

REPORT

REPORT ON PLANNING MEETING FOR FIELD TEST OF THE WHO EAR AND HEARING CARE SURVEY PROTOCOL IN INDIA

The planning meeting for “Field test of the WHO Ear and Hearing Care Survey Protocol in India” was conducted under the headship of Dr. Suneela Garg, Head of Department, Department of Community Medicine, Maulana Azad Medical College on 10th and 11th November 2016, in the Department of Community Medicine, Maulana Azad Medical College, New Delhi.

The planning meeting conducted under the guidance of Dr. Suneela Garg was attended by Dr. Shelly Chadha (Technical Officer, Prevention of Deafness and Hearing Loss, WHO HQ), Dr. Promila Gupta (DGHS), Dr. Arun Kumar Agarwal (DDG and President Sound Hearing), Dr. Abha Aggarwal (statistician at ICMR), Dr. Ishwar Singh (HoD, Department of ENT, MAMC) and Ms. Shilpi (audiologist).

The Principal Investigator for the “Field test of the WHO Ear and Hearing Care Survey Protocol in India” will be Dr. Suneela Garg, Head of Department, Department of Community Medicine, Maulana Azad Medical College. The Co-Principal Investigators will be Dr. MM Singh (Dir-Prof., Department of Community Medicine, MAMC), Dr. G.S. Meena (Dir-Prof., Department of Community Medicine, MAMC), Dr. Ishwar Singh (HoD, Department of ENT, MAMC) and Dr. J.C. Passey (Medical Superintendent, MAMC). The Investigators for the survey will be Lt. Col. (Dr.) Vipra Mangla (Ph.D scholar, Department of Community Medicine, MAMC), Senior Residents, Department of Community Medicine, MAMC- Dr. Charu, Dr. Archana, Dr. Pooja Ahlawat and Dr. Neha Dahiya.

The objectives of the planning meeting were to review the WHO Ear and Hearing Care Survey Protocol. 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 aspects covered in the planning meeting included- survey aims and objectives; survey population and area; Survey design, considerations for sample size and sampling methodology; Data collection tools and tests: Questionnaires; Hearing test, ear examination; Survey team and training; Pre-survey visit; Data management and analysis; Follow up of survey; Quality enhancement; Ethical considerations and Timelines for field test and next steps. Following decisions were taken with regard to the protocol.

a) Survey Aims and Objectives: The survey was titled “A Cross-sectional study on Prevalence of Hearing Loss and related factors in rural and urban areas of Delhi”. The primary objective of the survey will be:-

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 will be:-

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.

b) Survey population and area: The survey areas will include 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 will be 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) will be 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.

c) Survey design, considerations for sample size and sampling methodology: It was decided that for the sample size calculation the National figures for prevalence of hearing loss (6.3%) will be used as the data from Delhi is 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. Sampling unit - For the purpose of this survey, sampling unit refers to a household.
- d. Sample size: $n = \frac{Z^2_{1-\alpha/2} P(1-P)}{d^2}$, 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 loss, D = 2% absolute error

$$N = \frac{3.96 \times 0.063 \times 0.937}{0.02 \times 0.02} = 585$$

Considering 10% non response rate, the sample size came to be 585+60= 645. A total of 650 individuals will be considered for the study. Considering a family size of 5, a total of 130 households will be selected and all in individuals aged 3 months and above in the selected households will be included.

- e. Sampling – Population proportionate to size will be 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 will be taken from urban areas and 11% from rural area. Further in urban areas also, sample will be taken from proportionately from all 4 areas. In urban areas, the proportion of selected population will be as follows: - Gokulpuri -70%, Delhi Gate- 25%, Balmiki Basti- 3% and Vikram Nagar - 2%.

Of the total sample size of 650- 72 study subjects (14 households) will be taken from the rural area and 578 study subjects (116 households) will be taken from the urban area. The distribution of the study subjects in the urban area will be Gokulpuri 405 (81 households), Delhi Gate 144 (29 households), Balmiki Basti 17 (4 households) and Vikram Nagar 12 (2 households).

- f. Selection of study subjects: In each study area, the required number of households will be selected by systematic random sampling method.

d) Data collection tools and tests: Questionnaires: The modified data collection form for the survey in both Hindi and English has been attached as Appendix. Data collection from the deaf

persons will be carried out using the sign language through family members or through an interpreter.

e) Hearing test, ear examination: The hearing test and ear examination will be carried out using Hand held Oto-Acoustic Emission in children < 5 years of age and Pure Tone Audiometry in persons above 5 years of age.

f) Survey team and training: Checklist for each team will be prepared. The training of the survey teams will be carried out on the ENT OPD days of MAMC (Wednesday / Saturday). The standardization of training of survey teams will be carried out and the agreement levels will be maintained at 80%.

g) Pre-survey visit: The pre-survey visit will include pilot study - to test methodology / equipments / logistics and timing and for staff familiarization. The visit by the survey teams will be carried out to sensitize the community, 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 will also be carried out.

h) Data management and analysis: In data management, all forms will be checked on daily basis for accuracy and completeness, a Personal Identification Number (PIN) will be assigned to each participant, the confidentiality of participants will be respected and maintained, consistency will be maintained in data collection, recording and entry. The data coding and terminologies will be determined before finalising the forms and data back-up will be undertaken at regular intervals. The data entry will be carried out simultaneously with the data collection. SPSS version 17 will be used for data analysis.

i) Follow up of survey: The follow up survey will include 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 will be followed up. Such participants will be 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 will be referred to Maharishi Balmiki Hospital, Pooth Khurd, Lok Nayak Hospital and Guru Teg Bahadur Hospital.

j) Quality enhancement: For quality checking, 10% of the diagnosis made by the survey teams will be reviewed by the ENT specialist accompanying the survey teams. Double entry of the data in 10-15% of the sample subjects will be carried out.

k) Ethical considerations: All study participants will be explained about the survey purpose and objectives. Written informed consent will be taken from the study participants. Confidentiality of data will be maintained at all steps. Ethical clearance will be taken from the Institutional Ethical Committee of MAMC.

l) Statistical Test: All data will be analysed using SPSS (Version 17). Qualitative data will be represented by percentages and quantitative data will be shown as Mean \pm SD. Association between two qualitative variables will be found using Chi Square test / Fisher exact test.

m) Timelines for field test and next steps: The timeline and activities included in the survey will be 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).

n) Future Steps: The future steps will be the preparation and finalization of “Field test of the WHO Ear and Hearing Care Survey Protocol in India”.

Conclusion:

The planning meeting was successfully conducted in 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”.