TITLE OF SURVEY: A CROSS-SECTIONAL STUDY ON PREVALENCE OF HEARING LOSS AND RELATED FACTORS IN RURAL AND URBAN AREAS OF DELHI USING WHO PROTOCOL

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REPORT COMPILATION

Facilitator for field work

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We	are	highly	grateful	for	contribution	and	technical	support	provided	by
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- 1. World Health Organization, Geneva
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1: INTRODUCTION

Ability to hear is one of the five primary senses which help us to communicate properly with fellow human beings.¹ Consequences of hearing impairment/ loss

include inability to interpret speech sounds, often producing a reduced ability to communicate, delay in language acquisition, economic and educational disadvantage, social isolation and stigmatisation.² According to the World Health Organization, it is estimated that about 360 million individuals in the world have disabling hearing loss, of which 91% are adults and only 9% are children. Disabling hearing loss is >40 dB hearing loss in better ear in a person above the age of 15 years and >30 dB in better ear below the age of 15 years.³ Hearing loss is the second most common cause of years lived with disability (YLD) accounting for 4.7% of the total YLD.⁴ The majority of people with disabling hearing loss live in low- and middle-income countries.³ The prevalence of deafness in Southeast Asia ranges from 4.6% to 8.8% like Sri Lanka 8.8%, Myanmar 8.4% and Bangladesh 6.9%.⁴

Hearing impairment is a serious but grossly neglected condition in India.⁵ In India, 63 million people (6.3%) suffer from significant auditory loss.⁴ The major causes of hearing loss and ear diseases in India have been listed by the WHO survey. Ear wax (15.9%) was the most common cause of reversible hearing loss. Non infectious causes such as aging and presbycusis are the next most common causes of auditory impairment in India (10.3%). Middle ear infections such as chronic suppurative otitis media (5.2%) and serous otitis media (3%) are other leading causes of hearing loss. The other causes include dry perforation of tympanic membrane (0.5%) and bilateral genetic and congenital deafness (0.2%).¹

1.1 billion teenagers and young adults are at risk of hearing loss due to the unsafe use of personal audio devices, including smartphones, and exposure to damaging levels of sound at noisy entertainment venues such as nightclubs, bars and sporting events, according to WHO.⁶ In a study by Mishra A et al, overall hearing impairment was seen in 15.14% of rural as opposed to 5.9% of urban population and higher prevalence of disabling hearing impairment (DHI) is seen in

elderly and deafness in 0-10 years age group.⁷ Gender is not reported to be a significant determinant of deafness. Globally, males are reported to be more commonly affected than females.⁴

As per 58th round of National Sample Survey Organization survey in 2002, currently there are 291 persons per 100,000 populations who are suffering from severe to profound hearing loss. Of these, a large percentage is children between the ages of 0–14 years. The survey results revealed that hearing loss accounted for 9% of all disabilities in the urban and 10% in the rural areas and about 7% of people have a congenital hearing loss. In the same survey, about 32% of the people had profound (person could not hear at all or could hear only loud sounds), and 39% had a severe hearing disability (person could hear only shouted words).⁸

The high burden of deafness globally and in India is largely preventable and avoidable.⁶ It has been noted by World health Organization that half the causes of deafness are preventable and about 30%, though not preventable, are treatable or can be managed with assistive devices. Thus, about 80% of all deafness can be said to be avoidable.⁴ Hearing loss has potentially devastating consequences for physical and mental health, education and employment.⁹

WHO works to help develop community-based programmes for prevention, identification and management of hearing loss in low- and middle-income countries. The Government of India launched National Programme for Prevention and Control of Deafness in 2006. The programme aims to cover three levels of prevention and care: primary, secondary and tertiary ear care by provision of an appropriate response at these levels. It aims at preventing avoidable hearing loss on account of disease or injury, identifying early and treating major ear problems, and medically rehabilitating persons with deafness of all age groups. It envisages strengthening existing intersectoral linkages and developing institutional capacity for ear care services. For the prevention of auditory impairments, it

promotes outreach activities and public awareness through innovative and effective information, education and communication (IEC) strategies.¹¹

Lacunae in existing knowledge

There is paucity of studies on burden of hearing loss and its associated factors in Indian context. There is a dearth of standardized tool for measuring the burden of ear and hearing morbidities in developed and developing countries. There was a felt need of community based studies to study the population distribution of hearing loss using standardized tool. As a result, this study was planned to provide information about the same so that it can be used in future for policy making and planning.

2: REVIEW OF LITERATURE

In 2012, WHO released new estimates on the magnitude of disabling hearing loss. The estimates are based on 42 population-based studies. There are 360 million

persons in the world with disabling hearing loss (5.3% of the world's population). 328 million (91%) of these are adults (183 million males, 145 million females). 32 (9%) million of these are children. The prevalence of disabling hearing loss in children is greatest in South Asia, Asia Pacific and Sub-Saharan Africa. Approximately one-third of persons over 65 years are affected by disabling hearing loss. The prevalence of disabling hearing loss in adults over 65 years is highest in South Asia, Asia Pacific and Sub-Saharan Africa. 12

Causes of hearing loss and deafness³

The causes of hearing loss and deafness can be divided into congenital causes and acquired causes.

Congenital causes

Congenital causes may lead to hearing loss being present at or acquired soon after birth. Hearing loss can be caused by hereditary and non-hereditary genetic factors or by certain complications during pregnancy and childbirth, including:

- Maternal rubella, syphilis or certain other infections during pregnancy;
- Low birth weight;
- Birth asphyxia (a lack of oxygen at the time of birth);
- Inappropriate use of particular drugs during pregnancy, such as aminoglycosides, cytotoxic drugs, antimalarial drugs and diuretics;
- Severe jaundice in the neonatal period, which can damage the hearing nerve in a newborn infant.

Acquired causes

Acquired causes may lead to hearing loss at any age, such as:

- Infectious diseases such as meningitis, measles and mumps;
- Chronic ear infections;

- Collection of fluid in the ear (otitis media);
- Use of particular drugs, such as some antibiotic and antimalarial medicines;
- Injury to the head or ear;
- Excessive noise, including occupational noise such as that from machinery and explosions, and recreational noise such as that from personal audio devices, concerts, nightclubs, bars and sporting events;
- Ageing, in particular due to degeneration of sensory cells;
- Wax or foreign bodies blocking the ear canal.

Among children, chronic suppurative otitis media (CSOM) is the leading cause of hearing loss.

Definition

As per WHO, any person who is not able to hear as well as someone with normal hearing – hearing thresholds of 25 dB or better in both ears – is said to have hearing loss. Disabling hearing loss refers to hearing loss greater than 40 dB in the better hearing ear in adults and greater than 30 dB in the better hearing ear in children.³

The global prevalence of hearing impairment \geq 35 dBHL among children 5–14 years of age was 1.4%. Hearing impairment was greater for males than females; globally, the prevalence of hearing impairment \geq 35 dBHL for males aged \geq 15 years was 12.2% (9.7–16.2%), whereas for females aged \geq 15 years it was 9.8% (7.7–13.2%). The prevalence of severe hearing impairment was 0.8% (0.6–1.2%) for adult males and 0.6% (0.4–1.0%) for females. Profound and complete hearing impairment have a combined global prevalence of 0.5% (0.3–0.8%) for adult males and 0.3% (0.2–0.7%) for females.¹³

A study conducted by Olusanya et al. in Nigeria in 2009 found that loss to follow up in infant screening for hearing loss was a major factor at community level. 285

out of 2,003 eligible infants were referred after the first-stage screening out of which 148 (51.9%) did not return for the second-stage, while 32 (39.0%) of the 82 infants scheduled for diagnostic evaluation defaulted. No other factors correlated with follow-up compliance for screening and diagnostic services. ¹⁴ Gondim et al did a population-based survey in Brazil in 2012 based on a World Health Organization protocol. The study found that 74.1% of residents had normal hearing, 18.9% had mild hearing loss, 5.1% had moderate hearing loss, 1.9% had severe hearing loss. ¹⁵

Baraky et al. did a descriptive study in 2012 in Brazil among 349 households with 1,050 individuals with age ranging between 4 days and 95 years. Disabling hearing loss (DHL) prevalence was estimated at 5.2%, moderate in 3.9%, severe in 0.9% and profound in 0.4%. They found correlation between DHL and tinnitus; age over 60 years and low educational level. A cross-sectional household survey based on the World Health Organization Ear and Hearing Disorders Survey Protocol was conducted in 298 households in the urban area of Monte Negro, Rondonia, Northern Brazil, from 2005 to 2007. The results showed that 3.8% of population were classified in the disabling hearing impairment category. The prevalence of moderate hearing impairment was 3.4%; severe impairment was 0.4%; and profound hearing impairment was not found. The gender and age distribution of subjects with disabling hearing impairments indicated a difference between men and women, with a greater proportion of men with statistically significant difference. ¹⁷

Kovalova et al. analyzed sample comprised 4988 participants in Czech Republic. In females aged 45 to 74 years, statistically significant differences were found. In males, hearing loss was observed as early as 18 years of age. When comparing males and females at risk for occupational noise, statistically significant differences were more frequent than in employees not exposed to noise. ¹⁸ Bauer et

al. interviewed 7315 elderly individuals in 59 cities in the state of Rio Grandedo Sul, Brazil. Hearing loss complaint rate was 28% among the elderly, showing differences between genders, ethnicity, income, and social participation. Multiple logistic regression observed that protective factors for hearing complaints were: higher level of schooling, contributing to the family income and having received health care in the last six months. Risk factors for hearing complaints were: older age, male gender, experiencing difficulty in leaving home and carrying out social activities.¹⁹

Yilmazer et al. screened a total of 5985 newborns in Turkey in 2016 using the transient evoked otoacoustic emission test as the first two steps and automated auditory brainstem response (ABR) test as the third step. Of 5985 newborns, 5116 (85.5%) completed the screening. Of 53 newborns who were referred to a tertiary hospital, 13 (0.25%) had a hearing impairment. Among the risk factors for hearing impairment, neonatal intensive care (60%) and consanguineous marriage (50%) were the most common ones that were encountered.²⁰ Absalan et al. did a cross-sectional study in South East of Iran in 2013 wherein 1,500 students from 30 elementary schools of Zahedan were screened for hearing loss. In total, 300 males and females per age were included in the study. Conductive hearing loss in males and females was 8.8% and 7.1%, respectively. Results indicated that 20.2% of students of elementary schools in Zahedan needed medical treatment for their problems.²¹ A cross-sectional study was conducted on 543 police personnel who had undergone periodic medical examination over a 12-month period by Win et al. The prevalence of noise induced hearing loss was 34.2%, with a higher prevalence in males (37.7%) than in females (23.9%). The study also showed strong associations with male sex, and hypertension.²²

Another study done by Kasliwal et al among 1828 subjects in India in 2004 who underwent surgery at centre for chronic suppurative otitis media from the year

1982 to 2001, out of which 510 cases were selected who had unilateral chronic suppurative otitis media (normal tympanic membrane in contralateral ear). Normal contralateral ear served as control because it eliminated variables such as noise, hereditary or congenital causes and presbyacusis. Of the 510 patients studied, the disease was in 254 (49.8%) right and 256 (50.2%) left ears. Male to female ratio and side of the ear affected were the same.²³

A total of 13,800 children were examined during a study done by Aggarwal et al in India. An assessment of the profile of morbidities related to ear and hearing was carried out among selected children belonging to age group of 0-14 years of age. It was observed that the prevalence of abnormality of external ear was 0.2% while the prevalence of abnormality in tympanic membrane was 5.4%. The prevalence of hearing test abnormality among the children was 6.4%. On clinical examination it was found that the most common ear problem among children was impacted wax which was found in 30.5% of children who were suffering from ear problems and 1.4% children having CSOM. The prevalence of ear problems was most in the urban slums with 38% of children suffering from ear problems belonging to these areas followed by rural areas (34%). The prevalence of ear problems was least in urban areas.²⁴

3. STEPS IN CONDUCT OF STUDY

- 1. Conceptualization of the proposal and adopting it for Indian settings.
- 2. Obtaining consensus from the World Health Organisation (WHO) to conduct the study in India.

3. Conduct of planning meeting: The planning meeting was conducted under the guidance of Dr. Suneela Garg, HoD on 10th and 11th November 2016 in the Department of Community Medicine, MAMC.

The planning meeting was attended by following

- 1) Dr. Arun Kumar Agarwal (Ex ADGHS, Ex Dean, MAMC and President Sound Hearing),
- 2) Dr. Shelly Chadha (Technical Officer, Prevention of Deafness and Hearing Loss, WHO HQ),
- 3) Dr. Promila Gupta (DDG, DGHS- National Program for prevention Deafness, Ministry of Health and Family Welfare, Govt of India)
- 4) Dr. Abha Aggarwal (statistician at ICMR),
- 5) Dr. Ishwar Singh (HoD, Department of ENT, MAMC) and
- 6) Ms. Shilpi (Educator from Alps Foundation).

The Principal Investigator for the "Field test of the WHO Ear and Hearing Care Survey Protocol in India" was Dr. Suneela Garg, Head of Department, Department of Community Medicine, Maulana Azad Medical College.

The Co-Principal Investigators are:

- 1) Dr. M.M. Singh (Director Professor, Department of Community Medicine, MAMC),
- 2) Dr. G.S. Meena (Director Professor, Department of Community Medicine, MAMC),
- 3) Dr P K Rathore (HoD, Department of ENT, MAMC)
- 4) Dr. Ishwar Singh (Director Professor, Department of ENT, MAMC) and
- 5) Dr. J.C. Passey (Medical Superintendent, MAMC).

The field coordinators for the survey are:

- 1) Lt. Col. (Dr.) Vipra Mangla (Ph.D scholar, Department of Community Medicine, MAMC),
- 2) Senior Residents, Department of Community Medicine, MAMC Dr Archana, Dr. Charu and Dr. Neha Dahiya

In the planning meeting the WHO Ear and Hearing Care Survey Protocol was reviewed and the preparation and finalization of "Field test of the WHO Ear and Hearing Care Survey Protocol in India" was carried out. The rationale of the protocol was looked into and presentations on following topics were deliberated upon:

- (a) Hearing loss: Global, Regional, National and Local Overview by Dr. Arun Kumar Agarwal.
- (b) Importance of studying the Prevalence and Causes of Hearing Loss by Dr. Suneela Garg.
- (c) National Programme on Prevention and Control of Deafness in India by Dr. Promila Gupta.
- (d) WHO Revised Survey Handbook: an outline by Dr. Shelly Chadha. The minutes of the meetings were shared with Shroff Hospital which has been an integral part of training for Society for Sound Hearing International-India Office.

The aspects covered in the planning meeting included -

- 1) Survey aims and objectives;
- 2) Survey population and area;

- 3) Survey design, considerations for sample size and sampling methodology;
- 4) Data collection tools and tests: Questionnaires; Hearing test, ear examination; Survey team and training;
- 5) Pre-survey visit;
- 6) Data management and analysis;
- 7) Follow up of survey;
- 8) Quality enhancement;
- 9) Ethical considerations and
- 10) Timelines for field test and next steps.

Following decisions were taken with regard to the protocol.

- 1) Adoption and suitable changes in performa.
- 2) Development of Patient Information Sheet, Consent forms, Assent forms in English and translated to Hindi
- 3) Pre-testing of the performas.
- 4) Finalisation of the protocol.
- 5) Ethical clearance from the Institutional Ethical Committee, Maulana Azad Medical College, New Delhi.
- 6) Refinement / Revision of the performa
- 7) Data entry and analysis.
- 8) Report writing.

4. AIMS AND OBJECTIVES

The primary objectives of the survey were:-

- 1. To determine the prevalence and causes of hearing loss among people aged 3 months and above in selected areas of Delhi.
- 2. To determine the socio-demographic correlates of hearing loss in the study population.

The secondary objectives of the survey were:-

- 1. To test the feasibility of revised WHO handbook on Survey for prevalence and causes of hearing loss.
- 2. To raise awareness about hearing loss in target population.

5. MATERIAL AND METHODS

a) Survey population and area: The survey areas included both rural and urban areas of Delhi which are the field practice areas of MAMC. The area of Delhi has

10% rural population and 90% urban population. From the rural area – Barwala village in North-West District of Delhi, located at a distance of 30 Kms from MAMC, New Delhi was selected. In the urban Area –Gokulpuri (resettlement colony in North East district of Delhi), Delhi Gate (near Daryaganj, located at a distance of 1 Km from MAMC, New Delhi), Balmiki Basti (slum area behind Indian Express building and is located in Central Delhi) and Vikram Nagar (adjacent to Balmiki Basti, located at a distance of 500 metres from MAMC, New Delhi) were selected.

- a. The total population of Barwala village is 5000 which comprises of 1150 children till 9 years of age, 1000 adolescents, 2450 adults in 20-60 years of age and 400 geriatric population.
- b. The total population of Gokulpuri urban area is 30000 which comprises of 6900 children till 9 years of age, 6000 adolescents, 14700 adults in 20-60 years of age and 2400 geriatric population.
- c. The total population of Delhi Gate urban area is 7700 which comprises of 1413 children till 9 years of age, 1368 adolescents and 525 geriatric population.
- d. The total population of Balmiki Basti urban area is 1000 which comprises of 230 children till 9 years of age, 200 adolescents, 490 adults in 20-60 years of age and 80 in geriatric population.

e. The total population of Vikram Nagar urban area is 849 which comprises of 196 children till 9 years of age, 170 adolescents, 416 adults in 20-60 years of age and 67 in geriatric population.

STUDY AREA	POPULATION	NO. OF HOUSEHOLDS
Barwala	5186	1038
Gokulpuri	29940	5988
Balmiki basti	1270	254
Delhi gate	10656	1800
Vikram nagar	849	170
Total	47901	9250

- b) Survey design, considerations for sample size and sampling methodology: For the sample size calculation, the National figures for prevalence of hearing loss (6.3%) were used as the data from Delhi was not available.
 - a. Survey design- A community based cross sectional study.
 - b. Study population Population aged 3 months and above of selected areas of Delhi.
 - c. Study duration: Study duration was for 6 months from January 2017 to June 2017.
 - d. Sampling unit For the purpose of this survey, sampling unit refers to a household.

e. Sample size: $n=Z^2_{1-\alpha/2}$ P(1-P)/d2, where n=sample size, $Z^2_{1-\alpha/2}$ confidence interval, P=estimated proportion, d=desired precision, $Z^2_{1-\alpha/2}$ (1.96)²= 3.84 (value of standard normal variate at significance level of 0.05), P= Prevalence of hearing loss = 6.3% of hearing loss²⁵, D=2% absolute error

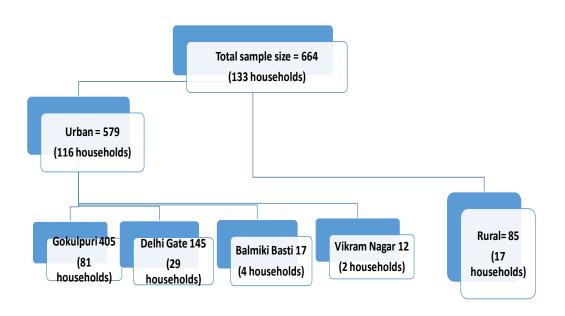
 $N = 3.96 \times 0.063 \times 0.937$ 0.02×0.02

= 585

Considering 10% non response rate, the sample size came to be 585+60=645. A total of 664 individuals were considered for the study. Considering a family size of 5, a total of 133 households were selected and all in individuals aged 3 months and above in the selected households were included.

f. Sampling – Population proportionate to size was used to select the study subjects. Total population- Rural + Urban = 5186+29940+1270+10656+849 = 47901. Urban and rural areas constitute- 89% and 11% of total population respectively. Thus, 89% of the required sample size was taken from urban areas and 11% from rural area. Further in urban areas also, sample was taken from proportionately from all 4 areas. In urban areas, the proportion of selected population was as follows: - Gokulpuri -70%, Delhi Gate-25%, Balmiki Basti-3% and Vikram Nagar - 2%.

Of the total sample size of 664- 85 study subjects (17 households) were taken from the rural area and 579 study subjects (116 households) were taken from the urban area. The distribution of the study subjects in the urban area was Gokulpuri 405 (81 households), Delhi Gate 145 (29 households), Balmiki Basti 17 (4 households) and Vikram Nagar 12 (2 households).



g. Selection of study subjects: In each study area, the required number of households was selected by systematic random sampling method.

h. Inclusion criteria:

All residents of selected areas who are 3 months and older who will give informed consent for participation in the study.

i. Exclusion criteria:

- i. Participants who are unable to follow simple commands or unable to remain alert during the duration of the hearing test device
- ii. Any other physical or mental disability where air conduction audiometry is not possible
- iii. If the study participant is not available even after 3 visits to the household.

j. Study outcomes

- i. Primary Outcome
 - 1. Prevalence of hearing loss in study areas
 - 2. Socio demographic associates of hearing loss

ii. Secondary Outcome

- 1. To comment upon feasibility of revised WHO handbook on Survey for prevalence and causes of hearing loss.
- c) Data collection tools and tests: Questionnaires: The modified data collection form for the survey in both Hindi and English has been attached as Annexure A. Data collection from the deaf persons was carried out using the sign language through family members or through an interpreter. Data was collected by door to

door survey and all members of selected household were included after taking written informed consent.

The semi structured questionnaire had items on following:

- Personal Demographic details of the subject.
- Relevant history assessing the hearing loss or any exposure to conditions predisposing to hearing loss
- Findings of ear examination on inspection, otoscopy and tympanometry and the provisional diagnosis based on the findings.

Definitions

1. Hearing loss

Following classification was considered for hearing disability (given by WHO³)

Table 1: Classification of hearing disability

S. No	Grade	Severity
1	Mild	26-40 dB
2	Moderate	41-60 dB
3	Severe	61-80 dB
4	Profound	Over 81 dB

Disabling hearing loss: refers to hearing loss greater than 40 dB in the better hearing ear in adults and greater than 30 dB in the better hearing ear in children.

2. Education status:

Number of completed years of schooling was taken from study subjects

3. Occupation categories:

Following categories were taken for classification:

- i. <u>Unskilled</u>: Work requiring neither education nor training e.g porter, peon, watchman, domestic servant
- ii. <u>Semi-skilled</u>: Work requiring some training e.g. factory labourer, lab attended, petty shopkeeper

- iii. <u>Skilled</u> workers: Complicated work requiring long training e.g. carpenter, mason, mechanic, car driver, telephone operator
- iv. <u>Semi-professional</u> Occupation requiring post high school or college education e.g. engineers, lecturers, insurance inspectors
- v. <u>Professional</u>: Involved in decision making process, policy ,execution e.g. Doctors, senior administrative officers ,senior lecturers , readers and professors, college principles, advocates, engineers, estate planters , auditors, newspaper editors, expert musicians , architect, managing directors of industrial & business firms, managers
- vi. Others: Training in arithmetic, reading and writing, essentially repetitive nature of work e.g. clerk, typist, accountant, salesman, farm owner

4. Type of family:

- Nuclear: Individuals living together and sharing common kitchen and are related by blood, marriage or adoption. It includes those who were living alone
- ii. Joint: More than one couple living together and sharing common kitchen.
- d) Hearing test, ear examination: The hearing test and ear examination was carried out using Hand held Oto-Acoustic Emission (OAE) in children < 5 years of age and Pure Tone Audiometry in persons above 5 years of age. OAE results for children below five years for both the ears were expressed as passed or refer. The Tympanometry results for adults were carried out at frequency of 500, 1000, 2000, 4000, 6000 and 8000 Hertz and the final estimation of hearing threshold was based on the averages of the above mentioned frequencies and assigning a probable cause of hearing loss if possible. The cause of hearing loss in each ear was also assigned and recommendations for further management were made.

- e) Survey team and training: Checklist for each team was prepared. The training of the survey teams was carried out in the ENT OPD days of MAMC (Wednesday / Saturday) and Shroff Eye Hospital. The standardization of training of survey teams was carried out and the agreement levels were maintained at 80%. All teams went to the study areas on designated days. The survey team comprised of 4 teams and each team comprised of the following members
 - a. Two 3rd Year Post Graduate (MD Community Medicine) Students
 - b. One Senior Resident (SR)
 - c. One Health Worker
 - d. Teams were assisted by audiologists and senior resident from Department of Otorhinolaryngology.
- f) Pre-survey visit: The visit by the survey teams was carried out to sensitize the community (through its leaders, like Sarpanch or community volunteers like anganwadi workers), promote the survey in the community about the need of the survey and for obtaining consent of the community. Mapping of the area and site identification to locate a suitable (quiet and central) site for conduct of ear and hearing assessment was also carried out. The team visited the area a short time in advance of conducting the study. The field workers for the field team were identified. A pilot study was carried out covering 10% of the total sample size to test the methodology, equipment, logistics and timing of each part of the survey and to familiarize the staff with the conduct of the survey.



















- g) Data management and analysis: In data management, all forms were checked on daily basis for following:
 - i. Accuracy
 - ii. Completeness,
- iii. Personal Identification Number (PIN) was assigned to each participant,
- iv. Confidentiality of participants was respected and maintained,
- v. Consistency was maintained in data collection, recording and entry.

The data coding and terminologies was determined before finalising the forms and data back-up was undertaken at regular intervals. The data entry was carried out

simultaneously with the data collection. SPSS version 17 was used for data analysis.

- h) Follow up of survey: The follow up survey included participants requiring repeat testing due to any reason or re-examination of the patients who had presented with ear discharge during the next visit (after 1 week). Missed participants who could not be examined during the first visit due to non-availability or any other reason were followed up. Such participants were declared as missed/ non participation in case they could not be examined even after three visits. Patients identified with hearing loss or ear diseases who require diagnostic or therapeutic interventions were referred to Maharishi Balmiki Hospital, (Pooth Khurd) Lok Nayak Hospital and Guru Teg Bahadur Hospital.
- i) Quality enhancement: For quality checking, 10% of the diagnosis made by the survey teams was reviewed by the ENT specialist accompanying the survey teams. Double entry of the data in 10-15% of the sample subjects was carried out.
- j) Ethical considerations: All study participants were explained about the survey purpose and objectives. Written informed consent was taken from the study participants. Confidentiality of data was maintained at all steps. Ethical clearance was taken from the Institutional Ethical Committee of MAMC. All subjects who required intervention were referred to health centers situated in study areas.
- k) Statistical Test: Data was entered in MS EXCEL and then analysed using SPSS V. 17. Qualitative data was expressed in proportions (frequency and percentage) and quantitative data as mean and standard deviation. Association

between two qualitative variables was found using Chi Square test / Fisher exact test. p value less than 0.05 was considered statistically significant.

1) Timelines for field test and next steps: The timeline and activities included in the survey were as follows:- Questionnaire finalization (7 days), Training (14 days), Refining of the protocol (21days), Ethical clearance (30 days), Pilot Testing (35 days), Conduct of survey (7 days), Follow up Survey (7 days), Data Entry (15 days), Data Analysis (15 days) and Report Writing and Submission (21 days).

Interim report

Interim report presentation meeting was held in London School of Hygiene and Tropical Medicine, UK which was attended by Dr Suneela Garg.





Figure: Interim meeting at London School of Hygiene and Tropical Medicine

6. RESULTS

Socio-demographic profile

A total of 664 subjects were included in the study. Mean (\pm SD) and median age of study subjects was 32.17 \pm 20.85 years and 29 years respectively. Range of age was 93 (1 year to 94 years). 25th quartile was 15 years, 50th quartile was 29 years and 75th quartile was 48 years. Mean (\pm SD) and median per capita income of study subjects was Rs 2943.09 \pm 3191.48 and Rs 2000 respectively. The range was Rs 24,700.

Table 1 : Area wise distribution of age

Age groups		Area					
		Barwala	Balmiki	Delhi	Gokulpuri	Vikram	-
		N=85	Basti	Gate	N= 405	Nagar	
			N= 17	N= 145		N=12	
0-5years	N	8	0	5	56	0	69
o by cars	%	9.4	0.0	3.4	13.8	0.0	10.4
6-9 years	N	6	1	11	20	0	38
0 y years	%	7.1	5.9	7.6	4.9	0.0	5.7
10-19 years	N	7	2	24	61	1	95
10 17 years	%	8.2	11.8	16.6	15.1	8.3	14.3
20-39 years	N	22	8	37	155	1	223
20 37 year s	%	25.9	47.1	25.5	38.3	8.3	33.6
40-59 years	N	19	5	38	77	6	145
10 37 years	%	22.4	29.4	26.2	19.0	50.0	21.8
>60 years	N	23	1	30	36	4	94
, co jeuis	%	27.1	5.9	20.7	8.9	33.3	14.2
Total	N	85	17	145	405	12	664
	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 1 shows area wise distribution of age. 10.4% children were in 0-5 years age group, 5.7% were in 6-9 years age group, 14.3% were in 10-19 years age group,

33.6% were in 20-39 years age group, 21.8% were in 40-59 years age group and 14.2% study subjects were in >60 years age group.

Table 2: Area wise distribution of gender

Gender		Area	Area					
		Barwala	Balmiki	Delhi	Gokulpuri	Vikram		
		N=85	Basti	Gate	N= 405	Nagar		
			N= 17	N= 145		N=12		
Female	N	33	10	70	171	6	290	
remate	%	38.8	58.8	48.3	42.2	50.0	43.7	
Male	N	52	7	75	234	6	374	
Iviale	%	61.2	41.2	51.7	57.8	50.0	56.3	
Total	N	85	17	145	405	12	664	
Total	%	100	100	100	100	100	100	

Table 2 shows area wise distribution of gender. The number of males were 374 (56.3%) and females were 290 (43.7%).

Table 3: Area wise distribution of religion

Religion		Area						
		Barwala	Balmiki	Delhi	Gokulpuri	Vikram		
		N=85	Basti	Gate	N= 405	Nagar		
			N= 17	N= 145		N=12		
Hindu	N	84	16	69	359	10	538	
IIIIdu	%	98.8	94.1	47.6	88.6	83.3	81	
Muslim	N	1	0	76	46	0	123	
Wiusiiii	%	1.2	0	52.4	11.4	0	18.5	
Sikh	N	0	1	0	0	2	3	
SIKII	%	0	5.9	0	0	16.7	0.5	
Total	N	85	17	145	405	12	664	
1 otal	%	100	100	100	100	100	100	

Table 3 shows area wise distribution of religion. The number of Hindus were 538 (81%), Muslims were 123 (18.5%) and Sikhs were 3 (0.5%).

Table 4: Area wise distribution of type of family

Type of Family		Area					
		Barwala	Balmiki	Delhi	Gokulpuri	Vikram	
		N=85	Basti	Gate	N= 405	Nagar	
			N= 17	N= 145		N=12	
Nuclear	N	41	7	90	178	7	323
Nuclear	%	48.2	41.1	62.0	43.9	58.3	48.6
Joint	N	44	10	55	227	5	341
Joint	%	51.8	58.9	38.0	56.1	41.7	51.4
Total	N	85	17	145	405	12	664
Total	%	100	100	100	100	100	100

Table 4 shows area wise distribution of type of family. The number of study subjects residing in nuclear family were 323 (48.6%) and joint family were 341 (51.4%).

Table 5: Area wise distribution of education status

Number of completed		Area					
years of educati	ion (in	Barwala	Balmiki	Delhi	Gokulpuri	Vikram	
years)		N=85	Basti	Gate	N= 405	Nagar	
			N= 17	N= 145		N=12	
Nil (Includes	N	32	3	44	125	0	204
children upto 5 years of age)	%	37.6	17.6	30.3	30.9	0.0	30.7
<5	N	7	2	36	87	0	132
	%	8.2	11.8	24.8	21.5	0.0	19.9
5-8	N	14	5	30	69	1	119
3-8	%	16.5	29.4	20.7	17.0	8.3	17.9
9-10	N	18	5	20	57	4	104
9-10	%	21.2	29.4	13.8	14.1	33.4	15.7
11-12	N	2	0	0	22	1	25
	%	2.4	0.0	0.0	5.4	8.3	3.8
>12	N	12	2	15	45	6	80
/12	%	14.0	11.8	10.4	11.1	50.0	12.0
Total	N	85	17	145	405	12	664
Total	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 5 shows area wise distribution of education status of study subjects. The number of study subjects who did not receive any formal education were 204 (30.7%); <5 years of education were received by 132 (19.9%) subjects; 5-8 years of education were received by 119 (17.9%) subjects; 9-10 years of education were

received by 104(15.7%) subjects; 11-12 years of education by 25 (3.8%) subjects and >12 years of education were received by 80 (12%) subjects.

Table 6: Area wise distribution of occupation status

Occupation		Area						
		Barwala	Balmiki	Delhi	Gokulpuri	Vikram		
		N=85	Basti	Gate	N= 405	Nagar		
			N= 17	N= 145		N=12		
Unemployed	N	56	6	105	328	6	501	
	%	65.9	35.3	72.4	81.0	50.0	75.5	
Unskilled worker	N	6	2	17	27	0	52	
	%	7.1	11.8	11.7	6.7	0.0	7.8	
Semiskilled worker	N	4	7	10	26	3	50	
	%	4.7	41.2	6.9	6.4	25.0	7.5	
Skilled worker	N	10	2	3	10	0	25	
Skilled worker	%	11.8	11.8	2.1	2.5	0.0	3.8	
Sami professional	N	2	0	5	2	1	10	
Semi- professional	%	2.4	0.0	3.4	0.5	8.3	1.5	
Professional	N	4	0	3	5	2	14	
Professional	%	4.7	0.0	2.1	1.2	16.7	2.1	
Othors	N	3	0	2	7	0	12	
Others	%	3.5	0.0	1.4	1.7	0.0	1.9	
Total	N	85	17	145	405	12	664	
Total	%	100.0	100.0	100.0	100.0	100.0	100.0	

Table 6 shows area wise distribution of occupation status. 501(75.5%) study subjects were unemployed, 52(7.8%) were unskilled workers, 50 (7.5%) were semiskilled workers, 25(3.8%) were skilled workers, 10(1.5%) were semi-professionals, 14(2.1%) were professionals and 12 (1.9%) were employed in other occupations.

Table 7: Area wise distribution of hearing loss in study subjects more than 5 years of age

Hearing loss		Area					Total
		Barwala	Balmiki	Delhi	Gokulpuri	Vikram	
		N=77	Basti	Gate	N= 349	Nagar	
			N= 17	N= 140		N=12	
Absent	N	52	16	115	246	6	435
	%	67.5	94.1	82.1	70.5	50.0	73.1
Conductive hearing	N	3	0	6	50	2	61
loss	%	3.9	0.0	4.3	14.3	16.7	10.3
Sensory neural	N	22	1	15	52	4	94
hearing loss	%	28.6	5.9	10.7	14.9	33.3	15.8
Mixed hearing loss	N	0	0	4	1	0	5
Whited hearing loss	%	0.0	0.0	2.9	0.3	0.0	0.8
Total	N	77	17	140	349	12	595
1 Otal	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 7 shows area wise distribution of hearing loss in study subjects more than 5 years of age. Prevalence of hearing loss was 26.9% among study subjects.

Conductive hearing loss was present among 61(10.3%) subjects, mixed hearing loss was found among 5(0.8%) subjects and sensorineural hearing loss among 94(15.8%) subjects. Hearing loss was absent among 435(73.1%) subjects.

Table 8: Area wise distribution of hearing loss in children less than equal to 5 years of age

Hearing loss		Area					Total
		Barwala	Balmiki	Delhi	Gokulpuri	Vikram	
		N=8	Basti	Gate	N= 56	Nagar	
			N=0	N= 5		N=0	
Pass (OAE)	N	8	0	5	49	0	62
	%	100	0.0	100	87.5	0.0	89.9
Refer (OAE)	N	0	0	0	7	0	7
Kelei (O/KL)	%	0.0	0.0	0.0	12.5	0.0	10.1
Total	N	8	0	5	56	0	69
Total	%	100.0	0	100.0	100.0	100.0	100.0

Table 8 shows area wise distribution of hearing loss in children less than equal to 5 years of age. On Oto-acoustic Emission (OAE), 62 (89.9%) children passed the test and 7 (10.1%) were referred.

Table 9: Area wise distribution of severity of hearing loss

Severity of hearing los	S	Area					Total
		Barwala	Balmiki	Delhi	Gokulpuri	Vikram	=
		N=25	Basti	Gate	N=110	Nagar	
			N=1	N=25		N=6	
Mild	N	8	1	7	34	1	51
Willu	%	32	100	28	31	16.7	30.5
Moderate	N	0	0	8	13	3	24
Woderate	%	0.0	0.0	32	11.9	50	14.4
Severe	N	14	0	10	58	2	84
Severe	%	56	0.0	40	52.8	33.3	50.3
Profound	N	3	0	0	5	0	8
Tiolound	%	12	0.0	0.0	4.5	0.0	4.8
Total	N	25	1	25	110	6	167
Total	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 9 shows area wise distribution of severity of hearing loss. Mild hearing loss was seen in 51 (30.5%), mild to moderate hearing loss in 24(14.4%), moderate to severe hearing loss in 84 (50.3%) and profound hearing loss in 8 (4.8%) study subjects. 116 (19.49%) subjects were having disabling hearing loss.

Table 10: Area wise distribution of site of hearing loss

Site of hear	ing loss	Area	Area							
		Barwala	Balmiki	Delhi	Gokulpuri	Vikram				
		N=25	Basti	Gate	N=110	Nagar				
			N=1	N=25		N=6				
Bilateral N		19	1	23	70	2	115			
Difateral	%	76	100	92	63.6	33.3	68.9			
Unilateral	N	6	0	2	40	4	52			
Omaterar	%	24	0	8	36.4	66.7	31.1			
Total	N	25	1	25	110	6	167			
Total	%	100.0	100.0	100.0	100.0	100.0	100.0			

Table 10 shows area wise distribution of site of hearing loss. Bilateral hearing loss was seen in 115(68.9%) and unilateral hearing loss in 52 (31.1%) study subjects. Left sided hearing loss was seen in 25 (15%) and right sided hearing loss in 27(16.1%) study subjects.

Table 11: Area wise distribution of reported problem with hearing during conversation in quiet surroundings among study subjects

Response		Area					Total
		Barwal	Balmiki	Delhi	Gokulpu	Vikram	(n=664)
		a	Basti	Gate	ri	Nagar	
		(n=85)	(n=17)	(n=145)	(n=405)	(n=12)	
No problem	No.	60	16	120	295	6	497
	%	70.6	94.1	82.8	72.8	50	74.8
Some Problem	No.	12	1	22	85	5	125
	%	14.1	5.9	15.2	21	41.7	19
Problem most	No.	7	0	2	12	1	22
of the time	%	8.2	0.0	1.3	3	8.3	3.3
Problem	No.	6	0	1	12	0	19
always	%	7.1	0.0	0.7	3	0.0	2.7
Cannot hear at	No.	0	0	0	1	0	1
all	%	0.0	0.0	0.0	0.2	0.0	0.2
Total	N	85	17	145	405	12	664
Total	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 11 shows area wise distribution of reported problem with hearing during conversation in quiet surroundings among study subjects. 74.8% study subjects did not have any problem, 19% had some problem, 3.3% had problem most of the time, 2.7% had problem always and 0.2% could not hear at all.

Table 12: Area wise distribution of reported problem with hearing during conversation in noisy surrounding

Response		Area					Total
		Barwala	Balmiki	Barwala	Balmiki	Barwala	(n=664)
		(n=85)	Basti	(n=85)	Basti	(n=85)	Balmiki
			(n=17)		(n=17)		Basti
							(n=17)
No problem	No.	60	16	120	295	6	497
	%	70.6	94.1	82.8	72.8	50	74.8
Some	No.	12	0	24	69	5	110
Problem	%	14.1	0.0	16.5	17	41.7	16.6
Problem most	No.	8	1	0	24	1	34
of the time	%	9.4	5.9	0.0	6	8.3	5.1
Problem	No.	5	0	1	15	0	21
always	%	5.9	0.0	0.7	3.7	0.0	3.2
Cannot hear at	No.	0	0	0	2	0	2
all	%	0.0	0.0	0.0	0.5	0.0	0.3
Total	N	85	17	145	405	12	664
10181	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 12 shows area wise distribution of reported problem with hearing during conversation in noisy surrounding. 74.8% study subjects did not have any problem, 16.6% had some problem, 5.1% had problem most of the time, 3.2% had problem always and 0.3% could not hear at all.

Table 13: Area wise distribution of experience of ringing, roaring, or buzzing in ears during 12 months prior to survey

Response		Area					Total
		Barwala	Balmiki	Delhi Gate	Gokulpuri	Vikram	
		(n=85)	Basti	(n=145)	(n=405)	Nagar	
			(n=17)			(n=12)	
Yes	N	9	4	23	90	2	172
103	%	10.6	23.5	17.2	32.5	16.7	26.0
No	N	76	13	122	315	10	492
140	%	89.4	76.5	82.8	67.4	83.3	74.1
Total	N	85	17	145	405	12	664
10141	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 13 shows area wise distribution of experience of ringing, roaring, or buzzing in ears during 12 months prior to survey. 26% study subjects experienced ringing, roaring, or buzzing in ears during 12 months prior to survey and 74% study subjects did not have any problem.

Table 14: Area wise distribution of history of ear infections among study subjects

History of	ear	Area					Total
infections		Barwala	Balmiki	Delhi	Gokulpuri	Vikram	-
		(n=85)	Basti	Gate	(n=405)	Nagar	
			(n=17)	(n=145)		(n=12)	
Yes	N	18	2	19	98	2	139
105	%	21.2	11.8	13.1	24.2	16.7	21.0
No	N	67	15	126	307	10	525
140	%	78.8	88.2	86.9	75.8	83.3	79.1
Total	N	85	17	145	405	12	664
Total	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 14 shows area wise distribution of history of ear infections among study subjects. 21% study subjects had history of ear infection while 79.1% study subjects did not have history of ear infections.

Table 15: Area wise distribution of history of frequency of ear pain

Frequency of	ear	Area					Total
pain		Barwala	Balmiki	Delhi Gate	Gokulpuri	Vikram	
		(n=85)	Basti	(n=145)	(n=405)	Nagar	
			(n=17)			(n=12)	
Never	N	56	4	95	257	10	422
	%	65.9	23.5	65.5	63.5	83.3	63.6
Once a month	N	19	8	47	87	2	163
or less	%	22.4	47.1	32.4	21.5	16.7	24.5
2-3 times per	N	4	2	1	29	0	36
month	%	4.7	11.8	0.7	7.2	0.0	5.4
On an a revent	N	2	2	1	17	0	22
Once a week	%	2.4	11.8	0.7	4.2	0.0	3.3
Almost every	N	4	1	1	15	0	21
day	%	4.7	5.9	0.7	3.7	0.0	3.2
	N	85	17	145	405	12	664
Total	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 15 shows area wise distribution of history of frequency of ear pain. 63.6% study subjects did not have history of ear pain, 24.5% had once a month or less, 5.4% had 2-3 times per month, 3.3% had once a week and 3.2% had almost every day history of ear pain.

Table 16: Area wise distribution of history of acute ear pain in the last 2-3 days prior to survey

History		Area								
		Barwala	Balmiki	Delhi Gate	Gokulpuri	Vikram				
		(n=85)	Basti	(n=145)	(n=405)	Nagar				
			(n=17)			(n=12)				
Yes	N	7	2	21	64	0	94			
168	%	8.2	11.8	14.5	15.8	0.0	14.2			
No	N	78	15	124	341	12	570			
NO	%	91.8	88.2	85.5	84.2	100.0	85.8			
Total	N	85	17	145	405	12	664			
Total	%	100.0	100.0	100.0	100.0	100.0	100.0			

Table 16 shows area wise distribution of history of acute ear pain in the last 2-3 days prior to survey. 14.2% study subjects had and 85.8% did not have history of acute ear pain in the last 2-3 days prior to survey.

Table 17: Area wise distribution reported frequency of exposure to loud noise in workplace

Frequency	of	Area					Total
exposure		Barwala	Balmiki	Delhi	Gokulpuri	Vikram	
		(n=85)	Basti	Gate	(n=405)	Nagar	
			(n=17)	(n=145)		(n=12)	
Never	N	80	15	121	360	11	587
INEVEL	%	94.1	88.2	83.4	88.8	91.7	88.5
Once a month	N	0	0	7	25	1	33
or less	%	0.0	0.0	4.8	6.2	8.3	5.0
2-3 times per	N	1	0	1	7	0	9
month	%	1.2	0.0	0.7	1.7	0.0	1.4
Once a week	N	0	0	3	1	0	4
Office a week	%	0.0	0.0	2.1	0.2	0.0	0.6
Almost every	N	4	2	13	12	0	31
day	%	4.7	11.8	9.0	3.0	0.0	4.7
Total	N	85	17	145	405	12	664
Total	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 17 shows area wise distribution of reported frequency of exposure to loud noise in workplace. 88.5% study subjects did not have history of exposure to loud noise in workplace, 5% had once a month or less, 1.4% had 2-3 times per month, 0.6% had once a week and 4.7% had almost every day exposure to loud noise in workplace.

Table 18: Area wise distribution of reported frequency of exposure to loud noise in residence

Frequency	of	Area					Total
exposure		Barwala	Balmiki	Delhi	Gokulpuri	Vikram	
		(n=85)	Basti	Gate	(n=405)	Nagar	
			(n=17)	(n=145)		(n=12)	
Never	N	72	8	116	349	10	555
Nevel	%	84.7	47.1	80.0	86.1	83.3	83.6
Once a month	N	0	2	12	27	0	41
or less	%	0.0	11.8	8.3	6.7	0.0	6.2
2-3 times per	N	3	0	2	10	0	15
month	%	3.5	0.0	1.4	2.5	0.0	2.3
Once a week	N	1	0	3	3	1	8
Office a week	%	1.2	0.0	2.1	0.7	8.3	1.2
Almost every	N	9	7	12	16	1	45
day	%	10.6	41.2	8.3	4.0	8.3	6.8
Total	N	85	17	145	405	12	664
Total	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 18 shows area wise distribution of reported frequency of exposure to loud noise in residence. 83.6% study subjects did not have history of exposure to loud noise in residence, 6.2% had once a month or less, 2.3% had 2-3 times per month, 1.2% had once a week and 6.8% had almost every day exposure to loud noise in residence.

Table 19: Area wise distribution of reported frequency of listening to loud music through headphones/earphones

Frequency	of	Area					Total
exposure		Barwala	Balmiki	Delhi Gate	Gokulpuri	Vikram	
		(n=85)	Basti	(n=145)	(n=405)	Nagar	
			(n=17)			(n=12)	
	N	79	12	118	365	10	584
Never	%	92.9	70.6	81.4	90.1	83.3	88.0
Once a week or	N	2	1	12	19	1	35
less	%	2.4	5.9	8.3	4.7	8.3	5.3
2-3 times per	N	0	1	9	7	0	17
week	%	0.0	5.9	6.2	1.7	0.0	2.6
Every day	N	4	3	6	14	1	28
	%	4.7	17.6	4.1	3.5	8.3	4.2
Total	N	85	17	145	405	12	664
TOTAL	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 19 shows area wise distribution of reported frequency of listening to loud music through headphones/earphones. 88% study subjects did not have history of exposure to listening to loud music through headphones/earphones, 5.3% had once a week or less, 2.6% had 2-3 times per week and 4.2% had almost every day exposure to listening to loud music through headphones/earphones.

Table 20: Area wise distribution of any ear or hearing problem ever diagnosed among study subjects

Ear or hea	ring	Area	Area					
problem		Barwala	Balmiki	Delhi Gate	Gokulpuri	Vikram		
		(n=85)	Basti	(n=145)	(n=405)	Nagar		
			(n=17)			(n=12)		
Yes	N	9	5	24	42	4	84	
103	%	10.6	29.4	16.6	10.3	33.3	12.7	
No	N	76	12	121	363	8	580	
NO	%	89.4	70.6	83.4	89.6	66.7	87.3	
Total	N	85	17	145	405	12	664	
10111	%	100.0	100.0	100.0	100.0	100.0	100.0	

Table 20 shows area wise distribution of any ear or hearing problem ever diagnosed among study subjects. 12.7% study subjects had while 87.3% did not have ear or hearing problem ever diagnosed.

Table 21: Area wise distribution of having undergone any ear surgery or procedure any time in the past

Ear surgery or Area						Total	
procedui	re in past	Barwala	Balmiki	Delhi Gate	Gokulpuri	Vikram	
		(n=85)	Basti	(n=145)	(n=405)	Nagar	
			(n=17)			(n=12)	
	N	3	2	6	7	1	19
Yes	%	3.5	11.8	4.1	1.7	8.3	2.9
	N	82	15	139	398	11	645
No	%	96.5	88.2	95.9	98.3	91.7	97.1
Total	N	85	17	145	405	12	664
10tai	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 21 shows area wise distribution of having undergone any ear surgery or procedure any time in the past. 2.9% study subjects had undergone while 97.1% study subjects had not undergone any ear surgery or procedure any time in the past.

Table 22: Area wise distribution of nature of reported ear procedure / surgery

Ear procedure	or	Area					Total
surgery		Barwala	Balmiki	Delhi	Gokulpuri	Vikram	
		(n=3)	Basti	Gate	(n=9)	Nagar	
			(n=2)	(n=4)		(n=1)	
Cleaning of ear	N	0	2	3	0	0	5
Creaming of car	%	0.0	100	75	0.0	0.0	26.3
Foreign body	N	0	0	0	0	1	1
removal	%	0.0	0.0	0.0	0.0	100	5.3
Myzingoplosty	N	1	0	0	1	0	2
Myringoplasty	%	33.3	0.0	0.0	11.1	0.0	10.5
Wax removal	N	2	0	0	7	0	9
wax temovai	%	66.7	0.0	0.0	77.8	0.0	47.4
Tymnononlosty	N	0	0	1	1	0	2
Tympanoplasty	%	0.0	0.0	25	11.1	0.0	10.5
Total	N	3	2	4	9	1	19
Total	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 22 shows area wise distribution of nature of reported ear procedure / surgery. 26.3% study subjects had undergone cleaning of ear, foreign body removal in 5.3%, myringoplasty in 10.5%, wax removal in 47.4% and tympanoplasty in 10.5% study subjects.

Table 23: Area wise distribution of using any hearing device (e.g. hearing aid or cochlear implant) among study subjects

Response		Area	Area						
		Barwala	Balmiki	Delhi	Gokulpuri	Vikram	-		
		(n=85)	Basti	Gate	(n=405)	Nagar			
			(n=17)	(n=145)		(n=12)			
Yes	N	0	0	0	1	0	1		
108	%	0.0	0.0	0.0	0.2	0.0	0.2		
No	N	85	17	145	404	12	663		
INO	%	100.0	100.0	100.0	99.8	100.0	99.8		
Total	N	85	17	145	405	12	664		
	%	100.0	100.0	100.0	100.0	100.0	100.0		

Table 23 shows area wise distribution of using any hearing device (e.g. hearing aid or cochlear implant) among study subjects. 0.2% study subjects used while 99.8% study subjects did not use any hearing device (e.g. hearing aid).

Table 24: Area wise distribution of using sign language to communicate among study subjects

Response		Area					Total
		Barwala	Balmiki	Delhi	Gokulpuri	Vikram	-
		(n=85)	Basti	Gate	(n=405)	Nagar	
			(n=17)	(n=145)		(n=12)	
Never	N	84	17	145	403	12	661
	%	98.8	100.0	100.0	99.6	100.0	99.6
Vac	N	1	0	0	2	0	3
Yes	%	1.2	0.0	0.0	0.4	0.0	0.4
Total	N	85	17	145	405	12	664
	%	100.0	100.0	100.0	100.0	100.0	100.0

Table 24 shows area wise distribution of using sign language to communicate among study subjects. 99.6% study subjects never used sign language to communicate, 0.4% study subjects used sign language to communicate.

Feasibility of protocol

- Sampling unit Household (difficult to get working members, school/college going students for survey)
- Difficult to set up audiometry in community based set up; centre based approach was used which increased the attrition rate
- If it is a child/adolescent subject Some questions in the performa are not applicable like education, marital status, occupation etc. (performa needs to be modified slightly)
- Lack of adequate space
- Control of background noise sound proof room requirement
- Availability of ENT personnel
- Availability of audiologist
- Difficult to mobilize community and follow up visits and to motivate health workers

Suggested modifications in the data collection tool

Following are suggested modifications:

Add the following items in data collection tool-

- 1. Address
- 2. Religion
- 3. Type of family
- 4. Education
- 5. Occupation
- 6. Total number of family members
- 7. Per capita family income

Exclusion Criteria: Add - If the study participant is not available even after 3 visits to the household

Instructions: Move to section C to do ear examination.

Section B:

Add instruction- Following questions should be asked from caregiver in case of under five child or from any reliable family member in case of person with hearing difficulty.

All questions should be numbered. Some modified questions are as follows:

- 1- Do you have any problem with hearing and understanding during conversation with another person sitting close to you in a quiet room?
 1=No problem; 2=Some Problem; 3=Problem most of the time; 4= Problem always; 5=Cannot hear at all
- 2- Do you have any problem with hearing and understanding during conversation with another person sitting close to you in a noisy room or when in conversation with many people?
 - 1=No problem; 2=Some Problem; 3=Problem most of the time ;4= Problem always ; 5=Cannot hear at all
- 3- Is there any history of ear infections: Yes/No- Add a) duration to make it specific and b) type of ear infection. Specify the term "Infection". Local terminology/language for symptoms of ear infection should be used like discharge/itching/pain/fullness/fever etc.
- 4- Are/Were you exposed to loud noise in your workplace/residence?
 1=Never;2=once a month or less;3=2-3 times per month; 4=Once a week;
 5=Almost every day (Add duration to make it specific)
 If almost every day, please specify for how long you are working/living in such area-.....
- 5- Do you listen to loud music through headphones/earphones? 1=Never;2=once a week or less;3=2-3 times per week; 4= Every day
- 6- Any other relevant information

Any records available- If yes

Diagnosis-.....

Management-

Section C

Make it in tabular form for right and left ear separately

Section F

Add coding for normal ear also

In the end:

Checklist for observer for environment

1. Household surroundings- Clean-1 Not Clean-2

2. Environmental Noise level- Low-1 Moderate-2 High-3

Very High-4

3. If under 5 child, Fully Vaccinated till age-1 Partially vaccintated-2 Unvaccinated-3

General:

- 1. All responses should be numbered.
- 2. For socio demographic profile, if respondent is less than 18 years of age, parent's details should be taken and it should be specified in instructions.

Modified data collection form is added for reference in Annexure A.

Conclusion:

The survey was successfully conducted by the Department of Community Medicine, Maulana Azad Medical College, New Delhi for the preparation and finalization of "Field test of the WHO Ear and Hearing Care Survey Protocol in India". The WHO handbook was a good tool to plan the survey but some

modifications needs to be done in the same. Some modifications are suggested under barriers and challenges.

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Annexure A

DATA COLLECTION FORM

A CROSS-SECTIONAL STUDY ON PREVALENCE OF HEARING LOSS AND RELATED FACTORS IN RURAL AND URBAN AREAS OF DELHI

SECTION-A

Participant demographic information							
Participant d	etails						
Participant	Identification	number	(PIN)	(to	be		
allocated)			_				
A1. Name:							
A2. Age (in ye	ears):						
A3. Sex: Male	=1 Female=2	Other=3	(please c	ircle)			
A4. Address:							
A5. Religion-	Hindu-1 Musli	m- 2 Sikh-	3 Otl	her-4			
A6. Type of fa	amily- Nuclear-1	Joint-3	Three g	eneratio	n-3		
Living alone-4	Į.						
A7. Marital	status- Marrie	d-1	U	nmarrie	d-2		
Divorced/sepa	rated-3 Widow	/widower-4					
A8. Area- Bar	rwala-1 De	lhi Gate-2	Balm	iki Bast	i=3		
Vikram Nagar	=4 Gokulpur	i=5					
A9. Education	n of respondent	Illiterate-1		Primar	y-2		
Middle-3	High school-4	1					
Post high scho	ool-5 B.A./	Bsc. degree-6	5 P	rofessio	nal		
degree/ Hons./	M.A. & above-7						

A10. Occupation of respondent -Unemployed-1 Unskilled

worker-2 Semiskilled worker-3

Skilled worker-4 Clerical, shop owner, farm owner-5 Semi-

professional-6 Professional-7

- A11. Total number of family members-
- A12. Total monthly family income (in INR)-
- A13. Per capita family income per month (in INR)-
- A14. Contact number:
- A15. House address-
- A16. Date/s of interview:
- A1. Name of interviewer-

Exclusion Criteria: (please tick box if present)

- 1. Participants or legal guardian not willing to give consent for inclusion in the study
- 2. Participants who are unable to follow simple commands or unable to remain alert during the duration of the hearing test device
- 3. Any other physical or mental disability where air conduction audiometry is not possible and/or the use of earphones is not possible.
- 4. If the study participant is not available even after 3 visits to the household.

 If no exclusion criteria ticked above, then please assign PARTICIPANT IDENTIFICATION NUMBER (PIN) and proceed to testing.

Move to section C to perform ear examination. Patients may be excluded after ear examination (section C) in case of acute pain, ear deformities which would be inconsistent with proper audiometric examination or refusal for further examination.

SECTION- B

DATA COLLECTION FORM (TO BE FILLED IN AT TESTING)

	Participant Identification Number:
	Note- Following questions should be asked from caregiver in
	case of under five child or from any reliable family member in
	case of person with hearing difficulty.
B1	Do you have any problem with hearing and understanding what
	is said in a conversation with another person sitting close to you
	in a quiet room?
	1=No problem; 2=Some Problem; 3=Problem most of the time
	;4= Problem always ; 5=Cannot hear at all
B2	Do you have any problem with hearing and understanding what
	is said in a conversation with another person sitting close to you
	in a noisy room or when in conversation with multiple people?
	1=No problem; 2=Some Problem; 3=Problem most of the time
	;4= Problem always ; 5=Cannot hear at all
В3	Have you experienced ringing, roaring, or buzzing in your ears
	that lasts for 5 minutes or longer (over the last 12 months):
	Yes=1/No=2
B3.1	If Yes; does this sound affect your ability to sleep, work or
	perform other activities? 1=Never;2=once a month or less;3=2-3
	times per month; 4=Once a week; 5=Almost every day 6=
	NA If No, skip to Q B 4
B4	Is there any history of ear infections in past 1 year: Yes=1/No=2

B5	Is there any history of having pain in the ear: 1=Never;2=once a
	month or less;3=2-3 times per month; 4=Once a week;
	5=Almost every day
B6	Is there any history of acute ear pain in the last 2-3 days?
	Yes=1/No=2
B7	Are you exposed to loud noise in your workplace?
	1=Never;2=once a month ;3=2-3 times per month; 4=Once a
	week; 5=Almost every day
B7.1	If almost every day, please specify for how long you are
	working in such areayearsmonthsdays
B8	Are you exposed to loud noise in your residence?
	1=Never;2=once a month ;3=2-3 times per month; 4=Once a
	week; 5=Almost every day
B8.1	If almost every day, please specify for how long you are living
	in such areayearsdays
В9	Do you listen to loud music through headphones/earphones?
	1=Never;2=once a week or less;3=2-3 times per week; 4= Every
	day
B10	Have you ever been diagnosed with any ear or hearing problem?
	Yes=1 No=2
	If yes; please specify:
	B10.1 Nature:
	B10.2 Duration:
	B10.3 Symptoms:
	B11.3.1 Ear discharge
	B10.3.2 Ear pain B10.3.3 Ringing in ears

	B10.3.4	Itching in ears	B11.3.8	Others,
	specify	_		
			If No, s	kip to Q
	B 11			
B11	Have you ever undergo	one any procedure o	r surgery of th	ne ear? Ye
	If yes; please specify:			
	B11.1 Nature:			
	B11.2 Time since	(in years):		
			If No, sl	cip to Q
	B 12			
B12	Do you use any hear	ing device (e.g. hea	aring aid or o	cochlear i
	No=2			
	If yes, please specify:			
	B12.1 Type of de	vice:		
	B12.2 Being used	l since (in years):		
			If No, sl	kip to Q
	B 13			
B13	Do you use sign langu	age to communicate	? 1=Never;2=	Yes, but
	3=Yes, only sign langu	uage		
		I	f No, skip to	Q B 14
B14	Any other information			
	Any records available-	- If yes		
	B14.1 Diagnosis			
	B14.2 Managemen	nt-		

SECTION C

		Right Ear	Left Ear
C	Ear Examination findings		
C.1	Normal ear	Yes=1	Yes=1
		No=2	No=2
C.2	Impacted wax:	Yes=1	Yes=1
		No=2	No=2
C.3	Ear discharge:	Yes=1	Yes=1
		No=2	No=2
C.4	Inflammation of canal	Yes=1	Yes=1
	walls:	No=2	No=2
C.5	Foreign body/ies in ear	Yes=1	Yes=1
	canal	No=2	No=2
C.5	Fungus in the ear canal	Yes=1	Yes=1
		No=2	No=2
C.6	Canal atresia:	Yes=1	Yes=1
		No=2	No=2
C.7	Dry perforation:	Yes=1	Yes=1
		No=2	No=2
C.8	Perforation with discharge	Yes=1	Yes=1
		No=2	No=2
C.9	Cholesteatoma/retraction	Yes=1	Yes=1
	pocket:	No=2	No=2

C.10	Retracted TM:	Yes=1	Yes=1
		No=2	No=2
C.11	Middle ear effusion:	Yes=1	Yes=1
		No=2	No=2
C.12	Inflammed tympanic	Yes=1	Yes=1
	membrane:	No=2	No=2
C.13	Any other (describe):	62. Yes=1	Yes=1
	If yes; describe	No=2	No=2
C.14	Tympanometry: Type of	A-1/A-2/C-3/A _{S-}	A-1/A-2/C-
	curve:	$4/A_{D-5}$	$3/A_{S-}4/A_{D-}5$
C.15	Diagnosis of ear condition:		
	C.15.1 Normal	1	1
	C.15.2 Impacted wax	2	2
	C.15.3 Otitis Externa	3	3
	C.15.4 Foreign body in	4	4
	ear	5	5
	C.15.5 Fungal infection	6	6
	of ear	7	7
	C.15.6 Canal atresia	8	8
	C.15.7 Acute otitis	9	9
	media	10	10
	C.15.8 Adhesive OM	11	11
	C.15.9 Otitis media	12	12
	witheffusion		
	C.15.10 Chronic		
	suppurative otitis media		

Dry TM		
Any		
••••		
	·	

SECTION D

D Hearing test

OAE result (in case of participants below 5 years):

		Right ear	Left ear
D.1	1 st OAE test	Pass=1/Refer=2	Pass=1/Refer=2
D.2	2 nd OAE test (only where indicated)	Pass=1/Refer=2	Pass=1/Refer=2
D.3	3 rd OAE test (only where indicated)	Pass=1/Refer=2	Pass=1/Refer=2
D.4	Final OAE evaluation	Pass=1/Refer=2	Pass=1/Refer=2

Hearing threshold evaluation in participants above 5 years

	Frequency	500	1000	2000	4000	6000	8000
	(Hz)						
D.6	Hearing	1	2	3	4	5	6
	Threshold						
	Right						
	Ear(dB)						
D.7	Hearing	1	2	3	4	5	6
	Threshold						

Left Ea	:			
(dB)				

SECTION E

E. Final estimation of hearing thresholds

		Right ear	Left ear
E.1	Hearing threshold: average of hearing threshold at 500, 1000, 2000 and 4000 Hz		
E.2	High frequency hearing threshold: average of hearing threshold at 4000, 6000 and 8000 Hz		
E.3	Probable cause/s of hearing loss (list only if identified with certainity. If this is not possible, please list as uncertain)		

SECTION F

F. Cause of hearing loss (in case of hearing threshold above 25 dB in one or both ears)

In your estimation, what is the probable cause of hearing loss?

Right ear	Left ear

F.1 No hearing loss-0		No hearing loss-0			
F.2 Undetermined-1	Undetermined-1	Undetermined-1			
F.3 Impacted wax-2		Impacted wax-2			
F.4 Otitis externa-3		Otitis externa-3			
F.5 Foreign body in ear-4		Foreign body in ea	ar-4		
F.6 Fungal infection of ear-5		Fungal infection of	of ear-5		
F.7 Canal atresia-6		Canal atresia-6			
F.8 Acute Otitis media-7		Acute Otitis Medi	a-7		
F.9 Adhesive OM-8		Adhesive OM-8			
F.10Otitis media with effusion-9	-9 Otitis media with effusion				
F.11 Chronic Suppurative Otitis media-10		Chronic Suppur	ative Otitis		
F.12 Dry TM perforation-11		Media-10			
Congenital hearing loss-12		Dry TM perforation	Dry TM perforation-11		
Age-related hearing loss-13		Congenital hearin	g loss-12		
Noise exposure-14		Age-related hearing	ng loss-13		
Any other: 15		Noise exposure-14	4		
		Any	other:		
		15			
SECTION G					
G. Further action recommended					
G.1 No action- Yes-1 No-2					
G.2 Medication advised- Yes- 1 No-2					

If yes, specify

G.3 Recommended for hearing aid fitting-	
Yes- 1 No-2	
G.4 Referred to ENT specialist for evaluation-	
Yes- 1 No-2	
G.5 Referred to ENT specialist for urgent evaluation	
Yes- 1 No-2	
G.6 Referred to audiologist for evaluation	
Yes- 1 No-2	
G.7 Language rehabilitation recommended	
Yes- 1 No-2	
G.8 Any other-	

Checklist for observer for environment

- G.9 Household surroundings- Clean-1 Not Clean-2
- G.10 Environmental Noise level- Low-1 Moderate-2 High-3 Very High-4
- G.11 If under 5 child, Fully Vaccinated till age-1 Partially vaccintated-2 Unvaccinated-3

ANNEXURE-B

MAULANA AZAD MEDICAL COLLEGE AND ASSOCIATED LOK NAYAK, G.B. PANT AND GURU NANAK EYE CENTRE NEW DELHI - 110002 DEPARTMENT OF COMMUNITY MEDICINE PATIENT INFORMATION SHEET (>18 YEARS)

You are invited to participate in a research study. Before you take part in this research study, we wish to explain the study to you and give you the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the informed consent form.

Study information-

Title: "A Cross-sectional study on Prevalence of Hearing Loss and related factors in rural and urban areas of Delhi." Principal Investigator:

Dr. Suneela Garg, Head of the Department, Community Medicine,

Maulana Azad Medical College, New Delhi-110002

Purpose of the research study: The present study aims to address the socio-demographic profile, prevalence and causes of hearing loss in the community so as to help in care of patients of hearing loss and further reduce its burden. You are selected as a possible study subject because you belong to selected study area and in the desired age group. The study will recruit 650 individuals from different sites over a period of 6 months. We will recruit all randomly selected subjects from the community for this study.

Study procedures and visit schedule: If you agree to take part in this study, you will be interviewed only for one time. In the interview, investigator will ask certain questions regarding identification data, hearing problem and associated factors etc and will examine your ears. The interview and ear examination will take about 15-20 minutes.

Withdrawal from study: You are free to withdraw your consent and discontinue your participation from the study at any time without any consequence. If you decide to stop taking part in the study, you should tell the principal investigator. Your doctor can stop your participation in the study at any time due to following reasons:

- 1. Failure to follow the instructions of the study staff
- 2. The principal investigator decides that continuing your participation may be harmful.
- 3. The study is cancelled
- 4. Other administrative reasons.

Possible risks, discomforts and inconveniences: Your participation in the study will not entail any risk to your health.

Potential benefits: This study will include thorough examination of your ears that will help to diagnose early if there are some treatable conditions and may be helpful in preventing hearing loss.

Subject's rights: Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction. You are free to withdraw from the study at any time. If you choose to withdraw from the study, health facility will continue to provide care and treatment in the same way.

Confidentiality of study and medical records: All of your information will be kept strictly confidential and will be used for scientific purposes only. Your records, to the extent of applicable laws and regulations will not be made publicly available. Only investigators will have access to your information. In event of any publication of this study, your identity will remain confidential.

Costs of participation: There would be no cost for participation on you in this study. You will not receive any compensation for participating in this study.

Research related injury and compensation: The hospital does not make any provisions to compensate study subjects for research related injury. However, you would be treated for the same at no additional costs at the health facility.

If you have any questions, you are free to ask. We request you to be a part of this study.

Contact: In the course of the study, if you would like to know information at any time, kindly contact the following:

Dr. Suneela Garg Department of Community Medicine, Maulana Azad Medical College, New Delhi-110002

Contact No: 9968604242

ANNEXURE-C

□□□□□□, □□□□□□□□ □□□□□□, □□□□□□ □□□□□□, नई
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ANNEXURE D

MAULANA AZAD MEDICAL COLLEGE AND ASSOCIATED LOK NAYAK, G.B. PANT AND GURU NANAK EYE CENTRE NEW DELHI - 110002 DEPARTMENT OF COMMUNITY MEDICINE PATIENT INFORMATION SHEET ASSENT FORM (CHILDREN 7-13 yrs)

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about "A Cross-sectional study on Prevalence of Hearing Loss and related factors in rural and urban areas of Delhi.". You are being asked to join the study because you belong to selected study area and in the desired age group.

If you agree to join this study, you will be asked to answer a few questions related to hearing problems and a ear examination will be done. The interview and ear examination will take about 15-20 minutes.

Your participation in the study will not entail any risk to your health.

We expect that the study will help you because you will undergo an ear examination and any problem you might have will be picked up early.

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don't want to be in the study or if you join the study and change your mind later and stop.

Before you say **yes or no** to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question.

If you have any questions about this study please feel free to contact

Dr. Suneela Garg

Department of Community Medicine,

Maulana Azad Medical College, New Delhi-110002

Contact No: 9968604242

ASSENT FOR PARTICIPATION IN THE STUDY

I/my parent or legal guardian has read the previous page(s) of the consent form and the investigator has explained the details of the study. I/my parent or legal guardian understands that I am free to ask additional questions.

I/my parent or guardian understands that participation in this study entitled about "A Cross-sectional study on Prevalence of Hearing Loss and related factors in rural and urban areas of Delhi." is voluntary and I/my parent or legal guardian may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I/my parent or legal guardian, acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I agree to participate in the study and have been given a copy of this form.

Signature of Participant	Date
Name of Participant	
Signature of Person who explained this form	Date
Name of Person who explained form	_
I have discussed this clinical research study with	using language which is understandable and

appropriate for the participant. I believe that I have fully informed him/her of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assent to participate in this study

ANNEXURE E

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ANNEXURE F

MAULANA AZAD MEDICAL COLLEGE AND ASSOCIATED LOK NAYAK, G.B. PANT AND GURU NANAK EYE CENTRE NEW DELHI - 110002 DEPARTMENT OF COMMUNITY MEDICINE PATIENT INFORMATION SHEET ASSENT FORM (CHILDREN 13-17 yrs)

Title: "A Cross-sectional study on Prevalence of Hearing Loss and related factors in rural and urban areas of Delhi.".

Study Investigator: Dr. Suneela Garg

Why am I here?

This is a research study. Only people who choose to take part are included in research studies. You are being asked to take part in this study because you belong to selected study area and in the desired age group. Please take time to make your decision. Talk to your family about it and be sure to ask questions about anything you don't understand.

Why are they doing this study?

This study is being done to find out Prevalence of Hearing Loss and related factors in rural and urban areas of Delhi

What will happen to me?

If you agree to join this study, you will be asked to answer a few questions related to hearing problems and a ear examination will be done. The interview and ear examination will take about 15-20 minutes.

How long will I be in the study?

You will be in the study for 15-20 minutes.

Will the study help me?

We expect that the study will help you because you will undergo an ear examination and any problem you might have will be picked up early.

Will anything bad happen to me?

Your participation in the study will not entail any risk to your health.

Do my parents or guardians know about this? (If applicable)

This study information has been given to your parents/guardian. You can talk this over with them before you decide.

What about confidentiality?

Every reasonable effort will be made to keep your records (medical or other) and/or your information confidential, however we do have to let some people look at your study records.

We will keep your records private unless we are required by law to share any information. The law says we have to tell someone if you might hurt yourself or someone else. The study doctor can use the study results as long as you cannot be identified.

What if I have any questions?

If you have any questions about this study please feel free to contact

Dr. Suneela Garg

Department of Community Medicine,

Maulana Azad Medical College, New Delhi-110002

Contact No: 9968604242

Do I have to be in the study?

You don't have to be in this study if you don't want to or you can stop being in the study at any time. Please discuss your decision with your parents and researcher. No one will be angry if you decide to stop being in the study

ASSENT FOR PARTICIPATION IN THE STUDY

I/my parent or legal guardian has read the previous page(s) of the consent form and the investigator has explained the details of the study. I/my parent or legal guardian understands that I am free to ask additional questions.

I/my parent or guardian understands that participation in this study entitled about "A Cross-sectional study on Prevalence of Hearing Loss and related factors in rural and urban areas of Delhi." is voluntary and I/my parent or legal guardian may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I/my parent or legal guardian, acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I agree to participate in the study and have been given a copy of this form.

Signature of Participant	Date
Name of Participant	_
Signature of Person who explained this form	 Date
Name of Person who explained form	_

ANNEXURE G

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