

1 **Diagnostic accuracy of non-specialist health workers in comparison to**
2 **specialist health workers in diagnosis of hearing loss and ear disease in**
3 **Malawi**

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14 **Abstract**

15 **Background**

16 Population-based surveys of hearing loss are resource-intensive, requiring specialist health
17 professionals and expensive equipment. This study aimed to determine the accuracy of non-specialist
18 health workers (community health workers and mid-level health workers) in assessing presence and
19 causes of hearing loss compared to specialists (highly-skilled health workers - audiologists and Ear
20 Nose and Throat specialists (ENTs)).

21 **Methods**

22 A clinic-based diagnostic accuracy study was undertaken in Malawi. Consecutive sampling of
23 participants ≥ 18 years was conducted. Each participant had their hearing tested, using a validated
24 tablet-based audiometer (hearTest) by an audiologist (gold-standard), an audiology officer, a nurse
25 and a community health worker (CHW). Otoscopy for diagnosis of ear pathologies was conducted by
26 an ENT specialist (gold-standard), an ENT clinical officer, a CHW, an ENT nurse, and a general
27 nurse. Sensitivity, specificity and kappa (k) were calculated. Cut-offs of 80% sensitivity, 70%
28 specificity, and kappa of 0.6 were considered adequate.

29 **Results**

30 617 participants were included. High sensitivity ($>90\%$) and specificity ($>85\%$) in detecting bilateral
31 hearing loss was obtained by all non-specialists. For otoscopy, sensitivity and specificity were $>80\%$
32 for all non-specialists in diagnosing any pathology except for the ENT nurse. Agreement in diagnoses
33 for the ENT clinical officer was good ($k=0.7$) in both ears. For other assessors, moderate agreement
34 was found ($k=0.5$).

1 **Conclusion**

2 A non-specialist can be trained to accurately assess hearing using mobile-based audiometry. However,
3 accurate diagnosis of ear conditions requires at least an ENT clinical officer(or equivalent). Further
4 studies are required in other locations to determine generalisability. Conducting surveys of hearing
5 loss with non-specialists could lower costs and increase data collection, particularly in low and
6 middle-income countries, where a dearth of specialist human resources for ENT exists.

7

1 **Background**

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

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

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

25 This paper forms part of a wider study to develop a rapid assessment of hearing loss (RAHL) survey
26 methodology. Previous evidence has shown that hearing loss prevalence increases rapidly with age,
27 and >70% of hearing loss is experienced by those aged 50+.[6, 7] Focussing on people aged 50+ can
28 help to simplify the current examination protocol recommended by WHO.[8, 9] This WHO protocol
29 recommends expensive objective tests such as otoacoustic emissions (OAE), and auditory brainstem
30 response (ABR) testing for children <4 years, and audiometry for people 4 years +.[9] To help
31 establish the causes of hearing loss, otoscopy (ear examination), tympanometry (test of middle ear
32 function), and data on clinical history is recommended for all ages. Focussing on people aged 50+
33 means the protocol for assessing hearing can be simplified to audiometry alone, OAE and ABR are
34 objective screening tests that are more suitable for the paediatric population.[10-12] A growing body
35 of evidence suggests that mobile-based audiometry can be used instead of more expensive portable

1 audiometers, which helps to reduce costs and improve logistics.[13, 14] Assessing the exact causes of
2 hearing loss is more complex.[1, 6] Hearing loss is often described by type, of which there are two
3 main categories – sensorineural (problem in cochlear or auditory nerve) and conductive (problem in
4 outer or middle ear). In a clinical setting, for conductive hearing loss, causes can often be established
5 through clinical history, visualisation of the tympanic membrane through otoscopic examination,
6 alongside the results of audiometry and tympanometry. For sensorineural hearing loss, a similar
7 battery of tests are used to determine possible causes, however the exact causes are often
8 undetermined. This is because there are a multitude of, sometimes overlapping, risk factors such as
9 noise exposure, ototoxic drugs, ageing and infectious diseases. In a survey setting, where portable and
10 low cost equipment are key, otoscopic examination is an essential part of the protocol, however
11 interpretation is subjective and causes of sensorineural hearing loss cannot be established through this
12 method. The utility of tests such as tympanometry and tuning forks for use in a prevalence survey is
13 not well-understood. These tests may be useful in determining type, and in the diagnosis of otitis
14 media, however the evidence on this is not clear-cut.[15, 16] Therefore the key essential tests for a
15 rapid survey of hearing loss include audiometry and otoscopy.

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

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

29 **Methods**

30 *Sample*

31 A clinic-based diagnostic accuracy study was conducted in Malawi in May-August 2018. All
32 individuals aged ≥ 18 years presenting to the ENT and Audiology departments at Queen Elizabeth
33 Central Hospital (QECH), Blantyre were invited to participate using consecutive sampling until the
34 target sample size was reached. Based on an estimated proportion of either hearing loss/ear disease in

1 patients presenting to clinic of 50%, a sample size of 300 was required to allow us to detect 80%
2 sensitivity/specificity to +/- 8% accuracy for both audiometry and otoscopy.

3 *Data collection tools*

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

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

26 *Health workers included*

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

34 **Phase one**

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

- 3 • Gold/reference standard: The most experienced (specialist) clinician was defined as the
4 gold standard and their results were compared to each of the other personnel. For
5 audiometry, this was an audiologist and for ear examination – an ENT surgeon. Both have
6 >5 years of clinical experience (see Table 2).
- 7 • Index testers: Two index (non-specialist) assessors each for audiometry and ear
8 examination were included for comparison to gold standard.
 - 9 ○ Audiometry: audiology clinical officer, and trained nurse
 - 10 ○ Ear examination: ENT clinical officer, and trained CHW

11 **Phase two**

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

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

23 The comparisons are summarised in **Table 1**.

24

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		

2

3 *Background on experience of health workers*

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

6 **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

7

8 *Study training*

9 All personnel were trained for 5-7 days by TB and MP on study procedures, clinical testing, and
10 ethical considerations. Those performing otoscopy received an additional 14 hours of training over 6-

1 7 days by a skilled ENT (WM) and audiologist (MP). This included both theoretical training using the
2 WHO Primary Ear Care manual (intermediate level), and practical sessions under supervision.[26]

3 *Data collection protocol*

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

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

14 *Data analysis*

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

17 For hearing assessment:

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

28 For otoscopic examination:

- 29 • *Sensitivity and specificity*: Using a diagnostic criteria of normal vs abnormal ear examination.
30 Abnormal ear examination was made up of seven main conditions in our study (AOM, OME,
31 CSOM, dry perforation, impacted wax, foreign body, otitis externa, other).
- 32 • *Agreement in specific diagnosis of middle ear conditions*: Cohen's kappa agreement was
33 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, however 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 were 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

1 participants received detailed information about the study purposes and procedures both verbally from
2 the study co-ordinator and in written form on an information sheet in the local language. Informed
3 consent was obtained by signature or thumbprint.

4

1 **Results**

2 617 people participated in the study overall – 313 in phase one and 304 in phase two. In phase one,
3 306 participants underwent audiometry, and 308 otoscopic examination. Some participants were not
4 examined by all assessors, so the numbers in each comparison vary (e.g. 305 for ENT clinical officer
5 vs ENT specialist, and 308 for community health worker vs ENT specialist). In phase two, 302
6 participants underwent audiometry and 304 otoscopy.

7 In phase one, the proportion of participants with any level of hearing loss (pure tone average >25dB
8 HL in the better ear) was 26% (95%CI=21.0, 31.4). The proportion of participants with any ear
9 disease in either ear was 31% (left ear 20% (95%CI=16.0, 24.7), right ear 21% (16.0, 25.7)). In phase
10 two, the proportion of participants presenting with any level of hearing loss was 20% (95%CI=16.0,
11 24.8). The proportion of participants with any ear disease in either ear was 22% (left ear 14%
12 (95%CI=10.0, 18.3), right ear 14% (95%CI= 11.0, 18.9). The vast majority of tests were performed in
13 appropriate levels of background noise, however ambient noise exceeded MPANLs more often at
14 lower frequencies (500 and 1000Hz) (Appendix 2).

15 Regarding test order, for phase one 24% of participants had their hearing tested first by the
16 audiologist, 25% by the audiology clinical officer and 51% by the nurse. For otoscopy, ENT was the
17 first examiner for 22%, ENT clinical officer for 37%, and the CHW for 42%. In phase two, 42% of
18 participants were assessed by the audiologist first, and 58% by the CHW. For otoscopy, 55% were
19 assessed by the ENT first, 25% by the ENT nurse, and 20% by the general nurse.

20 ***Audiometry comparison***

21 **Table 4** shows the accuracy of the index assessors at detecting any level of hearing loss compared to
22 the audiologist (gold standard). There was high sensitivity (>90%) and specificity (>85%) for each of
23 the CHW, general nurse, and audiology officer (Table 4). By ear, the sensitivity and specificity for the
24 left ear was >90% for all three health workers. In the right ear, the sensitivity was 89% for the
25 audiology officer, 90% for the nurse, and 98% for the community health worker. The specificity was
26 98% for the audiology officer, 91% for the nurse, and 89% for the CHW.

27

1 **Table 4:** Sensitivity and specificity results for hearing loss diagnosis by audiologist (gold standard) vs index
 2 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

3

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

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

		500		1000		2000		4000	
<i>Right</i>		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				
<i>Left</i>									
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				
<i>Right</i>		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				
<i>Left</i>									
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				
<i>Right</i>		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				
<i>Left</i>									
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				

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

10

1 **Ear examination comparison**

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

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

	Left ear				Kappa	Right ear				
	Sensitivity		Specificity			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 (n=303)	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
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

9

10 **Table 7** provides details on the differences and similarities in diagnoses made by the ENT specialist
 11 in comparison to the other health workers in the left and right ears. Dangerous errors are also
 12 indicated. The ENT clinical officer made fewer dangerous errors than other cadres (ENT clinical
 13 officer n=28 (4% of ears); nurse (general) n=53 (9% ears); CHW n=75 (12% ears); ENT nurse n=117
 14 (19%).

1 **Table 7:** Differences in diagnosis between ENT and other assessors

		ENT clinical officer																				Community health worker																	
		Left ear (k=0.7)									Right ear (k=0.7)											Left ear (k=0.6)									Right ear (k=0.5)								
		AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other	AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other			AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other	AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other
ENT specialist	AOM	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	ENT specialist	AOM	1	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0		
	OME	0	3	1*	0	0	0	8	0	0	4	1*	0	0	2	0	3*	0		OME	3	0	2*	0	0	1	3*	4*	0	3	0	1*	0	0	0	1	5	1	
	CSOM	0	0	6	0	0	0	1	0	1	0	0	6	1*	0	0	2	0		0	CSOM	0	0	5	0	0	0	3	0	0	1*	0	3	1*	0	1*	3	0	0
	IW	0	0	0	21	1	0	0	1*	0	0	0	0	22	1	3	0	1*		1	IW	0	0	0	23	0	0	0	0	0	0	0	0	27	0	0	1*	0	0
	FB	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0		0	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	OE	0	0	4*	0	0	0	3*	1*	0	0	0	3*	0	0	0	2	2	0
	DP	0	0	1	0	0	0	2	0	0	0	0	1	0	0	0	6	0		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	Normal	1*	0	0	11*	2*	1*	7*	222	3*	1*	0	0	16*	2*	0	5*	220	0
	Other	0	0	0	1	0	0	0	1	1	0	0	0	0	0	0	0	1		0	Other	0	0	0	1	0	1	0	2	0	0	0	0	0	0	0	0	1	0
		ENT nurse																				General nurse																	
		Left ear (k=0.3)									Right ear (k=0.3)											Left ear (k=0.6)									Right ear (k=0.5)								
		AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other	AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other			AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other	AOM	OME	CSOM	IW	FB	OE	DP	Normal	Other
ENT specialist	AOM	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	ENT specialist	AOM	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0		
	OME	0	1	0	0	0	1	0	1*	1	0	0	1	0	0	0	0	3		OME	0	1	0	1	0	1	0	1*	0	0	0	1	1	0	2*	0	0		
	CSOM	0	0	1	0	0	0	0	0	0	0	0	3	0	0	0	2	0		0	CSOM	0	0	2	0	0	0	0	0	1*	1*	3	0	0	0	0	0	0	0
	IW	0	0	0	26	0	0	1*	0	3	0	0	0	19	0	0	1*	1*		3	IW	1*	1*	0	25	0	0	0	3*	0	0	1	1*	18	0	0	0	4*	0
	FB	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	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	OE	0	0	0	0	0	0	0	0	1	0	1*	0	0	0	0	4*	0	
	DP	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0		0	DP	0	0	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0	0
	Normal	3*	2*	0	10*	0	6*	17*	177	46*	1*	3*	1*	6*	1*	9*	6*	180		52	Normal	2*	2*	6*	10*	0	1*	3*	238	0	1*	0	1*	4*	0	0	3*	232	1
	Other	0	0	0	3	0	0	1	1	0	0	0	0	5	0	0	1	0		0	Other	0	0	0	3	0	1	0	1	0	1	0	1	4	0	0	0	0	0

2

3 *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;*

4 *k=kappa; * Dangerous error*

1 **Discussion**

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

18

19 *Comparison to previous studies*

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

32

33 A small number of studies have compared agreement in diagnoses within cadres. In a study by
34 Sebothoma et al. (2018), agreement in diagnoses between two ENTs was high.[33] Pichichero
35 reported that within cadres, the diagnoses were highly consistent, however data was not provided on
36 level of agreement.[34] In another study, agreement between attending physicians was found to be

1 moderate (kappa 0.4).[35] These studies highlight that some variation can exist even within clinicians
2 with the same level of training, likely due to the subjective nature of the examination. However, the
3 variation is not expected to be as pronounced as that found across cadres.

4
5 Few studies have compared diagnoses made by non-specialist health workers in LMICs. Mulwafu et
6 al. (2017) found that training CHWs for three days using the WHO primary ear and hearing care
7 manuals resulted in improvements in knowledge. This study also found that CHWs could identify and
8 refer members of their community with a suspected ear disorder or hearing loss, however the accuracy
9 of this identification was not reported.[17] Our study agrees with the finding from this study that
10 training CHW to undertake primary ear and hearing care identification is feasible, and provides
11 evidence on the accuracy of this exercise. In a survey of ear disease amongst school children in Kenya
12 in 1992, ENT clinical officers were involved in ear and hearing screening, however the diagnostic
13 accuracy of these clinicians was not reviewed in depth.[36] Therefore our study adds to the limited
14 evidence base.

15
16 Studies comparing diagnostic accuracy of different clinical cadres in hearing testing are lacking. A
17 study by Yousuf-Hussein et al. (2015) suggested that CHWs in South Africa could screen for hearing
18 loss in community settings using smartphone-based hearing screening (hearScreen).[13] However,
19 they did not make comparisons with a gold standard assessor. Several studies have described the role
20 of “non-specialist health workers”, such as nurses, in newborn hearing screening programmes,
21 however none to date have made comparisons in the accuracy of this screening compared to a gold-
22 standard tester.[37-39] The Joint Position Statement on Infant Hearing (2007), asserts that screening
23 technologies that are automated are necessary to eliminate individual test interpretation, reduce effects
24 of tester error on test outcome. The need to detect diagnostic accuracy in automated tests may seem
25 counter-intuitive given that automated suggests that tester decisions are minimised. However, given
26 testers still have to instruct participants, and press a button when the participant indicates they have
27 heard, testing the accuracy of different cadres is justified. Our study provides evidence that non-
28 specialist health workers can accurately carry out automated audiometry after training.

29 30 *Strengths and limitations of the study*

31 This study adds to the limited evidence base on diagnostic accuracy of non-specialist health workers
32 in detecting hearing loss and diagnosing ear disease. We attempted to standardise the training for non-
33 specialist health care workers – each cadre received the same number of hours of training by the same
34 person and used a WHO manual to deliver training.[26] The results of each examination was masked
35 to ensure independent assessments. A wide spectrum of patients were included in the sample, which
36 were representative of clinical practice. This helps to mitigate spectrum bias. The sample size was

1 approximately 300 in each study, which was based on an *a priori* sample size calculation. We
2 managed to achieve this sample size, which is a strength of our study.[40] In determining sample size
3 we expected 50% of participants to have ear disease or hearing loss, however, only 26% of
4 participants had hearing loss in phase one, and 20% in phase two. For ear disease these proportions
5 were 31% and 22% respectively. However post-hoc sample size calculations suggest the sample size
6 still provides adequate power. Our study was powered for sensitivity/specificity outcomes, and was
7 underpowered for Cohen's kappa analysis. However, the comparison of diagnosis in this study
8 provides important indications on where common errors in diagnosis are made.

9
10 This study was conducted in Malawi, and therefore findings may not be generalisable to other
11 settings. We tried to address this limitation by including a range of health care workers, which would
12 be common across different LMICs. For instance, not all countries have an ENT clinical officer cadre,
13 however ENT nurses may be more common. The results for ENT nurses were quite poor in
14 comparison to the ENT specialist, and thus further research in other settings is needed to understand
15 whether this finding is replicable, or whether nurses in other settings may perform better. We only had
16 one of each clinical cadre of health worker involved in the study which also limits generalisability of
17 the findings of this study. There are likely to be variations in skill level across health workers within
18 the same clinical cadre, which is another justification for further similar studies to be conducted. This
19 limitation could not be avoided due to substantial time and resource constraints. Finally, we used the
20 WHO recommended definitions of hearing loss for the analysis of this study. A range of alternative
21 definitions exist, such as that proposed by Stevens et al. (2011) which suggests a slightly lower cut-off
22 of >20dB for mild hearing loss, and also includes unilateral hearing loss.[41] Using this more
23 conservative definition may have resulted in a higher number of people identified as having any level
24 of hearing loss. However, given that we also compared thresholds obtained, and also considered ear-
25 specific findings in the analysis, the impact of an alternative definition on the results of the research is
26 unlikely to be substantial.

27 28 *Implications*

29 The lack and cost of human resources for ear and hearing services in LMICs is a barrier to conducting
30 surveys to understand the population need. To help to overcome these barriers, our findings suggest
31 that a nurse or CHW cadre of health worker can undertake reliable hearing assessments in the adult
32 population using mobile based audiometry (hearTest). However, a mid-cadre ENT health worker (e.g.
33 ENT clinical officer) or specialist-cadre (ENT specialist), is required to make accurate and safe
34 diagnoses in these surveys. Involving health workers below the level of clinical officer could result in
35 dangerous errors in population-based surveys – i.e. inappropriate referral, or treatment. This finding
36 reflects the complexities of diagnosing ear conditions. The advantage of a mid-cadre ENT is that they

1 are typically in greater supply, and less expensive than a specialist. For instance, in Malawi there are
2 approximately 30 ENT clinical officers compared to three ENT specialists. With the rapid
3 development of new technologies such as automated diagnosis based on images of the ear drum
4 through machine learning, it may be possible in future for diagnosis to be made by non-specialist
5 cadres. In this study, health workers who conducted otoscopy were trained over 3-5 days for a total of
6 14 hours. To enable greater diagnostic accuracy, further training may be required and this deserves
7 attention in future research.

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

22

23

1 **Conclusion**

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

15

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21

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18

1 **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

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3 **Appendix 2: Tests performed above and below the maximum permissible ambient noise levels**

4 **(MPANL) by frequency and by ear**

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	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)

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