1: Correct management options in the field by condition

	Management in field	**Referral**
CSOM	Dry mop	Yes, refer for possible surgery

Otitis externa	Dry mop	No
Wax	Remove wax	Yes, if unable to remove in the field
Foreign body	Remove foreign body	Yes, if unable to remove in the field
AOM	Medication	No
OME	Medication	No
Dry perforation	No	Yes, refer for possible surgery
Normal examination with disabling hearing loss	No	Yes, refer for diagnostic audiometry and possible hearing aids

Appendix 2: Tests performed above and below the maximum permissible ambient noise levels (MPANL) by frequency and by ear

	Below MPANL (%)	**Above MPANL (%)**	**Mean above MPANL (SD)**
Left			
500	**61.6**	**38.4**	**13.1 (0.4)**
1000	**68.2**	**31.8**	**10.7 (0.4)**
2000	**87.6**	**12.4**	**9.2 (0.5)**
4000	**97.0**	**3.0**	**5.7 (0.5)**
Right			
500	**62.3**	**37.7**	**13.3 (0.4)**
1000	**66.7**	**33.3**	**10.1 (0.3)**
2000	**88.8**	**11.2**	**9.1 (0.5)**
4000	**97.4**	**2.6**	**5.6 (0.6)**