VALIDATION OF THE USE OF HEAR SCREEN, A MOBILE PHONE APPLICATION AS A SCREENING TOOL FOR HEARING LOSS AT THE KENYATTA NATIONAL HOSPITAL

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A research thesis submitted in partial fulfilment of the requirements for the award of the degree of Masters of Medicine in Otorhinolaryngology Head and Neck Surgery at the University of Nairobi.

STUDENT'S DECLARATION

I declare that this research dissertation is my own original work and has not been presented for a degree in any university.

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

ABREVIATIONS

ABC –	Absolute Bone Conduction
AC -	Air Conduction
BC -	Bone Conduction
CHL -	Conductive Hearing Loss
dB -	Decibel
dBHL –	Decibel Hearing Level
ERC -	Ethics and Research Committee
ENT –	Ear Nose Throat
Hz –	Hertz
IAA –	Intra aural attenuation
iOS-	iPhone Operating system
KNH –	Kenyatta national hospital
M Health-	Mobile Health
NIHL-	Noise Induced Hearing Loss
PTA-	Pure tone audiometry
SNHL -	Sensory Neural Hearing Loss
TM –	Tympanic Membrane
UoN -	University of Nairobi
WHO -	World Health Organization

ABSTRACT

Background: Approximately 466 million people suffer from disabling hearing loss in the world. The greatest burden is seen in Pacific Asia and sub Saharan Africa with a prevalence of 9% in the latter. There is a huge gap in hearing care occasioned by constraints in number of and access to trained personnel and infrastructure especially in Kenya and other developing countries. The World Health Organization has recognized mobile health as part of the solution to bridge this gap.

Objective: To validate the mobile phone based application *Hear screen* as a screening tool for hearing loss at the Kenyatta National Hospital.

Methodology: This was a prospective study conducted in the Ear Nose and Throat department at Kenyatta National hospital on 40 patients referred for conventional Pure Tone Audiometry test which is the gold standard hearing test. Convenient sampling was done. A Repeated measures within subject study design was used where mobile based audiometry thresholds in 0.5 to 8 KHz frequency with ambient noise of quiet office (35dB) and normal clinic set up(45dB) was compared to conventional audiometry (21dB).

Data Collection and Analysis: Data was collected and univariate analysis was carried out to determine the mean age with standard deviation. Hearing was compared across all frequencies in all modalities with proportion and 95% confidence interval determined. Regression analysis was done to compare agreement of smartphone and convectional PTA and presented on two way scatter plots. T tests were also carried out to determine if the mean time taken in testing was statistically different for the tests. Fishers test was done to determine whether age or level of education influenced the preference for the mode of testing.

Results: The mean age of the study population was 42 years with 35% males and 65% females. There was no statistical difference between smartphone and conventional PTA across all frequencies with a regression coefficient of 1.26 and a p value of < 0.01.Time taken to do the tests had no statistical difference $p < 0.01$. Majority of the respondents preferred to use conventional audiometry with no correlation (p value of 1.00) between this preference and their age or level of education.

Conclusion: *Heartest* the threshold version of *hearscreen* provides thresholds comparable to convectional PTA in both the quiet office set up and normal clinic set up and can thus be used reliably as a screening tool.

Recommendations: Smart phone based audiometry should be used as a method of screening in resource depleted settings.

1.0 CHAPTER ONE - INTRODUCTION

1.1 Introduction

Approximately 466 million people in the world have disabling hearing loss with the highest burden being in Pacific Asia and Sub Saharan Africa where the prevalence of hearing impairment in Sub-Saharan Africa is estimated at 9% [(1).] Hearing loss has a great impact in the social, cultural, developmental and economic aspect of the individual thus early detection and timely intervention can help curb these effects. Availability of ENT healthcare professionals in developing countries is limited with an estimate of less than one audiologist for every one million people and less than one Ear Nose Throat (ENT) specialist for every one million people in Sub-Saharan Africa [(2)].

In 2005 all the World Health Organisation (WHO) member states made a commitment to strive and achieve universal health coverage [(3)]. Universal health coverage means that all people should have access to the health services they need without the risk of financial ruin [(3)].This is in line with the sustainable development goals 2015 [(4)].The president of Kenya rolled out the BIG FOUR agenda in 2018 in which one of the major aims is to achieve universal health coverage for all by 2022. This plan has been in cooperated into our countries national strategy plan for ear health and hearing care.

Increase of innovative technology and global connectivity has resulted in mobile health being widely proposed as an affordable acceptable option to combat the shortage of and access to skilled health care professionals. The WHO has put a lot of focus on implementing primary health care services in hearing services and use of mobile health has been one of the strategies [(3)]. Research shows mobile health in form of commercially available smart phones or tablets is able to create low cost solutions in screening assessment and interventions even in settings with poor infrastructure and lack of resources [(5)].

Several tests are available for detection of hearing loss but the gold standard is considered to be Pure Tone Audiometry (PTA).This is a test that requires an audiologist who is a skilled health worker and equipment in form of an audiometer and should be carried out in a modified environment which is a sound proof room or booth. The test determines the sensitivity of a variety of sound ranging from low to high frequencies. These services are not readily available in our country and the developing world at large due to the lack of infrastructure, equipment and enough audiologists [(2)].Innovative use of technology and mobile phone applications would serve to bridge this gap.

There are several smart phone hearing test mobile applications available in the market on different mobile phone platforms [6].These are available for use in both the android and apple IOS system and in the form of both speech and pure tone audiometry. Some of the tests are validated while others are not. Furthermore there has been no validity study in our country. The purpose of this study was to investigate the validity of a threshold version of the validated *Hear Screen* a smart phone based application *hear test* using an inexpensive android smart phone and calibrated ear phones and test its reliability as a screening tool in our setup.

1.2 Smart Phone Based Audiometry

Smart phone based audiometry serves as a combination of both Mobile health and tele-health .The technology used is that of automated audiometry. This form of audiometry is controlled by a computer programme where the listener puts in the feedback after introduction of a stimuli which adjusts the parameters of the stimuli automatically according to the feedback [5]. Automated audiometry is widely used with computers, I pads, tablets and mobile phones. The last decade has seen mobile phones evolve from simple communication tools to mini computers. These devices are readily available all over the world with a majority of them having internet connectivity. These devices have thus been advocated to provide automated audiometry to people who cannot access the facilities [7]. The use of the device is considered to be cheap, accessible and easy to use [8].

Several applications have been developed for testing of hearing either by air conduction or speech audiometry and are readily available in the market .They are available for use in both Apple iOS system and in the android system [6]. Worldwide it is reported that the majority of the population (up to 80%) use android based phones. These various applications have been tested and validated in various areas of the world and a majority of them are readily available for use [6].

One such application is *hear screen* application which offers user friendly and affordable hearing test for children and adults. *Hear screen* is an application developed and validated by hear X group in the University of Pretoria South Africa [5]. It is designed to detect hearing problems and provide referrals by linking one up to the nearest health care providers and helps to keep records. It has a threshold version *hear test* which is an air conduction pure tone test that tests 500 to 8 KHz frequencies at intensity levels between 10 to 100 Db. This application works on android and iOS devices coupled with calibrated ear phones and the

average test takes 12 minutes, it also provides a personal profile that enables one to track their hearing levels with time. *Hear test* application is one of the few smartphone based applications that have been clinically validated in several peer review journals and calibrated according to ISO standards. Several countries have adopted *hear screen and hear test* and integrated it in to their National ear screening programmes. One such example is the *hear screen USA* version which was launched in 2018 in collaboration with the American Academy of Audiology for use in the USA. It is thus considered to be a reliable application to use. In this study we will be validating the threshold version of *hear screen* as a screening tool in Kenyatta national hospital.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Effects and Burden of Hearing Impairment

The WHO estimates the current global prevalence of disabling hearing loss at 466 million people of which 34 million are children [(1)]. Disabling hearing loss is defined as loss of 30 dB and above in the better hearing ear in persons under 14 years or a loss of 40 dB and above in the better hearing ear in persons above 15 years. Globally it is estimated that unaddressed hearing loss possess a total cost of 750 billion dollars annually in health sector costs (excluding hearing devices), cost of educational support loss of productivity and societal costs [(1)].The burden is projected to be on the rise with an estimate of over 900 million people projected to have disabling hearing loss by year 2050.

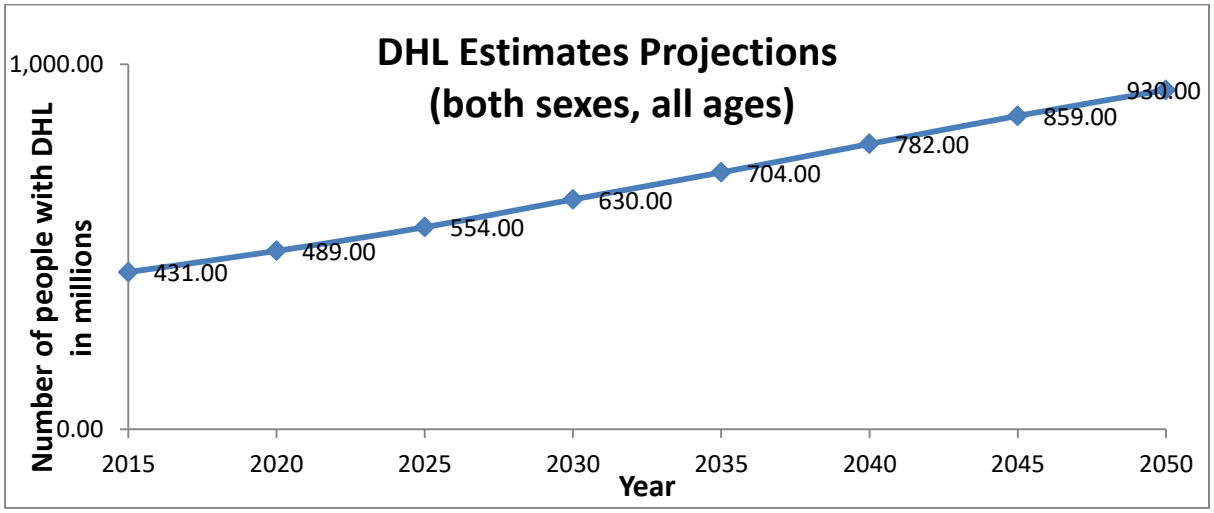

Figure 1: Global trends in hearing loss over the next 35 years (1)

The high burden is still projected to be more in the developing Countries than in developed countries [(7)]. The projected increase is due to the increase in ageing population, rapid industrialization with increased exposure to noise induced hearing loss (NIHL), use of ototoxic medication among other causes. It is estimated that over 1.1 billion young people ages between 18 and 35 are at risk of developing hearing loss from noise in recreational settings and entertainment[(1)].

Significant hearing impairment is detrimental to the normal day to day function of the individual. It has a negative impact in the social and economic progression. Some of the areas affected are listed below [8].

a) Damage to the development of speech, language and cognitive skills especially in children if not detected in time.

b) Poor performance in school.

c) Problems in obtaining, performing and keeping a job or career.

d) Poor socialization among peers and individuals leading to stigma and isolation.

The above effects are magnified in developing countries where there is lack of awareness, infrastructure, national plans and programmes and screening programmes targeting primary hearing care(2).The Kenyan Constitution has incorporated the Kenyan disability act 2003[9] which is an act of parliament that advocates for protection and provision of rights and rehabilitation of persons with disabilities with the aim of providing them with equal opportunities to enable them to carry out their day to day life. In spite of this being parts of the law minimal efforts have been made towards achieving this especially in the individuals with hearing disability.

In Kenya a majority of the population is at risk of hearing impairment in the following ways

a) Noise induced hearing loss – Rapid industrialization and lack of proper regulatory standards in occupational health and safety both in the formal and informal set up exposes the workers to occupational NIHL. The informal sector in Kenya comprises 82 % of employment[10]. People in this industry e.g. juakali workers, hawkers, public transport industry who are exposed to high levels of noise exceeding 85dB in their everyday work[11]. People working In the industries and telecommunication business on the other hand also lack proper protective gear and majority of them miss the routine screening and follow up [12]. Entertainment joints also put people at risk especially the young from the loud music played in various entertainment joints and also music played from personal devices.

b) Ear infections especially acute and chronic otitis media still remain one of the most common causes of hearing loss in the world. In Kenya the prevalence is estimated to be 15 in 1000 from a study conducted among school going children[13]. Active vigilance and screening is thus needed in these cases.

c) There is a rise in the prevalence of non-communicable diseases in the country. These include Diabetes, hypertension and cancer which pose individuals to the greatest risk of hearing impairment. Diabetes and hypertension are known to cause hearing loss to

the individuals. Cancer treatment on the other hand especially chemotherapeutic drugs and radiation therapy pose a risk of hearing loss to those receiving it. Currently it is estimated that there are 40,000 new cases of cancer each year with this number being expected to rise by 2030[14].

d) Other systemic infections such as HIV/AIDS and Tuberculosis are also highly prevalent in the country and a majority of them not only have direct effect on hearing but are treated with drugs that have a direct ototoxic effect[15]. Drugs such as streptomycin which are commonly used[16].

All the above reasons and more point to the need of a screening method that is accessible to the majority of the population in the country with the aim of early recognition intervention and follow up thus reducing the estimated burden in the coming years.

2.2 Hearing Screening Tests

The gold standard hearing test is a PTA which is a quantitative test that determines the type and level of hearing loss in a specific ear. This test specifically indicates the hearing thresholds in dB that are required by the ear to perceive sound in different frequencies. For this test to be carried out it requires the use of a calibrated audiometer coupled with calibrated ear phones. The test environment should be a sound proof room or booth that meets specified ISO standard's .Finally this test is performed by a qualified audiologist.

Screening tests are simple tests that help identify who should undergo a full audiometric evaluation. An ideal screening test is one which provides reasonable assessment or the risk to a disease or disorder to avoid unnecessary referrals and missed cases. It should also be easy to administer, quick, reproducible, affordable and should also not cause harm [17].

Screening of hearing impairment can be classified as screening of infants and new-born screening of older children and adults. The method used in screening of new-borns and infants include

a) Questionnaires – These ask the adults around the child on various responses to sounds and environmental noises.

b) Behavioural hearing tests which measure the babies to behaviour in response to surrounding noise or measuring devices such as toys.

c) Electrophysiological tests such as Otoacoustic emissions and auditory brainstem response, which have been found to be the most sensitive and specific.

Screening of older children and adults can be done using

a) Clinical tests that can be done by the bedside such as the watch tick test, finger rub test and whisper test

b) Use of questionnaires that help find out the social and emotional factors associated with hearing loss such as the Hearing Handicap Inventory for the Elderly screening.

c) Use of a screening audiometer which is a hand held device that is used to test air conduction at various hearing thresholds.

This study was looking at a screening tool for adults and older children who can follow instructions.

2.3 E Health

According to the WHO, E health is defined as the cost effective and secure use of information and communications technologies in support of health and health related fields, these include health care services, health surveillance, health literature and health education knowledge and research[3]. This is a strategy adopted by the WHO in 2005 as a key component to aid in the achievement of universal health for all [3].

Under E health , WHO has recommended various aspects which include Mobile Health, Tele health, E learning in health sciences, Electronic health records, Social media and a legal framework for E health[3].

2.3.1 Mobile Health

Mobile health is defined as use of mobile and wireless devices such as phones, tablets, patient monitoring devices, personal digital assistants and wireless devices for personal and public health services[5].This method makes services available to remote populations and underserved communities where there is little infrastructure and trained personal. WHO in 2016 recognised mobile health as an important resource in health services delivery and public health given their ease of use, broad reach and wide acceptance[3]. Mobile health programmes encompass the use of simple programmes such as telephone services calls and simple reminders for health services, access to patient information and storage of data. They are also used for Public health campaigns screening and surveillance programmes and emergency and disaster response and management.

Mobile health is rapidly evolving with the rapid development of technology and is replacing the traditional health service delivery. In 2015 there was a global estimate of 7 billion mobile subscriptions (>120/100 inhabitants) with the increase being greatest in the low and middle income countries[3].Supplying technology for mobile communications is considered to be cheaper than in personal services .Mobile technology and devices have also been shown to improve the quality of life through various aspects e.g. financial, social, entertainment and education. In 1998 WHO recognised the importance of internet and its potential to impact on health through advertising and promotion of products across the globe and availability of internet has widened the scope of mobile health from simple programmes to use of applications that can diagnose upload and synchronize data and help in interaction of the patient and the health care provider in spite of the distance between them[5].

Kenya as one of the member states of the UN has adopted some of the strategies in E health found in the Kenya National Health Policy 2016 to 2030[18].Although the implementation of the various programmes and policies is underway one of the major success stories have been in telemedicine and mobile health. A good example is the peek vision Kenya programme that has developed a unique smart phone based application that can be used for comprehensive eye care testing anywhere in the world[3]. The peek programme has been found to offer affordable accessible timely and objective tests that help bridge the existing gap in provision of eye care in the country.

The total mobile subscriptions worldwide according to the International Telecommunication union report 2016 is at 5 billion people worldwide and is expected to grow beyond the world's population in the coming years. 95% of the world's population live in areas with mobile network coverage and of this 84% have access to mobile broadband services(21) In Kenya mobile subscriptions stand at 44.1 million people giving a country wide mobile penetration of 88% as per data given by the communications authority of Kenya report 2017/2018[19].This rapid increase is opening new opportunities for healthcare in form of both telemedicine and mobile health. The data and internet market in the country is rapidly increasing with the estimated number of internet users in the country standing at 36.1 million, of these mobile contributions account for 99%[19].

Mobile services for testing air conduction thresholds have been part of the new methods for bridging the gap in hearing services especially in the underdeveloped world. These tests can be used as screening methods and also for self-assessment in patient with various hearing disorders such as fluctuating hearing loss[5].Mobile based hearing tests can also act as adjuncts in other mobile based otolaryngology programmes such as mobile based

endootoscopy and hearing aid adjustment. They can be used as a point of care screening where tests are carried out at community level by minimally trained personnel or as an end user product where individuals use for self-testing.

2.3.2 Smart Phone Based Tests

There is limited literature on smart phone based audiometry since it is a new technology .The studies have been done mainly in the developed world. In Africa studies have mainly be done in South Africa where one of the mostly used application was developed. In spite of this there are numerous mobile applications available for hearing tests. Tess et al conducted a review in 2015 of all the validated smart phone based apps for ear and hearing assessment in both apple based and iOS smartphones where it came out that most validation studies were carried out in high income countries and out of the 30 applications available only 11 had undergone eligible validity studies against the gold standard and have been peer reviewed. This shows the need for more validity studies especially in low Income countries where the greatest burden of hearing loss lies and the need to have smart phone based audiometry is high[(6)] .

Over the years most of the developing countries have been using a telephone based speech in noise screening test. This is where a series of three numbers are presented to the listener by a telephone receptionist in the background of noise and the listener is allowed to repeat as the number of correct responses is being recorded to test your hearing. Swanepoel et al adopted the same type of test but in a mobile phone with the view to increase penetration in the developing countries where there is poor landline connection. The tool developed was the Hear ZA which is an app developed for the South African population and is currently in use as their national screening tool. His study was in two phases where phase one was to identify the series of three numbers in the different languages commonly spoken in South Africa and to validate their use in form of a mobile application. In the second phase he looked at their accuracy in testing, the difference in the test results using different models of mobile phones and also using different types of head phones calibrated or not. This study proved that use of speech in noise is not only an accurate mode of screening for hearing loss but also cost effective as the need to use specially calibrated head phones is eliminated. There was no difference in the test result using different phone models or in between the different types of headphones. The application provided a cost effective, accessible and acceptable mode of screening for hearing loss in South Africa [(24)].

2.3.3 Validity and Time Efficiency of *Hear Screen* Application

A study done in the University of Pretoria looking at the validity and time efficiency of *hear test* the validated threshold version of *hear screen* application, found That the application was a reliable tool and can be used as a good screening tool for hearing loss. This is the same application that was used in this study. The greatest limitation of this tool was the fact that it can only test for air conduction thus is not able to clearly distinguish the type of hearing loss. In terms of time taken to do the test according to this study they divided the patient population into two groups. Out of a total of 90 participants 30 comprised of the older population who had pre-existing hearing loss and were attending a hearing aid fitting or audiology clinic and 60 were young adults selected from the university with normal hearing thresholds. Both groups had similar outcomes in terms of the accuracy of the test but in time it was noted that the elderly population took longer than the young ones[(20)].

Renda et al from turkey validated *hearing test* a different validated android based mobile application developed by P.audiologia against the gold standard which is the conventional PTA. Their main objective was to compare hearing test results using a mobile application of a randomized group and compare with the PTA results. A hundred patients were tested and the validity analysis results showed that the smart phone hearing application test *hearing test* on both the hearing and the hearing impaired participants was excellent when compared with conventional PTA. The smart phone based test was also found to be easy and can be used in any place using any type of mobile phone[(21)].

2.3.4 Use of *Hear Screen* in Different Environments

Sandstorm et al conducted a validation study on the application *Hear screen* for purposes of its use in a primary healthcare setup. In his validation study he compared the accuracy of the test when done in a sound proof booth and while done in a primary health care clinic .In both cases the results were compared to the conventional audiometry. In the study they looked at validity and time efficiency and the *hear screen* test was proven to be an effective tool for use even in a primary health care set up without a sound proof booth [(23)] .This study is in line with our first and second secondary objectives where the same mobile application was tested for accuracy in two different environments a quiet office set up and in a normal clinic setup. It also addresses the third secondary objective that was looking at time efficiency and a comparison of time taken to do the conventional audiometry Vis a Vis the smart phone audiometry time was done.

2.3.5 Ease of use of *Hear screen*

A South African community based study investigated the feasibility of mobile application for screening of children in early child hood centres by a health worker in a community set up. The community health workers were trained on how to use *hear screen* a mobile application, they then carried out the test on a total of 6424 children between 3 to 6 years. The results showed that the applications ability to actively monitor noise during the test, the presence of a cloud for data storage and the referral features were a good tool that would help in underserved areas both for screening and surveillance. It also showed that mobile application as a screening tool does not require highly specialised training[22].A similar study was done in a similar community in South Africa by Mohammed et al which was a descriptive study aimed at investigating the feasibility of smart phone based audiometry as a community screening tool by community health workers. A total of 820 workers were examined over a 12 week period by community health workers. The health workers gave positive feedback on the mobile test in terms of usability. They only expressed concern on screening of children where it was more difficult. The study was conducted using *hear screen*[26].These two studies are in line with the last secondary objective which will be assessing the ease of use of the smart phone test compared to the pure tone audiometry.

2.4 Study Justification

WHO recognises mobile health as one of the feasible ways of achieving Universal Health Care. In Kenya, the mobile penetration is high at 44 million subscriptions with 36.1 million (81%) subscribers inclined to mobile internet use. In sub-Saharan Africa, there is a huge discordance between access to ENT/audiology services, with few ENT/audiology professionals and institutions against an increasing population. There is also a projected increase in hearing impairment in this population which is attributable to, among others, occupational and entertainment NIHL, ototoxicity and chronic ear infections. These countries, including Kenya, lack an existing national screening program for hearing.

In line with the *big four* development agenda 2018-2022 and the national strategy of hearing and ear care, *Hear Screen* or other mobile audiometry applications may offer a solution in access to universal hearing care. This tool *Hear Screen* thus needs to be validated as a viable option for screening in our set up.

3.0 CHAPTER THREE: METHODOGY

3.1 Study Objectives

3.1.1 Research Question

Can *Hear Screen* a smart phone based mobile application be used as a screening tool in KNH?

3.1.2 Primary Objective

To validate the threshold version of the application *Hear Screen*, as a hearing screening tool in Kenyatta National Hospital.

3.1.3 Secondary Objectives

a) To compare the hearing thresholds smart phone based PTA in the normal clinic set up with conventional PTA

b) To compare the hearing thresholds of smartphone based PTA in an office setup with conventional PTA

c) To determine the time frame taken to carry out each of the tests

d) To determine the preference of use of the tests

3.2 Study Design

This was a prospective study where a repeated measure within subject design was employed. In this case the participants were recruited once they were referred for PTA which is the gold standard hearing test. After doing this they underwent the *hear screen* test both in a quiet office and in the normal clinic environment.

3.3 Study Setting

The study was carried out in the ENT department in Kenyatta National Hospital among patients who were sent for PTA. The conventional PTA was carried out in the sound proof booths within the audiology section of the clinic which have an ambient noise level of 21dB as per the ISO 1989 standards. The smart phone test was carried out in a quiet room and in the clinic. The quiet room was the head of department office in the clinic. This is suitable as it is a corner office with two doors accessing it, not along a corridor and with very little traffic thus has very little interference from outside noise and had an average ambient noise level of 35 dB. The clinic set up was in one work station within the ENT filter clinic as the normal activities in the clinic go on, along a corridor with an average ambient noise level of 45dB.

3.4 Study Population

The study population included all patients referred to the ENT department for a PTA in the audiology department for the period of the study.

3.4.1 Inclusion Criteria

The following participants were included in the study

a) All patients sent for PTA who are above 18 years and consent to participate in the study.

3.4.2 Exclusion Criteria

The following participants were excluded from the study.

a) Deaf patients

b) Single sided deafness

3.5 Sample Size

The sample size will be calculated using the equation stated by Brujang and Baharum 2017(23)

$$n = 1 + \frac{2(Z\alpha + Z\beta)^2 k}{(\varepsilon n C_\theta)^2 (k-1)}$$

Where, $C\theta = \frac{1+k\theta_0}{1+k\theta_1}$

$$\theta_0 = \frac{R_0}{1-R_0} \ , \ \theta_1 = \frac{R_1}{1-R_1}$$

If κ=3(3observations per subject; convectional PTA and smart phone based PTA in 2 different environments)

R_0 = 0.9 (Initial level of agreement estimated at 90%)

R_1=0.97 (expected level of agreement 97%)

α= 0.05; Z_α= -1.65

Power set at 90 %; (β= 1-0.9 = 0.1) Z_β=-1.28

$\theta_0 = \frac{0.9}{1-0.9} = 9$; $\theta_1 = \frac{0.97}{1-0.97} = 32$ $C_0 = \frac{1+2(9)}{1+2(32)} = 0.29$

n= 1+[$(2(-1.65 + -1.28)^2\ 2) \div ((\ell\eta 0.29)^2(2-1))$] = 28

Allowance of 20% in case participants opt to drop out =40.

40 ears is the ideal sample size but each ear was analysed separately thus a total of 80 ears were tested.

3.6 Sampling Procedure

Convenient sampling was done on 67 patients referred to the audiology department. All patients referred to do the PTA test were recruited, informed consent was sought and 40 patients who consented to participate in the study were included. Each subject was given a unique code and proceeded to do the tests.

3.7 Equipment

The following equipment was used in the study

- **a)** Standard otoscope and speculums
- **b)** 512 Hz tuning fork
- **c)** Mobile Phone Samsung galaxy A3
- **d)** Sennheiser HD280 PRO supra aural earphones
- **e)** Clinical Audiometer – Inter-acoustic AC33
- **f)** Telephonic TDH39 supra aural earphones for pure tone audiometry

3.8 Data Collection Procedure

The research team consisted of the principle investigator and a research assistant. Patients referred to the audiology clinic for PTA were selected. Selection was done by the research assistant based on who was willing to participate. The research assistant was a high school leaver with no background of medical knowledge. Consent was obtained from each patient. A brief history was taken from each patient, followed by Otoscopy, Rinnes' and Webers' test using the 512 tuning fork. History was taken by the research assistant based on the data collection sheet while otoscopy and tuning fork tests were carried out by the principle investigator and the results entered in the data collection sheet. All patients did the conventional PTA which was our gold standard. All the conventional PTAs were done by the same qualified audiologist using one audiometer Inter-acoustic AC33 and the results for each patient recruited in the study entered in the data sheet. The method used was the modified Hughson Westlake procedure for threshold seeking. The time taken to test each patient was measured with a stop watch and the time recorded. Ambient noise levels were also recorded for each test

The patients then underwent the smart phone test with the *hear screen* application. Each patient underwent the smartphone based test in a quiet room then in a normal clinic set up The smart phone test utilized the ISO shortened ascending method(ISO8253-1,2010)

protocol. This test was carried out by the research assistant where the patient was asked to raise up their hand in response to the beep sound from the smart phone and the tester would press the button on the phone. A positive response led to the tone automatically increasing by 10 dB and a negative response lead to the tone decreasing by 5dB automatically and threshold determined by two out of three responses per frequency. Smart phone measurements were taken using Calibrated supra-aural sennheiser HD280 pro ear phones connected to Samsung galaxy A3.The phone model utilizes the android version 8.1 Oreo and comes with the *hear screen* test installed and the earphones calibrated by the *hear screen* manufacturer in South Africa. This application generates pure tone signals with a calibration function to the required reference equivalent threshold sound pressure level. It is also unique in the sense that it has real time noise monitoring and whenever the ambient noise is above 40dB as a particular tone is being tested the application repeats automatically. The application also tests for accuracy of the responses and alerts the tester in case of irregularities in the response who repeats the instructions and the test again. Each test was timed using a stop watch and time recorded ambient noise levels were also measured. Results from each smart phone based test automatically uploaded in the international mobile health data base for hearing loss and saved in the health cloud that is set and synchronized with *hear screen*. Only air conduction thresholds were recorded. Each result from both the PTA and smart phone audiometry were coded and entered for comparison and data analysis. Results for each ear were recorded and analysed separately.

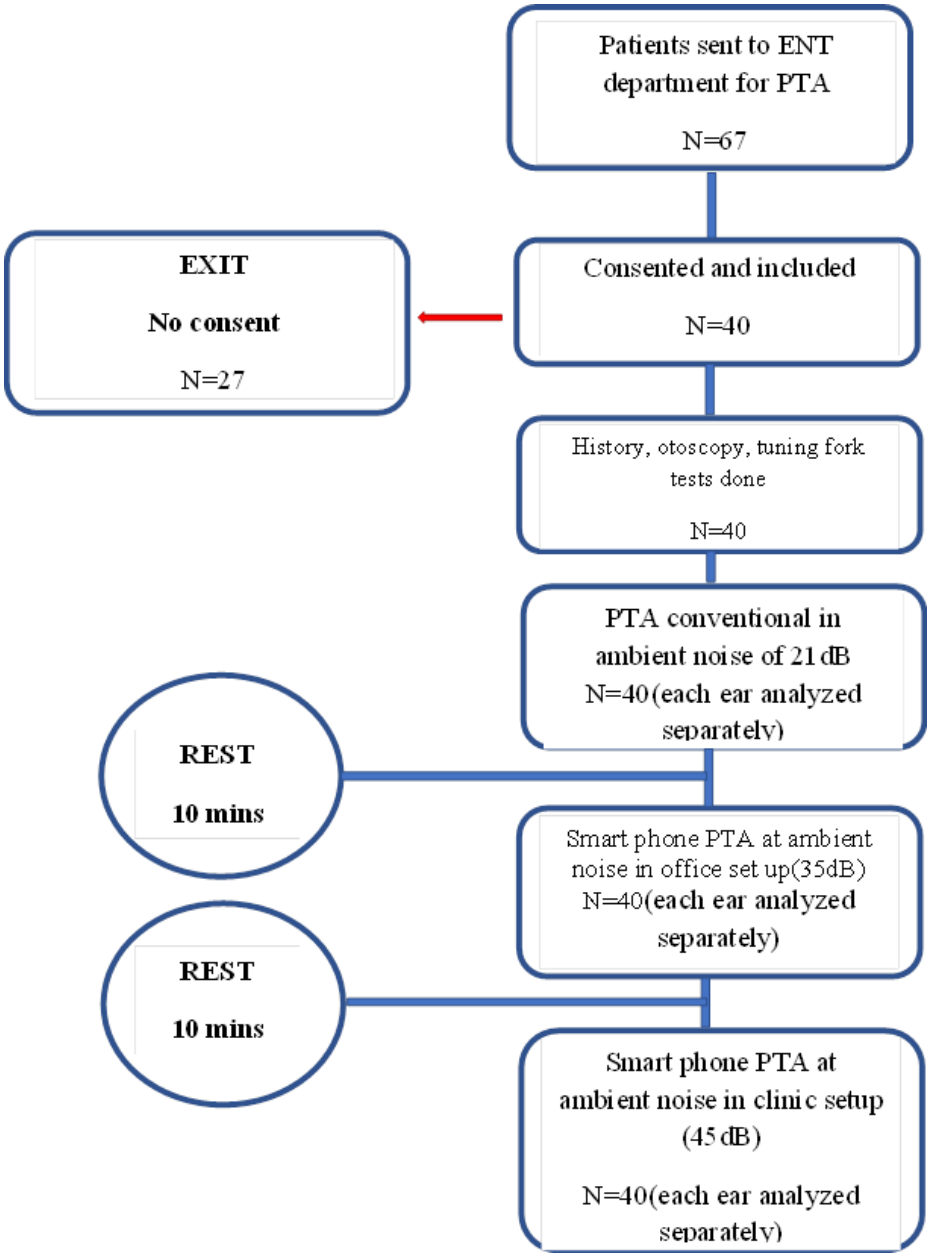

Figure 2: Flow chart showing the Data collection procedure

3.9 Quality Control

History was taken from participants using a standard questionnaire and examination of all patients was carried out by the principle investigator. All the patients received the same instructions before undergoing the convectional or the smartphone based PTA using English or Kiswahili based on what they understood best. All the PTAs were done in the same room using the same audiometer which had been serviced and calibrated in decibels hearing level according to the International Organization for Standardization. At the start of each test the

ambient noise levels were measured and confirmed using a sound meter that is installed in the *hear screen* application. The study participants used telephonic TDH 39 supra-aural earphones for the pure tone audiometry. PTA was done by same qualified audiologist. Mobile audiometry was conducted by one person using the same phone and ear phones.

3.10 Ethical Considerations

The study was carried out after approval by the KNH/UON Ethics and Research Committee. Recruitment was by consent. The participants received full disclosure of the nature of the study. No extra cost was encountered by the patient. The cost for the PTA was incurred by the patient as it was part of their standard of care and smart phone audiometry was not charged. Confidentiality was maintained by making their bio data anonymous with codes and questionnaires locked and secure. At the end of the study the raw data was coded and backed up for further study. The results will be published in scientific journals and presented in medical conferences, regular print and electronic media where necessary for the benefit of the lay public. The recommendation of the study will be presented to the Kenya ENT society for considerations of recommending the use of the test by various health workers in the country as a screening tool. The study population will be given their results and those found to have hearing impairment will be recruited to the otology clinic for rehabilitation and follow up. There are no conflicts of interest or otherwise in this study by the principle investigator, supervisors and the hospital or with the original manufacturers of the application. The patient had the right to withdraw from the study without victimisation.

3.11 Data Management

All the data was recorded in data collection sheets. Each sheet was coded with the code assigned to the patient. The data collection sheets were stored in a lockable cabinet at the end of each day. After data collection was complete the data was coded and entered in Google sheets for analysis. Results from each ear were recorded and analysed separately.

3.12 Data Analysis

Data analysis was conducted with Stata 14.0 and MS excel. Univariate analysis was carried out to determine the mean age of the participants and their gender distribution. The mean durations with standard durations of length for testing procedure between all arms of the study was calculated. Proportion with 95% confidence intervals was calculated to determine grading of hearing loss. For the comparison of repeated measures the Wilcoxon singed rank test was used. Students tests was carried out to determine if the meantime taken was significantly different between the tests Fishers exact test was used to determine whether

degree of education or age in years impacted on the choice of modality between convectional PTA and smart phone PTA Each ear was analysed separately. Two way scatter plots were derived after regression fit analysis (with 95% confidence interval) to compare agreement of smartphone in clinic setting and office setting versus gold standard PTA.

3.13 Study Results Dissemination Time

The study will be disseminated to the medical fraternity through publications made in at least one peer reviewed journal. The dissertation hard copy will be available at the UoN Library (KNH).A soft copy of the dissertation will be available at the UoN e-repository on the UoN website. The results will be presented in scientific meetings and recommendations sent to the national ear and hearing care committee

4.0 CHAPTER FOUR RESULTS

4.1 Demographics

The study had a total of 40 subjects with a mean age of 42.8 years (18 to 82) years. Males accounted for 35% (n=14) of the sample and females 65% (n=26). Majority of the subjects 19 had tertiary education 14 had secondary education while only 6 had primary education and 30 respondents had subjective hearing loss while 10 did not have any subjective hearing loss. Weber's was central in 23(57.5%) and lateralized in 17 (42.5%) with Rhine's positive in 37 ears and negative in 3 ears.

Table 1: Characteristics of subjects

Subjects	**40**
Age ,median (IQR)	**41years(18 – 82)years**
Male	**35%(n=14)**
Female	**65%(n=26)**
Level of Education	
Primary	**17.5%(n=7)**
Secondary	**35%(n=14)**
Tertiary	**47.5%(n=19)**
Subjective hearing loss	
Yes	**75%(30)**
No	**25%(10)**
Weber's	
Central	**23(57.5%)**
Lateralizing	**17(42.5%)**
Rhine's	
Positive	**R 37(92.5%) L 28(70%)**
Negative	**R 3(7.5%) L 12(30%)**

Each ear analysed separately n=80

Majority of the subjects were females who were almost twice the number of males. Half of our subjects had tertiary level of education.

4.2 Mean Thresholds across all Frequencies in all the Three Tests

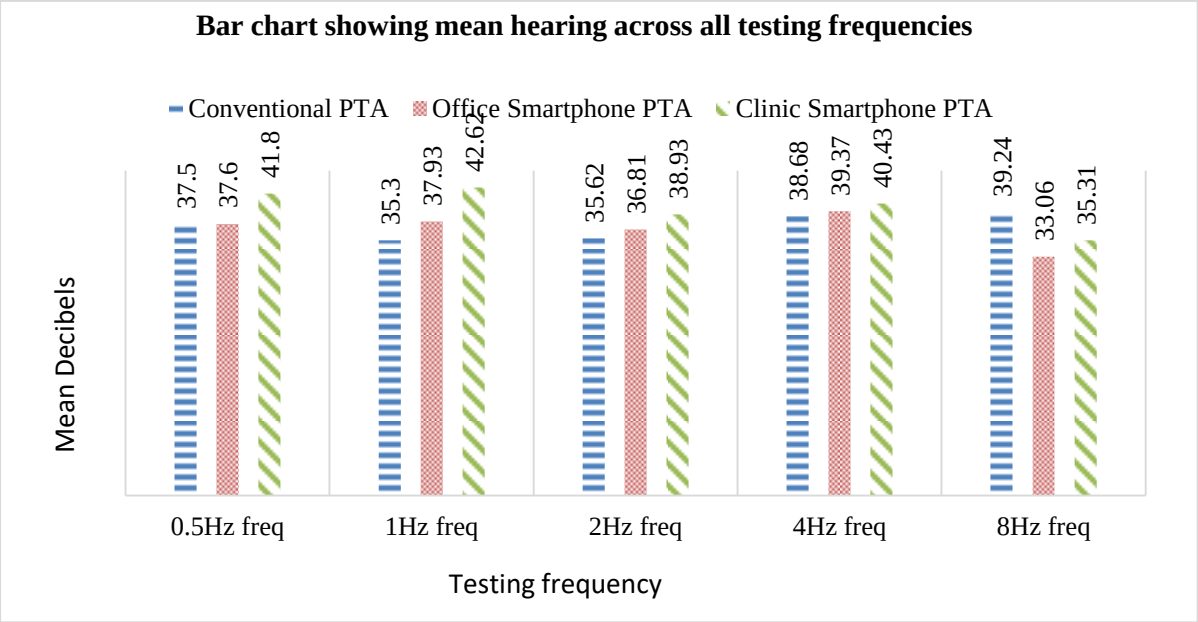

Figure 3: Bar charts showing mean thresholds across all testing frequencies

The mean decibels for each test carried out on each frequency were almost similar and within 5dB of the conventional PTA except in the 8 Hz frequency which was within 10 db. All were within the accepted audiological limits

4.3 Percentage distribution of the degree of hearing loss from pure tone average (95 % confidence interval)

As shown in the table below pure tone averages were obtained from the mean thresholds of 0.5, 1, 2,4khz.This is done to determine the level of hearing, all the three tests were comparable with a difference that is not statistically significant with p value of < 0.01. However it should be noted that the threshold increases with the increase in the ambient noise levels as depicted in the clinic based smart phone test result

Table 2: Percentage distribution of the degree of hearing loss from pure tone average (95 % confidence interval)

	Conventional PTA		**Smart phone office**		**Smart phone Clinic**	
	Right	left	Right	Left	Right	Left
Normal	52.5%(36.6-67.9)	50%(34.3-65.8)	42.5% (27.7-58.7)	47.5%(32.1-63.3)	37.5%(23.5-53.9)	35%(21.4-51.5)
Mild	12.5%(5.1-27.5)	7.5% (2.3-21.7)	20%(10.0-36.0)	10%(3.6-24.6)	22.5%(11.7-38.7)	22.5%(11.7-38.7)
Moderate	22.5%(11.7-38.6)	15%(6.6 – 30.4)	15%(6.6 – 30.4)	17.5%(8.2-33.2)	22.5%(11.7-38.7)	10%(3.6-24.6)
Severe	2.5%(0.3-16.9)	12.5%(5.1-27.5)	12.5%(5.1- 27.5)	12.5%(5.1-27.5)	10% (3.6-24.6)	20% (10-35.9)
profound	10%(0.3-24.6)	15% (6.6 -30.4)	15%(6.6-30.4)	12.5%(5.1-27.5)	7.5%(2.3- 21.7)	12.5%(5.19-27.5)

4.3 Comparison of smart phone PTA in office setup at 35 dB ambient noise level and conventional PTA

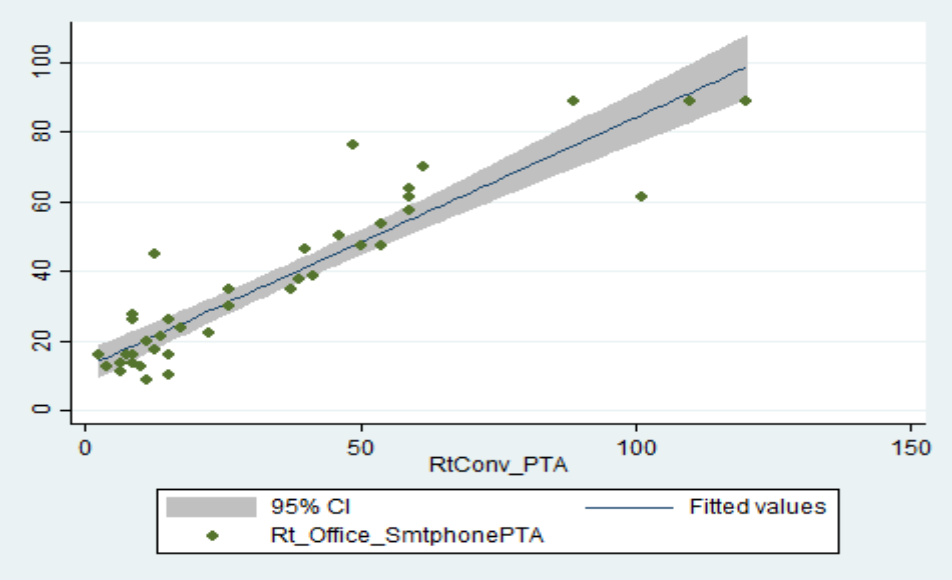

Figure 4:Two way scatter plot with regression fit comparing conventional PTA to clinic smartphone Right ear Regression coefficient is 1.18 (95% CI 1.00-1.34) p-value <0.001

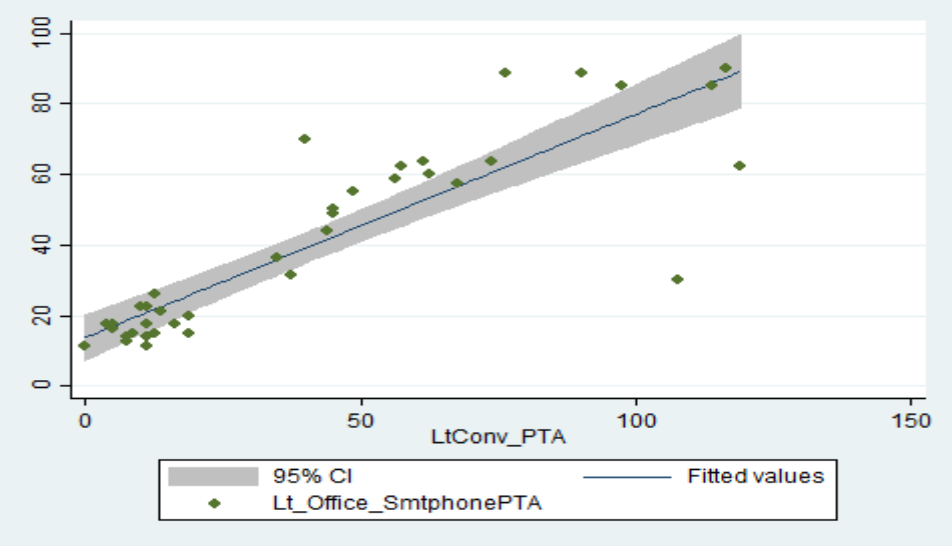

Figure 5:Two way scatter plot with regression fit comparing conventional PTA to office smartphone left ear Regression coefficient Is 1.18 (95% CI 0.96-1.41) p-value <0.001

When smart phone based PTA done in an office with ambient noise level of 35Db was compared with conventional PTA, based on the line of regression with a 95% confidence interval there is a strong agreement between conventional PTA and smart phone PTA both in the left and right ear.

4.4 Conventional PTA compared with smart phone PTA in clinic set up 45dB Ambience noise level

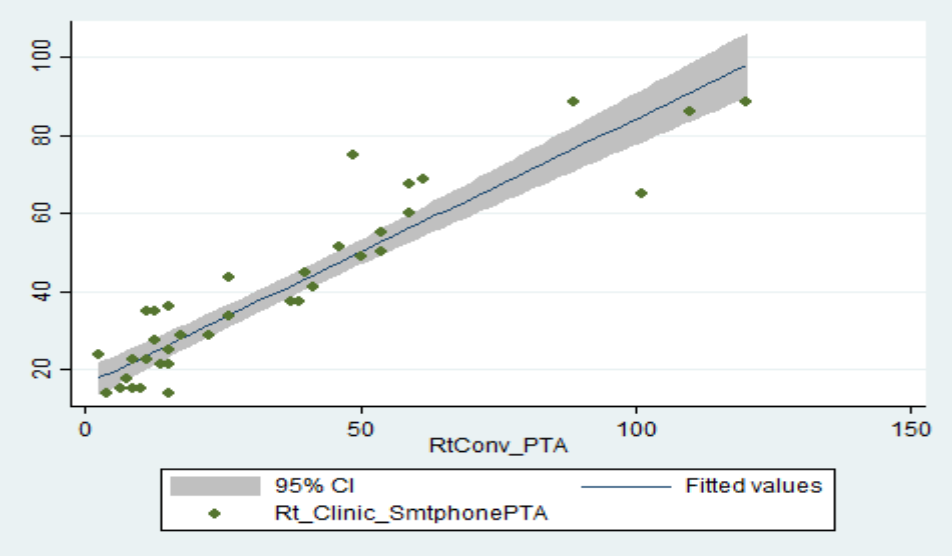

Figure 6: Two way scatter plot with regression fit comparing conventional PTA to clinic smartphone Right ear. Regression coefficient of 0.90 (95% CI 0.81-0.99) p value of <0.01

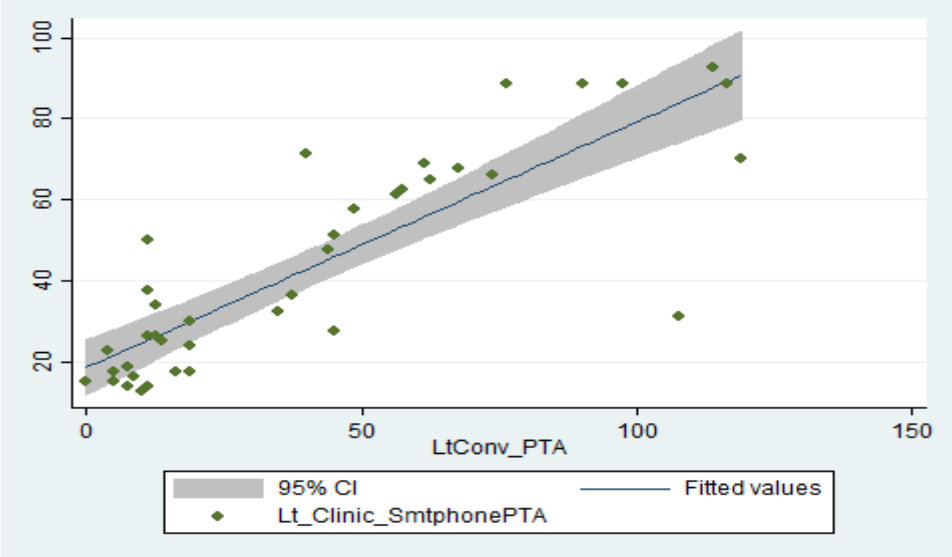

Figure 7: Two way scatter plot comparing conventional PTA to clinic smartphone left ear. Regression coefficient 0.93(95%CI 0.83-1.03) p value <0.01

When smart phone based PTA done in the clinic with ambient noise level of 45Db was compared with conventional PTA, based on the line of regression with a 95% confidence interval there is a strong agreement between conventional PTA and smart phone PTA in both the left and right ears.

4.5 Time taken to do the Tests

Table 3: Mean time taken and the standard deviations

Mean (Standard deviation)	Conventional PTA	Smartphone Clinic	Smartphone Office
	522.9 (SD 172.4) sec	678 (SD 133.9) sec	609.8 (SD 148.2) sec

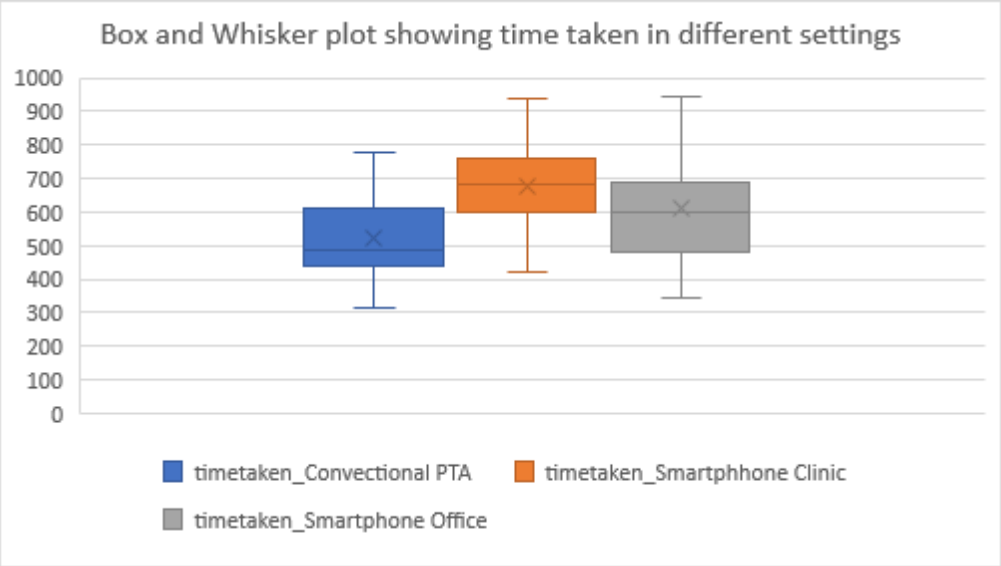

Figure 8: Comparison of time taken to do each of the tests

When you compare the time taken on office smartphone to time taken in the conventional PTA the p value is 0.04 thus there is a significant difference. In comparing smartphone clinic PTA conventional PTA the P value is > 0.01 this time taken for conventional PTA was significantly less. As for the office smart phone test compared to the clinic test the P value was >0.05 meaning the clinic time had a significantly greater mean time taken. However there was a significant overlap within the 95% confidence interval therefore ignoring the null hypothesis thus no statistical difference in the time taken to do the tests.

4.6 Comparison of Preference between Smartphone PTA and Conventional Audiometry

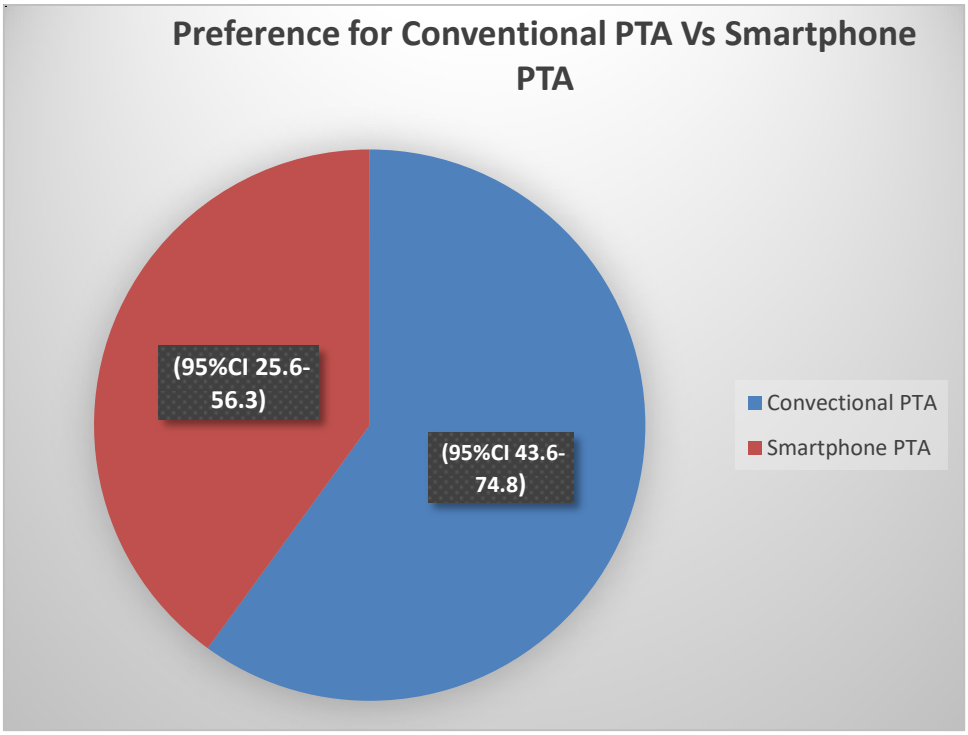

Figure 9 : Preference for Conventional PTA vs Smartphone PTA

In terms of preference 60% of the subjects preferred conventional PTA while 40% opted for smart phone PTA.

Table 4: Correlation between the age and the preference of the mode of PTA.

AGE	EASE OF USE OF PTA(n=subjects)		TOTAL
	CONVENTIONAL PTA	SMART PHONE PTA	
Young Adults(18-35 yrs)	2	1	3
Middle Age(36 – 59yrs)	21	14	35
Elderly (>60 yrs)	1	1	2
TOTAL	24	16	40

Fishers exact p=1.00

Fishers exact test with a p value of 1.00 show no correlation between the age and the preference of the mode of PTA.

Table 5: Correlation between the level of education and the preference of the mode of PTA

EDUCATION LEVEL	EASE OF USE n=subjects		TOTAL
	CONVENTIONAL PTA	SMART PHONE PTA	
Primary	5	2	7
Secondary	8	6	14
Tertiary	11	8	19
Total	24	16	40

Fishers exact - P = 1.0

Fishers exact test with a p value of 1.00 show no correlation between the level of education and the preference of the mode of PTA.

5.0 CHAPTER FIVE: DISCUSSION

Validating a method of screening for hearing loss requires it to be compared to conventional PTA. Hearing thresholds of 10dB or less between two methods is accepted as subclinical in clinical diagnostic audiometry (OSHA 1983). In spite of this it is important to keep in mind that in children a difference of 10dB can make a major clinical difference and is considered to be significant. This study compared thresholds obtained from *hear test* the threshold version of *hear screen* (smart phone based mobile application) carried out in two different setups (quiet office 35dB, normal Clinic 45dB) to the conventional PTA done in a sound proof booth (21dB).There was no statistically significant differences between smart phone and convectional PTA thresholds across all frequencies. Majority of the thresholds obtained via smartphone clinically differed from conventional PTA by 5dB or less except at 8 khz which was 10dB and were all within our 95% confidence interval. Other studies done comparing mean threshold difference between conventional audiometry and automated audiometry using the same smartphone application agree with this study Van tonder et al[(20)].The results from our study also tally with the original clinical validity study done on the application Swanepoel et al(8) where the thresholds obtained from smart phone audiometry and manual audiometry were within a 5dB difference both in normal ears and diseased ears.

Pure tone average is important as it helps to determine the level of hearing in an ear. Though there was no study found that compared the pure tone average obtained from the different tests, we calculated the means of the pure tone average obtained from the different tests as shown in table two and all were within the 95% confidence interval .This shows that in terms of pure tone average results from pure tone audiometry are comparable to conventional audiometry.

Automated audiometry is reliable and efficient and allows patient to test themselves or the test to be conducted by persons with limited training Swanepoel et al [(8)]. The smart phone test in this study was conducted by a high school lever with no knowledge or training in audiometry or any medical field. This shows that it is possible to bridge the gap of lack of specially trained personnel just as study by Mohammed et al where he used community health workers (22).As a result the skilled personnel can focus more of their time in the more complex aspect of intervention and patient management. The use of unskilled personnel does not compromise the quality of the results or the efficiency of carrying out the test as shown in this study. This was also shown in study done by Yancey et al [(27)] in a community based

study carried out in Malindi Kenya where they used community health workers to test school going children using the *hear screen* mobile application.

Comparison of thresholds obtained in areas with different ambient noise levels show no statistical difference .This results agree with study done by Mohammed et al on screening in schools and community health centres[23]. In spite of there been no statistical difference we found that an increase in the ambient noise led to higher thresholds. One advantage of the smart phone test is that for accuracy in areas with high ambient noise levels, it has a real time noise monitoring which automatically leads to repetition of any pure tone presented at ambient levels above 40 dB. With this in mind the increase in threshold with the rise in ambient noise levels could be attributed to other factors such as patient distraction or poor concentration and not to the test accuracy. This opens up avenues for comprehensive ear screening that can be set up in community health facilities negating the need for a specialized equipment and infrastructure thus saving cost and improving accessibility. The fact that the smart phone test can be installed into a basic smart phone also makes it portable and affordable thus would improve in the penetration of hearing services to the remote areas which have mobile and internet connectivity. Moreover the smart phone test like hear screen have additional settings like instant data capturing and storage in a cloud based database which would be ideal for record keeping and patient monitoring , referrals and follow up.

There was no statistically significant difference in the time taken to do the tests though overall the convectional PTA took a shorter time than the automated audiometry. Generally this could be due to the fact that automated audiometry in the application comes with a standard waiting period between the result and presentation of the next tone in order for it to upload and save the results. Conventional audiometry on the other hand relies on the speed of the response from the participant and the familiarity of the test protocol by the audiologist. The results of our study compare with the study done by Van tonder et al [20] where there was no significant difference in time though the smart phone test took longer. Contrary to our study Sandstorm et al shows that smart phones were more efficient and took less time compared to conventional audiometry in her study [24].The average time taken to do the smart phone test in ambient noise of 35 dB was shorter than the one done in 45 dB. This can be explained by the fact that the test repeats presentation of any tone presented at ambient noise levels above 40 dB and there is an increase in the number of false responses thus it took much longer to do the test in the normal clinic set up due to the higher ambient noise levels.

In terms of ease of use majority of our population preferred the conventional audiometry to the smartphone based test. This differs from studies done by Swanepoel, Mohammed et al

[22,24] where their participants preferred smart phone audiometry. This preference could probably be due to the fact that we conducted the smart phone test twice and thus took longer time and hence creating a bias. We did not find any correlation between the preference of mode of test with level of education or age of participants. Since our study had very few participants and could not give a true representation of the community at large we recommend a community based or a Kaps study in order for us to make a valid conclusion on the preferred mode of testing.

5.1 Conclusion

Hear test the threshold version of *hear screen* provides hearing thresholds comparable to conventional PTA when done both in a quiet office and in a normal clinic set up. It can thus be used reliably as a screening tool to identify patients with hearing loss in a community level with limited human resources and infrastructure. It can also be efficiently used in follow up and monitoring of threshold changes in patients attending oncology clinics or the TB clinics where they are exposed to ototoxic medication. The application can help in help monitoring of patients with fluctuating hearing loss and those exposed to occupational noise. It provides a solution in the achievement of most of the objectives in the Kenya National Strategy for ear and hearing care 2016 - 2020.

Recommendations

a) The use of smartphone based audiometry should be adopted in the National strategy for ear and hearing care as a screening method for hearing loss.

b) Large community based studies should be carried out on larger population to evaluate if it is an acceptable and practical mode of screening in different communities in the country.

5.2 Study Limitations

a. Smart phone test could not do masking especially in patients with a large inter-aural difference of more than 40dB.This was apparent in one of the patients in the study who had unilateral profound hearing loss and a normal ear who exceeded the percentage of false responses and thus the phone application was unable to attain threshold levels.

b. Lack of a specialized feature or settings for patients presenting with tinnitus e.g warble tones thus increasing the rate of increased false responses during the test and increasing the test duration.

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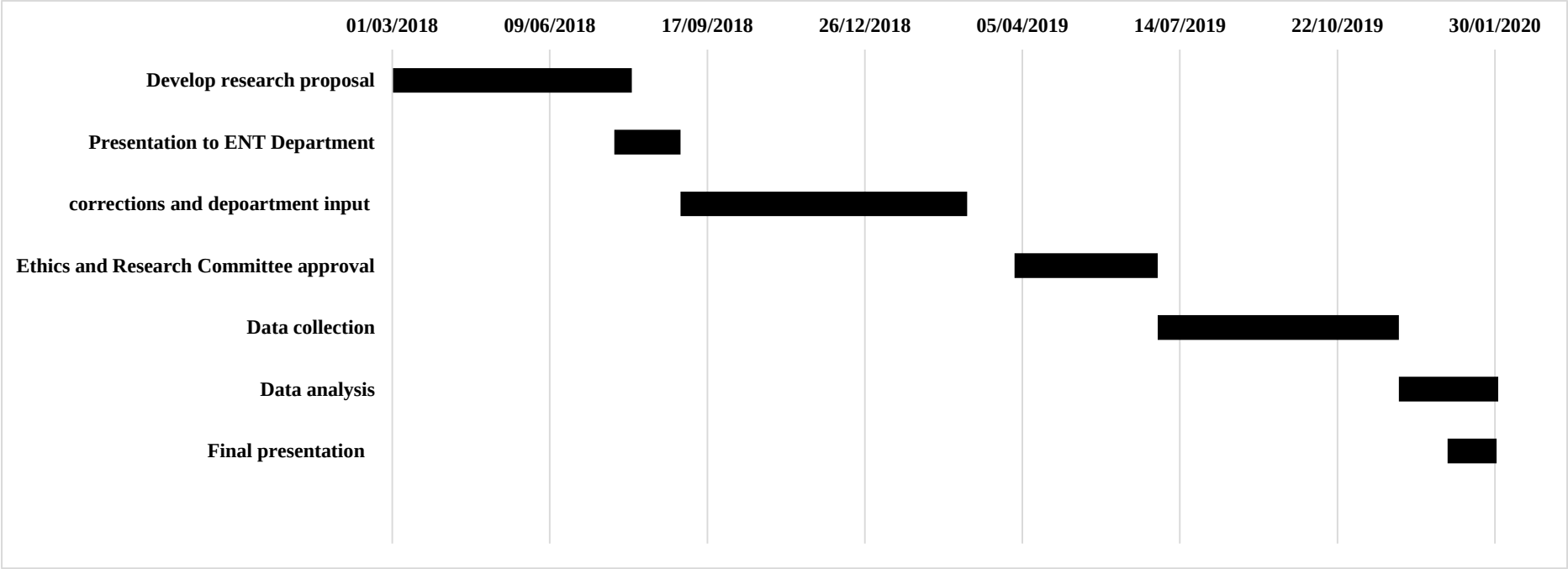
28. Kenya National strategy for ear and hearing care 2016-2020

TIMELINE


01/03/2018
09/06/2018
17/09/2018
26/12/2018
05/04/2019
14/07/2019
22/10/2019
30/01/2020
Develop research proposal
Presentation to ENT Department
corrections and depoartment input
Ethics and Research Committee approval
Data collection
Data analysis
Final presentation

BUDGET

Stationery	Ksh 40,000
Syringing	Ksh 5,000
Samsung J7	Ksh 20,000
Statistician	Ksh 30,000
Research Assistants	Ksh 40,000
Miscellaneous	Ksh 15,000
TOTAL	Ksh 150,000

Budget Justification

Stationery 40,000 will cater for printing of the proposal and the final document for submission and for departmental presentations. This includes copies for each and every member of the department on the day of presentation. It will also cater for printing of data collection sheets and pens and papers to be used in the analysis.

Any patient found to have impacted wax which can interfere with the test results will undergo ear syringing to remove the wax. This is done in Kenyatta hospital at a cost of 300 ksh which I will cover.

A phone which the study application *hear screen* will be installed into will be purchased. This is a Samsung J7 which goes for 20,000.

The statistician will be paid 30,000.Methodology development 10,000 and 20,000 for data analysis and the research assistant will be paid 40,000 for the study period.

Miscellaneous will cater for any extra cost incurred.

APPENDICES

Appendix I: General Patient Information Form and consent form (English Version)

My name is Dr. Lillian Wairimu Mokoh. I am the principal researcher in this study. The study has been approved by the KNH/UON Ethics and Research Committee.

I am conducting a study entitled **VALIDATION OF THE USE OF HEAR SCREEN A MOBILE PHONE APPLICATION AS A SCREEING TOOL FOR HEARING LOSS IN KENYATTA NATIONAL HOSPITAL**

The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research:

i) Your decision to participate is entirely voluntary
ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities.

We will give you a copy of this form for your records.

May I continue? YES / NO

How you will participate?

a) I will ask you questions regarding your current complains and the history of your condition

b) I will carry out a complete Ear, Nose, Throat, Head and Neck examination.

c) Pure tone audiometry test will be conducted on you from the convectional audiometer and from a smart phone

d) You will incur no extra financial costs and the confidentiality will be maintained at all times.

e) There will be no monetary benefits for participating in the study and it will be purely on a voluntary basis.

f) You will be informed about investigations and importance of the results.

g) You will reserve the right to withdraw from the study at any time without discrimination

Are there any risks involved?

There are no known risks anticipated in your participation in this study.

Is there any penalty for refusing to participate in the study?

No, there are no penalties and the patient will receive treatment as prescribed

What benefits will I get for participating in the study?

Any abnormalities found in your hearing will be attended to by an ENT specialist.

What about confidentiality?

All the information that we obtain will be kept confidential.

Are there any extra costs involved?

There are no extra costs involved in the participation in this study. The patient will however be subject to any standard fees charged by the Kenyatta National Hospital as part of their management.

Are you satisfied with the information provided?

In case of any questions or inquiries, contact the following:

Secretary, KNH/UoN-ERC

P.O.BOX 20723KNH, Nairobi 00202

Tel 020726300-9

E-mail: uonknh-erc@uonbi.ac.ke

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MSC Clinical Audiology

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Part 2: Consent Certificate by the patient/Next of kin

Patient study number: ……

Consent by patient:

I…….of……do hereby give consent to be included in this study on validation of hear screen a smart phone based audiometry test as a screening tool in KNH.

The nature of the study has been explained to me by the doctor.

I Dr……..confirm that I have explained to the patient the nature of the study.

Date……..Signed…….

Patient /next of kin:

Date ……Signed …….

Appendix II: General Patient Information Form and consent form (Swahili version)

Fomu ya maelezo:

Utangulizi

Mimi ni daktari Lilian Wairimu Mokoh. Mimi ni mwanafunzi katika idara ya upasuaji wa maskio, pua na koo. Ninakuomba idhini yako kushiriki katika utafiti huu

Utashiriki jinsi gani

a) Nitakuuliza maswali kuhusu malalamiko yako ya sasa na historia ya hali yako
b) Nitapima hali ya ugonjwa wako wa masikio.
c) Tutatumia mashini na simu kupima masikio yako
d) Hutakuwa na gharama za ziada za kifedha na usiri utahifadhiwa wakati wote
e) Hakutakuwa na faida ya fedha kwa ajili ya kushiriki katika utafiti na itakuwa tu kwa msingi wa hiari.
f) Utatambuliwa kuhusu uchunguzi na umuhimu wa matokeo.
g) Utakuwa na haki ya kujiondoa kwenye utafiti wakati wowote bila ubaguzi.

Kushiriki kutakuathirije?

a) Utafiti huu hautakuathiri kwa njia yoyote

Kuna hatari yoyote katika ushiriki wako au kutoshiriki kwako?

a) Hakuna
b) Kukataa kushiriki katika utafiti huu hautaathiri ubora wa huduma utakayopokea.

Tutafanya nini na habari tutakayopata

Tutashiriki matokeo yetu na watu wengine kufanya masomo sawa na tunaweza kuchapisha matokeo yetu katika magazeti ya kisayansi au kuwasilisha katika mikutano ya kisayansi. Usiri wa wagonjwa wote utahifadhiwa.

Je, unastahili na taarifa iliyotolewa?

Ikiwa umeridhika na ufafanuzi wetu na uko tayari kushiriki, basi tafadhali saini fomu ya ridhaa hapa chini.

SEHEMU YA PILI: Fomu ya makubaliano

Numbari ya utafiti: ……

Kibali cha utafiti:

Mimi Bi/Bwana…… nimekubali kushiriki katika utafiti huu.

Sahihi yangu ni thibitisho ya kwamba nimeelewa umuhimu wa utafiti huu na kwamba habari yoyote nitakayotoa itawekwa siri.

Tarehe……Sahihi ……...

Mimi daktari …… nadhibitisha ya kwamba nimeeleza mgonjwa kuhusu utafiti huu.

Tarehe ……..Sahihi……..

Ukiwa na maswali yeyote au Kwa maelezo zaidi kuhusu utafiti huu unaweza kuwasiliana na;

Mtafiti mkuu

Daktari Lilian Wairimu Mokoh
Mwanafunzi wa upasuaji wa masikio,mapua na koo,
Chuo kikuu cha Nairobi,
Simu : 0720 710617
Barua pepe:wairimumokoh@gmail.com

Wasimamizi

Professor Herbert Oburra
Daktari wa upasuaji wa Masikio, mapua na koo
Idara ya upasuaji,
Chuo kikuu cha Nairobi,
SLP 20723 -2002002
Nairobi

Daktari Samuel Nyaga
Daktari wa upasuaji wa Masikio, mapua na koo
Idara ya upasuaji,
Hospitali kuu ya Kenyatta,
20723-2002002
Nairobi

Binti Serah Ndegwa
Mhadiri wa Audiologia
Chuo Kikuu Cha Nairobi
20723-2002002
Nairobi

utafiti yanaweza kutumwa kwenye *Kenyatta National Hospital/UON- Ethics and Research Committee (KNH/UON-ERC)* by numbari *2726300 Ext. 44355*.

Appendix III: Data Collection Tool

Code…….....Age (years) ……... Sex- Male/Female

Residence……

Level of education.....……

Other relevant history.....

(Head trauma, medication, comorbidity, nasal or nasopharyngeal disease, allergies).If present specify.

1. Focused Otologic History

	YES(√) or NO (x)		Comments
	Right	Left	
a. Ear Pain			
b. Reduced hearing			
c. Ear Discharge			
d. Tinnitus			
e. Vertigo			
f. Known ear disease			
g. Previous ear surgery			

2. Ear exam, otoscopy and tuning fork test (Indicate if normal or the specify findings)

	Right		Left
a. Post auricular			
b. Preauricular			
c. Pinna			
d. EAC			
e. Tympanic Membrane			
f. Rinnes' test			
g. Webers' test	Right	Central	Left

3. Convectional PTA vs Smart phone based PTA

FREQUENCY IN KHZ	Convectional PTA		SmartPhone PTA Office		Smart phone PTA clinic	
	Right Ear	Left Ear	Right Ear	Left Ear	Right	Left
0.5						
1						
2						
4						
8						

Smart phone based PTA environment ……

4. Time taken for each test ……..

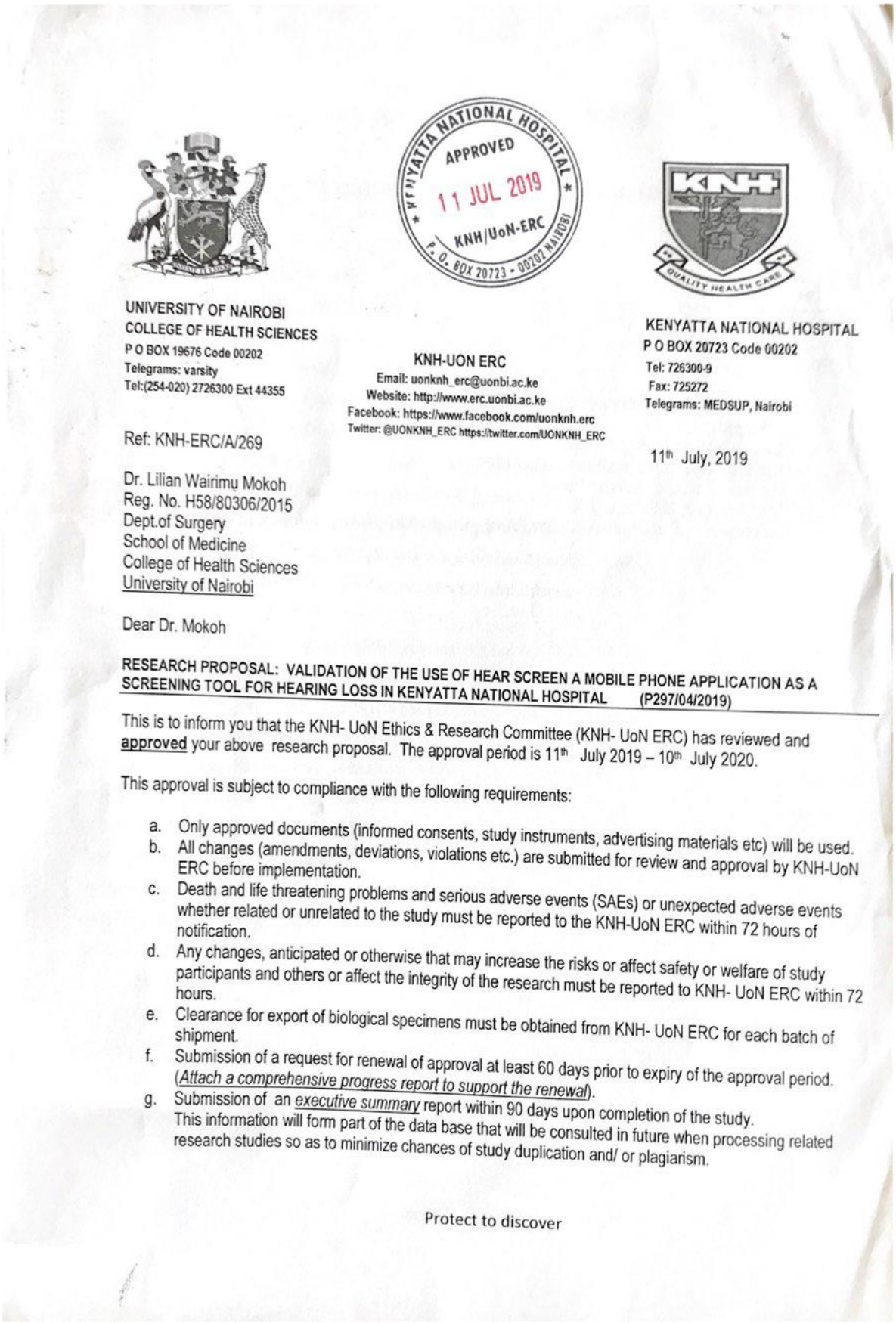
5. Of the two modes of testing you have undergone which would you prefer ? ……
……
……..……

Appendix IV: Images

Smart phone based PTA results

Image of the phone and head phones to be used in the study

Appendix V: KNH/UON-ERC Letter of Approval



KENYATTA NATIONAL HOSPITAL
APPROVED
11 JUL 2019
KNH/UoN-ERC
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Ref: KNH-ERC/A/269

11th July, 2019

Dr. Lilian Wairimu Mokoh
Reg. No. H58/80306/2015
Dept.of Surgery
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Mokoh

RESEARCH PROPOSAL: VALIDATION OF THE USE OF HEAR SCREEN A MOBILE PHONE APPLICATION AS A SCREENING TOOL FOR HEARING LOSS IN KENYATTA NATIONAL HOSPITAL (P297/04/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 11th July 2019 – 10th July 2020.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

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

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Surgery, UoN
Supervisors: Prof. Herbert Oburra,(UON), Dr. Samuel Nyaga(KNH),Ms. Serah Ndegwa(UON)

Appendix VI: Certificate of Plagiarism

 Turnitin Originality Report

VALIDATION OF THE USE OF HEAR SCREEN, A MOBILE PHONE APPLICATION AS A SCREEING TOOL FOR HEARING LOSS AT THE KENYATTA NATIONAL HOSPITAL by Lilian Wairimu Mokoh

From Otorhinolaryngology, Head and Neck Surgery (Master of Medicine)

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