PREVALENCE OF OTITIS MEDIA AND ASSOCIATED FACTORS IN P ATIENTS ATTENDING EAR, NOSE AND THROAT CLINIC AT MNAZI MMOJA HOSPITAL, ZANZIBAR

Bihila A. Bakari, (BSc-MLS)

Master of Science in Epidemiology and Laboratory Management

University of Health and Allied Sciences

October, 2021

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

SCHOOL OF PUBLIC HEALTH AND SOCIAL SCIENCES

PREVALENCE OF OTITIS MEDIA AND ASSOCIATED FACTORS IN PATIENTS ATTENDING EAR, NOSE AND THROAT CLINIC AT MNAZI MMOJA HOSPITAL, ZANZIBAR

By

Bihila A. Bakari

A Dissertation Submitted in Partial Fulfilment of the Requirements for the Degree of Master of Science in Epidemiology and Laboratory Management of the Muhimbili University of Health and Allied Sciences

October, 2021

CERTIFICATION

We, undersigned certify that we have read and hereby recommend for acceptance by Muhimbili University and allied sciences a dissertation/thesis entitled: prevalence of otitis media and associated factors in patients attending ear, nose and throat clinic at Mnazi Mmoja Hospital, Zanzibar, in partial fulfilments of the requirements for the award of the degree of Master of Science in Epidemiology and Laboratory Management of Muhimbili University of Health and Allied Sciences

_____

Professor Said Aboud

(Supervisor)

_____

Date

_____

Dr. Amir Juya

(Co-supervisor)

_____

Date

DECLARATION

I, **Bihila A. Bakari,** Reg. No. HD/MUH/T.837/2019 do hereby declare that this dissertation submitted for the Degree of Master of Science in Epidemiology and Laboratory Management at Muhimbili University of Health and Allied Sciences is my original work and it has not been submitted for a similar purpose in any other university.

Signature …….Date ……...

COPYRIGHT

ACKNOWLEDGEMENTS

First and foremost, I am grateful to the Almighty God for blessing me with the gift of health, energy, wisdom, and passion throughout the process of developing the proposal and conduct of the research study.

I convey my sincere and innermost gratitude to my supervisor Professor Said Aboud and co-supervisor Dr Amir Juya for their tireless efforts and dedicating time and expertise in coaching and guiding me through the entire process of this work.

Furthermore, I would also like to extend my appreciation to the academic and administrative staff of the Muhimbili University of Health and Allied Sciences (MUHAS) for their instructions, constructive criticism, and guidance that steered me towards the accomplishment of this work.

I would also like to acknowledge staff from the Tanzania Field Epidemiology and Laboratory Training Program (FELTP) for their tireless support in the development and completion of this dissertation work.

My sincere appreciation should go to Zanzibar Ministry of Health, Community Development, Gender, Elderly, and Children for granting me permission and financial support and Mnazi Mmoja Referral Hospital for allowing me to do data collection on their premises.

I wish to extend my acknowledgement, to my study participants and research assistants (ENT and Pathology Laboratory staff) for sparing their time and willingness to participate and their technical assistance, respectively. My sincere appreciation to Mr. Mohammed Abdallah for his technical and advisory support.

Special thanks go to my lovely husband, my parents, and the rest of my relatives for their patience, love, and encouragement that gave me the strength to strive this far.

Last but not least, the accomplishment of this study could not be possible without assistance from my FELTP Cohort 12 classmates.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

AOM	Acute Otitis Media
AST	Antimicrobial Susceptibility Test
CLSI	Clinical Laboratory Standard Institute
COR	Chronic Otitis Media
ENT	Ear, Nose and Throat
HI	Hearing Impairment
HMIS	Health Management Information System
OM	Otitis Media
OME	Otitis Media with Effusion
OPD	Outpatient Department
ORL	Otorhinolaryngology
WHO	World Health Organization

DEFINITIONS OF TERMS

Otitis media: Is an inflammation of the middle ear especially the eardrum, tympanic membrane, and tissue surrounding it.

Otitis media with effusion: Is an inflammation of the middle ear characterized by the accumulation of fluid without perforation of the tympanic membrane; this fluid is a result of either upper respiratory infection, cold, allergy, or sore throat.

Acute otitis media: Rapid onset of symptomatic middle ear infection that can be characterized by one or more signs or symptoms such as fever, ear pain, fever, headache, feeling of pressure in the ear, trouble sleeping, unusual baby crying, and sometimes ear discharge.

Chronic suppurative otitis media: This is defined as a persistent inflammatory process following acute infection, which is associated with a perforated tympanic membrane and sometimes with draining exudate for more than 6 weeks and can be associated with cholesteatoma without a sign of acute otitis media.

Hearing impairment: Is an inability to hearing sound well in either one or both ears.

Suppurative otitis media: Is an accumulation of fluid in the middle ear with recurrent or persistent mucopurulent otorrhea draining in the ear canal.

Non-suppurative otitis media: This is an ear infection that occurs abruptly and is characterized by swelling without fluid formation in the middle ear.

ABSTRACT

Background: Otitis media (OM) is an inflammation of the middle ear tissue especially the eardrum and tissue surrounded. OM is a major public health problem worldwide. Its prevalence and incidence are high in both developed and developing countries. OM can be in acute or chronic form and is characterized by suppurative or non-suppurative conditions. Acute suppurative otitis media (ASOM) is a common childhood illness and chronic suppurative otitis media CSOM is a disease condition of ear cleft characterized by the presence of persistent perforation of the tympanic membrane with recurrent or persistent mucoid or mucopurulent discharge for at least eight (8) weeks. OM can be due to bacterial, fungal, viral, or respiratory infection with underlying conditions including asthma allergy, and sore throat. Objective: To determine the prevalence, etiological agents, antimicrobial susceptibility testing patterns, and factors associated with otitis media (OM) in patients attending Ear Nose and Throat (ENT) clinic at Mnazi Mmoja Hospital

Methodology: A hospital-based analytical cross-sectional study was conducted. The study population included all outpatients attending ENT clinic with ear complaints with an age range of 0 to 60 years. Data on social demographic characteristics, medical history and a physical examination were collected using a structured questionnaire. Clinical diagnosis was performed by the attending clinician using required otorhinolaryngology tests and pus swabs were taken from infected ears using sterile tipped cotton swabs. Laboratory method; Samples were tested for culture, identification of pathogens (gram stain and biochemical test) and antimicrobial susceptibility testing using Kirby Bauer disc diffusion method, at Mnazi Mmoja Hospital Pathology Laboratory.

Result: A total of 205 patients were recruited in the study. The overall median age of the study participants was 11years. Male and female participants were 120 (58.5%) and 85 (41.5%), respectively. Many of the participants, 74 (35.9%), were children who have not started school and the majority of the participants 125 (61%), were from the Urban West region. Of 205 study participants, 98 (48%) were clinically diagnosed with otitis media (OM) of whom 52 (25%) were laboratory-confirmed with bacterial infection, 46 (22%) had ear wax and 61 (30%) had other ear problems. The study found that the most prevalent

pathogens; 44 (21.4%) were gram-negative. The most common bacteria isolated were P. aeruginosa (26, 12.7%), P. mirabilis (12, 5.8%), K. pneumoniae (10, 4.8%), S. aureus (7, 3.4%), and E. coli (6, 2.6%). All isolated pathogens were sensitive to ciprofloxacin (90% to 100%) and Gentamicin ranged from 75% to 100%. Multi drugs resistance has been noted to some of the common organisms; P. mirabilis to different common antibiotics: Meropenem 33%, Amoxiclav 67%, Ampicillin, Ceftazidime & Ceftriaxone 75%, The study found that self-ear cleaning using cotton bud was significantly associated with OM (ARR = 0.79, 95% CI = 0.72-0.86).

Conclusions: About a quarter of the study participants had laboratory-confirmed OM. The prevalence of multiple microbial nature and antimicrobial resistance among isolates OM cases warrants the need for culture and sensitivity on the diagnosis of OM.

Recommendations: Health education on ear care and early seeking behavior for diagnosis and treatment of OM are needed for inpatients and the community to prevent progression to chronic disease. A study with a large sample size to the community is needed.

CHAPTER ONE

INTRODUCTION

1.1 Background

Otitis media (OM) is an inflammation of the middle ear tissue especially the eardrum and tissue surrounded. OM is a major public health problem worldwide. Its prevalence and incidence are high in both developed and developing countries. OM can be in acute or chronic form and is characterized by suppurative or non-suppurative conditions. Acute suppurative otitis media (ASOM) is a common childhood illness and progress to chronic suppurative otitis media and CSOM is a disease condition of ear cleft characterized by the presence of persistent perforation of the tympanic membrane with recurrent or persistent mucoid or mucopurulent discharge for at least eight (8) weeks (1). OM is one of the most common childhood infections especially in pre-school-aged children and childhood morbidity. There are three forms of otitis media, acute otitis media (AOM), otitis media with effusion (OME), and chronic suppurative otitis media (CSOM) (2) . AOM is a rapid onset of middle ear infection associated with accumulation of fluid in the middle ear accompanied with pain, perforation of the eardrum, and purulent ear discharge (suppurative). Otitis media with effusion is a form of chronic middle ear infection characterized by the presence of fluid in middle ear cavities without signs of acute infection or perforation of the tympanic membrane, this inflammation leads to epithelial metaplasia and collection of fluid in the middle ear with mucus or sero-mucus in nature(3,4). CSOM is the persistence of middle ear infection following after acute infection and causes ongoing damage of middle ear, it starts painlessly and prolonging for more than six weeks with persistent or recurrent ear discharge through a perforated tympanic membrane(5,6). Signs and symptoms of OM include ear pain, fever, headache, feeling of pressure in the ear, ear discharge, trouble in hearing and sleeping and children crying more than usual (5,6). Globally, it is estimated that the incidence rates of AOM and CSOM are 10.9% and 4.8% with the occurrence of 51.0% and 22.6%, respectively, in under-five children (7). OM is diagnosed clinically following otoscopic examination, binocular microscope, or telescopic

video-otoscopy which is used particularly in children. Treatment with antibiotics is recommended together with systemic and intranasal corticoids to reduce the local inflammation(3,4).The commonest bacteria isolated from the infected middle ear and implicated for causing OM are *P. aeruginosa, E. coli, S. pyogenes, P. mirabilis, and Klebsiella species* (1,8,9).

Young children are more prone to AOM and OME due to the fact the eustachian tube is shorter, more flexible, and horizontal. This makes it easy for the nasopharyngeal pathogens to enter the middle ear. Previous studies also identified some factors associated with OM. These include host risk factors; age (<5years old), low birth weight (<2.5kg), premature birth (<37 gestation weeks), male sex, craniofacial abnormalities such as cleft palate, atopy, gene abnormalities (TLR4 and FBX011), down syndrome and adenoids hypertrophy, allergy but pathway unclear, immune system impairment example HIV patients (10,11). Environmental factors include season of birth (spring and summer), lack of breastfeeding, daycare attendance, number of siblings in the family, level of education of parents (low level), low socioeconomic status, personal and family history of ear infection, exposure to cigarette smoke during the prenatal and postnatal period (13–16). Other factors include overcrowding, poor living conditions and lack of access to medical care, group daycare, and season of year relate to microbial load (10,11). Frequent upper respiratory tract infections and family history have been associated with the development of OM (17). In Tanzania the prevalence of CSOM is 1.4% for common pathogens responsible with OM infection include; *E. coli,* Staphylococcus species, *K. pneumoniae, P. mirabilis P. aeruginosa* and fungi (Candida albicans)(18) also prolonged illness duration without seeking medical attention significantly predicts disease complications(19) The study aims to determine the prevalence, aetiologic agents antimicrobial sensitivity pattern and factors associate with OM.

1.2 Statement of the problem

Otitis media is a public health problem in Tanzania with the prevalence of 1.4%(18), also is one of the public health problems in Zanzibar for a long time and among of the top ten

diseases. Even though the Zanzibar Standard Treatment Guideline (Third Edition of 2009) is in place since 2009, OM patients are still treated empirically by attending clinicians and the choice of antibiotics is not based on the laboratory results (20) According to the HMIS report of 2009, the prevalence of OM in Zanzibar was reported to be 5.7% (20,21). Through outreach programs, several interventions have been implemented including health education to communities on OM, training of clinicians to improved case management and strengthening of laboratory services to accurately diagnose and treat OM cases(21). Further, there is a paucity of data on the prevalence, etiological agents, antimicrobial susceptibility testing patterns, and factors associated with OM in Zanzibar.

1.3 Conceptual framework

Many factors can influence OM and can be grouped into one or more of the three major determinants namely social demographics, microbial agents, and medical characteristics. The interaction between these factors determines the risk for OM. Independent variables for the study include social demographics, microbial agents, and medical presentation while the dependent variable would be OM.

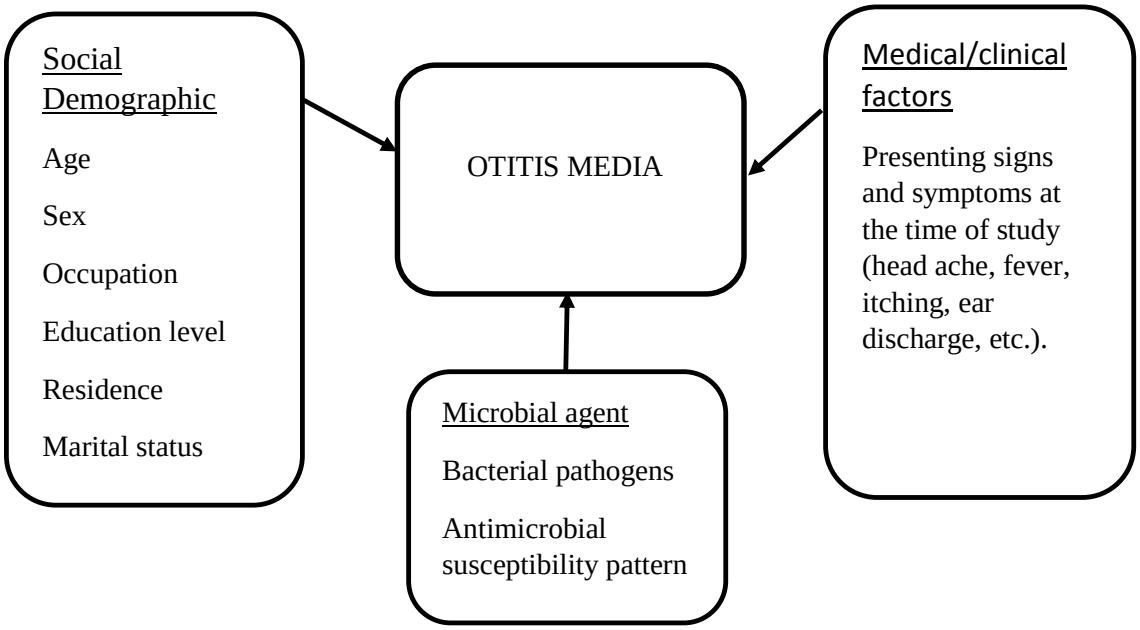


Figure 1: Conceptual framework of OM

1.4 Rationale of the study

Findings generated from this study will influence changes in the guidelines for the management of patients with OM, policy, and decision making. Findings from this study will also inform clinicians on the best practices to manage patients with OM based on evidence of laboratory results. This will minimize empirical treatment of OM by the attending clinicians.

1.5 Research questions

2. What is the prevalence and distribution of OM in patients attending the ENT clinic at MMH in Zanzibar?

3. What are the etiological agents and antimicrobial susceptibility testing patterns associated with OM in patients attending the ENT clinic at MMH in Zanzibar?

4. What are the factors associated with OM in patients attending ENT clinic at MMH in Zanzibar?

1.6 Study objectives

1.6.1 Broad

To determine the prevalence, etiological agents, antimicrobial susceptibility testing patterns, and factors associated with OM in patients attending the ENT clinic at MMH in Zanzibar

1.6.2 Specific

1. To determine the prevalence of OM in patients attending ENT clinic at MMH in Zanzibar

2. To identify microbial agents responsible for OM in patients attending ENT clinic at MMH in Zanzibar

3. To determine antimicrobial susceptibility testing patterns of pathogens isolated from patients with OM attending ENT clinic at MMH in Zanzibar

4. To determine factors associated with OM in patients attending ENT clinic at MMH in Zanzibar

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Prevalence of OM

Otitis media is highly prevalent worldwide and is the main cause of hearing impairment in resource-constrained countries. World Health Organization (WHO) reported that, prevalence shows the global burden of illness from CSOM involve 65-330 million individuals with draining ears 60% of whom 29-200 million suffer from significant hearing impairments (22).

The prevalence of OM varies in different countries. Studies around the world reported that the prevalence of AOM varies from 2.3% to 20%, CSOM from 4% to 33.3%, and OME from 1.3% to 31.3% (23). Globally (low, middle, and high-income countries), a systematic review on the epidemiology of OM in children showed the prevalence of 9.2% in Nigeria, 10% in Egypt, 6.7% in China, 9.2% in India, 9.1% in Iran, and 5.1–7.8% in Russia. (2)

In Central Europe, the incidence rate of OM is 3.6% (AOM & CSOM) whereby 40% of cases occur in children aged 0–5years and Asian Pacific have the incidence rates of 24.2% and 1.6% for AOM and CSOM, respectively (7). A study done to the population of Nunavik in Canada on middle ear abnormalities revealed that the prevalence of OM is 50% in under-5 children and 17% at the age of 5 years (24).

Most published data show a varied prevalence of OM in African countries. In South Africa, the prevalence of OM is 8.2% (25). In the Nigeria community prevalence of OM was 14.7% with 9.2% prevalence in under 5 years children in 2005 (26,27). In sub-Saharan Africa, the prevalence of OM is 87% and pediatric OM is 86% (28).

In some of East African countries like Kenya, a study done on school children at Kiambu district showed the prevalence of OM was 1.1% CSOM and 2.4% with the perforated membrane (AOM) (26). In Rwanda in the Gasabo District of Kigali City, the prevalence of middle ear infections is 5.8% (29).

In Tanzania, a previous study done in September 2015 and February 2016 at Otorhinolaryngology (ORL) Department of Muhimbili National Hospital the prevalence of CSOM was 1.4% (18) also, from the study done at Morogoro hospital among patients living with HIV observed the high prevalence of 93.4% with bacteria associated OM (30) and Zanzibar there is no current data on the prevalence of OM.

2.2 Pathogens of OM

A systematic review and meta-analysis of bacteria responsible for OM in sub-Saharan Africa revealed several pathogens including *P. aeruginosa*, *S. aureus*, *Proteus*, and *Klebsiella species* (8,17). A previous study conducted in Yemen in 2016 on bacterial and antibiogram of OM revealed Enterococcus species, *S. pneumoniae* and Enterobacter species as causative agents (8). Also, a study done at Kenya, Garissa district on the bacteriology of CSOM, *Proteus* species, *Enterococcus*, *S. aureus* and *Pseudomonas* species were isolated with participants aged 13 and 14 years (31). Like the previous study in Ethiopia the pathogen responsible for OM revealed Porteous species, *S. aureus*, Pseudomonas species, *E. coli*, Klebsiella species, Citrobacter and Enterobacter species, with predominant age of 16 to 35 years (32). From the study done at Mulago hospital-Uganda, the same organisms was isolated with high prevalence to above 18 years patients (33). In Tanzania the study done at a tertiary hospital on prevalence and aetiologic agents of CSOM report: staphylococcus species (54%), *K. pneumoniae* (20%) *P, mirabilis* (17.8%) *S. aureus* (21.1%) and *E. coli* (21.1%) as the commonest bacteria isolates from the patients with CSOM (18). A study in Tanzania, tertiary hospital - Mwanza (20016), on antimicrobial sensitivity pattern pathogen reported were; Staphylococcus aureus (MRSA), Pseudomonas species, Klebsiella species and Acinetobacter. (19)

2.3 Factors associated with OM

A New Zealand study on factors associated with middle ear infection revealed that individuals regularly suffering from ear discharge, snoring, home treated children from breathing problems, exposed children to a large number of other children and daycare babies were more affected with ear diseases than others (34,35). In Nigeria, a study

conducted in 2007 showed that sociodemographic risk factors were low socioeconomic status, living in congested houses, families with more than 5 children, indoor-cooking and daycare attendance, supine bottle feeding, exposure to cigarette smoking as well as clinical risk factors that included respiratory, allergy, adenoid hypertrophy and malnutrition (36). A study done in Tanzania in a tertiary hospital, Mwanza (20016) report observed, poor treatment outcome, smoking and prolonged illness duration before seeking medical attention was also found to be associated with disease complications (CSOM) (19).

2.4 Clinical manifestation of OM

Clinical manifestations of OM include bulging of the tympanic membrane, ear discharge, or visible discharge in the external ear canal, inflammation of the external ear canal, perforation of the tympanic membrane (37). Others are spontaneous otorrhea, mastoiditis, cholesteatoma, and periauricular cellulitis (38). From Tanzania study, clinical manifestation of OM reported ear discharge and hearing loss and pre-morbid illness (19).

2.5 Pathogenesis of OM

Otitis media is a multifactorial infection, involving the adaptive and native immune system, eustachian-tube dysfunction, viral and bacterial load, genetic and environmental factors (10,39). Its pathogenesis starts with early and dense microbial colonization in the upper respiratory tract, nasopharynx to the middle ear through a eustachian tube with early onset of AOM. The establishment of acute inflammation in the middle ear results in continued exposure to infective agents including bacterial persistence in the middle ear through biofilm formation, viral infections, and finally severe chronic ear disease (37).

2.6 Diagnosis of OM

Clinical diagnosis of OM is done either by otoscopy or photomicroscope and it is assessed by symptom severity scale. Pneumatic otoscopy is the primary diagnostic modality for OME, with photomicroscope and tympanometry as adjunct measures. Acoustic reflectometry can be used by parents to assess OME (15,35).

Laboratory diagnosis is the technique used to obtain information on microbial species, monitoring resistance as well as epidemiological purposes. The laboratory technique used in the lab is microscopy (known as Gram stain reactivity), culture method using a suitable media to isolate bacteria colony, biochemical test to identify isolated organisms, antimicrobial susceptibility testing to identify antibiotics that the isolated organisms are susceptible to, and characterization of microbial agents using molecular methods (40)

2.7 Management of OM

Management of otitis media is focused on the treatment of ear pain and fever with analgesics at the appropriate age-adjusted dose as the mainstay of OM therapy (37)(41) Antimicrobial therapy is indicated for the management of AOM and OME; selection of antibiotics based on the specific pathogen that commonly causes illness and clinician is very important and to know the organisms most likely to be responsible for the infection (42). The best choice of an appropriate antimicrobial agent, decongestants, and antihistamines may provide some comfort for the patient (39). Topical antibiotics and aural toilet are the mainstays of medical management of CSOM (38).

2.8 Prevention and control of OM

OM is a multifactorial disease and thus various strategies can be used for prevention. Prevention and control strategies mainly focus on reducing modifiable risk factors, such as bacterial and viral infections and environmental risks. Chemoprophylaxis using antibiotics and surgical interventions are used to reduce the burden of OM (1,43).

Pneumococcal conjugate vaccines (PCV) in children are used in the prevention of OM. Breastfeeding protects children against recurrence of OM. Avoiding cigarette smoke exposure and adenoidectomy in children less than 2 years old with recurrent AOM are also recommended. Physician's advice to parents whose children have severe or recurrent or risk factors for middle ear infections may reduce the incidence of infection through breastfeeding, enrolling children in a small group rather than large group daycare centers, and reducing exposure to tobacco smoke (44,45)

CHAPTER THREE

METHODOLOGY

3.1 Study design

A hospital-based analytical cross-sectional study was conducted between April to June 2021.

3.2 Study area

The study was conducted at MMH which is a referral hospital in Zanzibar located in Urban West of Unguja Island and has three campuses. The main campus is MMH located in Stone Town, with a total of 521 beds (2008) Others are Mwembeladu Maternity Home with 39 beds and Kidongo Chekundu Mental Hospital 68 beds. Kidongo Chekundu and Mwembeladu maternity are located within the city limits of Stone Town but outside of the downtown area. MMH has been mandated to provide health care services as a referral hospital in Zanzibar including obstetrics and gynecology, diagnostic services, and more specialized services such as neurosurgery, oncology, intensive care, ENT, ophthalmology, acupuncture, advanced physiotherapy and orthotics, prosthetics, and pathology laboratory. It is also used as a teaching hospital.

ENT service is offered by ENT specialists and the operating room is working daily but clinics are operating five (5) days per week (working days only) with about 3,780 patients per year (ear nose and throat cases). MMH Pathology laboratory is well organized with 24 hours services that include hematological, parasitological, histopathological, clinical chemistry as well as a microbiological test (bacteriology, virology, etc.).

3.3 Study population

All patients attending the ENT OPD clinic at MMH with ear complain were involved and those with symptoms and sign of ear infection, a pus swab sample was taken for laboratory confirmation.

3.3.1 Inclusion criteria

All patients presenting with ear complain with a minimum age of 0 and above.

3.3.2 Exclusion criteria

Patients within the antibiotic medication.

3.4 Sampling method

Non-probability sampling technique was used. All patients attending at ENT clinic with ear complain were included and pus swab samples were taken to those with presenting symptoms and signs of ear infection until the required sample size is reached as shown in figure 2.

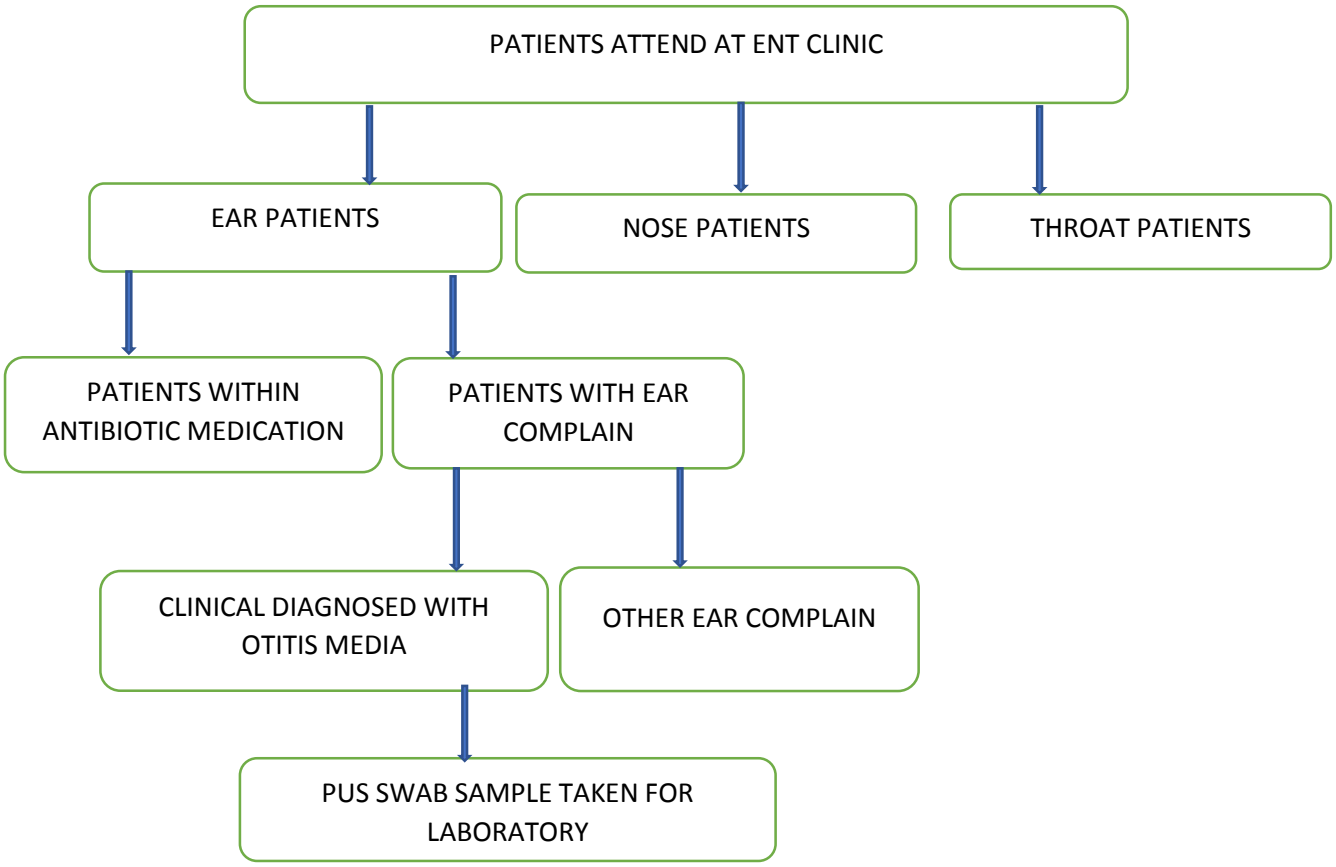


Figure 2 Show how patients were recruited from the patients attending at ENT clinic at MMH-Zanzibar, April to June 2021

3.5 Sample size estimation

The sample size was calculated using the following formula.

$N = z^2p\ (1\text{-}p)/\ e^2$

Where;

N = Sample size required

Z = standard normal deviation corresponding to 95% confidence interval, which is equal to 1.96

P = the known Prevalence of otitis media is 14% (19)

E = margin of error estimated was 5%

Thus,

$N = z^2p\ (1\text{-}p)/\ e^2$

$N = 1.96^2 * 0.14 * (1 - 0.14)/\ 0.05^2$ **OR** $N = 1.96^2 * 14*(100 - 14)/5^2$ **N=185**

To adjust for 10% of non-responses, the calculated sample size was as follows:

Non-response rate (n) =N /100% - 10% = N/90% =N/0.9

N = N/0.9= 185/0.9

= 205

Using the above formula, the required sample size was 205 participants.

3.6 Data collection

Data were collected using a structured questionnaire from the study participants. All patients with ear complain were consents until the required sample reaches 205 and those patients with symptoms and signs of ear infection, a pus swab sample were taken for laboratory analysis. A structured questionnaire was administered by two research assistants from ENT staff. Data on socio-demographic questions, presenting symptoms, and associated factors were obtained.

3.7 Sample collection

Physical examination was done by the attending clinician using a head mirror with a bright light source and a battery-powered keeler auroscope to view the auditory canal and

tympanic membrane. The external ear was cleaned with 70% alcohol before taking the sample, a sample was taken using a sterile cotton-tipped swab with the help of a special magnifying tool, safety precaution has been considered during pus swab sample collection, Amies transport media has been used and the sample was sent to MMH Pathology Laboratory in the same day for laboratory processing.

3.8 Laboratory investigations

Each specimen was inoculated in blood agar and MacConkey agar media (aerobically at37°C) and was incubated for 24 hours. For those culture media plates with no growth, have been re-incubated for more 24 hours, and for those with mixed growth, purified plate culture was done to get pure growth. Identification of pathogens was based on microscopy, colony characteristics (colony morphology, hemolysis on blood agar, changes in the physical appearance of the differential media), and Gram stain was performed. Biochemical identification tests including urease, citrate utilization, Klingler iron agar (KIA), motility, indole, and ornithine (MIO) were performed to identify the species of pathogens isolated.

Antimicrobial susceptibility testing of isolated pathogens using the Kirby Bauer disc diffusion method was performed and results were interpreted according to the guidelines of the Clinical and Laboratory Standard Institute (CLSI 2018). A colony suspension with a concentration equivalent to 0.5 McFarland solution was prepared for each identified isolate and inoculated into Mueller Hinton-Agar (Oxoid, UK). Appropriates selected antibiotic discs (Oxoid Ltd, Wade Road, Basingstoke, Hants, United Kingdom) were placed into the media and incubated at 37°C for 24 hours. Antibiotic disc used to Gramm positive bacteria (Staph aureus) was Clindamycin (2 µg) Erythromycin (15 µg), Gentamicin (10 µg), Ciprofloxacin (5µg), Trimethoprim/sulfamethoxazole (25µg), Cefoxitin (30 µg). Chloramphenicol (30 µg). Gram negative bacteria were Ampicillin (10 µg), Ceftriaxone (30 µg), Gentamicin (10 µg), Ciprofloxacin (5µg), Amoxicillin/clavulanate (20/10 µg), Trimethoprim/sulfamethoxazole (25µg), Amikacin (30 µg) and Meropenem (10 µg).

Pseudomonas aeruginosa were tested against Gentamicin (10 μg), Ciprofloxacin (5 μg), Ceftazidime (10 μg) Meropenem (10 μg) Cefepime (10 μg) and Amikacin (10 μg). Reference strains used for quality control were *S. aureus* (American Type Culture Collection; ATCC 29213), *E. coli* (ATCC25922), *P. aeruginosa* (ATCC2785)

3.9 Data management

Data cleaning was done including screening data for duplication and resurveying, transcriptional errors, consistency, out of range, invalid values, and outliers. Only authorized personnel had access to the data collected. The primary data was entered and cleaned by the Principal Investigator of the study using Epi info version 7.0. Logistic regression model was used to test for association. Variables with a statistical significance of a p-value ≤ of 0.2 in the bivariate models, were included in multivariate analysis

3.10 Data analysis

Data were entered in an excel sheet and exported in Epi Info version 7.2 for analysis. Dependent variables were prevalence and microbial agents of OM and antimicrobial susceptibility testing patterns. Independent variables included socio-demographic characteristics (age, sex, education level, occupation, and residence) and medical factors (presenting symptoms and individual risk factors). Descriptive analysis of data was done and expressed in percentage (social demographic, presenting symptoms, isolated organisms, and susceptibility pattern). The relationship between associated factors (family history, infection recurrent, family smoke, age, sex, underlying condition, sleeping habit, occupation, bottle-feed at back position, and cotton bud ear clearing) and otitis media infection. Bivariate and Multivariate analysis of associated factors was performed using a logistic regression model. In multivariate analysis, variables with a statistical significance of a p-value ≤ 0.2 in the bivariate models were included. Strength of association was expressed using risk ratio and 95% confidence intervals. Results were presented as proportions, risk ratio, and a 95% CI. A p-value of <0.05 was regarded as statistically significant.

3.11 Ethical considerations

Ethical clearance of the study was obtained from the Research and Ethics Committee of Muhimbili University of Health and Allied Sciences. In Zanzibar, permission to conduct the study was obtained from Zanzibar Health Research Ethics Committee (ZAHREC) as well as MMH Director. Written informed consent was obtained from the study participants before recruitment in the study. For children, the parent or guardian was responsible to provide assent. Participants that were found to have ear infection were managed according to the existing Zanzibar treatment guidelines. All patient's information was kept confidential to MMH Pathology Laboratory (Bacteriology Department) as well as the ENT clinic while issuing results.

CHAPTER FOUR

RESULTS

4.1 Social demographic characteristics of study participants

A total of 205 study participants were enrolled in the study. Table 1 presents the baseline social-demographic characteristics of study participants. The median age of the study participants was 11 years. One hundred and twenty (120, 58.5%) were male and over half of the participants were adults above 10 years (107, 52.2%).

Table 1: The social-demographic characteristics of the study participants (N=205)

Characteristic	Frequency	Percentage
Age categories (Years)		
1 to 10	98	47.8
11 to 60	107	52.2
Sex		
Female	85	41.5
Male	120	58.5
Education level		
Informal	7	3.4
University	21	10.2
Primary school	48	23.4
Secondary school	55	26.8
Not applicable	74	36.1
Marital status		
Married	21	10.2
Single	64	31.2
Not applicable	120	58.6
Occupation		
Un employee	31	15.1
Students	46	22.4
Employed	52	25.4
Not applicable	76	37.1
Residence		
North	17	8.3
South	63	30.7
Urban west	125	61.0

4.2 Presenting symptoms of OM in study participants

Table 2 shows presenting symptoms and signs by clinically diagnosed OM. Nighty eight (98) out of 205 (47.8%) study participants were diagnosed with OM based on presenting symptoms and signs to the attending physician. The most common presenting symptoms were ear discharge and ear itching, **see table 2**. The majority of participants possess multiple presenting symptoms. The most predominant multiple combinations presenting symptoms were; 35% (ear discharge, itching, ear pain, fever) followed by 12% (unusually baby cry, sleeping trouble, ear rubbing, itching). **As shown in figure 3**

Table 2: Presenting symptoms of the study participants with their OM diagnosed status **(N=205)**

Presenting symptoms		**Frequency n (%)**	**OM present n (%)**	**OM absent n (%)**	**P. value**
Ear pain	Yes	109 (53.2)	33 (30.2) (	76 (69.7)	0.09
	No	96 (46.8)	19 (19.8)	77 (80.2)	
Ear discharge	Yes	178 (86.8)	44 (29.6)	134 (75.3)	0.58
	No	27 (13.3)	8 (29.6)	19 (70.4)	
Ear itching	Yes	142 (69.3)	40 (28.2)	102 (71.8)	0.16
	No	63 (30.7)	12 (19.1))	51 (80.9)	
headache	Yes	30 (14.6)	9 (30.0)	21 (70.0)	0.52
	No	175(85.3)	43 (24.6)	132 (75.4)	
fever	Yes	45 (21.9)	11 (24.4)	34 (75.6)	0.87
	No	160 (78.1)	41 (25.6)	119 (74.4)	
Sleeping trouble	Yes	80 (39.0)	28 (35.0)	52 (65.0)	0.01
	No	125 (61.0)	24 (19.2)	101 (80.8)	
Trouble hearing	Yes	65 (31.7)	18 (27.7)	47 (72.3)	0.60
	No	140 (68.3)	34 (24.3)	106 (75.7)	
Unusual baby crying	Yes	35 (19.1)	11 (31.4)	24 (68.5)	0.38
	No	170 (82.9)	41 (24.1)	129 (75.9)	
Rubbing of the ear (child)	yes	47 (22.9)	17 (36.2)	30 (63.8)	0.05
	No	158 (77.1)	35 (22.2)	123 (77.8)	

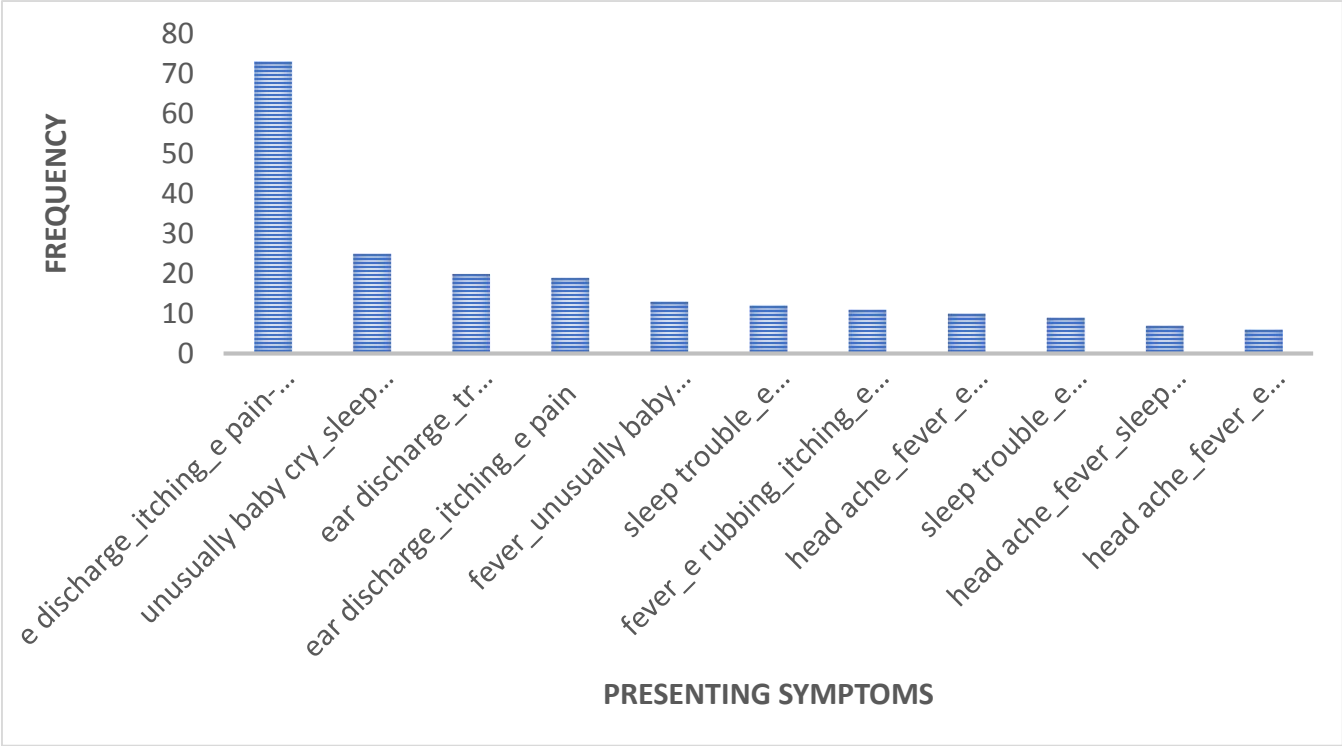


Figure 3 Show the frequency of Multiple presenting symptoms of OM among participants attending ENT clinic at MMH-Zanzibar, April to June 2021.

4.3 Prevalence of OM

The prevalence of OM based on laboratory results was found to be 25% (52/205) (Table 3). Most affected population belonged to the age group of above 11 years 53.8%. Males were more affected than females.

Table 3: Confirmed cases of OM among study participants (N=52)

VARIABLES	OM yes (%)	OM no (%)	P. value
Age			
<1 to 10 years	24 (24.5)	74 (75.5)	**0.783**
11 to 60	28 (26.2)	79 (73.8)	
Sex			
Female	21 (25.8)	64 (75.3)	**0.855**
Male	31 (21.8)	89(75.3)	
Level of education			
Non	23 (28.4)	58 (71.6)	**0.425**
Education	29 (23.4)	95 (76.6)	
Occupation			
Employee	14 (28.9)	38 (73.1)	**0.768**
Non-employed	38 (24.8)	115(75.2)	
Marital status			
Married	20 (31.3)	44 (68.7)	**0.202**
Not married	68 (48.2)	73 (51.8)	
Residence (region)			
Urban west	28 (22.4)	97 (77.6)	**0.71**
South	22 (34.9)	41 (65.1)	
North	2 (11.8)	15 (82.3)	

4.4 Etiological agents of OM

Table 4 summarizes the distribution of pathogens isolated. *P. aeruginosa* was the most common pathogen isolated followed by *P. mirabilis* and *K pneumoniae*. Thirty-seven (71.2%) samples isolated a single pathogen (Table 4). The majority of pathogens isolated were Gram-negative bacteria.

Table 4: Microbial agents isolated responsible with OM

Isolated organism	Frequency (%)
P. aeruginosa	26 (12.7)
P. mirabilis	12 (5.8)
K. pneumoniae	10 (4.8)
S. aureus	7 (4.9)
E. coli	6.(2.9)
Serratia marcescens	6 (2.9)
Citrobacter	3 (1.5)
Providencia rettgeri	2 (1)

4.5 The most prevalent pathogens, were gram-negative bacteria 44 (86.6%), 5 (9.6%) were Gram-positive and 3 (5.8%) were mixed (gram-positive and negative). The most common bacteria isolated from participants were *P. aeruginosa* 26 (12.7%), *S. aureus* 7 (3.4%), *P. mirabilis* 12 (5.8%), *E. coli* 6 (2.6%) and *K. pneumoniae* 10 (4.8%). Some participant possesses multiple bacterial infections.

4.6 Antimicrobial susceptibility testing patterns of isolated organisms

P. mirabilis was seen to be resistant to different common antibiotics: Meropenem 33%, Amoxiclav 67%, Ampicillin, Ceftazidime & Ceftriaxone 75% respectively.

Table 5: Antimicrobial susceptibility testing patterns of each isolated organism

Organism's name	n	Sensitivity pattern	GN (%)	MEM (%)	CR0 (%)	AMK (%)	CIP (%)	CEFT (%)	ERY (%)	CL (%)	CN (%)	CEF (%)	AMX (%)	AMP (%)	CTX (%)
P. aeruginosa	26	S R I	15(58) 10(38) 1(4)	16 (61) 10 (39) 0 (0)	-	24 (92) 2 (8)0 (0)	26 (100 0 (0) 0 (0)	26 (100 0 (0) 0 (0)	-	-	-	13 (50) 13 (50) 0 (0)	-	-	-
P. mirabilis	12	S R I	9 (75) 3 (25) 0 (0)	5 (42) 4 (33) 3 (25)	2 (16) 9 (75) 1 (8)	11 (92) 1 (8) 0 (0)	10 (82) 1 (8) 1 (8)	2 (17) 9 (75) 1 (8)	-	9 (75) 1 (13) 2 (17)	-	1 (8) 0 (0) 11(92)	0 (0) 8 (67) 4(33)	(0) 9 (75) 3 (25)	0 (0) 0 (0) 12(100)
K. pneumoniae	10	S R I	5 (50) 4 (40) 1 (10)	6 (60) 3 (30) 1 (10)	3 (30) 3 (30) 4 (40)	7 (70) 0 (0) 0(0)	9(90) 0 (0) 1 (10)	0 (0) 1(10) 9 (90)	-	5(50) 4 (40) 1 (10)	-	O (0) 1 (10) 9 (90)	1(10) 1(10) 8(80)	2 (20) 0 (0) 8 (80)	1 (10) 0 (0) 9 (90)
S. aureus	7	S R I	6 (86) 1 (14) 0 (0)	-	-	-	7 (100) 0 (0) 0 (0)		4 (57) 3 (43) 0 (0)	3 (43) 3 (43) 1 (14)	1 (14) 0 (0) 6 (86)	-	-	-	0 (0) 0 (0) 7 (100)
E. coli	6	S R I	5 (81) 0 (0) 1 (17)	2 (33) 0 (0) 4 (67)	1 (17) 0 (0) 5 (81	1 (17) 1 (17) 4 (66)	6 (100) 0 (0) 0 (0)	0 (0) 1 (17) 5 (83)	-	3 (50) 3 (50) 0 (0))	-	1 (17) 0 (0) 5 (83)	0 (0) 6 (100) 0 (0)	0 (0) 0 (0) 6 (100	2 (33) 1 (17) 3 (50)
Other gram-negative bacteria	11	S R I	9 (82) 2 (18) 0 (0)	7 (63) 1 (9) 3 (27)	6 (54) 1 (9) 4 (36)	8 (73) 3 (27) 0 (0)	11 (100) 0 (0) 0 (0)	5 (45) 3 (27) 3 (27)		6 (54) 4 (36) 1 (9)		8 (73) 1 (9) 2 (18)	1 (9) 4 (36) 6 (54)	1 (9) 5 (45) 5 (45)	6 (54) 1 (9) 4 (36)

Key note: Other gram-negative bacteria are Citrobacter, *P. rettgeri* and *S. marcescens*. GN=gentamicin, MEM=meropenem, CRO=ceftriaxone, AMK=amikacin, CIP=ciprofloxacin, AMX=amoxiclav, AMP=ampicillin, CTX=trimethoprim, CEFT=ceftazidime=erythromycin, CL-chloramphenicol, CN=clindamycin, CEF-cefepime, S=sensitive, I=intermediate-R=resistance.

4.6 Factors associated with OM

From the study participants, different factors associated with OM were observed from each participant through questionnaire these were family history 63.4%, family smoke 18.1% (exposure to cigarette smoke), underlying condition 42.9%, cotton bud ear clearing 63.4%, sleeping habit 12.7%, a season of infection recurrent 10.7% and bottle feed at back position 3.4%. Cotton bud ear cleaning (63.4%) and family history (63%) were seen to have high frequency followed by an underlying condition (42%) compared to other factors

4.7 Bivariate analysis of factors associated with OM

Bivariate analysis of factors associated with OM, cotton bud ear cleaning and underlying condition seen as the most significant factors.

Table 6: Bivariate analysis of factors associated with OM

VARIABLES	OM yes (%)	OM no (%)	CRR (95%CI)	P-value
Age				
<1 to 10 years	24 (24.5)	71 (75.5)	0.99 **(0.90-1.09)**	**0.783**
11 to 60	28 (26.2)	79 (73.8)		
Sex				
Female	21 (25.8)	64 (75.3)	0.99 **(0.90 -1.09)**	**0.855**
Male	31 (21.8)	89(75.3)		
Level of education				
Non	23 (28.4)	58 (71.6)	1.04 **(0.94-1.15)**	**0.425**
Education	29 (23.4)	95 (76.6)		
Occupation				
Employee	14 (28.9)	38 (73.1)	0.98 **(0.88-1.10)**	**0.768**
Non-employed	38 (24.8)	115(75.2)		
Marital status				
Married	20 (31.3)	44 (68.7)	0.93 **(0.84-1.04)**	**0.202**
Not married	68 (48.2)	73 (51.8)		
Family history				
Yes	31 (23.8)	99(76.1)	0.97 **(0.88-1.07)**	**0.515**
No	29 (38.6)	46 (61.3)		
family smoker				
Yes	7 (18.9)	30 (81.1)	0.94 **(0.83-1.06)**	**0.291**
No	77 (45.8)	91 (54.8)		
Underlying condition				
Yes	9 (10.2)	79(89.7)	0.81 **(0.74-0.88)**	**< 0.001**
No	43 (63.5)	74 (63.3)		
Cotton buds ear cleaning				
Yes	41(29.5)	98 (70.5)	1.11 **(1.01-122)**	**0.035**
No	11 (16.7)	55 (83.3)		
Infection recurrent				
Yes	6 (27.3)	16 (72.7)	1.02 **(0.87-1.19)**	**0.831**
No	86 (47.2)	97(52.6)		
Bottle feed at back position (baby)				
Yes	3 (42.8)	4 (57.1)	1.15 **(0.88-1.49)**	**0.310**
No	93 (47.0)	105 (53.0)		
Sleeping habits				
Proper	8 (30.8)	18(69.2)	1.05 **(0.91-1.21)**	**0.513**
No specific side	44 (24.6)	135 (75.4)		

Underlying conditions - asthma, allergy, URTI etc. OM; otitis media. CRR; crude risk ratio

4.8 Multivariate analysis of factors associated with OM

Table 7 presents the results of multivariate analysis of factors associated with OM. Cleaning using cotton ear bud was significantly associated with OM infection. Underlying ENT condition is less likely to gain OM.

Table 7: Multivariate analysis of factors associated with OM (N = 205)

VARIABLES	OM yes (%)	OM no (%)	CRR (95%CI)	P-value	ARR (95%CI	P-value
Marital status						
Married	20 (31.3)	44 (68.7)	0.93 **(0.84-1.04)**	**0.202**	0.95 **(0.86-1.05)**	**0.315**
Not married	68 (48.2)	73 (51.8)				
Underlying condition						
Yes	9 (10.2)	79(89.7)	0.81 **(0.74-0.88)**	**< 0.001**	**0.79 (0.72-0.86)**	**< 0.001**
No	43 (63.5)	74 (63.3)				
Cotton buds ear cleaning						
Yes	41(29.5)	98 (70.5)	1.11 **(1.01-122)**	**0.035**	**1.14 (1.03-1.26)**	**0.012**
No	11 (16.7)	55 (83.3)				
Family smoke						
Yes	7 (18.9)	30 (81.1)	0.94 **(0.83-1.06)**	**0.291**	0.96 **(0.86-1.07)**	**0.470**
No	77 (45.8)	91 (54.8)				

Underlying conditions - asthma, allergy, URTI etc. OM; otitis media; CRR; crude risk ratio, ARR; adjusted risk ratio

CHAPTER FIVE

DISCUSSION

OM is one of the common inflammatory disorders of the middle ear which is one of public health importance in early life as well as in adults. This is the first study in Zanzibar to investigate the prevalence of OM in patients attending ENT clinic at MMH.

This study revealed that the prevalence of OM in patients who attended ENT clinic at MMH was 25%. The prevalence found in this study is higher compared to the prevalence of 14% from the study done in Tanzania at the Department of ENT, Muhimbili National Hospital (46). However this result is low as compared to Tanzania study from tertiary hospital-Mwanza, patients with CSOM was 62.1 % with positive bacterial culture (19). The observed difference may be since MNH is the national referral hospital therefore many cases of OM are handled at lower-level facilities in Dar-es-Salaam that can manage the cases. This is not the case for MMH, it is the only referral hospital for Zanzibar where all cases are referred to and lower-level facilities have limited capacity to diagnose and manage OM cases. Another study done in Rwanda Gasabo district showed a prevalence of 5.8% (26) which is lower than that found in this study. Also, this prevalence is much lower compared to 87% and 86% in sub-Saharan Africa (Ethiopia) reported in Pediatric patients (28) A previous study done in the population of Nunavik in Canada on middle ear abnormalities reported the prevalence of 50% in under 5 children and 17% at the age of 5 years (24). In this study above 10 years of age showed a high prevalence (26.2%) of OM, compared to other age groups. This finding differs in Kenya from primary school children report 1.1% CSOM and 2.4% AOM (26). Therefore, results from this study showed that the prevalence of OM is higher in adults of above 10 years.

A full understanding of the etiologic agent for OM could be very beneficial for the treatment as well as prevention of the disease as this study objective said. The study found that the most prevalent pathogens, 44 (21.4%) were gram-negative bacteria, 5 (2.4%) where Gram-positive Similar findings were reported from the study done in a tertiary

hospital of Northcentral Nigeria on the pattern of bacterial isolates in the middle ear discharge showed that Gram-negative organisms were high (71.6%) while Gram-positive organisms were (27.6%) (1) The most common bacteria isolated from study participants were *P. aeruginosa* (26, 12.7%), *P. mirabilis* (12, 5.8%), *K. pneumoniae* (10, 4.8%), *S. aureus* (7, 3.4%) and *E. coli* (6, 2.6%). Similar results found from the study done in tertiary hospital Mwanza-Tanzania report the majority of isolates were gram-negative bacteria with P. aeruginosa as the predominant organisms(19). As the study on bacterial profile and antibiogram responsible with OM among children in Yemen, the same organisms were the most isolated bacteria (8). Also, a report from a systematic review and meta-analysis of bacteria responsible for otitis media in sub-Saharan Africa revealed pathogens like *P. aeruginosa* and *S. aureus, Proteus species* and *Klebsiella species* (8,17) Likewise, from the study done at Turku University Hospital and the Department of virology and medical microbiology, report the commonest bacteria isolated from the infected middle ear and implicated for causing OM are *P. aeruginosa, P. mirabilis and Klebsiella species* (9) Also, from the study Also, from the study in Iraq at Diyala University 2018 *P. aeruginosa* (35%), *S. aureus* (25.0%), *Proteus spp*. (24.0%), *E. coli* (7.0%), *Klebsiella pneumonia* (2%) were reported (47). In contrast with the study in a tertiary hospital of Tanzania *K. pneumoniae* reported as the predominant isolated bacteria followed by *P. Mirabilis* (18). The predominant pathogen in this study is *P. aeruginosa.* this suggests people are at high risk of infection due to poor hygienic environment since this is associated with wet environmental conditions as well as coliform organisms (*E. coli* and *K. pneumoniae*) which are known to be fecal bacteria.

From this study, antimicrobial susceptibility test, *P. mirabilis* show multidrug resistance with different common antibiotics include; Meropenem 33%, Amoxiclav 67%, Ampicillin, Ceftazidime and Ceftriaxone 75%, respectively. This finding is quite differentiated from the study done at Morogoro hospital in Tanzania among HIV people that reports *P. mirabilis* were resistant to erythromycin, gentamicin and ampicillin (30). Also, This finding differs from the study done in India on Microbiological profile with antibiotic sensitivity pattern of CSOM among children revealed *P. mirabilis* were susceptible to Ceftriaxone, Ceftazidime and Amikacin (48). The most predominant isolate was P.

aeruginosa that were resistant to amikacin 58% and cefepime 50% and show a susceptible with 100% ciprofloxacin, 92% gentamicin, 61% meropenem and 50% ceftazidime. The above finding is differ with study done at Mwanza, Tanzania, that report pseudomonas species to be resistant to amoxicillin/clavulanic acid, ceftazidime, gentamicin, meropenem and ciprofloxacin respectively(19). This increases of gram-negative isolate resistance (P. mirabilis) to third-generation cephalosporin to commonly prescribed antibiotics (ceftazidime & ceftriaxone) alarming the need for standardizing antimicrobial resistance surveillance and antibiotic stewardship program in Tanzania.

The most of isolated pathogens were sensitive to ciprofloxacin (90% to 100%) and Gentamicin (75% to 100%), this is nearly similar to results reported from the Tanzania study on prevalence and etiological agents for chronic suppurative otitis media in a tertiary hospital revealed: the majority of isolates were sensitive to Ciprofloxacin, Gentamicin, ceftriaxone and amikacin (18).

Therefore, this drug susceptibility variation may be due to random use of an antibiotic that could be due to easily availability from a private pharmacy or incomplete of doses.

Regarding associated factors, this study found that self-ear cleaning using cotton bud was significantly associated with OM (ARR = **0.79,** 95% CI = **0.72-0.86**). This finding is different from Tanzania study done at tertiary hospital-Mwanza, which confirmed that otalgia, multidrug resistance and prolonged illness duration without seeking medical attention is significantly predicted disease complications (19). This study has observed that underlying ENT conditions, less likely associated with OM infection (ARR=**1.14,** 95% CI = **1.03-1.26**). Findings, from the study on African countries, reported that, underlying condition is a predominant factors with OM (adenoid hypertrophy, allergic rhinitis in children) (49). A similar study done in the South Indian population on risk factors associate with OM, reveal that upper respiratory tract infection is the predominant associated factor with OM infection (23). The observed finding in this study may be due to geographical distribution, socioeconomic status or awareness.

5.1 Conclusions and recommendations

5.1.1 Conclusions

About a quarter of the study participants had laboratory-confirmed OM. Prevalence of double microbial nature and antimicrobial resistance among isolates OM cases warrants the need for culture and sensitivity. Ciprofloxacin and Gentamicin can be recommended as the first-line management in patients with OM. Self-ear cleaning is the main factors associated with OM.

5.1.2 Recommendations

Health education on ear health, ear care, proper ear cleaning and early seeking behavior on diagnosis and treatment of OM is needed to the patients and community to prevent chronic progression of the disease. The treatment guideline should be revised and updated on care and treatment. The same study with a large sample size to the community is needed.

5.2 Study limitations and mitigation

5.2.1 Limitations

There was a challenge of patient flow due to the referral system. This prevalence is from the study among the patient who was treated with MMH, ENT OPD clinic only.

Fungus culture were not able to perform and we couldn't explore the role of anaerobic bacteria in otitis media.

5.2.2 Mitigation

A visit of two available regional hospitals (Makunduchi and Kivunge cottage hospitals) and some of the public health care units was done to aware the hospital staff with the study in terms of referral of ear infection patients since they have no ENT clinics no bacteriological laboratory procedure is done. A study with a large sample size to the general population will represent overall prevalence.

There is a lack of instruments and laboratory capacity for fungus isolation.

Due to the lack of anaerobic culture facilities, the role of anaerobic bacteria in otitis media couldn't explore.

REFERENCES

1. Oa A, Ag S, Fe O, Nwabuisi C, Cc N. Pattern of bacterial isolates in the middle ear discharge of patients with chronic suppurative otitis media in a tertiary hospital in North central Nigeria. 2012;12(3).

2. Deantonio R, Yarzabal J, Philip J, Schmidt JE, Kleijnen J. International Journal of Pediatric Otorhinolaryngology Epidemiology of otitis media in children from developing countries : A systematic review. Int J Pediatr Otorhinolaryngol [Internet]. 2016;85:65–74. Available from: http://dx.doi.org/10.1016/j.ijporl.2016.03.032

3. Vanneste P, Page C. Otitis media with effusion in children : Pathophysiology , diagnosis , and treatment . A review. J Otol [Internet]. 2019;14(2):33–9. Available from: https://doi.org/10.1016/j.joto.2019.01.005

4. Kucur C, Eda Ş, Kuduban O, İsa Ö. Prevalence of and risk factors for otitis media with effusion in primary school children : case control study in Erzurum , Turkey. 2015;230–5.

5. Organization WH. Report of the International Workshop on Primary Ear and Hearing Care, Cape Town, South Africa, 12-14 March 1998. World Health Organization; 2000.

6. Kong K, Coates HLC. Natural history, definitions, risk factors and burden of otitis media. Med J Aust. 2009 Nov;191(S9):S39—43.

7. Monasta L, Ronfani L, Marchetti F, Montico M, Brumatti LV, Bavcar A, et al. Burden of Disease Caused by Otitis Media : Systematic Review and Global Estimates. 2012;7(4).

8. Bin Mohanna MA, Bahannan AA. Bacterial Profile And Antibiogram Of Otitis Media Among Children In Yemen. J Ayub Med Coll Abbottabad. 2016;28(3):480–3.

9. Ruohola A, Meurman O, Nikkari S, Skottman T, Salmi A, Waris M, et al. Microbiology of Acute Otitis Media in Children with Tympanostomy Tubes : Prevalences of Bacteria and Viruses. 2006;43:1417–22.

10. Darrow DH, Derkay CS. Otitis media. Complicat Pediatr Otolaryngol. 2005;363:443–75.

11. Lubianca Neto JF, Hemb L, Silva DB e. Systematic literature review of modifiable risk factors for recurrent acute otitis media in childhood. J Pediatr (Rio J). 2006;82(2):87–96.

12. Jacoby PA, Coates HL, Arumugaswamy A, Elsbury D, Stokes A, Monck R, et al. The effect of passive smoking on the risk of otitis media in Aboriginal and non-Aboriginal children in the Kalgoorlie-Boulder region of Western Australia. Med J Aust. 2008;188(10):599–603.

13. Hoffman HJ, Daly KA, Bainbridge KE, Casselbrant ML, Home P, Kvestad E, et al. Panel I: Epidemiology, natural history, and risk factors. Otolaryngol - Head Neck Surg (United States). 2013;148(4 SUPPL.).

14. Macintyre EA, Heinrich J. Otitis Media in Infancy and the Development of Asthma and Atopic Disease. 2012;547–50.

15. Black M. The laryngoscope. Laryngoscope. 1902;12(4):259.

16. Rye MS, Wiertsema SP, Scaman ESH, Oommen J, Sun W, Francis RW, et al. FBXO11, a regulator of the TGFβ pathway, is associated with severe otitis media in Western Australian children. Genes Immun. 2011 Jul;12(5):352–9.

17. Tesfa T, Mitiku H, Sisay M, Weldegebreal F, Ataro Z. Bacterial otitis media in sub-Saharan Africa : a systematic review and meta-analysis. 2020;1–12.

18. Abraham ZS, Ntunaguzi D, Kahinga AA, Mapondella KB, Massawe ER, Nkuwi EJ, et al. Prevalence and etiological agents for chronic suppurative otitis media in a tertiary hospital in Tanzania. BMC Res Notes [Internet]. 2019;12(1):1–6. Available

from: https://doi.org/10.1186/s13104-019-4483-x

19. Mushi MF, Mwalutende AE, Gilyoma JM, Chalya PL, Seni J, Mirambo MM, et al. Predictors of disease complications and treatment outcome among patients with chronic suppurative otitis media attending a tertiary hospital, Mwanza Tanzania Ear disorders. BMC Ear, Nose Throat Disord [Internet]. 2016;16(1):1–8. Available from: http://dx.doi.org/10.1186/s12901-015-0021-1

20. Ministry of Health & Social Walfare, Zanzibar Health Management Information Systerm Unit Health information bulletin 2008. 2009;

21. Ali AO. The Zanzibar hospital service pakage in Zanzibar. 2009;(March).

22. Acuin J. Chronic suppurative otitis media. Clin Evid (Online). 2004;(12):710–29.

23. Santoshi M, Madhavi J, Bala N, Raja K, Jyothy A. Prevalence and associated risk factors of otitis media and its subtypes in South Indian population. Egypt J EAR, NOSE, THROAT ALLIED Sci [Internet]. 2016; Available from: http://dx.doi.org/10.1016/j.ejenta.2016.04.001

24. Wals P De, Lemeur JB, Ayukawa H, Proulx JF. Middle ear abnormalities at age 5 years in relation with early onset otitis media and number of episodes , in the Inuit population of Nunavik , Quebec , Canada. Int J Circumpolar Health [Internet]. 2019;78(1). Available from: https://doi.org/10.1080/22423982.2019.1599269

25. Halama AR, Voogt GR, Musgrave GM. Prevalence of otitis media in children in a black rural community in Venda (South Africa). Int J Pediatr Otorhinolaryngol. 1986;11(1):73–7.

26. Mukara KB, Lilford RJ, Tucci DL, Waiswa P. Prevalence of Middle Ear Infections and Associated Risk Factors in Children under 5 Years in Gasabo District of Kigali City , Rwanda. 2017;2017.

27. Amusa YB, Ijadunola IKT, Onayade OO. Epidemiology of otitis media in a local tropical African population. West Afr J Med. 2005;24(3):227–30.

28. Tesfa T, Mitiku H, Sisay M, Weldegebreal F, Ataro Z, Motbaynor B, et al. Bacterial otitis media in sub-Saharan Africa: a systematic review and meta-analysis. BMC Infect Dis. 2020;20(1):225.

29. Hatcher J, Smith A, Mackenzie I, Thompson S, Bal I, Macharia I, et al. A prevalence study of ear problems in school children in Kiambu district, Kenya, May 1992. Int J Pediatr Otorhinolaryngol. 1995 Nov;33(3):197–205.

30. Mwambete KD, Eulambius M. High Prevalence of Antibiotic-Resistant Otitis Media–Associated Bacterial Flora of Asymptomatic People Living with HIV at Morogoro Hospital, Tanzania. J Int Assoc Provid AIDS Care. 2018;17:1–8.

31. Aduda DSO, Macharia IM, Mugwe P, Oburra H, Farragher B, Brabin B, et al. Bacteriology of chronic suppurative otitis media (CSOM) in children in Garissa district, Kenya: A point prevalence study. Int J Pediatr Otorhinolaryngol [Internet]. 2013;77(7):1107–11. Available from: http://dx.doi.org/10.1016/j.ijporl.2013.04.011

32. Argaw-Denboba A, Abejew AA, Mekonnen AG. Antibiotic-resistant bacteria are major threats of otitis media in wollo area, northeastern Ethiopia: A ten-year retrospective analysis. Int J Microbiol. 2016;2016.

33. Justin R, Tumweheire G, Kajumbula H, Ndoleriire C. Chronic suppurative otitis media: bacteriology, susceptibility and clinical presentation among ENT patients at Mulago, Uganda. South Sudan Med J. 2018;11(2):31–5.

34. Paterson JE, Carter S, Wallace J, Ahmad Z, Garrett N, Silva PA. Pacific Islands Families Study: Risk factors associated with otitis media with effusion among Pacific 2-year-old children. Int J Pediatr Otorhinolaryngol. 2007;71(7):1047–54.

35. Zhang Y, Xu M, Zhang J, Zeng L, Wang Y, Zheng QY. Risk factors for chronic and recurrent otitis media-A meta-analysis. PLoS One. 2014;9(1).

36. Lasisi AO, Olaniyan FA, Muibi SA, Azeez IA, Abdulwasiu KG, Lasisi TJ, et al. Clinical and demographic risk factors associated with chronic suppurative otitis

media. Int J Pediatr Otorhinolaryngol. 2007;71(10):1549–54.

37. Schilder AGM, Chonmaitree T, Cripps AW, Rosenfeld RM, Casselbrant ML, Haggard MP, et al. Otitis media. Nat Rev Dis Prim [Internet]. 2016;2:1–19. Available from: http://dx.doi.org/10.1038/nrdp.2016.63

38. Chen Y, Hsieh Y, Huang Y, Chiu C. Clinical manifestations and microbiology of acute otitis media with spontaneous otorrhea in children. J Microbiol Immunol Infect [Internet]. 2013;(5). Available from: http://dx.doi.org/10.1016/j.jmii.2013.04.001

39. Mittal R, Lisi C V, Gerring R, Mittal J, Mathee K, Narasimhan G, et al. Current concepts in the pathogenesis and treatment of chronic suppurative otitis media. 2015;1103–16.

40. Nwaokorie F, Nwokoye N, Chukwu E. Application of Anaerobic Techniques in Laboratory Diagnosis of Otitis Media in Nigeria: A Review. 2018;5(10):11–27.

41. Gunasekera H, O'Connor TE, Vijayasekaran S, del Mar CB. Primary care management of otitis media among Australian children. Med J Aust. 2009;191(SUPPL. 9):55–9.

42. Wilium Wilkin. Ten_year_review_of_otitis_media_pathogens.2 - Pediatr. Inf. Dis. J 1992. Copyright © pdf.

43. Abraham ZS, Tarimo O, Kahinga AA, Ntunaguzi D, Mapondella KB, Massawe ER. Prevalence and clinical characteristics of otitis externa among patients attending Otorhinolaryngology Department at Muhimbili National Hospital, Tanzania. Int J Otorhinolaryngol Head Neck Surg. 2019;5(4):826.

44. Klein J. Otitis Media Author (s): Jerome O . Klein Published by : Oxford University Press Stable URL : http://www.jstor.org/stable/4458141 State-of-the art clinical article Otitis Media. 2016;19(5):823–32.

45. Heikkinen T, Ruuskanen O, Waris M, Ziegler T, Arola M, Halonen P. Influenza

Vaccination in the Prevention of Acute Otitis Media in Children. Am J Dis Child. 1991;145(4):445–8.

46. Manni JJ, Lema PN. Otitis media in Dar es Salaam, Tanzania. J Laryngol Otol. 1987 Mar;101(3):222–8.

47. Hassooni HR, Fadhil SF, Hameed RM, Alhusseiny AH, Ahmed S, Jadoo A. Upper respiratory infection and otitis media are clinically and microbiologically associated. 2018;1(1):29–33.

48. Madana J, Yolmo D, Kalaiarasi R, Gopalakrishnan S, Sujatha S. Microbiological profile with antibiotic sensitivity pattern of cholesteatomatous chronic suppurative otitis media among children. Int J Pediatr Otorhinolaryngol [Internet]. 2011;75(9):1104–8. Available from: http://dx.doi.org/10.1016/j.ijporl.2011.05.025

49. Choffor-Nchinda E, Bola Siafa A, Nansseu JR. Otitis media with effusion in Africa-prevalence and associated factors: A systematic review and meta-analysis. Laryngoscope Investig Otolaryngol. 2020;5(6):1205–16.

APPENDICES

Appendix I: Informed Consent Form (English Version)

Title: Prevalence of otitis media and associated factors in patients attending ear, nose and throat clinic at Mnazi Mmoja Hospital, Zanzibar. Consent to participate in the study

Greetings: I am Bihila Abdalla a postgraduate student doing research on prevalence and factors associate with otitis media among patients attending ENT clinic at MMH.

Purpose of the Study: To determine the prevalence and factors associate with otitis media among patients attending ENT clinic at MMH- 2020 - 2021.

What participation involves: If you agree to participate in this study, you will be asked questions about your health related to your ear condition and examined

Confidentiality: All information collected will be kept confidential and the collected data will be entered into computer with only an identification number; no name will be included.

Risk: We expect no harm to happen to you during the course of this study.

Rights to withdraw: Taking part in this study is completely voluntary and refusal to participate or withdrawal will not involve penalty or loss of any benefits to which you are entitled. You will be treated and followed up as per the usual treatment protocol regarding ear infection.

Benefits: If you agree to participate in this study, you will be followed-up closely and be assessed on the progress of your condition by the investigating doctor. We hope that the obtained information from this study will benefit others.

Who to contact: If you have any other questions regarding this study, feel free to contact the investigator Bihila Abdalla. Tel no.0655867175 or 0777867175.

If you have any questions concerning your rights as a participant, you may contact my supervisors from Muhimbili University of Health and Allied Sciences: Prof. Said Aboud. Telephone: 0754301962. OR Dr Amir Juya Telephone:0755696867 OR Zanzibar Health Research Ethics Committee (Phone Number: +255 776 264 880 email zahreczahri@gmail.com) in case of ethical issue of this study you are required to contact

Patient Assent

Do you agree to participate? .....

Participant does not agree…….

I have read the consent form and I agree to participate in this study.

Signature of Participant……...

Signature of Investigator…….

Date of signed consent…….

Appendix 2: Informed Consent Form (Swahili Version)

Title: prevalence of otitis media and associated factors in patients attending ear, nose and throat clinic at Mnazi Mmoja Hospital, Zanzibar

Ruhusa ya Kushiriki Utafiti

Mimi naitwa Bihila Abdalla, ni mwanafunzi wa uzamili Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili. Nachunguza ukubwa wa tatizo la maambukizi ya sikio na visababishi vinavyopelekea kupata maambukizi kwa wagonjwa wanaopata huduma ya masikio katika kliniki ya masikio, pua, na koo katika Hospitali ya Rufaa ya Mnazi Mmoja. Zanzibar-2020

Dhumuni la utafiti huu: Kuchunguza ukubwa wa tatizo la maambukizi ya sikio na visababishi vinavyopelekea kupata maambukizi kwa wagonjwa wapatao huduma ya masikio katika kliniki ya masikio, pua, na koo katika Hospitali ya Rufaa ya Mnazi Mmoja. Zanzibar-2020 - 2021

Ushiriki: Kama unakubali kushiriki kwenye utafiti huu, utaulizwa maswali na utachunguzwa kwa kina katika kliniki yetu.

Usiri: Taarifa zote za uchunguzi zitaingizwa kwenye kompyuta na nambari ya utambulisho; jina halitanukuliwa.

Madhara: Tunategemea kwamba hakuna madhara yoyote yatokanayo na utafiti huu

Haki ya kujitoa kwenye utafiti: Kushiriki katika utafiti huu ni hiari, na kutokubali kushiriki au kujitoa hautaadhibiwa au kupoteza haki yako ya matibabu. Utatibiwa na kuendelea kufuatiliwa kama taratibu za hospitali zinavyoelekeza.

Faida ya kushiriki kwenye utafiti: Kama utakubali kushiriki kwenye utafiti huu, Faida utakazopata ni pamoja na kuonwa na kufuatiliwa kwa ukaribu na daktari wanaohusika. Tunatumaini kwamba taarifa zitakazopatikana zitawanufaisha wengine pia.

Kwa mawasiliano zaidi: Kama una maswali au maelezo kuhusu utafiti huu, uwe tayari kuwasiliana na mtafiti, Bihila Abdalla. Simu namba-0655867175 au 0777867175.
Au kama una maswali kuhusu haki zako za ushiriki unaruhusiwa kuwasiliana na wasimamizi wangu kutoka Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili ambao ni Prof. Said Aboud. 0754301962. au Dr. Amir Juya 0755696867

Patient's assent

Je, umekubali kushiriki? .....

Mshiriki haja kubali kushiriki……

Nimesoma maelezo na kuyaelewa vizuri na nimekubali kushiriki kwenye utafiti huu.
Sahihi ya Mshiriki……...
SahihiyaMtafiti……Tarehe……

Appendix 3: Questionnaire

Title: Prevalence and associated factors of otitis media among patient attending at ear, nose and throat clinic at MMH, Zanzibar

A. Socio-demographic information

1. Hospital Reg. No.....
2. Address .....
3. Age .....
4. Sex Male ☐ Female ☐
5. Education level (if patient is a child skip question 5 and 6)

a. Non

b. Primary education

c. Secondary education

d. College education

e. University

6. Occupation…….

B. Otitis media presenting symptoms

Are you presenting with any of the following symptoms? If is the child ask the parent/s or guardian.

S/No.		PRESENT SIGN AND SYMPTOMS	YES	NO	ONSET	DURATION
I.		Ear pain				
II.		Fever				
III.		Headache				
IV.		Crying more than usual (child)				
V.		Troubling of sleeping				
VI.		Ear drainage (discharge)				
VII.		Trouble of hearing				
VIII.		Rubbing ear (child)				
IX.		Ear itching				
X.		Prior use of antibiotic				

C. Risk factors

How often are you presenting with any of the symptoms?

a. Autumn
b. Winter
c. Any time

Is there any family member had otitis media or history getting ear infection?

a. Yes
b. No

If yes, what is the relationship with the patient.

c. Mother
d. Father
e. Sibling

Is there any cigarette smoker among your family member?

a. Yes
b. No

Any underlying condition

a. Allergy
b. Asthma
c. Other (specify)……

Sleeping position

a. Left side
b. Right side
c. Other (specify**)**

Child is raised in in child care centers. (if the patient is not a child skip to question 10)

a. Yes
b. No

Bottle feeding with back sleeping position (baby suck bottle while lying on his/her back)

a. Yes
b. No

Do you use cotton buds to clean your ear?

a. Yes
b. No

Appendix 4: Dodoso la Kiswahili

Utafiti Kuhusu kujua ukubwa wa tatizo la maambukizi ya sikio na visababishi vinavyopelekea kupata maambukizi kwa wagonjwa wapatao huduma ya masikio katika kliniki ya masikio, pua, na koo katika Hospitali ya Rufaa ya Mnazi Mmoja. Zanzibar

A. Taarifa binafsi na kimakazi

1. Namba ya dodoso.....
2. Tarehe...../...../.....
3. Namba ya usajili ya hospitali.....
4. Anuani .....
5. Umri (miaka).....
6. Jinsia i. Mume ☐ ii. Mke ☐
7. Kiwango cha elimu (kama mgonjwa ni mtoto ruka swali la 7 na 8)
    a. Hajasoma
    b. Elimu ya msingi
    c. Elimu ya sekondari
    d. Elimu ya chuo
    e. Chuo kikuu
8. Kazi…….

B. Dalili za maambukizi ya sikio

Je una dalili zifuatazo? Kwa mtoto muulize mzazi wake.

S/No.	DALILI ZILIZOPO	NDIO	HAPANA	YAMEANZA/IMEANZA LINI	NI MUDA GANI SASA?
I.	Maumivu ya sikio				
II.	Homa				
III.	Maumivu ya kichwa/homa				
IV.	Mtoto kulia kuliko kawaida				

V.	Kutokulala vizuri				
VI.	Kutoa uchafu/majimaji/usaha ndani ya sikio				
VII.	Kutosikia vizuri				
VIII.	Kupigapiga au kuvuta sikio (mtoto)				
IX.	Sikio kuwasha				
X.	Je unatumia dawa kwa sasa				

C**.** Visababishi vinavyohusiana na maambukizi

1. Ni kipindi gani hua unarudia huu ugonjwa
   a. Kipindi cha baridi (autumn)
   b. Kipindi cha baridi kali Zaidi (winter)
   c. Muda wowote
2. Kuna mwanafamilia ambae anaugua huu ugonjwa au alishawahi kuugua.
   a. Ndio
   b. Hapana
3. Kama ndio, je uhusiano wako ni upi?
   a. Baba
   b. Mama
   c. Ndugu
4. Je kuna mwanafamilia ambae anavuta sigara?
   a. Ndio
   b. Hapana
5. Hali hatarishi (Any underlying condition)

a. Mzio (Allergy)
b. Pumu

c. Mengine (taja)……

6. Mtoto ananyonya chupa akiwa amelalia mgongo

a. Ndio

b. Hapana

7. Sikio gani lenye maambukizi

a. Kushoto

b. Kulia

c. Sikio la kushoto na kulia

8. Je uliwahi kupata chanjo za mfumo wa hewa (ARTI)

a. Ndio

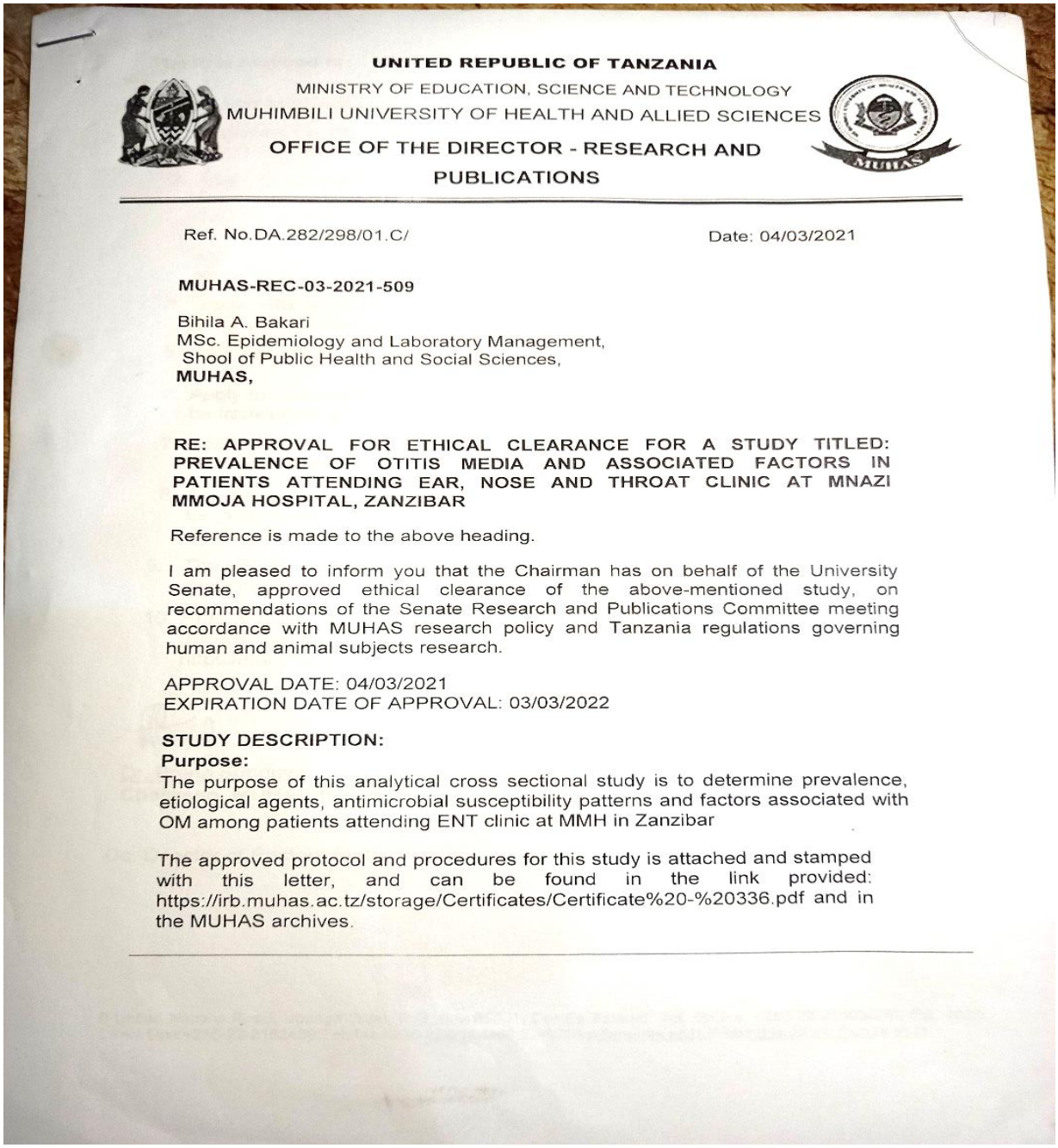
b. Hapana

12. Je unasafisha masikio kwa kutumia vijiti vya pamba

a. Ndio

b. Hapana

Appendix 5: Ethical clearance



UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR - RESEARCH AND PUBLICATIONS

Ref. No.DA.282/298/01.C/ Date: 04/03/2021

MUHAS-REC-03-2021-509

Bihila A. Bakari
MSc. Epidemiology and Laboratory Management,
Shool of Public Health and Social Sciences,
MUHAS,

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: PREVALENCE OF OTITIS MEDIA AND ASSOCIATED FACTORS IN PATIENTS ATTENDING EAR, NOSE AND THROAT CLINIC AT MNAZI MMOJA HOSPITAL, ZANZIBAR

Reference is made to the above heading.

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.

APPROVAL DATE: 04/03/2021
EXPIRATION DATE OF APPROVAL: 03/03/2022

STUDY DESCRIPTION:
Purpose:
The purpose of this analytical cross sectional study is to determine prevalence, etiological agents, antimicrobial susceptibility patterns and factors associated with OM among patients attending ENT clinic at MMH in Zanzibar

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-%20336.pdf and in the MUHAS archives.

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

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research & Publications
Box 65001

Cc: Director of Postgraduate Studies

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1038; Direct Line:+255-22-2152489;Telefax:+255-22-2152489;E-mail:drp@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix 6: Permission letter

ZANZIBAR HEALTH RESEARCH INSTITUTE

Ministry of Health, Social Welfare, Elderly, Gender and Children
P.O Box 236-Zanzibar Tel: +255(0) 776 264 880
Email: info@zahri.org Website: www.zahri.org

Ref: NO. ZAHREC/04/ST/APRIL/2021/24 6th April, 2021

Bihila A. Bakari,
Student Researcher,
Muhimbili University of Health and Allied Science.

PROTOCOL TITLE: "Prevalence of otitis media and associated factors in patients attending ear, nose and throat clinic at Mnazi Mmoja Hospital, Zanzibar."

RE: ETHICAL CLEARENCE FOR CONDUCTING HEALTH RESEARCH IN ZANZIBAR:

This is to certify that research protocol titled **"Prevalence of otitis media and associated factors in patients attending ear, nose and throat clinic at Mnazi Mmoja Hospital, Zanzibar."** was received and reviewed by the Zanzibar Health Research Ethical Committee (ZAHREC) on the 24th March, 2021.

We would like to inform you that your proposal has been **"Approved"** for implementation.

The permission to undertake data collection is for **six month** beginning from the date of this letter.

The principal investigators has to provide progress report after three months and final report to be submitted ZAHREC.

Kindly, seek permission to publish your findings from ZAHRI.

Any changes made to the protocol need to be submitted to the ZAHREC for approval prior to its implementation.

Thanks in advance,

DATE.....

Dr. Mayassa S. Ally,
DIRECTOR GENERAL,
ZANZIBAR HEALTH RESEARCH INSTITUTE,
BINGUNI,
ZANZIBAR.

Dr. Abdullah Suleiman Ali,
DIRECTOR GENERAL,
MINISTRY OF HEALTH,
SOCIAL WELFARE, ELDERLY,
GENDER AND CHILDERN,
ZANZIBAR.

HOSPITALI YA MNAZI MMOJA ZANZIBAR

Simu Namba: + 255 24 223 19 87

Nukushi : + 255 24 223 19 87
Baruapepe: mmrefhospital@hotmail.com

Wizara ya Afya, Ustawi wa Jamii
Wazee Jinsia na Watoto
S. L. Posta 672
Zanzibar

Kumbu Na: DTR/MMH/2021
Bihila A. Bakari
Chuo Kikuu cha Muhimbili
Dar es salaam Tanzania

15, April, 2021

KUH: RUHUSA YA KUFANYA UTAFITI.

Mada ya hapo juu inahusika na barua hii.
Ombi lako la kudadisi baadhi ya wagonjwa kwa lengo la kukamilisha Utafiti huo limepokewa na kuzingatiwa. Ruhusa imetolewa kuja au kuleta wasaidizi wako kwa ajili ya udadisi huo utaohusisha "Prevalence of otitis media and associated factors in patients attending ear,nose and throat clinic at MMH" kuanzia tarehe ya barua hii hadi 31, July, 2021.
Unatakiwa kuwasilisha matokeo ya utafiti wako ofisini kwa Mkurugenzi Mtendaji mara baada ya kuri ya uandishi wa ripoti hiyo kumalizika na kuwasilisha kwenye Taasisi husika.
unatakiwa kuvaa kitambulisho chako cha utambuzi wako muda wote wa kazi hii kwenye maeneo ya hospitali.
Pia uwe na kopi ya barua hii pamoja na barua ya ridhaa kutoka Baraza la Utafiti la Wizara ya Afya. Kutokana na upungufu wawafanyakazi hospitalini hapa huruhusiwi kutumia wafanyakazi wa hospitali kwa kazi yako hii. Ruhusa hii haiondoi kufuata taratibu zote za uingiaji maeneo ya Hospitali na ridhaa ya mshiriki kufanyiwa udadisi huu.

Natanguliza shukurani za dhati kwa mashirikiano.

Ahsante

Abubakar Kh. Hamad
/Mkurugenzi Matunzo na Utafiti
Hospitali Mnazi mmoja.
Zanzibar

MMOJA HOSPITAL ZANZIBAR Date.....

Nakla:

Mkuu wa Idara ya ENT –HMM
Mkuu wa Idara ya Maabara –HMM