

## Listen Up, New Zealand: Study Protocol

### Risk of non-occupational Noise Induced Hearing Loss (NIHL) in New Zealand adolescents

#### Literature Review

New Zealand data on the incidence of hearing impairment in the under-24 age group ranges from 10% to 15% (categorisation as available in Statistics New Zealand and Listen Hear New Zealand report, 2018). The disability survey 2013 data suggests 1% of children up to the age of 14 and 2% of 15 to 44 years olds experience moderate to severe hearing loss (the incidence rising to 34% of men and 23% of women over the age of 65). The incidence of hearing impairment from all causes is higher amongst ethnic minorities such as Maori and Pasifika people, and socioeconomically deprived sections of New Zealand society, even after adjusting for confounders. The Deafness Notification Database report of 2017 further confirms this, reporting most of the 1561 notifications of deafness since 2010 were from high deprivation areas (NZDep 2013 scores of 8, 9 and 10). Initially managed by the National Audiology Centre (NAC), the database was, until 2005, the only source information on the number of New Zealand children diagnosed with different types of hearing impairments. It was launched again in 2010 by the New Zealand Audiological Society to prevent any missed cases for the purposes of planning and accurate monitoring of trends. Its 2017 report lists 1561 newly diagnosed cases of hearing loss in children from birth to 18 years of age since 2010, when the database was relaunched. The Ministry of Health's Well Child/Tamariki Ora programme funds comprehensive health checks, including hearing screening, for four-year olds. The B4School Check (MoH, 2019) compliments the new-born hearing screening conducted just before a child goes home from hospital/delivery rooms and the two are meant to pick up any hearing impairment early and provide treatment. The above two screening programmes do not take into account the enhanced risk of impairment among adolescents and youth during their school years due to health and lifestyle factors including infections, lack of immunisations, injury or exposure to loud music for extended periods. In 2000, Northland District Health Board began a comprehensive health and lifestyle screening of year 9 students from low decile schools in the region. The HEEADSSS (Home environment, Eating and exercise, Education/employment, Activities, Drugs and Alcohol, Sexuality, Suicide and mood, Safety) programme found some evidence of this hearing loss, but did not take into account the degree of loss and the causes thereof, or the strategies to address them before the youth leave school and enter the workforce. Under the HEEADSSS programme, 1830 students were screened, of which 56 (3.05%) were referred to either an audiologist or an ear nurse for failed audiogram or tympanometry test (HEEADSSS, 2000).

#### Cost to the health system

Unaddressed hearing loss poses huge costs to the healthcare system and to the economy as a whole. Academic and/or learning difficulties, bullying, mental health problems, low employability etc. are all associated with unaddressed hearing loss (Freeburg, 1991) (Furlonger, 1998) (Gilani, 2017) (Hall, 2018). Research suggests uncorrected hearing loss impedes learning (Pittman, 2011) and youth with deafness or hard of hearing (DHH) face significant barriers while transitioning from school to community, primarily due to communication problems with the general public and difficulties obtaining employment. This often leads to broader problems such as difficulty in forming adult identity, low self-esteem, social isolation and lack of assertiveness.

#### Lower rate of education, employment or training

Youth with any kind of disability, including DHH, also have fewer qualifications and are twice as likely to be unemployed or underemployed. When they do manage to find gainful employment, they earn less than their peers without disability. NZ's Labour Market Statistics (Disability) June 2019 quarter shows 43% of disabled youth aged 15–24 years were not in employment, education, or training (NEET). This was more than four times the NEET rate of non-disabled 15–24-year-olds. The labour force participation rate for people aged 15–24 years with a disability was 31%, well below that of non-disabled people in the same age group (61%). The 2018 Statistics NZ figures showed 41% of disabled youth had no qualification, compared with 19% of non-disabled youth.



### *Global economic impact*

The World Health Organization report titled “Global costs of unaddressed hearing loss and cost effectiveness of interventions” puts the annual cost of unaddressed hearing loss in the range \$750–790 billion USD globally, primarily towards education, healthcare, loss of productivity and the societal cost resulting from social isolation, communication difficulties and stigma attached to hearing disabilities (World Health Organisation, 2019).

The costs are calculated on the basis of the monetary value attached to avoidance of a year lived with disability and draw upon disability-adjusted life years (DALYs) attributed to hearing loss. However, it takes no account of certain aspects of hearing loss such as the costs of providing informal care, or preschool learning and higher education for people with unaddressed hearing loss. Such costs are not well documented in the literature.

### *Study Background*

The Principal researcher for this study will be Natasha Gallardo, the CEO of the National Foundation for the Deaf and Hard of Hearing.

Secondary schools (M/F) will be selected to provide a representative sample of the demographic diversity of New Zealand, and each year, a cohort of year 9 students will be tested. The purpose of this is to identify trends in hearing loss in the population. At each school, all students of the appropriate year group will be included as potential participants.

### *Expected benefits and merit of the research, and how they outweigh the harms*

The majority of adolescents and youth globally now have access to personal hearing devices including smart phones and iPods that they use to listen to music, using headphones and earbuds, often at high volumes for extended periods. This, combined with regular attendance at music and other noisy recreational events, is contributing to what is now seen as a global trend of increase in non-occupational noise-induced hearing loss. The World Health Organisation (WHO) estimates at least one billion people aged between 12-35 years are at risk of hearing loss due to such preventable recreational risk factors.

To determine whether the global trend was following a similar path in New Zealand, the National Foundation for Deaf and Hard of Hearing (NFDHH) embarked on a pilot programme in 2019 of auditory screening of Year 9 high school pupils at secondary schools throughout New Zealand. Data collected since the commencement of this programme suggest that student are listening to music every day on personal devices for extended periods, and a number of students’ above what the World Health Organisation’s Safe Listening Standards prescribe for maintaining hearing health. The proposed approach minimises the risk of harm for participants as a result of the study.

### *Summary of the proposed research*

Secondary schools across New Zealand, representative of the diversity in New Zealand’s population, will be selected. The Foundation will approach the school’s Deputy Principal and/or Nurse, and acquire consent of parents/guardians prior to study commencement through the schools’ consent process. Based on the number of participants per school, the NFDHH staff members will conduct hearing screening checks according to the B4 school hearing screening programme. We will screen current year 9 students each year.

The audiometric screening will include a series of tones between 500 and 4000 Hertz (Hz) at 20 to 40 Decibels (dB). Prior to each instance of screening, the hearing screening questionnaire is filled out by the student.

In case the study uncovers previously unknown hearing loss, results may be shared with the school so long as the parent/guardian has given consent, and the parents/guardians will then be informed via the Deputy Principal and/or Nurse. Researchers will refrain from giving an opinion about how the hearing loss should be dealt with by a health professional, so as not to interfere with the health professional-patient relationship. If prior consent is given by parents/guardians, the Foundation will seek information of the outcomes of the full assessment for research purposes.

### *Hypotheses or objectives*

The objective of this study is to follow the trends in noise-induced audiometry threshold shifts over a period of time and identify potential future risk of non-occupational NIHL among students in year 9 in New Zealand.



#### Main outcome(s) of interest

- Extent of and trends in hearing loss in adolescent populations in NZ
- Risk between hearing loss with personal device usage

#### Risk Management

##### *Description of the ethical and regulatory aspects, including the ethical risks and considerations raised by the study, and how researchers propose to deal with them*

There are not considered to be significant ethical risks relevant to this study. Burdens and benefits are equitably distributed through selecting demographically representative schools. Parents/guardians of students with previously unidentified hearing loss will be informed and enabled to seek advice from medical professionals. This study does not provide any clinical medical advice to participants, however it does provide an optional referral letter for a free diagnostic test (covered by the District Health Board or Triton Hearing Clinic) to be used by the parents/guardian should they decide to follow up on an impaired hearing result. There is also funding available for hearing aids, should these be required.

We acknowledge that detection of hearing loss may cause concern, and we provide support if required. Participants may, at any point, terminate their participation in the study and they will be made aware that if they have any concerns or questions, they can talk to us, their school or their parents/ guardians.

We will work with schools to ensure that we and our researchers take a culturally appropriate approach which considers the needs and experiences of the range of ethnicities involved.

##### *Description of consultation undertaken, and how researchers have incorporated feedback into the research design*

The hearing screening provided by the Foundation will follow the processes and procedures of the Foundation.

##### *Partnership arrangements in place with whānau, hapū and iwi*

As schools will be selected to be representative of New Zealand's demographic, partnerships with iwi are not relevant to this study.

##### *Detailed description of, and clear justification for, the study design:*

The audiometric screening given to the cohorts of year 9 students is a standard hearing test as used by the Foundation. The frequencies, order of frequencies and loudness used in this screening will not vary, in order to enable comparative data analysis.

Prior to each screening event, students are asked to fill out the pre-screening questionnaire in a quiet room at the screening venue within the school premises, as designated by the school administration, under supervision by the screening technician. The questionnaire includes questions on demographics (including age, gender, ethnicity), family history of hearing impairment, medical history (ear, nose, throat infections), and lifestyle factors (including regularly listening to music on high volume for long hours, living near a noisy environment etc.).

The inner structure of the ears will be examined (non-invasive) using an otoscope, to examine the ear canal for any obstruction (e.g. wax) and the condition of the eardrum, which can indicate inflammation, scarring or middle ear infections. HearX digital screening tool will play a series of tones through headphones in each ear, separately. The screening consists of the following steps, as described in the B4 school hearing programme from the Ministry of Health:

1. A tone of 1000 Hz at 40 dB in the right ear
2. A tone of 1000, 2000 and 4000 Hz at 20 dB in the right ear
3. A tone of 500 Hz at 30 dB in the right ear
4. A tone of 1000 Hz at 40 dB in the left ear
5. A tone of 1000, 2000 and 4000 Hz at 20 dB in the left ear
6. A tone of 500 Hz at 30 dB in the left ear

##### *Criteria for including or excluding potential participants, with justifications*

Any student of participating schools in year 9, with individual consent as well as consent from parents/guardians, will be included in the study, with the exception of those who had an acute illness in the six weeks prior to the screening, and those who have previously been diagnosed hearing loss of any degree.

##### *Criteria for terminating the study, if appropriate*

The study will be terminated if funding is not available.



#### *Actual or potential conflicts of interest, and how researchers will manage them*

The study design and objectives do not give rise to any conflicts of interest.

## Data Management

#### *What data will be collected, stored and used, and how it will be collected, stored, used and kept private*

Prior to each screening event, students will fill out an online pre-screening questionnaire, via a URL on the NFDHH hearing hub website. This area is secured through a log-in that only the Foundation staff have access to. Collected data will be downloaded and stored in a secure cloud server by the Foundation that only the Chief Executive has access to. This data will be stored for a maximum of 10 years. Collected data includes demographics (including age, gender, ethnicity), family history of hearing impairment, medical history (ear, nose, throat infections), and lifestyle factors (including regularly listening to music on high volume for long hours, living near a noisy environment etc.). During the HearX screening, a screening report is also collected and saved in a cloud server (located in Australia) by the Foundation that is accessible only by the Chief Executive. The HearX report contain identifiable data (name) and will be assessed and analysed for trends, and then the underlying data will be deleted.

Results of the questionnaires and the HearX screening will not be shared with anyone beyond the researchers (the Foundation), the participant, their parents/ guardians (if they opt-in to receiving results) and anyone they or their parents/ guardians authorise. If the parents/ guardians give their consent, the child's school will receive the test results if hearing loss is detected, so they can provide the appropriate support. However, parents may choose to receive the results directly instead. Screening results will be made available to healthcare professionals should they be involved, with parent/ guardian consent. Children and parents/ guardians have the right to access their own data at any point.

The Foundation will securely hold all information for a period of 10 years as described in their privacy policy. Participants and parents/guardians are able to access the data stored about them at any time.

#### *Number of participants required to achieve the study objectives, and how the researchers determined this, for example using statistical methods*

This study is designed to enable comparative data analysis in order to observe trends and correlations as stated under the study objectives. Because of the observational and potentially beneficial nature of the study to participants, we assume the majority of students in year 9 who are eligible to participate. As a result of this, there is no specific number of participants, nor is the study design sensitive to incomplete data sets.

#### *Analysis plan appropriate to the study design*

To perform comparative data analysis, standard statistical methods will be used. These are likely to include:

- Trend analysis, including regression analysis using Excel or R, to identify correlations between listening behaviours and hearing loss over a five-year period
- Analysis to identify any correlations between relevant demographic factors and hearing loss

#### *How the study results will be shared publicly and communicated to participants*

Individuals' screening results will be communicated to students and their parents/guardians as per the study design. A collective report of the aggregated data will be publically published through the NFDHH's website. This report will not include any identifiable information and/or disclose the study participants.

#### *Disposal of study data*

Data will be retained by NFDHH as per our privacy policy. This includes holding all research information securely for a period of 10 years for auditing purposes.



## References

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