Field test of the Rapid Assessment of Hearing Loss survey protocol in Ntcheu district, Malawi

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Conflicts of interest

The fifth author (DW) is a scientific advisor to the hearX group. His relationship includes equity and consulting.

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Introduction

Hearing loss and the lack of prevalence data

Population-based surveys that estimate the prevalence and causes of hearing loss in low and middle-income countries (LMICs) are limited, particularly countries in sub-Saharan Africa. Only eight published all-age population-based surveys of hearing loss exist across 48 countries in the region (<17%).[1] The lack of data is despite evidence from global estimations that prevalence is likely to be high. Approximately 466 million people are affected by disabling hearing loss globally, according to 2018 World Health Organisation (WHO) estimations.[2] Hearing loss is also the second leading cause of years lived with disability in the Global Burden of Disease 2016 study – more common than depression, uncorrected refractive error or diabetes.[3] These global estimates are often generated in high-income contexts, using complex statistical methods and assumptions to account for sparse data, and these figures have limited relevance at the local level. Pisani and colleagues argue that *"of all the types of knowledge produced, locally determined empirical measures are most likely to be used in ways that directly affect health service provision"*.[4] Country-specific data is needed to plan, monitor, and implement hearing services relevant to the local context. These services are vital due to the substantial short and long-term consequences of hearing loss on an individual's life – including on speech development, communication, education, employment and poverty.[5-7]

Background on development of the rapid assessment of hearing loss (RAHL) protocol

A survey methodology has been developed in response to the need for locally derived prevalence estimates, in order to gather data in a low-cost and rapid manner - the Rapid Assessment of Hearing Loss (RAHL). The RAHL protocol was developed using several key steps. First, a secondary data analysis of all-age population-based surveys conducted in India and Cameroon in 2013-2014 was conducted to assess whether the study population could be restricted to older adults.[8-10] This study found that the majority of hearing loss was experienced by people aged 50+ (>70%), and the distribution of causes in the older age group are representative of the total population. Focussing on this age group reduces survey costs, through lowering the required sample size and the limiting the range of clinical tests required to measure hearing and understand the probable causes of hearing loss. These aspects are what make the survey rapid. This approach has been used for many years in the field of visual impairment with the Rapid Assessment of Avoidable Blindness (RAAB) survey.[11, 12] The second step of the development was to review the clinical tools for use in the survey protocol, considering accuracy and costs. Third, a questionnaire was developed through literature review, expert consultation, and pilot testing. This included the development of an algorithm for the assignment of conductive causes. Fourth, pilot study in Malawi, in a small number of villages was conducted to determine the cluster size, based on the number of people it was feasible to examine in one day. Finally, a clinic-based diagnostic accuracy study was conducted to determine which cadre of health care worker should be involved in conducting hearing tests and ear examinations in the survey.[13] Field-testing of the RAHL in different settings is required to refine and finalise the protocol.

Malawi is a low-income country in southern Africa, with a population of approximately 17.5 million people.[14] Ear and hearing services are extremely limited, with only two qualified Ear Nose and Throat (ENT) surgeons in the country. In 2012, Malawi developed the first 4-year National Plan for Ear and Hearing Care, which has made an important contribution. One of the key objectives of the National Plan is to obtain locally derived population-based survey data, to help develop and implement plans based on population needs. Against this backdrop, this study aimed to i) report on the feasibility of conducting the RAHL survey in a rural African setting; ii) to assess the prevalence and causes of hearing loss in one district of Malawi (Ntcheu district), providing data on the first population-based survey of hearing loss in the country.

Methods

Study location

This study took place in Ntcheu district, Central Malawi between November and December 2018. Ntcheu district has a population of 659,608 people (9% aged 50 years and above), across 834 villages and is predominantly rural. The district has one secondary level district hospital, which provides basic ENT services.

Sample size calculation

The required sample size of this study was estimated with an expected prevalence of moderate or greater ("disabling") hearing loss of 11.5% (based on a previous survey in Cameroon)[9], 95% confidence, design effect of 1.4, margin of error of 20% (around the estimate), and response rate of 90%. This resulted in a required sample size of 1149. Consequently, 38 clusters of 30 individuals (50+ years) were selected.

Study design and sampling

The RAHL survey is a cross-sectional population-based survey. A two-stage sampling procedure was used.[15] First, 38 clusters (villages) were selected from the most recent census (2008), using probability-proportionate-to-size sampling. Next, households within clusters were selected using compact segment sampling, whereby a village was divided into segments, each containing approximately 30 people aged 50 years and older. This cluster size was determined feasible based on pilot work in Malawi. Segments were numbered and one segment was drawn at random. This segmentation used sketch maps of the village, including the boundaries, number and approximate location of houses. All people aged 50+ who had been living in the selected household at least 6 months of the previous year were considered eligible for inclusion in the survey. Community sensitisation was conducted in advance of the survey to assist in maximising response rates.

Teams and training

Two teams were trained for five days on study procedures, clinical testing and ethical considerations. The training included an inter-observer variation assessment in the ENT department, and a field pilot in one village of Blantyre. Each team consisted of four people, and included:

- One nurse to enumerate eligible participants, and complete a questionnaire
- Two people to complete hearing screening; one audiology officer and one nurse [13]
- One ENT clinical officer to complete an ear examination using otoscopy [13]

In addition, a survey co-ordinator was involved in arranging the survey logistics. As part of the training, inter-observer variation (IOV) between ENT clinical officers, and hearing testers, was measured to ensure that it was acceptable.

Data collection protocol

A paper-based household roster was completed in selected households with individuals aged 50+, recording basic information about eligible members of the household. Next, mobile-based data collection was used to collect questionnaire data, using the Open Data Kit (ODK) platform. A general questionnaire covering demographics, poverty indicators (e.g. asset ownership), self-reported hearing loss, and risk factors for hearing loss was completed. Then, all participants had their hearing screened in their homes by an audiology officer or a nurse using a validated mobile-based automated audiometry system, hearTest (hearX group, South Africa), paired with calibrated circumaural attenuating headphones (Sennheiser HD280).[16, 17] Thresholds were obtained at 500, 1000, 2000, 4000Hz in each ear. High levels of ambient noise can elevate hearing thresholds. Using circumaural headphones and testing in a quiet location can help to reduce ambient noise. Ambient noise was monitored, through the hearTest app's built-in noise monitoring capability. Prior to fieldwork, the equipment was calibrated to ISO audiological standards. Finally, all participants had their ears examined using otoscopy by an ENT clinical officer to indicate causes of hearing loss, and/or presence of ear disease. Those with any level of hearing loss (>25dB pure tone average) or any ear disease in either ear were asked about previous care seeking for the condition and reasons for not seeking ear and hearing services.

Assignment of causes of hearing loss

The probable causes of hearing loss were assigned by an ENT clinical officer in the field, using a combination of clinical judgement, clinical history of hearing loss, ear examination, and hearing test results.

For causes related to the middle ear (chronic otitis media (dry or wet perforation), otitis media with effusion, acute otitis media) and outer ear (otitis externa, wax, foreign body), a decision support algorithm based on features of the ear exam (e.g. colour of ear drum, presence of discharge, pain etc), programmed into ODK was used to guide the examiner. This algorithm was developed using a review of the literature, and expert consultation, and a pilot-test in a clinic-based study in Malawi.[13] Following the examination built-in prompts appear within the questionnaire. For example, *"[Name] has a red, bulging ear drum, and experiences pain. The diagnosis is acute ototis media. Do you agree?".* If the examiner did not agree with the diagnosis, they were required to specify the reason. If a certain ear condition was not included in the possible options, the clinician could choose "other ear condition" and specify.

For causes not related to the middle ear and/or sensorineural causes, (e.g. congenital, noise-induced, ototoxic medication, non-infectious disease, infectious disease, presbyacusis or unknown), the assignment was based on clinical history of hearing loss and risk factors (obtained from the questionnaire), the results of the ear examination, and hearing test. Sensorineural causes were grouped in to acquired, and congenital.

Causes were grouped in to broad type categories, as probable conductive, sensorineural, or mixed. If the ear examination had abnormal findings, it was assumed that hearing loss was conductive, unless the clinician specified otherwise in the questionnaire. If the ear examination was normal, it was assumed that the hearing loss was sensorineural, unless the clinician specified otherwise. Prompts to check the type of hearing loss appeared in the mobile-based questionnaire, which were triggered based on the results of the ear examination. For example, if the cause was assigned as "otitis media with effusion" the ODK form would prompt the ENT specialist *"Based on the ear examination, [name] is likely to have a conductive hearing loss. Do you agree?".* At this stage, the clinician could agree or disagree, and if disagreed, the reason specified. Consistency in the assignment of type was also checked at analysis stage. For example, if wax was assigned as the cause, but the degree of hearing loss was severe or greater, then the type was reassigned as mixed.

Service needs and coverage

The need for services in the population was determined based on the diagnosis. Service needs included diagnostic audiology assessment and possible hearing aid fitting; surgical assessment; medication; impacted wax or foreign body removal; and review ("watchful waiting"). The definitions of these service needs are provided as Appendix 1.

Hearing aid coverage was calculated as the proportion of people with any level of bilateral hearing loss, probable mixed or sensorineural in nature, who reported that they owned a hearing aid for the left, right or both ears. The calculation used was as follows:

$$HAC = \frac{a}{(a+b)} * 100$$

Where,

- *a* is the number of participants with any level of hearing loss (bilateral), probable mixed or sensorineural in nature in both ears, who reported that they owned a hearing aid (met need);
- *b* is the number of people with any level of hearing loss (bilateral), probable mixed or sensorineural in nature in both ears, who reported not owning a hearing aid (unmet need)

This excludes people with pure conductive hearing loss as we assumed that these individuals would need medical or surgical interventions prior to any hearing aid fitting to manage residual permanent conductive loss. For those who reported owning hearing aids, they were asked about hearing aid use.

For people with ear disease or hearing loss in either ear, they were asked about previous care seeking behaviour, and barriers to accessing care.

Definitions

This study used the WHO definitions of hearing loss to estimate prevalence, which are based on the better hearing ear, and average of pure-tone audiometry thresholds at 500, 1000, 2000, 4000Hz. The WHO definition of “disabling” hearing loss, referred to as moderate or greater hearing loss in this paper, is a pure tone average of ≥41dB HL. For any level of hearing loss the cut off is ≥26dB HL. For the degree of hearing loss, the following pure tone average cut off values were used: mild 26-40dBHL; moderate 41-60dB HL, severe 61-80dB HL, and profound ≥81dB HL.

Data entry and analysis

Stata version 15.0 (StataCorp LP, College Station, Texas) was used to manage and analyse the data.

<u>Feasibility:</u> To assess the feasibility of the RAHL protocol, outcomes included: cluster completion (i.e. response rate and the percentage of clusters completed in one day); time taken to obtain consent (observation in first 2 weeks of survey); time taken per participant to complete the questionnaires (recorded through mobile data forms); proportion of refusals; and field observations on survey logistics with notes taken throughout the study. The time was recorded when the survey form was opened, and again at the end of the questionnaire. Shapiro-Wilk tests of normality were conducted for time variables. For non-normal variables, medians and interquartile ranges (IQR) were obtained, and means and standard deviations for normally distributed data. Feasibility was judged according to the number of people that could be assessed in a day. A target of 30 per day was determined based on the cluster size.

<u>RAHL outcomes:</u> The cluster design was accounted for in the analysis using the “svy” command. Data from the 2018 Malawian Population Housing Census was used to adjust the analysis for age and sex. Outcomes included the prevalence of moderate or greater, and any level of hearing loss; degree of hearing loss; and probable causes of hearing loss, and these were disaggregated by age, and sex. The prevalence of ear disease was also estimated. Logistic regression analysis was conducted to examine the importance of risk factors in contributing to hearing loss in the population. Exposure variables included age, sex, literacy, socioeconomic position (SEP), and risk factors for hearing loss (e.g. noise exposure, ototoxic medication, history of infectious diseases, head trauma, diabetes, high blood pressure). SEP was measured using the Equity Tool which uses DHS data to derive a simplified assets-based measure. In the analysis, a wealth quintile was assigned according to the national wealth quintile.[18] In addition, proxy measures of SEP, including education and literacy, were included.[19]

Ethical considerations

Ethics approval was obtained from London School of Hygiene & Tropical Medicine Research Ethics Committee (United Kingdom), and the College of Medicine Research Ethics Committee (COMREC)

(Malawi). All participants provided written (either signature or thumbprint) informed consent. For those with profound hearing loss, or those with communication difficulties, a family member was asked to assist in explaining the study to participants, and the information sheet given out to the participant to read. Consent was obtained from the study participant when possible, or a proxy family member on behalf of the research participant. For anyone identified as having ear conditions, or hearing loss, participants were either treated in the field (simple conditions such as wax removal), or referred onwards to the nearest appropriate services.

Results

Feasibility of RAHL protocol

Response rate

Of 1153 participants enumerated, 1080 completed the study (93.7% response rate). Of the remainder, 5.6% were unavailable, and 0.7% refused. Of 1080 participants who agreed to take part, 1062 completed the hearing test – with 19 (1.8%) missing tests due to illnesses or inability to communicate (e.g. dementia). We captured whether these people had hearing loss using the self- or proxy-reported questions on hearing difficulties.

Cluster completion

Five of 38 clusters could not be completed in one day (i.e. 30 people could not be enumerated or response rate <90%) and needed return visits (13% of clusters). Reasons for return visits included: a long duration of travel time to cluster, limiting time available for data collection (n=2), and missing >10% people on days of field work (people in the field or at the market) (n=3). In four clusters (10.8%), two teams were involved in completing data collection; this was pre-arranged due to the anticipated long duration of travel time. Thus, overall 24% of clusters were not completed in one day by one team.

Time to complete survey

According to the Shapiro-Wilk tests time data was not normally distributed. The median time to complete the questionnaire was 2.0 minutes (IQR 1.0), hearing test 7.3 minutes (IQR=1.6), and the ear exam 7.0 minutes (IQR=4.0). The time to complete consent ranged from 5-15 minutes with a median of 7.0 minutes. The median duration of the whole procedure on each participant was 23.7 minutes (IQR=5.2).

Prevalence and causes of hearing loss

Overview of the study population

Compared to the census population, the survey slightly under-sampled the younger population groups (50-59 years), and over sampled the older age groups (70-79 years and 80-89 years) and females (Table 1; Appendix 2). Participants who were absent were more likely to be younger (aged 50-59 years 47.7%; and 60-69 years 33.9%). Given the differences between the census and the sample, our analyses were weighted to account for the differences in age, and sex in comparison to the population.

Table 1: Demography of coverage, absenteeism, and refusals by age and sex, n (%)

	Population in Malawi	**Available**	**Not available**	**Refused**	**Total**
Overall (aged 50+)	1,586,500 (100.0)	1080 (93.7)	65 (5.6)	8 (0.7)	1153 (100.0)
Male	718,400 (45.3)	375 (34.7)	34 (52.3)	2 (25.0)	411 (35.7)
Female	868,000 (54.7)	705 (65.2)	31 (47.7)	6 (75.0)	742 (64.3)
Age group					
50-59	694,700 (43.8)	414 (38.3)	31 (47.7)	2 (25.0)	447 (38.8)
60-69	475,400 (30.0)	320 (29.7)	22 (33.9)	4 (50.0)	346 (30.1)
70-79	269,500 (17.0)	217 (20.1)	7 (10.8)	1 (12.5)	225 (19.5)
80-89	118,400 (7.5)	106 (9.8)	5 (7.7)	1 (12.5)	112 (9.7)
90+	28,400 (1.8)	22 (2.0)	0 (0.0)	0 (0.0)	9 (1.9)

Prevalence of hearing loss and ear disease

Table 2 shows the weighted prevalence of hearing loss in the population, by degree of hearing loss. The prevalence of moderate or greater hearing loss in the 50+ population of Malawi was estimated to be 10.0% (95%CI=7.9, 12.5) and for any level of hearing loss 35.9% (95%CI=31.6, 40.2) (age range 50-103 years). An increase in prevalence of moderate or greater hearing loss and any hearing loss was seen with age. For example, moderate or greater hearing loss increased from 6.3% (95%CI=3.6, 10.9) in those aged 50-59 years to 33.0% (95%CI=24.9, 42.3) in those aged 80+ years. No significant differences were seen in prevalence by sex. The prevalence decreased with increasing severity – from 26.1% (95%CI=22.8, 29.7) with mild hearing loss, to 0.6% (95%CI=0.2, 1.6) with profound loss. The vast majority of tests (n=881; 83%) were conducted in areas where ambient noise was below the minimum permissible ambient noise levels (MPANLs). There did not appear to be a relationship between MPANL and hearing loss (see Appendix 3).**Table 2:** Distribution of the prevalence of hearing loss by degree, and gender

	All		**Male**		**Female**	
	N	% (95% CI)	N	% (95% CI)	N	% (95% CI)
Moderate or greater hearing loss (>40dB better ear)						
All	122	10.0 (7.9, 12.5)	57	11.9 (8.4,16.6)	65	8.2 (6.6, 10.1)
50-59	21	6.3 (3.6, 10.9)	12	9.1 (4.7, 16.9)	9	3.4 (1.7, 6.6)
60-69	17	4.9 (3.1, 7.7)	8	5.9 (2.8, 12.0)	9	4.2 (2.4, 7.2)
70-79	38	19.7 (14.7, 25.9)	19	25.4 (17.3, 35.9)	19	15.6 (10.4, 22.7)
80+	46	33.0 (24.9, 42.3)	18	31.7 (19.2, 47.8)	28	33.7 (24.2,44.7)
Any level (>25dB ear better ear)						
All	447	35.9 (31.6, 40.2)	162	33.9 (27.8, 40.6)	285	37.5 (33.2, 41.9)
50-59 years	94	23.3 (18.5, 28.9)	30	22.7 (16.0, 31.2)	64	23.9 (18.9, 29.6)
60-69 years	117	34.8 (28.9, 41.1)	42	35.2 (26.5, 45.0)	75	34.4 (27.3, 42.2)
70-79 years	132	63.3 (55.9, 70.2)	53	65.2 (51.3, 76.9)	79	62.0 (52.3, 70.8)
80+ years	104	80.1 (72.4, 86.2)	37	78.9 (64.5, 88.5)	67	80.9 (71.4, 87.8)
Degree (better ear)						
None (0-25dB)	620	63.8 (59.4, 68.0)	212	65.9 (59.2, 72.1)	361	61.9 (57.4, 66.2)
Mild (26-40dB)	325	26.1 (22.8, 29.7)	105	22.1 (17.8, 27.2)	292	29.7 (26.0, 33.8)
Moderate (41-60dB)	78	6.6 (5.1, 8.4)	38	8.2 (5.4, 12.2)	92	5.1 (3.9, 6.6)
Severe (61-80 dB)	36	2.9 (2.1, 4.1)	17	3.5 (2.1, 5.7)	27	2.4 (1.6, 3.6)
Profound (81 dB +)	8	0.6 (0.2, 1.6)	2	0.3 (0.1, 1.4)	6	0.9 (0.3, 2.9)

***13 missing hearing tests; included in denominator as not having hearing los*

The prevalence of ear disease was 18.7% (95%CI 16.0, 21.8) in the left and 18.6% (95%CI 15.5, 22.2) in the right. Table 3 shows the key types of ear disease present in each ear. The main types of ear disease were impacted wax (14.9% left; 14.1% right), and chronic otitis media (wet or dry).

Table 3: Age and sex adjusted prevalence and causes of ear disease

	Left		**Right**	
	N	% (95% CI)	N	% (95% CI)
Normal	869	81.3 (78.1, 84.0)	871	81.3 (77.8, 84.5)
Abnormal	206	18.7 (16.0, 21.8)	202	18.6 (15.5, 22.2)
Acute otitis media	2	0.3 (0.07, 1.4)	0	-
Otitis media with effusion	2	0.09 (0.02, 0.4)	1	0.04 (0.006, 0.4)

Chronic otitis media – wet perforation	13	1.2 (0.6, 2.7)	17	1.7 (0.9, 3.0)
Chronic otitis media – dry perforation	10	1.3 (0.6, 2.5)	10	1.5 (0.8, 2.8)
Impacted wax	167	14.9 (12.5, 17.6)	161	14.1 (11.6, 16.9)
Foreign body	3	0.2 (0.07, 0.8)	2	0.2 (0.05, 0.9)
Otitis externa	2	0.2 (0.02, 1.2)	0	-
Other middle ear	5	0.3 (0.1, 0.9)	7	0.6 (0.2, 1.7)

Probable causes of hearing loss

Table 4 shows the main probable causes of any level of hearing loss in the population. By ear, the majority of hearing loss was probable sensorineural in nature (72.0% left and 73.6% right). Less than a quarter of causes were probable conductive in nature. The main conductive causes included impacted wax (15.2% left; and right overall); chronic otitis media (dry perforation) (0.9% left; 1.1. right overall). Mixed hearing losses were the cause in 7.6% of left and 7.4% of right ears. The main causes of the conductive component of the mixed hearing loss were chronic otitis media (wet perforation) (2.2% left; 2.5% right); and impacted wax (4.5% left; 4.0% right).

Table 4: Probable cause and type of hearing loss (by ear and by individual) amongst those with any level of hearing loss (>25dB in the better ear), and extrapolated to the total population of Ntcheu

	Left ear (n=447)		**Right ear (n=447)**	
	N	%	N	%
Probable conductive				
OME	1	0.2	0	0.0
Chronic otitis media – wet	3	0.7	3	0.7
Chronic otitis media – dry	4	0.9	5	1.1
Impacted wax	68	15.2	68	15.2
Foreign body	1	0.2	2	0.5
Otitis externa	1	0.2	0	0.0
Other middle ear	1	0.2	0	0.0
Total	**79**	**17.7**	**79**	**17.7**
Probable sensorineural				
Acquired	321	71.8	328	73.4
Congenital	1	0.2	1	0.2
Total	**322**	**72.0**	**329**	**73.6**
Probable mixed				
Impacted wax	20	4.5	18	4.0
OME	1	0.5	1	0.2
Chronic otitis media - wet	9	2.0	11	2.5
Chronic otitis media – dry	4	0.9	3	0.7
Total	**34**	**7.6**	**33**	**7.4**
Missing	12	2.7	7	1.6

Population needs and coverage of services

Nearly one third of participants (30.9%) were in need of diagnostic audiology and possible hearing aid or other rehabilitation services (Table 5). Extrapolating these figures to the population of Ntcheu equates to an estimated 20,400 people aged 50+ needing such services. In total, 14.4% of people needed wax or foreign body removal, equating to an estimated 9,500 people aged 50+ across the district. Surgical assessments were needed for 3.1% of the population (2,000 people) and 2.3% of ears (3,100 ears). Finally, 2.3% needed medication (1,500 people).

Coverage of ear and hearing services was low. Only one person with a diagnosis of mixed hearing loss (CSOM and severe loss), had hearing aids (HAC=0.3%). This person reported wearing their hearing aids every day. Only 45 of 687 (6.6%) with any level of hearing loss or ear disease in either ear had previously sought care. Of these, the majority sought care at the health centre (48.9%) or public hospital (42.2%). The vast majority received medication (55.6%) or no treatment at all (26.7%). For those that did not seek care, the majority did not feel the need (76.5%) or were unaware that treatment was possible (13.4%).

Table 5: Needs for services in the population of Ntcheu district, Malawi

		People in need			**Ears**		
		Sample (n=1080)		Population*	Sample (n=1080*2)		Population*
	Definition of need	N	%	n	N	%	n
Diagnostic audiology (possible hearing aid)	Bilateral sensorineural or mixed type of hearing loss (>25dB)	334	30.9	20,400	-	-	-
Surgical assessments	COM (any) with or without hearing loss	33	3.1	2,000	50	2.3	3,100
Medication	AOM, OE, COM (wet) with or without hearing loss	25	2.3	1,500	34	1.6	2,100
Wax or foreign body removal	Impacted wax with hearing loss (>25 dB) in either ear	155	14.4	9,500	228	10.6	13,900
Watchful waiting	OME; Hearing loss >25dB HL in either ear	2	0.2	100	3	0.1	200

**Based on 10% of the Ntcheu population (total 660,000) aged 50+ (66,000 people); rounded to the nearest 100*

Factors associated with hearing loss

Table 6 shows the univariable and multivariable analysis of the factors associated with hearing loss. In univariate regression, any level of hearing loss increased with age with 9% increase in odds of hearing loss for each year (OR=1.09; 95%CI=1.07, 1.10). The odds of hearing loss decreased with increasing SEP, higher education school attendance and history of infectious disease. The odds increased for people with diabetes, and history of TB. In multivariable analysis, increasing age, diabetes, and TB, remained significantly associated with an increased risk of hearing loss whilst higher educational levels and infectious disease history were protective. Although noise and malaria, were not found to be associated with hearing loss, the prevalence of these self-reported exposures was high.

Table 6: Association between any level hearing loss and risk factors

	N (%)	**Univariate**		**Multivariate (adjusting for all other variables in the model)**	
		aOR^ (95%CI)	P value	OR (95%CI)	P-value
Age (continuous)		1.09 (1.07, 1.10)	**0.001**	1.09 (1.07, 1.10)	**<0.01**
Sex					
Male	375 (34.7)	1.0 (baseline)	-	-	-
Female	705 (65.3)	1.03 (0.74, 1.643)	0.87	0.91 (0.64, 1.30)	0.60
SEP quintile					
1 - poorest	342 (31.7)	1.0 (base)	-	1.0 (base)	-
2	105 (9.7)	0.59 (0.34, 1.03)	0.06	0.63 (0.36, 1.10)	0.10
3	201 (18.6)	1.00 (0.55, 1.83)	0.44	1.05 (0.58, 1.90)	0.87
4	329 (30.5)	0.80 (0.53, 1.20)	0.27	0.89 (0.60, 1.31)	0.53
5 - richest	103 (9.5)	0.47 (0.23, 0.97)	**0.04**	0.53 (0.25, 1.11)	0.09
Literacy					
Unable to read	624 (57.8)	1.0 (base)	-	-	-
Able to read	456 (42.2)	0.69 (0.46, 1.03)	0.07	-	-
Education					
Never attended	538 (49.8)	1.0 (base)	-	1.0 (base)	-
Primary or greater	542 (50.2)	0.61 (0.44, 0.83)	**<0.01**	0.68 (0.50, 0.93)	**0.02**
Noise exposure	138 (12.8)	1.03 (0.58, 1.84)	0.92	-	-
Hypertension	230 (21.4)	1.09 (0.72, 1.67)	0.68	-	-
Diabetes	9 (0.8)	3.90 (1.22, 12.41)	**0.02**	3.59 (1.30, 10.00)	**0.02**
Cancer medication	5 (0.5)	3.28 (0.56, 19.32)	0.18	-	-
Solvent exposure	14 (1.3)	0.47 (0.1, 2.9)	0.40	-	-
Trauma	25 (2.3)	2.17 (0.66, 7.13)	0.20	-	-
HIV	71 (6.6)	0.99 (0.56, 1.76)	0.98	-	-
Malaria	1041 (96.4)	0.94 (0.39, 2.29)	0.90	-	-
TB	50 (4.6)	2.23 (1.16, 4.28)	**0.02**	2.37 (1.21, 4.63)	**0.01**
Other infectious disease*	704 (65.2)	0.63 (0.42, 0.94)	**0.03**	0.65 (0.43, 0.97)	**0.04**

*meningitis, chicken pox, pneumonia, herpes zoster, syphilis, mumps, measles (excludes TB, HIV and malaria); aOR: adjusted odds ratio; ^adjusted for age and sex

Discussion

Review of findings

This was the second field-test of the RAHL survey in Ntcheu district, Malawi; and to the best of our knowledge, the first population-based survey of hearing loss in the country. In terms of feasibility of RAHL, the response rate was high (>90%), and the survey was completed in 24 days (5 weeks) by two teams. Mobile-based screening using hearTest worked well, was relatively quick (median 7.3 minutes) and was acceptable for participants with only a small number of eligible participants having missing hearing data (n=19; 1.6%). For the majority of clusters, it was feasible to complete the survey in one day (i.e. 30 people enumerated with ≥90% response rate). However, a quarter of clusters required repeat visits or both teams to complete. The reasons for this include logistical challenges some of which could be overcome with more time spent on planning/sensitisation. Spending two days to complete one cluster may be required when travel distances are particularly long. The time taken per participant was a median of 23.7 minutes, however there were some outliers with the maximum duration 75.3 minutes. The maximum duration may be longer due to difficult to test participants, or it may be due to the method used to collect time data (i.e. opening and saving the ODK questionnaire).

The estimated prevalence of any level of hearing loss was 35.9% (95%CI=31.6, 40.2), moderate or greater hearing loss was 10.0% (95%CI=7.9, 12.5). The prevalence of hearing loss increased with age and there was no significant difference by sex. The most common probable causes of hearing loss in this population was acquired sensorineural ihearing loss. Impacted wax was also common (15.2% left and right). Close to one third of the population (30.9%) need diagnostic audiology services and possible hearing aid fitting, equating to nearly 20,400 people aged 50+. Wax removal was the next most common service need (14.4%) with close to 10,000 people 50+ in need of services in the district..

Previous all-age estimates from sub-Saharan Africa, suggest that the prevalence of hearing loss ranges between 6-27%.[1, 20, 21] However, variation in the methods used to assess hearing and definitions of hearing loss used have varied across previous studies making comparisons to our data difficult. Table 7 summarises the prevalence of hearing loss across different studies in sub-Saharan Africa. The prevalence of hearing loss among people aged 50+ was extracted from these studies for comparison, and ranged between 15-90%. Again, there was variation in cut points used to make the estimates of hearing loss, making direct comparisons difficult. However, our estimates do concur with those found in studies in Nigeria and South Africa (43.2%; 32.8% respectively compared to 35.9% found in our study) which used the same definition as the current study.

Table 7: Prevalence of hearing loss in population-based surveys in sub-Saharan Africa (adapted from Mulwafu et. al)

Location	Publication year	Sample	Pure tone average (PTA) cut-off	Prevalence (%)	Prevalence in older people	Causes (if reported)
Uganda **[22]**	2008	6041; all ages	≥31	18.0	Not reported	All ages: Undetermined 55% Otitis media 18% Impacted wax 10% Other 17%
Madagascar **[23]**	2003	6613; all ages	≥26	26.6	Data not available	Not reported
Cameroon [9]	2014	3567; all ages	≥35 children ≥40 adults	3.6	14.8 (50+)	People aged 50+: Undetermined 30.9% Otitis media 2.1% Impacted wax 33.0% Age related 30.9% Noise 2.1% Otitis externa 1.1%
Ethiopia **[24]**	2006	24453; >5 years	N/A (self-report)	8.3	Not reported	Not reported
Nigeria **[25]**	2010	1302; > 65 years	N/A (self-report)	6.1	6.1 (65+)	Not reported
Nigeria **[26]**	2000	8975; all ages	≥26	17.9	43.2 (45+ years)*	Not reported
South Africa **[27]**	2016	2494; >=4 years	≥26	12.4	32.8 (50+)*	Not reported
Malawi (current study)		1080; 50+	≥26 ≥41		35.6 (50+) 9.9 (50+)	People aged 50+ Undetermined 41.4% left 40.9% right Otitis media left 5.4%; 4.9% right Impacted wax 16.3% left; 16.1% right Age related 24.8% left; 26.9% right Noise 2.0% left; 2.2% right Otitis externa 0.2% left 0.0% right Other causes 7.6% left; 7.8% right

*Crude estimate made by author (unweighted)

Regionally, the WHO estimates that the all-age prevalence of moderate or greater hearing loss is 10.6% in sub-Saharan Africa.[28] These estimates were based on 11 available studies, only two of which were all-age samples. Given our focus on people aged 50+, direct comparisons of these estimates to our data are difficult. However, given the prevalence in people aged 50+ in individual all-age studies is similar to what is found in our study, the overall prevalence in these populations is likely to be similar to these studies. Extrapolations of the prevalence in people aged 50+ to the all-age population is an area that deserves further attention.

The main causes of hearing loss in this survey were likely sensorineural in nature (72.0% left and 73.6% right). This contrasts to findings from the systematic review by Mulwafu et al. which found that the most common causes of hearing loss were middle ear disease (36%) or wax (24%) when results were pooled across studies. When comparing to the individual studies from the systematic review shown in Table 6, the proportion of causes due to impacted wax in our study (15.2% left and right) were similar to estimates for Uganda (10%) and slightly lower than Cameroon (33%). Other studies did not report causes. The proportion related to middle ear disease (otitis media) in our study was 2.0% left and 1.8% in the right. This is lower than the proportion found in Uganda (18.0%) and Cameroon (3.6%). The reasons for differences may be due to the methods used to assign causes, or due to genuine differences in Malawi compared to other populations. With no previous studies in Malawi we have no comparison study for this population. The methods used to establish causes vary across studies, and many previous studies do not provide adequate information about how causes were assigned. Another possible reason for the differences in cause distribution may be the age group of the study population. However, previous research that provided the rationale for the RAHL study demonstrated the distribution of the causes in the all-age population of Cameroon and India were comparable to the total population.[10] Further evidence may be needed to verify these assumptions in other populations.

Age, history of tuberculosis, and history of diabetes were associated with significantly increased odds of hearing loss. Higher education was protective, those with primary or greater education had lower odds of hearing loss. This contrasts with a study in South Africa which found that education and diabetes were not associated with hearing loss, whilst gender and hypertension were.[27] This may be related to different risk factors present in the two populations. However, the South African study did find a relationship with age, as in our study and others.[1, 20] Unexpectedly, infectious disease was a protective factor in our study. This may be explained by recall or other measurement bias or residual confounding. A high proportion of participants reported infectious disease (60.4%) and there may therefore be insufficient variation in the sample. However, diseases such as measles and mumps are known risks for development of hearing loss.[29]

Implications for Malawi

This survey has highlighted the high unmet need for diagnostic audiology and rehabilitation for the district of Ntcheu. Coverage of hearing aids was extremely low, and very few people in need have previously sought care.

At present there are no audiology services in the district and nearest services are at QECH or Kamuzu Central Hospital in Lilongwe. The survey provides important data to advocate scale-up of service delivery, including outreach, in the district. In Thyolo district, community health workers have been trained to identify children and adults with potential hearing loss living in the community and this is feasible and acceptable.[30] This type of community ear care programme may be beneficial in Ntcheu in light of the huge lack of human resources in the district.

The prevalence of risk factors for hearing loss, including malaria, HIV, and other infectious diseases were high. Given the association with hearing loss, hearing screening could be integrated into existing HIV and malaria programmes to ensure that early intervention can be provided for those in need.[31] This is an area that warrants further attention.

Strengths and limitations

The strengths of this study include the high response rate (>90%), use of smartphone-based automated audiometry, and a structured, standardised approach taken to examine ears and determine causes. Although tests were carried out in natural (non-soundproof) conditions, background noise was not a substantial issue in this survey and therefore unlikely to have resulted in false positives. This may be due to the type of headphones used, and because testing was conducted within households.

The survey uses a pragmatic approach, to collect key information for service-planning purposes, that is feasible and affordable in LMICs. The trade-off is some limitations in terms of detail on clinical diagnosis. The exact underlying causes of probable sensorineural hearing loss is this and many other surveys is unknown. However, for sensorineural causes, the management does not vary substantially by cause, as with conductive hearing loss. For these individuals, management includes diagnostic audiometry (air and bone conduction hearing acuity), speech audiometry, and a range of other possible tests. The majority of people with sensorineural hearing loss will likely benefit from hearing aids, unless they have profound hearing loss. Our definition of hearing aid coverage highlighted the complexities of developing a clear definition of coverage. We took a pragmatic approach to our definition and this will be tested and refined based on future surveys.

The 2008 census was used to conduct probability proportionate to size sampling. The 2018 census had been conducted at the time of the study, however results had not yet been released. The implications of this are less confidence that the selected sample was representative. However, this was the best available data we could obtain for the district, and compared to the recently released 2018 census the proportion aged 50+ in the central region had not changed (9%).[14]

This survey was undertaken in one district (Ntcheu) and may not be generalisable to the rest of the country. However, according to census data Ntcheu has a similar age and sex distribution to the national figures. The population density is also typical of other districts in the southern and central regions of Malawi, and the literacy rate is comparable.[14] Test duration estimates were based on the opening and saving of the ODK questionnaire and may not accurately reflect the duration of all exams. Some may have been opened in advance of starting an exam to record participant details others may have been counselled and given basic medication before forms were saved. The added value of the logistic regression analysis, conducted to understand factors associated with hearing loss in the population, may be limited. The questions used to ascertain population risks also may be at risk of recall bias (under or over reporting). Consideration of whether this analysis should be included in future surveys is warranted.

Implications for survey protocol

Assigning causes of hearing loss is challenging. In this survey the causes of sensorineural hearing loss were based on clinical judgement. There may be scope to standardise this assignment, for example, the development of definitions for each of the sensorineural causes (e.g. noise, ototoxicity) programmed in to the mobile based data collection (ODK) questionnaires in order to achieve greater consistency across examiners. Development of standardised definitions warrants further attention. In addition, forthcoming surveys will look at the value of adding tympanometry for diagnosis of middle ear pathologies to the protocol. Future technological developments may allow additional tools to improve diagnostic accuracy, such as low-cost validated bone conduction audiometry. In previous work, we found that to determine the causes of hearing loss, a clinician with expertise (at least an ENT clinical officer) is needed.[13] However, this cadre of health worker is often not available in LMICs. Further research is required from other settings to determine whether non-specialist health workers could be trained to make these diagnoses, or whether the RAHL protocol could be refined to allow this. This may help to reduce barriers to conducting population-based surveys in LMICs.

Another area for future research is to investigate how the prevalence and causes of hearing loss can be extrapolated to the all-age population. Further data from all-age population-based surveys is needed to determine this.

The median time for a participant to complete the entire RAHL assessment was 24 minutes. Although this duration was deemed feasible, given 30 participants could be completed in a day, there may be ways in which the process could be streamlined further. For example, the time taken for consent ranged from 5-15 minutes, with a median of 7 minutes. Informed consent could instead be obtained during the sensitisation process (i.e. prior to the day of data collection).

Conclusions

In conclusion, this field test in Malawi suggests that RAHL is a rapid and feasible survey method that generates useful data for evidence-based advocacy and service planning. This population-based survey found the prevalence of any level of hearing loss was 35.9%, and 10.0% for moderate or greater hearing loss among people aged 50 years and above from this community in Malawi. The majority of hearing loss was probable sensorineural in nature. Data of this nature can be used for planning locally appropriate and responsive services in a setting where population-based data is scarce.

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