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Bright, T; Mactaggart, I; Kuper, H; Murthy, GV; Polack, S; (2018) Prevalence of Hearing Impairment in Mahabubnagar District, Telangana State, India. Ear and hearing. ISSN 0196-0202 DOI: https://doi.org/10.1097/AUD.00000000000599

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1 Abstract

2 Objectives: To estimate the prevalence of hearing impairment (HI) in Mahbubnagar district,
3 Telengana State, India.

4 Methods: A population-based prevalence survey of hearing impairment was undertaken in 2014. Fifty-one clusters of 80 people aged 6 months and older were selected using 5 6 probability-proportionate-to-size sampling. A two-stage hearing screening was conducted 7 using otoacoustic emissions (OAE) on all participants followed by pure-tone audiometry on those aged 4 years and older who failed OAE. Cases of HI were defined using the World 8 9 Health Organization (WHO) definition of disabling hearing impairment: a pure tone average 10 of thresholds at 500, 1000, 2000, and 4000Hz of \geq 41dBHL for adults and \geq 31dBHL for 11 children based on the better ear. Possible causes of hearing impairment were ascertained by a certified audiologist. Self-reported hearing difficulties were also measured in this survey and 12 13 compared with audiometry results.

Results: 3,573 people were examined (response rate 87%), of whom 52% were female. The 14 prevalence of disabling HI was 4.5% (95% Confidence Interval (CI)=3.8,5.3). Disabling HI 15 prevalence increased with age from 0.4% in those aged 4-17 years (95%CI=0.2, 1.1), to 16 34.7% (95%CI=28.7, 41.1) in those aged >65 years. No difference in prevalence was seen by 17 sex. Ear examination suggested the possible cause of disabling hearing impairment was 18 chronic suppurative otitis media for 6.9% of cases, and dry perforation for 5.6% cases. For 19 the vast majority of people with disabling hearing impairment, a possible cause could not be 20 established. The overall prevalence of self-reported or proxy reported hearing impairment 21 was 2.6% (95%CI=2.0, 3.4) and this ranged from 0.6% (95%CI=0.08, 4.4) in those aged 0-3 22 years to 14.4% (95%CI=9.8, 20.7) in those aged 65+. 23

1 Conclusions: Disabling HI in Telengana State is common, affecting approximately one in

2 twenty-three people overall, and a third of people aged over 65 years. This substantial level

3 of hearing loss could benefit from improved access to low cost interventions.

4 Keywords: Hearing impairment, South Asia, India, Surveys

5 Introduction

In 2012, the World Health Organisation (WHO) estimated that 360 million people (5.3% of 6 the global population) are affected by disabling hearing impairment (defined as hearing 7 impairment in the better ear of \geq 41 decibels (dBHL) in adults and \geq 31 dBHL in children) 8 (World Health Organization 2012). The highest prevalence of disabling hearing impairment 9 10 is seen in South Asia, Asia Pacific and sub-Saharan Africa (World Health Organization 11 2012). Untreated hearing impairment can have a significant impact on affected individuals and their families, including difficulties with communication, exclusion from education, 12 13 health care and employment, social isolation and poor mental health (World Health Organization 2016). The WHO estimates that one audiologist exists for between 0.5 and 6.25 14 million people in low and middle income countries (LMIC) compared to one per 25,000 in 15 high-income countries (Fagan et al. 2009, World Health Organization 2013). The dearth of 16 hearing healthcare professionals in affected regions poses a significant challenge for meeting 17 the demand for ear and hearing care services (Swanepoel de et al. 2010). 18

Data on the magnitude of hearing impairment in India is limited and not up-to-date. Three
previous prevalence estimates from India using the WHO definition of hearing impairment
range from 6% to 15%, however the most recent estimate was made over 10 years ago (Singh
et al. 1980, Mishra et al. 2011, Stevens et al. 2013). The WHO estimates the prevalence of
hearing impairment in the region of South Asia varies between 4.6% and 8.8% (Stevens et al.
2013).

The Indian National Programme for Prevention and Control of Deafness was initiated in 2007 1 2 and is currently undergoing country-wide expansion (Ministry of Health and Family Welfare 2012, Naik 2013). The programme's objective is to prevent and control major causes of 3 4 hearing impairment and deafness in order to reduce the disease burden to less than 1% by 2030 (World Health Organization 2013). The focus of the programme is on awareness-raising 5 6 and service strengthening (World Health Organization 2013). Updated data on the magnitude 7 of hearing impairment in India is needed in order to monitor the progress of this plan, and identify areas for further policy improvements. The aim of this study was to estimate the all-8 9 age prevalence of hearing impairment in Mahbubnagar district, Telengana state India.

10 Materials and Methods

11 Study location, design and sampling

This population-based survey was conducted in the Northern part of Mahbubnagar
District (estimated population size: 4,053,000) in Telangana State between February and
April 2014. The expected prevalence of hearing impairment was conservatively
estimated to be 4% (World Health Organization 2011). This required a sample of 4,056,
assuming precision of 20%, 95% confidence, a design effect of 1.5 (an adjustment to
sample size to account for cluster as opposed to simple random sampling) and 20% nonresponse.

19

We used a two-stage sampling procedure. Fifty-one clusters of 80 people each were
selected using probability-proportionate-to-size sampling using the 2011 census data as
the sampling frame. Within clusters, households were selected using compact segment
sampling. Existing maps or maps drawn by team members in collaboration with
community leaders showing the approximate distribution of the population were divided

1 into segments of approximately 80 people and one segment was selected at random by

- 2 drawing lots. Enumerators visited all households door-to-door in the segment until 80
- 3 people aged 6 months and older were identified.

4 Training

5 Three field teams composed of enumerators, interviewers, and an audiologist were
6 trained for a 9-day period on, disability awareness, project protocols and data collection
7 methods prior to pilot testing. This included training on standardised hearing impairment
8 assessment protocols and examination to determine probable type. All team members had
9 at least university level education.

10 Data collection

At the household, a roster was compiled by enumerators to record the name, age, sex and 11 contact details of each household member. Household members were informed about the 12 survey and invited to attend a previously identified central location for hearing 13 examination over the next two days. We made every effort to choose a quiet location 14 (ambient noise \leq 40dBA) in each cluster, and these were typically schools or community 15 health centres. In order to maximise response rates, if an eligible person did not attend 16 the central location, the enumerators visited their household to encourage attendance. If 17 18 they were unable to travel to the central location, the survey team visited them at their household at the end of the second day and conducted hearing assessments. Whilst quiet 19 testing locations were chosen, due to time constraints, testing was not postponed if levels 20 21 were above 40dBA.

1 Screening for hearing impairment

Screening for hearing impairment was conducted by trained interviewers and monitored 2 by an audiologist. Initial screening of all participants was through an otoacoustic 3 emissions (OAE) test. Two types of OAE equipment were utilised for the study: two 4 5 Otocheck LE devices with Distortion Product OAEs and one Otoport Lite Transient Evoked OAEs (both from Otodynamics). Each team was assigned one device. The 6 7 collection parameters for DPOAEs included F2 frequencies of 2, 3, 4, 6kHz with an 8 intensity level of 65 dB SPL for F1 and 55 dB SPL for F2. A typical F2/F1 ratio of 1.22 9 was used. TEOAEs screened the following frequencies: 1, 1.5, 2, 3, 4 kHz. The pass criteria for both instrument was set to signal to noise ratio of 6dB and a minimum signal 10 of >-5dBSPL in at least three frequencies. This test configuration results in a 99.99% 11 confidence level in the presence of OAEs (Otodynamics 2016). Participants aged 4 years 12 and older who failed this test in both ears underwent Pure Tone Audiometry (PTA) 13 screening to assess the level of hearing impairment using an Interacoustics screening 14 15 audiometer (model AS608). Participants were fitted with TDH-39 headphones mounted inside circumaural audiocups for additional noise attenuation. Prior to field work, 16 equipment was calibrated according to ISO389-1 and ANSI-S3.6 standards. Hearing 17 18 thresholds in each ear were determined at 1kHz, 2kHz, 4kHz, 0.5kHz and again at 1kHz to assess reliability. Test re-test reliability at 1kHz of \pm 5dB was considered acceptable. 19 20 If this was not obtained, testing was repeated. When calculating the pure-tone average, the original 1kHz threshold was utilised. Children under 4 years underwent OAE testing 21 only, as PTA is often not feasible for this age group. Prior to any evaluation of hearing 22 for each participant, ambient noise was measured and recorded using a sound level meter 23 and recorded. Efforts were made to keep the ambient noise below the recommended 24 40dBA for both OAE and pure-tone audiometry (World Health Organization 1999). 25

1 Hearing impairment case definitions

2 The primary outcome for this study was disabling hearing impairment. Cases of disabling
3 hearing impairment were defined as follows:

4	• Aged 4 years and older: pure-tone average of thresholds at 0.5, 1, 2, 4 kHz in the
5	better ear of \geq 41dBHL in adults (\geq 18 years) and \geq 31dBHL in children (4-17
6	years) (World Health Organization 1999, Stevens et al. 2013). In addition, if
7	participants aged 4 years and older could not undertake PTA, but failed OAE in
8	both ears, they were considered cases.

• Aged 6 months to 3 years 11 months: participants who failed OAE in both ears.

Prevalence estimates were established according to this case definition. In addition, the
prevalence of any level of hearing impairment was estimated using the WHO definition
of mild impairment or greater (≥26dBHL) (aged 4 years and older). Children aged 6
months to 3 years 11 months who failed OAE in both ears were also included in this
estimate.

Amongst those who completed PTA, hearing impairment was also categorised by
severity dependent on the pure tone average in the better ear as: hearing thresholds within
normal limits (<26dBHL), mild impairment (26-40dBHL adults; 26-30dBHL children),
moderate (41-60dBHL adults; 31-60dBHL children, severe (61-80dBHL), and profound
(≥81dBHL).

20 Possible causes of disabling hearing impairment

Whilst it is challenging to determine exact causes of hearing impairment in any setting,
we attempted to understand some of the possible causes of hearing impairment in the
sample. A qualified audiologist examined all people identified as having disabling

hearing impairment. The presence of middle and outer ear pathologies were determined 1 through otoscopy and a structured questionnaire provided by WHO (Appendix 1). In 2 addition, participants were asked about the clinical history of their hearing loss. This 3 4 included questions about: duration of hearing difficulties, history of infectious diseases including during pregnancy (e.g. Rubella, Meningitis, or Measles), presence of genetic 5 6 conditions (e.g. Pendred's Syndrome, Down's Syndrome) and, history of non-infectious conditions (e.g. diabetes, thyroid disease, exposure to noise at work over a long period of 7 time). The WHO Ear and Hearing Disorders Survey Protocol was used to guide the 8 9 audiologist's clinical judgement (Appendix 2).

10 Self-reported hearing difficulty

In addition to clinical screening, participants were also screened for self-reported 11 12 functional limitations using the Washington Group Extended Set of Functioning questionnaire (adult or child version) (National Centre for Health Statistics 2015). These 13 14 questions are designed to assess functional disability and to identify those who 15 experience restricted participation in society, and thus were not designed to measure hearing impairment. For children under 8 years, the primary caregiver was interviewed as 16 a proxy. This questionnaire included a domain on hearing difficulties ("do you have 17 difficulty hearing?" or, if the participant wore hearing aids "do you have difficulty 18 hearing even if wearing hearing aids?") assessed using a four-point response scale ("no 19 difficulty", "some difficulty", "a lot of difficulty" or "cannot do at all". We compared 20 these responses with hearing impairment measured using audiometry (completed on 21 those who failed OAE) in order to understand how self-report could be utilised in surveys 22 23 of hearing impairment.

1 Data entry and analysis

2 Data were analysed using STATA version 14.0. Prevalence estimates accounted for the3 cluster sampling design.

4 Hearing impairment data were stratified by age, sex, severity and types. We used the 5 previously mentioned case definitions to estimate the overall prevalence. Univariable 6 logistic regressions were performed to statistically compare prevalence between by age group and sex. Mantel-Haenzel logistic regression was performed to assess for trend in 7 prevalence by age group. In order to compare self-reported to hearing impairment 8 measured using audiometry, a McNemar's chi-squared test was performed. Sensitivity, 9 10 specificity, positive and negative predictive values were estimated for self-reported hearing impairment using audiometry as the gold standard. The WHO definition of 11 disabling hearing impairment was used as a cut off for comparison. Two different cut-off 12 criteria were used for the Washington Group questions: a broad definition of hearing 13 difficulties (i.e. "some" or more difficulty reported) and a more restrictive definition (i.e. 14 "a lot" or more difficulty). These definitions are based on recommendations from the 15 Washington Group on disability statistics (National Centre for Health Statistics 2015). 16

17 Ethics approval and consent

Ethical Approval for the study was granted by the London School of Hygiene & Tropical
Medicine, the Public Health Foundation of India Institutional Ethics Committee and the
Government of India Health Ministry Screening Committee. Referral services available
in the region were identified and location mapped to ensure appropriate onward referral
for any individuals identified with unmet healthcare needs.

- 1 Informed written/thumb-print consent was obtained from all study participants. For
- 2 children (<18 years), a caregiver was required to provide consent and to remain present
- 3 throughout the screening.

4 **Results**

5 A total of 4,125 eligible people were enumerated, of whom 3,573 were screened for hearing 6 impairment (response rate 87%). Of the non-responders 541 (98%) were not available at the time of data collection and 11 (2%) refused. The majority of individuals who refused were 7 male (82%). Figure 1 shows the flow of participants through the screening protocol. In total 8 3,484 completed OAE, and 366 participants completed PTA. The mean pure-tone average 9 10 threshold in the better ear amongst those tested was 56.3 (range 31.3-97.5). The median thresholds at 500Hz, 1000Hz, 2000Hz, and 4000Hz in the better ear were 50.0 (range 25-95), 11 50.0 (range 25-90), 50 (range 25-95), and 57.5 (range 15-95) respectively. The mean ambient 12 noise level was 54dBA (range 19-73dBA). The vast majority of tests were performed with 13 ambient noise levels >40dBA (90%). 14

15 [Figure 1 here]

The distribution of the study population closely aligned with that of the local census data
from Andhra Pradesh (Telengana formerly part of Andhra Pradesh) (Table 1). The mean age
was 28.6 years with fairly even distribution of males (48%) and females (52%).

19 [Table 1 here]

20 Prevalence of disabling hearing impairment

- 21 The all-age prevalence estimate of disabling hearing impairment was 4.5% (95% confidence
- interval (CI)=3.8, 5.3) (Table 2). The prevalence increased significantly with age from 0.4%
- 23 (95%CI=0.2, 1.1) in the 4 to 17-year age group, 1.3% (95% CI 0.7, 2.2) in people aged 18-35
- 24 years, 3.6% (95%CI=2.3, 5.7) in people aged 36-50 years, 12.8% (95%CI=9.1, 17.1) in

1 people aged 51-64 years and 34.7% (95%CI=28.7, 41.1) in people aged 65 years and older

- 2 (p<0.05) (Table 2). Hearing loss increased significantly with increasing age (p<0.001). There
- 3 were no differences by sex overall and across all age groups (p>0.05).
- 4 A total of 76.6% (95%CI=74.4, 84.1) of children below 4 years (n=280) passed OAE testing

5 in either ear, 1.8% (95%CI=0.7, 4.8) failed in both ears (cases), and the remaining 18.6%

6 (95%CI=14.6, 23.3) had incomplete results (Table 1, Figure 1). Incomplete results were due

7 to poor co-operation of the child, or crying.

8 Prevalence of any level of hearing impairment

9 The all-age prevalence estimate of any level of hearing impairment (>26dBHL) was 8.9%

10 (95% CI=7.5, 10.5) (Table 2). No difference in prevalence was found by sex, regardless of

11 age group (p>0.05). As with disabling hearing impairment, the prevalence increased with age

- 12 from 0.7% (95%CI=0.3, 1.5) in those aged 4-17 years to 52.5% (95%CI=45.3, 59.5) in those
- aged 65+ years. Hearing loss of any degree also increased with increasing age (p < 0.001).
- 14 [Table 2 here]

15 Hearing impairment severity

- 16 Table 3 shows decreasing prevalence of hearing impairment by severity: 4.9% (95%CI=3.8,
- 17 6.1) of people had mild hearing impairment, 3.2% (95%CI=2.5, 3.9) moderate, 1.0%
- 18 (95%CI=0.7, 1.5) severe and 0.5% (95%CI=0.2, 0.9) profound. This pattern was consistent
- across all age groups, except 65 and older where 17.8% (95%CI=12.5, 24.8) had mild, 23.3%
- 20 (95%CI=18.3, 29.1) had moderate, 9.4% (95%CI=5.7,15.2) had severe and 2.0%
- 21 (95%CI=0.8, 5.1) had profound hearing loss. No differences were seen between males and
 22 females.

23 [Table 3 here]

Possible causes of disabling hearing impairment 1 The results of the ear examination and clinical history amongst those with disabling hearing 2 impairment are presented in Table 4. The majority of cases of disabling hearing impairment 3 had normal ear examination (n=132; 82.5%). Data was missing for three participants (1.9%). 4 5 Amongst people with disabling hearing impairment, the most common possible cause established from ear examination was chronic suppurative otitis media (6.9%), followed by 6 dry perforation (5.6%), otitis media with effusion (2.5%), and impacted wax (<1%) (Table 4). 7 8 In terms of possible causes of disabling hearing impairment based on clinical history, 23.1% of participants reported a history of non-infectious conditions (diabetes, ototoxicity, noise 9 exposure); and one reported hearing loss since birth (congenital <1%). The remaining 58.7% 10 of individuals with disabling hearing impairment did not report a history of factors 11 associated with hearing impairment and thus the possible aetiology was undetermined. 12 The proportion of individuals with abnormal ear examination findings decreased with 13 advancing age from 20.0% in those aged 18-35 years, to 8.6% in those aged 65 years and 14 older. 15 Possible causes of hearing impairment were undetermined in the majority of cases, across all 16 age groups, with 70.0% in people aged 65 years and older. For children aged 0-17 years, 17 possible causes could not be determined based on otoscopy or clinical history for all but one 18 19 participant who was classified as having sensorineural hearing impairment due congenital causes. Thus, the possible causes of hearing impairment were unknown for the majority of 20 hearing impairment in this age group. 21

22 [Table 4 here]

1	Comparison of clinically measured and self-reported hearing difficulties
2	The prevalence of self-reported hearing impairment was 2.6% (95%CI=2.0, 3.4) using a
3	narrow definition of "a lot of difficulty" or greater. This was significantly lower than the
4	prevalence of clinically measured impairment (p<0.05). The prevalence of self-reported
5	hearing impairment increased with age. In those aged 0-3 year age group, the prevalence was
6	0.6% (95%CI=0.08, 4.4), 0.4% (95%CI=0.1, 1.1) in those aged 4-17 years, 1.0%
7	(95%CI=0.5, 1.9) in people aged 18-35 years, 2.6% (95%CI=1.5, 4.5) in people 36-50 years,
8	8.4% (95%CI=5.4, 12.9) in those aged 51-64 years, and 14.2% (95%CI=9.8, 20.7) in those
9	aged 65+ years. The sensitivity of self-report in detecting a clinically measured impairment
10	was 50.7% (95%CI=42.4, 58.9) whilst the specificity was 98.2% (95%CI=95.5, 99.5) (Table
11	6). The positive and negative predictive values were 95% (95%CI=87.7, 98.6) and 74.7%
12	(95%CI=69.3, 79.5) respectively. If the broader definition of "some difficulty" or greater was
13	used, the prevalence of self-reported hearing difficulties increased to 12.6% (95%CI=11.2,
14	14.1). The prevalence of self-reported hearing impairment using this definition also increased
15	with age. In those aged 0-3 year age group, the prevalence was 1.8% (95%CI=0.6, 5.5), 3.7%
16	(95%CI=2.6, 5.2) in those aged 4-17 years, 6.8% (95%CI=5.4, 8.7) in people aged 18-35
17	years, 17.4% (95%CI=14.4, 20.7) in people 36-50 years, 29.3% (95%CI=23.9, 35.3) in those
18	aged 51-64 years, and 53.7% (95%CI=46.8, 60.5) in those aged 65+ years. The sensitivity
19	increased to 82.7% (95%CI=75.6, 88.4) whilst the specificity decreased to 65.3%
20	(95%CI=58.7, 71.6) (Table 6). Positive and negative predictive values were 61.7%
21	(95%CI=54.6, 68.4) and 84.8 (95%CI=78.5, 89.8) respectively.

22 [Table 5 and 6 here]

1 **Discussion**

2 Summary of findings

3 The overall prevalence of disabling hearing impairment in Mabubnagar district, Telangana

4 state, India was 4.4% (95%CI=3.7, 5.2). If hearing impairment of any degree (>26dBHL) is

5 included, the estimated prevalence was higher at 8.9% (95%CI=7.5, 10.5). The prevalence of

6 disabling hearing impairment was low amongst children aged under 4 years (1.8%;

7 95%CI=0.7, 4.8) and aged 4-17 years (0.4%; 95%CI=0.2, 1.1). Amongst adults the

8 prevalence increased from 1.3% (95%CI=0.7, 2.2) in the 18-35 year age group to 12.8%

9 (95%CI=9.1, 17.7) in those aged 51-64 years and 34.7% (95%CI=28.7, 41.1) in those aged

10 65 years and older. No variation was seen by sex, regardless of age group.

Five previous surveys of hearing impairment for people of all ages were identified for the 11 South Asia region, one each Bangladesh and Nepal and three in India (Singh et al. 1980, 12 13 Little et al. 1993, Mishra et al. 2011, Stevens et al. 2013, Tarafder et al. 2015). Of the studies conducted in India, two were conducted in Lucknow district (Uttar Pradesh state, Northern 14 India), and one in Vellore district (Tamil Nadu state, Southern India). Of those conducted in 15 16 Lucknow, the study conducted by Singh et al. (1976) found a prevalence of deafness of 19.4% amongst people of all ages. However, this study used a definition of "deafness" of 17 >15dB and did not specify the frequencies tested making comparisons to our study difficult. 18 19 The second Lucknow study conducted by Mishra et al. (2011) found a prevalence of hearing impairment 6% using the WHO definition amongst people aged 6 months and above. The 20 21 final Indian study, conducted in Vellore District by Mackenzie et al. (1997) used the same definition as our study and found a prevalence of 5.9% in urban areas and 15.1% in rural 22 23 areas amongst individuals aged 6 months and older. In Bangladesh, a study by Tarafder et al. 24 (2015) conducted in multiple districts found an all-age prevalence of 9.6%, using the WHO definition. Finally, Little et al. (1993) found an all-age prevalence of 16.6% in Nepal, 25

however a definition of hearing impairment of thresholds >30dB HL at 1-4kHz and >50dB at 1 2 0.5kHz was used, and so is not directly comparable to our estimate. Thus, in comparison to the three studies that used the same definition of disabling hearing impairment as our study, 3 4 we found a slightly lower prevalence than previous studies from the region. Despite the differences, our findings do agree with global WHO estimates from the South Asia region of 5 6 4.6 to 8.8%. The age pattern found in our study concurs with previous studies the prevalence 7 of hearing impairment, where a sharp increase seen with increasing age (Stevens et al. 2013, Tarafder et al. 2015). Our study found that children aged 0-3 years had a higher prevalence of 8 9 disabling hearing impairment than those aged 4-17 years. Caution with interpretation of this finding is warranted given the low number of children with disabling hearing impairment, 10 however, this difference may be due to the difference in testing methodology and the 11 12 possibility of false positives using OAE for those under 4 years. In contrast to global estimates studies, which report a higher prevalence in males than females, we did not observe 13 a difference by sex (Stevens et al. 2013). However, two previous surveys in Bangladesh and 14 15 India respectively have also found no difference in prevalence by sex (Singh et al. 1980, Tarafder et al. 2015). This may be attributed to the pattern of exposures to risk factors in 16 these locations such as occupational noise exposure, or ototoxic drugs and this warrants 17 further investigation. 18

Overall, 15.9% of cases of disabling hearing impairment in our study had abnormal ear examination findings. Chronic suppurative otitis media was a possible cause in 6.9% of cases, and dry perforation in 5.6%. A further 23.7% had normal ear examination, and a clinical history suggesting the possible cause was due to non-infectious or congenital conditions. In over half (58.7%) of cases of disabling hearing impairment in this study possible causes were not able to be determined. In those aged 65 years and older, the majority of undetermined possible causes are likely to be presbyacusis or age-related hearing impairment. There were

very few cases of hearing impairment in children (n=9), and otoscopic examination alongside
clinical history revealed possible causes for only one case, with the remaining
underdetermined. Our findings align with previous studies in the African region, which found
on average the cause of hearing impairment could not be established for 35% of cases
(Mulwafu et al. 2016). In contrast to previous surveys in low and middle-income settings,
wax impaction and middle ear disease were not major determinants of hearing impairment in
this population (Mishra et al. 2011, Mulwafu et al. 2016).

Comparing self-reported hearing difficulties to clinically measured impairment suggested that 8 9 screening using self-report alone would over- or under-estimate the prevalence of hearing impairment in the population depending on the cut-off definition used. Comparison of self-10 reported hearing impairment to clinically measured hearing impairment in other surveys has 11 found it to be a useful tool to detect moderate or worse hearing impairment. (Diao et al. 2014, 12 Choi et al. 2016) Including self-reported measures as a first stage screen for adults, followed 13 14 by audiometry, may be useful where resources are scarce. Our findings suggests that using a definition of "a lot of difficulty" would result in significant proportion of people with 15 disabling hearing impairment being missed. Therefore, using a cut off of "some difficulty" or 16 17 greater, which had a sensitivity of 82.7%, would be recommended for this purpose (Mactaggart et al. 2016). However, it is important to recognise that the Washington Group 18 questions are not designed to measure impairments, but rather to assess how the individual 19 functions in his or her environment and to identify those who are at a greater risk than the 20 general population of experiencing limited or restricted participation in society. 21

22 Strengths and limitations

23 This study had several strengths. The survey was population-based and included all ages.

24 Clinical measurement of hearing impairment was conducted by trained interviewers using

standardised procedures and monitored by an audiologist. An experienced audiologist was 1 2 available in the field for diagnostic purposes. Self-reported measures were also included in the survey to allow us to make important comparisons between different tools. 3 4 Our study had several limitations that need to be taken into account. We used a two-stage 5 screening approach in people aged > 4 years whereby people with a fail result in both ears in 6 OAEs underwent PTA. The WHO Ear and Hearing Disorders survey protocol suggests a two-7 stage screening in the absence of sufficient time to conduct PTA on all participants, as was 8 relevant for our survey (World Health Organization 1999). However, first stage screening 9 with OAE introduces the possibility of false negatives which would lead to an underestimation of disabling hearing impairment in the population (World Health 10 Organization 1999). We found 42% of those who failed OAE in both ears had a pure tone 11 average of <31 dB HL (children) or <41 dB HL (adults) (i.e. not disabling hearing 12 impairment). We did not assess the sensitivity of OAE in our study. The limitation in using 13 14 OAEs is not unique to our research, and represents challenges of undertaking field surveys of hearing impairment that could benefit from further attention (Pascolini et al. 2009, Stevens et 15 al. 2013, Mulwafu et al. 2016). Our case definition for both adults and children focussed on 16 17 the better hearing ear, based on WHO definitions. Using this approach, we have not been able to estimate the prevalence of unilateral hearing loss in the population. However, evidence 18 19 shows that unilateral hearing loss can have an adverse effect on speech and language development, as well as school performance. The WHO definition of "disabling hearing loss" 20 21 may need to be updated to reflect this evidence. We tested four frequencies (500-4000Hz) to 22 obtain a pure tone average. Therefore, we could not detect high frequency hearing loss. Further, whilst pure tone audiometry can provide a summary of hearing thresholds, evidence 23 suggests that some people, particularly those with a history of noise exposure may have 24 25 normal thresholds, but experience difficulties with speech discrimination (Liberman et al.

2016, Bramhall et al. 2017). Therefore, we may have missed some individuals with hearing
 difficulties that were not detected through audiometric methods. Self-reported hearing
 difficulties may help to detect these individuals, in the absence of more sophisticated
 techniques such as speech-in-noise testing.

5 Due to financial constraints, we used one TEOAE screener and two DPOAE screeners. 6 TEOAEs provide an overall wideband look at cochlear function, whereas DPOAEs provide 7 more frequency specificity (Abdala et al. 2001). If TEOAE or DPOAEs are absent, this 8 indicates either the presence of middle ear pathology or hearing impairment greater than a 9 mild or moderate degree respectively (Abdala et al. 2001, Singh et al. 2012, Ramos 2013). This means that people with mild hearing impairment may have been missed when screening 10 using DPOAEs. Some studies report that DPOAEs are present in individuals with thresholds 11 up to 50dB (Abdala et al. 2001, Ramos 2013). This may have resulted in an underestimation 12 of the prevalence of hearing impairment in the population, and may help to explain why our 13 14 estimate is lower than others from the region. Despite the differences, previous large scale screening studies have reported both types of OAEs to have a have sensitivity >95% and 15 specificity >90%, with a rate of false negatives of less than 5% when compared to diagnostic 16 17 gold standard (White et al. 1994, Eiserman et al. 2008).

Further, high levels of ambient noise was a significant limitation in our study. We attempted to ensure a quiet testing environment for audiometry and OAE testing, and used circumaural headphones for additional attenuation. Although threshold elevation with circumaural headphones has been shown to be minimal, the vast majority of tests in our study were conducted with ambient noise above 40dBA (average 54dBA, range 19 to 73) (Berger et al. 1989). This may have led to an over-estimation of the prevalence of hearing impairment and this should be taken in to account when interpreting results. The lack of a soundproof testing,

1 and high levels of ambient noise are commonly reported challenges in surveys of hearing

2 impairment.

3 The possible causes of hearing impairment presented in this study should be interpreted with caution. In the absence of more resource intensive methods such as examination of medical 4 5 records, tympanometry, or bone conduction audiometry, we used questions about hearing 6 history and otoscopy and questions to understand possible causes of hearing impairment. 7 Otoscopic examination is subjective and further cannot establish causes hearing impairment with an inner-ear site of lesion. Bone conduction audiometry would provide greater precision 8 9 about the types hearing impairment present in the population (conductive, sensorineural or mixed); however, it was not possible to complete this within the scope of the study. Some of 10 the hearing impairment in this study could be attributed to conditions such as otosclerosis 11 which is more difficult to determine from questions or otoscopy. Further, using this survey 12 method we were unable to establish the prevalence of other hearing disorders such as tinnitus. 13

Due to the way the Washington Group questions are phrased, someone with a hearing impairment who wears hearing aids may not self-report any difficulties because the hearing aid allowed them to overcome them. This was not a substantial issue in our study as none of the participants with hearing impairment wore hearing aids. However, if the aim is to understand the prevalence of self-reported hearing loss (i.e. without assistive devices), future researchers may consider asking about hearing difficulties without hearing aids for those that use them.

Finally, the sample size of this survey is powered adequately to detect the all-age prevalence
of hearing impairment. To understand the prevalence and causes of hearing impairment
amongst children in greater depth, a much larger sample size would be required.

1 Implications for India

Our results suggest that nearly one in twenty three people in Mabubnagar district, Telengana State, India experience hearing impairment and are in need of ear and hearing services. The prevalence increases dramatically with age, with the highest prevalence seen in those aged 65 years and older (35%). The study adds to the knowledge base by providing an up-to-date prevalence estimate of hearing impairment in a district of India where no surveys of hearing impairment have been conducted previously. It also provides evidence for planning prevention, treatment and rehabilitation services.

9 If left untreated, the impact of hearing impairment on the individual, their families and society as a whole is substantial (The Lancet 2016). Provision of hearing aids, rehabilitation, 10 as well as management of middle ear conditions is important for this population. However, 11 12 human resources for managing ear and hearing disorders are still lacking in many LMIC including India. The number of audiologists in the Indian population is estimated to be one 13 14 per 9 million people, whilst the number of ENT specialists is estimated at one per 140,000. 15 Further, the distribution of these hearing health care professionals is not even throughout the country with the majority concentrated in urban areas (World Health Organization 2007). 16 Thus, building a stronger health workforce for hearing healthcare in India should be 17 prioritised. At the primary level, wax impaction and management of infections of the outer 18 ear can be managed by health workers and referrals can be made for complex conditions and 19 diagnosis. The WHO Primary Ear and Hearing Care training manuals are already being used 20 21 in India and have been translated in to several Indian languages (World Health Organization 2013, World Health Organization Undated). The use of these training manuals should be 22 scaled up across the country, and particularly in rural areas hearing health care professionals 23 24 are scarce.

1 Implications for future surveys of hearing impairment

2 This study has highlighted some of the general challenges of conducting surveys of hearing
3 impairment in low-resource settings including: establishing the causes of hearing impairment,
4 and limitations with screening methodology.

5 The WHO Ear and Hearing Disorders survey was published in 1999, with the aim of standardising survey methodologies, definitions of hearing impairment and generate more 6 7 data (World Health Organization 1999). The protocol aims to screen for hearing impairment, 8 rather than generate accurate diagnostic results. This is a valid approach, given the testing for surveys often occurs in remote low-resource settings. However, adhering to this protocol does 9 not allow for accurate data on the types or indeed the causes of hearing impairment in the 10 population. Using the current WHO approach, we have only been able to ascertain possible 11 12 causes of hearing impairment. Establishing the causes or types of hearing impairment in surveys in a low-cost and feasible manner is an area that warrants further attention. In 13 14 addition, data on the prevalence and causes of hearing impairment from low and middle-15 income country contexts is still lacking due to the significant resources required to conduct the surveys. Low-cost alternatives to expensive equipment, such as self-reported measures or 16 smartphone-based audiometry could be included in future updates to the survey protocol 17 (Bright et al. 2016). 18

Considering the screening protocol, PTA testing for children under 4 years is often
challenging given it requires the child to reliability respond to sound stimuli behaviourally
(e.g. by raising hand). Based on the WHO protocol, we screened this age group with OAE
testing alone, and thus we were unable to determine the severity of hearing impairment.
OAEs testing in children is influenced by factors such as crying or lack of cooperation as we
found in this study (Figure 1). In addition, OAEs measure outer hair cell function, rather than

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hearing directly (Abdala et al. 2001). However, if emissions are present, this indicates normal
hearing in most cases (Abdala et al. 2001, Kemp 2002). Using OAE alone to screen children
(<4 years) may mean that some cases could be missed; particularly those at risk of auditory
neuropathy resulting in an underestimate of hearing impairment in this age group (Rance et
al. 1999). Improved methods for testing children < 4 years in surveys is an area that deserves
further attention.

7 Further, the current WHO protocol for surveys of hearing loss recommends ambient noise should not exceed 40dBA, however hearing testing should continue even if noise exceeds this 8 9 level. We followed this procedure; however, the majority of ambient noise measurements recorded in our study were above 40dBA prior to testing, potentially overestimating hearing 10 impairment. This is a substantial concern for future population-based studies of hearing 11 impairment, and methods to reduce ambient noise in village settings should be explored. 12 Further guidance on how to correct prevalence estimates based on ambient noise 13 14 measurements are required.

1 Conclusions

- 2 Disabling hearing impairment is common, affecting 4.5% of the population in Mahbubngar
- 3 district, Telengana state, India. The prevalence of any level of hearing impairment is even
- 4 greater at 8.9%. The prevalence is greatest people aged over 65 years. Scaling up hearing
- 5 services in India is an important priority. This study has also highlighted some of the
- 6 common challenges of conducting surveys in low resource settings and highlights areas for
- 7 further development.

8 Funding

- 9 This study was funded by CBM. The funders had no role in the design of the study, data
- 10 extraction, analysis, interpretation or writing of the report.

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