DETECTION OF HIGH-FREQUENCY HEARING LOSS AMONG HOSPITAL STAFFS EXPOSED TO OCCUPATIONAL NOISE USING EXTENDED PURE TONE AUDIOMETRY

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ABSTRAK

Objektif : Menentukan kadar kelaziman bagi hilang pendengaran frekuensi tinggi lanjutan, kaitan di antara pendedahan kebisingan dan hilang pendengaran frekuensi lanjutan dan faktor-faktor berkaitan dengannya di kalangan staf hospital yang bekerja di persekitaran yang bising.

Kaedah: Kajian ini adalah kajian perbandingan keratan-rentas melibatkan 140 orang peserta (70 orang peserta mewakili kumpulan terdedah kepada bunyi bising dan 70 orang mewakili kumpulan tidak terdedah bunyi bising sebagai kumpulan kawalan). Tahap pendengaran setiap peserta diuji dengan audiometri nada tulen konvensional dan frekuensi lanjutan sehingga 16 kHz.Kelaziman hilang pendengaran frekuensi tinggi lanjutan ditentukan.Ujian ‘chi-square’ digunakan untuk menentukan kaitan di antara pendedahan kebisingan dan hilang pendengaran frekuensi konvensional dan frekuensi lanjutan.Ujian ‘chi-square’ juga digunakan untuk menentukan kaitan di antara tempoh pendedahan kebisingan dan hilang pendengaran frekuensi lanjutan.Ujian ‘multiple logistic regression’ digunakan untuk mengenalpasti faktor-faktor yang mempengaruhi hilang pendengaran frekuensi lanjutan.Kadar ‘*p*-value’ kurang daripada 0.05 diambil kira sebagai signifikan.

Keputusan: Kadar kelaziman bagi hilang pendengaran frekuensi konvensional di kalangan peserta yang terdedah bunyi bising adalah 22.9% dan hilang pendengaran frekuensi tinggi lanjutan adalah 81.4%. Manakala, di kalangan kumpulan kawalan, hilang pendengaran frekuensi konvensional dan hilang pendengaran frekuensi tinggi lajutan masing-masing adalah sebanyak 15.7% dan 75.7%. Keputusan tersebut menunjukan tiada kaitan signifikan di antara pendedahan kepada bunyi bising dan kadar hilang pendengaran bagi kedua-dua

frekuensi. Namun, terdapat kaitan yang signifikan bagi tempoh pendedahan kepada bunyi bising dan hilang pendengaran frekuensi tinggi lanjutan. Umur adalah faktor yang signifikan berkaitan dengan kadar hilang pendengaran frekuensi tinggi lajutan, manakala jantina, tabiat merokok dan pededahan kepada bunyi adalah faktor-faktor yang tidak signifikan.

Kesimpulan: Kajian ini menunjukkanaudiometri nada tulen frekuensi lanjutan tidak memberi manfaat tambahan kepada audiometri nada tulen konvensional sedia ada dalam pengesanan masalah pendengaran akibat terdedah bunyi bising. Namun, audiometri nada tulen frekuensi lanjutan boleh menjadi ujian pelengkap tambahan kepada audiometri nada tulen konvensional dalam pengesanan awal masalah pendengaran akibat terdedah bunyi bising.

ABSTRACT

Detection of high-frequency hearing loss among hospital staffs exposed to occupational noise using extended high-frequency pure tone audiometry

Objectives: To determine the prevalence of extended high-frequency (EHF) hearing loss, the association between noise exposure and EHF hearing loss and its associated factors among hospital staff working in noisy environment.

Methods: This was a comparative cross-sectional study involving 140 hospital staffs (70 participants from noise-exposed group and 70 participants from non-noise exposed group). The hearing was tested using conventional and EHF pure tone audiometry (PTA) up to 16 kHz. The prevalence of EHF hearing loss was calculated.The chi-squares tests were performed to determine the association between noise exposure and conventional PTA and EHF PTA hearing loss. The chi-square test was also used to determine the association between duration of noise exposure and EHF hearing loss. Multiple logistic regression analysis was performed to determine the factors associated with EHF hearing loss. The *p*-value of less than 0.05 was considered as statistically significant.

Results: The prevalence of abnormal conventional PTA in noise-exposed hospital staff was 22.9%, while the EHFhearing loss was 81.4%. Meanwhile, among the control group the abnormal conventional PTA was seen in 11 participants (15.7%), with 53 participants (75.7%) have an abnormal EHF PTA. We found that there was no significant association between noise exposure and EHF hearing loss. However, there was a significant association between duration of noise exposure and EHF hearing loss. Age was a significant factor for

an exposed participants to have EHF hearing loss, while gender, smoking and noise exposure were not.

Conclusion: The present study showsthat EHF PTA gives no additional benefit compared with conventional PTA in detecting noise-induced hearing loss. However, EHF PTA can be used as an adjunct to conventional PTA for early detection of hearing loss among noise-exposed workers.

Keyword Noise-induced hearing loss; High-frequency hearing loss; Hospital staff

Chapter 1:

INTRODUCTION

1.1 INTRODUCTION

Hospital as a working place has faced a technology advancement which has improved the productivity and time of doing a particular task. With increasing of the national population, such advancement has helped in managing high hospital demand in patient care on a daily basis. However, like in other work place, such technology advancement also brings along their by-product, which is noise. There are lists of occupational hazards, but none of it is so common and widespread likenoise pollution. Noise is one of the environmental and occupational hazard listed in the Malaysian Factories and Machinery (Noise Exposure) Regulations in 1989 [1]. The regulation stipulates the permissible exposure limit (PEL) of not exceeding equivalent continuous sound level of 90 dB (A) or not exceeding the limits specified in the First Schedule or the daily noise dose of unity. It also stipulates that no employee shall be exposed to noise level exceeding 115 dB (A) at any time [1]. The cut-off safe PEL taken by the regulations is below 85 dB (A). The new Malaysian Occupational Safety and Health (Noise Exposure) Regulations in 2019 which was gazette in March 2019 and will come to operation in June 2019, has revoked the Factories and Machinery (Noise Exposure) Regulations in 1989. However, we are taking the 1989 regulation as our reference since this study was performed and completed prior to the operation of the 2019 regulations.

The magnitude of noise-induced hearing loss (NIHL) is estimated to account for 16% of hearing impairment worldwide and seems to be among the five most frequent occupational diseases [2]. In Malaysia, there was a marked increase in confirmed cases of Occupational Noise-Related Hearing Disorder (including NIHL, hearing impairment and permanent standard threshold shift) reported by the Department of Occupational Safety and Health (DOSH) which was 1563 cases in 2015 and 2478 cases in 2017 [3].

Hearing loss is classified into three types which are conductive, sensorineural and mixed hearing loss (a combination of conductive and sensorineural element). Disease affecting the external or middle ear may cause a conductive hearing loss. PTA of a conductive hearing loss individual will show an air-bone gap of 10 dB or more with normal bone conductive threshold [4]. Meanwhile, diseases affecting cochlear or a retro-cochlear lesion will cause sensorineural hearing loss, which include presbycusis (commonly seen in elderly), post viral or bacterial labyrinthitis,noise-induced hearing loss, or tumor such as vestibular schwannoma. PTA of a sensorineural type will show an air-bone gap of 10 dB or less with an average bone conduction threshold greater than 25 dB[4].Decibel (dB) is a unit of intensity of loudness and commonly used to describe the degree of hearing loss. The degree of hearing loss can be classified into normal (0-24 dB), mild (25-40 dB), moderate (41-55 dB), moderately severe (56-70 dB), severe (71-90 dB) and profound hearing loss (more than 91 dB) [5].

NIHL refers to auditory acuity reduction secondary to noise exposure [6]. The reduction can be further divided into temporary threshold shift (TTS) or permanent threshold shift (PTS). TTS is a temporary hearing loss associated with noise exposure and the affected person may regain back his or her normal hearing threshold once the noise element is removed. While in PTS, there is a permanent hearing loss even after removal of the noise exposure. PTS may occur after episode of multiple TTS or after a single exposure to aloud noise. The single exposure to an intense sound leads to an immediate hearing loss is referred as ‘acoustic trauma’ [6].

The standard subjective hearing assessment in clinical practice is the conventional PTA test evaluating the hearing loss at a frequency of 250 Hz to 8 kHz.

Thecharacteristicnotched audiometric configuration in conventional PTA associated with NIHL is well-known, whereby there isa maximum reduction in the range of 3-6 kHz with immediate recovery at 8 kHz [6]. However, this notch appears after chronic repeated exposure to occupational noise and may not be detected in an early stage of exposure. It is well understood that the higher frequency tone is affected first insensorineural type of hearing loss. The theory behind this is the association of cochleotopic gradient of susceptibility is expressed functionally as a high-frequency hearing loss. As the cochlear damage becomes more extensive, this effect will progressively extends to include lower frequencies [6]. There are increasing evidences on EHFPTA which allows to detect the earliest changes of high-frequency hearing loss mentioned above, which cannot be detected by the conventional PTA[7-9].

Due to the raising interest in EHF PTA, we conducted this studywith the objectives of todetermine the prevalence of EHF hearing loss, the association between noise exposure and EHF hearing loss and its associated factors among hospital staff working in noisy environment.

1.2 OBJECTIVES

1.2.1 GENERAL OBJECTIVES

To study extended high frequency hearing loss among hospital staff working in noisy environment

1.2.2 SPECIFIC OBJECTIVES

1. To determine theprevalence ofextended high-frequency hearing loss among hospital staff exposed to occupational noise
2. To determine the association between presence of noise exposure and extended high-frequency hearing loss
3. To determine the association between the duration of noise exposure and extended high frequency hearing loss

Chapter 2:

STUDY PROTOCOL

2.1 STUDY PROTOCOL

Study Title

Detectionof high-frequency hearing loss among hospital staff exposed to occupational noise using extended high-frequency pure tone audiometry

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Introduction

Hospital as a working place has faced a technology advancement which has improved the productivity and time of doing a particular task. This advancement has helped in managing high hospital demand in patient care on daily basis. However, like in other working place, such technology advancement also bring along their by-product, which is noise. There are a lot of occupational hazards, but none of it is so common and widespread like the noise pollutions. The magnitude of noise-induced hearing loss (NIHL) is estimated to account for 16% of hearing impairment worldwide and seems to be among the five most frequent occupational diseases [1]. In Malaysia, cases of NIHL investigated by the Department of Occupational Safety and Health (DOSH) had increased from 120 cases in 2007 to 427 cases in 2009 [2,3]. Noise induced hearing loss refers to reduction in auditory acuity associated with noise exposure [4]. This situation may be temporary (temporary threshold shift, TTS) or permanent (permanent threshold shift, PTS). PTS may occur as repeated TTS

or following a single episode of noise exposure. ‘Acoustic trauma’ described the situation where a single exposure to an intense sound lead to an immediate hearing loss. Noise is one of the environmental and occupational hazards listed in the Factory and Machinery Act 1967 [5].

In Malaysia, studies have been done in airport, industrial area and small/medium size enterprise workers [6-8]. No study has been done in hospital settings as yet. Abroad, a few studies were done in hospital settings involving noise level but they were not exceeding the safety limits (85dB) [9-12]. Most of the studies used conventional pure tone audiometry as a screening and monitoring tools for workers with noise exposure. Previous studies with conventional pure tone audiometry (PTA) measurements did not take into account the fact that the effects of noise are additive, and consequently, the number of years that a worker has been exposed to industrial noise might differentiate his needs regarding early detection of NIHL. On the other hand, there is accumulating evidence that extended high-frequency (EHF) PTA may also have a role in the early detection of hearing loss due to occupational noise- exposure [13-16].

Rationale and Significant of study

High-frequency tone will be first affected in the case of sensorineural hearing loss thus by detecting the high-frequency hearing loss, alteration in the management may be done to prevent hearing loss from extending into the speech frequencies. Central Sterile Supply Department (CSSD) in HUSM, kitchen and linen are the noisy work environment (noise level range 89 dB to 98.8 dB) and no study has been conducted in such working environment before. It is hoped that the input from this study will greatly help the hospital

management team to anticipate and able to take necessary measurement to prevent noise-induced hearing loss amongst its high risk staffs.

Research question

1. What is theprevalence of extendedhigh-frequency hearing loss in noise-exposure subjects and non noise- exposure subjects*?*
2. Is there any association between presence of noise exposure and extended high-frequency hearing loss?
3. Is there any association between the duration of noise exposure and extended high-frequency hearing loss?

Objectives of study

General objective

To study extended high-frequency hearing loss among hospital staff working in noisy environment

Specific objectives

1. To determine theprevalence ofextended high-frequency hearing loss among hospital staff exposed to occupational noise
2. To determine the association between presence of noise exposure and extended high-frequency hearing loss
3. To determine the association between the duration of noise exposure and extended high-frequency hearing loss

Hypothesis

Alternative hypothesis

There is significant early changes in high-frequency sensorineural hearing loss in the noise induced hearing loss subjects.

Literature review

Malaysian Factories and Machinery (Noise exposure) Regulations in 1989 has stated the permissible exposure limits according to hours of exposure per day with the cutoff point is 85dB exposure(Appendix Table 1) [5]. Noraita *et al* found that eighteen manufacturing industries in Malaysia have noise level of 86-90dB and eight industries have noise level more than91dB [6]. Ibrahimzulbil *et al*performed a study in Malaysian airport monitoring and fire-fighting unit with noise level of 87 dB and 88 dB respectively. They found that the hearing impairment prevalence of up to 88.24% [7]. Sam et al found that the prevalence of hearing loss among small and medium enterprise workers in Malaysia was 73.3% and 80% of them are working more than 10 years [8].

Marcelo et al discussed regarding hospital setting environmental noise pollution by measuring the noise level in different hospital environments, and found that the sound level in average was 63.7 dB(A) [8]. Few other studies also done in other settings such as operating theatre (average 71.3 dB), otolaryngological surgery (particularly mastoidectomy noise above 75 dB), dentist clinic (70.4 to 83.6 dB) and chemotherapy daycare (55-60 dB) [9-12].

In sensorineural type of hearing loss, the higher frequency tone is affected first. It is due to the cochleotopic gradient of susceptibility is expressed functionally as a high-frequency hearing loss, which extends to include progressively lower frequencies as the cochlear damage becomes more extensive [5]. EHF PTA to reveal the earliest shifts of functions of the inner ear in both the patients with initial forms/stages of hearing disorders and in the patients with progressive hearing loss of a various origin, which cannot be detected by conventional PTA [13].Korres *et al*found that EHF PTA is a useful adjunct to conventional PTA in the audiological assessment of subjects exposed to occupational noise [14]. Riga *et al* found that EHF PTA able to identify the first signs of NIHL, much earlier than conventional PTA, and suggested it to be implemented in the screening examinations especially of workers with less than 1 decade of employment [15]. Amir H *et al* research in 2011 also found that EHF PTA is more sensitive to detect NIHL than conventional PTA and it can be useful for early diagnosis of hearing sensitivity to noise, thus preventing hearing loss in lower frequencies especially speech frequencies [16].

Research design

This is a comparativecross sectional study.

Study area

Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan

Reference population

- All HUSM staff working in CSSD, kitchen, dobby unit (for participant) working environment (noise exposure more than 85dB)
- All HUSM staff working in specialist clinic Opthalmology, Psychiatry or Dermatology specialist clinic (for control) (noise exposure less than 85db)

Source population

- All HUSM staff working in CSSD, kitchen, dobby Unit (for subject) available during study duration
- All HUSM staff working in specialist clinic Opthalmology, Psychiatry or Dermatology specialist clinic (for control) available during study duration
- All HUSM staff working in CSSD, kitchen, dobby Unit (for subject) following inclusion and exclusion criteria
- All HUSM staff working in specialist clinic Opthalmology, Psychiatry or Dermatology specialist clinic (for control) following inclusion and exclusion criteria

Sampling time frame

December 2017 until June 2018

Sample size estimation

(To determine theprevalence of extended high frequency hearing loss in noise exposure)

$$N = \frac{Z\alpha^2 \quad P(1-P)}{\Delta}$$

$Z\alpha = 1.96$

P = 87.6 % (High Frequency audiometry- A means for early diagnosis of noise induced hearing loss Amir H et al, 2011)

Δ = precision=10%

n = 42 subjects

Considering 10% non-response rate

N = 46 respondent

Objective 2

To determine the association between presence of noise exposure and extended high frequency hearing loss

Based on two proportion formula using PS software:

P_0 = Probability of exposure in controls

=The probability of noise exposure with NIHL using Conventional PTA (in literature 54%, Amir *et al*, 2011)

P1 = probability of exposure in cases

= The proportion of noise exposure in EHF PTA (in literature 87.6%, Amir et al 2011)

N = 29 + 10% drop-out

= 32 respondent

Objective 3

To determine the association between the duration of noise exposure and extended high frequency hearing loss

Based on two proportion formula using PS software:

P_0 = Probability of exposure in controls

=The probability of < 10 years exposure with no hearing loss detected using EHF PTA (by literature 57%)

P_1 = probability of exposure in cases

= The probability of < 10 years exposure with hearing loss detected using EHF PTA (expert opinion 80%)

N = 63 + 10% non-response

= 70 respondents

Thus, since the objective 3 is 70, therefore 70 respondents will be taken in noise-exposed group (subject) and 70 respondents for non noise-exposed group (control)

Sampling method and subject recruitment

Convenience sampling method will be used. All staff working in CSSD, kitchen and dobby unit will fall into subject group and staff from Opthalmology, Psychiatry or Dermatology specialist clinic will be the control group. They will be screened for inclusion and exclusion criteria. For that purpose proper history taking includes demographic data, past medical history, past surgical history, smoking history and medication history, will be done. Then thorough physical examination includes otoscopy will be performedto confirm the diagnosis. Participants fulfilling the criteria will be recruited. Consented participants will then undergo EHF PTA until 16 kHz frequency. The audiometry will be done at fourteen hours of quiet period intervals to let the cochlea recover from the temporary threshold shift. Participants can be tested on 9 o'clock in the morning onwards during working days before going to work on the audiometry test day. This audiometry test will last about one hour. Data will be collected and will be interpreted.

Inclusion criteria

1) Staff working in CSSD, kitchen unit or dobby unit (for participant)
2) Staff working at Opthalmology, Psychiatry or Dermatology specialist clinic (for control)

3) Working at least 6 months or above in the working area stated above
4) You must be age of 60 years old or below

Exclusion criteria

1) Previous or active ear infection
2) Previous history of intake of systemic ototoxic medications or exposure recreational noise
3) First degree relatives with childhood hearing loss
4) Previous history of otological disorders that affects hearing such as history of ontological surgery, Menière disease or cholesteatoma
5) Medical illness: Diabetes Mellitus, hyperlipidemia

Withdrawal criteria

Participation in this study is entirely voluntary. Participants may refuse to take part in the study or may stop participation in the study at anytime, without a penalty or loss of benefits. Participation also may be stopped by the study doctor or sponsor without your consent.

Research tools and materials

1) Otoscopy examination

Otoscope (WelchAllyn-rigid & with speculum) is used to examine the external auditory canal and tympanic membrane.

2) Extended high frequency pure tone audiometer

- Diagnostic Audiometer AD226- valid from serial no. 139356 - software version 3.07
- Sound Proof Cabin
- Head phones

Methods:

1. Participant will be seated in the sound proof cabin, in comfortable position.

2. The headphone will be applied to the ear for air conduction threshold test.

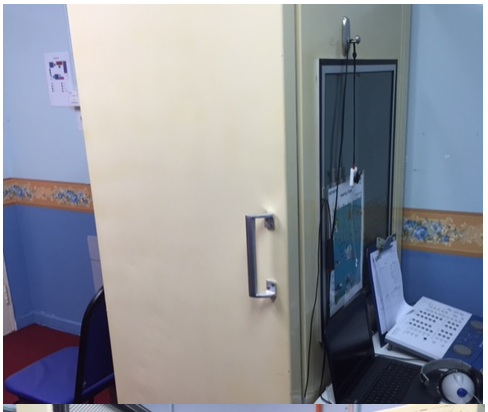
3. Participantis requested to response to the sound “tut” heard during the test by pressing the response button.

4. Participant is to release the response button once the sound “tut” disappeared.

5. The bone conductor will be applied over the mastoid bone for bone conduction test, repeat step 3.

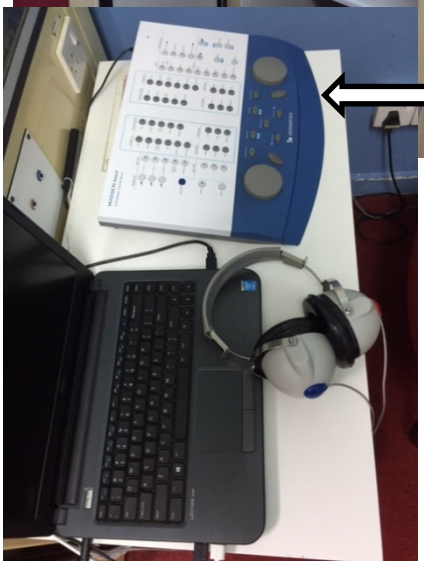
6. The audiogram results will be documented and saved.

The audiogram in ORL clinic was done by the trained technician in audiology. There were audiograms done during the follow up in the clinic. The consistency of the audiograms is evaluated by comparing the findings of each audiogram. Reliability is based on the consistent of the findings. In case of poor consistent noted, that particular audiogram is considered unreliable and is excluded from this study.



Sound proof cabin

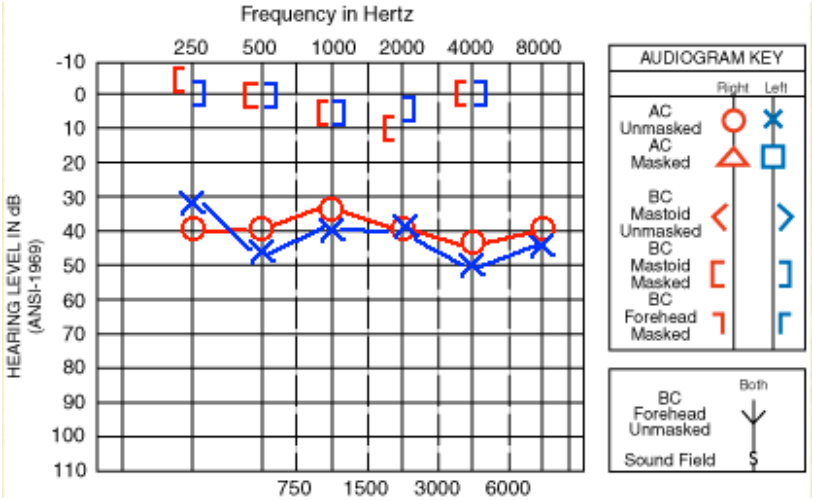
Extended high frequency pure tone audiometer



Headphone

Data collection method

A proforma (as attached) is prepared and all the collected data will be charted in an audiogram. Audiogram will be used to collect all the data and will be interpreted type of hearing loss. Below is the example of audiogram used. However in this study, the frequency used is up to 20 kHz, which is also the limit of the machine audiometer.



Proposed Data analysis

Data analysis will be performed with SPSS software version 22.0.

For specific objective 1, proportion of subjects with extended high frequency hearing loss in noise-exposed group and non noise-exposed group will be calculated at 95% confidence interval.

For specific objective 2, Chi-square test will be used to determine the association between extended high frequency hearing loss in noise-exposure and non-noise-exposure group

For specific objective 3, Chi-square test will be used to determine the association between duration of noise exposure and extended high frequency hearing loss.

Handling Privacy & confidentiality issue

Medical information of subject will be kept confidential by the study doctor and staff and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify subject individually will be published for knowledge purposes.

Participant's original medical records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying clinical trial procedures and/or data. Participant's medical information may be held and processed on a computer.

Subject vulnerabality

Participant is well consented and voluntary to participate in this study. There is no reported case of complication of extended frequency pure tone audiometry and also the normal protocol in management of noise-induced hearing loss is not breached.

Community sensitivities and benefits

Participant will be informed regarding the result of the hearing test done during the study. Participant will benefit from the screening by able to know the current status of their hearing. If hearing loss is detected, participant will be referred to Otorhinolaryngology clinic for futher management and follow up. This study will benefits the community by providing new information regarding prevalence of high frequency sensorineural hearing

loss in noise-exposure hospital staff. It is also important to determine the association between the duration of noise exposure and hearing loss and thus, establish our local database.

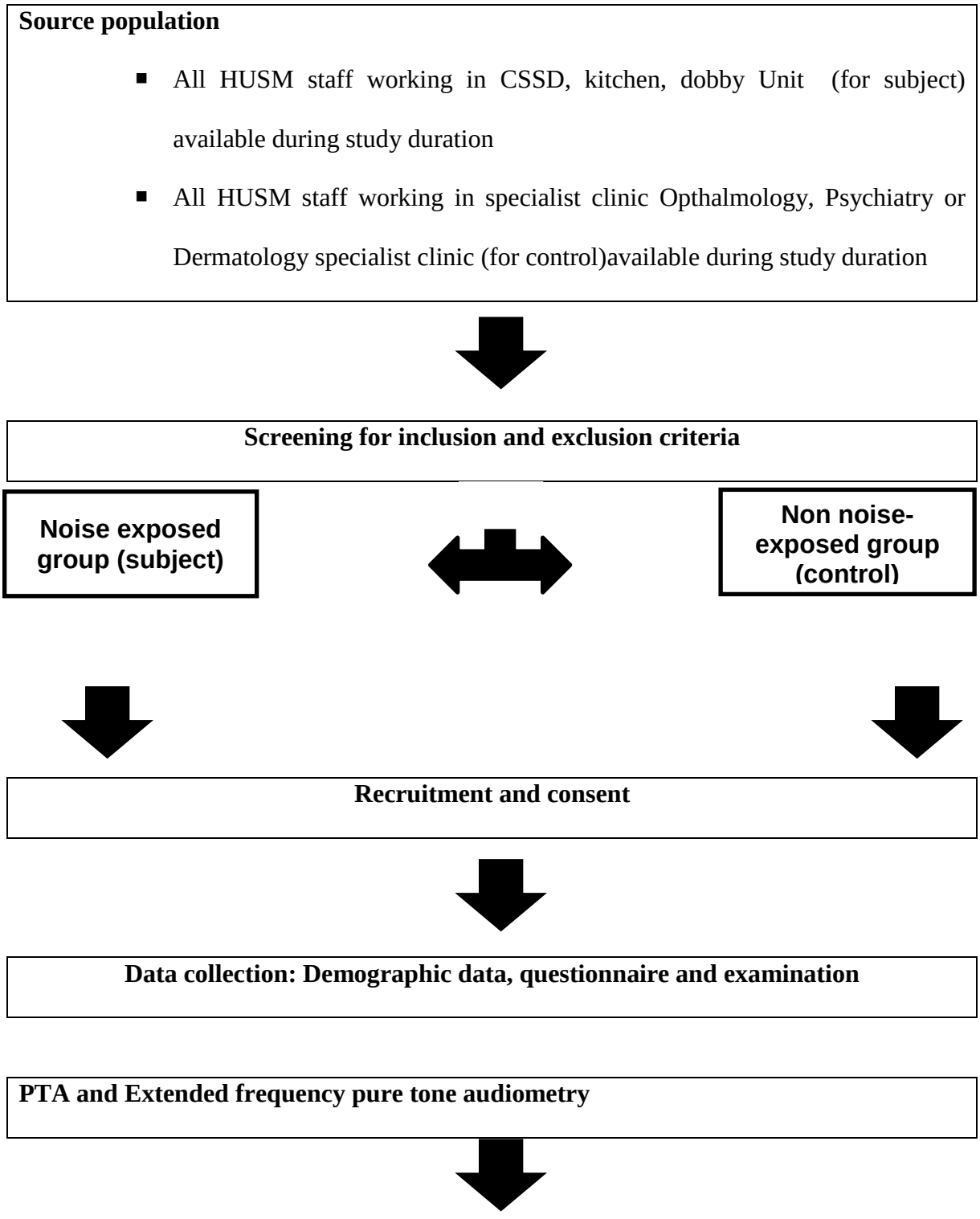
Declaration of absence of conflict of interest

No conflict of interest

Honorarium

Each participant will receive an honorarium of RM 20 per person.

Flow chart


Source population
All HUSM staff working in CSSD, kitchen, dobby Unit (for subject) available during study duration
All HUSM staff working in specialist clinic Opthalmology, Psychiatry or Dermatology specialist clinic (for control)available during study duration
Screening for inclusion and exclusion criteria
Noise exposed group (subject)
Non noise-exposed group (control)
Recruitment and consent
Data collection: Demographic data, questionnaire and examination
PTA and Extended frequency pure tone audiometry

Data analysis

Expected Dummy tables

Table 1: Range of ambient noise level in each workplace

Workplace	Range of ambient noise level dB (A)
Central sterile services department (CSSD)	
Kitchen	
Dobby	
Medical Specialist clinic	
Ophthalmology clinic	
Psychiatry clinic	

dB (A) : decibels (Ambient)

Table 2: Sociodemographic profiles of the participants (n= 140)

	Noise exposed hospital staff (n=70)	Non noise-exposed hospital staff (n= 70)
Gender		
Male		
Female		
Ethnicity		
Malay		
Chinese		

Indian	
Smoking status	
Smoking	
Not smoking	

Table 3:Association between the noise exposure and PTA findings using chi-square test (n= 140)

Workplace	PTA findings		X^2-statistics[a]	*p*-value
	Normal n(%)	Abnormal n(%)	(df)	
Noise-exposed				
Non noise-exposed				

Pearson's chi square

PTA: pure tone audiometry

Table 4:Association between the noise exposure and EHF hearing loss using chi-square test (n= 140)

Workplace	EHF PTA findings		X^2-statistics[a]	*p*-value
	Normal n(%)	Abnormal n(%)	(df)	

Noise-exposed				
Non noise-exposed				

Pearson's chi-square

EHF PTA: extended high-frequency pure tone audiometry

Table 5: Association between noise exposure and EHF hearing loss among participants working 10 years and less using chi-square test (n= 57)

Workplace	EHF PTA findings		*p*-value
	Normal n(%)	Abnormal n(%)	
Noise			
Non-noise			

Pearson's chi-square

EHF PTA: extended high-frequency pure tone audiometry

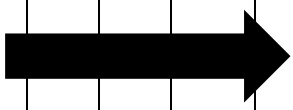
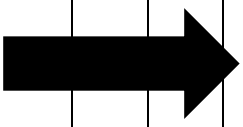
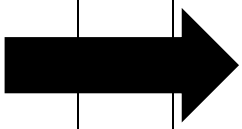
Table 6: Multiple logistic regression analysis of age, gender and smoking status with EHF hearing loss

Variables	Cr OR (95% CI)	Adj OR (95% CI)	Wald stat	*p*-value
Age				

Gender	
Smoking	
Noise exposure	
	Hosmer and Lemeshow Test [$x^2(8) =$ $p =$]
	Area Under the Curve

Note: Significant levels, $p < 0.05$

Gantt chart

PROJECT ACTIVITIES	**Jan –September 2018**	**October -December 2018**	**Jan-May 2019**
DATA RECRUITMENT AND COLLECTION			
DATA ANALYSIS			
REPORT WRITING AND SUBMISSION OF REPORT			

Appendix

Table 1

(Regulation 5 (1))

Permissible Exposure Limits

Noise Level (dB (A)-slow)	Duration of Exposure Permitted per day (hours-minute)
85	16-0
86	13-56
87	12-8
88	10-34
89	9-11
90	8-0
91	6-58
92	6-4
	[*Am. P.U.(A) 106/89*]
93	5-17
94	4-36
95	4-0
96	3-29
97	3-2
98	2-50
99	2-15
100	2-0
101	1-44
102	1-31
103	1-19
104	1-9
105	1-0
106	0-52
107	0-46
108	0-40
109	0-34
110	0-30
111	0-26
112	0-23
113	0-20
114	0-17
115	0-15

ATTACHMENT 1
USM/JEPeM/17110665

ID			

Research tittle: Detection of high-frequency hearing loss among hospital staff exposed to occupational noise using extended high frequency pure tone audiometry

CLINICAL PROFORMA : CONFIDENTIAL								
REGISTRATION NO					CONTACT NO			
AGE					DATE OF BIRTH			
GENDER		MALE			FEMALE			
SMOKING		YES			NO			
OCCUPATION								
WORKING AREA/UNIT								
YEARS OF WORKING								
JOB POSITION								
ETHNIC	MALAY		CHINESE		INDIAN		OTHERS	

BACKGROUND INFORMATION				
HEARING		NORMAL		ABNORMAL
RECREATIONAL NOISE EXPOSURE*		NO		YES
FIRST DEGREE RELATIVES WITH HEARING LOSS SINCE CHILDHOOD		NO		YES
MEDICAL CONDITIONS 1. DIABETES 2. HYPERLIPIDEMIA 3. OTHERS		NO		YES
		NO		YES
	STATE:			
OTOLOGICAL DISEASE 1. EAR INFECTION 2. CHOLESTEATOMA 3. OTOLOGY SURGERY 4. MENIERE'S DISEASE 5. OTHER		NO		YES
		NO		YES
		NO		YES
		NO		YES
	STATE:			
OTOTOXIC DRUG 1. CHEMOTHERAPY		NO		YES
		NO		YES

2. TB TREATMENT 3. GENTAMICIN		NO		YES	
EAR EXAMINATION					
EXTERNAL AUDITORY CANAL	R		L		
TYMPANIC MEMBRANE	R		L		
PURE TONE AUDIOMETRY (PTA)					
CONVENTIONAL PTA		NORMAL		ABNORMAL	
EXTENDED PTA					
RIGHT	9K Hz		LEFT	9K Hz	
	10K Hz			10K Hz	
	11K Hz			11K Hz	
	12K Hz			12K Hz	
	14K Hz			14K Hz	
	16K Hz			16K Hz	

*Recreational hearing loss: Unsafe levels of sound frequently experienced in variety of non-occupational settings such as nigh clubs, discotheques, pubs, bars, cinemas, conserts, live sporting events, personal music players, video games, shooting/hunting hobby and fitness classes. (WHO 2015)

ATTACHMENT 1

The sound intensity levels involved in various common pastimes and activities have been reported[b]

Recreational activity	**Intensity of sound (dB)**	**Average time of activity**	**Reference**
Rattles and squeaky toys	110 (max.)		*30*
Musical toys, drums and horns	120 (max.)		*30*
Toy phones	Range 123-129		*30*
Toy guns	150 (max.)		*30*
Ice hockey game	Range 103.1-110.7	>3 hours	

Ice hockey game	Range 81-97, peak 105-117		*136*
Soccer match	92.7	90 minutes	
Soccer match	100.5		*127*
Basketball game	84.64	2 hours	
Sporting event	Range 85 □100		*3*
Sporting event	Mean 93	2.5 hours	
Aerobics class	89.6		*140*
Fitness class	Range 73-96		*141*
Fitness class	Mean 87.1, range 83.4-90.7		*142*
Fitness class	Range 78-106	60 minutes	
Fitness class	Mean 98.8	52.8 minutes	
Fitness class	Range 74-97		*3*
Fitness class	Mean 86	Mean 1.4 hours	
Nightclub	Average 110.2, range 107.8-112.2	4 hours a week	
Entertainment venue	Mean exceeded 95	5 hours per session	
Concert, live music venue	Range 82-105		*3*
Concert, live music venue	Mean 92	Mean 3 hours	
Nightclub	Mean estimated sound pressure level is 101, range 85-10 5	Mean 4.3 hours/week	
Clubs	Average 97.9	5 hours per week	
Discotheque	Ranged 104.3–112.4		34
Club	Range 94.9-106.7		7
Nightclub	Exceeded 87		146
Nightclub	Range 89-106		3
Nightclub	Mean 97	3.3 hours	
Pub bar, registered club	Range 71-96		3
Pub or registered club	Mean 84	2.7 hours/visit	

[b]Hearing loss due to recreational exposure to loud sounds: a review. WHO 2015 (http://www.who.int)

2.3 **PATIENT INFORMATION AND CONSENT FORM**

LAMPIRAN A

MAKLUMAT KAJIAN

Tajuk Kajian:	Pengesanan masalah kurang pendengaran jenis sensorineural frekuensi tinggi di kalangan staf hospital yangterdedah kepada bunyi berterusan menggunakan ujian *extended high-frequency pure tone audiometer* atau ujian audiometri nada tulen berfrekuensi tinggi tambahan.
Nama penyelidik	: Dr Norsyamira Aida Bt Mohamad Umbaik,MMC 50539(ORL-HNS)
Penyelia	: Assoc Prof Irfan Bin Mohamad, MMC (ORL-HNS)
Penyelia	: Assoc Prof Rosdan B Salim, MMC 30604 (ORL-HNS)
Penyelia	: Dr Mohd Nazri Shafei, MMC 34454 (Dept Community Health)

PENGENALAN

Anda dipelawa untuk menyertai satu kajian penyelidikan secara sukarela tentang pengesanan kurang pendengaran jenis sensorineural frekuensi tinggi kerana pendedahan bunyi menggunakan ujian *extended high frequency pure tone audiometer* atau ujian audiometri nada tulen berfrekuensi tinggi tambahan. Kurang pendengaran jenis sensorineural adalah komplikasi pendedahan bunyi yang berterusan yang biasanya menjejaskan frekuensi tinggi pendengaran dan boleh dikesan menggunakan ujian *convensional pure tone audiometer* atau ujian audiometri nada tulen konvensional. Namun begitu dengan kemajuan teknologi, kurang pendengaran jenis sensorineural boleh dikesan lebih awal lagi dengan ujian *extended high frequency pure tone audiometer* atau ujian audiometri nada tulen berfrekuensi tinggi tambahan.

Adalah penting bagi anda membaca dan memahami maklumat kajian sebelum anda bersetuju untuk menyertai kajian penyelidikan ini. Sekiranya anda menyertai kajian ini, anda akan menerima satu salinan borang ini untuk simpanan anda.

Penyertaan anda di dalam kajian ini dijangka mengambil masa satu sejam.
Seramai 140 orang akan menyertai kajian ini.

TUJUAN KAJIAN

Tujuan kajian ini adalah untuk menentukan prevalensi kurang pendengaran jenis sensorineural frekuensi tinggi kerana pendedahan bunyi berterusan menggunakan ujian *extended high frequency pure tone audiometer* atau ujian audiometri nada tulen berfrekuensi tinggi tambahan dan juga kaitannya dengan pendedahan bunyi. Ianya juga bertujuan untuk pengesanan awal kurang pendengaran jenis

sensorineural kerana pendedahan bunyi berterusan. Jika masalah kurang pendengaran ini dapat dikesan lebih awal, maka peserta akan dirujuk kepada Klinik Pakar Otorinolaringology untuk konsultasi dan rawatan susulan.

KELAYAKAN PENYERTAAN

Doktor yang bertanggungjawab dalam kajian ini atau salah seorang kakitangan kajian telah membincangkan kelayakan untuk menyertai kajian ini dengan anda. Adalah penting anda berterus terang dengan doktor dan kakitangan tersebut tentang sejarah kesihatan anda. Anda tidak seharusnya menyertai kajian ini sekiranya anda tidak memenuhi semua syarat kelayakan.

Beberapa keperluan untuk menyertai kajian ini adalah:

- Anda bekerja di Unit Penyediaan Alat Steril (CSSD), Unit Dapur dan Unit Dobi (untuk peserta)
- Anda bekerja di Klinik Pakar Oftalmologi, Psikiatri dan Kulit (untuk control)
- Anda mestilah berumur dibawah 60 tahun
- Telah bekerja selama sekurang-kurangnya enam bulan di unit anda bekerja kini

Anda tidak boleh menyertai kajian ini sekiranya:

- Anda mempunyai sejarah atau sedang menghidapi masalah jangkitan kuman pada telinga
- Anda mempunyai keluarga terdekat yang menghadapi masalah kurang pendengaran semenjak kanak-kanak
- Anda pernah menggunakan ubat toksik kepada telinga atau atau terdedah kepada pencemaran bunyi rekreasi*
- Anda mempunyai sejarah penyakit berkaitan telinga yang mengganggu pendengaran seperti sejarah pembedahan telinga, Meniere's disease dan cholesteatoma
- Anda mengidap penyakit kencing manis atau hiperlipidemia

PROSEDUR-PROSEDUR KAJIAN

Sekiranya anda setuju menyertai kajian ini, anda akan diminta memberi maklumat tentang data dermografi anda, sejarah perubatan, sejarah pembedahan, sejarah merokok dan ubat yang anda sedang ambil. Anda juga akan diperiksa telinga menggunakan alat otoskopi dan mikroskop. Jika anda didapati sesuai, anda akan dimasukkan ke dalam kajian ini.

Kemudian andaakan melalui ujian *extended high frequency pure tone audiometry* atau ujian audiometri nada tulen berfrekuensi tinggi tambahan. Ujian ini amat selamat dan hanya memerlukan pesakit berada di dalam kabin kedap bunyi dan memakai *headphone*. Bunyi 'tut' akan dibunyikan bagi setiap frekuensi yang diuji. Ujian ini memerlukan pesakit memberi respon kepada nada tulen yang didengar melalui *headphone* dengan menekan butang yang diberikan dan melepaskan butang apabila bunyi hilang. Kemudian ujian ini akan diulang bagi ujian 'bone conduction' pula. Hasil ujian akan dicatatkan di dalam borang audiogram di dalam bentuk graf. Ujian ini mengambil masa lebih kurang satu jam.

RISIKO

Extended high frequency pure tone audiometry atau ujian audiometri nada tulen berfrekuensi tinggi tambahan adalah ujian bukan invasif dan bertujuan untuk menilai tahap pendengaran anda. Anda mungkin mengalami sedikit ketidakselesaan dengan *headphone* yang digunakan. Walau bagaimanapun, kajian ini tidak mempunyai risiko dan kesan sampingan.

Sila maklumkan kepada kakitangan kajian sekiranya anda menghadapi sebarang masalah atau mempunyai sebarang maklumat penting yang mungkin mengubah persetujuan anda untuk terus menyertai kajian ini.

MELAPORKAN PENGALAMAN KESIHATAN (Jika Kajian Melibatkan Kesihatan SAHAJA)

Jika anda mengalami apa-apa kecederaan, kesan buruk, atau apa-apa pengalaman kesihatan yang luarbiasa semasa kajian ini, pastikan anda memberitahu jururawat atau Dr Norsyamira Aida Bt Mohamad Umbaik [No. Pendaftaran Penuh Majlis Perubatan Malaysia: 50539] di talian +60129634731 secepat mungkin. Anda boleh membuat panggilan pada bila-bila masa, siang atau malam, untuk melaporkan pengalaman sedemikian.

PENYERTAAN DALAM KAJIAN

Penyertaan anda dalam kajian ini adalah secara sukarela. Anda berhak menolak untuk menyertai kajian ini atau menamatkan penyertaan anda pada bila-bila masa, tanpa sebarang kehilangan manfaat yang sepatutnya anda perolehi.

Penyertaan anda juga mungkin boleh diberhentikan oleh kakitangan kajian ini tanpa persetujuan anda sekiranya anda didapati tidak sesuai untuk meneruskan kajian ini berdasarkan protokol kajian. Kakitangan kajian akan memaklumkan anda sekiranya anda perlu diberhentikan dari menyertai kajian ini.

MANFAAT YANG MUNGKIN [Manfaat terhadap Individu, Masyarakat, Universiti]

Prosedur kajian ini akan diberikan kepada anda tanpa kos. Anda akan diterangkan maklumat tentang kesihatan pendengaran anda daripada pemeriksaan yang dilakukan dalam kajian ini. Anda mendapat faedah daripada ujian saringan pendengaran yang akan dijalankan dengan mengetahui tahap pendengaran anda yang terkini. Jika masalah kurang pendengaran dikesan semasa ujian dilakukan, maka peserta akan dirujuk kepada Klinik Pakar Otorinolaringology untuk konsultasi dan rawatan susulan. Hasil atau maklumat kajian ini juga diharapkan dapat memberi manfaat kepada pesakit-pesakit lain pada masa hadapan.

PERSOALAN

Sekiranya anda mempunyai sebarang soalan mengenai prosedur kajian ini atau hak-hak anda, sila hubungi;

Dr Norsyamira Aida Bt Mohamad Umbaik, No. MMC 50539
Jabatan Otorinolaringologi, Pembedahan Kepala dan Leher
Pusat Pengajian Sains Perubatan
USM Kampus Kesihatan
+60129634731

Sekiranya anda mempunyai sebarang soalan berkaitan kelulusan Etika atau sebarang pertanyaan dan masalah berkaitan kajian ini, sila hubungi;

En. Mohd Bazlan Hafidz Mukrim
Setiausaha Jawatankuasa Etika Penyelidikan (Manusia) USM
Bahagian Penyelidikan dan Inovasi (P&I)
USM Kampus Kesihatan.
No. Tel: 09-767 2354 / 09-767 2362
Email : bazlan@usm.my or jepem@usm.my

KERAHSIAAN

Maklumat yang anda berikan akan dirahsiakan oleh kakitangan kajian. Ianya tidak akan dedahkan secara umum melainkan jika ia dikehendaki oleh undang-undang.

Data yang diperolehi dari kajian ini tidak akan mengenalpasti anda secara perseorangan. Hasil kajian mungkin akan diterbitkan untuk tujuan perkongsian ilmu.

Semua borang kajian dan data yang anda berikan termasuk rekod perubatan yang asal mungkin akan disemak oleh pihak penyelidik, Lembaga Etika kajian ini dan pihak berkuasa regulatori bagi tujuan mengesahkan prosedur dan/atau data kajian klinikal. Maklumat anda akan disimpan dalam komputer dan hanya kakitangan kajian yang dibolehkan sahaja dibenarkan untuk mendapatkan dan memproses data tersebut.

Dengan menandatangani borang persetujuan ini, anda membenarkan penelitian rekod, penyimpanan maklumat dan pemprosesan data seperti yang dihuraikan di atas.

TANDATANGAN

Untuk dimasukkan ke dalam kajian ini, anda atau wakil sah anda mesti menandatangani serta mencatatkan tarikh halaman tandatangan (Lihat contoh Borang Keizinan Peserta di LAMPIRAN S atau LAMPIRAN P).

Borang Keizinan Peserta
(Halaman Tandatangan)

Tajuk Kajian: Pengesanan masalah kurang pendengaran jenis sensorineural frekuensi tinggi di kalangan staf hospital yangterdedah kepada bunyi berterusan menggunakan ujian *extended high frequency pure tone audiometer* atau ujian audiometri nada tulen berfrekuensi tinggi tambahan.

Nama penyelidik : Dr Norsyamira Aida Bt Mohamad Umbaik,MMC 50539(ORL-HNS)

Penyelia : Assoc Prof Irfan Bin Mohamad, MMC (ORL-HNS)

Penyelia : Assoc Prof Rosdan B Salim, MMC 30604 (ORL-HNS)

Penyelia : Dr Mohd Nazri Shafei, MMC 34454 (Dept Community Health)

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini. Dengan menandatangani mukasurat ini, saya mengesahkan yang berikut:

- Saya telah membaca semua maklumat dalam Borang Maklumat dan Keizinan Pesakit ini termasuk apa-apa maklumat berkaitan risiko yang ada dalam kajian dan saya telah pun diberi masa yang mencukupi untuk mempertimbangkan maklumat tersebut.
- Semua soalan-soalan saya telah dijawab dengan memuaskan.
- Saya, secara sukarela, bersetuju menyertai kajian penyelidikan ini, mematuhi segala prosedur kajian dan memberi maklumat yang diperlukan kepada doktor, para jururawat dan juga kakitangan lain yang berkaitan apabila diminta.
- Saya boleh menamatkan penyertaan saya dalam kajian ini pada bila-bila masa.
- Saya telah pun menerima satu salinan Borang Maklumat dan Keizinan Peserta untuk simpanan peribadi saya.

_____
Nama Peserta

_____
No. Kad Pengenalan Peserta

_____ Tandatangan Peserta atau Wakil Sah	_____ Tarikh (dd/MM/yy) (Masa jika perlu)
_____ Nama & Tandatangan Individu yang Mengendalikan Perbincangan Keizinan	_____ Tarikh (dd/MM/yy)
_____ Nama Saksi dan Tandatangan	_____ Tarikh (dd/MM/y

Nota: i) Semua peserta yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

Borang Keizinan bagi Penerbitan Bahan yang berkaitan dengan Peserta Kajian
(Halaman Tandatangan)

Tajuk Kajian: Pengesanan masalah kurang pendengaran jenis sensorineural frekuensi tinggi di kalangan staf hospital yangterdedah kepada bunyi berterusan menggunakan ujian *extended high frequency pure tone audiometer* atau ujian audiometri nada tulen berfrekuensi tinggi tambahan.

Nama penyelidik : Dr Norsyamira Aida Bt Mohamad Umbaik,MMC 50539(ORL-HNS)

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Penyelia : Assoc Prof Rosdan B Salim, MMC 30604 (ORL-HNS)

Penyelia : Dr Mohd Nazri Shafei, MMC 34454 (Dept Community Health)

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini.
Dengan menandatangani mukasurat ini, saya memahami yang berikut:

- Bahan yang akan diterbitkan tanpa dilampirkan dengan nama saya dan setiap percubaan yang akan dibuat untuk memastikan ketanpanamaan saya. Saya memahami, walaubagaimanapun, ketanpanamaan yang sempurna tidak dapat dijamin. Kemungkinan sesiapa yang menjaga saya di hospital atau saudara dapat mengenali saya.
- Bahan yang akan diterbitkan dalam penerbitan mingguan/bulanan/dwibulanan/suku tahunan/dwi tahunan merupakan satu penyebaran yang luas dan tersebar ke seluruh dunia. Kebanyakan penerbitan ini akan tersebar kepada doktor-doktor dan juga bukan doktor termasuk ahli sains dan ahli jurnal.
- Bahan tersebut juga akan dilampirkan pada laman web jurnal di seluruh dunia. Sesetengah laman web ini bebas dikunjungi oleh semua orang.
- Bahan tersebut juga akan digunakan sebagai penerbitan tempatan dan disampaikan oleh ramai doktor dan ahli sains di seluruh dunia.
- Bahan tersebut juga akan digunakan sebagai penerbitan buku oleh penerbit jurnal.
- Bahan tersebut tidak akan digunakan untuk pengiklanan ataupun bahan untuk membungkus.

Saya juga memberi keizinan bahawa bahan tersebut boleh digunakan sebagai penerbitan lain yang diminta oleh penerbit dengan kriteria berikut:

- Bahan tersebut tidak akan digunakan untuk pengiklanan atau bahan untuk membungkus.
- Bahan tersebut tidak akan digunakan di luar konteks – contohnya: Gambar tidak akan digunakan untuk menggambarkan sesuatu artikel yang tidak berkaitan dengan subjek dalam foto tersebut.

_____ _____

Nama Peserta

_____ _____ _____

No. Kad Pengenalan Peserta T/tangan Peserta Tarikh (dd/MM/yy)

_____ _____

Nama & Tandatangan Individuyang Mengendalikan Perbincangan Keizinan Tarikh (dd/MM/yy)

Nota: i) Semua peserta yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

RESEARCH INFORMATION

Research Title	: Detection of high frequency hearing loss among hospital staff exposed to occupational noise using extended high frequency pure tone audiometry
Principal investigator	: Dr Norsyamira Aida Bt Mohamad Umbaik,MMC 50539(ORL-HNS)
Main Supervisor	: Assoc Prof Irfan Bin Mohamad, MMC (ORL-HNS)
Co-supervisor	: Assoc Prof Rosdan B Salim, MMC 30604 (ORL-HNS)
Co-supervisor	: Dr Mohd Nazri Shafei, MMC 34454 (Dept Community Health)

INTRODUCTION

You are invited to take part voluntarily in a research study of detection of high frequency sensorineural hearing loss in hospital staff exposed to occupational noise using extended high frequency pure tone audiometry. Sensorineural hearing loss is one of the complications of noise exposure which affect higher frequency first and can normally be detected using conventional pure tone audiometer. Nowadays with the advancement in technology, sensorineural hearing loss can be detected much earlier at higher frequency using extended high frequency pure tone audiometer. This is a safe study and you are required to wear headphone. Pure tone audiometry requires you respond to the tone given via the headphone by pressing the button given. This test is expected to complete for 1 hour.

Before agreeing to participate in this research study, it is important that you read and understand this form. If you participate, you will received a copy of this form to keep for your records.

There will be about 140 participants will be participating in this study.

PURPOSE OF THE STUDY

The purpose of this study is to determine the prevalence of extended frequency hearing loss in hospital staff exposed to occupational noise. This study will also detect early sensorineural hearing loss in hospital staff exposed to occupational noise. If the hearing loss is detected, participant will be refered to Otorhinolaryngology clinic for further management and follow up.

PARTICIPANTS CRITERIA

The doctor in charge of this study or a member of the study staff has discussed with you the requirements for participation in this study. It is important that you are completely truthful with the doctor and staff about your health history. You should not participate in this study if you do not meet all qualifications.

Some of the requirements to be in this study are:

- You are working in Unit Penyediaan Alat Steril (UPAS), Kitchen Unit or Dobby Unit (for participant)
- You are working at Opthalmology, Psychiatry or Dermatology specialist clinic (for control)
- Working at least 6 months or above in the working area stated above
- You must be age of 60 years old or above

You cannot participate in this study if:

- Previous or active ear infection
- Previous history of intake of systemic ototoxic medications or exposure to recreational noise*
- First degree relatives with childhood hearing loss
- Previous history of otological disorders that affects hearing such as history of ontological surgery, Menière disease or cholesteatoma
- Medical illness: Diabetes Mellitus or hyperlipidemia

STUDY PROCEDURES

If you agreed to participate in this study, you will be asked to provide information about your demographic data, past medical history, past surgical history, smoking history and medicines that you are taking. You will undergo a thorough otoscopy and microscopic ear examination. If you are deemed suitable, you will be recruited in this study.

You will undergo extended high frequency pure tone audiometry for about 1 hour procedure. During the test, participant will be seated in the sound proof cabin, in comfortable position. The headphone will be applied to the ear for air conduction threshold test. Participant is requested to response to the sound “tut” heard during the test by pressing the response button. Participant is to release the response button once the sound “tut” disappeared.The bone conductor will be applied over the mastoid bone for bone conduction test, repeat step 3. The audiogram results will be documented and saved.

RISKS

Extended high frequency pure tone audiometry is a non invasive test to assess your hearing level. You may experience discomfort with the headphone. However, there is no reported risk or side effect of the procedure.

If any important new information is found during this study that may affect you wanting to continue to be part of this study, you will be told about it right away.

REPORTING HEALTH EXPERIENCES.

If you have any injury, bad effect, or any other unusual health experience during this study, make sure that you immediately tell the nurse or Dr Norsyamira Aida Bt Mohamad Umbaik [MMC Registration No. 50539] at +60129634731. You can call at anytime, day or night, to report such health experiences.

PARTICIPATION IN THE STUDY

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop participation in the study at anytime, without a penalty or loss of benefits to which you are otherwise entitled. Your participation also may be stopped by the study doctor or sponsor without your consent.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]

Study procedures will be provided at no cost to you. You will be informed regarding the result of the hearing test done during the study. You will benefit from the screening by able to know the current status of your hearing. If hearing loss is detected, you will be referred to Otorhinolaryngology clinic for futher management and follow up. We hope that the outcome and information regarding this research will beneficial to future patients.

QUESTIONS

If you have any question about this study or your rights, please contact;

Dr Norsyamira Aida Bt Mohamad Umbaik [MMC Registration No. 50539]
Department of Otorhinolaryngology, Head and Neck Surgery
School of Medical Sciences
USM Health Campus
+60129634731

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Division of Research & Innovation (R&I)
USM Health Campus
Tel. No. : 09-767 2354 / 09-767 2362
Email : bazlan@usm.myor jepem@usm.my

CONFIDENTIALITY

Your information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Your information may be held and processed on a computer. Only research team members are authorized to access your information.

By signing this consent form, you authorize the record review, information storage and data process described above.

SIGNATURES

To be entered into the study, you or a legal representative must sign and data the signature page [ATTACHMENT S or ATTACHMENT G (for genetic sample only) or ATTACHMENT P]

ATTACHMENT S

Participant Information and Consent Form (Signature Page)

Research Title	: Detection of high frequency hearing loss among hospital staff exposed to occupational noise using extended high frequency pure tone audiometry
Principal investigator	: Dr Norsyamira Aida Bt Mohamad Umbaik,MMC 50539(ORL-HNS)
Main Supervisor	: Assoc Prof Irfan Bin Mohamad, MMC (ORL-HNS)
Co-supervisor	: Assoc Prof Rosdan B Salim, MMC 30604 (ORL-HNS)
Co-supervisor	: Dr Mohd Nazri Shafei, MMC 34454 (Dept Community Health)

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form including any information regarding the risk in this study and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

_____
Participant Name

_____
Participant I.C No

_____ _____
Signature of Participant or Legal Representative Date (dd/MM/yy)

_____
Name of Individual
Conducting Consent Discussion

_____ _____
Signature of Individual Date (dd/MM/yy)
Conducting Consent Discussion

_____ _____
Name & Signature of Witness Date (dd/MM/yy)

Note: i) All participants who are involved in this study will not be covered by insurance.

Participant's Material Publication Consent Form
Signature Page

Research Title	: Detection of high frequency hearing loss among hospital staff exposed to occupational noise using extended high frequency pure tone audiometry
Principal investigator	: Dr Norsyamira Aida Bt Mohamad Umbaik,MMC 50539(ORL-HNS)
Main Supervisor	: Assoc Prof Irfan Bin Mohamad, MMC (ORL-HNS)
Co-supervisor	: Assoc Prof Rosdan B Salim, MMC 30604 (ORL-HNS)
Co-supervisor	: Dr Mohd Nazri Shafei, MMC 34454 (Dept Community Health)

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By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalist worldwide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors worldwide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
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_____

Participant Name

_____ _____ _____

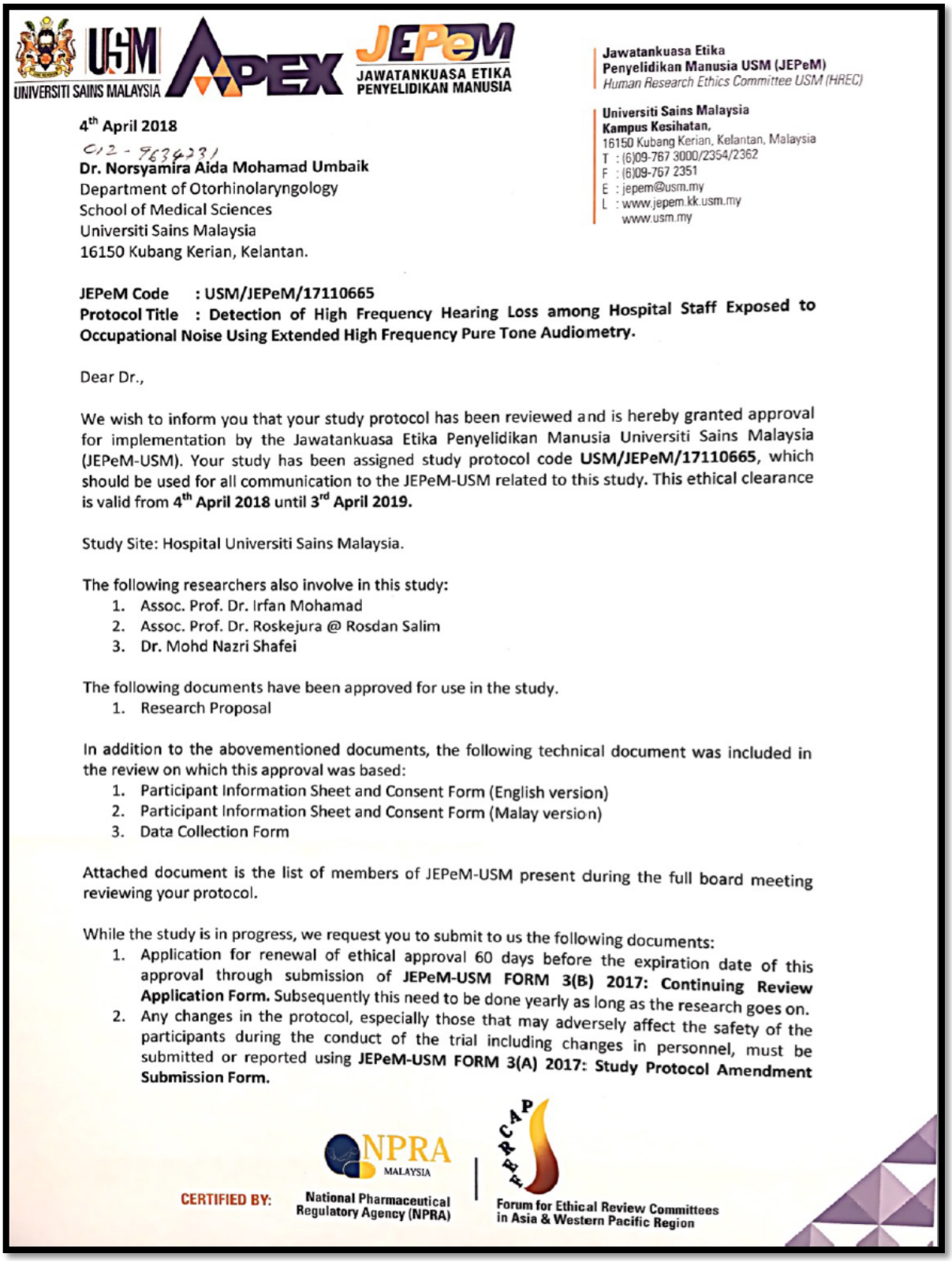
Participant I.C No. Participant's Signature Date (dd/MM/yy)

_____ _____

Name and Signature of Individual Conducting Consent Discussion Date (dd/MM/yy)

Note: i) All participants who are involved in this study will not be covered by insurance.

2.3 Ethical approval letter



UNIVERSITI SAINS MALAYSIA

JEPeM JAWATANKUASA ETIKA PENYELIDIKAN MANUSIA

Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)
Human Research Ethics Committee USM (HREC)

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4th April 2018

C12 - 9634231

Dr. Norsyamira Aida Mohamad Umbaik
Department of Otorhinolaryngology
School of Medical Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

JEPeM Code : USM/JEPeM/17110665
Protocol Title : Detection of High Frequency Hearing Loss among Hospital Staff Exposed to Occupational Noise Using Extended High Frequency Pure Tone Audiometry.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/17110665**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **4th April 2018** until **3rd April 2019.**

Study Site: Hospital Universiti Sains Malaysia.

The following researchers also involve in this study:

1. Assoc. Prof. Dr. Irfan Mohamad
2. Assoc. Prof. Dr. Roskejura @ Rosdan Salim
3. Dr. Mohd Nazri Shafei

The following documents have been approved for use in the study.

1. Research Proposal

In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:

1. Participant Information Sheet and Consent Form (English version)
2. Participant Information Sheet and Consent Form (Malay version)
3. Data Collection Form

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:

1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2017: Continuing Review Application Form.** Subsequently this need to be done yearly as long as the research goes on.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2017: Study Protocol Amendment Submission Form.**

CERTIFIED BY: NPRA MALAYSIA — National Pharmaceutical Regulatory Agency (NPRA)

PERCAP — Forum for Ethical Review Committees in Asia & Western Pacific Region

3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2017: Study Protocol Amendment Submission Form.**
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2017: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2017.**
6. Any event which may have ethical significance.
7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2017: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website: **www.jepem.kk.usm.my**

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Thank you.

"ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

PROF. DR. HANS AMIN VAN ROSTENBERGHE
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia

UNIVERSITI SAINS MALAYSIA

JAWATANKUASA ETIKA PENYELIDIKAN MANUSIA

Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM)
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Date of meeting : 31st January 2018
Venue : Meeting Room, Division of Research & Innovation, USM Kampus Kesihatan.
Time : 9.00 a.m – 2.00 p.m
Meeting No : 379

Members of Committee of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia who reviewed the protocol/documents are as follows:

Member (Title and Name)		Occupation (Designation)	Male/ Female (M/F)	Tick (✓) if present when above items, were reviewed
Chairperson: Professor Dr. Hans Amin Van Rostenberghe		Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Chairperson)
Deputy Chairperson: Associate Professor Dr. Azlan Husin		Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Deputy Chairperson)
Secretary: Mr. Mohd Bazlan Hafidz Mukrim		Science Officer	M	✓
Members :				
1.	Mr. Harry Mulder	Community Representative	M	✓
2.	Associate Professor Dr. Hamid Jan Jan Mohamed	Lecturer, School of Health Sciences	M	✓
3.	Associate Professor Dr. Haslina Taib	Lecturer, School of Dental Sciences	F	✓
4.	Professor Dr. Nik Hazlina Nik Hussain	Lecturer, School of Medical Sciences	F	✓
5.	Associate Professor Dr. Nor Azwany Yaacob	Lecturer, School of Medical Sciences	F	✓
6.	Professor Dr. Nor Hayati Othman	Lecturer, School of Medical Sciences	F	✓
7.	Associate Professor Oleksandr Krasilshchikov	Lecturer, School of Health Sciences	M	✓
8.	Assoc. Prof. Siti Hawa Ali	Lecturer, School of Health Sciences	F	✓
9.	Mrs. Zawiah Abu Bakar	Community Representative	F	✓

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

PROFESSOR DR. HANS AMIN VAN ROSTENBERGHE
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia), JEPeM
Universiti Sains Malaysia

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Chapter 3:

MANUSCRIPT

3.1 Title page

Detection of high-frequency hearing loss among hospital staffs exposed to occupational noise using extended high-frequency pure tone audiometry

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3.2 Abstract

Objectives: To determine the prevalence of extended high-frequency (EHF) hearing loss, the association between noise exposure and EHF hearing loss and its associated factors among hospital staff working in noisy environment.

Methods: This was a comparative cross-sectional study involving 140 hospital staffs (70 participants from noise-exposed group and 70 participants from non-noise exposed group). The hearing was tested using conventional and EHF pure tone audiometry (PTA) up to 16 kHz. The prevalence of EHF hearing loss was calculated. The chi-squares tests were performed to determine the association between noise exposure and conventional PTA and EHF PTA hearing loss. The chi-square test was also used to determine the association between duration of noise exposure and EHF hearing loss. Multiple logistic regression analysis was performed to determine the factors associated with EHF hearing loss. The *p*-value of less than 0.05 was considered as statistically significant.

Results: The prevalence of abnormal conventional PTA in noise-exposed hospital staff was 22.9%, while the EHF hearing loss was 81.4%. Meanwhile, among the control group the abnormal conventional PTA was seen in 11 participants (15.7%), with 53 participants (75.7%) have an abnormal EHF PTA. We found that there was no significant association between noise exposure and EHF hearing loss. However, there was a significant association between duration of noise exposure and EHF hearing loss. Age was a significant factor for an exposed participants to EHF hearing loss, while gender, smoking and noise exposure were not.

Conclusion: The present study shows that EHF PTA gives no additional benefit compared with conventional PTA in detecting noise-induced hearing loss. However, EHF PTA can be used as an adjunct to conventional PTA for early detection of hearing loss among noise-exposed workers.

KeywordsNoise-induced hearing loss; High-frequency hearing loss; Hospital staff

3.3 Introduction

Hospital as a working place has faced a technology advancement which has improved the productivity and time of doing a particular task. With increasing of the national population, such advancement has helped in managing high hospital demand in patient care on a daily basis. However, like in other work place, such technology advancement also brings along their by-product, which is noise. There are lists of occupational hazards, but none of it is so common and widespread likenoise pollution. Noise is one of the environmental and occupational hazard listed in the Malaysian Factories and Machinery (Noise Exposure) Regulations in 1989 [1]. The regulation stipulates the permissible exposure limit (PEL)of not exceeding equivalent continuous sound level of 90 dB (A) or not exceeding the limits specified in the First Schedule or the daily noise dose of unity. It also stipulates that no employee shall be exposed to noise level exceeding 115 dB (A) at any time [1]. The cut-off safe PEL taken by the regulations is below 85 dB (A). The new Malaysian Occupational Safety and Health (Noise Exposure) Regulations in 2019 which was gazette in March 2019 and will come to operation in June 2019, has revoked the Factories and Machinery (Noise Exposure) Regulations in 1989. However, we are taking the 1989 regulation as our reference since this study was performed and completed prior to the operation of the 2019 regulations.

The magnitude of noise-induced hearing loss (NIHL) is estimated to account for 16% of hearing impairment worldwide and seems to be among the five most frequent occupational diseases [2]. In Malaysia, there was a marked increase in confirmed cases of Occupational Noise-Related Hearing Disorder (including NIHL, hearing impairment and permanent standard threshold shift) reported by the Department of Occupational Safety and Health (DOSH) which was 1563 cases in 2015 and 2478 cases in 2017 [3].

Hearing loss is classified into three types which are conductive, sensorineural and mixed hearing loss (a combination of conductive and sensorineural element). Disease affecting the external or middle ear may cause a conductive hearing loss. PTA of a conductive hearing loss individual will show an air-bone gap of 10 dB or more with normal bone conductive threshold [4]. Meanwhile, diseases affecting cochlear or a retro-cochlear lesion will cause sensorineural hearing loss, which include presbycusis (commonly seen in elderly), post viral or bacterial labyrinthitis,noise-induced hearing loss, or tumor such as vestibular schwannoma. PTA of a sensorineural type will show an air-bone gap of 10 dB or less with an average bone conduction threshold greater than 25 dB[4].Decibel (dB) is a unit of intensity of loudness and commonly used to describe the degree of hearing loss. The degree of hearing loss can be classified into normal (0-24 dB), mild (25-40 dB), moderate (41-55 dB), moderately severe (56-70 dB), severe (71-90 dB) and profound hearing loss (more than 91 dB) [5].

NIHL refers to auditory acuity reduction secondary to noise exposure [6]. The reduction can be further divided into temporary threshold shift (TTS) or permanent threshold shift (PTS). TTS is a temporary hearing loss associated with noise exposure and the affected person may regain back his or her normal hearing threshold once the noise element is removed. While in PTS, there is a permanent hearing loss even after removal of the noise exposure. PTS may occur after episode of multiple TTS or after a single exposure to aloud noise. The single exposure to an intense sound leads to an immediate hearing loss is referred as ‘acoustic trauma’ [6].

The standard subjective hearing assessment in clinical practice is the conventional PTA test evaluating the hearing loss at a frequency of 250 Hz to 8 kHz.

Thecharacteristicnotched audiometric configuration in conventional PTA associated with NIHL is well-known, whereby there isa maximum reduction in the range of 3-6 kHz with immediate recovery at 8 kHz [6]. However, this notch appears after chronic repeated exposure to occupational noise and may not be detected in an early stage of exposure. It is well understood that the higher frequency tone is affected first insensorineural type of hearing loss. The theory behind this is the association of cochleotopic gradient of susceptibility is expressed functionally as a high-frequency hearing loss. As the cochlear damage becomes more extensive, this effect will progressively extends to include lower frequencies [6]. There are increasing evidences on EHFPTA which allows to detect the earliest changes of high-frequency hearing loss mentioned above, which cannot be detected by the conventional PTA[7-9].

Due to the raising interest in EHF PTA, we conducted this studywith the objectives of todetermine the prevalence of EHF hearing loss, the association between noise exposure and EHF hearing loss and its associated factors among hospital staff working in noisy environment.

3.4.Materials and Methods

3.4.1 Study design and Participants

This was a comparative cross-sectional study conducted in Hospital Universiti Sains Malaysia, Health Campus Kubang Kerian, Kelantan, Malaysia from 4th April 2018 until 3rd April 2019.

Based on two-proportion formula using PS software[10], the largest and feasible required sample sizewas 140 hospital staffs, with ratio of one-to-one (70 staffs from noise-exposed working area and 70 staffs as control). The noise-exposed staffs were working in hospital kitchen, dobby unit and central sterile services department (CSSD) with environmental noise level of higher than 85 dB (A) for 8 hours a day or more than 40 hours per week (Table 1). While the non-exposed group were among staffs working in the specialist clinics (Ophthalmology, Psychiatry and Medical Specialist Clinic) with noise exposure of less than 85 dB (A) (Table 1).

The participants were selected using a convenience sampling method based on inclusion and exclusion criteria. The staffs whose age of 60 years old and belowand working for at least six months in the selected working area were included in the study. Whereas, the staffs with previous or active ear infection, previous history of taking systemic or local ototoxic medications (including chemotherapy drugs, anti-tuberculosis drugs and gentamicin ear drop) or being exposed to recreational noise, has first degree relatives with childhood hearing loss, previous history of otological disorders that affects hearing such as history of otological surgery, Menière disease or cholesteatoma and has medical illness such as diabetes mellitus and hyperlipidemia were excluded from the study. Written consent (in Bahasa Malaysia) was obtained from each participant.

3.4.2 Ethical issues consideration

This study was approved by the Human Research Ethics Committee USM (USM/JEPeM/17110665). The study was performed according to the Helsinki Declaration. Confidentiality of the data was maintained at the highest level as possible that only the researchers has access to the data. Every participant was kept anonymous using a specific identification number.

3.4.3 Instruments and procedure

Consented participants were required to fill up a proforma, which consisted of the demographic data, past medical and surgical history as well as, smoking and medication history. Otoscopic examination was performed using the Welch Allyn otoscope (Model 25020) from the United States of America to examine the external ear and tympanic membrane. This examination specifically done to detectpresence of impacted ear wax, ear discharge including pus or blood, aural polyp, tumour or other occlusion in the external ear canal. Ear toileting under microscope using Zeiss OPMI Sensera/S7 microscope from Germany was done for participants with ear wax occlusion. Participants with abnormal findings other than ear wax will be withdrawn from the study and referred to the Otorhinolaryngology-Head & Neck Surgery (ORL-HNS) clinic for further management.

Participants will then undergo conventional audiometry followed by EHF PTA until 16 kHz frequency. Diagnostic Audiometer Madsen Astera AD226 from Denmark with supra-aural headphoneswas used to test for conventional and EHFPTA. The modified down-10 and up-5 methodology was carried out during the test[11]. Other specific advice to the participant was to refrain from chewing to avoid interference with the audiometric evaluation. The participants were asked to press the button once they heard a sound.The

EHF PTA evaluation was done in otorhinolaryngology clinic in a sound proof cabin by Industrial Acoustic Company model 800a (from the United Kingdom) which was placed in a sound-treated room. All participants were interviewed, examined and clinically assessed by the researchers. The audiometric evaluations were done by two trained audiology technicians.

In the present study, the hearing levels of conventional and EHF PTA were categorized into mild, moderate, severe and profound hearing loss based on WHO grades of hearing impairment for adult [12]. In the noise-exposed group, the audiometric test was done at fourteen hours of quiet period intervals to let the cochlea recover from the TTS[1]. Participants were thus tested after9 o'clock in the morning during the working days before going to work on the audiometric test day. This audiometric test lasted for about twenty minutes to 45 minutes for each participant.

3.4.4 Statistical analyses

The data were entered and analyzed using theStatistical Package for Social Science (SPSS) version 24. For numerical variables, mean (SD) or median (IqR) were presented based on their normality distributions. Meanwhile, for categorical variables, frequencies and percentages were calculated. The prevalence of EHF hearing loss was calculated to determine the burden of the problem. The association between the noise exposure and PTA/EHF PTA was done using chi-square test. The association between duration of noise exposure and hearing loss detected using EHF PTA was also performed using chi-square test.

The factors associated with EHF hearing loss weredetermined by multiple logistic regression (MLogR) analysis. Firstly, simple logistic regression (SLogR) was performed to

select the preliminary variables that have an association with EHF hearing loss (as dependent variable). The independent variables were the age of participants, gender and smoking status. Variables with *p*-value of less than 0.25 from SLogR were selected for MLogR. By comparing model using backward Likelihood Ratio and forward Likelihood Ratio methods, the preliminary main effect model was obtained. Hosmer-Lemeshow goodness of fit test, the classification table and area under receiver operation characteristics (ROC) curve were performed to test for fitness of the model. The Hosmer-Lemeshow goodness of fit test with the *p*-value more than 0.05 (which was not significant) was selected, therefore the model was fit. Classification table showed more than 70% was considered a good model. The final model was presented with adjusted odds ratio (AOR) and 95% confidence interval (CI), Wald statistics and *p*-value. The criterion for statistical significance was set at *p*-value of less than 0.05.

3.5 Result

The ranges of ambient noise level in each workplace are showed in Table 1. The age of the participants is ranged from 22 to 58 years old with the mean age of 42.8 years old. The mean age for noise-exposed group and non-noise exposed group were 41.87 and 43.75 years old respectively (Table 2). Majority of the participants in the study was female (65%) and Malay (95%). The minimum years of working for both groups are 6 months. The maximum working duration is 35 years (mean 10.41) and 30 years (mean 8.27), for noise-exposed group and non-noise exposed group respectively (Table 2).

Table 1: Range of ambient noise level in each workplace

Workplace	Range of ambient noise level dB (A)
Central sterile services department (CSSD)	87 to 99
Kitchen	80 to 98
Dobby	88 to 100
Medical Specialist clinic	65 to 77
Ophthalmology clinic	66 to 78
Psychiatry clinic	60 to 70

dB (A) : decibels (Ambient)

Table 2: Sociodemographic profiles of the participants (n= 140)

	Noise exposed hospital staff (n=70)	Non noise-exposed hospital staff (n= 70)
Gender		
Male	36 (51.4)	13 (18.6)
Female	34 (48.6)	57 (81.4)
Ethnicity		
Malay	69 (98.6)	64 (91.4)
Chinese	1 (1.4)	5 (7.2)
Indian	0 (0.0)	1 (1.4)
Smoking status		
Smoking	20 (28.6)	4 (5.7)
Not smoking	50 (71.4)	66 (94.3)

Among the noise-exposed group, 12 (17.1%) of them found to have reduced hearing symptoms. Meanwhile, among the non-noise exposed group, only 1 (1.4%) of themfound to have reduced hearing symptoms. The proportion of abnormal conventional PTA in noise-exposed hospital staff was 22.9%, while the EHFhearing loss was 81.4% (Table 3 and 4). This finding was also seen in control group whereby the abnormal conventional PTA was seen in 11 participants (15.7%), with 53 participants (75.7%) have an abnormal EHF PTA.

Table 3:Association between the noise exposure and PTA findings using chi-square test (n= 140)

Workplace	PTA findings		X^2-statistics[a]	*p*-value
	Normal n(%)	Abnormal n(%)	(df)	
Noise-exposed	54 (77.1)	16 (22.9)	1.147 (1)	0.284
Non noise-exposed	59 (84.3)	11(15.7)		

Pearson's chi square

PTA: pure tone audiometry

Table 4:Association between the noise exposure and EHF hearing loss using chi-square test (n= 140)

Workplace	EHF PTA findings		X^2-statistics[a]	*p*-value
	Normal n(%)	Abnormal n(%)	(df)	
Noise-exposed	13 (18.6)	57 (81.4)	0.679 (1)	0.410
Non noise-exposed	17 (24.3)	53 (75.7)		

Pearson's chi-square

EHF PTA: extended high-frequency pure tone audiometry

From all participants, 40 (57.1%) from noise-exposed group and 53 (75.7%) from non-noise exposed group are working 10 years and less at their current workplace. 33 participants from noise-exposed group and 24 participants from non-noise-exposed group with normal PTA were selected to look for early detection of hearing loss using EHF PTA. Within the noise-exposed group, 24 participants (72.7%) who are working less than 10 years duration has an abnormal extended frequency PTA,with a significant *p*-value (Table 5).

Table 5: Association between noise exposure and EHF hearing loss among participants working 10 years and less using chi-square test (n= 57)

Workplace	EHF PTA findings		*p*-value
	Normal n(%)	Abnormal n(%)	
Noise	9 (27.3)	24 (72.7)	0.029
Non-noise	14 (58.3)	10 (41.7)	

Pearson's chi-square

EHF PTA: extended high-frequency pure tone audiometry

The MLogR statistic (Table 6) showed that age has a significant association with the EHF hearing loss. A person with an increase of 1 year of age has 1.16 times the odds to have an EHF hearing loss (95% CI: 1.09 to 1.28, p = <0.01) when adjusted for gender, smoking and noise exposure. Gender, smoking and noise exposure however, have no significant association with EHF hearing loss.

Table 6: Multiple logistic regression analysis of age, gender and smoking status with EHF hearing loss

Variables	Cr OR (95% CI)	Adj OR (95% CI)	Wald stat	*p*-value
Age	1.16 (1.09, 1.23)	1.16 (1.09, 1.24)	21.53	<0.01
Gender	1.10 (0.47, 2.60)	1.33 (0.41, 4.38)	0.23	0.635
Smoking	0.47 (0.13, 1.70)	0.40 (0.07, 2.36)	1.01	0.314
Noise exposure	1.41 (0.62, 3.17)	2.01 (0.75, 5.38)	1.93	0.164
	Hosmer and Lemeshow Test [$x^2(8) = 14.223$, $p = 0.076$]			
	Area Under the Curve 0.825			

Note: Significant levels, $p< 0.05$

3.6 Discussion

In this study, we found three important findings which are 1) Overall, EHF PTA has no significant different with conventional PTA in detecting noise-induced hearing loss, 2) EHF PTA is useful in early detection of hearing loss for workers working less than 10 years, and3) Age has a significant association in EHF hearing loss.

The current practice in occupational health for detecting and diagnosing noise-induced hearing loss is by using a conventional PTA. However, there is a raise in awareness regarding the need for early detection of noise-induced hearing loss by using other methods such as otoacoustic emission (OAE), evoked potential technique and extended high-frequency audiometry[13, 14]. In this study, 70 participants from noise-exposed workplace and 70 participants from non-noise-exposed workplace were studied on the association between the noise exposure and detection of EHF hearing loss using EHF PTA.

In this study, the proportion of EHFhearing loss among noise-exposed group is 57 participants (81.4%). This finding was also seen in control group whereby the EHF hearing loss was found in 53 participants (75.7%). However, there was no significant association between them. Our finding is contradicting with studies by Somma *et al.* [15], and Mehrparvar *et al.* [14] who found that the prevalence of EHF hearing loss is higher in the noise-exposed participants compared to control. However, Mehrparva *et al.* has excluded participants age 50 years and above in their study thus eliminating the effect of age in the result. While Somma *et al.* included participants up to 60 years of age but dividing the participants into few age groups, which later showed that the higher prevalence of EHF hearing loss were within the younger age groups compared to older age group.

As our study participants have an almost equal mean age, the effect of age has played an important predictor in this finding of extended PTA, which was proved by multiple logistic regression analysis. This finding also observed by Wiley *et al* whereby they found that older age participants have a higher threshold for EHF audiometry which means higher amplitude needed to actually being heard by the participants[16]. This finding also found by H.O. Ahmed [17] whereby the sensitivity is reducing with an increase of frequency even in the subject less than 40 years old with no noise exposure. Similar findings also found by Macca *et al*. [18]. From the multiple logistic regression analysis, we could see that for each year increase of age, there is 1.16 times the odds for a worker exposed to noise to have an EHF hearing loss. Thus, it is important to reinforce the recommendation for yearly hearing test to be done in the noise-exposed workers especially in workers with hearing complaints [1]. We also should consider the healthy-worker bias effect in this study, whereby there might be rotation of unhealthy workers to the non-noise exposed workplace from the noise-exposed workplace as one of the preventive measures by the employee. This healthy-workers effect might has confounded the result of EHF hearing loss in this study.

The dip at 4kHz finding on conventional PTA was proposed by the hydrodynamic effects to the cochlea which contributes to the vulnerability at the base of the cochlea to noise exposure. These effects include 1) the travelling wave amplitude is greater at the base of the cochlea, 2) the acoustic load is greater at the base, and 3) The basal locus of noise impulse energy was falsely conducted to the cochlea [19]. Extended PTA has successfully detecting ototoxicity from ototoxicity drugs such as cisplatin and aminoglycosides before the effect shown on conventional PTA [20] and the similar pathway of hair cell degeneration in response to noise and aminoglycosides has been suggested [21]. However,

we found that the usage of EHF audiometry has no significant result compared to conventional audiometry. Our findings are similar with Balatsouras *et al.* [22] whereby they explained in the study that the noise effect to the auditory system is a very complicated phenomenon due to the complex structure and function of the cochlea. The detection of hearing loss by EHF PTA thus adds no additional information to conventional PTA.

Schmuziger *et al.* [23] also found the similar results in studying the effect of intense loud sound in a non-professional pop/rock musicians to threshold shift whereby the temporary threshold shift was only detected on conventional audiometry, and not in the extended PTA. Kuronen *et al.* [13] however, found a significant extended frequency hearing loss of temporary threshold shifts in military pilots flying a jet fighter. The differences between these two studies were the amplitude of noise exposure to the military pilots was higher and the military pilots were using the hearing protection and helmets during the noise exposure. These differences may cause the different result seen in these two studies as NIHL is affected by the amplitude of noise exposure and also attenuation of noise by the hearing protection [24].

In the other hand, we found a significant *p*-value when studying on the effectiveness of extended PTA in early detection of extended frequency hearing loss. Our findings are supported by other studies such as Wang *et al.* [25], Somma *et al.* [15], Riga *et al.* [9] and Macca *et al.* [18]. This is especially true for workers who are working 10 years and less. However, Osterhammel [26] found that there is no benefit of extended PTA in early detection of hearing loss as the findings were almost similar with conventional PTA.

The present study has a few limitations which include 1) unable to detect high frequency of 18kHz and 20kHz due to machine limit 2) a longitudinal or prospective study are better to indicate the causal relationship between occupational noise and deterioration of

extended high-frequency threshold, 3) we should take account of other exclusion criteria such as staff riding motorcycle to work which can also adding to the noise exposure and 4) the effect of ‘healthy-worker effect’ bias.

3.7 Conclusion

This study indicate that EHF loss is an age-dependent phenomenon and an EHF PTA has no additive information to conventional PTA when used for monitoring hearing loss for workers of all ages. However, extended PTA is useful in early detection of EHF hearing loss for workers working 10 years and less.

3.8 Acknowledgement

This research was supported by Incentive Grant-in-aid for Postgraduate Studies Development (TIPPS) 2018 from School of Medical Sciences, Universiti Sains Malaysia Health Campus and was given to each of the participants as an honorarium for participation in this study.

3.9 Conflict of interest

Authors declared no conflict of interest in this study.

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3.11 Figures

Figure 1: Welch Allyn otoscope (Model 25020) from the United States of America to examine the external ear canal and tympanic membrane.

Figure 2: Zeiss OPMI Sensera/S7 microscope from Germany

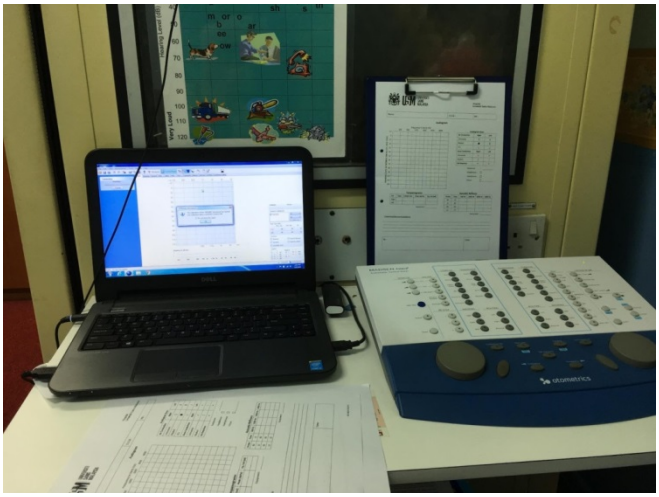

Figure 3: Computerized controlled Diagnostic Audiometer Madsen Astera AD226 from Denmark with supra-aural headphones for conventional and extended pure tone audiometry tests.

Figure 4.1Sound proofcabin by Industrial Acoustic Company model 800a (from the United Kingdom) which was placed in a sound-treated room.

Figure 4.2: Participant sitting in the sound proof cabin with supra-aural headphone ready to be tested for conventional and extended pure tone audiometry once the door is closed.

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Chapter 4:

APPENDICES

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We thank the School of Medical Sciences, Universiti Sains Malaysia for providing financial support for this study via Incentive Grant-in-aid for Postgraduate Studies Development (TIPPS) 2018. Approval for this study was obtained from the Human Ethics Committee of Universiti Sains Malaysia.

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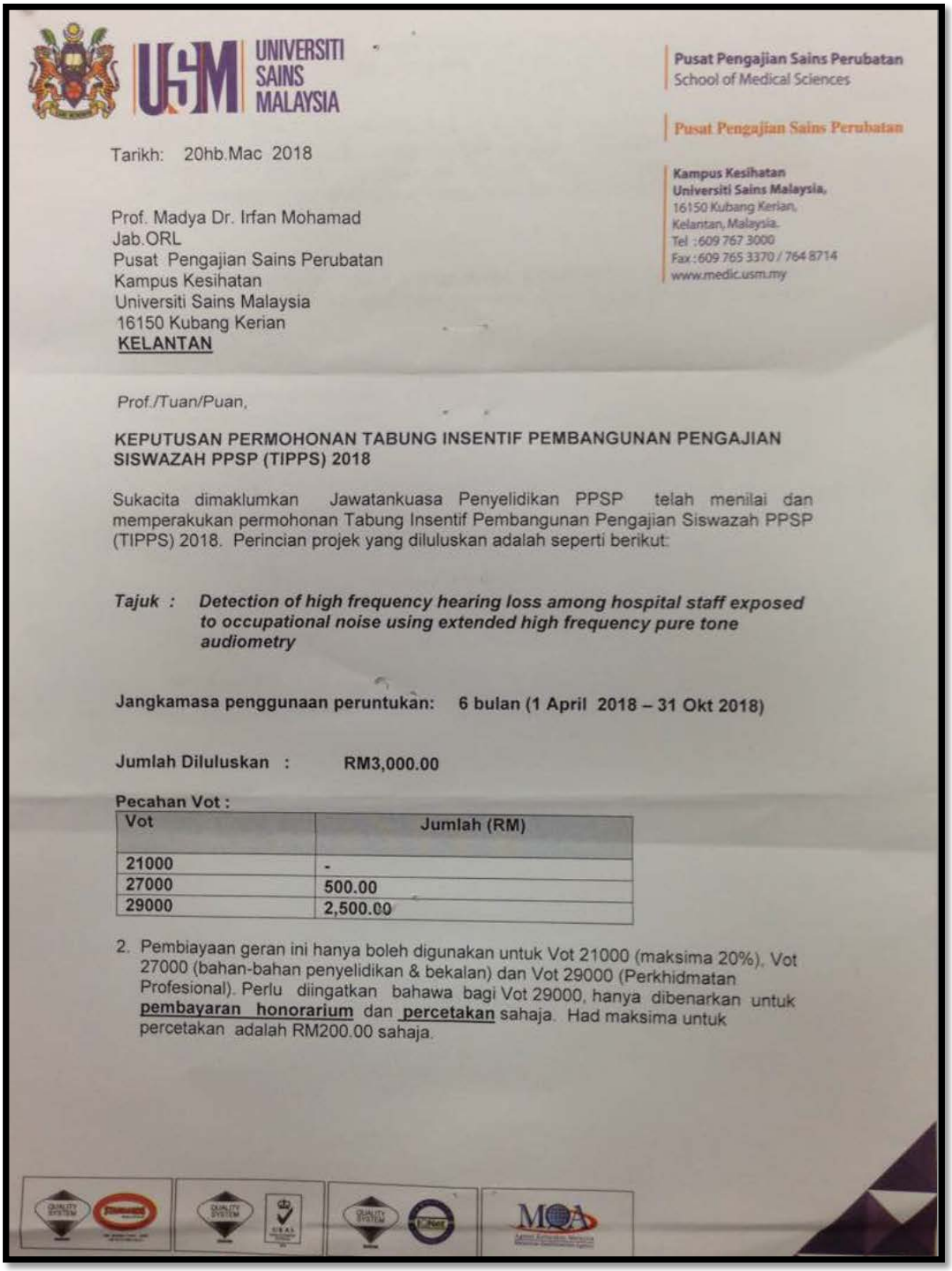

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Prof./Tuan/Puan,

KEPUTUSAN PERMOHONAN TABUNG INSENTIF PEMBANGUNAN PENGAJIAN SISWAZAH PPSP (TIPPS) 2018

Sukacita dimaklumkan Jawatankuasa Penyelidikan PPSP telah menilai dan memperakukan permohonan Tabung Insentif Pembangunan Pengajian Siswazah PPSP (TIPPS) 2018. Perincian projek yang diluluskan adalah seperti berikut:

Tajuk : ***Detection of high frequency hearing loss among hospital staff exposed to occupational noise using extended high frequency pure tone audiometry***

Jangkamasa penggunaan peruntukan: 6 bulan (1 April 2018 – 31 Okt 2018)

Jumlah Diluluskan : RM3,000.00

Pecahan Vot :

Vot	Jumlah (RM)
21000	-
27000	500.00
29000	2,500.00

2. Pembiayaan geran ini hanya boleh digunakan untuk Vot 21000 (maksima 20%), Vot 27000 (bahan-bahan penyelidikan & bekalan) dan Vot 29000 (Perkhidmatan Profesional). Perlu diingatkan bahawa bagi Vot 29000, hanya dibenarkan untuk **pembayaran honorarium** dan **percetakan** sahaja. Had maksima untuk percetakan adalah RM200.00 sahaja.

4.2 ADDITIONAL REFERENCES

References

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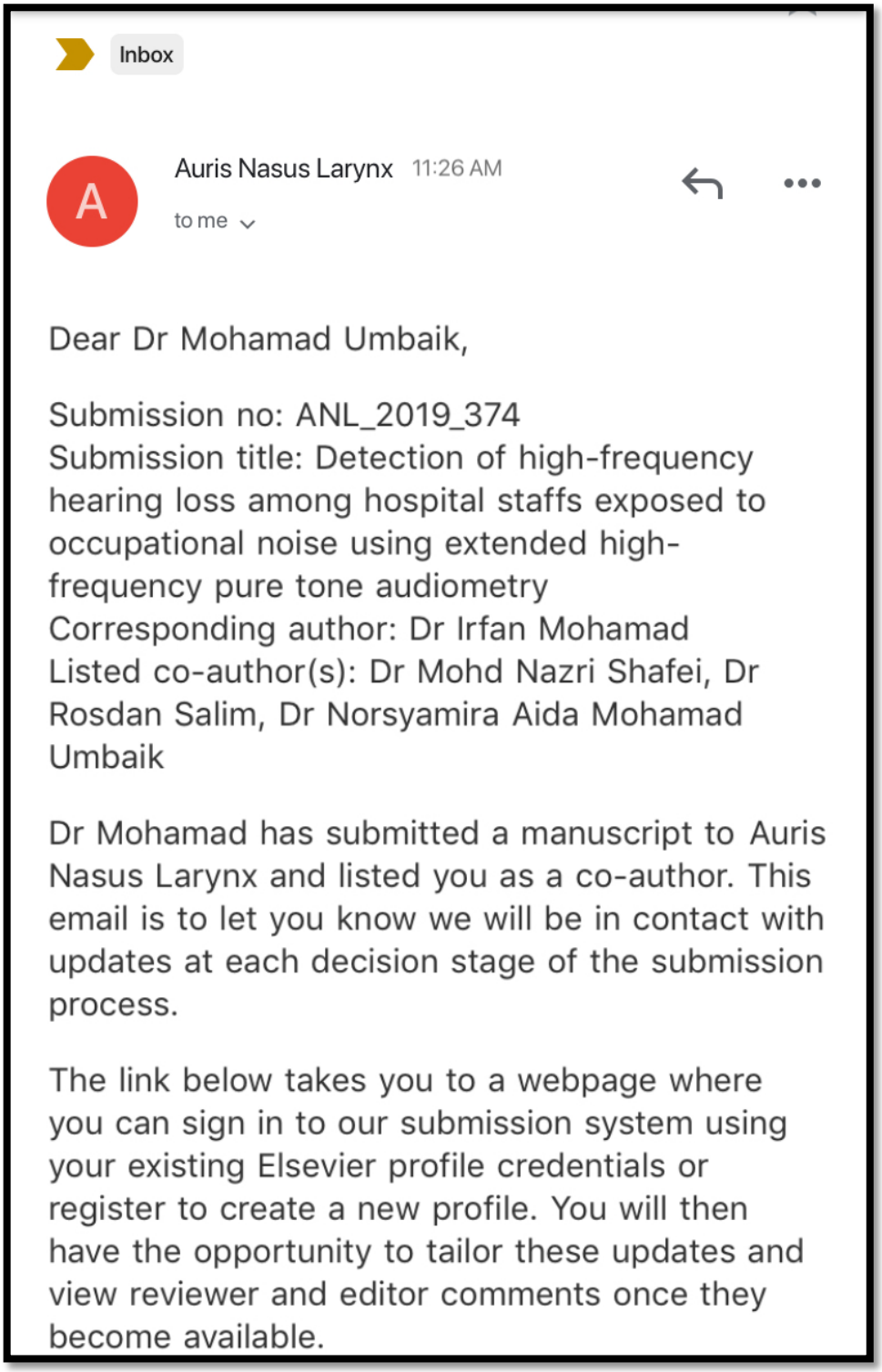
4.3 Evidence of submission to the journal



Inbox

A

Auris Nasus Larynx 11:26 AM

to me

Dear Dr Mohamad Umbaik,

Submission no: ANL_2019_374
Submission title: Detection of high-frequency hearing loss among hospital staffs exposed to occupational noise using extended high-frequency pure tone audiometry
Corresponding author: Dr Irfan Mohamad
Listed co-author(s): Dr Mohd Nazri Shafei, Dr Rosdan Salim, Dr Norsyamira Aida Mohamad Umbaik

Dr Mohamad has submitted a manuscript to Auris Nasus Larynx and listed you as a co-author. This email is to let you know we will be in contact with updates at each decision stage of the submission process.

The link below takes you to a webpage where you can sign in to our submission system using your existing Elsevier profile credentials or register to create a new profile. You will then have the opportunity to tailor these updates and view reviewer and editor comments once they become available.

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Auris Nasus Larynx

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4.4 RAW DATA ON SPSS SOFT COPY