THE EFFECTS OF RECREATIONAL NOISE EXPOSURE ON THE AUDITORY SYSTEM IN YOUNG ADULTS IN MEDICAL SCHOOL IN NAIROBI, KENYA.

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H58/74972/2014

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A dissertation submitted in part fulfilment of the requirements for the Degree of Master of Medicine in Otorhinolaryngology, Head and Neck Surgery, University of Nairobi.

2019
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This is my original work which has not been presented for a degree award at any other university.

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ACKNOWLEDGMENTS

I would like to acknowledge my supervisors, Dr Ayugi, Ms Ndegwa and Dr Kipingor for their help. The faculty, my colleagues in the ENT Department, as well as the nursing staff and clinical officers were essential to my development as an ENT surgeon.

I would also like to thank my parents for the example they set, the mentorship and the unwavering support throughout the journey. Thank you to my siblings for standing by me.

Most importantly, I would like to thank God.
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<td>Compound Action Potential</td>
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<td>SCENIHIR-</td>
<td>Scientific Committee For Emerging And Newly Identified Health Risks</td>
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SOAES - Spontaneous Oto Acoustic Emissions
SPL - Sound Power Level
TEOAES - Transient Evoked Oto Acoustic Emissions
WHO - World Health Organization
OPERATIONAL DEFINITIONS

A-Weighting- Measurement of noise that filters and emphasizes the frequencies that a human is sensitive to (narrow range between 500Hz and 8000Hz). Decibels that have been a-weighted are abbreviated as dBA or dB(A).

Hearing Loss- A hearing threshold of 25db or better in both ears. It may be mild (26-40dB), moderate (41-60dB), severe (61-80dB) or profound (>81dB). (25)

Hearing Protection Devices- A device worn to reduce (not eliminate) the level of sound entering the ear. (26)

Leq- The sound power level indicates the total acoustic energy that a vibrating source radiates to the environment to describe sound levels that fluctuate with time, leq (equivalent continuous sound level). Leq that has been A-weighted is abbreviated LAeq or L(A)eq.33

Lex, 8 hr- The equivalent sound exposure level of noise averaged over 8 hours.

Noise- Noise is any unwanted disturbance within a frequency band. It may be continuous, intermittent or impulsive.33

Noise Induced Hearing Loss- A permanent decrement in hearing threshold levels (HTLs), with a characteristic reduction of hearing sensitivity at the frequencies of 3, 4 and/or 6 KHz, and relatively better hearing sensitivity at surround frequencies (i.e. 2 and 8 KHz)

Noise Induced Permanent Threshold Shift- Synonymous with permanent NIHL.

Noise Induced Temporary Threshold Shift- NIHL that results from exposure to noise but recovers after enough time spent in low noise conditions.
**Personal Listening Devices** - These are listening devices with insert or supra-aural earphones which allow you to adjust the intensity of the sound.

**Recreational Noise** - Non-occupational noise commonly encountered during leisure or recreational activities.

**Recommended Exposure Levels** - Environmental Protection Agency on the minimum health and safety requirements regarding the exposure of people to the risks arising from noise are fixed at exposure limit value 75dBA.
ABSTRACT

Introduction

Exposure to hazardous noise levels can lead to hearing related problems like noise induced hearing threshold shifts (NITS), tinnitus and noise sensitivity. Recreational noise is on the rise and young adults are increasingly exposing themselves to dangerous sound levels from recreational activities. Noise induced hearing loss is permanent. Health-orientated behaviour of young adults might be linked to their attitudes toward noise and hearing loss. We do not have any data in Kenya on recreational noise sources nor their auditory effects.

Objectives

The objective of the study was to examine the effect of recreational noise exposure on the auditory system of young adults (18-35 years) in The University of Nairobi medical school.

Methodology

This was a cross sectional study performed in the ENT department of KNH of young adults in medical school aged 18-35 years. Subjects were recruited via convenient sampling after which they completed a recreational hearing habits questionnaire. Hearing was evaluated using Pure Tone Audiometry and Distortional Product Oto Acoustic Emissions. Data analysis was conducted using SPSS version 18. During the initial descriptive analysis each variable in the database was analysed, in turn. For continuous data including age, mean and standard deviation was calculated. Frequency distribution was used to summarize the categorical variables

Results

Subjects recruited and evaluated were 163 in number with a mean age of 24.6 years and a M:F sex ratio of 1.04:1.

The highest weekly noise exposure in equivalent SPLs was found for going to night clubs (82.9 dBA). The median weekly equivalent noise exposure for all activities was 67.7 dBA. 15.3% of subjects exceeded the Environmental Protection Agency limit of 75 dBA. After noise exposure, 58.6% experienced self-reported ear complaints.

With regards to the DPOAE, the 5000Hz frequency band recorded referrals of above 30.7%.
The crude prevalence rate of hearing loss was 6.1%. There was no statistical difference in hearing loss between groups with intermediate and high noise exposure.

Conclusions

The median weekly noise exposure levels produced self-reported hearing complaints and suggestions of sub-clinical hearing loss. However, there was no statistically significant clinical hearing loss experienced by the cohort. Longitudinal studies are required to follow cohorts to ascertain if sub-clinical hearing loss progresses to clinical hearing loss.
CHAPTER ONE:

1.1 INTRODUCTION

1.1.1 Introduction

The rise of non-occupational hearing loss is concerning and has been documented to have tripled in the last 20 years. Excessive noise exposure can lead to hearing-related problems such as noise-induced threshold shifts (NITS), tinnitus, noise sensitivity and eventually noise-induced hearing loss (NIHL). Hearing is not damaged typically by day to day sounds. However, the possibility for noise induced hearing loss is increased if one engages in loud activities for prolonged periods of time.

Whereas, there are no studies on the effects of recreational noise exposure in Kenya, investigators from other parts of the world have not only reported the prevalence of recreational noise exposure in some countries but also a shown a trend towards increasing NIHL from this exposure. Among the young adults in Australians between 18-35 years, 14.1% are at risk of hearing damage from recreational noise. Among U.S American adolescents, the prevalence of hearing loss rose from 3.5% to 5.3% between 1994 and 2006. (Although the prevalence of recreational noise exposure in Kenya is unknown; occupational NIHL has a prevalence of between 15-42%.)

The hearing threshold shifts attributable to noise alone are termed as noise-induced threshold shifts (NITS). NITS can be temporary or permanent depending on the duration and intensity of the hazardous sound. The first audiometric sign of NITS is loss at 3000, 4000 or 6000 Hz with recovery at 8000 Hz. However, distortion product oto acoustic emissions (DPOAEs) have the potential of detecting preclinical stages of cochlea dysfunction due to noise.

Sources of recreational noise include sports events, movie theatre, fireworks as well as amplified music from night clubs, outdoor festivals and personal listening devices (PLDs).

The consequences of hearing loss and tinnitus include loss of self-esteem, confidence, job opportunities and increased incidence of anxiety, depression, and early-onset dementia.

Public legislation and recommended exposure levels have been set in place to reduce both occupational and non-occupational noise. Occupational exposure to noise is well documented. Recommended exposure levels (RELS) have been established by regulators such as National Institute of Occupational Health (NIOSH) and Environmental Protection.
Agency (EPA). Locally, the regulatory agency charged with non-occupational noise regulation is the National Environmental Management Agency (NEMA).

It is imperative to note that the Kenyan law, both NEMA and the Factories Act sets a noise ceiling of between 25 dB(A) and 55 dB(A) for non-occupational noise. Sounds at those levels are neither harmful to the ear. These restrictions are not in keeping with either EPA or WHO standards or other scientific literature and require to be realigned.

1.1.2 Problem Statement

Recreational noise has tripled in the last decades. Exposure to loud and prolonged noise leads to auditory damage. Young adults are increasingly engaging in recreational activities, some of which expose them to hazardous noise levels.

The aim of this project is to investigate the non-occupational noise sources within our Kenyan context and expose the consequences on the auditory system in young adults.

1.2 Background

1.2.1 Anatomy of the Inner Ear

The inner ear is a highly organized structure. The Organ of Corti is found within the cochlea. The sensory cells of the Organ of Corti are arranged as one row of inner hair cells (IHCs) and three rows of outer hair cells (OHCs). These cells are perched on the basilar membrane, backed up by supporting cells which provide metabolic and structural support to the Organ of Corti.

The hair cells are characterized by an apical bundle of hairs projecting into the endolymph called stereocilia with a single kinocilium at one end. The stereocilia of the OHCs attach to the tectorial membrane while those of the IHCs do not. Each hair cell may have 20-300 stereocilia, with each been attached to the neighbour by tip links. The OHCs dramatically contributes to frequency selectivity (ability to distinguish between adjacent frequencies) and cochlea sensitivity (ability to hear quiet sounds) as well as producing spontaneous oto-acoustic emissions. The cochlea is organized in a tonotopic manner with high frequencies encoded at the base and lower frequencies encoded at more apical locations. The histologic structure is more vulnerable to noise at the base than that at the apex.
The lateral wall of the labyrinth consists of the metabolically active stria vascularis, made up of three layers of cells, and the spiral ligament which is made up of fibrocytes and connective tissue.

1.2.2 Physiology of Hearing

Sound pressure waves hit the tympanic membrane and set up vibrational movements which are transferred by the malleus and incus to the stapes which sends a sound wave across the oval window to the perilymph. The perilymph in turn sets up a travelling wave in the endolymph. Each frequency in the travelling wave stimulates a different part of the basilar membrane with the position of the peak amplitude governed by the stimulus frequency moving the basilar membrane up and down. At the tips of the hair cells are located stereocilia. These bend with basilar membrane motion. The deflection of the stereocilia leads to stimulation of the IHCs and OHCs which in turn produces a nerve impulse in their neurones.

The cochlea acts both as an active and a passive filter. The passive filtering properties of the cochlea create a tonotopic distribution of the frequency spectrum. Hence, every point of the basilar membrane has a particular frequency to which it is tuned to. The active filtering properties are demonstrated by the electromotile properties evoked by depolarization of the OHC. This generates force which mechanically amplifies the basilar membrane motion. Somatic contractility, as the predominant force generator, is driven by a voltage-dependent conformational change in the protein, prestin. The energy required for audition comes from the cochlea stria vascularis which is metabolically active and maintains the ionic composition and the endolymphatic potential. Higher frequencies are more damaging than lower frequencies at the same energy level.

1.2.3 Mechanism of Damage

The molecular mechanisms that explain how noise exposure damages the hair cells and auditory nerves are principally two; the metabolic theory and the mechanical theory.

The mechanical theory proclaims that noise initially leads to destruction of rootlets of the hair cells and dissociation of the OHCs from the tectorial membrane. Excess noise further uncouples the organ of corti from the basilar membrane, disrupts cellular junctions and mixes endolymph with perilymph.
OHCs are more sensitive to noise than IHCs. This is because OHCs experience a direct shearing force at their stereocilia whereas IHCs are stimulated via viscous drag. OHCs have their longitudinal axis exposed as opposed to IHCs which are safeguarded by supporting cells.

The metabolic theory states that cell death through apoptosis is triggered by various biochemical pathways. These theories concentrate on oxidative stress. Exposure to loud noise leads to excessive generation of reactive oxygen species (ROS) and reactive nitrogen species (RNS). The free radicals damage the cellular architecture and overwhelm the antioxidant molecules such as superoxide dismutase, glutathione reductase, glutathione peroxidase and catalase. Oxidative stress is detected in the cochlear immediately and persists for 7-10 days, inducing a delayed and continuous damage to the cochlea. The reactive oxygen and nitrogen species trigger caspases leading to apoptosis, starting from the basal end of the Organ of Corti and spreading apically.27

Excessive noise also leads to an immediate increase in free calcium in the hair cells. This calcium comes from intracellular stores as well as through ion channels. The calcium induces apoptosis both through the ROS formation and independent of it.27

The traditional pathway of NIHL injury is excess glutamate release at the IHC afferent synapse due to intense noise exposure. Glutamate is the neurotransmitter at the post synaptic nerve fibre. An overstimulated post synaptic cochlea nerve fibre ends up with oedema of cell bodies and dendrites.30 This is due to an influx of calcium and other cations which lead to an osmotic imbalance. The cellular degeneration, courtesy of mitochondrial pathways leads to synaptopathy and neural degeneration weeks and months after the exposure.27,31,32 This may account for the phenomenon of “hidden hearing loss” whereby injury to the peripheral auditory system, including cochlea synaptopathy, does not manifest as elevated audiometric thresholds.

1.2.4 Histopathology

Prolonged noise exposure leads to certain histopathologic changes. Shortening of the rootlets is the initial sign of hair cell injury. This makes the stereocilia floppy and is partly reversible. The irreversible damage due to a permanent threshold shift is manifested by loss of intercilial connections and actual fracture of the rootlet33 resulting in injured stereocilia, loss of hair cells, oedema of afferent dendrites and spiral ganglion neurons. The organ of Corti is compressed due to destruction of the supporting pillar cells, reduction of the stria vascularis, and depletion of fibrocytes in the spiral limbus and spiral ligament.27
1.2.5 Young People and Sources of Sound and Noise

Social noise exposure in young people has increased three-fold from 6.8% to 18.6% in a period of 20 years. Various sources of sound produce different sound levels.

Attending a night club is a common recreational activity among the youth with reported mean noise levels in night clubs of 97.9 dB with a range of 90-105 dB.

The ubiquity of music exposure has hearing health care professionals’ worried. Henderson et al reported a 75% increase in popularity of personal listening devices between 1990 and 2005. Torre et al reported 90% of youth between 18-30 years used personal listening devices. Using in-ear probe microphones, the average dB SPL levels was found to be 62 dB for low, 71 dB for comfortable, 88 dB for loud and 98 dB for very loud. Swanepoel and colleagues performed sound level measurements in a stadium and described a range between 113 dB and 130 dB.

The utility of hearing protection devices is low among people exposed to high intensity noise.

1.2.6 Clinical Features of NIHL

People with NIHL initially complain of difficulty discerning speech in the presence of ambient background noise especially consonants and higher frequencies. As NIHL progresses, recruitment creeps in. This is reduction in the dynamic range of hearing and is perceived as abnormal increase in loudness. They also complain of bilateral tinnitus.

1.2.7 Diagnosis of NIHL

Elimination of wax impaction and other middle ear diseases as a source of the hearing loss via otoscopy and tympanometry is the initial step. The classic audiogram on PTA shows a dip centred at 4 kHz with recovery at 8 kHz and sparing of the lower frequencies. DPAOE can be used in NIHL screening because they correlate well with audiometric testing in differentiating ears with NIHL from those with normal hearing, as well as obtaining information not assessed by the PTA such as sub-clinical change, pre-clinical hearing loss and susceptibility to NIHL.

1.2.8 Recommended exposure level

Today, the environmental noise standards are primarily two. The US Environmental Protection Agency (EPA) established a limit of Lex,8hr 75 dBA. Twenty-five years later, the World
Health Organization (WHO) adopted Community Noise Guidelines designed to protect NIHL. They too adopted a recommended exposure limit of $L_{\text{Ex,8hr}}$ 75 dBA.\(^9\)

The European Union Directive 2003/10/EC\(^{43}\) set exposure limit values and exposure action values for occupational noise. The exposure action values in respect of the daily noise exposure levels and peak sound pressure are fixed at:

(a) Upper exposure action values: $L_{\text{EX,8h}}$ 85 dBA

(b) Lower exposure action values: $L_{\text{EX,8h}} = 80$ dBA

The Legal Notice Number 61 by National Environmental Management Agency (NEMA) of 2009,\(^{13}\) The Environmental Management and Coordination (Noise and Excessive Vibration Pollution) (Control) Regulations, provides sound and noise restrictions during the day of between 30-50dBA and 25 dBA at night. The Legal Notice 25 by the Ministry of Labour and Human Resource Development, The Factories and Other Places Of Work Act, Cap 514,\(^{14}\) cites the acceptable range of noise in the workplace to have lower limits of 85 dBA and upper limits of 90 dBA. Non occupational noise which in the Cap 514 is determined to be, “noise outside the workplace” has been limited to 55 dBA during the day and 45 dBA at night.

1.2.9 Prevention of NIHL

The effect of noise on hearing, according to WHO, is cumulative, permanent and treatment is limited.\(^{38}\) However, NIHL is 100% preventable.

Many prevention strategies can be utilized.\(^{39}\) They will hinge on the source of the loud sound and the motivation of the individual. The motivation in turn depends on the attitude and perception of the individual towards sound. A poor attitude will not prioritize ear care.

Using the duration, intensity and distance from loud sounds, one can formulate strategies to prevent NIHL by shortening the duration, reducing the intensity and increasing the distance. Such strategies include reducing the volume, wearing carefully fitted ear buds, monitoring noise exposure, limiting time spent in noisy activities, moving away from loud sounds, regular hearing check-ups and being aware.

1.3 Justification

Young people willingly engage in hazardous noise activities and hence are most vulnerable to recreational and leisure noise-induced hearing loss.
Hearing loss leads to loss of communication, reduced social engagement, poor performance in school and college, lost productivity and early onset dementia. Permanent tinnitus may lead to anxiety and depression. Furthermore, the cost of health care including hearing devices, educational support programs as well as productivity impact the economy. Noise induced hearing loss increases exponentially in the early years of exposure, is irreversible and treatment is limited; however, it is preventable.

Medical students were used because most of them have not been exposed to occupational noise and they were readily available to the principle investigator and compromised of a homogenous subject population.

1.4 Objectives of the study

1.4.1 Research Question

What is the effect of recreational noise exposure on the auditory system of young adults in medical school?

1.4.2 Main Objective

To determine the effect of recreational noise exposure on the auditory system of young adults in medical school.

1.4.3 Specific Objective

1. To determine the amount of recreational noise exposure among young adults in medical school using the Recreational Noise Questionnaire.

2. To assess the hearing level of young adults in medical school using pure tone audiometry.

3. To assess the hearing level of young adults in medical using oto-acoustic emissions.
CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Non-occupational sources of noise play a large role in NIHL. However, epidemiological data is showing a variation in prevalence of noise levels and hearing loss. Locally, efforts to assess individual sources of noise in our country are documented. However, there are no studies that cumulate the exposure to multiple noise sources and attempt to investigate the deterioration of the auditory system.

The literature review will focus on previous studies of authors which are relevant to the area of study. The first segment is an overview of the recreational noise sources. The second section is an overview of the auditory effects of noise.

Several online databases were used to search for peer-reviewed literature for the present study. These include ScienceDirect, PubMed, Web of Science, the Cochrane Library, SciELO (Scientific Electronic Library Online), JSTOR, Ovid and the World Health Organization database. Google Scholar was also used to retrieve open access articles. The following search words were used: recreational noise, noise-induced hearing loss, youth hearing impairment, concerts, nightclubs, music festivals and personal listening devices. Variants of these terms were used to establish comprehensive results. All references were managed using Mendeley.

2.2 Studies on recreational noise sources in the youth

There is heterogeneity in the global literature of recreational noise because some literature looked at solitary sources of noise exposure whereas others looked at noise in the context of multiple recreational activities.

Vogel\textsuperscript{20} using questionnaires on self-reported music exposure from variable sources reported that 54.4\% of participants exceeded the noise limit. In that study, they revised the safety threshold and hence their findings may not be universally accepted. Keppler\textsuperscript{23} who also using a questionnaire concerning recreational noise exposures, placed the subjects into 3 self-reported groups of low, intermediate and high noise exposure. The average weekly noise exposure was 70.09 dBA. One third of the subjects were exposed to noise higher than 75dBA. Henderson et al\textsuperscript{1}, who using data from 1988-1994 and 2005-2006 National Health and Nutrition Examination Survey (NHANES), investigated trends in NITS and exposure to noise. In this study, 4310 adolescents ranging 12-19 years, an overall increase in exposure to loud noise and use of PLDs among US adolescents from 19.8\% to 34.8\% was found between the
two time periods. However, the questionnaire used did not capture hazardous noise sources such as attending night clubs or discotheques.

Jokitullpo\textsuperscript{19} demonstrated that 50% of Finnish youth had an average weekly noise exposure of 80dBA with 27% of Finnish conscripts being exposed to noise levels over the 85 dBA risk limit. The most frequent activities that exposed them to recreational noise were watching TV (94%), listening to a home stereo (94%) and going to night clubs (83%).

Going to night clubs regularly can be a cause of high noise exposure according to William’s et al.\textsuperscript{4} The mean noise levels were 97.9 dBA. Interestingly, as the evening moved on, the noise levels tended to rise progressively from 9 pm onwards. The second part of the study found that 60% of the recommended noise exposure levels an entire lifetime is acquired during the short 10-year period where clubbing is a regular activity. This underlined the notion that going to a night club provides a significant source of noise for young people.

Young adults are immersed in social activities that may be dangerous to their hearing and wellbeing. The term “ipod oblivion” is used to describe the inattentiveness of those engrossed with PLDs.\textsuperscript{10} This may lead to risk or injury because of lack of awareness and an enabling attitude towards noise and hearing loss. This is clear when a survey showed 45% of adolescents did not know there was a program that could limit the noise output on their PLDs. Despite the awareness, most adolescents indicated they would not utilize such technology.\textsuperscript{10}

These findings therefore support the notion that cumulative exposure to combined sources of non-occupational noise is hazardous.

\subsection*{2.3 Studies on the auditory effects of recreational noise}

Some studies found no correlation or a slight correlation between noise and hearing loss. Others found a clear correlation. The difference may be due to spectrum, dynamic and temporal variation in noise and music.

Vogel\textsuperscript{20} showed 45.2% of participants of those exposed to sound levels of 90 dBA had a greater incidence experiencing auditory symptoms. Degeest\textsuperscript{21} using the PTA and DPOAEs and TEOAEs found 436 (84.3%) participants were classified with normal hearing, and 81 (15.7%) participants were classified with sub-clinical hearing loss. There were no subjects in the study that were classified with clinical hearing loss. This may be because the pattern of exposure shows less frequent exposure and for a relatively short overall fraction of lifetime.
Nisker\textsuperscript{18} in 1988-1994 NHANES III, investigated US children and the prevalence of NITS. Among prepubescent and adolescent US children (6-19 years), the prevalence of unilateral or bilateral NITS was 12.5\% (approximately 5.2 million). Adolescents between 12-19 years (15.5\%) had significantly higher point prevalence of NITS than children aged 6-12 years (8.5\%). The data suggests a trend that NITS increases with age. This was in contrast with Henderson et al\textsuperscript{1} who investigated trends in NITS among 4310 adolescents ranging 12-19 years. The overall NITS did not change in the time period discussed despite the increase in exposure to noise. Individual vulnerability to noise may play a part in the variation of findings. Another reason may be that attitudes and beliefs towards noise affect the risk of hearing loss. People who find noise to be unproblematic have a higher deterioration of hearing whereas those with more neutral or negative attitudes had better hearing.\textsuperscript{36,21,40,41}

Jokitullpo\textsuperscript{19} reported the occurrence of hearing symptoms related with noise exposure was manifested in 67\% of the subjects while 19\% of conscripts had greater than 20dB hearing loss in either ear.

In a study in high school teenagers in Mexico City, 32\% of subjects were exposed to one type of music source while 10\% were exposed to a combination.\textsuperscript{22} Audiometric loss was seen in 21\% of the students with a moderate association with attending concerts and discotheques. However, the study had 12\% of subjects with tympanic effects and 20\% with abnormal tympanometry findings which does not rule out outer and middle ear causes.
CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study Design

This was a cross sectional study

3.2 Study Area

This study was conducted at Kenyatta National Hospital Ear Nose and Throat outpatient clinic.

3.3 Study Population

The target population were students between the ages of 18-35 years recruited from University of Nairobi School of medicine.

3.4 Inclusion Criteria

Subjects between the ages of 18-35 years who had a normal otoscopy and a normal middle ear function as assessed by tympanometry.

3.5 Exclusion Criteria

1. History of ototoxic medication
   a. Aminoglycosides
   b. Cisplatin
   c. Salicylates
   d. Quinine
   e. Loop diuretics
   f. Erythromycin
   g. Glycopeptides
2. Conductive hearing loss
   a. History of middle ear infection
   b. Chronic or intermittent otorrhea
   c. Persistent tympanic membrane perforation
3. History of ear surgery
4. History of brain surgery
5. History of occupational noise exposure
6. History of familial hearing loss
3.6 Sampling Procedure and Sample Size

3.6.1 Sample Procedure

Study subjects were recruited via consecutive sampling from the University of Nairobi School of Medicine as they rotated through the ENT department.

3.6.2 Sample size

Cochrane’s formula was used for calculating sample size in cross sectional studies.

\[
\text{sample size} = \frac{Z_p (1 - p)}{d^2}
\]

Z=1.96 representing standard normal deviate for 95% confidence intervals

P=prevalence of NITS (estimated at 12% according to Nisker\(^{18}\))

\(1-p= 1-0.12\)

d=precision or absolute error

Sample size =1.96 x 0.12 (1-0.12)/0.05²

Sample size = 162

3.7 Data collection instrument and procedure

3.7.1 Data collection

Data collection was done by the principle investigator using a standardized structured questionnaire (recreational habits questionnaire) to document bio data and recreational hearing habits.

3.7.2 Materials

1. Questionnaires
2. Head light
3. Otoscope
4. Aural speculums
5. Jobson probe
6. Pure tone audiometer (AC33)
7. Tympanometer
8. Oto acoustic emission device (AUDX PRO DPOAE 580-AXPRO1-R)
3.7.3 Flow Chart

1. Subjects recruited
   Consents performed.

2. Otoscopy
   Tympanometry performed.

3. PTA
   DPOAEs performed.

4. Recreational habits questionnaire

3.7.4 Procedure

The Principle Investigator recruited subjects from medical students rotating through the ENT department. The subjects’ participation in the study was voluntary. The risks and benefits were explained before consenting was performed. Physical examination included otoscopy. Thereafter, a hearing assessment using tympanometry, PTA and DPOAEs was performed in a soundproof booth in the audiology section of the ENT department at Kenyatta National Hospital.

The external ear canal (EAC) and tympanic membrane were examined. The ear canal and ear drum were assessed using a mini F.O ZI-F-786 Otoscope. The EAC was examined for any presence of inflammation, wax compaction, otorrhea or any other abnormality. The tympanic membrane was assessed for position, colour, perforation and mobility.

Tympanometry was performed to verify normal middle-ear function. Any subjects meeting the exclusion criteria were eliminated at this stage.

The Hughson-Westlake method of threshold determination was used for presenting the pure tones for frequencies 0.5, 1, 2, 3, 4, 6 and 8 kHz which were recorded on the audiogram by one audiologist. The same equipment was used for each test to reduce interpersonal and inter instrument bias. PTAs were done in a soundproof audiology room and the procedure clearly explained to the subjects in a language he/she understood. The audiometer used was the Interacoustics Clinical Audiometer AC33.
After confirmation of normal auditory thresholds and middle ear function, the module AUDX PRO DPOAE 580-AXPRO1-R was used to record DPOAEs. They were conducted in a soundproof room, consistent with ISO8253-1.

Then the demographic information, recreation noise exposure levels were collected using a questionnaire (see appendix 3). The recreational habits questionnaire was based on Jokitulpo,19 Keppler23,36 and Degeeste,21 regarding recreational noise exposure. It included questions on exposure to noise, frequency of exposure, subjective loudness of exposure and use of hearing protection devices during exposure. The sources of recreational noise exposure were evaluated in time spent per week or month, the total time of exposure (in years), and subjective estimation of loudness. The scale of loudness referred to the following sound levels:

1. A normal conversation, (60 dB)
2. A loud conversation, (70 dB)
3. If one must shout over 1 m, (80 dB)
4. If one must shout over a near distance, (90 dB)
5. Where communication is impossible. (100dB)

This self-estimated loudness corresponded to A-weighted equivalent sound pressure levels (SPLs) ranging from 60 dBA to 100 dBA for ratings 1 to 5, respectively.

The weekly equivalent noise exposure per activity was calculated as

\[ L_{A_{eq,w}} = L_{A_{eq}} + 10\log_{10} \left( \frac{T_w}{T_0} \right), \]

where;

- \( L_{A_{eq}} \) = the A-weighted equivalent SPLs from 60 dBA to 100 dBA,
- \( T_w \) = the time spent per week in h, and
- \( T_0 \) = the 40-h reference of a workweek.
Accordingly, the lifetime equivalent noise exposure per activity was computed as

\[ L_{Aeq,l} = L_{Aeq,w} + 10 \times \log_{10}(T_y), \]

where;

\[ T_y = \text{the time of exposure in years}. \]

The weekly and lifetime equivalent noise exposures for all activities \( L_{Aeq,w\ all} \) and \( L_{Aeq,l\ all} \) were determined by calculating the logarithm of the average \( L_{Aeq,w} \) and \( L_{Aeq,l} \) in Pa, respectively. These calculations were adopted from Jokitulppo. Subjects were divided into 3 groups. This was based on the quartiles of the \( L_{Aeq,w\ all} \) and \( L_{Aeq,l\ all} \). The subjects with low, intermediate and high recreational noise exposure were represented by the lower quartile, the interquartile range and the upper quartile.

3.8 Quality Control

The principal investigator carried out all the ear assessments while the audiologist performed the Pure Tone Audiograms using the same Interacoustics clinical audiometer AC33 and tympanometer AT235 Impedance audiometer.

3.9 Data Management

Data entry into password-secured computer databases was performed. Data cleaning was conducted in SPSS version 18 through inspecting each variable for outlying or invalid values as appropriate and inspecting ranges and means for continuous variables.

3.10 Data Analysis

Data analysis was conducted using SPSS version 18. During the initial descriptive analysis each variable in the database was analysed, in turn. For continuous data including age, mean and standard deviation was calculated. Frequency distribution was used to summarize the categorical variables (e.g hearing loss). A cut off value of 0.05 was used to determine statistical significance.

3.11 Ethical Considerations

1. Approval was granted by the KNH – UON Ethics and Research Committee.
2. Confidentiality was maintained by making the bio data with numbers and individual files locked and secured.
3. No extra cost was incurred by the participants.
4. Consent was sought from the participants.
5. Participants found to have other ENT diseases or fail the PTA were referred to the ENT clinic at KNH for further management.

6. There was no compensation to the subjects.

7. To ensure privacy, data collection was done within the soundproof booths of the audiology section in the ENT department.

8. The author declares no conflicts of interest or bias.
CHAPTER FOUR: RESULTS

The study population consisted of 163 subjects ranging from 22-29 years with a mean age of 24.6 years (SD 1.1). There was an almost equal representation with a sex ratio of M:F 1.01:1

Table 1: Recreational Noise Characteristics

<table>
<thead>
<tr>
<th>Activity</th>
<th>Percentage of subjects (%)</th>
<th>L\text{aeq,w} (dBA)</th>
<th>L\text{aeq, l} (dBA)</th>
<th>Time Spent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Per week</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(hours)</td>
</tr>
<tr>
<td>Watch TV</td>
<td>84</td>
<td>61.7</td>
<td>70.8</td>
<td>9.0</td>
</tr>
<tr>
<td>Listen to music via headphones</td>
<td>82</td>
<td>55.3</td>
<td>66.5</td>
<td>10.7</td>
</tr>
<tr>
<td>Go to the movie theatre</td>
<td>80</td>
<td>66.2</td>
<td>73.8</td>
<td>5.9</td>
</tr>
<tr>
<td>Listen to music via speakers</td>
<td>77</td>
<td>68.0</td>
<td>74.4</td>
<td>12.1</td>
</tr>
<tr>
<td>Go to night clubs</td>
<td>41</td>
<td>82.9</td>
<td>88.2</td>
<td>5.3</td>
</tr>
<tr>
<td>Exercise to music</td>
<td>38</td>
<td>62.9</td>
<td>65.7</td>
<td>4.4</td>
</tr>
<tr>
<td>Play videogames</td>
<td>29</td>
<td>61.5</td>
<td>67.8</td>
<td>7.9</td>
</tr>
<tr>
<td>Attend musical concerts</td>
<td>28</td>
<td>71.4</td>
<td>76.0</td>
<td>2.3</td>
</tr>
<tr>
<td>Attend or participate in indoor sports events</td>
<td>20</td>
<td>59.5</td>
<td>64.6</td>
<td>5.1</td>
</tr>
<tr>
<td>Practice a musical instrument</td>
<td>15</td>
<td>63.1</td>
<td>68.6</td>
<td>3.6</td>
</tr>
<tr>
<td>Use of tools</td>
<td>5</td>
<td>63.0</td>
<td>68.9</td>
<td>1.8</td>
</tr>
<tr>
<td>Play with Fireworks</td>
<td>4</td>
<td>71.3</td>
<td>76.9</td>
<td>2.4</td>
</tr>
<tr>
<td>Play in a band</td>
<td>4</td>
<td>63.6</td>
<td>71.6</td>
<td>2.3</td>
</tr>
</tbody>
</table>
The results support the fact that a high percentage of young adults in the study engaged in recreational activities. The most commonly engaged activities among the subjects were watching TV (84%), listening to music via headphones (82%) and going to the movie theatre (80%). However, none of the individual activities was above the noise threshold. The activities with the most spent hours per week were 12.1 hours at night clubs, 10.7 hours listening to music via headphones and 9 hours watching TV. The average total sum of spent hours per week for all activities was 5.6 hours (range, 1.8-12.1 hours) with a median of 5.1 hours. The average total sum of spent hours per year was 293.2 hours (range, 93.6 – 629.2 hours) with a median of 265 hours.

The only activity that crossed the threshold of the LAeq,w of 75 dBA was going to night clubs at 82.9 dBA among 41% of responders. Playing with fireworks and attending music concerts were the next activities with high noise exposures of LAeq,w of 71.2 dBA and 71.4 dBA respectively. However, playing with fireworks had a very low engagement levels of 4% and less than a third of subjects attended music concerts. The average for the total weekly noise exposure was 65.41 dBA (range, 55.3-82.9 dBA). The average for the total lifetime noise exposure was 71.83 dBA (range, 63.2-88.2 dBA).
Altogether, 15.3% of subjects were exposed weekly to noise levels above the 75 dBA risk limit set by the EPA. Only 4.9% of subjects exceeded the minimum action value of 80 dBA set by the European Union Directive 2003/10/EC (2003). Using the least stringent criteria, the maximum allowable limit of the European Union Directive 2003/10/EC (2003), a paltry 1.2% exceeded the 85 dBA limit.

This highlights the issue that plagues global research of noise exposure; different regulatory agencies in different jurisdictions using different recommended exposure limits.
<table>
<thead>
<tr>
<th>Group</th>
<th>Noise exposure</th>
<th>Distribution</th>
<th>Laeq, w, all (dBA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>Low</td>
<td>Lowest quartile (n=41)</td>
<td>46.7-61.1</td>
</tr>
<tr>
<td>Group 2</td>
<td>Intermediate</td>
<td>Inter-quartile range (n=81)</td>
<td>61.2-73.1</td>
</tr>
<tr>
<td>Group 3</td>
<td>High</td>
<td>Highest quartile (n=41)</td>
<td>73.1-89.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Median (standard deviation)</td>
<td>67.7 (8.3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Range</td>
<td>46.7-89.2</td>
</tr>
</tbody>
</table>

For the weekly noise exposure to all activities the lowest 25% ranged between 46.7-61.1dBA, the intermediate 50% between 61.2-73.1dBA and the highest 25% ranged between 73.1-89.2dBA.

The median weekly noise exposure for all activities was 67.7 dB (SD 8.3 dBA) with a range of 46.7-89.2 dBA. The median noise exposure was below the recommended exposure levels. This demonstrates most young people are not exposed to harmful noise levels. However, there is a small minority at risk.
Table 3: Self-Reported Auditory Symptoms After Noise Exposure

<table>
<thead>
<tr>
<th>Hearing disorders</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporary Tinnitus</td>
<td>95(58.6%)</td>
</tr>
<tr>
<td>Otalgia</td>
<td>63(38.3%)</td>
</tr>
<tr>
<td>Distortion</td>
<td>49(29.8%)</td>
</tr>
<tr>
<td>Temporary threshold shifts</td>
<td>34(21.0%)</td>
</tr>
</tbody>
</table>

This study demonstrates that more than half of the subjects developed at least one symptom after noise exposure. Ninety-five subjects (58.6%) experienced temporary tinnitus and 38.3% experienced ear pain after noise exposure. Distortion was noted in 49(29.8%) of respondents while only 34(21%) of respondents developed temporary hearing loss after noise exposure.

Table 4: Referral Pattern Of DPOAE

<table>
<thead>
<tr>
<th>Frequency (Hz)</th>
<th>Refer rate (%)</th>
<th>Left</th>
<th>Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>5000</td>
<td>35.0</td>
<td>30.7</td>
<td></td>
</tr>
<tr>
<td>4000</td>
<td>7.4</td>
<td>4.3</td>
<td></td>
</tr>
<tr>
<td>3000</td>
<td>1.2</td>
<td>1.3</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>0.0</td>
<td>12.5</td>
<td></td>
</tr>
</tbody>
</table>

With regards to the DPOAE, the referral rate was greater at higher frequencies and much less at the lower frequencies. At the 5000Hz frequency band, the referral rate was 35% on the left ear and 30.7% on the right. If there was a refer at 5000Hz then the machine automatically tested the 2000Hz frequency. This revealed a refer rate of 0% on the left ear and 12.5% on the right. The 4000Hz frequency band showed 7.4% refer on the left and 4.3% on the right. At 1.2% and 1.3% for the left and right ear respectively, the 3000Hz frequency band demonstrated the lowest referral percentage. This is consistent with noise exposure.
Table 5: Correlating Recreational Noise Groups with Bilateral DPOAE Results

<table>
<thead>
<tr>
<th>DPOAEs</th>
<th>Recreational groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group 1</td>
</tr>
<tr>
<td></td>
<td>Right Refer</td>
</tr>
<tr>
<td></td>
<td>n (%)</td>
</tr>
<tr>
<td>5000 Hz</td>
<td>11 (6.7)</td>
</tr>
<tr>
<td>4000 Hz</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>3000 Hz</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>2000 Hz</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

The correlation between high frequency referral rate and intermediate (14% and 18% for the left and right ear respectively) and high noise exposure (9.2% and 9.8% for the left and right ear respectively) is evident. However, the intermediate group has a higher referral rate than the high noise exposure group. Consistently there was a drastic decline in the referral rate in the lower frequencies.

Table 6: Hearing Loss

<table>
<thead>
<tr>
<th>Audiometric outcome measurement</th>
<th>Normal hearing dB</th>
<th>Hearing loss</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Right</td>
<td>Left</td>
</tr>
<tr>
<td>NITS frequencies (3, 4, and 6 kHz)</td>
<td>153 (93.9%)</td>
<td>154 (94.5%)</td>
</tr>
</tbody>
</table>
The pure tone audiometry demonstrated a crude prevalence rate of hearing loss of one or both ears was 10 (6.1%).

**Table 7: Correlating Recreational Noise Groups with the NITS**

<table>
<thead>
<tr>
<th>Recreational noise groups</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal n(%)</td>
<td>Hearing loss n(%)</td>
</tr>
<tr>
<td>Group 1</td>
<td>37 (22.7%)</td>
<td>4 (2.5%)</td>
</tr>
<tr>
<td>Group 2</td>
<td>75 (46.0%)</td>
<td>5 (3.1%)</td>
</tr>
<tr>
<td>Group 3</td>
<td>41 (25.1%)</td>
<td>1 (0.6%)</td>
</tr>
<tr>
<td>Total</td>
<td>153 (93.9%)</td>
<td>10 (6.1%)</td>
</tr>
</tbody>
</table>

*Note.* P value = 0.15

Based on the quartiles of the LAeqw, all subjects were divided into three groups, where the lower quartile, the interquartile range, and the upper quartile represented participants with low, intermediate, and high recreational noise exposure, respectively. The intermediate group had the highest rate of hearing loss with a left ear demonstrating more loss at 3.7% and the right ears showing 3.1%. Group 3 had the highest noise exposure but accounted for 0.6% hearing loss on the right ear and 1.2% on the left. There was no correlation between the different noise groups and hearing loss patterns.
CHAPTER FIVE: DISCUSSION

5.1 Discussion

This is the first report of the prevalence of recreational noise in young adults in Kenya and its effect on the auditory system. These results suggest that young adults are being exposed to hazardous levels of noise, and their auditory systems are vulnerable to these exposures.

Consistent with previous research, recreational noise exposure has negative consequences on the hearing system, albeit temporarily. Over half the participants (58%) observed temporary tinnitus after exposure to noise. This brings to light the vulnerability of the auditory system of young people. According to several surveys, a section of youth does not believe that PLDs puts them at risk of auditory damage. The temporary tinnitus that is experienced can therefore be showcased as a forbearer to further injury.

A large number (15.3%) of youth expose themselves to harmful noise above the recommended exposure level of 75dBA. Studies elsewhere showed a prevalence of 11%-50%. In the other studies, participants attended night clubs, pop concerts and indoor sports events almost thrice as much as the subjects in this study. This may be due to the higher variety of leisure activities available in European countries. The prevalence in this study of noise exposure among young adults is crucial because these young adults have not yet been exposed to occupational noise nor have they undergone the steady auditory degeneration of increasing age. Furthermore, the prevalence of recreational noise is on the increase.

Even though the 5 activities most engaged in brought the most concern in the media and modern discourse, none of these recreational activities were above the EPA limit of 75 dBA and as such none are sources of hazardous noise. Despite the worrisome popularity of PLDs, there are other sources of recreational noise which require our attention. This compares similarly with other studies that showed use of PLDs doesn’t give the highest noise exposure.

Going to a night club was a common recreational activity among the subjects (41% attendance) with a mean of 5.3 hours per week which agreed with Jokitulpo and Williams. Characteristically, going to a night club produced the highest sound, 82 dBA, which is above the maximum weekly noise exposure permitted. The high noise output in night clubs is in
keeping with other studies that looked at noise and going to night clubs.\textsuperscript{3,4,36,21} Regularly going to a night club is an element of youth culture which embraces high noise exposure. A continuous period of regular club attendance with exposure to noise hazards contributes to a significant portion of lifetime exposure to noise. The EU's Scientific Committee on Emerging and Newly Identified Health Risks estimated that 5-10\% who listen to music at sound levels exceeding 89 dBA for 1 hour per week are at risk of permanent hearing loss after 5 years or more.\textsuperscript{16}

The prevalence of hearing loss demonstrated was 6.1\%. Continued excessive recreational noise exposure may lead to progression or increased severity. Permanent NIHL is irreversible. It may lead to difficulty discriminating words and miscommunication. Among young adults, NIHL is the result of accumulated exposure over time.\textsuperscript{18} The addition of occupational noise exposure, age related hearing disorders and acquired middle ear structural disorders will compound and increase the current prevalence. The development of NIHL is influenced by the duration of exposure, the loudness and quality of the noise, the distance of the ear from the source of sound and concurrent alcohol and drug use (both legal and illegal). The hearing loss affects communication skills which impact on education, job opportunities, social engagements and quality of life.

The results of the pure tone audiometry between the three groups were not statistically significant. The pattern of hearing loss witnessed may be due to the characteristics of recreational noise exposed to\textsuperscript{21,23} It may also be due to individual susceptibility to noise.\textsuperscript{27} Furthermore, NIHL is slow to develop and progress. Leisure noise exposure, as a part of youth culture, probably accounts for only a short period in life. It is also a possibility that it may be too soon to detect permanent auditory effects of recent advances in technology such as PLDs. Genetic polymorphism might also contribute to the wide hearing variability after noise exposure.\textsuperscript{31,20}

The DPOAEs had refers in both ears above 30\% at 5000 Hz but less than 2\% at 3000Hz. The physiological measurement of hearing threshold has demonstrated a higher sensitivity than the behavioural measurement. This infers there is sub-clinical damage.\textsuperscript{44} This subclinical damage puts young adults potentially at risk if they continue to expose themselves to hazardous noise. Synaptopathy may explain the fact that sub-clinical damage can lead to hearing loss. The awareness about this hidden hearing loss will prompt early educational
action and activation of hearing health prevention and promotion campaigns to clarify the need to reduce time spent in noisy spaces.

Prevention of recreational noise-induced hearing loss begins with identifying the sources of noise young people expose themselves to. The determination of sources of harmful noise that young adults exposure themselves to in Nairobi will provide evidence that can be used in developing strategies against recreational NIHL.

5.2 Conclusion

According to this study, the prevalence of 15.3% of subjects were exposed weekly to hazardous recreational noise levels. The prevalence of hearing loss among the respondents was 6.1% with a distinct referral rate on DPOAE confined to the high frequencies. However, there was no statistical difference in hearing loss between groups with intermediate and high noise exposure. Greater than half the subjects complaining of at least one auditory symptom after loud noise exposure.

5.3 Study Limitations

This was a cross sectional study and may have led to a recall bias or errors in the calculation of A-weighted weekly and lifetime equivalent noise exposure values.

The noise levels vary during the activities, unlike the steady noise in occupational settings. The unavailability of ultra-high frequency audiogram may have led to the pattern of hearing loss demonstrated.

Medical students may have more conservative recreational habits than other young adults hence preventing the generalization of these results.

5.4 Recommendations

Noise management is crucial. Night club goers require to be informed and warned about the dangers they are exposing themselves to and the auditory effects of their activities. The development of standards or guidelines to regulate recreational noise exposure should be revised. Hearing loss is cumulative hence a long-term prospective study following a cohort and measuring their occupational and recreational noise exposure would provide the natural history of NIHL secondary to recreational noise exposure. Physicians should start notifying the youth, their parents and teachers and society on the importance of hearing health care. This high incidence of self-reported auditory symptoms after exposure to noise should be
highlighted as a warning system by the body and might be utilized in hearing loss prevention campaigns.

The current research was limited by it being a cross sectional study. More research is needed to evaluate ultra-high frequency audiograms in a cohort of young people. Further work into the specific factors relating to risk-taking behaviour regarding recreational noise exposure, and how these can be targeted. These recommendations are useful for young people and noise regulators. These results will be disseminated in ENT and audiology conferences and peer reviewed journals.
REFERENCES

13. Legal notice no. 61 The Environmental Management And Coordination (Noise And Excessive Vibration Pollution) (Control) Regulations, 2009


APPENDICES

Appendix I: Kiambatisho; Fomu ya Maaelezo Kuhusu Idhini ya Wateja

Kitangulizi

Mimi ni daktari Ian Macharia anaye endelea na masomo ya juu ya kitengo cha upasuaji wa masikio, mapua, koo, kichwa na shingo katika chuo kikuu cha Nairobi. Ningependa kuomba idhini yako ya kushiriki katika utafiti wenyewe lengo la kujua kama kupotea kuhisi kuskia ni juu ya sauti na makelele.

Jinsi ya kushiriki

Baada ya kupeana idhini ya kushiriki nitaangalia maskio yako, utajibu maswali halafu utafamyiwa majoribio ya kusikia. Hautalipishwa gharama yoyote zaidi na hakuna madhara yoyote ya kushiriki kwa utafiti huu.

Una haki ya kujiondoa kutoka kwa utafiti huu wakati wowote bila adhabu yoyote na utapewa habari kuhusu uchunguzi utakaofanywana umuhimu wa matooke.

Jinsi gani kushiriki kwako kunaweza kuleta madhara?

Utafiti huu hautakudhuru kwa njia yoyote; taarifa yote kuhusu mgaonjwa itakuwa ni siri, utambulizo hautatangazwa, na baada ya utimifu wa utafiti maarifa yatakayopatikana yatazaidia kuboresha uduma na matibabu ya wagonjwa waliopasuliwa koo.

Je tutafanyia nini matooke ya utafiti huu?

Maarifa tutakayopata yatazaidia kuboresha uduma ya wagonjwa waliopasuliwa koo

Kuna uwezekano wa kuchapishwa kwa matooke ya utafiti huu katika majarida ya kisayansi au kuwekwa katika mikutano ya kisayansi.

Je umeridhika?

Ukiridhika na maaelezo haya na uko tayari kushiriki, tafadhali weka sahihi yako kwene fomu ya idhini.
(ii) Sehemu ya pili – Idhini ya mgonjwa.

Mimi (Jina)……………………………………………………………………………………………..
kwa hiari yangu, nimekubali kushiriki katika utafiti huu ambao unafanywa na Daktari Ian Macharia. Nimeelezewa manufaa na madhara ya utafiti huu kwa undani na nimeelewa.

Jina la Mgonjwa…………………………………..

Sahihi……………………………………………………………..

Tarehe……………………………………………………………..

Nambari ya utafiti………………………………………..

Jina la Shahidi…………………………………..

Sahihi……………………………………………………………..

Tarehe……………………………………………………………..
Appendix II: General Information and Consent

PARTICIPANT INFORMATION AND CONSENT FORM FOR ENROLLMENT IN THE STUDY

Title of Study: THE EFFECTS OF RECREATIONAL NOISE EXPOSURE ON THE AUDITORY SYSTEM IN YOUNG ADULTS IN MEDICAL SCHOOL IN NAIROBI, KENYA.

Principal Investigator and institutional affiliation: DR IAN MACHARIA, PGY4 ENT, UNIVERSITY OF NAIROBI

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal

iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. P671/11/2017

WHAT IS THIS STUDY ABOUT?

The researcher listed above is interviewing individuals who are between the ages of 18-35 years. The purpose of the interview is to find out the effects of recreational noise on the hearing of young adults. Participants in this research study will be asked questions about recreational
noise exposure. Participants will also undergo hearing tests. There will be approximately 162 participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen: You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 10 minutes. The interview will cover recreational noise. After the interview has finished, your hearing shall be tested using two methods. The PTA is one method, you shall wear earphones and a tone sound shall be heard and you shall be expected to note when you hear the sound. The DPOAE is another hearing test, you shall wear earphones and the machine will automatically test your hearing, there shall be no need to respond to any sound. We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include clarification on answers provided in the questionnaire.

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be secure, so it is still possible that someone could find out you were in this study and could find out information about you. Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview. It may be embarrassing for you to have your hearing tested. We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews.

There will be no discomfort when you perform the hearing tests. There will be no bruise or swelling. In case of an injury, illness or complications related to this study, contact the study
staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving free hearing testing. We will refer you to a hospital for care and support where necessary. Also, the information you provide will help us better understand the relationship between recreational noise exposure and hearing damage. This information is a contribution to science and audiology.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

No, there are no costs to be incurred.

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

No, there are no refunds as there are no costs.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

CONSENT FORM (STATEMENT OF CONSENT)

Participant’s statement I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counsellor. I have had my questions answered in a language that I understand. The risks and
benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

I agree to provide contact information for follow-up: Yes No

Participant printed name: _______________________________________________________

Participant signature / Thumb stamp ______________ Date ______________

Researcher’s statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher’s Name: Dr Ian Macharia Date: ______________

Signature __________________________

Role in the study: __________________________

For more information contact

Dr John Ayugi. Senior Lecturer, University of Nairobi, 0722-883041.

Dr Musa Kipingor. Consultant ENT. KNH. 0722-749196

Ms Serah Ndegwa. Consultant Audiologist. University of Nairobi. 0721-310657

Name ___________________________ Contact information ___________________________

Signature /Thumb stamp: ______________ Date: ______________
Appendix III: Recreational Hearing Questionnaire

THE EFFECTS OF RECREATIONAL NOISE EXPOSURE ON THE AUDITORY SYSTEM IN YOUNG ADULTS IN MEDICAL SCHOOL IN NAIROBI, KENYA.

Study Number     DoB     Age     Gender M F     Date

The purpose of this questionnaire is to determine your personal noise exposure.

Please estimate the sound level of your leisure-time activities using a rating of 1 (quiet) to 5 (very loud). Please also mark the exposure time per week or per year.

As a guide, estimate loudness by referring to the sound levels:

1. Normal conversation.
2. Loud conversation.
3. Must shout over 1 metre (over table) to be heard.
4. Normal sound of disco music which you must shout over a distance to be heard.
5. Loud disco music which makes communication almost impossible.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Hours/Week Spent performing activity</th>
<th>Estimation of loudness (only 1 cross)</th>
<th>Total time in years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you Play in a band or orchestra?</td>
<td></td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Do you Practice a musical instrument?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you Listen to music via speakers?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you Listen to music via headphones/earphones?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you Watch TV?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you Play videogames?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you Watch movies or go to the theatre?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you Go to night clubs?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you Use tools (e.g. drill, lawn mower)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you Attend musical concerts?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you play with Fireworks or other impulse sound exposure?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you Attend or participate in indoor sports events?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you Exercise to music (e.g. aerobics, gym?)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The hearing disorders

Mark the suitable option for the following questions with an X (only one x per question)

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Sometime</th>
<th>Often</th>
<th>Continuously</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have you had ringing in your ears after noise exposure?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Have you had pain in your ears due to noise exposure?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Have you noticed sound distortion in your ears?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Have you noticed temporary hearing loss due to noise exposure?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If your answer to Q1 was sometime, often or continuously then
A> How long have you had the ringing in your ears continuously?
   Years   Weeks   Days
B> How long have you had ringing in your ears altogether?
   Years   Weeks   Days
C> Has the ringing in your head been
   Moderate   Annoying   Very annoying
D> Where is the ringing in your head located?
   Right ear   Left ear   Both ears   Middle of head   Other

FOR AUDIOLOGIST ONLY

Audiometric screening:

<table>
<thead>
<tr>
<th>kHz</th>
<th>0.5</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>6</th>
<th>8</th>
<th>Tympanometry</th>
</tr>
</thead>
<tbody>
<tr>
<td>dB</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dB</td>
<td>L</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DPOAE screening:

<table>
<thead>
<tr>
<th>kHz</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>dB</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dB</td>
<td>L</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix IV: KNH Ethical Approval Letter

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P.O. BOX 19676 Code 00202
Telegrams: uonery
Tel.: (254-2) 272300 Ext 44355

KENYATTA NATIONAL HOSPITAL
P.O. BOX 20723 Code 00202
Tel.: 278309-9
Fax.: 725272
Telegrams: NEDSUP, Nairobi

Ref.: KNH-ERC/188

Dr. Ian Macharia Muthure
Reg. No.458/74972/2014
Dept. of ENT Surgery
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Macharia

RESEARCH PROPOSAL – THE EFFECTS OF RECREATIONAL NOISE EXPOSURE ON THE AUDITORY SYSTEM IN YOUNG ADULTS IN NAIROBI, KENYA (P671/11/2017)

This is to inform you that the KNH-UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above revised proposal. The approval period is from 7th March 2018 – 6th March 2019.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period.
   (Attach a comprehensive progress report to support the renewal).
f) Submission of an executive summary report within 60 days upon completion of the study.

This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH-UoN ERC website http://www.erc.uonbi.ac.ke

7th March, 2018

Protect to discover
Yours sincerely,

PROF. M. C. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
     The Deputy Director, CS, KNH
     The Chairperson, KNH-UON ERC
     The Assistant Director, Health Information, KNH
     The Dean, School of Medicine, UoN
     The Chair, Dept. of ENT Surgery, UoN
Supervisors: Dr. John Ayugi, Dr. Musa Kepingor, Ms. Serah Ndegwa