

**PREVALENCE OF HEARING LOSS AND ASSOCIATED
FACTORS AMONG NEONATES BORN IN ZANZIBAR**

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**MMed (Otorhinolaryngology) Dissertation
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**PREVALENCE OF HEARING LOSS AND ASSOCIATED
FACTORS AMONG NEONATES BORN IN ZANZIBAR**

By

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**A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the degree
of Master of Medicine (Otorhinolaryngology) of
Muhimbili University of Health and Allied Sciences**

**Muhimbili University of Health and Allied Sciences
October 2017**

CERTIFICATION

The undersigned certify that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences, a dissertation entitled, “*Prevalence of hearing loss and associated factors among neonates born in Zanzibar*”, in (partial) fulfillment of the requirements for the degree of Master of Medicine (Otorhinolaryngology) of Muhimbili University of Health and Allied Sciences.

Prof; Ndeserua Moshi

(Supervisor)

Date

DECLARATION AND COPYRIGHT

I, **Khalid Alawy** declare that this **dissertation** is my own 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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DEDICATION

To Almighty Allah

To my beloved parents

To all my family

This work is dedicated.

ABSTRACT

Introduction: Hearing loss is one among the major abnormalities present at birth. If undetected will impair speech, language and cognitive development. The critical period for language and speech development is generally regarded as the first three years of life. Children who are identified with hearing at early stage of life and receive early and appropriate interventions have significantly higher developmental functions than those with late identification and intervention.

Objective: The study aimed at determining the prevalence of hearing loss among neonates born in Zanzibar, which is part of United Republic of Tanzania.

Study design

Hospital-based, prospective cross sectional study

Method: This was prospective cross sectional study and conducted in three hospitals and one health Centre where neonatal hearing screening was done in Zanzibar. All babies born from May to October 2016 and whose parents/caretakers consented, enrolled in the study. Data collected using a three staged protocol neonatal hearing screening with OAE and AABR, and other information was collected clinically using specialized forms and check list. A total of 600 neonates were recruited in this study and the data analyzed using the SPSS program.

Results

This study included 600 neonates. Among these, 323 (53.8%) were females and 277 (46.2%) were males. Neonates who underwent 1st OAE, 36.2% **failed** the test and went for second test. For those who underwent 2nd OAE, 13.8% failed the test and went for AABR. 41.4% of those who went for AABR **failed** and went for Diagnostic ABR and among these only 3 (25%) **failed**. Three neonates were diagnosed with hearing loss and they were all males, with bilateral SNHL, making a prevalence of 0.5%. Among those with hearing loss 33.3% had severe SNHL and 66.7% profound SNHL. The most frequent risk factor was ototoxic medication use (11.8%) followed by low apgar score (11%) and family history of childhood hearing loss (7%) and hyperbilirubinemia (2.5%).

Hyperbilirubinemia **was** the only risk factor significantly associated with hearing loss (p=0.001)

Conclusion

The prevalence of hearing loss in neonates was 0.5%, more common in males, bilateral, sensorineural type and associated with risk factors.

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ABBREVIATIONS

ABR-AUDITORY BRAINSTEM RESPONSE

AABR- AUTOMATED AUDITORY BRAINSTEM RESPONSE

CHL- CONDUCTIVE HEARING LOSS

EAC- EXTERNAL AUDITORY CANAL

ENT- EAR NOSE AND THROAT

HL- HEARING LOSS

JCIH- JOINT COMMITTEE ON INFANT HEARING

MNH- MUHIMBILI NATIONAL HOSPITAL

MMH-MNAZI MMOJA HOSPITAL

NICU- NEONATAL INTENSIVE CARE UNIT

NHS-NEONATAL HEARING SCREENING

ORL- OTORHINOLARYNGOLOGY

OAE- OTOACAUSTIC EMISSION

SPSS- STATISTICAL PACKAGE FOR SOCIAL SCIENCES

SNHL- SENSORINEURAL HEARING LOSS

UNHS- UNIVERSAL NEONATAL HEARING SCREENING

US- UNITED STATES

WHO- WORLD HEALTH ORGANIZATION

Definition of key terms

Hearing loss: Also known as hearing impairment, or anacusis, is a partial or total inability to hear in one or both ears. An affected person may be described as hard of hearing. A deaf person is the one with significant hearing loss in both ears. It can also be defined as any degree of impairment of the ability to apprehend the sound. Sound pressure is measured in decibel. A decibel (dB) is a unit of sound pressure or intensity in a logarithmic scale, where the smallest audible sound pressure is 0 dB.

Disabling hearing loss: refers to hearing loss greater than 40 dB in the better hearing ear in adults (15 years or older) and greater than 30 dB in the better hearing ear in children (0 to 14 years).

Neonate: A new born infant aging from 1 day to one month.

Screening: Can be defined as a medical service that aimed at the early detection of a particular condition in a population of those likely to have it.

PASS: The test results that signify that the hearing of a neonate is at least 30 dB or better.

REFER: The results that signify the hearing of a neonate is not normal and will benefit from further diagnostic work up.

Tympanometry: Is an examination used to test the condition of middle ear and mobility of the tympanic membrane and ossicles

Underweight: Birth weight less 1.5kg

Birth asphyxia: Apgar score less than 4 at 1 minute or less than 6 at 5 minutes

Infant: A newborn baby less than a year.

Child: A newborn aging one year to 12 years

CHAPTER ONE

1.0 BACKGROUND INFORMATION AND LITERATURE REVIEW

1.1 INTRODUCTION

Hearing impairment is the most frequent sensory deficit in human populations, affecting more than 360 million people in the world (1,2,3). Consequences of hearing impairment include inability to interpret speech sounds, often producing a reduced ability to communicate, delay in language acquisition, economic and educational disadvantage, social isolation and stigmatization (1). Hearing loss is an important public health concern with a lot of economic costs and social consequences. Hearing aids, for example, account for only a small percentage of the overall medical costs for hearing impairment. In Europe, untreated hearing loss is estimated to cost €213 billion a year (3). In United States, a child with untreated hearing loss has estimated direct educational costs of \$400,000 and lifetime societal costs due to lost productivity of \$1,000,000 (1,35).

It is officially estimated in Tanzania that there are approximately 20,000 deaf children. However comparisons with other neighboring countries puts this figure four to five times higher, thus it is possible to find over 80,000 deaf children in towns and hidden in villages (35).

About seven formal deaf schools have been established across Tanzania since the start of deaf education in 1963 at Tabora in the Northwest region. Those schools cater for only 700 out of 20,000 children with severe to profound hearing impairment in the country (36).

Permanent hearing loss can occur at any age but about 25% of the current burden is of childhood onset. About two to four babies per 1,000 live births are born annually in developed countries with permanent hearing impairment and this range may extend to six per 1,000 live births within the neonatal period in developing countries (4).

Adequate auditory stimulation, in early childhood in particular, is very potential for good speech development, language and literacy skills acquisition. Failure to detect early and

effectively manage within the first year of life a permanent hearing impairment that is congenital or that originates in the neonatal period has been associated with significant deficits in speech, linguistic, cognitive, and educational development (4,5,6).

1.2 BACKGROUND

Properties of sound wave.

Sound waves have three most important properties for audio works. These are:

- **Wave length:** The distance between any point on a wave and the equivalent point on the next phase. Literally, the length of the wave.

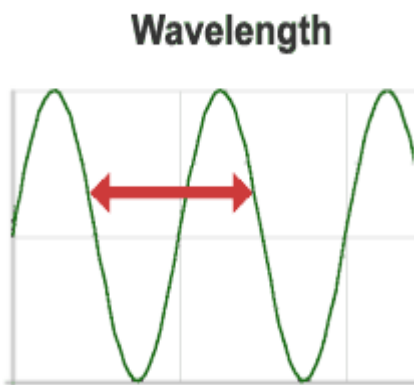


Fig 1. Wavelength of a sound wave (mediacollege.com).

- **Amplitude:** The strength or power of a wave signal. The "height" of a wave when viewed as a graph. Higher amplitudes are interpreted as a higher volume, hence the name "amplifier" for a device that increases amplitude.

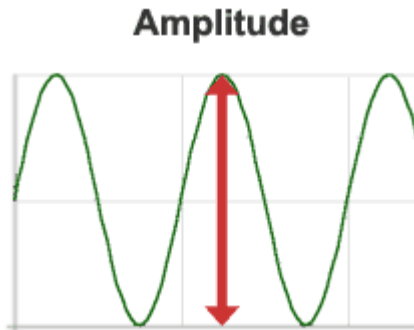


Fig 2. Amplitude of a sound wave (mediacollege.com).

- **Frequency:** The number of times the wavelength occurs in one second. Measured in kilohertz (Khz), or cycles per second. The faster the sound source vibrates, the higher the frequency.

Higher frequencies are interpreted as a higher pitch. For example, when you sing in a high-pitched voice you are forcing your vocal chords to vibrate quickly

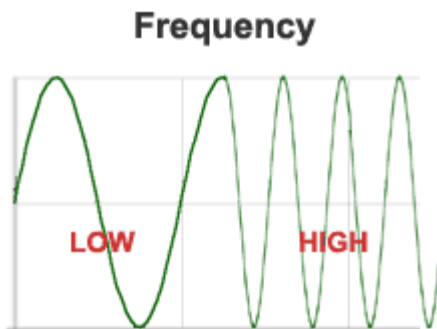


Fig 3. Frequency of a sound wave (mediacollege.com).

Anatomy and physiology of hearing.

The External Ear:

The external ear consists of the pinna (auricle) and the external auditory canal from the meatus to the tympanic membrane. The pinna of humans is composed mostly of cartilage and has no useful muscles. The center of the pinna, the concha, leads to the external auditory meatus, which is about 2.5 cm long. The lateral third of the canal is the cartilaginous portion.

It contains cerumen-producing glands and hair follicles. The remaining medial two thirds is the bony portion, including an epithelial lining over the tympanic membrane. The pinna deflects the incoming sound waves into the external auditory canal. The external auditory canal conveys sound waves to the ear drum. Ear canal amplifies sound wave at a range of 2KHz-5KHz to 10times (7).

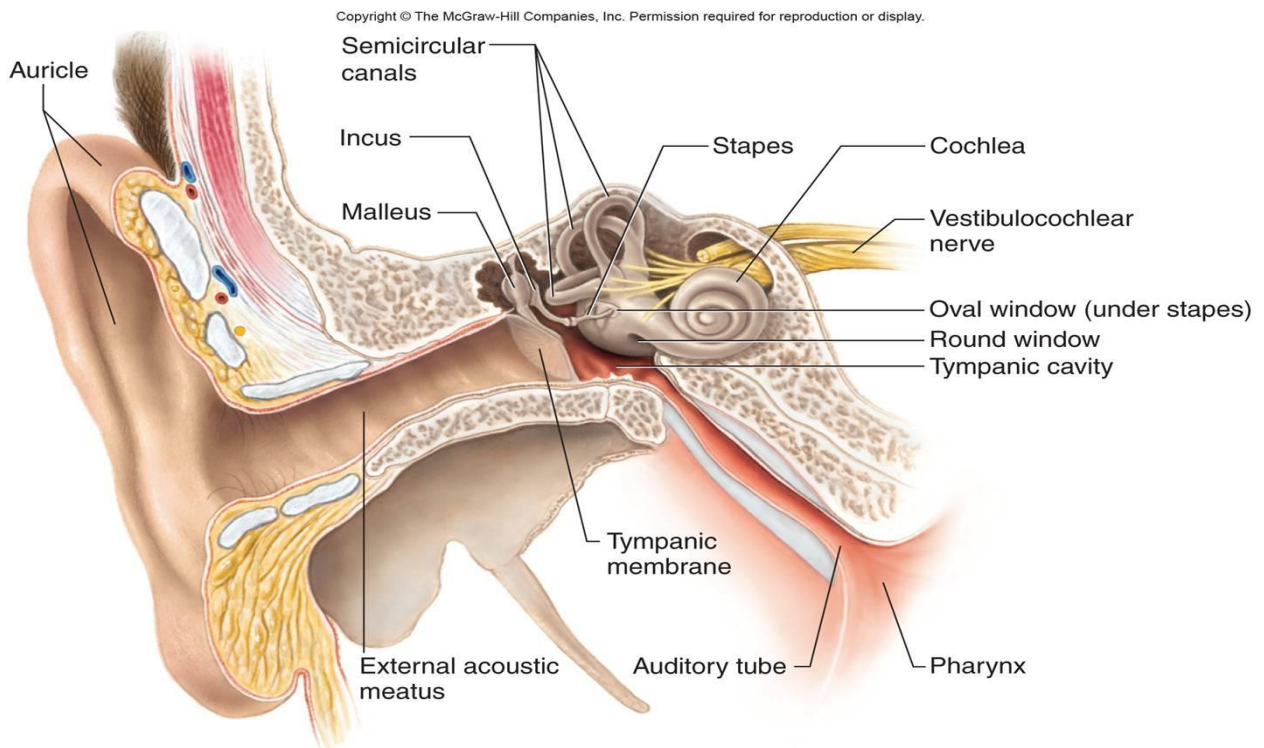


Fig 4. Anatomy of the ear (image courtesy of hearing world).

The Middle Ear

Composed of three ear ossicles, malleus incus and stapes which are articulating each other forming an ossicular chain. The malleus is attached to the ear drum by the handle of malleus and the stape is attached to the oval window of the inner ear by a stape foot plate. The middle ear transmits acoustic energy from the air-filled EAC to the fluid-filled cochlea. It functions as an impedance-matching device in as much as it couples the low impedance of air to the high impedance of the fluid-filled cochlea. The impedance match is achieved in three ways. The

first and most important factor is that the effective vibratory area of the tympanic membrane is approximately 17 to 20 times greater than the effective vibratory area of the stapes footplate. A second factor involves the lever action of the ossicular chain. The arm of the long process of the incus is shorter, by a factor of 1.3, than the length of the manubrium and neck of the malleus. A third and minor factor is the shape of the tympanic membrane. The combined result of these three factors is a pressure gain of approximately 25 to 30 dB (7).

The Inner Ear (Cochlea)

The human cochlea is a coiled, bony tube approximately 35 mm long, divided into the scala vestibuli, scala media, and scala tympani. The scalae vestibuli and tympani contain perilymph, an extracellular fluid-like material with a potassium concentration of 4 mEq/L and a sodium concentration of 139 mEq/L. The scala media is bounded by the Reissner membrane, the basilar membrane and osseous spiral lamina, and the lateral wall. It contains endolymph, an intracellular-like fluid with a potassium concentration of 144 mEq/L and a sodium concentration of 13 mEq/L. The scala media has a positive direct current resting potential of approximately 80 mV that decreases slightly from base to apex. This endocochlear potential is produced by the heavily vascularized stria vascularis of the lateral wall of the cochlea (7,8).

Acoustic energy enters the cochlea through the piston-like action of the stapes footplate on the oval window and is coupled directly to the perilymph of the scala vestibuli. The perilymph of the scala vestibuli communicates with the perilymph of the scala tympani through a small opening at the apex of the cochlea known as the helicotrema. The organ of Corti rests on the basilar membrane and osseous spiral lamina. The major components of the organ of Corti are the outer and inner hair cells, supporting cells, tectorial membrane, and the reticular lamina plate complex (8).

Outer and inner hair cells of the organ of Corti are important in transduction of mechanical (acoustic) energy into electrical (neural) energy. Transduction is initiated by displacement of the basilar membrane in response to displacement of the stapes due to acoustic energy. The displacement pattern of the basilar membrane is a traveling wave. The basilar membrane is stiffer at the base than in the apex. The stiffness component is distributed continuously. Therefore, the traveling wave always progresses from base to apex. Traveling waves produced

by high-frequency sounds have maximal displacement near the base of the cochlea, whereas the waves to low-frequency sounds have the maximum toward the apical region (9–11)

Auditory pathway

Sound waves are transmitted as electrical waves through the 8th nerve to the cochlear nuclei on each side of medulla (which has two nuclei dorsal and ventral cochlear nucleus). Fibers from ventral nucleus (which is concerned in time difference) will relay into the superior olivary complex in the pons, and some little fibers from dorsal cochlear nucleus will relay there too. Most fibers from the dorsal cochlear nucleus (concerned in quality of sound) go directly to the inferior colliculus of midbrain. The inferior colliculus also receives fibers from superior olivary nucleus. The lateral lemniscus is a tract of axons in the brainstem that connects the previous nuclei together and carrying auditory signal in-between. From the inferior colliculus Then fibers go to the medial geniculate body in the thalamus, then to the primary auditory cortex in the temporal lobe, the Brodmann's area 41,42 (9,7).

Types of hearing loss

- **Conductive Hearing Loss:** Hearing loss caused by something that stops sounds from getting through the outer or middle ear.
- **Sensorineural Hearing Loss:** Hearing loss that occurs when there is a problem in the inner ear or hearing nerve pathways.
- **Mixed Hearing Loss:** Hearing loss that includes both a conductive and a sensorineural hearing loss.
- **Central Auditory Hearing Deficit:** In this type of hearing loss, the EAC, middle ear, cochlear and auditory nerve are normal but lesion is in the nuclear cortex, e.g infarct of auditory **cortex** (12).

Other descriptors associated with hearing loss

Bilateral versus unilateral: Bilateral hearing loss means hearing loss in both ears. Unilateral hearing loss means that hearing is normal in one ear but there is hearing loss in the other ear.

Symmetrical versus asymmetrical: Symmetrical means the degree and configuration of hearing loss are the same in each ear. Asymmetrical means the degree and configuration are different from each ear.

Progressive versus sudden hearing loss: Progressive means that hearing loss becomes worse over time. Sudden means that the loss happens quickly.

Fluctuating versus stable hearing loss: Fluctuating means hearing loss that changes over time, sometimes getting better, sometimes getting worse. Stable hearing loss does not change over time and remains the same (11).

Degree and Severity of hearing loss

Hearing loss can also be categorized as mild, moderate, severe or profound according to the level of the hearing a person can hear. Degree of hearing loss refers to the severity of the loss (12).

Below is a WHO classification of hearing loss. The numbers are representative of the patient's hearing loss range in decibels (dB HL).

- Mild: between 20 and 40 dB HL
- Moderate: between 41 and 55 dB HL
- Moderately severe: between 56 and 70 dB HL
- Severe: between 71 and 90 dB HL
- Profound: 90 dB HL or greater (47).

Configuration of Hearing Loss

The configuration of the hearing loss refers to the degree and pattern of hearing loss across frequencies (tones) as illustrated in a graph called an audiogram.

For example, a hearing loss that only affects the high tones would be described as a high frequency loss. Its configuration would show good hearing in the low tones and poor hearing in the high tones. On the other hand, if only the low frequencies were affected, the configuration would show poorer hearing for low tones and better hearing for high tones (11).

Hearing loss in infants and children

The child can be born with hearing loss (congenital hearing loss) or can acquire the defect later in life or very soon after delivery (acquired hearing loss). Hearing loss can be caused by environmental factors as well as genetic factors. It is estimated that 50–75% of all childhood deafness is due to hereditary causes. There are two main forms of genetic hearing loss: syndromic and nonsyndromic. Children with syndromic hearing loss have other clinical features in addition to hearing loss. About 30% of the hereditary hearing loss is syndromic, whereas the vast majority (70%) is nonsyndromic (13,14).

Both conductive and sensorineural hearing loss may be caused by a wide variety of genetic, non-genetic and acquired (after birth) factors. Nongenetic factors account for about 25% of congenital hearing loss. Nongenetic factors that are known to cause hearing loss include: Maternal infections, such as rubella, cytomegalovirus, or herpes simplex virus, Prematurity, Low birth weight, Birth injuries, Toxins including drugs and alcohol consumed by the mother during pregnancy, Complications associated with the Rh factor in the blood, such as jaundice, Maternal diabetes, Lack of oxygen (15,16,17).

Hearing loss from genetic defects can be present at birth or develop later on in life. Most genetic hearing loss can be described as autosomal recessive or autosomal dominant. Other, rarer types of genetic hearing loss include X-linked (related to the sex chromosome) or mitochondrial inheritance patterns. Genetic syndromes have a group of signs and symptoms that together indicate a specific disease. There are many genetic syndromes that include hearing loss as one of the symptoms. Examples include: Down syndrome, Usher syndrome,

Treacher-Collins syndrome, Crouzon syndrome, Alport syndrome, Waardenburg syndrome (12,13).

Acquired hearing loss is a hearing loss that appears after birth. The hearing loss can occur at any time in one's life, as a result of an illness or injury. The following are examples of conditions that can cause acquired hearing loss in children: Ear infections, Medications that are toxic to the ear, Meningitis, Measles, Encephalitis, Chicken pox, Flu, Mumps, birth injury (12).

Some childhood hearing losses have a later onset and will not be identified through newborn screening methods. Late onset or progressive hearing loss can be due to hereditary factors, infection, trauma, noise exposure or teratogens. Studies vary in how "significant hearing loss" is defined. As a result, the prevalence of late onset hearing loss is not well defined. In general there is a trend toward increasing rates of hearing loss as children get older. In some instances, mild hearing loss that is present at birth may progress to more severe hearing loss after the child goes home from the hospital. Rapidly progressive hearing loss can be associated with several congenital conditions, including Cytomegalovirus (CMV) and Large Vestibular Aqueduct (LVA) as well as some genetically inherited losses (18,19).

As noted out earlier that hearing loss is associated with language and cognitive development impairment to the affected children, hence the early detection of hearing loss by screening at, or shortly after birth, with appropriate intervention, is important to language and cognitive development in hearing-impaired children (20).

Neonatal hearing screening

The American Academy of Pediatrics, The U.S. Joint Committee on Infant Hearing (JCIH) and National Institutes of Health recommend universal neonatal screening to detect and manage hearing loss in early life stages using otoacoustic emissions (OAE) and Auditory Brainstem Response (ABR) (4,21).

Otoacoustic emissions

The normal cochlea does not just receive sound; it also produces low-intensity sounds called OAEs. These sounds are produced specifically by the cochlea and, most probably, by the cochlear outer hair cells as they expand and contract. The presence of cochlear emissions was hypothesized in the 1940s on the basis of mathematical models of cochlear nonlinearity. However, OAEs could not be measured until the late 1970s, when technology created the extremely sensitive low-noise microphones needed to record these responses (11).

There are 3 types of otoacoustic emissions:

- Spontaneous otoacoustic emissions (SOAEs) - Sounds emitted without an acoustic stimulus (ie, spontaneously).
- Transient otoacoustic emissions (TOAEs) or transient evoked otoacoustic emissions (TEOAEs) - Sounds emitted in response to an acoustic stimuli of very short duration; usually clicks but can be tone-bursts.
- Distortion product otoacoustic emissions (DPOAEs) - Sounds emitted in response to 2 simultaneous tones of different frequencies (11,38).

In order to obtain correct otoacoustic emissions results the following must be observed: Unobstructed outer ear canal, Sealing of the ear canal with the proper probe, Optimal positioning of the probe, Absence of middle ear pathology, Functioning cochlear outer hair cells, A very calm patient: excessive movement or vocalization may give false results, Relatively quiet recording environment: a sound booth is not required, but a noisy environment may preclude accurate recording (38). As outlined earlier, Otoacoustic emissions are used to assess cochlear integrity and are physiologic measurements of the response of the outer hair cells to acoustic stimuli. They serve as a fast, objective screening tests for normal pre-neural cochlear function. To measure OAEs, a probe assembly is placed in the ear canal, tonal or click stimuli are delivered, and the OAE generated by the cochlea is measured with a

highly sensitive microphone (21). Most of the modern OAE machines are automated meaning they give PASS or REFFER results and do not require screener interpretation.

Auditory Brainstem Response

Automated auditory brainstem response (AABR) is an electrophysiological measurement that is used to assess auditory function from the eighth nerve through the auditory brainstem. These measurements are generally obtained by placing disposable surface electrodes high on the forehead, on the mastoid, and on the nape of the neck. The click stimulus (usually set at 35 dB hearing level) is delivered to the infant's ear via small disposable earphones designed to attenuate background noise. Most AABR systems compare an infant's wave-form with that of a template developed from normative ABR infant data. A pass or fail response is determined from this comparison (11,21). Both OAE and ABR technologies provide noninvasive recordings of physiologic activity underlying normal auditory function, both are easily performed in neonates, and both have been successfully used for UNHS (22).

Risk factors for neonatal hearing loss

The JCIH position statements pointed out a list of risk factors that are associated with hearing loss in neonates. These risk factors include: family history of hereditary childhood sensorineural hearing loss, in utero infections, craniofacial anomalies, birth weight less than 1500 g, hyperbilirubinemia requiring exchange transfusion, ototoxic medications, bacterial meningitis, Apgar score of 0–4 at 1 minute or 0–6 at 5 minutes after birth, mechanical ventilation lasting 5 days or longer, and stigmata associated with a syndrome known to include a sensorineural or conductive hearing loss (23,24).

Early intervention

According to JCIH the initiation of early intervention services should begin as soon as possible after diagnosis of hearing loss at no later than 6 months of age. Studies revealed that

infants and children with mild-to-profound hearing loss who are identified in the first 6 months of life and provided with immediate and appropriate intervention have significantly better outcomes than later-identified infants (6,23,24).

Audiological habilitation.

Hearing Aids: these are medical devices that delivers an amplified acoustic signal into the ear canal. Through amplification, hearing aids increase the audibility of sounds, including speech , the effectiveness of hearing aids depends on the degree and configuration of hearing loss (25,26). Several styles are available now days: Behind The Ear (BTE), In The Ear (ITE), In The Canal (ITC), Completely In the Canal (CIC), Body worn aids, Bone Anchored Hearing Aids (BAHA). The JCIH recommend that if the family chooses personal amplification for its infant, hearing-aid selection and fitting should occur within 1 month of initial confirmation of hearing loss even when additional audiological assessment is ongoing (24).

Cochlear implantation: Cochlear implants seek to replace a nonfunctional inner-ear hair-cell transducer system by converting mechanical sound energy into electrical signals that can be delivered to the cochlear nerve in profoundly deaf patients (8). It should carefully be considered for any child who seems to receive limited benefit from a trial of at least 3 months with appropriately fitted hearing aids (24). According to US Food and Drug Administration guidelines, infants with profound bilateral hearing loss are candidates for cochlear implantation at 12 months of age and children with bilateral severe hearing loss are eligible at 24 months of age (20).

Speech and language therapy: This must involve family, speech and language therapist. The audiologic habilitation plan for infants is guided by the type of communication method the family is using with the child. A variety of communication methods are available: listening and spoken language (also referred to as auditory-verbal or auditory-oral), cued speech or cued language (this method utilizes specific hand shapes and placements around the face to clarify the ambiguity of lip-reading) and sign language (21).

1.3 LITERATURE RIVIEW

Several studies has been done in US and indicate variance in the prevalence of neonates with hearing loss. However the overall estimates are between 1 to 6 per 1,000 newborns (35, 36).

In a study done in Colorado, out of 41796 neonates screened, 126 (3/1,000) were identified with hearing loss. Of those with hearing loss, 94 (75%) had SNHL, 32 (25%) had CHL. Among those with SNHL 75 (79.8%) had bilateral SNHL and 19 (20.2%) had unilateral SNHL (22).

A study done in Italy revealed that out of 532 neonates, 3 (0.56%) were diagnosed to have hearing loss. Among those with hearing loss, 2 (0.38%) were detected with unilateral sensorineural hearing loss, and 1 newborn (0.19%) with bilateral sensorineural hearing loss.

The overall prevalence of hearing loss was 5.6 per 1000 live birth (27).

A study done in Jordan, 63 041 neonates were included, hearing loss was confirmed in 966 infants (1.5% of the entire cohort), of which 477(49.4%) were male and 489 (50.6%) were female. Of 966 hearing loss infants, 590 (61.1%) was sensorineural, 311 (32.2%) was conductive, and 65 (6.7%) was mixed. Hearing loss was mild, moderate, severe and profound in 182 (18.9%) 320 (33.1%), 195 (20.2%), and 269 (27.8%) infants, respectively (28).

In Turkey, out of 11575 neonates who underwent hearing screening, 22 of them were diagnosed as SNHL. 15 (68.18%) of the 22 (0.19%) neonates with SNHL had bilateral HL whereas 7 (31.82%) of them had unilateral hearing loss (29).

Hemmati et al (30) reported that, two out of 12573 neonates were identified with profound bilateral congenital hearing impairment. Both of them were male, full term and had family history of congenital hearing **loss** (30).

Oliveira et al (15) did a study in Brazil to assess the risk factors for hearing loss between rooming in neonates and those admitted to N ICU. Among 1,146 (100%) enrolled neonates, 1,064 (92.8%) passed and 82 (7.2%) failed the hearing screening. One hundred and sixty neonates were at high risk for hearing problems, 76 (34.5%) used ototoxic drugs and 38 (17.2%) had a family history of hearing loss in childhood (15). Among 82 infants who failed the NHS, two (2.4%) were identified as having hearing loss: one with conductive mild type

and another with severe sensorineural hearing loss. Both NBs were from rooming-in units and did not present risk indicators for childhood hearing loss .

In a study done in Thailand about the risk factors of hearing loss in 3,120 neonates; the risk factors were found to be low birth weight (RR =1.6, 95% CI 1.1–2.6), APGAR score <6 at 5 minutes (RR =2.2, 95% CI 1.1–4.4), craniofacial anomalies (RR =2.5, 95% CI 1.6–4.2), sepsis (RR =1.8, 95% CI 1.0–3.2), and ototoxic exposure (RR =4.1,95% CI 1.9–8.6) (31).

Abu Shaheen et al (28) reported that neonates with at least one JCIH risk factor for hearing loss had a 1.9-fold increased risk for hearing loss compared with those without any of these 10 risk factors. Also there was a statistically significant association between hearing loss and each risk factor examined, with the exception of meningitis and rubella 4.5[0.62 – 34.94], 1.2 [0.06, 6.32] respectively.

In Iran, a study was done about the risk factors for SNHL, the statistical analysis showed no significant association between SNHL and neonates' age (P = 0.52), sex (P =0.5), or sepsis (P = 0.94). However, SNHL was significantly associated with gestational age (P = 0.045), birth weight (P < 0.001), length of hospital stay (P < 0.001), pathological jaundice (P = 0.033), antibiotic treatments (P = 0.007), and total serum bilirubin level (P = 0.01). Moreover, a significant association was found between SNHL and use of ototoxic drugs (P < 0.001). Also, there was a significant correlation between SNHL and duration of antibiotic treatments (P < 0.001) (32).

In a prospective cohort study of 150 neonates conducted at the NICU and well-baby nursery populations, in Ain Shams University Hospital in Egypt. The most frequent risk factor was consanguinity (46%) followed by mechanical ventilation (42%), very low birth weight (40%), ototoxic drugs (25%), sepsis (23%), low Apgar score (16%), and hyperbilirubinemia (12%). Stigmata of syndromes that are known to be associated with deafness accounted for 8% of cases in the targeted-screening group (33). Other less frequent factors include positive family history of hearing loss (2%) and craniofacial abnormalities (1%). The most frequent risk factor for hearing loss among high-risk neonates was mechanical ventilation for more than 5 days (41/50) followed by birthweight less than 1500 gm (27/50), whereas consanguinity was the most frequent risk factor for hearing loss (25/50) among neonates of the low-risk group

followed by birth weight less than 1500 gm (13/50). However none of the risk factors were significantly related to HL ($P>0.05$) (33).

In a pilot study on neonatal hearing screening in Lagos, Nigeria consisting of a two-stage screening with transient evoked OAE and automated ABR followed by confirmatory test with diagnostic ABR, six (21.4%) of the 28 full-term neonates (total screened: 761 infants <3 months) confirmed with hearing loss had neonatal jaundice and/or neonatal sepsis from hospital or medical records (34). The study further showed that two of the neonates were kernicteric and had severe bilateral hearing loss with poor neck control (34). The third baby had mild bilateral hearing loss with no other noticeable neurological deficits (34). Also 2 babies had neonatal jaundice along with sepsis and were found to have moderate bilateral hearing loss (34).

Minja et al (39) found that out of 36 deaf pupils whom their onset of deafness was congenital, only ten pupils was diagnosed before 2 years of age (39).

1.4 PROBLEM STATEMENT

Every year more than 800 000 neonates globally are estimated to be born with, or acquire permanent bilateral hearing loss within the first few weeks of life. More than 90% of these neonates reside in developing countries, where limited data describing the epidemiology of hearing impairment exists as a result of limited systematic or routine screening programs. In the absence of a systematic effort to screen infants with hearing loss the average age of detection is well beyond the potential period of language skills acquisition. In Tanzania most of the deaf children are diagnosed after two years of age. Every year extra budget has to be made for the deaf children in order to facilitate their education. Moreover they are increasingly sent abroad every year for cochlear implants, adding further preventable burden to the government. Limited similar studies have been done in East Africa that estimates the magnitude of the problem.

1.5 RATIONALE OF THE STUDY

Considering the known impact of neonatal hearing loss on cognitive function and psychosocial development, it is vital to know the extent of the problem so that measures can be taken to intervene as early as possible.

The study intends to give an overview of the prevalence of HL in neonates in our country, together with the associated risk factors for the problem at this particular age group. Moreover the results of the study will be presented at the Ministry of Health so that it can help the Ministry of Health to plan preventive and treatment strategies for the problem. Also the study will motivate health authorities concerned to adopt UNHS and establish the screening programs in our country together with taking early interventions to the diagnosed ones. On the other hand this study will open the door for other studies to be done in our country, regarding neonatal hearing loss.

Lastly, this is primarily done as a requirement in the fulfillments of my Masters of Medicine degree in Otorhinolaryngology.

1.6 OBJECTIVES

1.6.1 Broad objective:

To determine the prevalence of HL and associated factors among neonates born in Zanzibar from May to October 2016.

1.6.2 Specific objectives:

- i. To determine the prevalence of HL among neonates by sex.
- ii. To determine the prevalence of HL among neonates by lateralization.
- iii. To determine the prevalence of neonatal hearing loss by type.
- iv. To determine the prevalence of neonatal hearing loss by severity.
- v. To determine the factors associated with HL among neonates born in Zanzibar.

1.7 RESEARCH QUESTIONS

The primary research question of this research is; what is the magnitude of hearing loss and associated risk factors among neonates in Zanzibar?

The secondary research questions are;

- a. Does the sex have anything to contribute to the hearing loss inherited or acquired during neonatal period?
- b. What is the common type of hearing loss in neonates
- c. What is the severity pattern or the degree of the common type of hearing loss inherited or acquired during neonatal period?
- d. Does the hearing loss inherited or acquired during neonatal period commonly affect one or both ears?
- e. How significant are the risk factors associated with hearing loss in neonates?

CHAPTER TWO

2.0 METHODOLOGY

2.1 Study Area

This study was conducted at four of the government hospitals in Zanzibar where screening is done. Neonatal hearing screening was established recently with the help of a non-government organization called Zanzibar Outreach Program (ZOP) in collaboration with Doctors Worldwide. Hospitals in which hearing screening is done currently include:

1. Mnazi Mmoja Hospital, a 440 bed, government run referral hospital located in Stone Town, the island's capital. It is staffed by both local and international doctors and is reasonably well equipped for a developing world hospital. ORL department is located in a one floor building with one ward, operating theatre, outpatient room and two audiology rooms, one with a special designed sound proof booth. In addition to the OAE test; AABR test, and diagnostic ABR are only done in this hospital
2. Kivunge district hospital, located at Northern district outside of Zanzibar town. It has facilities for basic inpatient care and laboratory services. It provide 24-hour services, including delivery services, and radiologic services. Only OAE test is done in this hospital
3. Muembeladu maternity hospital, a 50 bed capacity hospital which specializes in obstetric and midwifery, is located in Zanzibar town. The hospital has a prenatal (ante-natal) station and a maternity unit, including post-natal care. The maternity unit consists of examination rooms, recovery rooms and a brand new surgery/operating theatre which is fully equipped with modern medical supplies. In this hospital only OAE test is done.
4. Mpendae health centre, also located in Zanzibar town and only OAE test is done

2.2 Study design

This study was hospital based prospective cross-sectional study design.

2.3 Study duration.

This study was conducted from May 2016 to October 2016.

2.4 Study population

All **neonates** born at the above mentioned hospitals and health centers during the period when the study conducted.

2.5 Inclusion criteria

- All neonates born at these hospitals during the period of data collection.

2.6 Exclusion criteria

- Newborn babies beyond one month of age.
- **Neonates** born at home.

2.7 Data collection

Screening was done by the principal investigator in collaboration with an audiologist of MMH. In addition to an Audiologist other three research assistants who are the trained staff of the screening protocols and methods, underwent a brief training session for three days on the purpose of the study, familiarizing with data collection tool and practical skills sessions on how to assess the **neonate**, how to collect the data and how to discuss test procedures and results with parents and caretakers and will continue to do the screening at their respective centers. In addition they were given a document that summarizes the clinical features of most common syndromes associated with neonatal hearing loss. For the period of one month PI stayed in Zanzibar collecting data and collaborating with research assistants and the remaining months PI was visiting Zanzibar weekly and oversees the process of data collection.

PI together with the audiologist centered at the referral hospital (MMH) where AABR and diagnostic test was done and they were visiting other centers that were nearby whenever feasible to assess the completed forms and to check for omissions and inappropriate responses. This improved the quality of data collection. For Kivunge center which is a bit outside of Zanzibar town, the PI and the Audiologist were paying a visit weekly or twice weekly for the same purpose.

Physical examination was done to every **neonate** before initial screening to rule out anomalies associated with neonatal hearing loss. The head, and the face was inspected and palpated, and the mouth opened using tongue depressor and inspected, and ear canals inspected using

otoscope to rule out craniofacial anomalies. The skin of the **neonate** and eyes inspected for yellowish discoloration and this was considered as a sign of hyperbilirubinemia. Apgar score, history of meningitis, mechanical ventilation, and ototoxic drug use were obtained from the files. Family history of hearing loss was obtained from the parents or caretakers. Every new born whose parents/caretakers consented for the study, was screened initially using OAE before hospital discharge. In this study the OAE and AABR machines that was used are automated, i.e. they give PASS or REFFER results on the screen ready to be read and recorded and do not requires screener's interpretation. If the result was PASS, parents/ caretakers counseled and the neonate was discharged home. If the results was FAIL/REFFER, the neonate discharged and parents counseled and rescheduled for second screening using OAE in two weeks period. For PASS results, baby discharged home, but for FAIL/REFFER results baby was referred to MMH for AABR in one week period. Before commencement of AABR, otoscopy and tympanometry was done by PI and Audiologist to rule out middle ear pathology (conductive pathology) and results recorded, and then AABR was done by the Audiologist on the same day. If the results were PASS, the neonate was discharged. For the REFFER result, the baby was scheduled for diagnostic ABR in one week period. The neonate was given chlorohydrate solution to achieve a calmness situation, then a Diagnostic ABR was done to confirm the retro cochlear pathology and gave the severity of the problem. Infants confirmed with hearing loss, with type and severity noted were sent to ORLst for further management. Neonates who passed the initial screening and discharged, but readmitted again few days before neonatal period to end was included in the study and rescreened again after discharge and was considered as new candidates. Special designed forms was used to collect and compile all information. These forms consisted of 5 parts:

- **Part one: general information**

This consisted of name of the screening Centre, serial number of the form, telephone number of the parent/caretaker and sex of the baby.

- **Part two: risk factors assessment**

All of the JCIH named risk factors was assessed with the exception of intrauterine infections which was not investigated in MMH at the time of study

- **Part three: screening results.**
All PASS and REFFER results was recorded in this part.
- **Part four: type and severity**
The type and severity of the confirmed hearing loss was recorded in this part
- **Part five: typanometry results**
Tymanometry results, including the type of tymanometry graph was recorded here

2.8 Sampling and Sample size estimation

Convenient sampling, where by the available babies at the time of screening was studied

The estimated sample size N was computed using the **Fischer's formula** as shown below,

$$N = \frac{z^2 pq}{d^2}$$

Where;

N = Estimated Sample Size

Z = is the standard normal deviate, which is 1.96 using the 95% confidence interval.

P= estimated Proportion of neonates with hearing loss which is 0.6 % (recently reported prevalence rates in south African public health sectors, Swanepoel et al)

q = (1-P) = proportion of neonates without hearing loss

d= margin of error= 1 %

Therefore;

$$N = \frac{1.96^2 \times 0.06 \times 0.94}{0.02^2}$$

N= 542

Adjusting for non-response, we add 10 % of the estimated sample size. Therefore, the Estimated Sample Size was about 600.

2.9 Data handling and analysis

Neonates who passed their initial screening results, their information (data collected) was kept in a computer the same day of screening. Forms of those who fail the initial screening was kept in separate bags and stored in medical in charges offices until the next scheduled day for rescreening. For those referred to MMH, their data was taken together with them by the Centre Screeners to MMH. All information was confidentially stored in locked cabinets and computer data was stored on secured computers.

Data collected was analyzed using SPSS with a consultation from biostatistician for analysis and interpretation. A p-value of less than 0.05 was considered as statistically significant. Prevalence calculated by taking all neonates confirmed with HL as a numerator divided by all neonates screened in all hospitals during the study period as the denominator

2.10 Ethical considerations

Ethical review and clearance to conduct the study was sought from Muhimbili University of Health and Allied Sciences Ethical Review Board. Permission to conduct the study was requested from the Ministry of Health Zanzibar and from respective hospitals.

Parents of the candidates were informed about the study and what it comprised and confidentiality was assured. For those interested, the informed consent was carefully reviewed to them. The benefits and risks of participations was stated clearly in the consent form, though risks were not expected in this study. Also all clients were informed that, there would be no financial gain obtained by participating in this study.

2.11 Study Limitation

Intrauterine infections as one of JCIH risk factor for neonatal hearing loss could not be assessed.

The study enrolled only babies born in four hospitals and therefore cannot be a representative of all neonates.

CHAPTER THREE

3.0 RESULTS

Descriptive results

Table 1: Distribution of gender among neonates screened

		Neonates	Percentage (%)
Gender	Female	323	53.8
	Male	277	46.2
	Total	600	100

The table shows that, among 600 neonates included in the study, 323 (53.8%) were females and 277 (46.2%) were males with a ratio of 1:1

Table 2: The prevalence of neonatal hearing loss by gender

Gender	Hearing loss		Total	P value
	Yes	No		
Female	0(0%)	323(53.8%)	323(53.8%)	0.0001
Male	3(0.5%)	274(45.7%)	277(46.2%)	
Total	3(0.5%)	597(99.5%)	600(100%)	

Among all neonates (600) who participated in the study only 3(0.5%) were confirmed with hearing loss and they were all males

Table 3: The prevalence of hearing loss among neonates screened

		Lateralization					P value
Hearing loss		Right ear	Left ear	Bilateral	Normal	Total	0.0001
	Yes	0(0%)	0(0%)	3(0.5%)	0(0%)	3(0.5%)	
	No	0(0%)	0(0%)	0(0%)	597(99.5%)	597(99.5%)	
Total	0(0%)	0(0%)	3(0.5%)	588(98%)	600(100%)		

Among neonates screened only 3 diagnosed to have hearing loss and they were all bilateral.

Table 4: The prevalence of hearing loss by type among neonates screened

		Hearing loss		Total	P value
		Yes	No		
Type of HL	CHL	0(0%)	0(0%)	0(0%)	0.0001
	MHL	0(0%)	0(0%)	0(0%)	
	SNHL	3(0.5%)	0(0%)	3(0.5%)	
	NORMAL	0(0%)	597(99.5%)	597(99.5%)	
	Total	3(0.5%)	597(99.5%)	600(100%)	

Among neonates screened only 3 confirmed and all have SNHL

Table 5: The distribution of hearing loss by severity among neonates screened

		Hearing loss			
		Yes	No	Total	P value
Severity	Mild	0(0%)	0(0%)	0(0%)	0.0001
	Moderate	0(0%)	0(0%)	0(0%)	
	Severe	1(33.3%)	0(0%)	1(0.2%)	
	Profound	2(66.7%)	0(0%)	2(0.3%)	
	Normal	0(0%)	597(100%)	597(99.5%)	
	Total	3(100%)	597(100%)	600(100%)	

Among those confirmed with hearing loss 1neonate (33.3%) had severe SNHL and 2 neonates (66.7%) have profound SNHL

Table 6: The risk factors associated with hearing loss among neonates screened

Risk factors	Hearing loss			P value
	Yes	No	Total	
Family history	1(0.2%)	42(7%)	43(7.2%)	0.078
	3(0.5%)	597(99.5%)	600(100%)	
Underweight	0(0%)	12(2%)	12(2%)	0.804
	3(0.5%)	597(99.5%)	600(100%)	
Craniofacial anomaly	0(0%)	10(1.7%)	10(1.7%)	0.821
	3(0.5%)	597(99.5%)	600(100%)	
Syndromic hearing loss	0(0%)	1(0.2%)	1(0.2%)	0.943
	3(0.5%)	597(99.5%)	600(100%)	
Birth asphyxia	0(0%)	66(11%)	66(11%)	0.542
	3(0.5%)	597(99.5%)	600(100%)	
Hyperbilirubinemia	1(0.2%)	15(2.5%)	16(2.7%)	0.001
	3(0.5%)	597(99.5%)	600(100%)	
Ototoxic medication use	1(0.2%)	71(11.8%)	72(12%)	0.254
	3(0.5%)	597(99.5%)	600(100%)	
Assisted ventilation	0(0%)	26(4.3%)	26(4.3%)	0.712
	3(0.5%)	597(99.5%)	600(100%)	

On multiple regression hyperbilirubinemia was found to be significantly associated with neonatal hearing loss [*P* value (*Pearson's X²*) at 95%CI = 0.001].

CHAPTER FOUR

4.0 DISCUSSION

Many studies on hearing loss have been done in developing countries but, most of them concentrate on certain groups like mining workers, school children and elders. Few studies on hearing loss in neonates and infants have been done particularly in East Africa countries where Tanzania is included.

In this study 600 neonates were included, 323 (53.8%) were females and 277 (46.2%) were males. These include 200 neonates delivered at Mnazi MMoja referral hospital, 150 neonates delivered at Kivunge hospital, 150 delivered at Mwembeladu maternity hospital and 100 neonates from Mpendae health center.

Among 600 neonates screened 3 neonates were confirmed to have hearing loss making a prevalence of 0.5%. This prevalence fall in the same overall estimate of prevalence of neonatal hearing loss globally, which is between 0.1% to 0.6% (1, 2).

Findings in this study were comparable to those published by De Capua et al (27) in Italy. He reported that 3(0.56%) babies to have hearing loss.

Findings of this study were slightly higher compared to the study by Mehl et al (22) 0.3%, Ulusoy et al (29) 0.1%, Oliveira et al (15) 0.2% and Hemmati et al (30) 0.1% .This could be explained by poor economic status of Zanzibar population which increases the occurrence of risk factors and hence high prevalence. Also these differences may be explained by different screening protocols and real difference in hearing loss incidence in the world.

Abu Shaheen et al (28), reported a prevalence of 1.5% which is higher compared to the findings of this study. The difference may be explained by large sample size of the Abu Shaheen study.

Al-Meqbel et al (40) in Kuwait reported that, the prevalence of neonatal hearing loss was 11.5%. This is higher compared to the findings of this study. The reason for higher prevalence is that, in his study Al-Meqbel enrolled only neonates at risk for hearing loss (40).

A study by Gouri et al (41) in India revealed a prevalence of 5.3%. The findings are higher compared to this study. In his study Gouri, included both neonates at risk and those without risk factors. And he also included other risk factors apart from those mentioned by JCIH. (41).

Among all neonates (600) who participated in this study only 3(0.5%) were confirmed with hearing loss and they were all males. This corresponds to a study by Hemmati et al (30) who diagnosed 2 males to have hearing loss out of the total neonates screened. Also the findings corresponds to the study by Dora Jerina Jose et al (42) in Trivandram, India who confirmed 2 male neonates to have hearing loss. The findings are contrasted by Abu Shaheen et al (28) in Jordan and Al Maqbel et al (41) in Kuwait which showed no gender predominance on neonatal hearing loss. Since this study employed every baby appeared at the screening Centre, male predominance over females might be an incidental findings and still no known anatomical and genetic differences between male and females in ear structures.

Among neonates screened in this study only 3 diagnosed to have hearing loss and they were all bilateral. This corresponds to the study done by Hemmati et al (30) who reported 2 neonates with bilateral hearing loss. Ulusoy et al (29) reported that 68.18% of the babies with hearing loss were bilateral and 31.82% had unilateral loss. In Colorado, Mehl et al (22). Reported 79.8% of bilateral cases in contrast to 20.2% of unilateral. These findings suggest that hearing loss in infants most commonly is bilateral. The reason is that most of the risk factors associated with neonatal hearing loss exerts their effects bilaterally (43,44).

In this study, all neonates (100%) with hearing loss had SNHL. This corresponds with most of the studies. De capua et al (27) reported 100% of neonates diagnosed with hearing loss had SNHL. The same observation was reported by Himmati et al (30) and Dora Jerina Jose et al (42) in Trivandram, India.

Mehl et al (22) reported that 75% of the neonates with hearing loss had SNHL while 25% had CHL. Abu Shaheen et al (28) concluded that of those with hearing loss 61.1% was sensorineural, 32.2% was conductive and 6.7% was mixed. In his study, Abu Shaheen enrolled both babies born and attended different health sectors and he also enrolled babies beyond 1 month of age. These observations concluded that hearing loss in neonates most commonly is of sensorineural type and this can be explained by the effects of mentioned risk factors and genetic on cochlea and auditory pathways.

In this study; 33.3% of those confirmed with hearing loss had severe SNHL and 66.6% had profound SNHL. This corresponds to study by Hemmati et al (30) who reported two infants with hearing loss had profound SNHL. Abu Shaheen et al (28) reported that 18.9% had mild, 33.1% had moderate, 20.2% had severe and 27.8% had profound hearing loss. The difference may be due to large sample size and different screening protocols.

In this study 246 neonates were at risk of having hearing loss. 72 (12%) used ototoxic medication, 66(11%) had low apgar score, 43 (7.2%) had positive family history of childhood hearing loss, 26 (4.3%) had assisted ventilation 16 (2.7%) had hyperbilirubinemia, 12 (2%) had low birth weight, 10 (1.7%) had craniofacial anomalies, 1 (0.2%) had down syndrome.

Hyperbilirubinemia was significantly associated with hearing loss in neonates ($p=0.001$) in this study. This correspond to Al Maqbel et al (40), Alae E.et al (32), Olusanya et al (34) in Nigeria, Abu Shaheen et al (28). Hyperbilirubinaemia causes selective damage to the brainstem auditory nuclei and may also damage the auditory nerve and spiral ganglion cells by interfering with neuronal intracellular calcium homeostasis (44). Findings are contrasted by Maqbool et al (46) in India. The reason, may be attributed by timely intervention of neonates with hyperbilirubinemia at GB Pant Hospital.

A baby with hyperbilirubinemia in this study, had also a positive family history of hearing loss and used ototoxic medication, while other babies with single risk factors were not proved to have hearing loss. This explains the synergistic role of risk factors in neonatal hearing loss as reported (45).

Ototoxic medication use was not statistically correlated with hearing loss, in contrast to Abu shaheen et al (28), Alae E et al (32), though we had large number of babies who used ototoxic drug. This may have been attributed by low dosage given and duration of exposure, as literature reports ototoxicity is related to the dose, time and concurrent use of other ototoxic drug (43, 44).

Findings in this study showed that family history was not significant as a risk factor for hearing loss in contrast to Hemmati et al (30) and Abuu Shaheen et al (28). This may have been attributed by the wrong response of the caretakers as they could have understood the family history of hearing loss as any loss, instead of permanent childhood hearing loss caused by genetic and mentioned risk factors.

Forty three (7.2%) of the babies in this study had low apgar score but the p value was not statistically significant. However Abu shaheen et al (28) showed significant association. The lack of association in this study is probably due to the smaller sample size. Twelve out of the 600(2%) babies born had a birth weight of less than 1.5kg. None of these babies had hearing loss. The association with low birth weight was not found to be statistically significant ($p=0.804$). This is against the findings of Abu Shaheen, et al (28) and could be due to the smaller sample size in the present study. The same applied to assisted ventilation, craniofacial anomalies and syndromic features.

In this study, it is found that 2 babies with hearing loss had no identifiable risk factors similar to study done by Oliveira et al (15) in Brazil. This explains the role of consanguinity(which is highly practiced in Zanzibar) and genetics, in new-born hearing loss, as literature reports that 50%-75% of childhood deafness is due to hereditary causes and among those, 70% are non syndromic (13,14).

CHAPTER FIVE

5.0 CONCLUSION

The prevalence of neonatal hearing loss in the study participants was found to be 0.5%, all occurring in males, bilateral and associated with risk factors.

Hyperbilirubinemia was a main risk factor of hearing loss in this study, and this finding should be incorporated into protocols for healthcare providers in Tanzania.

Findings of this study were corresponding well with majority of the findings in literature, though contrasted with some, and this could be explained by different screening protocols and sample size used by other studies.

5.1 RECOMMENDATIONS

- Other studies with large sample size should be done.
- Also studies that will focus on associations of hearing loss and the mentioned risk factors should be done
- The results of this study should be used by policy makers to introduce neonatal hearing screening in our country.
- Those identified with hearing loss should receive early interventions to avoid of sequel of hearing loss.
- Those identified with mentioned risk factors should be followed to rule out late onset hearing loss.
- Health education about the risk factors should be given to the community
- Health care providers should provide preventive measures and early treatment plans for those diagnosed to have hypebilirubinemia

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Appendix 1

INFORMED CONSENT

Consent to participate in a study titled **“Prevalence of hearing loss and associated factors among neonates born in Zanzibar.”**

Greetings! My name is Dr. Khalid Yussuf Alawy from Muhimbili University of Health and Allied Sciences department of Otorhinolaryngology. I am conducting a study to explore the extent of hearing loss among all babies born in Zanzibar. You and your baby happen to be one of those who will be participating in this study. If you agree to join the study, your baby will be examined physically and will be screened using specialized instruments and you (guardian) will be required to answer only one question. Participation in this study will be completely voluntary. Information obtained from you will be kept confidential. Only phone number will be written on screening form, and all information collected will be entered into computers with only the form identification number. The results of the study will be reported as group results.

We do not expect any harm will happen to you because of joining in this study. You may refuse to participate or withdraw from the study at any time. Refusal to participate or withdrawal from the study will not involve penalty or loss of any benefit to which your baby is otherwise entitled. There will be no specific benefits to your baby. Your baby will be treated and followed up as per the usual treatment protocol; the results of the study will contribute to the present knowledge about neonatal hearing loss.

If you ever have questions about this study, you should contact the principal investigator Dr. Khalid Yussuf Alawy, Muhimbili University of health and Allied Sciences cell phone number 0773250524, P.O. Box 65001, Dar es Salaam; or **you may contact my Supervisor Professor Ndeserua Moshi cell phone number 0754279738.**

If you ever have questions about your rights as a participant, you may call **Professor S. Aboud**, Director of Research and Publication MUHAS, P.O. Box 65001, Dar es Salaam. Telephone: 2150302/6.

Do you agree?

Participant agrees:.....

Participant does NOT agree.....

I,.....have read the contents in this form and understood. I agree to participate in this study.

Signature of Participant.....

Signature of Research Assistant.....

Date of Signed consent.....

Appendix I I: Informed Consent form – Kiswahili Version

Ruhusa ya Kushiriki Utafiti Kuhusu kuangalia ukubwa wa tatizo la ukiziwi kwa watoto wachanga wanaozaliwa Zanzibar 2016.

Salaam!Mimi naitwa Dr. Khalid Yussuf Alawy ni mwanafunzi wa udhamili chuo kikuu cha tiba Muhimbili. Nachunguza ukubwa wa tatizo la ukiziwi kwa watoto wachanga wanaozaliwa Zanzibar mwaka 2016. Mtoto wako imetokezea kuwa ni mmoja ya watakao shiriki katika uchunguzi huu. Kama unakubali kushiriki kwenye utafiti huu, mtoto wako atachunguzwa na kupimwa maskio yake kwa vifaa maalum na wewe mama (mlezi) utaulizwa swali,moja tu. Kushiriki katika utafiti huu ni hiari, na matokeo yatakua ni siri. Ni nambari ya simu ndiyo itaingizwa kwenye fomu tu. Taarifa zote za uchunguzi zitaingizwa kwenye kompyuta na nambari ya fomu. Tunategemea kwamba hakutakua na madhara yoyote yatokanayo na utafiti huu . Taarifa zitakazopatikana zitakuwa ni za watoto wote. Hatutarajii kama mtoto wako atapatwa na dhara lolote lile ikiwa tu utakubali kushiriki katika utafiti huu . Unaweza kuamua kushiriki ama kujitoa katika utafiti huu mda wowote ule, na huko kujitoa kwako hakutokusababisha kupata adhabu au kunyimwa huduma yeyote ile ambayo mtoto wako alitarajiwa kuipata hata kama usingeshiriki katika utafiti huu. Hakuna faida ya moja kwa moja itakayo kuhusu wewe,ama mtoto wako; ila atatibiwa na kuendelea kufuatiliwa kama taratibu za hospitali zinavyoelekeza kwa mtoto mwenye ukiziwi; na matokeo ya utafiti huu yatachangia kujua ukubwa wa tatizo la ukiziwi.

Kama una maswali au maelezo kuhusu utafiti huu, uwe tayari kuwasiliana na mtafiti, Dr. Khalid Yussuf Alawy, Hospitali ya Taifa Muhimbili, P.O. Box 65000, simu: 0773250524 DSM. Au unaweza **kuwasiliana na Professor Ndeserua Moshi msimamizi wangu katika utafiti huu.** Kama una maswali kuhusu haki yako kama mshiriki wasiliana na **Prof. S. Aboud**, Mkurugenzi wa Idara ya utafiti, P.O. Box 65001, DSM. Simu 2150302/6.

Je, umekubali kushiriki?

Mshiriki hajakubali kushiriki.....

Mimi..... nimesoma maelezo na kuyaelewa vizuri, na nimekubali kushiriki kwenye utafiti huu.

Sahihi ya Mshiriki.....

Sahihi ya Mtafiti.....

Saini ya Msaidizi Mtafiti.

Tarehe

Appendix III

NEONATAL HEARING SCREENING FORM AND RISK FACTORS ASSESSMENT CHECKLIST FOR THE STUDY TITLED “ PREVALENCE OF HEARING LOSS AMONG NEONATES BORN IN ZANZIBAR 2016”

SCREENING CENTRE.....

FORM NUMBER.....

PHONE NUMBER (PARENT/CARETAKER).....

PART ONE: GENERAL INFORMATION.

1. Sex of the Baby.....

PART TWO: RISK FACTORS ASSESSMENTS

SN	ASSOCIATED FACTORS	TICK	SN	ASSOCIATED FACTORS	TICK
2	Family history of hearing loss		7	meningitis	
3	Birth weight less than 1.5 kg		8	Ototoxic medication use(mother or baby)	
4	Craniofacial anomalies		9	Assisted ventilation >5 days	
5	Apgar score <4 at 1 minute or < 6 at 5minutes		10	Physical features associated with syndromes known to include hearing loss	
6	Hyperbilirubinemia				

PART THREE: SCREENING RESULTS

SCREEN	PASS		FAIL/REFER	
	RT	LT	RT	LT
11. 1 st OAE	a. <input type="checkbox"/>	b. <input type="checkbox"/>	c. <input type="checkbox"/>	d. <input type="checkbox"/>
12. 2 nd OAE	a. <input type="checkbox"/>	b. <input type="checkbox"/>	c. <input type="checkbox"/>	d. <input type="checkbox"/>
13. AABR	a. <input type="checkbox"/>	b. <input type="checkbox"/>	c. <input type="checkbox"/>	d. <input type="checkbox"/>
14. DIAGNOSTIC ABR	a. <input type="checkbox"/>	b. <input type="checkbox"/>	c. <input type="checkbox"/>	d. <input type="checkbox"/>

PART FOUR: TYPE AND SERVERITY

15: TYPE SNHL CHL MIXED HL

 a. b. c.

16: MILD MODERATE SEVERE PROFOUND

SERVERTY a. b. c. d.

PART FIVE: TYMANOMETRY RESULTS

17: TYPE: A B C

 a. RT b. LT c. RT d. LT e. RT f. LT