

Etiology of ear infection and associated factors among patients attending otorhinolaryngology clinic at muhimbili national hospital

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**MSc (Microbiology and Immunology) Dissertation
Muhimbili University of Health and Allied Sciences
October, 2021**

Muhimbili University of Health and Allied Sciences

Department of Microbiology and Immunology



**ETIOLOGY OF EAR INFECTION AND ASSOCIATED FACTORS
AMONG PATIENTS ATTENDING OTORHINOLARYNGOLOGY
CLINIC AT MUHIMBILI NATIONAL HOSPITAL**

By

Aminiel Robert Shangali

**A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree
of Master of Science (Microbiology and Immunology) of**

**Muhimbili University of Health and Allied Sciences
October, 2021**

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled; **“Etiology of ear infection and associated factors among patients attending Otorhinolaryngology clinic at Muhimbili National Hospital”**, in (partial) fulfillment of the requirements for the degree of the of Master of Science (Microbiology and Immunology) degree of Muhimbili University of Health and Allied Sciences.

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(Supervisor)

Date

Dr. Willybroad Massawe

(Supervisor)

Date

DECLARATION AND COPYRIGHT

I, **Aminiel Robert Shangali**, declare that this **dissertation** is my original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature.....

Date.....

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ACKNOWLEDGEMENTS

First and foremost, I would like to express my deepest gratitude to my Almighty God followed by my research supervisor, Dr Doreen Kamori for her assistance and dedicated support in every step throughout the process. Her guidance helped me in all the time of research and writing of this dissertation. I could not have imagined having a better advisor and mentor for my master's study. Additionally, I wish to thank my co-supervisor Dr. Willybroad Massawe from the department of Otorhinolaryngology, Muhimbili National Hospital (MNH) for his support during proposal development and data collection.

I would also like to thank the rest of the academic members of the Department of Microbiology and Immunology, Muhimbili University of Health and Allied Sciences (MUHAS); including Prof. Mecky Matee, Prof. Eligius Lyamuya, Prof. Said Aboud, Dr Mtebe Majigo, Dr Agricola Joachim, Dr Joel Manyahi, Dr Frank Msafiri, Dr Salim Masoud, Ms Upendo Kibwana and Ms Lilian Nkinda for their encouragement and support during my residency Programme.

I also acknowledge and extend my appreciation to staff members of the Otorhinolaryngology clinic from MNH for their assistance, advice and cooperation. Also, I wish to thank all staff members of Microbiology laboratory at MUHAS and Central Pathology Laboratory, MNH for their support and cooperation.

Last but not least I express special thanks to my family and colleagues for their encouragement, advice and challenges during the whole study period.

DEDICATION

This dissertation is dedicated to my late father Mr Robert A. Shangali and my beloved mother Mrs Patricia R. Shangali.

ABSTRACT

Background: Ear infection is a global problem with high incidence in developing countries that tends to subject individual to prolonged antibiotic use which increases risks of multidrug resistant bacteria thus increase cost of treatment and decrease quality of life. Early and effective detection and management of ear infection together with knowledge of factors associated with ear infection will decrease complications that could arise.

Methodology: The study was a hospital-based cross-sectional study, conducted for a period of 3 months in Otorhinolaryngology clinic at Muhimbili Nation Hospital (MNH), Tanzania. A standardized questionnaire and patient's medical records were used to obtain participant's social demographic, behavioural and clinical information. All the patients attending otorhinolaryngology clinic at MNH with ear complaints such as accumulation of fluid in the middle ear, bulging of the eardrum, ear pain, ear itching, perforation of the eardrum and ear discharge (otorrhea) consented or assented to participate in the study were included. Patients with other hearing disorders (congenital malformations, physical head injury, etc.) and patients who are on regular checkups were excluded. Culture and sensitivity was done. Data was stored in MS Excel program and processed by using SPSS v23. Mean and median will be used to describe continuous variables depending upon the distribution of the data. Logistic regression was used to determine the association for categorical variables. Statistical significance was defined at a p-value of < 0.05 .

Results: This study recruited 255 participants with a median age of 31 years (IQR: 15- 49). The majority of the participants 134 (52.5%) were males and majority had otitis externa (OE) (45.1%). 65.9% study participants who presented with ear infection had positive cultures. The overall distribution of the bacteria *spp* indicated that the predominant bacteria isolated were *S. aureus* with the frequency of 36/132(27.3%) and *Pseudomonas aeruginosa* with the frequency of 32/132(24.2%). Regarding fungi, *Candida spp* (63.8%) and *Aspergillus spp* (36.2%) were the most frequently isolated fungi organisms. Regarding antimicrobial susceptibility patterns, 94% of isolated bacteria were resistant to Amoxy/clav and 75.5% resistant to ceftazidime. In this study, the proportion of ESBL and MRSA were 34.4% and 47%, respectively.

Furthermore the study revealed that ear infection was associated with cotton buds use (AOR 2.66, 95%CI 1.03-6.91, p 0.044), preference for cerumen impaction (AOR 13.94, 95%CI 2.93-66.33, p=0.001), preference for recurrent URTI (AOR 3.0, 95%CI 1.01-8.93, p=0.047) and nasal congestion/discharge (AOR 3.14, 95% CI 1.20-8.23, p = 0.020)

Conclusion and recommendations: The present study revealed that the leading etiological agent of ear infection in our setting are bacteria; and that there is a significant proportion of Extended Spectrum Beta-Lactamase producing bacteria and Methicillin-resistant *Staphylococcus aureus* causing infection. In addition, ear infection was associated with recurrent URTI, nasal congestion, cotton buds use and cerumen impaction. Therefore, these findings suggest that empirical treatment should be avoided and indicate that there is a need to improve community awareness on proper ear hygiene and knowledge on cotton bud use. Also early diagnosis and treatment of URTI and cerumen impaction to prevent ear infection and the potential complications.

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LIST OF ABBREVIATIONS

ATCC:	American Type Culture Collection
AOM:	Acute otitis media
BA:	Blood agar
CA:	Chocolate Agar
CLSI:	Clinical and Laboratory Standards Institute
CSOM:	Chronic suppurative otitis media
MCA:	Mac Conkey Agar
MDR	Multidrug Resistance
MNH:	Muhimbili National Hospital
OME:	Otitis Media with Effusion
SDA:	Sabouraud Dextrose Agar
SIM:	Sulphur Indole and Motility
TM	Tympanic membrane
TSI:	Triple Sugar Iron
URTI:	Upper Respiratory Tract Infection

DEFINITION OF TERMS

Ear infection: Ear infection is a generalized terminology that incorporates a wide range of ear inflammatory disorders presenting with fever, accumulation of fluid in the middle ear, bulging of the eardrum, ear pain, perforation of the eardrum and ear discharge (otorrhea) confirmed by positive culture results.

Etiological agents of diseases: Material known or reasonably expected to be viruses, fungi, bacteria, and parasites that can cause disease in humans or animals.

Antimicrobial resistance: Ability of microorganisms to resist the effects of medication that once could successfully treat the microbe.

Otorhinolaryngology: A surgical subspecialty within medicine that deals with surgical and medical management of ears, nose, and neck surgery.

Antimicrobial susceptibility testing: This is testing done to assure the susceptibility to drugs of choice for particular infections or to detect resistance in individual bacterial isolates.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Ear infection is a generalized terminology that incorporates a wide range of ear inflammatory disorders due to inhabitation of bacteria or fungi infection in the ear, including (Otitis externa), acute otitis media (AOM), otitis media with effusion (OME), Chronic Suppurative Otitis Media (CSOM) and labyrinthitis (1,2). Most patients with ear infections delay seeking medical attention, hence present with complications including perforation of the tympanic membrane, meningitis, brain abscesses, mastoiditis and subsequently preventable hearing loss (3).

Bacteria and fungi are reported to be causative agents of ear infection. (3–8). Fungi infections are always attributed to prolonged antibiotic use and immunosuppression state but still underestimated especially in developing countries. Due to poor diagnostic methods, most ear infections triggered by fungi go undiagnosed especially in resource-limited countries (8). Lack of updated treatment guidelines of ear infection contributes to an increase in multidrug resistance (MDR) bacteria, since most ear infection cases are managed symptomatically without considering laboratory diagnosis. The resulting burden of MDR bacteria subsequently increases treatment costs and affects treatment outcomes. (5). Furthermore, the frequency of occurrence of ear infection has been linked to several factors including use and sharing of earphones, frequent use of cotton buds, age, underlying ear diseases, immunosuppression, swimming habit, cerumen impaction, URTI, nasal blockage or discharge and parental cigarette smoking (4,5,9–12).

However, due to scarce of data and change in trend over time and geographical location of etiological agents causing ear infection makes this study of great value. Also, it is essential to characterize the current antimicrobial susceptibility patterns of the isolated bacteria species causing ear infection in our local setting and determine the extent to which factors are associated with ear infections in our local setting. Therefore, this study aimed to determine etiological agent, associated factors and antimicrobial susceptibility pattern of isolated bacteria.

1.2 Problem Statement

The burden of ear infection in developing countries including Tanzania is high compared to the developed world. This can be due to a lack of community awareness, low income, poor hygiene, low access to medical care and lack of updated management guidelines

Ear infection is among the leading causes of hospitalization, antibiotic prescription and hearing loss. Inappropriate diagnosis and mismanagement of ear infection can increase the risk of multidrug resistance bacteria which affect the management, quality of life and upsurge the cost of treatment and death.

Currently, in our local setting, there is limited information on etiological agents and the associated factors of ear infection. Furthermore, there are no updated data on antimicrobial susceptibility patterns of the bacteria isolates associated with ear infection.

Therefore, the present study aimed to determine the etiology of ear infection and factors associated with ear infection. In addition, this study determined the antimicrobial susceptibility patterns of bacteria causing ear infections among the patients attending the Otorhinolaryngology clinic at MNH.

1.3 Conceptual Framework

Ear infection is a global problem commonly caused by both bacterial and fungal agents. Studies show there is an association between ear infection with several factors including frequent use of earphones and cotton buds, swimming, smoking habits, URTI, nasal blockage, cerumen impaction and age whereby, children are more affected compared to adults. Furthermore, ear infection caused by bacteria species may contribute to an increase in MDR bacterial infection.

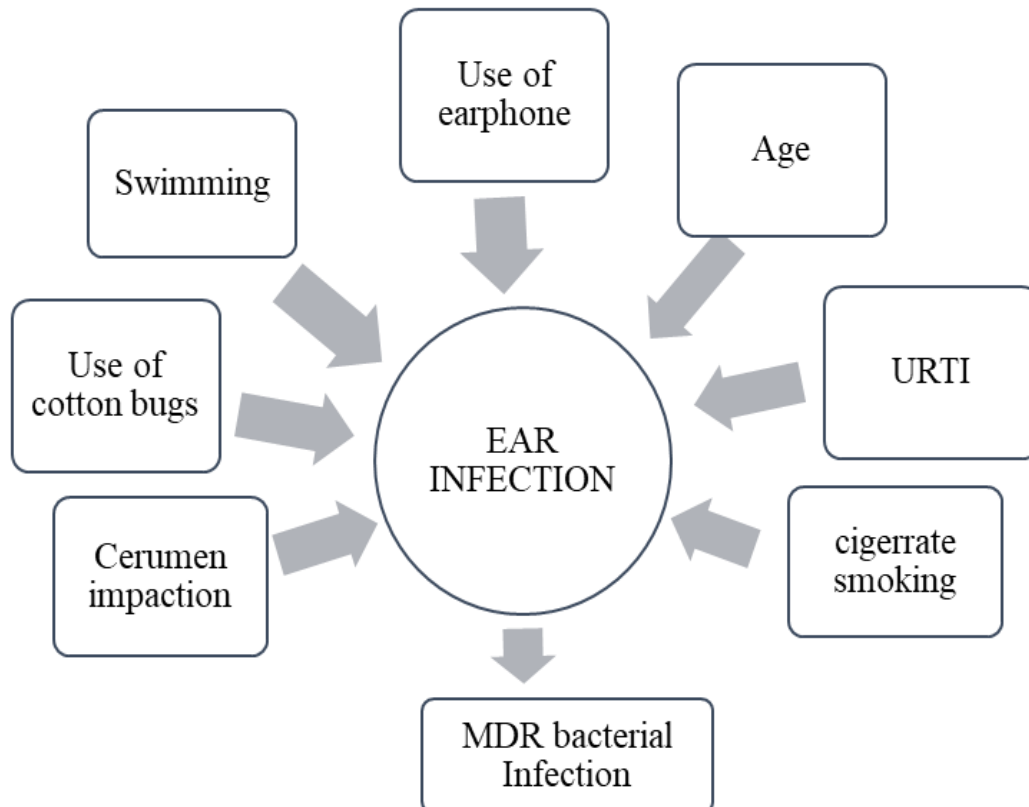


Figure 1: Illustrates the factors associated with ear infection

1.4 Rationale of the study

The proposed study aimed to determine the etiology of ear infection among patients attending the Otorhinolaryngology clinic at MNH and identified the factors associated with ear infection. Such information will be useful in devising appropriate interventions such as providing health education, knowledge and awareness on proper ear hygiene.

Also, the study revealed the antibiotic susceptibility profiles of the isolated bacteria. These findings will be useful in our local settings as a reference and will be used to provide an update on treatment choice and management of ear infection. Also, the data will form a baseline for ongoing antimicrobial resistance surveillance in the country.

1.5 Research Questions

1. What bacterial and fungal species are associated with ear infection in patients attending Otorhinolaryngology clinic at MNH?

1.6 Study Objectives

1.6.1 Broad Objective

To determine the etiological agents, associated factors and antimicrobial susceptibility patterns of bacteria species causing ear infection among patients attending Otorhinolaryngology clinic at MNH

1.6.2 Specific Objectives

1. To determine bacterial species and proportion of fungi causing ear infection among patients attending otorhinolaryngology clinic at MNH.
2. To determine the antimicrobial susceptibility patterns of bacteria isolates causing ear infection among patients attending otorhinolaryngology clinic at MNH
3. To identify factors associated with ear infection in patients attending otorhinolaryngology clinic at MNH.

1.7 Literature Review

1.7.1 Bacteria species associated with ear infection

Ear infection may emerge due to persistent colonization of bacteria in the nasopharynx. Bacteria including *Streptococcus pneumoniae*, *H. influenzae* and *Moraxella catarrhalis* may ascend to the middle ear via eustachian tube forming a biofilm that protects bacteria against immune response and antibacterial agents (3).

Globally studies on ear infection show a decrease in ear infection incidences in developed countries due to vaccination against the virus causing URTI which tend to co-exist with bacterial colonization in the nasopharynx. However, studies done in the USA, Spain, Australia, UK, Asia (China, Syria, Nepal, Pakistan, India, Singapore and Iran) to determine bacterial etiology among individuals with ear infection showed a dominance of *Pseudomonas spp*, *Staphylococcus aureus*, *M. catarrhalis*, *S. epidermidis*, *Streptococcus pneumoniae*, *H. influenzae* and *Proteus spp* (13–21)

In Africa, studies show an increase in the incidence of ear infection compared to the developed world. This exhibits a clear snapshot that the burden of ear infection varies with economic status (3). Studies done in South Africa, Nigeria, Egypt, Sudan, and Ethiopia showed *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Proteus mirabilis*, *Klebsiella pneumoniae*, *Enterobacter spp*, *Citrobacter spp*, *H. influenzae*, *Moraxella catarrhalis*, *Streptococcus pyogenes*, *Streptococcus pneumoniae* and *Escherichia coli* as the most common bacteria associated with ear infection (22–27)

In Tanzania, there are few studies done in Dar es Salaam, Mwanza and Morogoro; these studies found *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Escherichia coli*, as the most common isolates (5,10,12); however, this trend may change over time.

1.7.2 Fungal species associated with ear infection

Ear fungal infection is also referred to as otomycosis when is caused by colonization of fungi in the outer or middle ear. Studies were done in the USA and Australia to determine fungal

aetiology of ear infection showed *Aspergillus spp* and *Candida spp* to be the most isolated fungi (19). Furthermore, studies in China, Syria, Nepal, Turkey, Pakistan, India, Singapore and Iran showed *Aspergillus spp* and *Candida spp* to be the most common fungal isolates to cause ear infection (13–17,28,29). However, studies done in African countries i.e. Nigeria, South Africa, Egypt, Sudan, and Ethiopia described *Aspergillus spp*, *Candida spp*, *Penicillium spp* and *Mucor spp* to be the most common isolated fungi among individuals with an ear infection (22,23,25,30).

In Tanzania, there's limited information on fungal as an etiological agent of ear infection, so far there is only one study done in Mwanza city; this study observed that *Candida spp*, *Aspergillus spp* and *Penicillium spp* were the most common isolates (8). Therefore, further studies are warranted to assess the burden of fungal associated ear infections

1.7.3 Antimicrobial susceptibility profile

Due to poor diagnosis procedures and outdated treatment guidelines the risk of developing MDR bacteria increases among patients with ear infection. Studies from different countries show bacterial isolates with resistance to different antibiotics. Studies done in Asia, Nepal, Pakistan, Singapore and Korea show most bacterial isolates were resistant to penicillin, chloramphenicol and ampicillin (13–16,31). Also, studies in African countries like Egypt, Ethiopia and Nigeria showed most isolated bacteria were resistant to tetracycline, clindamycin, oxacillin, chloramphenicol, ampicillin and amoxicillin/clavulanic acid. But ciprofloxacin and meropenem were high susceptible antimicrobial agent(22–25).

Furthermore, studies done in Tanzania had a similar resistant pattern. Most of the isolated gram-positive bacteria were resistant to erythromycin and ampicillin while amoxicillin/clavulanic acid and ceftazidime was resisted by most Gram-negative bacteria (GNB) (5,6,12).

1.7.4 Factors associated with ear infection factors

Ear infection has been linked with several associated factors which hasten disease progression. Much of what we know on factors associated with an ear infection is due to various studies conducted in different regions of the world. Studies conducted in the USA, Romania, Canada, Brazil UK, Asia in countries like India, Nepal, Israel, Malaysia and Iran demonstrated the following parameters as factors associated with ear infection; age in which children are more affected compared to adults, social-economic status, swimming, and cerumen buildup. In addition, nasal diseases, inadequate antibiotic treatment, underlying immune deficiency diseases, middle ear diseases, poor living conditions, poor hygiene practices, lack of access to medical care, passive smoking habits, obesity, breastfeeding, recurrent URTI, use of earphones and habit to seek medical care were also reported to be associated with ear infection. (6,9,39–44,13,32–38).

However, in Tanzania, we have limited information on factors associated with ear infections, but few studies did show analogous outcomes on the factors associated with ear infection, including immunosuppression, smoking, poor treatment outcome, and delay in seeking medical care (5,6,10).

CHAPTER TWO

2.0 MATERIALS AND METHODS

2.1 Study Design

This study was a hospital-based cross-sectional study.

2.2 Study Area

The study was conducted in otorhinolaryngology clinic at MNH located in Dar es Salaam city, Tanzania. The hospital serves as a national referral, research and teaching hospital. The otorhinolaryngology department in the facility has inpatients department with 2 wards and an outpatient department. About 40 to 60 patients attend the outpatient clinic per day.

2.3 Study Duration

The study was conducted for a period of 3 months, from March to June 2021

2.4 Study Population

The study included all patients including children and adults with ear infection attending otorhinolaryngology clinic.

2.5 Selection Criteria

2.5.1 Inclusion Criteria

- All the patients attending otorhinolaryngology clinic at MNH with ear complaints such as accumulation of fluid in the middle ear, bulging of the eardrum, ear pain, ear itching, perforation of the eardrum and ear discharge (otorrhea)
- Patients who consented or assented to participate in the study.

2.5.2 Exclusion Criteria

- Patients with other hearing disorders (congenital malformations, physical head injury, etc.).
- Patients who are on regular checkups

2.6 Sampling Procedures

A simple random sampling method was used to recruit every patient visiting the otorhinolaryngology clinic with an ear infection until the estimated sample size was attained.

2.7 Sample Size Estimation

The sample size was estimated by using the Kish Leslie formula (1965) using the prevalence of 62% obtained from a study done in Tanzania (5).

$$N = \frac{Z^2 P (1-P)}{D^2}$$

Whereby

Z=standard deviation of the normal distribution = 1.96 (confidence level at 95%)

P=prevalence 62.1% (5)

D=Margin of error 6%

N=251

The minimum required sample size was 251 participants with ear infections.

2.8 Variables of the study

2.8.1 Dependent variables

Ear infection

2.8.2 Independent variables

Age, sex, education level, breastfeeding, use of hearing aid instrument, use of earphones, swimming, marital status, cigarette smoking, nose congestion, recurrent URTI, cerumen impaction and frequent use of cotton buds.

2.9 Data Collection

A well-structured data collection tool/ questionnaire was used to collect the demographic, clinical and behavioral information of patients with ear infection attending otorhinolaryngology clinic. Demographic information included age, sex, marital status, occupation and educational background. Behavioral information will include swimming

behavior, frequent use of earphones and cotton buds, use of sharp objects, and cigarette smoking. In addition, clinical information including the type of ear infection, use of hearing aid, use of antibiotic, nose congestion or blockage, recurrent URTI and cerumen impaction were also collected from the patient's medical records and during physical examination.

2.10 Specimen Collection

A sterile swab was used to collect the specimen, whereby a pus swab was collected aseptically using a flexible shaft swab from the external ear canal. The swab was kept in Amies or Stuart transport media. All samples were transported to CPL, MNH for processing and testing.

2.11 Laboratory Procedures

2.11.1 Sample processing

The specimen was inoculated in selective and non-selective agar: Chocolate agar (CA), Sheep-Blood agar (sBA), MacConkey agar (MCA), and Sabouraud dextrose agar (SDA) if otomycosis suspected. Bacterial isolates were identified by interpretation of colonial morphologies and microscopic examination (gram stain). Biochemical tests such as catalase test, coagulase test, DNase and bile esculin were used to identify gram-positive bacteria. While citrate, urease, Kliger Iron Agar (KIA) test, oxidase, and indole were carried out to aid the identification of gram-negative bacteria. Further, phenotypical identification and confirmation of bacterial isolates were performed by biochemical tests API 20E and API 20NE.

For fungi isolates, growth on the SDA plate was used preliminary to classify mould or yeast based on the colony morphology and colour. Yeast colonies were identified as the growth of creamy to white colonies while moulds were identified as the filamentous colonies. A germ tube test was used to identify *Candida albicans* as a proportion of fungal isolates.

Antibiotic Susceptibility Test (AST) for bacterial isolates was performed using the Kirby Bauer disc diffusion technique on Mueller-Hinton Agar (MHA) following the 2021 Clinical and Laboratory Standard Institute. Zones of inhibition were measured in millimeters and

interpreted to either susceptible, resistant or intermediate according to CLSI guideline but all intermediate results were regarded as resistant. During analysis percentage of resistance was obtained by computing the number of particular bacteria species that resisted a specific drug over a total number of isolated bacteria of the same species.

1. Gram-Positive Bacteria – antibiotic discs: ciprofloxacin (5µg), trimethoprim/sulphamethoxazole (1.25/23.75µg), gentamycin (10µg), Clindamycin and erythromycin (15µg). Cefoxitin (30µg) was used to detect MRSA.
2. Gram Negative Bacteria – antibiotic discs: ciprofloxacin (5µg), trimethoprim/sulphamethoxazole (1.25/23.75µg), gentamycin (10µg), meropenem (10µg), amoxicillin/clavulanic acid (20µg), ceftriaxone (30µg) and ceftazidime (30µg). Double disc synergy method for ESBL confirmation was used whereby cefotaxime (30µg), ceftazidime (30µg) together with Amoxyclav were used.

2.11.2 Quality control

Quality control was done to ensure sterility of the newly prepared media by using the control strain *E. coli* ATCC-25922 and *S.aureus* ATCC-27065 which was inoculated onto MCA for lactose fermenting and *S. aureus* ATCC-25922 was cultured onto BA as a control for hemolysis, both of the above was used to evaluate the performance of our media and method. The sterility control was done by incubating newly prepared plates media at 35⁰c to 37⁰c, for 18-24 hours. After incubation, if no growth then sterilization is achieved and if there was growth means sterilization was not achieved or contamination occurred during media preparations. Drug susceptibility test quality control was done to test the sensitivity of the drug and media prepared. Furthermore, control organisms were used to test the quality of each reagent or test done. All stains and other reagents were clearly labelled, and stored correctly. The operating room, refrigerator and incubator temperatures were monitored and documented daily. Also to insure quality of collected specimen, proper sample collection, transportation and storage at 4⁰c to 8⁰c was guaranteed. Then gram stain was done observing epithelial cells and PMN cells. An increase PMN cells while normal range of epithelial cells suggests for infection. This was a baseline used to differentiate colonization from infection.

2.11.3 Validity and reliability

Results from this study depended on good practice in the pre-analytic stage including correct procedures during sample collection, proper labelling of the specimen and safe transportation of the sample including proper storage and temperature (2°C– 8°C) to the laboratory and this was guided by standard operating procedures. Clinical and demographic data for each study participant was obtained by using a standardized questionnaire and patients' medical records. The use of a standard questionnaire is said to be reliable because all participants were subjected to the same questionnaire when evaluating the factors associated with ear infection.

2.12 Data management and analysis

2.12.1 Data management

Demographic information, clinical information from questionnaires and laboratory data was stored in a logbook. Then data was cross-checked, and fed into computer Microsoft excel program.

2.12.2 Data Analysis

The data saved in the Microsoft excel program was transferred and analyzed using SPSS v23 software. To address the first specific objective which is to determine bacterial species and proportion of fungi causing ear infection among patients attending otorhinolaryngology clinic at MNH, the percentage was calculated. In which, percentage was obtained by computing positive culture growth divide by all collected samples multiply by a hundred percent.

In the second objective which is to determine the antimicrobial susceptibility patterns of bacteria isolates causing ear infection among patients attending otorhinolaryngology clinic at MNH, the percentage was used to represent the magnitude of resistance for each isolated bacteria.

To identify factors associated with ear infection in patients attending otorhinolaryngology clinic at MNH. Logistic regression was used to determine the strength of independent association between independent and dependent variables considering odds ratio with a 95% Confidence Interval (CI) and statistically significant association was defined at a p-value of < 0.05.

2.13 Ethical Consideration

The study was carried out as per Ethical Guidelines. Ethical clearance was obtained from MUHAS Senate Research and Publication Committee. Ethical clearance reference number was DA.282/298/01.C/. The permission to conduct this study was provided by the Muhimbili National Hospital. A written informed consent form was obtained from adult patients, assent was requested from adolescents and consent was requested from children's parents/ guardians, before including them in a study. Patient-related information was treated confidential and stored carefully using codes. Results on antimicrobial susceptibility testing were timely reported to the attending ENT specialist to guide in the selection of appropriate antimicrobial therapies for the patients recruited.

2.15 Dissemination of the findings

Following data analysis, copies of the report will be submitted to the director of MNH and the head of the department of Otorhinolaryngology, MNH. Conference presentations and seminars will be done and at least one manuscript will be submitted for publication in a peer-reviewed journal.

CHAPTER THREE

3.0 RESULTS

3.1 Socio-demographic characteristics of the study participants.

A total of 255 patients with ear infection were recruited, whereby 134 (52.5%) were males and 121 (47.5%) were females. The median age of the study population was 31 years (IQR: 15-49). Majority 53.7%, of the study participants were single and 32.9% of study participants achieved a higher learning education. The demographic characteristics of the study participants are summarized in Table 1.

Table 1: Socio-demographic characteristics of the study participants (n=255)

Variables	n	Percentage (%)
AGE		
Median age	31 years IQR: (15 - 49)	
AGE (Years)		
0-10	45	17.6
11-20	46	18
21-30	30	11.8
31-40	42	16.5
41-50	26	10.2
>51	66	25.9
SEX		
Male	134	52.5
Female	121	47.5
MARITAL STATUS		
Single	137	53.7
Married	107	42.0
Divorced/separated	11	4.3
OCCUPATION		
Self-employed	56	22.0
Civil servants	62	24.3
Retired/Jobless	49	19.2
Others	9	3.5
Students	77	30.2
Housewife/husband	2	0.8
EDUCATION		
Primary	75	29.4
Secondary	59	23.1
College	84	32.9
Illiterate	37	14.5
RESIDENCE		
Within Dar es salaam	215	84.3
Outside Dar es salaam	40	15.7

3.2 Clinical and behavior characteristics of study participants

Among 255 study participants, the median duration time of ear infection was 210 days (IQR: 21 to 1095). OE was the most common type of ear infection accounting for 45.1% (115/255) of all cases followed by CSOM that accounted for 41.2% (105/255) of the study participants (Figure 2). In this study almost half 49.1% of the participants had a history of antibiotic use in which ciprofloxacin ear drop was the most prescribed topical antibiotic and the least prescribed was chloramphenicol. Additionally, 33.3% of study participants had nasal congestion/blockage/discharge while 28.2% had recurrent URTI and 43.9% of study participants were cotton bud users. 17.6% of participants had cerumen impaction and 46.7% had ear cleaning habits using cotton buds or wet clean cloth. The clinical and behavior characteristics of the study participants are summarized in Table 2.

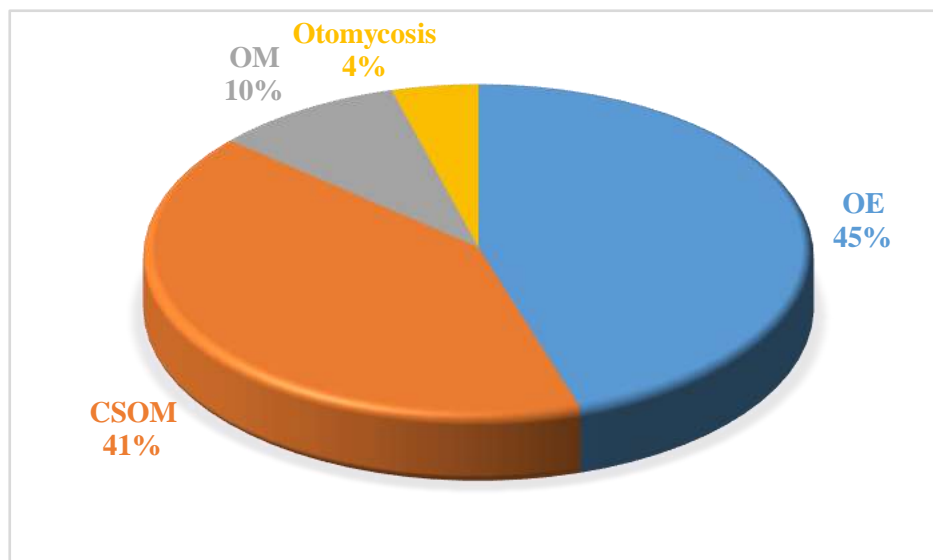


Figure 2: Illustrates distribution of type of ear infection among study participant (n=255)

3.3 Distribution of bacteria and fungi isolates causing ear infection among patients attending otorhinolaryngology clinic, MNH

In this study 168 out of 255 (65.9%) study participants had positive aerobic culture for either bacteria or fungi organisms within 48 hours of incubation (Figure 3). A total of 151 bacteria isolates and fungi were identified. Out of 151 isolates, 132/151 (87.4%) were bacteria and 19/124 (12.6%) were fungi species (Figure 4). Out of isolated bacteria, gram negatives were 94/132 (71.2%) whereby 34.4% were ESBL producing bacteria; and *Klebsiella spp* was the leading ESBL producing bacteria accounting to 33.3%. Gram positives bacteria were 38/132(28.8%) of which 47% were MRSA. The overall distribution of the bacteria *spp* indicated that the predominant bacteria isolated were *S. aureus* with the frequency of 36/132(27.3%) and *Pseudomonas aeruginosa* with the frequency of 32/132(24.2%). Other isolated bacteria included *Klebsiella spp* 21/132(15.9%), followed by *Acinetobacter spp* 10/132(7.6%), *Proteus mirabilis* 9/132(6.8%), *E.coli* 8/132(6.1%) and *Enterobacter spp* 6/132(4.5%) (Figure 5). All coagulase negative Staphylococcus and Bacillus *spp* were excluded from the analysis, they were considered as normal flora of the skin or contaminants.

In this study only two fungal organisms were identified, *Candida spp* and *Aspergillus spp* and accounted for 63.2% (12/19) and 36.8% (7/19) of the fungi isolates obtained, respectively. In addition, 32/168(19.0%) had polymicrobial infection meaning mixed growth of either two different bacteria or bacterial and fungal infection.

Further stratification of isolated pathogens per type of ear infection revealed that in patients with OE the predominant bacteria isolate were *S. aureus* and *Pseudomonas aeruginosa*; and patients with CSOM, *Pseudomonas aeruginosa* and *S. aureus* were also the dominant isolates (Figure 6). In contrast, fungal isolates were predominantly isolated in patients with otomycosis, OE and CSOM.

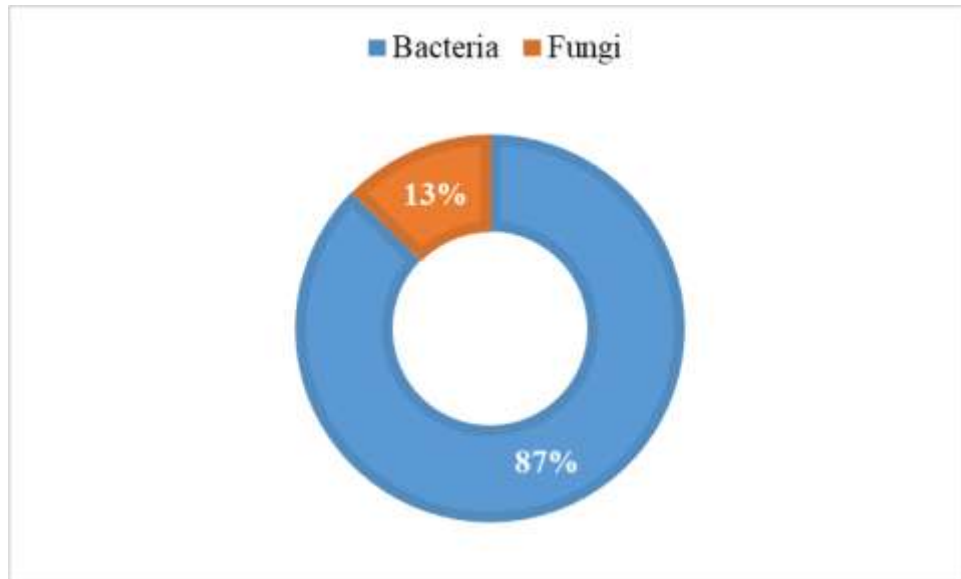


Figure 3: Depicts the distribution of isolates obtained from study participant (n=151)

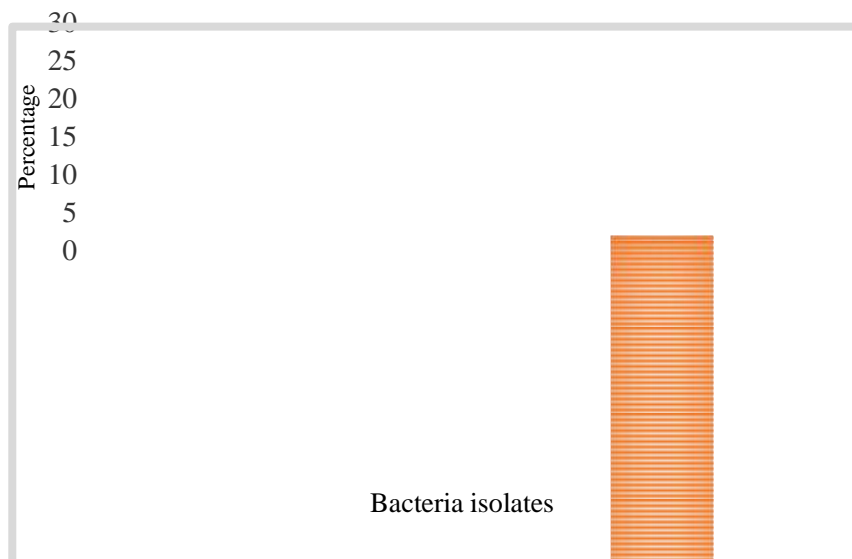


Figure 4: Illustrates distribution in percent of bacterial isolates (n=132)

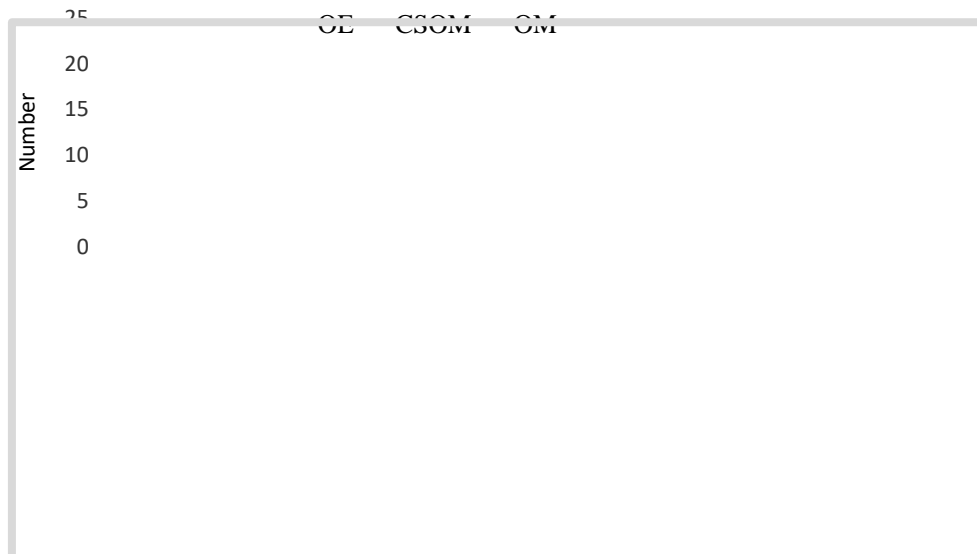


Figure 5: Depicts the distribution of bacterial isolates according to type of ear infection (n=132)

3.4 Antimicrobial Susceptibility pattern of bacteria isolates causing ear infection at MNH

In this study 94% of all the isolated *Enterobacteriaceae* family of bacteria were resistant to Amoxy/clav, more so *E. coli* and *Acinetobacter spp* were 100% resistant to Amoxy/clav. Also, 75.5% of isolated gram negative bacteria were resistant to ceftazidime whereby *Pseudomonas aeruginosa* had a high resistant rate of 75% against Ceftazidime. In addition, trimethoprim-sulfamethoxazole had a resistance rate of 35.4% whereby *E.coli* was leading with a 75% resistance rate. *S. aureus* had 89% resistance rate against erythromycin. Most isolated bacteria had very low resistant rate against meropenem 4.3% and ciprofloxacin 21.5%. The resistance rates for bacterial isolates is summarized in Table 3.

Table 2: Anti-microbial resistance pattern for the isolated bacterial species

Bacteria isolates	N	RATE OF RESISTANCE (%)											
		AK	SXT	GEN	CIP	AMC	CRO	CAZ	CXT	MRP	E	CN	FOX
1 <i>S.aureus</i>	36	NA	56	36	31	NA	NA	NA	NA	NA	89	25	44
2 <i>P. aeruginosa</i>	32	25	NA	17	34	NA	NA	75	NA	6	NA	NA	NA
3 <i>Klebsiella spp</i>	21	19	33	43	5	86	43	81	43	0	NA	NA	NA
4 <i>Acinetobacter spp</i>	10	20	10	10	0	100	50	70	80	10	NA	NA	NA
5 <i>P.mirabilis</i>	9	0	22	56	0	89	56	89	56	11	NA	NA	NA
6 <i>E.coli</i>	8	25	75	13	25	100	63	63	63	0	NA	NA	NA
7 <i>Enterobacter spp</i>	6	50	67	17	33	83	50	67	50	0	NA	NA	NA
8 <i>P.vulgaris</i>	3	33	33	67	33	100	33	67	33	0	NA	NA	NA
9 <i>Citrobacter spp</i>	5	40	80	20	0	100	60	80	100	0	NA	NA	NA

AK-Amikacin, SXT- Sulfamethoxazole trimethoprim, GEN-Gentamicin, CIP-Ciprofloxacin, AMC-Amoxy/clav, CRO-Ceftriaxone, CAZ-Ceftazidime, CXT-Cefotaxime, MRP-Meropenem, E-Erythromycin, CN-Clindamicin, FOX-Cefoxitin, NA- Not applicable

3.5.1 Factors associated with ear infection among patients attending otorhinolaryngology clinic

Pearson's chi-square test was done to determine relationship between independent variables and ear infection with positive culture (dependent variable). The results showed that there was a statistically significant relationship between positive culture with a type of ear infection ($p < 0.005$) whereby, participants with CSOM had a high number of positive cultures. In addition, cerumen impaction, cotton bud use, recurrent URTI, nasal blockage or discharge, cigarette smoking, ear phone use and use of sharp objects to relieve itching ears were also associated with ear infection (dependent variable) ($p < 0.005$). Other factors including swimming, use of hearing aid device, age and sex were not statistically associated with ear infection ($p > 0.05$). Factors associated with ear infection are summarized in Table 2.

Table 3: Descriptive characteristics of study participants and ear infection based on positive culture (Chi-square test)

Variables	N (%)	Positive culture (%)	p-value
Type of ear infection			0.001
OE	115(45.1%)	65(56.5%)	
CSOM	105(41.2%)	84(80.0%)	
OM	24(9.4%)	11(47.8%)	
Otomycosis	11(4.3%)	8(72.7%)	
Nasal congestion or discharge			<0.005
YES	85(33.3%)	76(89.4%)	
NO	170(66.7%)	92(54.1%)	
Recurrent URTI			<0.005
YES	72(28.2%)	65(90.3%)	
NO	183(71.8%)	103(56.3%)	
Cotton buds use			<0.005
YES	112(43.9%)	95(84.8%)	
NO	143(56.8%)	73(51.1%)	
Ear Cleaning			<0.005
Yes	119(46.7%)	104(87.4%)	
No	136(53.3%)	64(47.1%)	
Use of sharp objects			0.008
YES	60(23.5%)	48(80.0%)	
NO	195(76.5%)	120(61.5%)	
Cerumen impaction			<0.005
YES	45(17.7%)	43(95.6%)	
NO	210(82.4%)	125(59.5%)	

3.5.2 Univariate analysis of factors associated with ear infection

In univariate analysis, participants with nasal blockage or discharge had of 7 times increased risk to develop positive culture compared to those without nasal discharge/blockage (cOR 7.16, 95%CI 3.37-15.22, p-value<0.001). Also, the study shows that individuals with recurrent URTI had 7 times increase risk of yielding positive culture compared to those without recurrent URTI (cOR 7.21, 95%CI 3.14-16.58, p-value <0.001). Individuals with increased frequency of ear cleaning habits had approximately 8 times increase risk of yielding ear infection positive culture compared to those without ear cleaning habit. (cOR 7.8, 95%CI 4.12-14.76, p-value <0.001). Also, there was an increased risk by nearly 5 times among cotton bud users compared to non-cotton bud users and the association was statistically significant (cOR 5.36, 95%CI 2.90-9.88, p-value<0.001). Furthermore, the study showed that individuals with cerumen impaction had 14 times increase odds to develop ear infection positive culture compared to individuals without cerumen impaction (cOR 14.6, 95%CI 3.45-61.97, P-value =0.008) (Table 5). Although not included in table 5, factors such as use of hearing aid, use of earphone, swimming behavior, use of sharp objects showed no statistical significant association with positive culture ear infection.

3.5.3 Multivariable analysis of factors associated with ear infection

The multivariate logistic regression analysis indicated that cotton buds use (AOR 2.66, 95%CI 1.03-6.91, p 0.044), preference for cerumen impaction (AOR 13.94, 95%CI 2.93-66.33, p=0.001), preference for recurrent URTI (AOR 3.0, 95%CI 1.01-8.93, p=0.047) and preference to nasal congestion/discharge (AOR 3.14, 95% CI 1.20-8.23, p = 0.020) were independently associated with ear infection after adjusting for confounders. In contrast, use of sharp objects (AOR 0.83, 95%CI 0.31-2.23, p=0.705) and earphone use (AOR 0.91, 95%CI 0.30-2.75, p=0.873) were not statistically significantly associated with ear infection positive culture after adjustment for other factors (Table 5).

Table 3: Bivariate and Multivariable analysis of factors associated with ear infection

Variables	Positive culture (%)	Bivariate Analysis		Multivariate analysis	
		cOR(95% CI)	P-value	aOR (95% CI)	p-value
Type of ear infection					
OE	65(56.5%)	RE			
CSOM	84(80.0%)	3.08(1.68-5.63)	<0.005	1.71(0.80-3.66)	0.172
OM	11(47.8%)	0.60(0.24-1.46)	0.255	0.60(0.20-1.82)	0.366
Otomycosis	8(72.7%)	2.05(0.52-8.13)	0.307	2.62(0.53-12.72)	0.233
Nasal congestion or discharge					
YES	76(89.4%)	7.16(3.37-15.22)	<0.001	3.14(1.20-8.23)	0.020
NO	92(54.1%)	RE			
Recurrent URTI					
YES	65(90.3%)	7.21(3.14-16.58)	<0.001	3.0(1.01-8.93)	0.047
NO	103(56.3%)	RE		RE	
Earphone use					
YES	33(80.5%)	2.41(1.06-5.48)	0.035	0.91(0.30-2.75)	0.873
NO	135(63.1%)	RE			
Cotton buds use					
YES	95(84.8%)	5.36(2.90-9.88)	<0.001	2.66(1.03-6.91)	0.044
NO	73(51.1%)	RE		RE	
Use of sharp objects					
YES	48(80.0%)	2.5(1.25-5.01)	0.010	0.83(0.31-2.23)	0.705
NO	120(61.5%)	RE			
Ear Cleaning habit					
Yes	104(87.4%)	7.8(4.12-14.76)	<0.001	3.44(1.42-8.34)	0.006
No	64(47.1%)	RE		RE	
Cerumen impaction					
YES	43(95.6%)	14.6(3.45-61.97)	<0.001	13.94(2.93-66.33)	0.001
NO	125(59.5%)	RE		RE	

Adjusted OR for cerumen impaction, nasal blockage/discharge, recurrent URTI, Ear cleaning habit and Cotton bug use

CHAPTER FOUR

4.0 DISCUSSION

Ear infection has been a problem in many developing countries. This study shows bacteria as the leading etiological agent of ear infection. *S. aureus* and *Pseudomonas aeruginosa* were the most isolated bacteria. Whereby *Candida spp* and *Aspergillus spp* were the only isolated fungi spp. The isolated bacteria were resistant to erythromycin, ceftazidime, amoxycylav and sulfamethoxazole trimethoprim. While the bacteria were sensitive to meropenem and ciprofloxacin which is a standard treatment for ear infection. None the less, ear infection was associated with recurrent URTI, nasal discharge or blockage, cotton bud usage, ear cleaning habit and cerume impaction.

4.1 Etiological agents of ear infection

The present study revealed bacteria as the leading causative agent of ear infection. Whereby, *S. aureus* and *Pseudomonas aeruginosa* were the most isolated bacteria. The high contribution of these bacteria isolates can be due to the minimum requirement for survival, natural habitat and ability to survive on body surface. These findings concur with findings from previous studies done in Tanzania, Nigeria, Angola, Kenya and India among individuals with an ear infection that found a high proportion of *S. aureus* and *P. aeruginosa* compared to other bacteria isolates (5,15,45,46). Furthermore, the study revealed *S. aureus* and *Pseudomonas aeruginosa* as dominant isolates in patients with CSOM and OE. These findings are similar to studies done in Tanzania, and elsewhere in Nigeria, Iran and Egypt that showed *S. aureus* and *Pseudomonas aeruginosa* were among the most frequently isolated bacteria in individuals with OE and CSOM (17,23,47).

Additionally, in the present study only two fungi organisms were identified whereby *Candida spp* was the most frequently isolated fungi followed by *Aspergillus spp*. The contribution of fungi etiology in ear infection in the present study was expected because a significant proportion of individuals had risk behaviors for fungal ear infections. This finding is consistent with previous findings reported in other studies done in Tanzania, and elsewhere in

Nigeria, Iran, Ethiopia, Egypt and India that showed *Candida spp* and *Aspergillus spp* as most common isolated fungi among patients with ear infection (5,6,8,17,48,49). The similarity of these findings can be attributed to ear cleaning habit by using items such as cotton buds and water splashes which reduce earwax (cerumen) that protects the lining of the ear from fungi organisms such as *Candida spp*, *Aspergillus spp* and other fungal isolates (50,51).

The present study identified almost 20% of patients had polymicrobial infections. In contrast, another study conducted in Tanzania by *Zephania_et_al* reported a higher proportion of polymicrobial isolation of microbes 52.2%. This difference can be due to the majority of study participants in the present study were subjected to antibiotic use which may reduce the chances of polymicrobial isolation.

4.2 Antimicrobial resistance pattern.

This study revealed Amoxy/clav as the most resisted antimicrobial agent, whereby *E. coli* and *Acinetobacter spp* were 100% resistant to amoxy/clav. Also, in this study, 75% of isolated gram-negative bacteria were resistant to ceftazidime and 35.4% resistant to trimethoprim-sulfamethoxazole, while gram-positive were more resistant to erythromycin. Despite that ciprofloxacin was the most prescribed antibiotic in the present study, results revealed that meropenem and ciprofloxacin were effective in the management of ear infection. These resistance patterns are similar to those reported in other studies in Tanzania, Kenya, Ethiopia, India, Egypt and Romania whereby Amoxy/clav, erythromycin and trimethoprim-sulfamethoxazole were among the most resisted antimicrobial agent while ciprofloxacin and meropenem were more susceptible (5,6,15,23–25,41,46).

The resistance patterns against these microbial agent is because they are more prescribed in the treatment of other bacterial infection and likely that most bacteria species have evolved resistant mechanisms against Amoxy/clav, trimethoprim-sulphamethoxazole, ceftazidime and erythromycin over time. . In contrast, bacteria isolates were susceptible to meropenem because it is less prescribed in the treatment of ear infections. No clinical reason why quinolones are still more effective in the treatment of ear infection despite the high prescription rate, but these

findings give reassurance on the effectiveness of quinolones as first-line topical antibiotics in the treatment of ear infection. In addition, the percentage of MRSA in this study was found to be 47% and ESBL was found to be 34.4%. This is low compared to the studies done in Tanzania, Kenya and Ethiopia which had a higher percentage of MRSA and ESBL(5,46). This can be due to sample size differences. Whereby the present study has a small sample size which contributes to low number of isolates compared to studies done in other regions.

4.3 Factors associated with ear infection

There are several factors associated with ear infection. In this study cotton bud use, recurrent URTI, nasal congestion/blockage, ear cleaning habit and cerumen impaction showed a significant association to the outcome which is ear infection positive culture after multivariate analysis. This could be due to poor ear hygiene, whereby people tend to use a cotton bud as ear cleaning tool hence traumatize the ear canal or TM causing ear infection. Furthermore, it can be due to the relationship between the ear and nasopharynx via the eustachian tube. In individuals with nasal blockage or recurrent URTI due to bacterial infection, microbes can easily ascend to middle ear via the eustachian tube causing ear infection. These findings are similar to studies done in India, Italy and Israel (52–54). The similarity of the findings can be attributed to high humidity, water exposure and high temperature in the ear canal causing maceration of the ear canal and itching to which the patient responds by scratching with a cotton bud or sharp object resulting in trauma and breaking the surface of the external auditory canal. Edema follows alongside inoculation of indigenous bacteria causing ear infection.

Nonetheless, other factors i.e. earphone use, smoking and swimming show statistically significant association with ear infection in other studies done in Italy (54), but did not show statistically significant association with the outcome variable in this study. This can be due to difference in behavioral characteristics of study participants, whereby in this study very few participants were swimmers, cigarette smokers and had a tendency of earphone usage.

CHAPTER FIVE

5.0 CONCLUSION AND RECOMMENDATION

5.1 Conclusion

The present study has revealed that the leading etiological agent of ear infection in our setting are bacteria; and that there is a significant proportion of ESBL and MRSA isolates causing infection implicating the need to proper diagnosis of ear infection. High percentage of isolated bacteria were susceptible to ciprofloxacin a drug of choice as per local ear infection treatment guideline. In addition, ear infection was associated with recurrent URTI, cotton bud use and cerumen impaction. Therefore, these findings suggest that empirical treatment should be avoided and indicate that there is a need to improve community awareness on proper ear hygiene and knowledge on cotton bud use. Also, early diagnosis and treatment of URTI and cerumen impaction to prevent ear infection and the potential complications.

5.2 Study limitation

1. The present study was not able to identify the fungi isolates to species level. This is due to insufficient funding and availability of resources. To mitigate this all fungi isolates were stored appropriately for future testing to specie level.
2. Due to financial constraints and lack of equipment, it was also not possible to isolate anaerobic bacteria from the collected pus specimen.

5.3 Recommendations

The present study has the following recommendations:

- i. Clinicians should avoid the use of empirical treatment by updating management guidelines of ear infection considering laboratory results before the antibiotic prescription. This will help to maintain the effectiveness of ciprofloxacin as per local ear infection treatment guideline

- ii. Also, clinicians should be sensitized on prompt management of URTI, nasal congestion/ blockage and proper management of cerumen impaction to evade the development of ear infection.
- iii. Lastly, health workers with aid from policymakers should promote community awareness on proper ear hygiene. Society should be advised on seeking medical care immediately after experiencing ear discomfort to avoid complications that may arise from delayed management of ear infection.

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APPENDICES

Appendix Ia: Informed consent form for Adults above 18 years (English version)

Title: The etiology of ear infection and associated factors among patients attending otorhinolaryngology clinic at Muhimbili National Hospital

Muhimbili University of Health and Allied Sciences (MUHAS).

Directorate of research and publications, MUHAS.

Identification Number _____

Greetings!

My name is **AMINIEL SHANGALI** from Muhimbili University of Health and Allied Sciences. I am a postgraduate student taking MSc in Microbiology and Immunology, researching to determine the etiology of ear infection and associated factors among patients attending otorhinolaryngology clinic at Muhimbili National Hospital

Study Purpose

The study aims to determine bacterial species and the proportion of fungi associated with ear infection among patients attending otorhinolaryngology clinic at MNH. Also, the study is designed to assess factors associated with ear infection and to determine the resistance profile of bacteria isolates causing ear at Muhimbili National Hospital in Tanzania.

Participants and Methods

If you agree to participate in this study, you will be registered and interviewed using a questionnaire, detailed information on social demographic characteristics, behavioural, hygiene practices, past and present medical history will be requested and ear swabs or middle ear aspirate will be collected.

Confidentiality

All the information obtained from the study participants will be kept confidential under medical laws and ethics and no one will be able to link your participation based on the

information you provide during an interview. No unauthorized persons will have access to the data collected.

Benefits

If you agree to participate in this study, the benefits may be direct or indirect. You will benefit by being informed on the culture result, and know if your ear infection is due to fungi or bacteria colonization. Appropriate medications will be prescribed and you will be advised accordingly. This information will also be helpful to the health care provider in the otorhinolaryngology clinic at MNH as the hospital will be aware of the common fungal and bacterial isolates of the patients with ear infection attending the clinic together with the antimicrobial resistance pattern. This will help the department and hospital in general to update the treatment guidelines.

Potential Risks

No harm is expected to occur to you because you participated in this study. Sometimes, minimal pain may occur when taking ear swabs or aspirate.

Costs: No payment will be demanded from you as a fee to participate in the study.

Rights to Withdraw and Alternatives

Your decision whether or not to participate in this study is voluntary. You can withdraw participation at any time of the course of the study. Refusal to participate or withdrawal from the study will not involve any penalty or loss of any benefits entitled to you.

Contacts

In case of any questions about this study, you may contact the study Principal Investigator: Aminiel Shangali or The Supervisor: Dr Doreen Kamori of Muhimbili University of Health and Allied Sciences, P. O. Box 65001, Dar es Salaam or The Chairperson of the Senate Research and Publications Committee, P. O. Box 65001, Telephone: +255 22 2152489, Dar es Salaam.

Mobile number: +255 719801162. E-Mail: aminielshangali8@gmail.com

Participant's agreement

I _____ have read and understand the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of the participant: _____ Date _____

Signature of the Witness: _____ Date _____

Signature of Principal Investigator: _____ Date _____

Appendix Ib: Assent form for Participants who are 13-17 years (English version)**Title: The etiology of ear infection and associated factors among patients attending Otorhinolaryngology clinic at Muhimbili National Hospital**

Muhimbili University of Health and Allied Sciences (MUHAS).

Directorate of research and publications, MUHAS.

Identification Number _____

Greetings!

My name is **AMINIEL SHANGALI** from Muhimbili University of Health and Allied Sciences. I am a postgraduate student taking MSc in Microbiology and Immunology, researching to determine the aetiology of ear infection and associated factors among patients attending the otorhinolaryngology clinic at Muhimbili National Hospital

Study Purpose

The study aims to determine bacterial species and the proportion of fungi associated with ear infection among patients attending otorhinolaryngology clinic at MNH. Also, the study is designed to assess factors associated with ear infection and to determine the resistance profile of bacteria isolates causing ear at Muhimbili National Hospital in Tanzania.

Participants and Methods

If you agree to participate in this study, you will be registered and interviewed using a questionnaire, detailed information on social demographic characteristics, behavioural, hygiene practices, past and present medical history will be requested and ear swabs or middle ear aspirate will be collected.

Confidentiality

All the information obtained from the study participants will be kept confidential under medical laws and ethics and no one will be able to link your participation based on the information you provide during an interview. No unauthorized persons will have access to the data collected.

Benefits

If you agree to participate in this study, the benefits may be direct or indirect. You will benefit by being informed on the culture result, and know if your ear infection is due to fungi or bacteria colonization. Appropriate medications will be prescribed and you will be advised accordingly. This information will also be helpful to the health care provider in the Otorhinolaryngology clinic at MNH as the hospital will be aware of the common fungal and bacterial isolates of the patients with ear infection attending the clinic together with the antimicrobial resistance pattern. This will help the department and hospital in general to update the treatment guidelines.

Potential Risks

No harm is expected to occur to you because you participate in this study. Sometimes, minimal pain may occur when taking ear swabs or aspirate.

Costs

No payment will be demanded from you as a fee to participate in the study.

Rights to Withdraw and Alternatives

Your decision whether or not to participate in this study is voluntary. You can withdraw participation at any time of the course of the study. Refusal to participate or withdrawal from the study will not involve any penalty or loss of any benefits entitled to you

Contacts

In case of any questions about this study, you may contact the study Principal Investigator: Aminiel Shangali or The Supervisor: Dr Doreen Kamori of Muhimbili University of Health and Allied Sciences, P. O. Box 65001, Dar es Salaam or The Chairperson of the Senate Research and Publications Committee, P. O. Box 65001, Telephone: +255 22 2152489, Dar es Salaam.

Mobile number: +255 719801162. E-Mail: aminielshangali8@gmail.com

Participant's agreement

I _____ have read and understand the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of the participant: _____ Date _____

Signature of the parent/guardian: _____ Date _____

Signature of the Witness: _____ Date _____

Signature of Principal Investigator _____ Date _____

Appendix Ic: Informed consent form for Parents/guardians whose participants are Children (below 13 years) (English version)

Title: The etiology of ear infection and associated factors among patients attending Otorhinolaryngology clinic at Muhimbili National Hospital

Muhimbili University of Health and Allied Sciences (MUHAS).

Directorate of research and publications, MUHAS.

Identification Number _____

Greetings!

My name is **AMINIEL SHANGALI** from Muhimbili University of Health and Allied Sciences. I am a postgraduate student taking MSc in Microbiology and Immunology, researching to determine the etiology of ear infection and associated factors among patients attending the Otorhinolaryngology clinic at Muhimbili National Hospital

Study Purpose

The study aims to determine bacterial species and the proportion of fungi associated with ear infection among patients attending Otorhinolaryngology clinic at MNH. Also, the study is designed to assess factors associated with ear infection and to determine the resistance profile of bacteria isolates causing ear at Muhimbili National Hospital in Tanzania.

Participants and Methods

If you agree your child to participate in this study, your child will be registered and you will be interviewed using a questionnaire, detailed information on social demographic characteristics, behavioural, hygiene practice, past and present medical history will be requested and ear swab or middle ear aspirate will be collected from your child.

Confidentiality

All the information obtained from the study participants will be kept confidential following medical laws and ethics and no one will be able to link your participation based on the

information you provide during an interview. No unauthorized persons will have access to the data collected.

Benefits

If you agree for your child to participate in this study, the benefits may be direct or indirect. You will benefit by being informed on culture results, and know if your ear infection is due to fungi or bacteria colonization. Appropriate medications will be prescribed and you will be advised accordingly. This information will also be helpful to the health care provider in the Otorhinolaryngology clinic at MNH as the hospital will be aware of the common fungal and bacterial isolates of the patients with ear infection attending the clinic together with the antimicrobial resistance pattern. This will help the department and hospital in general to update the treatment guidelines.

Potential Risks

No harm is expected to occur to your child because of the participation in this study. Sometimes, minimal pain may occur when taking ear swabs or aspirate.

Costs

No payment will be demanded from you as a fee to participate in the study.

Rights to Withdraw and Alternatives

Your decision whether or not your child to participate in this study is voluntary. You can withdraw participation at any time of the course of the study. Refusal to participate or withdrawal from the study will not involve any penalty or loss of any benefits entitled to you and/or your child

Contacts

In case of any questions about this study, you may contact the study Principal Investigator: Aminiel Shangali or The Supervisor: Dr Doreen Kamori of Muhimbili University of Health and Allied Sciences, P. O. Box 65001, Dar es Salaam or The Chairperson of the Senate

Research and Publications Committee, P. O. Box 65001, Telephone: +255 22 2152489, Dar es Salaam.

Mobile number: +255 719801162. E-Mail: aminielshangali8@gmail.com

Participant's agreement

I _____ have read and understand the contents in this form. My questions have been answered. I agree that my child can participate in this study.

Signature of the Parent: _____ Date _____

Signature of the Witness _____ Date _____

Signature of Principal Investigator _____ Date _____

**Kiambatanisho Id: Fomu ya ridhaa kwa watu wazima wenye umri zaidi ya miaka 18
(toleo la Kiswahili)**

**Utafiti: Etiolojia ya maambukizo ya sikio na sababu zinazohusiana kati ya wagonjwa
wanaotembelea kliniki ya sikio, pua na koo katika Hospitali ya Taifa Muhimbili**

Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili

Kurugenzi ya tafiti na uchapishaji

Namba ya utambulisho _____

Salaam.

Majina yangu ni **AMINIEL SHANGALI** kutoka Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili. Ni mwanafunzi wa shahada ya uzamili katika Mikrobiologia na Kinga. Ninafanya utafiti kuangalia etiolojia ya maambukizo ya sikio na sababu zinazohusiana kati ya wagonjwa wanaotembelea kliniki ya sikio, pua na koo katika hospitali ya taifa muhimbili.

Lengo la utafiti

Kusudi la utafiti huu ni kuangalia spishi za bakteria na sehemu ya kuvu inayohusiana na maambukizi ya sikio kati ya wagonjwa wanaohudhuria kliniki ya sikio, pua na koo kwenye hospitali ya rufaa ya taifa muhimbili. Pia utafiti huu umeundwa kutadhmini sababu zinazohusiana na maambukizo ya sikio na kujua muundo wa usugu wa dawa katika bakteria wanasababisha maambukizi ya sikio.

Jinsi ya kushiriki

Ikiwa ukakubali kushiriki katika utafiti huu, utasailiwa na utahojiwa kwa kujibu maswali kutoka kwenye dodoso lililoandaliwa. Utaulizwa kuhusu taarifa zako, tabia, usafi na historia ya matibabu ya zamani na ya sasa, pia utaombwa sampuli ya swabu ya sikio.

Usiri

Taarifa zitakazokusanywa kutoka kwako zitakuwa za siri kutokana na sheria na maadili ya matibabu. Hakuna mtu ambaye anaweza kuunganisha ushiriki wa mtu binafsi kutokana na taarifa uliyotoa kipindi cha mahojiano. Hairuhusiwi kwa mtu asiyeidhinishwa kupata taarifa zilizokusanywa kutoka kwako

Faida

Ikiwa utakubali kushiriki katika utafiti huu, faida zinaweza kuonekana kwako, kwa watu wengine na kwa idara ya sikio, pua na koo pia. Utafaidika kwa kupewa majibu ya sampuli yako na kujue kama maambukizi ya sikio lako yamesababishwa na kuvu au bakteria. Utapewa matibabu sahihi na utashauriwa ipasavyo. Tafiti hii itakuwa na manufaa katika idara ya sikio, pua na koo katika hositali ya rufaa ya taifa Muhimbili kwani watapata kujua spishi za bakteria na sehemu ya kuvu inayohusiana na maambukizi ya sikio. Pia, idara itaweza kutathmini sababu zinazohusiana na maambukizo ya sikio na kujua usugu wa dawa katika bakteria wanaosababisha maambukizi ya sikio. Hii itasaidia kwenye kusahihisha miongozo ya matibabu kwenye watu wenye maambukizi ya kikoi na kupunguza janga la usugu wa dawa.

Athari

Hakuna madhara au athari inayoweza kutokea kwako kwa sababu ya kushiriki katika utafiti huu. Ila, kunaweza kuwa na maumivu kidogo wakati wakuchukua sampuli ya swabu ya sikio.

Gharama

Hakuna gharama yoyote inayotakiwa ili uweze kushiriki katika utafiti huu.

Haki ya kujitua na mambo mbadala

Ushiriki wako katika utafiti huu ni wa hiari yako kabisa. Unaweza kusimamisha kushiriki kwenye utafiti huu katika hatua yeyote hata kama ulishatoa ridhaa. Kukataa kushiriki au kujitua katika ushiriki hautahusisha adhabu yeyote au kupoteza haki zako unazostahili.

Mawasiliano

Endapo utakuwa na swali lolote kuhusu utafiti huu unaweza kuwasiliana na mtafiti mkuu: Aminiel shangali, Chuo Kikuu Kishiriki cha Sayansi za Afya Muhimbili, S. L. P 65001, Dar es Salaam. Msimamizi Dk. Doreen Kamori wa Chuo Kikuu cha Afya na Sayansi Shirikishi (MUHAS) S.L.P 65001, Dar es Salaam au unaweza wasiliana na Mwenyekiti wa Utafiti, S.L.P 65001, namba ya simu: +255 22 2152489 Dar es Salam. Namba ya simu: +255 719801162. Barua pepe; aminielshangali8@gmail.com

Makubaliano ya mshiriki

Mimi _____ nimesoma na kuelewa yaliyomo katika fomu hii. Maswali yangu yamejibiwa. Ninakubali kushiriki kwenye utafiti huu.

Sahihi ya mshiriki _____ Tarehe _____

Sahihi ya shahidi _____ Tarehe _____

Sahihi ya mtafiti _____ Tarehe _____

Kiambatanisho Ie: Fomu ya ridhaa kwa watu wenye umri chini ya miaka 13-17 (toleo la Kiswahili)

Utafiti: Etiolojia ya maambukizo ya sikio na sababu zinazohusiana kati ya wagonjwa wanaotembelea kliniki ya sikio, pua na koo katika Hospitali ya Taifa Muhimbili

Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili

Kurugenzi ya tafiti na uchapishaji

Namba ya utambulisho

Salaam.

Majina yangu ni **AMINIEL SHANGALI** kutoka Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili. Ni mwanafunzi wa shahada ya uzamili katika Mikrobiologia na Kinga. Ninafanya utafiti kuangalia etiolojia ya maambukizo ya sikio na sababu zinazohusiana kati ya wagonjwa wanaotembelea kliniki ya sikio, pua na koo katika hospitali ya taifa muhimbili.

Lengo la utafiti

Kusudi la utafiti huu ni kuangalia spishi za bakteria na sehemu ya kuvu inayohusiana na maambukizi ya sikio kati ya wagonjwa wanaohudhuria kliniki ya sikio, pua na koo kwenye hospitali ya rufaa ya taifa muhimbili. Pia utafiti huu umeundwa kutadhmini sababu zinazohusiana na maambukizo ya sikio na kujua muundo wa usugu wa dawa katika bakteria wanasababisha maambukizi ya sikio.

Jinsi ya kushiriki

Ikiwa ukakubali kushiriki katika utafiti huu, utasailiwa na utahojiwa kwa kujibu maswali kutoka kwenye dodoso lililoandaliwa. Utaulizwa kuhusu taarifa zako, tabia, usafi na historia ya matibabu ya zamani na ya sasa, pia utaombwa sampuli swabu ya sikio.

Usiri

Taarifa zitakazokusanywa kutoka kwako zitakuwa za siri kutokana na sheria na maadili ya matibabu. Hakuna mtu ambaye anaweza kuunganisha ushiriki wa mtu binafsi kutokana na

taarifa uliyotoa kipindi cha mahojiano. Hairuhusiwi kwa mtu asiyeidhinishwa kupata taarifa zilizokusanywa kutoka kwako.

Faida

Ikiwa utakubali kushiriki katika utafiti huu, faida zinaweza kuonekana kwako, kwa watu wengine na kwa idara ya sikio, pua na koo pia. Utafaidika kwa kupewa majibu ya sampuli yako na kujua kama maambukizi ya sikio lako ni kwa sababu ya kuvu au bakteria. Utapewa matibabu sahihi na utashauriwa ipasavyo. Tafiti hii itakuwa na manufaa katika idara ya sikio, pua na koo katika hospitali ya rufaa ya taifa Muhimbili kwani watapata kujua spishi za bakteria na sehemu ya kuvu inayohusiana na maambukizi ya sikio. Pia, idara itaweza kutathmini sababu zinazohusiana na maambukizo ya sikio na kujua usugu wa dawa katika bakteria wanaosababisha maambukizi ya sikio. Hii itasaidia kwenye kusahihisha miongozo ya matibabu kwenye watu wenye maambukizi ya kikoi na kupunguza janga la usugu wa dawa.

Athari

Hakuna madhara au athari inayoweza kutokea kwako kwa sababu ya kushiriki katika utafiti huu. Ila, kunaweza kuwa na maumivu kidogo wakati wakuchukua sampuli ya swab ya sikio.

Gharama

Hakuna gharama yoyote inayotakiwa ili uweze kushiriki katika utafiti huu.

Haki ya kujitua na mambo mbadala

Ushiriki wako katika utafiti huu ni wa hiari yako kabisa. Unaweza kusimamisha kushiriki kwenye utafiti huu katika hatua yeyote hata kama ulishatoa ridhaa. Kukataa kushiriki au kujitua katika ushiriki hautahusisha adhabu yeyote au kupoteza haki zako unazostahili.

Mawasiliano

Endapo utakuwa na swali lolote kuhusu utafiti huu unaweza kuwasiliana na mtafiti mkuu: Aminiel Shangali, Chuo Kikuu Kishiriki cha Sayansi za Afya Muhimbili, S. L. P 65001, Dar es Salaam. Msimamizi Dk. Doreen Kamori wa Chuo Kikuu cha Afya na Sayansi Shirikishi (MUHAS) S.L.P 65001, Dar es Salaam au unaweza wasiliana na Mwenyekiti wa Utafiti,

S.L.P 65001, namba ya simu: +255 22 2152489 Dar es Salam. Namba ya simu: +255 719801162. Barua pepe; aminielshangali8@gmail.com

Makubaliano ya mshiriki

Mimi _____ nimesoma na kuelewa yaliyomo katika fomu hii. Maswali yangu yamejibiwa. Ninakubali kushiriki kwenye utafiti huu.

Sahihi ya mshiriki: _____ Tarehe _____

Sahihi ya mzazi: _____ Tarehe _____

Sahihi ya shahidi: _____ Tarehe _____

Sahihi ya mtafiti: _____ Tarehe _____

Kiambatanisho If: Fomu ya ridhaa kwa wazazi au walezi kwa niaba ya washiriki ambao ni watoto wenye umri chini ya miaka 13. (toleo la kiswahili)

Utafiti: Etiolojia ya maambukizo ya sikio na sababu zinazohusiana kati ya wagonjwa wanaotembelea kliniki ya sikio, pua na koo katika Hospitali ya Taifa Muhimbili

Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili

Kurugenzi ya tafiti na uchapishaji

Namba ya utambulisho

Salaam.

Majina yangu ni **AMINIEL SHANGALI** kutoka Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili. Ni mwanafunzi wa shahada ya uzamili katika Mikrobiologia na Kinga. Ninafanya utafiti kuangalia etiolojia ya maambukizo ya sikio na sababu zinazohusiana kati ya wagonjwa wanaotembelea kliniki ya sikio, pua na koo katika hospitali ya taifa muhimbili.

Lengo la utafiti

Kusudi la utafiti huu ni kuangalia spishi za bakteria na sehemu ya kuvu inayohusiana na maambukizi ya sikio kati ya wagonjwa wanaohudhuria kliniki ya sikio, pua na koo kwenye hospitali ya rufaa ya taifa muhimbili. Pia utafiti huu umeundwa kutadhmini sababu zinazohusiana na maambukizo ya sikio na kujua muundo wa usugu wa dawa katika bakteria wanasababisha maambukizi ya sikio.

Jinsi ya kushiriki

Ikiwa ukakubali mtoto wako kushiriki katika utafiti huu, mtoto wako utasailiwa na utahojiwa kwa kujibu maswali kutoka kwenye dodoso lililoandaliwa, Utaulizwa kuhusu taarifa za mwanao, tabia, usafi na historia ya matibabu ya zamani na ya sasa, pia utaombwa sampuli swab ya sikio kwa niaba ya mtoto.

Usiri

Taarifa zitakazokusanywa kutoka kwako zitakuwa za siri kutokana na sheria na maadili ya matibabu. Hakuna mtu ambaye anaweza kuunganisha ushiriki wa mtu binafsi kutokana na

taarifa uliyotoa kipindi cha mahojiano. Hairuhusiwi kwa mtu asiyeidhinishwa kupata taarifa zilizokusanywa kutoka kwako

Faida

Ikiwa utakubali mtoto wako kushiriki katika utafiti huu, faida zinaweza kuonekana kwake, kwa watu wengine na kwa idara ya sikio, pua na koo pia. Utafaidika kwa kupewa majibu ya sampuli ya mwanao na kujue kama maambukizi ya sikio la mwanao ni kwa sababu ya kuvu au bakteria. Mwanao atapewa matibabu sahihi na utashauriwa ipasavyo. Tafiti hii itakuwa na manufaa katika idara ya sikio, pua na koo katika hositali ya rufaa ya taifa Muhimbili kwani watapata kujua spishi za bakteria na sehemu ya kuvu inayohusiana na maambukizi ya sikio. Pia, idara itaweza kutathmini sababu zinazohusiana na maambukizo ya sikio na kujua usugu wa dawa katika bakteria wanaosababisha maambukizi ya sikio. Hii itasaidia kwenye kusahihisha miongozo ya matibabu kwenye watu wenye maambukizi ya kikoi na kupunguza janga la usugu wa dawa.

Athari

Hakuna madhara au athari inayoweza kutokea kwa mtoto wako kwa sababu ya kushiriki katika utafiti huu. Ila, kunaweza kuwa na maumivu kidogo wakati wakuchukua sampuli ya swab ya sikio.

Gharama

Hakuna gharama yoyote inayotakiwa ili uweze kushiriki katika utafiti huu.

Haki ya kujitua na mambo mbadala

Ushiriki wa mwanao katika utafiti huu ni wa hiari yako kabisa. Unaweza kumsimamisha mwanao katika kushiriki kwenye utafiti huu katika hatua yeyote hata kama ulishatoa ridhaa. Kukataa kushiriki au kumtoa mwanao katika ushiriki hautahusisha adhabu yeyote au kupoteza haki zako au za mwanao mnazostahili.

Mawasiliano

Endapo utakuwa na swali lolote kuhusu utafiti huu unaweza kuwasiliana na mtafiti mkuu: Aminiel shangali, Chuo Kikuu Kishiriki cha Sayansi za Afya Muhimbili, S. L. P 65001, Dar es Salaam. Msimamizi Dk. Doreen Kamori wa Chuo Kikuu cha Afya na Sayansi Shirikishi (MUHAS) S.L.P 65001, Dar es Salaam au unaweza wasiliana na Mwenyekiti wa Utafiti, S.L.P 65001, namba ya simu: +255 22 2152489 Dar es Salam. Namba ya simu: +255 719801162. Barua pepe; aminielshangali8@gmail.com

Makubaliano ya mshiriki

Mimi _____ nimesoma na kuelewa yaliyomo katika fomu hii. Maswali yangu yamejibiwa. Ninakubali mtoto wangu kushiriki katika uchunguzi huu.

Sahihi ya mzazi: _____ Tarehe _____

Sahihi ya shahidi: _____ Tarehe _____

Sahihi ya mtafiti: _____ Tarehe _____

Appendix IIa: Questionnaire

Title: The etiology of ear infection and associated factors among patients attending otorhinolaryngology clinic at Muhimbili national hospital

Identification number _____

Date of interview _____

Phone number _____

A. Participants socio-demographic information

1. District _____

2. Village/Street _____

3. Sex (a) Female (b) Male

4. Age in years _____

Note: If age is below 18 years skip question number 5

5. Marital status (a) Single (b) Married
(c) divorced (d) Widow

6. Education level: (a) None (b) Primary
(c) Secondary (d) University

7. Occupation: (a) Student (b) Self-employed
(c) Professionals (c) Retired
(d) Housewife/husband (e) others
Mention _____

B. Clinical information

Put a tick where appropriate on spaces provided

1. For how long have you been suffering from ear infection (in terms of number of days)?
-

2. What type of ear infection does the participant have (check medical history)?

(a)AOM (b) OE (c) CSOM
 (d)OME (e) Others

3. What is your HIV status? (a) Positive (b)Negative
 (c)Not known

4. (i)Are you under any antibiotic? (a)Yes (b)No
 (ii)If yes, mention -
-

(iii)What is the indication for antibiotic use?

(iv)For how long have you been using antibiotic?

5. Do you have any Nasal blockage or discharge? (a)Yes. (b)No
 (ii)For how long have you been suffering from this condition?
-

6. (i) For participants less than 3 years, did you breast fed your child?

(a)Yes (b)No

(ii) If yes, for how long have you breast fed your child?

(a)<6 month (b) 6 month to 1 year (c) 2 – 3 years

7. Have you ever experienced any of the following episodes of URTI (difficulty in breathing, snoring); 7 episodes per year, 5 episodes in 2 consecutive years or 3 episodes in 3 consecutive years

(a) Yes (b)No

8. (i)Do you use any Hearing aid? (a)Yes (b)No

(ii)If yes, for how long have you been using the hearing aid equipment?

(a) Less than 6 month (b) 7 months to 4 year (c) 5 to 10

(d)More than 11 years

(iv) How do you store the equipment if not used?

(v) How do you clean/disinfect the equipment?

(vi) How often do you disinfect/clean the equipment?

C. Behavioral information

Put a tick where appropriate on spaces provided

1. (i)Do you use earphones? (a)Yes (b)No

If the answer is No above skip to question number 2

(ii)When was the last time you used earphones?

(iii)How Frequent do you use earphone?

(a)Everyday (b)1 to 3 times in a week
 (c)Rarely (d) Never

(iv) For how long are you exposed to earphone in a single day?

(a) less than 30 minutes (b)1 to 3 hours

(c) 4 to 8 hours (d) More than 9 hours

(v) Do you share ear phones? (a) Yes (b) No

(vi) How do you store your earphone?

(vii) Do you disinfect your earphone before use? (a) Yes (b) No

(vii) If yes, what method do you use to disinfect?

2. (i) Do you go for swimming? (a) Yes (b) No

If the answer is No above skip to question number 3

(ii) When was the last time you went swimming?

(a) 1-6 days ago (b) 7 - 14 days ago

(c) 15-25 days ago (e) more than 26 days ago

(ii) How frequently do you go swimming?

(a) Everyday (b) 2-3 times a week (c) rarely

(iii) Where do you go for swimming?

(a) ocean (b) River (c) lake

(d) Swimming pool

(iii) What kind of swimming pool do you use?

(a) Private swimming pool (b) Public swimming pool

3. (i) Do you smoke a cigarette? (a) Yes (b) No

If the answer is No above skip to section D

(ii) How long have you been smoking? (a) <1 year (b) 1-2 years

(c) 3-5 years (d) more than 6 years

D. Hygiene practice

Put a tick where appropriate on spaces provided

1. (i) Do you use cotton buds? (a) Yes (b) No
- (ii) How often do you use cotton buds?
- (a) Everyday (b) once or twice a week
- (c) Rare
2. (i) Use of sharp object to scratch ears
- (a) Yes (b) No
- (ii) If yes, what object is used? Mention _____
3. Do you have a presence of waxy build-up?
- (a) Yes (b) No
4. (i) Do you clean your ears?
- (a) Yes (b) No
- (ii) If yes, how do you clean them? State _____
-

Kiambatanisho IIb: Dodoso

Namba ya utambulisho ya mshiriki _____

Tarehe ya Ushiriki _____

Namba ya simu _____

A. Taarifa za mshiriki

1. Wilaya atokayo _____

2. Kijiji/Mtaa atokao _____

3. Umri
_____**Kama umri ni chini ya miaka 18, usijibu hili swali**4. Jinsia (a)Mwaname (b)Mwanamke 5. Kiwango cha elimu (a) Sijasoma (b) Shule ya msingi
(c)sekondari (d) chuo kikuu 6. Hali ya ndoa (a)Sijaoa/kuolewa. (b)Nimeoa/kuolewa
(c)Nimeachika/mjane 7. Kazi: (a)Mwanafunzi (b)Nimejiajiri (c)Mtaaluma (c)Mstaafu (d)Mke/Mme wa nyumbani (e)Nyinginezo

Taja _____

B. Taarifa za afya

Weka tiki kwenye nafasi zilizoachwa wazi

1. Je, ni kwa muda gani ulikuwa unasumbuliwa na hili tatizo?

2. Aina gani ya maambukizi ya sikio mshiriki anayo (angalia kwenye historia ya matibabu)?

(a)AOM

(b) OE

(c)CSOM

(d)OME

(e)Nyinginezo (taja)

3. Una maambukizi ya VVU? (a) Ndio

(c)Sijui

(b)Hapana

4. (i)unatumia antibiotiki yoyote?(a)Ndio

(ii)Kama ndio, itaje -

(b)Hapana

(iii) Nini ilikuwa dalili ya matumizi ya antibiotiki?

(iv) Ni kwa muda gani ulikuwa unatumia hii antibiotiki?

5. Je, pua zako zimeziba au zinatoa kamasi?

(ii)Kama ndio, ni kwa muda gani?

6. (i) Kwa washiliki wenye umri chini ya miaka 3, Je, ulimnyonyesha mtoto wako?

(a)Ndio

(b)Hapana

(ii) Kama ndio, ni kwa muda gani mtoto amenyonyesha?

(a)< miezi 6

(b) miezi 6 mpaka mwaka 1

(c) Miaka 2 – 3

7. Umeshawahi kupatwa na vipindi vya maambukizi ya njia ya upumuaji kama hivi vifuatavyo. Vipindi 7 ndani ya mwaka 1, vipindi 5 kwa miaka 2 au au vipindi 3 ndani ya miaka 3

(a) Ndio (b)Hapana

8. (i)Unatumia Kifaa cha kusaidia kusikia?

(a)Ndio (b)Hapana

(ii)Kama ndio, ni kwa muda gani ulikuwa unatumia iko kifaa?

(a)chini ya miezi 6 (b) miezi 7 mpaka mwaka 4 (c) miaka 5 - 1

(d)Zaidi ya miaka 11

(iv)Una tunzaje kifaa chako?

(v)Unasafishaje kifaa chako?

(vi)Ni mara ngapi unasafisha kifaa chako? _____

C. Maelezo ya tabia

Weka tiki kwenye nafasi zilizoachwa wazi

1. (i)Unatumia vipokea sauti? (a)Ndio (b)Hapana

Kama ndio, jibu maswali yafuatayo

(ii)Mara ya mwisho kutumia ilikuwa ni lini? _____

(iii)Ni kwa mara ngapi unatumia vipokea sauti?

(a)Kila siku (b)mara 1- 3 kwa wiki

(c)mara chache (d) sijawahi kutumia

(iv)Ni kwa muda gani unatumia vipokea sauti ndani ya siku 1

(a)chini ya dakika 30 (b) saa 1- masaa 2

(c)masaa 3 - 5 (d)Zaidi ya masaa 6

(v)Je, unatumiaga vipokea sauti vya watu wengine au unagawa chako?

(a)Ndio (b)hapana

(vi) Unatunzaje vipokea sauti vyako?

 (vii) Je, una disinfekti vipokea sauti vyako? (a) Ndio (b) Hapana
 (vii) Kama ndio, ni njia gani unatumia kudisinfekti?

 2. (i) Je, unaendaga kuogelea? (a) Ndio (b) Hapana
 Kama ndio, jibu maswali yafuatayo.

(ii) Mara yako ya mwisho kwenda kuogelea ilikuwa ni lini?

(a) siku 1-6 zilizopita (b) siku 7-14 zilizopita
 (c) Siku 15 – 25 zilizopita (d) Zaidi ya siku 26 na kuendelea

(ii) Ni kwa mara ngapi unaenda kuogelea?

(a) Kila siku (b) Mara 2-3 kwa wiki (c) Mara chache

(iii) Unaendaga wapi kwa ajili ya kuogelea?

(a) Baharini (b) Mtoni (c) Ziwani
 (d) Bwawa la kuogelea

(iii) Ni bwawa gani la kuogelea unatumia?

(a) Binafsi (b) Jamii

3. (i) Unavuta sigara? (a) Ndio (b) Hapana

Kama ndio, jibu maswali yafuatayo.

(ii) Ni kwa muda gani sasa unavuta sigara?

(a) Chini ya mwaka 1 (b) Mwaka 1-2
 (c) Miaka 3-5 years (d) Zaidi ya miaka 6

D. Hali ya usafi

Weka tiki kwenye nafasi zilizoachwa wazi

1. (i) Unatumia pamba za masikio? (a) Ndio (b) Hapana

Kama ndio, jibu maswali yanayofuata.

(ii) Ni, kwa mara ngapi unatumia?

- (a) Kila siku (b) Mara 1 – 2 kwa wiki

- (c) Mara chache

2. (i) Unatumia vitu vyenye ncha kuingiza kwenye masikio

Kama ndio, jibu maswali yanayofuata.

- (a) Ndio (b) Hapana

(ii) Kama ndio, kitaje hicho kitu _____

3. Una mkusanyiko wa nta ya sikio?



- (a) Ndio (b) Hapana

4. (i) Unasafisha masikio wako?

- (a) Ndio (b) Hapana

(ii) Kama ndio, ni njia gani unatumia kusafisha masikio?

Appendix III: Approval for ethical clearance

	<p>UNITED REPUBLIC OF TANZANIA MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES OFFICE OF THE DIRECTOR - RESEARCH AND PUBLICATIONS</p>			
<table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Ref. No.DA.282/298/01.C/</td> <td style="width: 50%; text-align: right;">Date: 28/01/2021</td> </tr> </table>			Ref. No.DA.282/298/01.C/	Date: 28/01/2021
Ref. No.DA.282/298/01.C/	Date: 28/01/2021			
<p>MUHAS-REC-01-2021-473</p> <p>Aminiel Shangali MSc. Microbiology/Immunology, School of Medicine MUHAS</p>				
<p>RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: THE ETIOLOGY OF EAR INFECTION AND ASSOCIATED FACTORS AMONG PATIENTS ATTENDING OTORHINOLARYNGOLOGY CLINIC AT MUHIMBILI NATIONAL HOSPITAL</p>				
<p>Reference is made to the above heading.</p>				
<p>I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.</p>				
<p>APPROVAL DATE: 28/01/2021 EXPIRATION DATE OF APPROVAL: 27/01/2022</p>				
<p>STUDY DESCRIPTION:</p>				
<p>Purpose:</p>				
<p>The purpose of this hospital based cross sectional study is to determine the etiological agents, associated factors and antimicrobial susceptibility patterns of bacteria species causing ear infection among patients attending otorhinolaryngology clinic at MNH</p>				
<p>The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided: https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%20353.pdf and in the MUHAS archives,</p>				

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country.
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website <https://drp.muhas.ac.tz/>.



Dr. Bruno Sunguya
Chairman, MUHAS Research and Ethics Committee

Cc: Director of Postgraduate Studies, MUHAS

